DEC 1 1 2012

510(k) Summary: K122158

The following 510k Summary is provided in accordance with the requirements of 21 CFR 807.92.

1. Device Name and Classification

Device Trade Name:	PBP Total Hip System
Device:	Artificial Total Hip Replacement
Regulation Number and Description:	888.3358 - Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis 888.3350 - Hip joint metal/polymer semi-constrained cemented prosthesis) 888.3353 – Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Device Class:	II
Product Codes:	LPH - prosthesis, hip, semi-constrained, metal/polymer, porous uncemented JDI - prosthesis, hip, semi-constrained, metal/polymer, cemented OQG - hip prosthesis, semi-constrained, cemented, metal/polymer, + additive, porous, uncemented OQH - hip, semi-constrained, cemented, metal/polymer + additive, cemented MEH (hip, semi-constrained, uncemented, metal/polymer, non-porous, calcium-phosphate) LZO (Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis) OQI - hip, semi-constrained, cemented, metal/ceramic/polymer + additive, porous uncemented
Advisory Panel:	Orthopedic

2. Address and Registration

Submitter's Name:	Pipeline Biomedical Products, LLC
Address:	3 Wing Drive Suite 102 Cedar Knolls, NJ 07927
Contact Person:	Robert C. Cohen
Telephone Number:	(973) 267-8800
Fax Number:	(973) 267-8810

K122158

Date Summary Prepared: December 5, 2012
Establishment Registration Number: Not yet registered

3. Purpose of Submission

The purpose of this submission is to obtain 510k clearance for the PBP Total Hip System, a new device system for Pipeline Biomedical Products, LLC.

4. Identification of Legally Marketed Device to which Submitter Claims Equivalence

The subject PBP Total Hip System by Pipeline Biomedical Products is substantially equivalent to the predicate devices as outlined in the following table.

Table 1: Predicate Devices

Device Name	Company	510(k) Number	Clearance Date
Pipeline Total Hip System	Pipeline Orthopedics	K112802	3/9/2012
Tritanium® Peri-Apatite Acetabular Shell System	Howmedica Osteonics	K101072 K971206	4/11/2011 2/11/1998
Biolox *delta* Ceramic Femoral Head	Zimmer	K071535	11/19/2007

5. Device Description

The PBP Total Hip System is an artificial hip replacement system. The system includes femoral stems, femoral heads, acetabular shells, acetabular liners, acetabular bone screws and dome hole covers (occluders) for the holes in the acetabular shells.

The PBP Femoral Stems are forged titanium alloy and feature a proximal roughened surface (plasma-sprayed CP Titanium), a polished tapered neck, a flat tapered geometry with reduced A/P width (wedge design), and a contoured distal tip and reduced lateral shoulder. The PBP Femoral Stems come in a range of sizes, and are offered in two offset neck options per size.

The PBP Femoral Heads are available in a polished cobalt chromium alloy or a high purity alumina oxide ceramic compound (Biolox® *delta*). The heads come in a range of diameters and extension options. The variety of head and stem sizes and offsets accommodates differences in patient anatomy.

The PBP PST™ (Porous Structured Technology) Acetabular Shells are manufactured from titanium alloy and feature a porous structured surface or an HA porous structured surface. The shells feature a dome hole, are available with or without a cluster screw hole pattern for supplemental bone screw fixation, and come in a range of outer diameter sizes. The porous structured surface provides biologic fixation.

The PBP Acetabular Liners are manufactured from standard UHMWPE, or from highly crosslinked Vitamin E UHMWPE (XLVE™). The liners are mechanically assembled to the mating shells via engagement of the tightly toleranced liner taper and shell bore. The liners are available in a range of sizes and in neutral, high wall, and offset versions.

Optional components include a threaded acetabular dome hole occluder and acetabular bone screws, all manufactured from titanium alloy.

6. Intended Use

The PBP Total Hip System is indicated for use in skeletally mature individuals undergoing surgery for total hip replacement due to:

- A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis, or congenital hip dysplasia;
- Acute traumatic fracture of the femoral head or neck;
- Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty or total hip replacement.

The PBP Total Hip System hip stems and porous structured acetabular shells are intended for cementless or cemented fixation. The porous structured surface provides biological fixation when used in a cementless application.

The PBP Total Hip System HA porous structured acetabular shells are intended for cementless fixation. The HA porous structured surface provides biological fixation.

7. Comparison of Technological Characteristics

The PBP Total Hip System is manufactured from the same materials as the predicate device systems. In addition, the components are packaged, and sterilized using similar processes. The subject Total Hip System is substantially equivalent to the predicates based on comparisons of intended use, design features and technological characteristics.

8. Performance Testing

The following performance tests were provided to demonstrate substantial equivalence:

- Biocompatibility testing for the highly crosslinked Vitamin E Polyethylene:
  - Cytotoxicity, 10993-5
  - Maximization/Sensitization, 10993-10
  - Intracutaneous, 10993-10
  - Acute Systemic Toxicity, 10993-11
  - Sub-acute/Subchronic Systemic Toxicity, 10993-11
  - Genotoxicity, 10993-3
  - Muscle Implantation, 10993-6.
- Wear testing:
  - Testing was conducted on 28 mm, 36mm and 40mm inner diameter highly crosslinked Vitamin E poly liners, that had been EO-sterilized and accelerated aged in

accordance with ASTM F2003, and subject to wear testing in accordance with ISO 14242, using a standard walking gait cycle as specified by ISO 14242-1.

- Bidirectional pin-on-disc abrasive wear testing was also conducted to compare the wear rates of the highly-crosslinked Vitamin E poly material to conventional (standard) gamma sterilized poly under clean and abrasive conditions. The wear reduction for the Vitamin E poly over conventional poly is 35% (7.7 vs 5 mg/Mc) in clean serum and 58% (8.3 vs 3.5 mg/Mc) in an abrasive environment.

- Wear particle characterization was conducted.
- The highly-crosslinked Vitamin E Polyethylene underwent exhaustive extraction testing using both polar and non-polar solvents, with GCMS and LCMS analysis to determine all volatile, semi-volatile, and non-volatile extracts. The results were compared to a predicate material to demonstrate that no new radiation degradation products are released by the material.
- Highly-crosslinked Vitamin E Polyethylene liners underwent oxidation analysis per ASTM F2102-06 after accelerated aging per ASTM F2003, wear testing, and exhaustive extraction. The analysis was also conducted on gamma-sterilized GUR 1020 (standard poly) reference material for comparison. The highly crosslinked Vitamin E poly exhibited lower oxidation indices than the standard poly, demonstrating higher resistance to oxidation: mean surface oxidation index was 0.017 for Vitamin E and 0.097 for standard poly; maximum oxidation index was 0.029 for Vitamin E and 0.248 for standard poly; and bulk oxidation index was 0.009 for Vitamin E and 0.036 for standard poly.
- Highly-crosslinked Vitamin E Polyethylene liners were evaluated by polarized light microscopy and SEM analysis of freeze fractured surfaces, after accelerated aging per ASTM F2003 and wear testing, to demonstrate that the subject material has equivalent consolidation to a predicate material.
- Liner Assembly/Disassembly Testing: Testing of the worst case size Pipeline Hip System highly crosslinked Vitamin E poly acetabular liner and worst case size conventional poly liner were tested for push-out, lever out torque, and axial torque.
- Hip Stem Fatigue Testing was conducted for the worst case (smallest) hip stem according to the method described in ISO 7206-4:2010, Implants for surgery-Partial and total hip joint prostheses, Determination of Endurance Properties and Performance of Stemmed Femoral Components.
- Stem Neck Fatigue Testing of the worst-case size was conducted according to the methods described in ISO 7206-6:1992 Implants for surgery-Partial and total hip joint prostheses-Part 6 and ASTM F2068-03 Standard Specification for Femoral Prostheses – Metallic Implants.
- Pull off testing was conducted on the metal and ceramic femoral heads.
- Burst Strength testing was conducted on Biolox *delta* Femoral Heads according to ISO 7206-10.
- An analysis was conducted of the typical and worst case ranges of motion permitted by the designs of various liner size/style, head size/style, and stem size/style combinations. The ROM was reported for flexion/extension, abduction/adduction, and internal/external rotation per ISO 21535.

K122158

- Bone screw testing was conducted in accordance with ASTM F543-07, Standard Specification and Test Methods for Metallic Medical Bone Screws, for torsion (torque to failure) and screw pull-out (pull-out to failure).
- Characterization in accordance with relevant aspects of "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement," was completed for: 1) Acetabular Shell – PST Surface; 2) Acetabular Shell – HA PST Surface; 3) Hip Stem – Plasma-Spray Titanium Coating.
- Characterization in accordance with relevant aspects of "Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball HIP Systems" was completed for the ceramic femoral heads.
- The porous structured surface was evaluated in a transcortical canine model to assess the biological response, using histological and mechanical evaluations, at intervals up to 12 weeks.

9. Conclusions

The subject PBP Total Hip System shares the same indications for use as the predicate hip system, and a comparison of technological characteristics supported by performance testing demonstrates the Substantial Equivalence of the PBP Total Hip System to the predicate hip systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 11, 2012

Pipeline Biomedical Products, Llc
% Mr. Terry Powell
Senior Project Manager
901 King Street, Suite 200
Alexandria, Virginia 22314

Re: K122158
Trade/Device Name: PBP Total Hip System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis.
Regulatory Class: Class II
Product Code: OQI, LZO, MEH, OQH, OQG, JDI, LPH
Dated: November 14, 2012
Received: November 19, 2012

Dear Terry Powell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin L. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K122158

Device Name: PBP Total Hip System

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Prescription Use ___X___ AND/OR (Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Krishna Arundi

Division of Orthopedic Devices

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K122158 ORIGINAL

K122158: PBP Total Hip System

The following information is provided in response to an email dated August 22, 2012, from FDA Reviewer, Michael Kasser, requesting additional information via interactive review. Each of FDA's requests is shown in bold, and is followed by Pipeline's response.

Administrative Information

1. **FDA conducts a comprehensive review of the 510(k) Summary in accordance with 21 CFR 807.92 and the Required Elements for 510(k) Statements in accordance with 21 CFR 807.93. Based on our assessment of your 510(k) Summary, your Summary does not meet the regulation. Please address the following concerns regarding your 510(k) summary:**

   a. **Please add the procode OQI to the Summary.**

   b. **The device description includes multiple claims, such as (but not limited to), minimize potential for wear debris, bone-conserving, ease of insertion. These claims should be removed or provide additional data to substantiate them.**

   c. **The Summary should clarify the reason for the submission.**

   See revised 510k Summary provided as Exhibit 1.

   - We have added procode OQI.
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   - Zimmer claims of its Cancellous Structured Titanium (CSTi), "During the process, pores are created. This results in a unique porous coating that has optimally-sized, interconnected pores to allow bone ingrowth and a fine micro-roughness to provide secondary fixation." (See Exhibit 3, page 3.)

- DJO claims of its 3D Matrix porous coating, "The pore size of 100 to 500 microns has been shown to be optimal for bone ingrowth". (See Exhibit 4, page 1.)
- Smith & Nephew claims of its Stik-Tite porous surface that, "STIKTITE coating provides primary stability and long-term osseointegration. R3 Acetabular System utilizes STIKTITE - a revolutionary proprietary porous shell coating engineered to create additional shell stability while offering an architecture that encourages bony in-growth. The 60% porosity of STIKTITE creates a balance between long-term in-growth and intraoperative scratch-fit, reassuring positive feedback to the surgeon during impaction." (See exhibit 5, page 1)
- Biomet claims of its PPS porous plasma spray "Successful Osseointegration with PPS® Porous Plasma Spray: ...Biomet's proprietary application process distributes multiple coats of porous titanium alloy over the substrate, creating layers of varying pore sizes intended to maximize osseointegration" (See Exhibit 6, page 7.)
- Biomet claims for its Regenerex™ Porous Titanium Construct that it, "Unites clinical history of titanium with an enhanced interconnecting pore structure for rapid bone ingrowth. (See Exhibit 7, page 2.)
- Wright claims of its Biofoam Cancellous Titanium that it is "a true trabecular architecture. It is roughened to enhance immediate fixation during surgery, and bone in-growth through osteoconductive matrix" and "Over 200% greater bone growth in BIOFOAM™ as compared to sintered beads at 12 weeks, Full interconnecting porosity, Osteoconductive matrix." (See Exhibit 8, pages 6 and 8.)
- Stryker claims its Tritanium porous coating "...is a three-dimensional surface on the acetabular cup that helps hold the implant into the bone. The new Tritanium® technology was designed to resemble trabecular bone, a type of spongy bone tissue that provides skeletal support. Tritanium® technology allows for bone to grow into the component providing enhanced fixation." (See Exhibit 9.)

Pipeline's modified description of its PST surface within the 510k Summary, accompanied now by references to substantiating data, is consistent with descriptions of other predicate porous surfaces.

2. The submission includes a Truthful and Accurate Statement (TAS) that contains an electronic signature. Please supply a TAS with an original signature.

See TAS with an original signature provided as Exhibit 2.

Performance Testing

3. **The submission includes new Biolox delta ceramic heads and relies on testing from CeramTec to support the burst strength of the heads. However, this testing was performed on tapers that may differ from the tapers of the subject device. Therefore, in order to substantiate the applicability of the provided testing to the subject device please provide a comparison of the CeramTec tapers and the subject tapers.**

   See comparative table below. To assess the ball/cone overlap, the Pipeline Hip Stem cone, CeramTec test cone and Delta ceramic balls were sketched on 2D CAD software using nominal dimensions from their respective engineering drawings to align the ball/cone tapers and determine the nominal length of overlap per ball size. The analysis is documented in Exhibit 10, *TM 120819 – Evaluation of the Delta Ceramic Ball-Trunnion Overlap*.

	Pipeline taper	CeramTec test taper
Angle	5.688° Max to 5.646° min	5.708° max to 5.625° min
Length	14 mm ± 0.1mm	18.5mm no tolerance referenced
Straightness	0.003 mm	0.003mm
Roundness	0.008mm	0.008mm
Surface Roughness	0.4 Ra µm	Rz 6 + 14
Gage diameter	12.700 mm max to 12.670mm min at gage height 1.400	12.700 mm max to 12.640mm min at gage height 1.400
Ball/Cone Overlap*		
Ball Dia. Ball Size		
28mm L	7.321 mm	7.321 mm
32mm L	8.471 mm	8.471 mm
36mm XL	6.421 mm	6.421 mm
40mm XL	8.234 mm	8.234 mm

* Provided for each size of the Pipeline size offering burst tested in CeramTec test report (Exhibit 26 of the original 510k): Influence of diameter and neck length on burst strength of BIOLOX forte and BIOLOX delta ball heads with taper type 12/14 (Doc. 3300: 4/2/2011).

6 Truthful and Accurate Statement

Truthful and Accurate Statement

I certify that, in my capacity as Sr. Vice President Research & Development, I believe, to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate, and that no material fact has been omitted.

Robert C. Cohen

May 3 2012

Date

TRADITIONAL PREMARKET NOTIFICATION [510(K)]

PBP TOTAL HIP SYSTEM
K122158

(RESPONSE TO INTERACTIVE REVIEW QUESTIONS)

PIPELINE BIOMEDICAL PRODUCTS, LLC
3 WING DRIVE, SUITE 102
CEDAR KNOLLS, NJ 07927

AUGUST 31, 2012

- CONFIDENTIAL -

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Performance Testing

3. The submission includes new Biolox delta ceramic heads and relies on testing from CeramTec to support the burst strength of the heads. However, this testing was performed on tapers that may differ from the tapers of the subject device. Therefore, in order to substantiate the applicability of the provided testing to the subject device please provide a comparison of the CeramTec tapers and the subject tapers.

See comparative table below. To assess the ball/cone overlap, the Pipeline Hip Stem cone, CeramTec test cone and Delta ceramic balls were sketched on 2D CAD software using nominal dimensions from their respective engineering drawings to align the ball/cone tapers and determine the nominal length of overlap per ball size. The analysis is documented in Exhibit 10, *TM 120819 – Evaluation of the Delta Ceramic Ball-Trunnion Overlap*.

	Pipeline taper	CeramTec test taper
Angle	(b)(4)	
Length		
Straightness		
Roundness		
Surface Roughness		
Gage diameter		
Ball/Cone Overlap* Ball Dia. Ball Size 28mm L 32mm L 36mm XL 40mm XL		

* Provided for each size of the Pipeline size offering burst tested in CeramTec test report (Exhibit 26 of the original 510k): Influence of diameter and neck length on burst strength of BIOLOX forte and BIOLOX delta ball heads with taper type 12/14 (Doc. 3300: 4/2/2011).

Exhibit 1: Revised 510k Summary

510(k) Summary

The following 510k Summary is provided in accordance with the requirements of 21 CFR 807.92.

1. Device Name and Classification

Device Trade Name:	PBP Total Hip System
Device:	Artificial Total Hip Replacement
Regulation Number and Description:	888.3358 - Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis 888.3350 - Hip joint metal/polymer semi-constrained cemented prosthesis) 888.3353 – Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Device Class:	II
Product Codes:	LPH - prosthesis, hip, semi-constrained, metal/polymer, porous uncemented JDI - prosthesis, hip, semi-constrained, metal/polymer, cemented OQG - hip prosthesis, semi-constrained, cemented, metal/polymer, + additive, porous, uncemented OQH - hip, semi-constrained, cemented, metal/polymer + additive, cemented MEH (hip, semi-constrained, uncemented, metal/polymer, non-porous, calcium-phosphate) LZO (Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis) OQI - hip, semi-constrained, cemented, metal/ceramic/polymer + additive, porous uncemented
Advisory Panel:	Orthopedic

2. Address and Registration

Submitter's Name:	Pipeline Biomedical Products, LLC
Address:	3 Wing Drive Suite 102 Cedar Knolls, NJ 07927
Contact Person:	Robert C. Cohen
Telephone Number:	(973) 267-8800
Fax Number:	(973) 267-8810
Date Summary Prepared:	September 4, 2012

Establishment Registration Number: Not yet registered

3. Purpose of Submission

The purpose of this submission is to obtain 510k clearance for the PBP Total Hip System, a new device system for Pipeline Biomedical Products, LLC.

4. Identification of Legally Marketed Device to which Submitter Claims Equivalence

The subject PBP Total Hip System by Pipeline Biomedical Products is substantially equivalent to the predicate devices as outlined in the following table.

Table 1: Predicate Devices

Device Name	Company	510(k) Number	Clearance Date
Pipeline Total Hip System	Pipeline Orthopedics	K112802	3/9/2012
Tritanium® Peri-Apatite Acetabular Shell System	Howmedica Osteonics	K101072 K971206	4/11/2011 2/11/1998
Biolox *delta* Ceramic Femoral Head	Zimmer	K071535	11/19/2007

5. Device Description

The PBP Total Hip System is an artificial hip replacement system. The system includes femoral stems, femoral heads, acetabular shells, acetabular liners, acetabular bone screws and dome hole covers (occluders) for the holes in the acetabular shells.

The PBP Femoral Stems are forged titanium alloy and feature a proximal roughened surface (plasma-sprayed CP Titanium), a polished tapered neck, a flat tapered geometry with reduced A/P width (wedge design), and a contoured distal tip and reduced lateral shoulder. The PBP Femoral Stems come in a range of sizes, and are offered in two offset neck options per size.

The PBP Femoral Heads are available in a polished cobalt chromium alloy or a high purity alumina oxide ceramic compound (Biolox® *delta*). The heads come in a range of diameters and extension options. The variety of head and stem sizes and offsets accommodates differences in patient anatomy, allowing the surgeon to optimize soft tissue tension and restore joint mechanics.

The PBP PST™ (Porous Structured Technology) Acetabular Shells are manufactured from titanium alloy and feature a porous structured surface or an HA porous structured surface. The shells feature a dome hole, are available with or without a cluster screw hole pattern for supplemental bone screw fixation, and come in a range of outer diameter sizes. The porous

structured surface's interconnected porosity provides a scaffold for bone ingrowth as shown in the transcortical implant canine model[1,2,3]

The PBP Acetabular Liners are manufactured from standard UHMWPE, or from highly crosslinked Vitamin E UHMWPE (XLVE™) for increased resistance to wear and oxidative degradation as compared with standard UHMWPE (demonstrated by comparative wear testing and comparative oxidation analyses summarized in Section 8). The liners are mechanically assembled to the mating shells via engagement of the tightly toleranced liner taper and shell bore. The liners are available in a range of sizes and in neutral, high wall, and offset versions.

Optional components include a threaded acetabular dome hole occluder and acetabular bone screws, all manufactured from titanium alloy.

6. Intended Use

The PBP Total Hip System is indicated for use in skeletally mature individuals undergoing surgery for total hip replacement due to:

- A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis, or congenital hip dysplasia;
- Acute traumatic fracture of the femoral head or neck;
- Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty or total hip replacement.

The PBP Total Hip System hip stems and porous structured acetabular shells are intended for cementless or cemented fixation. The porous structured surface provides biological fixation when used in a cementless application.

The PBP Total Hip System HA porous structured acetabular shells are intended for cementless fixation. The HA porous structured surface provides biological fixation.

7. Comparison of Technological Characteristics

The PBP Total Hip System is manufactured from the same materials as the predicate device systems. In addition, the components are packaged, and sterilized using similar processes. The subject Total Hip System is substantially equivalent to the predicates based on comparisons of intended use, design features and technological characteristics.

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[1] Bobyn JD, Pilliar RM, Cameron HU, Weatherly GC: The optimum pore size for the fixation of porous-surfaced metal implants by the ingrowth of bone. Clin Orthop Rel Res150:263-270, 1980.

[2] Bobyn JD, Stackpool G, Toh K-K, Hacking SA, Tanzer M: Bone ingrowth characteristics and interface mechanics of a new porous tantalum biomaterial. J Bone Joint Surg 81-B:907-914, 1999.

[3] Data on file at Pipeline Biomedical Products, LLC and provided in the 510k.

8. Performance Testing

The following performance tests were provided to demonstrate substantial equivalence:

- Biocompatibility testing for the highly crosslinked Vitamin E Polyethylene:
  - Cytotoxicity, 10993-5
  - Maximization/Sensitization, 10993-10
  - Intracutaneous, 10993-10
  - Acute Systemic Toxicity, 10993-11
  - Sub-acute/Subchronic Systemic Toxicity, 10993-11
  - Genotoxicity, 10993-3
  - Muscle Implantation, 10993-6.
- Wear testing:
  - Testing was conducted on 28 mm, 36mm and 40mm inner diameter highly crosslinked Vitamin E poly liners, that had been EO-sterilized and accelerated aged in accordance with ASTM F2003, and subject to wear testing in accordance with ISO 14242, using a standard walking gait cycle as specified by ISO 14242-1.
  - Bidirectional pin-on-disc abrasive wear testing was also conducted to compare the wear rates of the highly-crosslinked Vitamin E poly material to conventional (standard) gamma sterilized poly under clean and abrasive conditions. The wear reduction for the Vitamin E poly over conventional poly is 35% (7.7 vs 5 mg/Mc) in clean serum and 58% (8.3 vs 3.5 mg/Mc) in an abrasive environment.
- Wear particle characterization was conducted.
- The highly-crosslinked Vitamin E Polyethylene underwent exhaustive extraction testing using both polar and non-polar solvents, with GCMS and LCMS analysis to determine all volatile, semi-volatile, and non-volatile extracts. The results were compared to a predicate material to demonstrate that no new radiation degradation products are released by the material.
- Highly-crosslinked Vitamin E Polyethylene liners underwent oxidation analysis per ASTM F2102-06 after accelerated aging per ASTM F2003, wear testing, and exhaustive extraction. The analysis was also conducted on gamma-sterilized GUR 1020 (standard poly) reference material for comparison. The highly crosslinked Vitamin E poly exhibited lower oxidation indices than the standard poly, demonstrating higher resistance to oxidation: mean surface oxidation index was 0.017 for Vitamin E and 0.097 for standard poly; maximum oxidation index was 0.029 for Vitamin E and 0.248 for standard poly; and bulk oxidation index was 0.009 for Vitamin E and 0.036 for standard poly.
- Highly-crosslinked Vitamin E Polyethylene liners were evaluated by polarized light microscopy and SEM analysis of freeze fractured surfaces, after accelerated aging per ASTM F2003 and wear testing, to demonstrate that the subject material has equivalent consolidation to a predicate material.
- Liner Assembly/Disassembly Testing: Testing of the worst case size Pipeline Hip System highly crosslinked Vitamin E poly acetabular liner and worst case size conventional poly liner were tested for push-out, lever out torque, and axial torque.
- Hip Stem Fatigue Testing was conducted for the worst case (smallest) hip stem according to the method described in ISO 7206-4:2010, Implants for surgery-Partial and

total hip joint prostheses, Determination of Endurance Properties and Performance of Stemmed Femoral Components.

- Stem Neck Fatigue Testing of the worst-case size was conducted according to the methods described in ISO 7206-6:1992 Implants for surgery-Partial and total hip joint prostheses-Part 6 and ASTM F2068-03 Standard Specification for Femoral Prostheses – Metallic Implants.
- Pull off testing was conducted on the metal and ceramic femoral heads.
- Burst Strength testing was conducted on Biolox *delta* Femoral Heads according to ISO 7206-10.
- An analysis was conducted of the typical and worst case ranges of motion permitted by the designs of various liner size/style, head size/style, and stem size/style combinations. The ROM was reported for flexion/extension, abduction/adduction, and internal/external rotation per ISO 21535.
- Bone screw testing was conducted in accordance with ASTM F543-07, Standard Specification and Test Methods for Metallic Medical Bone Screws, for torsion (torque to failure) and screw pull-out (pull-out to failure).
- Characterization in accordance with relevant aspects of "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement," was completed for: 1) Acetabular Shell – PST Surface; 2) Acetabular Shell – HA PST Surface; 3) Hip Stem – Plasma-Spray Titanium Coating.
- Characterization in accordance with relevant aspects of "Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball HIP Systems" was completed for the ceramic femoral heads.
- The porous structured surface was evaluated in a transcortical canine model to assess the biological response, using histological and mechanical evaluations, at intervals up to 12 weeks.

Conclusions

The subject PBP Total Hip System shares the same indications for use as the predicate hip system, and a comparison of technological characteristics supported by performance testing demonstrates the Substantial Equivalence of the PBP Total Hip System to the predicate hip systems.

Exhibit 2: Original Truthful & Accurate Statement

6 Truthful and Accurate Statement

Truthful and Accurate Statement

I certify that, in my capacity as Sr. Vice President Research & Development, I believe, to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate, and that no material fact has been omitted.

Robert C. Cohen

July 3, 2012

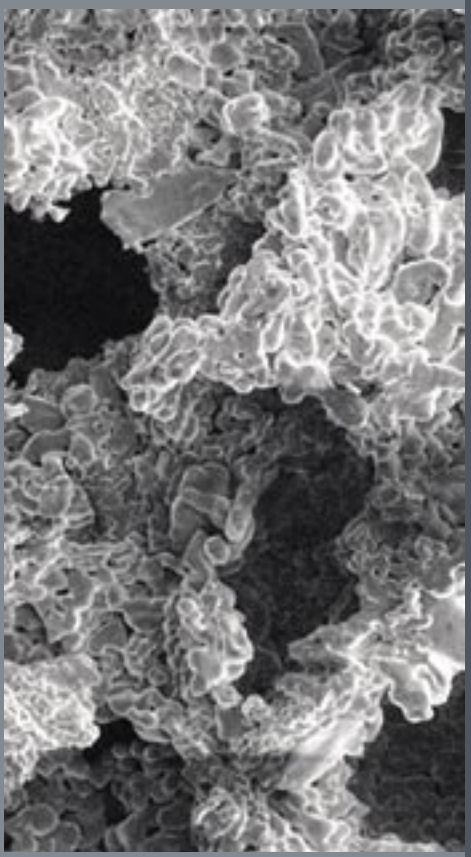
Date

Exhibit 3: Zimmer's Cancellous Structured Titanium

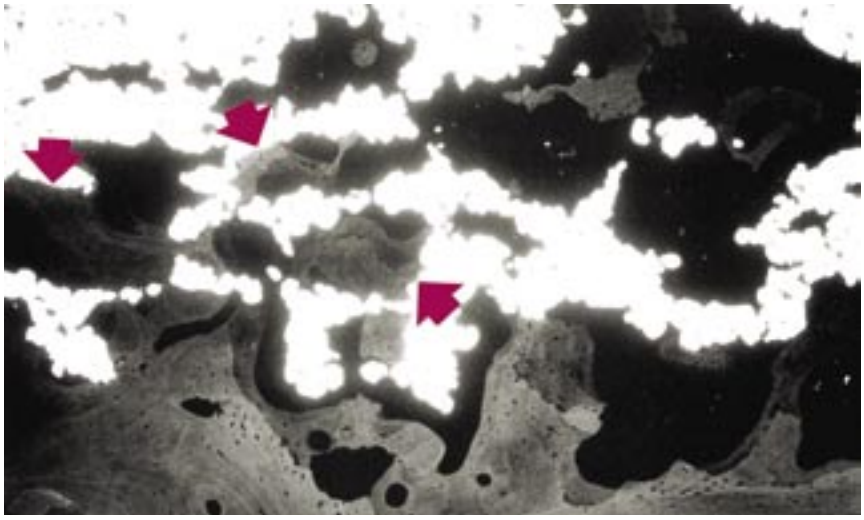
Product Information

Cancellous-Structured Titanium™ (CSTi™)

An optimal structure for bone ingrowth and fixation



zimmer

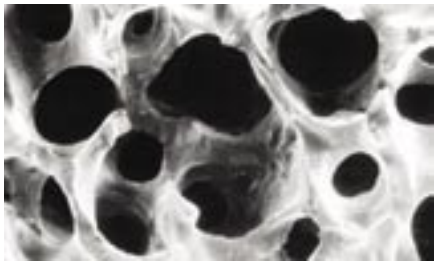


(50:1) Backscattered electron microphotograph of a section of a retrieved CSTi™-coated acetabular component. Note the direct bony attachment to the CSTi (indicated by the arrows) and the large area of neocortex at the interface.[1]

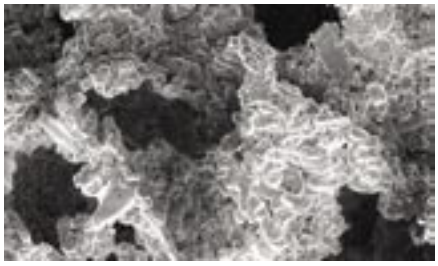
"We have evidence of bone remodeling and growth into the porous coating, CSTi, and evidence of large surface areas of attachment ... all in human bone."

- Roy Bloebaum, PhD.

CSTi™ Porous Coating
Structurally similar to human bone



(100:1) Human cancellous bone[2]. Pore size 400-500 µm. Pore volume 60-77%.



(100:1) CSTi. Pore size 480-560 µm. Pore volume 52-58%.

Cancellous-Structured Titanium refers to the microscopic appearance of CSTi porous coating. CSTi is structurally similar to human cancellous bone and provides interconnected pores for bone ingrowth.

CSTi porous coating combines the excellent biocompatibility of titanium with an optimal structure for bone ingrowth.

CSTi is manufactured through a proprietary process that sinters commercially pure titanium powder onto a titanium or CoCr alloy substrate. During the process, pores are created. This results in a unique porous coating that has optimally-sized, interconnected pores[3] to allow bone ingrowth and a fine micro-roughness to provide secondary fixation.

The CSTi process was originally developed for a titanium alloy substrate. The Sinterlock™ process was developed to apply CSTi onto CoCr-alloy femoral knee components. This bimetal combination was a major advancement that combined the biocompatible properties of CSTi on the bone-contacting side of the implant with excellent wear properties of CoCr for the bearing surface.

Our implant designs are well matched with the CSTi porous coating technology. We offer CSTi options with several of our product lines, including: the Natural-Knee® System, Natural-Hip™ and APR® hip stems, and Converge® CSTi acetabular porous components.

Why CSTi Works

- Excellent biocompatibility of titanium
- Optimal structure for bone ingrowth
- Fine micro-roughness for secondary fixation
- Sintering process results in excellent strength and fatigue properties

Clinical Experience
Over 15 years of clinical success

Summary of Clinical Results

Date	First Author	Implant Type	Number of Implants	Implantation Time	Results
1991	Bloebaum[4]	Tibial baseplate	1 CSTi 1 CoCr	19 mos. CSTi 25 mos. CoCr beads	67% ABI* (CSTi) 9% ABI (CoCr Beads) 22% ingrowth** (CSTi) 0% ingrowth (CoCr beads)
1991	Hofmann[5]	Natural-Knee tibia and femur	183	2 - 4 yrs.	96% good or excellent results
1996	Baldwin[6]	Natural-Knee	109	3 - 5 yrs.	96% good or excellent results 82% no lucencies
1997	Evanich[7]	Natural-Knee Patella	212	6 - 10 yrs.	96% survivorship No lucencies
1997	Hofmann[8]	Bone plug	36	Up to 1 yr.	24% ingrowth
1997	Bloebaum[1]	Acetabular shell	7	38 ± 21 mos.	84% ABI 12% ingrowth
1997	Bloebaum[9]	Tibial baseplate	8	47 ± 36 mos.	73% ABI 6% ingrowth
1998	Bloebaum[10]	Natural-Knee Patella	11	45 ± 36 mos.	86% ABI 13% ingrowth
2000	Hofmann[11]	Natural-Hip	90	81 ± 21 mos.	No subsidence or loosening
2000	Kang[12]	APR-II Hip	99	45 ± 36 mos.	99% good or excellent results 94% no lucencies
2001	Hofmann[13]	Natural-Knee	176	10 - 14 yrs.	10-yr survivorship: 99.1% femoral 99.6% tibial 95.1% patellar

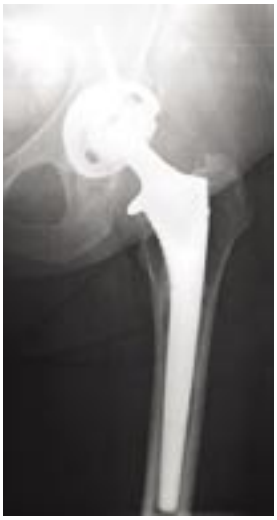
*ABI (appositional bone index) is a measure of the percent of bone in direct contact with the porous surface.

**Ingrowth is determined by the percent volume of bone in the total volume of pores available. This is determined through BSE (back-scattered electron microscopy).

CSTi porous coating has over 15 years of clinical experience with demonstrated success in both retrieval and long-term clinical studies.

The excellent results in these published clinical studies confirm the basic science research supporting CSTi.

Long-term follow-up x-rays and retrieval analysis clearly demonstrate successful fixation and bone ingrowth of CSTi-coated components.



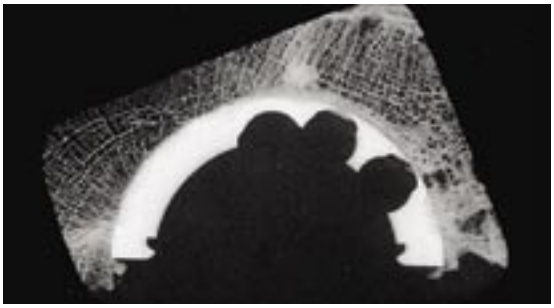
CSTi-coated hemispherical acetabular shell and Natural-Hip porous-coated collared stem. 11-year follow-up.

(Radiograph courtesy of Dr. A Hofmann, University of Utah, Salt Lake City).

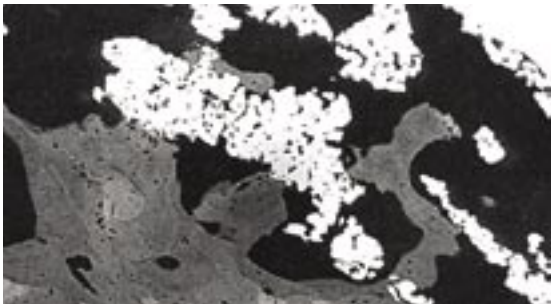
Natural-Knee 10-year follow-up.

(Radiograph courtesy of Dr. A Hofmann, University of Utah, Salt Lake City).

Post-mortem Retrieval Analysis of CSTi-coated Hemispherical Shell†



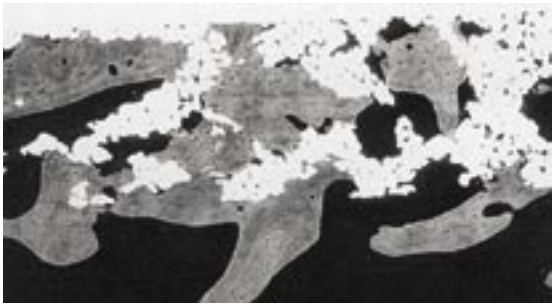
Microradiograph of a section of the shell and surrounding tissues demonstrating bone apposition.



(50:1) Backscattered electron micrograph demonstrating bone growth within pores of CSTi.

Post-mortem Retrieval Analysis of Natural-Knee Tibial Baseplate†

Microradiograph of a section of the tibial baseplate and surrounding tissues demonstrating bone apposition.



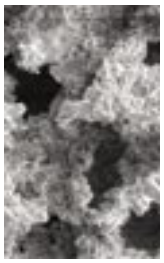
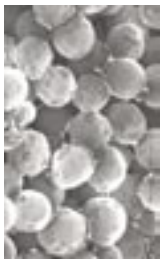
(50:1) Backscattered electron micrograph demonstrating bone growth within pores of CSTi.

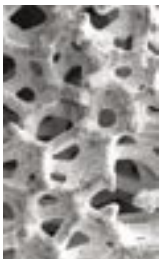
† Retrieval micrographs courtesy of Dr. Roy Bloebaum, Bone and Joint Research Laboratory, University of Utah.

CSTi vs. Other Porous Coatings

The clinical results speak for themselves

Bone Ingrowth / Biologic Fixation Comparison

	CSTi	CoCr Beads	Ti Fiber Mesh	Plasma Spray	Trabecular Metal*
Manufacturer	Centerpulse	Howmedics Osteonics J&J Depuy	Zimmer	Biomet	Zimmer
Pore Size	400 - 600 µm	variable	-	variable	300 µm
Pore Volume	50 - 60%	35%	68%	varaible	70%
Coating Material	Ti	CoCr	Ti	Ti	Ta
Retrieval Results					
% - Ingrowth Tibial Baseplates	6 - 22%[4,9]	6 - 9%[4,15]	9.5%[16]	NA	NA
ABI Tibial Baseplates	73%[9]	36%[15]	27%[16]	NA	NA
% - Ingrowth Acetabular Shells	12%[1]	0 - 10%[17]	12%[18]	NA	NA
ABI Acetabular Shells	84%[1]	NA	0-55%[18]	NA	NA
Clinical Advantages and Features					
Optimal Pore Size	■				■
Optimal Pore Volume	■		■		■
Bone Ingrowth Coating	■	■	■		■
Micro-Surface Texture	■			■	■
Bimetal (Ti coating on CoCr)	■			■	
Interconnected Pores	■	■	■		■
Coating does not Disassociate	■				■*

*Trabecular Metal implants have no substrate. Polyethylene is molded directly onto the metal structure, which also eliminates the possibility of modularity.

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Knees

Apollo® Knee System
Classic condylar knee replacement system

Durasul® Tribological System
Highly crosslinked polyethylene that resists wear and aging

Natural-Knee® System
Anatomic design for superior clinical results

UniSpacer™ Knee System
No bone cuts. No compromises.

Severe Revision/Limb Salvage

MOST Options™ System
Modular knee and hip options for severe bone loss, trauma and revision

Hips

Alloclassic® (Zweymüller™) Hip
Classic proven design with superior clinical results

Allofit™ Acetabular Cup System
Unique Ridgelock™ surface designed for easy implantation and stability

Apollo® Hip System
Designed for optimal results with low-demand patients

APR® Anatomical Hip System
The anatomic solution for bone matching

CLS™ (Spotorno™) Hip System
The standard of proximal press-fit design

Converge® CSTi™ Porous Acetabular Cup System
Where technology and experience meet

Durasul® Tribological System
Highly crosslinked polyethylene that resists wear and aging

FracSure™ Hip System
A classic design for hip fractures

Metasul® Metal-on-Metal Acetabular System
Over 15 years of clinical results & 200,000 implantations worldwide

MS-30™ Hip
A highly polished cemented stem

Natural-Hip™ System
A comprehensive system with a natural approach

Precedent™ Revision Hip System
A better solution for revision hips

SL Revision™ Hip System
A stable revision design with extensive sizes

Upper Extremities

Anatomical™ Shoulder System
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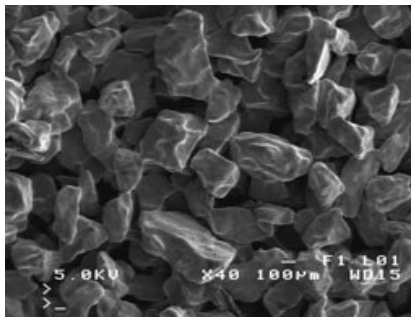
Exhibit 4: DJO's 3D Matrix Porous Coating

3DMatrix porous coating

DJO Surgical has chosen an innovative approach to an industry standard for porous coating on their implants. This coating consists of small, three-dimensional (non-spherical) beads. The porous material is either commercially pure titanium or CoCr alloy, depending on the base substrate. The non-spherical shape of the beads provides more points of contact and a much rougher surface area.

3DMatrix Porous Coating - 100x



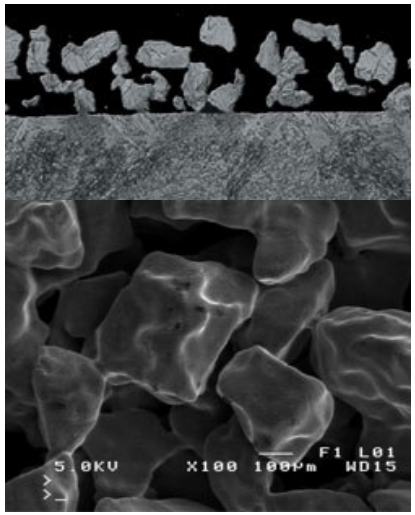
3DMatrix Porous Coating - 40x

Superior Surface Texture

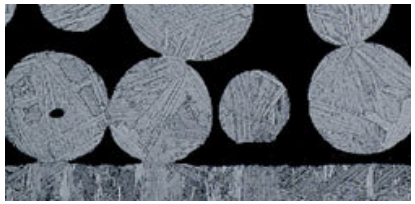
The 3DMatrix® porous coating is much rougher and aggressive than spherical beads, providing for more bone apposition. In a study for bone ingrowth, 3DMatrix porous coating outperformed spherical beads[2].

Aggressive Porous Coating

The 3DMatrix has a thickness of 0.5mm (a minimum of two bead layers), bead size 180-850 microns, and pore size of 250-450 microns. The porosity volume represents 61%. The pore size of 100 to 500 microns has been shown to be optimal for bone ingrowth[1,2].



3DMatrix Porous Coating (cross-section) - 50x



Competitor's Porous Coating (cross-section) - 50x

Bone Ingrowth Study

	Spherical Beads	3DMatrix
Interface sheer strength, MPa	33.29	40.3
Corital bone apposition, %	38.5	63.1
Cancellous bone apposition, %	13.6	22.0

1. Mont MA, Hungerford DS: Proximally Coated Ingrowth Prosthesis. A Review. ClinArthop 344: 139-149, 1997.
2. Data on file at DJO Surgical.

Exhibit 5: Smith & Nephew's StikTite Porous Coating

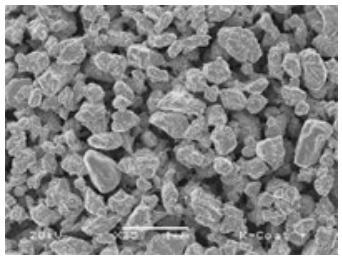
STIKTITE Porous Coating

STIKTITE◊ coating provides primary stability and long-term osseointegration

R3◊ Acetabular System utilizes STIKTITE◊ - a revolutionary proprietary porous shell coating engineered to create additional shell stability while offering an architecture that encourages bony in-growth.

The 60% porosity of STIKTITE◊ creates a balance between long-term in-growth and intraoperative scratch-fit, reassuring positive feedback to the surgeon during impaction.

Enhanced stability and fixation with STIKTITE◊ Porous Coating

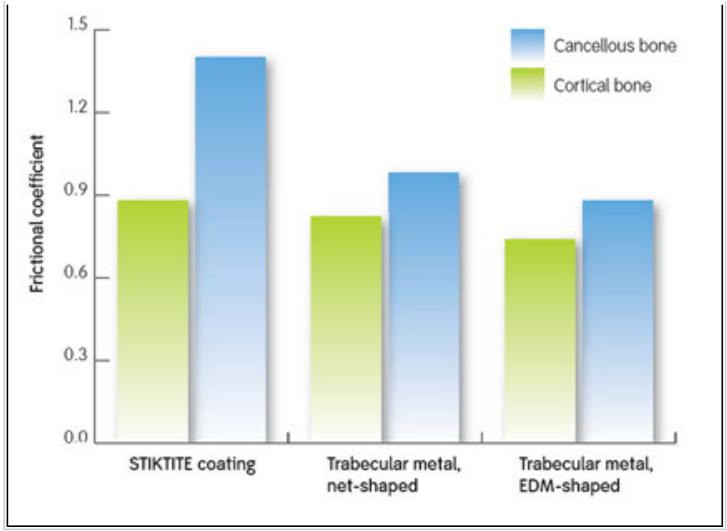


Utilizing STIKTITE◊ coating on the R3◊ Acetabular Shells allows for a true scratch-fit feel during the shell seating and a clinically proven ingrowth surface for long-term implant success.[1]

STIKTITE◊ Porous Coating demonstrated a higher coefficient of friction compared to trabecular metal when tested by the same method.[2] The mean coefficient of friction for STIKTITE◊ coating was higher than that of trabecular metal against both cancellous and cortical bone. These results indicate that STIKTITE◊ coating should have superior friction, scratch-fit feel and initial fixation stability as compared to trabecular metal.

Frictional coefficients of bone ingrowth structures against cancellous and cortical bone (n=96 to 100)[3]

Internal Fixation
Hip Replacement
Gynecology
Grafts/Dermal substitutes
External Fixation
Donor Sites
Diabetic Foot Ulcers
Deformity Correction
Computer Assisted Surgery
Burns
Biomaterials
Access / Fluid Management
Clinical Therapies



STIKTITE◊ coating is a sintered three-dimensional asymmetric titanium powder that has a porosity of about 60%. Increased porosity allows for potentially greater bone ingrowth, which can enhance long-term fixation and implant stability. STIKTITE◊ coating provides enhanced initial mechanical stability, which is particularly important in damaged or less biologically active bone. The average pore size of STIKTITE◊ coating (200 µm) is within the 100– to 500–µm range for optimal bone ingrowth.

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2 Barrack RL. Dislocation after total hip arthroplasty: implant design and orientation. J Am Acad Orthop Surg. 2003 Mar-Apr;11(2):89–99.

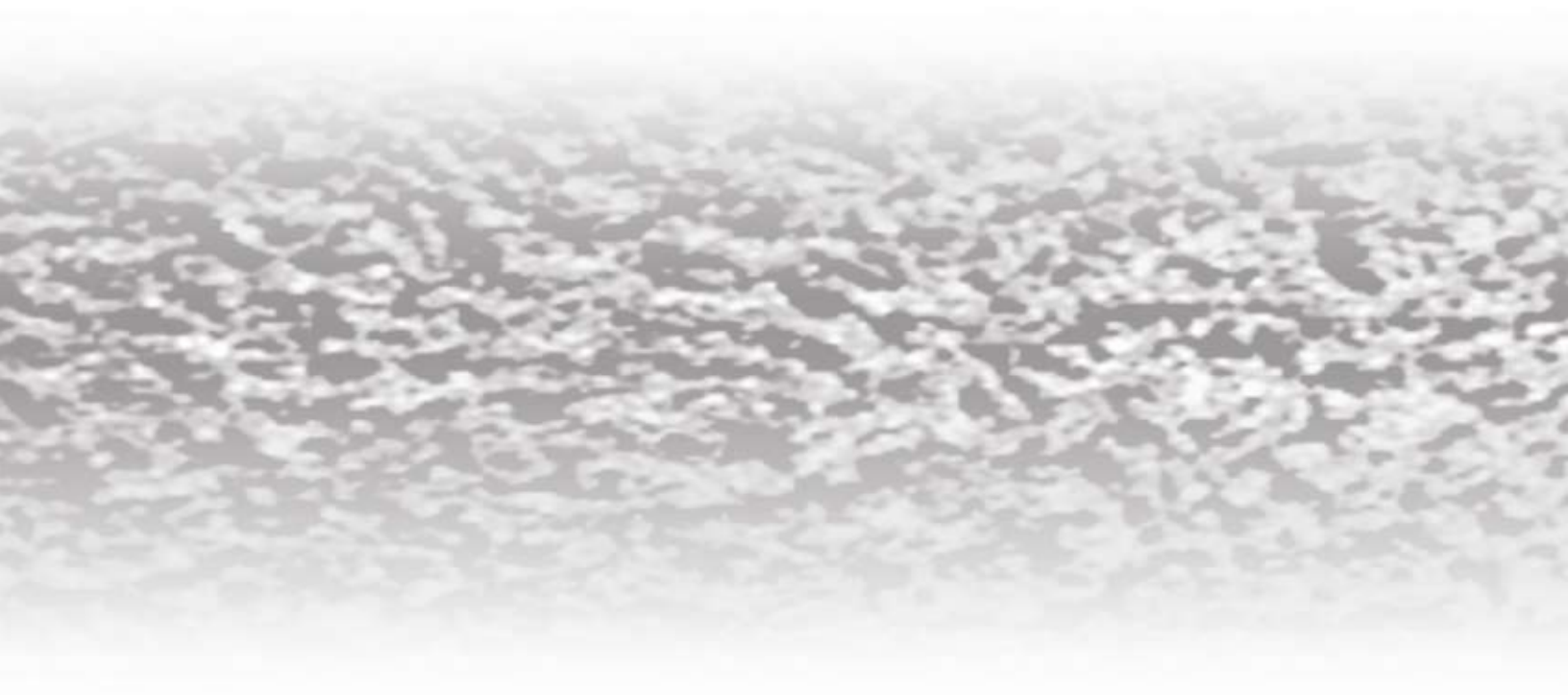
3 Heiner AD, Brown TD. Frictional coefficients of a new bone ingrowth structure. Poster no. 1623 presented at: Orthopaedic Research Society Annual Meeting; Feb 11–14, 2007; San Diego, CA.

Exhibit 6: Biomet's Porous Plasma Spray

Focus On Fixation

PPS® Porous Plasma Spray

BIOMET® ORTHOPEDICS



Focus On FIXATION

The implant surface area is the only aspect of a prosthesis to actually touch a patient's bone, meaning the efficacy of the surface coating is an important contributing factor to the long-term stability of cementless arthroplasty.

In determining which implant and surface coating is best for your patients, consider the following:

- *How are initial stability and fixation achieved?*
- *To what degree will osseointegration occur, and when?*
- *Will the coating successfully inhibit debris migration?*

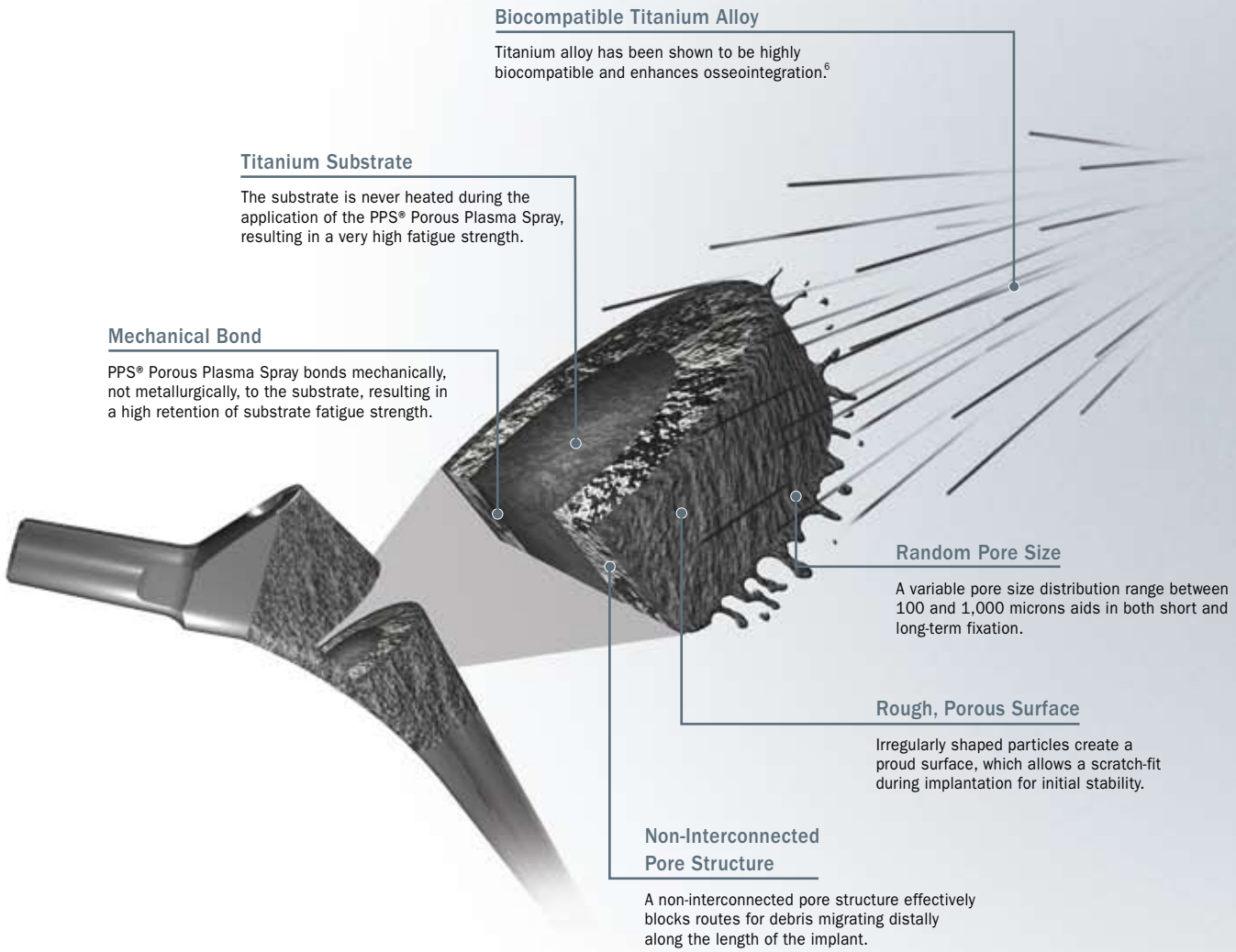
By addressing these issues since its introduction in 1981, Biomet's PPS® Porous Plasma Spray has achieved outstanding clinical success, as documented by numerous studies. At follow-up, many surgeons have observed extremely low rates of osteolysis and nearly 100% survivorship at over 10 years with PPS® coated prostheses.[1, 2, 3, 4]

PPS® Porous Plasma Spray

- Creates a mechanical interlock with the substrate, resulting in nearly a two-fold increase in fatigue strength when compared with sintered surface coatings.[5]
- Provides initial implant stability through a scratch-fit fixation obtained by enhanced surface roughness.
- Maximizes short and long-term ingrowth through random, non-interconnected pores and pore size distribution.
- Creates a barrier to migrating debris particles, reducing the likelihood of osteolysis.[3]

Focus On *Time-Proven Design & Process*

The application of Biomet's titanium porous plasma spray coating is a computer controlled process subject to strict manufacturing tolerances for particle size, voltage current and gas pressure. The resulting rough, mechanically bonded circumferential coating aids in short and long-term fixation and greatly reduces the risk of osteolysis through its non-interconnected pore structure. The figure below details engineering characteristics that contribute to Biomet's PPS® Porous Plasma Spray's continuing clinical success.



Focus On *Mechanical Properties*

All prostheses are subjected to extremely high loads once implanted, particularly in weight-bearing joints. Biomet uses specialized manufacturing procedures to optimize substrate quality and implant strength, allowing for long-term viability.

Substrate Preparation

To combat notch sensitivity (a phenomenon where small surface imperfections on the substrate can adversely affect fatigue strength), Biomet prepares the substrate surface to maximize fatigue strength and ensure strong mechanical bonding.

Shot Peening—Bombarding the titanium substrate with small beads induces compressive stress deep within the surface, increasing fatigue strength and reducing notch sensitivity.

Grit Blasting—The substrate's roughened surface aids in the mechanical interlocking between the implant and the PPS® Coating.

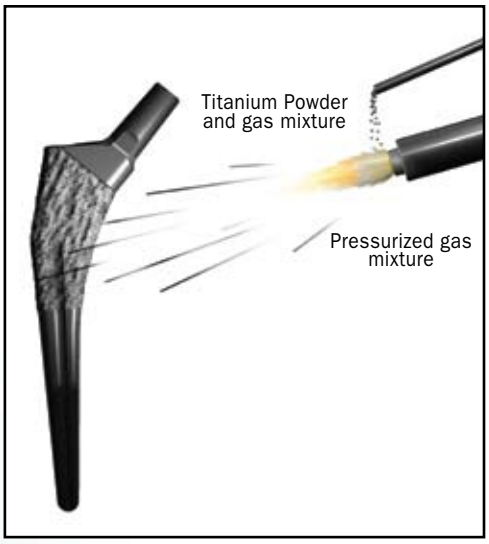
Titanium Alloy Coating—Within the plasma chamber, irregularly shaped titanium alloy powder is projected at high speeds through a high temperature plasma arc, striking the substrate in a semi-molten state. The molten outer shell of each particle flows over the grit-blasted roughened substrate surface and solidifies, resulting in a strong mechanical interlock with the substrate.

Bead Blasting—The finished prosthesis is bead blasted to remove any loose coating particles.

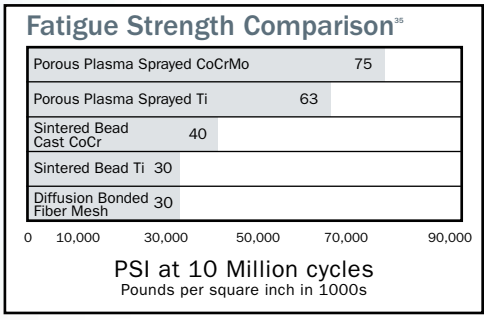
Result of Plasma Spray Process

Maintaining an implant's inherent fatigue strength allows for a stronger prosthesis that is better able to withstand daily patient demands with lower risk of breakage to provide for increased longevity.

Biomet's proprietary plasma spray application is unique in comparison to competitive methods due to the fact that only the titanium alloy powder is heated, not the substrate of the implant. "With the sintering or diffusion bonding techniques, the mechanical strength of the substrate is reduced by 50% or more…Plasma spray techniques allow the substrate material to retain 90% or more of the fatigue strength characteristics reported for uncoated titanium alloy implants."[5]



Biomet applies PPS® Porous Plasma Spray in a way that protects the substrate from heat damage, maintaining important fatigue strength properties and permitting the production of high fatigue strength components (such as the 5mm Taperloc® hip) for smaller patients.



Titanium PPS® Porous Plasma Spray being applied through a heated plasma arc.

Focus On *Scratch-Fit*

Biomet's PPS® Porous Plasma Spray is unique among surface coatings in its ability to attain immediate post-operative fixation. Unlike smooth beads and fiber mesh, the surface of plasma spray on a microscopic level is very rough, resulting in markedly higher coarseness and surface interlocking (Fig. 1).

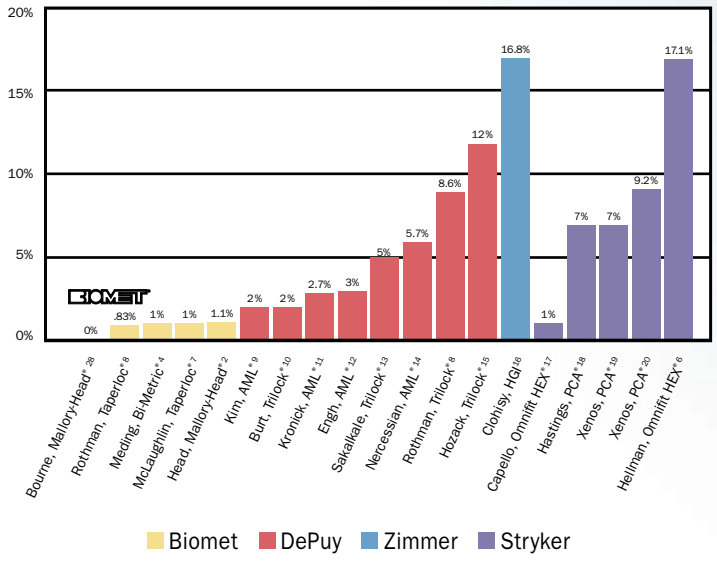
Achieving Immediate Fixation

All surface coatings may have varying degrees of surface roughness to the touch; however, roughness makes a difference in fixation at the microscopic and cellular level. PPS® Porous Plasma Spray's microscopic roughness is the result of irregularly shaped pores, inducing osseointegration by creating a "scratch-fit" between the porous coating and the cortical bone during prosthesis insertion. This scratch-fit action causes the rough titanium surface to scrape the walls of the femoral canal, filling the small pores with bone and providing excellent initial stability. Implants with a smooth surface profile (such as sintered beads) have limited microroughness.

Fig. 1: PPS® Plasma Spray.

Biomet's superior clinical results with cementless prostheses are a direct result of the immediate fixation achieved through titanium alloy PPS® Porous Plasma Spray.

Primary Cementless Hip Stem Failure Rates: 10+ Year Follow-Up



A study comparing the scratch-fit stability of acetabular shells with three different porous coatings concluded that PPS® Porous Plasma Sprayed cups were twice as strong in resistance to rim failure as the beaded or fiber mesh cups.[21]

Focus On *Pore Size Distribution*

Optimal fixation may be achieved as a result of an ideal pore size distribution attained through the PPS® Porous Plasma Spray application process (Figs. 3&4).

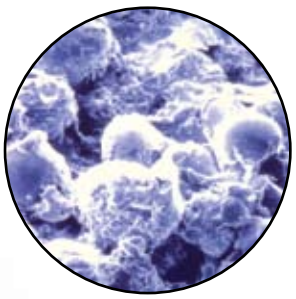


Fig. 3: The irregularly shaped titanium particles sprayed onto the substrate result in a wide pore size distribution, which allows optimal fixation through mechanical interlocking with the ingrowing bone.

Successful Osseointegration with PPS® Porous Plasma Spray

The engineering design of an implant's surface coating seeks to maximize cortical bone contact through a moderately proud profile and a wide distribution of pore sizes to encourage full osseointegration. In keeping with these principles, Biomet's proprietary application process distributes multiple coats of porous titanium alloy over the substrate, creating layers of varying pore sizes intended to maximize osseointegration. The circumferential coating also sits high enough off of the substrate to provide stable scratch-fit fixation.

Increasingly, surgeons are encouraging patients with Biomet's PPS® Porous Plasma Sprayed implants to weight-bear immediately post-op, which attests to the value of scratch-fit fixation.[22]

Fixation with Beads

In the case of large beads, the smooth beaded surface and large interconnected pores may fail to provide initial stability and a barrier to debris migration, which could potentially lead to micromotion, early loosening or dislocation.[23] Other sintered bead surfaces (Fig. 5) composed of only very small pore sizes may result in questionable long term fixation.[3] According to one study, "The strength of the interfaces [bone-to-prosthesis] formed by the PPS® coated specimens exceeded [sintered bead] porous coated specimens by 81%."[24] Similarly, the smooth surface of wire mesh combined with its large pore structure could fail to achieve successful initial fixation (Fig. 6).[23]

Fig. 4

Biomet's PPS® Porous Plasma Spray vs. Other Plasma Sprays

The fabrication process of Stryker Arc Deposition (Fig. 7) is similar to Biomet's in that it entails shooting titanium particles through a plasma flame but not in a fashion conducive to porosity, fixation and long-term stability. The Food & Drug Administration prohibits Stryker from marketing Arc Deposition as "promoting biological ingrowth" because it is a non-porous coating.[25]

Fig. 5: Uniform sized beads results in uniform sized pores.

Fig. 6: Large pore structure of fiber mesh is the result of similar sized wires.

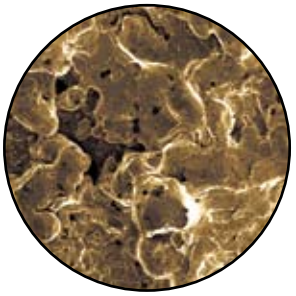


Fig. 7: Stryker Arc Deposition is defined as a non-porous surface and is not indicated for biological ingrowth.[25]

Focus On *Preventing Osteolysis*

PPS® Porous Plasma Spray is designed to prevent debris from migrating distally, minimizing the greatest threat to implant longevity: osteolysis.

Non-Interconnected PPS® Porous Plasma Spray

PPS® Porous Plasma Spray, by its design, has no defined pathways through which particle debris can travel due to its non-interconnected pore structure. Together, the seal between the titanium substrate and non-interconnected circumferential porous coating creates a barrier to particulate debris migration that helps reduce osteolysis and improve long-term fixation (Fig. 8).
Most modern coatings are fully circumferential; however, a fully circumferential coating may not guard against osteolysis, particularly if the coating's pore structure is interconnected, such as in sintered beads (Fig. 9).

This may result in a greater risk of particulate matter passing unobstructed proximally to distally.[26]

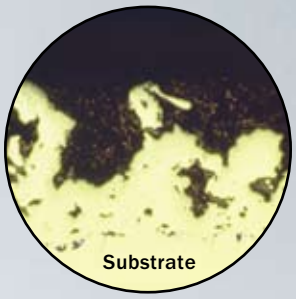
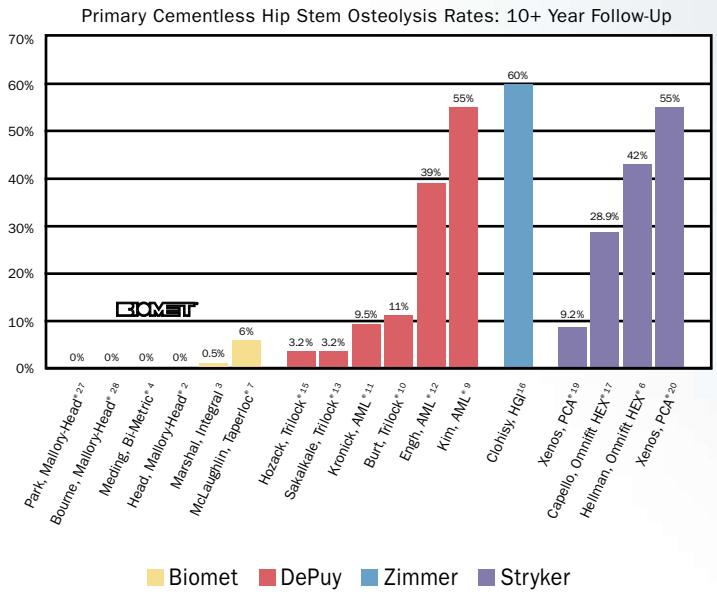


Fig. 8: 50x photomicrograph of the non-interconnected pores of PPS® Porous Plasma Spray

Fig. 9: 50x photomicrograph of the interconnected pores of a sintered bead coating

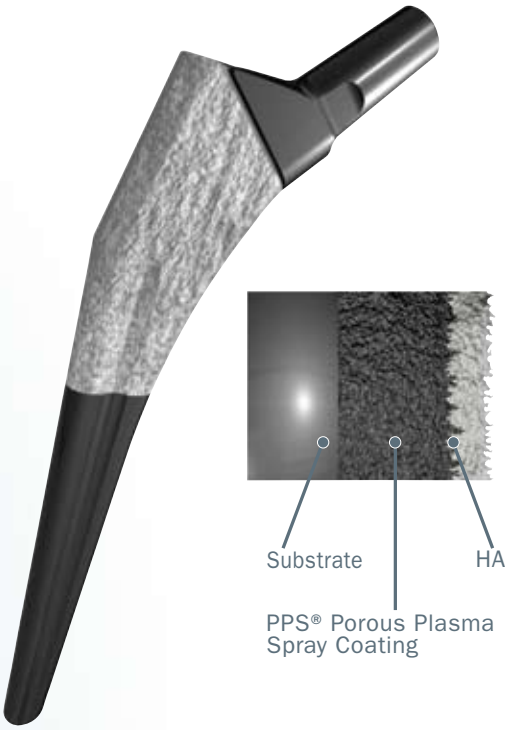
The construct of Biomet's non-interconnected PPS® Porous Plasma Spray is critical to the long-term performance of the prosthesis.



Focus On *Hydroxyapatite*

Biomet's Osteocoat® HA coating provides for accelerated bony ingrowth. A 2001 *JBJS* study demonstrated that Hydroxyapatite stimulates osteoblastic activity for optimal initial stability when applied over the top of the clinically proven PPS® Porous Plasma Spray.[29]

The following characteristics of Hydroxyapatite composition have a considerable impact on its clinical success.[30]



Features of Biomet's OsteoCoat® HA Coating

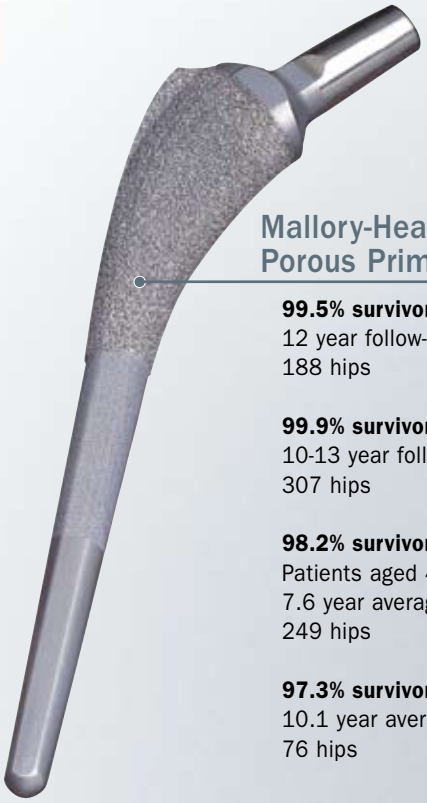
Pore Size- Hydroxyapatite enhances PPS® Porous Plasma Spray's proven clinical effectiveness by its thin surface coating (~ 75 microns) designed to enhance bony ingrowth. The resultant post-ingrowth pore size of plasma spray is entirely unaffected by the HA coating. When Hydroxyapatite is broken down and replaced by the body, the underlying titanium PPS® Porous Plasma Spray coating may be integrated to an even greater extent.

Crystallinity- Crystallinity is a measure of a substance's structural homogeneity. Although there is no recognized ideal crystallinity, an HA coating with a very high crystallinity is resorbed slowly, generating slow osseointegration. However, a very low crystallinity value results in rapid resorbtion, preventing the body from generating a meaningful bone producing response. Biomet's HA coating employs a crystallinity value greater than 50% but less than 70%, which allows the coating to perform as intended within the body.

Purity- HA is most effective when it is highly refined and contains very few extraneous substances. Biomet maintains a very high purity (95%+) for all HA products. The remaining phases are calcium phosphates.

Thickness- The process of breaking down HA and replacing it with natural bone can take months, but the immediate post-operative period is perhaps the most critical in determining success. An extremely thick HA coating (>100 microns) will act the same as a thin coating; however, the body is unlikely to resorb it fast enough to fully interdigitate bone with the prosthesis. Biomet applies a 75 micron layer over PPS® Porous Plasma Spray to maximize the body's natural bone-producing response and fully leverage the power of rapid fixation.

Focus On *Unparalleled Clinical Results*



Mallory-Head® Porous Primary Hip Stem

99.5% survivorship[2]
12 year follow-up
188 hips

99.9% survivorship[28]
10-13 year follow-up
307 hips

98.2% survivorship[33]
Patients aged 40 years and younger
7.6 year average follow-up
249 hips

97.3% survivorship[27]
10.1 year average follow-up
76 hips

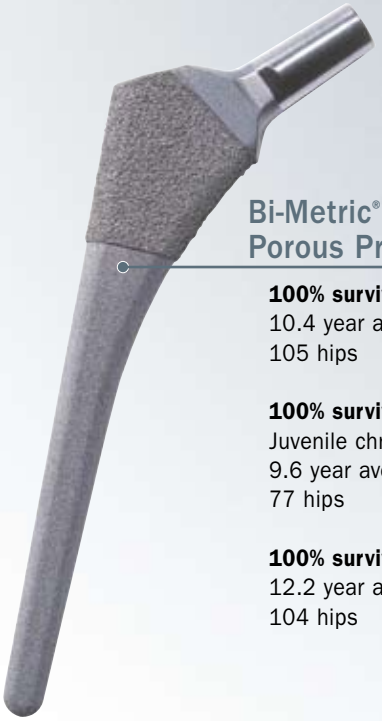
Taperloc® Hip Stem

99.6% survivorship[8]
12 year follow-up
4,750 hips

98% survivorship[7]
8-12 year follow-up
114 hips

100% survivorship[31]
Rheumatoid arthritis patients
5 year follow-up
50 hips

95% survivorship[32]
Obese patients
14.5 year average follow-up
100 hips



Bi-Metric® Porous Primary Hip Stem

100% survivorship[4]
10.4 year average follow up
105 hips

100% survivorship[34]
Juvenile chronic arthritis patients
9.6 year average follow-up
77 hips

100% survivorship[30]
12.2 year average follow-up
104 hips

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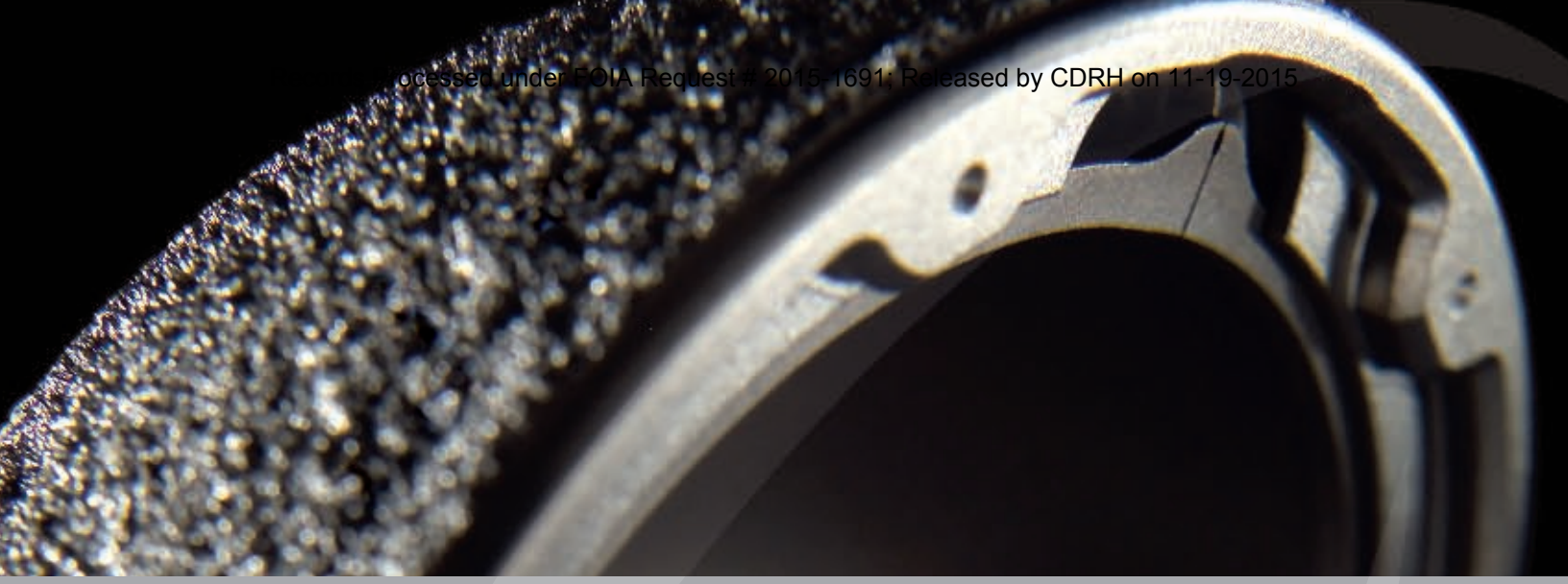
Exhibit 7: Biomet's Regenerex Porous Coating



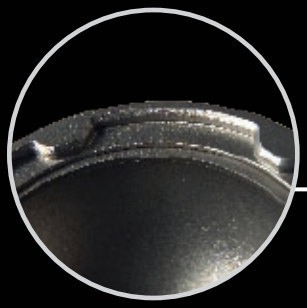
clinically proven material.
advanced porous technology.

REGENEREX™ RINGLOC®+
Modular Acetabular System

BIOMET® ORTHOPEDICS

RINGLOC®+: NEXT GENERATION CUP FEATURES

Building on the success of unparalleled RingLoc® technology, the new RingLoc®+ shell design offers next generation cup features paired with advanced Regenerex™ porous titanium construct.

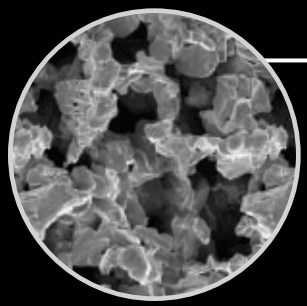


Extended rim +

Designed to prevent soft tissue entrapment between shell and liner

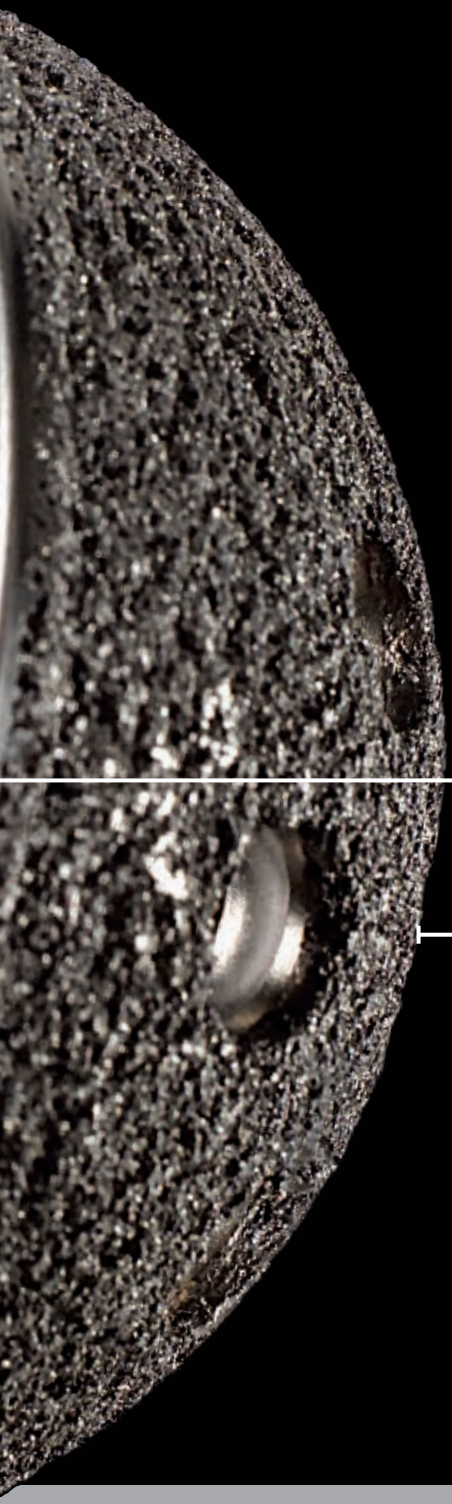
Regenerex™ Porous Titanium Construct

Unites clinical history of titanium with an enhanced interconnecting pore structure for rapid bone ingrowth.



regenerex™
porous titanium construct

RINGLOC®+
acetabular series



Un-lock/re-lock mechanism +

Allows for easy disassembly without damaging the liner**

Large dome hole +

Designed for ease of insertion

Solid

Limited hole

Multi-hole

**Any time the liner is removed, it is recommended that the locking ring be removed and replaced with a new one. If the liner is damaged in any way, a new liner should be utilized.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

RINGLOC®: UNPARALLELED LOCKING TECHNOLOGY

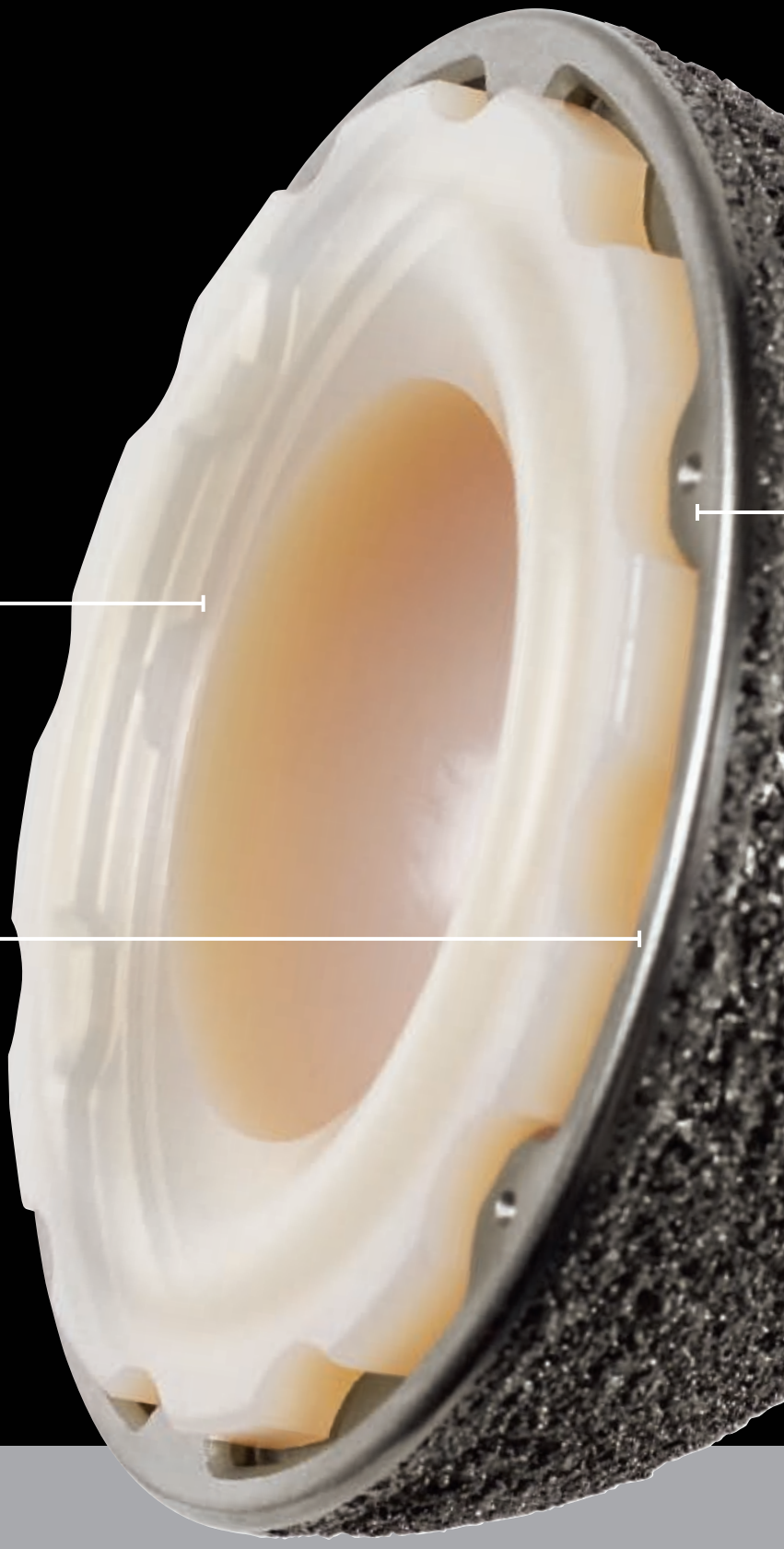
Biomet's RingLoc® acetabular components have redefined the standard of acetabular technology. Testing by independent laboratories has rated RingLoc® technology among the highest in terms of push-out, lever-out and congruity of the implant as well as the lowest in micromotion.[2–5]

Unparalleled RingLoc® locking technology

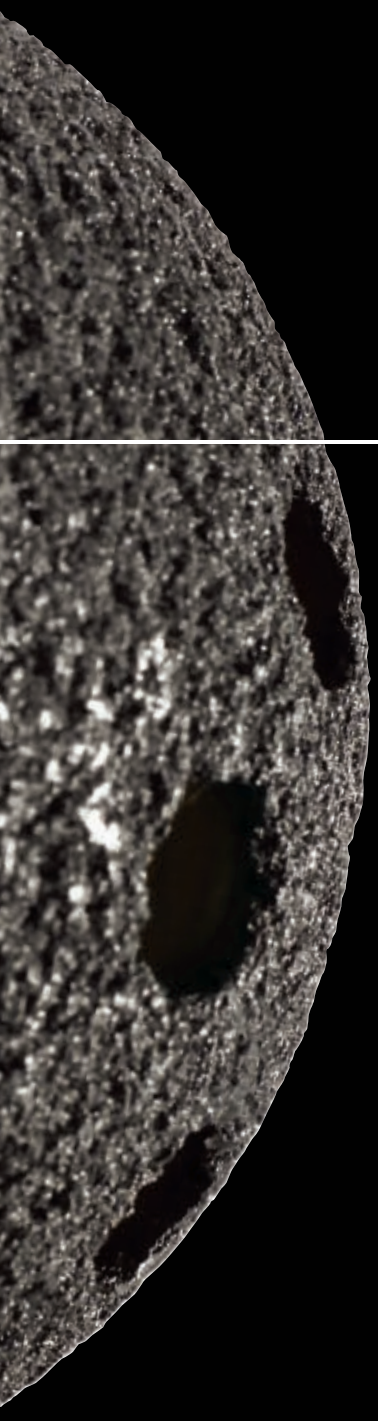
Achieves maximum push-out and lever-out strength with lowest micromotion of independently tested competitive systems[2–5]

Fully congruent design

Maximizes congruency at the liner-to-shell interface to help minimize micromotion

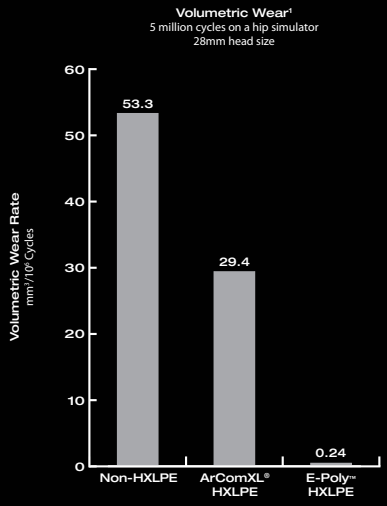


RINGLOC®+
acetabular series



Anti-rotational tabs

Six or eight tabs create an interference fit with the notches on the liner to provide for maximum rotational stability and minimum micromotion



Ultra-low wear with large heads

Combine with E-Poly™ HXLPE for the optimal combination of fixation and low wear. 40mm E-Poly™ liners demonstrated 95% lower wear than 36mm clinically proven ArCom® liners[6]

E-Poly™
HXLPE

regenerex™
porous titanium construct

VERSATILE MODULAR DESIGN FEATURING REGENEREX™ POROUS TITANIUM CONSTRUCT

Regenerex™ Porous Titanium Construct is a revolutionary technology engineered for rapid bone ingrowth by uniting the proven clinical history of titanium with an enhanced interconnecting pore structure.

Integrated with Biomet's unparalleled RingLoc® technology, only the Regenerex™ RingLoc®+ Modular Shell offers new next generation RingLoc®+ cup features, which have been engineered to meet the needs of the orthopedic community.

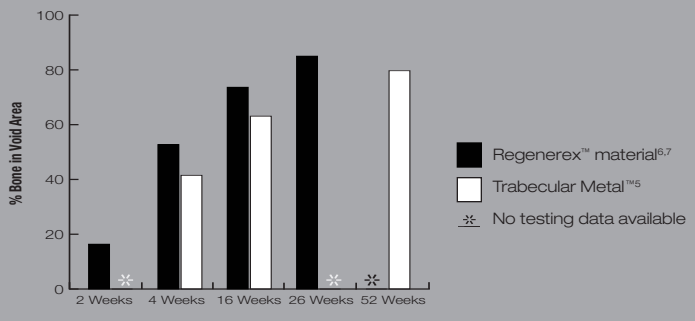
Rapid bone integration

- Two weeks after insertion, Regenerex™ implants displayed bony integration and vascularization.
- In similar canine studies, Regenerex™ material demonstrated more rapid ingrowth than Zimmer's Trabecular Metal.™[6]

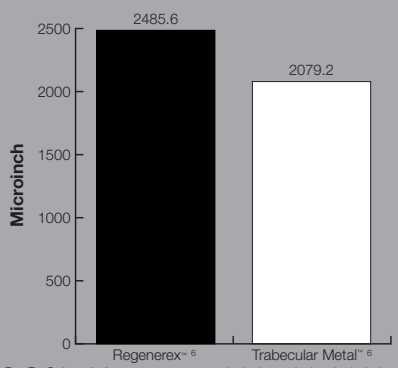
Initial stability

- 16% rougher than Trabecular Metal,™[6] the initial scratch-fit, stability and fixation of Regenerex™ implants is well-suited for acetabular reconstruction.

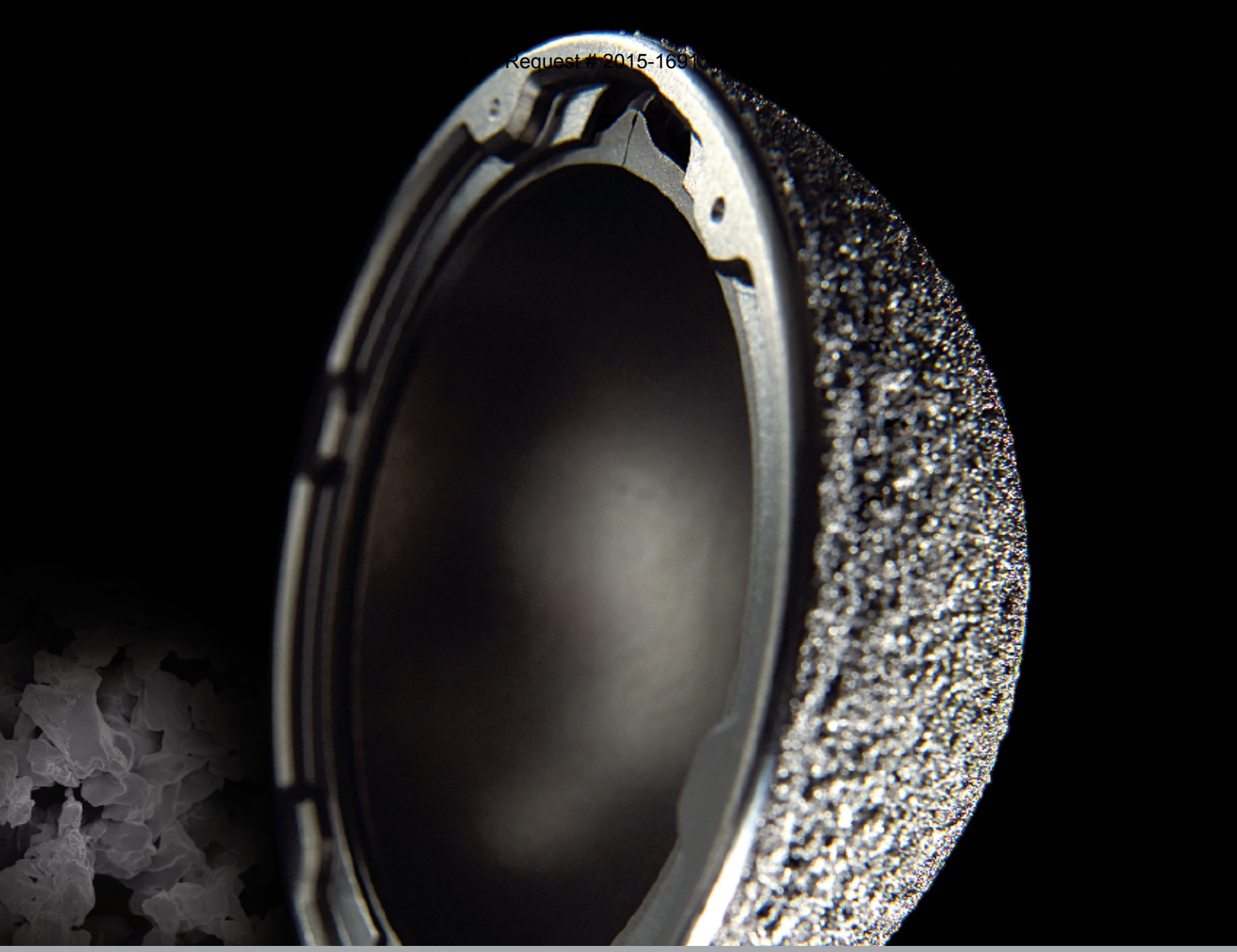
BONE INGROWTH[1,6]



AVERAGE ROUGHNESS (Ra)



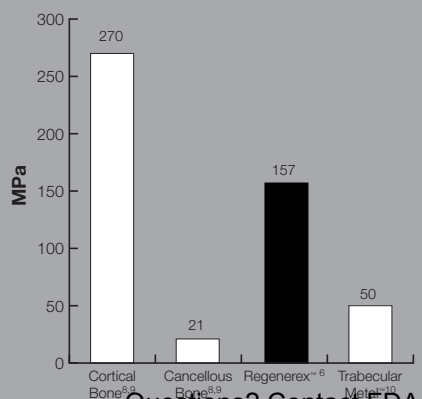
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118



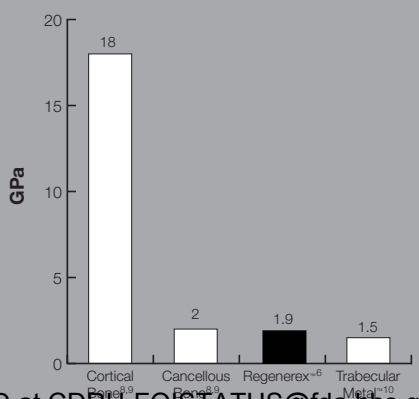
Strong, yet flexible

- 300% stronger than Trabecular Metal™ under compressive loads[1], which reduces the risk of material failure.
- Maintains a compressive modulus similar to cancellous bone.

PEAK COMPRESSIVE STRESS



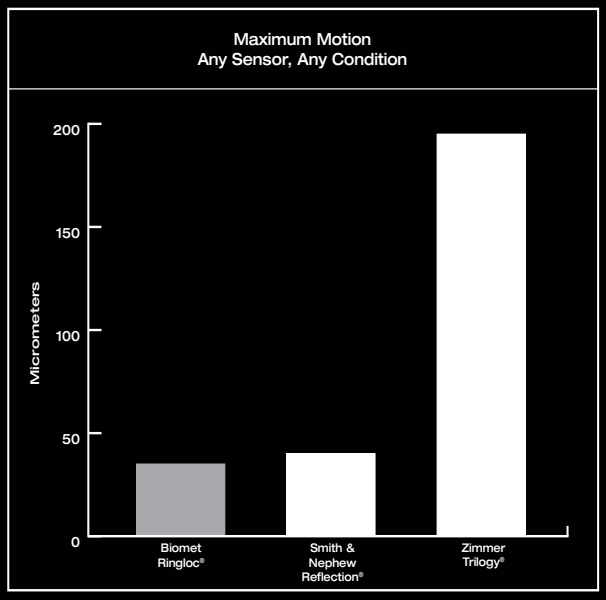
COMPRESSIVE MODULUS



RINGLOC® TECHNOLOGY: PROVEN AFTER 15 YEARS OF CLINICAL USE

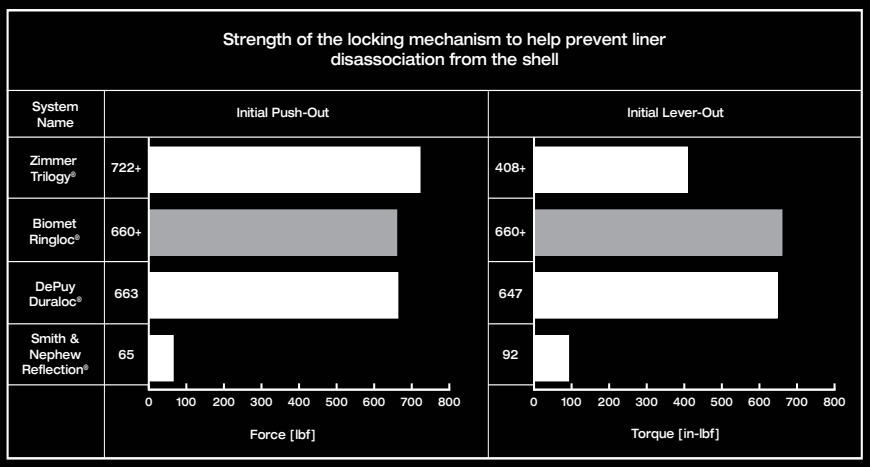
Various forces including toggling, levering and rotation are present during normal acetabular kinematics. To extend acetabular component life and help reduce potential debris generation, the shell-to-liner locking mechanism must be sound. Independent labs have consistently rated Biomet's RingLoc® cups among the best.

- Proven to be a superior locking mechanism for polyethylene liners[2–5]
- High strength of the locking mechanism helps prevent liner disassociation from the shell
- Fully supported liner for even stress distribution
- Lowest micromotion of all tested systems to help eliminate debris generation



Data derived from Fehring TK, Smith SE, Braun ER, Mobley CE, Wang PL, Griffin WL: Motion at the Modular Acetabular Interface: A Competitive Study. Scientific Exhibit presented at the American Academy of Orthopaedic Surgeons. 62nd Annual Meeting. Atlanta, GA. 1996.

RINGLOC®+
acetabular series



Trodonsky, S. *et al.*: Performance Characteristics of Two-Piece Acetabular Cups. Scientific Exhibit presented at the American Academy of Orthopaedic Surgeons. 59th Annual Meeting. San Francisco, CA. 1992.

Trodonsky, S. *et al.*: Performance Characteristics of Two-Piece Acetabular Cups Series II. Scientific Exhibit presented at the American Academy of Orthopaedic Surgeons. 62nd Annual Meeting. Atlanta, GA. 1996.

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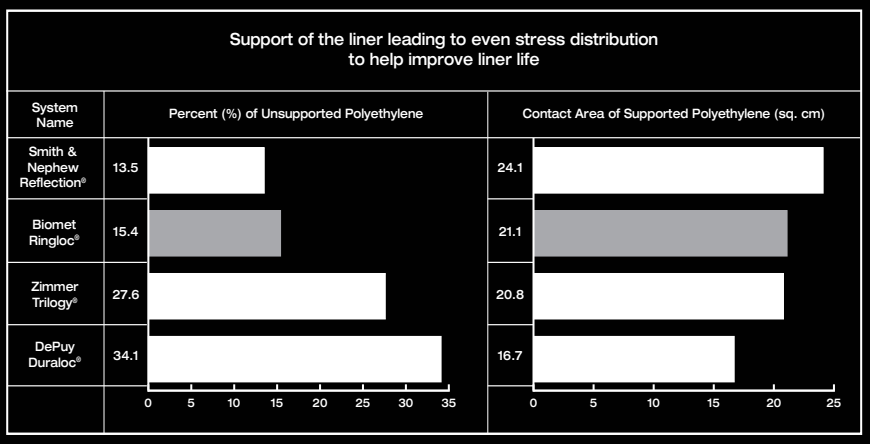


Data derived from Rosner BI, Postak PD, Greenwald AS: Cup Liner Conformity of Modular Acetabular Designs. Scientific Exhibit presented at the American Academy of Orthopaedic Surgeons. 61st Annual Meeting. Orlando, FL. 1995.

Data derived from Rosner BI, Postak PD, Greenwald AS: Cup/Liner Incongruity of Two Piece Acetabular Designs: Implications in the Generation Polyethylene Debris. Scientific Exhibit presented at the American Academy of Orthopaedic Surgeons. 60th Annual Meeting. New Orleans, LA. 1994.

This data is the property of the Orthopaedic Research Laboratories of the Mt. Sinai Medical Center, Cleveland Ohio. The reproduction and distribution of this data are restricted.

VERSATILITY WHEN YOU NEED IT MOST…

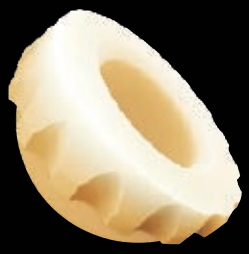
Multiple augment options

- Designed to help maximize acetabular stability
- Available in 12 sizes with multiple screw holes
- Augments can be stacked for complex reconstruction
- Ideal option for complicated revision surgery

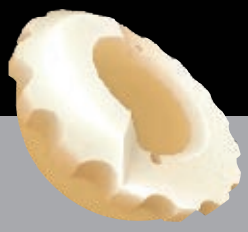
Multiple liner configurations

- Available in…

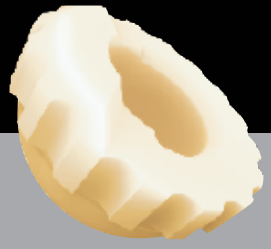
Max-Rom™ Liner



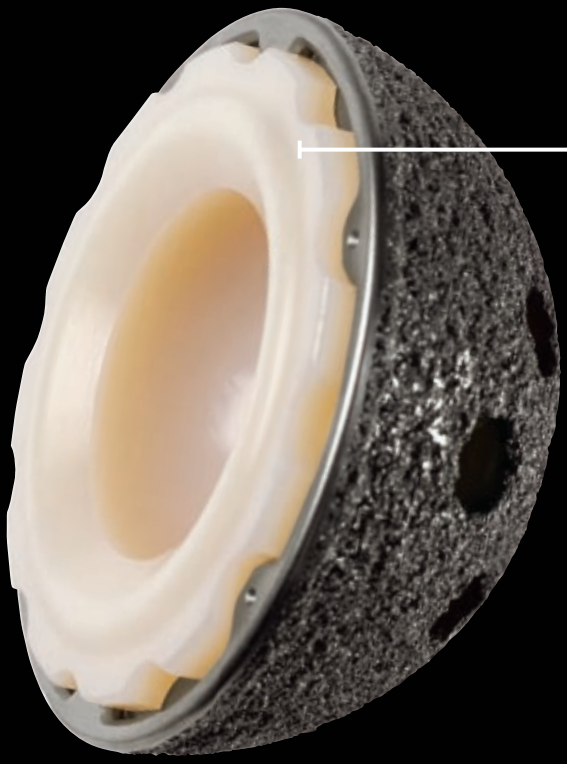
10-Degree Liner



Hi-Wall Liner



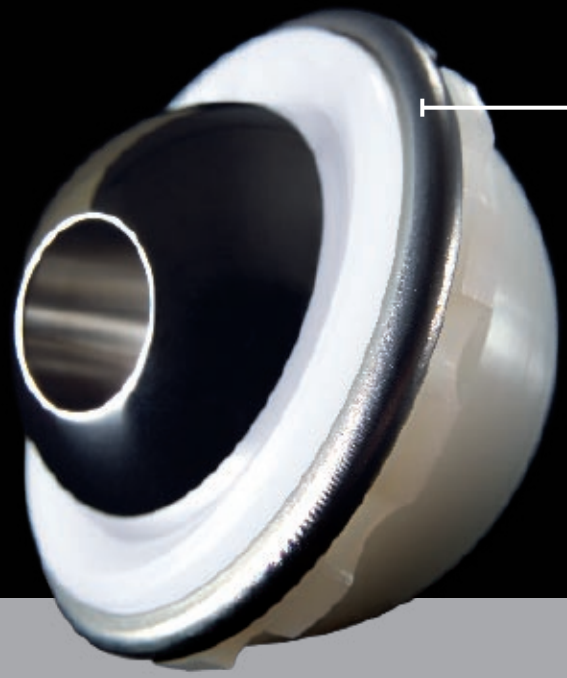
+5mm Hi-Wall Liner



Ultra-low wear with large heads

- Combine with E-Poly™ HXLPE for the optimum combination of fixation and low wear
- 40mm E-Poly™ liners demonstrated 95% lower wear than 36mm ArCom® liners[6]

E-Poly™ HXLPE



Maximum resistance to dislocation

- Combine with Biomet's Freedom® Constrained Liner for patients at high dislocation risk
- Allows for 110 degrees range of motion
- Multiple liner options

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

References

1. Data on file at Biomet. Bench test results not necessarily indicative of clinical performance.
2. Fehring, T.K. *et al.* Motion at the Modular Acetabular Interface: A Competitive Study. Scientific Exhibit presented at the American Academy of Orthopaedic Surgeons. 62nd Annual Meeting. Atlanta, GA. 1996.
3. Rosner, B.I. *et al.* Cup Liner Conformity of Modular Acetabular Designs. Scientific Exhibit presented at the American Academy of Orthopaedic Surgeons. 61st Annual Meeting. Orlando, FL. 1995.
4. Rosner, B.I. *et al.* Cup/Liner Incongruity of Two Piece Acetabular Designs: Implications in the Generation of Polyethylene Debris. Scientific Exhibit presented at the American Academy of Orthopaedic Surgeons. 60th Annual Meeting. New Orleans, LA. 1994.
5. Trodonsky, S. *et al.* Performance Characteristics of Two-piece Acetabular Cups. Scientific Exhibit presented at the American Academy of Orthopaedic Surgeons. 59th Annual Meeting. San Francisco, CA. 1992.
6. Data on file at Biomet. Testing done on animal models.
7. Bobyn, J.D. *et al.* Characteristics of Bone Ingrowth and Interface Mechanics of a New Porous Tantalum Biomaterial. *Journal of Bone and Joint Surgery (British).* 81-B(5): 907, 1999.
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BOI0052.0 • REV083107

Exhibit 8: Wright's Biofoam Porous Coating

BIOFOAM™

CANCELLOUS TITANIUM™ Matrix

Fixation with Bite.™

WRIGHT.

FIXATION WITH BITE

On behalf of the entire Wright Medical Corporate team we are pleased to announce the Launch of DYNASTY® BIOFOAM™ Acetabular Cup System. The addition of BIOFOAM™ adds an entirely new and exciting scope to this successful product line.

In keeping with the DYANSTY® tradition, surgeons will continue to have the advantages of BFH technology, A-CLASS® Metal, A-CLASS Poly, and the option for screw fixation. The addition of BIOFOAM™ makes this cup the ultimate Revision option. The configuration of these cups will allow for up to 10 screw holes on the larger diameter cups.

Included in this literature piece, you will find information on the following,

- Frequently Asked Questions
- BIOFOAM™ Talking Points
- Technical Data
- The BIOFOAM™ Process
- Competition
- Ordering Information
- Contact Information

KEY SELLING POINTS

- Immediate Rigid Fixation
- Greater Resistance to Spin-Out
- Multiple Bearing Surfaces with Big Heads.

FREQUENTLY ASKED QUESTIONS

Are the instruments the same for DYNASTY® and DYNASTY BIOFOAM™?

Yes, the instrumentation is the same.

How thick is the BIOFOAM™ CANCELLOUS TITANIUM™? How does this compare to beads?

The BIOFOAM™ is 1.5mm thick. Beads are 0.75mm thick. BIOFOAM™ CANCELLOUS TITANIUM™ is thicker because of the interconnectedness of its pores (which do not connect within a bead structure) allowing bone to grow all the way to the substrate.

What is BIOFOAM™ CANCELLOUS TITANIUM™ made from?

BIOFOAM™ is made of commercially pure Titanium. The modulus is similar to Tantalum (both around 3 GPa).

Is there an HA coated option for DYNASTY® BIOFOAM™?

No.

FREQUENTLY ASKED QUESTIONS

Will the DYNASTY® BIOFOAM™ shell feel different during implantation as compared to a porous coated shell?

Yes. The immediate fixation will feel a lot more solid due to the rougher surface and the increased coefficient of friction.

What is the pore volume of the BIOFOAM™ material?

Pores are roughly 500 microns in diameter.

What are the main points to address when selling BIOFOAM™ CANCELLOUS TITANIUM™?

BIOFOAM™ CANCELLOUS TITANIUM™ is a true trabecular architecture.

It is roughened to enhance immediate fixation during surgery, and bone in-growth through osteoconductive matrix

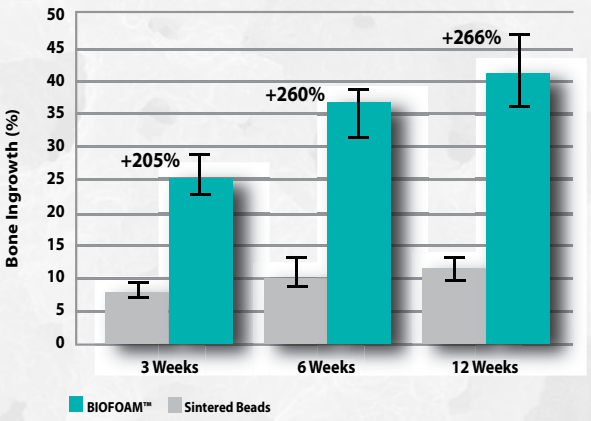
BIOFOAM™ TALKING POINTS

BIOFOAM™ is manufactured from Commercially Pure (CP) Titanium Metal and exhibits 60-70% porosity

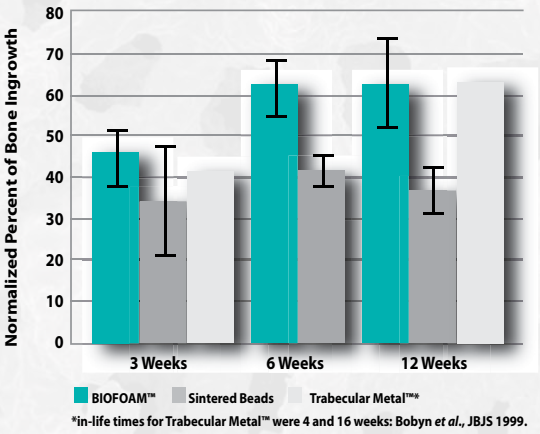
- Immediate rigid fixation compared to beads
- Decreased risk of spin-out
- Fixation with multiple bearings surfaces with big head technology
- Over 200% greater bone growth in BIOFOAM™ as compared to sintered beads at 12 weeks
- Full interconnecting porosity
- Osteoconductive matrix
- High friction to enhance immediate rigid fixation
- Compressive modulus similar to bone
- Accepts poly and cross-linked poly liners

TECHNICAL DATA

Bone In-Growth Compared to Beads

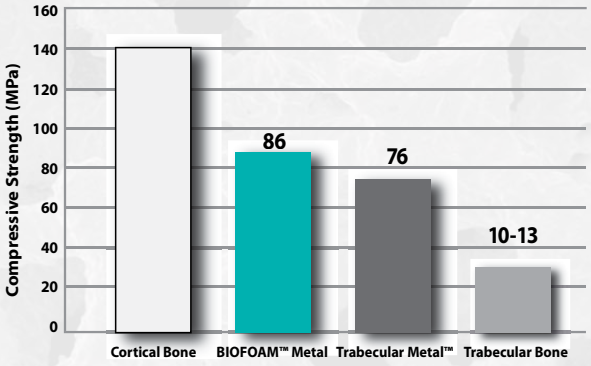


Percent Bone In-Growth

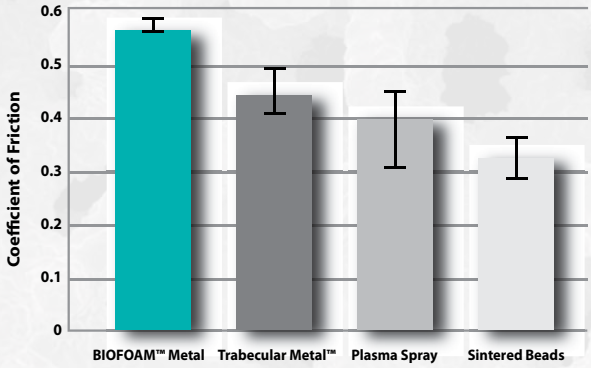


*in-life times for Trabecular Metal™ were 4 and 16 weeks: Bobyn *et al.*, JBJS 1999.

Compressive Strength



Coefficient of Friction



THE BIOFOAM™ PROCESS

Diffusion Bonding Process

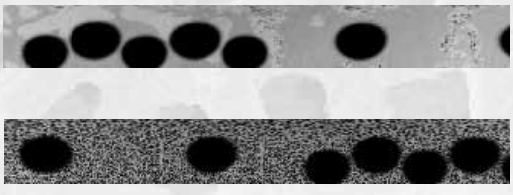
A thin wafer is cut from a BIOFOAM™ raw material

The wafer is cut to a specific shape and size

Wafers are placed on top of the shells

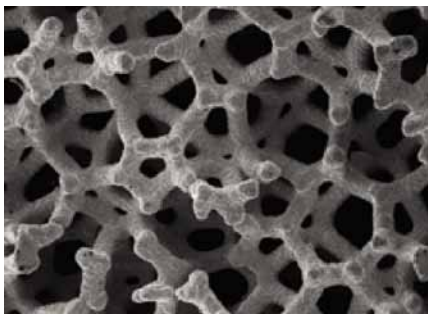
Pressure and heat are applied for a specified length of time to ensure a good bond

Advanced Ultrasonic Inspection techniques allow us to see inside the shell and view the bond between the BIOFOAM™ shell



BIOFOAM™ COMPETITION

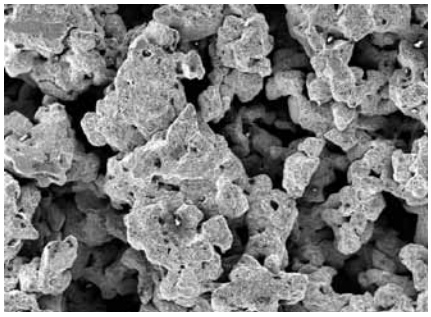
TRABECULAR METAL™ - Zimmer (Implex)



Tantalum, 70-80% avg. porosity, 200-600µm pore size6

- Provides a trabecular structure for bone
- Manufactured from tantalum and is not able to be directly sintered onto titanium substrate.
- No long-term clinical history of tantalum in orthopaedic devices as a bone growth material

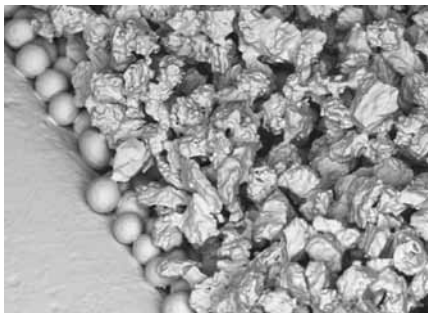
REGENEREX™ - BIOMET®



Ti6Al4V, 67% avg. porosity, 100-600µm pore4

- Not a trabecular structure
- High porosity, limited interconnecting porosity
- May limit bone growth down to the substrate

GRIPTION™ - DePuy

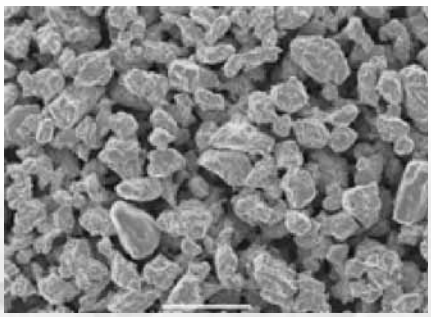


CP Ti, 63% avg. porosity, 300µm pore size3

100x Magnification

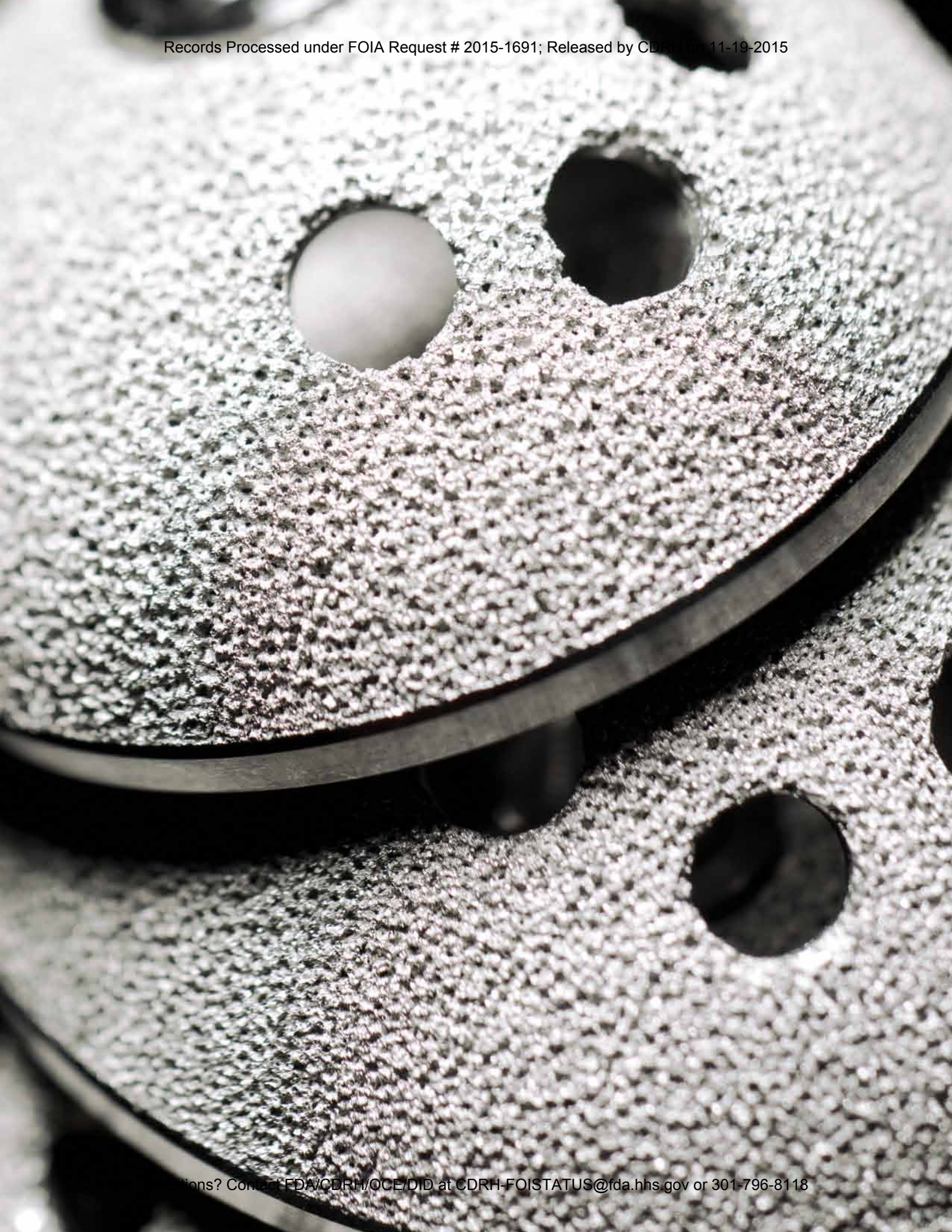
- Not a true trabecular structure
- Limited interconnecting porosity may limit bone growth down to the substrate
- Only available as implant coating

R3™ Acetabular Shells with STIKTITE™ - Smith and Nephew



Titanium powder, 60% porosity, average pore size 200 µm

- Head/shell ratios (36mm head size - 52mm shell size)
- Proprietary porous shell coating
- Higher coefficient of friction compared to trabecular metal



ORDERING INFORMATION

Acetabular Implants

DNFL - KITB - BIOFOAM™ Shells Sizes 46-68mm

DNFL - KITC - BIOFOAM™ Shells Sizes 70-76mm

CoCr Liners

DNFL - KITE - All Sizes

Poly Liners

DNFL - KITF - All Sizes

15° Poly Liners

DNFL - KITG - All Sizes

Revision Poly Liners

DNFL - KITH - All Sizes

Cup Instruments

DNFL - KIT1 - Core Instruments for Sizes 46-68

DNFL - KIT2 - Instruments for Large Sizes 70-76

Screw Instrumentation

2001 - KIT5 - Acetabular Screw Instruments

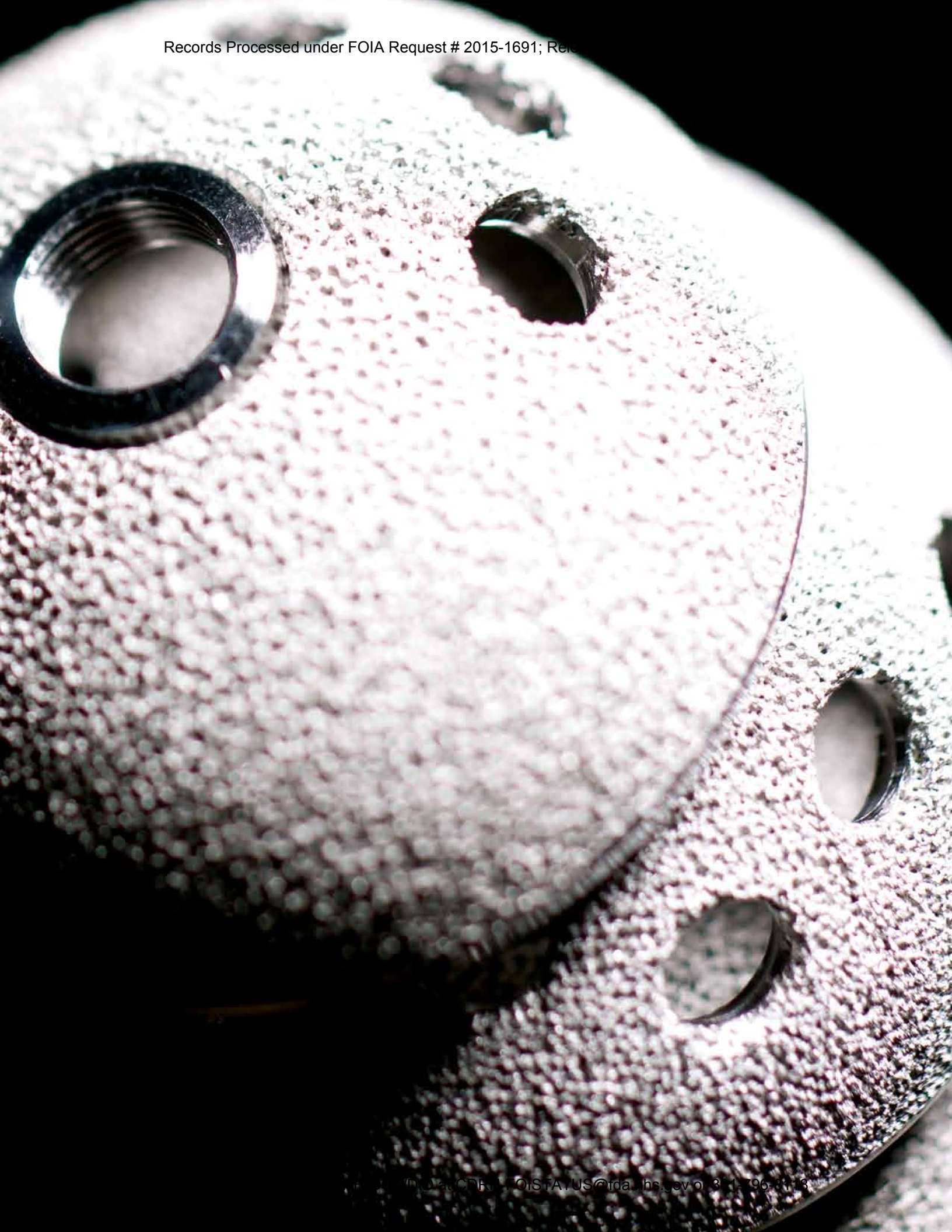
Acetabular Reamers

2001 - KIT5 - Precimed Reamers size 40-68mm

2006 - KIT1 - Cheese Grater Hemispherical Reamers Size 40-68mm

2002 - KIT2 ODYSSEY Low Profile Instruments Size 40-68mm

2007 - KIT1 - Precimed Reamers Size 69-76mm



CONTACT INFORMATION

Jason Watson

Sr Product Manager, Hip Marketing

(901) 867-4753

jwatson@wmt.com

Patrick Fisher

Sr Director, Hip Marketing

(901) 867-4408

pfisher@wmt.com

Tony Svarczkopf

Sr Process Engineer, Advanced Materials Processing

(901) 867-4451

tsvarczkopf@wmt.com

Wright Medical Technology, Inc.
5677 Airline Road
Arlington, TN 38002
901.867.9971 phone
800.238.7188 toll-free
www.wmt.com

Wright Medical EMEA
Krijgsman 11
1186 DM Amstelveen
The Netherlands
011.31.20.544.0100
www.wmt-emea.com

MH506-1009

Exhibit 9: Stryker's Tritanium Porous Coating

Hip Replacement Fit and Fixation

Your doctor will consider several factors when determining the appropriate hip implants for you. There are many factors that influence the durability of hip implants, and implant fixation to the bone is one of them. Some implants require bone cement to secure, or fix, the implant in place. Bone cement has been used since the earliest procedures were done and is still used today. Usually bone cement is used in patients with poor bone quality to help stabilize the hip components.

Other implants are manufactured with special coatings and rough surfaces that help your natural bone grow onto it to achieve fixation. An implant with a porous surface or tiny beads, and good quality bone are required for cementless fixation. Sometimes a combination of cement and cementless hip components are used. Most of the hip procedures done in the US are without bone cement.

Hip Replacement Facts

The majority of joint replacement osteoarthritis patients feel that their joint replacement feels either normal (47%) or natural (33%).

Overall, there has been an improvement in quality of life, participation in activities, and emotions toward the condition since joint replacement surgery.[6]

Femoral Stem Options

Stryker offers a wide variety of femoral stems options so your doctor can select the one that fits you best. The femoral stem your doctor chooses will depend on your bone quality, age, and clinical factors as well as surgeon preference. Some femoral stems, such as Accolade®, have a slimmer profile making it better for minimally invasive surgery, and also provides better stability when paired with anatomic femoral heads.

HA

Hydroxylapatite (HA) is a naturally occurring substance that closely resembles natural bone mineral. Bone mineral stores the body's supply of calcium and phosphorus – two minerals critical to one's health. In fact, the two major components of HA are calcium and phosphorus – the predominant components of bone and tooth enamel. HA is applied to some hip implants, particularly acetabular cups and femoral stems, to encourage bone to grow onto it.[1] Clinical studies with HA show that patients had early pain relief and rapid restoration of function.[1] HA coated femoral stems perform very well in young and active patients.[1]

Tritanium® Advanced Fixation Technology

Tritanium® is a three-dimensional surface on the acetabular cup that helps hold the implant into the bone.[2] The new Tritanium® technology was designed to resemble trabecular bone, a type of spongy bone tissue that provides skeletal support. Tritanium® technology allows for bone to grow into the component[2] providing enhanced fixation.[3]

Tritanium® is made from the highest quality commercially pure Titanium. Studies have shown that it improves bone ingrowth when compared to other alloys.[4] This technology may be especially beneficial for patients with low bone density and the 55% of Americans age 50 and older diagnosed with osteoporosis.[5]

References

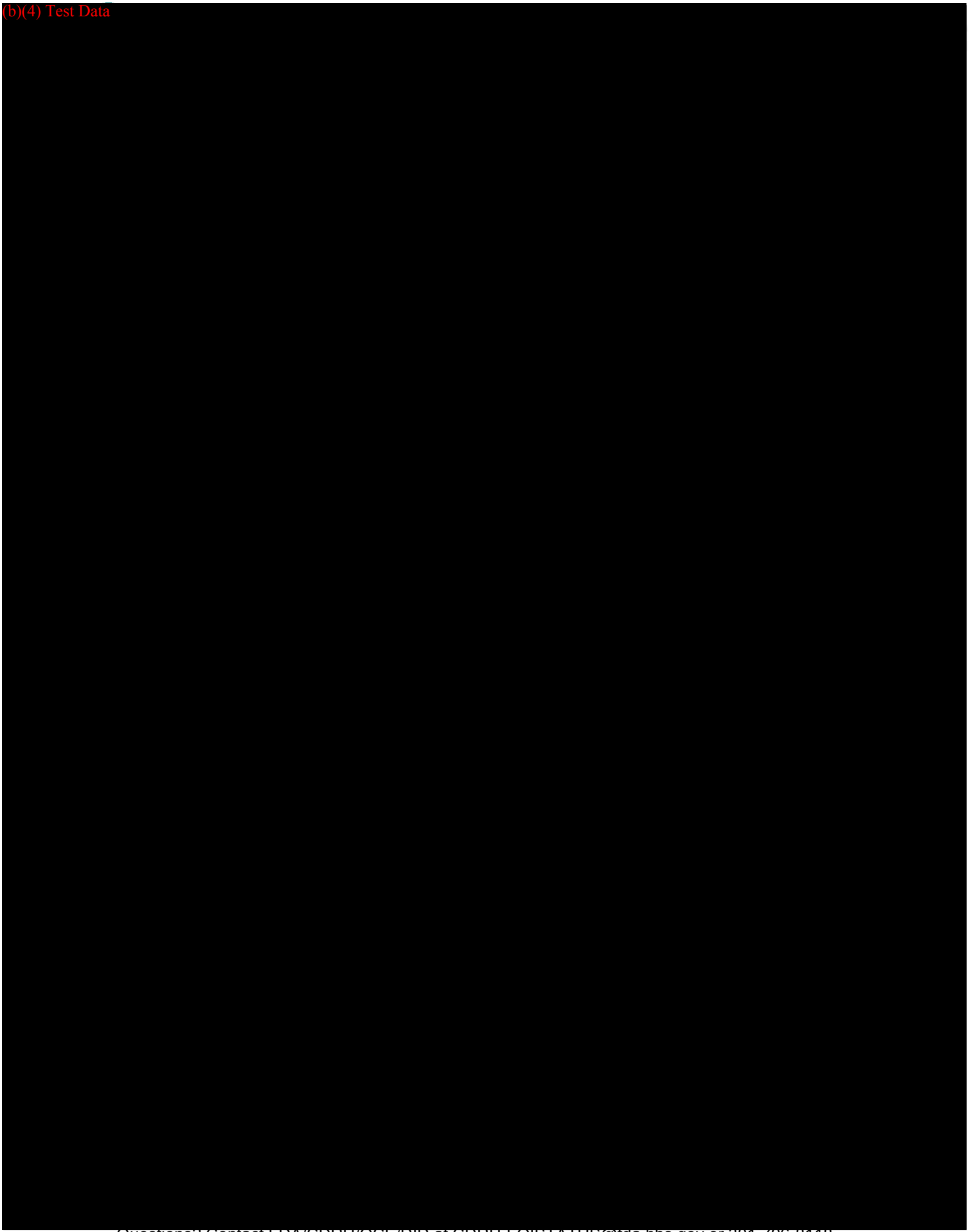
1. D'Antonio, et. al. Hydroxyapatitie Femoral Stems for Total Hip Arthroplasty: 10-13 Year Follow-up, CORR, Volume 393, Dec. 2001, pp. 101-111.
2. Stryker Test Report RD-08-009. Evaluation of bone response to porous surfaces using a canine total hip model.
3. Stryker Test Report RD-07-077.
4. Ricci J.L., Kauffman J., Jaffe, W., et al, "Comparison of Osseointegration and Bone Adhesion to Commercially Pure Titanium Alloy," 23rd Ann.Mtg. Society for Biomaterials, 1997.
5. National Osteoporosis Foundation.
6. Harris Interactive® Patient Study commissioned & conducted by Stryker, September 2003.

Exhibit 10: TM 120819 – Evaluation of the Delta Ceramic Ball-Trunnion Overlap

(b)(4) Test Data

[redacted]

(b)(4) Test Data



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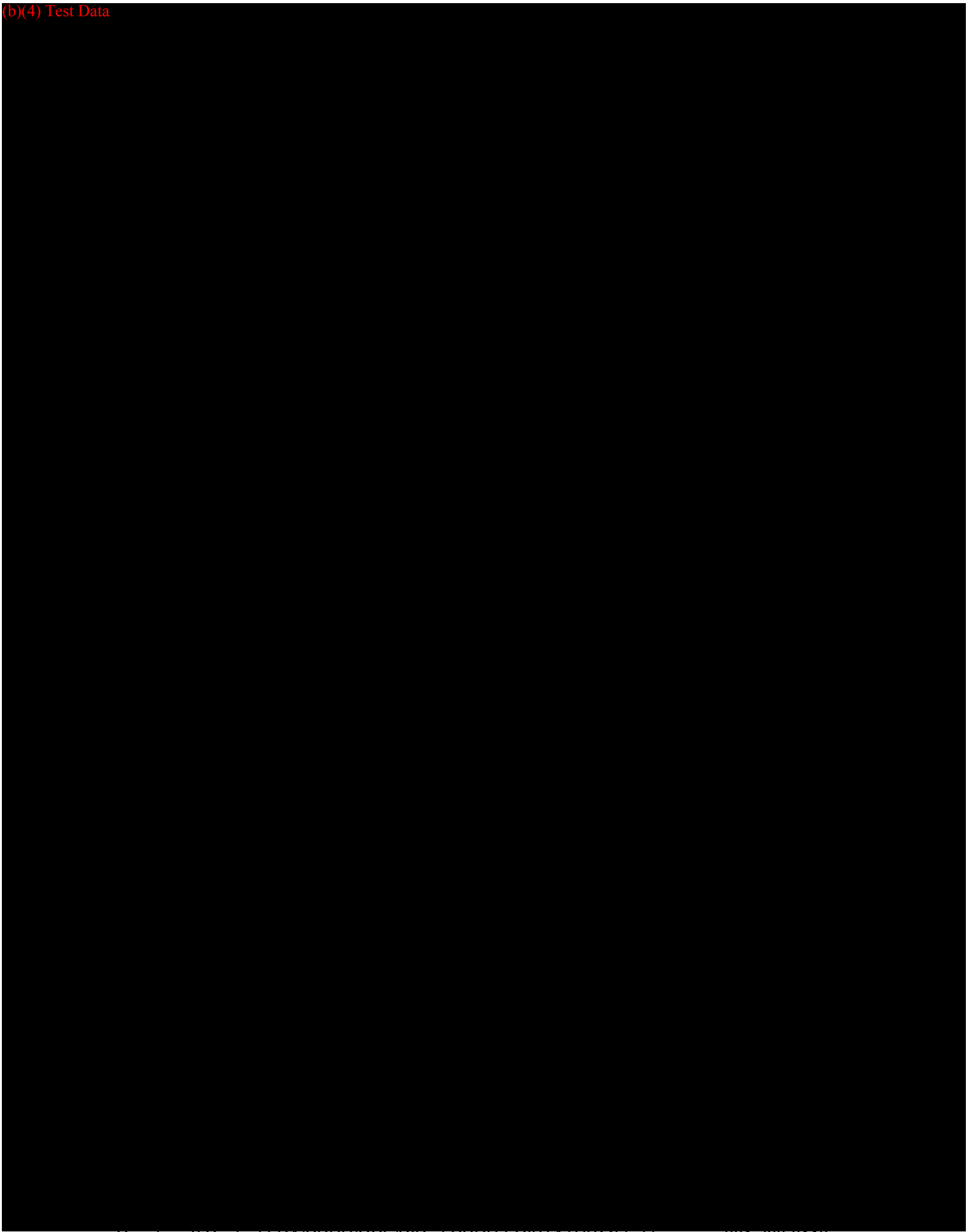

(b)(4) Test Data

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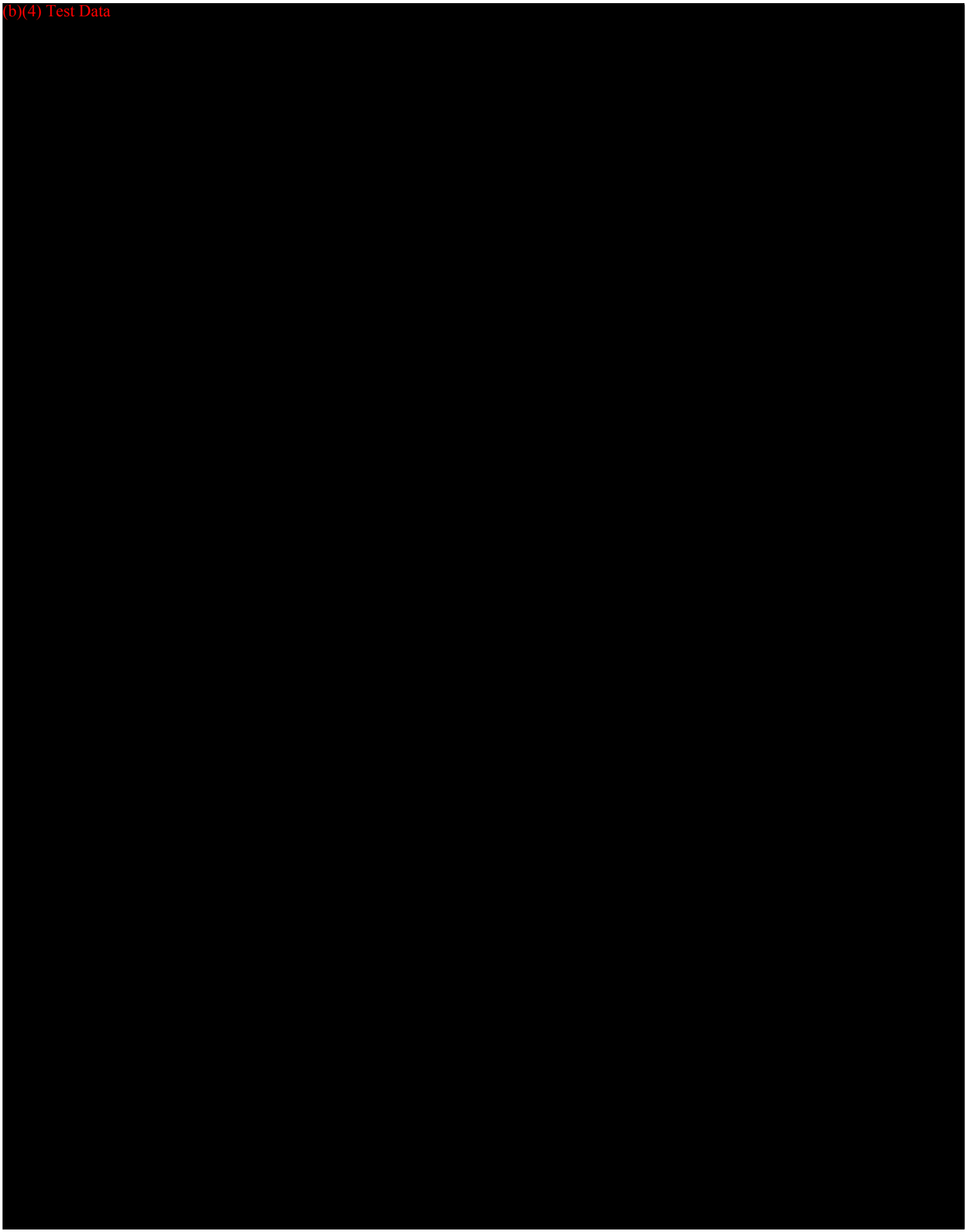
(b)(4) Test Data



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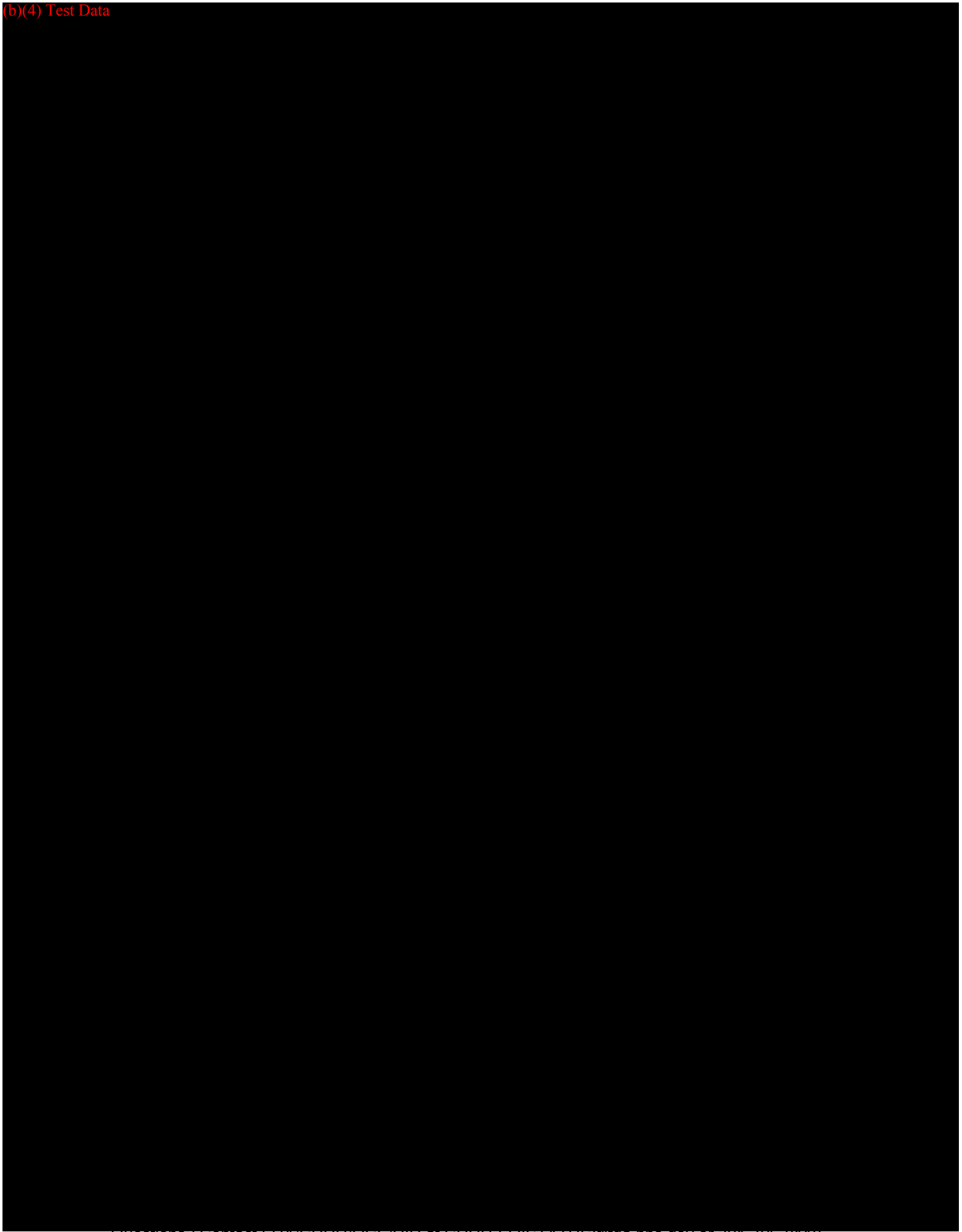

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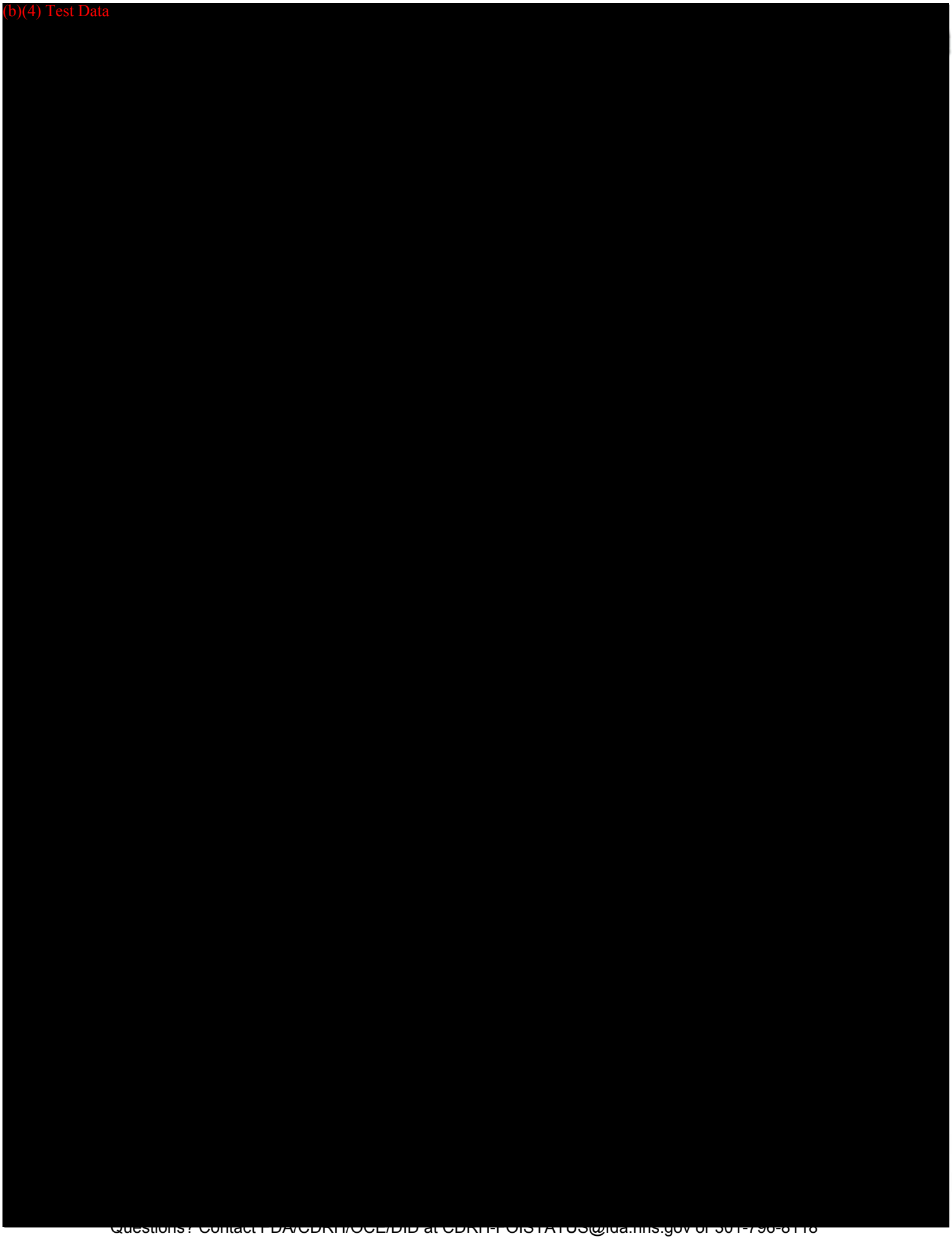

(b)(4) Test Data

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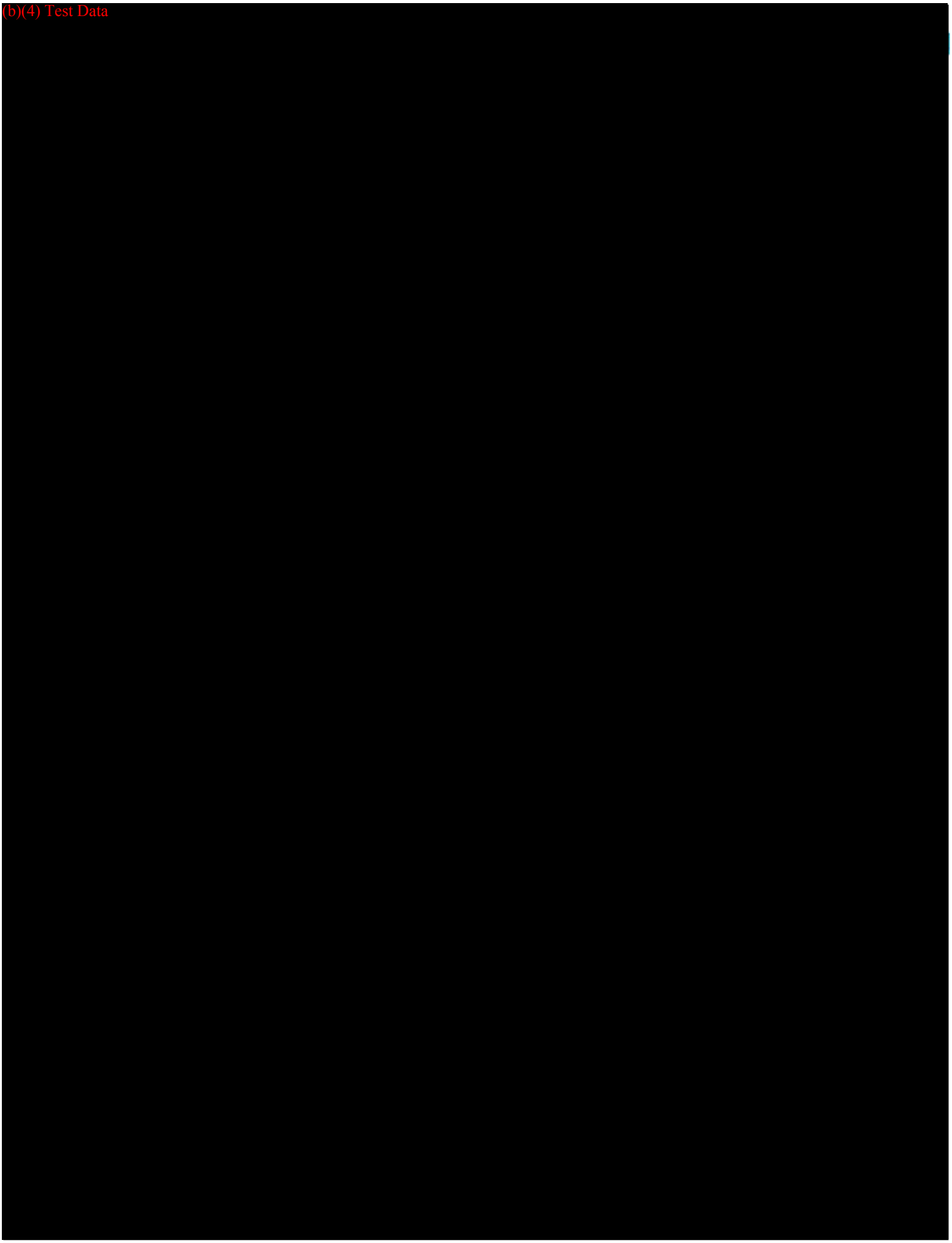
(b)(4) Test Data



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 11, 2012

Pipeline Biomedical Products, Llc
% Mr. Terry Powell
Senior Project Manager
901 King Street, Suite 200
Alexandria, Virginia 22314

Re: K122158
Trade/Device Name: PBP Total Hip System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis.
Regulatory Class: Class II
Product Code: OQI, LZO, MEH, OQH, OQG, JDI, LPH
Dated: November 14, 2012
Received: November 19, 2012

Dear Terry Powell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

(Please include 510(k) number here: K122158)

Digital Signature Concurrence Table	
Reviewer Sign-Off	
Branch Chief Sign-Off	
Division Sign-Off	Erin I. Keith 2012.12.11 14:21:05 -05'00'

f/t:MJK:tmj:12/7/12

Indications for Use Statement

510(k) Number (if known): K122158

Device Name: PBP Total Hip System

Indications for Use:

The PBP Total Hip System is indicated for use in skeletally mature individuals undergoing surgery for total hip replacement due to:

- A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis, or congenital hip dysplasia;
- Acute traumatic fracture of the femoral head or neck;
- Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty or total hip replacement.

The PBP Total Hip System hip stems and porous structured acetabular shells are intended for cementless or cemented fixation. The porous structured surface provides biological fixation when used in a cementless application.

The PBP Total Hip System HA porous structured acetabular shells are intended for cementless fixation. The HA porous structured surface provides biological fixation.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Krishna Arundi
Division of Orthopedic Devices

2012.12.10 16:53:59 -05'00'

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

November 19, 2012

PIPELINE BIOMEDICAL PRODUCTS, LLC
C/O M SQUARED ASSOCIATES, INC.
901 KING STREET
SUITE 200
ALEXANDRIA, VIRGINIA 22314
ATTN: TERRY POWELL

510k Number: K122158

Product: PBP TOTAL HIP SYSTEM

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

Pugh, Dominique *

From: Microsoft Outlook
To: tpowell@msquaredassociates.com
Sent: Monday, November 19, 2012 3:11 PM
Subject: Relayed: K122158 AI Letter

Delivery to these recipients or groups is complete, but no delivery notification was sent by the destination server:

tpowell@msquaredassociates.com (tpowell@msquaredassociates.com)

Subject: K122158 AI Letter

40

K122158/OR

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

October 10, 2012

PIPELINE BIOMEDICAL PRODUCTS, LLC
C/O M SQUARED ASSOCIATES, INC.
901 KING STREET
SUITE 200
ALEXANDRIA, VIRGINIA 22314
ATTN: TERRY POWELL

510k Number: K122158

Product: PBP TOTAL HIP SYSTEM

Extended Until: 03/08/2013

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Director, 510(k) Program
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Nichols, Karl *

From: Microsoft Outlook
To: 'tpowell@msquaredassociates.com'
Sent: Wednesday, October 10, 2012 2:56 PM
Subject: Relayed: K122158 Extension Letter

Delivery to these recipients or groups is complete, but no delivery notification was sent by the destination server:

'tpowell@msquaredassociates.com' (tpowell@msquaredassociates.com)
<mailto:tpowell@msquaredassociates.com>

Subject: K122158 Extension Letter

M SQUARED
ASSOCIATES, INC.

K10

October 5, 2012

U.S. Food and Drug Administration
Center for Devices and Radiological Health Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
USA

Reference: K122158 – Extension Request for PBP Total Hip System 510(k)

Dear Dr. Kasser,

Enclosed please find 2 revised copies of the extension request referenced above originally submitted on October 2, 2012 with the wrong K number reference (submitted as K112158 rather than K122158). The revision is a correction of the 510k number only.

Sincerely,

Terry Sheridan Powell, M Squared Associates Inc.
Consultant for Pipeline Biomedical Products, LLC
901 King Street, Suite 102
Alexandria, VA 22314
(T) 703-562-9800, x252
(F) 7013-562-9797
(E) tpowell@msquaredassociates.com

M SQUARED
ASSOCIATES, INC.

October 2, 2012

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
USA

Reference: K122158 – Extension Request for PBP Total Hip System 510(k)

Dear Dr. Kasser,

We have received FDA's request for additional information, dated September 7, 2012, for the above-cited 510(k). We request an extension of up to 180 days to respond to FDA's request.

Please confirm that FDA has received and granted this request for an extension. Thank you for your assistance.

Sincerely,

for

Terry Sheridan Powell, M Squared Associates Inc.
Consultant for Pipeline Biomedical Products, LLC
901 King Street, Suite 102
Alexandria, VA 22314
(T) 703-562-9800, x252
(F) 7013-562-9797
(E) tpowell@msquaredassociates.com

M SQUARED
ASSOCIATES, INC.

October 2, 2012

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
USA

Reference: K122158 – Extension Request for PBP Total Hip System 510(k)

Dear Dr. Kasser,

We have received FDA's request for additional information, dated September 7, 2012, for the above-cited 510(k). We request an extension of up to 180 days to respond to FDA's request.

Please confirm that FDA has received and granted this request for an extension. Thank you for your assistance.

Sincerely,

for

Terry Sheridan Powell, M Squared Associates Inc.
Consultant for Pipeline Biomedical Products, LLC
901 King Street, Suite 102
Alexandria, VA 22314
(T) 703-562-9800, x252
(F) 7013-562-9797
(E) tpowell@msquaredassociates.com

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

September 11, 2012

PIPELINE BIOMEDICAL PRODUCTS, LLC
C/O M SQUARED ASSOCIATES, INC.
901 KING STREET
SUITE 200
ALEXANDRIA, VIRGINIA 22314
ATTN: TERRY POWELL

510k Number: K122158
Product: PBP TOTAL HIP SYSTEM
On Hold As of 9/10/2012

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Director, 510(k) Program
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Mcdonald, Lisa *

om: Microsoft Outlook
To: tpowell@msquaredassociates.com
Sent: Tuesday, September 11, 2012 9:26 AM
Subject: Relayed: K122158 Hold Letter

Delivery to these recipients or groups is complete, but no delivery notification was sent by the destination server:

tpowell@msquaredassociates.com (tpowell@msquaredassociates.com)

Subject: K122158 Hold Letter

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Michael Lasky

Subject: 510(k) Number K122158

To: The Record

Please list CTS decision code TH

- ☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- ☑ Hold (Additional Information or Telephone Hold).
- ☐ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NU	NSE for new intended use AND new technology raising new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NS	NSE no response
☐	NL	NSE for lack of performance data AND no response
☐	NM	NSE pre-amendment device call for PMAs (515i)
☐	NC	NSE post-amendment device requires PMAs
☐	NH	NSE for new molecular entity requires PMA
☐	TR	NSE for transitional device

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III?			
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)?			
For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was			

conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)

Does this device include an Animal Tissue Source?

All Pediatric Patients age<=21

Neonate/Newborn (Birth to 28 days)

Infant (29 days -< 2 years old)

Child (2 years -< 12 years old)

Adolescent (12 years -< 18 years old)

Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)

Nanotechnology

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) *Contact OC.*

Regulation Number	**Class***	**Product Code**

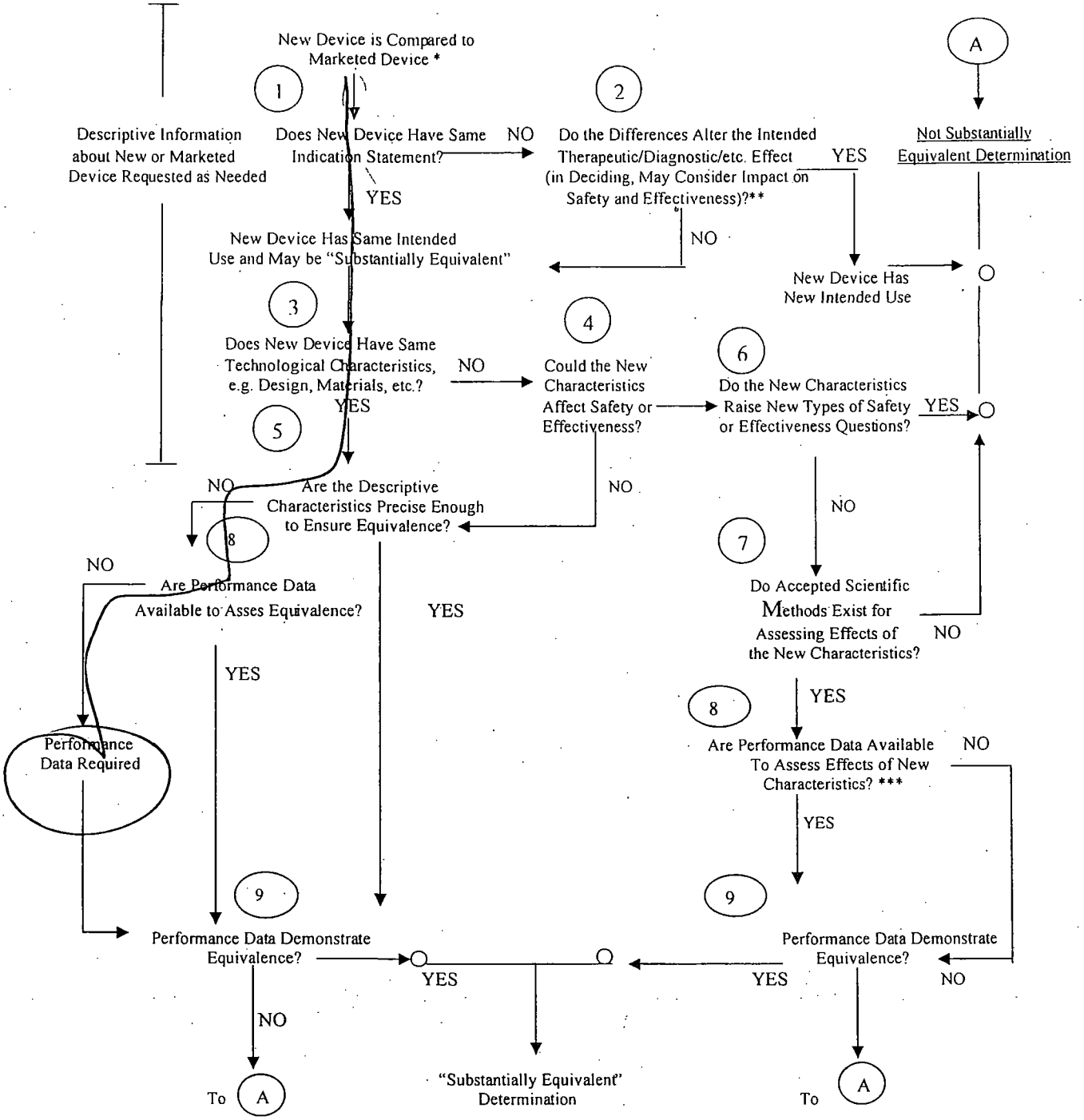
(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: Elizabeth R for (Branch Chief) OJDB (Branch Code) 9/10/12 (Date)

Final Review: Elizabeth R for (Division Director) 9/10/12 (Date)

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
Center for Devices & Radiological Health

ODE/DSORD/OJDB
20993-0002
301-796-6946

Premarket Notification [510(k)] Review

ate: September 7, 2012	
To: FILE	
From: Michael Kasser	
Subject: Traditional 510(k)# K122158	
Sponsor: Pipeline Biomedical Products, Llc	**Contact / Consultant:** Terry Powell
Phone: (703) 562-9800 Ext.252	**Email:** tpowell@msquaredassociates.com
Device Trade Name: Pbp total hip system	**FDA Received / Due Date:** July 20, 2012 / August 31, 2012
Reg # / Name / Class: 888.3358 / Hip Joint Metal/Polymer/Metal Semi-Constrained Porous-Coated Uncemented Prosthesis. / II	**Product Code(s):** OQI, LZO, MEH, OQH, OQG, JDI, LPH

Sponsor-Identified Predicate Devices:

510(k) #	Pro Code	Device Name	Company
K112802	OQG, OQH, LPH, JDI	Pipeline total hip system	Pipeline Orthopedics

Review Summary

The subject device is a Hip Joint Metal/Polymer/Metal Semi-Constrained Porous-Coated Uncemented Prosthesis. with the following Indications for Use: "The PBP TOTAL HIP SYSTEM IS INDICATED FOR USE IN SKELETALLY MATURE INDIVIDUALS UNDERGOING SURGERY FOR TOTAL HIP REPLACEMENT DUE TO:
- A SEVERELY PAINFUL AND/OR DISABLED JOINT FROM OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS, AVASCULAR NECROSIS, OR CONGENITAL HIP DYSPLASIA;
- ACUTE TRAUMATIC FRACTURE OF THE FEMORAL HEAD OR NECK;
- FAILED PREVIOUS HIP SURGERY INCLUDING JOINT RECONSTRUCTION, INTERNAL FIXATION, ARTHRODESIS, HEMIARTHROPLASTY, SURFACE REPLACEMENT ARTHROPLASTY OR TOTAL HIP REPLACEMENT.

THE PBP TOTAL HIP SYSTEM HIP STEMS AND POROUS STRUCTURED ACETABULAR SHELLS ARE INTENDED FOR CEMENTLESS OR CEMENTED FIXATION. THE POROUS STRUCTURED SURFACE PROVIDES BIOLOGICAL FIXATION WHEN USED IN A CEMENTLESS APPLICATION.

THE PBP TOTAL HIP SYSTEM HA POROUS STRUCTURED ACETABULAR SHELLS ARE INTENDED FOR CEMENTLESS FIXATION. THE HA POROUS STRUCTURED SURFACES PROVIDES BIOLOGICAL FIXATION. " It is for Rx use.

Recommendation

I recommend that the Pbp total hip system is/are in need of Additional Information (TH).

Review Team

Lead Reviewer Michael Kasser (ODE/DSORD/OJDB)

I. Purpose and Background

The purpose of this submission is a line extension (and rights transfer from Pipeline Orthopedics to Pipeline Biomedical Products). The new components are 40 mm CoCr head, 40 mm ID VE liners, Biolox delta ceramic heads, and HA coated porous acetabular shells (Ti porous coated shells previously cleared).

II. Administrative Information

Administrative Information	Present	Absent	Inadequate
Medical Device User Fee Cover Sheet [A]	☐	☒	☐
CDRH Premarket Review Submission Cover Sheet [B]	☒	☐	☐
510(k) Cover Letter [C]	☒	☐	☐
Indications for Use Page [D]	☐	☐	☐
Truthful and Accuracy Statement [E]	☐	☒	☒
510(k) Summary or Statement [F]	☐	☒	☒
Financial Certification and Disclosure Statement (Clinical) [H]	☐	☒	☐
Clinical Trials Cert Form (Clinical) [I]	☐	☒	☐
Standards Data Report for 510(k)s [K]	☒	☐	☐
Executive Summary	☒	☐	☐

Reviewer Decision

The administrative information is **not** acceptable. Summary should have OQI added. Device description contains claims. Clarify reason for submission and reduce supplied testing accordingly. TAS not original. In an email dated 8/31. the sponsor provided updated Summary and TAS. However, the Summary still contains the following claims, "allowing the surgeon to optimize soft tissue tension and restore joint mechanics." "The porous structured surface's interconnected porosity provides a scaffold for bone ingrowth as shown in the transcortical implant canine model" and "for increased resistance to wear and oxidative degradation as compared with standard UHMWPE (demonstrated by comparative wear testing and comparative oxidation analyses summarized in section 8)" that should be removed.

III. Device Description

Device Characteristics	Yes	No	Inadequate or Unknown
Is the intended use or fundamental technology new?	☐	☒	☐
Is the device life-supporting or life sustaining?	☐	☒	☐
Is the device or a component an implant? [1]	☒	☐	☐
Does the device use software/firmware?	☐	☒	☐
Does the device or a component need sterilization (by manufacturer or user)?	☒	☐	☐
Is the device or a component for single person use?	☒	☐	☐
Is the device or a component a reprocessed SUD? [2]	☐	☒	☐

Device Characteristics	Yes	No	Inadequate or Unknown
Is the patient contact component(s) reusable?	☐	☒	☐
Is the device a combination product? [3] N - Not a Part 3 Combination Product			☐
Is the device electrical (battery or wall powered)? The device is not electrical			☐

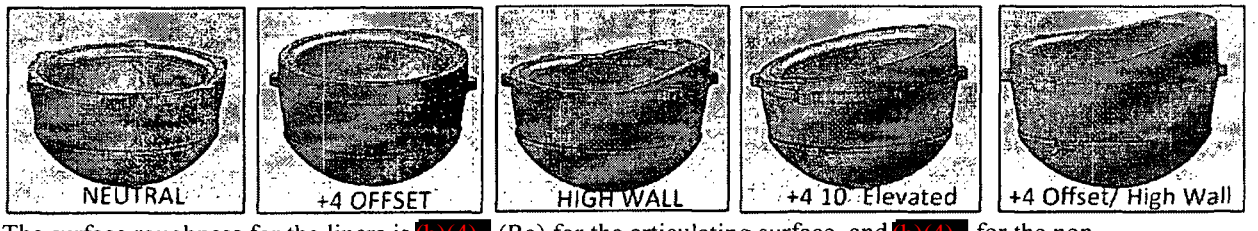
The Pipeline Total Hip System consists of femoral stems, femoral heads, acetabular liners, acetabular shells, and optional acetabular bone screws and acetabular dome hole occluders. A detailed description of each component is contained below. New components are **bolded** when first mentioned.

Acetabular Cups

The shells are hemi-spherical and are made from ASTM F1472 (wrought Ti-6Al-4V alloy). The shell's face is raised to house the scallops on the liner. There is also an inner groove at the taper to dome transition that locks with the rib on the acetabular insert. The locking mechanism is the same as cleared in K112802. The shells are available with two surfaces, porous structured (PST) and **porous structured HA coated** (HA PST). The PST is made from a novel direct metal laser sintering (DMLS) process that allows the Ti-6Al-4V material to be built layer by layer, as opposed to traditional deposition of a new coating on the surface. This coating was previously cleared in K112802. HA PST has a (b)(4) HA coating on top of the porous structure. This coating is characterized in MAF-339, see HA consult for additional information. All shells contain a threaded hole at the dome of the shell to allow attachment to the insertion instrumentation. Shells can also contain an optional three hole cluster pattern to accommodate additional screw fixation. The shells are available in 44 – 70 mm outer diameters, in 2 mm increments. The shells are intended for cemented and uncemented use.

Acetabular Liners

The liners contain a hemispherical base and tapered sides that match with the shell. The liner contains a rib at the taper to dome transition and six, external, anti-rotation scallops. The liners are available in 5 rim designs, neutral, +4 mm offset, high wall, +4 10° elevated, and +4 offset/high wall, see figure below. These options allow the center of rotation to be offset or provide extra coverage to reduce dislocation risk.



The surface roughness for the liners is (b)(4) (Ra) for the articulating surface, and (b)(4) for the non-articulating surfaces. The minimum liner thickness at the load bearing region is (b)(4) and (b) at the rim which occurs for the 32/48 and 28/44 (ID/OD) liners for the neutral and highwall configurations.
The liner is available in two materials, conventional and highly crosslinked Vit. E (XLVE). Conventional material is made from ASTM F648 UHMWPE that is gamma sterilized with 25 – 40 kGy of radiation in a nitrogen environment. Vitamin E polyethylene is made from GUR 1020 powder mixed with (b)(4) (b)) vitamin E then compression molded. After molding, the material is crosslinked with (b)(4) gamma radiation, machined, cleaned, and then EtO sterilized. The material is more fully characterized in MAF (b) and previously cleared in K112802. Please see the charts below for liner/shell sizing for both of these materials. **40 ID XLVE liners are being added in this submission.**

Acetabular Liner - Vitamin E Poly Sizing*					
Mating Shell Size OD (mm)	Inner Diameter (ID)/Head Size (mm)				
	22	28	32	36	40
44		X			
46		X			
48		X	X		
50		X	X		
52		X	X	X	
54		X	X	X	
56		X	X	X	X
58		X	X	X	X
60					
62		X	X	X	X
64					
66		X	X	X	X
68					
70					

Acetabular Liner - Standard Poly Sizing*					
Mating Shell Size OD (mm)	Inner Diameter (ID)/Head Size (mm)				
	22	28	32	36	
44	X				
46	X				
48	X	X			
50	X	X			
52	X	X	X		
54	X	X	X		
56	X	X	X		
58	X	X	X		
60					
62	X	X	X		
64					
66	X	X	X		
68					
70					

Acetabular Bone Screws

Screws are unchanged from what was cleared in K112802. Optional bone screws and occluders are made from ASTM F1472. The screws are self-tapping with a hex-head style. The major/minor screw diameter is 6.5/3.0 mm with a pitch of 2.75 mm. The screws are available in lengths of 15 – 60 mm, in 5 mm increments. Hole occluders, that screw into and fill unused screw holes in the shell are also available.

Femoral Stem

The stems are unchanged from what was cleared in K112802. Pipeline hip stems feature a flat, tapered, wedge geometry with the medial side remaining constant, but the lateral size tapering towards the distal end. The proximal end of the stem uses a 12/14 (b)(4) (b)(4) (b)(4) angled at 130°. The stems are made from forged Ti-6Al-4V ELI per ASTM F136 and F620). The proximal neck region is highly polished (b)(4) The proximal portion of the stem contains a rough, CP Ti plasma spray coating, characterized in MAF (b) , see K112802 for additional information. The distal end of the stem has a Ra of (b)(4) .
The stem is available in size ranges 2 – 12 (shoulder to tip length ranging from 111 – 138 mm). All stems are available in standard and high offsets (6 mm for size 2-4, 8 mm for size 5-12). The stems can be used for cementless or cemented applications.

Femoral Heads

Heads are available in CoCr and **Biolox Delta** (per ISO 6474-2).

CoCr heads are made from wrought CoCr per ASTM F1537. The heads have a surface roughness of (b) um (Ra) on articulating surfaces and (b) um on non-articulating surfaces. The heads contain a female 12/14 taper (specifications are circularity of (b)(4) , straightness of (b)(4) , and roughness of (b)(4) . See the chart below for available diameters and offsets, please note the larger offsets result in skirted heads. The heads are identical to those previously cleared in K112802 except that **40 mm CoCr heads** have been added.

Table 3: Metal Femoral Head Sizing

CoCr Heads					
Offset (mm)	Head diameters (mm)				
	22	28	32	36	40
-3.5		X	X	X	X
0	X	X	X	X	X
+3.5	X	X	X	X	X
+7		X*	X	X	X
+10.5		X*	X*	X*	X
* skirted design					

Table 4: Ceramic Femoral Head Sizing

Ceramic Heads					
Offset (mm)		Head diameters (mm)			
		28	32	36	40
S	-3.5	X	X	X	X
M	0	X	X	X	X
L	+3.5	X	X	X	X
XL	+7	NA	X	X	X

Ceramic heads are made by CeramTec from their Biolox delta material. The heads have a surface roughness of 0.020 um on the articulating surface. The heads contain a female 12/14 taper. See the chart above for available diameters and offsets.

For a table of device characteristics, see "Comparison of Technology to Predicate Devices" below.

Third-party Components and Accessories:

Reviewer Decision
The Device Description is acceptable.

IV. Comparison of Indications for Use to Predicate Devices

Comparison of Indications for Use	
Subject	
510(k) #: K122158	Rx/OTC: Rx
Intended Population: Adults	
Indications for Use: "The PBP TOTAL HIP SYSTEM IS INDICATED FOR USE IN SKELETALLY MATURE INDIVIDUALS UNDERGOING SURGERY FOR TOTAL HIP REPLACEMENT DUE TO: - A SEVERELY PAINFUL AND/OR DISABLED JOINT FROM OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS, AVASCULAR NECROSIS, OR CONGENITAL HIP DYSPLASIA; - ACUTE TRAUMATIC FRACTURE OF THE FEMORAL HEAD OR NECK; - FAILED PREVIOUS HIP SURGERY INCLUDING JOINT RECONSTRUCTION, INTERNAL FIXATION, ARTHRODESIS, HEMIARTHROPLASTY, SURFACE REPLACEMENT ARTHROPLASTY OR TOTAL HIP REPLACEMENT. THE PBP TOTAL HIP SYSTEM HIP STEMS AND POROUS STRUCTURED ACETABULAR SHELLS ARE INTENDED FOR CEMENTLESS OR CEMENTED FIXATION. THE POROUS STRUCTURED SURFACE PROVIDES BIOLOGICAL FIXATION WHEN USED IN A CEMENTLESS APPLICATION. THE PBP TOTAL HIP SYSTEM HA POROUS STRUCTURED ACETABULAR SHELLS ARE INTENDED FOR CEMENTLESS FIXATION. THE HA POROUS STRUCTURED SURFACES PROVIDES BIOLOGICAL FIXATION."	
Predicate(s)	
510(k)#: K112802	Rx/OTC: Rx
Intended Population:	
Indications for Use: PIPELINE TOTAL HIP SYSTEM IS INDICATED FOR USE IN SKELETALLY MATURE INDIVIDUALS UNDERGOING SURGERY FOR TOTAL HIP REPLACEMENT DUE TO: - A SEVERELY PAINFUL AND/OR DISABLED JOINT FROM OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS, AVASCULAR NECROSIS, OR CONGENITAL HIP DYSPLASIA; - ACUTE TRAUMATIC FRACTURE OF THE FEMORAL HEAD OR NECK; - FAILED PREVIOUS HIP SURGERY INCLUDING JOINT RECONSTRUCTION, INTERNAL FIXATION, ARTHRODESIS, HEMIARTHROPLASTY, SURFACE REPLACEMENT ARTHROPLASTY OR TOTAL HIP REPLACEMENT. THE PIPELINE TOTAL HIP SYSTEM IS INTENDED FOR CEMENTLESS OR CEMENTED FIXATION. THE POROUS STRUCTURED SURFACE PROVIDES BIOLOGICAL FIXATION WHEN USED IN A CEMENTLESS APPLICATION.	
Indications for Use Table: Compares the indications for use of the subject and predicate devices.	

Reviewer Decision

The Indications for Use are acceptable. They are identical to the predicate except that HA fixation has been added.

V. Comparison of Technology to Predicate Devices

Table 2: Total Hip System Comparison

System Component	PBP Total Hip System* K number to be assigned (Pipeline Biomedical Products)	Pipeline Total Hip System K112802 (Pipeline Orthopedics)
Femoral Stems	Titanium Alloy Sizes 2-12 Titanium plasma sprayed 12/14 Taper Standard (Neutral) offset High (6 mm Lateral) offset	Titanium Alloy Sizes 2-12 Titanium plasma sprayed 12/14 Taper Standard (Neutral) offset High (6 mm Lateral) offset
Femoral Heads	CoCr Alloy 22, 28, 32, 36, **and 40 mm** Offsets** of -3.5mm, 0mm, +3.5mm, +7mm, and +10.5mm **Biolox *delta*** **28, 32, 36, and 40 mm** **Offsets** of -3.5mm, 0mm, +3.5mm, +7mm**	CoCr alloy 22, 28, 32, and 36 mm Offsets of -3.5mm, 0mm, +3.5mm, +7mm, and +10.5mm
Acetabular Shells	Titanium alloy 44-70 mm Surface treatment options: • PST (Porous Structured) Surface • **HA PST (Porous Structured) Surface**	Titanium alloy 44-70 mm Surface treatment: • Porous Structured Surface
Acetabular Liners	Material Options: • Standard UHMWPE (ID sizes 22, 28, 32mm) • Highly Crosslinked Vitamin E UHMWPE (ID sizes 28, 32, 36, **40mm**) Offset options: Neutral, +4mm offset, high wall, +4mm offset/10° elevated, and +4mm offset/high wall versions	Material Options: • Standard UHMWPE (ID sizes 22, 28, 32mm) • Highly Crosslinked Vitamin E UHMWPE (ID sizes 28, 32, 36mm) Offset options: Neutral, +4mm offset, high wall, +4mm offset/10° elevated, and +4mm offset/high wall versions
Bone Screws	Titanium alloy 6.5 mm diameter 15-60mm long	Titanium alloy 6.5 mm diameter 15-60mm long
Dome Hole Occluder	Titanium alloy	Titanium alloy

* Differences shown in bold

Reviewer Decision
The Comparison of the Technology to Predicate Devices is acceptable.

VI. Labeling

Labeling Review Needed?	Yes ☒	No ☐
Usability Consult Needed?	Yes ☐	No ☒

A General Labeling Requirements

General Labeling Requirements	Yes	No	N/A
Has the prescription statement been provided in accordance with 21 CFR 801.109(b)(1)) or "Rx only".	☐	☐	☐
Adequate instructions for OTC use? [1]	☐	☐	☒
The indications for use are consistent with the IFU page?	☐	☐	☐
Appropriate contraindications provided?	☐	☐	☐
Appropriate warnings provided?	☐	☐	☐
Appropriate cautions provided?	☐	☐	☐
Instructions are in accordance with the guidance (if applicable)?	☐	☐	☐
Appropriate labeling inside device? [2]	☐	☐	☐
Appropriate label/indicator outside device? [3]	☐	☐	☐
Appropriate Manual labeling? [4]	☐	☐	☐

Package Label:

The package label contains a brief device description, lot number (pictographic), catalogue number (pictographic), expiration date (pictographic), manufacturer's contact info (pictographic), device material, device quantity, Radiation/EtO sterile (pictographic), do not reuse (pictographic), see instructions for use (pictographic), keep dry (pictographic), do not use if package is damaged (pictographic), and Rx only. All symbols are defined on the label.

Package Insert:

Two package inserts are supplied, one for the PBP system and one for the ceramic heads. The PBP system package insert includes general description of components in a hips system, indications, contraindications, adverse reactions, warnings (including that no MR testing has been performed), precautions, and sterilization information. The ceramic ball insert contains all of the warning recommended in the ceramic ball guidance document. A package insert for the manual surgical instruments was also supplied, but was not reviewed.

Surgical Procedure:

A technique for both the femoral and acetabular components is supplied that include the indications for use.

Reviewer Decision
The Labeling is acceptable.

VII. Cleaning, Sterilization, Shelf Life and/or Reuse

Sterility Review Needed?	Yes ☒	No ☐

Sterility Consult Needed?	Yes ☐	No ☒

Sterilization Information	Inadequate or Unknown
Identify the device(s)/component(s) that is sterilized All but XLVE liners	☐
Does the Manufacturer or User sterilize the device/component? Manufacturer	☐
Sterilization method description[1] Radiation	☐
Dose 25 - 40 kGy	☐
The standard(s) used for Validation ISO 11137-1:2006	☐
A description of the Validation Method for the sterilization cycle VDmax25 (for 25 kGy dose)	☐
Sterility Assurance Level (SAL) 10^-6	☐
Is it labeled "Pyrogen Free"? No	☐
A description of the packaging (not including package integrity test data) double PETG blisters with Tyvek Lids. Acetabular liners are also back-filled with nitrogen gas.	☐
Shelf Life 3 years	☐
Are there additional devices/components that are sterilized differently? Yes	☐
Identify the device(s)/component(s) that is sterilized XLVE liners	☐
Does the Manufacturer or User sterilize the device/component? Manufacturer	☐
Sterilization method description[1] Ethylene Oxide (EO, EtO)	☐
Sterilant residuals remaining on the device < 0.1 mg/day	☐
The standard(s) used for Validation ISO 11135	☐
A description of the Validation Method for the sterilization cycle Overkill Approach (e.g., Half-Cycle method)	☐
Sterility Assurance Level (SAL) 10^-6	☐
Is it labeled "Pyrogen Free"? No	☐
A description of the packaging (not including package integrity test data) LDPE mesh in double PETG blister with Tyvek lids	☐
Shelf Life 3 years	☐
Are there additional devices/components that are sterilized differently? Yes	☐
Identify the device(s)/component(s) that is sterilized reusable manual surgical instruments	☐
Does the Manufacturer or User sterilize the device/component? User	☐
Is 'Non-Sterile' prominent on the package labeling for it? Yes	☐
Sterilization method description[1] Steam (Moist Heat)	☐
Air Removal Method / Temperature / Exposure & Drying Time prevacumm/132C/4 min exposure 30 min drying	☐
The standard(s) used for Validation ISO 17665-1	☐
A description of the Validation Method for the sterilization cycle Overkill Approach (e.g., Half-Cycle method)	☐
Sterility Assurance Level (SAL) 10^-6	☐
Is it labeled "Pyrogen Free"? No	☐
A description of the packaging (not including package integrity test data) poly bags, sleeves, polyester tubes, and vinyl end caps	☐

Shelf Life N/A	☐
Are there additional devices/components that are sterilized differently? No	☐
Sterilization Table: Sterility information for the subject device	

Reviewer Decision
Sterilization, Shelf-Life and Reuse descriptions are unchanged from the predicate device and are acceptable.

VIII. Biocompatibility

Biocompatibility Review Needed?	Yes ☐	No ☒
Biocompatibility Consult Needed?	Yes ☐	No ☒

Reviewer Decision
The Biocompatibility is acceptable. Aside from hydroxyapatite, the device is made from the same materials as the predicate (CoCr, Ti alloy, cp Ti, UHMWPE, XLVE previously cleared in K112802). HA is a material common to hips and its biocompatibility is assessed via characterization.

IX. Software/Firmware

Software Review Needed?	Yes ☐	No ☒
Software Consult Needed?	Yes ☐	No ☒

Reviewer Decision
The Software is not applicable.

X. EMC & Electrical, Mechanical and Thermal Safety & Risk Analysis

Reviewer Decision
The EMC, EMT and Risk Analysis are not applicable

XI. Performance Testing

A Bench Testing

The submission includes all of the testing that was supplied in K112802 as ownership of the device is being transferred to Pipeline Biomedical Products LLC from Pipeline Orthopedics. For review of that testing please see K11802 memos. Only new testing is included here.

FDA Guidance Document Testing Report, Surface Dynamics, Report #1130501, 11/3/11

HA characterization testing was reviewed by Dr. Sun, please see her attached consult.

Hip Simulator Wear Resistance of Highly Crosslinked, Vitamin E Blended UHMWPE, Harris Orthopaedic Laboratory, 11/23/11

Wear testing was performed on the thinnest 28 and 40 mm ID liners that were aged per ASTM F2003 [redacted] (b)(4) Test Data [redacted]). 6 liners were tested and liners were used as a soak control. 5 Mc of loading (profile was per ISO 14242-1) was applied at 1 Hz. Lubricant was diluted bovine serum (18.5 g/L protein

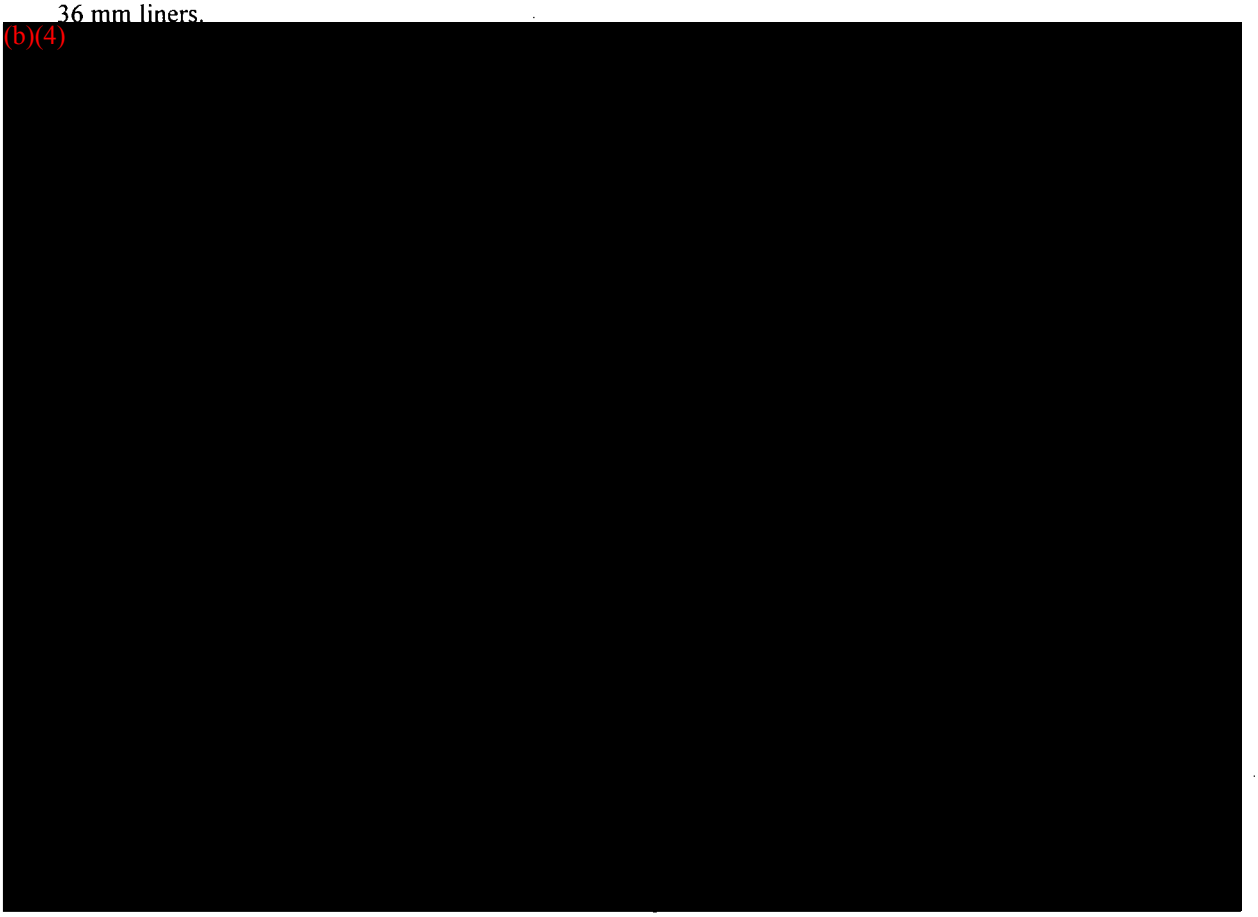
concentration) at 37C which was changed every 0.5 Mc. Gravimetric wear measurements were performed every 1 Mc after correction with a soak control. Wear particle analysis was performed on wear debris taken from the 4.0 – 4.5 Mc interval and analyzed via SEM. The wear results, as well as those from previous testing are summarized in the table below.

Device	Wear rate, mg/Mc
Subject (28 mm)	(b)(4)
K112802 (36 mm)	(b)(4)
Subject (40 mm)	(b)(4)
K094035*	20.2
K111481*	1.84 ± 1.02

*Comparative data I have added from other XLVE submissions.

The figures below compare the particle size and inverse aspect ratio to the previously tested wear from the 36 mm liners.

(b)(4)



Reviewer Comment: *Effect of size on wear has been adequately characterized and supports the use of new 40 mm liners. Particle size distribution and shape appears relatively independent of size. Although wear testing against ceramic heads has not been performed, testing of similar systems has shown that CoP systems generally produce less wear than MoP systems. Therefore additional testing is not required. The supplied testing is adequate.*

Range of Motion Study, Pipeline Uncemented System, Pipeline Orthopedics, TM110906, Joshua Weiss, Sept. 22, 2011

ROM was analyzed using SolidWorks 2011. When skirted heads were analyzed, no stems were included in the analysis as the ROM was limited by liner contacting the skirt, not the stem's neck. A table summarizing the testing can be seen below. The 22mm +0 heads were not affected by choice of stem (std or offset, size 2

or size 12, or choice of hi wall liner (hi wall or offset). This was not the case for 28 mm heads. The use of a hi wall liner does not affect the A/P direction.

Table 24: Range of Motion Analyses

(b)(4)

Reviewer Comment: *The new 40 mm components have a greater ROM.*

Comparison of Values for Rotational Stability and Pulloff Forces for Biolox Delta and Biolox Forte Ball Heads on Different Taper Materials, CeramTec AG, Doc. 3799, June 7, 2008.

Pulloff and rotational testing was performed on Forte 28 mm 12/14 L heads on 3 stem materials. Testing was also performed on similarly sized delta head and on forte head with maximum contact area between taper and ball head. 5 samples were tested for each material/size. The test report includes engineering diagrams of the tapers that shows they are equivalent to the subject device. The results of the testing are summarized in the table below.

Head	Stem	Pulloff, N	Rotational Moment, Ncm
Forte 28 L mm	Ti alloy	(b)(4)	(b)(4)
Forte 28 L mm	SS	(b)(4)	(b)(4)
Forte 28 L mm	CoCr	(b)(4)	(b)(4)
Delta 28 L mm	Ti alloy	(b)(4)	(b)(4)
Forte 32 S mm	Ti alloy	(b)(4)	(b)(4)

Reviewer Comment: *The subject report adequately demonstrates the pulloff and rotational strength of the forte and delta heads. Only the delta heads are relevant to the subject device and testing was not performed on the subject tapers. However, this testing is not typically requested. Additionally, as the sponsor asserts that greatest clinical distraction loads are 250 N, there is a substantial safety margin. The supplied testing is not required.*

Influence of Diameter and Neck Length on Burst Strength of BIOLOX forte and BIOLOX delta ball heads with 12/14 Taper, CeramTec AG, Doc. 3300, Apr. 2, 2011

Testing per ISO 7206-10 at 2 mm/min was performed on various heads on a 12/14 taper. The effect of ceramic material (forte vs. delta), head diameter (28 – 44 mm), neck length (-4 - +4 mm), and neck material (Ti, SS, and CoCr) were investigated. The results show burst strength decreases with increasing neck length and decreasing head diameter. Delta is also stronger than forte, and head strength is reduced by the use of a CoCr neck (Ti alloy and SS are equivalent.)
Upon request (email dated 8/31), the sponsor has provided a side-by-side comparison of the subject device taper (all three stem systems have the same taper) and the taper tested in the CeramTec report.

	Pipeline taper	CeramTec test taper
Angle	(b)(4)	
Length		
Straightness		
Roundness		
Surface Roughness		
Gage diameter		
Ball/Cone Overlap*		
Ball Dia. / Ball Size		
28mm L		
32mm L		
36mm XL		
40mm XL		

The following relevant heads were tested on Ti alloy stems in this test report

Material	Diameter, mm	Offset, mm	Burst Strength, kN
Delta	32	+7	(b)
Delta	28	+3.5	(b

Reviewer Comment: *The provided testing includes testing of the two worst-case heads. However, testing was not performed on the subject stem. At this point in time, I have seen this test report in multiple submissions. The provided information demonstrates that the tested and subject tapers are adequately similar that a 50% in burst strength is not expected. The provided testing is adequate.*

B Animal Testing

Not provided.

C Clinical Testing

Not provided.

Reviewer Decision

The Performance Testing is acceptable.

XII. Kit Certification

XIII. Manufacturing Information

XIV. References

XV. Original Deficiencies

Administrative Information

1. FDA conducts a comprehensive review of the 510(k) Summary in accordance with 21 CFR 807.92 and the Required Elements for 510(k) Statements in accordance with 21 CFR 807.93.

Based on our assessment of your 510(k) Summary, your Summary does not meet the regulation. Please address the following concerns regarding your 510(k) summary:

a. Please add the procode OQI to the Summary.

Response: OQI Added.

b. The device description includes multiple claims, such as (but not limited to), minimize potential for wear debris, bone-conserving, ease of insertion. These claims should be removed or provide additional data to substantiate them.

Response: Some, but not all, claims were removed. Bone ingrowth claim common in competitor's literature.

c. The Summary should clarify the reason for the submission.

Response: Added.

2. The submission includes a Truthful and Accurate Statement (TAS) that contains an electronic signature. Please supply a TAS with an original signature.

Response: Signed document provided.

Performance Testing

3. The submission includes new Biolox delta ceramic heads and relies on testing from CeramTec to support the burst strength of the heads. However, this testing was performed on tapers that may differ from the tapers of the subject device. Therefore, in order to substantiate the applicability of the provided testing to the subject device please provide a comparison of the CeramTec tapers and the subject tapers.

	Pipeline taper	CeramTec test taper
Angle		
Length		
Straightness		
Roundness		
Surface Roughness		
Ball/Cone Overlap		

Response: An adequate comparison of the subject and CeramTec tapers has been provided.

Please note that a complete review of the testing related to the hydroxyapatite coating has not been completed at this time. Additional deficiencies regarding the coating may arise.

Please provide revised copies of your 510(k) Summary and Indications for use page, as well as redlined copies of all other sections (e.g., labeling (including promotional material), etc), which reflect all modifications related to the above deficiencies.

This letter reflects the current progress of our review of your application. Please be advised that further substantive review of your application or any response to this letter may result in additional deficiencies.

A1 Deficiencies

1. The Food and Drug Administration (FDA) has reviewed the information that you have provided to Pipeline Orthopedics for their 510(k) submission, i.e., Answers to FDA 510(k) Guidance Questions within Orchid Bio-Coat Mater File MAF-(b), as well as the referenced Amendment 27 in the MAF-(b). Regarding your Answer #4, it appears that the test coupon used for the bonding tests is made of the same material as the Pipeline Orthopedics' device to be cleared, i.e., Ti6Al4V. However, the test coupon does not contain a porous surface as the subject device. It is not clear how the porous surface will affect the bonding strength of the HA coating. Therefore, please either provide the bonding strength tests using HA-coated test coupons with a porous surface (the porous surface should be manufactured in the same way as the subject device), or provide rationales as to why the test results that you have provided are adequate for the HA-coated subject device.

2. You have interactively supplied and updated 510(k) Summary with some, but not all, claims removed. Please remove/modify the following claims from the device description section. Alternatively, you may supply adequate information within the text of the claim to support it and give it adequate context.

   i. "Allowing the surgeon to optimize soft tissue tension and restore joint mechanics,"

   ii. "The porous structured surface's interconnected porosity provides a scaffold for bone ingrowth as shown in the transcortical implant canine model." You may state the coating allows for biological fixation as the subject coating meets FDA's definition of porous.

   iii. "For increased resistance to wear and oxidative degradation as compared with standard UHMWPE (demonstrated by comparative wear testing and comparative oxidation analyses summarized in section 8)."

3. Please provide a statement that no enhanced claims regarding your plasma sprayed coating will be made for this device. Enhanced claims such as osseointegration for example would be considered unsubstantiated and should be excluded in the submission.

4. Engineering drawings of the subject device are provided in Section xx of the submission. The engineering drawings doesn't seem to contain the HA coating information. Please reference the draft Guidance '510(k) Information Needed for Hydroxyapatite Coated Orthopedic Implants'

(http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080224.htm)

for the total surface area of the implantable portion of the coated implant as recommended in #1 of the guidance, and provide updated engineering drawing in which the area or location of the HA coating on the subject device should be clearly depicted.

ADVISORY

5. For the plasma sprayed hydroxyapatite coating, please be advised that FDA recommends that you include all characterization parameters per the draft Guidance "510(k) Information Needed for Hydroxyapatite Coated Orthopedic Implants" in your specifications on file as part of your design controls. All testing characterization should be performed on final, sterilized devices. Should you use alternative methods other than those provided in the guidance, FDA will review accordingly. Should you make any modifications to your coating, then FDA recommends that you provide the full characterization per the draft Guidance in a future 510(k) submission. Additionally, we recommend you have the shelf life data (see below) on file as part of your design controls.

   Some calcium phosphate coatings may be affected by aging in addition to shipping and storage conditions such as humidity, temperature extremes, mechanical forces, and packaging. Full characterizations per the "510(k) Information Needed for Hydroxyapatite Coated Orthopedic Implants" are recommended at the end of your requested shelf life, as well as at the beginning, unless there is reasonable evidence that the coating is relatively unaffected by the aging, shipping and storage conditions. Please provide the Ca/P ratio per wet chemistry methods and the solubility product on the coating at the initial time and at the proposed shelf life time (in addition to interim time points) exposed to humidity and temperature extremes. FDA recommends that the calcium phosphate coated products tested be in the same packaging that would be used for the marketed product and exposed to the appropriate test variables. We would entertain accelerated aging on devices with plasma sprayed calcium phosphate coatings. Please note that we are concerned about how the coated product in its packaging (sterile barrier) is affected by not only the shelf aging of the product but by the environmental conditions for which the coating would be exposed. For example, although the coating may be aged at ambient temperatures with low relative humidity at the manufacturer, the coated product may be exposed to different environmental conditions prior to being stored in a hospital facility. The coated product may encounter winter-like conditions and/or hot, humid conditions prior to hospital storage at ambient temperature. It is these fluctuations of the environmental conditions for which we are most concerned, and we recommend that you incorporate the worst case temperature and humidity fluctuations in addition to an aging process. Please note that depending on your information, additional information may be needed to support your shelf life.

   For the solubility product information, we recommend an initial comparison with the National Institute of Standards & Technology (NIST) standard reference material (SRM), #2910 or #2910(a) – Calcium Hydroxyapatite. Alternatively, you may provide solubility product testing on your coating using the NIST method. The NIST method and/or SRM #2910 or #2910(a) standard reference material information are available at http://ts.nist.gov/srm. Please provide the solubility product, (Ksp) at 37°C. The pH changes of the solution should be recorded. The

solubility product (Ksp) should be calculated based on the Ca5(PO4)3(OH) formula. Please note that the solubility product parameters should be provided for the coatings scraped from the implant and not coupons. If plasma spraying deposition techniques are used and solubility product testing is provided from the scrapings from a coupon or test component other than the implant, we request that you provide a rationale as to how the solubility product determined from scrapings from a coupon for example is appropriate for the subject implant. We recommend using your worst case coating thickness (e.g., thinnest thickness criterion) and comparing your Ca/P ratio and solubility product at the aged condition (which has been exposed to temperature and humidity extremes) to those at the initial time point. Should these values differ significantly, then your coating may not be considered stable or reliable. In this case, additional testing may be needed to determine the appropriate shelf-life, etc.

Finally, note that some calcium phosphate coating ISO standards reference a calcining heat treatment. Unless calcining is considered a post deposition heat treatment to a coating for which the coating will be shipped for clinical use, we recommend that you analyze the final, sterilized, non-calcined coating. We are willing to accept calcined samples for the analysis of the Ca/P ratio. Please acknowledge this advisory.

XVI. Contact History

Date (MM/DD/YY)	Contact Method	Subject
08/22/12	Email	Interactive deficiencies sent to sponsor
08/31/12	Email	Ineractive response recieved

Lead Reviewer Sign-off:	Michael Kasser (ODE/DSORD/OJDB)	9/7/12 Date
Branch Level Sign-off: for	Branch Chief (Office Location)	9/10/12 Date
Division Level Sign-off: for		9/10/12 Date

Kasser, Michael

From: Kasser, Michael
Sent: Friday, September 07, 2012 11:44 AM
To: 'tpowell@msquaredassociates.com'
Subject: ADDITIONAL INFORMATION REQUESTED FOR K122158, Pbp total hip system

To: Terry Powell
Pipeline Biomedical Products, Llc
Phone: Pipeline Biomedical Products, Llc
E-Mail: tpowell@msquaredassociates.com

Subject: Additional information requested / Telephone hold for K122158 Pbp total hip system

CC: Record

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. This 510(k) will be placed on telephone hold. To complete the review of your submission, we require the following additional information:

Administrative Information

1. The Food and Drug Administration (FDA) has reviewed the information that you have provided to Pipeline Orthopedics for their 510(k) submission, i.e., Answers to FDA 510(k) Guidance Questions within Orchid Bio-Coat Mater File MAF-339, as well as the referenced Amendment 27 in the MAF-339. Regarding your Answer #4, it appears that the test coupon used for the bonding tests is made of the same material as the Pipeline Orthopedics' device to be cleared, i.e., Ti6Al4V. However, the test coupon does not contain a porous surface as the subject device. It is not clear how the porous surface will affect the bonding strength of the HA coating. Therefore, please either provide the bonding strength tests using HA-coated test coupons with a porous surface (the porous surface should be manufactured in the same way as the subject device), or provide rationales as to why the test results that you have provided are adequate for the HA-coated subject device.
2. You have interactively supplied and updated 510(k) Summary with some, but not all, claims removed. Please remove/modify the following claims from the device description section. Alternatively, you may supply adequate information within the text of the claim to support it and give it adequate context.
   i. "Allowing the surgeon to optimize soft tissue tension and restore joint mechanics,"
   ii. "The porous structured surface's interconnected porosity provides a scaffold for bone ingrowth as shown in the transcortical implant canine model." You may state the coating allows for biological fixation as the subject coating meets FDA's definition of porous.
   iii. "For increased resistance to wear and oxidative degradation as compared with standard UHMWPE (demonstrated by comparative wear testing and comparative oxidation analyses summarized in section 8)."
3. Please provide a statement that no enhanced claims regarding your plasma sprayed coating will be made for this device. Enhanced claims such as osseointegration for example would be considered unsubstantiated and should be excluded in the submission.

4. Engineering drawings of the subject device are provided in Section xx of the submission. The engineering drawings doesn't seem to contain the HA coating information. Please reference the draft Guidance '510(k) Information Needed for Hydroxyapatite Coated Orthopedic Implants'

(http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080224.htm)

for the total surface area of the implantable portion of the coated implant as recommended in #1 of the guidance, and provide updated engineering drawing in which the area or location of the HA coating on the subject device should be clearly depicted.

ADVISORY

5. For the plasma sprayed hydroxyapatite coating, please be advised that FDA recommends that you include all characterization parameters per the draft Guidance "510(k) Information Needed for Hydroxyapatite Coated Orthopedic Implants" in your specifications on file as part of your design controls. All testing characterization should be performed on final, sterilized devices. Should you use alternative methods other than those provided in the guidance, FDA will review accordingly. Should you make any modifications to your coating, then FDA recommends that you provide the full characterization per the draft Guidance in a future 510(k) submission. Additionally, we recommend you have the shelf life data (see below) on file as part of your design controls.

Some calcium phosphate coatings may be affected by aging in addition to shipping and storage conditions such as humidity, temperature extremes, mechanical forces, and packaging. Full characterizations per the "510(k) Information Needed for Hydroxyapatite Coated Orthopedic Implants" are recommended at the end of your requested shelf life, as well as at the beginning, unless there is reasonable evidence that the coating is relatively unaffected by the aging, shipping and storage conditions. Please provide the Ca/P ratio per wet chemistry methods and the solubility product on the coating at the initial time and at the proposed shelf life time (in addition to interim time points) exposed to humidity and temperature extremes. FDA recommends that the calcium phosphate coated products tested be in the same packaging that would be used for the marketed product and exposed to the appropriate test variables. We would entertain accelerated aging on devices with plasma sprayed calcium phosphate coatings. Please note that we are concerned about how the coated product in its packaging (sterile barrier) is affected by not only the shelf aging of the product but by the environmental conditions for which the coating would be exposed. For example, although the coating may be aged at ambient temperatures with low relative humidity at the manufacturer, the coated product may be exposed to different environmental conditions prior to being stored in a hospital facility. The coated product may encounter winter-like conditions and/or hot, humid conditions prior to hospital storage at ambient temperature. It is these fluctuations of the environmental conditions for which we are most concerned, and we recommend that you incorporate the worst case temperature and humidity fluctuations in addition to an aging process. Please note that depending on your information, additional information may be needed to support your shelf life.

For the solubility product information, we recommend an initial comparison with the National Institute of Standards & Technology (NIST) standard reference material (SRM), #2910 or #2910(a) – Calcium Hydroxyapatite. Alternatively, you may provide solubility product testing on your coating using the NIST method. The NIST method and/or SRM #2910 or #2910(a) standard reference material information are available at http://ts.nist.gov/srm. Please provide the solubility product, (Ksp) at 37°C. The pH changes of the solution should be recorded. The solubility product (Ksp) should be calculated based on the Ca5(PO4)3(OH) formula. Please note that the solubility product parameters should be provided for the coatings scraped from

the implant and not coupons. If plasma spraying deposition techniques are used and solubility product testing is provided from the scrapings from a coupon or test component other than the implant, we request that you provide a rationale as to how the solubility product determined from scrapings from a coupon for example is appropriate for the subject implant. We recommend using your worst case coating thickness (e.g., thinnest thickness criterion) and comparing your Ca/P ratio and solubility product at the aged condition (which has been exposed to temperature and humidity extremes) to those at the initial time point. Should these values differ significantly, then your coating may not be considered stable or reliable. In this case, additional testing may be needed to determine the appropriate shelf-life, etc.

Finally, note that some calcium phosphate coating ISO standards reference a calcining heat treatment. Unless calcining is considered a post deposition heat treatment to a coating for which the coating will be shipped for clinical use, we recommend that you analyze the final, sterilized, non-calcined coating. We are willing to accept calcined samples for the analysis of the Ca/P ratio. Please acknowledge this advisory.

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) for determining substantial equivalence of your device.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations (21 CFR 812).

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, 'FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment' at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089738.pdf

If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning the contents of the letter, please contact Michael Kasser at 301-796-6946. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely,

Michael Kasser, PhD
Materials Engineer
CDRH/ODE/DSORD/OJDB
(301) 796 6946
michael.kasser@fda.hhs.gov

K122158/MAF339 Consult Review Memorandum

TO: Michael Kasser, Reviewer, ODE/DSORD/ Orthopedic Joint Devices Branch

FROM: Limin Sun, Reviewer, ODE/DSORD/Orthopedic Joint Devices Branch

DATE: August 29, 2012

SUBJECT: Coating Consult #CON 1215156

SUBMISSION: K122158 BPB Total Hip system

REFERENCE: Bio-Coat Device Master File MAF339

RECOMENDATION

I reviewed the HA coating characterization and recommend the lead reviewer give the deficiencies and advisory listed at the end of memo.

DEVICE DESCRIPTION

The PBP Total Hip System is an artificial hip replacement system comprised of femoral stems and mating metal heads; modular acetabular cups (acetabular shell and a mating acetabular liner), optional acetabular bone screws and optional acetabular dome hole occluders. The PBP Total Hip System subject of this 510(k) contains the same components as the predicate Pipeline Total Hip System (K112802), with the addition of a larger head size and associated acetabular liners, ceramic femoral heads and the addition of HA coated porous structured acetabular shells.

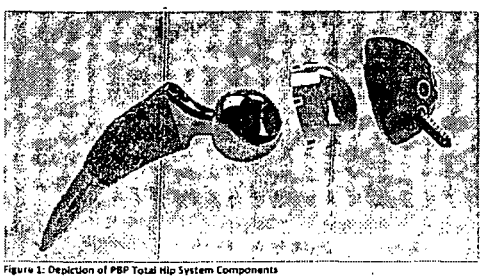


Figure 1: Depiction of PBP Total Hip System Components

The PBP Acetabular Shells (with the exception of the available HA coating option) are made entirely from Ti6Al4V alloy and both the shell substrate and the porous layer (Porous Structure Technology, PST) meet the chemical requirements of ASTM F-1472 and the applicable mechanical properties (tensile and yield strength). The shell's porous surface has a relatively large volumetric fully interconnected porosity that is integral with the shell body and hence not an applied coating. The HA PST surface for the subject PBP Acetabular Shell has the same surface as the predicate Pipeline Acetabular Shells (K112802) with the addition of a thin layer (b)(4)) of HA.

The HA coating is applied by (b)(4) . A letter of access to (b)(4) Master file is provided in Exhibit A-5. Additional information on the coating is provided according to FDA's guidance "510(k) Information Needed for Hydroxyapatite Coated Orthopedic Implants" revised on 2/20/1997 in Exhibit E-24: Orchid Orthopedics Answers to FDA 510(k) Guidance Questions within Orchid Bio-Coat Master file MAF(b) 9. The report included in E-24 references the location of the data as outlined in FDA's guidance. References are made to the specific locations in the Master file and two additional reports that are provided in this submission as follows:

- E-28: Evaluation of Orchid Bio-coat HA Coating on Porous Rods Provided by Pipeline Orthopedics (TR-434: 3/12/2012); and

- E-29: Dissolution Testing for Pipeline Orthopedics Porous Rods Coated with Orchid Bio-Coat HA Coating (TR-435: 3/13/2012).

REVIEW

Guidance: "510(k) Information Needed for Hydroxyapatite Coated Orthopedic Implants" Prepared by Dr. Pei Sung and dated March 10, 1995 (revised 2/20/97) (Item #1-10).

Note to lead reviewer: The hydroxyapatite (HA) coating in MAF339 was previously cleared for K120739 Aequalis adjustable modular reverse shoulder system. While most of the characterization data are similar, the current review is focused on the items specific for the HA coating used in the subject device, including HA coating pore size and volume and total surface area (#1 in the guidance), thickness and cross section picture (#2), the bonding strength test (#4) and solubility(#5) and dissolution test (#6).

- Device/substrate: Ti6Al4V; the substrate is grit blasted to (b)(4) before coating.
- Deposition Process: Atmospheric Plasma Spray

1. The average porosity size, the overall pore volume and the total surface area of the implantable portion of the coated implant:

- Average Porosity Size:
  - Method: ASTM1854 (Amendment 27: TR-421, Page 2)
  - Result: (b)(4) (Amendment 27: TR-421, Page 4)

- Average% Porosity:
  - Method: ASTM1854 (Amendment 27: TR-421, Page 2)
  - Result: (b) (Amendment 27: TR-421, Page4)

Reviewer' comment: *The porosity is relative low (typical values are (b)(4)) implying a very dense coating. However, since there is no acceptance criterion for coating porosity, no additional information will be requested. Additionally, the above porosity and pore size were obtained on the coupon but not the subject device. Our current practice requires that all these characterizations be performed on final, sterilized devices as the geometry of the subject device (hip stem) is very different from that of the coupon (typically flat). The MAF holder provided the following rationale, which is accepted:*

An attempt was made to measure the pore size and porosity of (b)(4) HA coating on the pipeline orthopedics porous circular rod. Measurements were performed on the cross-section along the radius of the rod. Due to limitations of the ASTM 1854-09 measurement technique (see section 8.1.2.3) as well as the dimensions of the coating (b)(4) (b) thickness), it is not viable to measure the pore size and porosity of this coating not only on curved surface (hip cup or a rod with radius of curvature 44-68mm and 4mm respectively) but also on the flat solid surface. Thickness measurements have been recorded on the pipeline orthopedics porous rod (see #2 below).

High magnification SEM image provided in response to #2 below clearly show the integrity of the HA coating on the pipeline orthopedics circular porous rods. Given the porosity, pore size of the actual substrate material (b)(4) (b)(4) porosity and pore size even for a 50 µm thick HA coating is negligible. Hence the pore size and porosity measurements for the (b)(4) HA coating would certainly be negligible.

Moreover the SEM picture of 15±10 µm HA coating on the pipeline orthopedics porous circular rod represents the worst case scenario as the radius of curvature of the porous rod (4mm) is much smaller than the radius of curvature of the pipeline orthopedics hip cup (44-48mm). Hence the SEM images of the HA coated pipeline orthopedics hip cup were not obtained.

- Total surface area of the implantable portion of the coated implant: Implant Specific

Reviewer' comment: *Regarding the total surface area of the implantable portion of the coated implant, our current practice is to ask the sponsor to make sure that the area or location of the HA coating on the implant is clearly depicted in the engineering drawing. Therefore, please check if the engineering drawing is adequate; if not, a deficiency should be given to the sponsor, but not the MAF holder (see deficiency to the sponsor at the end of memo). Note to the leader reviewer.*

2. SEM and cross-sectioned pictures of the metal particle - and the HA coated implant surfaces. Include coating thickness.

Orchid Bio-Coat evaluated the thickness of Orchid Bio-Coat HA coating on porous rods provided by pipeline orthopedics

- Thickness:
  - Method: ASTM1854 (TR434, Page 1; Exhibit E-28 of the submission)
  - Result: (b)(4) (TR434, Page 1)

- SEM surface and cross-sectional pictures are provided in TR434.

Reviewer's comment: *Although these data were not measured on the subject device, they are accepted based on the rationale provided in #1 above.*

4. Bonding strength between HA and titanium alloy or metal:

- Static Tensile Strength (64 samples)
  - Method: ASTM F1147 (Amendment 27: TR-311, Page 2)
  - Results: (b)(4) (Amendment 27: TR-311, Page 4)
  - Failure Areas: Adhesion/Glue (Amendment 27: TR-311, Page 4)

- Static Shear Strength (5 samples)
  - Method: ASTM F1044 (Amendment 27: TR-311, Page 2)
  - Results: (b)(4) (Amendment 27: TR-311, Page 5)
  - Failure Areas: Adhesion/Glue (Amendment 27: TR-311, Page 5)

- Shear Fatigue Strength (5 samples)
  - Method: ASTM F1160 (Amendment 27: TR-311, Page 3)
  - Results: (b)(4) (Amendment 27: TR-311, Page 6)
  - Failure Areas: Adhesion/Glue (Amendment 27:TR-311, Page 6 submitted to FDA on December 21, 2011)

Rationale: Bond strength measurements are performed on *50±10 µm HA coating which is the worst case for pipeline orthopedics since their parts are coated at* (b)(4). *Hence no separate measurements have been performed at* (b)(4).

Reviewer's comment: *The above tests were performed on 5 or more coupons and the results meet our acceptance criteria (if such criteria exist). However, although the coupon used for the bonding tests is made of the same material as the Pipeline Orthopedics' acetabular shell, i.e., Ti6Al4V, the coupon does not contain a porous (PST) surface as the subject device. It is not clear how the PST surface will affect the bonding strength of the HA coating. The sponsor will be asked to repeat the above tests using HA-coated test coupons with PST surface or provide rationales as to why the above test results are adequate for the HA coated subject device. MAF comment #1*

5. Solubility products of HA particles before and after coating:

Powder Form:

- Method: ADA Method using dilute phosphoric acid@ 37°C (Amendment 27: TR-313, Page 2)
- 24 Hours Results: pK_{sp} (HA) =(b)(4) (TCP) =(b)(4) (Amendment 27: TR-313, Page 3)
- 2 Weeks Results: pKsp (HA) = (b)(4) (TCP) =(b)(4) (Amendment 27: TR-313, Page 3)
- Initial pH=(b)(4) (Amendment 27: TR-313, Appendix A Raw Data)
- Final pH=(b)(4) (Amendment 27: TR-313, Appendix A Raw Data)

Coating Form:

- Method: ADA Method using dilute phosphoric acid@ 37°C (Amendment 32: TR-447, Page 5, Table 3)
- 24 Hours Results: pK_{sp}(HA) = (b)(4) pK_{sp}(TCP) = (b)(4) (Amendment 32: TR-447, Page 5, Table 3)
- 2 Weeks Results: pK_{sp}(HA) = (b)(4), pK_{sp}(TCP) (b)(4) 2 (Amendment 27: TR-313, Page 3)
- Initial pH=(b)(4) (Amendment 32: TR-447, Page 102)
- Final pH=(b)(4) (Amendment 32: TR-447, Page 102)

Rationale: The coating thickness requirement for pipeline orthopedics hip cup implant is (b)(4). Solubility testing requires scrapping off the coating from the substrate material. It is not only difficult to scrap off the coating but it is also hard to collect enough material that is required for the solubility measurements. Hence the solubility product measurements were carried out on a 25±10µm thick HA coating.

Reviewer's comment: *The above test method, test results and rationale are accepted.*

6. Dissolution rate of HA particles before and after coating:

Powder Form:

- Method: ADA Method using pH 4.65 @ 37°C (Amendment 27: TR-313, Page 2)
- Results: (b)(4) mM/sec (Amendment 27: TR-313, Page 3)
- Initial (b)(4) (Amendment 27: TR-313, Raw data)
- Final pH=(b)(4) (Amendment 27: TR-313, Raw data)

Coating Form:

- Method: ASTM F1926 TRIS buffere solution (Amendment 27: 1R-313, Page 2)
- Results: (b)(4)
  (b)(4)

Reviewer's comment: *The above test methods and results are adequate.*

PROPOSED DEFICIENCIES AND ADVISORY TO THE SPONSOR:

Note to the leader reviewer: ***Please send the following two deficiencies to the sponsor as needed:***

1. Please provide a statement that no enhanced claims regarding your plasma sprayed coating will be made for this device. Enhanced claims such as osseointegration for example would be considered unsubstantiated and should be excluded in the submission.

2. Engineering drawings of the subject device are provided in Section xx of the submission. The engineering drawings doesn't seem to contain the HA coating information. Please reference the draft Guidance '510(k) Information Needed for Hydroxyapatite Coated Orthopedic Implants' (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080224.htm) for the total surface area of the implantable portion of the coated implant as recommended in #1 of the guidance, and provide updated engineering drawing in which the area or location of the HA coating on the subject device should be clearly depicted.

ADVISORY

1. For the plasma sprayed hydroxyapatite coating, please be advised that FDA recommends that you include all characterization parameters per the draft Guidance "510(k) Information Needed for Hydroxyapatite Coated Orthopedic Implants" in your specifications on file as part of your design controls. All testing characterization should be performed on final, sterilized devices. Should you use alternative methods other than those provided in the guidance, FDA will review accordingly. Should you make any modifications to your coating, then FDA recommends that you provide the full characterization per the draft Guidance in a future 510(k) submission.

Additionally, we recommend you have the shelf life data (see below) on file as part of your design controls.

Some calcium phosphate coatings may be affected by aging in addition to shipping and storage conditions such as humidity, temperature extremes, mechanical forces, and packaging. Full characterizations per the "510(k) Information Needed for Hydroxyapatite Coated Orthopedic Implants" are recommended at the end of your requested shelf life, as well as at the beginning, unless there is reasonable evidence that the coating is relatively unaffected by the aging, shipping and storage conditions. Please provide the Ca/P ratio per wet chemistry methods and the solubility product on the coating at the initial time and at the proposed shelf life time (in addition to interim time points) exposed to humidity and temperature extremes. FDA recommends that the calcium phosphate coated products tested be in the same packaging that would be used for the marketed product and exposed to the appropriate test variables. We would entertain accelerated aging on devices with plasma sprayed calcium phosphate coatings. Please note that we are concerned about how the coated product in its packaging (sterile barrier) is affected by not only the shelf aging of the product but by the environmental conditions for which the coating would be exposed. For example, although the coating may be aged at ambient temperatures with low relative humidity at the manufacturer, the coated product may be exposed to different environmental conditions prior to being stored in a hospital facility. The coated product may encounter winter-like conditions and/or hot, humid conditions prior to hospital storage at ambient temperature. It is these fluctuations of the environmental conditions for which we are most concerned, and we recommend that you incorporate the worst case temperature and humidity fluctuations in addition to an aging process. Please note that depending on your information, additional information may be needed to support your shelf life.

For the solubility product information, we recommend an initial comparison with the National Institute of Standards & Technology (NIST) standard reference material (SRM), #2910 or #2910(a) – Calcium Hydroxyapatite. Alternatively, you may provide solubility product testing on your coating using the NIST method. The NIST method and/or SRM #2910 or #2910(a) standard reference material information are available at http://ts.nist.gov/srm. Please provide the solubility product, (Ksp) at 37°C. The pH changes of the solution should be recorded. The solubility product (Ksp) should be calculated based on the $Ca_5(PO_4)_3(OH)$ formula. Please note that the solubility product parameters should be provided for the coatings scraped from the implant and not coupons. If plasma spraying deposition techniques are used and solubility product testing is provided from the scrapings from a coupon or test component other than the implant, we request that you provide a rationale as to how the solubility product determined from scrapings from a coupon for example is appropriate for the subject implant. We recommend using your worst case coating thickness (e.g., thinnest thickness criterion) and comparing your Ca/P ratio and solubility product at the aged condition (which has been exposed to temperature and humidity extremes) to those at the initial time point. Should these values differ significantly, then your coating may not be considered stable or reliable. In this case, additional testing may be needed to determine the appropriate shelf-life, etc.

Finally, note that some calcium phosphate coating ISO standards reference a calcining heat treatment. Unless calcining is considered a post deposition heat treatment to a coating for which the coating will be shipped for clinical use, we recommend that you analyze the final, sterilized, noncalcined coating. We are willing to accept calcined samples for the analysis of the Ca/P ratio. Please acknowledge this advisory.

PROPOSED COMMENTS TO MAF HOLDER (NOT SPONSOR)

1. The Food and Drug Administration (FDA) has reviewed the information that you have provided to Pipeline Orthopedics for their 510(k) submission, i.e., Answers to FDA 510(k) Guidance Questions within (b)(4) Mater File (b)(4), as well as the referenced Amendment 27 in the MAF-(b). Regarding your Answer #4, it appears that the test coupon used for the bonding tests is made of the same material as the Pipeline Orthopedics' device to be cleared, i.e., Ti6Al4V. However, the test coupon does not contain a porous surface as the subject device. It is not clear how the porous surface will affect the bonding strength of the HA coating. Therefore, please either provide the bonding strength tests using HA-coated test coupons with a porous surface (the porous surface should be manufactured in the same way as the subject device), or provide rationales as to why the test results that you have provided are adequate for the HA-coated subject device.

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

July 23, 2012

PIPELINE BIOMEDICAL PRODUCTS, LLC
C/O M SQUARED ASSOCIATES, INC.
901 KING STREET
SUITE 200
ALEXANDRIA, VIRGINIA 22314
ATTN: TERRY POWELL

510k Number: K122158

Received: 7/20/2012

Product: PBP TOTAL HIP SYSTEM

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm
for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html. In addition, the 510(k) Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm .

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

Grayson, Giovanna *

From: Microsoft Outlook
To: 'tpowell@msquaredassociates.com'
Sent: Monday, July 23, 2012 8:36 AM
Subject: Relayed: ack letter

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'tpowell@msquaredassociates.com'

Subject: ack letter

Sent by Microsoft Exchange Server 2007

Grayson, Giovanna *

From: Grayson, Giovanna *
Sent: Monday, July 23, 2012 8:36 AM
To: 'tpowell@msquaredassociates.com'
Subject: ack letter
Attachments: image002.png

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

July 23, 2012

POWELL
TERRY
PIPELINE BIOMEDICAL PRODUCTS, LLC
C/O M SQUARED ASSOCIATES, INC.
901 KING STREET
SUITE 200
ALEXANDRIA, VIRGINIA 22314
ATTN: TERRY POWELL

510k Number: K122158
Received: 7/20/2012
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Sincerely,

510(k) Staff

3 Cover Letter

July 19, 2012

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
USA

Reference: Pipeline Biomedical Products - 510(k) Premarket Notification
Traditional 510(k): PBP Total Hip System

In accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act, as amended, and in conformance with Title 21 of the Code of Federal Regulations Part 807 (21 CFR §807), Subpart E, this 510(k) Premarket Notification is being submitted prior to the date when Pipeline Biomedical Products proposes to introduce into interstate commerce, for commercial distribution, the PBP Total Hip System.

The hip system included in this submission contains the same components as Pipeline Orthopedics' Pipeline Total Hip System cleared through K112802. Pipeline Biomedical Products and Pipeline Orthopedics are both wholly owned subsidiaries of Pipeline Biomedical Holdings; however, since Pipeline Biomedical Products is a separate business entity from Pipeline Orthopedics, a new 510(k) is being filed so that Pipeline Biomedical Products also holds a 510k for the device system. In addition to the components that were previously cleared through K112802, line additions to the system are included in this 510(k) submission. To facilitate the 510(k) review, this 510(k) submission is closely modeled after K112802 and the response to all questions from the FDA on the original 510(k) have been incorporated into the text.

Per the instructions accessed at http://www.fda.gov/cdrh/elecsub.html, an electronic copy is being provided with this submission and it is an exact duplicate of the original paper submission.

This submission contains methods, data, and analysis of these data which the Sponsor considers "Trade Secret", commercially privileged and confidential. In accordance with 21 CFR §20.61, this information may not be disclosed to the public in accordance with Freedom of Information (FOI) Act. This submission follows the format suggested in FDA's *Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s*, dated August 12, 2005. In accordance with Appendix A of the referenced guidance, the following details are being provided in this cover letter:

- Recommended classification regulation: 888.3358 (hip joint metal/polymer/metal, semi-constrained porous-coated uncemented prosthesis), 888.3350 (Hip joint metal/polymer semi-constrained cemented prosthesis), 888.3353 (hip joint metal/ceramic/polymer semi-

constrained cemented or nonporous uncemented prosthesis)

- Class: II
- Panel: Orthopedic
- Product Code: LPH (prosthesis, hip, semi-constrained, metal/polymer, porous, uncemented), JDI (prosthesis, hip, semi-constrained, metal/polymer, cemented), OQG (hip prosthesis, semi-constrained, cemented, metal/polymer, + additive, porous, uncemented), OQH (hip, semi-constrained, cemented, metal/polymer + additive, cemented), MEH (hip, semi-constrained, uncemented, metal/polymer, non-porous, calcium-phosphate), LZO (Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis)
- Basis for submission: New device
- Design and use of the implant components:

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		--
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?	X	

- Design and use of the reusable instruments:

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		--
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?		X

The official contact person for this submission is the undersigned. Your early attention to this submission is appreciated.

Sincerely,

Terry Sheridan Powell,
M Squared Associates Inc., Consultants for Pipeline Biomedical Products, LLC.
901 King Street, Suite 200
Alexandria, VA 22314
(T) 703-562-9800, x252
(F) 7013-562-9797
(E) tpowell@msquaredassociates.com

6 Truthful and Accurate Statement

Truthful and Accurate Statement

I certify that, in my capacity as Sr. Vice President Research & Development, I believe, to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate, and that no material fact has been omitted.

Robert C. Cohen

July 3, 2012

Date

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: December 31, 2013
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
July 19, 2012	(b)(4) [redacted]	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA &HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Pipeline Biomedical Products, LLC	None Yet		
Division Name *(if applicable)*	Phone Number *(including area code)*		
	973-267-8800		
Street Address	FAX Number *(including area code)*		
3 Wing Drive Suite 102	973-267-8810		
City	State / Province	ZIP Code	Country
Cedar Knolls	NJ	07927	USA
Contact Name			
Robert C. Cohen			
Contact Title	Contact E-mail Address		
Sr. Vice President Research & Development	rcohen@pipelineortho.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
M Squared Associates, Inc			
Division Name *(if applicable)*	Phone Number *(including area code)*		
	703-562-9800 Ext. 252		
Street Address	FAX Number *(including area code)*		
901 King Street, Suite 200	703-562-9797		
City	State / Province	ZIP Code	Country
Alexandria	VA	22314	USA
Contact Name			
Terry Powell			
Contact Title	Contact E-mail Address		
Sr. Project Manager	tpowell@msquaredassociates.com		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify)*:

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	LPH	2	JDI	3	OQG	4	OQH
5	MEH	6	LZO	7		8	

Summary of, or statement concerning, safety and effectiveness information
☒ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number	*Trade or Proprietary or Model Name*	*Manufacturer*
1	K112802	Pipeline Total Hip System	Pipeline Orthopedics
2	K101072	Tritanium Peri-Apatite Acetabular Shell	Howmedical Osteonics
3	K071535	Biolox delta Femoral Heads	Zimmer
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification
Artificial total hip replacement

	Trade or Proprietary or Model Name for This Device		Model Number
1	PBP Total Hip System	1	N/A
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 N/A	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission
☒ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code
LPH, JDI, OQG, OQH, MEH, LZO

C.F.R. Section *(if applicable)*
888.3358 and 888.3350 and 888.3353

Classification Panel
Orthopedic

Device Class
☐ Class I ☒ Class II
☐ Class III ☐ Unclassified

Indications *(from labeling)*

PBP Total Hip System is indicated for use in skeletally mature individuals undergoing surgery for total hip replacement due to:

- A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis, or congenital hip dysplasia;
- Acute traumatic fracture of the femoral head or neck;
- Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty or total hip replacement.

The PBP Total Hip System hip stems and porous structured acetabular shells are intended for cementless or cemented fixation. The porous structured surface provides biological fixation when used in a cementless application. The PBP Total Hip System HA porous structured acetabular shells are intended for cementless fixation.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H — MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number: None Yet	☒ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler

Company / Institution Name	Establishment Registration Number
Pipeline Biomedical Products, LLC	None yet – company has no product in commercial distribution yet
Division Name *(if applicable)*	Phone Number *(including area code)*: 973-267-8800
Street Address: 3 Wing Drive, Suite 102	FAX Number *(including area code)*: 973-267-8810

City	State / Province	ZIP Code	Country
Cedar Knolls	NJ	07927	USA

Contact Name	Contact Title	Contact E-mail Address
Robert C. Cohen	Sr. Vice President Research & Development	rcohen@pipelineortho.com

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number: (b)(4)	☐ Manufacturer ☐ Contract Manufacturer ☒ Contract Sterilizer ☐ Repackager / Relabeler

Company / Institution Name	Establishment Registration Number
(b)(4)	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer ☒ Contract Sterilizer ☐ Repackager / Relabeler

Company / Institution Name	Establishment Registration Number
Division Name *(if applicable)*	Phone Number *(including area code)*
Street Address	FAX Number *(including area code)*

City	State / Province	ZIP Code	Country

Contact Name	Contact Title	Contact E-mail Address

SECTION I	UTILIZATION OF STANDARDS				
Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.					
1	Standards No.	Standards Organization	Standards Title Please see FDA Forms 3654 for utilization of standards information.	Version	Date
2	Standards No.	Standards Organization	Standards Title	Version	Date
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date
Please include any additional standards to be cited on a separate page.					

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Department of Health and Human Services
Food and Drug Administration
Office of the Chief Information Officer)
1350 Piccard Drive, Room 400
Rockville, Maryland 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TRADITIONAL PREMARKET NOTIFICATION [510(K)]

PBP TOTAL HIP SYSTEM

PIPELINE BIOMEDICAL PRODUCTS, LLC
3 WING DRIVE, SUITE 102
CEDAR KNOLLS, NJ 07927

JULY 18, 2012

- CONFIDENTIAL -

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The Medical Device User Fee Cover Sheet is provided as Exhibit A-1.

2 CDRH Premarket Review Submission Cover Sheet and Related FDA forms

See Exhibit A-2 for FDA Form 3514 (CDRH cover sheet).

See Exhibit A-3 for FDA Form 3674 (Certification of Compliance with Clinicaltrials.gov).

See Exhibits A-4 for FDA Forms 3654 (Standards Data Reports).

3 Cover Letter

July 19, 2012

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
USA

Reference: Pipeline Biomedical Products - 510(k) Premarket Notification
Traditional 510(k): PBP Total Hip System

In accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act, as amended, and in conformance with Title 21 of the Code of Federal Regulations Part 807 (21 CFR §807), Subpart E, this 510(k) Premarket Notification is being submitted prior to the date when Pipeline Biomedical Products proposes to introduce into interstate commerce, for commercial distribution, the PBP Total Hip System.

The hip system included in this submission contains the same components as Pipeline Orthopedics' Pipeline Total Hip System cleared through K112802. Pipeline Biomedical Products and Pipeline Orthopedics are both wholly owned subsidiaries of Pipeline Biomedical Holdings; however, since Pipeline Biomedical Products is a separate business entity from Pipeline Orthopedics, a new 510(k) is being filed so that Pipeline Biomedical Products also holds a 510k for the device system. In addition to the components that were previously cleared through K112802, line additions to the system are included in this 510(k) submission. To facilitate the 510(k) review, this 510(k) submission is closely modeled after K112802 and the response to all questions from the FDA on the original 510(k) have been incorporated into the text.

Per the instructions accessed at http://www.fda.gov/cdrh/elecsub.html, an electronic copy is being provided with this submission and it is an exact duplicate of the original paper submission.

This submission contains methods, data, and analysis of these data which the Sponsor considers "Trade Secret", commercially privileged and confidential. In accordance with 21 CFR §20.61, this information may not be disclosed to the public in accordance with Freedom of Information (FOI) Act. This submission follows the format suggested in FDA's *Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s*, dated August 12, 2005. In accordance with Appendix A of the referenced guidance, the following details are being provided in this cover letter:

- Recommended classification regulation: 888.3358 (hip joint metal/polymer/metal, semi-constrained porous-coated uncemented prosthesis), 888.3350 (Hip joint metal/polymer semi-constrained cemented prosthesis), 888.3353 (hip joint metal/ceramic/polymer semi-

constrained cemented or nonporous uncemented prosthesis)

- Class: II
- Panel: Orthopedic
- Product Code: LPH (prosthesis, hip, semi-constrained, metal/polymer, porous, uncemented), JDI (prosthesis, hip, semi-constrained, metal/polymer, cemented), OQG (hip prosthesis, semi-constrained, cemented, metal/polymer, + additive, porous, uncemented), OQH (hip, semi-constrained, cemented, metal/polymer + additive, cemented), MEH (hip, semi-constrained, uncemented, metal/polymer, non-porous, calcium-phosphate), LZO (Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis)
- Basis for submission: New device
- Design and use of the implant components:

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		--
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?	X	

- Design and use of the reusable instruments:

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		--
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?		X

The official contact person for this submission is the undersigned. Your early attention to this submission is appreciated.

Sincerely,

Terry Sheridan Powell,
M Squared Associates Inc., Consultants for Pipeline Biomedical Products, LLC.
901 King Street, Suite 200
Alexandria, VA 22314
(T) 703-562-9800, x252
(F) 7013-562-9797
(E) tpowell@msquaredassociates.com

4 Indications for Use Statement

510(k) Number (if known): K_____to be assigned

Device Name: PBP Total Hip System

Indications for Use:

The PBP Total Hip System is indicated for use in skeletally mature individuals undergoing surgery for total hip replacement due to:

- A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis, or congenital hip dysplasia;
- Acute traumatic fracture of the femoral head or neck;
- Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty or total hip replacement.

The PBP Total Hip System hip stems and porous structured acetabular shells are intended for cementless or cemented fixation. The porous structured surface provides biological fixation when used in a cementless application.

The PBP Total Hip System HA porous structured acetabular shells are intended for cementless fixation. The HA porous structured surface provides biological fixation.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

5 510(k) Summary

The following 510k Summary is provided in accordance with the requirements of 21 CFR 807.92.

5.1. Device Name and Classification

Device Trade Name:	PBP Total Hip System
Device:	Artificial Total Hip Replacement
Regulation Number and Description:	888.3358 - Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis 888.3350 - Hip joint metal/polymer semi-constrained cemented prosthesis) 888.3353 – Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Device Class:	II
Product Codes:	LPH - prosthesis, hip, semi-constrained, metal/polymer, porous uncemented JDI - prosthesis, hip, semi-constrained, metal/polymer, cemented OQG - hip prosthesis, semi-constrained, cemented, metal/polymer, + additive, porous, uncemented OQH - hip, semi-constrained, cemented, metal/polymer + additive, cemented MEH (hip, semi-constrained, uncemented, metal/polymer, non-porous, calcium-phosphate) LZO (Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis)
Advisory Panel:	Orthopedic

5.2. Address and Registration

Submitter's Name:	Pipeline Biomedical Products, LLC
Address:	3 Wing Drive Suite 102 Cedar Knolls, NJ 07927
Contact Person:	Robert C. Cohen
Telephone Number:	(973) 267-8800
Fax Number:	(973) 267-8810
Date Summary Prepared:	July 19, 2012
Establishment Registration Number:	Not yet registered

5.3. Identification of Legally Marketed Device to which Submitter Claims Equivalence

The subject PBP Total Hip System by Pipeline Biomedical Products is substantially equivalent to the predicate devices as outlined in the following table.

Table 1: Predicate Devices

Device Name	Company	510(k) Number	Clearance Date
Pipeline Total Hip System	Pipeline Orthopedics	K112802	3/9/2012
Tritanium® Peri-Apatite Acetabular Shell System	Howmedica Osteonics	K101072 K971206	4/11/2011 2/11/1998
Biolox *delta* Ceramic Femoral Head	Zimmer	K071535	11/19/2007

5.4. Device Description

The PBP Total Hip System is an artificial hip replacement system. The system includes femoral stems, femoral heads, acetabular shells, acetabular liners, acetabular bone screws and dome hole covers (occluders) for the holes in the acetabular shells.

The PBP Femoral Stems are forged titanium alloy and feature a proximal roughened surface (plasma-sprayed CP Titanium) for interlocking press fit and stability, a polished tapered neck to minimize potential for wear debris generation, a bone-conserving flat tapered geometry with reduced A/P width (wedge design), and a contoured distal tip and reduced lateral shoulder for ease of insertion. The PBP Femoral Stems come in a range of sizes, and are offered in two offset neck options per size.

The PBP Femoral Heads are available in a polished cobalt chromium alloy or a high purity alumina oxide ceramic compound (Biolox® *delta*). The heads come in a range of diameters and extension options. The variety of head and stem sizes and offsets accommodates differences in patient anatomy, allowing the surgeon to optimize soft tissue tension and restore joint mechanics.

The PBP PST™ (Porous Structured Technology) Acetabular Shells are manufactured from titanium alloy and feature a porous structured surface or an HA porous structured surface. The shell's osteoconductive porous surface has a relatively large volumetric fully interconnected porosity. The shells feature a dome hole, are available with or without a cluster screw hole pattern for supplemental bone screw fixation, and come in a range of outer diameter sizes. The porous structured surface is designed to interlock with bone, providing a high-friction bone-interfacing surface for initial stability, and 62% - 70% fully interconnected porosity designed for bone ingrowth.

The PBP Acetabular Liners are manufactured from standard UHMWPE, or from highly crosslinked Vitamin E UHMWPE (XLVE™) for increased resistance to wear and oxidative degradation (as compared with standard UHMWPE). The liners are mechanically assembled to

the mating shells via engagement of the tightly toleranced liner taper and shell bore. The liners are available in a range of sizes and in neutral, high wall, and offset versions.

Optional components include a threaded acetabular dome hole occluder and acetabular bone screws, all manufactured from titanium alloy.

5.5. Intended Use

The PBP Total Hip System is indicated for use in skeletally mature individuals undergoing surgery for total hip replacement due to:

- A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis, or congenital hip dysplasia;
- Acute traumatic fracture of the femoral head or neck;
- Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty or total hip replacement.

The PBP Total Hip System hip stems and porous structured acetabular shells are intended for cementless or cemented fixation. The porous structured surface provides biological fixation when used in a cementless application.

The PBP Total Hip System HA porous structured acetabular shells are intended for cementless fixation. The HA porous structured surface provides biological fixation.

5.6. Comparison of Technological Characteristics

The PBP Total Hip System is manufactured from the same materials as the predicate device systems. In addition, the components are packaged, and sterilized using similar processes. The subject Total Hip System is substantially equivalent to the predicates based on comparisons of intended use, design features and technological characteristics.

5.7. Performance Testing

The following performance tests were provided to demonstrate substantial equivalence:

- Biocompatibility testing for the highly crosslinked Vitamin E Polyethylene:
  - Cytotoxicity, 10993-5
  - Maximization/Sensitization, 10993-10
  - Intracutaneous, 10993-10
  - Acute Systemic Toxicity, 10993-11
  - Sub-acute/Subchronic Systemic Toxicity, 10993-11
  - Genotoxicity, 10993-3
  - Muscle Implantation, 10993-6.
- Wear testing:
  - Testing was conducted on 28 mm, 36mm and 40mm inner diameter highly crosslinked Vitamin E poly liners, that had been EO-sterilized and accelerated aged in

accordance with ASTM F2003, and subject to wear testing in accordance with ISO 14242, using a standard walking gait cycle as specified by ISO 14242-1.

- Bidirectional pin-on-disc abrasive wear testing was also conducted to compare the wear rates of the highly-crosslinked Vitamin E poly material to conventional (standard) gamma sterilized poly under clean and abrasive conditions. The wear reduction for the Vitamin E poly over conventional poly is 35% (7.7 vs 5 mg/Mc) in clean serum and 58% (8.3 vs 3.5 mg/Mc) in an abrasive environment.

- Wear particle characterization was conducted.
- The highly-crosslinked Vitamin E Polyethylene underwent exhaustive extraction testing using both polar and non-polar solvents, with GCMS and LCMS analysis to determine all volatile, semi-volatile, and non-volatile extracts. The results were compared to a predicate material to demonstrate that no new radiation degradation products are released by the material.
- Highly-crosslinked Vitamin E Polyethylene liners underwent oxidation analysis per ASTM F2102-06 after accelerated aging per ASTM F2003, wear testing, and exhaustive extraction. The analysis was also conducted on gamma-sterilized GUR 1020 (standard poly) reference material for comparison. The highly crosslinked Vitamin E poly exhibited lower oxidation indices than the standard poly, demonstrating higher resistance to oxidation: mean surface oxidation index was 0.017 for Vitamin E and 0.097 for standard poly; maximum oxidation index was 0.029 for Vitamin E and 0.248 for standard poly; and bulk oxidation index was 0.009 for Vitamin E and 0.036 for standard poly.
- Highly-crosslinked Vitamin E Polyethylene liners were evaluated by polarized light microscopy and SEM analysis of freeze fractured surfaces, after accelerated aging per ASTM F2003 and wear testing, to demonstrate that the subject material has equivalent consolidation to a predicate material.
- Liner Assembly/Disassembly Testing: Testing of the worst case size Pipeline Hip System highly crosslinked Vitamin E poly acetabular liner and worst case size conventional poly liner were tested for push-out, lever out torque, and axial torque.
- Hip Stem Fatigue Testing was conducted for the worst case (smallest) hip stem according to the method described in ISO 7206-4:2010, Implants for surgery-Partial and total hip joint prostheses, Determination of Endurance Properties and Performance of Stemmed Femoral Components.
- Stem Neck Fatigue Testing of the worst-case size was conducted according to the methods described in ISO 7206-6:1992 Implants for surgery-Partial and total hip joint prostheses-Part 6 and ASTM F2068-03 Standard Specification for Femoral Prostheses – Metallic Implants.
- Pull off testing was conducted on the metal and ceramic femoral heads.
- Burst Strength testing was conducted on Biolox *delta* Femoral Heads according to ISO 7206-10.
- An analysis was conducted of the typical and worst case ranges of motion permitted by the designs of various liner size/style, head size/style, and stem size/style combinations. The ROM was reported for flexion/extension, abduction/adduction, and internal/external rotation per ISO 21535.

- Bone screw testing was conducted in accordance with ASTM F543-07, Standard Specification and Test Methods for Metallic Medical Bone Screws, for torsion (torque to failure) and screw pull-out (pull-out to failure).
- Characterization in accordance with relevant aspects of "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement," was completed for: 1) Acetabular Shell – PST Surface; 2) Acetabular Shell – HA PST Surface; 3) Hip Stem – Plasma-Spray Titanium Coating.
- Characterization in accordance with relevant aspects of "Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball HIP Systems" was completed for the ceramic femoral heads.
- The porous structured surface was evaluated in a transcortical canine model to assess the biological response, using histological and mechanical evaluations, at intervals up to 12 weeks.

5.8. Conclusions

The subject PBP Total Hip System shares the same indications for use as the predicate hip system, and a comparison of technological characteristics supported by performance testing demonstrates the Substantial Equivalence of the PBP Total Hip System to the predicate hip systems.

6 Truthful and Accurate Statement

Truthful and Accurate Statement

I certify that, in my capacity as Sr. Vice President Research & Development, I believe, to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate, and that no material fact has been omitted.

Robert C. Cohen

July 3, 2012

Date

7 Class III Summary and Certification

Not applicable. This device is Class II

8 Financial Certification or Disclosure Statement

Not applicable. No clinical study data is provided in support of this submission.

9 Declarations of Conformity and Summary Reports

Declarations of Conformity and Summary Reports are not provided as this is not an Abbreviated 510(k) Submission.

Summaries of performance testing are presented in Section 18.

Standards Data Forms (FDA Form 3654) for FDA Recognized Consensus material standards are provided in Exhibit A-4 as follows:

- ASTM F620 - 06 Standard Specification for Alpha Plus Beta Titanium Alloy Forgings for Surgical Implants
- ASTM F 136-08e1, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications
- ASTM 1580 - 07 Standard Specification for Titanium and Titanium-6 Aluminum-4 Vanadium Alloy Powders for Coatings of Surgical Implants
- ASTM F1537-08, Standard Specification for Wrought Cobalt-28-Chromium-6-Molybdenum Alloys for Surgical Implants
- ASTM F1472-08e1, Standard Specification for Wrought Titanium -6Aluminum - 4Vanadium Alloy for Surgical Implant Applications (Acetabular Shells)
- ASTM F648-07e1, Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants
- ASTM F2695 - 07 Standard Specification for Ultra-High Molecular Weight Polyethylene Powder Blended With Alpha-Tocopherol (Vitamin E) and Fabricated Forms for Surgical Implant Applications
- ASTM F2565 - 06 Standard Guide for Extensively Irradiation-Crosslinked Ultra-High Molecular Weight Polyethylene Fabricated Forms for Surgical Implant Applications
- ASTM F1472-08e1, Standard Specification for Wrought Titanium -6Aluminum - 4Vanadium Alloy for Surgical Implant Applications (Screws and Dome Hole Occluder)

10 Executive Summary

10.1. Concise description of device:

The PBP Total Hip System is an artificial hip replacement system comprised of femoral stems and mating metal heads; acetabular shells and mating acetabular liners; optional acetabular bone screws; and optional acetabular dome hole occluders.

Femoral Stems are forged titanium alloy, feature a proximal roughened surface (titanium plasma-sprayed), come in a range of sizes, and are offered in two offset neck options per size. Femoral Heads are available in a polished cobalt chromium alloy or a high purity alumina oxide ceramic compound (Biolox *delta*). The heads come in a range of diameters and extension options.

Acetabular Shells are manufactured from titanium alloy with a Porous Structured Technology (PST)[1] surface either with or without an HA coating. The shells feature a dome hole, are available with or without a cluster screw hole pattern for supplemental bone screw fixation, and come in a range of outer diameter sizes.

Acetabular Liners are manufactured from ultrahigh molecular weight polyethylene (standard UHMWPE or highly crosslinked Vitamin E UHMWPE). The liners are mechanically assembled to the mating shells via engagement of the liner taper with the shell bore. Locking is achieved through engagement of interrupted poly rib at the taper to sphere transition of the liner with a mating groove on the shell. Poly tabs of the liner mate with scallops on the face of the shell to prohibit rotation of the liner. The liners are available in a range of sizes, and are available in neutral, high wall, +4mm offset, +4mm offset/10° elevated, and +4mm offset/high wall options.

Optional components include threaded acetabular dome hole occluders and acetabular bone screws, all manufactured from titanium alloy.

[1] Note that the terms "PST" and "Porous Structured" terms are interchangeable as they refer to the same surface texture.

10.2. Device comparison:

Note: The PBP Total Hip System described in the subject 510k and submitted by Pipeline Biomedical Products contains the same components as the Pipeline Total Hip System submitted previously by Pipeline Orthopedics in 510k #K112802, and determined substantially equivalent. Pipeline Biomedical Products and Pipeline Orthopedics are both wholly owned subsidiaries of Pipeline Biomedical Holdings; however, since Pipeline Biomedical Products is a separate business entity from Pipeline Orthopedics, a new 510(k) is being filed so that Pipeline Biomedical Products will also hold a 510k for the device system. In addition to the components that were included in the predicate 510(k), the following new components are included in this submission: 40 mm CoCr Femoral Heads and corresponding highly crosslinked Vitamin E Acetabular Liners, Biolox *delta* Ceramic Femoral Heads, and PST (Porous Structured Technology) Acetabular Shells coated with HA (PST Acetabular Shells without HA have already been determined Substantially Equivalent).

The PBP Total Hip System has the same indications for use as the predicate Pipeline Total Hip System (K112802), modified only to reflect that the HA-coated components are for cementless use.

The metal components of the PBP Total Hip System are manufactured from cobalt chromium alloy, titanium alloy (Ti6Al4V), and commercially-pure titanium that comply with applicable ASTM standards for implantable grade materials, and that are the same materials used for the predicate Pipeline Total Hip system (K112802). The subject Total Hip System features acetabular liners that are "standard" UHMWPE, meaning they are machined from UHMWPE (GUR 1020, per ASTM F-648), packaged in inert gas (Nitrogen), and sterilized by gamma radiation at 25-40kGy, in the same way as the predicate hip system (K112802). The subject Total Hip System also features acetabular liners machined from highly crosslinked Vitamin E UHMWPE (GUR 1020 E per ASTM F-2695 and ASTM F-2565) that are sterilized via EO in the same way as the predicate hip system (K112802). The Ceramic Femoral Heads are manufactured from a high purity alumina oxide ceramic compound (Biolox *delta*) that conforms to ISO 6474-2: 2012-04. This is the same material used to manufacture the predicate Zimmer Biolox *delta* Femoral Heads (K071535).

The hip stems feature a proximal plasma-sprayed CP titanium coating identical to the coating on the predicate hip stem (K112802). Performance testing has been provided in accordance with well-established hip testing methods, such as stem/neck fatigue testing, and qualification of the head/taper connection. Performance testing of Biolox *delta* Femoral Heads on titanium tapers has been conducted in accordance with applicable test standards and FDA guidance.

The modular acetabular cups, like the predicate hip system (K112802), have acetabular shells with the same hemi-spherical design with optional supplemental screw holes and the same size range offering as the predicate system. The shell/liner assembly method—involving engagement of an interrupted poly rib at the taper to sphere transition of the liner with a mating groove on the shell, and liner poly tabs that mate with scallops on the face of the shell—is the same as for the predicate system (K112802). The modular shells include a PST surface or an HA PST surface. The PST surface is created during a single direct metal laser sintering operation during manufacture of the shell. The direct metal laser sintering (DMLS) process used for the shells is the same process used for the predicate Pipeline Total Hip System (K112802). Characterization of the PST surface and the HA PST surface supports the substantial equivalence of the surfaces.

The optional threaded dome hole occluders and the bone screws have the same design as the predicate occluder and screw components (K112802).

10.3. Concise summary of performance testing:

Performance testing includes:

- Characterization in accordance with relevant aspects of "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement," was completed for: 1) Acetabular Shell – PST Surface; 2) Acetabular Shell – HA PST Surface; 3) Hip Stem – Plasma-Spray Titanium Coating.
- Characterization in accordance with relevant aspects of "Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball HIP Systems" was completed for the ceramic femoral heads.

- UHMWPE Characterization in accordance with the FDA guidance document "Data Requirements for Ultrahigh Molecular Weight Polyethylene (UHMWPE) Used in Orthopedics", dated March 28, 1995, as well as additional parameters identified by Pipeline as relevant to the performance of standard polyethylene and highly crosslinked Vitamin E polyethylene. Additional testing conducted on the highly crosslinked Vitamin E polyethylene includes the following:
  - The highly crosslinked Vitamin E Polyethylene underwent exhaustive extraction testing using both polar and non-polar solvents, with GCMS and LCMS analysis to determine all volatile, semi-volatile, and non-volatile extracts.
  - Highly-crosslinked Vitamin E Polyethylene liners underwent oxidation analysis per ASTM F2102-06 after accelerated aging per ASTM F2003, wear testing, and exhaustive extraction. The analysis was also conducted on gamma-sterilized GUR 1020 reference material for comparison.
  - Highly-crosslinked Vitamin E Polyethylene liners were evaluated by polarized light microscopy and SEM analysis of freeze fractured surfaces, after accelerated aging per ASTM F2003 and wear testing, to demonstrate that the subject material has equivalent consolidation to a predicate material.
- Hip Stem Fatigue Testing was conducted for the worst case (smallest) hip stem according to the method described in ISO 7206-4:2010, Implants for surgery-Partial and total hip joint prostheses, Determination of Endurance Properties and Performance of Stemmed Femoral Components. The hip stems passed 5 million cycles without failure, under minimum and maximum cyclic loading of 300N and 2,300N, respectively.
- Stem Neck Fatigue Testing was conducted according to the methods described in ISO 7206-6:1992 Implants for surgery-Partial and total hip joint prostheses-Part 6 and ASTM F2068-03 Standard Specification for Femoral Prostheses – Metallic Implants. The worst case hip stem (smallest with high offset version) completed 10 million cycles without failure, under minimum and maximum cyclic loading of 534N and 5340N, respectively.

- Head/Taper Strength testing was conducted on the metal femoral heads and the average pull off force was (b)(4) for the size 22mm +3.5 head, and (b)(4) for the 28mm +10.5 head.
- Head/Taper Strength testing was conducted on the ceramic femoral heads and the average pull off force was (b)(4) for the size 28mm +3.5 head.
- Burst Strength testing was conducted on Biolox *delta* Femoral Heads sizes 28 L, 32 XL, 36 XL, and 40 XL. The femoral heads were tested axially according to ISO 7206-10 on tapers manufactured from titanium (Ti-6Al-4V). Testing confirmed that the 28 mm L (+3.5 mm) head size is the worst case size in the current offering and has a burst strength of (b)(4) which is above the average fracture strength required in FDA guidance (46kN). In addition, no ball head failed at less than 20 kN.
- An analysis was conducted of the typical and worst case ranges of motion with the results reported per ISO 21535.
- Liner push-out, lever out, and axial torque testing of the worst case size highly crosslinked Vitamin E and standard poly acetabular liner was conducted. All testing confirmed that the Total Hip System Acetabular Liners have equivalent performance when compared to predicate devices.
- Hip wear simulator testing was conducted on 28mm, 36mm, and 40mm inner diameter highly crosslinked Vitamin E poly liners, that had been EO-sterilized and accelerated aged in accordance with ASTM F2003, and subject to wear testing in accordance with ISO 14242, using a standard walking gait cycle as specified by ISO 14242-1. Wear particle characterization was also conducted. The calculated gravimetric wear rate for the highly crosslinked Vitamin E polyethylene liners is reported below:
  - 28mm: (b)(4)
  - 36mm:
  - 40mm:

  Additional wear testing was not provided for the standard poly liners because the standard poly liners use UHMWPE that is equivalent to predicate standard polyethylene with regard to UHMWPE composition and material properties, and because the standard polyethylene

liners are not thinner than or of larger inner diameter than the predicate standard poly liners.

- Bidirectional pin-on-disc abrasive wear testing was also conducted to compare the wear rates of the highly-crosslinked Vitamin E poly material to conventional gamma sterilized poly under clean and abrasive conditions.
- Bone screw testing was conducted in accordance with ASTM F543-07, Standard Specification and Test Methods for Metallic Medical Bone Screws. Testing of 6.5mm diameter (the only diameter available), 60mm long screws was conducted for torsion (torque to failure) and screw pull-out (pull-out to failure), and passed the pre-established acceptance criteria.

11 Device Description

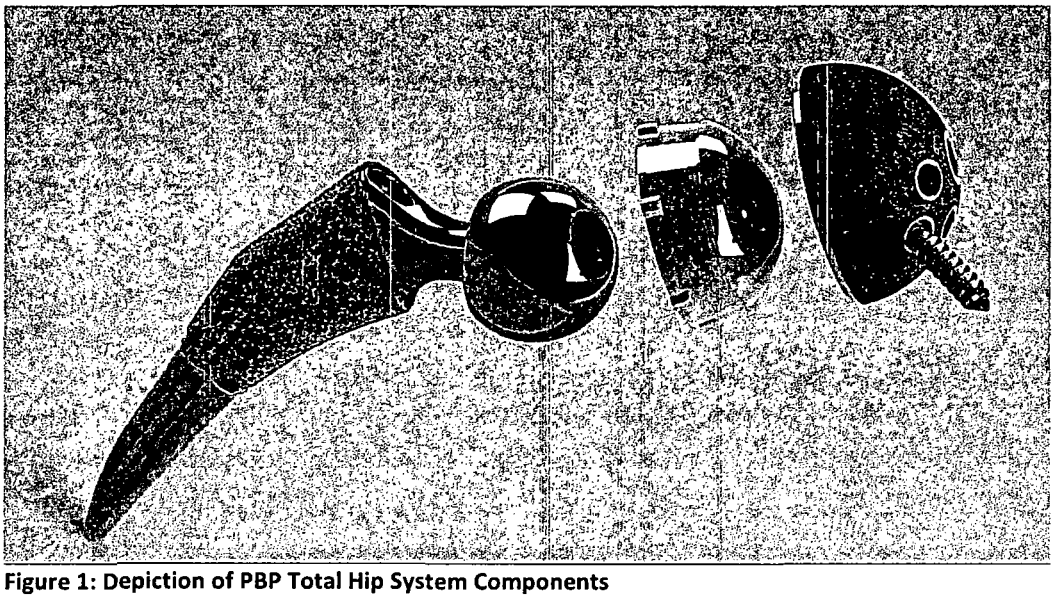


Figure 1: Depiction of PBP Total Hip System Components

11.1. System Overview

The PBP Total Hip System is an artificial hip replacement system comprised of femoral stems and mating metal heads; modular acetabular cups (acetabular shell and a mating acetabular liner); optional acetabular bone screws; and optional acetabular dome hole occluders. The PBP Total Hip System subject of this 510(k) contains the same components as the predicate Pipeline Total Hip System (K112802), with the addition of a larger head size and associated acetabular liners, ceramic femoral heads and the addition of HA coated porous structured acetabular shells. Therefore, comparisons to the predicate system are made throughout the submission. For FDA's reference, a comparison of the exhibits included in K112802 and this 510(k) is provided in Exhibit B-1 and the 510(k) summary for the Pipeline Total Hip System (K112802) is provided in Exhibit B-2.

An overview of the two systems is provided in the following table.

Table 2: Total Hip System Comparison

System Component	PBP Total Hip System* K number to be assigned (Pipeline Biomedical Products)	Pipeline Total Hip System K112802 (Pipeline Orthopedics)
Femoral Stems	Titanium Alloy Sizes 2-12 Titanium plasma sprayed 12/14 Taper Standard (Neutral) offset High (6 mm Lateral) offset	Titanium Alloy Sizes 2-12 Titanium plasma sprayed 12/14 Taper Standard (Neutral) offset High (6 mm Lateral) offset
Femoral Heads	CoCr Alloy 22, 28, 32, 36, **and 40 mm** Offsets** of -3.5mm, 0mm, +3.5mm, +7mm, and +10.5mm **Biolox *delta*** **28, 32, 36, and 40 mm** **Offsets** of -3.5mm, 0mm, +3.5mm, +7mm**	CoCr alloy 22, 28, 32, and 36 mm Offsets of -3.5mm, 0mm, +3.5mm, +7mm, and +10.5mm
Acetabular Shells	Titanium alloy 44-70 mm Surface treatment options: • PST (Porous Structured) Surface • **HA PST (Porous Structured) Surface**	Titanium alloy 44-70 mm Surface treatment: • Porous Structured Surface
Acetabular Liners	Material Options: • Standard UHMWPE (ID sizes 22, 28, 32mm) • Highly Crosslinked Vitamin E UHMWPE (ID sizes 28, 32, 36, **40mm**) Offset options: Neutral, +4mm offset, high wall, +4mm offset/10° elevated, and +4mm offset/high wall versions	Material Options: • Standard UHMWPE (ID sizes 22, 28, 32mm) • Highly Crosslinked Vitamin E UHMWPE (ID sizes 28, 32, 36mm) Offset options: Neutral, +4mm offset, high wall, +4mm offset/10° elevated, and +4mm offset/high wall versions
Bone Screws	Titanium alloy 6.5 mm diameter 15-60mm long	Titanium alloy 6.5 mm diameter 15-60mm long
Dome Hole Occluder	Titanium alloy	Titanium alloy

* Differences shown in bold

** See Section 11.3 for specific offset offering for each head size.

Additional information on the system components is provided in the sections that follow. Depictions of the implant components are provided in the draft catalogue pages provided in

Exhibit D-7. Engineering drawings for all implant components and associated trials and rasps are also provided in Exhibit C-2.

11.2. Femoral Stems

Design

The PBP Femoral Stems subject of this 510(k) have the same design as the predicate Pipeline Femoral Stems included in K112802. The stem design has a number of anatomy-preserving features that facilitate posterior, posterior-lateral, anterior-lateral, and direct anterior approaches. Detailed description information is as follows.

- The Femoral Stems feature a flat, tapered, wedge geometry which narrows medially-laterally and is thin in the anterior posterior plane. The stem design incorporates a medial geometry that remains constant, while the lateral is incrementally offset to provide medial-lateral locking. The stem design is classified as Type 1 according to Khanuja et al (Reference provided as Exhibit B-6). The tapered stem is designed to minimize the amount of bone removed from the patient as compared to other stem designs. Specifically, the reduced superior-lateral aspect of the stem body enhances preservation of the greater trochanter, the thin stem cross section and taper minimizes cancellous bone removal, and the reduced distal M/L width enhances preservation of distal cortical bone similar to the Depuy TriLock reference device. (See page 1, 3 and 5 of TriLock Bone Preservation System Design Rationale provided as Exhibit B-7.)
- The proximal portion of the stem features a plasma-sprayed commercially pure (CP) titanium coating for secure interlocking press-fit and initial stability.
- The thin proximal AP wedge geometry allows some version control by directing the broach during preparation. Torsional stability is provided by the wedging and broad flat geometry. The stem's wedge shape and consistent intervals between component sizes allow fine tuning of the stem seating height and corresponding leg length adjustment. Two offsets of each size are provided to allow tissue tensioning without affecting leg length.

- The contoured lateral aspect of the distal tip eases insertion of the stem while preserving soft tissue, especially during anterior approaches similar to the Depuy TriLock reference device. (See page 5 of TriLock Bone Preservation System Design Rationale provided as Exhibit B-7.)
- High neck cut preserves calcar bone and improves proximal support similar to the Depuy TriLock reference device. (See page 5 of TriLock Bone Preservation System Design Rational provided as Exhibit B-7.)
- The stems feature a 12/14 locking taper for assembly to the mating cobalt-chromium alloy femoral heads. The taper specifications are:
    - Angle: (b)(4) [redacted].
    - Length: (b)(4) [redacted]
    - Diameter: (b)(4) [redacted]
    - Straightness: (b)(4) [redacted]
    - Surface Texture: (b)(4) [redacted]
    - Surface Roughness: (b)(4) [redacted]
    - Taper engagement range is (b)(4) [redacted] across the range of proposed head sizes
- The neck is designed with two flats that increase the range of motion prior to the potential for impingement and dislocation to occur similar to the Exactech Novation Comprehensive Hip System. (See page 1 of Novation Operative Technique provided as Exhibit B-8.) In addition, the neck is highly polished which may reduce the creation of polyethylene wear particles during incidental impingement. The neck is also designed with a reduced geometry which optimizes the available range of motion similar to the Stryker Accolade stem. (See page 2 and 4 of the Accolade System Brochure provided as Exhibit B-9.)

Engineering drawings of the Femoral Stems are provided in Exhibit C-2.

Materials/Surfaces

The Femoral Stems subject of this 510(k) are manufactured from the same materials and methods as the predicate Pipeline Femoral Stems included in K112802. The Femoral Stems are forged Ti6Al4V ELI alloy (ASTM F-620 and ASTM F-136). The necks are polished to a typical roughness of 0.2 Ra micrometers (8 Ra microinches), with anterior and posterior flats to reduce acetabular neck impingement. The proximal portion of the stem features a plasma-sprayed commercially pure (CP) titanium coating (manufactured from CP Ti per ASTM F-1580) for increased surface roughness to support initial stability. The plasma sprayed surface has been fully characterized in section 11.9.2 of this submission in accordance with FDA Guidance, Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements," dated February 2, 2000. The roughness of the distal stem surface is a maximum of 4.5 micrometers (190 Ra microinches).

Sizing

The stems are available in 11 stem sizes from #2 to #12. The anterior/posterior widths and stem lengths increase with stem size. Each stem size is available in two femoral neck offsets: standard and high offset. Both offset options have the same neck angle and same height for head center, but the medial-lateral offset is 6-8mm greater (depending on stem size) for the high offset version to improve medial-lateral stability.

Fixation

The Femoral Stems are intended primarily for cementless fixation, but can also be used in cemented applications at the discretion of the surgeon.

11.3. Femoral Heads

Femoral heads are available in either metal or ceramic materials. These two types of heads are described in the sections that follow.

11.3.1. Metal Femoral Heads

Design

The Femoral Heads subject of this 510(k) have the same design and are manufactured from the same materials as the predicate Pipeline Femoral Heads included in 510(k) #K112802, except that the subject 510(k) adds heads in an additional diameter (40 mm).

The articulating surface of the heads is polished to a surface roughness of (b)(4) all non articulating surfaces are a maximum of (b)(4)). The heads feature a bore for assembly to the 12/14 taper of the mating hip stems. The bore characteristics are:

- Diameter: There is no constant diameter. See bore detail on engineering drawings
- Circularity: (b)(4)
- Straightness: (b)(4)
- Roughness: (b)(4)

Engineering drawings of the Femoral Heads and bore details are provided in Exhibit C-2.

Materials/Surfaces

The Femoral Heads are manufactured from ASTM F-1537 wrought CoCr alloy.

Sizing

They are available in outer diameter (OD) sizes of 22, 28, 32, 36, and 40 mm and are available in offsets of -3.5mm, 0mm, +3.5mm, +7mm, and +10.5mm, depending on head size. Select sizes have a "skirted" design. Information on the sizes of the Femoral Heads is provided in the following table.

Table 3: Metal Femoral Head Sizing

CoCr Heads					
Offset (mm)	Head diameters (mm)				
	22	28	32	36	40
-3.5		X	X	X	X
0	X	X	X	X	X
+3.5	X	X	X	X	X
+7		X*	X	X	X
+10.5		X*	X*	X*	X
* skirted design					

11.3.2. Ceramic Femoral Heads

Design

The PBP Biolox *delta* Femoral Heads are for use with the PBP Femoral Stems as described in Section 11.2 and PBP Acetabular Cups as described in Section 11.4. The ball and cone design of the Biolox *delta* Femoral Heads is provided on the drawings provided in Exhibit C-2.

Materials/Surfaces

The PBP Biolox *delta* Femoral Heads are manufactured from a high purity alumina oxide ceramic compound that conforms to ISO 6474-2: 2012-04.

Sizing

They are available in outer diameter (OD) sizes of 28, 32, 36, and 40 mm and are available in offsets of -3.5mm, 0mm, +3.5mm, +7mm, depending on head size. Information on the sizes of the Ceramic Femoral Heads is provided in the following table.

Table 4: Ceramic Femoral Head Sizing

Ceramic Heads					
Offset (mm)		Head diameters (mm)			
		28	32	36	40
S	-3.5	X	X	X	X
M	0	X	X	X	X
L	+3.5	X	X	X	X
XL	+7	NA	X	X	X

11.4. Acetabular Cups

The PBP Acetabular Cups (shell and liner) subject of this 510(k) differ from the predicate Pipeline Acetabular Cups included in 510(k) #K112802 in two ways:

- The liners are available in an additional inner diameter size (40mm) to accommodate the new 40mm femoral heads; and
- The acetabular shells, previously available with only a PST (Porous Structured Technology) surface, are now also offered in an HA PST surface.

The PBP Acetabular Cup design is comprised of a modular UHMWPE liner and a Titanium Alloy (Ti6Al4V alloy) shell. The shells are generally hemi-spherical and are offered in two surface

treatment options: PST surface and HA PST surface. The PST acetabular shells can be used in cemented or cementless applications, while the HA PST shells are intended for cementless use. The liners are mechanically assembled to the mating shells via engagement of the liner taper with the shell bore. Locking is achieved through engagement of interrupted poly rib at the taper to sphere transition of the liner with a mating groove on the shell. Poly tabs of the liner mate with scallops within the face of the shell to resist rotation of the liner.

11.4.1. Acetabular Shells

Design

The design of the PBP Acetabular Shells is the same as the predicate Pipeline Acetabular Shells, except that the subject 510(k) expands the product line to offer an HA-coated porous surface option.

The shells feature the same hemi-spherical porous outer geometry. The shell face is raised from the hemi-sphere to house the scallops that mate with the poly tabs of the liner. The shells have a PST surface. The acetabular shells feature a threaded dome hole for attachment of the shells to the insertion/extraction instruments used during hip arthroplasty. The shells are available in designs with no screw holes, or with a three-hole cluster pattern to accommodate supplemental bone screw fixation. The shells feature an inner groove at the bore-to-dome transition which locks with the interrupted poly rib on the liner, and also feature scallops on the shell face which engage with poly tabs on the liner for anti-rotation. The shell geometry and locking mechanism have the same design as the predicate Pipeline Acetabular Shells (K112802).

The shell geometry and locking mechanism are shown in the engineering drawings in Exhibit C-2.

Materials/Surfaces

There are two surface treatment options available for the shells: Porous Structured Technology (PST) surface and HA PST surface. The only difference between the two surface treatments is the addition of HA to the shell for the HA Porous Structured shell. The PBP Acetabular Shells (with the exception of the available HA coating option) are made entirely from Ti6Al4V alloy and

both the shell substrate and the porous layer meet the chemical requirements of ASTM F-1472 and the applicable mechanical properties (tensile and yield strength). The shell's osteoconductive porous surface has a relatively large volumetric fully interconnected porosity that is integral with the shell body and hence not an applied coating. The roughness of surfaces other than the porous surfaces is a minimum of (b)(4)

The porous surface is characterized in accordance with relevant FDA guidance in section 11.9.1 of this submission. The HA porous surface is characterized in accordance with relevant FDA guidance in section 11.9.2 of this submission.

Sizing

The shells are available in outer diameter (OD) sizes from 44mm to 70mm, in 2mm increments. Shell sizes 44mm to 56mm each have their own specific inner diameter for one-to-one sizing with the corresponding acetabular liners; whereas the larger shell sizes share common inner diameters for sizes 58mm-60mm, 62mm-64mm, and 66mm-70mm allowing corresponding acetabular liners to fit more than one shell size as shown in Table 5. Overall dimensions for each size are provided in the engineering drawings in Exhibit C-2. There is no change to the sizing offering as compared with predicate 510(k) #K112802.

Fixation Methods

The non-HA coated shells are intended for cemented or cementless fixation to the prepared acetabulum, while the HA-coated shells are intended for cementless fixation. The shells are assembled to their mating acetabular liners via mechanical interlock.

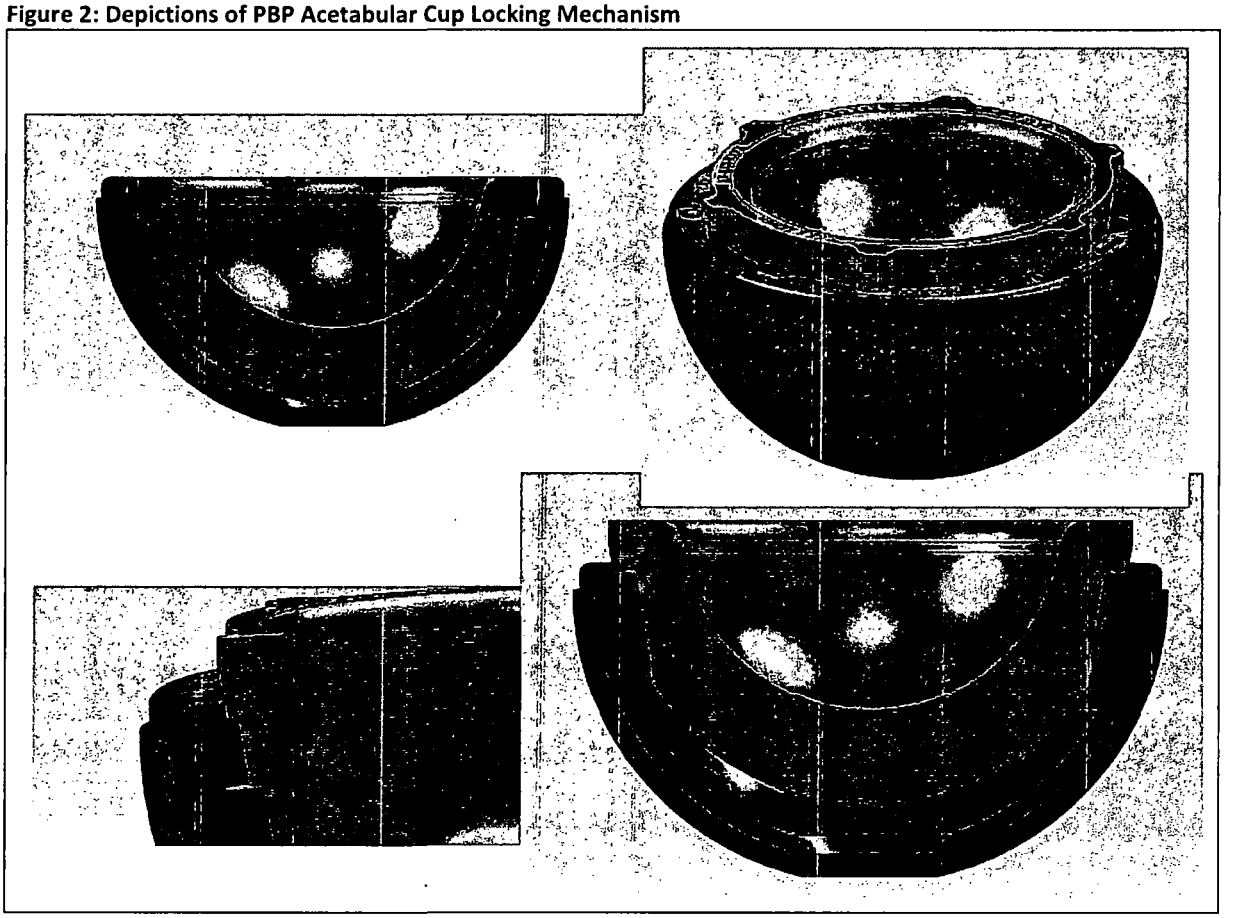
11.4.2. Acetabular Bearing Liners

The PBP Acetabular Liners subject of this 510(k) have the same design and are manufactured from the same materials as the predicate Pipeline Acetabular Liners included in 510(k) #K112802. The only difference is the addition of highly crosslinked Vitamin E UHMWPE Acetabular Liners that mate with 40 mm heads.

Design

The PBP Acetabular Liners are intraoperatively assembled to the mating PBP Acetabular Shells via engagement of the tightly tolerance liner taper and shell bore. Locking is achieved through engagement of interrupted poly rib at the taper to sphere transition of the liner with a mating groove on the shell. Poly tabs of the liner mate with scallops within the face of the shell to resist rotation of the liner (See Figure 2). The tabs of all liner configurations are designed to seat flush within the face of the shell and provide a smooth tactile feel when the liner is fully seated. These features provide stability of the liner and resistance to disassociation.

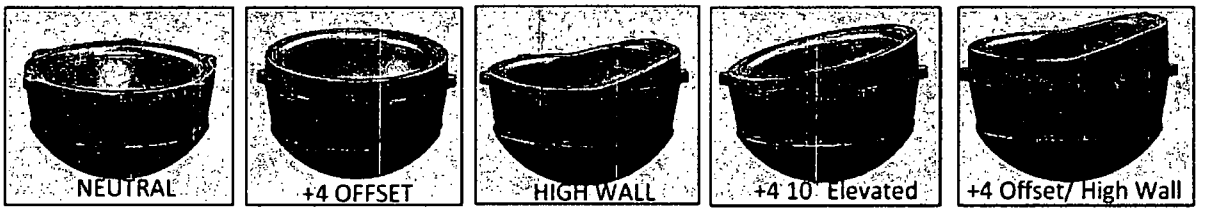
Figure 2: Depictions of PBP Acetabular Cup Locking Mechanism



Testing of the locking mechanism in accordance with applicable FDA guidance has been conducted, as described in Section 18 of this 510k. The liners have been designed for precise fit within their mating acetabular shells, with gaps less than 0.20 mm where no interior shell recesses (i.e., holes, grooves, or slots) exist. The liners are available in neutral, +4mm offset,

high wall, +4mm offset/10° elevated, and +4mm offset/high wall versions, as shown in the figure below.

Figure 3: Acetabular Liner Styles



Additional descriptive information on each style follows.

- The neutral liners have a face perpendicular to the central axis of the hemisphere, and the face of the liner sits flush with the face of the shell when assembled. The center of rotation of the inside diameter falls within 1 mm of the face of the shell for the liners with ID of 22, 28, 32, and 36 mm and 2 mm for the liners with ID of 40 mm
- The +4mm offset liners have a 4mm offset inner diameter and face relative to the neutral liner of the corresponding size, and feature a face perpendicular to the central axis of the hemisphere (0-degree, neutral face).
- The high wall liners have a similar shape and alignment to the neutral liner with the addition of an elevated rim that extends 4mm above the face in one section, then tapers back to the face. The rim can be rotated into a position that provides extra coverage as required by the surgeon.
- The +4mm offset/10° elevated liners have a face created at a ten degree angle from the face of the shell. It initiates at the outside diameter of the tabs and results in an corresponding articulating center that is offset from the corresponding neutral size liner's by approximately 4 mm. The elevated rim can be rotated into a position that provides extra coverage as required by the surgeon.
- The +4mm offset/high wall liners have an offset of 4mm of the ID, face, and elevated rim relative to the high wall liners of the corresponding size. The elevated rim can be rotated into a position that provides extra coverage as required by the surgeon.

The surface roughnesses of the PBP Acetabular Liners are (b)(4) for the articulating surfaces and (b)(4) for the non-articulating surfaces.

Engineering drawings of the PBP Acetabular Liners are provided in Exhibit C-2, and tables describing the minimum polyethylene thickness for each size and style are provided in Exhibit C-1. The minimum polyethylene thickness in the load bearing area across all sizes and styles is (b)(4) which occurs in the sizes 32mm x 48mm, and 28mm x 44mm in neutral and highwall configurations.

Materials

The PBP Acetabular Liners subject of this 510(k) are manufactured from the same materials as the predicate Pipeline Acetabular Liners included in K112802. The liners are available in standard and highly crosslinked Vitamin E ultrahigh molecular weight polyethylene (UHMWPE):

- Standard Liners: Machined from Ultra High Molecular Weight Polyethylene (GUR 1020 UHMWPE per ASTM F-648)
- Highly-Crosslinked Vitamin E (XLVE™) Liners: Machined from Vitamin E UHMWPE (GUR 1020 E per ASTM F-2695 and ASTM F-2565)

Characterization of the UHMWPE materials, in accordance with FDA Guidance "Data Requirements for Ultrahigh Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic Devices, Draft, March 28, 1995", is provided in Section 11.10 of this submission.

Sizing

The liners accommodate head sizes of 22, 28, 32, 36, and 40 mm, depending on UHMWPE choice (standard or highly crosslinked Vitamin E) and mating shell size as shown in Table 5.

Table 5: Acetabular Shell and Liner Sizing and Compatibility

Acetabular Liner - Vitamin E Poly Sizing*					
Mating Shell Size OD (mm)	Inner Diameter (ID)/Head Size (mm)				
	22	28	32	36	40
44		X			
46		X			
48		X	X		
50		X	X		
52		X	X	X	
54		X	X	X	
56		X	X	X	X
58		X	X	X	X
60					
62		X	X	X	X
64					
66		X	X	X	X
68					
70					
Acetabular Liner - Standard Poly Sizing*					
Mating Shell Size OD (mm)	Inner Diameter (ID)/Head Size (mm)				
	22	28	32	36	
44	X				
46	X				
48	X	X			
50	X	X			
52	X	X	X		
54	X	X	X		
56	X	X	X		
58	X	X	X		
60					
62	X	X	X		
64					
66	X	X	X		
68					
70					
* Available in Neutral, high wall, +4mm Offset, +4mm offset/10° elevated, and +4mm offset/ high wall options					

11.5. Optional Bone Screws and Dome Hole Occluder

The PBP Bone Screws and Dome Hole Occluders subject of this 510(k) have the same design and are manufactured from the same materials as the predicate Pipeline Bone Screws and Dome Hole Occluders included in K112802. Bone screws are provided for optional supplemental fixation of the acetabular shells. The bone screws are self-tapping, hex-head style, 6.5mm diameter screws offered in lengths from 15-60mm, in 5mm increments. A threaded dome hole occluder is provided for optional occlusion of the shell dome hole features. The dome hole occluder and bone screws are manufactured from wrought Ti6Al4V alloy (ASTM F-1472).

11.6. Instruments

The Instruments subject of this 510(k) have the same design and are manufactured from the same materials as the predicate Pipeline Instruments included in K112802. The PBP Total Hip System is implanted using a variety of orthopaedic manual surgical instruments, which are nonpowered hand-held devices intended for medical purposes to manipulate tissue or to use with other devices in orthopaedic surgery. Acetabular reamers, drill bits, starter awl, and calcar planers are also compatible for use with commercially-available, powered operating room equipment. All instruments are reusable surgical instruments provided non-sterile and intended for sterilization by the hospital before each use. The instruments are manufactured from medical grade stainless steel and from polyphenylsulfone (Radel), acetal copolymer, and polyetherimide. Handle components are manufactured from stainless steel, aluminium alloy, polyphenylsulfone (Radel), polytetrafluoroethylene (Teflon), and silicone. All have a long history of use in orthopaedic instrumentation. A listing of the surgical instruments provided for use with the PBP Total Hip System is provided in the draft catalogue pages provided in Exhibit D-7. Instruments are provided with Pipeline-instrument-specific instrument trays.

All instruments of the PBP Total Hip System are classified under 21 CFR §888.4540 and §878.4820, and are Class 1 devices exempt from 510(k) requirements subject to the limitations of 21 CFR §888.9, and §878.9.

In addition to the surgical instruments, the PBP Total Hip System also provides pre-operative x-ray templates to aid the surgeon in pre-planning the correct implant sizes for the patient. These

templates are classified under 21 CFR §888.4800, and are Class 1 medical devices exempt from 510(k) requirements subject to the limitations of 21 CFR §888.9.

11.7. Kinematics (Range of Motion)

Pipeline has conducted an analysis of the ranges of motion for flexion/extension, abduction/adduction, and internal/external rotation as specified per ISO 21535. The results are reported in Section 18.4.

11.8. Ceramic Femoral Head Characterization

The PBP Biolox *delta* Femoral Heads have been characterized according the FDA's "Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball HIP Systems" dated January 10, 1995. The characterization is provided in the sections that follow.

11.8.1. Identification of the Stem

The PBP Biolox *delta* Femoral Heads are for use with the PBP Femoral Stems as described in Section 11.2. The PBP Femoral Stems are manufactured from titanium alloy (ASTM F136). Drawings of the PBP Femoral Stems are included in Exhibit C-2.

11.8.2. Cone Design

Dimensioned engineering design drawings outlining the cone design are provided in Exhibit C-2.

11.8.3. Identification of the Ball

The PBP Biolox *delta* Femoral Heads are designed and manufactured by CeramTec GmbH. The model numbers for the subject Biolox *delta* Femoral Heads are provided in the table that follows.

Table 6: Biolox delta Femoral Head Part Number List

Offset		Head Diameter (mm)			
Descr.	mm	28 mm	32 mm	36 mm	40 mm
S	-3.5	11-101-2893-00	11-101-3293-00	11-101-3693-00	11-101-4093-00
M	0	11-101-2800-00	11-101-300-00	11-101-3600-00	11-101-4000-00
L	3.5	11-101-2803-00	11-101-3203-00	11-101-3603-00	11-101-4003-00
XL	+7	NA	11-101-3207-00	11-101-3607-00	11-101-4007-00

As stated previously, the Biolox *delta* Femoral Heads are manufactured by CeramTec from a high purity alumina oxide ceramic compound (ISO 6474-2: 2012-04) which is the same manufacturer and material used for the predicate Biolox *delta* Femoral Head marketed by Zimmer (K071535). Information on the material composition is included in CeramTec's Masterfile (Reference MAF 197 Amendendment 9, Appendix 10). A letter of access for the Masterfile is included in Exhibit A-5.5.

A description of the surface engravings is provided in Exhibit E-27.

11.8.4. Ball Design

Dimensioned engineering drawings outlining the ball design for the Biolox *delta* Femoral Heads are provided in Exhibit C-2.

Information on the Biolox *delta* material (grain size, purity, composition, specific gravity) is included in CeramTec's Masterfile (Reference MAF 197 Amendment 9, Appendix 10).

11.8.5. Mechanical Testing

Pull-off and static compression was conducted and is summarized in Section 18.8 and 18.9, respectively.

11.8.6. Labelling

Information on the draft labelling for the PBP Biolox *delta* Femoral Heads is included in Section 13.2. Information specific to the ceramic femoral heads has been incorporated in the IFU as shown in Exhibit D-6.

11.9. Surface/Coating Characterizations

11.9.1. Acetabular Shell – PST Surface

The PST surface for the subject PBP Acetabular Shell is the same as the porous structured surface for the predicate Pipeline Acetabular Shells (K112802). In support of the Pipeline Total Hip submission, an appropriate surface/coating characterization was conducted and the data is provided in the sections that follow. Note that all of the data included in this section was previously provided in support of the Pipeline Total Hip System (K112802).

Description of the Surface and Manufacturing Process

The PST surface is not technically a "coating", because the porous region is not applied to a previously manufactured acetabular shell. Rather, the acetabular shell itself is manufactured via the Direct Metal Laser Sintering (DMLS) process such that the porous structure is "built" as the shell is being produced. The shell and its porous surface are formed together during the same manufacturing operation. The PST shells manufactured through the DMLS process are annealed, and the substrate and porous layer test specimens are subjected to the annealing process per production specifications. Additional information on the DMLS process follows.

The DMLS process is an additive layer manufacturing technology where a laser sinters titanium alloy particles into a Pipeline-developed configuration. Applications for this manufacturing technology currently include medical devices as well as automotive and aerospace. The DMLS works by laser-sintering very fine layers of metal powders on a layer-by-layer basis allowing the gradual build-up of a metallic structure. In a typical DMLS cycle a 'first layer' of fine metal powder is deposited onto a platform inside the laser-sintering system. The first layer is sintered using a laser which is precisely controlled through mirrors in the X and Y coordinates to achieve the desired part shape and tolerances as specified in the CAD models. The platform then lowers and a fresh layer of powder is deposited onto the previously sintered layer. The new layer is then laser-sintered to create a bond with the previous sintered one. The resulting parts have excellent mechanical properties, high detail resolution and exceptional surface quality in that the metal powder is sintered entirely to create a fully dense, fine, homogenous structure. A fine particle size, such as the (b)(4) particle size used for Pipeline's process, can be used to obtain extremely fine detail and component features.

The DMLS process is considered self-passivating, as the process itself creates an oxide layer. Therefore, no separate passivation process is employed for manufacture of the PST shells/surface. (Pipeline's implant cleaning process, however, includes a nitric acid bath for the purpose of reducing microbial count and other metallic and non-metallic surface contaminants.)

The PBP Acetabular Shells with the PST surface are produced using direct metal laser sintering equipment developed by EOS GmbH (Electro Optical Systems), Munich, Germany.

The location of the porous surface is illustrated in the engineering drawings in Exhibit C-2.

Surface Characterization

The PST surface has been characterized in accordance with the recommendations given in "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone Or Bone Cement," dated April 28, 1994. The complete test report is provided in Exhibit E-13, Porous Coating Analysis for 510K Submission (K112802: Original 510(k)-Exhibit E-13), and the data are summarized in Table 7 and Table 8.

Table 7: PST Surface - Metallurgical Analysis of Materials

Parameter	Result
Composition and trace elements	Two representative samples were sectioned from both the porous layer and from the substrate for chemical analysis. (b)(4) [redacted] (b) [redacted].
Grain size	The average ASTM E112 grain size number for the substrate was (b)(4) [redacted] (b)(4) [redacted]).
Phases	The microstructure is relatively free of internal voids, is very uniform in appearance, and does not appear to have any interconnected phases. Overall, the microstructure is very consistent and appears to be similar to a wrought or forged component.
Corrosion	Not applicable: This requirement applies only if the implanted device assembly is made of material combinations with limited or no history of successful use in orthopedic implant applications. The shell is manufactured entirely from Ti6Al4V alloy that complies with the chemical requirements of ASTM F-1472, and which has a long history of use in orthopedic implant applications.

Table 8: PST Surface - Microstructure of the Modified Surface

Parameter	Description
Number of coating layers:	Not Applicable – the PST surface is not an applied coating. The components in this submission were developed in a continuous processing step in which both the substrate and porous coating were processed at nearly the same time. Based on the continuous processing methodology, the porous coating can be considered a single continuous layer metallurgically bonded to the substrate.
Coating thickness:	The porous layer is an integral component of the shell, and is fabricated simultaneously with the solid inner layer. The porous layer is a constant nominal thickness of (b)(4)) around the entirety of the shell for all sizes. The average coating thickness was measured to be (b)(4) (b)(4)).
Location of the modified surface:	See manufacturing drawings provided in Exhibit C-2 showing the location of the modified surface
Approximate shape of the particles or material between the pores	The interconnected pores are created by a structure of titanium alloy formed into generally round cylindrical struts.
Diameter/width (average, standard deviation and range) of the particles or material between the pores	Strut thickness: (b)(4) Strut thickness range: (b)(4)
Diameter or area of the welds (average, standard deviation) between coating particles	Not applicable – The PST surface is not formed by applying coating particles. The Ti6Al4V powder particles are completely melted into the shell shape with porous structure during the DMLS process.
Supply microphotographs	Please see report in Exhibit E-13 for microphotographs
Pore diameter (average and standard deviation) at the surface:	Pore diameter: (b)(4))
Minimum void intercept length or minimum pore diameter (average, standard deviation and range):	Pore diameter range: (b)(4)
Estimation of Porosity:	Average (b)(4) Range (b)(4)

As the PST surface for the subject PBP Acetabular Shell is the same as the porous structured surface for the predicate Pipeline Acetabular Shells (K112802), the metallurgical characteristics and the microstructure of the surface are also the same and thus substantially equivalent.

Physical Properties of the Untreated Substrate Surface

There is no "untreated" substrate surface because the porous surfaced shell is fabricated through a single manufacturing process; however, drawings of the resulting shell are provided in Exhibit C-2.

Roughness of all surfaces in micrometers (Ra): Please see the manufacturing drawings in Exhibit C-2, which provide the roughness of all surfaces.

Mechanical Properties - Modified Surface

The mechanical properties of the modified surface have been evaluated as documented in test report J1108POI-189 Rev. B, Exhibit E-14, and test report Abrasion Resistance, Study 6986, Exhibit E-16 (K112802: Response dated February 21, 2012-email attachment). Note: Study 6986, Exhibit E-16 refers to the porous structured samples as "450 abrasion disks". The test results are summarized in Table 9.

Table 9: PST Surface - Mechanical Properties

Property	Test Method	Result
Shear Fatigue Strength	ASTM F1160	(b)(4) [redacted]
Static Shear Strength	ASTM F1044	
Static Tensile Strength	ASTM F1147	
Abrasion	ASTM F1978	
Plastic Deformation (for materials with low rigidity)	Not applicable – the material does not have low rigidity as shown by the tensile strength properties.	

* Negative number indicates mass gain. Mass gain attributed to small amounts of dust from the abrasive wheel not removed by sonication step.

Figure 4: (b)(4)

Mechanical Properties – Substrate

The mechanical properties of the substrate were evaluated as documented in Exhibit E-18, report VERP-1101-VERR01 and E-19, report VERP1111-VERR01 (K112802: Original 510(k)-Exhibits E-18 and E-19, respectively). The testing was conducted on solid samples manufactured from Pipeline's direct metal laser sintering process, and representative of the Porous Structured acetabular shells. Note that because the Porous Structured surface is not an applied coating, this testing cannot be performed on "surface modified" and "non-modified" samples, as is normally performed to characterize modified metallic surfaces. The test results are summarized in Table 10.

Table 10: PST Substrate - Mechanical Properties

Property	Test Method	Result
Cyclic Fatigue	ASTM E466	S-N Curve: (b)(4)
Yield and Ultimate Tensile	ASTM E8/8M	Yield: (b)(4)

Strength		Ultimate: (b)(4)

High cycle fatigue testing of solid Ti6Al4V pieces created through the laser sintering process was completed and reported in Exhibit E-19. The endurance strength of the material was determined to be at least (b)(4) with one sample surviving to 10 million cycles at (b)(4) As presented to FDA in the January 30, 2012 AI response for Pipeline Total Hip System (K112802), these values are comparable to cast titanium alloy which has been used in orthopedic devices. They are also equal or superior to wrought or forged Ti-6Al-4V which has been processed through a sintering step for the attachment of a porous coating such as beads or wires or has had a layer of titanium plasma spray applied. Smith et. al., as summarized in the ASM Handbook of Materials for Medical Devices,[2] reports that sintering for application of bead or wire porous coatings typically reduces the high cycle fatigue strength of the Ti-6Al-4V material to less than 200 MPa, while application of a plasma sprayed coating typically reduces the HCF strength to 370 MPa. Therefore, the fatigue endurance strength of the substrate material for the subject Pipeline material is equivalent to conventional porous coated Ti-6Al-4V.

The substrate material and the manufacture processes used for the Acetabular Shells are exactly the same as used for the Pipeline Acetabular Shells included in K112802. Therefore, the mechanical properties of the substrate material are also equivalent.

Biocompatibility

The PBP Acetabular Shells are manufactured entirely from Ti6Al4V alloy that complies with the chemical requirements of ASTM F-1472, as outlined previously in Table 7 . To characterize the steady state biological response of the DMLS material, a quantitative histological evaluation of the tissue response and mechanical testing of device osseointegration was conducted. Pipeline commissioned J. Dennis Bobyn, Ph.D., Professor of Surgery and Biomedical Engineering at McGill University, Montreal, to conduct a histological and mechanical evaluation of the bone ingrowth response to the porous structured titanium surface, using the canine transcortical plug model.

[2] Smith T. The effect of plasma-sprayed coatings on the fatigue of titanium alloy implants, JOM, Feb. 1994, p54-56, *as cited in* Davis JR. Handbook of Materials for Medical Devices, ASM International, 2003, Chapter 9, page181.

Samples were evaluated histologically and mechanically at 4 weeks, 8 weeks, and 12 weeks. Results were compared to previous studies of predicate porous coatings, conducted by Dr. Bobyn using the same methods. The predicate porous coating results used for comparison were porous tantalum (marketed first by Implex as "Hedrocel" and then by Zimmer as "Trabecular Metal", 510k #K001759 and others) and cobalt-chromium sintered beaded coatings, representing the pore size ranges of 50-200µm and 200-400µm identified in previous research as optimum for implant fixation .

Bone ingrowth was observed in all the DMLS porous structured test implants at all time periods. At 4 weeks immature cortical bone had developed within the outermost pores of the implants adjacent to native cortex and to a lesser extent within the central third of the implant and within the intramedullary canal. By 8 weeks dense and more uniform bone had filled most of the implant pores adjacent to the native cortex, across the entire implant width. Of note also at 8 weeks was the conductive formation of new bone along the titanium implant struts within the intramedullary canal. At 12 weeks the histology was similar to 8 weeks, with relatively complete bone ingrowth adjacent to the cortex and dense bone formation throughout the implant pores. The mean extent of bone ingrowth at 4, 8, and 12 weeks was (b)(4) respectively.

None of the DMLS porous structured test implants demonstrated mechanical failure or compressive collapse of the porous structure during mechanical testing. The mean shear strength at both 8 weeks (b)(4) and 12 weeks (b)(4)) was statistically significantly greater ($p<0.01$) than at 4 weeks (b)(4) There was no statistically significant difference in the mean shear strength between 8 weeks and 12 weeks.

The extent of bone ingrowth for the DMLS porous structured implants was virtually the same as for the predicate tantalum porous structured implants, and the interface shear strength was statistically significantly greater at all time points for the DMLS porous structured implants than for the predicate beaded CoCr implants. Therefore, the test demonstrated that the biological response to the DMLS porous structured surface is satisfactory, comparing favorably to performing the predicate porous surfaces.

Please see Exhibit E-20 for the complete study report.

As stated previously, the materials and manufacturing processes are the same for the subject PBP Acetabular Shells and the Pipeline Acetabular Shells included in K112802. Therefore, the materials are substantially equivalent and suitable for long term implantation.

Summary

As the PST surface for the subject PBP Acetabular Shell is the same as the porous structured surface for the predicate Pipeline Acetabular Shells (K112802), the surface characterization, physical properties of the untreated substrate surface, mechanical properties of the modified surface, mechanical properties of the substrate, and material biocompatibility are also the same and thus substantially equivalent.

11.9.2. Acetabular Shell – HA PST Surface

The HA PST surface for the subject PBP Acetabular Shell has the same surface as the non-porous PBP Porous Structured Shells and the predicate Pipeline Acetabular Shells (K112802) with the addition of a thin layer (b)(4)) of HA. Appropriate surface/coating characterizations were conducted on the HA Porous Structure Surface and the data is provided in the sections that follow.

Description of the Surface and Manufacturing Process

As the PST surface is the same for both PBP Acetabular Shells, the surface and manufacturing process is the same as outlined in section 11.9.1.

HA Surface Characterization

The HA coating is applied by Orchid Orthopedic Solutions. A letter of access to Orchid's Masterfile is provided in Exhibit A-5. Additional information on the coating is provided according to FDA's guidance "510(k) Information Needed for Hydroxyapatite Coated Orthopedic Implants" revised on 2/20/1997 in Exhibit E-24: Orchid Orthopedics Answers to FDA 510(k) Guidance Questions within Orchid Bio-Coat Masterfile MAF-339. The report included in E-24 references the location of the data as outlined in FDA's guidance.[3] References are made to the

[3] Note that the results in response to item #1 in Exhibit E-24 are intentionally blacked out. The specific results are included in the location as noted in the Masterfile.

specific locations in the Masterfile and two additional reports that are provided in this submission as follows:

- E-28: Evaluation of Orchid Bio-coat HA Coating on Porous Rods Provided by Pipeline Orthopedics (TR-434: 3/12/2012); and
- E-29: Dissolution Testing for Pipeline Orthopedics Porous Rods Coated with Orchid Bio-Coat HA Coating (TR-435: 3/13/2012).

HA PST Surface Characterization

An analysis of the characterization that was conducted on the porous structured surface (included in section 11.9.1) was conducted to determine if the addition of the HA affected the surface parameters. As the layer of HA coating is very thin (b)(4)), the HA layer will have minimal effects on the surface microstructure, physical properties and mechanical properties. The characterization including the addition of the HA layer is provided in the following tables and corresponding paragraphs. Unless noted otherwise, the testing referenced in this section is included in Exhibit E-13, Porous Coating Analysis for 510K Submission.

Table 11: HA PST Surface - Metallurgical Analysis of Materials

Parameter	Result
Composition and trace elements	Please see #3 in Exhibit E-24 which provides the location of the data in Orchid's Masterfile for the chemical analysis of the HA powders before and after coating, Ca/P ratios, and elemental analysis. For the PST surface, the material composition and trace elements will be the same as for the PST surface outlined in Table 7.
Grain size	Please see #1 in Exhibit E-24 which provides the location of the data in Orchid's Masterfile for particle size and particle size distribution of the powders used for the coating. For the PST surface, the grain size will be the same as for the PST Surface outlined in Table 7.

Parameter	Result
Phases	Please see #1 in Exhibit E-24 which provides the location of the data in Orchid's Masterfile for particle size and particle size distribution of the powders used for the coating. For the PST surface, the phases will be the same as for the PST Surface outlined in Table 7.
Corrosion	Not applicable: This requirement applies only if the implanted device assembly is made of material combinations with limited or no history of successful use in orthopedic implant applications. The PST shell is manufactured from Ti6Al4V alloy that complies with the chemical requirements of ASTM F-1472, as outlined in Table 7, and from HA feedstock powder that complies with ASTM F-1185. Both of these materials have a long history of use in orthopedic implant applications.

Table 12: HA PST Surface - Microstructure of the Modified Surface

Parameter	Description
Number of coating layers	The PST surface will be coated with a thin layer of HA with a coating thickness of approximately (b)(4). Scanning electron microscopy pictures of the HA coating surface along with pictures of the cross-section area of the device are provided in Exhibit E-24, Figure 3. As the PST surface is not an applied coating, this parameter is not applicable to the porous structured surface.
Coating thickness	See preceding row for HA coating thickness information. For the PST surface, the porous layer is an integral component of the shell, and is fabricated simultaneously with the solid inner layer. The porous layer is a constant nominal thickness of (b)(4) around the entirety of the shell for all sizes. The average coating thickness was measured to be (b)(4)
Location of the modified surface	See manufacturing drawings provided in Exhibit C-2 showing the location of the modified surfaces.
Approximate shape of the particles or material between the pores	As the HA thickness is very thin (b)(4)), the interconnected pores are created by a structure of titanium alloy formed into generally round cylindrical struts.
Diameter/width (average, standard deviation and range) of the particles or material between the pores	As the HA thickness is very thin (b)(4)), it is not expected to change the porosity of the underlying PST surface, for which strut characteristics are provided below. Strut thickness: (b)(4)) Strut thickness range: (b)(4)

Parameter	Description
Diameter or area of the welds (average, standard deviation) between coating particles	Not applicable – The PST surface is not formed by applying coating particles. The Ti6Al4V powder particles are completely melted into the shell shape with porous structure during the DMLS process.
Supply microphotographs	Please see report in Exhibit E-24 (Figures 1-3) for microphotographs.
Pore diameter (average and standard deviation) at the surface:	As the HA thickness is very thin (b)(4)), it is not expected to change the porosity of the underlying PST material, for which the pore diameter is characterized below. Pore diameter: (b)(4) Pore diameter range: (b)(4) Please see Exhibit E-24 for additional information on the HA coating.
Minimum void intercept length or minimum pore diameter (average, standard deviation and range):	
Estimation of Porosity:	As the HA thickness is very thin (b)(4)), it is not expected to change the porosity of the underlying PST material, for which the estimation of porosity is given below. Average (b)(4) Range (b)(4) Please see Exhibit E-24 for additional information on the HA coating.

Physical Properties of the Untreated Substrate Surface

As outlined previously, there is no "untreated" substrate surface because the PST Acetabular Shells are fabricated through a single manufacturing process.

Mechanical Properties - Modified Surface

As the layer of HA coating is very thin (b)(4)), the addition of the HA layer should have no effect on the mechanical properties. Therefore, the mechanical properties will be the same as described for the PBP Acetabular Shells in Section 11.9.1, **Mechanical Properties-Modified Surface**. Please see Exhibit E-24 for additional information.

Mechanical Properties – Substrate

The mechanical properties of the substrate will be the same as for the non-HA coated PBP PST Acetabular Shells. Information on the mechanical properties of the substrate is provided in Section 11.9.1, **Mechanical Properties – Substrate.**

Biocompatibility

As stated previously, except for the HA coating feature, the Acetabular Shells are manufactured from the same materials and manufacturing processes as the predicate Pipeline Acetabular Shells included in K112802. The metal portion of the shells is made entirely from Ti6Al4V alloy that complies with the chemical requirements of ASTM F-1472, and Section 11.9.1, Biocompatibility, provides additional biocompatibility testing information on the metal portion of the shell.

The HA coating is manufactured from feedstock that complies with ASTM F1185. Please also refer to Orchid's Masterfile for biocompatibility information on the HA coating. The referenced testing and conformance to applicable materials standards provide assurance that the HA material is suitable for long term implantation.

Therefore, both materials are suitable for long term implantation for orthopedic applications, and are substantially equivalent with regard to biocompatibility to materials used for predicate devices.

Summary

As the PST surface for the subject PBP Acetabular Shell is the same as the PST surface for the predicate Pipeline Acetabular Shells (K112802), the surface characterization, physical properties of the untreated substrate surface, mechanical properties of the modified surface, mechanical properties of the substrate, and material biocompatibility are also the same and thus substantially equivalent.

For the HA PBP Acetabular Shells, the PST surface is also the same as for the predicate Pipeline Acetabular Shells (K112802). As the HA coating is very thin, the HA coating should have minimal effects on the surface characterization. Based on the comparisons and the HA data included in Orchid's Masterfile, it can be determined that the surface characterization, physical properties of the untreated substrate surface, mechanical properties of the modified surface, mechanical properties of the substrate, and material biocompatibility are at least equivalent to the predicate device and that the thin HA layer does not add new issues of safety and effectiveness.

11.9.3. Femoral Stem – Plasma-Sprayed Coating

As stated previously, the PBP Femoral Stem is the same device (same design, material, and manufacturing methods) as the predicate Pipeline Femoral Stem (K112802). Therefore, the roughened surface on the subject PBP Femoral Stem is the same as the roughened surface on the predicate Pipeline Femoral Stem. In support of the Pipeline Total Hip submission, an appropriate surface/coating characterization was conducted and the data is provided in the sections that follow. Note that all of the data included in this section was previously provided in support of the Pipeline Total Hip System (K112802 original application and request for additional information).

Description of the Surface and Manufacturing Process

The PBP Hip Stems feature a plasma-sprayed CP titanium coating on the proximal area of the titanium alloy stems as shown in the engineering diagrams in Exhibit C-2. The roughened surface is applied by Pipeline's vendor, Surface Dynamics (Cincinnati, OH or Bartlett, TN).

Surface Characterization

Complete characterization of the roughened surface was performed and the results are included in E-2, Test Report 1130501 (K112802: Response dated January 12, 2012-Exhibit 11). Table 13 summarizes the characteristics of the plasma-sprayed CP Titanium coating featured on the PBP Hip Stems, in accordance with FDA's "Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements," dated February 2, 2000.

Table 13: Plasma-Spayed CP Titanium Roughened Surface Characterization

Parameter	Characterization Data*
Metallurgical Analysis	
Composition Trace Elements Grain Size Phases	Raw materials and coating elemental analysis conform to ASTM F1580-07.
Corrosion	Corrosion: Not applicable – The FDA guidance does not require corrosion testing for material combinations that are not new and that have a history of successful clinical use in orthopedics.

Parameter	Characterization Data*
Microstructure of the Modified Surface	
Number of Coating Layers	One
Coating Thickness	Mean: (b)(4) Std. Dev.: (b)(4)
Engineering drawings showing location of modified surface and intended variations in surface thickness	Engineering drawing noting the location of the roughened surface are provided in Exhibit C-2.
Porosity Analysis	Mean percent porosity: (b)(4)
Photomicrographs of coating	Photomicrographs are included in test report.
Mechanical Properties of Modified Surface	
Shear Fatigue	There was no coating failure. Runout to 10 million cycles at (b)(4))
Static Shear	Average Rotating was (b)(4))
Static Tensile	Average Rotating was (b)(4))
Abrasion	All samples (b)(4)
Plastic Deformation	Plastic Deformation: Not applicable – coating does not have low rigidity

* All data is included in Test Report 1130501 unless noted otherwise.

Manufacturing

The plasma-sprayed coating of the final PBP Hip Stems and the test specimens used for the preceding coating characterization is produced by a (vacuum) controlled atmosphere plasma spray (CAPS) process in which molten CP Titanium is applied to the Ti6Al4V alloy substrate. The CP Ti powder is injected into a very high temperature plasma flame, where it is rapidly heated and accelerated to a high velocity. The hot material impacts on the substrate surface and rapidly cools forming a coating.

Pipeline Biomedical Products will use Surface Dynamics, Cincinnati, Ohio as the principal vendor for application of the plasma-sprayed coating; however, alternate vendors who demonstrate satisfaction of Pipeline's plasma-sprayed coating specifications may be added in accordance with Pipeline's vendor qualification process.

Summary

As the plasma-sprayed surface for the subject Femoral Stems is the same as the plasma-sprayed surface for the predicate Pipeline Femoral Stems (K112802), the surface characterization, physical properties of the untreated substrate surface, mechanical properties of the modified surface, mechanical properties of the substrate, and material biocompatibility are also the same and thus substantially equivalent.

11.10. UHMWPE Characterizations

The subject PBP Acetabular Liners have the same design and are manufactured from the same materials as the predicate Pipeline Acetabular Liners (K112802). Specifically, the PBP Acetabular Liners are machined from Ultra High Molecular Weight Polyethylene as follows:

- grade GUR 1020 UHMWPE that complies with ASTM F-648 for the standard polyethylene liners, and
- grade GUR 1020 E that complies with ASTM F-2695 and ASTM F-2565 for the highly crosslinked Vitamin E polyethylene liners.

Each material was characterized in consideration of FDA guidance document "Data Requirements for Ultrahigh Molecular Weight Polyethylene (UHMWPE) Used in Orthopedics", dated March 28, 1995, as well as additional parameters identified by Pipeline as relevant to the performance of standard polyethylene and highly crosslinked Vitamin E polyethylene. The material characterization is provided in the sections that follow. Note that all of the data included in this section was previously provided in support of the Pipeline Total Hip System (K112802).

11.10.1. Standard Poly

Pipeline Biomedical Products' standard polyethylene begins with GUR 1020 resin (Ticona GmbH, Sulzbach, Germany, Letter of Access to Ticona MAF 588 is provided in Exhibit A-5) that complies with ASTM F-648. The resin is compression molded by Pipeline's vendor, Orthoplastics Limited (Lancashire, England), according to the process described in Orthoplastics Masterfile #1781. (The MAF, which described the compression molding process applicable to both GUR 1020 resin

and GUR 1020 E resin, is on file at FDA, and a Letter of Access is provided in Exhibit A-5). The UHMWPE is then machined to final form, cleaned and packaged, and gamma sterilized at 25-40 kGy. (The gamma sterilization vendor is Steris Isomedix Services, Mentor OH.) The characteristics of the resulting UHMWPE material are summarized below. The test complete report is provided in Exhibit E-10: Report Number TP0373-2 (K112802: Original 510(k)-Exhibit E-10).

Table 14: Characterization of Standard Poly

Property	Value
Ultimate tensile strength	(b)(4) [redacted]
Yield Strength	
% Elongation	
Density	
Crystallinity	
Thermal Properties (ASTM F2625-07) Mass normalized heat of fusion of the test sample (ΔHs) Melting temperature at the peak of the melting endotherm (Tp) Onset temperature of the melting endotherm (To)	
Izod Impact Strength (ASTM D256-06a / F648-07)	
Small Punch Testing (ASTM F2183-02) Peak load Ultimate load Ultimate displacement Work to failure	
Oxidation Index Analysis (ASTM F2102-06) Surface oxidation index (SOI) Maximum oxidation index (MOI) Bulk oxidation index (BOI)	
Trans-Vinylene Index Analysis (ASTM F2381-04) Surface Trans-Vinylene Index (STVI) Maximum Trans-Vinylene Index (MTVI) Bulk Trans-Vinylene Index (BTVI)	

As stated previously, the subject PBP Acetabular Liners have the same design and are manufactured from the same material using the same processes as the predicate Pipeline Acetabular Liners (K112802), and are therefore substantially equivalent.

11.10.2. Highly-Crosslinked Vitamin E Poly

The subject PBP Acetabular Liners are manufactured from the same materials as the predicate Pipeline Acetabular Liners (K112802). The highly-crosslinked Vitamin E Polyethylene begins with resin type GUR 1020 (Ticona GmbH, Sulzbach, Germany, Letter of Access to Ticona MAF 588 is provided in Exhibit A-5) that complies with ASTM F648 – Standard Specification for Ultra-High Molecular Weight Polyethylene Powder and Fabricated Form for Surgical Implants. Vitamin E is added by the raw material supplier to the base resin at a concentration of 1000 ± 100 ppm, thus becoming GUR 1020 E resin in compliance with ASTM F 2695 - Standard Specification for Ultra-High Molecular Weight Polyethylene Powder Blended with Alpha-Tocopherol (Vitamin E) and Fabricated Forms for Surgical Implant Applications. The resin is next compression molded by Pipeline's vendor, Orthoplastics Limited (Lancashire, England), according to the process described in Orthoplastics Masterfile #1781 (on file at FDA, Letter of Access provided in Exhibit A-5) and then highly crosslinked by gamma irradiation at a dose of (b)(4) The resulting material complies with ASTM F 2565 – Standard Guide for Extensively Irradiation-Crosslinked Ultra-High Molecular Weight Polyethylene Fabricated Forms for Surgical Implant. The material is then machined to its final form, cleaned and packaged, and terminally sterilized via Ethylene Oxide. (The EO sterilization vendor is Professional Contract Sterilization, Inc., Tauton, MA). The characteristics of the resulting UHMWPE material are summarized below in Table 15. Refer to the following exhibits for further details of test methods employed:

- Exhibits E-1: Orthoplastics Test Report TP0373-1 rev 2, Highly Crosslinked GUR 1020-E Materials Characterization (K112802: Response dated Janary 12, 2012-Exhibit 10);
- Exhibit E-4: Material Characterization of Pipeline Biomedical Products' 100kGy 1020-E UHMWPE (K112802: Response dated Janary 12, 2012-Exhibit E-4);

- Exhibit E-5: FCP Behavior of one UHMW Polyethylene Material (K112802: Response dated Janary 12, 2012-Exhibit E-5);
- Exhibit E-6: J Behavior of one UHMW Polyethylene Material (K112802: Response dated Janary 12, 2012-Exhibit E-6);
- Exhibit E-21: Pin-on-Disk Wear Resistance of Conventional UHMWPE and Vitamin E Blended and Irradiated UHMWPE Under Clean and Abrasive Conditions (K112802: Response dated January 12, 2012-Exhibit 12: Abrasive conditions testing. Updated report includes clean conditions not reported in K112802); and
- Exhibit E-22: Pipeline Orthopedics Cambridge Polymer Group (CPG) Report 11497 – Radiation degradation products, accelerated aging, consolidation verification of EPoly liners (K112802: Response dated January 12, 2012-Exhibit 5).

Table 15: Characterization of Highly Crosslinked Vitamin E UHMWPE

Parameter	Value
Ultimate tensile strength	(b)(4) [redacted]
Yield Strength	
Young's Modulus (Modulus of Elasticity)	
Poisson's Ratio	
% Elongation	
Molecular Weight	
Density	
Crystallinity	

Parameter	Value
Creep	Pipeline has substituted the more clinically relevant acetabular cup hip wear simulator testing (see Section 18.10 of this 510k) for the less relevant creep test.
Wear	Method: pin-on-disc per ASTM F-732. The total wear rate results reported as average and standard deviation are: Cycles (MC) Total wear rate [mg/MC] (b)(4) [redacted] Note: wear data has been load soak corrected to account for fluid absorption during testing. See exhibit E-4.
Wear	Method: Bidirectional pin-on-disk testing that approximates the crossing motion of the total hip Gravimetric linear wear rate for abrasive conditions at $1.128x10^6$ cycles: Vitamin E blended PE pins = (b)(4) [redacted] Conventional PE pins = (b)(4) [redacted] Gravimetric linear wear rate for clean conditions at $1.128x10^6$ cycles: Vitamin E blended PE pins = (b)(4) [redacted] Conventional PE pins = (b)(4) [redacted] See exhibit E-21.
Fatigue	Separate fatigue testing was not conducted as Pipeline considers the Crack Propagation testing, summarized below, to be a more relevant test.
Crack Propagation	The Paris regime results were: Exponent (m) = (b) [redacted] Coefficient (C) = (b)(4) [redacted] $\Delta K_{inception}$ (cst) $MPa(m)^{1/2}$ = (b) [redacted] See test report for the da/dn vs. ΔK behavior for the 3 specimens. Method per ASTM E647 See Exhibit E-5.
J Integral	The coefficient and exponent for the $J = C_1 \Delta a C^2$ power law relationship was: (b)(4) [redacted] See test report for the J-R curve. (3 point bend using multiple specimen method per ASTM D6068) See Exhibit E-6.
Thin Sectioned Photomicrograph	See test report, Exhibit E-4 (Figure 9 and Appendix G for additional images), for photomicrographs of the material.

Parameter	Value
IR Spectra and Chemical Structure	(b)(4) [redacted] See test report for FTIR spectra. See Exhibit E-4.
Free Radical Concentration	10^{14} spins/g – Aged: (b)(4) [redacted] 10^{14} spins/g – Non-aged: (b)(4) [redacted] Method: electron spin resonance (ESR) spectroscopy See Exhibit E-4.
Lamellae thickness	Average (b)(4) [redacted] See Exhibit E-4.
Thermal Properties (ASTM F2625-07) Mass normalized heat of fusion of the test sample (ΔHs) Melting temperature at the peak of the melting endotherm (Tp) Onset temperature of the melting endotherm (To)	(b)(4) [redacted]) (b)(4) [redacted] (b)(4) [redacted] See Exhibit E-1.
Izod Impact Strength (D 256-06a/F648-07)	(b)(4) [redacted]) See Exhibit E-1.
Small Punch Testing (ASTM F2183-02) Peak load Ultimate load Ultimate displacement Work to failure	(b)(4) [redacted] See Exhibit E-1.
Oxidation Index Analysis (ASTM F2102-06) Surface oxidation index (SOI) Maximum oxidation index (MOI) Bulk oxidation index (BOI)	Average oxidation index (OI) for samples: (b)(4) [redacted]) (b)(4) [redacted] (b)(4) [redacted]

Parameter	Value
Oxidation Index Analysis (ASTM F2102-06) Average oxidation index (OI)	Average oxidation index (OI) for samples subsequent to accelerated aging: (b)(4) See Exhibit E-22.
Trans-Vinylene Index Analysis (ASTM F2381-04) Surface Trans-Vinylene Index (STVI) Maximum Trans-Vinylene Index (MTVI) Bulk Trans-Vinylene Index (BTVI)	(b)(4) (b)(4) (b)(4) See Exhibit E-1.
Polarized light microscopy and SEM analysis of freeze fractured surfaces	(b)(4) See Exhibit E-22.
Extraction Testing	(b)(4) See Exhibit E-22.

As stated previously, the subject PBP Acetabular Liners are manufactured from the same material using the same methods as the predicate Pipeline Acetabular Liners (K112802), and the materials are therefore substantially equivalent.

12 Substantial Equivalence Discussion

12.1. Identification of Predicate Devices

The PBP Total Hip System subject of this 510(k) is substantially equivalent to the predicates listed in the following table.

PBP Total Hip System Components (Subject Devices)	Competitive Hip System Components (Predicate Devices)	510(k) Number	Predicate Device Exhibits
Femoral Stems	Pipeline Femoral Stems	K112802	B-2
Metal Femoral Heads	Pipeline Femoral Heads	K112802	B-2
Biolox *delta* Femoral Heads	Zimmer Biolox *delta* Femoral Heads	K071535	B-5
Acetabular Shells - PST (Porous Structured) Surface - HA PST (Porous Structured) Surface	Pipeline Porous Structured Surface Acetabular Shells Howmedica Osteonics Tritanium® Peri-Apatite Acetabular Shell System	K112802 K101072 K971206	B-2 B-3 B-4
Acetabular Liners - Highly Crosslinked Vitamin E polyethylene - Standard polyethylene	Pipeline Acetabular Liners - Highly Crosslinked Vitamin E polyethylene - Standard polyethylene	K112802	B-2
Bone Screws and Dome Hole Occluder	Pipeline Bone Screws and Dome Hole Occluder	K112802	B-2

Information comparing the intended use, design, technology, materials composition, and performance is provided in the sections that follow.

12.2. Intended Use Comparison

The PBP Total Hip System is indicated for use in skeletally mature individuals undergoing surgery for total hip replacement due to:

- A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis, or congenital hip dysplasia;
- Acute traumatic fracture of the femoral head or neck;

- Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty or total hip replacement.

The PBP Total Hip System hip stems and porous structured acetabular shells are intended for cementless or cemented fixation. The porous structured surface provides biological fixation when used in a cementless application.

The PBP Total Hip System HA porous structured acetabular shells are intended for cementless fixation. The HA porous structured surface provides biological fixation.

These are the same indications cleared for the predicate Pipeline Total Hip System (K112802), with the clarification that the HA-coated components are intended for cementless use.

12.3. Design/Technology/Materials Comparison

The PBP Total Hip System components, design features, and materials are similar to the components in the predicate systems as summarized in Table 16.

Table 16: Component/Design/Materials Comparison to Predicate Devices

Component/Attribute	Subject Device	Predicate Device
Hip Stems	**PBP Total Hip System***	**Pipeline Hip System (K112802)**
Substrate Material	Ti6Al4V ELI alloy (ASTM F620 and F136)	Ti6Al4V ELI alloy (ASTM F620 and F136)
Roughened Surface	Plasma-Spayed CP Ti (ASTM F1580)	Plasma-Spayed CP Ti (ASTM F1580)
Taper	12/14	12/14
Sizing	11 sizes from size 2 to 12	11 sizes from size 2 to 12
Neck Options	Standard or High Offset	Standard or High Offset
Fixation	Cementless or Cemented	Cementless or Cemented
Metal Femoral Heads	**PBP Total Hip System**	**Pipeline Hip System (K112802)**
Material	CoCr Alloy (ASTM F1537)	CoCr Alloy (ASTM F1537)
Sizes for outer diameter and offset (neck length)	Offset (mm) / Diameter (mm): 22, 28, 32, 36, **40** -3.5: X X X X **X** 0: X X X X X **X** +3.5: X X X X X **X** +7: X* X X X **X** +10.5: X* X* X* **X** * = skirted	Offset (mm) / Diameter (mm): 22, 28, 32, 36 -3.5: X X X X 0: X X X X X +3.5: X X X X X +7: X* X X X +10.5: X* X* X* * = skirted
Ceramic Femoral Heads	**PBP Total Hip System**	**Biolox *delta* Ceramic Femoral Head (K071535)**
Material	Biolox *delta*	Biolox *delta*
Sizes for outer diameter and offset (neck length)	Offset (mm) / Diameter (mm): 28, 32, 36, 40 -3.5: X X X X 0: X X X X +3.5: X X X X +7: -- X X X	Offset (mm) / Diameter (mm): 28, 32, 36, 40 -3.5: X X X X 0: X X X X +3.5: X X X X +7: -- X X X
Acetabular Shells	**PBP Total Hip System**	**Pipeline Hip System (K112802)**
Substrate Material	Ti6Al4V alloy (ASTM F1472)	Ti6Al4V alloy (ASTM F1472)
Porous Surface	PST (Porous Structured) Surface (ASTM F1472) **HA PST (Porous Structured) Surface (ASTM F1472 and F1185)**	Porous Structured Surface (ASTM F1472)
Overall Geometry	Hemisphere	Hemisphere
Sizes (outer diameter)	44mm – 70mm	44mm – 70mm
Dome Hole?	Yes	Yes
Screw Hole Patterns	Solid or 3-hole	Solid or 3-hole

Component/Attribute	Subject Device	Predicate Device
Locking Mechanism	Engagement of interrupted poly rib at the taper to sphere transition of the liner with a mating groove on the shell. Poly tabs of the liner mate with scallops on the face of the shell.	Engagement of interrupted poly rib at the taper to sphere transition of the liner with a mating groove on the shell. Poly tabs of the liner mate with scallops on the face of the shell.
Fixation Options	Porous surface for cementless or cemented use **(HA for cementless only)**	Porous surface for cementless or cemented use
Acetabular Liners	**PBP Total Hip System**	**Pipeline Hip System (K112802)**
Material	Standard Version: UHMWPE, GUR 1020, ASTM F-648 Highly Crosslinked Vitamin E Version: UHMWPE, GUR020E, ASTM F-2695 and ASTM F-2565	Standard Version: UHMWPE, GUR 1020, ASTM F-648 Highly Crosslinked Vitamin E Version: UHMWPE, GUR020E, ASTM F-2695 and ASTM F-2565
Sizes (inner diameter)	Standard Version: 22, 28, 32mm Highly Crosslinked Vitamin E Version: 28, 32, 36, **40mm**	Standard Version: 22, 28, 32mm Highly Crosslinked Vitamin E Version: 28, 32, 36mm
Head orientation options	Neutral, Highwall, +4mm Offset, +4mm Offset/10-degree elevated, and +4mm Offset/Highwall	Neutral, Highwall, +4mm Offset, +4mm Offset/10-degree elevated, and +4mm Offset/Highwall
Bone Screws	**PBP Total Hip System**	**Pipeline Hip System (K112802)**
Material	Ti6Al4V alloy (ASTM F1472)	Ti6Al4V alloy (ASTM F1472)
Self Tapping	Yes	Yes
Lengths	15-60mm in 5mm increments	15-60mm in 5mm increments
Diameter	6.5mm	6.5mm
ome Hole Occluders	**PBP Total Hip System**	**Pipeline Hip System (K112802)**
Material	Ti6Al4V alloy (ASTM F1472)	Ti6Al4V alloy (ASTM F1472)
Optional	Yes	Yes
Threaded	Yes	Yes

* Differences shown in bold

12.4. Materials Comparison

The PBP Total Hip System components are manufactured from the following materials.

- Hip Stems – Ti6Al4V ELI alloy substrate (AFTM F620 and F136) with plasma-sprayed coating made from CP Ti (ASTM F1580)
- Femoral Heads: CoCr alloy (ASTM F-1537) and Biolox *delta* (ISO 6474-2: 2012-04)
- Acetabular Shells –T6Al4V alloy (ASTM F1472)
- HA Acetabular Shells-T6Al4V alloy (ASTM F1472 and ASTM F1185)
- Acetabular Liners – Standard Poly: UHMWPE (GUR 1020 per ASTM F-648)
- Acetabular Liners – Highly Crosslinked Vitamin E Poly: UHMWPE (GUR 1020E per ASTM F F-2695 and ASTM F-2565)
- Bone Screws: Ti6Al4V alloy (ASTM F1472)
- Dome Hole Occluder: Ti6Al4V alloy (ASTM F1472)

Except for the additional HA coating and the ceramic material, the materials used for the subject PBP Total Hip Components are the same as used for the predicate Pipeline Total Hip System (K112802). Information on these two materials follows.

- HA Coating: The HA coating on the HA PST Acetabular Shells, manufactured from feedstock that complies with ASTM F1185, is prepared and coated by Orchid Orthopedics. The HA Masterfile prepared by Orchid includes a complete material characterization. The HA PST Acetabular Shells are similar to the Howmedica Osteonics Tritanium® Peri-Apatite Acetabular Shell System (K971206) in that they are both roughened surfaces that are coated with a thin layer of calcium phosphate.
- Ceramic Material: The Biolox *delta* Femoral Heads are manufactured by CeramTec from a high purity alumina oxide ceramic compound (ISO 6474-2: 2012-04) which is the same manufacturer and material used for the predicate Biolox *delta* Femoral Head marketed by Zimmer (K071535).

12.5. Performance Testing Comparison

Performance testing was conducted and details of the testing are provided in Section 18. The performance testing supports a determination of substantial equivalence in consideration of the following.

- Characterization in accordance with relevant aspects of "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement," was completed for: 1) Acetabular Shell – PST Surface; 2) Acetabular Shell – HA PST Surface; 3) Hip Stem – Plasma-Spray Titanium Coating.
- Characterization in accordance with relevant aspects of "Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball HIP Systems" was completed for the ceramic femoral heads.
- UHMWPE Characterization was conducted in accordance with the FDA guidance document "Data Requirements for Ultrahigh Molecular Weight Polyethylene (UHMWPE) Used in Orthopedics", dated March 28, 1995, as well as additional parameters identified by Pipeline as relevant to the performance of standard polyethylene and highly crosslinked Vitamin E polyethylene. Additional testing conducted on the highly crosslinked Vitamin E polyethylene included the following.
    - The highly crosslinked Vitamin E Polyethylene underwent exhaustive extraction testing using both polar and non-polar solvents, with GCMS and LCMS analysis to determine all volatile, semi-volatile, and non-volatile extracts.
    - Highly-crosslinked Vitamin E Polyethylene liners underwent oxidation analysis per ASTM F2102-06 after accelerated aging per ASTM F2003, wear testing, and exhaustive extraction. The analysis was also conducted on gamma-sterilized GUR 1020 reference material for comparison.
    - Highly-crosslinked Vitamin E Polyethylene liners were evaluated by polarized light microscopy and SEM analysis of freeze fractured surfaces, after accelerated aging per

ASTM F2003 and wear testing, to demonstrate that the subject material has equivalent consolidation to a predicate material.

- Hip stem fatigue testing in accordance with ISO 7206-4 has demonstrated that the worst case Hip Stem could withstand 5 million cycles without failure under minimum and maximum cyclic loading of 300N and 2,300N, respectively.
- Hip stem neck fatigue testing in accordance with ISO 7206-6 and ASTM F2068-03 has demonstrated that the worst case Hip Stems can withstand 10 million cycles without failure under minimum and maximum cyclic loading of 534N and 5,340N, respectively.
- The range of motion analysis demonstrated that the design of the Total Hip System components provide appropriate range of motion equivalent to the predicate system. An analysis was conducted of the typical and worst case ranges of motion with the results reported per ISO 21535.
- The Head/Taper locking mechanism uses a traditional 12/14-style taper design, and pull-off testing for the metal heads of the worst case sizes demonstrated an average pull-off strength of 1184N (±104N) for the 22mm +3.5mm offset head and 980N (±54N) for the 28mm +10.5mm offset head. The average pull off force for the ceramic heads was 1300 N for the size 28mm +3.5 head.
- Burst Strength testing was conducted on Biolox *delta* Femoral Heads sizes 28 L, 32 XL, 36 XL, and 40 XL. The femoral heads were tested axially according to ISO 7206-10 on tapers manufactured from titanium (Ti-6Al-4V). Testing confirmed that the 28 mm L (+3.5 mm) head size is the worst case size in the current offering and has an average burst strength of 83kN which is above the average fracture strength required in FDA guidance (46kN). In addition, no ball head failed at less than 20 kN.
- The Shell/Liner locking mechanism has been tested for push-out, lever out, and axial torque. The Hip System locking mechanism exceeded several predicate device locking mechanisms with regard to push-out and lever-out resistance, and exceeded the pre-established acceptance criterion for axial torsion of 12.0 N-meter.

- Hip wear simulator testing was conducted on 28mm, 36mm, and 40mm inner diameter highly crosslinked Vitamin E poly liners, that had been EO-sterilized and accelerated aged in accordance with ASTM F2003, and subject to wear testing in accordance with ISO 14242, using a standard walking gait cycle as specified by ISO 14242-1. Wear particle characterization was also conducted. The calculated gravimetric wear rate for the highly crosslinked Vitamin E polyethylene liners is reported below:
  - (b)(4)
  - [redacted]
  - [redacted]

  The results compare favourably to the median wear rates reported for the predicate Stryker Orthopedics N2/Vac polyethylene liners, which ranged from 45.3 mm^3/Mc to 59.6 mm^3/Mc for 28mm and 32mm liners articulating with CoCr heads. (See discussion in Section 18.10.1 for further details.)

- Bidirectional pin-on-disc abrasive wear testing with wear particle characterization was also conducted to compare the wear rates of the highly-crosslinked Vitamin E poly material to conventional gamma sterilized poly under clean and abrasive conditions.

- Testing of the 6.5mm diameter bone screws (size 60mm long) was conducted in accordance with ASTM F543-07, for torsion (torque to failure) and screw pull-out (pull-out to failure), and results met the acceptance criteria for ASTM F-543 and ASTM F-1839.

12.6. Substantial Equivalence Decision Tree

Table 17 summarizes the path to Substantial Equivalence that Pipeline believes is supported within this submission.

Table 17: SE Decision Tree

Substantial Equivalence Decision Tree	YES	NO	
1. Is Product a Device?	X		If NO = Stop
2. Is Device Subject To 510(k)?	X		If NO = Stop
3. Same Indication Statement?	X		If YES = Go To 5
4. Do Differences Alter The Effect or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?		X	If YES = Go To 7
6. Could the New Characteristics Affect Safety or Effectiveness?	X		If YES = Go To 8
7. Descriptive Characteristics Precise Enough?			If NO = Go To 10 If YES = Stop SE
8. New Types of Safety or Effectiveness Questions?		X	If YES = Stop NE
9. Accepted Scientific Methods Exist?	X		If NO = Stop NE
10. Performance Data Available?	X		If NO = Request Data
11. Data Demonstrate Equivalence?	X		Final Decision: SE

13 Labeling

13.1. Package Labels

Draft package labels for one size of each PBP Total Hip System implant component and style are provided in Exhibit D-1. In accordance with the requirements of 21 CFR 801.109 and FDA guidance "Alternative to Certain Prescription Device Labeling Requirements" the implant package labels warn of the device's prescription only status by bearing the symbol "Rx Only." In addition, as is customary for orthopedic implants, Pipeline will include interior patient chart sticker labels, which will contain component identification information, to allow operating room staff to easily record the implant identification information in the patient charts.

13.2. Instructions for Use

A draft package insert (Instructions for Use) for the implants is provided in Exhibit D-2. A separate draft package insert for the ceramic femoral heads are provided in Exhibit D-6.

Draft instructions for cleaning, sterilizing/resterilizing the Hip System Instruments are provided in Exhibit D-3.

Draft surgical technique manuals for the hip stems/heads and acetabular cups are provided in Exhibits D-4 and D-5, respectively.

Draft catalogue pages are provided in Exhibit D-7.

14 Sterilization, Packaging, Shelf Life

The sterilization methods, corresponding validations, packaging and shelf life information as described in the sections that follow are the same as used for the predicate Pipeline Total Hip System and described in the 510(k) submission #K112802.

14.1. Sterilization

14.1.1. Sterilization of Implants

All implant components are provided sterile. The highly crosslinked Vitamin E polyethylene acetabular liners are sterilized by EO at Professional Contract Sterilization (Massachusetts, US). All other implants are sterilized by gamma irradiation at Steris Isomedix Services (Massachusetts, US).

For implants sterilized by gamma irradiation:

- Validation Method: Sterilization will be validated according to ISO 11137-1:2006: Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices; and to ISO 11137-2:2006: Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose.
- The source of the gamma radiation is Cobalt 60.
- Radiation Dose: The minimum and maximum radiation doses are 25 kGy and 40 kGy, respectively.
- Packaging Styles:
    - For acetabular shells, hip stems, metal and ceramic femoral heads, and acetabular liners made from standard polyethylene: the components are in a vacuum-sealed foil wrap, packaged in double PETG blisters with Tyvek lids, placed in paperboard boxes, labeled, and shrink wrapped. For the acetabular liners, the foil wrap is also backfilled with inert gas (Nitrogen) to reduce oxidative degradation during on-the-shelf storage as compared with polyethylene gamma-irradiated /packaged in air.

- For bone screws and for dome hole occluders: the components are placed in a polyethylene tube in double Tyvek/Film pouches, which are then packed in a paperboard box and shrink wrapped.

- Pyrogen testing: Not applicable - The implants are not labeled "pyrogen free."
- Sterility Assurance Level: The SAL is 10^{-6}

For implants sterilized by Ethylene Oxide (the highly crosslinked Vitamin E polyethylene acetabular liners):

- Validation: Sterilization will be validated according to AAMI/ISO 11135: Medical devices — Validation and routine control of ethylene oxide sterilization.
- Packaging: The components are packaged in low density polyethylene mesh, and then in double PETG blisters with Tyvek lids, which are placed in paperboard boxes, labeled, and shrink wrapped.
- Pyrogen testing: Not applicable - The implants are not labeled "pyrogen free."
- Sterility Assurance Level: The SAL is 10^{-6}
- Residual Levels: The maximum levels of residuals of EO and ethylene chlorohydrin that remain on the device will not exceed the maximum allowable limits described in AAMI/ISO 10993-7: Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residues for permanent contact devices as follows:
  - The average daily dose of EO to patient shall not exceed 0.1mg/d. In addition the maximum EO dose shall not exceed 4mg in the first 24 hours; 60mg in the first 30 days; and 2.5 grams in a lifetime.
  - The average daily dose of ECH to patient shall not exceed 0.4mg/d. In addition the maximum ECH dose shall not exceed 9mg in the first 24 hours; 60mg in the first 30 days' and 10 grams in a lifetime.

  The 0.1 mg/d and 0.4 mg/d are limits on continuous doses, and do not apply because the EO and ECH do not elute from the polyethylene. To confirm the limits, residual testing

was conducted on Acetabular Liner components. The measured residuals for EO and ethylene chlorohydrin on the tested components at 12 and 24 hours were well below the maximum allowable limits described by AAMI/ISO 10993-7, as shown in the table that follows.

Table 18: EO and ECH Residuals measured for EO Sterilized PBP Acetabular Liners

Cup Size	12 hours (mg/sample)		24 hours (mg/sample)		48 hours (mg/sample)	
	EO	ECH	EO	ECH	EO	ECH
Small	0.183	<0.10	0.112	<0.10	TBD	TBD
Large	0.409	<0.20	0.280	<0.20	0.269	<0.20

All sterility validation testing will be completed according to the methods given above to demonstrate an SAL of 10^{-6}, prior to release of any product for sale.

The sterilization methods and parameters used for the PBP Total Hip System are the same as used for the predicate Pipeline Total Hip System (K112802).

14.1.2. Sterilization of Instruments

The instruments provided for use with the PBP Total Hip System are reusable, are provided non-sterile, and must be sterilized/re-sterilized by the user/hospital prior to each use. Instructions for cleaning and sterilizing the instruments are provided in the draft Instructions for Use provided in Exhibit D-3, and recommended sterilization parameters are consistent with those outlined in Table 5 and 6 in ANSI/AAMI ST79:2006 as shown in the following table.

Table 19: Recommended Sterilization Parameters for Instruments

Method	Temperature	Time	Drying Time
Prevacuum	270°F (132°C)	4 minutes minimum	30 minutes minimum

Pipeline uses AAMI/ANSI/ISO 17665-1:2006 *Sterilization of Health Care Products – Moist Heat – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices*, for validation of the recommended sterilization parameters to meet a sterility assurance level (SAL) of 10^{-6} using the half cycle method. Validation of the recommended instrument sterilization methods/parameters provided in the Instructions for Use will be completed in accordance with the above-referenced standard, and per the

validation protocol (Nelson Labs) provided in Exhibit E-11, prior to the release of any Total Hip System instruments to the market. The parameters for the validation of the recommended instrument sterilization method are summarized in Table 20.

Table 20: Summary of Validation Parameters for Recommended Sterilization Method for Instruments

Description	Parameter
Sterilizer Type	Pre-vacuum
Preconditioning pulses	3
Temperature	132 degrees Celsius
Half cycle time	02 minutes
Dry time	30 minutes
Sample configuration	Tray double wrapped with 1-ply polypropylene wrap (Kimguard KC600)
SAL validation method	"Overkill method" as outlined in Annex D of ISO 17665-1 2006
Wraps used	Kimguard KC600, by Kimberly Clark, which the sterility validation vendor (Nelson Labs) verifies has 510k clearance (K082554)

The sterilization methods and parameters described in this section are the same as those for the instruments associated with the predicate Pipeline Total Hip System (K112802).

14.2. Packaging

Packaging for the implants is described in section 14.1. All packaging styles have been extensively and routinely used for packaging orthopedic implants as well as many other medical devices, and are suitable for protecting the implants and maintaining sterility during anticipated shipping and storage conditions. Pipeline conducts package qualification testing in accordance with the following standards:

- ASTM D4169, Performance testing of shipping containers, and ANSI/AAMI/ISO 11607:2003, Packaging for terminally sterilized medical devices,
- ASTM F1886, Standard Test Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection
- ASTM F88, Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F1980, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

- ASTM F2096, Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test)

All package qualification testing will be completed prior to the release of any product to market.

Reusable instruments, provided non-sterile, are packed in poly bags or sleeves, or polyester tubes and vinyl end caps. The choice of packaging depends upon the size and shape of the instrument being packaged. All packages include a label identifying the component, manufacturer, and non-sterile state.

The packaging used for the subject PBP Total Hip System and described in this section is the same as the packaging used for the predicate Pipeline Total Hip System (K112802).

14.3. Shelf Life

The packaging materials used by Pipeline have a long and successful history of use for orthopedic implants and many other medical devices. Testing by Pipeline's packaging supply vendors has demonstrated that the packaging materials maintain seal strength for at least 5 years, based on accelerated (Tyvek pouches) or real-time (Tyvek/sealant/PETG) aging studies, and are therefore capable of maintaining the sterile barrier for at least 5 years if packages are not damaged. However, Pipeline is independently verifying the shelf life of its specific package configurations using these materials.

The PBP Hip System implant components will be initially labeled with a 3 year shelf life, and the ability of the packages to maintain sterility for the labeled shelf life has been confirmed based on accelerated aging testing in accordance with ASTM F1980, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.

Product will be released with a 5-year shelf life upon successful package testing of 5-year samples prepared according to either of the sets of accelerated aging parameters described below, with concurrent real-time aging of filled packages ongoing.

- Empty packages aged at 60° C for 135 days (27 days at 60° C represents one year of real time aging) and
- Filled packages aged at 55° C for 190 days (38 days at 55° C represents one year of real time aging).

This section has been updated accordingly with new validation testing that has been completed (3-year) since the filing of the predicate Pipeline Total Hip System (K112802).

15 Biocompatibility

15.1. Implant Materials

The PBP Total Hip System implantable components are manufactured from the materials shown in Table 21. These materials are the same materials used to manufacture the components in the predicate devices. The materials comply with recognized standards for long-term implantable materials, and are the same materials used to manufacture one or more of the predicate devices.

Table 21: Materials Used in PBP Total Hip System Implant Components

PBP Total Hip System Component	Material Composition	Applicable Material Standards for Chemical Composition
Hip Stems	Substrate: Ti6Al4V ELI alloy Porous Surface: CP Titanium	ASTM F-620 and F-136 ASTM F-1580
Metal Femoral Heads	CoCr alloy	ASTM F-1537
Ceramic Femoral Heads	Biolox *delta*	ISO 6474-2: 2012-04
Acetabular Shells	Ti6Al4V alloy HA coating (feedstock powder)	ASTM F1472 ASTM F1185
Acetabular Liners Standard Poly Highly Crosslinked Vitamin E Poly	 UHMWPE UHMWPE	 ASTM F648 ASTM F-2695 and ASTM F-2565
Bone Screws and Dome Hole Occluder	Ti6Al4V alloy	ASTM F1472

Independent biocompatibility studies on these materials are not needed to demonstrate Substantial Equivalence, because these materials have decades-long successful clinical histories as materials for hip implant components, and they comply with recognized implantable materials standards, and are used to manufacture predicate devices. As biocompatibility testing was provided for the Highly-Crosslinked Vitamin E polyethylene material included in K112802, the same testing is provided in this 510(k) for reference purposes. Note that all of the testing provided in the following section was also provided in the Pipeline Total Hip 510(k) K112802 (either the original submission or the request for additional information). See Exhibit B-1 for an exhibit comparison showing the location of the data in the original 510(k) submission (K112802).

15.2. Summary of Biocompatibility Testing for Highly Crosslinked Vitamin E UHMWPE

Pipeline's highly crosslinked Vitamin E polyethylene complies with implantable material standards ASTM F-2695 and ASTM F-2565. In addition, Pipeline has commissioned NAMSA [Northwood, Ohio] to conduct biocompatibility testing, and Table 22 summarizes the biocompatibility studies undertaken for Pipeline's highly crosslinked Vitamin E UHMWPE in accordance with the applicable sections of ISO 10993. Note that the NAMSA reports refer to the test article as "crosslinked Vitamin E UHMWPE", which is the same as the material Pipeline refers to as "highly crosslinked Vitamin E UHMWPE".

Table 22: Biocompatibility Testing for Pipeline EO Sterilized Highly Crosslinked Vitamin E UHMWPE

Test	Method	Results
Cytotoxicity	ISO10993-5 MEM Extract	Passed – see test report in Exhibit F-1.
Maximization Sensitization	ISO 10993-10: 0.9% NaCl Extract	Passed – see test report in Exhibit F-2.
	ISO 10993-10: Sesame Oil, NF Extract	
Intracutaneous Study	ISO 10993-10 : 0.9% NaCl Extract	Passed – see test report in Exhibit F-3
	ISO 10993-10: Sesame Oil, NF Extract	
Systemic Toxicity	ISO 10993-11: 0.9% NaCl Extract	Passed – see test report in Exhibit F-4.
	ISO 10993-11: Sesame Oil, NF Extract	
	ISO 10993-11: 4 Week Systemic Toxicity Study in Rats Following Subcutaneous Implant	Passed - see test report in Exhibit F-5.
	ISO 10993-11: 13 Week Systemic Toxicity Study in Rats Following Subcutaneous Implant	Passed - see test report in Exhibit F-6.
Genotoxicity	ISO 10993-3: Bacteria Reverse Mutation – 0.9% NaCl Extract	Passed – see test report on Exhibit F-7.
	ISO 10993-3: Bacteria Reverse Mutation – Ethanol	
	ISO 10993-3: Mouse Peripheral Blood Micronucleus Study – 0.9% NaCl Extract	Passed – see test report in Exhibit F-8.
	ISO 10993-3: Mouse Peripheral Blood Micronucleus Study – Sesame Oil, NF Extract	
Muscle Implantation	ISO 10993-6: 2 Week Muscle Implantation Study w/ Histopathology	Passed – see test report in Exhibit F-9.
	ISO 10993-6: 26 Week Muscle Implantation Study w/ Histopathology	Passed - see test report in Exhibit F-10.

Additional information on the biocompatibility testing is provided in the sections that follow.

15.2.1. Cytotoxicity

NAMSA conducted an *in vitro* study to evaluate Pipeline's highly crosslinked Vitamin E UHMWPE for potential cytotoxic effects following the guidelines of ISO 10993-5. A single preparation of the test article was extracted in single strength Minimum Essential Medium (1X MEM) at 37°C for 24 hours. The negative control, reagent control, and positive control were similarly prepared. Triplicate monolayers of L-929 mouse fibroblast cells were doused with each extract and incubated at 37°C in the presence of 5% CO_2 for 48 hours. Following incubation, the monolayers were examined microscopically for abnormal cell morphology and cellular degeneration.

The test article extract showed no evidence of causing cell lysis or toxicity. The test article extract met the requirements of the test since the grade was less than a grade 2 (mild reactivity).

See test report in Exhibit F-1.

15.2.2. Maximization/Sensitization

NAMSA evaluated the test article, Pipeline's highly crosslinked Vitamin E UHMWPE, for its potential to cause delayed dermal contact sensitization in a guinea pig maximization test. The study was conducted based on the requirements of ISO 10993-10. The test article was extracted in 0.9% sodium chloride USP and sesame oil, NF. Each extract was intradermally injected and occlusively patched to ten test guinea pigs (per extract). The extraction vehicle was similarly injected and occlusively patched to five control guinea pigs (per vehicle). Following a recovery period, the test and control animals received a challenge patch of the appropriate test article and the vehicle control. All sites were scored for dermal reactions at 24 and 48 hours after patch removal.

The test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig. The test article extracts were not considered to be sensitizers in the guinea pig maximization test.

See test report in Exhibit F-2.

15.2.3. Intracutaneous Reactivity

NAMSA evaluated the potential for the test article, Pipeline's highly crosslinked Vitamin E UHMWPE, to cause irritation following intracutaneous injection in rabbits based on ISO 10993-10. The test article was extracted in 0.9% sodium chloride USP solution (SC) and sesame oil, NF (SO). A 0.2 mL dose of the appropriate test article extract was injected intracutaneously into five separate sites on the right side of the back of each of three animals. Similarly, the extract vehicle alone (control) was injected on the left side of the back of each animal. The injection sites were observed immediately after injection. Observations for erythema and edema were conducted at 24, 48, and 72 hours after injection.

There was no erythema and no edema from the SC test article extract injected intracutaneously into rabbits. There was very slight erythema and very slight edema from the SP test article extract injected intacutaneously into rabbits. Each test article extract met the requirements of the test since the difference between the test article extracts overall mean score and corresponding control overall mean score was less than 1.0.

See test report in Exhibit F-3.

15.2.4. Systemic Toxicity

Acute Toxicity

NAMSA conducted a study to evaluate the test article, Pipeline's highly crosslinked Vitamin E UHMWPE, for acute systemic toxicity in mice based on ISO 10993-11. The test article was extracted in 0.9% sodium chloride USP solution and sesame oil, NF. A single dose of the appropriate test article extract was injected into a group of five animals. Similarly, a separate group of five animals was dosed with each corresponding extraction vehicle alone (control). The animals were observed for signs of systemic toxicity immediately after injection and at 4, 24, 48, and 72 hours after injection. Body weights were recorded prior to dosing and on Days 1, 2, and 3.

There was no mortality or evidence of systemic toxicity from the test article extracts. The test article extracts met the requirements of the study.

See test report in Exhibit F-4.

Subacute/Subchronic and Chronic Toxicity

NAMSA conducted a study to evaluate the test article, Pipeline's highly crosslinked Vitamin E UHMWPE, in a rat surgical implantation subcutaneous tissue model to evaluate potential systemic toxicity and local tissue response at the implantation site. A separate group of animals was similarly implanted to serve as the control group.

Six male and six female animals were randomly assigned to either the test or control group. Animals were observed daily for overt signs of toxicity. Detailed clinical examinations were conducted weekly. Animals were weighed prior to implantation and at weekly intervals. At 4 weeks, the animals were euthanized and blood samples were collected for hematology and clinical chemistry analysis. A necropsy was conducted, selected organs were collected and weighed, and implantation sites were excised and examined macroscopically. A microscopic evaluation of the implantation sites and collected organs was conducted.

Clinical observations, body weights, necropsy results, organ weights, organ/body weight ratios, and organ/brain weight ratios were similar between test and control groups. There were no change in hematology or clinical chemistry values which were considered related to treatment with the test article. Microscopic evaluation of collected organs revealed no evidence of a treatment related response. Microscopic evaluation of the implantation sites indicated no significant difference in the local tissue response between the control and test articles.

There was no evidence of systemic toxicity from the test article following subcutaneous implantation in the rat. Local macroscopic tissue reaction at the test article implantation sites was not significant compared to the control article. Microscopically, the test article was classified as a nonirritant as compared to the control article.

See test report in Exhibit F-5.

An additional study was conducted by NAMSA to evaluate the potential systemic toxicity of Pipeline's highly crosslinked Vitamin E UHMWPE following subcutaneous implantation in the rat for 90 days (13 weeks). In addition, the local tissue response to the test article at the implantation sites was evaluated. The study was conducted based on ISO 10993-11, and in accordance with Good Laboratory Practices, 21 CFR Part 58. The test article was smooth round discs of Pipeline's crosslinked Vitamin E UHMWPE, and the negative control was HDPE discs which were sterilized in the same way as the test article.

Clinical observations, body weights, necropsy results, organ weights, organ/body weight rations, and organ/brain weight ratios were similar between test and control groups. There were no changes in hematology or clinical chemistry values considered related to treatment with the test article. Microscopic evaluation of collected organs revealed no evidence of a treatment related response. Microscopic evaluation of the implantation sites indicated no significant difference in the local tissue response between the control and test articles.

There was no evidence of systemic toxicity from the test article following subcutaneous implantation in the rat. Local macroscopic tissue reaction at the test article implantation sites was not significant compared to the control article. Microscopically, the test article was classified as a non-irritant as compared to the control article.

The test report is provided in Exhibit F-6.

For chronic toxicity evaluation, please see discussion of 26 week muscle implantation study in the rabbit in section 15.2.6.

15.2.5. Genotoxicity

A bacterial reverse mutation assay was conducted to evaluate whether ethanol extract and a saline extract of Pipeline's highly crosslinked Vitamin E UHMWPE would induce reverse mutations at the histidine locus of the *Salmonella typhimurium* tester strains TA98, TA100, TA1535, and TA1537 or at the tryptophan locus of *Escherichia coli* strain WP2*uvrA*. The assay was conducted in the presence and absence of metabolic activation.

Tubes containing molten top agar were inoculated with culture from one of the five tester strains, along with the ethanol and saline test article extracts. An aliquot of sterile water for injection or rat liver S9 homogenate, providing metabolic activation, was added. The mixture was poured across triplicate plates. Parallel testing was conducted with negative controls (extraction vehicle alone) and positive controls. The mean number of revertants for the test extract plates was compared to the mean number of revertants of the negative control plates for each of the five tester strains.

The ethanol and saline test article extracts were considered to be nonmutagenic to *S. typhimurium* tester strains TA98, TA100, TA1535, and TA 1537, and to *E. coli* tester strain WP2*uvrA*.

See test report in Exhibit F-7.

A mouse peripheral blood micronucleus study was also conducted by NAMSA to evaluate genotoxicity of Piepline's highly crosslinked Vitamin E polyethylene. The test article was extracted in 0.9% sodium chloride USP solution and sesame oil, NF. The extracts were evaluated for the potential to produce cytogenetic damage, resulting in micronuclei formation in the mouse peripheral blood micronucleus model.

For three consecutive days, twelve mice per test article extract (six per sex) were injected intraperitoneally with the test article extracts. Similarly, six animals per sex were dosed with either the appropriate vehicle as the negative control or methyl methanesulfonate as a positive control. All animals were observed immediately following dosing and daily for assessment of general health. On Day 4, blood was collected from the tail veins and reticulocytes were evaluated for the presence of micronuclei by flow cytometry.

The test article extracts did not induce micronuclei in the mice.

See test report in Exhibit F-8.

15.2.6. Muscle Implantation

Muscle Implantation – 2 Weeks

A muscle implantation study was conducted by NAMSA. The test article, Pipeline's highly crosslinked Vitamin E UHMWPE, was implanted in muscle tissue of the rabbit to evaluate the local tissue response in accordance with ISO 10993-6.

Implant test articles and negative control articles were sterilized by ethylene oxide and then degassed for 5 days. The test article and negative control were intramuscularly implanted and animals were euthanized 2 weeks later. Muscle tissues were excised and the implant sites examined macroscopically. A microscopic evaluation of representative implant sites from each animal was conducted to further define any tissue response.

The macroscopic reaction was not significant as compared to the negative control article. Microscopically, the test article was classified as a nonirritant as compared to the negative control article.

See test report in Exhibit F-9.

Muscle Implantation – 26 Weeks

A longer-term muscle implantation study was conducted by NAMSA. The test article, Pipeline's Crosslinked Vitamin E UHMWPE, was implanted in muscle tissue of the rabbit and was evaluated after 26 weeks of implantation to assess the local tissue response in accordance with ISO 10993-6, and as compared with a control.

The implant test article and negative control articles were sterilized by ethylene oxide and then degassed for 5 days. The test article and negative control were intramuscularly implanted and animals were euthanized 26 weeks later. Muscle tissues were excised and the implant sites examined macroscopically. A microscopic evaluation of representative implant sites from each animal was conducted to further define any tissue response.

The macroscopic reaction was not significant as compared to the negative control article. Microscopically, the test article was classified as a nonirritant as compared to the negative control article.

The test report is provided in Exhibit F-10.

16 Software

Not applicable. The device has no software.

17 Electromagnetic Compatibility and Electrical Safety

Not applicable. The device is not electronic.

18 Performance Testing – Bench

18.1. Risk Analysis and Test Plan

To identify risks associated with the subject PBP Total Hip System, a review of the hip system design and potential failure modes was conducted. The risks that were identified and the corresponding risk mitigation measure are shown in the following table.

Table 23: Risks and the Corresponding Risk Mitigation Measure

Identified Risk	Mitigation Measure
Adverse tissue reaction	Manufacture implants from implant grade materials. Manufacture instruments from materials identified as acceptable for transient usage. Conduct Biocompatibility testing for highly crosslinked Vitamin E polyethylene. Conduct canine implant bone ingrowth study for PST material.
Infection	Sterilize implants according to a validated traditional method.
Pain and/or loss of function	Perform analysis of component design and interaction to ensure satisfactory range of motion. • Range of Motion Analysis Ensure that component surface treatments provide/maintain satisfactory interface with bone or bone cement during anticipated use conditions. • Characterization of porous and HA porous surfaces in accordance with relevant FDA guidance documents.
Revision	Ensure that component designs, materials, and locking mechanisms are able to withstand expected *in vivo* loading. • Stem Fatigue Testing • Neck Fatigue Testing • Head/Taper Pull-Off Testing • Liner/Shell Push-out, Lever-out, and Torque Testing • Acetabular Liner Wear Testing • Bone Screw Testing • Burst Strength Testing

The testing conducted to demonstrate that the subject PBP Hip System has the mechanical characteristics necessary to perform as intended and to endure anticipated physiologic loading

are summarized in Sections 18.2 to 18.12, below. Additional testing to characterize the ceramic material, porous and HA porous surfaces and the UHMWPE materials is summarized in Section 11 of this 510k. Testing and information demonstrating the biocompatibility of the implant materials is summarized in Section 15 of this 510k. Measures taken to ensure the sterility of the components are summarized in Section 14 of this 510k.

As stated previously, the subject PBP Total Hip System includes the same components (same design, materials, manufacturing methods) as the predicate Pipeline Total Hip System (K112802), as well as the following additional components: Biolox *delta* Femoral Heads, 40mm heads and corresponding liners (in Vitamin E Poly version), and an HA PST Shell. Therefore, performance testing conducted on the predicate Pipeline Total Hip System is equally applicable to the subject PBP Total Hip System. Testing summarized and included in this submission that was previously included in the 510(k) for the predicate Pipeline Total Hip System (K112802) is identified below, and any new testing to address the additional Biolox *delta* Femoral Heads, 40mm heads/liners or the HA PST Shells is identified as such.

18.2. Stem Fatigue Testing

This testing is the same testing presented for predicate Pipeline Total Hip System (K112802: Original 510(k)-Exhibit E-15).

Fatigue testing was conducted according to the method described in ISO 7206-4:2010, Implants for surgery-Partial and total hip joint prostheses, Determination of Endurance Properties and Performance of Stemmed Femoral Components.

Pipeline selected size #2, high offset hip stems as the worst case stem size, because it is the smallest stem size with the smallest stem body cross-section; and selected size 28mm +10.5mm offset head as the worst case head size because +10.5mm is the longest offset moment arm to apply the test loads. The load is applied through the center of the head, therefore the head diameter of size 28mm was chosen for ease of manufacturability. Per ISO 7206-4:2010 and evaluation of the test part stem length, the test criteria for stem lengths greater than 120mm and less than or equal to 250mm was applied.

A sinusoidal load controlled compressive load was applied to the femoral head at 10 Hz. The peak compressive load was 2,300 N. The minimum compressive load was 300 N. Testing was conducted in ambient air. An axial displacement limit of 5 mm was used for all specimens. A maximum compressive load limit of 2,346 N was used for all specimens. A target run-out life of 5,000,000 was used. Six hip stem/head constructs were tested, and all samples withstood 5 million cycles without failure, satisfying the acceptance criteria given in ISO 7206-8:1995. Therefore, the endurance properties of the Hip Stems are sufficient to satisfy the intended clinical purpose.

Please see Exhibit E-15, report number J1109POI-199, for the complete test report.

18.3. Stem Neck Fatigue Testing

This testing is the same testing presented for predicate Pipeline Total Hip System (K112802: Original 510(k)-Exhibit E-15).

Fatigue testing was conducted according to the methods described in ISO 7206-6:1992 Implants for surgery-Partial and total hip joint prostheses-Part 4, Clause 7.2 and ASTM F2068-03 Standard Specification for Femoral Prostheses – Metallic Implants. ISO 7206-6 was used for fixturing and test procedure, while ASTM F2068-3 was used for the acceptance criteria of 10 million cycles with minimum and maximum cyclic loading of 534N and 5340N, respectively.

The worst case stem size identified for this test was the size 2 stem with high offset (6mm lateral offset) because it is the smallest stem with the largest neck offset. Six (6) of Size 2, high offset were used for testing. Six (6) Size 28mm +10.5mm offset heads were used. Size 28mm +10.5 offset was chosen as the worst case as it includes the longest offset moment arm to apply the test loads. The test load is applied through the center of the head, therefore the head diameter of size 28mm was chosen for ease of manufacturability.

A sinusoidal load controlled compressive load was applied to the femoral head at 20 Hz. The peak compressive load was 5,340 N. The minimum compressive load was 534 N. Testing was conducted in ambient air. The axial displacement limit was determined by adding 3 mm to the observed displacement at 1,200 cycles. A maximum compressive load limit of 5,447 N was used for all specimens. A target run-out life of 10,000,000 was used. Six samples were tested, and all

withstood 10 million cycles without failure, satisfying the pre-established acceptance criteria. Therefore, the endurance properties of the subject Hip Stems are sufficient to satisfy the intended clinical purpose.

Please see Exhibit E-15, report number J1109POI-199, for the complete test report.

18.4. Kinematics (Range of Motion)

This testing is the same testing presented for predicate Pipeline Total Hip System (K112802: Response dated January 12, 2012, Question 9).

Pipeline has conducted an analysis of the ranges of motion for the subject PBP Total Hip System. The results are reported for flexion/extension, abduction/adduction, and internal/external rotation as specified per ISO 21535 in the following table.

Table 24: Range of Motion Analyses

Neutral, Elevated and +4 offset liners			
	Abduction/Adduction	Flexion/Extension	Internal/External Rotation
22+0	(b)(4)		
22+3.5			
28+10.5			
32+10.5			
36+10.5			
40+10.5			
Hi wall and +4 hi wall liners			
	Abduction/Adduction	Flexion/Extension	Internal/External Rotation
22+0	(b)(4)		
22+3.5			
28+10.5			
32+10.5			
36+10.5			
40+10.5			

Range of motion limitations of implant systems occur when the stem neck, taper or skirted head impinges on the rim of the liner. The worst case conditions for the PBP Hip System occur when the skirt is used on the 28mm and larger diameter heads, and when the largest portion of the taper diameter interferes on the rim of 22mm liners. The addition of 40mm heads in the subject 510(k) does not create a new worst case.

As the design of the subject PBP Total Hip System is the same as for the predicate Pipeline Total Hip System (K112802), the range of motion is the same and therefore substantially equivalent.

18.5. Assembly/Disassembly Loads: Vitamin E UHMWPE

18.5.1. Liner Push-Out Testing

This testing is the same testing presented for predicate Pipeline Total Hip System (K112802: Original 510(k)-Exhibit E-7).

Pipeline commissioned a study by Orthopaedic Research Laboratories (Cleveland, OH) to test the locking mechanism strength of the Hip System Acetabular Cups. Please see Exhibit E-7, Report Number 550-6505-0811, for the complete study test report. Locking mechanism strength was evaluated by measuring the force required to push out a fully seated polyethylene liner following the methods of Tradonsky et al.[4] and ASTM F1820-97 (2009) Standard Test Method for Determining the Axial Disassembly Force of a Modular Acetabular Device.

The push-out test used six (6) Hip System 28x44mm Highly Crosslinked Vitamin E UHMWPE Liners, sterilized via EO, and a 44mm machined Ti64 shell. The 28 x 44mm liner was selected for testing because the poly liner rib is the weakest feature of the extraction test, and the size 44 shell has the shortest resulting circumferential length of the rib, therefore representing the weakest attachment. (The 28 x 44mm liner is the smallest liner in the smallest shell size for the Vitamin E UHMWPE product). Additionally, the tested design was an earlier embodiment with a shorter circumferential length than the proposed configuration.

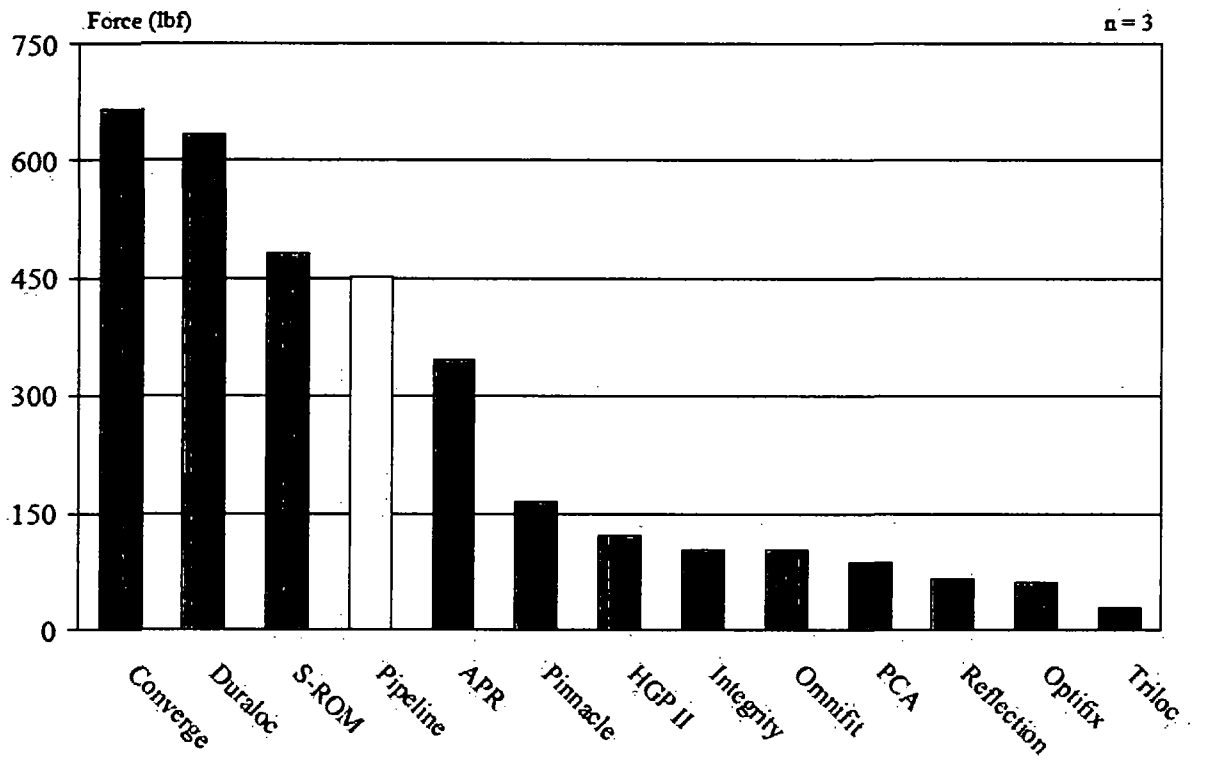
All liner assembly and push out tests were conducted on a closed-loop, servo-hydraulic testing machine (MTS Mini-Bionics, model 358.AT, MTS Corporation, Eden Prairie, MN, USA). A matched femoral head was utilized to fully seat the liner at a constant displacement rate of 0.2 inches per minute until 450 lbf of axial compression is achieved. The force-displacement curve of insertion was recorded. The push out strength was measured by supporting the rim of the cup and applying a constant displacement at 0.2 inches per minute to the liner via a 1/4 inch steel pin inserted through an apical hole (see test report for depictions of test set-up). The

[4] Tradonsky S, Postak PD, Froimson AI and Greenwald AS: A comparison of disassociation strength of modular acetabular components. Clin Orthop 296:154, 1993

force-displacement curve of disassembly was recorded. The maximum push out force, averaged for six new components, is presented as a measure of the locking mechanism strength.

The Acetabular Liner demonstrated a mean push out force of 451 pounds force, (lbf), with a standard deviation, (SD), of 48 lbf prior to disassociation. Comparative locking mechanism strength data for previously tested contemporary two piece, acetabular cup designs performed by the same researchers using the same methodology are presented in Figure 5. The Hip System acetabular cup locking mechanism design employing crosslinked vitamin E UHMWPE (Ticona GUR 1020 E) was within the range of locking mechanism strengths for the contemporary commercially-available predicate acetabular cup designs, and is therefore substantially equivalent to the predicate acetabular cups with regard to locking mechanism strength.

Figure 5: Comparative Push-out Results for Pipeline (n=6) versus Other Contemporary Acetabular Cups



18.5.2. Liner Lever Out Testing

This testing is the same testing presented for predicate Pipeline Total Hip System (K112802: Original 510(k)-Exhibit E-8).

Pipeline commissioned a study by Orthopaedic Research Laboratories (Cleveland, OH) to test the locking mechanism strength of the Hip System Acetabular Cups. Please see Exhibit E-8, Report Number 551-6505-0811, for the complete study test report. Locking mechanism strength was evaluated by measuring the force required to lever out a fully seated polyethylene liner following the methods of Tradonsky et al.[5] and ASTM F1820-97 (2009) Standard Test Method for Determining the Axial Disassembly Force of a Modular Acetabular Device.

The lever out test each used six (6) Hip System 28x44mm Highly Crosslinked Vitamin E UHMWPE Liners, sterilized via EO, and a 44mm machined Ti64 shell. The 28 x 44mm liner was selected for testing because the poly liner rib is the weakest feature of the extraction test, and the size 44 shell has the shortest resulting circumferential length of the rib, therefore representing the weakest attachment. (The 28 x 44mm liner is the smallest liner in the smallest shell size for the Vitamin E UHMWPE product). Additionally, the tested design was an earlier embodiment with a shorter circumferential length than the proposed configuration.

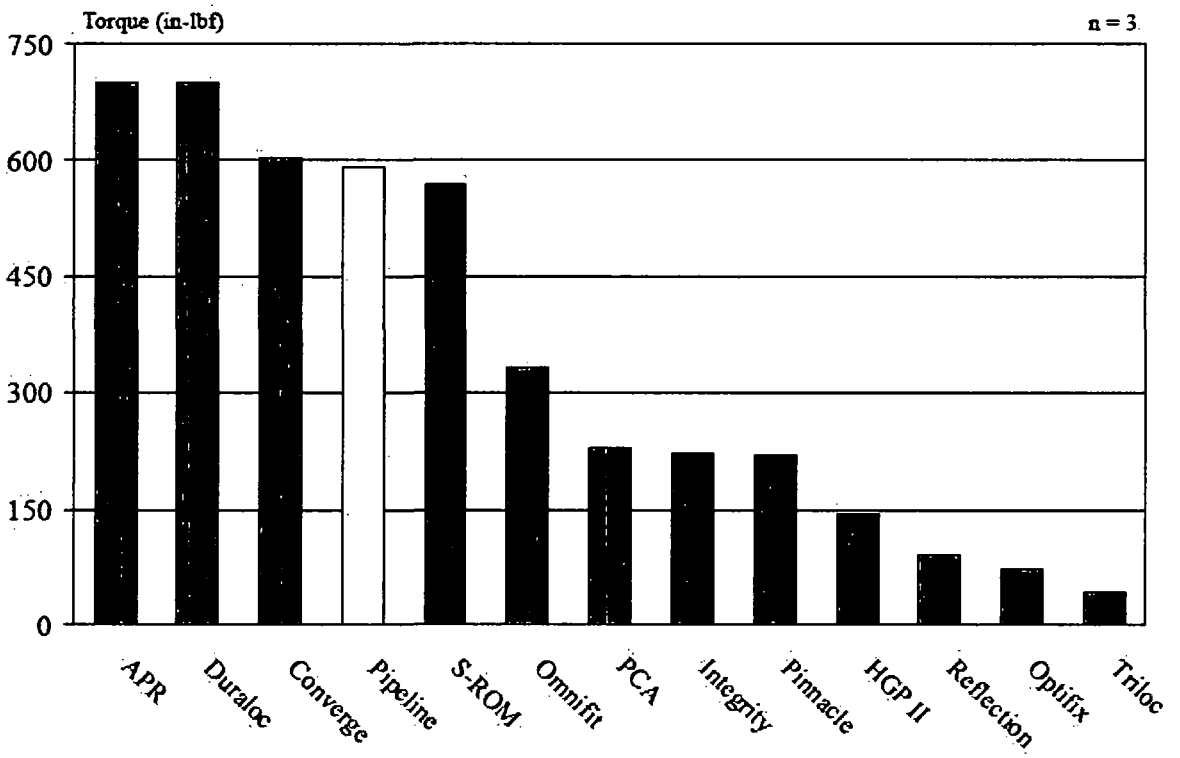
All liners were assembled on a closed-loop, servo-hydraulic testing machine (MTS Mini-Bionics, model 358.AT, MTS Corporation, Eden Prairie, MN, USA) utilizing a matched femoral head to fully seat the liner at a constant displacement rate of 0.2 inches per minute until 450 lbf of axial compression is achieved. The force-displacement curve of insertion was recorded. The lever out tests were conducted on a Instron Model 1115 electro-mechanical testing machine, (Instron Corporation, Canton, Massachusetts). To ensure measurement of the lever out strength was not affected by polyethylene liner deformation, the femoral head articulation of the liner was filled with epoxy. The cup was then rigidly secured and a force applied to the liner via a cylindrical lever bar inserted into a 1/4 inch hole drilled into the epoxy 3/8 inches below the lip. The lever bar was loaded at a rate of 1.1 radians per minute about a fulcrum located at liner level and immediately outside the shell (see test report for depictions of test set-up). The length of the

[5] Tradonsky S, Postak PD, Froimson AI and Greenwald AS: A comparison of disassociation strength of modular acetabular components. Clin Orthop 296:154, 1993

lever arm from the fulcrum to the point of loading was 1.9 inches. The direction of this force was such that it lifted the edge of the liner away from the cup. A force-displacement curve of disassembly was recorded. The maximum lever out torque, (calculated by the maximum force multiplied by the lever arm length), averaged for six new components, is presented as a measure of the locking mechanism strength.

The Acetabular Liner demonstrated a mean lever out torque of 591 inch pounds force, (in-lbf), with a standard deviation, (SD), of 80 in-lbf prior to disassociation. Comparative locking mechanism strength data for previously tested contemporary two piece, acetabular cup designs performed by the same researchers using the same methodology are presented in Figure 6. The Pipeline Hip System acetabular cup locking mechanism design employing crosslinked vitamin E UHMWPE (Ticona GUR 1020 E) was within the range of locking mechanism strengths for the contemporary commercially-available predicate acetabular cup designs, and is therefore substantially equivalent to the predicate acetabular cups with regard to locking mechanism strength.

Figure 6: Comparative Lever-out Results for Pipeline (n=6) versus Other Contemporary Acetabular Cups



18.5.3. Liner Axial Torque Testing

This testing is the same testing presented for predicate Pipeline Total Hip System (K112802: Original 510(k)-Exhibit E-9).

Pipeline commissioned a study by Orthopaedic Research Laboratories (Cleveland, OH) to test the locking mechanism strength of the Pipeline Hip System Acetabular Cups. Please see Exhibit E-9, test report 522-6500-0811, for the complete study test report. Locking of the Hip System poly liners is achieved through engagement of interrupted poly rib at the taper to sphere transition of the liner with a mating groove on the shell. Poly tabs of the liner mate with scallops on the face of the shell to prohibit rotation of the liner. In this test, locking mechanism strength was evaluated by measuring the torque required to axially dislodge a fully seated polyethylene liner.

The test samples used were six (6) 28 x 44mm Highly Crosslinked Vitamin E UHMWPE Liners, sterilized via EO, and a 44mm shell. The size 28 x 44mm liner was selected for testing because

the poly tabs are the weakest feature of the torsion test, and the size 44 has the shortest supporting moment arm length, therefore representing the weakest torsional support. (The 28 x 44mm liner is the smallest liner in the smallest shell size for the Vitamin E UHMWPE product). Additionally, the tested design was an earlier embodiment with a thinner tab than the proposed configuration.

All liner assembly and axial torque tests were conducted on a closed-loop, servo-hydraulic testing machine (MTS Mini-Bionics, model 358.AT, MTS Corporation, Eden Prairie, MN, USA). A matched femoral head was utilized to fully seat the liner at a constant displacement rate of 0.05 mm per second until 2000 N of axial compression is achieved. The force-displacement curve of insertion was recorded. The axial torque was measured by rigidly fixing the acetabular shell to the torque cell and loading the liner axially to 2450 N of joint force.11 The liner was driven at a constant 1.0 degree per sec via an epoxy embedded, steel coupling nut (see test report for depiction of test set up). The torque-displacement curve was recorded. The maximum axial torque, averaged for six new components, is presented as a measure of the axial locking mechanism strength.

The Hip System crosslinked vitamin E UHMWPE (Ticona GUR 1020 E) acetabular liner demonstrated a mean resistive axial torque of 20.38 N-m, with a standard deviation, (SD), of 1.14 N-m prior to disassociation. The results and the corresponding torque-displacement curves are provided in the test report. The mean axial torque exceeded the pre-established acceptance criterion, which was a maximum average torque of at least 12.0 N-meters.

The FDA Guidance, "Guidance Document for Testing Acetabular Cup Prostheses" dated May 1, 1995, states that the torque due to friction at the ball-liner interface is about 2.4 N-meters, and that "the locking mechanism should exceed this by some safety factor (e.g., 12 N-meter (105 in-lb) for a safety factor of five" based on research by Semlitsch.[6] The Hip System acetabular cup locking mechanism demonstrated a mean resistive axial torque of 20.38 N-m, which exceeds the recommended safety factor. Therefore, the Pipeline Hip System acetabular cup locking

[6] Semlitsch, M., Lehmann, M., Weber, H.. "New Prospects for a Prolonged Functional Life-Span of Artificial Hip Joints by Using the Material Combination Polyethylene/Aluminum Oxide Ceramic/Metal." J. Biomed. Mater. Res., 11, 537-552 (1977)

mechanism will withstand anticipated physiological loading, and can be considered substantially equivalent to other acetabular cup systems with regard to locking mechanism torsional strength.

18.6. Assembly/Disassembly Loads: Standard UHMWPE

18.6.1. Liner Push-Out Testing

This testing is the same testing presented for predicate Pipeline Total Hip System (K112802: Response dated January 12, 2012, Exhibit 7).

The push-out testing of six samples of the 22/44mm standard poly GUR 1020 Acetabular Liners was conducted using the same method as the previously tested 28/44mm GUR 1020-E liners described in Section 18.5.1. (The 22 x 44mm liner is the smallest liner in the smallest shell size for the Standard UHMWPE product.) Please see Exhibit E-12, Report Number J1112POI-241, for the complete study test report.

The average push-out for the 22/44mm liners was (b)(4) which is higher than several of the competitive designs presented in Figure 5. Therefore, the 22/44mm GUR 1020 liners are substantially equivalent with regard to push-out strength.

18.6.2. Liner Lever Out Testing

This testing is the same testing presented for predicate Pipeline Total Hip System (K112802: Response dated January 12, 2012, Exhibit 7).

The lever out testing of six samples of the 22/44mm standard poly GUR 1020 Acetabular Liners was conducted using the same method as the previously tested 28/44mm GUR 1020-E liners described in section 18.5.2. (The 22 x 44mm liner is the smallest liner in the smallest shell size for the Standard UHMWPE product.) Test results are included in Exhibit E-12, Report Number J1112POI-241.

The average lever out for the 22/44mm liners was (b)(4)), which exceeds several of the competitive designs presented in Figure 6. Therefore, the 22/44mm GUR 1020 liners are substantially equivalent with regard to lever-out strength.

18.6.3. Liner Axial Torque Testing

This testing is the same testing presented for predicate Pipeline Total Hip System (K112802: Response dated January 12, 2012, Exhibit 7).

The axial torque testing of six samples of the 22/44mm standard poly GUR 1020 Acetabular Liners was conducted using the same method as the previously tested 28/44mm GUR 1020-E liners described in section 18.5.3. (The 22 x 44mm liner is the smallest liner in the smallest shell size for the Standard UHMWPE product.) Test results are included in Exhibit E-12, Report Number J1112POI-241.

The mean resistive axial torque for the 22/44mm liners was (b)(4) which exceeds the pre-established acceptance criterion, which was a maximum average torque of at least 12.0 N-meters. Therefore, the 22/44mm GUR 1020 liners are substantially equivalent with regard to torsional strength.

18.7. Head/Stem Taper Pull-Off Testing: Metal Femoral Heads

This testing is the same testing presented for predicate Pipeline Total Hip System (K112802: Original 510(k)-Exhibit E-15).

Pipeline commissioned a study to evaluate the force required to disassemble the modular cobalt-chrome femoral head taper connection from the mating stem taper. The test was conducted in accordance with the method described in ASTM F2009-00: Standard Test Method for Determining the Axial Disassembly Force of Taper Connections of Modular Prostheses. See Exhibit E-15, report number J1109POI-199, for the complete study test report.

The test samples used included six (6) size 28mm +10.5 offset heads, six (6) size 22mm +3.5 offset heads, and twelve (12) taper test fixtures. The 28mm +10.5 offset head was identified as a worst case because it incorporates full length taper engagement with the thinnest wall in the taper region of the head. The 22mm +3.5 offset head was also identified as a worst case because it incorporates the shortest taper length engagement.

The average pull off force for the size 22mm +3.5 was (b)(4) and for the 28mm +10.5 (b)(4)

Note that the proposed final stem and mating head taper designs have a narrower angular tolerance than the tested specimens. Both the final design and test specimens have a nominal angle of (b)(4) 67° (b)(4) The mating head tapers were modified accordingly, ensuring locking with the thickest portion of the stem taper (b)(4) The fit of the final design results in a lesser potential mismatch between the mating stem and head tapers (tested (b)(4) The looser fit of the test specimens represents a worse case for this test as compared with the final design, and the test results can therefore be relied upon to qualify the performance of the final design.

18.8. Head/Stem Taper Pull-Off Testing: Ceramic Femoral Heads

This is a new test not previously submitted for predicate Pipeline Total Hip System (K112802).

Testing was conducted to determine the pull-off forces for the Biolox *delta* Femoral Head. In order to determine the influence of neck length, the Biolox forte Femoral Heads with the smallest and greatest contact area between the taper and femoral head (28 12/14 L and 36 12/14 S, respectively) were tested. The Biolox *delta* Femoral Head size 28 L was also tested on test tapers representative of the subject hip stems in that they are a 12/14 taper design manufactured from titanium (Ti-6Al-4V). Five (5) samples were tested for each combination.

Note: Rotational stability testing was also conducted. However, this testing was performed for informational purposes only and does not replicate a failure mechanism seen in vivo. Therefore, only the pull-off testing is included in this summary.

By definition, the pull-off test evaluates the femoral head and stem construct behavior under axial distraction. During actual use, the femoral head and stem are not subjected to traction forces as they are under compression. Ground reaction forces, bodyweight, muscle and tendon forces are combined to create the compression forces which keep the femoral head and stem attached. Additionally, several strong ligaments help maintain the desired hip joint position while acting as compressive forces on the stem. The only time the femoral head and stem

construct undergo even minor traction forces is during repositioning of a dislocated femoral head. During this procedure, the physician may move the femoral head and stem construct alongside the acetabular (os ilium). During this manipulation, the physician has to overcome the tension of muscles and ligaments in the area. These forces are roughly equivalent to body weight. Based on this information, the distraction force acting on the femoral head can be estimated to be roughly 250 N corresponding to a force pulling a 25 kg weight. Therefore, the minimum acceptance criterion for the pull-off testing has been defined as 250 N.

The results from the testing are provided in the following table.

Table 11: Results from Pull-off Testing

Table 25: Results from Pull-off Testing			
	28 12/14 L *delta* on Ti-6Al-4V	28 12/14 L *forte* on Ti-6Al-4V	36 12/14 S *forte* on Ti-6Al-4V
Average	(b)(4)	(b)(4)	(b)(4)
Minimum Value			

With respect to the head size, a t-test showed no significant difference between the 28 mm 12/14 L forte and 36 12/14 S forte femoral heads. Therefore, there is no significant influence of the taper length on the pull-off values.

The average and minimum pull-off forces for the 28 mm 12/14 L *delta* femoral heads on titanium tapers was well above the 250 N acceptance criteria. In addition, a t-test concluded that there was no significant difference between the mean values for the 28 mm 12/14 L forte and 28 mm 12/14 L *delta* femoral heads. Therefore, the Biolox *delta* Femoral Heads met with minimum acceptance criteria as previously defined. See Exhibit E-25, report number 3799, for the test report.

18.9. Burst Strength Testing: Ceramic Femoral Heads

This is a new test not previously submitted for predicate Pipeline Total Hip System (K112802).

Burst Strength testing was conducted on Biolox *delta* Femoral Heads. Testing was conducted on Biolox *delta* Femoral Heads sizes 28 L, 32 XL, 36 XL, and 40 XL.[7] The femoral heads were tested axially according to ISO 7206-10 on test tapers representative of the subject hip stems in that they are a 12/14 taper design manufactured from titanium (Ti-6Al-4V). See Exhibit E-26, report number 3300, for the complete study test report.

Testing confirmed that the 28 mm L head size is the worst case size in the current offering and has an average burst strength of (b)(4) which is above the average fracture strength required in FDA guidance (46kN). In addition, no ball head failed at less than 20 kN.

18.10. Wear Testing

Two sets of hip simulator wear testing are presented below: the first test, done with 36mm heads, qualified the size range originally determined substantially equivalent in predicate 510k #K112802; the second test, done with 28 mm and 40mm heads, qualifies the additional sizes (40mm heads and corresponding liners) included in the subject 510k.

18.10.1. Hip Simulator Wear Testing of Pipeline's Highly Crosslinked Vitamin E UHMWPE (36 mm Heads to qualify original size range)

This testing is the same testing presented for predicate Pipeline Total Hip System (K112802: Response dated January 12, 2012-Exhibit 9).

Pipeline commissioned the Harris Orthopaedic Laboratory at Massachusetts General Hospital to conduct a hip simulator wear study of Pipeline's highly crosslinked Vitamin E polyethylene material. See test report in Exhibit E-3.

The acetabular cup test specimens used for wear testing were outer diameter size 52 mm and inner diameter size 36 mm. The design/size chosen for wear testing represents the worst case because it combines the largest head size available (36mm) with a thinner polyethylene (6.36 mm) than offered in the subject hip system. They were machined from the highly crosslinked Vitamin E blended polyethylene sterilized according to the EO method described in this 510k. The design of the liner test specimens differs from the final design of the Pipeline Acetabular

[7] Note that additional testing is included in the report for components not subject of this 510(k). Specifically, the Biolox forte heads and the Biolox *delta* 22 and the 44 mm ceramic femoral heads are not included in this 510(k).

Liners primarily with regard to the locking mechanism design as shown in the figure that follows. (The table "Pipeline Orthopedics" represents the final product, and the table "total joint orthopedics" represents the test specimens.)

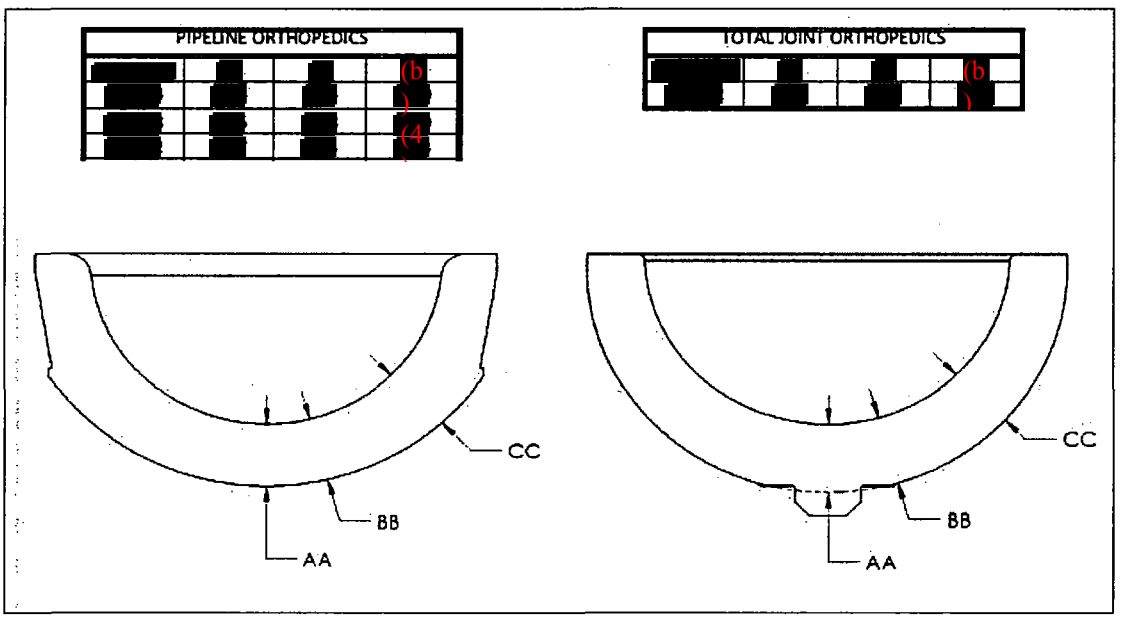


Figure 7: Comparison of Wear Tested Design to Final Pipeline Design

As shown in the preceding figure, the minimum polyethylene thickness in the typical load bearing region (labeled dimension "CC") is (b) mm for the test specimen (36mm x 52mm), which is thinner than the minimum polyethylene thickness in the typical load bearing region of the final Pipeline Acetabular Liner design for 28mm, 32mm, and 36mm heads used with the vitamin E poly liners. Since the test specimens and the final Acetabular Liner design are manufactured from the same material and have similar polyethylene loading conditions, and the test specimens feature the largest head size available for the original size range of the Total Hip System (36mm) with thinner polyethylene in the typical load bearing area than the thinnest Acetabular Liner for each head size offering, the test specimen design is a worst case test condition and is representative of the performance of the Acetabular Liners.

The liners were coupled with CoCr acetabular heads. The acetabular shells had a "test" orientation, to allow removal of the PE liners required for gravimetric analysis of wear. The test orientation did not allow locking of the liners to their shells using the acetabular cup's own

locking mechanism; therefore, a ring was added to the test fixtures to hold the liners in the shells during testing.

Prior to testing, all liner samples were accelerated aged per ASTM F2003. Eight (8) total hip constructs (femoral head, liner, shell) were tested on AMTI 12-station hip simulators: Six (6) were subjected to both motion and load, while two (2) were subjected to load without motion. These two "load soak components" were used to correct for fluid uptake into the polyethylene during testing. A standard walking gait cycle as specified by ISO 14242-1 was used. Stations were temperature controlled at 37°C with circulating bovine serum stabilized by ethylenediamine tetraacetate and penicillin-streptomycin solution and diluted with deionized water to 25% bovine serum per ISO 14242. The study was performed at a rate (b)(4) (b)(4) The simulator was interrupted after every $1x10^6$ cycles for gravimetric assessment of wear. See test report for description of methods used for cleaning/weighing samples, and for calculations of wear rate.

The images of the cups post-wear testing showed no indication of fracture, delamination, or any gross failure. The calculated gravimetric wear rate for the highly crosslinked Vitamin E polyethylene liners was (b)(4) This compared favorably to the wear rates reported by Stryker Orthopaedics for their legally marketed N2/Vac polyethylene, as summarized in Table 26, which ranged from a median of 45.3 mm^3/Mc to 59.6 mm^3/Mc. The wear resistance of the Pipeline highly crosslinked Vitamin E polyethylene liners has been shown to be no worse than, and therefore substantially equivalent to, the wear resistance of the predicate devices.

Table 26: Wear Rates Reported for Predicate Stryker N2/Vac Acetabular Liners

Absolute wear rates in N2/Vac Liners in MTS Hip Simulators under comparable loading and clean lubrication conditions (i.e., abrasive free)							
Component Design	Femoral Head Material	Head Diameter (mm)	No. of Tested Liners	Wear Rate (mm^3/MC)			
				Median	IQR	Min	Max
Series II	CoCr	28mm	4	50.9	10.1	42.3	59.7
Series II	CoCr	32mm	6	57.8	14.5	41.3	76.3
System 12	CoCr	32mm	3	59.6	8.2	58.2	69.1

Trident	Alumina	28mm	4	49.0	2.8	47.1	51.8
Trident	CoCr	32mm	3	45.3	7.3	40.1	49.8

Data are for three Stryker Orthopaedics Liner design all legally marketed in the US in N2/Vac polyethylene. 510k numbers are believed to include KK010170, K983382, K934060 and others.
IQR = interquartile range
Data were published in: Kurtz SM, Manley M, Wang A, Taylor S, Dumbleton J. Comparison of the properties of annealed crosslinked (Crossfire) and conventional polyethylene as hip bearing materials. Bull Hosp Jt Dis. 2002-2003;61(1-2):17-26.

Wear particles produced during the hip simulator test of Pipeline's highly-crosslinked, vitamin E-containing polyethylene acetabular liners were characterized and found to range in size from (b)(4). The majority were in the (b)(4). (See Figure 5 from test report in E-3, reproduced below). These finding were similar to data reported by Scott et. al. in 2001.[8] In their study they found that conventional non-sterilized polyethylene wear testing generated particles of 0.206 ± 0.012 micron while those generated from wear testing of 10 MRad (100kGy) irradiated material were 0.091 ± 0.003 micron. More recently, Williams and Clarke[9] studied wear particles generated from four different types of polyethylene and found the majority of the particles to be in the 0.1 to 1 micron range.

(b)(4)

[8] Scott M, Widding K, Ries M, Shanbhag A. Wear particle analyses of conventional and crosslinked UHMWPE tested in an anatomic hip simulator. 47th Annual Mtg, Orthopaedic Research Society, Feb 25-28, 2001, San Francisco, CA.
[9] Williams PA, Clarke IC. A unified approach for evaluation of UHMWPE performance in a hip simulator using wear volume and debris size distribution: Effect of fabrication method. 53rd Annual Mtg, Orthopaedci Research Society, Poster No. 1651

The shape of the vitamin e poly tested particles was found to have an inverse aspect ratio (width/length) of mostly(b)(4). (See Figure 6 from test report in E-3, reproduced as follows). This equates to an aspect ratio (length/width) of (b)(4). Williams et al.[10] reported particle analysis from hip wear studies of gamma sterilized and highly crosslinked polyethylene in several conditions and found particles to have aspect ratios of 1.513 to 1.784.

(b)(4)

The particle analysis demonstrates that the particles generated during wear testing of Pipeline's highly crosslinked Vitamin E polyethylene were comparable in size and shape to particles described for other commercially available conventional and highly crosslinked polyethylene materials.

18.10.2. Hip Simulator Wear Testing of Pipeline's Highly Crosslinked Vitamin E UHMWPE (28 and 40 mm Heads)

This is a new test not previously submitted for predicate Pipeline Total Hip System (K112802).

[10] Williams PA, Bowsher JG, Donaldson TD, Clarke IC. Wear particle morphology of sequentially irradiated/annealed polyethylene with a 'severe' wear hip simulator. 52nd Annual Mtg, Orthopaedic Research Society, Paper No. 0630.

Pipeline commissioned the Harris Orthopaedic Laboratory at Massachusetts General Hospital to conduct a hip simulator wear comparison of Pipeline's highly crosslinked Vitamin E polyethylene material. See test report provided in Exhibit E-23.

Acetabular liners representing the thinnest 28 mm ID and thinnest 40 mm ID (smallest and largest head sizes available for highly crosslinked Vitamin E UHMWPE) were machined from the highly crosslinked Vitamin E blended polyethylene sterilized according to the EO method described in this 510k.

The liners were coupled with corresponding CoCr acetabular heads (28mm and 40mm). The acetabular shells had a "test" orientation, to allow removal of the PE liners required for gravimetric analysis of wear. The test orientation did not allow locking of the liners to their shells using the acetabular cup's own locking mechanism; therefore, a ring was added to the test fixtures to hold the liners in the shells during testing.

Prior to testing, all liner samples were accelerated aged per ASTM F2003. Eight (8) total hip constructs (femoral head, liner, shell) were tested on AMTI 12-station hip simulators: Six (6) were subjected to both motion and load, while two (2) were subjected to load without motion. These two "load soak components" were used to correct for fluid uptake into the polyethylene during testing. A standard walking gait cycle as specified by ISO 14242-1 was used. Stations were temperature controlled at 37°C with circulating bovine serum stabilized by ethylenediamine tetraacetate and penicillin-streptomycin solution and diluted with deionized water to 25% bovine serum per ISO 14242.

The study was performed at a rate of (b)(4) (b)(4) . The simulator was interrupted after every $1x10^6$ cycles for gravimetric assessment of wear. See test report for description of methods used for cleaning/weighing samples, and for calculations of wear rate.

The images of the cups post-wear testing showed no indication of fracture, delamination, or any gross failure. The calculated gravimetric wear rate for the 28 mm ID highly crosslinked, vitamin E blended PE acetabular liners was (b)(4) (b)(4) The calculated gravimetric wear rate for the

40 mm ID highly crosslinked, vitamin E blended PE acetabular liners was [redacted]

This compared favorably to the wear rates reported by Stryker Orthopaedics for their legally marketed N2/Vac polyethylene, as summarized in Table 27, which ranged from a median of 45.3 mm^3/Mc to 59.6 mm^3/Mc. The wear resistance of the Pipeline highly crosslinked Vitamin E polyethylene liners has been shown to be better than the conventional poly reference device, and is therefore substantially equivalent.

Table 27: Wear Rates Reported for Predicate Stryker N2/Vac Acetabular Liners

Absolute wear rates in N2/Vac Liners in MTS Hip Simulators under comparable loading and clean lubrication conditions (i.e., abrasive free)							
Component Design	Femoral Head Material	Head Diameter (mm)	No. of Tested Liners	Wear Rate (mm^3/MC)			
				Median	IQR	Min	Max
Series II	CoCr	28mm	4	50.9	10.1	42.3	59.7
Series II	CoCr	32mm	6	57.8	14.5	41.3	76.3
System 12	CoCr	32mm	3	59.6	8.2	58.2	69.1
Trident	Alumina	28mm	4	49.0	2.8	47.1	51.8
Trident	CoCr	32mm	3	45.3	7.3	40.1	49.8

Data are for three Stryker Orthopaedics Liner design all legally marketed in the US in N2/Vac polyethylene. 510k numbers are believed to include KK010170, K983382, K934060 and others.
IQR = interquartile range
Data were published in: Kurtz SM, Manley M, Wang A, Taylor S, Dumbleton J. Comparison of the properties of annealed crosslinked (Crossfire) and conventional polyethylene as hip bearing materials. Bull Hosp Jt Dis. 2002-2003;61(1-2):17-26.

Wear particles produced during the hip simulator test of Pipeline's highly-crosslinked, vitamin E-containing polyethylene acetabular liners were characterized and found to range in size from [redacted]. (See Figure 8, below). These finding were similar to data reported by Scott et. al. in 2001.[11] In their study they found that conventional non-sterilized polyethylene wear testing generated particles of 0.206 ± 0.012 micron while those generated from wear testing of 10 MRad (100kGy) irradiated material were

[11] Scott M, Widding K, Ries M, Shanbhag A. Wear particle analyses of conventional and crosslinked UHMWPE tested in an anatomic hip simulator. 47th Annual Mtg, Orthopaedic Research Society, Feb 25-28, 2001, San Francisco, CA.

0.091 ± 0.003 micron. More recently, Williams and Clarke[12] studied wear particles generated from four different types of polyethylene and found the majority of the particles to be in the 0.1 to 1 micron range.

(b)(4)

Figure 8: Particle size distribution observed for both the 28mm ID and the 40mm ID highly crosslinked, Vitamin E blended UHMWPE acetabular liners. This graph represents size distribution only and is not indicative of the total/cumulative particle counts.

The shape of the Vitamin E poly tested particles was found to have an inverse aspect ratio (width/length) (b)(4). (See Figure 9, below). This equates to an aspect ratio (length/width) (b)(4) Williams et al.[13] reported particle analysis from hip wear studies

[12] Williams PA, Clarke IC. A unified approach for evaluation of UHMWPE performance in a hip simulator using wear volume and debris size distribution: Effect of fabrication method. 53rd Annual Mtg, Orthopaedci Research Society, Poster No. 1651

[13] Williams PA, Bowsher JG, Donaldson TD, Clarke IC. Wear particle morphology of sequentially irradiated/annealed polyethylene with a 'severe' wear hip simulator. 52nd Annual Mtg, Orthopaedic Research Society, Paper No. 0630.

of gamma sterilized and highly crosslinked polyethylene in several conditions and found particles to have aspect ratios of 1.513 to 1.784.

(b)(4)

The particle analysis demonstrates that the particles generated during wear testing of Pipeline's highly crosslinked Vitamin E polyethylene were comparable in size and shape to particles described for other commercially available conventional and highly crosslinked polyethylene materials.

18.10.3. Pin-on-disc Wear Testing of Pipeline's Highly Crosslinked Vitamin E UHMWPE under Clean and Abrasive Conditions

The testing under abrasive conditions is the same testing presented for predicate Pipeline Total Hip System (K112802: Response dated January 12, 2012-Exhibit 12). The testing under clean conditions is new data not previously submitted.

Pipeline commissioned Harris Orthopaedic Laboratory at Massachusetts General Hospital to conduct pin-on-disc wear testing under clean and abrasive conditions for Pipeline's highly crosslinked Vitamin E Poly following EO sterilization (referred to as "vitamin E blended and irradiated" in the test report) compared with conventional polyethylene (machined UHMWPE terminally sterilized by gamma irradiation).

The researchers used a bidirectional pin-on-disc wear tester that approximates the crossing motion of the total hip. This wear tester has been shown to produce wear rates that are similar to what is obtained in hip simulator wear testing. The wear rates were measured for the UHMWPE specimens articulating against polished cobalt-chrome lubricated by bovine serum. For the abrasive phase of the study, third body particles (PMMA bone cement) were added to the bovine serum lubricant to create an adverse testing environment. Each test was conducted at 2 Hz; the test was started on a Friday and set to run over the weekend for a bedding in period of at least 0.5×10^6 cycles. The test was then stopped at approximately every 0.157×10^6 cycles daily for gravimetric assessment of wear until a total of 1.128×10^6 cycles.

The calculated gravimetric linear wear rates are shown in the following table.

Table 28: Pin-on-Disk Gravimetric Wear Rates

Pin Material	Gravimetric Linear Wear Rate (mg/MC)	Range (mg/MC)
Clean Conditions		
Conventional PE Pins	(b)(4)	(b)(4)
Highly Crosslinked Vitamin E Poly*	(b)(4)	(b)(4)
Abrasive Conditions		
Conventional PE Pins	(b)(4)	(b)(4)
Highly Crosslinked Vitamin E Poly*	(b)(4)	(b)(4)

* Vitamin E blended and irradiated PE pins

As determined by pin-on-disc wear testing, the vitamin E blended and irradiated PE components (Pipeline's highly crosslinked Vitamin E Poly) are more wear resistant than conventional PE, and exhibited a 58% reduction in wear as compared to the conventional PE components under

abrasive conditions, and a 36% reduction in wear as compared to the conventional PE components under clean conditions.

The complete test report for the pin-on-disc wear study is provided Exhibit E-21.

18.10.4. Wear Testing of Pipeline's Standard UHMWPE

This justification for not wear testing the standard UHMWPE is the same justification presented for predicate Pipeline Total Hip System (K112802: Original 510(k)-Section 18.6.2).

Pipeline did not conduct separate testing of its standard polyethylene Acetabular Liners. Pipeline has considered the following factors:

- The Pipeline standard polyethylene liners are manufactured from compression molded UHMWPE that complies with ASTM F-658, that is gamma sterilized at 25-40 kGy, and packaged in inert gas (Nitrogen), and that is therefore substantially equivalent in terms of its chemical and mechanical properties to predicate standard polyethylene liners (called "N2/Vac") legally marketed by Stryker Orthopaedics (510(k)#K010170), as presented in predicate Pipeline Total Hip System 510(k) #K112802.
- The worst case inner diameter liner size in terms of wear potential is the largest inner diameter size. Pipeline's largest ID for the standard polyethylene liners is 32mm, which is not larger than the 32mm ID of predicate standard polyethylene (called "N2/Vac") legally marketed by Stryker Orthopaedics[14]. Both the Pipeline standard polyethylene liners and the predicate Stryker Orthopaedics liners are intended for use with CoCr or ceramic heads.
- The thinnest sizes/styles of Pipeline's standard UHMWPE acetabular liners have a minimum polyethylene thickness of (b)(4) in the load bearing area (size 32mm x 48mm and size 28mm x 44mm in neutral and high wall configurations), which exceeds the minimum thickness of 4mm for metal backed acetabular cups recommended in FDA's "Guidance Document for Testing Acetabular Cup Prostheses, draft, May 1, 1995".

[14] Kurtz SM, Manley M, Wang A, Taylor S, Dumbleton J. Comparison of the properties of annealed crosslinked (Crossfire) and conventional polyethylene as hip bearing materials. Bull Hosp Jt Dis. 2002-2003;61(1-2):17-26.

Because Pipeline's standard polyethylene liners use UHMWPE that is equivalent to the predicate standard polyethylene in terms of UHMWPE composition and material properties, and because the Pipeline standard polyethylene liners and the predicate liners both articulate with CoCr heads, and because the Pipeline standard polyethylene liners do not have a larger inner diameter than predicate liners or a thinner polyethylene bearing than recommended in FDA guidance, Pipeline concludes that additional wear testing of the standard polyethylene Pipeline Acetabular Liners is not necessary to demonstrate Substantial Equivalence to the predicate standard polyethylene acetabular liners.

18.11. Porous Coatings/Surfaces Testing

Please see the following 510k sections for testing conducted to characterize the Pipeline Hip System's porous surfaces in accordance with relevant FDA guidance documents.

- Section 11.9.1: Acetabular Shell – PST Surface
- Section 11.9.2: Acetabular Shell – HA PST Surface
- Section 11.9.3: Femoral Stem – Plasma-Sprayed Coating

18.12. Bone Screw Testing

This testing is the same testing presented for predicate Pipeline Total Hip System (K112802: Original 510(k)-Exhibit E-17).

Bone screw testing was conducted in accordance with ASTM F543-07, Standard Specification and Test Methods for Metallic Medical Bone Screws. The PBP Hip System Bone Screws are available in 6.5mm diameter, and in lengths from 15mm to 60mm. The size 6.5mm diameter, 60mm length bone screws were chosen for testing because this length ensures proper thread engagement and fixturing required by ASTM F543-07. Testing was conducted for torsion (torque to failure) and screw pull-out (pull-out to failure).

Torsional Properties: Six samples were tested for torsional properties. The mean torsional strength was 4.5 Nm (±0.15 Nm). The mean maximum torque was 7.4 Nm (±0.03 Nm). The mean breaking angle was 224° (±7.2°). All specimens fractured at the 5th thread below the head.

These values all exceeded the ASTM543 minimum requirements for torsional strength (6.2 Nm) and breaking angle (90 degrees) for the corresponding sized screw type and size.

- Axial Pull Out Force: The average axial pull out force for 6 screws was 1043 N (±17.3 N), and all specimens exceeded the 770 N minimum acceptance criterion established in ASTM F1839. The failure mode was test block fracture with no damage to the screws.

Please see Exhibit E-17, test report J1109POI-199, for further details.

18.13. Performance Testing Summary

All performance testing confirms that the identified risks for the PBP Total Hip System are appropriately mitigated. In addition, testing confirms that the PBP Total Hip System is capable of withstanding expected *in vivo* loading and is substantially equivalent to the predicate devices.

19 Performance Testing - Animal

A histological and mechanical evaluation of the bone ingrowth response to Pipeline's porous structured titanium surface, using the canine transcortical plug model, is described in section 11.9.1 of this 510k, and is the same study previously reviewed by FDA in predicate Pipeline Total Hip System 510(k) (K112802: Response dated January 12, 2012-Exhibit 1) .

20 Performance Testing - Clinical

Not applicable. The bench and animal testing is sufficient to demonstrate the substantial equivalence of the subject device.

Form Approved: OMB No. 0910-511. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4)
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

PIPELINE BIOMEDICAL PRODUCTS LLC
3 Wing Drive
Suite 102
Cedar Knolls NJ 07927
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
*****8374

2. CONTACT NAME
Robert Cohen
2.1 E-MAIL ADDRESS
rcohen@pipemed.net
2.2 TELEPHONE NUMBER (include Area code)
973-2678800
2.3 FACSIMILE (FAX) NUMBER (Include Area code)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).
[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT
Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b)(4) 03-Jul-2012

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: December 31, 2013
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
July 19, 2012	(b)(4) [redacted]	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA &HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Pipeline Biomedical Products, LLC	None Yet		
Division Name *(if applicable)*	Phone Number *(including area code)*		
	973-267-8800		
Street Address	FAX Number *(including area code)*		
3 Wing Drive Suite 102	973-267-8810		
City	State / Province	ZIP Code	Country
Cedar Knolls	NJ	07927	USA
Contact Name			
Robert C. Cohen			
Contact Title	Contact E-mail Address		
Sr. Vice President Research & Development	rcohen@pipelineortho.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
M Squared Associates, Inc			
Division Name *(if applicable)*	Phone Number *(including area code)*		
	703-562-9800 Ext. 252		
Street Address	FAX Number *(including area code)*		
901 King Street, Suite 200	703-562-9797		
City	State / Province	ZIP Code	Country
Alexandria	VA	22314	USA
Contact Name			
Terry Powell			
Contact Title	Contact E-mail Address		
Sr. Project Manager	tpowell@msquaredassociates.com		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Process change:
  - ☐ Manufacturing
  - ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Response to FDA correspondence:

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

☐ Other Reason *(specify)*:

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	LPH	2	JDI	3	OQG	4	OQH
5	MEH	6	LZO	7		8	

Summary of, or statement concerning, safety and effectiveness information
☒ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K112802		Pipeline Total Hip System		Pipeline Orthopedics
2	K101072		Tritanium Peri-Apatite Acetabular Shell		Howmedical Osteonics
3	K071535		Biolox delta Femoral Heads		Zimmer
4					
5					
6					

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification
Artificial total hip replacement

	Trade or Proprietary or Model Name for This Device		Model Number
1	PBP Total Hip System	1	N/A
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 N/A	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission
☒ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code
LPH, JDI, OQG, OQH, MEH, LZO

C.F.R. Section *(if applicable)*
888.3358 and 888.3350 and 888.3353

Classification Panel
Orthopedic

Device Class
☐ Class I ☒ Class II
☐ Class III ☐ Unclassified

Indications *(from labeling)*

PBP Total Hip System is indicated for use in skeletally mature individuals undergoing surgery for total hip replacement due to:

- A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis, or congenital hip dysplasia;
- Acute traumatic fracture of the femoral head or neck;
- Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty or total hip replacement.

The PBP Total Hip System hip stems and porous structured acetabular shells are intended for cementless or cemented fixation. The porous structured surface provides biological fixation when used in a cementless application. The PBP Total Hip System HA porous structured acetabular shells are intended for cementless fixation.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number: None Yet	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name: Pipeline Biomedical Products, LLC		Establishment Registration Number: None yet – company has no product in commercial distribution yet	
Division Name *(if applicable)*		Phone Number *(including area code)*: 973-267-8800	
Street Address: 3 Wing Drive, Suite 102		FAX Number *(including area code)*: 973-267-8810	
City: Cedar Knolls		State / Province: NJ	ZIP Code: 07927 / Country: USA
Contact Name: Robert C. Cohen	Contact Title: Sr. Vice President Research & Development	Contact E-mail Address: rcohen@pipelineortho.com	

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number: (b)(4)	☐ Manufacturer ☐ Contract Manufacturer	☒ Contract Sterilizer ☐ Repackager / Relabeler

(b)(4) [redacted]

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☒ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City		State / Province / ZIP Code / Country	
Contact Name	Contact Title	Contact E-mail Address	

SECTION I	UTILIZATION OF STANDARDS				
Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.					
1	Standards No.	Standards Organization	Standards Title Please see FDA Forms 3654 for utilization of standards information.	Version	Date
2	Standards No.	Standards Organization	Standards Title	Version	Date
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of the Chief Information Officer)
1350 Piccard Drive, Room 400
Rockville, Maryland 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR/APPLICANT/SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
Pipeline Biomedical Products LLC

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
July 10, 2012

3. ADDRESS *(Number, Street, State, and ZIP Code)*
3 Wing Drive, Suite 102
Cedar Knolls, NJ 07927

4. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) 973-267-8800
(Fax) 973-267-8810

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

PBP Total Hip System — Artificial Total Hip Replacement

Class II

Product Codes LPH, JDI, OQG, OQH, MEH

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER *(If number previously assigned)*

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES *(See instructions for additional information and explanation)*

☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/ SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES *(Attach extra pages as necessary)*

NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.
Warning: A willfully and knowingly false statement is a criminal offense. U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)

12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11
(Name) Robert Cohen
(Title) Senior VP, Research & Development

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12)*
3 Wing Drive, Suite 102
Cedar Knolls, NJ 07927

14. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) 973-267-8800
(Fax) 973-267-8810

15. DATE OF CERTIFICATION

PSC Graphics: (301) 443-1090 EF

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services

Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)S

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F 620-06, Standard Specification for Alpha Plus Beta Titanium Alloy Forgings for Surgical Implants. (Materials)

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 8-130	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
)oes this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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[6] The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

[redacted]STM F 620-06, STANDARD SPECIFICATION FOR ALPHA PLUS BETA TITANIUM ALLOY FORGINGS FOR SURGICAL IMPLANTS. [redacted]MATERIALS)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
	Components of the Pipeline Hip System comply with specifications described in this standard.	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

[redacted]CTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Department of Health and Human Services

Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)S

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F 136-08e1, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401).

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 8-164	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: ____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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[6] The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

STM F 136-08E1, STANDARD SPECIFICATION FOR WROUGHT TITANIUM-6 ALUMINUM-4 VANADIUM ELI (EXTRA LOW TERSTITIAL) ALLOY FOR SURGICAL IMPLANT APPLICATIONS (UNS R56401)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
	Components of the Pipeline Hip System comply with specifications described in this standard for surgical implants.	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Food and Drug Administration

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F1580 - 07 Standard Specification for Titanium and Titanium-6 Aluminum-4 Vanadium Alloy Powders for Coatings of Surgical Implants

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 8-155	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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[6] The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

PSC Graphics: (301) 443-1090 EF

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

'TM F1580 - 07 STANDARD SPECIFICATION FOR TITANIUM AND TITANIUM-6 ALUMINUM-4 VANADIUM ALLOY POWDERS FOR OATINGS OF SURGICAL IMPLANTS

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
	Components of the Pipeline Hip System comply with specifications described in this standard.	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

'CTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Food and Drug Administration

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F1537-08, Standard Specification for Wrought Cobalt-28-Chromium-6-Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539).

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 8-182	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: ____

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

ASTM F1537-08, STANDARD SPECIFICATION FOR WROUGHT COBALT-28-CHROMIUM-6-MOLYBDENUM ALLOYS FOR SURGICAL IMPLANTS (UNS R31537, UNS R31538, AND UNS R31539)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
	Components of the Pipeline Hip System comply with specifications described in this standard for surgical implants.	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Food and Drug Administration

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F1472-08e1, Standard Specification for Wrought Titanium -6Aluminum -4Vanadium Alloy for Surgical Implant Applications (UNS R56400).

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 8-168	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
oes this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☒	☐
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☒	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1, 2, 3, 4, 5	Scope, Referenced Documents, Terminology, Product Classification, Ordering Information	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Material and Manufacture	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ECTION NUMBER	Chemical Requirements	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

STM F1472-08E1, STANDARD SPECIFICATION FOR WROUGHT TITANIUM -6ALUMINUM -4VANADIUM ALLOY FOR SURGICAL IMPLANT APPLICATIONS (UNS R56400)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8	Mechanical Requirements	☐ Yes ☒ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
Section Adaptation

DESCRIPTION
The implant material conforms to the manufacturer's internal material specification,which adapts the same mechanical requirements for tensile and yield strength as ASTM F1472, but which does not adapt the standard's requirements for elongation and reduction of area.

JUSTIFICATION
The material subject of this standards form is used to manufacture acetabular shells. The elongation and reduction of area requirements of ASTM F1472 are not applicable to the performance of acetabular shells. Device-application-specific testing in accordance with relevent FDA Guidance provide additional data on material properties to demonstrate that the acetabular shells posess adequate mechanical properties for the particular application.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
9, 10, 11, 12	Special Requirements, Significance of Numerical Limits, Certification, Quality System Requirements	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
13	Keywords	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F648-07e1, Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants. (Materials)

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 8-178	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http:/www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

ASTM F648-07E1, STANDARD SPECIFICATION FOR ULTRA-HIGH-MOLECULAR-WEIGHT POLYETHYLENE POWDER AND FABRICATED FORM FOR SURGICAL IMPLANTS. (MATERIALS)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
	Components of the Pipeline Hip System comply with specifications described in this standard for surgical implants.	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services

Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)S

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F2695 - 07 Standard Specification for Ultra-High Molecular Weight Polyethylene Powder Blended With Alpha-Tocopherol (Vitamin E) and Fabricated Forms for Surgical Implant Applications.

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3] # _____		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http:/www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

STM F2695 - 07 STANDARD SPECIFICATION FOR ULTRA-HIGH MOLECULAR WEIGHT POLYETHYLENE POWDER BLENDED WITH ALPHA-TOCOPHEROL (VITAMIN E) AND FABRICATED FORMS FOR SURGICAL IMPLANT APPLICATIONS

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
	Components of the Pipeline hip system complys with specifications described in this standard for surgical implants.	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

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Department of Health and Human Services

Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)S

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F2565 - 06 Standard Guide for Extensively Irradiation-Crosslinked Ultra-High Molecular Weight Polyethylene Fabricated Forms for Surgical Implant Applications.

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3] # _____		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http:/www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ASTM F2565 - 06 STANDARD GUIDE FOR EXTENSIVELY IRRADIATION-CROSSLINKED ULTRA-HIGH MOLECULAR WEIGHT POLYETHYLENE FABRICATED FORMS FOR SURGICAL IMPLANT APPLICATIONS

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
	Components of the Pipeline Hip System comply with specifications described in this standard for surgical implants.	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Paperwork Reduction Act Statement

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Department of Health and Human Services

Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)S

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F1472-08e1, Standard Specification for Wrought Titanium -6Aluminum -4Vanadium Alloy for Surgical Implant Applications (UNS R56400).

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 8-168	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: ____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] *The summary report should include:* any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http:/www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

STM F1472-08E1, STANDARD SPECIFICATION FOR WROUGHT TITANIUM -6ALUMINUM -4VANADIUM ALLOY FOR SURGICAL MPLANT APPLICATIONS (UNS R56400)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
	Components of the Pipeline Hip System comply with the specifications for the chemical, mechanical, and metallurgical requirements for wrought annealed titanium-6aluminum-4vanadium alloy (UNS R56400) covered in this standard for the manufacture of surgical implants.	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

* *For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.*

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(b)(4) [redacted]

July 27, 2011

Dale Swartz
Pipeline Orthopedics, Inc.
3 Wing Drive, Suite 200
Cedar Knolls, NJ 07927

Reference: (b)(4) Addendum 1

Dear Dale,

This letter is to authorize the Food and Drug Administration to include by reference information in our device master file, **MAF-(b)(4) Addendum 1 – (b)(4) -** (b)(4) " for Pipeline Orthopedics Inc. 510(k) for any orthopedic implant or associated product .

Sincerely yours,

(b)(4) [redacted]

President

(b)(4) [redacted]

[redacted]

Pipeline Orthopedics
3 Wing Drive, Suite 200
Cedar Knolls, NJ 07927

To Whom It May Concern:

Subject: Authorisation for Review of Orthoplastics Ltd MAF [redacted]

This letter authorises the FDA to reference Orthoplastics Ltd. Device Master File No. [redacted] to support the 510(k) Application submitted by **Pipeline Orthopedics** This MAF is currently up-to-date.

Orthoplastics hereby authorises **Pipeline Orthopedics** to incorporate information, by reference from our Device Master File No. [redacted], into the above mentioned regulatory document for their product components. It is asserted that incorporation by reference does not constitute public disclosure and that confidentiality of the referenced material will be preserved.

We are authorising the FDA to cross reference the MAF in support of the regulatory submission by **Pipeline Orthopedics** Specific reference is given to the processing conditions under 'Processing – Specifics – Compression Moulding' in the main body of the MAF and graphically in Attachment 2.

If there are any questions on this, please contact me at [redacted]

Sincerely

[redacted]

Quality and Compliance Director
18th July 2011

(b)(4)

July 19, 2011

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Subject: Authorization for Review of Ticona Device Master File (MAF) (b)

To Whom It May Concern:

This letter will serve as authorization for opening, by FDA personnel, (b)(4) Device Master File (MAF) (b) and using the information contained therein to support regulatory documents to be submitted by:

Pipeline Orthopedics, Inc.
3 Wing Drive, Suite 200
Cedar Knolls, NJ 07927

(b)(4) hereby authorizes Pipeline Orthopedics, Inc. to incorporate information, by reference from our Device Master File (b) into any MAF with respect to components for total hip replacement and total knee replacement products. The products in which this customer has interest are (b)(4)

It is asserted that incorporation by reference does not constitute public disclosure and that confidentiality of the referenced material will be preserved. The MAF was last updated on October, 10 2010. (b)(4) hereby certifies that all information contained in our MAF is accurate to the best of our knowledge and complies with the statements made within it. The material furnished will be manufactured in accordance to MAF (b) and good manufacturing practices according to 21 CFR 174.5. Notifications to Pipeline Orthopedics, Inc. and the appropriate notifications to the FDA and this file will be made for changes that impact the subject materials in this letter.

(b)(4)

(b)(4)

Ticona
Performance Driven Solutions™

(b)(4)

The following information listed in the October 7, 2010 MAF (b) amendment will be of specific interest:

(b)(4)

Please contact me at the phone number or email listed above if there are any questions. Thank you for your assistance.

Sincerely,

(b)(4)

Sr. Product Stewardship Specialist

(b)(4)

(b)(4)

July 9, 2012

Dale Swarts
Pipeline Biotechnology, LLC
3 Wing Drive
Suite 102
Cedar Knolls, NJ 07927

Dear Dale:

Per your request, I have enclosed two original copies giving permission to access the Bio-Coat's Master Device File MAF-(b)(4)

If you have any questions please feel free to contact me at (b)(4) [redacted]
(b)(4) [redacted]

Sincerely,

(b)(4) [redacted]

General Manager

Enclosures

(b)(4) [redacted]

July 9, 2012

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center -- WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Sir/Madam:

I hereby give authorization for the FDA to access (b)(4) [redacted] Master Device Files MAF(b)(4) [redacted] in support of any regulatory submission, submitted for review by Pipeline Biotechnology, LLC (Cedar Knolls, 07927).

Thank you in advance for your assistance.

Sincerely,

(b)(4) [redacted]

General Manager

(b)(4) [redacted]

July 9, 2012

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center -- WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Sir/Madam:

I hereby give authorization for the FDA to access (b)(4) Master Device Files MAF-(b)(4) in support of any regulatory submission, submitted for review by Pipeline Biotechnology, LLC (Cedar Knolls, 07927).

Thank you in advance for your assistance.

Sincerely,

(b)(4) [redacted]

General Manager

(b)(4)

(b)(4)

(b)(4)
Pipeline Orthopaedics
Mr. Mike Florentino
3 Wing Dr
Suite 200
Cedar Knolls, NJ 07927
USA

(b)(4)

Letter of Authorization Device Master File MAF (b)(4),

Dear Mr. Florentino,

by this letter (b)(4)) authorizes the Food and Drug Administration (FDA) to include by reference, data and information in (b)(4) Device Master File MAF (b)(4) Amendments 8, 9 and 10 for the 510(k) submission of Pipeline Orthopaedics for a hip prosthesis system that incorporates the ceramic ball heads manufactured by (b)(4).

If you have any questions regarding this authorization, please contact (b)(4)

(b)(4)

Sincerely,

(b)(4)

6 Truthful and Accurate Statement

Truthful and Accurate Statement

I certify that, in my capacity as Sr. Vice President Research & Development, I believe, to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate, and that no material fact has been omitted.

Robert C. Cohen

July 3, 2012

Date

K122158

V. 2

Predicate 510(k) Exhibit Comparison

PBP Total Hip System	Pipeline Total Hip System Location in K112802
Administrative Forms	
A-1: UPDATED MDUFMA User Fee Cover Sheet	Not applicable-New form prepared for new 510(k)
A-2: UPDATED FDA Form 3514 (CDRH cover sheet)	Not applicable-New form prepared for new 510(k)
A-3: UPDATED FDA Form 3674 (Certification of Clinical Trials)	Not applicable-New form prepared for new 510(k)
A-4: FDA Forms 3654[1] (Standards Data Forms) A-4.1: ASTM F620 - 06 A-4.2: ASTM F 136-08e1 A-4.3: ASTM 1580 - 07 A-4.4: ASTM F1537-08 A-4.5: UPDATED ASTM F1472-08e1 (Ace. Shells) A-4.6: ASTM F648-07e1 A-4.7: ASTM F2695 - 07 A-4.8: ASTM F2565 - 06 A-4.9: ASTM F1472-08e1 (screws and dome hole occluder)	A-4: FDA Forms 3654 (Standards Data Forms) A-4.1: ASTM F620 - 06 A-4.2: ASTM F 136-08e1 A-4.3: ASTM F 648-07e1 A-4.4: ASTM F1472-08e1 A-4.5: ASTM F1537-08 A-4.6: ASTM F2565 - 06 A-4.7: ASTM F2695 - 07 A-4.8: ASTM 1580 - 07
A-5: Letters of Access A-5.1: Surface Dynamics A-5.2: Orthoplastics A-5.3: Ticona GmbH A-5.4: NEW Orchid Orthopedics A-5.5: NEW CeramTec GmbH	A-5: Letters of Access A-5.1: Surface Dynamics A-5.2: Orthoplastics A-5.3: Ticona GmbH
Predicate Device Identification	
B-1: NEW Predicate 510(k) Exhibit Comparison (subject document) B-2: NEW Pipeline Total Hip K112802 B-3: NEW Howmedica Osteonics Tritanium Peri-Apatite Acetabular Shell System K112802 B-4: NEW Howmedica Osteonics Tritanium Peri-Apatite Acetabular Shell System K971206 B-5: NEW Zimmer Biolox delta Ceramic Femoral Heads K071535 B-6: Khanuja, H. S., Vakil, J. J., Goddard, M. S., & Mont, M. A. (2011). Cementless Femoral Fixation in Total Hip Arthroplasty. The Journal of Bone and Joint Surgery, 93, 500-9. B-7: Depuy TriLock Bone Preservation Stem Design Rational (K974740 and K001982) B-8: Exactech Novation Operative Technique-pages 1 to 3 (K042842 and K102487) B-9: Stryker Accolade System (K052542)	Not applicable-New predicate exhibits prepared for new 510(k)
Device Description	
C-1: UPDATED Poly Liner Thickness Charts C-2: UPDATED and NEW Engineering Drawings (as applicable)	Not applicable-New exhibits prepared for new 510(k)
Sample Labelling and Instructions for Use	
D-1: UPDATED Draft Implant Package Labels	Not applicable-New exhibit prepared for new 510(k)
D-2: UPDATED Draft Instructions for Use - Implants	Not applicable-New exhibit prepared for new 510(k)

[1] Standards forms were re-ordered to match order in new 510(k).

Predicate 510(k) Exhibit Comparison

PBP Total Hip System	Pipeline Total Hip System Location in K112802
D-3: UPDATED Draft Instructions for Use – Instruments	Not applicable-New exhibit prepared for new 510(k)
D-4: UPDATED Draft Surgical Technique Manual – Femoral	Not applicable-New exhibit prepared for new 510(k)
D-5: UPDATED Draft Surgical Technique Manual – Acetabular	Not applicable-New exhibit prepared for new 510(k)
D-6: NEW Draft Instructions for Use – Ceramic Femoral Heads	
Performance Test Reports	
E-1: Highly Crosslinked GUR1020-E Materials Characterisation (Orthoplastics Project TP0373-1 rev 2: 11/16/2011)	Response dated January 12, 2012, Exhibit 10
E-2: FDA Guidance Document Testing Report for Characterization of Plasma-Sprayed CP-Titanium Coating per Pipeline Specifications (Surface Dynamics Test Report Number 1130501: 11/3/2011)	Response dated January 12, 2012, Exhibit 11
E-3: Hip Simulator Wear Resistance of Highly Crosslinked, Vitamin E Blended UHMWPE (11/23/2011)	Response dated January 12, 2012, Exhibit 9
E-4: Material Characterization of Pipeline Biomedical Products' 100kGy 1020-E UHMWPE (Exponent report: 8/9/2011)	E-4: Material Characterization of Pipeline Biomedical Products' 100kGy 1020-E UHMWPE (Exponent report: 8/9/2011)
E-5: FCP Behavior of one UHMW Polyethylene Material (7/20/2011)	E-5: FCP Behavior of one UHMW Polyethylene Material (7/20/2011)
E-6: J Behavior of one UHMW Polyethylene Material (7/21/2011)	E-6: J Behavior of one UHMW Polyethylene Material (7/21/2011)
E-7: Performance Characteristics of the Pipeline Acetabular Cup Design: Push-Out of Vit E Poly (8/29/2011)	E-7: Performance Characteristics of the Pipeline Acetabular Cup Design: Push-Out (8/29/2011)
E-8: Performance Characteristics of the Pipeline Acetabular Cup Design: Lever Out of Vit E Poly (8/29/2011)	E-8: Performance Characteristics of the Pipeline Acetabular Cup Design: Lever Out (8/29/2011)
E-9: Performance Characteristics of the Pipeline Modular Acetabular Cup Design: Axial Torque of Vit E Poly (8/29/2011)	E-9: Performance Characteristics of the Pipeline Modular Acetabular Cup Design: Axial Torque (8/29/2011)
E-10: GUR 1020 Material Characterisation (Orthoplastics Project TP 0373-2: 9/8/2011)	E-10: GUR 1020 Material Characterisation (Orthoplastics Project TP 0373-2: 9/8/2011)
E-11: Nelson Labs – Instrument Sterilization Validation Protocol (STP0086)	E-11: Nelson Labs – Instrument Sterilization Validation Protocol (STP0086)
E-12:Push-out, lever-out, and torque testing of the 22/44 mm GUR 1020 (conventional poly) liners (J1112POI-241: 1/27/2012)	Response dated January 12, 2012, Exhibit 7
E-13: Porous Coating Analysis for 510 K Submission -Porous Structured Surface (9/21/2011)	E-13: Porous Coating Analysis for 510 K Submission - Porous Structured Surface (9/21/2011)
E-14: Mechanical Testing of Porous Structured Surface Rev. B (J1108POI-189: 2/6/2012)	Response dated February 21, 2012, Email attachment
E-15: Hip Stem Endurance Testing and Taper Disassembly Testing (J1109POI-199: 9/21/2011)	E-15: Hip Stem Endurance Testing and Taper Disassembly Testing (J1109POI-199: 9/21/2011)
E-16: Abrasion Resistance –Porous Structured Surface (Study 6986: 9/22/2011)	E-16: Abrasion Resistance –Porous Structured Surface (Study 6986: 9/22/2011)
E-17: Bone Screw Testing (J1109POI-199: 9/21/2011)	E-17: Bone Screw Testing (J1109POI-199: 9/21/2011)
E-18: Uniaxial Tensile Testing of Porous Structured Substrate (VERP1101-VERR01: 9/21/2011)	E-18: Uniaxial Tensile Testing of Porous Structured Substrate (VERP1101-VERR01: 9/21/2011)

Predicate 510(k) Exhibit Comparison

PBP Total Hip System	Pipeline Total Hip System: Location in K112802
E-19: High Cycle Fatigue Testing of Porous Structured Substrate (VERP1111-VERR01: 9/22/2011)	E-19: High Cycle Fatigue Testing of Porous Structured Substrate (VERP1111-VERR01: 9/22/2011)
E-20: Bone Ingrowth Characteristics of a Porous Structured Titanium Biomaterial -Canine Transcortical Plug Model (1/24/2012)	Response dated January 12, 2012, Exhibit 1
E-21: UPDATED Pin-on-Disk Wear Resistance of Conventional UHMWPE and Vitamin E Blended and Irradiated UHMWPE Under Clean and Abrasive Conditions (2/24/2012)	Response dated January 12, 2012-Exhibit 12: Abrasive conditions testing Updated report includes clean conditions not reported in K112802.
E-22: Radiation degradation products, accelerated aging, consolidation verification of EPoly liners (Pipeline Orthopedics Cambridge Polymer Group (CPG) Report 11497: 1/10/2012)	Response dated January 12, 2012, Exhibit 5
E-23: NEW REPORT Effect of Acetabular Head Size on Hip Simulator Wear Resistance of Highly Crosslinked, Vitamin E Blended UHMWPE (3/25/2012)	Not applicable-New report prepared for new components
E-24: NEW REPORT Orchid Orthopedics Answers to FDA 510(k) Guidance Questions within Orchid Bio-Coat Masterfile MAF-339	Not applicable-New report prepared for new components
E-25: NEW REPORT Comparison of values for rotational stability and pull-off forces for Biolox delta and Biolox forte ball heads on different taper materials (Doc. 3799: 5/21/08)	Not applicable-New report prepared for new components
E-26: NEW REPORT Influence of diameter and neck length on burst strength of BIOLOX forte and BIOLOX delta ball heads with taper type 12/14 (Doc. 3300: 4/2/2011)	Not applicable-New report prepared for new components
E-27: NEW REPORT Laser engraving on Biolox delta (4 26 2004)	Not applicable-New report prepared for new components
E-28: NEW REPORT Evaluation of Orchid Bio-coat HA Coating on Porous Rods Provided by Pipeline Orthopedics (TR-434: 3/12/2012)	Not applicable-New report prepared for new components
E-29: NEW REPORT Dissolution Testing for Pipeline Orthopedics Porous Rods Coated with Orchid Bio-Coat HA Coating (TR-435: 3/13/2012)	Not applicable-New report prepared for new components
Biocompatibility Test Reports	
F-1: Cytotoxicity Study Using the ISO Elution Method	F-1 Cytotoxicity Study Using the ISO Elution Method
F-2: ISO Guinea Pig Maximization Sensitization Test - Extract	F-2 ISO Guinea Pig Maximization Sensitization Test - Extract
F-3: ISO Intracutaneous Study in Rabbits	F-3 ISO Intracutaneous Study in Rabbits
F-4: ISO Systemic Toxicity Study in Mice – Extract	F-4 ISO Systemic Toxicity Study in Mice – Extract
F-5: Systemic Toxicity Study in Rats Following Intracutaneous Implantation, 4 Week	F-5 Systemic Toxicity Study in Rats Following Intracutaneous Implantation, 4 Week
F-6: NEW Systemic Toxicity Study in Rats Following Intracutaneous Implantation, 13 Week	Protocol submitted in original 510(k). Final test report provided in current submission.
F-7: Genotoxicty Bacterial Reverse Mutation Study	F-7 Genotoxicty Bacterial Reverse Mutation Study
F-8: Genotoxicity Mouse Peripheral Blood Micronucleus Study	F-8 Genotoxicity Mouse Peripheral Blood Micronucleus Study
F-9: ISO Muscle Implantation Study in Rabbits, 2 Week	F-9 ISO Muscle Implantation Study in Rabbits, 2 Week

Predicate 510(k) Exhibit Comparison

PBP Total Hip System	Pipeline Total Hip System Location in K112802
F-10: ISO Muscle Implantation Study in Rabbits, 26 Weeks	Response dated January 12, 2012, Exhibit 8

MAR - 9 2012

510(k) Summary – K112802

The following 510k Summary is provided in accordance with the requirements of 21 CFR 807.92.

Device Name and Classification

Device Trade Name:	Pipeline Total Hip System
Device:	Artificial Total Hip Replacement
Regulation Number and Description:	888.3358 - Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Device Class:	II
Product Codes:	LPH - prosthesis, hip, semi-constrained, metal/polymer, porous uncemented JDI - prosthesis, hip, semi-constrained, metal/polymer, cemented OQG - hip prosthesis, semi-constrained, cemented, metal/polymer, + additive, porous, uncemented OQH - hip, semi-constrained, cemented, metal/polymer + additive, cemented
Advisory Panel:	Orthopedic

Address and Registration

Submitter's Name:	Pipeline Orthopedics
Address:	3 Wing Drive Suite 102 Cedar Knolls, NJ 07927
Contact Person:	Robert C. Cohen
Telephone Number:	(973) 267-8800
Fax Number:	(973) 267-8810
Date Summary Prepared:	March 2, 2012
Establishment Registration Number	Not yet registered

Identification of Legally Marketed Device to which Submitter Claims Equivalence

The subject device is substantially equivalent to the following hip systems or components:

System Components	Predicates
Acetabular Shells – Porous Structured	Biomet Regenerex Ringloc Plus - K070369
Acetabular Shells – Beaded Surface	Consensus Acetabular Shells – K060635

K112802

Acetabular Liners – highly crosslinked Vitamin E polyethylene	StelKast Exp Acetabular Liners – K094035
Acetabular Liners – standard polyethylene	Stryker Trident Acetabular Shell System - K010170
Bone Screws and Dome Hole Occluder	Biomet: Regenerex Ringloc Plus Acetabular Shell System - K070369
Femoral Stems and CoCr Heads	Exactech AcuMatch P-Series Hip Stems – plasma sprayed – K102487, K042842, K041906 Or Smith & Nephew Anthology Plasma Sprayed Hip Stems – K052792

Device Description

The Pipeline Total Hip System is an artificial hip replacement system comprised of femoral stems and mating metal heads; acetabular shells and mating acetabular liners; optional acetabular bone screws; and optional acetabular dome hole occluders.

The Pipeline Femoral Stems are forged titanium alloy, feature a proximal roughened surface (plasma-sprayed CP Titanium), come in a range of sizes, and are offered in two offset neck options per size. The Pipeline Femoral Heads are polished cobalt chromium alloy and come in a range of diameters and extension options.

The Pipeline Acetabular Shells are manufactured from titanium alloy and feature a porous structured surface (titanium alloy). The shells feature a dome hole, are available with or without a cluster screw hole pattern for supplemental bone screw fixation, and come in a range of outer diameter sizes. The Pipeline Acetabular Liners are manufactured from ultrahigh molecular weight polyethylene (standard UHMWPE or highly crosslinked Vitamin E UHMWPE). The liners are mechanically assembled to the mating shells via engagement of the liner taper with the shell bore. Locking is achieved through engagement of interrupted poly rib at the taper to sphere transition of the liner with a mating groove on the shell. Poly tabs of the liner mate with scallops on the face of the shell to prohibit rotation of the liner. The liners are available in a range of sizes, and are available in neutral, high wall, +4mm offset, +4mm offset/10° elevated, and +4mm offset/high wall options.

Optional components include a threaded acetabular dome hole occluder and acetabular bone screws, all manufactured from titanium alloy.

Intended Use

Pipeline Total Hip System is indicated for use in skeletally mature individuals undergoing surgery for total hip replacement due to:

- A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis, or congenital hip dysplasia;
- Acute traumatic fracture of the femoral head or neck;

K112802

- Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty or total hip replacement.

The Pipeline Total Hip System is intended for cementless or cemented fixation. The porous structured surface provides biological fixation when used in a cementless application.

Comparison of Technological Characteristics

The metals and standard UHMWPE material from which the components are manufactured are the same materials used in the predicate hip systems and comply with applicable implantable materials standards. The highly crosslinked Vitamin E UHMWPE material complies with applicable implantable materials standards, and the Vitamin E raw material blend in the polyethylene is the same as the predicate highly crosslinked Vitamin E polyethylene. Testing in accordance with the relevant sections of ISO 10993 demonstrates the highly crosslinked Vitamin E polyethylene material's biocompatibility. Further, wear testing demonstrates the suitability of the highly crosslinked Vitamin E UHMWPE for use as an acetabular bearing material in this hip system.

A comparison of design features of the Pipeline Total Hip System to the predicate hip systems, characterization of all porous surfaces in accordance with applicable FDA guidance, and performance testing confirm that the Pipeline Total Hip System is capable of withstanding the anticipated physiological conditions associated with the indications for use and is substantially equivalent to the predicate devices.

Performance Testing

The following performance tests were provided to demonstrate substantial equivalence:

- Biocompatibility testing for the highly crosslinked Vitamin E Polyethylene:
  - Cytotoxicity, 10993-5
  - Maximization/Sensitization, 10993-10
  - Intracutaneous, 10993-10
  - Acute Systemic Toxicity, 10993-11
  - Sub-acute/Subchronic Systemic Toxicity, 10993-11
  - Genotoxicity, 10993-3
  - Muscle Implantation, 10993-6.
- Wear testing: Testing was conducted on 36mm inner diameter highly crosslinked Vitamin E poly liners, that had been EO-sterilized and accelerated aged in accordance with ASTM F2003, and subject to wear testing in accordance with ISO 14242, using a standard walking gait cycle as specified by ISO 14242-1. Bidirectional pin-on-disc abrasive wear testing was also conducted to compare the wear rates of the highly-crosslinked Vitamin E poly material to conventional gamma sterilized poly under abrasive conditions.
- Wear particle characterization was conducted.
- The highly-crosslinked Vitamin E Polyethylene underwent exhaustive extraction testing using both polar and non-polar solvents, with GCMS and LCMS analysis to determine all

volatile, semi-volatile, and non-volatile extracts. The results were compared to a predicate material to demonstrate that no new radiation degradation products are released by the material.

- Highly-crosslinked Vitamin E Polyethylene liners underwent oxidation analysis per ASTM F2102-06 after accelerated aging per ASTM F2003, wear testing, and exhaustive extraction. The analysis was also conducted on gamma-sterilized GUR 1020 reference material for comparison.
- Highly-crosslinked Vitamin E Polyethylene liners were evaluated by polarized light microscopy and SEM analysis of freeze fractured surfaces, after accelerated aging per ASTM F2003 and wear testing, to demonstrate that the subject material has equivalent consolidation to a predicate material.
- Liner Assembly/Disassembly Testing: Testing of the worst case size Pipeline Hip System highly crosslinked Vitamin E poly acetabular liner and worst case size conventional poly liner were tested for push-out, lever out torque, and axial torque.
- Hip Stem Fatigue Testing was conducted for the worst case (smallest) hip stem according to the method described in ISO 7206-4:2010, Implants for surgery-Partial and total hip joint prostheses, Determination of Endurance Properties and Performance of Stemmed Femoral Components.
- Stem Neck Fatigue Testing of the worst-case size was conducted according to the methods described in ISO 7206-6:1992 Implants for surgery-Partial and total hip joint prostheses-Part 6 and ASTM F2068-03 Standard Specification for Femoral Prostheses – Metallic Implants.
- Head/Taper Strength: The average pull off force was demonstrated for the worst-case sizes.
- An analysis was conducted of the typical and worst case ranges of motion permitted by the designs of various liner size/style, head size/style, and stem size/style combinations. The ROM was reported for flexion/extension, abduction/adduction, and internal/external rotation per ISO 21535.
- Bone screw testing was conducted in accordance with ASTM F543-07, Standard Specification and Test Methods for Metallic Medical Bone Screws, for the worst-case diameter for torsion (torque to failure) and screw pull-out (pull-out to failure).
- Characterization in accordance with relevant aspects of "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement," was completed for: 1) Hip Stem – Plasma-Spray Titanium Coating; and 2) Acetabular Shell – Porous Structured Surface.
- The porous structured surface was evaluated in a transcortical canine model to assess the biological response, using histological and mechanical evaluations, at intervals up to 12 weeks.

Conclusions

The Pipeline Hip System shares the same indications for use as the predicate hip systems, and a comparison of materials and design features, supported by mechanical testing, wear testing, and biocompatibility testing, demonstrates the Substantial Equivalence of the Pipeline Total Hip System to one or more of the predicate hip systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Pipeline Orthopedics
% Ms. Terry Powell
M-Squared Regulatory Consultant
901 King Street, Suite 200
Alexandria, Virginia 22314

MAR - 9 2012

Re: K112802
Trade/Device Name: Pipeline Total Hip System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: OQG, OQH, LPH, JDI
Dated: January 30, 2012
Received: February 1, 2012

Dear Ms. Powell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K112802

Device Name: Pipeline Total Hip System

Indications for Use:

Pipeline Total Hip System is indicated for use in skeletally mature individuals undergoing surgery for total hip replacement due to:

- A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis, or congenital hip dysplasia;
- Acute traumatic fracture of the femoral head or neck;
- Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty or total hip replacement.

The Pipeline Total Hip System is intended for cementless or cemented fixation. The porous structured surface provides biological fixation when used in a cementless application.

Prescription Use ___X___ AND/OR *Over-The-Counter Use* _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112802

APR 1 1 2011

510(k) Summary

K101072 p1/3

Sponsor

Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, NJ 07430

Contact Person

Karen Ariemma
Project Manager, Regulatory Affairs/Regulatory Compliance
Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, NJ 07430
Phone: (201) 831-5718

Date Prepared: April 8, 2011

Proprietary Name: Tritanium® Peri-Apatite™ Acetabular Shell System

Common Name: Artificial Hip Replacement Components - Acetabular

Classification Name:
21 CFR §888.3358: Hip joint metal/polymer/metal semi-constrained and porous-coated uncemented prosthesis

21 CFR §888.3310: Hip joint metal/polymer constrained cemented or uncemented prosthesis.

21 CFR §888.3353: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis:

21 CFR §888.3360 - Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis.

21 CFR §888.3350 - Hip joint metal/polymer semi-constrained cemented prosthesis

Product Codes: LPH, MEH, LZO, KWZ, LWJ and JDI

Legally Marketed Device to Which Substantial Equivalence is Claimed:
Howmedica Osteonics Tritanium Acetabular Shell System: K081171
Howmedica Osteonics Vitalock Solid Back Acetabular Shell with Peri-Apatite: K971206
Landos Inc. Corail Stem: K953111
Aesculap BiContact Hip System with μ-CaP K043079
Smith& Nephew, Smith & Nephew Hip Systems with HA Coating: K090982.

Device Description: The Tritanium® Peri-Apatite ™ acetabular shells are available in both solid backed and cluster screw-hole designs for cementless, biologic fixation. The Howmedica Osteonics Tritanium® Peri-Apatite™ Acetabular Shell consists of a hemispherical, metallic acetabular shell with a Tritanium® (CPTi) coating referred to as a Particle Sintered Foam (PSF) coating with an overlying Peri-Apatite coating (precipitated calcium phosphate coating). The Peri-Apatite™ coating process is identical to that cleared in K971206 but to a greater thickness range of 35-75 microns. The Tritanium® CPTi PSF coating originally manufactured from material conforming to ASTM F67 was modified to conform to ASTM F1580. The dual coating (Peri-Apatite™ overlying the PSF coating) at

the thickest specification met the definition of a porous coating per 21 CFR 888.3358 with no additional claims over biologic fixation. The dome hole plugs are optional devices which are available to seal the Howmedica Osteonics Tritanium® Acetabular Shells. The plugs are to be threaded into the dome holes of the shell.

The shells will be available in sizes 44-72 mm outside diameter (OD) in 2 mm increments. The acetabular shells are forged from Ti-6Al-4V alloy per ASTM F136; the Tritanium® coating is fabricated from Commercially Pure Titanium per ASTM F1580; and the Peri-Apatite™ coating is a precipitated calcium phosphate coating per ASTM F-1609.

The Tritanium® Peri-Apatite™ Acetabular Shells are compatible with polyethylene Trident® inserts, constrained liners and modular dual mobility liners. The subject shells have an identical insert locking mechanism to that employed with compatible Tritanium acetabular shell system predicates. All shells are single use devices. The outer surface of the acetabular shell has the identical geometry as the predicate Tritanium® Acetabular Shell System determined substantially equivalent via 510(k) K081171.

Intended Use: The Tritanium® Peri-Apatite™ Acetabular Shell is a sterile, single-use device intended for use in primary and revision total hip arthroplasty to alleviate pain and restore function.

Indications:

The indications for use of the total hip replacement prostheses include:

1. Painful, disabling joint disease of the hip resulting from: non-inflammatory degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis, or late stage avascular necrosis.
2. Revision of previous failed femoral head replacement, shell arthroplasty or other procedure.
3. Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
4. Where bone stock is of poor bone quality or inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

Additional indications for use when using constrained liners: The device is indicated for use as a component of a total hip prosthesis in primary and revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease, or intra-operative instability.

Additional indications for use when using modular dual mobility (MDM) liners: The device is indicated for use as a component of a total hip prosthesis and include:

1. Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
2. Rheumatoid arthritis;
3. Correction of functional deformity;
4. Revision procedures where other treatments or devices have failed;
5. Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; and
6. Dislocation risks

The MDM liners are intended for cementless use only. The acetabular shell is intended for cementless use only.

Summary of Technologies: The technology characteristics are the same basic principles as the predicates with minor differences occurring in the material of Tritanium underlying surface and the Peri-Apatite thickness.

Non-Clinical Testing: Non-clinical laboratory testing was performed to determine substantial equivalence. Non-clinical testing was provided as outlined in the FDA Guidance Document entitled "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement (28 April 1994)" for the underlying Tritanium surface which included additional testing on the CPTi Tritanium conforming to ASTM F1580 in terms of static tensile, static shear and shear fatigue bond strength testing. The dual coating/surface was characterized per the FDA Guidance document entitled "510(k) Information Needed for Hydroxyapatite Coated Orthopaedic Implants (February 20, 1997)." All characterization parameters on the final dual coating/surface were provided. The NIST SRM 2910(a) material was used as a comparator for the Xray diffraction, dissolution rate and solubility product parameters. The dual coating/surface underwent additional characterization to demonstrate that the definition of porosity was met per 21 CFR 888.3358 at the thickest specification. Additionally, four-point bend fatiguing, abrasion, and fatigue strength of the subject acetabular shell were performed. Third body wear information was provided to address the theoretical risk. All of the observed results indicate that the subject Tritanium® Peri-Apatite™ Acetabular Shell System is substantially equivalent to devices currently cleared for marketing.

Clinical Testing: None provided as a basis for substantial equivalence.

Conclusion: The Tritanium® Peri-Apatite™ Acetabular Shell System is substantially equivalent to the predicate devices identified in this premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Howmedica Osteonics Corp.
% Ms. Karen Ariemma, RAC
Project Manager, Regulatory Affairs/
Regulatory Compliance
325 Corporate Drive
Mahwah, New Jersey 07430

APR 1 1 2011

Re: K101072
Trade/Device Name: Tritanium® Peri-Apatite™ Acetabular Shell System
(Tritanium® Peri-Apatite™ Acetabular Solid-backed Shell and
Tritanium® Peri-Apatite™ Acetabular Cluster Screw-hole Shell)
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, MEH, LZO, KWZ, LWJ, JDI
Dated: March 31, 2011
Received: April 04, 2011

Dear Ms. Ariemma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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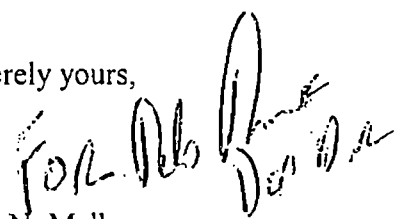
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101072

Device Name: Tritanium® Peri-Apatite™ Acetabular Shell System

Indications for Use:

The indications for use of the total hip replacement prostheses include:

1. Painful, disabling joint disease of the hip resulting from: non-inflammatory degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis, or late stage avascular necrosis.
2. Revision of previous failed femoral head replacement, shell arthroplasty or other procedure.
3. Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
4. Where bone stock is of poor bone quality or inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

Additional indications for use when using constrained liners: The device is indicated for use as a component of a total hip prosthesis in primary and revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease, or intra-operative instability.

Additional indications for use when using modular dual mobility (MDM) liners: The device is indicated for use as a component of a total hip prosthesis and include:

1. Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
2. Rheumatoid arthritis;
3. Correction of functional deformity;
4. Revision procedures where other treatments or devices have failed;
5. Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; and
6. Dislocation risks

The MDM liners are intended for cementless use only. The acetabular shell is intended for cementless use only.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101072

K97 1206

FEB 11 1998

510(k) Summary

Device: Meridian® ST Femoral Stem and Vitalock® Solid Back Shell with Peri-Apatite™ Coating

Classification Name and Reference:

Hip Joint Metal/Polymer/Metal Semi-Constrained Porous Coated Uncemented Prosthesis 21 CFR 888.3358

Proposed Regulatory Class: Class II (reclassified 1-8-93)

For information contact: Margaret F. Crowe
Manager, Regulatory Affairs
Howmedica Inc.
359 Veterans Boulevard
Rutherford, NJ 07070
Telephone: (201) 507-7431
Fax: (201) 507-6870

The Meridian® ST Femoral Stem and Vitalock® Solid Back Shell with Peri-Apatite™ Coating are intended to be used in the primary uncemented reconstruction of the proximal femur and acetabulum damaged as a result of non-inflammatory joint disease, avascular necrosis or trauma. These devices are identical to the Meridian® ST femoral stem and Vitalock® Solid Back shell previously released under K940307, K930223, and K952397 respectively, except for the presence of a thin layer of hydroxyapatite coating applied to the porous coated surface.

The Meridian™ ST Femoral Stem and Vitalock® Solid Backed Acetabular Shell with Peri-Apatite™ Coating are equivalent to other legally marketed devices in commercial distribution. These products are listed below:

1. Meridian™ ST Femoral Stem - Howmedica
2. Vitalock® Solid Backed Acetabular Shell - Howmedica
3. Osteolock™ HA Femoral Stem - Howmedica

This equivalence is based upon similarities in intended use, material, design, and operational principles to the legally marketed devices.

Testing to characterize the Peri-Apatite™ coating was presented, along with the results of an animal study.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Margaret F. Crowe
Group Manager, Regulatory Affairs
Howmedica Inc.
Pfizer Hospital Products Group
359 Veterans Boulevard
Rutherford, New Jersey 07070-2584

FEB 11 1998

Re: K971206
Meridan™ ST Femoral Stem and Vitalock® Solid Back Shell with Peri-Apatite Coating
Regulatory Class: II
Product Codes: LPH and MEH
Dated: November 12, 1997
Received: November 13, 1997

Dear Ms. Crowe:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). This decision is based on consideration of the specific design of stem and coating composition detailed in this application. You may, therefore, market the device, subject to the general controls provisions of the Act and the following limitation:

> You may not label or in any way promote these devices for "biological attachment, enhanced clinical or radiographic performance, enhanced fixation and/or long-term stable fixation." The data presented support equivalence with no additional claims over a conventional press-fit hip prosthesis (i.e., mechanical interlock, only).

Additional limitations for more specific claims of safety and effectiveness may be forthcoming. Should additional limitations be applied you will be contacted in writing to inform you of the additional labeling limitations.

The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

You may market your device under the above limitations as class II devices. These devices would be considered not substantially equivalent to a legally marketed predicate device if labeled with other intended uses and/or claims of safety or effectiveness. Any other intended uses or claims may cause the device to be classified into Class III under Section 513(f) of the Act. Class III devices are required to have an approved premarket approval (PMA) application prior to marketing.

Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be

obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Device Name: **Meridian™ ST Femoral Stem and Vitalock® Solid Back Acetabular Shell with Peri-Apatite™ Coating**

Indications for Use:

The Meridian™ ST Femoral Stem and Vitalock® Solid Back Acetabular Shell with Peri-Apatite™ Coating are intended to be used in the primary uncemented reconstruction of the proximal femur and acetabulum damaged as a result of non-inflammatory joint disease, avascular necrosis or trauma.

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Restorative Devices
510(k) Number K971206

K071535

Summary of Safety and Effectiveness

NOV 19 2007

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Patricia Jenks Specialist, Corporate Regulatory Affairs Telephone: (574) 371-8354 Fax: (574) 372-4605
Date:	June 4, 2007
Trade Name:	BIOLOX® *delta** Ceramic Femoral Head
Common Name:	Ceramic Femoral Head Prosthesis
Classification Name and Reference:	Hip joint metal/ceramic/polymer semiconstrained cemented or nonporous uncemented prosthesis 21 CFR § 888.3353
Predicate Device(s):	36mm Biolox *delta* Ceramic Heads, manufactured by Biomet, K061312, cleared June 6, 2006 DePuy Delta Ceramic Femoral Head, manufactured by DePuy, K062748, cleared November 30, 2006 V40™ Biolox delta Ceramic Femoral Heads, manufactured by Howmedica Osteonics, K052718, cleared October 27, 2005
Device Description:	The BIOLOX *delta* Ceramic Femoral Heads are fabricated from an alumina matrix composite and are available in diameters of 28, 32, 36, and 40 mm with a range of offsets to accommodate various patient anatomies. They serve as an alternative to both metal and alumina ceramic femoral heads for use in total hip arthroplasty.

* Trademark of CeramTec AG

Intended Use:	The BIOLOX *delta* Ceramic Femoral Heads are modular components used in total hip arthroplasty and indicated for the following: Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, and nonunion of previous fractures of the femur; patients with congenital hip dysplasia, protrusio acetabuli, or slipped capital femoral epiphysis; patients suffering from disability due to previous fusion; patients with previously failed endoprostheses and/or total hip components in the operative extremity; and patients with acute neck fractures.
Comparison to Predicate Device(s):	The BIOLOX *delta* Ceramic Femoral Heads are substantially equivalent to the femoral heads listed above as predicate devices. Both the proposed and predicate designs are intended to function as a modular femoral head component in total hip arthroplasty and are manufactured from the same materials.
Performance Data (Nonclinical and/or Clinical):	Non-Clinical Performance and Conclusions: Mechanical testing was performed and results indicate that the BIOLOX *delta* Ceramic Femoral Heads are equivalent to devices currently on the market and capable of withstanding *in vivo* loading. Clinical Performance and Conclusions: Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 19 2007

Zimmer, Inc.
c/o Ms. Patricia Jenks
Specialist, Corporate Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K071535
Trade/Device Name: Biolox® *delta* Ceramic Femoral Head
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO
Dated: October 25, 2007
Received: October 26, 2007

Dear Ms. Jenks:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K071535

Indications for Use

510(k) Number (if known):

Device Name:

BIOLOX® *delta** Ceramic Femoral Head

Indications for Use:

The BIOLOX *delta* Ceramic Femoral Heads are modular components used in total hip arthroplasty and indicated for the following:

Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, and nonunion of previous fractures of the femur; patients with congenital hip dysplasia, protrusio acetabuli, or slipped capital femoral epiphysis; patients suffering from disability due to previous fusion; patients with previously failed endoprostheses and/or total hip components in the operative extremity; and patients with acute neck fractures.

Prescription Use _X_ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchop

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

*Trademark of CeramTec AG

510(k) Number K071535

Zimmer Institute & Medical Education

Product Brochures, Surgical Techniques

Trabecular Metal Technology

MIS

Jointline: Loan Kit Service

Clinical Feedback Programme

Recycling (WEEE)

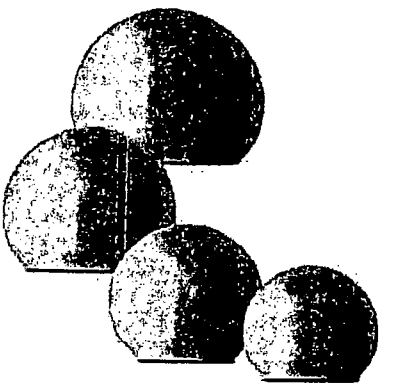
About Us: Zimmer UK

Zimmer Spine EU website

Contact Us

Medical Professional Home

BIOLOX®* delta Ceramic Femoral Head



The new alumina matrix composite *BIOLOX* delta meets the increased demands in hip replacement. While this high performance ceramic offers the same advantages as third generation alumina ceramic, i.e. excellent biocompatibility, low wear, high hardness, outstanding chemical and hydrothermal stability, its wear and mechanical properties are even superior to those of alumina ceramic.

The *BIOLOX* delta Ceramic Femoral Head is made from a new alumina matrix composite developed by CeramTec AG. This material is a high-performance ceramic that meets the increased demands regarding durability of the implants in young, active and/or heavy patients.

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Benefits

- Improved mechanical properties compared to alumina heads
- Additional neck length for diameter > 32mm
- Additional diameters providing more ROM and stability
- Same benefits as *BIOLOX* forte remain for *BIOLOX* delta, i.e. appropriate for patients who are sensitive to specific metal elements

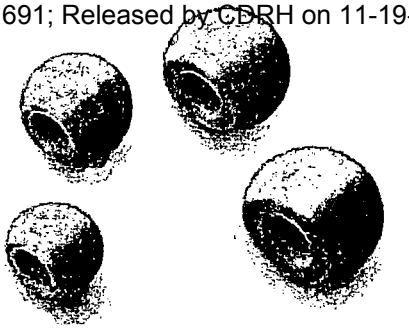
Sizing

Diameter/ Neck Length	28mm	32mm	36mm	40mm
S/ -3.5mm	•	•	•	•
M/ 0	•	•	•	•
L/ +3.5mm	•	•	•	•
XL/ +7.0mm	n/a	•	•	•

Caution: Must only be used in combination with new, undamaged 12/14 stem tapers!

Science behind BIOLOX delta Material

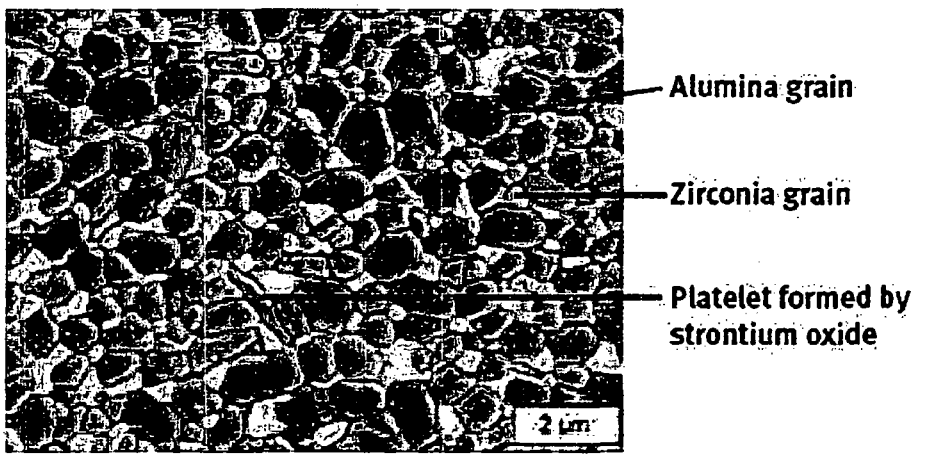
BIOLOX delta is an aluminum oxide matrix composite ceramic consisting of approx. 75% alumina (Al_2O_3),



24% zirconia (ZrO_2) and other trace elements. The pink color is due to the chromium oxide (Cr_2O_3) that improves the hardness of the composite material.

Alumina provides the material's hardness and wear resistance, while zirconia, together with other additives, provides improved mechanical properties. These properties are achieved, among other things, as a result of the high strength, the high density of the material and the very small grain size of the alumina matrix.

The result is a high-performance ceramic that offers the same advantages as *BIOLOX* forte: excellent biocompatibility, low wear, high hardness, good mechanical performance, outstanding chemical and hydrothermal stability.



Microstructure of BIOLOX delta (Courtesy of CeramTec AG).

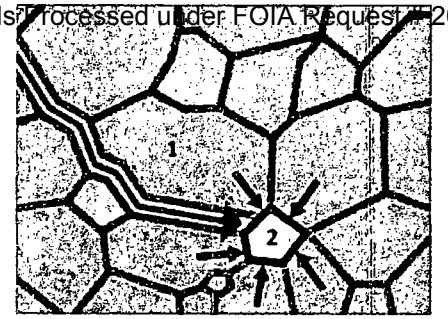
The Microstructure

The first toughening mechanism used in *BIOLOX* delta material results from the introduction of small, homogeneously distributed yttria-stabilized tetragonal zirconia particles (Y-TZP) in a stable alumina matrix. The spatial separation of these zirconia particles reduces the likelihood of structural transformation and prevents the initiation or propagation of cracks.

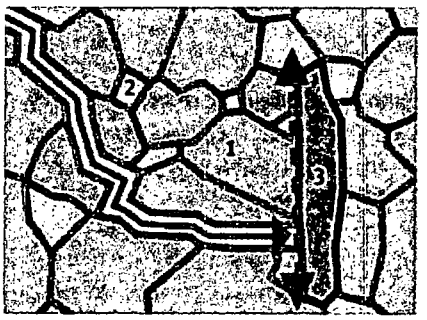
The principle of transformation toughening by small zirconia particles, which are dispersed in the alumina matrix.

1. Alumina grain;

2. Zirconia grain.



The second toughening mechanism is achieved by the addition of strontium oxide, which forms platelet-like crystals. These platelets dissipate energy by deflecting cracks, thereby increasing material strength and toughness.



The principle of reinforcement by platelet-like crystals in an alumina matrix.

1. Alumina grain;
2. Zirconia grain;
3. Platelet-like crystal..

Improved Mechanical Properties

The excellent flexural strength and reduced grain size of BIOLOX delta material explain its value as an alternative bearing material against polyethylene.

Mechanical Properties and Benefits of Third Generation Alumina and Alumina Matrix Composite Ceramic

Property	Provides	Third-generation alumina	BIOLOX delta
Bending strength (MPa)	Improved mechanical properties	≥550	950
Hardness (HV)	High hardeness – low wear	2000	1925
Microstructure (µm)	Small grain size – increased strength	≤1.8	1.1-0
Density (g/cm³)	High density – better surface finish	3.98	4.37
Young's modulus (GPa)	High Young's modulus – good stability (low deformation)	380	350
Laser marking	Improved product safety	yes	yes
Hipped	Reduced grain size, homogenous distribution	yes	yes
Proof tested (100%)	Quality control process	yes	yes
Bearing combination	Ceramic-on-polyethylene	yes	yes

Low Wear with Large Ceramic Heads

The advantages of ceramic materials in wear couples become even more evident with large diameter heads. In the past, large ceramic or metal head sizes in combination with conventional polyethylene resulted in higher wear.

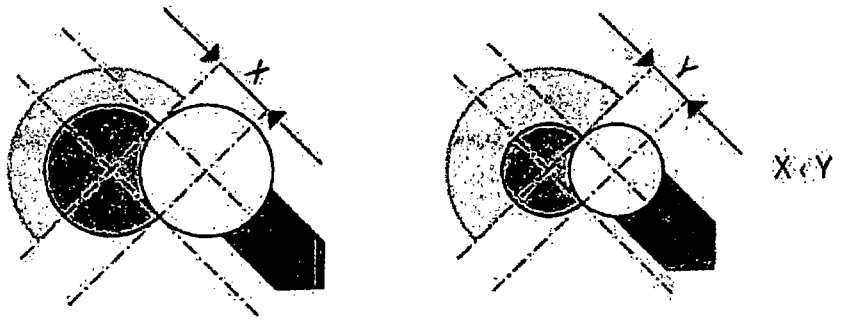
Recent hip joint simulator studies have shown that even with the use of 36 mm ceramic head diameters against ceramic or highly cross-linked polyethylene, the wear rates remain very low. (1, 2)

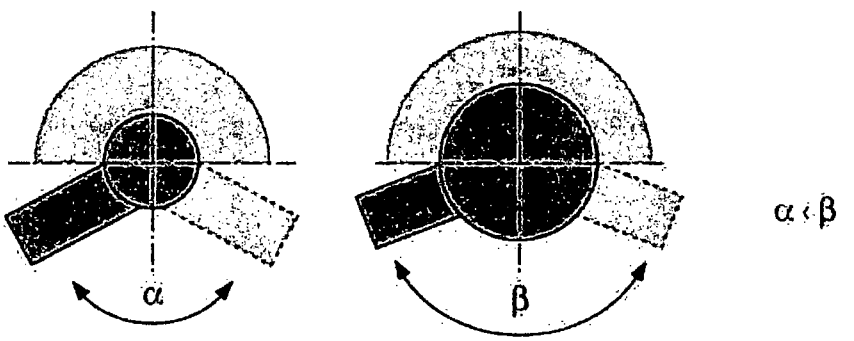
size, and can choose the best option for the patient.

More Stability and Range of Motion

A large diameter articulation offers increased stability due to the increased displacement distance (X < Y) and a greater technical range of motion (a <b) compared to a conventional 28 mm articulation. These obvious clinical benefits, in combination with low-wear alternative bearings (ceramic on highly cross-linked polyethylene), result in improved functionality and durability.

Clinical studies have reported that there is a statistically significant decrease in impingement, subluxation and dislocations with 36 mm ceramic-on-ceramic coupling (0.88%) when compared to 28 mm femoral heads (4.64%) in THR.(3)





Note: Wear couples with ceramics or with metal are prohibited in the U.S.

Handling of Alumina and BIOLOX delta Standard Heads

The alumina ceramic femoral head and *BIOLOX* delta ceramic femoral head may only be used with Zimmer stems, and in combination with highly cross-linked or conventional Zimmer polyethylene.

Use of Trial Heads

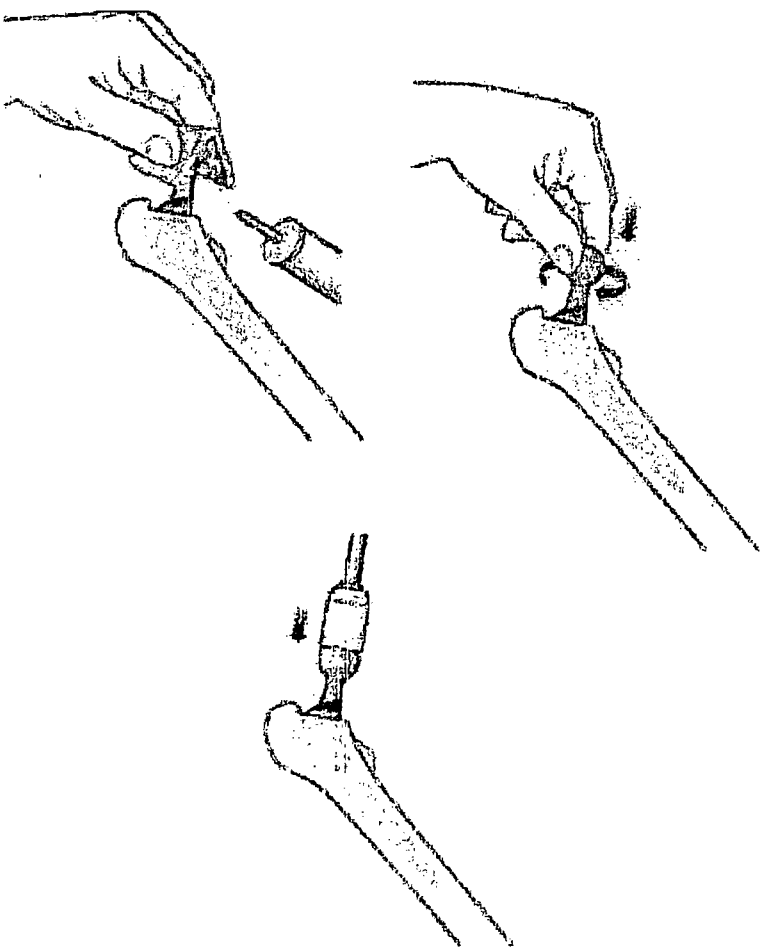
- Determine the neck length
- Check tissue balance
- Check range of motion

Check Implant Prior to Use

- Are the mating surfaces completely intact? It is absolutely essential that the taper of the femoral stem fit perfectly with the taper of the head.
- Is the correct ceramic femoral head selected? (With regard to diameter, taper size, neck length, material, manufacturer, etc.)

Careful Setting

- Remove any blood or debris from the stem taper.
- Prior to impacting of the femoral head onto a femoral stem, examine the inside of the femoral head to ensure that no foreign particles are present.
- Implant parts must be thoroughly cleaned and dried before they are used.
- Set the head with a rotary motion until it is immovable.
- To seat the ceramic femoral head, use a femoral head driver with a plastic face and a light hammer.



**BIOLOX is a trademark of CeramTec AG.*

References

(1) Clark IC, et al: Severe simulation test for run-in wear of all-alumina compared to alumina

composite THR. In D'Antonio JA, Dietrich M (eds), Bioceramics and Alternative Bearings in Joint Arthroplasty, Darmstadt, Steinkopff, 2005, 11–20

(2) Fisher J, et al: Wear of highly crosslinked polyethylene against cobalt chrome and ceramic femoral heads. In Benazzo F, Falez F, Dietrich M (eds), Bioceramics and Alternative Bearings in Joint Arthroplasty. Darmstadt, Steinkopff, 2006, 185–188

(3) Zagra L, et al: THA ceramic-ceramic coupling: The evaluation of the dislocation rate with bigger heads. In Lazennec JY, Dietrich M (eds): Bioceramics in Joint Arthroplasty, Darmstadt, Steinkopff, 2004, 163–168

CURRENT CONCEPTS REVIEW

Cementless Femoral Fixation in Total Hip Arthroplasty

By Harpal S. Khanuja, MD, Jeffrey J. Vakil, MD, Maria S. Goddard, MD, and Michael A. Mont, MD

Investigation performed at the Center for Joint Preservation and Replacement, The Rubin Institute for Advanced Orthopedics, Sinai Hospital of Baltimore, Baltimore, Maryland

- A number of cementless femoral stems are associated with excellent long-term survivorship.
- Cementless designs differ from one another in terms of geometry and the means of obtaining initial fixation.
- Strict classification of stem designs is important in order to compare results among series.
- Loosening and thigh pain are less prevalent with modern stem designs.
- Stress-shielding is present in most cases, even with newer stem designs.

In 1995, the NIH (National Institutes of Health) Consensus Development Panel on Total Hip Replacement supported the use of hybrid fixation with a cemented stem and a noncemented cup because of excellent long-term results[1]. However, today, 60% to 90% of the approximately 200,000 total hip arthroplasties performed yearly in the United States involve both a cementless cup and a cementless stem[2,3]. There are a variety of cementless femoral stems that have been associated with excellent long-term clinical and radiographic outcomes[4-12]. We reviewed these stem designs and geometries and summarize their long-term outcomes. This review does not include prostheses that were designed for fixation in the femoral neck, as they are used less commonly and long-term follow-up data are not available.

Basic Science of Cementless Fixation

In 1981, on the basis of human retrieval studies, Albrektsson et al. described "osseointegration" as the attachment of lamellar bone to implants without intervening fibrous tissue[13]. Both animal studies and human retrieval analyses of implants have led to a better understanding of this process, which takes approximately four to twelve weeks after implantation and may continue for up to three years[14,15]. Adequate osseous contact and firm fixation of the implant minimize micromotion[14]. Micromotion of >150 μm leads to fibrous tissue formation, between 40 and 150 μm leads to a combination of bone and fibrous tissue formation, and <20 μm results in predominantly bone formation[16-18].

Initial fixation is obtained by press-fitting a slightly oversized component. A number of factors that influence the initial stability or primary fixation will be discussed. These include geometry, roughness and coating of the stem, technique of preparation, and bone quality.

Surfaces and Coatings

Ingrowth occurs when bone grows inside a porous surface. Ongrowth occurs when bone grows onto a roughened surface. The surface characteristics of an implant determine which occurs.

Ingrowth requires a pore size between 50 and 400 μm, and the percentage of voids within the coating should be between 30% and 40% to maintain mechanical strength[13,19]. Ingrowth surfaces include sintered beads, fiber mesh, and porous metals. Sintered beads are microspheres of either cobalt-chromium or titanium alloy attached by the use of high temperatures[20,21]. Fiber mesh coatings are metal pads attached by diffusion bonding[20]. Porous metals have a uniform three-dimensional network[22], with high interconnectivity of the

Disclosure: The authors did not receive any outside funding or grants in support of their research for or preparation of this work. One or more of the authors, or a member of his or her immediate family, received, in any one year, payments or other benefits in excess of $10,000 or a commitment or agreement to provide such benefits from commercial entities (Stryker and Wright Medical Technology).

voids and a high porosity (75% to 85%) compared with that of sintered beads and fiber metal coatings (30% to 50%).

Ongrowth surfaces are created by grit blasting or plasma spraying. Grit blasting creates a textured surface by bombarding the implant with small abrasive particles such as aluminum oxide (corundum). The surface roughness ranges from 3 to 5 μm[15,23]. Grit blasting may be used as an adjunct below fiber mesh or sintered beads.

Plasma spraying involves mixing metal powders with an inert gas that is pressurized and ionized, forming a high-energy flame. The molten material is sprayed onto the implant, creating a textured surface. There is less interconnecting porosity than with the ingrowth surfaces; however, 90% of the implant fatigue strength is retained, whereas only 50% is retained after diffusion bonding and sintering[20,24,25].

Hydroxyapatite is a calcium phosphate compound that is plasma sprayed directly on the implant alone or over a porous coating. It is osteoconductive and enhances growth of mineralized bone onto the implant[26-28]. There is concern about interface strength when these coatings have been applied to an underlying porous surface[29-32]. Interface degradation could lead to implant loosening[31-33]. The optimal thickness of the coating is 50 μm, which does not compromise its strength[28,31,34]. Studies have demonstrated no difference in the clinical and radiographic outcomes when stems with hydroxyapatite were compared with the same stems without hydroxyapatite[35-37].

It is generally accepted that fixation surfaces need to be circumferential and continuous[38-46]. These qualities enhance metaphyseal osseointegration and proximal stress transfer and decrease bone loss from stress-shielding[47]. Stems without circumferential coating have been found to have high failure rates[46,48,49]. Circumferential coating also provides a seal, which minimizes migration of wear particles and prevents distal osteolysis[39,40,48]. Emerson et al. found that stems without circumferential coating were associated with significantly greater distal osteolysis than the same stems with circumferential coating ($p = 0.0004$)[39].

Cobalt-chromium-molybdenum alloys and titanium-aluminum-vanadium alloys are most commonly used for cementless femoral stem designs. The modulus of elasticity of titanium alloys is closer to that of bone than is that of cobalt-chromium alloys. Theoretically, this should produce less thigh pain and stress-shielding[50]. Thigh pain, however, is believed to be a result of not only the stiffness of the metal, but also the stem geometry. Comparison of implants that had the same design but were made of different alloys showed no significant difference in the outcomes or rates of thigh pain[51,52].

Designs Utilized in Cementless Fixation

Cementless fixation design principles have evolved since the first outcomes were reported in 1979[53]. Various femoral stem geometries are currently in use. The implant shape determines cortical contact and initial stability. Porous surfaces are located where fixation is desired. The aim of each design is to obtain initial stability and osseous contact.

TABLE I Classification System of Cementless Femoral Stem Designs

General Category	Type	Geometry	Description	Location of Fixation
Straight stems				
Tapered proximal fixation	1	Single wedge	Narrows medially-laterally. Proximally coated. Flat stem, thin in anterior-posterior plane	Metaphyseal
Tapered proximal fixation	2	Double wedge, metaphyseal filling	Narrows distally in both medial-lateral and anterior-posterior planes. Wider than Type 1. Fills metaphyseal region	Metaphyseal
Tapered proximal fixation	3A	Tapered, round	Rounded tapered conical stem with porous coating at proximal two-thirds	Metaphyseal-diaphyseal junction
Tapered distal fixation	3B	Tapered, splined	Conical taper with longitudinal raised splines	Metaphyseal-diaphyseal junction and proximal diaphyseal
Tapered distal fixation	3C	Tapered, rectangular	Rectangular cross section with four-point rotational support in metaphyseal-diaphyseal region	Metaphyseal-diaphyseal junction and proximal diaphyseal
Distally fixed	4	*Cylindrical, fully coated*	*Extensive porous coating. Proximal collar to enhance proximal bone oading and axial stability*	*Primarily diaphyseal*
Modular	5		Metaphyseal and diaphyseal components prepared independently	Metaphyseal and diaphyseal
Curved, anatomic stem	6		Proximal portion is wide in both lateral and posterior planes. Posterior bow in metaphysis, anterior bow in diaphysis	Metaphyseal

The first cementless stems were classified as straight or curved and engaged the femur in the metaphysis and distally[43]. Today, stems are often referred to as *proximally porous-coated tapered* or *fully-coated cylindrical*. While these simplifications are acceptable general categories, they miss important design characteristics and make comparisons misleading. As current designs are followed for longer periods and newer ones evolve, a comprehensive classification system will aid in comparisons of results.

Cementless stems can be categorized according to distinct geometries that govern where fixation is obtained. We define six general types based on shape, which are a modification of the four categories described by Berry[54] (Table I). This system is based on the amount of osseous contact and the progression of stem fixation from proximal to distal. It does not include designs that rely predominantly on femoral neck fixation.

In this classification, Types 1 through 4 are straight stems, and as the number increases so does the fixation area. Types 1, 2, and 3 are tapered, designed to obtain more proximal fixation, and Type 4 is fully coated to obtain distal fixation. Type 5 is a modular prosthesis, and Type-6 stems are curved, anatomic designs and are used less commonly (Table I, Fig. 1). While future prostheses may not fit into one of these categories, this classification system represents the great majority of the cementless stems currently in use and with long-term follow-up.

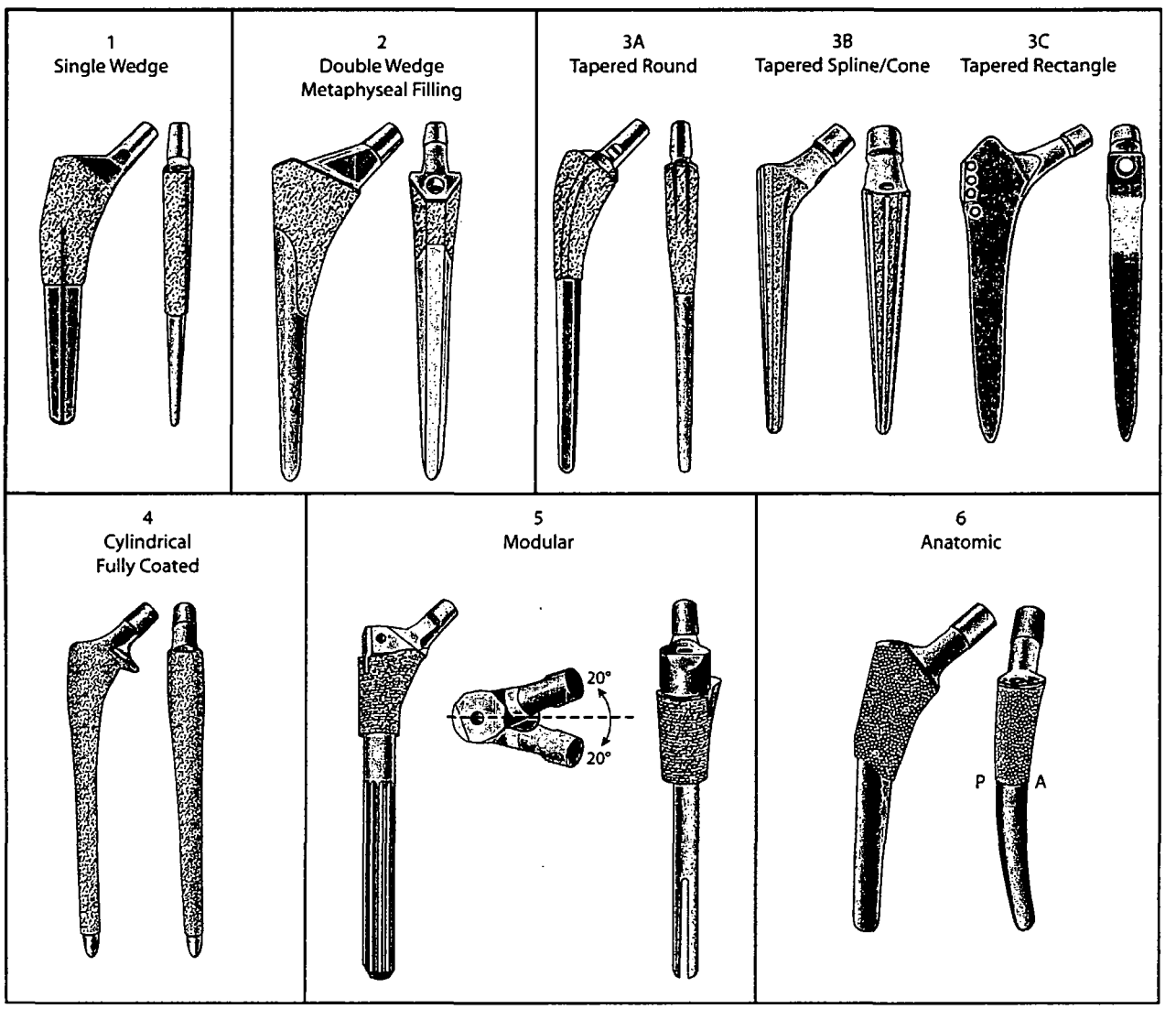


Fig. 1

Schematic drawings illustrating the classification of the cementless femoral stem designs. Type 1 is a single wedge, Type 2 is a double wedge, Type 3A is tapered and round, Type 3B is tapered and splined, Type 3C is tapered and rectangular, Type 4 is cylindrical and fully coated, Type 5 is modular, and Type 6 is anatomic. P = posterior and A = anterior. (Reprinted with permission of Sinai Hospital of Baltimore, Inc., 2010.)

Type 1

Type-1 stems, also called *single-wedge prostheses,* are designed to engage metaphyseal cortical bone in one plane: medial to lateral. They are flat and thin in the anterior-posterior plane. The component narrows proximally, primarily in the medial-lateral plane, and tapers distally. The coating is typically on the proximal one-third to five-eighths of the implant[49,55]. Initial stability is obtained by wedge fixation in the medial-lateral plane or three-point fixation along the stem length[56,57]. With three-point fixation, the implant contacts the femoral canal posteriorly, proximally, and distally, as well as anteriorly in its midportion. Rotational stability is achieved by the broad flat shape[55,56]. A collarless implant allows full seating into the prepared canal[56].

Preparation requires broaching and no distal reaming. This theoretically lessens the risk to the endosteal blood supply, making the stem less invasive than a fully-coated or diaphyseal-engaging stem[56]. Attention to the native metaphyseal-diaphyseal anatomy and the component shape is important. If the femoral diaphysis narrows substantially, the implant may engage only distally. If a proximally porous-coated prosthesis engages only below the coating, osseointegration may not occur.

Type 2

In contrast to Type 1, Type-2 stems were designed to obtain proximal cortical contact in two planes: anterior-posterior and medial-lateral. They are considered to be double-wedge or metaphyseal-filling designs. They are wider than single-wedge stems in the anterior-posterior plane. The distal portion may be tapered or rounded for canal fill. Diaphyseal engagement is necessary to enhance the rotational stability of some Type-2 designs[48,58]. When splines are used to engage the endosteum distally, they are often combined with longitudinal slots or flutes to decrease stem stiffness. These modifications reduce the elastic modulus to minimize stress-shielding and thigh pain (Fig. 2). Preparation involves distal femoral reaming and proximal broaching.

Type 3

Type-3 stems have a long, consistent taper in both the medial-lateral and the anterior-posterior plane. Unlike Types 1 and 2, there is no abrupt change in geometry or coating and fixation is obtained more at the metaphyseal-diaphyseal junction than in the metaphysis. We divided Type-3 stems into three subgroups on the basis of their shape and means of fixation.

Type-3A components are tapered, rounded conical designs. Most have porous coating on the proximal two-thirds and obtain three-point fixation[3,5]. Proximal fins or ribs may be added for rotational stability[59]. Preparation requires reamers distally and broaches proximally.

Type-3B stems have a conical taper with longitudinally-raised splines for fixation. The sharp edges cut into bone and provide rotational stability[59]. Given the stem's narrow profile proximally, there is freedom in controlling version, making it useful in complex cases with distorted proximal femoral anatomy[59-61]. Conical reamers are used to prepare a matching canal for these stems.

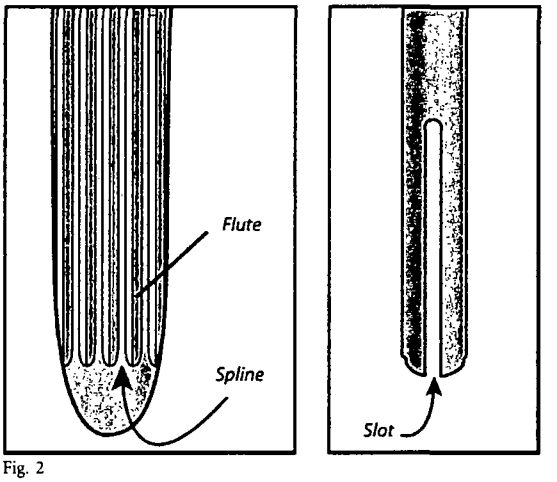


Fig. 2

Illustration of spline, flute, and slot modifications to a cementless stem, designed to reduce the modulus of elasticity. (Reprinted with permission of Sinai Hospital of Baltimore, Inc., 2010.)

Type 3C is a rectangular, tapered, conical stem that is grit-blasted across its entire length. It has a rectangular cross section that obtains three-point fixation in the metaphyseal-diaphyseal junction and proximal part of the diaphysis. Its cross section provides four-point rotational support[62]. This stem does not require the use of reamers for femoral preparation, only rectangular femoral broaches.

Type 4

This design relies on fixation along the entire prosthesis engaging cortical bone in the diaphysis. The majority of this cylindrical prosthesis is coated with an ingrowth surface. A proximal collar enhances axial stability and transmits forces to the calcar, which is more important with this stem than it is with tapered designs.

Preparation requires distal reaming and proximal broaching. Endosteal bone engagement induces cortical bone ingrowth[63]. The distal diameter of the prosthesis is typically 0.5 mm larger than the last reamer to obtain a so-called diaphyseal scratch-fit.

Type 5

Modular designs allow independent preparation and separate components for the metaphysis and diaphysis[64]. They offer a combination of proximal and distal fixation and are typically reserved for complex operations. Indications include anatomic abnormalities and rotational malalignments, such as are seen with hip dysplasia.

Successful designs consist of a separate metaphyseal sleeve and diaphyseal stem. Preparation involves diaphyseal reaming for the stem to obtain cortical contact, and the metaphysis and calcar are machined over the distal stem or stem trial[64].

Type 6

Type-6 prostheses are curved, anatomic stems that match the proximal femoral endosteal geometry[65,66]. They are wider proximally, both laterally and posteriorly. In the lateral plane, they bow posteriorly in the metaphysis and anteriorly in the diaphysis[66]. These stems have anteversion of the neck and are produced for right or left femora. Distally, they are either tapered or cylindrical. Stability is achieved through metaphyseal fill and the distal curve[24,65,67]. Preparation, consisting of distal reaming and metaphyseal broaching, is less forgiving because of the close match of the shape of the prosthesis to the femoral canal.

Results of the Use of Cementless Stems

Initially, problems with cementless stems included proximal femoral fractures, loosening, thigh pain, and stress-shielding. The long-term results of successful designs of each type are presented in the Appendix.

Type 1

This stem has been the subject of more published reports than any other design. Results with first-generation implants are encouraging[5,49,59,68-73]. Müller et al. described the results, after a mean of seventeen years (range, fifteen to eighteen years) of follow-up, in eighty hips with a titanium wedge taper stem with a rough grit-blasted surface and proximal rotational ribs[74]. Survivorship at seventeen years was 98.8%. However, there was a 25% prevalence of thigh pain and an 84% prevalence of proximal stress-shielding. In another study in which stems of the same design were followed in 115 patients who were less than fifty-five years old, the twenty-year survivorship was 90% and no thigh pain was reported[68]. Thus, this first-generation design has demonstrated excellent results, although there have been high rates of thigh pain and stress-shielding.

Modifications to Type-1 designs primarily included the addition of porous coatings, and long-term follow-up results are now available for those stems. A study of a titanium-plasma-sprayed component in sixty-five hips followed for a mean of twenty years (range, eighteen to 22.6 years) showed a twenty-two-year survivorship, with aseptic loosening as the end point, of 99%[69]. Two (3%) of sixty-five stems were associated with thigh pain.

In a study of forty-two young patients (mean age, fifty years) with a total of forty-nine Dorr Type-A or B hips (Fig. 3) treated with a cobalt-chromium stem with sintered beads, three stems failed and only 2% were associated with thigh pain at the time of final follow-up at a minimum of ten years[73]. The prevalence of thigh pain decreased from 5% at two years. Decreases in thigh pain over time have been reported by others[75].

As Type-1 stems proved reliable, indications for their use expanded. In a retrospective review of fifty hips in patients with rheumatoid arthritis, Purtill et al. reported no radiographic evidence of loosening and thigh pain in 2% at a mean of fifteen years (range, 14.5 to 16.9 years) postoperatively[71]. These authors reported a 100% survivorship at five years in seventy-eight hips in octogenarians. Keisu et al.[76] demonstrated a 100% survivorship in ninety-two hips in octogenarians, including 26% with Dorr Type-C bone, after a mean of five years (range, two to eleven years) of follow-up[49]. Four patients had mild thigh pain.

The long-term results of Type-1 stems with porous coating are excellent. Thigh pain is present in up to 6% of

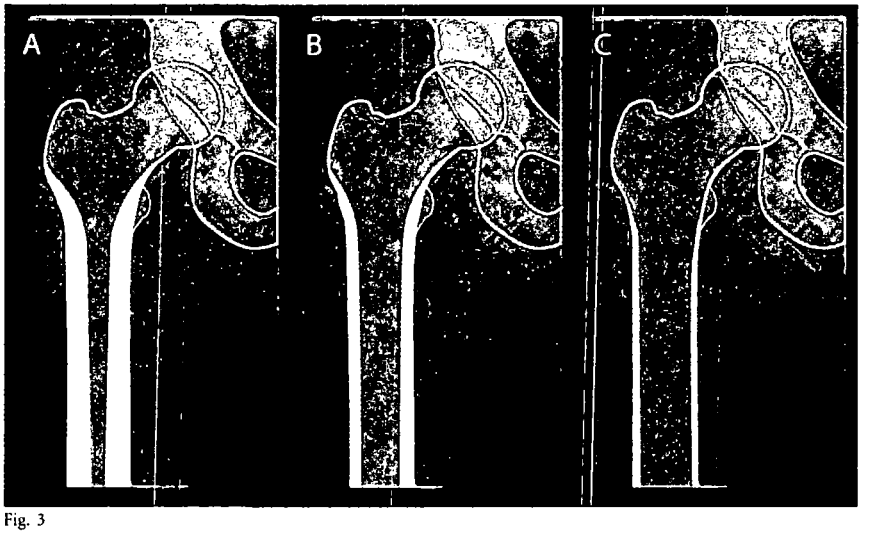


Fig. 3

Dorr classification of femoral bone quality. Dorr Type A indicates thick medial and lateral cortices and a large posterior cortex, giving a champagne-flute appearance. Dorr Type B indicates bone loss at the medial and posterior cortices. Dorr Type C indicates a stovepipe appearance due to complete loss of both the medial and the posterior cortex and a widened intramedullary diameter. (Reprinted with permission of Sinai Hospital of Baltimore, Inc., 2009.)

patients[49]. These stems are good options for younger and older patients and those with type-C bone.

Type 2

Studies have demonstrated excellent medium and long-term results after the use of Type-2 stems[6,36,77,78]. Epinette and Manley reported on 571 hips in 504 patients (mean age, sixty-five years) followed for fifteen to twenty years after treatment with a titanium-alloy stem that was collarless, grit-blasted, and hydroxyapatite-coated on its proximal one-third[77]. There were four femoral revisions (0.7%), and survivorship at seventeen years was 99.2%. Capello et al. reported 99.5% survivorship, with aseptic loosening as the end point, in a study of 166 hips followed for a minimum of fifteen years after treatment with the same prosthesis[7].

In a study of patients under the age of fifty years followed for a minimum of ten years, the failure rate was 4.5% (five of 111 hips); one failure was due to aseptic loosening, and four were due to thigh pain[6]. Lee et al. reported 100% survivorship in a study of eighty-five hips (mean age, fifty-two years; range, twenty-seven to seventy-eight years) followed for a mean of 10.3 years (range, seven to twelve years)[78].

Modifications to the original design comprise offset options and changes to enhance rotational stability, including distal splines and flutes, and a slotted distal stem to decrease stiffness[79]. At the time of short-term follow-up, there was no reported loosening but the prevalence of thigh pain was 12% (ten of eighty-one hips)[79]. Ten patients (12%) had Dorr Type-C bone. At the time of mid-term follow-up (at five to ten years) of the same hydroxyapatite-coated stem, there were no femoral failures, although the prevalence of thigh pain was not reported[36].

There has been long-term success of Type-2 prostheses with a first-generation design. Reported prevalences of thigh pain are as high as 12%, but most cases are mild. Success has been shown in hips with Dorr Type-C bone[36,79].

Type 3

Excellent long-term results have been achieved with use of Type-3A designs[3,5,80]. Lombardi et al. reviewed the results of 1866 arthroplasties done with use of a titanium prosthesis[3]. The proximal third was plasma-sprayed and had rotational fins, the middle third was grit-blasted, and the distal third was smooth. Only twelve femoral revisions (1%) were related to ingrowth failure. Survivorship with revision as the end point was 95.5% at twenty years.

Bourne et al. reviewed the results in a study of 307 hips that had been treated with this type of femoral stem and followed for a minimum of ten years[5]. Stem survivorship was 99%. Ten (4%) of 283 patients reported mild-to-moderate activity-related thigh pain. Mild stress-shielding was noted proximally in 153 hips (50%). Another group of authors demonstrated a rate of proximal shielding of 88% in seventy-six hips[80], suggesting that fixation may be more distal with this design.

Use of this stem has been successful in young and elderly patients and in those with Dorr Type-C bone. Ellison et al. studied 249 hips in 201 patients with an age of forty years or younger and reported survivorship to be 98.2% at up to eighteen years[81]. Reitman et al. reported no revisions in thirty-three patients with Type-C femora who had been followed for a mean of 13.2 years[82].

Mid-term results are available for a newer design that has grit-blasting in the distal two-thirds and a polished bullet tip. In one study, survivorship was 99.5% at seventy-five months[83]. Thigh pain occurred in 2.4% (five) of 210 hips, but it resolved in three patients. Cortical thickening was seen in 14% (twenty-one) of 155 patients. Calcar changes occurred in 54% (eighty-three patients); these changes included rounding off of the calcar without height loss in sixty patients and calcar resorption of between 2 and 7 mm in twenty-three patients.

The long-term survivorship of Type-3A stems has been excellent, with success in hips with Dorr Type-C bone. Up to 4.4% of patients have activity-related thigh pain[80]. There is a high prevalence of proximal stress-shielding, which is indicative of the more distal fixation compared with the fixation of Type-1 and 2 stems.

The survivorship for ninety-four Type-3B femoral stems that had been followed for a mean of 11.5 years (range, ten to fourteen years) was 91.5% with eight revisions, only three of which were for aseptic loosening[60]. The majority were complex cases, including hips with dysplasia and prior intertrochanteric osteotomies. Proximal radiolucent lines were seen in twenty-seven cases, with findings of distal fixation in eighteen. Of the first 100 reported cases in which a Type-3B femoral stem had been used, twenty-one had distal engagement of the prosthetic tip[59]. The authors stressed the importance of templating and canal preparation so that the prosthetic midportion engages the canal and the tip is free[59]. Failure to accomplish this results in more distal fixation. This stem has not been modified from its original design. While not commonly used in routine cases, the design has proven useful in revision settings[84,85].

Type-3C stems have been widely used in Europe[86-89]. Grübl et al. reviewed the results in ninety-two hips in eighty-seven patients who had been followed for a mean of 15.5 years (range, fifteen to 17.3 years)[87]. Only three stems were revised. The stem survival rate was 98% at fifteen years, and 2% (two) of the eighty-seven patients reported thigh pain.

Suckel et al. reported similar findings in 320 hips after a minimum duration of follow-up of fifteen years (range, fifteen to seventeen years)[89]. The stem survival rate was 98%. One stem (0.3%) was revised because of aseptic loosening. Proximal stress-shielding was observed in one-third of hips. In another study, of seventy-five hips in seventy patients who had a mean age of fifty-two years (range, twenty-four to sixty-eight years), survivorship was 95% at a mean of sixteen years (range, fifteen to eighteen years)[88]. Two revisions were due to aseptic loosening.

In summary, Type-3C stems have excellent long-term survivorship. There have been no substantial modifications of the original design. The rate of proximal stress-shielding suggests a more distal femoral loading. Despite this, the prevalence of thigh pain remains low. The shape of the stem and the ability

to obtain fixation along its entire length makes it an attractive option for hips with Dorr Type-C bone.

Type 4

There have been a number of long-term studies demonstrating excellent outcomes with Type-4 stem designs[8,90,91]. Belmont et al. reported on a cobalt-chromium stem with porous coating on 80% of its proximal portion[90]. One hundred and nineteen hips had survivorship of 98% at a mean of twenty-two years (range, 20.0 to 25.0 years); only six of 223 stems had loosened.

This design has done well in younger patients. McAuley et al. reported survivorship of 96.1% at fifteen years in 293 hips in patients under fifty years (range, sixteen to fifty years) of age[91]. Moyer et al. found component survival of 99.1% at a mean of 8.6 years (range, five to ten years) in 115 hips in patients who had a mean age of 39.6 years (range, seventeen to fifty years)[92].

Type-4 stems are associated with proximal stress-shielding and reports of thigh pain[93-95]. Engh et al. studied 1545 extensively porous-coated components to determine if larger stem sizes resulted in poorer outcomes[9]. The prevalence of activity-limiting thigh pain was 3.9% (sixty-one hips); the overall survival rate was 97.9% at fifteen years; and there was no difference in survivorship, pain, or satisfaction among stems of different diameters.

Modifications of the original designs have included full surface coating, a medial cutout, and the addition of a polished bullet tip. These changes were made to limit micromotion, decrease implant stiffness, and prevent pain at the distal part of the stem. A study of 100 consecutive second-generation stems in patients who had a mean age of forty-eight years (range, eighteen to seventy-two years) and who had been followed for a mean of 11.4 years (range, ten to twelve years) showed a 100% survival rate with thigh pain in 2%[96].

The survivorship of Type-4 stems has been excellent at twenty years. Thigh pain has been a concern, but the prevalence has been reduced by modifications that decrease the stiffness of second-generation designs. These stems are options for most patients, but studies have not adequately addressed the use of these stems in femora with Dorr Type-C bone.

Type 5

The most popular modular design, a titanium proximal sleeve with a distal slotted stem with flutes, has been studied with long-term follow-up by several investigators. This stem is often reserved for complex arthroplasties[97-99]. In a study of 795 primary hip arthroplasties followed for a mean of eleven years (range, two to seventeen years), Cameron et al. reported two cases of aseptic femoral loosening (0.25%) and five cases of thigh pain (1.8%)[98]. Biant et al. studied the results of primary hip arthroplasties in patients with unusual anatomy (50% had developmental dysplasia) and reported 100% survivorship in fifty-five hips followed for a mean of ten years (range, five to sixteen years)[100]. Christie et al. reported a 0.6% rate of femoral failures (one of 175) at the time of follow-up at a mean of 5.3 years (range, four to 7.8 years); eleven patients (6%) had thigh pain[99].

Modifications to modular designs include the addition of a variety of proximal and distal geometries and coatings allowing versatility in revision settings. Although they are not used as commonly as nonmodular designs in primary arthroplasty, Type-5 stems are excellent options for cases with abnormal anatomy. While most studies of the use of these stems in primary arthroplasty did not address bone type, the implants have been used in Dorr Type-C femora. Modular femoral prostheses are more costly than one-piece designs. Because multiple combinations of proximal and distal segments are possible, a larger inventory of components is necessary. The economic implications of these two factors need to be considered before modular stems are chosen for routine cases.

Type 6

The first generation of these components performed poorly[4,101-105]. There was a high prevalence of thigh pain (up to 36%) and loosening. Heekin et al. studied 100 hips managed with a cobalt-chromium anatomic prosthesis with sintered porous coating and found a 5% failure rate by five years, with 15% of the patients having thigh pain[102]. Kim et al. found a clinical failure rate of 9% (eleven of 116 hips) and thigh pain in 28% (thirty-two of 116 hips) at a mean of six years[106].

Modifications were made to the initial design to obtain more reliable fixation[65]. The proximal and lateral metaphyseal portions were widened for more fill, and a gentle curve was added to the stem tip to minimize endosteal abutment. At the time of follow-up, at a minimum of five years postoperatively, only one of 115 of these stems had been revised[65].

Results have been design-dependent. A study of seventy-two hips treated with a titanium proximally porous-coated and distally grit-blasted prosthesis showed 100% survivorship at ten years[107]. A study of seventy-eight hips treated with another design, with fiber metal coating, demonstrated 100% survivorship at ten years[108], with seven patients (9%) having thigh pain.

In a recent study of a titanium anatomic stem in 471 patients (601 hips) who had a mean age of fifty-three years (range, twenty to sixty-two years) and were followed for a mean of 8.8 years (range, five to twelve years), no components required revision[109]. There was no thigh pain or radiographic loosening.

Historically, Type-6 stems have been associated with a higher rate of thigh pain and inferior results. Modifications to the stem design to enhance rotational stability and a better understanding of cementless fixation have led to improved outcomes. Studies of these stems have not consistently addressed bone type.

Short-Stem, Bone-Preserving Designs

With less invasive hip arthroplasty, attention is turning to bone-conserving designs. Collectively, these stems have not had long-term follow-up. Many newer short designs are modifications of one of the above stems, with no more than two years of follow-up[110-112]. Others designs have distinct geometries for more proximal fixation in the femoral neck or for metaphyseal bone conservation. A short stem with a unique trapezoidal, tapered

wedge shape was designed to minimize osseous engagement in the proximal metaphysis. One study of 159 hips showed survivorship of 98.2% at ten years[113]. A neck-engaging titanium threaded design demonstrated results comparable with those provided by a cemented total hip replacement in a study of forty hips followed for two years[114,115]. A curved design that engages the neck demonstrated excellent mid-term results, with 99% survivorship at just over six years[116]. With further follow-up the utility of these designs, the improvements that they may represent over previous designs may become apparent.

Overview

Cementless femoral fixation is generally associated with excellent long-term results. Despite marked differences in their design principles and methods of femoral preparation, the six types of cementless stems have similar survival rates. Differences in currently used materials and fixation surfaces do not appear to affect outcomes as much as differences in geometric design do. Results also depend on operative technique, which is influenced by the stem geometry and the location of femoral fixation. It is important for the practicing surgeon to understand these principles. Any design may be acceptable for routine cases. When there is major deformity or when distal fixation is needed, Types 3B, 3C, 4, and 5 are useful, with the choice governed by the surgeon's familiarity with each type of stem.

Failure rates have decreased with these designs, although no type is completely free of thigh pain or stress-shielding. Cementless femoral fixation is durable in young patients and has had promising results in older patients, although limitations of the current literature make it difficult to assess and compare different designs to determine optimal indications for each type.

The outcomes associated with newer materials and designs will need to be compared with these excellent long-term results. The basic classification system described in this article will need to be expanded, but most designs fit into one of the six categories. A separate classification should be considered for short-stem designs, which do not fit into one of the categories.

Future studies of cementless implants should consistently address patient age, activity level, bone type, and deformities so that more definitive conclusions can be made about when to use each design. Investigators should report their clinical findings and all radiographic osseous changes.

Appendix

(eA) Tables summarizing the results associated with the six types of cementless femoral stems are available with the electronic version of this article on our web site at jbjs.org (go to the article citation and click on "Supporting Data"). ■

Harpal S. Khanuja, MD
Maria S. Goddard, MD
Michael A. Mont, MD
Center for Joint Preservation and Replacement,
The Rubin Institute for Advanced Orthopedics,
Sinai Hospital of Baltimore,
2401 West Belvedere Avenue, Baltimore, MD 21215.
E-mail address for H.S. Khanuja: paulkhanuja@gmail.com

Jeffrey J. Vakil, MD
Orthopaedicare, 2400 Maryland Road,
Willow Grove, PA 19090

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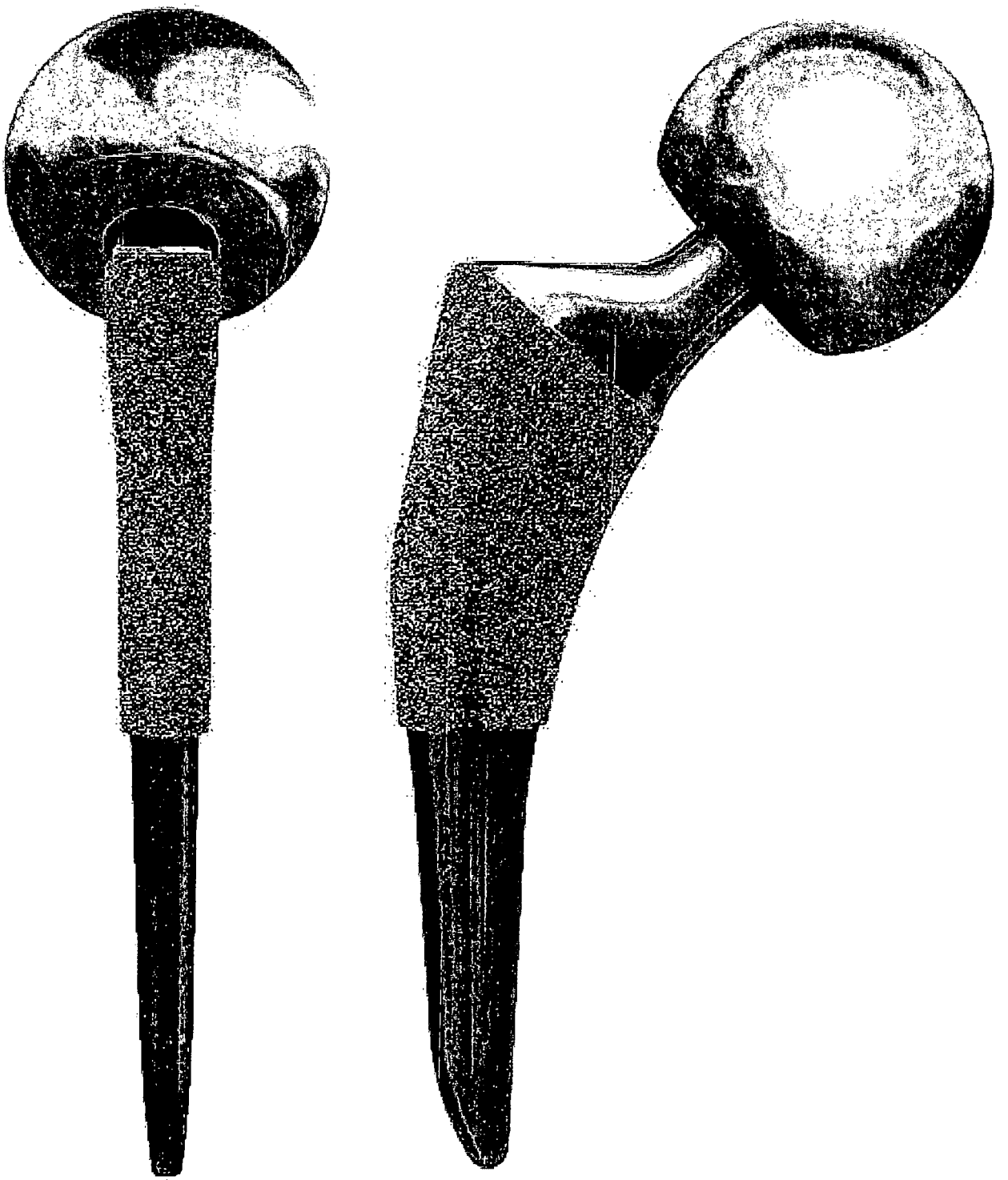
TRI·LOCK®

BONE PRESERVATION STEM

Design Rationale

DePuy
a Johnson & Johnson company

FEATURING GRIPTION™ TECHNOLOGY



Optimum implant geometry

Extending proven Tri-Lock® heritage

The original Tri-Lock® was introduced in 1981. This implant was the first proximally coated tapered-wedge hip stem available to orthopaedic surgeons and their patients. Since its introduction, Tri-Lock has demonstrated 98% survivorship.[1]

Preserving the natural anatomy

The reduced lateral shoulder, thin geometry and optimized length of the Tri-Lock Bone Preservation Stem minimize the amount of bone removed from the patient. These same features, along with approach enabling instrumentation, allow the surgeon to perform minimally invasive techniques.

Delivering stable, predictable performance

The Tri-Lock Bone Preservation Stem incorporates Gription™ fixation technology. Gription is designed to help provide consistent implant seating height and additional initial stability that helps maximize the potential for long-term bony ingrowth.

Restoring high level function

The Tri-Lock Bone Preservation Stem neck geometry has been optimized to improve range-of-motion. Progressive dual offsets with direct lateralization provide the ability to optimize soft tissue tension. An extensive size range and consistent intervals between sizes help achieve proper fit and aid in recreating leg length.

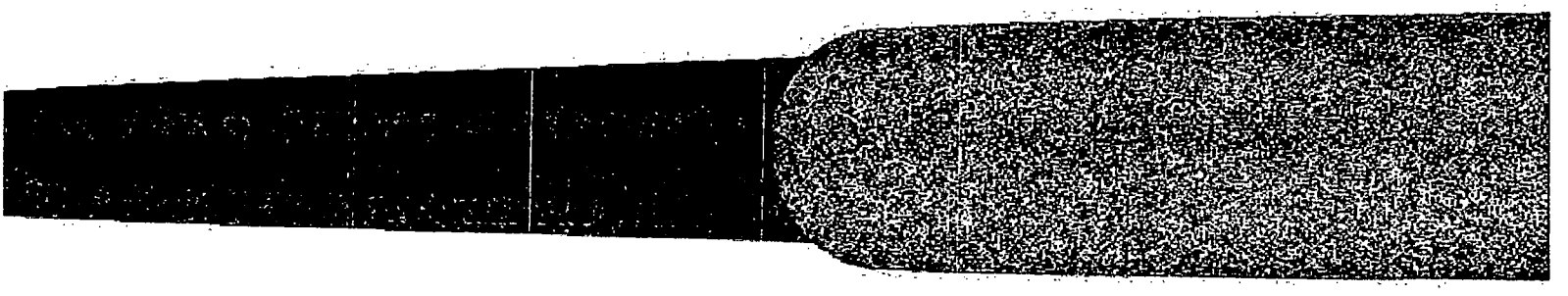
Providing advanced bearing options

The Tri-Lock Bone Preservation Stem's 12/14 Articul/eze® taper enables the use of the most advanced bearing options available today. The Pinnacle® Acetabular Cup System gives the surgeon a choice of bearing materials, and the option for screw fixation. The DePuy ASR™ XL metal-on-metal system maximizes head-to-shell ratio, providing an exceptional range-of-motion and outstanding hip stability.

Enabling a simple, reproducible technique

Today's total hip surgeon demands proven performance, OR efficiency, and surgical approach flexibility. The new Tri-Lock Bone Preservation Stem delivers on all fronts. The broach-only technique and wide range of instrumentation enable both traditional and less-invasive surgical approaches.

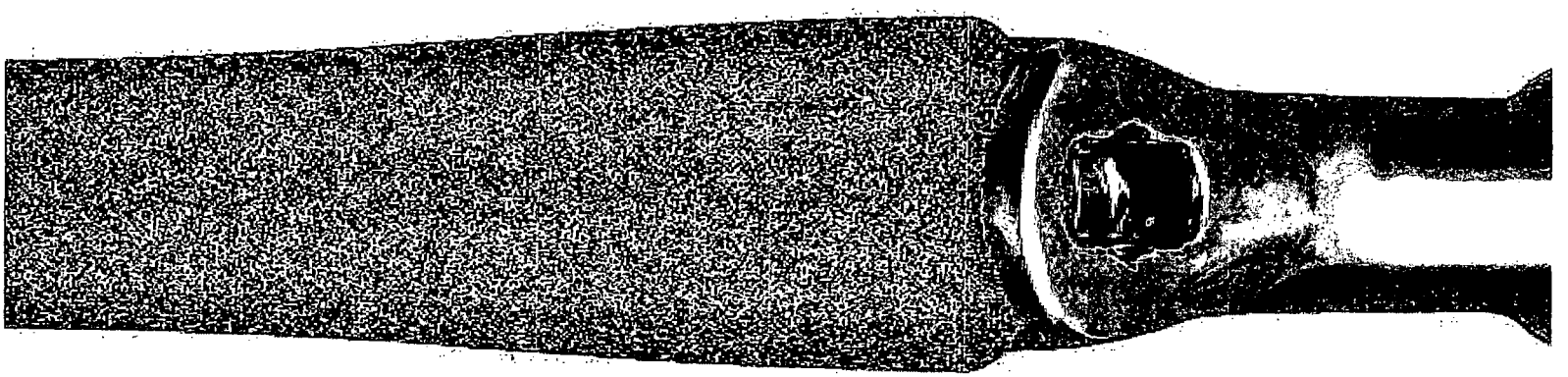
Extending proven Tri-Lock® heritage



98%

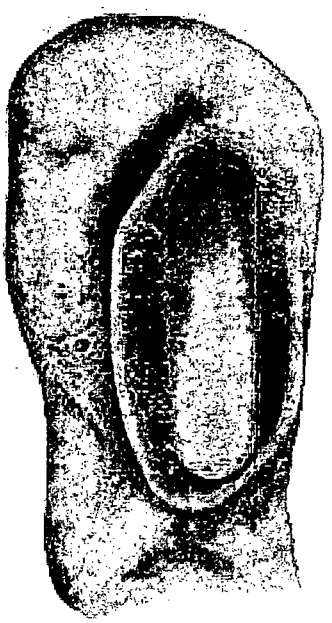
Survivorship at 10 years.[1]

The original Tri-Lock was introduced in 1981. This implant was the first proximally coated tapered wedge hip stem available to orthopaedic surgeons and their patients. Since its introduction, the success of Tri-Lock has been well documented in published studies. Using component revision for aseptic loosening as the end point, the numbers are convincing.



Axial stability

The Tri-Lock Bone Preservation Stem achieves axial stability within the femur by making intimate cortical contact at the medial and lateral endosteal cortices. The natural taper of the femoral canal is reflected in Tri-Lock's proximal-to-distal taper, as viewed in an A/P radiograph. This taper prohibits distal migration when cortical contact is achieved.

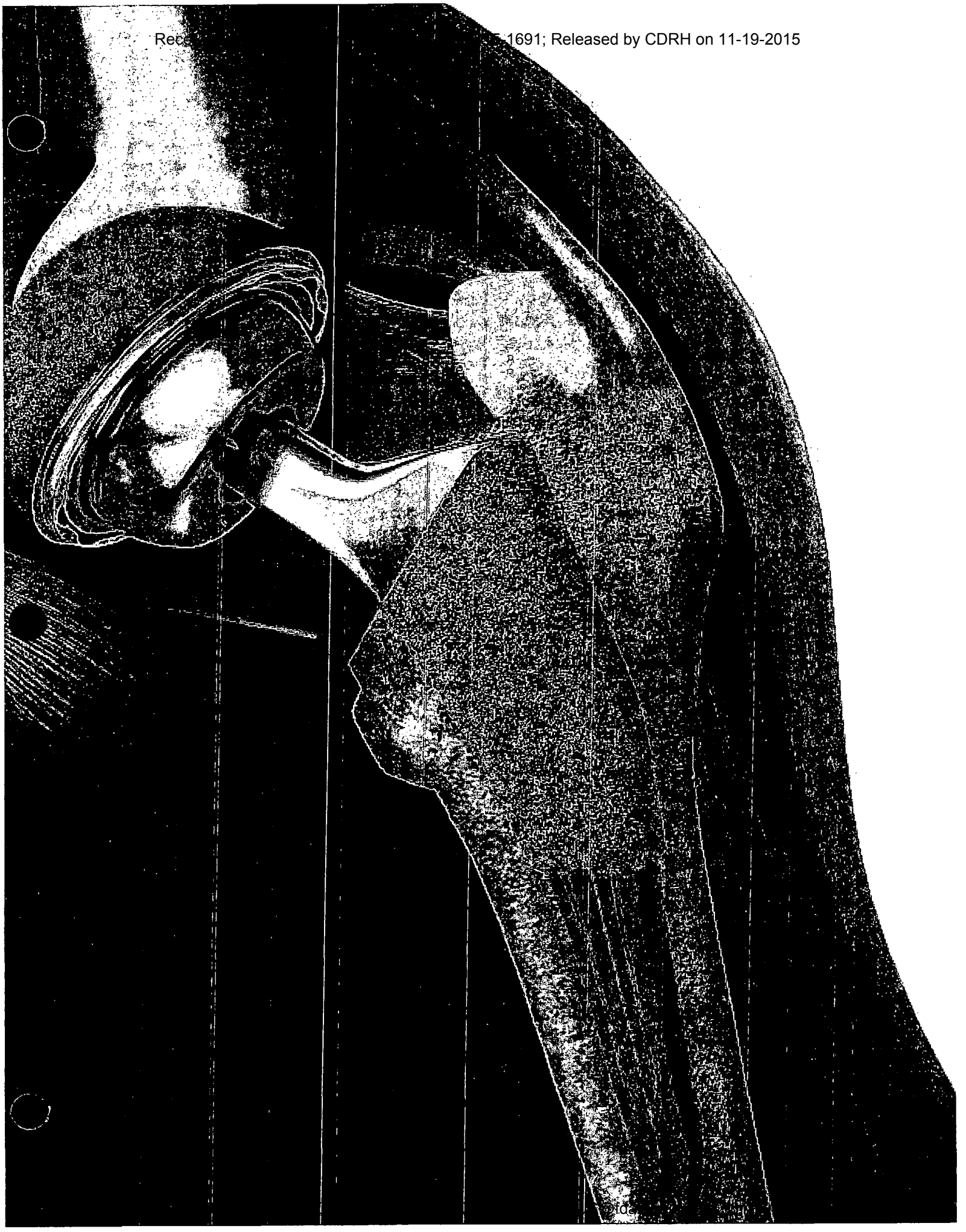


Rotational stability

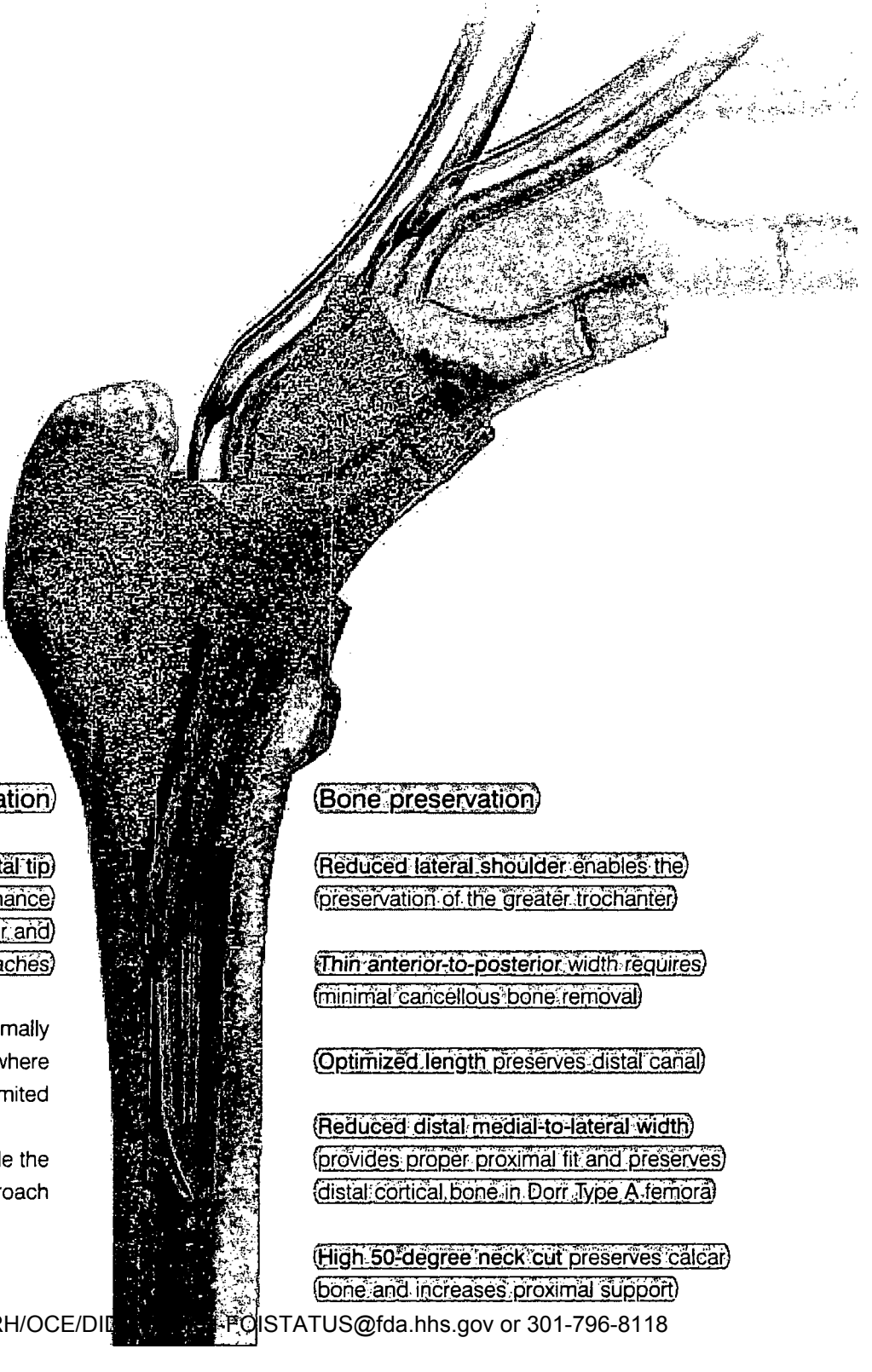
The inherent rotational stability of the Tri-Lock Bone Preservation Stem is a result of the narrow anterior-to-posterior width of the stem. This narrow geometry allows the stem to be sized to fill the largest dimension of the femoral canal (the medial-to-lateral width). Since the M/L width of the implant is larger than the A/P width of the femoral canal, the Tri-Lock Bone Preservation Stem maintains excellent rotational stability.

Long-term osteointegration

The initial axial and rotational stability of the Tri-Lock Bone Preservation Stem provide the opportunity for long-term osteointegration. Initial stability limits micromotion at the implant to cortical bone interface, resulting in a higher probability for bony ingrowth.



Preserving the natural anatomy



Soft tissue preservation

Optimized length, contoured distal tip and reduced lateral shoulder enhance stem insertion through the anterior and *antero-lateral approaches*

Broach only technique enables minimally invasive surgical approaches where access with straight reamers is limited

Instrumentation designed to enable the surgeons' preferred approach

Bone preservation

Reduced lateral shoulder enables the preservation of the greater trochanter

Thin anterior-to-posterior width requires minimal cancellous bone removal

Optimized length preserves distal canal

Reduced distal medial-to-lateral width provides proper proximal fit and preserves distal cortical bone in Dorr Type A femora

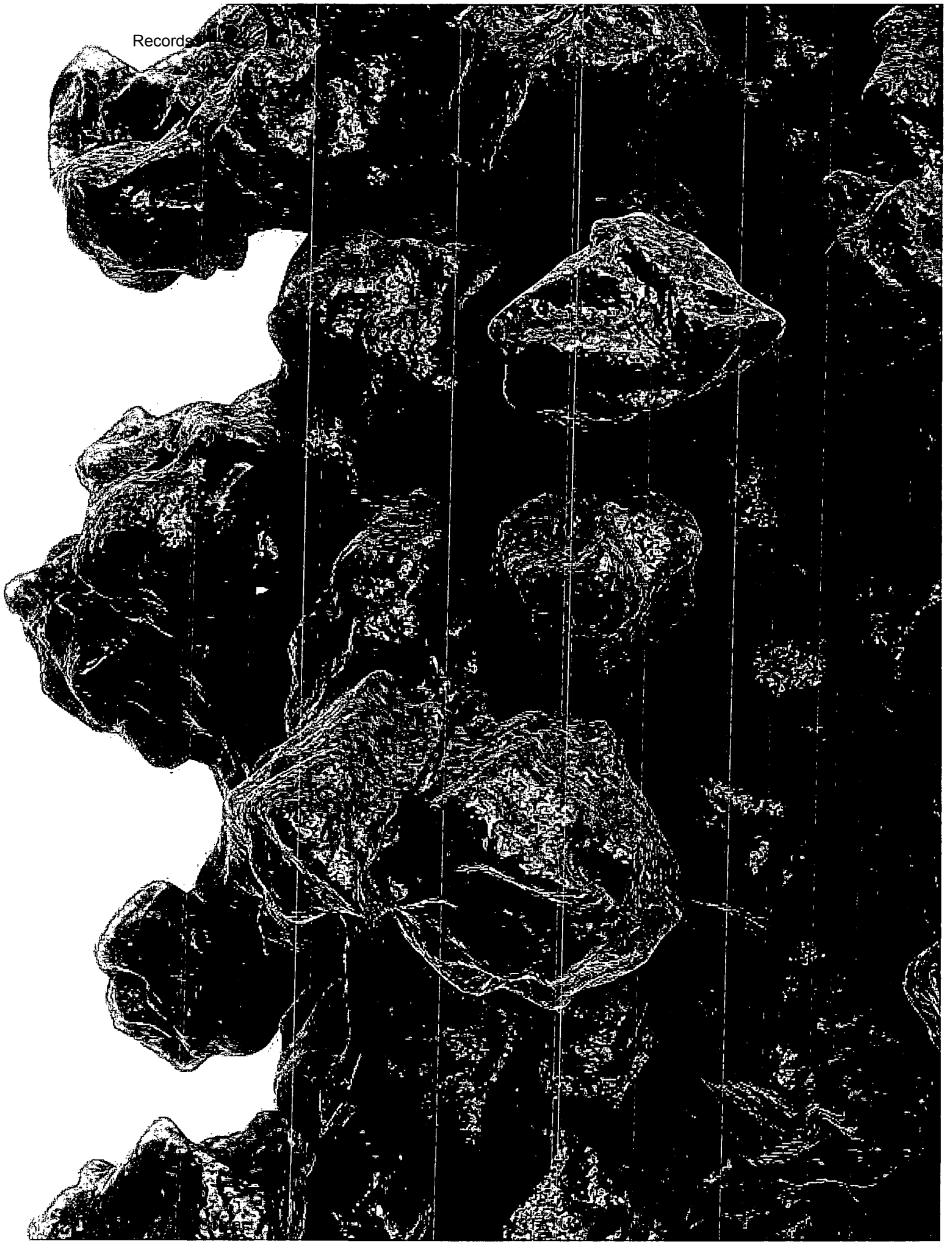
High 50-degree neck cut preserves calcar bone and increases proximal support

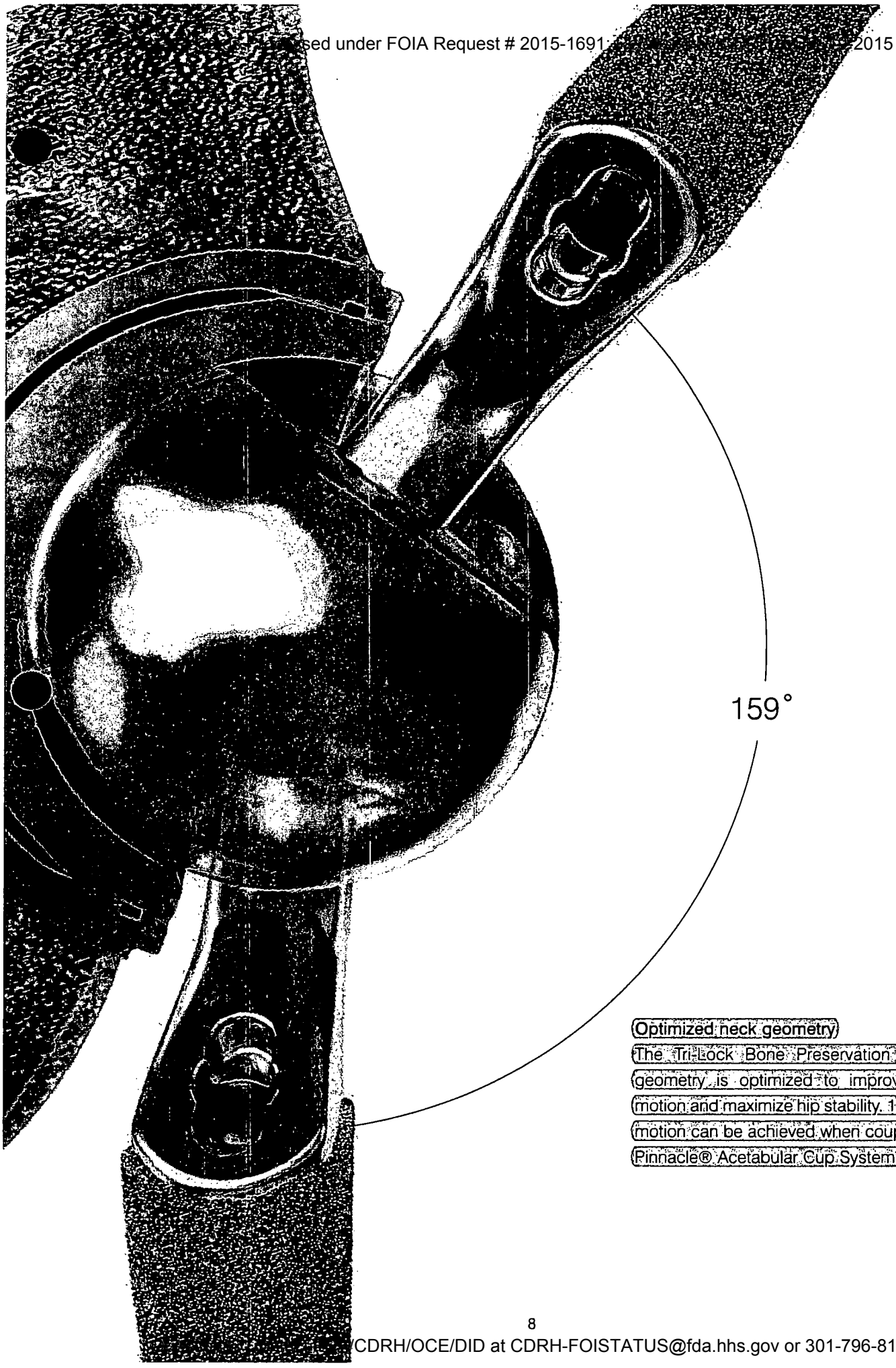
Delivering stable, predictable performance

GRIPTION™ fixation technology

- Gription's predicted 1.2 coefficient of friction exceeds that of plasma spray and porous tantalum material.[2]
- The volume porosity of Gription reaches 63% at the surface. This increased porosity allows for higher oxygenation and revascularization of bony tissue.
- Gription provides a clinically advantageous 300-micron average pore size. This pore size has been proven optimal for osteointegration.[3]
- Gription is highly microtextured. This microtexture provides an increased surface area for osteoblast cells to adhere and proliferate.
- The Tri-Lock Bone Preservation Stem and Gription coating are composed of titanium, a material with proven biocompatibility and a low modulus of elasticity.

The Tri-Lock Bone Preservation Stem incorporates Gription fixation technology. Gription is an evolutionary advancement in implant coating technology. This advanced coating technology builds upon DePuy's 30-year tradition of cementless implant excellence. The critical coating properties that Porocoat® has proven effective for long-term survivorship have been replicated in Gription. Advanced technology has allowed DePuy to optimize Gription's properties, providing consistent implant seating height, exceptional initial stability and a maximized potential for long-term osteointegration.

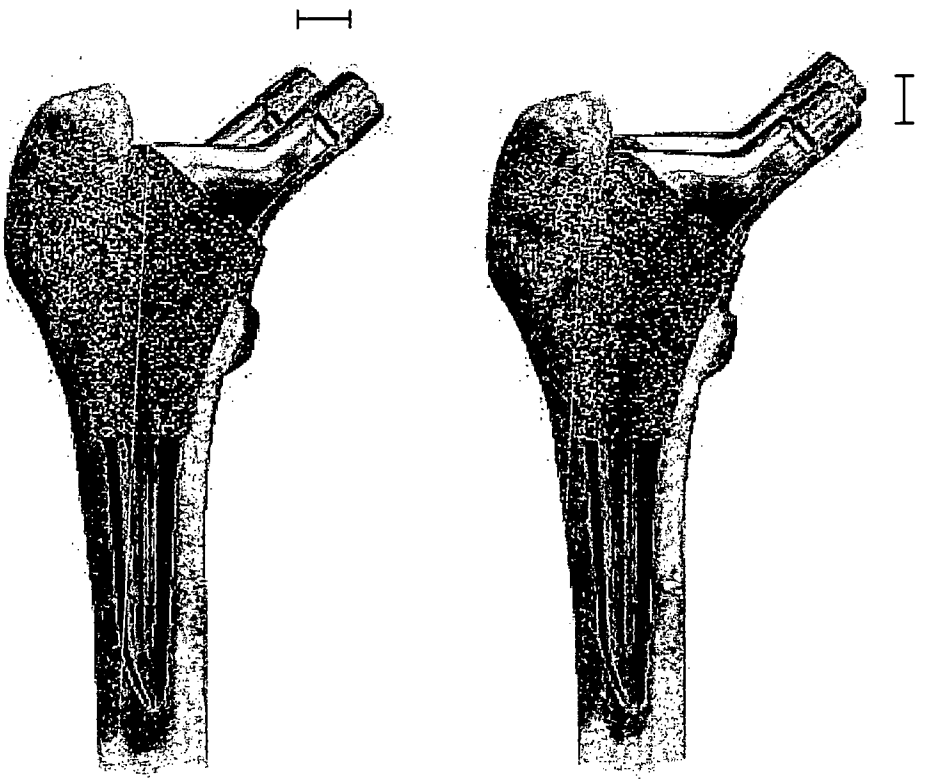




Optimized neck geometry

The Tri-Lock Bone Preservation Stem neck geometry is optimized to improve range of motion and maximize hip stability. 159° range of motion can be achieved when coupled with the Pinnacle® Acetabular Cup System.

Restoring high level function



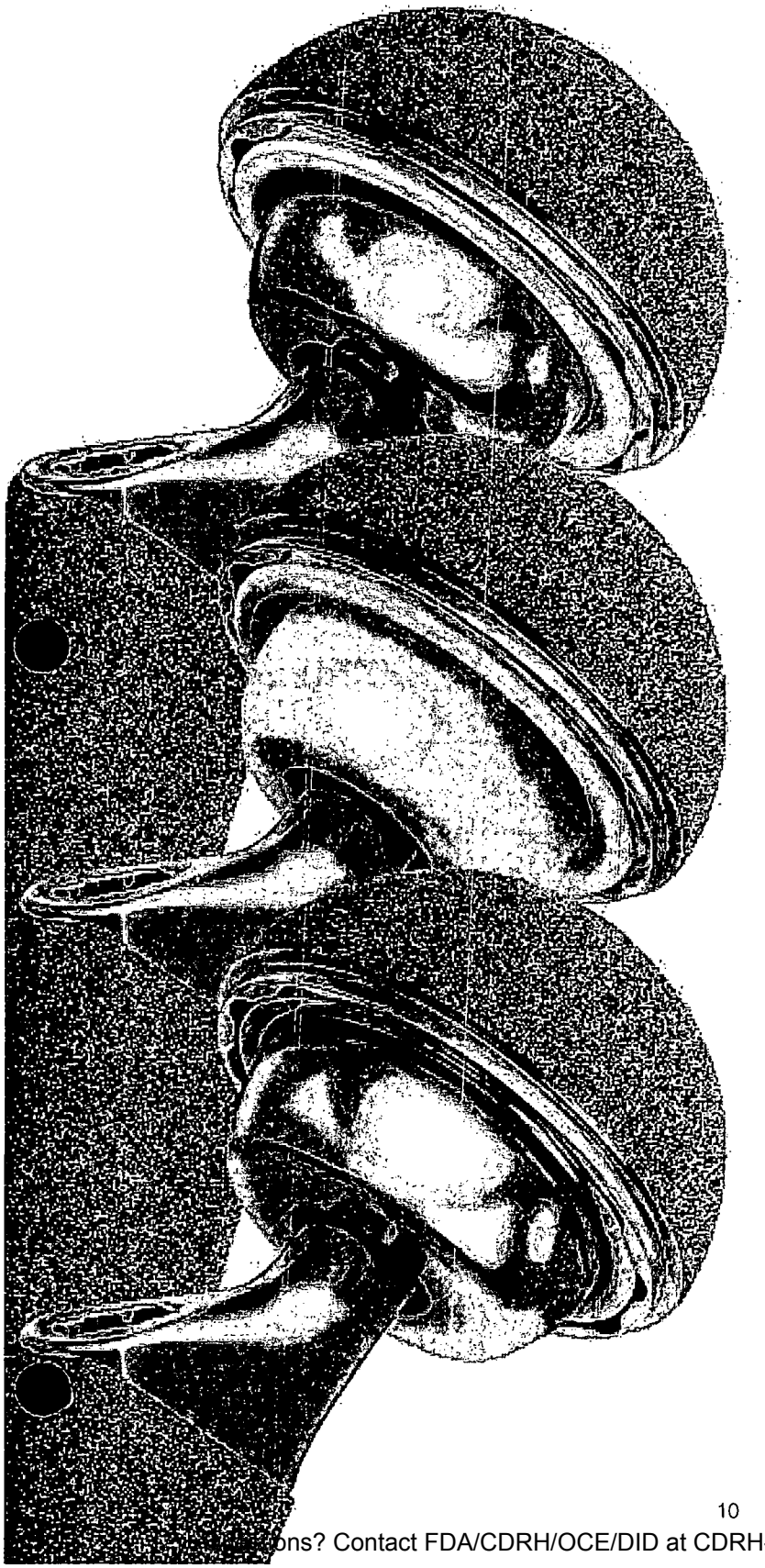
Progressive dual offset

Stem offset is proportional to stem size. Each stem size offers a standard and high offset option. The high offset option lateralizes the stem 6 – 8 mm depending on size. By maintaining a constant 130° neck angle, tissue tension can be increased without affecting leg length.

Extensive size range

The Tri-Lock Bone Preservation Stem system features 13 stem sizes, allowing the surgeon to address the larger patient population. Consistent intervals between each stem size help achieve proper fit within the femur. Component sizing can also be used to fine tune seating height and adjust leg length.

Providing advanced bearing options

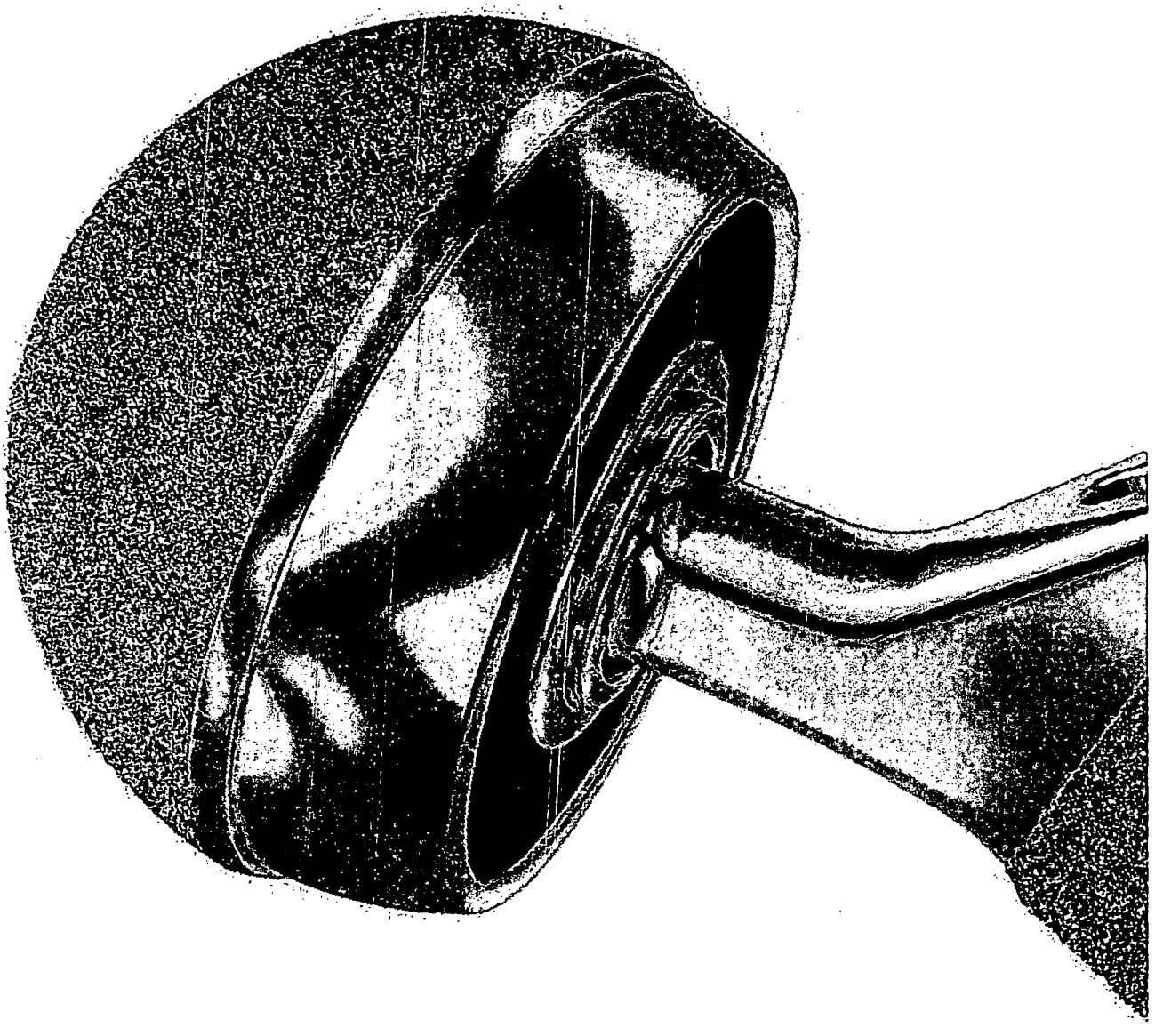


Pinnacle® with Marathon™. Marathon polyethylene combines mechanical integrity with wear resistance. This moderately cross-linked (5 Mrad) polyethylene is manufactured to have zero oxidative potential.

Pinnacle® with AltrX™. This moderately cross-linked polyethylene (7.5 megarads) demonstrates mechanical toughness and zero oxidative potential, while providing a 92 percent reduction in wear.[2]

Pinnacle® with Ultamet®. Ultamet metal-on-metal bearings are designed and manufactured to reduce wear and increase stability, while offering modularity and adjunct fixation. Made with highly polished, high-carbon cobalt chrome, Ultamet bearings have optimized diametrical clearance and sphericity to provide true fluid film lubrication and low wear.

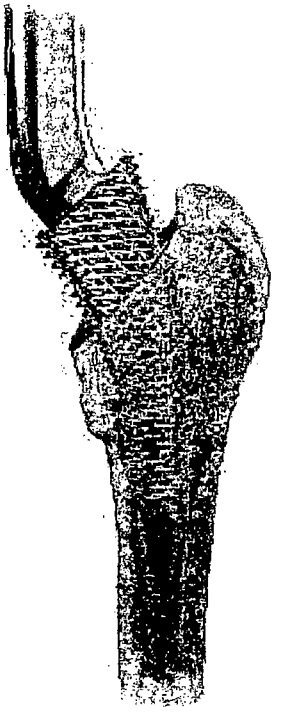
DePuy ASR XL. As a monoblock metal-on-metal system, ASR XL provides the largest head size possible for a given acetabulum. Large head metal-on-metal articulation improves hip stability and enhances fluid film lubrication.



The Tri-Lock Bone Preservation Stem 12/14 Articul/eze taper enables the use of the most advanced bearing options available today. The Pinnacle Acetabular Cup System gives the surgeon choice in bearing materials. The DePuy ASR XL metal-on-metal system maximizes head-to-shell ratio, providing an exceptional range of motion and outstanding hip stability.

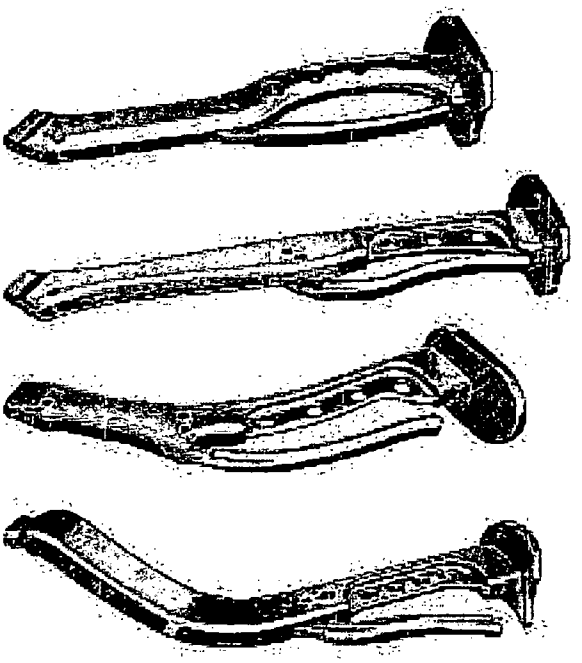
Enabling a simple, reproducible technique

Step 1: Neck osteotomy

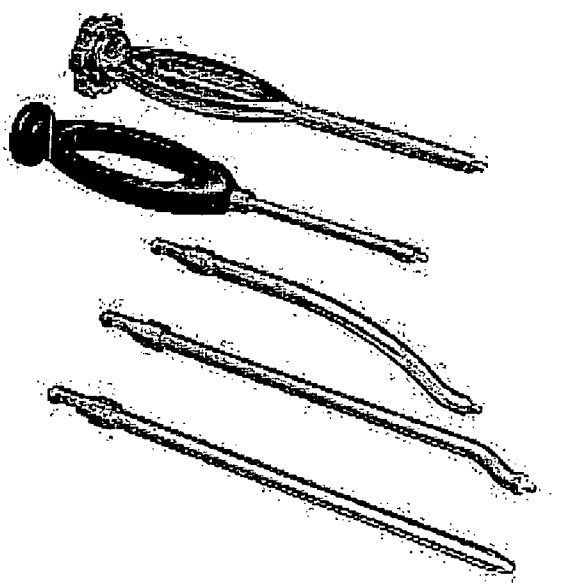


Step 2: Femoral canal preparation

Step 3: Femoral component insertion



Approach enabling broach handle options



Approach enabling stem inserter options

References:

1. Burt CF et al. A Femoral Component Inserted without Cement in Total Hip Arthroplasty. A Study of the Tri-Lock Component with an Average Ten Year Duration of Follow-up. JBJS 1998 Jul 80(7) 952-60.

2. Data on file at DePuy

3. Bolyn, et al. The Optimum Pore Size for the Fixation of Porous Surfaced Metal Implants by the Ingrowth of Bone. CORR, 150, 1980.

DePuy
a Johnson & Johnson company

DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, IN 46581-0988
USA
Tel: +1 (800) 366 8143
Fax: +1 (574) 371 4865

DePuy International Ltd
St Anthony's Road
Leeds LS11 8DT
England
Tel: +44 (0)113 387 7800
Fax: +44 (0)113 387 7890

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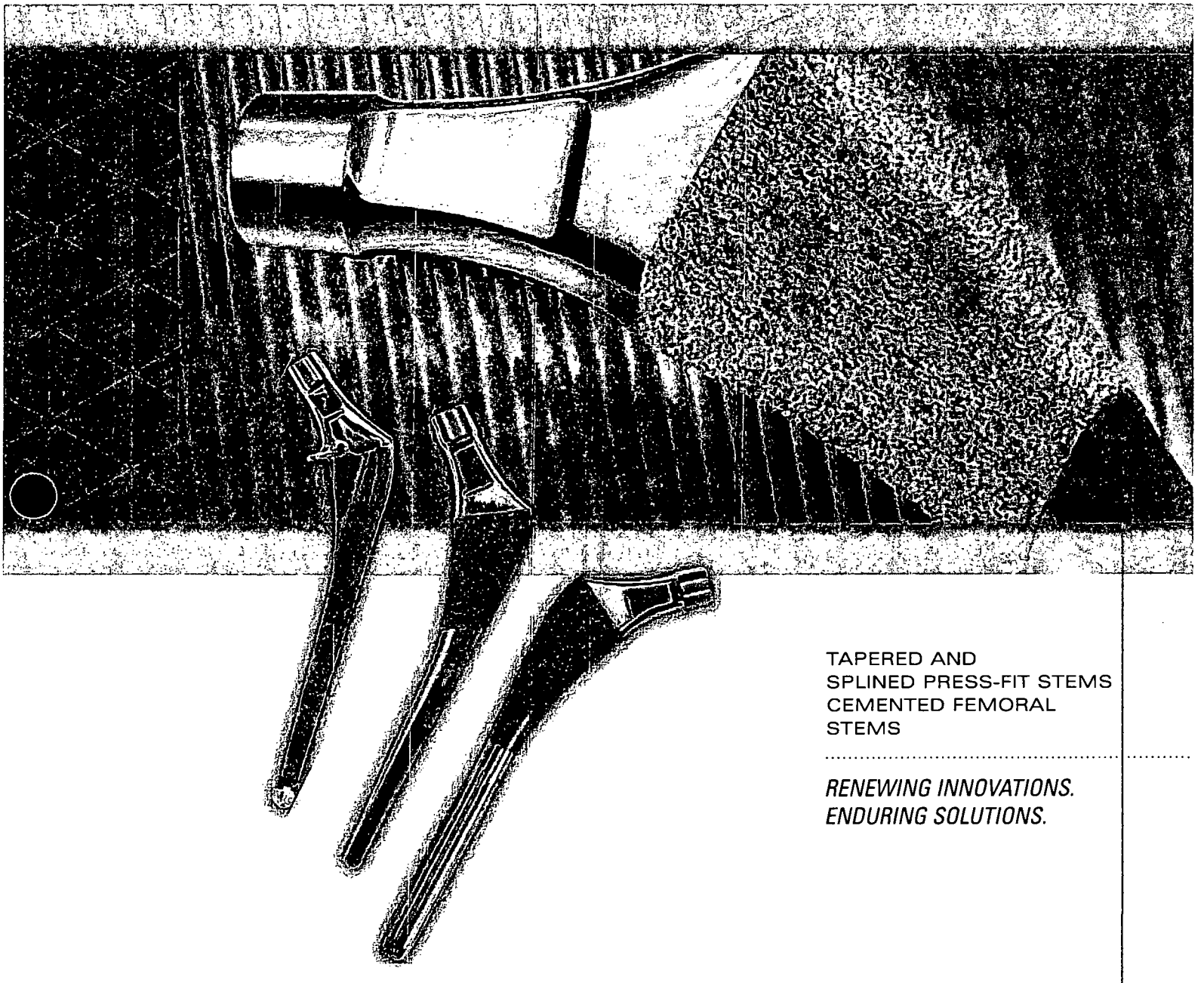
NOVATION®
Comprehensive Hip System

Operative Technique

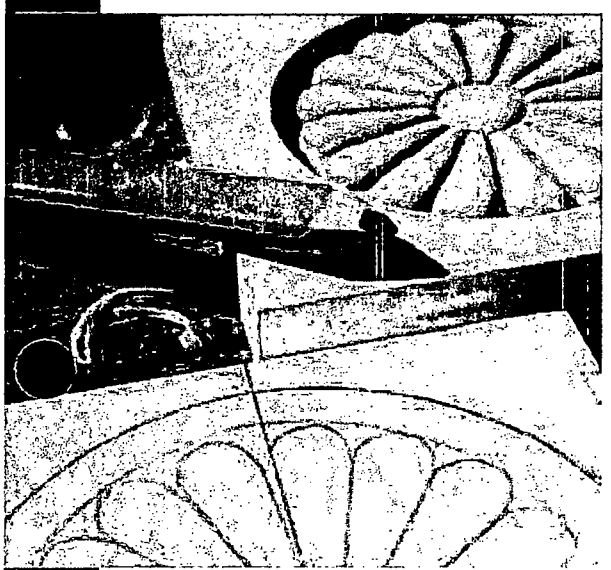


TAPERED AND
SPLINED PRESS-FIT STEMS
CEMENTED FEMORAL
STEMS

RENEWING INNOVATIONS.
ENDURING SOLUTIONS.

Exactech®

TABLE OF CONTENTS



NOVATION® COMPREHENSIVE HIP SYSTEM FEMORAL STEM DESIGN TEAM:

Wael K. Barsoum, MD
Cleveland Clinic Foundation

Richard A. Boiardo, MD
St. Michael's Medical Center – Catholic Health East

Norman A. Johanson, MD
Drexel University College of Medicine

Raymond P. Robinson, MD
University of Miami Hospital

Ajoy J. Sinha, MD
New York Queens Medical Center

INTRODUCTION

Like the art of fine woodworking, the Novation® Comprehensive Hip System design began with the end in mind. Before launching into development, Exactech's engineers and design team surgeons established a comprehensive plan. Their goal: to provide a system of femoral stems, acetabular components and surgical instrumentation that would address any situation encountered during primary total hip replacement.

They let science be their guide and conducted an extensive research review to identify the best of the best in design and materials. These proven features were blended with masterfully crafted innovations. The result: a comprehensive hip system that provides stable reconstruction of the widest range of anatomies, state-of-the-art bearing surfaces and low profile instrumentation and implants that are compatible with a multitude of surgical approaches.

DESIGN PHILOSOPHIES - SCIENCE FIRST

The Novation Comprehensive Hip System features both splined and tapered press-fit femoral stems as well as collared, matte finish cemented stems. All stems within the Novation high-demand, primary hip platform are available in a standard and extended offset.

UNIVERSAL FEATURES

All Novation high-demand femoral stems also share many mutual design features. The neck flats increase the range of motion of the stem before the potential for impingement and dislocation can occur. A 12/14 taper allows coupling with a wide range of bearing surfaces. The highly polished neck is intended to reduce the generation of polyethylene wear particles during incidental impingement.

PRESS-FIT STEMS

Novation tapered and splined designs are manufactured from a proprietary forged titanium alloy and are proximally coated with titanium plasma spray, which uses advanced manufacturing technologies.

The Novation Tapered stems share many attributes of other clinically successful tapered stems. Tapered stems rely on proximal fixation and three-point contact for initial stability. The dual-taper design, with a gradual 3-degree taper in the M/L plane and a more rapid transition (5-degree taper) in the A/P plane, accommodates the anterior bow of the femur while providing the wedge effect needed for stability.

The Novation Splined stems share the same proximal geometry as the Tapered stem. However, the distal portion of the stem incorporates a coronal slot and highly polished splines. The coronal slot increases stem flexibility while the splines add rotational stability when engaged with the diaphysis.

In addition to the standard distal geometry of the Splined stems, the Splined RDD (Reduced Distal Diameter) option allows the stem to be used with femoral anatomy exhibiting smaller diaphyseal canals, allowing the preservation of the diaphyseal cortices while maximizing the proximal fixation in the metaphysis.

CEMENTED STEMS

The Novation Cemented femoral stems are designed to utilize the same instruments used with the press-fit femoral stem preparation. This allows for simple preparation and ease of intra-operative transition to a cemented stem, should the need arise. Features such as the cobra flange, *longitudinal grooves, medial collar and distal centralizer* are designed to help optimize cement pressurization and stem placement. In addition, the offset and leg length of the corresponding press-fit stems are identical, allowing for accurate replication of leg length and offset following trial reduction.

PRE-OPERATIVE PLANNING

TOOLS

- A/P and lateral radiographs
- Pencil that will not damage radiograph
- Straight edge
- Novation templates with 120 percent magnification rule
- Goniometer/protractor

Traditional templating methods may be used. For an estimated determination of required offset, vertical limb length and stem size, the following detailed templating method may be used to help guide the surgeon in final implant choice.

Note: *For digital templating, follow the software manufacturer's instructions for use while following the instructions regarding placement and implant fit.*

ESTABLISHMENT OF REFERENCE POINTS

On the radiograph, a straight line is drawn across the bottom of the pelvis touching both ischial tuberosities equally. The line is extended far enough to reach each lesser trochanter. Such a line should be perpendicular to the vertically oriented pubic symphysis. If the line is not vertically oriented, it should be confirmed that the patient's pelvis was not tilted when the radiograph was taken. If the ischial tuberosities are poorly defined, the line should be drawn through the most inferior portion of both obturator foramina or the inferior aspect of both teardrops. Templating is recommended to determine the unique anatomic and mechanical features of the patient, and to establish pre-operative reference points that assist in the reconstruction of the patient's normal femoral anatomy.

DETERMINATION OF LIMB LENGTH

The Novation femoral template is positioned over the radiograph so that the central axis of the stem is in line with the central axis of the femoral canal.

The template should then be moved vertically until the desired neck length choice is approximately at the center of rotation of the templated acetabulum. ***Note:*** *Most of the time the chosen prosthetic head (neck length) does not line up with the center of rotation of the acetabulum or even with a mark in the center of the femoral head. The appropriate lateral offset, either Standard or Extended, can be recorded at this time. The head usually is positioned proximal and medial to the center of rotation of the acetabulum. In effect, at the end of the operation the surgeon will be pulling on the limb and lifting the prosthetic femoral head into the acetabulum, thereby recreating the desired femoral offset and length.*

When the template is in proper position, the level of the femoral neck cut is marked through the punch-outs provided on the template. The distance of the neck cut above the lesser trochanter can then be measured and recorded.

STEM SIZING

After placing the Novation templates on the radiograph over the proximal femur at the femoral height determined by the previous steps, the surgeon can choose a size that allows the desired canal fill. The template can now be used over the lateral radiograph to verify estimated size. In addition, notice that the broach cavity/cement mantle is indicated on the Cemented templates.

Note: *Due to the Standard and Extended offset options and numerous neck lengths of the heads, final implant selection will be made intra-operatively.*

The anticipated stem size can now be recorded.

CONTRAINDICATIONS FOR USE

Use of the Exactech Hip Systems is contraindicated in the following situations:

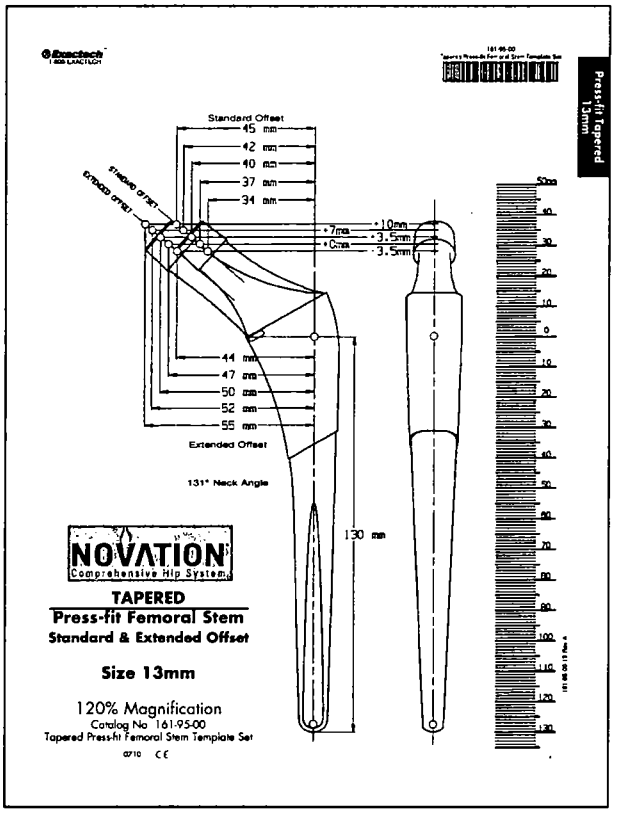
- Patients with suspected or confirmed systemic infection or a secondary remote infection.
- Patients with inadequate or malformed bone that precludes adequate insertion or fixation of the prosthesis.
- Patients with neuromuscular disorders that do not allow control of the joint.
- The unipolar and bipolar endoprostheses are also contraindicated for use in patients with evidence of degenerative changes in the acetabulum and/or pelvic fractures.
- Patient's age, weight or activity level would cause the surgeon to expect early failure of the system.

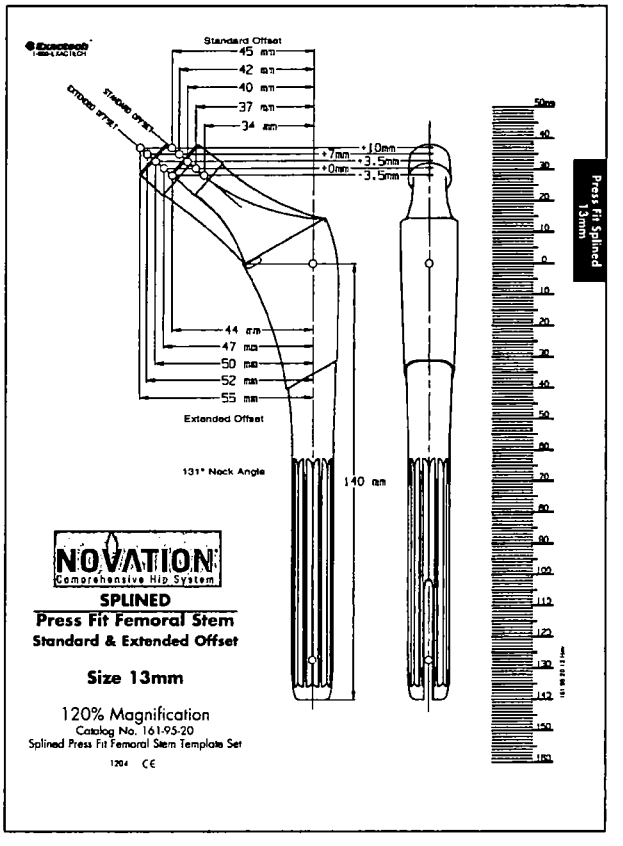
Note: For ceramic-on-ceramic articulation, please see additional package insert (700-096-070 Novation Ceramic AHS® System).

INDICATIONS FOR USE

All Exactech Hip Systems are indicated for use in skeletally mature individuals undergoing primary surgery for hip replacement due to osteoarthritis, rheumatoid arthritis, osteonecrosis, post-traumatic degenerative problems of the hip and for treatment of proximal femoral fractures where prosthetic replacement is determined by the surgeon as the preferred treatment. Components of Exactech Hip Systems are also potentially indicated for ankylosing spondylitis, congenital hip dysplasia, revision of failed previous reconstructions where sufficient bone stock is present and to restore mobility resulting from previous fusion.

- Cemented femoral stems and cemented acetabular cups are intended for cemented fixation only.
- Press-fit femoral stems and acetabular cups are intended for press-fit fixation.
- Femoral heads and endoprostheses are intended for use in cemented and press-fit applications.


Press-fit Tapered 13mm
Standard Offset
45 mm
42 mm
40 mm
37 mm
34 mm
STANDARD OFFSET
EXTENDED OFFSET
+7mm
+0mm
+10mm
+3.5mm
+3.5mm
44 mm
47 mm
50 mm
52 mm
55 mm
Extended Offset
131° Neck Angle
130 mm
NOVATION
Comprehensive Hip System
TAPERED
Press-fit Femoral Stem
Standard & Extended Offset
Size 13mm
120% Magnification
Catalog No 161-95-00
Tapered Press-fit Femoral Stem Template Set
0710 CE


Press Fit Splined 13mm
Standard Offset
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42 mm
40 mm
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STANDARD OFFSET
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+3.5mm
+3.5mm
44 mm
47 mm
50 mm
52 mm
55 mm
Extended Offset
131° Neck Angle
140 mm
NOVATION
Comprehensive Hip System
SPLINED
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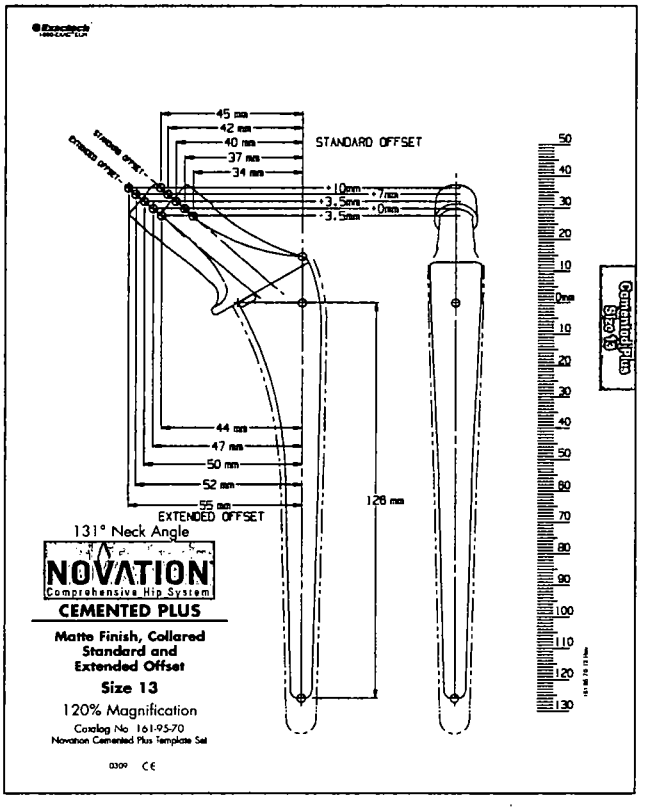
Standard & Extended Offset
Size 13mm
120% Magnification
Catalog No. 161-95-20
Splined Press Fit Femoral Stem Template Set
1204 CE


Centralign Plus Stem
45 mm
42 mm
40 mm
37 mm
34 mm
STANDARD OFFSET
EXTENDED OFFSET
+10mm
+3.5mm
+3.5mm
+7mm
+0mm
44 mm
47 mm
50 mm
52 mm
55 mm
EXTENDED OFFSET
131° Neck Angle
126 mm
NOVATION
Comprehensive Hip System
CEMENTED PLUS
Matte Finish, Collared
Standard and
Extended Offset
Size 13
120% Magnification
Catalog No 161-95-70
Novation Cemented Plus Template Set
0309 CE

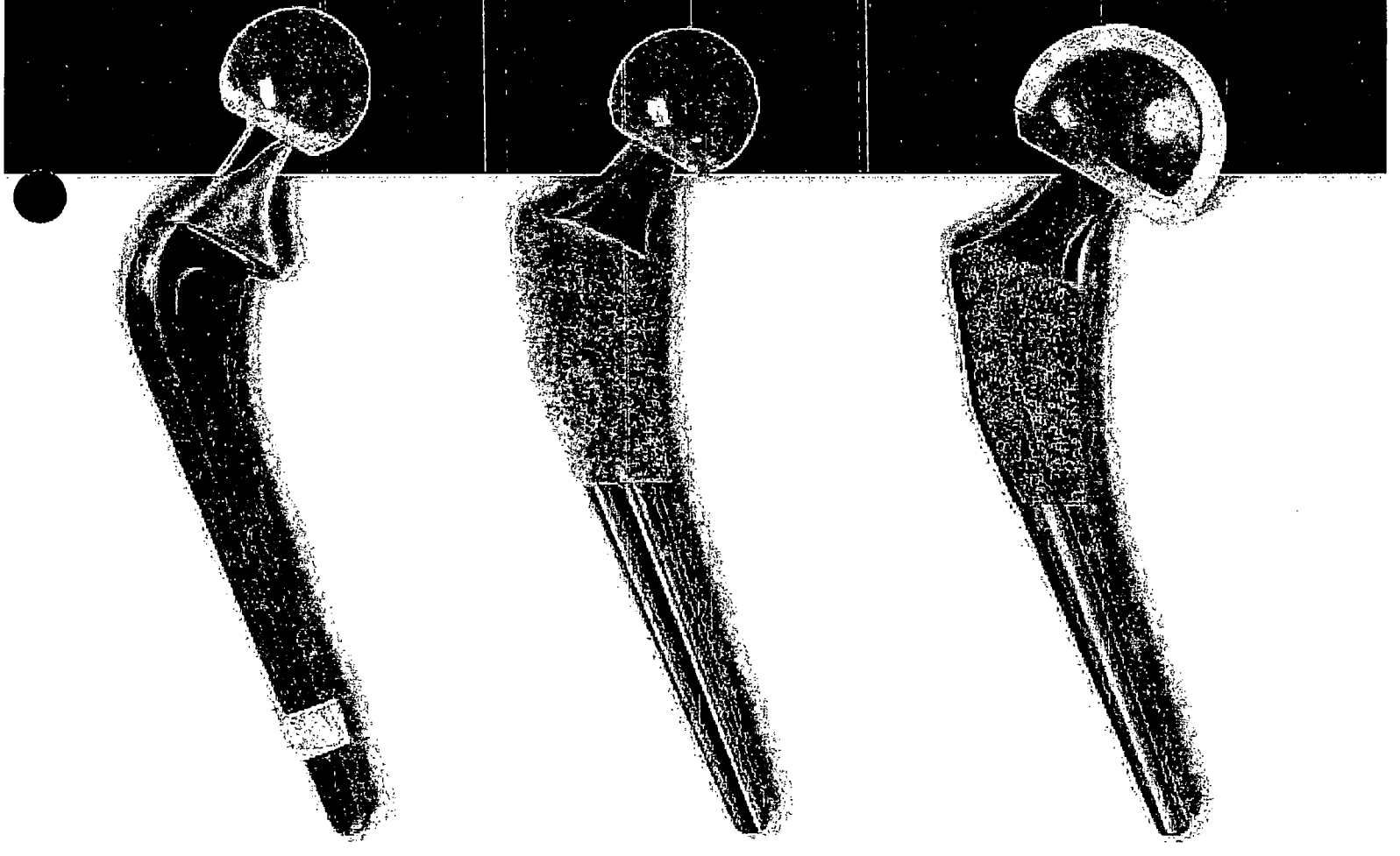
stryker

Orthopaedics

Accolade® System Brochure

Achieving Perfect Balance

Cemented and Cementless
Femoral Hip System



Accolade®
Cemented Hip System

Potential for Perfect Balance

The Accolade® C Femoral Component:

A perfect balance of successful design and innovative technology

The Accolade® C Femoral Component integrates well established, clinically successful design features with the highest standards of technology to help achieve a new benchmark for surgical efficiency and clinical performance.

Material

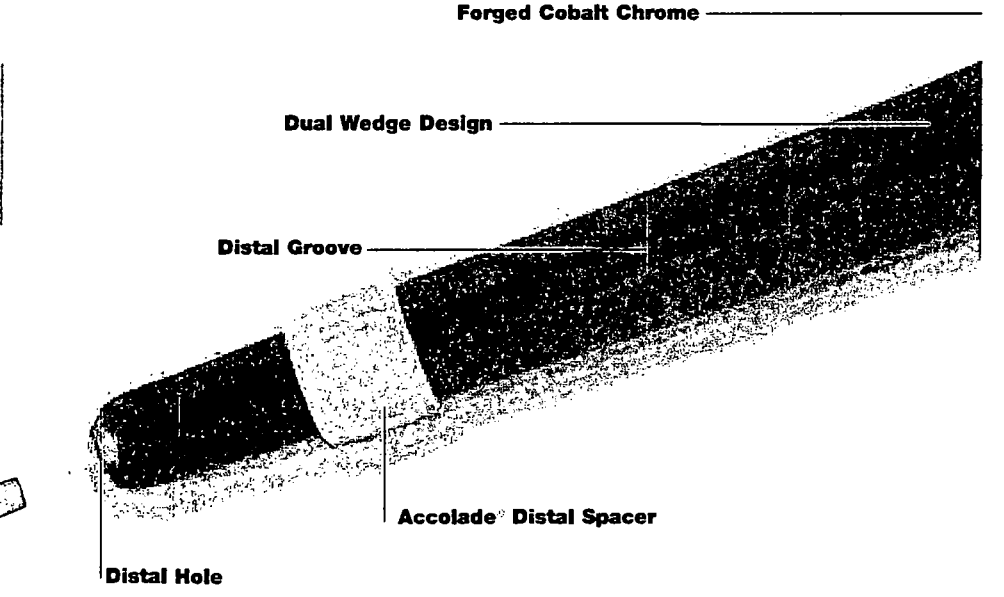
- **Forged Cobalt-Chrome Alloy** – enjoys a long and proud track record of clinical success in cemented total hip arthroplasty. The Accolade® C Femoral Component employs a stringent forged cobalt chrome specification to provide increased material strength and to allow for a significantly reduced neck geometry.

Design

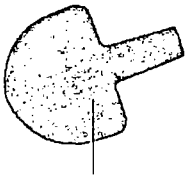
- **Dual Wedge Design** – designed to reduce shear loads at the stem-cement interface and increase rotational stability of the stem in the cement.
- **Proximal Macro-Normalization** – designed to convert shear forces into compressive forces in the area of highest intended load transfer.
- **Distal Groove** – further enhances rotational stability.
- **Centralizer Options** – designed to accommodate either a Universal Distal Spacer or ring centralizer to match surgeon preference.
- **Soft Tissue Balance** – an offering of standard (132°) and extended (127°) offset options enhance soft tissue tensioning without significantly affecting leg length when adjusting joint stability.
- **Proportional Neck Lengths** – relative to body geometry, neck lengths grow proportionally in size to accommodate a wide patient population using a standard femoral head.
- **Reduced Neck Geometry** – features a narrow, ovoid neck design to optimize available range of motion while maintaining strength.

Compatibility

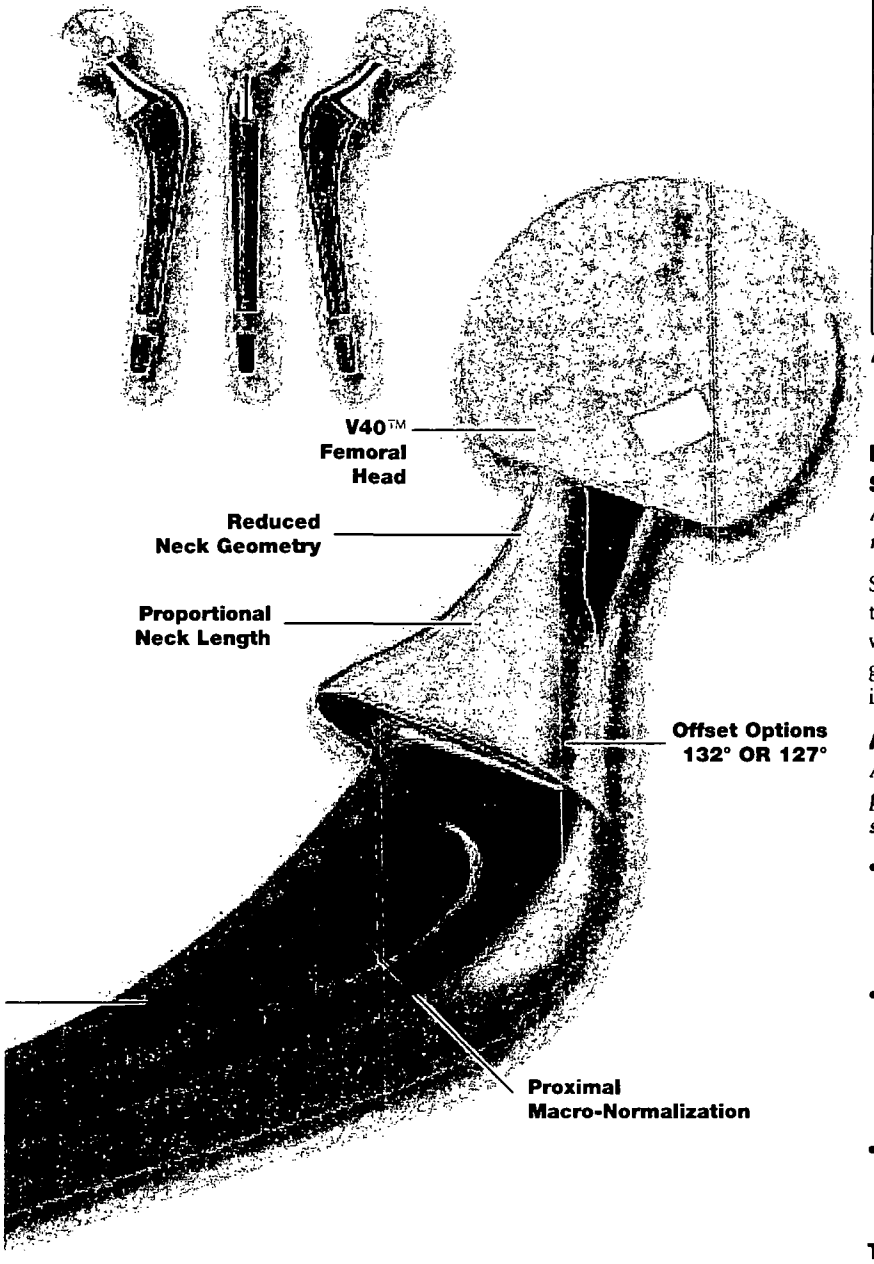
- **Large Selection of Femoral Heads** – the V40™ Femoral Heads offer a large range of offsets and are available in forged Vitallium® alloy, alumina and delta ceramic.
- **Bearing Surface Options** – the Trident® Acetabular System offers a selection of shell geometries compatible with standard polyethylene, Crossfire® or X3™ highly crosslinked polyethylene and ceramic inserts to accommodate the demands of a broader patient population.

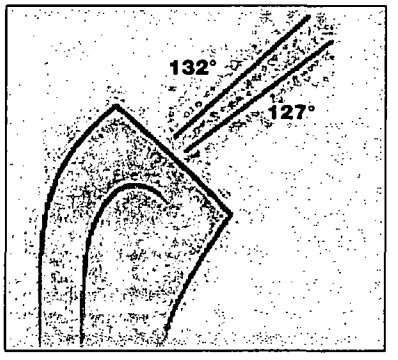


Universal Distal Plug (Optional for use with the Accolade® Distal Spacer)



Universal Distal Spacer (Alternate for Accolade® Distal Spacer)





Available in Two Offsets

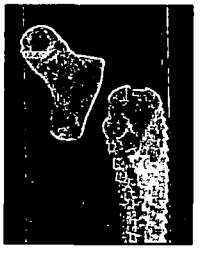
Range of Motion and Ligament Stability

A perfect balance of improved range of motion and enhanced patient quality of life

Standard and extended offset options help the surgeon to enhance soft tissue tensioning without significantly affecting leg length. The goal is to enhance patient quality of life by improving joint stability and range of motion.

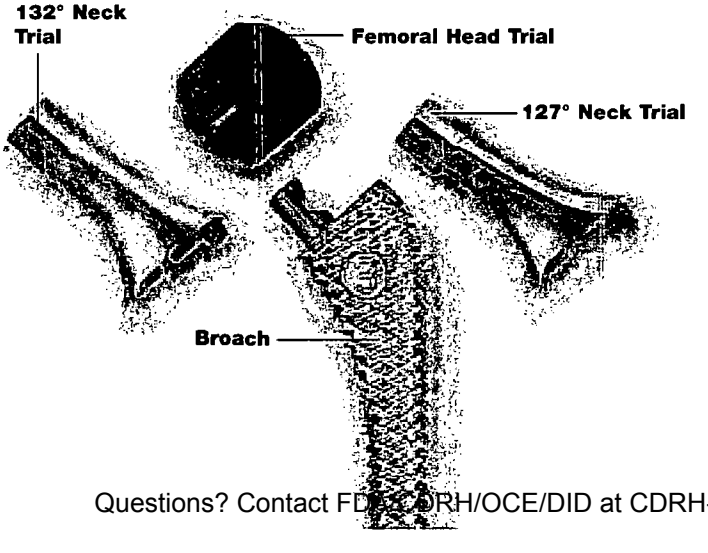
Accolade® Instrument System

A perfect balance of simplicity and precision - the perfect complement to a surgeon's skills



- **Consolidated 2 Tray System** – maximizes Operating Room efficiency.
- **Ergonomically Designed** – to accommodate a broad range of surgeon techniques and requirements.
- **Easier Use** – color coded indicators on neck trials and broach bodies provide a more intuitive use of the instrument system.

Dual Angle Neck Trials Provide Intraoperative Flexibility



The Accolade® C Femoral Component and Simplex™ P Bone Cement:

A perfect balance of technology and reliability

Simplex™ P Bone Cement is the most widely tested and documented cement, with over 40 years of successful clinical performance. Trusted by tens of thousands of surgeons, it is one of the most reliable and predictable bone cements on the market. Together, Simplex™ P Bone Cement and the Accolade® C Femoral Component provide the perfect balance of technology and reliability. Simplex™ P Bone Cement with Tobramycin is also available for revision cases.*

*See Simplex™ P Bone w/ Tobra package insert for prescribing information.

Accolade®
Cementless Hip System

Achieving Perfect Balance

The Accolade® TMZF® Femoral Component

A perfect balance of successful design and innovative technology

The Accolade® TMZF® Femoral Component merges clinically successful concepts with the highest standards of science and technology into a single system.

Material

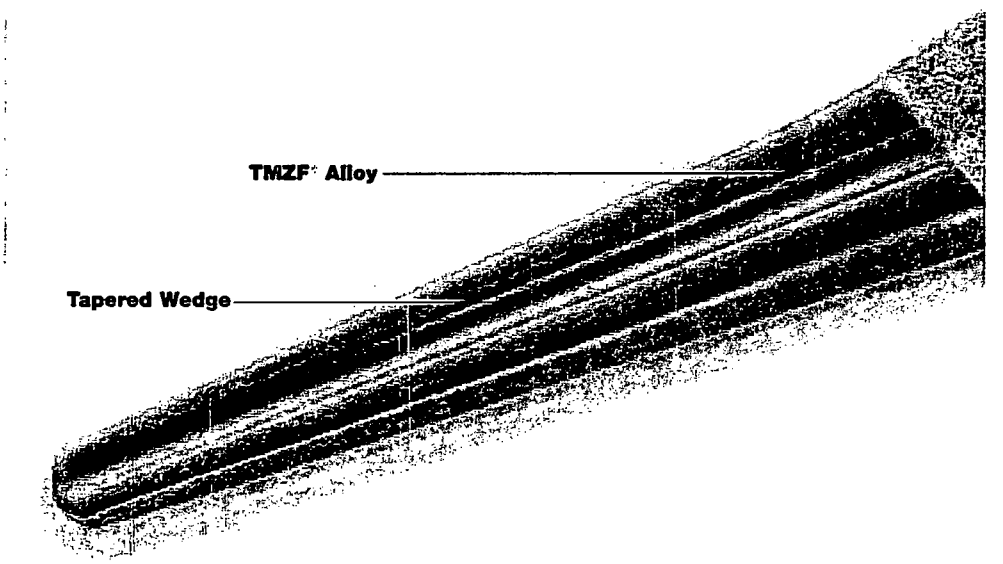
- TMZF® – this proprietary beta titanium alloy offers an impressive 25% greater flexibility than Ti-6Al-4V, yielding a modulus that more closely approximates that of bone. In addition, this alloy maintains a 20% higher tensile strength than Ti-6Al-4V.[1]
- PureFix™ HA Coating – Stryker's clinically successful, 50µm (nominal thickness) PureFix™ HA coating demonstrates unprecedented clinical results in a multicenter study followed for more than 13 years.[2]
- Circumferential Plasma Spray – a circumferential titanium plasma spray surface over the proximal body assists with mechanical engagement in bone, and provides an optimum interface for application of PureFix™ HA coating.

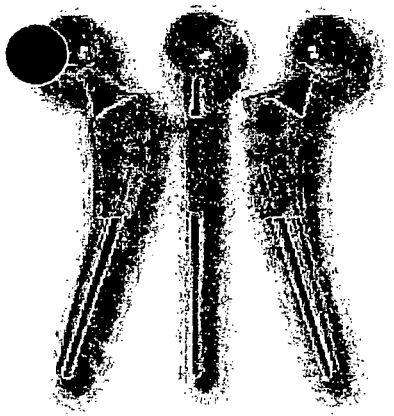
Design

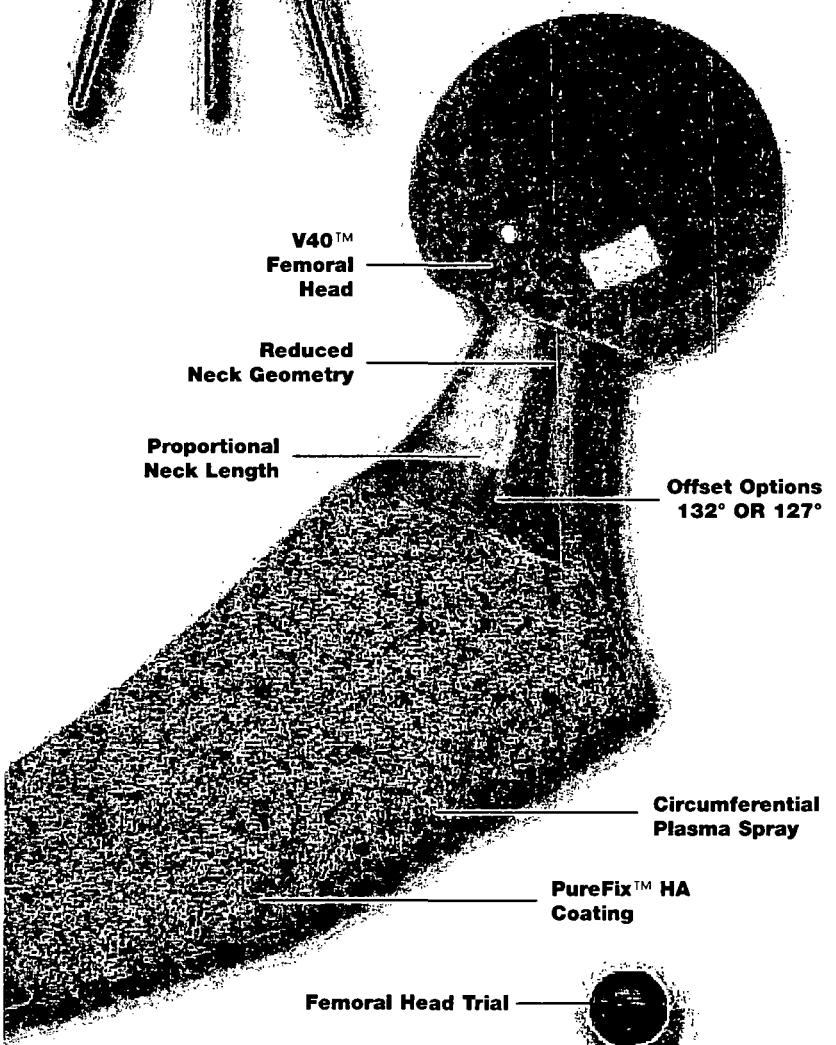
- Tapered Design – the tapered wedge design of the Accolade® TMZF® Femoral Component helps provide firm mediolateral stability within the femoral canal. This design philosophy is supported by extensive long-term clinical experience.[3,4] This low profile, bone sparing design easily accommodates either a standard[1] or small incision approach.[5]
- Soft Tissue Balance – an offering of standard (132°) and extended (127°) offset options enhance soft tissue tensioning without significantly affecting leg length when adjusting joint stability.
- Wide Range of Sizes – The Accolade® TMZF® offers a wide range of sizes to accommodate patient anatomy. Thirteen sizes in each of two offsets for a total of twenty six sizes.
- Proportional Neck Lengths – relative to body geometry, neck lengths grow proportionally in size to accommodate a wide patient population using a standard femoral head.
- Reduced Neck Geometry – the TMZF® alloy provides the opportunity to reduce the neck geometry thus optimizing the available range of motion while maintaining strength.[6]

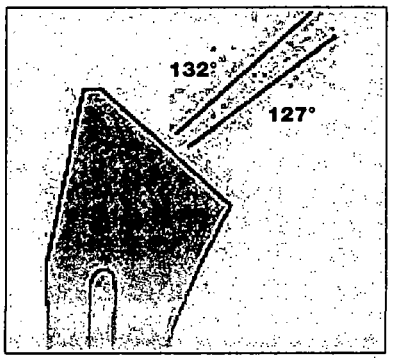
Compatibility

- Large Selection of Femoral Heads – the V40™ Femoral Heads offer a large range of offsets and are available in forged Vitallium® alloy, alumina and delta ceramic.
- Bearing Surface Options – the Trident® Acetabular System offers a selection of shell geometries compatible with standard polyethylene, Crossfire® or X3™ highly crosslinked polyethylene and ceramic inserts to accommodate the demands of a broader patient population.









Available in Two Offsets

Range of Motion and Ligament Stability

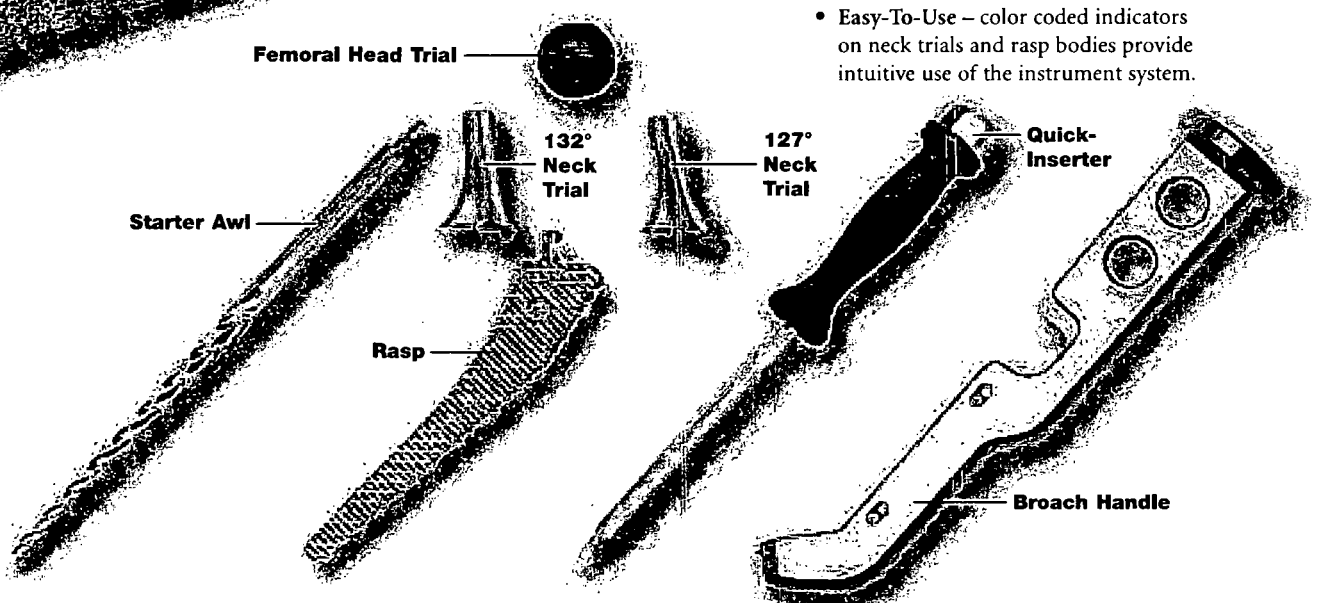
A perfect balance of improved range of motion and enhanced patient quality of life

Standard and extended offset options help allow the surgeon to enhance soft tissue tensioning without significantly affecting leg length. The goal is to help enhance patient quality of life by improving joint stability and range of motion.

Accolade® Instrument System

A perfect balance of simplicity and precision - the perfect complement to a surgeon's skills

- Consolidated 2 Tray System – maximizes Operating Room efficiency.
- Rasp Only Procedure – eliminating endosteal reaming preserves bone while reducing intraoperative steps.
- Ergonomically Designed – to accommodate a broad range of surgeon techniques.
- Easy-To-Use – color coded indicators on neck trials and rasp bodies provide intuitive use of the instrument system.



Accolade®
Cementless Hip System

Achieving Perfect Balance

The Accolade® HFx™ Femoral Component

A perfect balance of successful concepts and design for fracture indications

The Accolade® HFx™ Femoral Component merges clinically successful concepts and designs into a cementless system for fracture indications.

Material

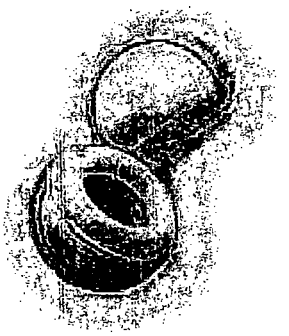
- **Forged Cobalt Chrome Alloy –** The Accolade® HFx™ Femoral Component employs a stringent forged cobalt chrome specification to provide increased material strength.
- **Circumferential Plasma Spray –** a circumferential titanium plasma spray surface over the proximal body assists with mechanical engagement in bone.

Design

- **Tapered Design –** the tapered wedge design of the Accolade® HFx™ Femoral Component provides firm mediolateral stability within the femoral canal. This design philosophy is supported by extensive long-term clinical experience.[3,4]
- **Proportional Neck Lengths –** relative to body geometry, neck lengths grow proportionally in size to accommodate a wide patient population using a standard femoral head.

Compatibility

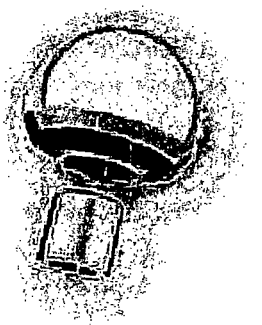
- **Large Selection of Femoral Heads –** The Accolade® HFx™ designed specifically with the fracture patient in mind incorporates a V40™ taper.



UHR® Universal Head Bipolar System

The Stryker® UHR® Universal Head is a leader among bipolar component designs. The UHR® BiPolar has established effectiveness with over 20 years of positive clinical use.[5-12]

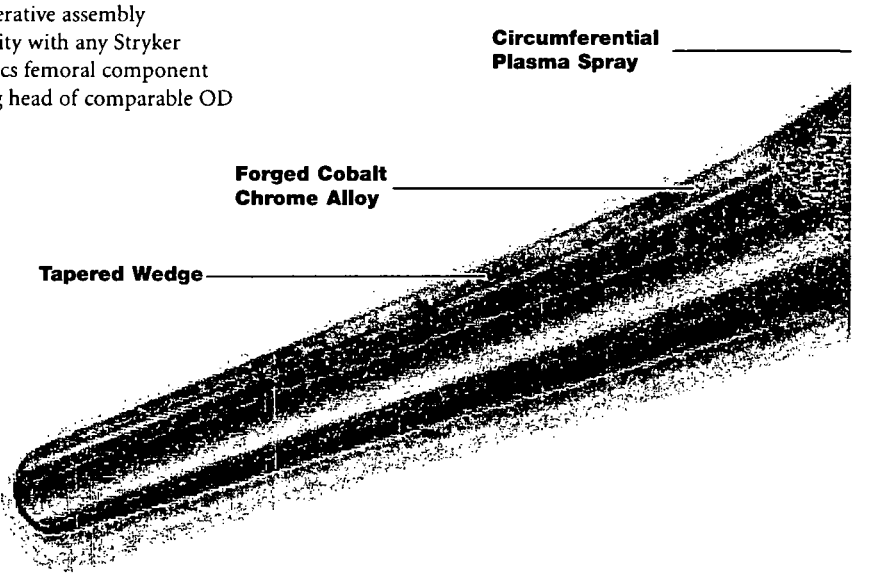
- Dynamic Valgus Alignment
- Large array of OD sizes (41-72mm) allow for precise patient matching
- One-Piece Locking Mechanism
- Beveled Lip
- No interoperative assembly
- Compatibility with any Stryker Orthopaedics femoral component and bearing head of comparable OD

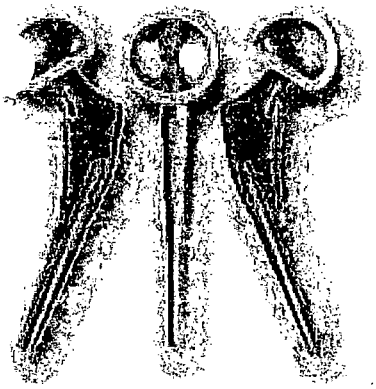


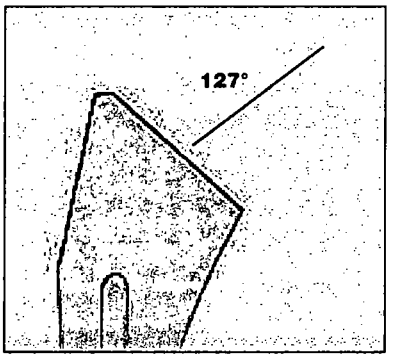
Unitrax® UniPolar System

The Stryker® Unitrax® UniPolar System provides the surgeon with numerous options for endoprosthesis surgery. No other modular endoprosthesis system has such a wide range of neck length and head size options.

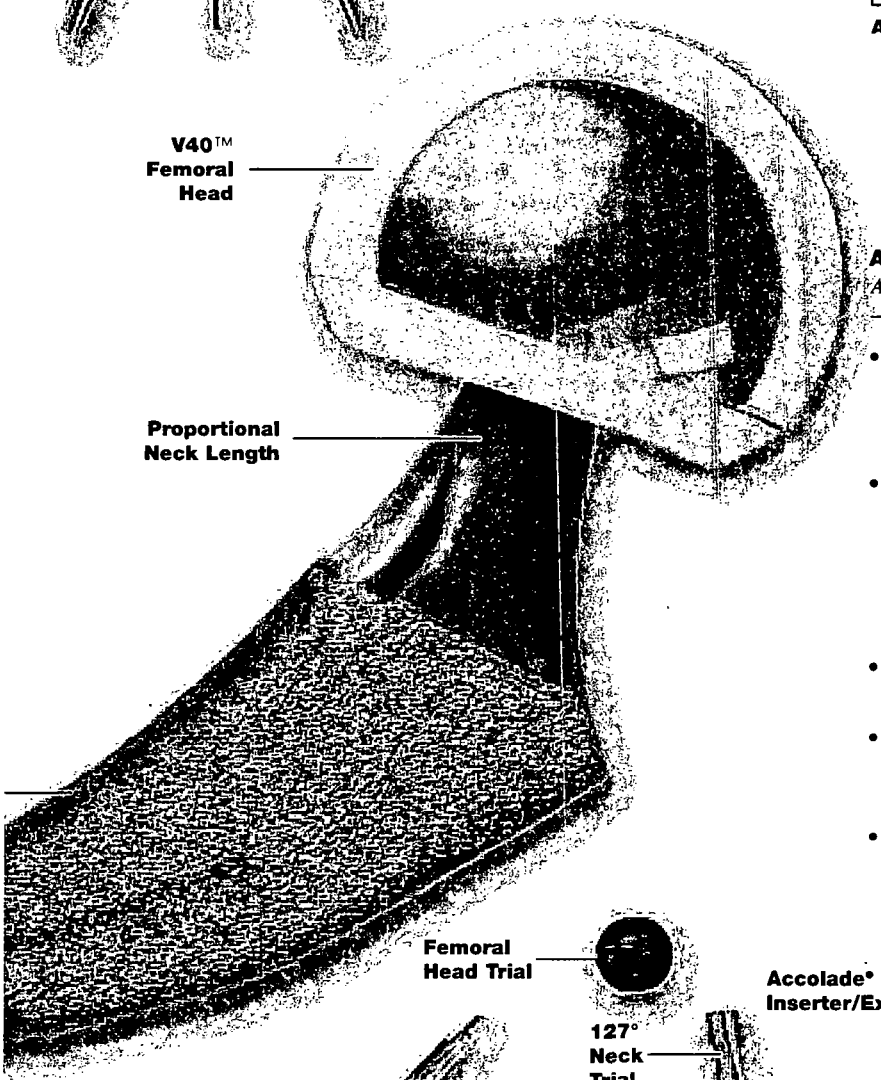
- Provides a large range of sizing and neck length options (38-61mm)
- Independent sizing of acetabulum and femur
- Modular sleeve for interoperative flexibility and head revision without stem removal







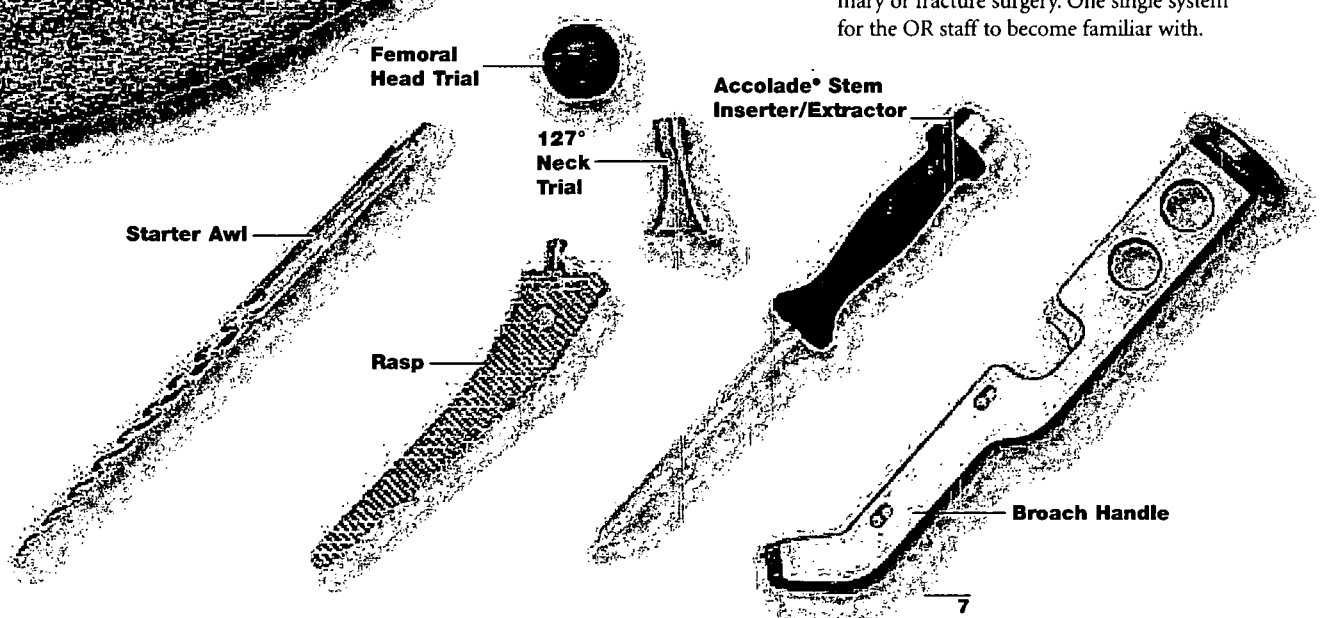
Available in Only One Offset



Accolade® Instrument System

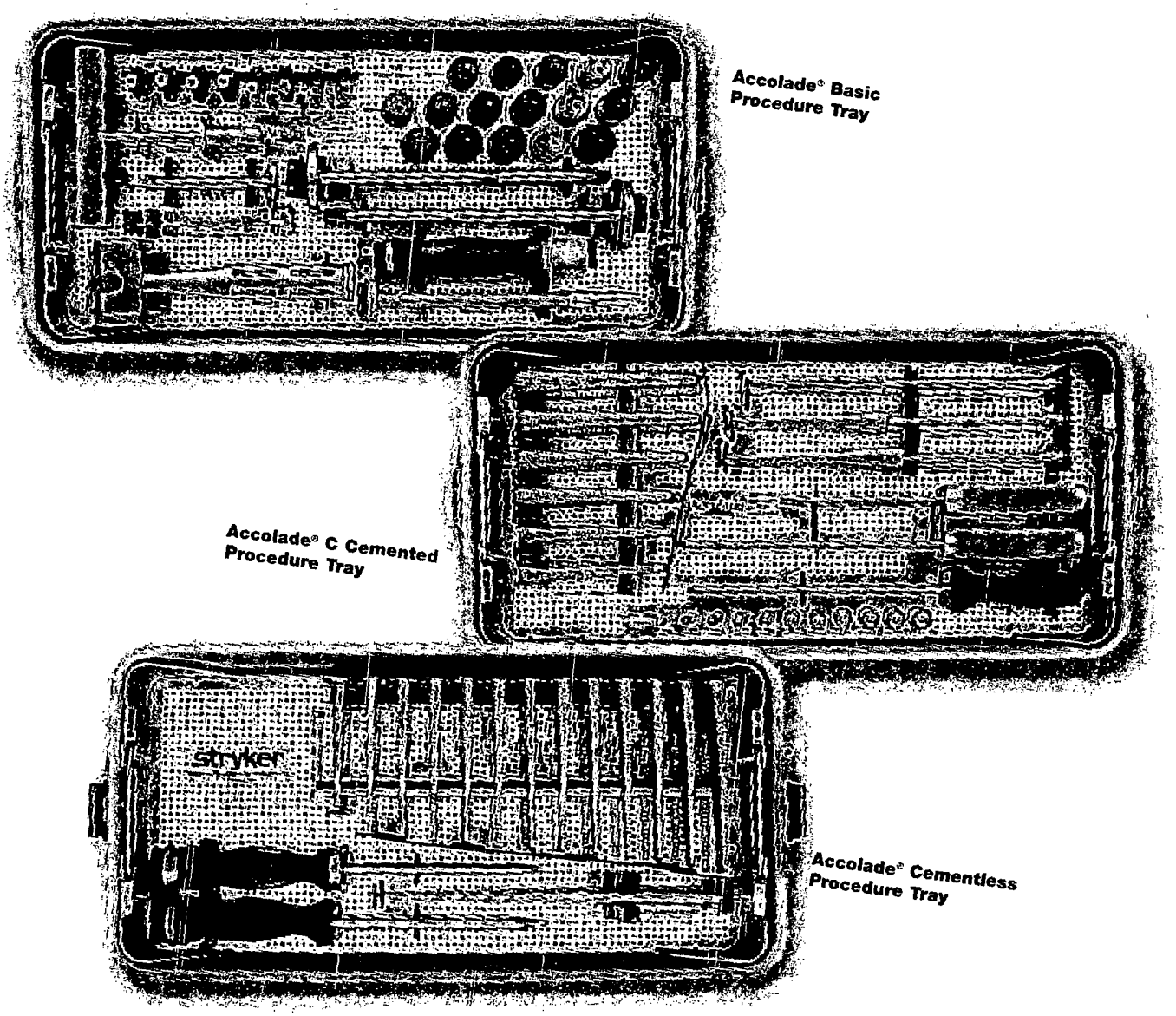
A perfect balance of simplicity and precision – the perfect complement to a surgeon's skill

- **Consolidated 2 Tray System** – maximizes Operating Room efficiency.
- **Rasp Only Procedure** – eliminating endosteal reaming preserves bone while reducing intraoperative steps.
- **Ergonomically Designed** – to accommodate a broad range of surgeon techniques.
- **Easy-To-Use** – color coded indicators on neck trials and rasp bodies provide intuitive use of the instrument system.
- **System Consistency** – one set of instruments to perform either a cementless primary or fracture surgery. One single system for the OR staff to become familiar with.



Accolade® System
Femoral Hip System

Achieving Perfect Balance



Accolade® C Femoral Stems

Accolade® C Cemented Femoral Stem (127° Neck Angle)				
Catalog Number	**Stem Size**	**Stem Length (from Drive Hole)**	**Neck Length**	**Offset (+0mm)**
6057-0230D	2	124mm	30mm	39mm
6057-0335D	3	131mm	35mm	43mm
6057-0435D	4	137mm	35mm	46mm
6057-0537D	5	145mm	37mm	48mm
6057-0637D	6	158mm	37mm	49mm
6057-0740D	7	158mm	40mm	52mm

Accolade® C Cemented Femoral Stem (132° Neck Angle)				
Catalog Number	**Stem Size**	**Stem Length (from Drive Hole)**	**Neck Length**	**Offset (+0mm)**
6058-0230D	2	124mm	30mm	35mm
6058-0335D	3	131mm	35mm	39mm
6058-0435D	4	137mm	35mm	42mm
6058-0537D	5	145mm	37mm	44mm
6058-0637D	6	158mm	37mm	45mm
6058-0740D	7	158mm	40mm	48mm

Accolade® C Distal Spacers (Ring Style)

Catalog Number	Spacer Type	Outer Diameter
1059-2310	Small (Use with stem sizes 2 and 3)	10mm
1059-2311	Small (Use with stem sizes 2 and 3)	11mm
1059-2312	Small (Use with stem sizes 2 and 3)	12mm
1059-2313	Small (Use with stem sizes 2 and 3)	13mm
1059-2314	Small (Use with stem sizes 2 and 3)	14mm
1059-2315	Small (Use with stem sizes 2 and 3)	15mm
1059-4512	Medium (Use with stem sizes 4 and 5)	12mm
1059-4513	Medium (Use with stem sizes 4 and 5)	13mm
1059-4514	Medium (Use with stem sizes 4 and 5)	14mm
1059-4515	Medium (Use with stem sizes 4 and 5)	15mm
1059-4516	Medium (Use with stem sizes 4 and 5)	16mm
1059-4517	Medium (Use with stem sizes 4 and 5)	17mm
1059-6713	Large (Use with stem sizes 6 and 7)	13mm
1059-6714	Large (Use with stem sizes 6 and 7)	14mm
1059-6715	Large (Use with stem sizes 6 and 7)	15mm
1059-6716	Large (Use with stem sizes 6 and 7)	16mm
1059-6717	Large (Use with stem sizes 6 and 7)	17mm
1059-6718	Large (Use with stem sizes 6 and 7)	18mm
1067-0002	Universal Distal Hole Plug (Optional for use with ring style spacers)	

Stryker® Universal Distal Cement Spacer			
Catalog Number	**Outer Diameter**	**Catalog Number**	**Outer Diameter**
1067-0008	8mm	1067-0014	14mm
1067-0009	9mm	1067-0015	15mm
1067-0010	10mm	1067-0016	16mm
1067-0011	11mm	1067-0017	17mm
1067-0012	12mm	1067-0018	18mm
1067-0013	13mm		

Simplex™ P Bone Cement	
Catalog Number	
6191-1-001	Full-Dose–Individual Pack
6191-1-010	Full-Dose–10 Pack
6188-1-001	Half-Dose–Individual Pack
6188-1-010	Half-Dose–10 Pack
Simplex™ P with Tobramycin Bone Cement	
6197-9-010	Full-Dose–10 Pack

Accolade® System

Femoral Hip System

Accolade® TMZF® Femoral Stems

Accolade® TMZF® Cementless Femoral Stem (127° Neck Angle)				
Catalog Number	**Stem Size**	**Stem Length (from Medial Calcar)**	**Neck Length**	**Offset (+0mm)**
6021-0030	0	86mm	30mm	37mm
6021-0130	1	110mm	30mm	38mm
6021-0230	2	115mm	30mm	39mm
6021-2530	2.5	118mm	30mm	40mm
6021-0335	3	120mm	35mm	43mm
6021-3535	3.5	124mm	35mm	43mm
6021-0435	4	125mm	35mm	44mm
6021-4535	4.5	129mm	35mm	45mm
6021-0537	5	130mm	37mm	48mm
6021-5537	5.5	133mm	37mm	49mm
6021-0637	6	135mm	37mm	49mm
6021-0740	7	140mm	40mm	53mm
6021-0840	8	145mm	40mm	54mm

Accolade® TMZF® Cementless Femoral Stem (132° Neck Angle)				
Catalog Number	**Stem Size**	**Stem Length (from Medial Calcar)**	**Neck Length**	**Offset (+0mm)**
6020-0030	0	86mm	30mm	33mm
6020-0130	1	110mm	30mm	34mm
6020-0230	2	115mm	30mm	35mm
6020-2530	2.5	118mm	30mm	36mm
6020-0335	3	120mm	35mm	39mm
6020-3535	3.5	124mm	35mm	39mm
6020-0435	4	125mm	35mm	40mm
6020-4535	4.5	129mm	35mm	41mm
6020-0537	5	130mm	37mm	44mm
6020-5537	5.5	133mm	37mm	45mm
6020-0637	6	135mm	37mm	45mm
6020-0740	7	140mm	40mm	48mm
6020-0840	8	145mm	40mm	49mm

*Available through Loaner Bank only.

Accolade® HFx™ Femoral Stems

Accolade® HFx™ Cementless Femoral Stems (127° Neck Angle)				
Catalog Number	**Stem Size**	**Stem Length (from Medial Calcar)**	**Neck Length**	**Offset (+0mm)**
6077-0130	1	110mm	30mm	38mm
6077-0230	2	115mm	30mm	39mm
6077-0335	3	120mm	35mm	43mm
6077-0435	4	125mm	35mm	44mm
6077-0537	5	130mm	37mm	48mm
6077-0637	6	135mm	37mm	49mm
6077-0740	7	140mm	40mm	53mm
6077-0840	8	145mm	40mm	54mm

Accolade® System Instrumentation

Basic Procedure Tray	
Catalog Number	**Instrument**
1020-1100	Neck Resection Guide
1101-2100	T-Handle
1120-1000	Mallet
1020-1400	Offset Rasp Handle
1020-2730	127 deg, 30mm Neck Trial
1020-2735	127 deg, 35mm Neck Trial
1020-2737	127 deg, 37mm Neck Trial
1020-2740	127 deg, 40mm Neck Trial
1020-3230	132 deg, 30mm Neck Trial
1020-3235	132 deg, 35mm Neck Trial
1020-3237	132 deg, 37mm Neck Trial
1020-3240	132 deg, 40mm Neck Trial
6264-8-026	26mm -3mm V40™ Trial Head
6264-8-126	26mm STND V40™ Trial Head
6264-7-226	26mm +4mm V40™ Trial Head
6264-8-326	26mm +8mm V40™ Trial Head
6264-8-426	26mm +12mm V40™ Trial Head
6264-8-028	28mm -4mm V40™ Trial Head
6264-8-928	28mm -2.7mm V40™ Trial Head
6264-8-128	28mm STND V40™ Trial Head
6264-8-228	28mm +4mm V40™ Trial Head
6264-8-328	28mm +8mm V40™ Trial Head
6264-8-428	28mm +12mm V40™ Trial Head
6264-8-032	32mm -4mm V40™ Trial Head
6264-8-132	32mm STND V40™ Trial Head
6264-8-232	32mm +4mm V40™ Trial Head
6264-8-332	32mm +8mm V40™ Trial Head
6264-8-432	32mm +12mm V40™ Trial Head
1020-2700	Calcar Planar
6266-0-140	Head Impactor
1113-1001 or 6266-5-005	Box Chisel
1020-6000	Basic Procedure Tray
8000-0100	Outer Case

(Optional) Minimally Invasive Instrumentation	
5900-0050	T-Handle
1440-1040	Quick Connect Handle
1440-1050	Alignment Rod
1440-1700	Neck Trial Forceps
1440-1010	Femoral Head Extractor
1440-1400	Straight Accolade Rasp Handle
1440-1000	Neck Resection Guide
1440-1070	Femoral Head Impactor
1440-0040	Tray

Cemented Procedure Tray	
Catalog Number	**Instrument**
1101-0304	Starter Reamer
1020-2200	Trochanteric Reamer - Small
1020-2201	Trochanteric Reamer - Large
1020-2100	Distal Sizer
1020-2104	Propeller Sizer
1212-0005	Trial Distal Tip - 8mm
1212-0009	Trial Distal Tip - 9mm
1212-0010	Trial Distal Tip - 10mm
1212-0011	Trial Distal Tip - 11mm
1212-0012	Trial Distal Tip - 12mm
1212-0013	Trial Distal Tip - 13mm
1212-0014	Trial Distal Tip - 14mm
1212-0015	Trial Distal Tip - 15mm
1212-0016	Trial Distal Tip - 16mm
1212-0017	Trial Distal Tip - 17mm
1212-0018	Trial Distal Tip - 18mm
1020-2002	Size 2 Broach
1020-2003	Size 3 Broach
1020-2004	Size 4 Broach
1020-2005	Size 5 Broach
1020-2006	Size 6 Broach
1020-2007	Size 7 Broach
1020-2500	Stem Inserter
1020-7000	Cemented Procedure Tray

Cementless Procedure Tray	
Catalog Number	**Instrument**
1020-0000L 1020-5100	Size 0 Rasp
1020-1001L 1020-5101	Size 1 Rasp
1020-1002L 1020-5102	Size 2 Rasp
1020-1025L 1020-5125	Size 2.5 Rasp
1020-1003L 1020-5103	Size 3 Rasp
1020-1035L 1020-5135	Size 3.5 Rasp
1020-1004L 1020-5104	Size 4 Rasp
1020-1045L 1020-5145	Size 4.5 Rasp
1020-1005L 1020-5105	Size 5 Rasp
1020-1055L 1020-5155	Size 5.5 Rasp
1020-1006L 1020-5106	Size 6 Rasp
1020-1007L 1020-5107	Size 7 Rasp
1020-1008L 1020-5108	Size 8 Rasp
1020-1200	Axial Starter Reamer
1020-1500	Stem Inserter
1020-1600	Accolade® Stem Inserter/Extractor
1020-8500	Cementless Procedure Tray

*Compatible with Accolade® TMZF® implants sizes 2.5 to 8 only.

NOTE: Broach family 1020-10XX and broach family 1020-51XX are not to be used interchangeably.

[1] Wang K, Gustavson L, Dumbleton J. The Characterization of Ti-12Mo-6Zr-2Fe – a New Biocompatible Titanium Alloy Developed for Surgical Implants. In: Beta Titanium Alloys in the 1990's, Edited by Eylon D, Boyer RR, Koss DA. The Minerals, Metals & Materials Society, 1993.

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[3] McLaughlin JR, Lee KR. Total Hip Arthroplasty in Young Patients: 8-13 Year Results Using an Uncemented Stem. CORR. 373 153-163, 2000.

[2] Sakalkale D, Rothman R, et al. Minimum 10-Year Results of a Tapered Cementless Hip Replacement. CORR. 362: 138-144, 1999.

[5] Green S, Moore T, Proanao F. Bipolar Prosthetic Replacement for the Management of Unstable Intertrochanteric Hip Fractures in the Elderly. Clinical Orthopaedics and Related Research. November 1957;224:169-177.

[6] Bowman AJ Jr, Walker MW, Kilfoyle RM, O'Brien PI, McConville JF. Experience with the Bipolar Prosthesis in Hip Arthroplasty: A Clinical Study. Orthopedics. April 1985;8(4):460-467.

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A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate the breadth of Stryker product offerings. A surgeon must always refer to the package insert, product label and/or instructions for use before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

Literature Number: **LASB Rev. 3**
MS/GS 00/10

Printed in USA

(b)(4) Schematic Diagrams

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PIPELINE BIOMEDICAL

Pipeline Biomedical Products
3 Wing Drive, suite 102 - Cedar Knolls, NJ - 07927

Tapered Hip Stem
Standard Neck, 12/14 Taper

QTY 1

Size: XX

Use by:
YYYY-MM

REF

LOT XXXXXXXXXX

STERILE R Sterilized using irradiation.

Consult instructions for use.

Caution

Keep Dry

Single use only

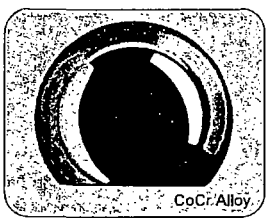
Do not use if package is damaged.

℞ ONLY

Trademarks registered in the United States. Trademark Registration pending in other jurisdictions.

PIPELINE BIOMEDICAL

Pipeline Biomedical Products
3 Wing Drive, suite 102 - Cedar Knolls, NJ - 07927



Femoral Head

12/14 Taper

Size: ØXXmm XXXXXmm

QTY 1

Use by:
YYYY-MM

REF XXXXXX-XX

LOT XXXXXXXXXX

Single use only | Consult instructions for use. | Caution | Keep Dry

STERILE R Sterilized using irradiation. | Do not use if package is damaged. | Rx ONLY

PIPELINE BIOMEDICAL

Pipeline Biomedical Products
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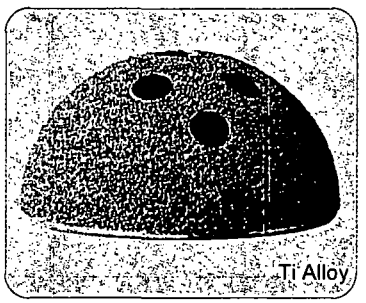


PST™ Acetabular Shell

QTY 1

Cluster Hole

Size: øXXmm

Use by: YYYY-MM

REF XXXXXX-XX

LOT XXXXXXXXXX

Single use only

Consult instructions for use.

Caution

Keep Dry

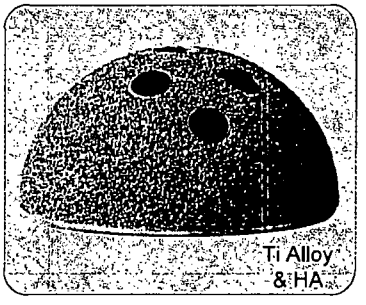
STERILE R Sterilized using irradiation.

Do not use if package is damaged.

℞ ONLY

PIPELINE BIOMEDICAL

Pipeline Biomedical Products
3 Wing Drive, suite 102 - Cedar Knolls, NJ - 07927



PST™ Acetabular Shell with Hydroxyapatite

Cluster Hole

Size: øXXmm

QTY 1

Use by: YYYY-MM

REF XXXXXX-XX

LOT XXXXXXXXXX

Single use only

Consult instructions for use.

Caution

Keep Dry

STERILE R Sterilized using irradiation.

Do not use if package is damaged.

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PIPELINE BIOMEDICAL

Pipeline Biomedical Products
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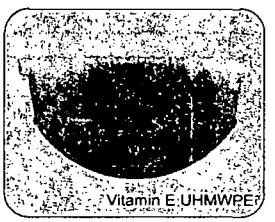

XLVE™ Acetabular Liner

QTY 1

Neutral

Size: ØXXmm ID: ØXXmm

Use by: YYYY-MM

REF XXXXXX-XX

LOT XXXXXXXXXX

Single use only | Consult instructions for use. | Caution | Keep Dry

STERILE EO Terminally sterilized, ethylene oxide.

Do not use if package is damaged.

℞ ONLY

PIPELINE BIOMEDICAL

Pipeline Biomedical Products
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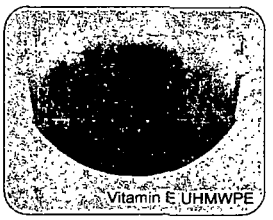


XLVE™ Acetabular Liner

QTY 1

+4 Offset

Size: ØXXmm ID: ØXXmm

Use by: YYYY-MM

REF XXXXXX-XX

LOT XXXXXXXXXX

Single use only | Consult instructions for use. | Caution | Keep Dry

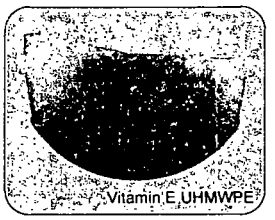
STERILE EO Terminally sterilized, ethylene oxide.

Do not use if package is damaged.

℞ ONLY

PIPELINE BIOMEDICAL

Pipeline Biomedical Products
3 Wing Drive, suite 102 - Cedar Knolls, NJ - 07927



XLVE™ Acetabular Liner

QTY 1

High Wall

Size: ØXXmm ID: ØXXmm

Use by: YYYY-MM

REF XXXXXX-XX

LOT XXXXXXXXXX

Single use only | Consult instructions for use. | Caution | Keep Dry

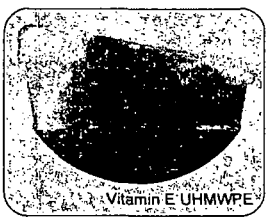
STERILE EO Terminally sterilized, ethylene oxide.

Do not use if package is damaged.

℞ ONLY

PIPELINE BIOMEDICAL

Pipeline Biomedical Products
3 Wing Drive, suite 102 - Cedar Knolls, NJ - 07927



XLVE™ Acetabular Liner

QTY 1

+4 Elevated

Size: ØXXmm ID: ØXXmm

Use by:
YYYY-MM

REF **XXXXXX-XX**

LOT **XXXXXXXXXX**

Single use only | Consult instructions for use. | Caution | Keep Dry

STERILE EO Terminally sterilized, ethylene oxide.

Do not use if package is damaged.

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Pipeline Biomedical Products
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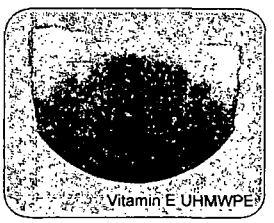


XLVE™ Acetabular Liner

QTY 1

+4 High Wall

Size: ØXXmm ID: ØXXmm

Use by: YYYY-MM

REF XXXXXX-XX

LOT XXXXXXXXXX

Single use only | Consult instructions for use. | Caution | Keep Dry

STERILE EO Terminally sterilized, ethylene oxide.

Do not use if package is damaged.

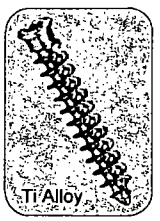
℞ ONLY

PIPELINE BIOMEDICAL

Ø6.5mm Bone Screw
XXmm L

PIPELINE BIOMEDICAL

Pipeline Biomedical Products
3 Wing Drive, suite 102 - Cedar Knolls, NJ - 07927



ø6.5mm Bone Screw
Size: XXmm L

REF XXXXXX-XX

LOT XXXXXXXXXX

(01)0084848600XXXX(17)YYMMDD(10)XXXXXXXXXX

Use by:
YYYY-MM

Manufactured in the U.S.A.

QTY 1

Single use only

Consult instructions for use.

Caution

Keep Dry

STERILE R Sterilized using irradiation.

Do not use if package is damaged.

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Trademarks registered in the United States.
Trademark Registration pending in other jurisdictions.

PIPELINE
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TOTAL HIP SYSTEM - INSTRUCTIONS FOR USE

DEVICE DESCRIPTION – TOTAL HIP PROSTHESIS:
Pipeline Biomedical Products Total Hip System is comprised of an individually packaged metal femoral hip stem, modular metal femoral head, porous metal acetabular shell, with or without hydroxyapatite, vitamin E polyethylene acetabular bearing liner, acetabular shell dome hole occluder and metal screws designed to replace the natural articular surface of the hip joint. All components are available in a range of sizes to fit varying anatomical requirements and are designed for single use only.

MATERIALS:

Femoral Stem:	Titanium Alloy and CP Titanium Plasma Spray Coating
Femoral Heads:	CoCr Alloy
Acetabular Shells:	Titanium Alloy with or without Hydroxyapatite
Acetabular Occluders:	Titanium Alloy
Acetabular Liners:	Highly Cross-linked Vitamin E UHMWPE (GUR 1020 E)
Acetabular Screws:	Titanium Alloy

The Tapered Hip Stem is manufactured from titanium alloy. The proximal portion of the stem is plasma sprayed with commercially pure titanium for increased surface roughness to support scratch fit and initial stability. Metal bearing heads are fabricated from wrought CoCr.

The PST™ Acetabular Shell, acetabular dome hole occluders, and acetabular bone screws are manufactured from titanium alloy. The porous structured outer shell is configured for increased surface roughness and porosity to support stability. RESTORIS® XLVE™ acetabular liners are machined from vitamin E blended UHMWPE (GUR 1020 E) that is highly-crosslinked.

CAUTION:
Federal Law (USA) restricts this device to sale by or on the order of a physician.

PACKAGING:
Tapered Hip Stems, PST™ Acetabular Shells, acetabular dome hole occluders, femoral head components, acetabular liners, and acetabular bone screws are individually packaged and supplied STERILE. Femoral stems, acetabular shells, femoral head components, and acetabular liners are supplied in a double nested blister-tray manufactured from PET-G material. Each tray contains a Tyvek® lid. Acetabular bone screws and acetabular dome hole occluders are packaged in double Tyvek® pouches. After appropriate implant size is determined, remove from the package using aseptic technique. If the seal or package is breached, then the component should not be used.

INDICATIONS FOR USE:
Pipeline's Total Hip System is indicated for use in skeletally mature individuals undergoing surgery for total hip replacement due to:

- A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis, or congenital hip dysplasia.
- Acute traumatic fracture of the femoral head or neck.
- Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty or total hip replacement.

The Tapered Hip Stem and PST™ Acetabular Shell are intended for cementless or cemented fixation. The porous structured surface provides biological fixation when used in a cementless application.

The PBP Total Hip System HA porous structured acetabular shells are intended for cementless fixation. The HA porous structured surface provides biological fixation.

CONTRAINDICATIONS:
The following conditions are contraindications for total hip replacement:

- Active local or systemic infection.
- Neuromuscular disorders, muscular atrophy or vascular deficiency in the affected limb rendering the procedure unjustified.
- Patients with mental or neurological conditions which may be incapable of following instructions.
- Patients with insufficient quality or quantity of bone to allow appropriate insertion and fixation of the prosthesis.
- Blood supply limitations.
- Skeletal Immaturity.
- Physical conditions which tend to place extreme loads on implants, i.e. Charcot's or Paget's disease.

WARNINGS & PRECAUTIONS:
Familiarity with and attention to appropriate surgical technique for total hip replacement and Pipeline's Total Hip System is essential for success of the procedure.

Care should be utilized in the handling of the components to minimize contamination of the component surfaces. Do not allow porous surfaces to come in contact with cloth or any fiber-releasing material. In using cement for fixation, the surgeon should use care to ensure complete cement support on all parts of the prosthesis embedded in bone cement.

Only surgeons who have reviewed the literature regarding total hip replacement surgery and have had training in the technique should utilize the device. The surgeon or his designee should instruct patients as to the limitations of the prosthesis, and these patients should be taught to govern their activities accordingly.

Always use Pipeline's Total Hip instrumentation and trial prosthesis for trial purposes. Trials are not intended for permanent implantation. Implants must not be reused. The surgeon must use care and not allow damage to polished bearing surfaces because this may accelerate wear of the components. Any alteration or damage to a component may result in failure under load. Any prostheses so damaged must not be used. Implants and trial components from different manufacturers or implant systems should never be used together since articular and dimensional compatibility cannot be assured.

Femoral and acetabular components must be appropriately sized for their corresponding bone.

EXCESSIVE WEIGHT WARNING: Obese or excessive patient weight tends to impose severe loading of the hip, placing the patient at higher risk for implant failure.

The Total Hip System has not been evaluated for safety and compatibility in the MR environment. The Total Hip System has not been tested for heating or migration in the MR environment.

PRE-OPERATIVE:
Selection of Pipeline's Total Hip System depends on the judgment of the surgeon with regard to the requirements of the patient. The surgeon should become thoroughly familiar with the technique of implantation of the prostheses by: 1) appropriate reading of the literature, and 2) training in the operative skills and techniques required for total hip arthroplasty.

Refer to the Tapered Hip Stem and PST™ Acetabular Cup Planning and Surgical Technique Guide for a description and additional warnings regarding planning and the surgical technique for Pipeline's Total Hip System.

INTRA-OPERATIVE:
Correct selection of the implant is extremely important. It is recommended components at least one size smaller and one size larger than were preoperatively planned be available at surgery to accommodate changes in operative plans. All protective covers should remain on implants until just prior to use, and care taken not to scratch, bend or cut implant components during surgery. Do not allow any porous materials to come in contact with cloth or other fiber releasing material. Modular heads and femoral components should be from the same manufacturer to prevent mismatch of tapers. Prior to closure, ensure surgical site is thoroughly cleaned and free of surgical debris, cement, bone chips, and ectopic bone.

POST-OPERATIVE:
Strict adherence to surgeon directed postoperative care is extremely important. Surgeon-prescribed gradual weight bearing, as standard with total hip arthroplasty, should be provided through written instructions, including warnings and limitations to the patient prior to discharge. Postoperative therapy to regain muscle strength, as well as continued patient follow up, including periodic radiographs, are recommended. If radiographic changes are observed, such as changes in position, radiolucencies, bone resorption, loosening, cracking or bending, patients should be closely monitored.

Removal of Pipeline's Total Hip System Components: After removal of implanted components from Pipeline's Total Hip System, care should be given during handling, examination and storage of the components to ensure that they are not damaged or altered. Pipeline Total Hip System components that are removed should be cleaned and sterilized before returned to Pipeline Biomedical Products. Steam autoclave the metal components of the Total Hip System. Use ethylene oxide to sterilize or glutaraldehyde to disinfect XLVE™ polyethelyne components. For returning removed Total Hip System components to Pipeline Biomedical Products, package the components in a manner which minimizes the potential for breakage, surface damage and possible contamination of the environment or exposure of those handling the package during transit.

ADVERSE EFFECTS:
As with any hip system, potential adverse effects include early or late infection, loosening of the components, wear of the components, breakage or bending of the components, or change in position of the components. There have been reports of sensitivity reactions to the components of hip replacement systems. Other potential adverse effects of hip surgery include tissue reactions, osteolysis, neurovascular damage, dislocation, thromboembolic disease, and other less common adverse effects.

STERILIZATION:
All components are supplied STERILE. A minimum of 25 kGy of gamma radiation is utilized for all femoral stems, acetabular cup shells, acetabular dome hole occluders, femoral head components and acetabular bone screws. XLVE™ highly cross-linked vitamin E UHMWPE components are subjected to ethylene oxide (EtO) sterilization. Do not use any component if the package has been breached, or if the expiration date has been exceeded. Once opened, the component must be used or discarded. Do not re-sterilize components.

Packaging Labels Legend:


Manufactured by

℞ Prescription only

STERILE Sterile, terminally sterilized device


Do not use if package is damaged


Do not reuse / Single use only

REF Catalog / Reorder number

LOT Manufacturer's lot number


Use by date

PST™ and XLVE™ are trademarks of Pipeline Biomedical.

PIPELINE
BIOMEDICAL

3 Wing Drive, Suite 102| Cedar Knolls, NJ 07927 | 973-267-8800

Introduction

Pipeline Orthopedics manual surgical instruments and instrument cases are generally composed of aluminum, stainless steel, and polymeric materials. The cases are both single and double layered with various internal brackets and trays designed to hold surgical instrumentation in place during handling, sterilization and storage. The instrument cases are perforated to allow steam to penetrate, which, when placed in a steam autoclave allows sterilization of the contents.

Purpose

This manual is recommended for the care, cleaning, maintenance and sterilization of reusable Pipeline Orthopedics manual surgical instruments. All Pipeline Orthopedics reusable instruments must be cleaned and sterilized to prepare them for use. This document is intended to assist health care personnel in safe handling practices, effective reprocessing and maintenance of Pipeline Orthopedics reusable devices.

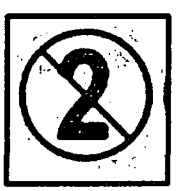
Hospital personnel, including those in receiving and central sterile supply departments, as well as in the operating room, may be directly involved in handling instruments purchased or consigned from Pipeline Orthopedics. Hospital directors and other management in each of these departments should be informed of these instructions and recommendations to ensure safe and effective reprocessing and to prevent damage or misuse of reusable devices.

Scope

This instruction manual provides information on the care, cleaning, maintenance and sterilization of manual surgical instruments and is applicable to all reusable medical devices manufactured and distributed by Pipeline Orthopedics.

These instructions are NOT applicable to any air driven or electrically powered equipment.

These instructions do NOT apply to single use medical devices manufactured or distributed by Pipeline Orthopedics. Single use devices should not be reused, as they are not designed to perform as intended after the initial use. Devices that cannot be reused may be labeled with the following symbol:



Do not reuse / Single use only

General Warnings and Precautions

Orthopedic surgery requires instruments which are heavy and have multiple components, articulation or rotating parts, removable handles, plastic replacement parts and series of measuring devices in graduated sizes. Devices are usually supplied in sets and subdivided into trays and cases in which the devices may be arranged by size or in the order needed for a specific surgical procedure.

During musculoskeletal surgery, instruments become contaminated from blood, tissue, bone chips and marrow. Instruments may also become contaminated with body fluids containing hepatitis virus, HIV or other etiological agents and pathogens. Reference OSHA regulations 29 CFR 1910.1030 Occupational Exposure to Bloodborne Pathogens.

1. All health care workers should become familiar with the necessary Universal Precautions of preventing injuries caused by sharp instruments when handling these devices during and after surgical procedures and during reprocessing.
2. Personal protective Equipment (PPE) should always be worn when handling or working with contaminated or potentially contaminated materials, devices and equipment. PPE includes gowns, masks, goggles or face shields, gloves, and shoe covers.

Pipeline Orthopedics has validated the processes provided in these instructions to be capable of being effective. Equipment, operators, cleaning agents and procedures all contribute to the efficacy of cleaning and sterilization processing. The healthcare facility should ensure that the results of selected processing steps and factors are safe and effective.

Full cycle steam/moist heat is the recommended sterilization method for Pipeline Orthopedics reusable manual instruments. Immediate-Use steam sterilization (flash sterilization) of individual instruments or inside the instrument case should be avoided. Ethylene Oxide (EO), Gas Plasma, and dry heat sterilization methods are also not recommended.

Unless otherwise indicated, instrument sets are NOT STERILE and must be thoroughly cleaned and sterilized prior to use.

Instrument cases do not provide a sterile barrier and must be used in conjunction with an FDA approved sterilization wrap to maintain sterility.

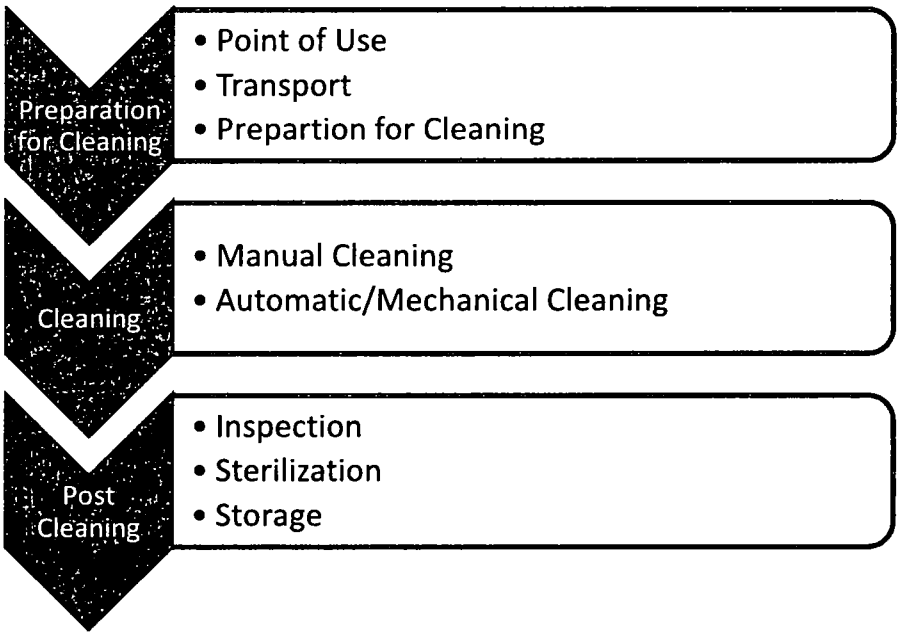
Repeated processing in accordance to the instructions in this manual has minimal effect on Pipeline Orthopedics reusable manual instruments. Service life for stainless steel surgical instruments is normally dictated by wear and damage due to intended surgical use and not from reprocessing.

Saline and other irrigation fluids are often used in copious amounts during surgical procedures and will exert a corroding effect on instruments.

Mineral oil or silicone lubricants should not be used because they coat microorganisms; prevent direct contact of the surface with steam; and they are difficult to remove.

The parameters for the sterilization process contained within this instruction manual are applicable within the USA only.

Process Overview



Preparation for Cleaning

Point of use

After use remove gross soil using absorbent, non-shredding, disposable wipes. Intensive rinsing of the re-usable instruments with fluent water or transfer of the medical devices into a bath with a proteolytic enzyme or aldehyde free disinfectant solution is recommended.

Transport to processing area

Avoid mechanical damage by ensuring that heavy devices do not get mixed with delicate ones. Pay particular attention to cutting edges, both to avoid personal injury and prevent damage to the re-usable instrument. Transport the re-usable instruments to the point where cleaning is to be performed as soon as practical. **Caution: Do not allow contaminated devices to dry prior to reprocessing.** If transfer to the processing area is likely to be delayed, consider covering the re-usable instruments with a damp cloth to avoid drying of soil.

Preparation for cleaning

Disassemble instruments as required. Specific instructions for instruments that require disassembly are provided in Appendix 1.

Cleaning

Two methods of cleaning Pipeline Orthopedics reusable manual instruments are provided in these instructions, a **manual method** and a mechanical method using an **automated washer disinfector**.

Whenever possible the automated method should be used. The automated cleaning process is more reproducible, and staff are less exposed to the contaminated devices and the cleaning agents used.

Caution: Automated cleaning using a washer/disinfector *alone* may not be effective for orthopedic instruments with lumens, cannulations, blind holes, mated surfaces, and other complex features.

A combination of manual and automated cleaning is recommended as described in this manual.

Whichever method is used, staff should use suitable protective clothing and equipment (PPE) at all times. In particular, take note of the instructions provided by the cleaning agent manufacturer for correct handling and use of the product.

Manual scrubbing with brushes should always be performed with the instrument below the surface of the cleaning solution to prevent formation of aerosols and splashing which may spread contaminants.

The guidance provided by the detergent manufacturer concerning concentrations and temperatures shall be observed. If these concentrations and temperatures are exceeded significantly, discoloration or corrosion could occur with some materials. This could also happen if rinsing after cleaning is insufficient.

For cleaning re-usable instruments neutral pH, enzymatic, formulated cleaning agents are recommended and preferred for cleaning Pipeline Orthopedics reusable manual instruments.

The quality of the water used for diluting cleaning agents and rinsing re-usable instruments should be carefully considered. Application of freshly prepared purified water is highly recommended for final rinses. Mineral residues from hard water, as well as higher contamination with microorganisms and endotoxins can result in staining of the device or prevent effective cleaning and decontamination.

Caution: Pipeline Orthopedic trays and cases are intended for transport, storage and sterilization of re-usable instruments. They are not designed for cleaning in the fully assembled state. The instruments must be removed from the tray for adequate cleaning results.

Manual cleaning

Equipment required:

- Cleaning bath or vessel large enough to allow complete immersion of the instruments
- Freshly prepared cleaning solution using a cleaning agent intended for manual cleaning
- Nylon Brushes – soft and firm, pipe cleaners, bottle brushes or cleaning wires for cannulations and channels
- Personal protective equipment as recommended by the cleaning agent supplier
- Absorbent paper
- Syringes (volumes 1 to 50 ml depending on the size of the channels to be rinsed)
- Ultrasonic bath large enough to allow complete immersion of the re-usable instrument. (A frequency of 40-44 kHz is recommended. Do not exceed the temperature stated by the detergent manufacturer.)
- Cleaning agent intended for manual cleaning and suitable for ultrasonic treatment. Do not exceed the concentration specified by the detergent manufacturer.
- Fresh purified water for final rinsing purposes.

Caution: To prevent damage to the instrument surfaces and finishes, *never* use metal brushes or steel wool for cleaning.

Procedure:

1. Remove gross soil using wipes and neutral pH solution of cleaning agent such as Enzol®.
2. Immerse re-usable instrument in solution of enzymatic or cleaning agent and soak for 15 minutes. Ensure that all surfaces are thoroughly wetted. Ensure that air is not trapped within features of the device when immersing in the solution.
3. Manually wash devices a. Use a syringe to ensure that the cleaning solution reaches all parts of cannulations. b. Using suitable soft bristle brushes clean the re-usable instrument thoroughly, paying particular attention to rough surfaces and features where soil may be impacted or shielded from the cleaning process. c. Use a firm bristle brush for cleaning bone-cutting features such as drill tips, reamer flutes and the teeth of broaches. d. Bend flexible devices in a U-shape and scrub the surface with a firm bristle brush. Repeat bending and brushing at several locations along the length to cover the entire device. e. Use a bottle brush of appropriate diameter and length for cannulations. Ensure that the brush passes the whole length of each cannulation. f. Operate articulating devices and those with moving parts.
4. Rinse in running water for a minimum of 3 minutes until all traces of cleaning solution are removed. Pay particular attention to cannulations and blind holes, as well as hinges and joints, between mating parts.
5. Visually inspect for any remaining soil and repeat the steps above if necessary.
6. Prepare an ultrasonic bath with a cleaning solution at the concentration and temperature specified by the detergent manufacturer.
7. Immerse the device completely and activate the bath for minimum of 15 minutes.
8. Using suitable brushes or cleaning wires, clean the device paying particular attention to rough surfaces and features that may be shielded from the ultrasonic action.
9. Rinse for at least 3 minutes in running water until all traces of cleaning solution are

removed. Pay particular attention to cannulations, blind holes, hinges, and joints between mating parts. Rinse cannulations at least three times with a syringe (volume 1-50ml).
10. If, after completion of the cleaning step in the ultrasonic bath, encrusted soil remains on the device, the cleaning step must be repeated as described above.

Automated/Mechanical cleaning using washer-disinfector

Equipment required:

- Cleaning bath or vessel large enough to allow complete immersion of the instruments
- Freshly prepared cleaning solution using a cleaning agent intended for manual cleaning
- Nylon Brushes – soft and firm, pipe cleaners, bottle brushes or cleaning wires for cannulations and channels
- Personal protective equipment as recommended by the cleaning agent supplier
- Absorbent paper
- Syringes (volumes 1 to 50 ml depending on the size of the channels to be rinsed)
- Washer-disinfector.
- Cleaning agent intended for use in washer-disinfector. Do not exceed the concentration and temperature recommended by the detergent manufacturer.

Procedure:

1. Remove gross soil using wipes and solution of cleaning agent.
2. Immerse re-usable instrument in solution of enzymatic or cleaning agent and soak for 15 minutes. Ensure that all surfaces are thoroughly wetted. Ensure that air is not trapped within features of the device when immersing in the solution.
3. Manually wash devices
   a. Use a syringe to ensure that the cleaning solution reaches all parts of cannulations.
   b. Using suitable soft bristle brushes clean the re-usable instrument thoroughly, paying particular attention to rough surfaces and features where soil may be impacted or shielded from the cleaning process.
   c. Use a firm bristle brush for cleaning bone-cutting features such as drill tips, reamer flutes and the teeth of broaches.
   d. Bend flexible devices in a U-shape and scrub the surface with a firm bristle brush. Repeat bending and brushing at several locations along the length to cover the entire device.
   e. Use a bottle brush of appropriate diameter and length for cannulations. Ensure that the brush passes the whole length of each cannulation.
   f. Operate articulating devices and those with moving parts.
4. Rinse in running water for a minimum of 3 minutes until all traces of cleaning solution are removed. Pay particular attention to cannulations and blind holes, as well as hinges and joints, between mating parts.
5. Load the re-usable instruments into the washer-disinfector.
   a. Avoid contact between devices as movement during washing could cause damage, and washing action could be obstructed.
   b. Arrange re-usable instruments so that cannulations are not horizontal and blind holes incline downwards to assist drainage. Articulating devices should be in the open position.
6. Operate the washer-disinfector cycle. The following table provides instructions for cleaning re-usable instruments:

Phase	Time	Temperature	Detergent/Concentration
Pre-Wash	2 min	Cold Tap Water	None

Enzyme Wash	1 min	Hot Tap Water	Enzol®/ 1 oz/gal
Wash	2 min	66° C	Renu-Klenz™/ 25oz/gal
Rinse	15 sec	Hot Tap Water	None
Pure Water Rinse	10 sec	66° C/Purified Water	None
Drying	7 min	115.5° C	None

7. Upon completion, unload the washer-disinfector. Visually inspect each device for remaining soil and dryness. If soil remains repeat the cleaning process. Remaining wetness may be removed with filtered, compressed air or clean, lint-free wipes.

Post Cleaning

Inspection

Before preparing for sterilization, all re-usable instruments should be inspected. Generally un-magnified, visual inspection under good light conditions is sufficient. All parts of the devices should be checked for visible soil and/or corrosion.

Verifying cleaning — After cleaning, visually inspect devices under normal lighting for the removal of visible soil.

- Inspect soil traps such as mating surfaces, hinges, shafts of flexible drill bits, and recessed features (holes, cannulations)
- Inspect features where soil may be impacted into the device, such as drill flutes adjacent to the cutting tip and sides of teeth on broaches and rasps
- For difficult to view design features, apply 3% hydrogen peroxide. Bubbling is indicative of the presence of blood

Functional checks and Inspections — Visually inspect for damage, wear, and functional anomolies

- Mating devices should be checked for proper assembly
- Check edges of cutting features for distortion or damage. Edges should be sharp and continuous
- Articulating surfaces should be smooth and free of cracks and deep nicks
- Inspect metal surfaces for corrosion and major deformations
- Instruments with moving parts should be operated to check correct operation
- Rotating instruments, such as multiple use drill bits, and reamers, should be checked for straightness. This can be achieved by simply rolling the instrument on a flat surface
- Flexible instruments should be checked for damage to the spiral element
- For devices that may be impacted check that the device is not damaged to the extent that it malfunctions or that burrs have been produced that could damage tissues or surgical gloves

Note: Pipeline Orthopedics does not define the maximum number of uses appropriate for re-usable instruments. The useful life of these devices depends on many factors, including the method and duration of each use, and the handling between uses. Careful inspection and functional test of the instrument before use is the best method of determining the end of serviceable life.

Sterile Packaging

The packaging for terminally sterilized re-usable instruments should be suitable for steam sterilization and grade appropriate for the weight of the instrument case. Cleaned and checked re-usable instruments should be assembled into the dedicated trays provided. Pipeline Orthopedics cases/trays should be wrapped during the steam sterilization process using FDA cleared wraps (e.g. KC600 Kimguard® Sterilization Wrap).

Warning: Pipeline Orthopedics does not recommend the use of rigid containers for steam sterilization. This configuration could limit steam penetration and prevent effective sterilization of the instruments.

Sterilization

Steam autoclave (moist heat) sterilization using a pre-vacuum (forced air removal) cycle is recommended. Autoclaves should comply with the requirements of, and be validated and maintained in accordance with ISO 17665, and ANSI/AAMI ST79.

Pipeline Orthopedics has validated an autoclave cycle for sterilization of complete re-usable instrument cases/trays. Instruments shall be sterilized in the assembled state as stored on the tray (i.e.: if the brackets or recessions in the tray are designed to accommodate multi-component instruments in their assembled state, there is no need to disassemble these instruments for sterilization.) The process parameters below are validated and recommended by Pipeline Orthopedics for sterilization.

Caution: Pipeline Orthopedics does not recommend the use of 'flash' or immediate use steam sterilization for re-usable instruments.

Warning: Single-use implants and instruments should not be re-sterilized.

USA Parameters for instrument cases up to 25lb (11kg)

Method	Moist heat sterilization according to ANSI/AAMI ST 79
Cycle	Dynamic Air removal Steam Sterilization (Pre-Vac)
Temperature	132°C (270°F)
Exposure Time[1]	4 minutes (minimum)
Drying Time[2]	30 minutes (minimum, in chamber)

1 Exposure time: Period for which the load and entire chamber is maintained at the sterilization temperature.

2 Drying time: Period during which steam is removed from the chamber and the chamber pressure is reduced to permit the evaporation of condensate from the load either by prolonged evacuation or by the injection and extraction of hot air or other gases. The drying time varies due to load configuration, wrapping method and material

Storage before Use

After sterilization, re-usable instruments should be stored the in the sterilization wrap in a dry and dust-free place to maintain the sterile condition. Care must be exercised in handling of wrapped cases to prevent damage to the sterile barrier. The user must be aware that maintenance of sterility is event-

related and that the probability of occurrence of a contaminating event increases over time, or with handling. The shelf life is dependent on the integrity of the sterile barrier employed, storage manner, environmental conditions and handling.

References

1. AAMI TIR12, *Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers*

2. AAMI TIR30, *A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices*

3. ANSI/AAMI 35: *Safe handling and biological decontamination of reusable medical devices in healthcare facilities and in nonclinical settings*

4. ANSI/AAMI ST79: *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health care Facilities*

5. ANSI/AAMI ST81, *Sterilization of medical devices – Information to be provided by the manufacture for the processing of resterilizable medical devices*

6. ISO 17664: *Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices*

7. ISO 17665: *Sterilization of health care products, moist heat*

Contact Information: **Pipeline Biomedical Products**
3 Wing Drive, Suite 102
Cedar Knolls, NJ 07927
PHONE: 973-267-8800
FAX: 973-267-8810

Appendix 1

Instruments Requiring Disassembly for Cleaning

Total Hip Arthroplasty Instruments

Catalog Number	Instrument Name	Disassembly Instructions
91-250-0003 91-250-0007 91-250-0013 91-250-0014	Broach Handles	Pull latch to allow release of locking lever and swing out of housing
91-250-0015 91-250-0016 91-250-0001	Femoral Head Impactor Head Femoral Head Impactor Handle	Unthread tip counter-clockwise to separate from handle
92-140-0002 92-140-0014 92-140-0003	Acetabular Reamer Handle and Sleeve Acetabular Reamer Handle, Offset	On the straight handle, remove the plastic sleeve by sliding over the end of the shaft. On the offset handle remove side handle and locking collar. The handle body separates into two halves to facilitate drive chain removal. Push the ring into the actuator and twist until the black line aligns with the slot. Once aligned slide the ring down the slot to allow access to actuator components.
92-255-0008	Depth Gage	Unthread cap of depth gage. Pull out inside
92-140-0007 92-140-0013 92-140-0005	Version Guide and Collet A-Frame	Remove collet from end of modular alignment guide and disassemble by unthreading from shell handle.
92-140-0001	Offset Shell Impactor	Depress knob to allow ratcheting end of tightening to pull from handle. Pull latch to allow release of drive mechanism and swing out of housing.

Pipeline Biomedical Products
3 Wing Drive, Suite 102
Cedar Knolls, NJ 07927

Tapered Hip Stem Surgical Technique Guide

Indications for Use

The PBP Total Hip System is indicated for use in skeletally mature individuals undergoing surgery for total hip replacement due to:

- A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis, or congenital hip dysplasia;
- Acute traumatic fracture of the femoral head or neck;
- Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty or total hip replacement.

The PBP Total Hip System hip stems and porous structured acetabular shells are intended for cementless or cemented fixation. The porous structured surface provides biological fixation when used in a cementless application.

The PBP Total Hip System HA porous structured acetabular shells are intended for cementless fixation. The HA porous structured surface provides biological fixation.

Preoperative Planning

The goal of hip reconstruction is to restore biomechanics and create a stable joint articulation with optimized range of motion. Preoperative planning assists in choosing the appropriate implant and size for the given patient's bone canal shape and pathology. This routine is essential in determining optimal position of the femoral stem implant. These steps are essential in determining stem size, femoral neck cut and proper head and stem offset combination. Templating must be done on the affected side, but should be performed on the contralateral hip to verify the templated stem size and offset.

Note: The Tapered Hip Stem may be used in a variety of approaches, however, to ensure proper placement, full visualization of the proximal femur is required.

An AP Pelvis radiograph should be used to determine if the patient has a leg length discrepancy preoperatively. Draw a reference line tangential across the bottom of the ischium. If the patient's legs are of equal length, the line should contact both femurs at the same level. Measure the distance from the lesser trochanter to the reference line drawn on each side. The difference in these measurements indicates the patient's leg length discrepancy.

Femoral Neck Osteotomy

The Neck Resection Guide is used to mark the level of neck resection for an accurate cut. Preoperatively determine the resection measuring the distance above the lesser trochanter. Place the resection guide on the femur using the predetermined value above the lesser trochanter and align with the resection guide along the femoral axis. This establishes the resection level and angle at 50 degrees from the femoral axis. When the appropriate level of resection has been determined, mark the resection line using methylene blue or electrocautery. Resect the femoral head and neck, taking care to maintain the correct angle.

Femoral Canal Initiation

Adequate visualization of the surgically created introitus of the proximal femoral canal is important to ensure proper placement of the endosteal canal opening tool. Use the Box Osteotome for initial entry into the femoral canal and to establish the version of the broach to facilitate positioning of the implant. This clears a channel laterally to accept the Starter Reamer without interference from the dense bone at the trochanter. A Femoral Rasp may also be used to remove additional bone from the medial aspect of the greater trochanter, if necessary, and ensure the initial reaming and/or broach tract is in neutral alignment with the femoral axis. The curve of the Femoral Rasp will follow the Calcar and provide a path of the broach.

Note: The Box Osteotome and Femoral Rasp are intended to open access axially into the femoral canal to ensure proper entry and alignment for broaching. Be sure to clear bone of the medial trochanter to avoid varus stem placement.

A Starter Reamer, attached to the T-Handle, can then be used to enter the femoral canal. The Starter Reamer has a sharpened point to facilitate entry and should be inserted to the depth of the final anticipated cutting, this will provide a reference of the femoral canal. As an option, a Starter Femoral Broach may be used to open up the medullary canal in preparation for the passage of sequential broaches.

Note: Correct position of the entry point will assist with avoidance of possible varus stem position.

Femoral Canal Preparation

Based on the surgical approach, choose the broach handle best suited for the procedure, and assemble the broach by inserting the post of the broach into the broach handle. Lock the handle onto the broach. If a Starter Femoral Broach is not used, begin with the smallest broach size.

Initiate broaching with a size at least two sizes smaller than the template stem size. Drive the broach down the femoral canal with a mallet, taking care to ensure proper axial alignment and version. Assess fit and resistance to movement. If the broach can be further advanced 2-3mm below the neck resection, use the next larger broach size. Continue broaching until the broach

cannot be advanced further down the canal, and stable contact is achieved between the broach and the medial and lateral cortices. The top of the broach should be in line with, or slightly proud of the neck resection. Do not force a broach further down the canal if it no longer advances. If the broach is difficult to seat, a smaller than templated stem size should be chosen to avoid fracturing of the femur. If this is the case, reassure the resection level and broach alignment is correct. The final size broach should be chosen when rotational stability is achieved. Disengage the broach handle and leave the final broach fully seated in the canal for Calcar planning (optional) and trial reduction.

Warning: Do not force a broach that is too large into the femoral canal. Excessive mallet blows can fracture the bone.

Calcar Preparation (Optional)

If calcar planing is desired, place the calcar planer over the final seated broach post. Machine the proximal femur to achieve a flat resection surface that coincides with the proximal broach face. Start the rotatory motion of the planar before seating it onto the broach to avoid fracture.

Trial Reduction

Select the appropriate size neck trial, either Standard (silver) or Extended Offset (gold), as determined by templating. Offset increases 6 - 8mm, depending on stem size, beyond that of the Standard Offset trial neck, and the Extended Offset provides increased offset without increasing leg length.

The neck trials are clearly marked to correspond to broach sizes with which they are compatible. Sizes are grouped to fit only with corresponding sized broaches; size 1-4, 5-8, 9-12 for both Standard and Extended Offset. Place the neck trial securely onto the broach post until fully seated.

Note: Visually verify there is no gap present between the lateral aspect of the Trial Neck and Broach.

Next, select the head diameter according to the desired mating cup size liner. Bearing heads are available in 28mm, 32mm and 36mm outer diameters. Select the neck length, -3.5mm, 0, +3.5mm, +7mm, +10.5mm, based on preoperative templating, and ensure it corresponds to the appropriate head diameter. Attach the head trial to the neck trial and perform a trial reduction of the hip, assessing the hip for stability, leg length, and over all range of motion.

Note: Trial heads can be easily dislodged by rocking back and forth gently on the taper.

Compare to preoperative templating measurement and assess what adjustments, if any, are required. Adjust the neck length by changing the femoral head trials to achieve desired results.

Once stability, leg length, and over all range of motion are satisfactory, remove the trials and the broach from the femur, noting size to be used for implants.

Note: Skirts are present on head sizes 28mm +7 and+10.5; 32mm and 36mm +10.5.

Prepared Canal

After removal of the broach, prior to insertion of the final implant, assure there is no loose bone or other tissue that may interfere with stem seating. Lavage may be carried out to remove loose bone or other tissue that may interfere with stem seating.

Femoral Implant Insertion

Select the femoral stem size that corresponds to the final broach. Introduce the femoral stem into the canal by hand, taking care to orient the implant with proper axial alignment and version. A variety of stem insertion instruments are available for different wound exposure and anatomy. Choose the desired instrument. Make sure the distal tip of the impactor is correctly mated to the insertion feature of the stem. For proper stem seating, ensure the stem inserter is not impinging on the trochanter. Using a mallet, tap the impactor to advance the stem into the canal until it is fully seated. Stem is considered seated when the top of the stem fixation coating reaches the level where the face of the broach previously sat. Do not use excessive force to seat the stem and do not continue to impact the stem if auditory and visual clues indicate the resting position of the stem has been reached. Remove the inserter when the stem is fully seated.

Warning: Do not use excessive force to seat a stem. Excessive mallet blows can fracture the bone.

Final Trial Reduction

A final trial reduction may be performed using trial femoral heads at this time to assess range of motion, joint stability, leg length and offset. Once confirmed, remove the trial femoral head noting the neck length chosen.

Femoral Head Impaction

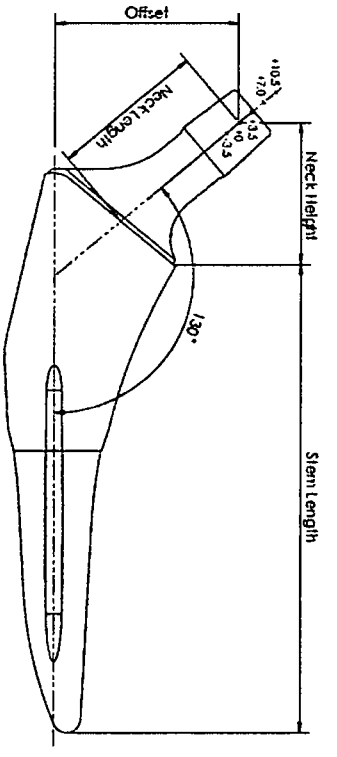
Clean and dry the neck taper with a sterile cloth. Place the appropriate sized femoral head onto the taper. Firmly impact the head with the femoral head impactor and a mallet.

Note: Do not impact the femoral head implant onto the femoral stem neck taper prior to fully seating the femoral stem as the head may loosen during impaction.

Reduce Joint and Close

Reduce the hip and assess range of motion, stability and leg length. The surgical site is then closed according to the surgeon's standard procedure for the surgical approach chosen.

TECHNICAL SPECIFICATIONS



	STEM LENGTH (mm)	OFFSET (mm)	NECK HEIGHT (mm)	NECK LENGTH (mm)
2 STANDARD	97	36	27	29
2 HIGH	97	42	27	33
3 STANDARD	99	38	28	31
3 HIGH	99	44	28	35
4 STANDARD	101	38	29	31
4 HIGH	101	44	29	35
5 STANDARD	103	40	31	33
5 HIGH	103	48	31	39
6 STANDARD	105	40	32	33
6 HIGH	105	48	32	39
7 STANDARD	107	42	33	35
7 HIGH	107	50	33	41
8 STANDARD	109	42	34	35
8 HIGH	109	50	34	41
9 STANDARD	111	44	35	37
9 HIGH	111	52	35	43
10 STANDARD	113	44	36	37
10 HIGH	113	52	36	43
11 STANDARD	115	46	36	38
11 HIGH	115	54	36	44
12 STANDARD	117	46	37	38
12 HIGH	117	54	37	44

Pipeline Biomedical Products
3 Wing Drive, Suite 102
Cedar Knolls, NJ 07927

PST™ Acetabular Cup Surgical Technique Guide

Indications for Use

The PBP Total Hip System is indicated for use in skeletally mature individuals undergoing surgery for total hip replacement due to:

- A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis, or congenital hip dysplasia;
- Acute traumatic fracture of the femoral head or neck;
- Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty or total hip replacement.

The PBP Total Hip System hip stems and porous structured acetabular shells are intended for cementless or cemented fixation. The porous structured surface provides biological fixation when used in a cementless application.

The PBP Total Hip System HA porous structured acetabular shells are intended for cementless fixation. The HA porous structured surface provides biological fixation.

Preoperative Planning

The goal of acetabular reconstruction is to restore biomechanics and create a stable articulation with an optimized range of motion. Thorough preoperative planning assists in choosing the appropriate implant style and size for the given patients pathology and is essential in determining optimal position of the acetabular implant. Templating must be done on the affected side, but should be performed on the contralateral hip to verify size. The acetabular component should be positioned no more medial than the cotyloid notch or against the radiographic teardrop.

Note: The PST Acetabular Shell may be used in a variety of approaches, however, to ensure proper placement and reduce soft tissue entrapment, full visualization of the acetabular rim is required.

Acetabular Reaming

As a result of templating and pre-operative planning, determine the desired head center position. Select an Acetabular Reamer that is at least 4mm smaller than the size of the Shell templated. Straight and Offset Reamer Handles are available depending on approach and exposure. Attach the first Reamer Basket to the Reamer Handle. Hold the Reamer steady and apply constant pressure while reaming, positioned at 45 degrees of abduction and 20 degrees of anteversion to ensure the proper position of the final implant. Reaming progresses in 1mm increments until exposing bleeding

cancellous bone is achieved. Care must be taken to assess bone quality, amount of interference and desired amount of reaming.

When implanting the PST Acetabular Shell, it is recommended the acetabulum be under-reamed by 1-2mm, depending on acetabular size, desired amount of interference, and bone quality. The Shell is hemispherical and is sized in increments of 2mm, from 44mm through 68mm. Each shell size corresponds to its nominal millimeter size as identified on the label, (i.e.: A size 54mm shell measures 54mm across its diameter).

Note: Hold the Reamer Handle steady and apply constant pressure in the final implant orientation; 20 degrees anteversion and 45 degrees abduction.

Note: If surgeon prefers, slight toggling of the Reamer Handle may result in a more accurate hemispherical radius.

Acetabular Trialing

Once reaming is complete, make sure the acetabulum is free of debris before seating the Trial Shell. Thread the Trial Shell onto the Cup Impactor; Straight and Offset versions are available. Use the Acetabular Shell Trial to confirm the position and accuracy of the reaming, as well as to verify the size and position of the intended shell. The Trial Shell is overall 2mm smaller than its corresponding implant to account for under reaming. Two rows of barbs along and just above the rim of the Trial Shell extend to the boundary of the implant and provide assessment of shell stability prior to determining implant size.

Select the appropriate Liner Trial size that corresponds to the planned acetabular shell; determine liner style and face angle, offset and femoral head diameter. A close fit has been designed into the Liner Trials, however, for a more secure fit, an optional Acetabular Liner Trial Locking Screw is available. Tighten the Locking Screw into the polar hole of the Liner Trial and Trial Shell using the Straight Hex Driver. With the Liner Trial and Trial Shell in place, perform a trial reduction at this time to evaluate the position of the final implant, assess leg length, offset, range of motion and stability of the components.

Note: Do not impact on the Liner Trial, as damage could occur.

Note: The Trial Liner Locking Screw is a small piece that can be easily dropped and lost in the wound. Care must be taken to keep secure and assure that the Screw is accounted for following the procedure. The Hex Screw Driver incorporates a design that helps hold the screw to preclude it from easily dropping off, but care must still be taken to guide any screw into its intended position.

A Trial Liner Extraction Tool is provided. Assemble the Liner Extractor and the T-Handle. Place the keyed end of the Liner Extractor into the mating hole of the Liner Trial. Twist the assembly clockwise ¼ turn to loosen the liner. Pull to remove the Liner Trial.

Acetabular Shell Insertion

To aid in correctly orienting the implant shell, a lateral Alignment Guide is available. Assemble the Shell Alignment Guide onto to the Shell Inserter Handle using the Version Guide Clamp. Upon verification of correct sizing, securely thread the appropriate size implant shell onto the Shell Impactor, taking care not to use excessive force, but ensuring the Shell is abutted to the Impactor. Insert into the prepared acetabulum. Reassess patient positioning; ensure the Alignment Guide is perpendicular to the long axis of the patient to achieve 45 degrees of abduction. Move the Shell Alignment Guide so the anteversion rod is parallel to the long axis of the patient to achieve 20 degrees of anteversion.

Note: Shell Alignment Guide should only be used as an aid for proper positioning, surgeon must also rely on anatomic landmarks to ensure proper positioning.

Note: The two dark lines on the face of the Shell identify the screw hole locations. They assist when aligning screw hole placement.

With the implant in the appropriate position and alignment, firmly impact the Inserter using a mallet until the shell is fully seated. Impaction required to properly seat the shell is dictated by the quality of the patient's bone and the size of the under-reaming. While impacting, note the position of the screw holes to obtain the optimal position for screw placement.

Gently toggle the Handle to assess the shell is stable and a tight press fit is achieved.

Note: Do not lever the Shell Inserter Handle, as damage to the threads may occur and the shell can inadvertently loosen.

Remove the Shell Alignment Guide and carefully disengage the Shell Inserter Handle from the acetabular shell. The dome hole can be filled with a Dome Hole Occluder once the Shell Inserter Handle has been removed.

Bone Screw Insertion

If adjunct screw fixation is desired, prepare the bone for the Screws utilizing the Drill Bits, Drill Guide and Flexible Drill Shaft to drill a pilot hole. The maximum angulation of the drill hole and screw is +/- 10 degrees from the central axis of the screw hole. Angulation of the Screw more than 10 degrees increases the likelihood that the Screw can be pulled through the screw hole, or that the screw head will protrude into the Shell ID, precluding the cup liner from fully seating. Measure the depth of the holes using the Depth Gauge and select the appropriate length 6.5mm diameter bone screw. Use the Screw Holding Forceps to hold the Screw. Attach the Screwdriver shaft to the end of the screw, place in the appropriate hole and secure in place. Ensure the screw is fully seated as not to interfere with liner placement. Avoid over tightening and potential advancement through the shell. Place additional Screws as required.

Note: Use the screw locational tick markings on the rim of the shell for Screw hole orientation during shell positioning and impaction. Avoid Screw placement into the anterior inferior and anterior superior quadrants of the acetabulum to prevent injury.

Note: Ensure Screw heads are countersunk to prevent the liner from contacting the Screw head and prohibiting the proper seating of the liner.

Liner Placement

Clear out any soft tissue from the perimeter of the shell and clean and dry the inner shell thoroughly. If an additional trial reduction is desired, place appropriate sized liner trial, as previously described, and evaluate the position of the final implant.

Once liner size and type is reconfirmed, insert the polyethylene liner implant into the implanted shell by hand. Rotate the liner to align the shell scallops with liner tabs taking care to orient the liner face in its desired position.

Note: Prior to impaction, the liner will not be flush with the shell rim. Ensure liner tabs are aligned with shell scallops prior to impaction.

Choose the appropriate sized Liner Impactor which will match the implant head size. Place the Impactor in the liner and firmly strike the handle until the liner is fully seated. Palpate the rim to ensure the liner is properly seated and fully aligned.

Note: Verify liner is properly seated by running a finger around the exposed portion of the face of the shell to ensure tabs are flush. The face may be proud depending upon liner design chosen.

Final Reduction

Once the liner is seated and locked in place, perform a final reduction to assess hip stability, leg length and range of motion and avoidance of impingement.

PIPELINE
BIOMEDICAL

CERAMIC FEMORAL HEADS - INSTRUCTIONS FOR USE

DEVICE DESCRIPTION – CERAMIC FEMORAL HEADS:
Pipeline Biomedical Products BIOLOX® delta Ceramic Femoral Heads are available in diameters of 28mm, 32mm, 36mm, and 40 mm and short, medium, long, and extra-long neck lengths. The BIOLOX® delta Femoral Heads are for use with the Pipeline Biomedical Products Total Hip System.

MATERIALS:
The BIOLOX® delta components are manufactured from a high purity alumina oxide ceramic compound.

CAUTION:
Federal Law (USA) restricts this device to sale by or on the order of a physician.

INDICATIONS FOR USE:
Pipeline's Total Hip System is indicated for use in skeletally mature individuals undergoing surgery for total hip replacement due to:

- A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis, or congenital hip dysplasia.
- Acute traumatic fracture of the femoral head or neck.
- Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty or total hip replacement.

CONTRAINDICATIONS:
The following conditions are contraindications for total hip replacement:

- Active local or systemic infection.
- Neuromuscular disorders, muscular atrophy or vascular deficiency in the affected limb rendering the procedure unjustified.
- Patients with mental or neurological conditions which may be incapable of following instructions.
- Patients with insufficient quality or quantity of bone to allow appropriate insertion and fixation of the prosthesis.
- Blood supply limitations.
- Skeletal Immaturity.
- Physical conditions which tend to place extreme loads on implants, i.e. Charcot's or Paget's disease.

WARNINGS & PRECAUTIONS:
Familiarity with and attention to appropriate surgical technique for total hip replacement and Pipeline's Total Hip System is essential for success of the procedure.

Care should be utilized in the handling of the components to minimize contamination of the component surfaces. Do not allow porous surfaces to come in contact with cloth or any fiber-releasing material. In using cement for fixation, the surgeon should use care to ensure complete cement support on all parts of the prosthesis embedded in bone cement.

Only surgeons who have reviewed the literature regarding total hip replacement surgery and have had training in the technique should utilize the device. The surgeon or his designee should instruct patients as to the limitations of the prosthesis, and these patients should be taught to govern their activities accordingly.

Always use Pipeline's Total Hip instrumentation and trial prosthesis for trial purposes. Trials are not intended for permanent implantation. Implants must not be reused. The surgeon must use care and not allow damage to bearing surfaces because this may accelerate wear of the components. Any alteration or damage to a component may result in failure under load. Any prostheses so damaged must not be used. Implants and trial components from different manufacturers or implant systems should never be used together since articular and dimensional compatibility cannot be assured.

Femoral and acetabular components must be appropriately sized for their corresponding bone.

EXCESSIVE WEIGHT WARNING: Obese or excessive patient weight tends to impose severe loading of the hip, placing the patient at higher risk for implant failure.

The Total Hip System has not been evaluated for safety and compatibility in the MR environment. The Total Hip System has not been tested for heating or migration in the MR environment.

PRE-OPERATIVE:
Selection of Pipeline's Total Hip System depends on the judgment of the surgeon with regard to the requirements of the patient. The surgeon should become thoroughly familiar with the technique of implantation of the prostheses by: 1) appropriate reading of the literature, and 2) training in the operative skills and techniques required for total hip arthroplasty.

Refer to the Tapered Hip Stem and PST™ Acetabular Cup Planning and Surgical Technique Guide for a description and additional warnings regarding planning and the surgical technique for Pipeline's Total Hip System.

INTRA-OPERATIVE:
Correct selection of the implant is extremely important. It is recommended components at least one size smaller and one size larger than were preoperatively planned be available at surgery to accommodate changes in operative plans. All protective covers should remain on implants until just prior to use, and care taken not to scratch, bend or cut implant components during surgery. Do not allow any porous materials to come in contact with cloth or other fiber releasing material. Modular heads and femoral components should be from the same manufacturer to prevent mismatch of tapers. Prior to closure, ensure surgical site is thoroughly cleaned and free of surgical debris, cement, bone chips, and ectopic bone.

Do not use a ceramic femoral head that has been scratched, dropped or blemished in some way as an imperfection could cause device failure. The bore of the ceramic head and the stem taper should be dry and free of contamination prior to seating the ceramic femoral head and a plastic or rubber hammer should be used to seat the ceramic femoral head. Use of a metallic hammer and/or excessive force may also damage the ceramic head and cause the head to fracture.

POST-OPERATIVE:
Strict adherence to surgeon directed postoperative care is extremely important. Surgeon-prescribed gradual weight bearing, as standard with total hip arthroplasty, should be provided through written instructions, including warnings and limitations to the patient prior to discharge. Postoperative therapy to regain muscle strength, as well as continued patient follow up, including periodic radiographs, are recommended. If radiographic changes are observed, such as changes in position, radiolucencies, bone resorption, loosening, cracking or bending, patients should be closely monitored.

ADVERSE EFFECTS:
As with any hip system, potential adverse effects include early or late infection, loosening of the components, wear of the components,

breakage or bending of the components, or change in position of the components. There have been reports of sensitivity reactions to the components of hip replacement systems. Other potential adverse effects of hip surgery include tissue reactions, osteolysis, neurovascular damage, dislocation, thromboembolic disease, and other less common adverse effects. Fractures of ceramic femoral heads have been reported.

STERILIZATION:

Prosthetic components are sterilized by exposure to a minimum dose of 25 kGy of gamma radiation. Do not use any component if the package has been breached, or if the expiration date has been exceeded. Once opened, the component must be used or discarded. Do not re-sterilize components.

Packaging Labels Legend:

	Manufactured by	Rx	Prescription only
STERILE	Sterile, terminally sterilized device		
	Do not use if package is damaged		
	Do not reuse / Single use only		
REF	Catalog / Reorder number		
LOT	Manufacturer's lot number		Use by date

PIPELINE
BIOMEDICAL

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PIPELINE
BIOMEDICAL

Pipeline Biomedical Products
3 Wing Drive, Suite 102
Cedar Knolls, NJ 07927

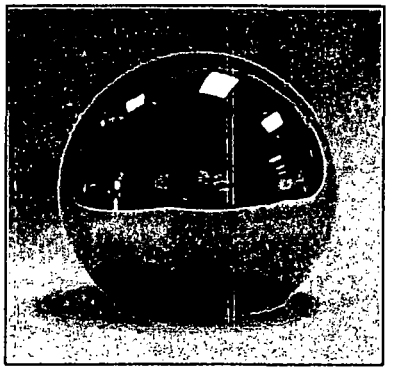
Pipeline Biomedical Products Implant & Instrument Catalog

Femoral Stem Standard Neck

Size	Catalog No.	Size	Catalog No.
2	11-200-0200	8	11-200-0800
3	11-200-0300	9	11-200-0900
4	11-200-0400	10	11-200-1000
5	11-200-0500	11	11-200-1100
6	11-200-0600	12	11-200-1200
7	11-200-0700		

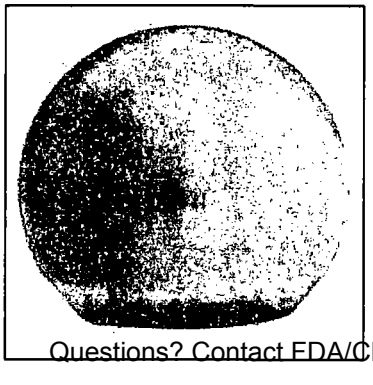
Femoral Stem High Offset Neck

Size	Catalog No.	Size	Catalog No.
2	11-200-0206	8	11-200-0808
3	11-200-0306	9	11-200-0908
4	11-200-0406	10	11-200-1008
5	11-200-0508	11	11-200-1108
6	11-200-0608	12	11-200-1208
7	11-200-0708		



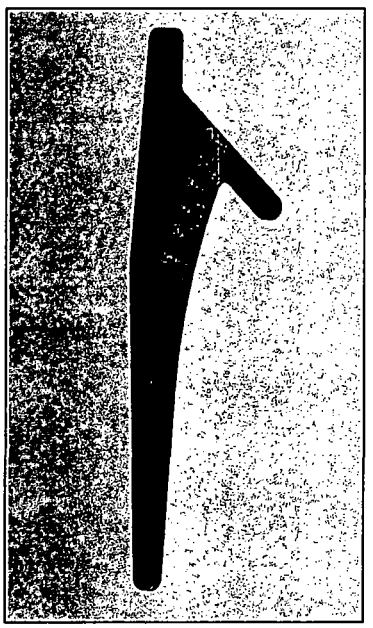
Femoral Heads, Cobalt Chromium, 12/14 Taper

Size	22mm	28mm	32mm	36mm	40mm
-3.5		11-100-2893	11-100-3293	11-100-3693	11-100-4093
0	11-100-2200	11-100-2800	11-100-3200	11-100-3600	11-100-4000
+3.5	11-100-2203	11-100-2803	11-100-3203	11-100-3603	11-100-4003
+7		11-100-2807	11-100-3207	11-100-3607	11-100-4007
+10.5		11-100-2810	11-100-3210	11-100-3610	11-100-4010

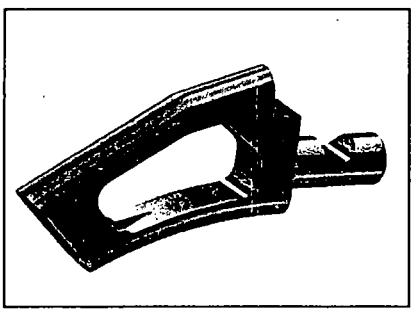


Femoral Heads, BIOLOX® Delta, 12/14 Taper

Size	28mm	32mm	36mm	40mm
Small	11-101-2893	11-101-3293	11-101-3693	11-101-4093
Medium	11-101-2800	11-101-3200	11-101-3600	11-101-4000
Large	11-101-2803	11-101-3203	11-101-3603	11-101-4003

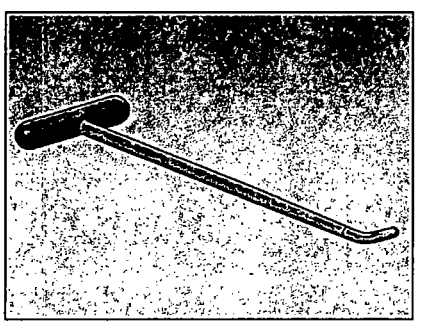


Femoral Neck Resection Guide Catalog No: 91-250-0000

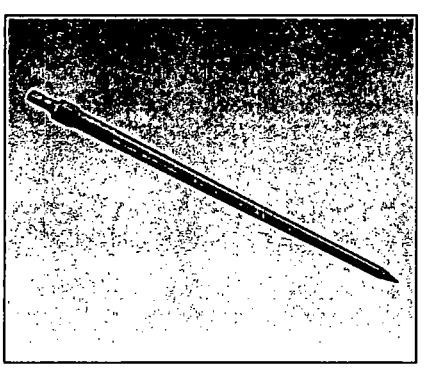


Box Osteotome, Modular Catalog No: 91-250-0004

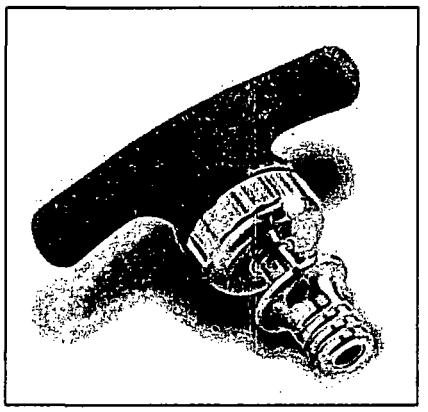
Box Osteotome, Fixed Catalog No: 91-250-0017



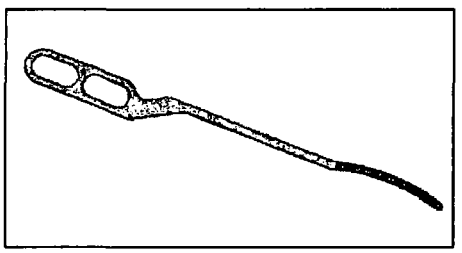
Canal Finder Catalog No: 91-250-0006



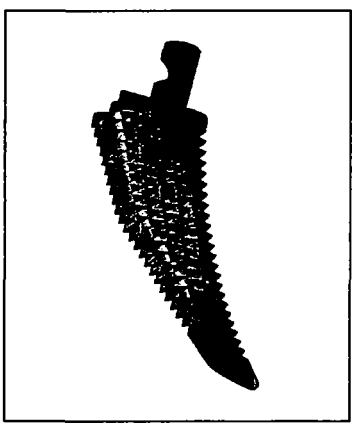
IM Starter Reamer Catalog No: 91-250-0005



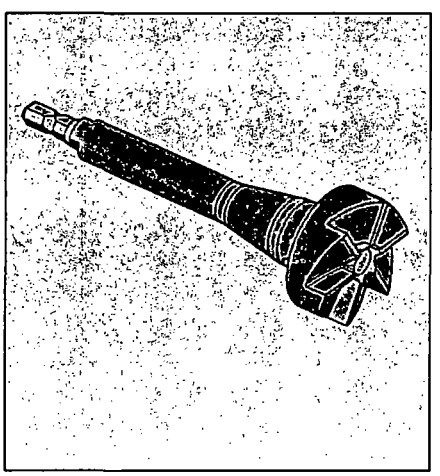
T-Handle Catalog No: 90-250-0001



Femoral Rasp Catalog No: 91-250-0009

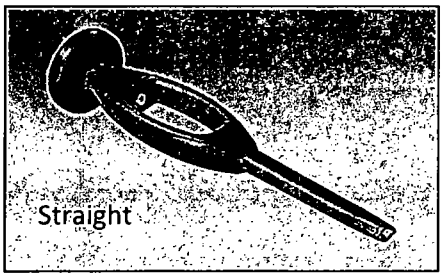


Starter Rasp Catalog No: 91-200-0000



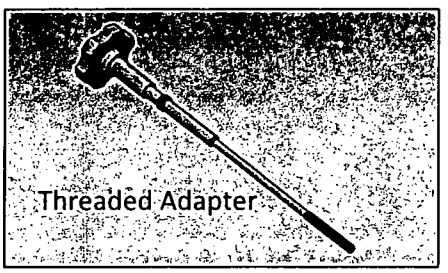
Calcar Planer Catalog No: 91-250-0002

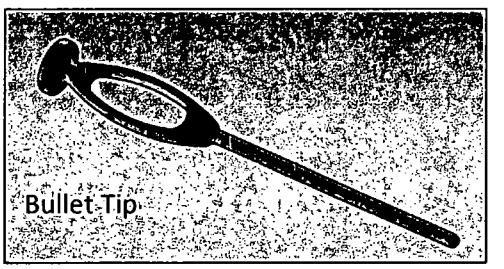
Calcar Planer, Large Catalog No: 91-250-0011

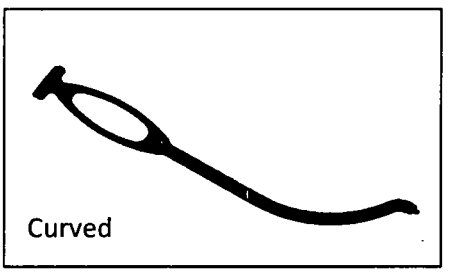


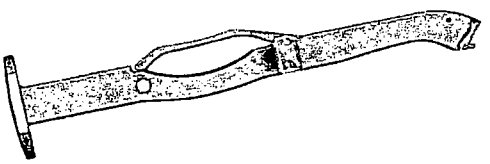
Femoral Stem Impactor

Straight	Catalog No: 91-250-0100
Threaded Adapter	Catalog No: 91-250-0101
Curved	Catalog No: 91-250-0203
Bullet Tip	Catalog No: 91-250-0202
Offset	Catalog No: 91-250-0201

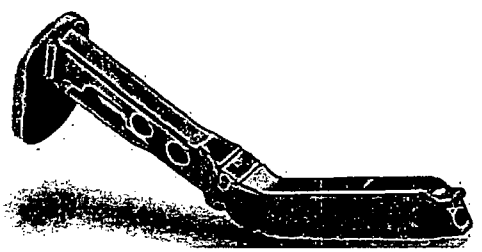




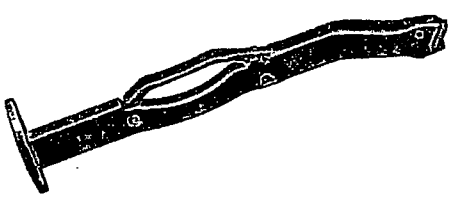




Straight Broach Handle Catalog No: 91-250-0003

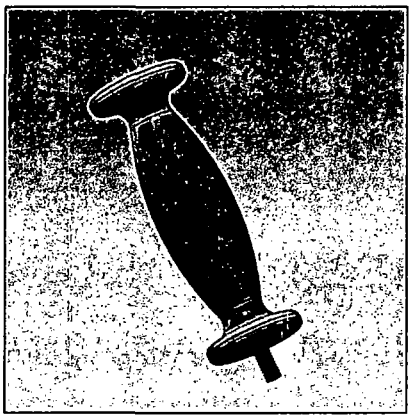


Curved Broach Handle Catalog No: 91-250-0007

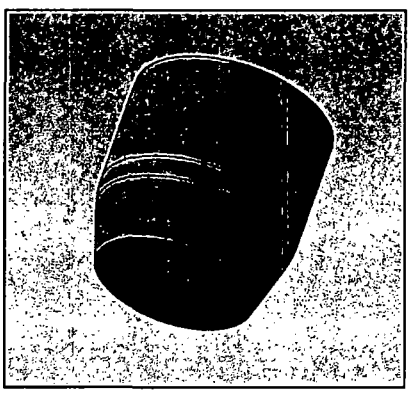


Offset Broach Handle, Left Catalog No: 91-250-0013

Offset Broach Handle, Right Catalog No: 91-250-0014

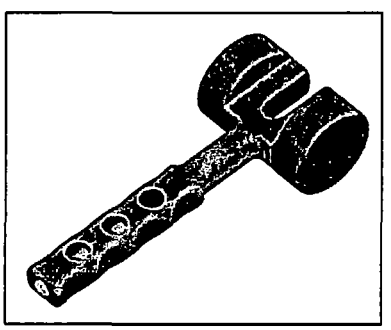


Femoral Head Impactor, Handle — Catalog No: 91-250-0001



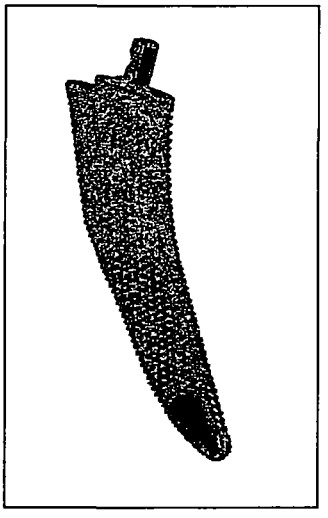
Femoral Head Impactor, Head — Catalog No: 91-250-0015

Femoral Head Impactor, Head, Large — Catalog No: 91-250-0016



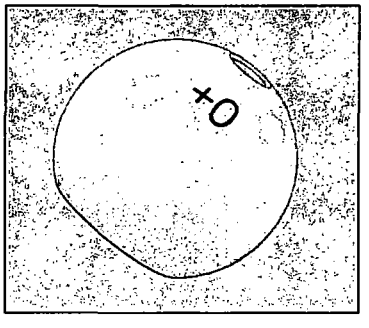
Slotted Mallet — Catalog No: 91-250-0010

Standard Offset Trial Neck		High Offset Trial Neck	
Size	Catalog No.	Size	Catalog No.
2-4	91-201-0100	2-4	91-201-0106
5-8	91-201-0500	5-8	91-201-0508
9-12	91-201-0900	9-12	91-201-0908



Femoral Broach

Size	Catalog No.	Size	Catalog No.
1	91-200-0100	7	91-200-0700
2	91-200-0200	8	91-200-0800
3	91-200-0300	9	91-200-0900
4	91-200-0400	10	91-200-1000
5	91-200-0500	11	91-200-1100
6	91-200-0600	12	91-200-1200



Femoral Head Trials

Size	22mm	28mm	32mm	36mm	40mm
-3.5		91-100-2893	91-100-3293	91-100-3693	91-100-4093
0	91-100-2200	91-100-2800	91-100-3200	91-100-3600	91-100-4000
+3.5	91-100-2203	91-100-2803	91-100-3203	91-100-3603	91-100-3603
+7		91-100-2807	91-100-3207	91-100-3607	91-100-4007
+10.5		91-100-2810	91-100-3210	91-100-3610	91-100-4010

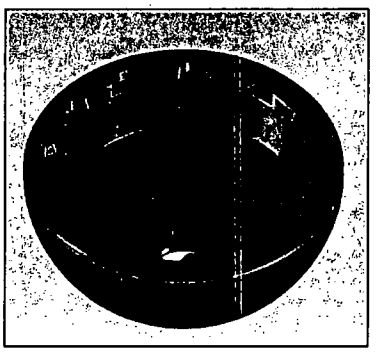
Version Bar 91-250-0020

Femoral Instrument Kit A Catalog No: 90-899-0001
- Contains Femoral Broaches, Femoral Neck Trials, Neck Resection Gude

Femoral Instrument Kit B Catalog No: 90-899-0002
- Contains Straight Femoral Broach Handles, Osteotome, IM Starter Reamer, T Handle, Canal Finder, Mallet, Femoral Head Trials, Calcar Planer, Femoral Stem Impactors

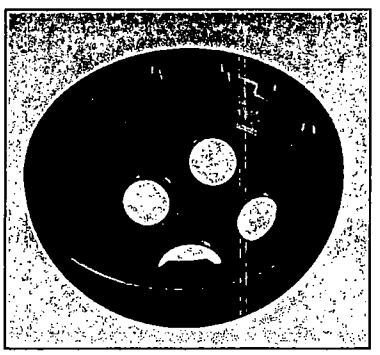
Femoral Instrument Kit C Catalog No: 90-899-0011
- Contains Offset and Curved Femoral Broach Handles, Mallet, Calcar Planer, Femoral Stem Impactors, Femoral Rasp

ACETABULAR CUP SYSTEM



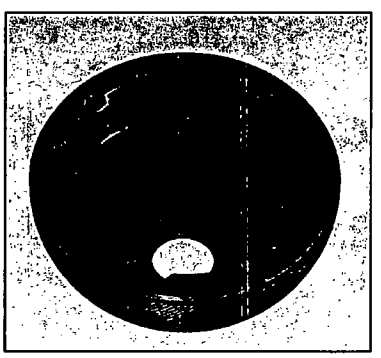
No-Hole PST (Porous Structured Technology) Acetabular Shell

OD (mm)	Catalog No.	OD (mm)	Catalog No.
44	12-120-0044	58	12-120-0058
46	12-120-0046	60	12-120-0060
48	12-120-0048	62	12-120-0062
50	12-120-0050	64	12-120-0064
52	12-120-0052	66	12-120-0066
54	12-120-0054	68	12-120-0068
56	12-120-0056	70	12-120-0070



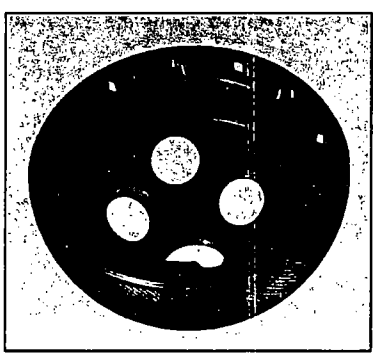
Cluster-Hole PST (Porous Structured Technology) Acetabular Shell

OD (mm)	Catalog No.	OD (mm)	Catalog No.
44	12-122-0044	58	12-122-0058
46	12-122-0046	60	12-122-0060
48	12-122-0048	62	12-122-0062
50	12-122-0050	64	12-122-0064
52	12-122-0052	66	12-122-0066
54	12-122-0054	68	12-122-0068
56	12-122-0056	70	12-122-0070



No-Hole PST Acetabular Shell with HA

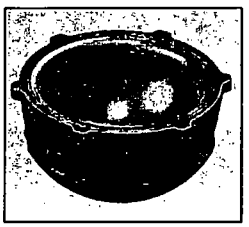
OD (mm)	Catalog No.	OD (mm)	Catalog No.
44	12-129-0044	58	12-129-0058
46	12-129-0046	60	12-129-0060
48	12-129-0048	62	12-129-0062
50	12-129-0050	64	12-129-0064
52	12-129-0052	66	12-129-0066
54	12-129-0054	68	12-129-0068
56	12-129-0056	70	12-129-0070

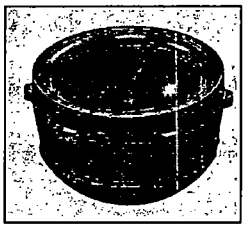


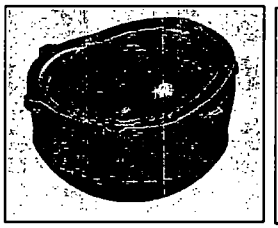
Cluster-Hole PST Acetabular Shell with HA

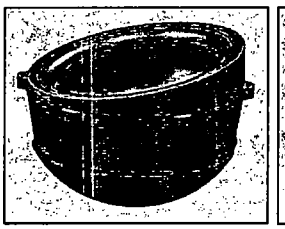
OD (mm)	Catalog No.	OD (mm)	Catalog No.
44	12-128-0044	58	12-128-0058
46	12-128-0046	60	12-128-0060
48	12-128-0048	62	12-128-0062
50	12-128-0050	64	12-128-0064
52	12-128-0052	66	12-128-0066
54	12-128-0054	68	12-128-0068
56	12-128-0056	70	12-128-0070

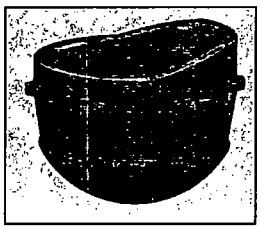
Acetabular Liner Highly Crosslinked Vitamin E UHMWPE


NEUTRAL


+4 OFFSET


HIGH WALL


+4, 10° Elevated

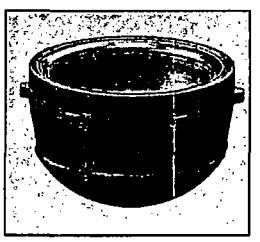

+4 Offset / High Wall

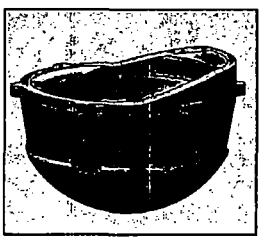
ID (mm)	OD (mm)	Neutral	+4 Offset	High Wall	+4 Offset/ 10° Elevated	+4 Offset / High Wall
28	44	12-270-2844	12-271-2844	12-272-2844	12-273-2844	12-274-2844
28	46	12-270-2846	12-271-2846	12-272-2846	12-273-2846	12-274-2846
28	48	12-270-2848	12-271-2848	12-272-2848	12-273-2848	12-274-2848
28	50	12-270-2850	12-271-2850	12-272-2850	12-273-2850	12-274-2850
28	52	12-270-2852	12-271-2852	12-272-2852	12-273-2852	12-274-2852
28	54	12-270-2854	12-271-2854	12-272-2854	12-273-2854	12-274-2854
28	56	12-270-2856	12-271-2856	12-272-2856	12-273-2856	12-274-2856
28	58/60	12-270-2858	12-271-2858	12-272-2858	12-273-2858	12-274-2858
28	62/64	12-270-2862	12-271-2862	12-272-2862	12-273-2862	12-274-2862
28	66/68/70	12-270-2866	12-271-2866	12-272-2866	12-273-2866	12-274-2866
32	48	12-270-3248	12-271-3248	12-272-3248	12-273-3248	12-274-3248
32	50	12-270-3250	12-271-3250	12-272-3250	12-273-3250	12-274-3250
32	52	12-270-3252	12-271-3252	12-272-3252	12-273-3252	12-274-3252
32	54	12-270-3254	12-271-3254	12-272-3254	12-273-3254	12-274-3254
32	56	12-270-3256	12-271-3256	12-272-3256	12-273-3256	12-274-3256
32	58/60	12-270-3258	12-271-3258	12-272-3258	12-273-3258	12-274-3258
32	62/64	12-270-3262	12-271-3262	12-272-3262	12-273-3262	12-274-3262
32	66/68/70	12-270-3266	12-271-3266	12-272-3266	12-273-3266	12-274-3266

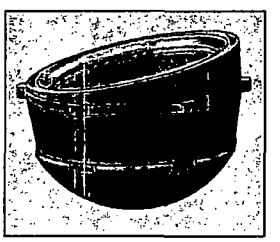
36	52	12-270-3652	12-271-3652	12-272-3652	12-273-3652	12-274-3652
36	54	12-270-3654	12-271-3654	12-272-3654	12-273-3654	12-274-3654
36	56	12-270-3656	12-271-3656	12-272-3656	12-273-3656	12-274-3656
36	58/60	12-270-3658	12-271-3658	12-272-3658	12-273-3658	12-274-3658
36	62/64	12-270-3662	12-271-3662	12-272-3662	12-273-3662	12-274-3662
36	66/68/70	12-270-3666	12-271-3666	12-272-3666	12-273-3666	12-274-3666
40	56	12-270-4056	12-271-4056	12-272-4056	12-273-4056	12-274-4056
40	58/60	12-270-4058	12-271-4058	12-272-4058	12-273-4058	12-274-4058
40	62/64	12-270-4062	12-271-4062	12-272-4062	12-273-4062	12-274-4062
40	66/68/70	12-270-4066	12-271-4066	12-272-4066	12-273-4066	12-274-4066

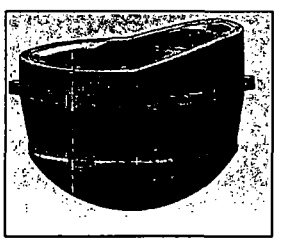
Acetabular Liner Standard UHMWPE


NEUTRAL


+4 OFFSET

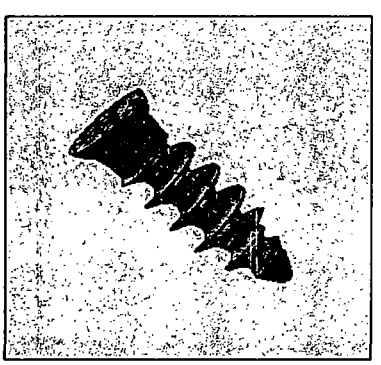

HIGH WALL


+4 10˚ Elevated


+4 Offset/ High Wall

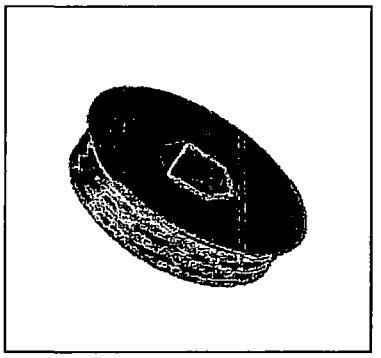
ID (mm)	OD (mm)	Neutral	+4 Offset	High Wall	+4 Offset/ 10˚ Elevated	+4 Offset / High Wall
22	44	12-290-2244	12-291-2244	12-292-2244	12-293-2244	12-294-2244
22	46	12-290-2246	12-291-2246	12-292-2246	12-293-2246	12-294-2246
22	48	12-290-2248	12-291-2248	12-292-2248	12-293-2248	12-294-2248
22	50	12-290-2250	12-291-2250	12-292-2250	12-293-2250	12-294-2250
22	52	12-290-2252	12-291-2252	12-292-2252	12-293-2252	12-294-2252
22	54	12-290-2254	12-291-2254	12-292-2254	12-293-2254	12-294-2254
22	56	12-290-2256	12-291-2256	12-292-2256	12-293-2256	12-294-2256
22	58/60	12-290-2258	12-291-2258	12-292-2258	12-293-2258	12-294-2258

22	62/64	12-290-2262	12-291-2262	12-292-2262	12-293-2262	12-294-2262
22	66/68/70	12-290-2266	12-291-2266	12-292-2266	12-293-2266	12-294-2266
28	44	12-290-2844	12-291-2844	12-292-2844	12-293-2844	12-294-2844
28	46	12-290-2846	12-291-2846	12-292-2846	12-293-2846	12-294-2846
28	48	12-290-2848	12-291-2848	12-292-2848	12-293-2848	12-294-2848
28	50	12-290-2850	12-291-2850	12-292-2850	12-293-2850	12-294-2850
28	52	12-290-2852	12-291-2852	12-292-2852	12-293-2852	12-294-2852
28	54	12-290-2854	12-291-2854	12-292-2854	12-293-2854	12-294-2854
28	56	12-290-2856	12-291-2856	12-292-2856	12-293-2856	12-294-2856
28	58/60	12-290-2858	12-291-2858	12-292-2858	12-293-2858	12-294-2858
28	62/64	12-290-2862	12-291-2862	12-292-2862	12-293-2862	12-294-2862
28	66/68/70	12-290-2866	12-291-2866	12-292-2866	12-293-2866	12-294-2866
32	48	12-290-3248	12-291-3248	12-292-3248	12-293-3248	12-294-3248
32	50	12-290-3250	12-291-3250	12-292-3250	12-293-3250	12-294-3250
32	52	12-290-3252	12-291-3252	12-292-3252	12-293-3252	12-294-3252
32	54	12-290-3254	12-291-3254	12-292-3254	12-293-3254	12-294-3254
32	56	12-290-3256	12-291-3256	12-292-3256	12-293-3256	12-294-3256
32	58/60	12-290-3258	12-291-3258	12-292-3258	12-293-3258	12-294-3258
32	62/64	12-290-3262	12-291-3262	12-292-3262	12-293-3262	12-294-3262
32	66/68/70	12-290-3266	12-291-3266	12-292-3266	12-293-3266	12-294-3266

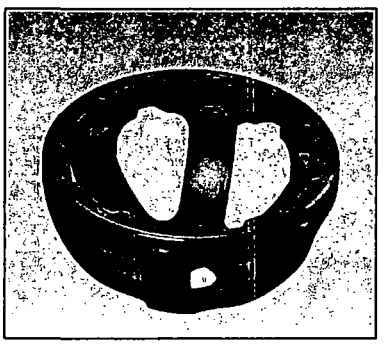


Acetabular Bone Screw, Self Tapping, 6.5mm Dia.

Length	Catalog No.	Length	Catalog No.
15mm	12-250-6515	40mm	12-250-6540
20mm	12-250-6520	45mm	12-250-6545
25mm	12-250-6525	50mm	12-250-6550
30mm	12-250-6530	55mm	12-250-6555
35mm	12-250-6535	60mm	12-250-6560

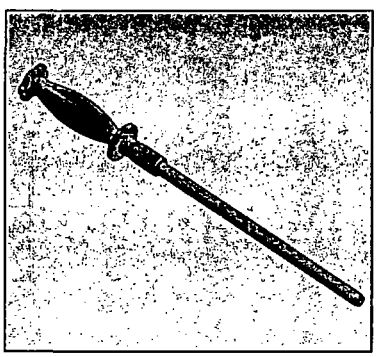


Dome Hole Occluder — Catalog No: 12-251-0001

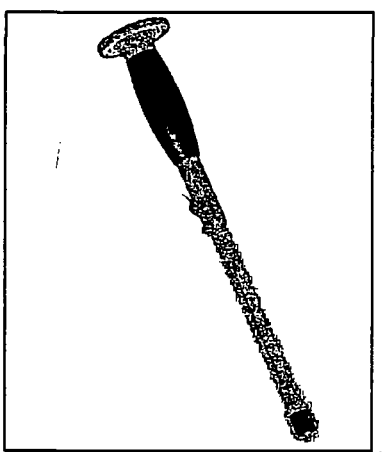


Acetabular Shell Trials

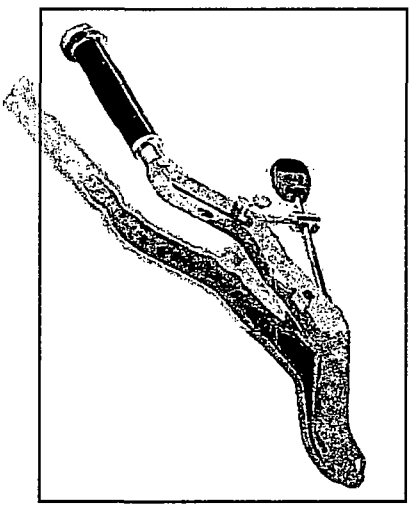
OD (mm)	Catalog No.	OD (mm)	Catalog No.
44	92-120-0044	58	92-120-0058
46	92-120-0046	60	92-120-0060
48	92-120-0048	62	92-120-0062
50	92-120-0050	64	92-120-0064
52	92-120-0052	66	92-120-0066
54	92-120-0054	68	92-120-0068
56	92-120-0056	70	92-120-0070



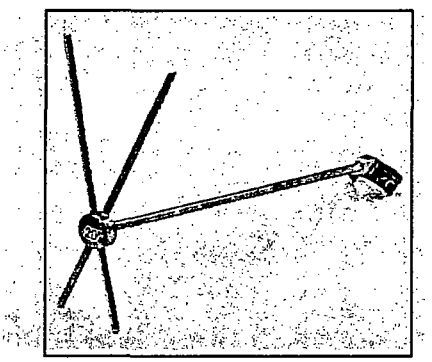
Straight Shell Impactor — Catalog No: 92-140-0000



Straight Shell Inserter — Catalog No: 92-140-0012

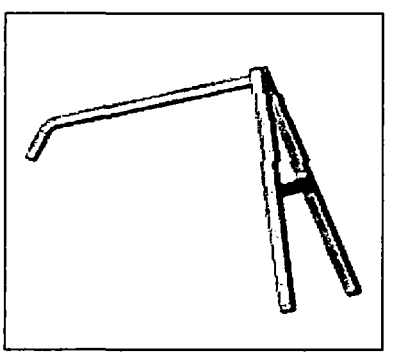


Offset Shell Impactor Catalog No: 92-140-0001

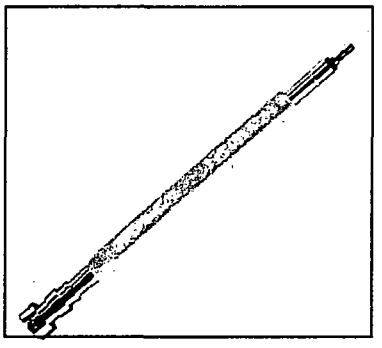


Shell Alignment Guide Catalog No: 92-140-0007
(For use with Straight Shell Inserter & Impactor and Offset Shell Impactor)

Alignment Guide Collet Catalog No: 92-140-0013
(For use with A-Frame Alignment Guide and Shell Impactors and Inserters)

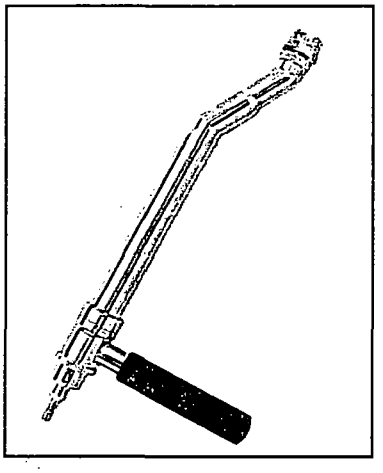


A-Frame Shell Alignment Guide Catalog No: 92-140-0005

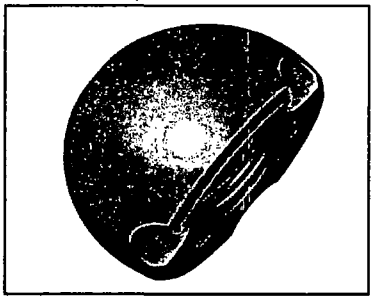


Straight Shell Reamer Handle Catalog No: 92-140-0002

Straight Shell Reamer Handle Sleeve Catalog No: 92-140-0014

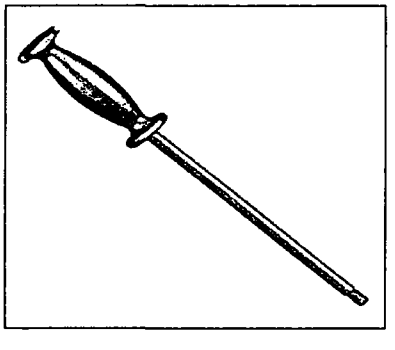


Offset Shell Reamer Handle Catalog No: 92-140-0003



Poly Liner Impactor Heads *(For use with Poly Liner Impactor Handle)*

OD	Catalog No.
22mm	92-140-0022
28mm	92-140-0028
32mm	92-140-0032
36mm	92-140-0036
40mm	92-140-0040

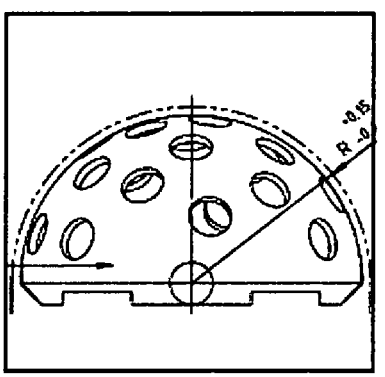


Poly Liner Impactor Handle Catalog No: 92-140-0008
(For use with Poly Liner Impactor Heads)

Acetabular Liner Trials

ID	OD	Neutral	+4 Offset	High Wall	+4 Offset / 10˚ Elevated	+4 Offset/ High Wall
22	44	92-270-2244	92-271-2244	92-272-2244	92-273-2244	92-274-2244
22	46	92-270-2246	92-271-2246	92-272-2246	92-273-2246	92-274-2246
22	48	92-270-2248	92-271-2248	92-272-2248	92-273-2248	92-274-2248
22	50	92-270-2250	92-271-2250	92-272-2250	92-273-2250	92-274-2250
22	52	92-270-2252	92-271-2252	92-272-2252	92-273-2252	92-274-2252
22	54	92-270-2254	92-271-2254	92-272-2254	92-273-2254	92-274-2254
22	56	92-270-2256	92-271-2256	92-272-2256	92-273-2256	92-274-2256
22	58/60	92-270-2258	92-271-2258	92-272-2258	92-273-2258	92-274-2258
22	62/64	92-270-2262	92-271-2262	92-272-2262	92-273-2262	92-274-2262
22	66/68/70	92-270-2266	92-271-2266	92-272-2266	92-273-2266	92-274-2266
28	44	92-270-2844	92-271-2844	92-272-2844	92-273-2844	92-274-2844
28	46	92-270-2846	92-271-2846	92-272-2846	92-273-2846	92-274-2846
28	48	92-270-2848	92-271-2848	92-272-2848	92-273-2848	92-274-2848
28	50	92-270-2850	92-271-2850	92-272-2850	92-273-2850	92-274-2850
28	52	92-270-2852	92-271-2852	92-272-2852	92-273-2852	92-274-2852
28	54	92-270-2854	92-271-2854	92-272-2854	92-273-2854	92-274-2854
28	56	92-270-2856	92-271-2856	92-272-2856	92-273-2856	92-274-2856
28	58/60	92-270-2858	92-271-2858	92-272-2858	92-273-2858	92-274-2858
28	62/64	92-270-2864	92-271-2864	92-272-2864	92-273-2864	92-274-2864
28	66/68/70	92-270-2866	92-271-2866	92-272-2866	92-273-2866	92-274-2866
32	48	92-270-3248	92-271-3248	92-272-3248	92-273-3248	92-274-3248
32	50	92-270-3250	92-271-3250	92-272-3250	92-273-3250	92-274-3250

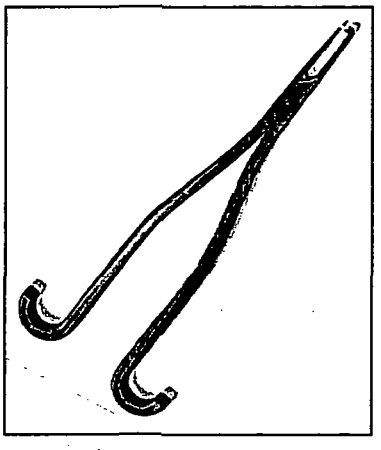
32	52	92-270-3252	92-271-3252	92-272-3252	92-273-3252	92-274-3252
32	54	92-270-3254	92-271-3254	92-272-3254	92-273-3254	92-274-3254
32	56	92-270-3256	92-271-3256	92-272-3256	92-273-3256	92-274-3256
32	58/60	92-270-3258	92-271-3258	92-272-3258	92-273-3258	92-274-3258
32	62/64	92-270-3262	92-271-3262	92-272-3262	92-273-3262	92-274-3262
32	66/68/70	92-270-3266	92-271-3266	92-272-3266	92-273-3266	92-274-3266
36	52	92-270-3652	92-271-3652	92-272-3652	92-273-3652	92-274-3652
36	54	92-270-3654	92-271-3654	92-272-3654	92-273-3654	92-274-3654
36	56	92-270-3656	92-271-3656	92-272-3656	92-273-3656	92-274-3656
36	58/60	92-270-3658	92-271-3658	92-272-3658	92-273-3658	92-274-3658
36	62/64	92-270-3662	92-271-3662	92-272-3662	92-273-3662	92-274-3662
36	66/68/70	92-270-3666	92-271-3666	92-272-3666	92-273-3666	92-274-3666
40	56	92-270-4056	92-271-4056	92-272-4056	92-273-4056	92-274-4056
40	58/60	92-270-4058	92-271-4058	92-272-4058	92-273-4058	92-274-4058
40	62/64	92-270-4062	92-271-4062	92-272-4062	92-273-4062	92-274-4062
40	66/68/70	92-270-4066	92-271-4066	92-272-4066	92-273-4066	92-274-4066



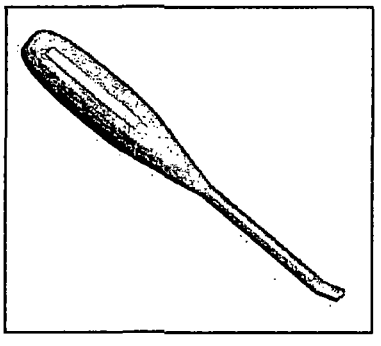
Reamer Baskets *(For use with Straight and Offset Reamer Handles)*

OD	Catalog No.	OD	Catalog No.
40mm	92-180-0040	55mm	92-180-0055
41mm	92-180-0041	56mm	92-180-0056
42mm	92-180-0042	57mm	92-180-0057
43mm	92-180-0043	58mm	92-180-0058
44mm	92-180-0044	59mm	92-180-0059
45mm	92-180-0045	60mm	92-180-0060
46mm	92-180-0046	61mm	92-180-0061
47mm	92-180-0047	62mm	92-180-0062
48mm	92-180-0048	63mm	92-180-0063
49mm	92-180-0049	64mm	92-180-0064
50mm	92-180-0050	65mm	92-180-0065
51mm	92-180-0051	66mm	92-180-0066

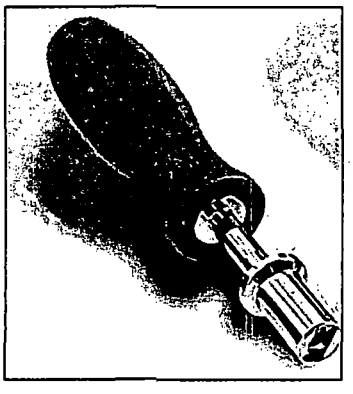
52mm	92-180-0052	67mm	92-180-0067
53mm	92-180-0053	68mm	92-180-0068
54mm	92-180-0054	69mm	92-180-0069
		70mm	92-180-0070



Liner Extractor Catalog No: 92-140-0009

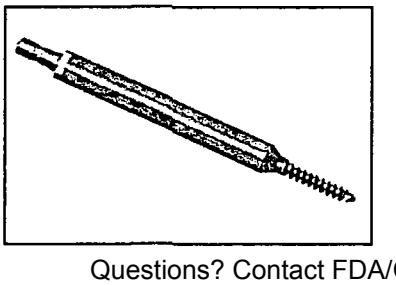


Rim Liner Extractor Catalog No: 92-140-0010



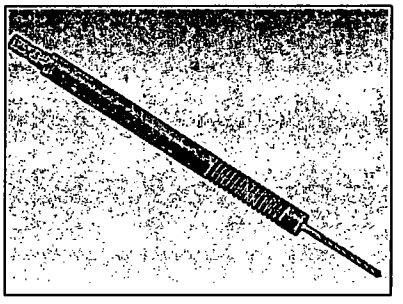
Screwdriver Handle Catalog No: 92-255-0002

(For use with Threaded Liner Extractor, Straight and Flexible Drill Bits, Straight and Flexible Drill Shafts, Straight and Hex Drivers)



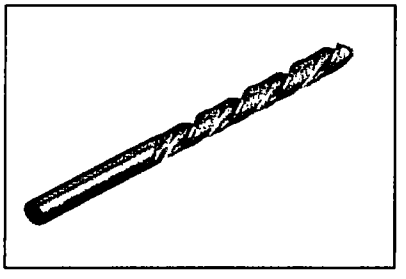
Threaded Liner Extractor Catalog No: 92-140-0011

(For use with Screwdriver Handle)



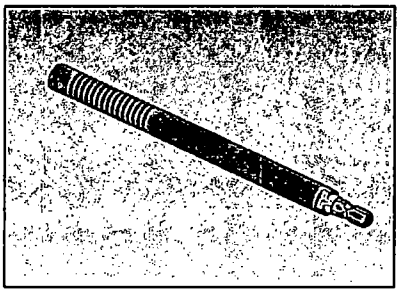
Flexible Drill Bit *(For use with Screwdriver Handle)*

3.2 dia. x 15mm	Catalog No: 92-256-3215
3.2 dia. x 30mm	Catalog No: 92-256-3230
3.2 dia. x 45mm	Catalog No: 92-256-3245
3.2 dia. x 60mm	Catalog No: 92-256-3260

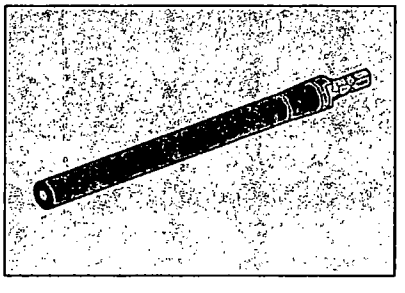


Modular Drill Bit *(For use with Flexible and Straight Drill Shafts)*

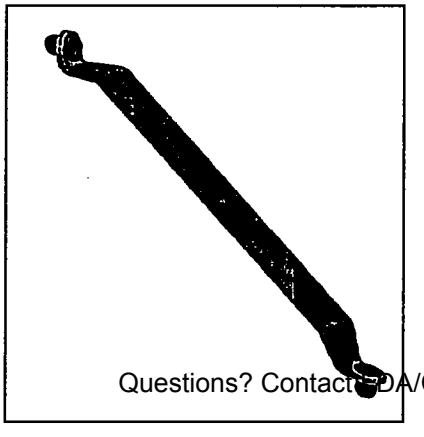
3.2 dia. x 15mm	Catalog No: 92-255-3215
3.2 dia. x 30mm	Catalog No: 92-255-3230
3.2 dia. x 45mm	Catalog No: 92-255-3245
3.2 dia. x 60mm	Catalog No: 92-255-3260



Flexible Drill Shaft Catalog No: 92-255-0005
(For use with Screwdriver Handle and Modular Bit)



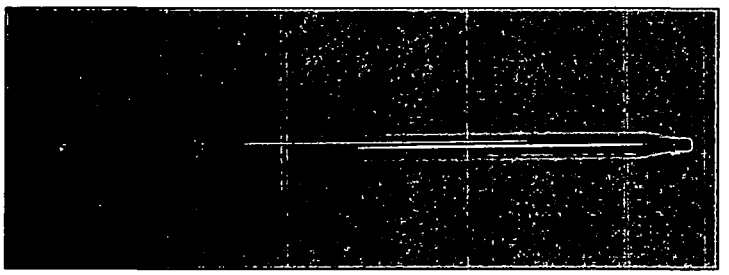
Straight Drill Shaft Catalog No: 92-255-0015
(For use with Screwdriver Handle and Modular Bit)



Drill Guide Catalog No: 92-255-0009

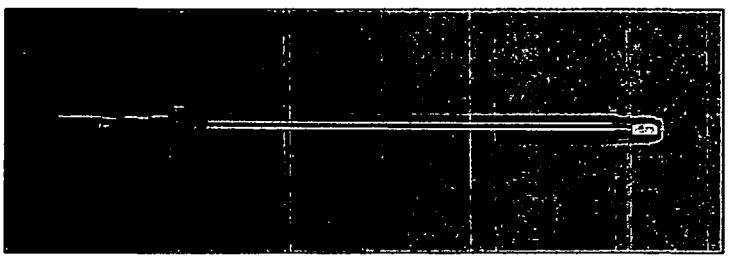
3.5mm Hex Driver, Straight
(For use with Screwdriver Handle)

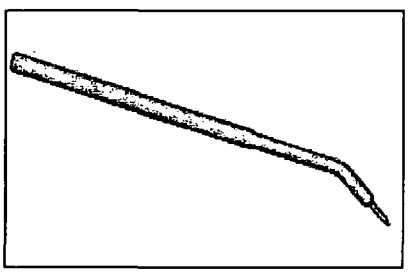
Catalog No: 92-255-0000



3.5mm Universal Hex Driver
(For use with Screwdriver Handle)

Catalog No: 92-255-0001



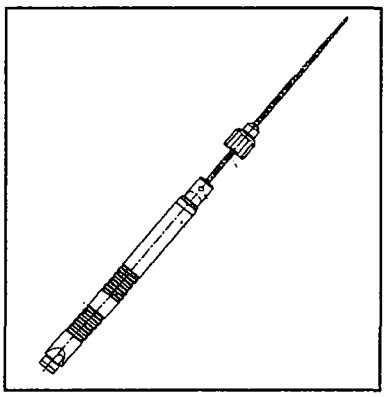


Screw Hole Punch

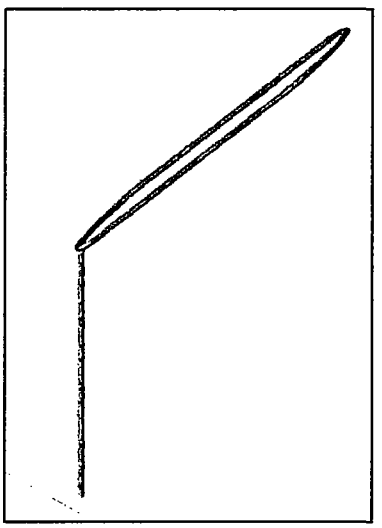
Catalog No: 92-255-0013

Screw Holding Forceps

Catalog No: 92-255-0006



Depth Gauge Catalog No: 92-255-0008



Depth Gauge Wire Catalog No: 92-255-0012

Acetabular Instrument Tray, Standard Reamers Catalog No: 90-899-0003

Acetabular Instrument Tray, Core Instruments Catalog No: 90-899-0004

- Contains Cup Impactors, Reamer Handles, Liner Impactors, Liner Extractors, All Drill Bits, Screwdriver Handle, All Drill Shafts and Guide, Screw Hole Punch, All Hex Drivers, Screw Holding Forceps, Depth Gauge

Acetabular Instrument Tray, Core Trials Catalog No: 90-899-0005

- Standard Trial Shells, 32mm & 36mm Neutral and +4 Offset High Wall Trials

Acetabular Instrument Tray, Small Shells Catalog No: 90-899-0006

- Small Trial Shells and Reamers, 28mm Neutral and +4 Offset High Wall Trials

Acetabular Instrument Tray Insert, Large Shells Catalog No: 90-899-0007

- Large Trial Shells and Reamers, some 36mm Neutral and +4 Offset High Wall Trials

Liner Instrument Tray, Optional Trial Set A Catalog No: 90-899-0008

- All sizes High Wall Liner Trials

Liner Instrument Tray, Optional Trial Set B — Catalog No: 90-899-0009

- All sizes +4 Offset / 10 Degree Elevated Liner Trials

Liner Instrument Tray, Optional Trial Set C — Catalog No: 90-899-0011

- All sizes +4 Offset Liner Trials

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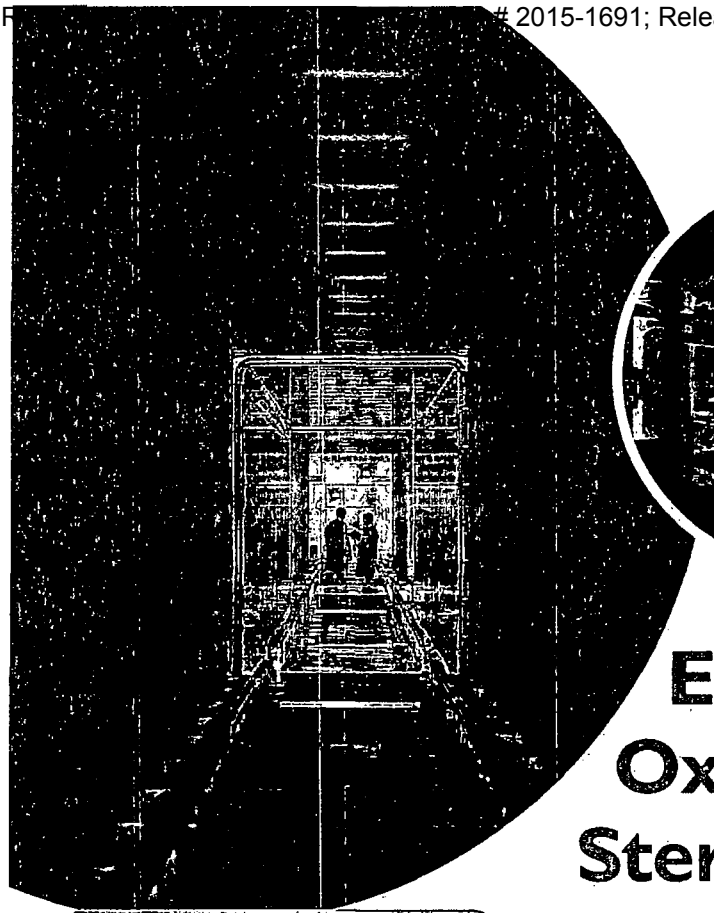

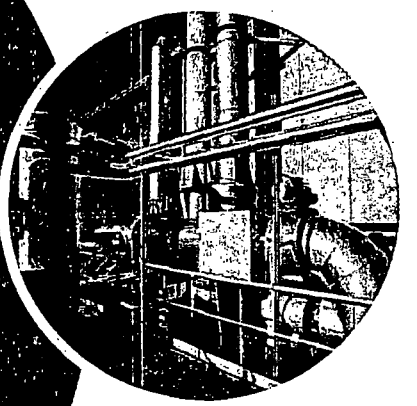

Ethylene Oxide Sterilisation

The Isotron EtO processing service offers customers:

- Flexible solutions to meet small and large volumes
- Unrivalled technical & regulatory expertise
- Safe & environmentally friendly facilities
- Efficient and cost effective processes

Isotron provide regulatory compliant and cost effective Ethylene Oxide sterilisation solutions for the healthcare industry.

The treatment of medical devices by Ethylene Oxide (EtO) has been one of the principal methods of sterilisation in the healthcare industry since 1960s. Today with technical advancements and increasing regulatory demands the requirements for a stable, reliable and compliant partner is critical.

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Designation: F1472 – 08ε1

Standard Specification for Wrought Titanium-6Aluminum-4Vanadium Alloy for Surgical Implant Applications (UNS R56400)[1]

This standard is issued under the fixed designation F1472; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

ε1 NOTE—Editorially corrected the ISO 5832–3 designation throughout in December 2008.

1. Scope*

1.1 This specification covers the chemical, mechanical, and metallurgical requirements for wrought annealed titanium-6aluminum-4vanadium alloy (UNS R56400) to be used in the manufacture of surgical implants.

1.2 The values stated in inch-pound units are to be regarded as standard. The values given in parentheses are mathematical conversions to SI units that are provided for information only and are not considered standard.

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E8 Test Methods for Tension Testing of Metallic Materials

E29 Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications

E290 Test Methods for Bend Testing of Material for Ductility

E527 Practice for Numbering Metals and Alloys in the Unified Numbering System (UNS)

E1409 Test Method for Determination of Oxygen and Nitrogen in Titanium and Titanium Alloys by the Inert Gas Fusion Technique

E1447 Test Method for Determination of Hydrogen in Titanium and Titanium Alloys by Inert Gas Fusion Thermal Conductivity/Infrared Detection Method

E2371 Test Method for Analysis of Titanium and Titanium Alloys by Atomic Emission Plasma Spectrometry

2.2 *ASQ Standard:*[3]

ASQ C1 Specifications of General Requirements for a Quality Program

[1] This specification is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.12 on Metallurgical Materials.

Current edition approved Oct. 1, 2008. Published October 2008. Originally published in 1993. Last previous edition approved in 2002 as F1472 – 02a. DOI: 10.1520/F1472-08E01.

[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203, http://www.asq.org.

***A Summary of Changes section appears at the end of this standard.**

2.3 *Aerospace Material Specifications:*[4]

AMS 2249 Chemical Check Analysis Limits, Titanium and Titanium Alloys

AMS 4911 Titanium Alloy Sheet, Strip, and Plate 6Al-4V Annealed

AMS 4928 Titanium Alloy Bars, Wire, Forgings, Rings, and Drawn Shapes 6Al-4V Annealed

AMS 4965 Titanium Alloy, Bars, Wire, Forgings, and Rings 6.0Al-4.0V Solution Heat Treated and Aged

2.4 *ISO Standards:*[5]

ISO 5832-3 Implants for Surgery—Metallic Materials—Part 3, Wrought Titanium-6Aluminum-4Vanadium Alloy

ISO 9001 Quality Management Systems—Requirements

2.5 *Society of Automotive Engineers Standard:*[4, 6]

SAE J1086 Practice for Numbering Metals and Alloys (UNS)

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.2 *lot, n*—the total number of mill products produced from one heat under the same conditions at essentially the same time.

4. Product Classification

4.1 *Strip*—Any product under 0.188 in. (4.76 mm) in thickness and under 24 in. (610 mm) wide.

4.2 *Sheet*—Any product under 0.188 in. (4.76 mm) in thickness and 24 in. (610 mm) or more in width.

4.3 *Plate*—Any product 0.188 in. (4.76 mm) thick and over and 10 in. (254 mm) wide and over, with widths greater than five times thickness. Plate up to 4.00 in. (102 mm) thick, inclusive, is covered by this specification.

4.4 *Bar*—Round bars and flats from 0.188 in. (4.76 mm) to 4.00 in. (102 mm) in diameter or thickness (other sizes and shapes by special order).

4.5 *Forging Bar*—Bar as described in 4.4, used in the production of forgings. This product may be furnished in the hot worked condition.

4.6 *Wire*—Rounds, flats, or other shapes less than 0.188 in. (4.76 mm) in diameter or thickness.

5. Ordering Information

5.1 Include with inquiries and orders for material under this specification the following information:

5.1.1 Quantity,

5.1.2 ASTM designation and date of issue,

5.1.3 Form (strip, sheet, plate, bar, forging bar, or wire),

5.1.4 Condition (see 6.3),

5.1.5 Mechanical properties (if applicable, for special conditions),

5.1.6 Finish (see 6.2),

5.1.7 Applicable dimensions including size, thickness, width, length, or drawing number,

5.1.8 Special tests, if any, and

5.1.9 Other requirements.

6. Materials and Manufacture

6.1 The various titanium mill products covered in this specification normally are formed with the conventional forging and rolling equipment found in primary ferrous and nonferrous plants. The alloy is usually multiple melted in arc furnaces (including furnaces such as plasma arc and electron beam) of a type conventionally used for reactive metals.

6.2 *Finish*—The mill product may be furnished to the purchaser as mechanically descaled or pickled, sandblasted, chemically milled, ground, machined, peeled, polished, combinations of these operations, or as specified by the purchaser. On billets, bars, plates, and forgings, it is permissible to remove minor surface imperfections by grinding if the resultant area meets the dimensional and surface finish requirements of this specification.

6.3 *Condition*—Material shall be furnished in the annealed or cold-worked condition.

7. Chemical Requirements

7.1 The heat analysis shall conform to the chemical composition of Table 1. Ingot analysis may be used for reporting all chemical requirements, except hydrogen. Samples for hydrogen shall be taken from the finished mill product. Supplier shall not ship material with chemistry outside the requirements specified in Table 1.

7.1.1 Requirements for the major and minor elemental constituents are listed in Table 1. Also listed are important residual elements. Analysis for elements not listed in Table 1 is not required to verify compliance with this specification.

7.2 *Product Analysis*:

7.2.1 Product analysis tolerances do not broaden the specified heat analysis requirements but cover variations in the measurement of chemical content between laboratories. The product analysis tolerances shall conform to the product tolerances in Table 2.

7.2.2 The product analysis is either for the purpose of verifying the composition of a heat or manufacturing lot or for determining variations in the composition within the heat.

7.2.3 Acceptance or rejection of a heat or manufacturing lot of material may be made by the purchaser on the basis of this product analysis. Product analyses outside the tolerance limits

TABLE 1 Chemical Requirements[A]

Element	Composition, %
Nitrogen, max	0.05
Carbon, max	0.08
Hydrogen, max[B]	0.015
Iron, max	0.30
Oxygen, max	0.20
Aluminum	5.5–6.75
Vanadium	3.5–4.5
Yttrium, max	0.005
Titanium[C]	balance

[A] Refer to AMS 4928.

[B] Billets shall have a maximum of 0.01 % hydrogen content.

[C] The percentage of titanium is determined by difference and need not be determined or certified.

[4] Available from Society of Automotive Engineers (SAE), 400 Commonwealth Dr., Warrendale, PA 15096-0001, http://www.sae.org.

[5] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

[6] New designation established in accordance with E527 and SAE J1086.

TABLE 2 Product Analysis Tolerance[A]

Element	Tolerance Under the Minimum or Over the Maximum Limit (Composition %)[B]
Nitrogen	0.02
Carbon	0.02
Hydrogen	0.002
Iron	0.10
Oxygen	0.02
Aluminum	0.40
Vanadium	0.15
Yttrium	0.0006

[A] See AMS 2249.
[B] Under minimum limit not applicable for elements where only a minimum percentage is indicated.

allowed in Table 2 are cause for rejection of the product. A referee analysis may be used if agreed upon by supplier and purchaser.

7.2.4 For referee purposes, use Test Methods E1409, E1447, and E2371 or other analytical methods agreed upon between the purchaser and the supplier.

7.3 Samples for chemical analysis shall be representative of the material being tested. The utmost care must be used in sampling titanium for chemical analysis because of its affinity for elements such as oxygen, nitrogen, and hydrogen. In cutting samples for analysis, therefore, the operation should be carried out insofar as possible in a dust-free atmosphere. Cutting tools should be clean and sharp. Samples for analysis should be stored in suitable containers.

8. Mechanical Requirements

8.1 The material supplied under this specification shall conform to the mechanical property requirements in Table 3. Alternative properties may be agreed upon between the purchaser and supplier.

8.2 Specimens for tension tests shall be machined and tested in accordance with Test Methods E8. Tensile properties shall be determined using a strain rate of 0.003 to 0.007 in./in./min (mm/mm/min) through yield and then the crosshead speed may be increased so as to produce fracture in approximately one additional minute.

8.3 For sheet and strip, the bend test specimen shall withstand being bent cold through an angle of 105° without fracture in the outside surface of the bent portion. The bend shall be made over a mandrel with a diameter equal to that shown in Table 3. Test conditions shall conform to Test Method E290.

8.4 *Number of Tests*:

8.4.1 *Bar, Forging Bar, Shapes, and Wire*—Perform at least one tension test from each lot in the longitudinal direction. Should any of these test specimens not meet the specified requirements, test two additional test pieces representative of the same lot, in the same manner, for each failed test specimen. The lot will be considered in compliance only if both additional test pieces meet the specified requirements.

8.4.2 Tensile tests results for which any specimen fractures outside the gage length shall be considered acceptable, if both the elongation and reduction of area meet the minimum requirements specified. Refer to Sections 7.11.4 and 7.12.5 of Test Methods E8. If either the elongation or reduction of area is less than the minimum requirement, discard the test and retest. Retest one specimen for each specimen that did not meet the minimum requirements.

8.4.3 *Sheet, Strip, and Plate*—Perform at least one tension test from each lot in the longitudinal direction. Perform at least one bend test from each lot in both the longitudinal and transverse directions. Tests in the transverse direction need be made only on product from which a specimen not less than 8.0 in. (200 mm) in length for sheet and 2.50 in. (64 mm) in length for plate can be taken. Should any of these test pieces not meet the specified requirements, test two additional test pieces representative of the same lot, in the same manner, for each failed test specimen. The lot shall be considered in compliance only if both additional test pieces meet the specified requirements.

TABLE 3 Annealed Mechanical Properties[A]

Size, Nominal Diameter or Distance Between Parallel Sides, in. (mm)	Tensile Strength,[B] psi, (MPa), min	Yield Strength,[B] at 0.2 % Offset, psi (MPa), min	Elongation[C] in 2 in. (50 mm), or 4D or 4T, %, min			Reduction of Area, %, min[D]		
			L	LT[E]	ST[E,F]	L	LT[E]	ST[E,F]
Bars and Forgings:								
Up to 2.0 (50), incl	135 000 (930)	125 000 (860)	10	...	...	25	...	...
Over 2.0 to 4.0 (50 to 100), incl	130 000 (895)	120 000 (825)	10	10	10	25	20	15
Over 4.0 to 6.0 (100 to 150), incl	130 000 (895)	120 000 (825)	10	10	8	20	15	15
Sheet, Strip, and Plate:								
Up to 0.008 (0.2), excl	134 000 (924)	126 000 (869)	...	...	...	...	...	...
0.008 to 0.025 (0.2 to 0.6), excl	134 000 (924)	126 000 (869)	6	...	...	...	...	...
0.025 to 0.063 (0.6 to 1.6), excl	134 000 (924)	126 000 (869)	8	...	...	...	...	...
0.063 to 0.1875 (1.6 to 4.8), excl	134 000 (924)	126 000 (869)	10	...	...	...	...	...
0.1875 to 4.00 (4.8 to 101.6), incl	130 000 (895)	120 000 (825)	10	10	10	20	20	15
Bending Parameters:								
Up to 0.07 (1.875), incl			bend factor[G] = 9T					
Over 0.07 to 0.1875 (4.8), excl			bend factor[G] = 10T					

[A] Mechanical properties for conditions other than those listed in this table may be established by agreement between the supplier and the purchaser.
[B] Tensile and yield strength requirements apply in both the longitudinal and transverse directions.
[C] Elongation of material 0.062 in. (1.575 mm) or greater in diameter or thickness shall be measured using a gage length of 2 in. or 4D or 4T. Elongation of material under 0.062 in. in diameter or thickness may be obtained by negotiation.
[D] Applies to bar, plate, and forgings only. L = longitudinal; LT = long transverse; ST = short transverse.
[E] Transverse requirements in Table 3 apply only to product from which a tensile specimen not less than 2.50 in. (63.5 mm) in length can be obtained.
[F] Material tested in the short transverse direction need not be tested in the long transverse direction.
[G] Bend test applicable to sheet and strip products: T = thickness of bend specimen in reference to diameter of bend. (Bend factor is the mandrel diameter.)

9. Special Requirements

9.1 The microstructure shall be a fine dispersion of the alpha and beta phases resulting from processing in the alpha plus beta field. There shall be no continuous alpha network at prior beta grain boundaries. There shall be no coarse, elongated alpha platelets.

9.2 Determine the beta transus temperature for each heat by a suitable method and report on the material certification if required by the purchaser.

9.3 Alpha case is not permitted for products supplied with a machined, ground, or chemically milled surface finish. For other products, there will be no continuous layer of alpha case when examined at 100× magnification.

10. Significance of Numerical Limits

10.1 The following applies to all specified numerical limits in this specification. To determine conformance to these limits, an observed or calculated value shall be rounded to the nearest unit in the last right hand digit used in expressing the specification limit, in accordance with the rounding method of Practice E29.

11. Certification

11.1 The supplier shall provide a certification that the material was tested in accordance with this specification and met all requirements. A report of the test results shall be furnished to the purchaser at the time of shipment.

12. Quality Program Requirements

12.1 The supplier shall maintain a quality program such as defined in ASQ C1, ISO 9001, or similar.

13. Keywords

13.1 metals (for surgical implants); orthopaedic medical devices; titanium alloys; titanium alloys (for surgical implants)

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 The purpose of this specification is to characterize the chemical, physical, mechanical, and metallurgical properties of wrought annealed titanium-6aluminum-4vanadium alloy to be used in the manufacture of surgical implants.

X1.2 The alloy composition covered by this specification has been used successfully in human implants, exhibiting a well-characterized level of local biological response since 1983. **(1, 2)**.[7]

X1.3 This alloy exhibits similar mechanical properties to Specification F136 required for the application of load-bearing orthopedic implants **(2-18)**.

X1.4 This titanium base alloy, UNS R56400, has been used extensively in the aerospace industry since the 1950's. Aerospace Material Specification AMS 4928 includes the chemical and mechanical properties for Titanium Alloy Bars, Wire, Forgings, Rings, and Drawn Shapes 6Al-4V Annealed. Aerospace Material Specification AMS 4911 includes the chemical and mechanical properties for Titanium Alloy Sheet, Strip, and Plate 6Al-4V Annealed. ISO 5832–3, Implants for surgery–Metallic materials–Part 3: Wrought titanium 6-aluminium4-vanadium alloy also describes titanium base alloy UNS R56400.

X1.5 This alloy can be solution treated and aged to achieve different properties according to, for example, AMS 4965 Titanium Alloy, Bars, Wire, Forgings, and Rings 6.0Al-4.0V Solution Heat Treated and Aged.

[7] The boldface numbers refer to references listed at the end of this standard.

X2. BIOCOMPATIBILITY

X2.1 The material composition covered by this specification has been used successfully in contact with soft tissue and bone since 1983 **(12)**.

X2.2 No known surgical implant material has ever been shown to be completely free from adverse reactions in the human body. Long-term clinical experience of the use of the material referred to in this specification, however, has shown that an acceptable level of biological response can be expected, if the material is used in appropriate applications.

X2.3 The material in this specification has been subjected to animal studies and has been shown to produce a well-characterized level of biological response that is equal to or less than that produced by the reference material titanium. This material has been used clinically since 1983 **(1, 2, 19)**.

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SUMMARY OF CHANGES

Committee F04 has identified the location of selected changes to this standard since the last issue (F1472 – 02a) that may impact the use of this standard. (Approved Oct. 1, 2008.)

(*1*) Removed Test Methods E120 and Practice F981 from Referenced Documents. Added Practice E29 and Test Method E2371 to Referenced Documents. Also added ISO 5832–3 and ISO 9001 to Referenced Documents.

(*2*) Added Section 10, Significance of Numerical Limits, and renumbered the subsequent sections.

(*3*) Made revisions, additions, and deletions to Sections 4, 5, 6, 7, 8, 11, and 12.

(*4*) Made minor changes in the text to conform with the latest titanium alloy template.

Designation: E8/E8M – 09

American Association State
Highway and Transportation Officials Standard
AASHTO No.: T68
An American National Standard

Standard Test Methods for Tension Testing of Metallic Materials[1]

This standard is issued under the fixed designation E8/E8M; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

This standard has been approved for use by agencies of the Department of Defense.

1. Scope*

1.1 These test methods cover the tension testing of metallic materials in any form at room temperature, specifically, the methods of determination of yield strength, yield point elongation, tensile strength, elongation, and reduction of area.

1.2 The gage lengths for most round specimens are required to be 4D for E8 and 5D for E8M. The gage length is the most significant difference between E8 and E8M Test Specimens Test specimens made from powder metallurgy (P/M) materials are exempt from this requirement by industry-wide agreement to keep the pressing of the material to a specific projected area and density.

1.3 Exceptions to the provisions of these test methods may need to be made in individual specifications or test methods for a particular material. For examples, see Test Methods and Definitions A370 and Test Methods B557, and B557M.

1.4 Room temperature shall be considered to be 10 to 38°C [50 to 100°F] unless otherwise specified.

1.5 The values stated in SI units are to be regarded as separate from inch/pound units. The values stated in each system are not exact equivalents; therefore each system must be used independently of the other. Combining values from the two systems may result in non-conformance with the standard.

1.6 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

A356/A356M Specification for Steel Castings, Carbon, Low Alloy, and Stainless Steel, Heavy-Walled for Steam Turbines

A370 Test Methods and Definitions for Mechanical Testing of Steel Products

B557 Test Methods for Tension Testing Wrought and Cast Aluminum- and Magnesium-Alloy Products

B557M Test Methods for Tension Testing Wrought and Cast Aluminum- and Magnesium-Alloy Products (Metric)

E4 Practices for Force Verification of Testing Machines

E6 Terminology Relating to Methods of Mechanical Testing

E29 Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications

E83 Practice for Verification and Classification of Extensometer Systems

E345 Test Methods of Tension Testing of Metallic Foil

E691 Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method

E1012 Practice for Verification of Test Frame and Specimen Alignment Under Tensile and Compressive Axial Force Application

E1856 Guide for Evaluating Computerized Data Acquisition Systems Used to Acquire Data from Universal Testing Machines

3. Terminology

3.1 *Definitions*—The definitions of terms relating to tension testing appearing in Terminology E6 shall be considered as applying to the terms used in these test methods of tension testing. Additional terms being defined are as follows:

3.1.1 *discontinuous yielding—in a uniaxial test,* a hesitation or fluctuation of force observed at the onset of plastic deformation, due to localized yielding. (The stress-strain curve need not appear to be discontinuous.)

3.1.2 *elongation at fracture*—the elongation measured just prior to the sudden decrease in force associated with fracture. For many materials not exhibiting a sudden decrease in force, the elongation at fracture can be taken as the strain measured just prior to when the force falls below 10 % of the maximum force encountered during the test.

3.1.3 *lower yield strength, LYS [FL^{-2}]—in a uniaxial test,* the minimum stress recorded during discontinuous yielding, ignoring transient effects.

3.1.4 *uniform elongation, El_u, [%]*—the elongation determined at the maximum force sustained by the test piece just prior to necking or fracture, or both.

[1] These test methods are under the jurisdiction of ASTM Committee E28 on Mechanical Testing and are the direct responsibility of Subcommittee E28.04 on Uniaxial Testing.

Current edition approved Dec. 1, 2009. Published December 2009. Originally approved in 1924. Last previous edition approved 2008 as E8/E8M – 08. DOI: 10.1520/E0008_E0008M-09.

[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

***A Summary of Changes section appears at the end of this standard.**

3.1.4.1 *Discussion*—Uniform elongation includes both elastic and plastic elongation.

3.1.5 *upper yield strength, UYS [FL^{-2}]—in a uniaxial test*, the first stress maximum (stress at first zero slope) associated with discontinuous yielding at or near the onset of plastic deformation.

3.1.6 *yield point elongation, YPE—in a uniaxial test*, the strain (expressed in percent) separating the stress-strain curve's first point of zero slope from the point of transition from discontinuous yielding to uniform strain hardening. If the transition occurs over a range of strain, the YPE end point is the intersection between *(a)* a horizontal line drawn tangent to the curve at the last zero slope and *(b)* a line drawn tangent to the strain hardening portion of the stress-strain curve at the point of inflection. If there is no point at or near the onset of yielding at which the slope reaches zero, the material has 0 % YPE.

4. Significance and Use

4.1 Tension tests provide information on the strength and ductility of materials under uniaxial tensile stresses. This information may be useful in comparisons of materials, alloy development, quality control, and design under certain circumstances.

4.2 The results of tension tests of specimens machined to standardized dimensions from selected portions of a part or material may not totally represent the strength and ductility properties of the entire end product or its in-service behavior in different environments.

4.3 These test methods are considered satisfactory for acceptance testing of commercial shipments. The test methods have been used extensively in the trade for this purpose.

5. Apparatus

5.1 *Testing Machines*—Machines used for tension testing shall conform to the requirements of Practices E4. The forces used in determining tensile strength and yield strength shall be within the verified force application range of the testing machine as defined in Practices E4.

5.2 *Gripping Devices*:

5.2.1 *General*—Various types of gripping devices may be used to transmit the measured force applied by the testing machine to the test specimens. To ensure axial tensile stress within the gage length, the axis of the test specimen should coincide with the center line of the heads of the testing machine. Any departure from this requirement may introduce bending stresses that are not included in the usual stress computation (force divided by cross-sectional area).

NOTE 1—The effect of this eccentric force application may be illustrated by calculating the bending moment and stress thus added. For a standard 12.5-mm [0.500-in.] diameter specimen, the stress increase is 1.5 percentage points for each 0.025 mm [0.001 in.] of eccentricity. This error increases to 2.5 percentage points/ 0.025 mm [0.001 in.] for a 9 mm [0.350-in.] diameter specimen and to 3.2 percentage points/ 0.025 mm [0.001 in.] for a 6-mm [0.250-in.] diameter specimen.

NOTE 2—Alignment methods are given in Practice E1012.

5.2.2 *Wedge Grips*—Testing machines usually are equipped with wedge grips. These wedge grips generally furnish a satisfactory means of gripping long specimens of ductile metal and flat plate test specimens such as those shown in Fig. 1. If, however, for any reason, one grip of a pair advances farther than the other as the grips tighten, an undesirable bending stress may be introduced. When liners are used behind the wedges, they must be of the same thickness and their faces must be flat and parallel. For best results, the wedges should be supported over their entire lengths by the heads of the testing machine. This requires that liners of several thicknesses be available to cover the range of specimen thickness. For proper gripping, it is desirable that the entire length of the serrated face of each wedge be in contact with the specimen. Proper alignment of wedge grips and liners is illustrated in Fig. 2. For short specimens and for specimens of many materials it is generally necessary to use machined test specimens and to use a special means of gripping to ensure that the specimens, when under load, shall be as nearly as possible in uniformly distributed pure axial tension (see 5.2.3, 5.2.4, and 5.2.5).

5.2.3 *Grips for Threaded and Shouldered Specimens and Brittle Materials*—A schematic diagram of a gripping device for threaded-end specimens is shown in Fig. 3, while Fig. 4 shows a device for gripping specimens with shouldered ends. Both of these gripping devices should be attached to the heads of the testing machine through properly lubricated spherical-seated bearings. The distance between spherical bearings should be as great as feasible.

5.2.4 *Grips for Sheet Materials*—The self-adjusting grips shown in Fig. 5 have proven satisfactory for testing sheet materials that cannot be tested satisfactorily in the usual type of wedge grips.

5.2.5 *Grips for Wire*—Grips of either the wedge or snubbing types as shown in Figs. 5 and 6 or flat wedge grips may be used.

5.3 *Dimension-Measuring Devices*—Micrometers and other devices used for measuring linear dimensions shall be accurate and precise to at least one half the smallest unit to which the individual dimension is required to be measured.

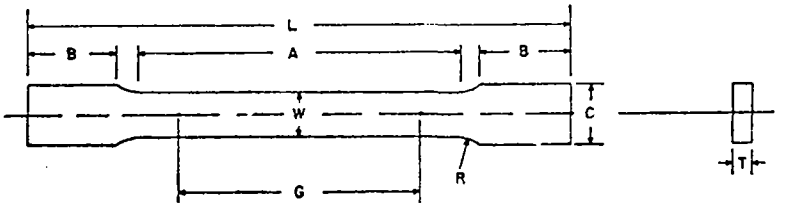
5.4 *Extensometers*—Extensometers used in tension testing shall conform to the requirements of Practice E83 for the classifications specified by the procedure section of this test method. Extensometers shall be used and verified to include the strains corresponding to the yield strength and elongation at fracture (if determined).

5.4.1 Extensometers with gage lengths equal to or shorter than the nominal gage length of the specimen (dimension shown as "*G*-Gage Length" in the accompanying figures) may be used to determine the yield behavior. For specimens without a reduced section (for example, full cross sectional area specimens of wire, rod, or bar), the extensometer gage length for the determination of yield behavior shall not exceed 80 % of the distance between grips. For measuring elongation at fracture with an appropriate extensometer, the gage length of the extensometer shall be equal to the nominal gage length required for the specimen being tested.

6. Test Specimens

6.1 *General*:

6.1.1 *Specimen Size*—Test specimens shall be either substantially full size or machined, as prescribed in the product specifications for the material being tested.



	Dimensions		
	Standard Specimens		Subsize Specimen
	Plate-Type, 40 mm [1.500 in.] Wide	Sheet-Type, 12.5 mm [0.500 in.] Wide	6 mm [0.250 in.] Wide
	mm [in.]	mm [in.]	mm [in.]
G—Gage length (Note 1 and Note 2)	200.0 ± 0.2 [8.00 ± 0.01]	50.0 ± 0.1 [2.000 ± 0.005]	25.0 ± 0.1 [1.000 ± 0.003]
W—Width (Note 3 and Note 4)	40.0 ± 2.0 [1.500 ± 0.125, -0.250]	12.5 ± 0.2 [0.500 ± 0.010]	6.0 ± 0.1 [0.250 ± 0.005]
T—Thickness (Note 5)		thickness of material	
R—Radius of fillet, min (Note 6)	25 [1]	12.5 [0.500]	6 [0.250]
L—Overall length, min (Note 2, Note 7, and Note 8)	450 [18]	200 [8]	100 [4]
A—Length of reduced section, min	225 [9]	57 [2.25]	32 [1.25]
B—Length of grip section, min (Note 9)	75 [3]	50 [2]	30 [1.25]
C—Width of grip section, approximate (Note 4 and Note 9)	50 [2]	20 [0.750]	10 [0.375]

NOTE 1—For the 40 mm [1.500 in.] wide specimen, punch marks for measuring elongation after fracture shall be made on the flat or on the edge of the specimen and within the reduced section. Either a set of nine or more punch marks 25 mm [1 in.] apart, or one or more pairs of punch marks 200 mm [8 in.] apart may be used.

NOTE 2—When elongation measurements of 40 mm [1.500 in.] wide specimens are not required, a minimum length of reduced section (*A*) of 75 mm [2.25 in.] may be used with all other dimensions similar to those of the plate-type specimen.

NOTE 3—For the three sizes of specimens, the ends of the reduced section shall not differ in width by more than 0.10, 0.05 or 0.02 mm [0.004, 0.002 or 0.001 in.], respectively. Also, there may be a gradual decrease in width from the ends to the center, but the width at each end shall not be more than 1 % larger than the width at the center.

NOTE 4—For each of the three sizes of specimens, narrower widths (*W* and *C*) may be used when necessary. In such cases the width of the reduced section should be as large as the width of the material being tested permits; however, unless stated specifically, the requirements for elongation in a product specification shall not apply when these narrower specimens are used.

NOTE 5—The dimension *T* is the thickness of the test specimen as provided for in the applicable material specifications. Minimum thickness of 40 mm [1.500 in.] wide specimens shall be 5 mm [0.188 in.]. Maximum thickness of 12.5 and 6 mm [0.500 and 0.250 in.] wide specimens shall be 19 and 6 mm [0.750 and 0.250 in.], respectively.

NOTE 6—For the 40 mm [1.500 in.] wide specimen, a 13 mm [0.500 in.] minimum radius at the ends of the reduced section is permitted for steel specimens under 690 MPa [100 000 psi] in tensile strength when a profile cutter is used to machine the reduced section.

NOTE 7—The dimension shown is suggested as a minimum. In determining the minimum length, the grips must not extend in to the transition section between Dimensions *A* and *B*, see Note 9.

NOTE 8—To aid in obtaining axial force application during testing of 6-mm [0.250-in.] wide specimens, the overall length should be as large as the material will permit, up to 200 mm [8.00 in.].

NOTE 9—It is desirable, if possible, to make the length of the grip section large enough to allow the specimen to extend into the grips a distance equal to two thirds or more of the length of the grips. If the thickness of 12.5 mm [0.500-in.] wide specimens is over 10 mm [0.375 in.], longer grips and correspondingly longer grip sections of the specimen may be necessary to prevent failure in the grip section.

NOTE 10—For the three sizes of specimens, the ends of the specimen shall be symmetrical in width with the center line of the reduced section within 2.5, 0.25 and 0.13 mm [0.10, 0.01 and 0.005 in.], respectively. However, for referee testing and when required by product specifications, the ends of the 12.5 mm [0.500 in.] wide specimen shall be symmetrical within 0.2 mm [0.01 in.].

NOTE 11—For each specimen type, the radii of all fillets shall be equal to each other within a tolerance of 1.25 mm [0.05 in.], and the centers of curvature of the two fillets at a particular end shall be located across from each other (on a line perpendicular to the centerline) within a tolerance of 0.2 mm [0.01 in.].

NOTE 12—Specimens with sides parallel throughout their length are permitted, except for referee testing, provided: *(a)* the above tolerances are used; *(b)* an adequate number of marks are provided for determination of elongation; and *(c)* when yield strength is determined, a suitable extensometer is used. If the fracture occurs at a distance of less than 2 W from the edge of the gripping device, the tensile properties determined may not be representative of the material. In acceptance testing, if the properties meet the minimum requirements specified, no further testing is required, but if they are less than the minimum requirements, discard the test and retest.

FIG. 1 Rectangular Tension Test Specimens

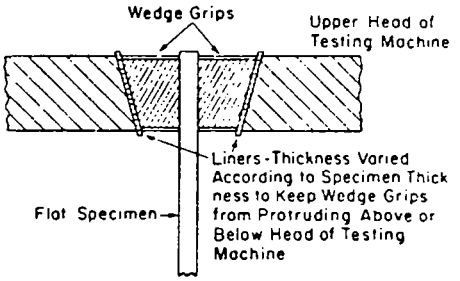


FIG. 2 Wedge Grips with Liners for Flat Specimens

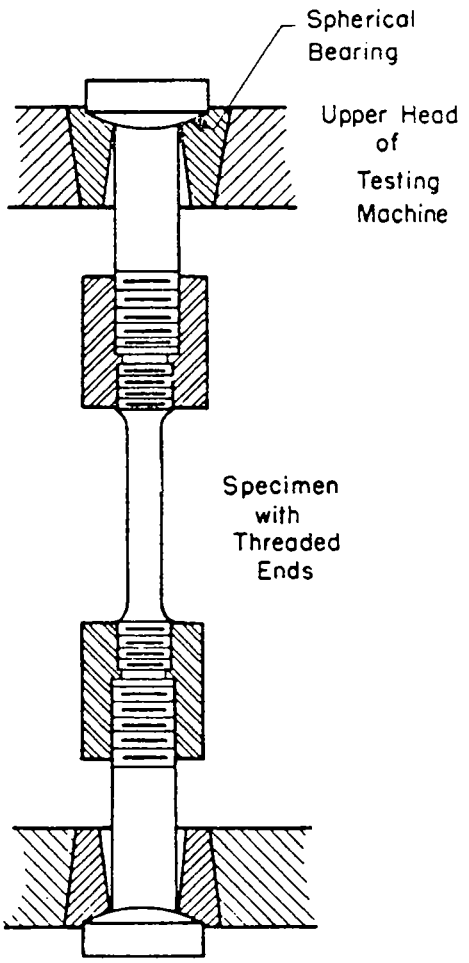


FIG. 3 Gripping Device for Threaded-End Specimens

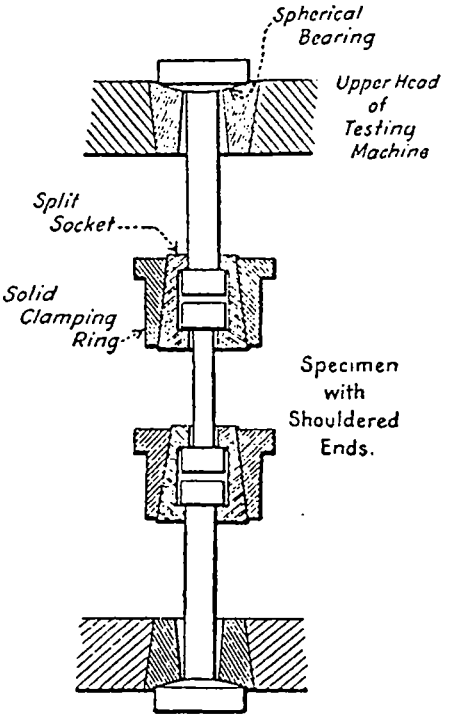


FIG. 4 Gripping Device for Shouldered-End Specimens

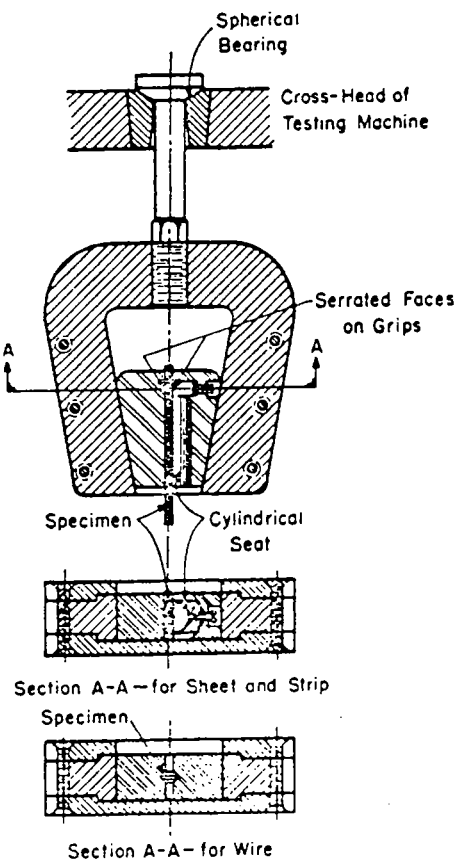


FIG. 5 Gripping Devices for Sheet and Wire Specimens

6.1.2 *Location*—Unless otherwise specified, the axis of the test specimen shall be located within the parent material as follows:

6.1.2.1 At the center for products 40 mm [1.500 in.] or less in thickness, diameter, or distance between flats.

6.1.2.2 Midway from the center to the surface for products over 40 mm [1.500 in.] in thickness, diameter, or distance between flats.

6.1.3 *Specimen Machining*—Improperly prepared test specimens often are the reason for unsatisfactory and incorrect test results. It is important, therefore, that care be exercised in the preparation of specimens, particularly in the machining, to maximize precision and minimize bias in test results.

6.1.3.1 The reduced sections of prepared specimens should be free of cold work, notches, chatter marks, grooves, gouges,

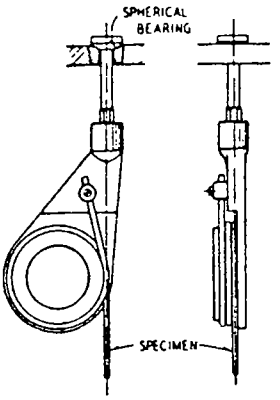


FIG. 6 Snubbing Device for Testing Wire

burrs, rough surfaces or edges, overheating, or any other condition which can deleteriously affect the properties to be measured.

NOTE 3—Punching or blanking of the reduced section may produce significant cold work or shear burrs, or both, along the edges which should be removed by machining.

6.1.3.2 Within the reduced section of rectangular specimens, edges or corners should not be ground or abraded in a manner which could cause the actual cross-sectional area of the specimen to be significantly different from the calculated area.

6.1.3.3 For brittle materials, large radius fillets at the ends of the gage length should be used.

6.1.3.4 The cross-sectional area of the specimen should be smallest at the center of the reduced section to ensure fracture within the gage length. For this reason, a small taper is permitted in the reduced section of each of the specimens described in the following sections.

6.1.4 *Specimen Surface Finish*—When materials are tested with surface conditions other than as manufactured, the surface finish of the test specimens should be as provided in the applicable product specifications.

NOTE 4—Particular attention should be given to the uniformity and quality of surface finish of specimens for high strength and very low ductility materials since this has been shown to be a factor in the variability of test results.

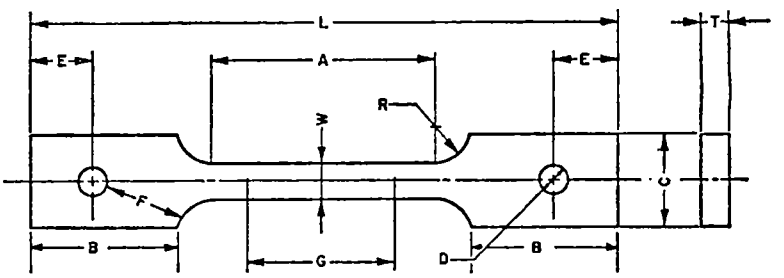
6.2 *Plate-Type Specimens*—The standard plate-type test specimen is shown in Fig. 1. This specimen is used for testing metallic materials in the form of plate, shapes, and flat material having a nominal thickness of 5 mm [0.188 in.] or over. When product specifications so permit, other types of specimens may be used, as provided in 6.3, 6.4, and 6.5.

6.3 *Sheet-Type Specimens*:

6.3.1 The standard sheet-type test specimen is shown in Fig. 1. This specimen is used for testing metallic materials in the form of sheet, plate, flat wire, strip, band, hoop, rectangles, and shapes ranging in nominal thickness from 0.13 to 19 mm [0.005 to 0.750 in.]. When product specifications so permit, other types of specimens may be used, as provided in 6.2, 6.4, and 6.5.

NOTE 5—Test Methods E345 may be used for tension testing of materials in thicknesses up to 0.15 mm [0.0059 in.].

6.3.2 Pin ends as shown in Fig. 7 may be used. In order to



Dimensions, mm [in.]	
G—Gage length	50.0 ± 0.1 [2.000 ± 0.005]
W—Width (Note 1)	12.5 ± 0.2 [0.500 ± 0.010]
T—Thickness, max (Note 2)	16 [0.625]
R—Radius of fillet, min (Note 3)	13 [0.5]
L—Overall length, min	200 [8]
A—Length of reduced section, min	57 [2.25]
B—Length of grip section, min	50 [2]
C—Width of grip section, approximate	50 [2]
D—Diameter of hole for pin, min (Note 4)	13 [0.5]
E—Edge distance from pin, approximate	40 [1.5]
F—Distance from hole to fillet, min	13 [0.5]

NOTE 1—The ends of the reduced section shall differ in width by not more than 0.1 mm [0.002 in.]. There may be a gradual taper in width from the ends to the center, but the width at each end shall be not more than 1 % greater than the width at the center.

NOTE 2—The dimension *T* is the thickness of the test specimen as stated in the applicable product specifications.

NOTE 3—For some materials, a fillet radius *R* larger than 13 mm [0.500 in.] may be needed.

NOTE 4—Holes must be on center line of reduced section within ± 0.05mm [0.002 in].

NOTE 5—Variations of dimensions *C*, *D*, *E*, *F*, and *L* may be used that will permit failure within the gage length.

FIG. 7 Pin-Loaded Tension Test Specimen with 50-mm [2-in.] Gage Length

avoid buckling in tests of thin and high-strength materials, it may be necessary to use stiffening plates at the grip ends.

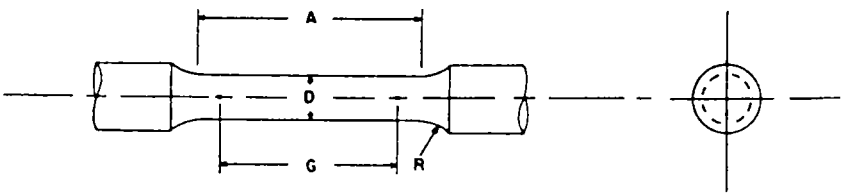
6.4 *Round Specimens*:

6.4.1 The standard 12.5-mm [0.500-in.] diameter round test specimen shown in Fig. 8 is used quite generally for testing metallic materials, both cast and wrought.

6.4.2 Fig. 8 also shows small-size specimens proportional to the standard specimen. These may be used when it is necessary to test material from which the standard specimen or specimens shown in Fig. 1 cannot be prepared. Other sizes of small round specimens may be used. In any such small-size specimen it is important that the gage length for measurement of elongation be four times the diameter of the specimen when following E8 and five times the diameter of the specimen when following E8M.

6.4.3 The shape of the ends of the specimen outside of the gage length shall be suitable to the material and of a shape to fit the holders or grips of the testing machine so that the forces may be applied axially. Fig. 9 shows specimens with various types of ends that have given satisfactory results.

6.5 *Specimens for Sheet, Strip, Flat Wire, and Plate*—In testing sheet, strip, flat wire, and plate, use a specimen type appropriate for the nominal thickness of the material, as described in the following:



Dimensions, mm [in.]
For Test Specimens with Gage Length Four times the Diameter [E8]

	Standard Specimen	Small-Size Specimens Proportional to Standard			
	Specimen 1	Specimen 2	Specimen 3	Specimen 4	Specimen 5
G—Gage length	50.0 ± 0.1 [2.000 ± 0.005]	36.0 ± 0.1 [1.400 ± 0.005]	24.0 ± 0.1 [1.000 ± 0.005]	16.0 ± 0.1 [0.640 ± 0.005]	10.0 ±0.1 [0.450 ± 0.005]
D—Diameter (Note 1)	12.5 ± 0.2 [0.500 ± 0.010]	9.0 ±0.1 [0.350 ± 0.007]	6.0 ± 0.1 [0.250 ± 0.005]	4.0 ± 0.1 [0.160 ± 0.003]	2.5 ± 0.1 [0.113 ± 0.002]
R—Radius of fillet, min	10 [0.375]	8 [0.25]	6 [0.188]	4 [0.156]	2 [0.094]
A—Length of reduced section, min (Note 2)	56 [2.25]	45 [1.75]	30 [1.25]	20 [0.75]	16 [0.625]

Dimensions, mm [in.]
For Test Specimens with Gage Length Five times the Diameter [E8M]

	Standard Specimen	Small-Size Specimens Proportional to Standard			
	Specimen 1	Specimen 2	Specimen 3	Specimen 4	Specimen 5
G—Gage length	62.5 ± 0.1 [2.500 ± 0.005]	45.0 ± 0.1 [1.750 ± 0.005]	30.0 ± 0.1 [1.250 ± 0.005]	20.0 ± 0.1 [0.800 ± 0.005]	12.5 ± 0.1 [0.565 ± 0.005]
D—Diameter (Note 1)	12.5 ± 0.2 [0.500 ± 0.010]	9.0 ± 0.1 [0.350 ± 0.007]	6.0 ± 0.1 [0.250 ± 0.005]	4.0 ± 0.1 [0.160 ± 0.003]	2.5 ± 0.1 [0.113 ± 0.002]
R—Radius of fillet, min	10 [0.375]	8 [0.25]	6 [0.188]	4 [0.156]	2 [0.094]
A—Length of reduced section, min (Note 2)	75 [3.0]	54 [2.0]	36 [1.4]	24 [1.0]	20 [0.75]

NOTE 1—The reduced section may have a gradual taper from the ends toward the center, with the ends not more than 1 % larger in diameter than the center (controlling dimension).

NOTE 2—If desired, the length of the reduced section may be increased to accommodate an extensometer of any convenient gage length. Reference marks for the measurement of elongation should, nevertheless, be spaced at the indicated gage length.

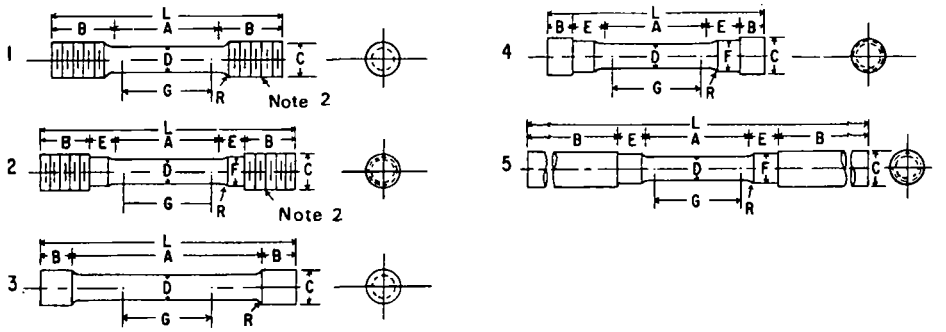
NOTE 3—The gage length and fillets may be as shown, but the ends may be of any form to fit the holders of the testing machine in such a way that the force shall be axial (see Fig. 9). If the ends are to be held in wedge grips it is desirable, if possible, to make the length of the grip section great enough to allow the specimen to extend into the grips a distance equal to two thirds or more of the length of the grips.

NOTE 4—On the round specimens in Figs. 8 and 9, the gage lengths are equal to four [E8] or five times [E8M] the nominal diameter. In some product specifications other specimens may be provided for, but unless the 4-to-1 [E8] or 5-to-1 [E8M] ratio is maintained within dimensional tolerances, the elongation values may not be comparable with those obtained from the standard test specimen.

NOTE 5—The use of specimens smaller than 6-mm [0.250-in.] diameter shall be restricted to cases when the material to be tested is of insufficient size to obtain larger specimens or when all parties agree to their use for acceptance testing. Smaller specimens require suitable equipment and greater skill in both machining and testing.

NOTE 6—For inch/pound units only: Five sizes of specimens often used have diameters of approximately 0.505, 0.357, 0.252, 0.160, and 0.113 in., the reason being to permit easy calculations of stress from loads, since the corresponding cross-sectional areas are equal or close to 0.200, 0.100, 0.0500, 0.0200, and 0.0100 $in.^2$, respectively. Thus, when the actual diameters agree with these values, the stresses (or strengths) may be computed using the simple multiplying factors 5, 10, 20, 50, and 100, respectively. (The metric equivalents of these five diameters do not result in correspondingly convenient cross-sectional areas and multiplying factors.)

FIG. 8 Standard 12.5-mm [0.500-in.] Round Tension Test Specimen and Examples of Small-Size Specimens Proportional to the Standard Specimen



Dimensions, mm [in.]
For Test Specimens with Gage Length Four times the Diameter [E8]

	Specimen 1	Specimen 2	Specimen 3	Specimen 4	Specimen 5
G—Gage length	50 ± 0.1 [2.000 ± 0.005]	50 ± 0.1 [2.000 ± 0.005]	50 ± 0.1 [2.000 ± 0.005]	50 ± 0.1 [2.000 ± 0.005]	50 ± 0.1 [2.000 ± 0.005]
D—Diameter (Note 1)	12.5 ± 0.2 [0.500 ± 0.010]	12.5 ± 0.2 [0.500 ± 0.010]	12.5 ± 0.2 [0.500 ± 0.010]	12.5 ± 0.2 [0.500 ± 0.010]	12.5 ± 0.2 [0.500 ± 0.010]
R—Radius of fillet, min	10 [0.375]	10 [0.375]	2 [0.0625]	10 [0.375]	10 [0.375]
A—Length of reduced section	56 [2.25] min	56 [2.25] min	100 [4] approximate	56 [2.25] min	56 [2.25] min
L—Overall length, approximate	145 [5]	155 [5.5]	155 [5.5]	140 [4.75]	255 [9.5]
B—Length of end section (Note 3)	35 [1.375] approximate	25 [1] approximate	20 [0.75] approximate	15 [0.5] approximate	75 [3] min
C—Diameter of end section	20 [0.75]	20 [0.75]	20 [0.75]	22 [0.875]	20 [0.75]
E—Length of shoulder and fillet section, approximate		15 [0.625]		20 [0.75]	15 [0.625]
F—Diameter of shoulder		15 [0.625]		15 [0.625]	15 [0.625]

Dimensions, mm [in.]
For Test Specimens with Gage Length Five times the Diameter [E8M]

	Specimen 1	Specimen 2	Specimen 3	Specimen 4	Specimen 5
G—Gage length	62.5 ± 0.1 [2.500 ± 0.005]	62.5 ± 0.1 [2.500 ± 0.005]	62.5 ± 0.1 [2.500 ± 0.005]	62.5 ± 0.1 [2.500 ± 0.005]	62.5 ± 0.1 [2.500 ± 0.005]
D—Diameter (Note 1)	12.5 ± 0.2 [0.500 ± 0.010]	12.5 ± 0.2 [0.500 ± 0.010]	12.5 ± 0.2 [0.500 ± 0.010]	12.5 ± 0.2 [0.500 ± 0.010]	12.5 ± 0.2 [0.500 ± 0.010]
R—Radius of fillet, min	10 [0.375]	10 [0.375]	2 [0.0625]	10 [0.375]	10 [0.375]
A—Length of reduced section	75 [3] min	75 [3] min	75 [3] approximate	75 [3] min	75 [3] min
L—Overall length, approximate	145 [5]	155 [5.5]	155 [5.5]	140 [4.75]	255 [9.5]
B—Length of end section (Note 3)	35 [1.375] approximate	25 [1] approximate	20 [0.75] approximate	15 [0.5] approximate	75 [3] min
C—Diameter of end section	20 [0.75]	20 [0.75]	20 [0.75]	22 [0.875]	20 [0.75]
E—Length of shoulder and fillet section, approximate		15 [0.625]		20 [0.75]	15 [0.625]
F—Diameter of shoulder		15 [0.625]		15 [0.625]	15 [0.625]

NOTE 1—The reduced section may have a gradual taper from the ends toward the center with the ends not more than 1 %. larger in diameter than the center.

NOTE 2—On Specimens 1 and 2, any standard thread is permissible that provides for proper alignment and aids in assuring that the specimen will break within the reduced section.

NOTE 3—On Specimen 5 it is desirable, if possible, to make the length of the grip section great enough to allow the specimen to extend into the grips a distance equal to two thirds or more of the length of the grips.

NOTE 4—The values stated in SI units in the table for Fig. 9 are to be regarded as separate from the inch/pound units. The values stated in each system are not exact equivalents; therefore each system must be used independently of the other.

FIG. 9 Various Types of Ends for Standard Round Tension Test Specimens

6.5.1 For material with a nominal thickness of 0.13 to 5 mm [0.005 to 0.1875 in.], use the sheet-type specimen described in 6.3.

6.5.2 For material with a nominal thickness of 5 to 12.5 mm [0.1875 to 0.500 in.], use either the sheet-type specimen of 6.3 or the plate-type specimen of 6.2.

6.5.3 For material with a nominal thickness of 12.5 to 19 mm [0.500 to 0.750 in.], use either the sheet-type specimen of 6.3, the plate-type specimen of 6.2, or the largest practical size of round specimen described in 6.4.

6.5.4 For material with a nominal thickness of 19 mm [0.750 in.], or greater, use the plate-type specimen of 6.2 or the largest practical size of round specimen described in 6.4.

6.5.4.1 If the product specifications permit, material of a thickness of 19 mm [0.750 in.], or greater may be tested using a modified sheet-type specimen conforming to the configuration shown by Fig. 1. The thickness of this modified specimen must be machined to 10 ± 0.5 mm [0.400 ± 0.020 in.], and must be uniform within 0.1 mm [0.004 in.] throughout the

reduced section. In the event of disagreement, a round specimen shall be used as the referee (comparison) specimen.

6.6 *Specimens for Wire, Rod, and Bar*:

6.6.1 For round wire, rod, and bar, test specimens having the full cross-sectional area of the wire, rod, or bar shall be used wherever practicable. The gage length for the measurement of elongation of wire less than 4 mm [0.125 in.] in diameter shall be as prescribed in product specifications. When testing wire, rod, or bar having a diameter of 4-mm [0.125-in.] or larger diameter, a gage length equal to four times the diameter shall be used when following E8 and a gage length equal to five times the diameter shall be used when following E8M unless otherwise specified. The total length of the specimens shall be at least equal to the gage length plus the length of material required for the full use of the grips employed.

6.6.2 For wire of octagonal, hexagonal, or square cross section, for rod or bar of round cross section where the specimen required in 6.6.1 is not practicable, and for rod or bar of octagonal, hexagonal, or square cross section, one of the following types of specimens shall be used:

6.6.2.1 *Full Cross Section* (Note 6)—It is permissible to reduce the test section slightly with abrasive cloth or paper, or machine it sufficiently to ensure fracture within the gage marks. For material not exceeding 5 mm [0.188 in.] in diameter or distance between flats, the cross-sectional area may be reduced to not less than 90 % of the original area without changing the shape of the cross section. For material over 5 mm [0.188 in.] in diameter or distance between flats, the diameter or distance between flats may be reduced by not more than 0.25 mm [0.010 in.] without changing the shape of the cross section. Square, hexagonal, or octagonal wire or rod not exceeding 5 mm [0.188 in.] between flats may be turned to a round having a cross-sectional area not smaller than 90 % of the area of the maximum inscribed circle. Fillets, preferably with a radius of 10 mm [0.375 in.], but not less than 3 mm [0.125 in.], shall be used at the ends of the reduced sections. Square, hexagonal, or octagonal rod over 5 mm [0.188 in.] between flats may be turned to a round having a diameter no smaller than 0.25 mm [0.010 in.] less than the original distance between flats.

NOTE 6—The ends of copper or copper alloy specimens may be flattened 10 to 50 % from the original dimension in a jig similar to that shown in Fig. 10, to facilitate fracture within the gage marks. In flattening the opposite ends of the test specimen, care shall be taken to ensure that the four flattened surfaces are parallel and that the two parallel surfaces on the same side of the axis of the test specimen lie in the same plane.

6.6.2.2 For rod and bar, the largest practical size of round specimen as described in 6.4 may be used in place of a test specimen of full cross section. Unless otherwise specified in the product specification, specimens shall be parallel to the direction of rolling or extrusion.

6.7 *Specimens for Rectangular Bar*—In testing rectangular bar one of the following types of specimens shall be used:

6.7.1 *Full Cross Section*—It is permissible to reduce the width of the specimen throughout the test section with abrasive cloth or paper, or by machining sufficiently to facilitate fracture within the gage marks, but in no case shall the reduced width be less than 90 % of the original. The edges of the midlength

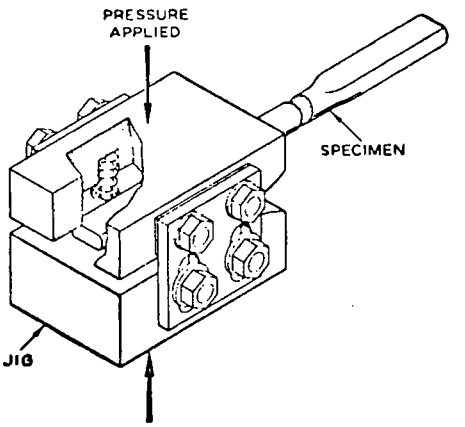


FIG. 10 Squeezing Jig for Flattening Ends of Full-Size Tension Test Specimens

of the reduced section not less than 20 mm [¾ in.] in length shall be parallel to each other and to the longitudinal axis of the specimen within 0.05 mm [0.002 in.]. Fillets, preferably with a radius of 10 mm [⅜ in.] but not less than 3 mm [⅛ in.] shall be used at the ends of the reduced sections.

6.7.2 Rectangular bar of thickness small enough to fit the grips of the testing machine but of too great width may be reduced in width by cutting to fit the grips, after which the cut surfaces shall be machined or cut and smoothed to ensure failure within the desired section. The reduced width shall not be less than the original bar thickness. Also, one of the types of specimens described in 6.2, 6.3, and 6.4 may be used.

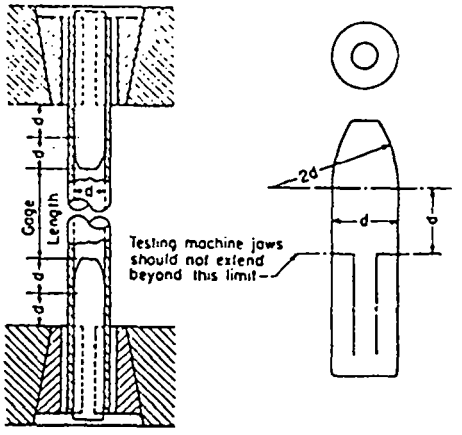
6.8 *Shapes, Structural and Other*—In testing shapes other than those covered by the preceding sections, one of the types of specimens described in 6.2, 6.3, and 6.4 shall be used.

6.9 *Specimens for Pipe and Tube* (Note 7):

6.9.1 For all small tube (Note 7), particularly sizes 25 mm [1 in.] and under in nominal outside diameter, and frequently for larger sizes, except as limited by the testing equipment, it is standard practice to use tension test specimens of full-size tubular sections. Snug-fitting metal plugs shall be inserted far enough into the ends of such tubular specimens to permit the testing machine jaws to grip the specimens properly. The plugs shall not extend into that part of the specimen on which the elongation is measured. Elongation is measured over a length of four times the diameter when following E8 or five times the diameter when following E8M unless otherwise stated in the product specification. Fig. 11 shows a suitable form of plug, the location of the plugs in the specimen, and the location of the specimen in the grips of the testing machine.

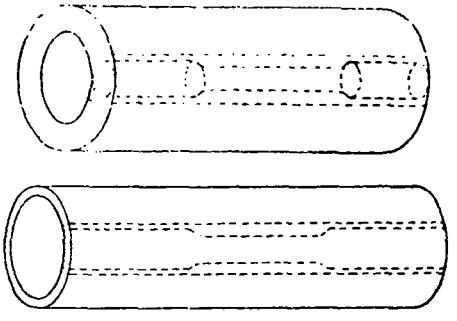
NOTE 7—The term "tube" is used to indicate tubular products in general, and includes pipe, tube, and tubing.

6.9.2 For large-diameter tube that cannot be tested in full section, longitudinal tension test specimens shall be cut as indicated in Fig. 12. Specimens from welded tube shall be located approximately 90° from the weld. If the tube-wall thickness is under 20 mm [0.750 in.], either a specimen of the form and dimensions shown in Fig. 13 or one of the small-size specimens proportional to the standard 12.5-mm [0.500-in.] specimen, as mentioned in 6.4.2 and shown in Fig. 8, shall be used. Specimens of the type shown in Fig. 13 may be tested



NOTE—The diameter of the plug shall have a slight taper from the line limiting the test machine jaws to the curved section.

FIG. 11 Metal Plugs for Testing Tubular Specimens, Proper Location of Plugs in Specimen and of Specimen in Heads of Testing Machine



NOTE—The edges of the blank for the specimen shall be cut parallel to each other.

FIG. 12 Location from Which Longitudinal Tension Test Specimens Are to be Cut from Large-Diameter Tube

with grips having a surface contour corresponding to the curvature of the tube. When grips with curved faces are not available, the ends of the specimens may be flattened without heating. If the tube-wall thickness is 20 mm [0.750 in.] or over, the standard specimen shown in Fig. 8 shall be used.

NOTE 8—In clamping of specimens from pipe and tube (as may be done during machining) or in flattening specimen ends (for gripping), care must be taken so as not to subject the reduced section to any deformation or cold work, as this would alter the mechanical properties.

6.9.3 Transverse tension test specimens for tube may be taken from rings cut from the ends of the tube as shown in Fig. 14. Flattening of the specimen may be either after separating as in *A*, or before separating as in *B*. Transverse tension test specimens for large tube under 20 mm [0.750 in.] in wall thickness shall be either of the small-size specimens shown in Fig. 8 or of the form and dimensions shown for Specimen 2 in Fig. 13. When using the latter specimen, either or both surfaces of the specimen may be machined to secure a uniform thickness, provided not more than 15 % of the normal wall thickness is removed from each surface. For large tube 20 mm [0.750 in.] and over in wall thickness, the standard specimen shown in Fig. 8 shall be used for transverse tension tests. Specimens for transverse tension tests on large welded tube to determine the strength of welds shall be located perpendicular to the welded seams, with the welds at about the middle of their lengths.

6.10 *Specimens for Forgings*—For testing forgings, the largest round specimen described in 6.4 shall be used. If round specimens are not feasible, then the largest specimen described in 6.5 shall be used.

6.10.1 For forgings, specimens shall be taken as provided in the applicable product specifications, either from the predominant or thickest part of the forging from which a coupon can be obtained, or from a prolongation of the forging, or from separately forged coupons representative of the forging. When not otherwise specified, the axis of the specimen shall be parallel to the direction of grain flow.

6.11 *Specimens for Castings*—In testing castings either the standard specimen shown in Fig. 8 or the specimen shown in Fig. 15 shall be used unless otherwise provided in the product specifications.

6.11.1 Test coupons for castings shall be made as shown in Fig. 16 and Table 1.

6.12 *Specimen for Malleable Iron*—For testing malleable iron the test specimen shown in Fig. 17 shall be used, unless otherwise provided in the product specifications.

6.13 *Specimen for Die Castings*—For testing die castings the test specimen shown in Fig. 18 shall be used unless otherwise provided in the product specifications.

6.14 *Specimens for Powder Metallurgy (P/M) Materials*—For testing powder metallurgy (P/M) materials the test specimens shown in Figs. 19 and 20 shall be used, unless otherwise provided in the product specifications. When making test specimens in accordance with Fig. 19, shallow transverse grooves, or ridges, may be pressed in the ends to allow gripping by jaws machined to fit the grooves or ridges. Because of shape and other factors, the flat unmachined tensile test specimen (Fig. 19) in the heat treated condition will have an ultimate tensile strength of 50 % to 85 % of that determined in a machined round tensile test specimen (Fig. 20) of like composition and processing.

7. Procedures

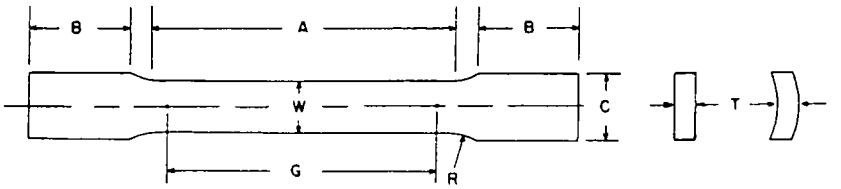
7.1 *Preparation of the Test Machine*—Upon startup, or following a prolonged period of machine inactivity, the test machine should be exercised or warmed up to normal operating temperatures to minimize errors that may result from transient conditions.

7.2 *Measurement of Dimensions of Test Specimens*:

7.2.1 To determine the cross-sectional area of a test specimen, measure the dimensions of the cross section at the center of the reduced section. For referee testing of specimens less than 5 mm [0.188 in.] in their least dimension, measure the dimensions where the least cross-sectional area is found. Measure and record the cross-sectional dimensions of tension test specimens as follows:

(1) Specimen dimension ≥ 5 mm [0.200 in.] to the nearest 0.02 mm [0.001 in.].

(2) 2.5 mm [0.100 in.] ≤ Specimen dimension < 5 mm [0.200 in.] to the nearest 0.01 mm [0.0005 in.].



	Dimensions						
	Specimen 1	Specimen 2	Specimen 3	Specimen 4	Specimen 5	Specimen 6	Specimen 7
	mm [in.]	mm [in.]	mm [in.]	mm [in.]	mm [in.]	mm [in.]	mm [in.]
G—Gage length	50.0 ± 0.1 [2.000 ± 0.005]	50.0 ± 0.1 [2.000 ± 0.005]	200.0 ± 0.2 [8.00 ± 0.01]	50.0 ± 0.1 [2.000 ± 0.005]	100.0 ± 0.1 [4.000 ± 0.005]	50.0 ± 0.1 [2.000 ± 0.005]	100.0 ± 0.1 [4.000 ± 0.005]
W—Width (Note 1)	12.5 ± 0.2 [0.500 ± 0.010]	40.0 ± 2.0 [1.5 ± 0.125-0.25]	40.0 ± 0.2 [1.5 ± 0.125,-0.25]	20.0 ± 0.7 [0.750 ± 0.031]	20.0 ± 0.7 [0.750 ± 0.031]	25.0 ± 1.5 [1.000 ± 0.062]	25.0 ± 1.5 [1.000 ± 0.062]
T—Thickness	measured thickness of specimen						
R—Radius of fillet, min	12.5 [0.5]	25 [1]	25 [1]	25 [1]	25 [1]	25 [1]	25 [1]
A—Length of reduced section, min	60 [2.25]	60 [2.25]	230 [9]	60 [2.25]	120 [4.5]	60 [2.25]	120 [4.5]
B—Length of grip section, min (Note 2)	75 [3]	75 [3]	75 [3]	75 [3]	75 [3]	75 [3]	75 [3]
C—Width of grip section, approximate (Note 3)	20 [0.75]	50 [2]	50 [2]	25 [1]	25 [1]	40 [1.5]	40 [1.5]

NOTE 1—The ends of the reduced section shall differ from each other in width by not more than 0.5 %. There may be a gradual taper in width from the ends to the center, but the width at each end shall be not more than 1 % greater than the width at the center.

NOTE 2—It is desirable, if possible, to make the length of the grip section great enough to allow the specimen to extend into the grips a distance equal to two thirds or more of the length of the grips.

NOTE 3—The ends of the specimen shall be symmetrical with the center line of the reduced section within 1 mm [0.05 in.] for specimens 1, 4, and 5, and 2.5 mm [0.10 in.] for specimens 2, 3, 6, and 7.

NOTE 4—For each specimen type, the radii of all fillets shall be equal to each other within a tolerance of 1.25 mm [0.05 in.], and the centers of curvature of the two fillets at a particular end shall be located across from each other (on a line perpendicular to the centerline) within a tolerance of 2.5 mm [0.10 in.].

NOTE 5—For circular segments, the cross-sectional area may be calculated by multiplying *W* and *T*. If the ratio of the dimension *W* to the diameter of the tubular section is larger than about ⅛, the error in using this method to calculate the cross-sectional area may be appreciable. In this case, the exact equation (see 7.2.3) must be used to determine the area.

NOTE 6—Specimens with *G/W* less than 4 should not be used for determination of elongation.

NOTE 7—Specimens with sides parallel throughout their length are permitted, except for referee testing, provided: *(a)* the above tolerances are used; *(b)* an adequate number of marks are provided for determination of elongation; and *(c)* when yield strength is determined, a suitable extensometer is used. If the fracture occurs at a distance of less than 2 W from the edge of the gripping device, the tensile properties determined may not be representative of the material. If the properties meet the minimum requirements specified, no further testing is required, but if they are less than the minimum requirements, discard the test and retest.

FIG. 13 Tension Test Specimens for Large-Diameter Tubular Products

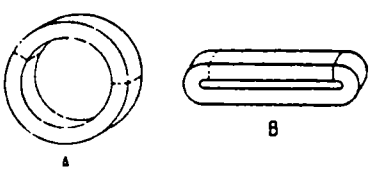


FIG. 14 Location of Transverse Tension Test Specimen in Ring Cut from Tubular Products

(3) 0.5 mm [0.020 in.] ≤ specimen dimension < 2.5 mm [0.100 in.] to the nearest 0.002 mm [0.0001 in.].

(4) Specimen dimensions < 0.5 mm [0.020 in.], to at least the nearest 1 % when practical but in all cases to at least the nearest 0.002 mm [0.0001 in.].

NOTE 9—Accurate and precise measurement of specimen dimensions can be one of the most critical aspects of tension testing, depending on specimen geometry. See Appendix X2 for additional information.

NOTE 10—Rough surfaces due to the manufacturing process such as hot rolling, metallic coating, etc., may lead to inaccuracy of the computed areas greater than the measured dimensions would indicate. Therefore, cross-sectional dimensions of test specimens with rough surfaces due to processing may be measured and recorded to the nearest 0.02 mm [0.001 in.]

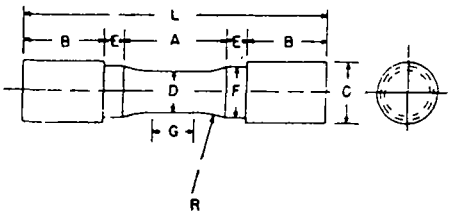
NOTE 11—See X2.9 for cautionary information on measurements taken from coated metal products.

7.2.2 Determine the cross-sectional area of a full-size test specimen of uniform but nonsymmetrical cross section by determining the mass of a length not less than 20 times longer than the largest cross-sectional dimension.

7.2.2.1 Determine the weight to the nearest 0.5 % or less.

7.2.2.2 The cross-sectional area is equal to the mass of the specimen divided by the length and divided by the density of the material.

7.2.3 When using specimens of the type shown in Fig. 13 taken from tubes, the cross-sectional area shall be determined as follows:



	Dimensions		
	Specimen 1	Specimen 2	Specimen 3
	mm [in.]	mm [in.]	mm [in.]
G—Length of parallel section	Shall be equal to or greater than diameter *D*		
D—Diameter	12.5 ± 0.2 [0.500 ± 0.010]	20 ± 0.4 [0.750 ± 0.015]	36.0 ± 0.6 [1.25 ± 0.02]
R—Radius of fillet, min	25 [1]	25 [1]	50 [2]
A—Length of reduced section, min	32 [1.25]	38 [1.5]	60 [2.25]
L—Overall length, min	95 [3.75]	100 [4]	160 [6.375]
B—Length of end section, approximate	25 [1]	25 [1]	45 [1.75]
C—Diameter of end section, approximate	20 [0.75]	30 [1.125]	48 [1.875]
E—Length of shoulder, min	6 [0.25]	6 [0.25]	8 [0.312]
F—Diameter of shoulder	16.0 ± 0.4 [0.625 ± 0.016]	24.0 ± 0.4 [0.94 ± 0.016]	36.5 ± 0.4 [1.438 ± 0.016]

NOTE—The reduced section and shoulders (dimensions *A*, *D*, *E*, *F*, *G*, and *R*) shall be as shown, but the ends may be of any form to fit the holders of the testing machine in such a way that the force can be axial. Commonly the ends are threaded and have the dimensions *B* and *C* given above.

FIG. 15 Standard Tension Test Specimen for Cast Iron

If $D/W \leq 6$:

$$A = \left[\left(\frac{W}{4}\right) \times \sqrt{(D^2 - W^2)}\right] + \left[\left(\frac{D^2}{4}\right) \times \arcsin\left(\frac{W}{D}\right)\right] - \left[\left(\frac{W}{4}\right) \times \sqrt{(D - 2T)^2 - W^2}\right] - \left[\left(\frac{D - 2T}{2}\right)^2 \times \arcsin\left(\frac{W}{D - 2T}\right)\right] \quad (1)$$

where:

A = exact cross-sectional area, mm^2 [in.^{2}],
W = width of the specimen in the reduced section, mm [in.],
D = measured outside diameter of the tube, mm [in.], and
T = measured wall thickness of the specimen, mm [in.].

arcsin values to be in radians

If $D/W > 6$, the exact equation or the following equation may be used:

$$A = W \times T \quad (2)$$

where:

A = approximate cross-sectional area, mm^2 [in.^{2}],
W = width of the specimen in the reduced section, mm [in.], and
T = measured wall thickness of the specimen, mm [in.].

NOTE 12—See X2.8 for cautionary information on measurements and calculations for specimens taken from large-diameter tubing.

7.3 *Gage Length Marking of Test Specimens*:

7.3.1 The gage length for the determination of elongation shall be in accordance with the product specifications for the material being tested. Gage marks shall be stamped lightly with a punch, scribed lightly with dividers or drawn with ink as preferred. For material that is sensitive to the effect of slight notches and for small specimens, the use of layout ink will aid in locating the original gage marks after fracture.

7.3.2 For materials where the specified elongation is 3 % or less, measure the original gage length to the nearest 0.05 mm [0.002 in.] prior to testing.

7.4 *Zeroing of the Testing Machine*:

7.4.1 The testing machine shall be set up in such a manner that zero force indication signifies a state of zero force on the specimen. Any force (or preload) imparted by the gripping of the specimen (see Note 13) must be indicated by the force measuring system unless the preload is physically removed prior to testing. Artificial methods of removing the preload on the specimen, such as taring it out by a zero adjust pot or removing it mathematically by software, are prohibited because these would affect the accuracy of the test results.

NOTE 13—Preloads generated by gripping of specimens may be either tensile or compressive in nature and may be the result of such things as:
— grip design
— malfunction of gripping apparatus (sticking, binding, etc.)
— excessive gripping force
— sensitivity of the control loop

NOTE 14—It is the operator's responsibility to verify that an observed preload is acceptable and to ensure that grips operate in a smooth manner. Unless otherwise specified, it is recommended that momentary (dynamic) forces due to gripping not exceed 20 % of the material's nominal yield strength and that static preloads not exceed 10 % of the material's nominal yield strength.

7.5 *Gripping of the Test Specimen*:

7.5.1 For specimens with reduced sections, gripping of the specimen shall be restricted to the grip section, because gripping in the reduced section or in the fillet can significantly affect test results.

7.6 *Speed of Testing*:

7.6.1 Speed of testing may be defined in terms of *(a)* rate of straining of the specimen, *(b)* rate of stressing of the specimen, *(c)* crosshead speed, *(d)* the elapsed time for completing part or all of the test, or *(e)* free-running crosshead speed (rate of movement of the crosshead of the testing machine when not under load).

7.6.2 Specifying suitable numerical limits for speed and selection of the method are the responsibilities of the product committees. Suitable limits for speed of testing should be specified for materials for which the differences resulting from the use of different speeds are of such magnitude that the test results are unsatisfactory for determining the acceptability of the material. In such instances, depending upon the material and the use for which the test results are intended, one or more of the methods described in the following paragraphs is recommended for specifying speed of testing.

NOTE 15—Speed of testing can affect test values because of the rate sensitivity of materials and the temperature-time effects.

7.6.2.1 *Rate of Straining*—The allowable limits for rate of straining shall be specified in mm/mm/min [in./in./min]. Some testing machines are equipped with pacing or indicating devices for the measurement and control of rate of straining, but in the absence of such a device the average rate of straining can be determined with a timing device by observing the time required to effect a known increment of strain.

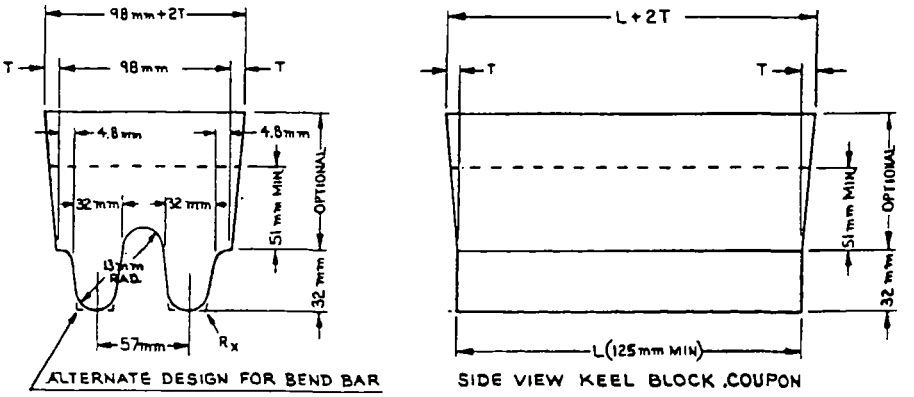
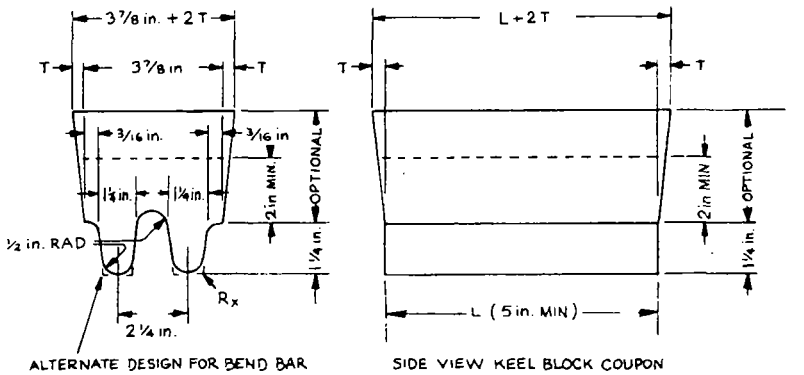
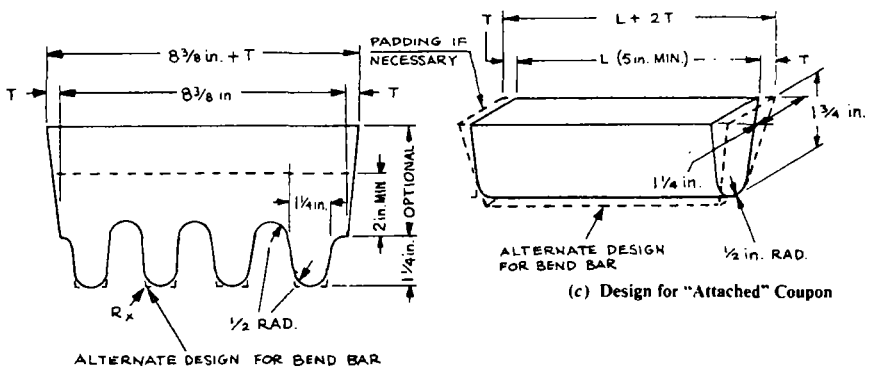


Fig. 16A Test Coupons for Castings (mm) (see Table 1 for Details of Design)



(a) Design for Double Keel Block Coupon



(b) Design for Multiple Keel Block Coupon (4 Legs)

(c) Design for "Attached" Coupon

Fig. 16B Test Coupons for Castings (in.) (see Table 1 for Details of Design)

FIG. 16 Test Coupons for Castings

7.6.2.2 *Rate of Stressing*—The allowable limits for rate of stressing shall be specified in megapascals per second [pounds per square inch per minute]. Many testing machines are equipped with pacing or indicating devices for the measurement and control of the rate of stressing, but in the absence of such a device the average rate of stressing can be determined with a timing device by observing the time required to apply a known increment of stress.

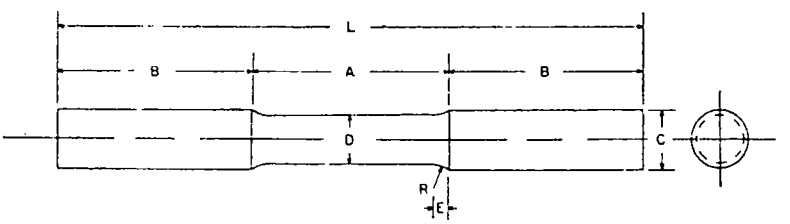
7.6.2.3 *Crosshead Speed*—The allowable limits for crosshead speed, during a test, may be specified in mm/min [in./min]; in this case, the limits for the crosshead speed should be further qualified by specifying different limits for various types and sizes of specimens. In cases where different length specimens may be used, it is often more practical to specify the crosshead speed in terms of mm [in.] per mm [in.] of length of the original reduced section of the specimen (or distance between grips for specimens not having reduced sections) per minute. Many testing machines are equipped with pacing or indicating devices for the measurement and control of the crosshead speed during a test, but in the absence of such

TABLE 1 Details of Test Coupon Design for Castings (see Fig. 16)

NOTE 1—*Test Coupons for Large and Heavy Steel Castings:* The test coupons in Fig. 16A and B are to be used for large and heavy steel castings. However, at the option of the foundry the cross-sectional area and length of the standard coupon may be increased as desired. This provision does not apply to Specification A356/A356M.

NOTE 2—*Bend Bar:* If a bend bar is required, an alternate design (as shown by dotted lines in Fig. 16) is indicated.

Log Design, 125 mm [5 in.]		Riser Design	
1. *L* (length)	A125 mm [5-in.] minimum length will be used. This length may be increased at the option of the foundry to accommodate additional test bars (see Note 1).	1. *L* (length)	The length of the riser at the base will be the same as the top length of the leg. The length of the riser at the top therefore depends on the amount of taper added to the riser.
2. End taper	Use of and size of end taper is at the option of the foundry.	2. Width	The width of the riser at the base of a multiple-leg coupon shall be *n* (57 mm) – 16 mm [*n* (2.25 in.) – 0.625 in.] where n equals the number of legs attached to the coupon. The width of the riser at the top is therefore dependent on the amount of taper added to the riser.
3. Height	32 mm [1.25 in.]		
4. Width (at top)	32 mm [1.25 in.] (see Note 1)		
5. Radius (at bottom)	13 mm [0.5 in.] max		
6. Spacing between legs	A13 mm [0.5 in.] radius will be used between the legs.		
7. Location of test bars	The tensile, bend, and impact bars will be taken from the lower portion of the leg (see Note 2).		
8. Number of legs	The number of legs attached to the coupon is at the option of the foundry providing they are equispaced according to Item 6.	3. *T* (riser taper) Height	Use of and size is at the option of the foundry. The minimum height of the riser shall be 51 mm [2 in.]. The maximum height is at the option of the foundry for the following reasons: *(a)* many risers are cast open, *(b)* different compositions may require variation in risering for soundness, or *(c)* different pouring temperatures may require variation in risering for soundness.
9. R_s	Radius from 0 to approximately 2 mm [0.062 in.]		



Dimensions, mm [in.]	
D—Diameter	16 [0.625]
R—Radius of fillet	8 [0.312]
A—Length of reduced section	64 [2.5]
L—Overall length	190 [7.5]
B—Length of end section	64 [2.5]
C—Diameter of end section	20 [0.75]
E—Length of fillet	5 [0.188]

FIG. 17 Standard Tension Test Specimen for Malleable Iron

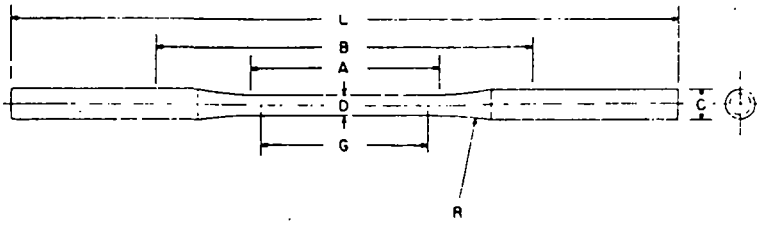
devices the average crosshead speed can be experimentally determined by using suitable length-measuring and timing devices.

NOTE 16—This method of specifying speed of testing, "Crosshead Speed", was previously called "Rate of Separation of Heads During Tests."

NOTE 17—For machines not having crossheads or having stationary crossheads, the phrase "crosshead speed" may be interpreted to mean the rate of grip separation.

7.6.2.4 *Elapsed Time*—The allowable limits for the elapsed time from the beginning of force application (or from some specified stress) to the instant of fracture, to the maximum force, or to some other stated stress, shall be specified in minutes or seconds. The elapsed time can be determined with a timing device.

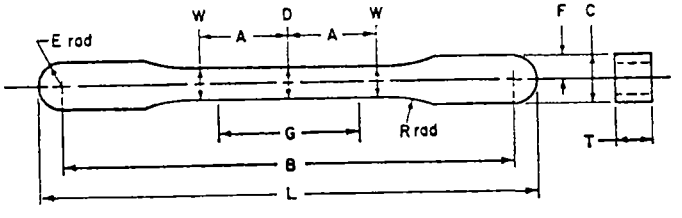
7.6.2.5 *Free-Running Crosshead Speed*—The allowable limits for the rate of movement of the crosshead of the testing machine, with no force applied by the testing machine, shall be specified in mm per mm [inches per inch] of length of reduced section (or distance between grips for specimens not having reduced sections) per second [minute]. The limits for the



Dimensions, mm [in.]	
G—Gage length	50 ± 0.1 [2.000 ± 0.005]
D—Diameter (see Note)	6.4 ± 0.1 [0.250 ± 0.005]
R—Radius of fillet, min	75 [3]
A—Length of reduced section, min	60 [2.25]
L—Overall length, min	230 [9]
B—Distance between grips, min	115 [4.5]
C—Diameter of end section, approximate	10 [0.375]

NOTE—The reduced section may have a gradual taper from the end toward the center, with the ends not more than 0.1 mm [0.005 in.] larger in diameter than the center.

FIG. 18 Standard Tension Test Specimens for Die Castings

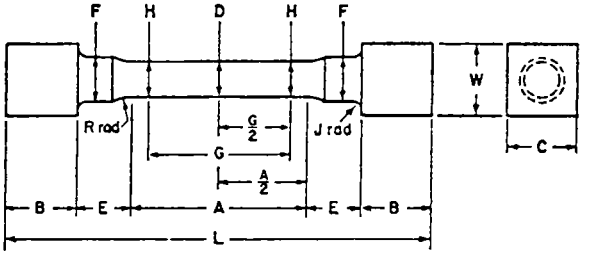


Pressing Area = 645 mm² [1.00 in.²]

Dimensions, mm [in.]	
G—Gage length	25.4 ± 0.08 [1.000 ± 0.003]
D—Width at center	5.72 ± 0.03 [0.225 ± 0.001]
W—Width at end of reduced section	5.97 ± 0.03 [0.235 ± 0.001]
T—Compact to this thickness	3.56 to 6.35 [0.140 to 0.250]
R—Radius of fillet	25.4 [1]
A—Half-length of reduced section	15.9 [0.625]
B—Grip length	80.95 ± 0.03 [3.187 ± 0.001]
L—Overall length	89.64 ± 0.03 [3.529 ± 0.001]
C—Width of grip section	8.71 ± 0.03 [0.343 ± 0.001]
F—Half-width of grip section	4.34 ± 0.03 [0.171 ± 0.001]
E—End radius	4.34 ± 0.03 [0.171 ± 0.001]

NOTE—Dimensions Specified, except *G* and *T*, are those of the die.

FIG. 19 Standard Flat Unmachined Tension Test Specimens for Powder Metallurgy (P/M) Products



Approximate Pressing Area of Unmachined Compact = 752 mm² [1.166 in.²] Machining Recommendations

1. Rough machine reduced section to 6.35-mm [0.25-in.] diameter
2. Finish turn 4.75/4.85-mm [0.187/0.191-in.] diameter with radii and taper
3. Polish with 00 emery cloth
4. Lap with crocus cloth

Dimensions, mm [in.]	
G—Gage length	25.4 ± 0.08 [1.000 ± 0.003]
D—Diameter at center of reduced section	4.75 ± 0.03 [0.187± 0.001]
H—Diameter at ends of gage length	4.85 ± 0.03 [0.191 ± 0.001]
R—Radius of gage fillet	6.35 ± 0.13 [0.250 ± 0.005]
A—Length of reduced section	47.63 ± 0.13 [1.875 ± 0.003]
L—Overall length (die cavity length)	75 [3], nominal
B—Length of end section	7.88 ± 0.13 [0.310 ± 0.005]
C—Compact to this end thickness	10.03 ± 0.13 [0.395 ± 0.005]
W—Die cavity width	10.03 ± 0.08 [0.395 ± 0.003]
E—Length of shoulder	6.35 ± 0.13 [0.250 ± 0.005]
F—Diameter of shoulder	7.88 ± 0.03 [0.310 ± 0.001]
J—End fillet radius	1.27 ± 0.13 [0.050 ± 0.005]

NOTE 1—The gage length and fillets of the specimen shall be as shown. The ends as shown are designed to provide a practical minimum pressing area. Other end designs are acceptable, and in some cases are required for high-strength sintered materials.

NOTE 2—It is recommended that the test specimen be gripped with a split collet and supported under the shoulders. The radius of the collet support circular edge is to be not less than the end fillet radius of the test specimen.

NOTE 3—Diameters *D* and *H* are to be concentric within 0.03 mm [0.001 in.] total indicator runout (T.I.R.), and free of scratches and tool marks.

FIG. 20 Standard Round Machined Tension Test Specimen for Powder Metallurgy (P/M) Products

crosshead speed may be further qualified by specifying different limits for various types and sizes of specimens. The average crosshead speed can be experimentally determined by using suitable length-measuring and timing devices.

NOTE 18—For machines not having crossheads or having stationary crossheads, the phrase "free-running crosshead speed" may be interpreted to mean the free-running rate of grip separation.

7.6.3 *Speed of Testing When Determining Yield Properties*—Unless otherwise specified, any convenient speed of testing may be used up to one half the specified minimum yield strength or up to one quarter of the specified minimum tensile strength, whichever is smaller. The speed above this point shall be within the specified limits. If different speed limitations are required for use in determining yield strength,

yield point elongation, tensile strength, elongation, and reduction of area, they should be stated in the product specifications. In all cases, the speed of testing shall be such that the forces and strains used in obtaining the test results are accurately indicated. Determination of mechanical properties for comparison of product properties against a specification value should be run using the same control method and rate used to determine the specification value unless it can be shown that another method yields equivalent or conservative results. In the absence of any specified limitations, one of the following control methods shall be used. Appendix X4 provides additional guidance on selecting the control method.

NOTE 19—In the previous and following paragraphs, the yield properties referred to include yield strength, yield point, and yield point elongation.

7.6.3.1 *Control Method A—Rate of Stressing Method for Determining Yield Properties* - In this method, the testing machine shall be operated such that the rate of stress application in the linear elastic region is between 1.15 and 11.5 MPa/s [10 000 and 100 000 psi/min]. The speed of the testing machine shall not be increased in order to maintain a stressing rate when the specimen begins to yield. It is not recommended that the testing machine be operated in closed-loop control using the force signal through yield; however closed-loop control of the force signal can be used in the linear-elastic portion of the test.

NOTE 20—It is not the intent of this method to maintain constant stress rate or to control stress rate with closed loop force control while determining yield properties, but only to set the crosshead speed to achieve the target stress rate in the elastic region. When a specimen being tested begins to yield, the stressing rate decreases and may even become negative in the case of a specimen with discontinuous yielding. To maintain a constant stressing rate through the yielding process requires the testing machine to operate at extremely high speeds and, in most cases, this is neither practical nor desirable. In practice, it is simpler to use either a strain rate, crosshead speed, or a free-running crosshead speed that approximates the desired stressing rate in the linear-elastic portion of the test. As an example, use a strain rate that is between 1.15 and 11.5 MPa/s divided by the nominal Young's Modulus of the material being tested. As another example, find a crosshead speed through experimentation that approximates the desired stressing rate prior to the onset of yielding, and maintain that crosshead speed through the region that yield properties are determined. While both of these methods will provide similar rates of stressing and straining prior to the onset of yielding, the rates of stressing and straining are generally quite different in the region where yield properties are determined.

NOTE 21—This method has been the default method for many years for testing materials that exhibit low strain rate sensitivity such as some steels and aluminum.

7.6.3.2 *Control Method B - Rate of Straining Control Method for Determining Yield Properties* —In this method, the testing machine shall be operated in closed-loop control using the extensometer signal. The rate of straining shall be set and maintained at 0.015 ± 0.006 mm/mm/min [in./in./min].

NOTE 22—Proper precautions must be observed when operating a machine in closed-loop strain control because unexpected crosshead movement may occur if the control parameters are not set properly, if proper safety limits are not set, or if the extensometer slips.

NOTE 23—A Rate of Straining at 0.005 mm/mm/min [in./in./min] is often required for aerospace, high-temperature alloys, and titanium applications and when specified, must be followed rather than the requirement above.

7.6.3.3 *Control Method C—-Crosshead Speed Control Method for Determining Yield Properties*–The testing machine shall be set to a crosshead speed equal to 0.015 ± 0.003 mm/mm/min [in./in./min] of the original reduced section (dimension A in Fig. 1, Fig. 7, Fig. 8, Fig. 9, Fig. 13, Fig. 15, Fig. 17, Fig. 18, and Fig. 20, and 2 times dimension A in Fig. 19) or distance between grips for specimens without reduced sections.

NOTE 24—It is recommended that crosshead speed be used for control in regions of discontinuous yielding.

NOTE 25—Using different Control Methods may produce different yield results especially if the material being tested is strain-rate sensitive. To achieve the best reproducibility in cases where the material may be strain-rate sensitive, the same control method should be used. Methods described in 7.6.3.2 or 7.6.3.3 will tend to give similar results in the case of a strain-rate sensitive material. The control method described in 7.6.3.1 should be avoided for strain rate sensitive materials if it is desirable to reproduce similar test results on other testing machines or in other laboratories.

7.6.4 *Speed of Testing When Determining Tensile Strength*—In the absence of any specified limitations on speed of testing, the following general rules shall apply for materials with expected elongations greater than 5 %. When determining only the tensile strength, or after the yield behavior has been recorded, the speed of the testing machine shall be set between 0.05 and 0.5 mm/mm [or in./in.] of the length of the reduced section (or distance between the grips for specimens not having a reduced section) per minute. Alternatively, an extensometer and strain rate indicator may be used to set the strain rate between 0.05 and 0.5 mm/mm/min [or in./in./min].

NOTE 26—For materials with expected elongations less than or equal to 5 %, the speed of the testing machine may be maintained throughout the test at the speed used to determine yield properties.

NOTE 27—Tensile strength and elongation are sensitive to test speed for many materials (see Appendix X1) to the extent that variations within the range of test speeds given above can significantly affect results.

7.7 *Determination of Yield Strength*—Determine yield strength by any of the methods described in 7.7.1 to 7.7.4. Where extensometers are employed, use only those which are verified over a strain range in which the yield strength will be determined (see 5.4).

NOTE 28—For example, a verified strain range of 0.2 % to 2.0 % is appropriate for use in determining the yield strengths of many metals.

NOTE 29—Determination of yield behavior on materials which cannot support an appropriate extensometer (thin wire, for example) is problematic and outside the scope of this standard.

7.7.1 *Offset Method*—To determine the yield strength by the offset method, it is necessary to secure data (autographic or numerical) from which a stress-strain diagram may be drawn. Then on the stress-strain diagram (Fig. 21) lay off *Om* equal to the specified value of the offset, draw *mn* parallel to *OA*, and thus locate *r*, the intersection of mn with the stress-strain diagram (Note 35). In reporting values of yield strength obtained by this method, the specified value of offset used should be stated in parentheses after the term yield strength. Thus:

$$\text{Yield strength (offset = 0.2 \%) = 360 MPa [52 000 psi]} \quad (3)$$

In using this method, a Class B2 or better extensometer (see Practice E83) shall be used.

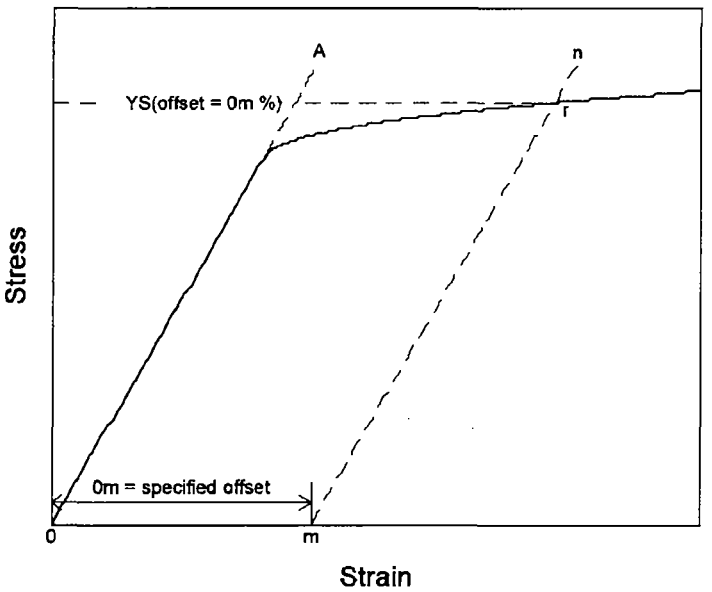


FIG. 21 Stress-Strain Diagram for Determination of Yield Strength by the Offset Method

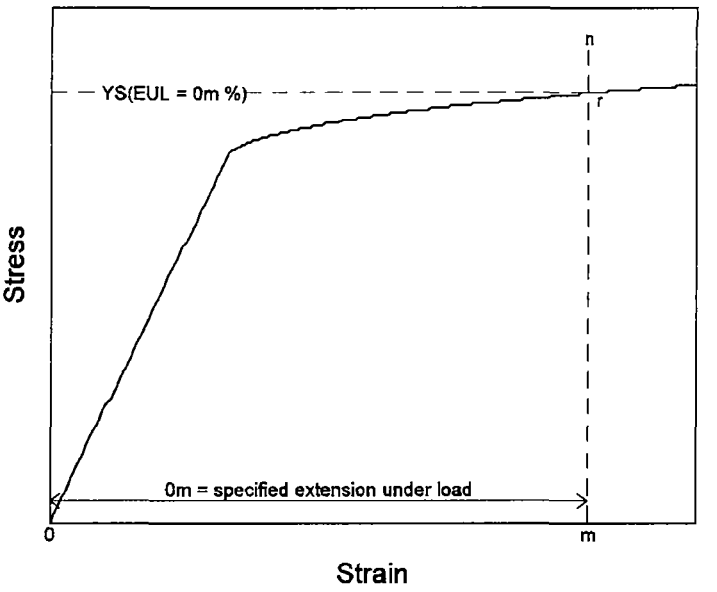


FIG. 22 Stress-Strain Diagram for Determination of Yield Strength by the Extension-Under-Load Method

NOTE 30—There are two general types of extensometers, averaging and non-averaging, the use of which is dependent on the product tested. For most machined specimens, there are minimal differences. However, for some forgings and tube sections, significant differences in measured yield strength can occur. For these cases, it is recommended that the averaging type be used.

NOTE 31—When there is a disagreement over yield properties, the offset method for determining yield strength is recommended as the referee method.

7.7.2 *Extension-Under-Load (EUL) Method*—Yield strength by the extension-under-load method may be determined by: *(1)* using autographic or numerical devices to secure stress-strain data, and then analyzing this data (graphically or using automated methods) to determine the stress value at the specified value of extension, or *(2)* using devices that indicate when the specified extension occurs, so that the stress then occurring may be ascertained (Note 33). Any of these devices may be automatic. This method is illustrated in Fig. 22. The stress at the specified extension shall be reported as follows:

$$\text{Yield strength (EUL = 0.5 \%)} = 52\,000 \text{ psi} \quad (4)$$

Extensometers and other devices used in determination of the extension shall meet or exceed Class B2 requirements (see Practice E83) at the strain of interest, except where use of low-magnification Class C devices is helpful, such as in facilitating measurement of YPE, if observed. If Class C devices are used, this must be reported along with the results.

NOTE 32—The appropriate value of the total extension must be specified. For steels with nominal yield strengths of less than 550 MPa [80 000 psi], an appropriate value is 0.005 mm/mm [or in./in.] (0.5 %) of the gage length. For higher strength steels, a greater extension or the offset method should be used.

NOTE 33—When no other means of measuring elongation are available, a pair of dividers or similar device can be used to determine a point of detectable elongation between two gage marks on the specimen. The gage length shall be 50 mm [2 in.]. The stress corresponding to the load at the instant of detectable elongation may be recorded as the approximate extension-under-load yield strength.

7.7.3 *Autographic Diagram Method (for materials exhibiting discontinuous yielding)*—Obtain stress-strain (or force-elongation) data or construct a stress-strain (or force-elongation) diagram using an autographic device. Determine the upper or lower yield strength as follows:

7.7.3.1 Record the stress corresponding to the maximum force at the onset of discontinuous yielding as the upper yield strength. This is illustrated in Figs. 23 and 24.

NOTE 34—If multiple peaks are observed at the onset of discontinuous yielding, the first is considered the upper yield strength. (See Fig. 24.)

7.7.3.2 Record the minimum stress observed during discontinuous yielding (ignoring transient effects) as the lower yield strength. This is illustrated in Fig. 24.

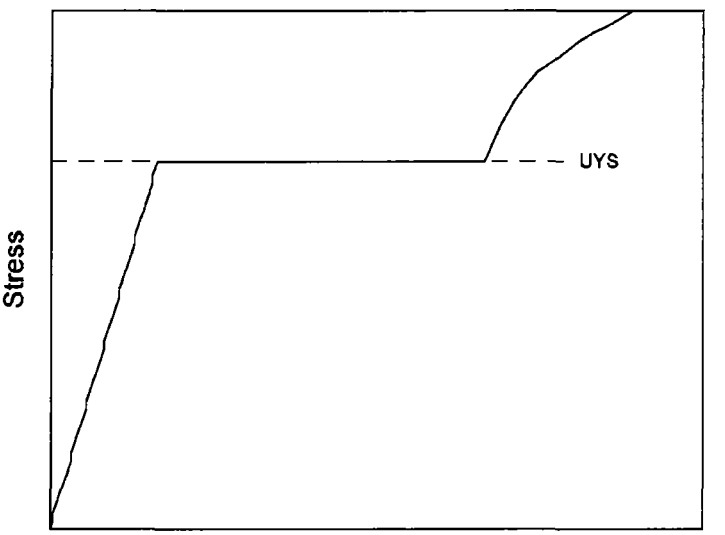


FIG. 23 Stress-Strain Diagram Showing Upper Yield Strength Corresponding with Top of Knee

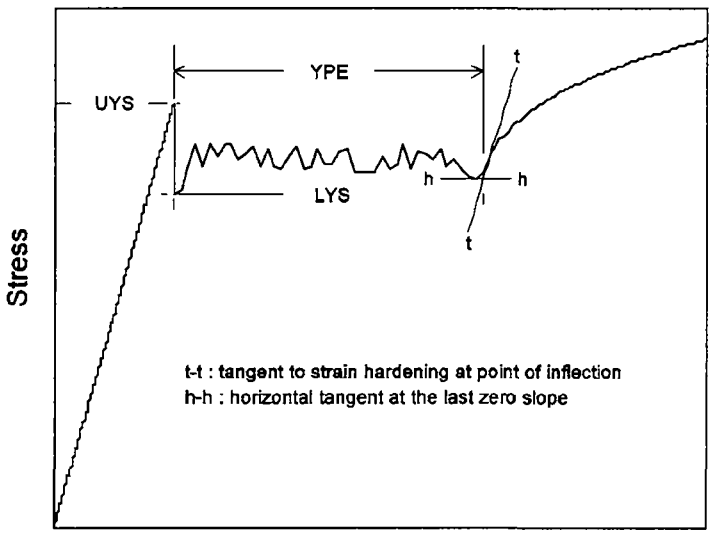


FIG. 24 Stress-Strain Diagram Showing Yield Point Elongation (YPE) and Upper (UYS) and Lower (LYS) Yield Strengths

NOTE 35—Yield properties of materials exhibiting yield point elongation are often less repeatable and less reproducible than those of similar materials having no YPE. Offset and EUL yield strengths may be significantly affected by stress fluctuations occurring in the region where the offset or extension intersects the stress-strain curve. Determination of upper or lower yield strengths (or both) may therefore be preferable for such materials, although these properties are dependent on variables such as test machine stiffness and alignment. Speed of testing may also have a significant effect, regardless of the method employed.

NOTE 36—Where low-magnification autographic recordings are needed to facilitate measurement of yield point elongation for materials which may exhibit discontinuous yielding, Class C extensometers may be employed. When this is done but the material exhibits no discontinuous yielding, the extension-under-load yield strength may be determined instead, using the autographic recording (see Extension-Under-Load Method).

7.7.4 *Halt-of-the-Force Method (for materials exhibiting discontinuous yielding)*—Apply an increasing force to the specimen at a uniform deformation rate. When the force hesitates, record the corresponding stress as the upper yield strength.

NOTE 37—The Halt-of-the-Force Method was formerly known as the Halt-of-the-Pointer Method, the Drop-of-the-Beam Method, and the Halt-of-the-Load Method.

7.8 *Yield Point Elongation*—Calculate the yield point elongation from the stress-strain diagram or data by determining the difference in strain between the upper yield strength (first zero slope) and the onset of uniform strain hardening (see definition of YPE in Terminology E6 and Fig. 24).

NOTE 38—The stress-strain curve of a material exhibiting only a hint of the behavior causing YPE may have an inflection at the onset of yielding with no point where the slope reaches zero (Fig. 25). Such a material has no YPE, but may be characterized as exhibiting an inflection. Materials exhibiting inflections, like those with measurable YPE, may in certain applications acquire an unacceptable surface appearance during forming.

7.9 *Uniform Elongation (if required)*:

7.9.1 Uniform elongation shall include both plastic and elastic elongation.

7.9.2 Uniform elongation shall be determined using autographic methods with extensometers conforming to Practice E83. Use a class B2 or better extensometer for materials having a uniform elongation less than 5 %. Use a class C or better extensometer for materials having a uniform elongation greater than or equal to 5 % but less than 50 %. Use a class D or better extensometer for materials having a uniform elongation of 50 % or greater.

7.9.3 Determine the uniform elongation as the elongation at the point of maximum force from the force elongation data collected during a test.

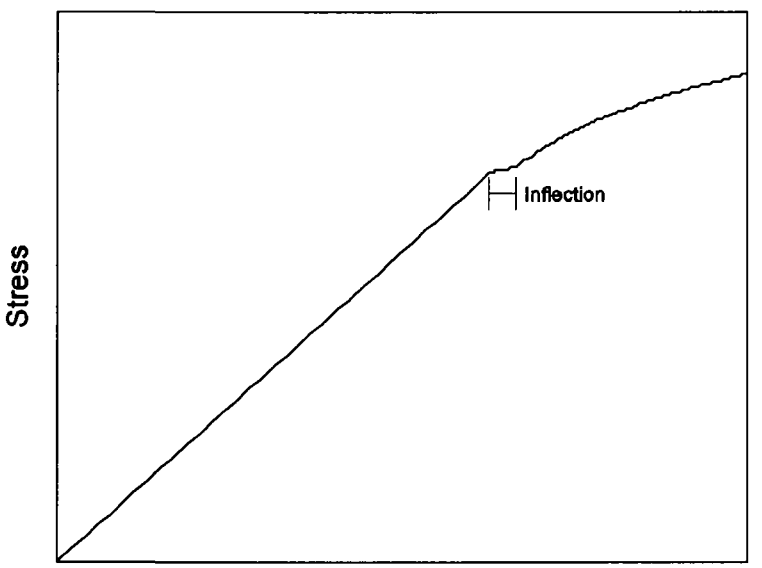


FIG. 25 Stress-Strain Diagram With an Inflection, But No YPE

7.9.3.1 Some materials exhibit a yield point followed by considerable elongation where the yield point is the maximum force achieved during the test. In this case, uniform elongation is not determined at the yield point, but instead at the highest force occurring just prior to necking (see Fig. 26).

7.9.3.2 Stress-strain curves for some materials exhibit a lengthy, plateau-like region in the vicinity of the maximum force. For such materials, determine the uniform elongation at the center of the plateau as indicated in Fig. 27 (see also Note 39 below).

NOTE 39—When uniform elongation is being determined digitally, noise in the stress-strain data generally causes many small, local peaks and valleys to be recorded in the plateau region. To accommodate this, the following procedure is recommended:

— Determine the maximum force recorded (after discontinuous yielding).

— Evaluate the sequence of force values recorded before and after the maximum force.

— Digitally define the "plateau" as consisting of all consecutive data points wherein the force value is within 0.5 % of the magnitude of the peak force value.

— Determine the uniform elongation as the strain at the mid-point of the "plateau."

7.9.3.3 *Discussion*—The 0.5 % value of Note 39 has been selected arbitrarily. In actual practice, the value should be selected so as to be the minimum figure that is large enough to effectively define the force plateau. This may require that the percentage be about 5 times the amplitude of the force fluctuations occurring due to noise. Values ranging from 0.1 % to 1.0 % may be found to work acceptably.

7.10 *Tensile Strength (also known as Ultimate Tensile Strength)*—Calculate the tensile strength by dividing the maximum force carried by the specimen during the tension test by the original cross-sectional area of the specimen.

NOTE 40—If the upper yield strength is the maximum stress recorded, and if the stress-strain curve resembles that of Fig. 26, it is recommended that the maximum stress after discontinuous yielding be reported as the tensile strength. Where this may occur, determination of the tensile strength should be in accordance with the agreement between the parties involved.

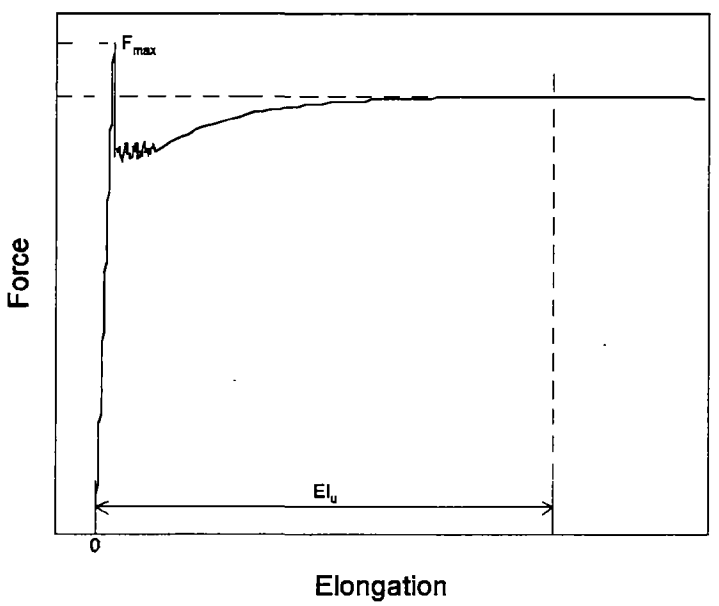


FIG. 26 Stress-Strain Diagram in Which the Upper Yield Strength is the Maximum Stress Recorded Method

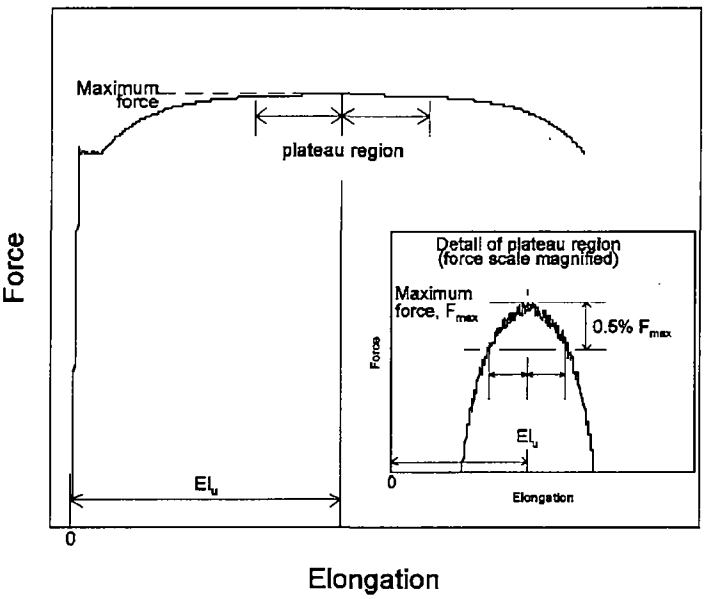


FIG. 27 Force-Elongation Diagram for Determination of Uniform Elongation of Steel Sheet Materials Exhibiting a Plateau at Maximum Force

7.11 *Elongation*:

7.11.1 In reporting values of elongation, give both the original gage length and the percentage increase. If any device other than an extensometer is placed in contact with the specimen's reduced section during the test, this also shall be noted.

Example: Elongation = 30 % increase (50−mm [2−in.] gage length) (5)

NOTE 41—Elongation results are very sensitive to variables such as: *(a)* speed of testing, *(b)* specimen geometry (gage length, diameter, width, and thickness), *(c)* heat dissipation (through grips, extensometers, or other devices in contact with the reduced section), *(d)* surface finish in reduced section (especially burrs or notches), *(e)* alignment, and *(f)* fillets and tapers. Parties involved in comparison or conformance testing should standardize the above items, and it is recommended that use of ancillary devices (such as extensometer supports) which may remove heat from specimens be avoided. See Appendix X1 for additional information on the effects of these variables.

7.11.2 When the specified elongation is greater than 3 %, fit ends of the fractured specimen together carefully and measure the distance between the gage marks to the nearest 0.25 mm [0.01 in.] for gage lengths of 50 mm [2 in.] and under, and to at least the nearest 0.5 % of the gage length for gage lengths over 50 mm [2 in.]. A percentage scale reading to 0.5 % of the gage length may be used.

7.11.3 When the *specified* elongation is 3 % or less, determine the elongation of the specimen using the following procedure, except that the procedure given in 7.11.2 may be used instead when the *measured* elongation is greater than 3 %.

7.11.3.1 Prior to testing, measure the original gage length of the specimen to the nearest 0.05 mm [0.002 in.].

7.11.3.2 Remove partly torn fragments that will interfere with fitting together the ends of the fractured specimen or with making the final measurement.

7.11.3.3 Fit the fractured ends together with matched surfaces and apply a force along the axis of the specimen sufficient to close the fractured ends together. If desired, this force may then be removed carefully, provided the specimen remains intact.

NOTE 42—The use of a force generating a stress of approximately 15 MPa [2000 psi] has been found to give satisfactory results on test specimens of aluminum alloy.

7.11.3.4 Measure the final gage length to the nearest 0.05 mm [0.002 in.] and report the elongation to the nearest 0.2 %.

7.11.4 Elongation measured per paragraph 7.11.2 or 7.11.3 may be affected by location of the fracture, relative to the marked gage length. If any part of the fracture occurs outside the gage marks or is located less than 25 % of the elongated gage length from either gage mark, the elongation value obtained using that pair of gage marks may be abnormally low and non-representative of the material. If such an elongation measure is obtained in acceptance testing involving only a minimum requirement and meets the requirement, no further testing need be done. Otherwise, discard the test and retest the material.

7.11.5 *Elongation at Fracture*:

7.11.5.1 Elongation at fracture shall include elastic and plastic elongation and may be determined with autographic or automated methods using extensometers verified over the strain range of interest (see 5.4). Use a class B2 or better extensometer for materials having less than 5 % elongation, a class C or better extensometer for materials having elongation greater than or equal to 5 % but less than 50 %, and a class D or better extensometer for materials having 50 % or greater elongation. In all cases, the extensometer gage length shall be the nominal gage length required for the specimen being tested. Due to the lack of precision in fitting fractured ends together, the elongation after fracture using the manual methods of the preceding paragraphs may differ from the elongation at fracture determined with extensometers.

7.11.5.2 Percent elongation at fracture may be calculated directly from elongation at fracture data and be reported instead of percent elongation as calculated in 7.11.2 to 7.11.3. However, these two parameters are not interchangeable. Use of the elongation at fracture method generally provides more repeatable results.

NOTE 43—When disagreements arise over the percent elongation results, agreement must be reached on which method to use to obtain the results.

7.12 *Reduction of Area*:

7.12.1 The reduced area used to calculate reduction of area (see 7.11.2 and 7.11.3) shall be the minimum cross section at the location of fracture.

7.12.2 *Specimens with Originally Circular Cross Sections*—Fit the ends of the fractured specimen together and measure the reduced diameter to the same accuracy as the original measurement.

NOTE 44—Because of anisotropy, circular cross sections often do not remain circular during straining in tension. The shape is usually elliptical, thus, the area may be calculated by $\pi \cdot d_1 \cdot d_2/4$, where d_1 and d_2 are the major and minor diameters, respectively.

7.12.3 *Specimens with Original Rectangular Cross Sections*—Fit the ends of the fractured specimen together and measure the thickness and width at the minimum cross section to the same accuracy as the original measurements.

NOTE 45—Because of the constraint to deformation that occurs at the corners of rectangular specimens, the dimensions at the center of the original flat surfaces are less than those at the corners. The shapes of these surfaces are often assumed to be parabolic. When this assumption is made, an effective thickness, t_e, may be calculated as follows: $(t_1 + 4t_2 + t_3)/6$, where t_1 and t_3 are the thicknesses at the corners, and t_2 is the thickness at mid-width. An effective width may be similarly calculated.

7.12.4 Calculate the reduced area based upon the dimensions determined in 7.12.2 or 7.12.3. The difference between the area thus found and the area of the original cross section expressed as a percentage of the original area is the reduction of area.

7.12.5 If any part of the fracture takes place outside the middle half of the reduced section or in a punched or scribed gage mark within the reduced section, the reduction of area value obtained may not be representative of the material. In acceptance testing, if the reduction of area so calculated meets the minimum requirements specified, no further testing is required, but if the reduction of area is less than the minimum requirements, discard the test results and retest.

7.12.6 Results of measurements of reduction of area shall be rounded using the procedures of Practice E29 and any specific procedures in the product specifications. In the absence of a specified procedure, it is recommended that reduction of area test values in the range from 0 to 10 % be rounded to the nearest 0.5 % and test values of 10 % and greater to the nearest 1 %.

7.13 *Rounding Reported Test Data for Yield Strength and Tensile Strength*—Test data should be rounded using the procedures of Practice E29 and the specific procedures in the product specifications. In the absence of a specified procedure for rounding the test data, one of the procedures described in the following paragraphs is recommended.

7.13.1 For test values up to 500 MPa [50 000 psi], round to the nearest 1 MPa [100 psi]; for test values of 500 MPa [50 000 psi] and up to 1000 MPa [100 000 psi], round to the nearest 5 MPa [500 psi]; for test values of 1000 MPa [100 000 psi] and greater, round to the nearest 10 MPa [1000 psi].

NOTE 46—For steel products, see Test Methods and Definitions A370.

7.13.2 For all test values, round to the nearest 1 MPa [100 psi].

NOTE 47—For aluminum- and magnesium-alloy products, see Methods B557.

7.13.3 For all test values, round to the nearest 5 MPa [500 psi].

7.14 *Replacement of Specimens*—A test specimen may be discarded and a replacement specimen selected from the same lot of material in the following cases:

7.14.1 The original specimen had a poorly machined surface,

7.14.2 The original specimen had the wrong dimensions,

7.14.3 The specimen's properties were changed because of poor machining practice,

7.14.4 The test procedure was incorrect,

7.14.5 The fracture was outside the gage length,

7.14.6 For elongation determinations, the fracture was outside the middle half of the gage length, or

7.14.7 There was a malfunction of the testing equipment.

NOTE 48—The tension specimen is inappropriate for assessing some types of imperfections in a material. Other methods and specimens employing ultrasonics, dye penetrants, radiography, etc., may be considered when flaws such as cracks, flakes, porosity, etc., are revealed during a test and soundness is a condition of acceptance.

8. Report

8.1 Test information on materials not covered by a product specification should be reported in accordance with 8.2 or both 8.2 and 8.3.

8.2 Test information to be reported shall include the following when applicable:

8.2.1 Reference to the standard used, i.e. E8 or E8M.

8.2.2 Material and sample identification.

8.2.3 Specimen type (see Section 6).

8.2.4 Yield strength and the method used to determine yield strength (see 7.7).

8.2.5 Yield point elongation (see 7.8).

8.2.6 Tensile Strength (also known as Ultimate Tensile Strength) (see 7.10).

8.2.7 Elongation (report original gage length, percentage increase, and method used to determine elongation; i.e. at fracture or after fracture) (see 7.11).

8.2.8 Uniform Elongation, if required (see 7.9).

8.2.9 Reduction of area, if required (see 7.12).

8.3 Test information to be available on request shall include:

8.3.1 Specimen test section dimension(s).

8.3.2 Equation used to calculate cross-sectional area of rectangular specimens taken from large-diameter tubular products.

8.3.3 Speed and method used to determine speed of testing (see 7.6).

8.3.4 Method used for rounding of test results (see 7.13).

8.3.5 Reasons for replacement specimens (see 7.14).

9. Precision and Bias

9.1 *Precision*—An interlaboratory test program[3] gave the following values for coefficients of variation for the most commonly measured tensile properties:

Coefficient of Variation, %

	Tensile Strength	Yield Strength Offset = 0.02 %	Yield Strength Offset = 0.2 %	Elongation Gage Length = 4 Diameter	Reduction of Area
CV $\%_r$	0.9	2.7	1.4	2.8	2.8
CV $\%_R$	1.3	4.5	2.3	5.4	4.6

CV $\%_r$ = repeatability coefficient of variation in percent within a laboratory
CV $\%_R$ = repeatability coefficient of variation in percent between laboratories

9.1.1 The values shown are the averages from tests on six frequently tested metals, selected to include most of the normal range for each property listed above. When these materials are compared, a large difference in coefficient of variation is found. Therefore, the values above should not be used to judge whether the difference between duplicate tests of a specific material is larger than expected. The values are provided to allow potential users of this test method to assess, in general terms, its usefulness for a proposed application.

9.2 *Bias*—The procedures in Test Methods E8/E8Mfor measuring tensile properties have no bias because these properties can be defined only in terms of a test method.

10. Keywords

10.1 accuracy; bending stress; discontinuous yielding; drop-of-the-beam; eccentric force application; elastic extension; elongation; extension-under-load; extensometer; force; free-running crosshead speed; gage length; halt-of-the force; percent elongation; plastic extension; preload; rate of stressing; rate of straining; reduced section; reduction of area; sensitivity; strain; stress; taring; tensile strength; tension testing; yield point elongation; yield strength

[3] Supporting data can be found in Appendix X1 and additional data are available from ASTM Headquarters. Request RR:E28-1004.

APPENDIXES

(Nonmandatory Information)

X1. FACTORS AFFECTING TENSION TEST RESULTS

X1.1 The precision and bias of tension test strength and ductility measurements depend on strict adherence to the stated test procedure and are influenced by instrumental and material factors, specimen preparation, and measurement/testing errors.

X1.2 The consistency of agreement for repeated tests of the same material is dependent on the homogeneity of the material, and the repeatability of specimen preparation, test conditions, and measurements of the tension test parameters.

X1.3 Instrumental factors that can affect test results include: the stiffness, damping capacity, natural frequency, and mass of moving parts of the tensile test machine; accuracy of force indication and use of forces within the verified range of the machine; rate of force application, alignment of the test specimen with the applied force, parallelness of the grips, grip pressure, nature of the force control used, appropriateness and calibration of extensometers, heat dissipation (by grips, extensometers, or ancillary devices), and so forth.

X1.4 Material factors that can affect test results include: representativeness and homogeneity of the test material, sampling scheme, and specimen preparation (surface finish, dimensional accuracy, fillets at the ends of the gage length, taper in the gage length, bent specimens, thread quality, and so forth).

X1.4.1 Some materials are very sensitive to the quality of the surface finish of the test specimen (see Note 4) and must be ground to a fine finish, or polished to obtain correct results.

X1.4.2 Test results for specimens with as-cast, as-rolled, as-forged, or other non-machined surface conditions can be affected by the nature of the surface (see Note 10).

X1.4.3 Test specimens taken from appendages to the part or component, such as prolongs or risers, or from separately produced castings (for example, keel blocks) may produce test results that are not representative of the part or component.

X1.4.4 Test specimen dimensions can influence test results. For cylindrical or rectangular specimens, changing the test specimen size generally has a negligible effect on the yield and tensile strength but may influence the upper yield strength, if one is present, and elongation and reduction of area values. Comparison of elongation values determined using different specimens requires that the following ratio be controlled:

$$L_o/(A_o)^{1/2} \quad \text{(X1.1)}$$

where:

L_o = original gage length of specimen, and
A_o = original cross-sectional area of specimen.

X1.4.4.1 Specimens with smaller $L_o/(A_o)^{1/2}$ ratios generally give greater elongation and reduction in area values. This is the case for example, when the width or thickness of a rectangular tensile test specimen is increased.

X1.4.4.2 Holding the $L_o/(A_o)^{1/2}$ ratio constant minimizes, but does not necessarily eliminate, differences. Depending on material and test conditions, increasing the size of the proportional specimen of Fig. 8 may be found to increase or decrease elongation and reduction in area values somewhat.

X1.4.5 Use of a taper in the gage length, up to the allowed 1 % limit, can result in lower elongation values. Reductions of as much as 15 % have been reported for a 1 % taper.

X1.4.6 Changes in the strain rate can affect the yield strength, tensile strength, and elongation values, especially for materials which are highly strain rate sensitive. In general, the yield strength and tensile strength will increase with increasing strain rate, although the effect on tensile strength is generally less pronounced. Elongation values generally decrease as the strain rate increases.

X1.4.7 Brittle materials require careful specimen preparation, high quality surface finishes, large fillets at the ends of the gage length, oversize threaded grip sections, and cannot tolerate punch or scribe marks as gage length indicators.

X1.4.8 Flattening of tubular products to permit testing does alter the material properties, generally nonuniformly, in the flattened region which may affect test results.

X1.5 Measurement errors that can affect test results include: verification of the test force, extensometers, micrometers, dividers, and other measurement devices, alignment and zeroing of chart recording devices, and so forth.

X1.5.1 Measurement of the dimensions of as-cast, as-rolled, as-forged, and other test specimens with non-machined surfaces may be imprecise due to the irregularity of the surface flatness.

X1.5.2 Materials with anisotropic flow characteristics may exhibit non-circular cross sections after fracture and measurement precision may be affected, as a result (see Note 40).

X1.5.3 The corners of rectangular test specimens are subject to constraint during deformation and the originally flat surfaces may be parabolic in shape after testing which will affect the precision of final cross-sectional area measurements (see Note 45).

X1.5.4 If any portion of the fracture occurs outside of the middle of the gage length, or in a punch or scribe mark within the gage length, the elongation and reduction of area values may not be representative of the material. Wire specimens that break at or within the grips may not produce test results representative of the material.

X1.5.5 Use of specimens with shouldered ends ("button-head" tensiles) will produce lower 0.02 % offset yield strength values than threaded specimens.

X1.6 Because standard reference materials with certified tensile property values are not available, it is not possible to rigorously define the bias of tension tests. However, by the use of carefully designed and controlled interlaboratory studies, a reasonable definition of the precision of tension test results can be obtained.

X1.6.1 An interlaboratory test program[3] was conducted in which six specimens each, of six different materials were prepared and tested by each of six different laboratories. Tables X1.1-X1.6 present the precision statistics, as defined in Practice E691, for: tensile strength, 0.02 % yield strength, 0.2 % yield strength, % elongation in 4D, % elongation in 5D, and % reduction in area. In each table, the first column lists the six materials tested, the second column lists the average of the average results obtained by the laboratories, the third and fifth columns list the repeatability and reproducibility standard deviations, the fourth and sixth columns list the coefficients of variation for these standard deviations, and the seventh and eighth columns list the 95 % repeatability and reproducibility limits.

X1.6.2 The averages (below columns four and six in each table) of the coefficients of variation permit a relative comparison of the repeatability (within-laboratory precision) and reproducibility (between-laboratory precision) of the tension test parameters. This shows that the ductility measurements exhibit less repeatability and reproducibility than the strength measurements. The overall ranking from the least to the most repeatable and reproducible is: % elongation in 4D, % elongation in 5D, % reduction in area, 0.02 % offset yield strength, 0.2 % offset yield strength, and tensile strength. Note that the rankings are in the same order for the repeatability and reproducibility average coefficients of variation and that the reproducibility (between-laboratory precision) is poorer than the repeatability (within-laboratory precision) as would be expected.

X1.6.3 No comments about bias can be made for the interlaboratory study due to the lack of certified test results for

these specimens. However, examination of the test results showed that one laboratory consistently exhibited higher than average strength values and lower than average ductility values for most of the specimens. One other laboratory had consistently lower than average tensile strength results for all specimens.

TABLE X1.1 Precision Statistics—Tensile Strength, MPa [ksi]

NOTE—X is the average of the cell averages, that is, the grand mean for the test parameter,
s_r is the repeatability standard deviation (within-laboratory precision) in MPa [ksi],
s_r/X is the coefficient of variation in %,
s_R is the reproducibility standard deviation (between-laboratory precision) in MPa [ksi],
s_R/X is the coefficient of variation, %,
r is the 95 % repeatability limits in MPa [ksi],
R is the 95 % reproducibility limits in MPa [ksi].

Material	X	s_r	s_r/X, %	s_R	s_R/X, %	r	R
EC-H19	176.9 [25.66]	4.3 [0.63]	2.45	4.3 [0.63]	2.45	12.1 [1.76]	12.1 [1.76]
2024-T351	491.3 [71.26]	6.1 [0.88]	1.24	6.6 [0.96]	1.34	17.0 [2.47]	18.5 [2.68]
ASTM A105	596.9 [86.57]	4.1 [0.60]	0.69	8.7 [1.27]	1.47	11.6 [1.68]	24.5 [3.55]
AISI 316	694.6 [100.75]	2.7 [0.39]	0.39	8.4 [1.22]	1.21	7.5 [1.09]	23.4 [3.39]
Inconel 600	685.9 [99.48]	2.9 [0.42]	0.43	5.0 [0.72]	0.72	8.2 [1.19]	13.9 [2.02]
SAE 51410	1253.0 [181.73]	0.25 [0.46]	0.25	7.9 [1.14]	0.63	8.9 [1.29]	22.1 [3.20]
		Averages:	0.91		1.30		

TABLE X1.2 Precision Statistics—0.02 % Yield Strength, MPa [ksi]

Material	X	s_r	s_r/X, %	s_R	s_R/X, %	r	R
EC-H19	111.4 [16.16]	4.5 [0.65]	4.00	8.2 [1.19]	7.37	12.5 [1.81]	23.0 [3.33]
2024-T351	354.2 [51.38]	5.8 [0.84]	1.64	6.1 [0.89]	1.73	16.3 [2.36]	17.2 [2.49]
ASTM A105	411.1 [59.66]	8.3 [1.20]	2.02	13.1 [1.90]	3.18	23.2 [3.37]	36.6 [5.31]
AISI 316	336.1 [48.75]	16.7 [2.42]	4.97	31.9 [4.63]	9.49	46.1 [6.68]	89.0 [12.91]
Inconel 600	267.1 [38.74]	3.2 [0.46]	1.18	5.2 [0.76]	1.96	8.8 [1.28]	14.7 [2.13]
SAE 51410	723.2 [104.90]	16.6 [2.40]	2.29	21.9 [3.17]	3.02	46.4 [6.73]	61.2 [8.88]
		Averages:	2.68		4.46		

TABLE X1.3 Precision Statistics—0.2 % Yield Strength, MPa [ksi]

Material	X	s_r	s_r/X, %	s_R	s_R/X, %	r	R
EC-H19	158.4 [22.98]	3.3 [0.47]	2.06	3.3 [0.48]	2.07	9.2 [1.33]	9.2 [1.33]
2024-T351	362.9 [52.64]	5.1 [0.74]	1.41	5.4 [0.79]	1.49	14.3 [2.08]	15.2 [2.20]
ASTM A105	402.4 [58.36]	5.7 [0.83]	1.42	9.9 [1.44]	2.47	15.9 [2.31]	27.8 [4.03]
AISI 316	481.1 [69.78]	6.6 [0.95]	1.36	19.5 [2.83]	4.06	18.1 [2.63]	54.7 [7.93]
Inconel 600	268.3 [38.91]	2.5 [0.36]	0.93	5.8 [0.85]	2.17	7.0 [1.01]	16.3 [2.37]
SAE 51410	967.5 [140.33]	8.9 [1.29]	0.92	15.9 [2.30]	1.64	24.8 [3.60]	44.5 [6.45]
		Averages:	1.35		2.32		

TABLE X1.4 Precision Statistics—% Elongation in 4D for E8 Specimens

NOTE—Length of reduced section = 6D.

Material	X	s_r	s_r/X, %	s_R	s_R/X, %	r	R
EC-H19	17.42	0.64	3.69	0.92	5.30	1.80	2.59
2024-T351	19.76	0.58	2.94	1.58	7.99	1.65	4.43
ASTM A105	29.10	0.76	2.62	0.98	3.38	2.13	2.76
AISI 316	40.07	1.10	2.75	2.14	5.35	3.09	6.00
Inconel 600	44.28	0.66	1.50	1.54	3.48	1.86	4.31
SAE 51410	14.48	0.48	3.29	0.99	6.83	1.34	2.77
		Averages:	2.80		5.39		

TABLE X1.5 Precision Statistics—% Elongation in 5D for E8M Specimens

NOTE—Length of reduced section = 6D.

Material	X	s_r	s_r/X, %	s_R	s_R/X, %	r	R
EC-H19	14.60	0.59	4.07	0.66	4.54	1.65	1.85
2024-T351	17.99	0.63	3.48	1.71	9.51	1.81	4.81
ASTM A105	25.63	0.77	2.99	1.30	5.06	2.15	3.63
AISI 316	35.93	0.71	1.98	2.68	7.45	2.00	7.49
Inconel 600	41.58	0.67	1.61	1.60	3.86	1.88	4.49
SAE 51410	13.39	0.45	3.61	0.96	7.75	1.25	2.89
		Averages:	2.96		6.36		

TABLE X1.6 Precision Statistics—% Reduction in Area

Material	X	s_r	s_r/X, %	s_R	s_R/X, %	r	R
EC-H19	79.15	1.93	2.43	2.01	2.54	5.44	5.67
2024-T351	30.41	2.09	6.87	3.59	11.79	5.79	10.01
ASTM A105	65.59	0.84	1.28	1.26	1.92	2.35	3.53
AISI 316	71.49	0.99	1.39	1.60	2.25	2.78	4.50
Inconel 600	59.34	0.67	1.14	0.70	1.18	1.89	1.97
SAE 51410	50.49	1.86	3.69	3.95	7.81	5.21	11.05
		Averages:	2.80		4.58		

X2. MEASUREMENT OF SPECIMEN DIMENSIONS

X2.1 Measurement of specimen dimensions is critical in tension testing, and it becomes more critical with decreasing specimen size, as a given absolute error becomes a larger relative (percent) error. Measuring devices and procedures should be selected carefully, so as to minimize measurement error and provide good repeatability and reproducibility.

X2.2 Relative measurement error should be kept at or below 1 %, where possible. Ideally, this 1 % error should include not only the resolution of the measuring device but also the variability commonly referred to as repeatability and reproducibility. (Repeatability is the ability of any operator to obtain similar measurements in repeated trials. Reproducibility is the ability of multiple operators to obtain similar measurements.)

X2.3 Formal evaluation of gage repeatability and reproducibility (GR and R) by way of a GR and R study is highly recommended. A GR and R study involves having multiple operators each take two or three measurements of a number of parts—in this case, test specimens. Analysis, usually done by computer, involves comparing the observed measurement variations to a tolerance the procedure is to determine conformance to. High GR and R percentages (more than 20 %) indicate much variability relative to the tolerance, whereas low percentages (10 % or lower) indicate the opposite. The analysis also estimates, independently, the repeatability and reproducibility.

X2.4 GR and R studies in which nontechnical personnel used different brands and models of hand-held micrometers have given results varying from about 10 % (excellent) to nearly 100 % (essentially useless), relative to a dimensional tolerance of 0.075 mm [0.003 in.]. The user is therefore advised to be very careful in selecting devices, setting up measurement procedures, and training personnel.

X2.5 With a 0.075 mm [0.003 in.] tolerance, a 10 % GR and R result (exceptionally good, even for digital hand-held micrometers reading to 0.001 mm [0.00005 in.]) indicates that the total variation due to repeatability and reproducibility is around 0.0075 [0.0003 in.]. This is less than or equal to 1 % only if all dimensions to be measured are greater than or equal to 0.75 mm [0.03 in.]. The relative error in using this device to measure thickness of a 0.25 mm [0.01 in.] flat tensile specimen would be 3 %—which is considerably more than that allowed for force or strain measurement.

X2.6 Dimensional measurement errors can be identified as the cause of many *out-of-control* signals, as indicated by statistical process control (SPC) charts used to monitor tension testing procedures. This has been the experience of a production laboratory employing SPC methodology and the best hand-held micrometers available (from a GR and R standpoint) in testing of 0.45 to 6.35 mm [0.018 to 0.25 in.] flat rolled steel products.

X2.7 Factors which affect GR and R, sometimes dramatically, and which should be considered in the selection and evaluation of hardware and procedures include:

X2.7.1 Resolution,
X2.7.2 Verification,
X2.7.3 Zeroing,
X2.7.4 Type of anvil (flat, rounded, or pointed),
X2.7.5 Cleanliness of part and anvil surfaces,
X2.7.6 User-friendliness of measuring device,
X2.7.7 Stability/temperature variations,
X2.7.8 Coating removal,
X2.7.9 Operator technique, and
X2.7.10 Ratchets or other features used to regulate the clamping force.

X2.8 Flat anvils are generally preferred for measuring the

dimensions of round or flat specimens which have relatively smooth surfaces. One exception is that rounded or pointed anvils must be used in measuring the thickness of curved specimens taken from large-diameter tubing (see Fig. 13), to prevent overstating the thickness. (Another concern for these curved specimens is the error that can be introduced through use of the equation $A = W \times T$; see 7.2.3.)

X2.9 Heavy coatings should generally be removed from at least one grip end of flat specimens taken from coated products to permit accurate measurement of base metal thickness, assuming *(a)* the base metal properties are what are desired, *(b)* the coating does not contribute significantly to the strength of the product, and *(c)* coating removal can be easily accomplished (some coatings may be easily removed by chemical stripping). Otherwise, it may be advisable to leave the coating intact and determine the base metal thickness by an alternate method. Where this issue may arise, all parties involved in comparison or conformance testing should agree as to whether or not coatings are to be removed before measurement.

X2.10 As an example of how the considerations identified above affect dimensional measurement procedures, consider the case of measuring the thickness of 0.40 mm [0.015 in.) painted, flat rolled steel specimens. The paint should be removed prior to measurement, if possible. The measurement device used should have flat anvils, must read to 0.0025 mm [0.0001 in.] or better, and must have excellent repeatability and reproducibility. Since GR and R is a significant concern, it will be best to use a device which has a feature for regulating the clamping force used, and devices without digital displays should be avoided to prevent reading errors. Before use of the device, and periodically during use, the anvils should be cleaned, and the device should be verified or zeroed (if an electronic display is used) or both. Finally, personnel should be trained and audited periodically to ensure that the measuring device is being used correctly and consistently by all.

X3. SUGGESTED ACCREDITATION CRITERIA FOR LABORATORIES PERFORMING TENSILE TESTS

X3.1 Scope

X3.1.1 The following are specific features that an assessor may check to assess a laboratory's technical competence, if the laboratory is performing tests in accordance with Test Methods E8 and/or E8M.

X3.2 Preparation

X3.2.1 The laboratory should follow documented procedures to ensure that machining or other preparation generates specimens conforming to applicable tolerances and requirements of Test Methods E8 or E8M. Particularly important are those requirements that pertain to the dimensions and finish of reduced sections, as found in the text and in applicable figures.

X3.2.2 Where gage marks are used, the laboratory should employ documented gage marking procedures to ensure that the marks and gage lengths comply with the tolerances and guidelines of Test Methods E8 or E8M.

X3.2.2.1 The gage marking procedure used should not deleteriously affect the test results.

NOTE X3.1—Frequent occurrence of fracturing at the gage marks may indicate that gage marks have excessive depth or sharpness and may be affecting test results.

X3.3 Test Equipment

X3.3.1 As specified in the Apparatus sections of Test Methods E8 and E8M, the axis of the test specimen should coincide with the center line of the heads of the testing machine, in order to minimize bending stresses which could affect the results.

X3.3.2 Equipment verification requirements of Practices E4 and E83 shall be met. Documentation showing the verification work to have been thorough and technically correct should be available.

X3.3.2.1 Verification reports shall demonstrate that force and extension readings have been taken at the prescribed intervals and that the prescribed runs have been completed.

X3.3.3 Extensometers used shall meet all requirements of Test Methods E8 or E8M as to the classification of device to be used for the results determined. For example, an extensometer not meeting the Class B2 requirements of Practice E83 may not be used in determination of offset yield strengths.

X3.3.4 Before computerized or automated test equipment is put into routine service, or following a software revision, it is recommended that measures be taken to verify proper operation and result interpretation. Guide E1856 addresses this concern.

X3.3.5 Micrometers and other devices used in measurement of specimen dimensions should be selected, maintained and used in such a manner as to comply with the appendixes of Test Methods E8 and E8M on measurement. Traceability to national standards should be established for these devices, and reasonable effort should be employed to prevent errors greater than 1 % from being generated as a result of measurement error, resolution, and rounding practice.

X3.4 Procedures

X3.4.1 The test machine shall be set up and zeroed in such a manner that zero force indication signifies a state of zero force on the specimen, as indicated in the Zeroing of the Test Machine sections of Test Methods E8 and E8M.

NOTE X3.2—Provisions should be made to ensure that zero readings are properly maintained, from test to test. These may include, for example, zeroing after a predetermined number of tests or each time, under zero force conditions, the indicator exceeds a predetermined value.

X3.4.2 Upon request, the laboratory should be capable of demonstrating (perhaps through time, force, displacement or extensometer measurements, or both) that the test speeds used conform to the requirements of Test Methods E8 or E8M, or other standards which take precedence.

X3.4.3 Upon request, the laboratory should be capable of demonstrating that the offsets and extensions used in determining yield strengths conform to the requirements of Test

Methods E8 or E8M and are constructed so as to indicate the forces corresponding to the desired offset strain or total strain.

NOTE X3.3—Use caution when performing calculations with extensometer magnification, because the manufacturer may report strain magnification, which relates the strain (not the elongation) to the x-axis displacement on the stress strain diagram. A user or assessor interested in an extensometer's magnification may use calibration equipment to determine the ratio between elongation and chart travel or may verify a reported magnification by calculating the Young's modulus from tests of specimens of a known nominal modulus.

X3.4.4 Measurement of elongation shall conform to requirements of Test Methods E8 or E8M.

NOTE X3.4—Test Methods E8 and E8M permit the measurement and reporting of elongation at fracture in place of elongation, as is often done in automated testing.

X3.4.5 Reduction of area, when required, shall be determined in accordance with the requirements of Test Methods E8 or E8M.

X3.4.6 Procedures for recording, calculating, and reporting data and test results shall conform to all applicable requirements of Test Methods E8 or E8M. In addition, wherever practical, the procedures should also be in accordance with widely accepted provisions of good laboratory practice, such as those detailed below.

X3.4.6.1 When recording data, personnel should record all figures that are definite, plus the best estimate of the first figure which is uncertain. (If a result is known to be approximately midway between 26 and 27, 26.5 should be the result recorded (not 26, 27, or 26.475).

X3.4.6.2 When performing calculations, personnel should avoid compounding of rounding errors. This may be accomplished by performing one large calculation, rather than several calculations using individual results. Alternatively, if multistep calculations are done, intermediate results should not be rounded before use in subsequent calculations.

X3.4.6.3 In rounding, no final result should retain more significant figures than the least-significant-figure measurement or data point used in the calculation.

X3.5 Retention

X3.5.1 A retention program appropriate for the nature and frequency of testing done in the laboratory should be maintained. Items that may warrant retention for defined time periods include:

X3.5.1.1 Raw data and forms,

X3.5.1.2 Force-elongation or stress-strain charts,

X3.5.1.3 Computer printouts of curves and test results,

X3.5.1.4 Data and results stored on computer discs or hard drives,

X3.5.1.5 Broken specimens,

X3.5.1.6 Excess material,

X3.5.1.7 Test reports, and

X3.5.1.8 Verification reports and certifications.

X3.6 Environment

X3.6.1 All test equipment should be located and connected to power sources in such a manner as to minimize the effects of vibrations and electrical disturbances on raw data collected, stress-strain charts, and operation of equipment.

X3.7 Controls

X3.7.1 Controlled procedures and work instructions should cover all aspects of specimen preparation, tensile testing, and result reporting. These documents should be readily available to all involved in the documented tasks.

X3.7.2 Clear, concise, operating instructions should be maintained for equipment used in specimen preparation and tensile testing. These instructions should be readily available to all qualified operators.

X3.7.3 All applicable verification requirements shall be met, as detailed in X3.3.2.

X3.7.4 It is recommended that special studies and programs be employed to monitor and control tensile testing, because tensile test results are easily affected by operators, measuring devices, and test equipment. Examples of such programs include but are not limited to:

X3.7.4.1 Round-robin studies, proficiency tests, or other cross-checks,

X3.7.4.2 Repeatability and reproducibility (R and R) studies,

X3.7.4.3 Control charting, and

X3.7.4.4 Determination of typical lab uncertainties for each result typically reported.

NOTE X3.5—For nondestructive testing, repeatability and reproducibility are often measured by conducting gage R and R studies, as discussed in Appendix X2 of Test Methods E8 and E8M. These studies involve repeated determination of a test result, using a single part or specimen, so gage R and Rs are not directly applicable to mechanical properties, which are obtained through destructive testing. (True differences between even the best duplicate specimens manifest themselves in the form of poorer R and R results than would be obtained for perfect duplicates.) Nevertheless, quasi-R and R studies conducted with these limitations taken into consideration may be helpful in analyzing sources of error and improving reliability of test results.

X4. ADDITIONAL INFORMATION ON SPEED OF TESTING AND EXAMPLES

X4.1 Many materials are strain-rate sensitive that is, the yield strength or tensile strength of the material is a function of the rate at which the material is being deformed. The yield strength of some materials can change by more than ten percent when tested with the slowest and then the highest speeds permitted by E8/E8M. In order to reproduce yield test results, for strain-rate sensitive materials, it is important that strain rates during the determination of yield are similar.

X4.2 The following paragraphs further explain the various Control Methods required to be used by E8/E8M when other guidance is not given. When other test speed requirements are

specified, those speeds must be followed to comply with this test method. For example, aerospace specifications often require a test speed when determining yield strength to be a strain rate equal to 0.005 ± 0.002 mm/mm/min [in./in./min]; when specified, that speed must be followed in order to comply with this standard.

X4.2.1 *Control Method A - Rate of Stressing Method for Determining Yield Properties* – This method has been the default method of control in E 8/E 8M for many years. In this method, the crosshead speed of the machine is adjusted during the linear elastic portion of the curve to achieve the desired stress rate (or the speed is set to a predetermined value known to achieve the desired stress rate). The crosshead speed is not adjusted when the material begins to yield. The advantage of this control method is that it does not require any transducers other than the load indicator itself, although, load pacers and stress-rate indicators can be helpful. This method of control has a limitation in that the strain rate of the specimen at yield depends on the slope of the stress-strain curve (tangent modulus) and the testing machine stiffness. Because of this, the strain rate of the specimen when yield is determined can be different for different specimen sizes, different specimen configurations, different gripping configurations, and different testing machines. This difference in strain rate can affect the reproducibility of yield strength in strain-rate-sensitive materials.

X4.2.1.1 It is not the intent of this method to run the testing machine in closed-loop force control, because as the material begins to yield the testing machine will speed up, possibly to its maximum speed. However, using closed-loop force control during the elastic region of the test and switching to an equivalent crosshead speed prior to yield is an acceptable method.

X4.2.2 *Control Method B —Rate of Straining Control Method for Determining Yield Properties* - This method is usually performed with a testing machine that has a closed-loop control system that uses feedback from an extensometer to automatically adjust the speed of the testing machine. However, some skilled operators can monitor a strain rate indicator attached to the extensometer and adjust the speed of the testing machine manually to maintain the required strain rate test speed. To maintain constant strain rate control during a test, the crosshead speed of the testing machine must slow down drastically when the specimen begins to yield. This method has three advantages. *(1)* The time to achieve yield results is short (about 20 to 40 s). *(2)* The reproducibility of yield strength test results from machine to machine and laboratory to laboratory is good. *(3)* The agreement with the results of Control Method C is good, because the strain rates are similar when the specimen's yield strength is determined. This method has three disadvantages. *(1)* The testing equipment is generally more expensive. *(2)* Proper control and safety depend on the control parameters to be properly set and that the extensometer integrity be maintained (accidental slippage of the extensometer can result in unexpected movement of the crosshead). Proper safety limits must be set to ensure safety of personnel and equipment. *(3)* When materials have yield points or yield discontinuously, a machine under closed-loop strain-rate control can behave erratically. This control method is not recommended for materials that yield discontinuously.

X4.2.3 *Control Method C - Crosshead Speed Control Method for Determining Yield Properties*—This method can be performed on any testing machine that has reasonably good crosshead speed control. This method has three advantages. *(1)* The reproducibility from machine to machine and laboratory to laboratory is good. *(2)* The agreement with Control Method B is good, because the strain rates are similar when the specimen's yield strength is determined. *(3)* This method of controlling a testing machine is excellent for materials that yield discontinuously. The disadvantage of this method of control is that the test time to yield can be more than three minutes, depending on the material being tested and the compliance of the testing machine including its grip assemblies.

X4.2.3.1 *An example using SI metric units of how to apply Control Method C* to testing Specimen 1 in Fig. 13 is as follows. The length of the reduced section, that is, dimension A in Fig. 13, is equal to 60 mm. The crosshead speed is determined per Control Method C by multiplying 60 mm by 0.015 mm/mm/min to arrive at a crosshead speed of 0.9 mm/min.

X4.2.3.2 *An example using U.S. customary units of how to apply Control Method C* to testing Specimen 1 in Fig. 13 is as follows. The length of the reduced section, that is, dimension A in Fig. 13 is equal to 2.25 in. The crosshead speed is determined per Control Method C by multiplying 2.25 in. by 0.015 in./in./min to arrive at a crosshead speed of 0.034 in./min.

SUMMARY OF CHANGES

Committee E28 has identified the location of selected changes to this standard since the last issue (E8/E8M-08) that may impact the use of this standard. (Approved Dec. 1, 2009.)

(*1*) 7.6.2.3 was revised
(*2*) 7.6.3 was revised
(*3*) Appendix X4 was added.

Committee E28 has identified the location of selected changes to this standard since the last issue (E8 – 04 and E8M – 04) that may impact the use of this standard. (Approved Feb. 1, 2008)

(*1*) The two separate standards have been combined into one standard.
(*2*) Specimen drawing figures have been updated to include both the 4D and 5D elongation.
(*3*) Figs. 21-27 have been redrawn and updated.
(*4*) Definitions from E6 and from the body of the text have been brought in to the Terminology section.
(*5*) Notes 1-3 which previously contained mandatory information have been incorporated into the Scope section.

(b)(4) Third Party Test Data

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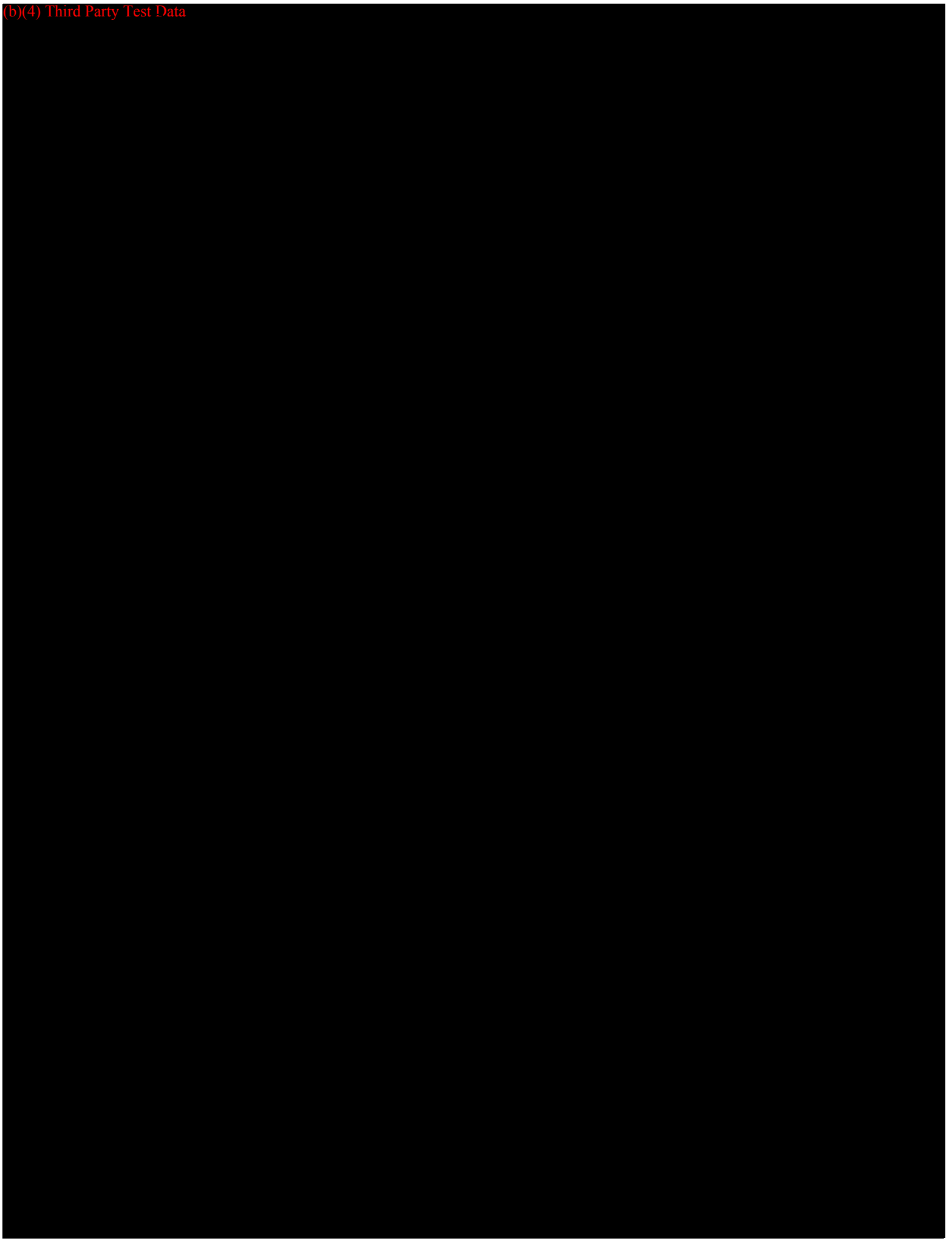
(b)(4) Third Party Test Data



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Testing Description:

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Calculated Results (b)(4)

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Designation: E466 – 07

Standard Practice for Conducting Force Controlled Constant Amplitude Axial Fatigue Tests of Metallic Materials[1]

This standard is issued under the fixed designation E466; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This practice covers the procedure for the performance of axial force controlled fatigue tests to obtain the fatigue strength of metallic materials in the fatigue regime where the strains are predominately elastic, both upon initial loading and throughout the test. This practice is limited to the fatigue testing of axial unnotched and notched specimens subjected to a constant amplitude, periodic forcing function in air at room temperature. This practice is not intended for application in axial fatigue tests of components or parts.

NOTE 1—The following documents, although not directly referenced in the text, are considered important enough to be listed in this practice:

E739 Practice for Statistical Analysis of Linear or Linearized Stress-Life (S-N) and Strain-Life (ε-N) Fatigue Data

STP 566 Handbook of Fatigue Testing[2]

STP 588 Manual on Statistical Planning and Analysis for Fatigue Experiments[3]

STP 731 Tables for Estimating Median Fatigue Limits[4]

2. Referenced Documents

2.1 *ASTM Standards:*[5]

E3 Guide for Preparation of Metallographic Specimens

E467 Practice for Verification of Constant Amplitude Dynamic Forces in an Axial Fatigue Testing System

E468 Practice for Presentation of Constant Amplitude Fatigue Test Results for Metallic Materials

E606 Practice for Strain-Controlled Fatigue Testing

E739 Practice for Statistical Analysis of Linear or Linearized Stress-Life (*S-N*) and Strain-Life (ε-*N*) Fatigue Data

E1012 Practice for Verification of Test Frame and Specimen Alignment Under Tensile and Compressive Axial Force Application

E1823 Terminology Relating to Fatigue and Fracture Testing

3. Terminology

3.1 *Definitions:*

3.1.1 The terms used in this practice shall be as defined in Terminology E1823.

4. Significance and Use

4.1 The axial force fatigue test is used to determine the effect of variations in material, geometry, surface condition, stress, and so forth, on the fatigue resistance of metallic materials subjected to direct stress for relatively large numbers of cycles. The results may also be used as a guide for the selection of metallic materials for service under conditions of repeated direct stress.

4.2 In order to verify that such basic fatigue data generated using this practice is comparable, reproducible, and correlated among laboratories, it may be advantageous to conduct a round-robin-type test program from a statistician's point of view. To do so would require the control or balance of what are often deemed nuisance variables; for example, hardness, cleanliness, grain size, composition, directionality, surface residual stress, surface finish, and so forth. Thus, when embarking on a program of this nature it is essential to define and maintain consistency a priori, as many variables as reasonably possible,

[1] This practice is under the jurisdiction of ASTM Committee E08 on Fatigue and Fracture and is the direct responsibility of Subcommittee E08.05 on Cyclic Deformation and Fatigue Crack Formation.

Current edition approved Nov. 1, 2007. Published November 2007. Originally approved in 1972. Last previous edition approved in 2002 as E466 – 96(2002)ε1. DOI: 10.1520/E0466-07.

[2] *Handbook of Fatigue Testing, ASTM STP 566*, ASTM, 1974.

[3] Little, R. E., *Manual on Statistical Planning and Analysis, ASTM STP 588*, ASTM, 1975.

[4] Little, R. E., *Tables for Estimating Median Fatigue Limits, ASTM STP 731*, ASTM, 1981.

[5] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

with as much economy as prudent. All material variables, testing information, and procedures used should be reported so that correlation and reproducibility of results may be attempted in a fashion that is considered reasonably good current test practice.

4.3 The results of the axial force fatigue test are suitable for application to design only when the specimen test conditions realistically simulate service conditions or some methodology of accounting for service conditions is available and clearly defined.

5. Specimen Design

5.1 The type of specimen used will depend on the objective of the test program, the type of equipment, the equipment capacity, and the form in which the material is available. However, the design should meet certain general criteria outlined below:

5.1.1 The design of the specimen should be such that failure occurs in the test section (reduced area as shown in Fig. 1 and Fig. 2). The acceptable ratio of the areas (test section to grip section) to ensure a test section failure is dependent on the specimen gripping method. Threaded end specimens may prove difficult to align and failure often initiates at these stress concentrations when testing in the life regime of interest in this practice. A caveat is given regarding the gage section with sharp edges (that is, square or rectangular cross section) since these are inherent weaknesses because the slip of the grains at sharp edges is not confined by neighboring grains on two sides. Because of this, a circular cross section may be preferred if material form lends itself to this configuration. The size of the gripped end relative to the gage section, and the blend radius from gage section into the grip section, may cause premature failure particularly if fretting occurs in the grip section or if the radius is too small. Readers are referred to Ref (1) should this occur.

5.1.2 For the purpose of calculating the force to be applied to obtain the required stress, the dimensions from which the area is calculated should be measured to the nearest 0.001 in. (0.03 mm) for dimensions equal to or greater than 0.200 in. (5.08 mm) and to the nearest 0.0005 in. (0.013 mm) for dimensions less than 0.200 in. (5.08 mm). Surfaces intended to be parallel and straight should be in a manner consistent with 8.2.

NOTE 2—Measurements of dimensions presume smooth surface finishes for the specimens. In the case of surfaces that are not smooth, due to the fact that some surface treatment or condition is being studied, the dimensions should be measured as above and the average, maximum, and minimum values reported.

5.2 *Specimen Dimensions*:

5.2.1 *Circular Cross Sections*—Specimens with circular cross sections may be either of two types:

5.2.1.1 *Specimens with tangentially blended fillets between the test section and the ends* (Fig. 1)—The diameter of the test section should preferably be between 0.200 in. (5.08 mm) and 1.000 in. (25.4 mm). To ensure test section failure, the grip cross-sectional area should be at least 1.5 times but, preferably for most materials and specimens, at least four times the test section area. The blending fillet radius should be at least eight times the test section diameter to minimize the theoretical stress concentration factor, K_t of the specimen. The test section length should be approximately two to three times the test section diameter. For tests run in compression, the length of the test section should be approximately two times the test section diameter to minimize buckling.

5.2.1.2 *Specimens with a continuous radius between ends* (Fig. 3)— The radius of curvature should be no less than eight times the minimum diameter of the test section to minimize K_t . The reduced section length should be greater than three times the minimum test section diameter. Otherwise, the same dimensional relationships should apply, as in the case of the specimens described in 5.2.1.1.

5.2.2 *Rectangular Cross Sections*—Specimens with rectangular cross sections may be made from sheet or plate material and may have a reduced test cross section along one dimension, generally the width, or they may be made from material requiring dimensional reductions in both width and thickness. In view of this, no maximum ratio of area (grip to test section) should apply. The value of 1.5 given in 5.2.1.1 may be considered as a guideline. Otherwise, the sections may be either of two types:

5.2.2.1 *Specimens with tangentially blended fillets between the uniform test section and the ends* (Fig. 4)— The radius of the blending fillets should be at least eight times the specimen test section width to minimize K_t of the specimen. The ratio of specimen test section width to thickness should be between two and six, and the reduced area should preferably be between 0.030 in.^{2} (19.4 mm^2) and 1.000 in.^{2} (645 mm^2), except in extreme cases where the necessity of sampling a product with an unchanged surface makes the above restrictions impractical. The test section length should be approximately two to three times the test section width of the specimen. For specimens that are less than 0.100 in. (2.54 mm) thick, special precautions are necessary particularly in reversed loading, such as $R = -1$. For example, specimen alignment is of utmost importance and

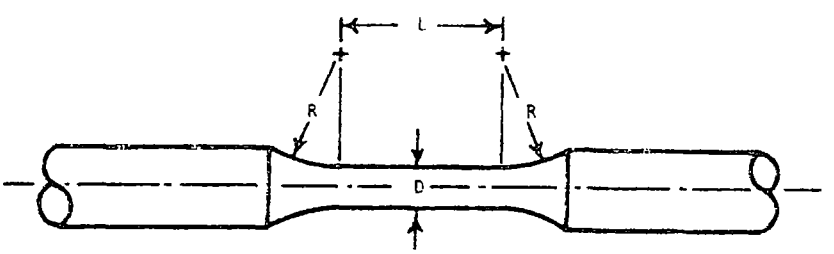

FIG. 1 Specimens with Tangentially Blending Fillets Between the Test Section and the Ends

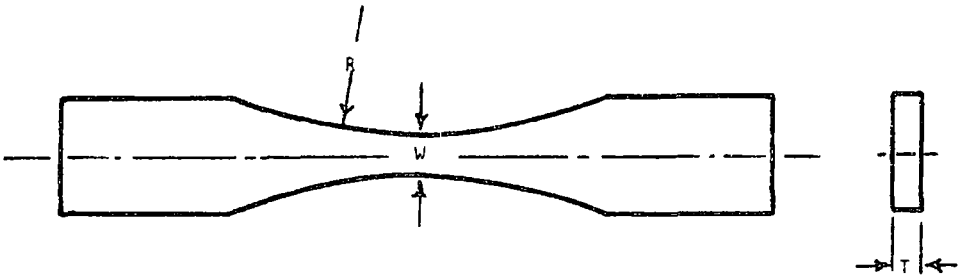

FIG. 2 Specimens with Continuous Radius Between Ends

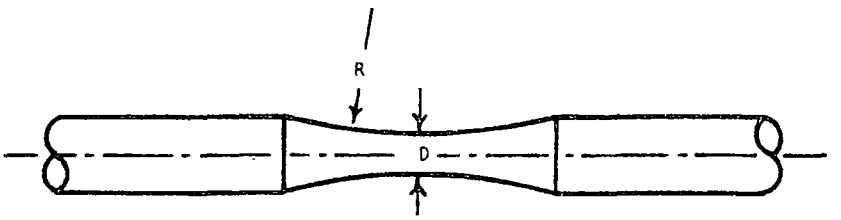

FIG. 3 Specimens with a Continuous Radius Between Ends

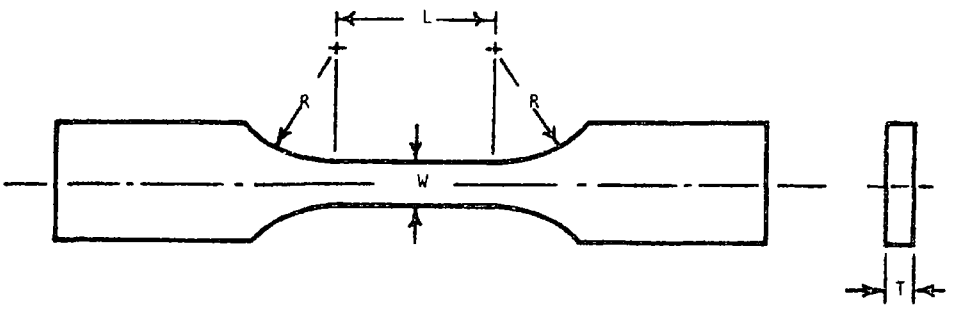

FIG. 4 Specimens with Tangentially Blending Fillets Between the Uniform Test Section and the Ends

the procedure outlined in Practice E606 would be advantageous. Also, Refs (2-5), although they pertain to strain-controlled testing, may prove of interest since they deal with sheet specimens approximately 0.05 in. (1.25 mm) thick.

5.2.2.2 *Specimens with continuous radius between ends (*Fig. 2*)*—The same restrictions should apply in the case of this type of specimen as for the specimen described in 5.2.1.2. The area restrictions should be the same as for the specimen described in 5.2.2.1.

5.2.3 *Notched Specimens*—In view of the specialized nature of the test programs involving notched specimens, no restrictions are placed on the design of the notched specimen, other than that it must be consistent with the objectives of the program. Also, specific notched geometry, notch tip radius, information on the associated K_t for the notch, and the method and source of its determination should be reported.

6. Specimen Preparation

6.1 The condition of the test specimen and the method of specimen preparation are of the utmost importance. Improper methods of preparation can greatly bias the test results. In view of this fact, the method of preparation should be agreed upon prior to the beginning of the test program by both the originator and the user of the fatigue data to be generated. Since specimen preparation can strongly influence the resulting fatigue data, the application or end use of that data, or both, should be considered when selecting the method of preparation. Appendix X1 presents an example of a machining procedure that has been employed on some metals in an attempt to minimize the variability of machining and heat treatment upon fatigue life.

6.2 Once a technique has been established and approved for a specific material and test specimen configuration, change should not be made because of potential bias that may be introduced by the changed technique. Regardless of the machining, grinding, or polishing method used, the final metal removal should be in a direction approximately parallel to the long axis of the specimen. This entire procedure should be clearly explained in the reporting since it is known to influence fatigue behavior in the long life regime.

6.3 The effects to be most avoided are fillet undercutting and residual stresses introduced by specimen machining practices. One exception may be where these parameters are under study. Fillet undercutting can be readily determined by inspection. Assurance that surface residual stresses are minimized can be achieved by careful control of the machining procedures. It is advisable to determine these surface residual stresses with X-ray diffraction peak shift or similar techniques, and that the value of the surface residual stress be reported along with the direction of determination (that is, longitudinal, transverse, radial, and so forth).

6.4 *Storage*—Specimens that are subject to corrosion in room temperature air should be accordingly protected, preferably in an inert medium. The storage medium should generally be removed before testing using appropriate solvents, if necessary, without adverse effects upon the life of the specimens.

6.5 *Inspection*—Visual inspections with unaided eyes or with low power magnification up to 20× should be conducted on all specimens. Obvious abnormalities, such as cracks, machining marks, gouges, undercuts, and so forth, are not acceptable. Specimens should be cleaned prior to testing with solvent(s) non-injurious and non-detrimental to the mechanical properties of the material in order to remove any surface oil films, fingerprints, and so forth. Dimensional analysis and inspection should be conducted in a manner that will not visibly mark, scratch, gouge, score, or alter the surface of the specimen.

7. Equipment Characteristics

7.1 Generally, the tests will be performed on one of the following types of fatigue testing machines:

7.1.1 Mechanical (eccentric crank, power screws, rotating masses),

7.1.2 Electromechanical or magnetically driven, or

7.1.3 Hydraulic or electrohydraulic.

7.2 The action of the machine should be analyzed to ensure that the desired form and magnitude of loading is maintained for the duration of the test.

7.3 The test machines should have a force-monitoring system, such as a transducer mounted in series with the specimen, or mounted on the specimen itself, unless the use of such a system is impractical due to space or other limitations. The test forces should be monitored continuously in the early stage of the test and periodically, thereafter, to ensure that the desired force cycle is maintained. The varying stress amplitude, as determined by a suitable dynamic verification (see Practice E467), should be maintained at all times within 2 % of the desired test value.

7.4 *Test Frequency*—The range of frequencies for which fatigue results may be influenced by rate effects varies from material to material. In the typical regime of 10^{-2} to 10^{+2} Hz over which most results are generated, fatigue strength is generally unaffected for most metallic engineering materials. It is beyond the scope of Practice E466 to extrapolate beyond this range or to extend this assumption to other materials systems that may be viscoelastic or viscoplastic at ambient test temperatures and within the frequency regime mentioned. As a cautionary note, should localized yielding occur, significant specimen heating may result and affect fatigue strength.

8. Procedure

8.1 *Mounting the Specimen*—By far the most important consideration for specimen grips is that they can be brought into good alignment consistently from specimen to specimen (see 8.2). For most conventional grips, good alignment must come about from very careful attention to design detail. Every effort should be made to prevent the occurrence of misalignment, either due to twist (rotation of the grips), or to a displacement in their axes of symmetry.

8.2 *Alignment Verification*—To minimize bending stresses (strains), specimen fixtures should be aligned such that the major axis of the specimen closely coincides with the load axis throughout each cycle. It is important that the accuracy of alignment be kept consistent from specimen to specimen. For cylindrical specimens, alignment should be checked by means of a trial test specimen with longitudinal strain gages placed at four equidistant locations around the minimum diameter. The trial test specimen should be turned about its axis, installed, and checked for each of four orientations within the fixtures. For rectangular cross section specimens, alignment should be checked by placing longitudinal strain gages on either side of the trial specimen at the minimum width location. The trial specimen should be rotated about its longitudinal axis, installed and checked in both orientations within the fixtures. The bending stresses (strains) so determined on either the cylindrical or rectangular cross section specimen should be limited to less than 5 % of the greater of the range, maximum or minimum stresses (strains), imposed during any test program. For specimens having a uniform gage length, it is advisable to place a similar set of gages at two or three axial positions within the gage section. One set of strain gages should be placed at the center of the gage length to detect misalignment that causes relative rotation of the specimen ends about axes perpendicular to the specimen axis. The lower the bending stresses (strains), the more repeatable the test results will be from specimen to specimen. This is especially important for materials with low ductility (that is, bending stresses (strains) should not exceed 5 % of the minimum stress (strain) amplitude).

NOTE 3—This section refers to Type A Tests, in Practice E1012.

9. Test Termination

9.1 Continue the tests until the specimen failure criterion is attained or until a predetermined number of cycles has been applied to the specimen. Failure may be defined as complete separation, as a visible crack at a specified magnification, as a crack of certain dimensions, or by some other criterion. In reporting the results, state the criterion selected for defining failure and be consistent within a given data set.

10. Report

10.1 Report the following information:

10.1.1 The fatigue test specimens, procedures, and results should be reported in accordance with Practice E468.

10.1.2 The use of this practice is limited to metallic specimens tested in a suitable environment, generally atmospheric air at room temperature. Since however, the environment can greatly influence the test results, the environmental conditions, that is, temperature, relative humidity, as well as the medium, should always be periodically recorded during the test and reported.

10.1.3 Generally, the fatigue tests may be carried out using a periodic forcing function, usually sinusoidal. However, regardless of the nature of the forcing function, it should be reported (sine, ramp, saw tooth, etc.).

10.1.4 When noticeable yielding occurs in the fatigue tests of unnotched specimens (for example, non-zero mean stress

fatigue test) the permanent deformation of the unbroken but tested specimens (for example, percent change in cross-section area of test section) should be reported.

10.1.5 A brief description of the fracture characteristics; results of post-test metallography or scanning election microscopy, or both; identification of fatigue mechanism; and the relative degree of transgranular and intergranular cracking would be highly beneficial.

APPENDIX

(Nonmandatory Information)

X1. EXAMPLE OF MACHINING PROCEDURE

X1.1 While the following procedure was developed for machining high-strength materials with minimal attendant surface damage and alteration, it can be successfully applied to materials of lower strength. As a conservative general measure, this procedure is recommended unless: (*1*) the experimental objective is to evaluate another given surface condition or, (*2*) it is known that the material under evaluation is relatively insensitive to surface condition.

X1.2 *Procedure:*

X1.2.1 In the final stages of machining, remove material in small amounts until 0.125 mm (0.005 in.) of excess material remains.

X1.2.2 Remove the next 0.1 mm (0.004 in.) of gage diameter by cylindrical grinding at a rate of no more than 0.005 mm (0.0002 in.)/pass.

X1.2.3 Remove the final 0.025 mm (0.001 in.) by polishing (Note X1.1) longitudinally to impart a maximum surface roughness of 0.2-μm (8-μin.) R_a, in the longitudinal direction.

NOTE X1.1—Extreme caution should be exercised in polishing to ensure that material is being properly removed rather than merely smeared to produce a smooth surface. This is a particular danger in soft materials wherein material can be smeared over tool marks, thereby creating a potentially undesirable influence on crack initiation during testing.

X1.2.4 After polishing (see Note X1.1) all remaining grinding and polishing marks should be longitudinal. No circumferential machining should be evident when viewed at approximately 20× magnification under a light microscope.

X1.2.5 Degrease the finished specimen.

X1.2.6 If heat treatment is necessary, conduct it before final machining.

X1.2.7 If surface observations are to be made, the test specimen may be electropolished in accordance with Methods E3.

X1.2.8 Imprint specimen numbers on both ends of the test section in regions of low stress, away from grip contact surfaces.

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(2) Miller, G. A., "Interlaboratory Study of Strain—Cycle Fatigue of 1.2 mm—Thick Sheet Specimens," Journal of Testing and Evaluation, JTEVA, Vol 13, No. 5, September 1985, pp 344–351.

(3) Miller, G. A. and Reemsnyder, H. S.," Strain—Cycle Fatigue of Sheet and Plate Steels I: Test Method Development and Data Presentation," *High Strength Steel for Automotive Use, P124*, SAE Paper No. 830175, Society of Automotive Engineers, Warrendale, PA, February 1983, pp 23–31.

(4) Miller, G. A. and Reemsnyder, H. S., "Strain—Cycle Fatigue of Sheet and Plate Steels II: Some Practical Considerations in Applying Strain—Cycle Fatigue Concepts," *High Strength Steel for Automotive Use, P124*, SAE Paper 830173, Society of Automotive Engineers, Warrendale, PA, February 1983, pp 33–41.

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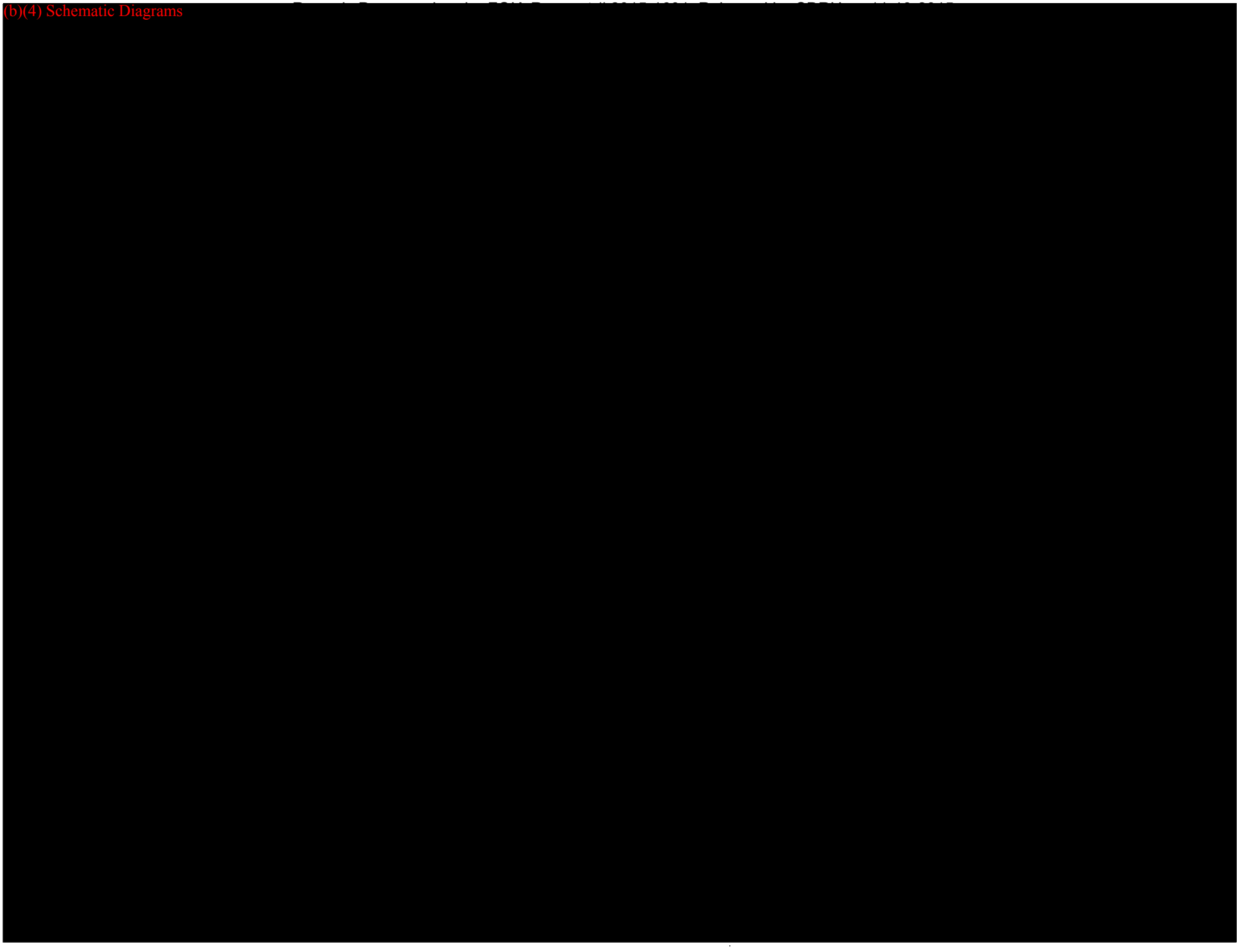
(b)(4) Schematic Diagrams



(b)(4) Schematic Diagrams

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* * * COMMUNICATION RESULT REPORT (DEC. 12. 2012 11:04AM) * * *

FAX HEADER 1:
FAX HEADER 2:

TRANSMITTED/STORED : DEC. 12. 2012 11:03AM FILE MODE OPTION	ADDRESS	RESULT	PAGE
1764 MEMORY TX	1-703-995-4600	OK	3/3

REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-2) BUSY
E-3) NO ANSWER
E-4) NO FACSIMILE CONNECTION

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 11, 2012

Pipeline Biomedical Products, Llc
% Mr. Terry Powell
Senior Project Manager
901 King Street, Suite 200
Alexandria, Virginia 22314

Re: K122158
Trade/Device Name: PBP Total Hip System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis.
Regulatory Class: Class II
Product Code: OQI, LZO, MEH, OQH, OQG, JDI, LPH
Dated: November 14, 2012
Received: November 19, 2012

Dear Terry Powell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Michael Kassy

Subject: 510(k) Number K122158/S001

To: The Record

Please list CTS decision code SE

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

☒ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NU	NSE for new intended use AND new technology raising new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NS	NSE no response
☐	NL	NSE for lack of performance data AND no response
☐	NM	NSE pre-amendment device call for PMAs (515i)
☐	NC	NSE post-amendment device requires PMAs
☐	NH	NSE for new molecular entity requires PMA
☐	TR	NSE for transitional device

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	Y	
510(k) Summary /510(k) Statement	*Attach Summary*	Y	
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III?			N
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		Y	
Is this a combination product? (Please specify category N/A, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			N/A
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			N/A
Is this device intended for pediatric use only?			N/A
Is this a prescription device? (If both prescription & OTC, check both boxes.)		Y	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			N/A
Is clinical data necessary to support the review of this 510(k)?			N
For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was			

conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.) N

Does this device include an Animal Tissue Source? N

All Pediatric Patients age<=21 N

Neonate/Newborn (Birth to 28 days) N

Infant (29 days -< 2 years old) N

Child (2 years -< 12 years old) N

Adolescent (12 years -< 18 years old) N

Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.) N

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old) N

Nanotechnology N

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) *Contact OC.* N

Regulation Number	**Class***	**Product Code**
888.3358	II	OQI

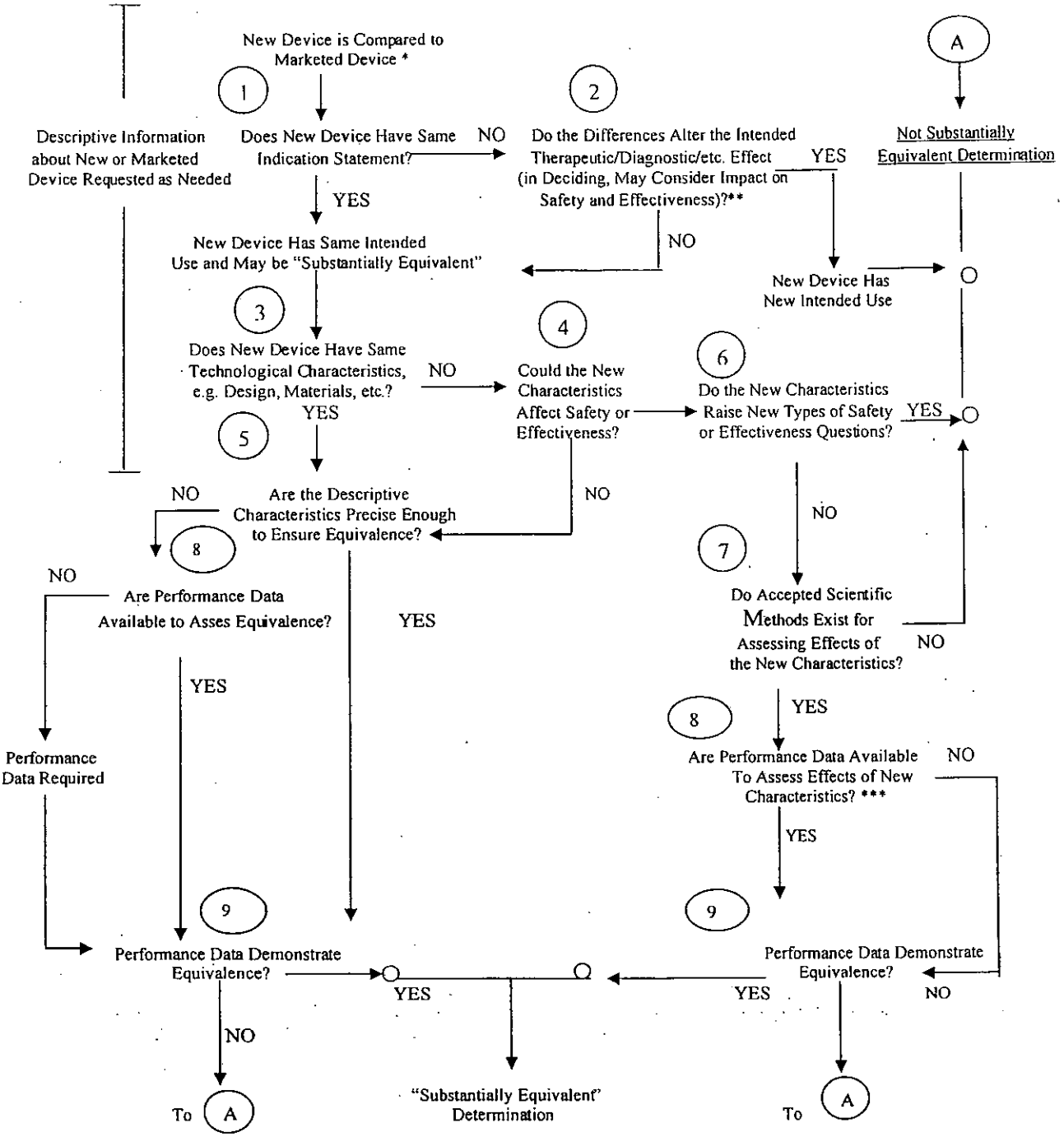
(*If unclassified, see 510(k) Staff)

Additional Product Codes: LPH, JDI, OQG, OQH, MEH, LZO

Review: K Ad 12/10/12
(Branch Chief) (Branch Code) (Date)

Final Review: E.C. Keith 12/11/12
(Division Director) (Date)

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
Center for Devices & Radiological Health

ODE/DSORD/OJDB
20993-0002
301-796-6946

Premarket Notification [510(k)] Review

ate: December 10, 2012	
To: FILE	
From: Michael Kasser	
Subject: Traditional 510(k)# K122158/S001	
Sponsor: Pipeline Biomedical Products, Llc	**Contact / Consultant:** Terry Powell
Phone: (703) 562-9800 Ext.252	**Email:** tpowell@msquaredassociates.com
Device Trade Name: Pbp total hip system	**FDA Received / Due Date:** July 20, 2012 / December 27, 2012
Reg # / Name / Class: 888.3358 / Hip Joint Metal/Polymer/Metal Semi-Constrained Porous-Coated Uncemented Prosthesis. / II	**Product Code(s):** OQI, LZO, MEH, OQH, OQG, JDI, LPH

Sponsor-Identified Predicate Devices:

510(k) #	Pro Code	Device Name	Company
K112802	OQG, OQH, LPH, JDI	Pipeline total hip system	Pipeline Orthopedics

Review Summary

The subject device is a total hip system whose acetabular components are made from a direct write laser method, leading to shell whose surface is highly porous. The system also uses Biolox delta heads and Vit E liners. The total hip system has been previously cleared in K112802, the only modification is the addition of a thin HA coating to the external surface of this shell and the addition of 40 mm heads and liners. Interactive deficiencies were sent to the sponsor on Aug. 22, 2012 and an adequate response to most concerns was received on Aug. 31, 2012. However, concerns regarding the applicability of the supplied HA testing on a non-porous substrate to the subject device were not addressed. The file was placed on hold on Sept. 10, 2012. S1 was received on Nov. 19, 2012. It contained new coating testing that is adequate as well as 2 claims. The claims were removed in an email dated Dec. 5, 2012.

Recommendation

I recommend that the Pbp total hip system is/are Substantially Equivalent to predicate devices.

Review Team

Lead Reviewer	Michael Kasser (ODE/DOD/JFTB)
HA expert	Limin Sun(ODE/DOD/JFTB)

I. Purpose and Background

The purpose of this submission is a line extension (and rights transfer from Pipeline Orthopedics to Pipeline Biomedical Products). The new components are 40 mm CoCr head, 40 mm ID VE liners, Biolox delta ceramic heads, and HA coated porous acetabular shells (Ti porous coated shells previously cleared). The system also adds ownership to Pipeline Biomedical Products LLC, who is related to, but not identical, to the company (Pipeline Orthopedics) that received clearance for K112802.

II. Administrative Information

Administrative Information	Present	Absent	Inadequate
Medical Device User Fee Cover Sheet [A]	☐	☒	☐
CDRH Premarket Review Submission Cover Sheet [B]	☒	☐	☐
510(k) Cover Letter [C]	☒	☐	☐
Indications for Use Page [D]	☒	☐	☐
Truthful and Accuracy Statement [E]	☒	☐	☐
510(k) Summary or Statement [F]	☒	☐	☐
Financial Certification and Disclosure Statement (Clinical) [H]	☐	☒	☐
Clinical Trials Cert Form (Clinical) [I]	☐	☒	☐
Standards Data Report for 510(k)s [K]	☒	☐	☐
Executive Summary	☒	☐	☐

Reviewer Decision

The updated administrative information is acceptable.

In the original submission, the summary should have OQI added the device description contains claims, the sponsor should clarify reason for submission and reduce supplied testing accordingly. Additionally, the TAS was not original. In an email dated 8/31, the sponsor provided updated Summary and TAS. However, the Summary still contains the following claims, "allowing the surgeon to optimize soft tissue tension and restore joint mechanics," "The porous structured surface's interconnected porosity provides a scaffold for bone ingrowth as shown in the transcortical implant canine model" and "for increased resistance to wear and oxidative degradation as compared with standard UHMWPE (demonstrated by comparative wear testing and comparative oxidation analyses summarized in section 8)" that should be removed. These were removed in S1, but official claims were added that, per new policy, need to be removed. This was done in an email dated Dec. 5, 2012.

III. Device Description

Device Characteristics	Yes	No	Inadequate or Unknown
Is the intended use or fundamental technology new?	☐	☒	☐
Is the device life-supporting or life sustaining?	☐	☒	☐
Is the device or a component an implant? [1]	☒	☐	☐
Does the device use software/firmware?	☐	☒	☐
Does the device or a component need sterilization (by manufacturer or user)?	☒	☐	☐
Is the device or a component for single person use?	☒	☐	☐
Is the device or a component a reprocessed SUD? [2]	☐	☒	☐
Is the patient contact component(s) reusable?	☐	☒	☐
Is the device a combination product? [3] N - Not a Part 3 Combination Product			☐

Device Characteristics		Yes	No	Inadequate or Unknown
Is the device electrical (battery or wall powered)?	The device is not electrical			☐

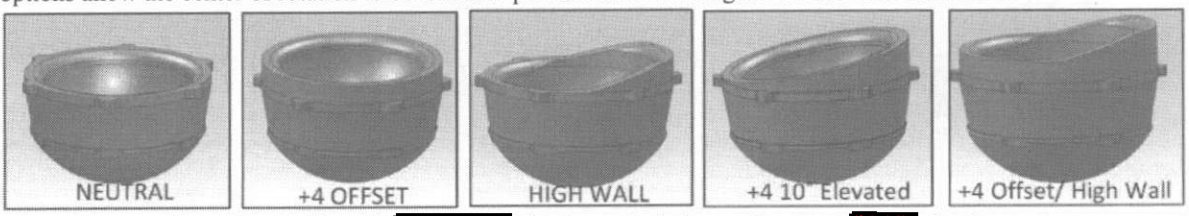
The Pipeline Total Hip System consists of femoral stems, femoral heads, acetabular liners, acetabular shells, and optional acetabular bone screws and acetabular dome hole occluders. A detailed description of each component is contained below. New components are **bolded** when first mentioned.

Acetabular Cups

The shells are hemi-spherical and are made from ASTM F1472 (wrought Ti-6Al-4V alloy). The shell's face is raised to house the scallops on the liner. There is also an inner groove at the taper to dome transition that locks with the rib on the acetabular insert. The locking mechanism is the same as cleared in K112802. The shells are available with two surfaces, porous structured (PST) and **porous structured HA coated** (HA PST). The PST is made from a novel direct metal laser sintering (DMLS) process that allows the Ti-6Al-4V material to be built layer by layer, as opposed to traditional deposition of a new coating on the surface. This coating was previously cleared in K112802. HA PST has a (b)(4) HA coating on top of the porous structure. This coating is characterized in MAF-339, see HA consult for additional information. All shells contain a threaded hole at the dome of the shell to allow attachment to the insertion instrumentation. Shells can also contain an optional three hole cluster pattern to accommodate additional screw fixation. The shells are available in 44 – 70 mm outer diameters, in 2 mm increments. The shells are intended for cemented and uncemented use.

Acetabular Liners

The liners contain a hemispherical base and tapered sides that match with the shell. The liner contains a rib at the taper to dome transition and six, external, anti-rotation scallops. The liners are available in 5 rim designs, neutral, +4 mm offset, high wall, +4 10° elevated, and +4 offset/high wall, see figure below. These options allow the center of rotation to be offset or provide extra coverage to reduce dislocation risk.



The surface roughness for the liners is (b)(4) for the articulating surface, and (b)(4) for the non-articulating surfaces. The minimum liner thickness at the load bearing region is (b)(4) at the rim which occurs for the 32/48 and 28/44 (ID/OD) liners for the neutral and highwall configurations.
The liner is available in two materials, conventional and highly crosslinked Vit. E (XLVE). Conventional material is made from ASTM F648 UHMWPE that is gamma sterilized with 25 – 40 kGy of radiation in a nitrogen environment. Vitamin E polyethylene is made from GUR 1020 powder mixed with (b)(4) 0 (b) vitamin E then compression molded. After molding, the material is crosslinked with (b) gamma radiation, machined, cleaned, and then EtO sterilized. The material is more fully characterized in MAF 1781 and previously cleared in K112802. Please see the charts below for liner/shell sizing for both of these materials. **40 ID XLVE liners are being added in this submission.**

Acetabular Liner - Vitamin E Poly Sizing*					
Mating Shell Size OD (mm)	Inner Diameter (ID)/Head Size (mm)				
	22	28	32	36	40
44		X			
46		X			
48		X	X		
50		X	X		
52		X	X	X	
54		X	X	X	
56		X	X	X	X
58		X	X	X	X
60					
62		X	X	X	X
64					
66		X	X	X	X
68					
70					

Acetabular Liner - Standard Poly Sizing*					
Mating Shell Size OD (mm)	Inner Diameter (ID)/Head Size (mm)				
	22	28	32	36	
44	X				
46	X				
48	X	X			
50	X	X			
52	X	X	X		
54	X	X	X		
56	X	X	X		
58	X	X	X		
60					
62	X	X	X		
64					
66	X	X	X		
68					
70					

Acetabular Bone Screws

Screws are unchanged from what was cleared in K112802. Optional bone screws and occluders are made from ASTM F1472. The screws are self-tapping with a hex-head style. The major/minor screw diameter is 6.5/3.0 mm with a pitch of 2.75 mm. The screws are available in lengths of 15 – 60 mm, in 5 mm increments. Hole occluders, that screw into and fill unused screw holes in the shell are also available.

Femoral Stem

The stems are unchanged from what was cleared in K112802. Pipeline hip stems feature a flat, tapered, wedge geometry with the medial side remaining constant, but the lateral size tapering towards the distal end. The proximal end of the stem uses a 12/14 taper [redacted] (b)(4) [redacted] 130°. The stems are made from forged Ti-6Al-4V ELI per ASTM F136 and F620). The proximal neck region is highly polished (Ra 0.2 um). The proximal portion of the stem contains a rough, CP Ti plasma spray coating, characterized in MAF1760, see K112802 for additional information. The distal end of the stem has a (b)(4).
The stem is available in size ranges 2 – 12 (shoulder to tip length ranging from 111 – 138 mm). All stems are available in standard and high offsets (6 mm for size 2-4, 8 mm for size 5-12). The stems can be used for cementless or cemented applications.

Femoral Heads

Heads are available in CoCr and **Biolox Delta** (per ISO 6474-2).

CoCr heads are made from wrought CoCr per ASTM F1537. The heads have a surface roughness of (b)(4) on articulating surfaces and (b)(4) on non-articulating surfaces. The heads contain a female 12/14 taper [redacted] See the chart below for available diameters and offsets, please note the larger offsets result in skirted heads. The heads are identical to those previously cleared in K112802 except that **40 mm CoCr heads** have been added.

Table 3: Metal Femoral Head Sizing

CoCr Heads					
Offset (mm)	Head diameters (mm)				
	22	28	32	36	40
-3.5		X	X	X	X
0	X	X	X	X	X
+3.5	X	X	X	X	X
+7		X*	X	X	X
+10.5		X*	X*	X*	X
* skirted design					

Table 4: Ceramic Femoral Head Sizing

Ceramic Heads					
Offset (mm)		Head diameters (mm)			
		28	32	36	40
S	-3.5	X	X	X	X
M	0	X	X	X	X
L	+3.5	X	X	X	X
XL	+7	NA	X	X	X

Ceramic heads are made by CeramTec from their Biolox delta material. The heads have a surface roughness of (b) um on the articulating surface. The heads contain a female 12/14 taper. See the chart above for available diameters and offsets.

For a table of device characteristics, see "Comparison of Technology to Predicate Devices" below.

Third-party Components and Accessories:

Reviewer Decision
The Device Description is acceptable.

IV. Comparison of Indications for Use to Predicate Devices

Comparison of Indications for Use	
Subject	
510(k) #: K122158	Rx/OTC: Rx
Intended Population: Adults	
Indications for Use: "The PBP TOTAL HIP SYSTEM IS INDICATED FOR USE IN SKELETALLY MATURE INDIVIDUALS UNDERGOING SURGERY FOR TOTAL HIP REPLACEMENT DUE TO: - A SEVERELY PAINFUL AND/OR DISABLED JOINT FROM OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS, AVASCULAR NECROSIS, OR CONGENITAL HIP DYSPLASIA; - ACUTE TRAUMATIC FRACTURE OF THE FEMORAL HEAD OR NECK; - FAILED PREVIOUS HIP SURGERY INCLUDING JOINT RECONSTRUCTION, INTERNAL FIXATION, ARTHRODESIS, HEMIARTHROPLASTY, SURFACE REPLACEMENT ARTHROPLASTY OR TOTAL HIP REPLACEMENT. THE PBP TOTAL HIP SYSTEM HIP STEMS AND POROUS STRUCTURED ACETABULAR SHELLS ARE INTENDED FOR CEMENTLESS OR CEMENTED FIXATION. THE POROUS STRUCTURED SURFACE PROVIDES BIOLOGICAL FIXATION WHEN USED IN A CEMENTLESS APPLICATION. THE PBP TOTAL HIP SYSTEM HA POROUS STRUCTURED ACETABULAR SHELLS ARE INTENDED FOR CEMENTLESS FIXATION. THE HA POROUS STRUCTURED SURFACES PROVIDES BIOLOGICAL FIXATION. "	
Predicate(s)	
510(k)#: K112802	Rx/OTC: Rx
Intended Population:	
Indications for Use: PIPELINE TOTAL HIP SYSTEM IS INDICATED FOR USE IN SKELETALLY MATURE INDIVIDUALS UNDERGOING SURGERY FOR TOTAL HIP REPLACEMENT DUE TO: - A SEVERELY PAINFUL AND/OR DISABLED JOINT FROM OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS, AVASCULAR NECROSIS, OR CONGENITAL HIP DYSPLASIA; - ACUTE TRAUMATIC FRACTURE OF THE FEMORAL HEAD OR NECK; - FAILED PREVIOUS HIP SURGERY INCLUDING JOINT RECONSTRUCTION, INTERNAL FIXATION, ARTHRODESIS, HEMIARTHROPLASTY, SURFACE REPLACEMENT ARTHROPLASTY OR TOTAL HIP REPLACEMENT. THE PIPELINE TOTAL HIP SYSTEM IS INTENDED FOR CEMENTLESS OR CEMENTED FIXATION. THE POROUS STRUCTURED SURFACE PROVIDES BIOLOGICAL FIXATION WHEN USED IN A CEMENTLESS APPLICATION.	
Indications for Use Table: Compares the indications for use of the subject and predicate devices.	

Reviewer Decision

The Indications for Use are acceptable. They are identical to the predicate except that HA fixation has been added.

V. Comparison of Technology to Predicate Devices

Table 2: Total Hip System Comparison

System Component	PBP Total Hip System* K number to be assigned (Pipeline Biomedical Products)	Pipeline Total Hip System K112802 (Pipeline Orthopedics)
Femoral Stems	Titanium Alloy Sizes 2-12 Titanium plasma sprayed 12/14 Taper Standard (Neutral) offset High (6 mm Lateral) offset	Titanium Alloy Sizes 2-12 Titanium plasma sprayed 12/14 Taper Standard (Neutral) offset High (6 mm Lateral) offset
Femoral Heads	CoCr Alloy 22, 28, 32, 36, **and 40 mm** Offsets** of -3.5mm, 0mm, +3.5mm, +7mm, and +10.5mm **Biolox *delta*** **28, 32, 36, and 40 mm** **Offsets** of -3.5mm, 0mm, +3.5mm, +7mm**	CoCr alloy 22, 28, 32, and 36 mm Offsets of -3.5mm, 0mm, +3.5mm, +7mm, and +10.5mm
Acetabular Shells	Titanium alloy 44-70 mm Surface treatment options: • PST (Porous Structured) Surface • **HA PST (Porous Structured) Surface**	Titanium alloy 44-70 mm Surface treatment: • Porous Structured Surface
Acetabular Liners	Material Options: • Standard UHMWPE (ID sizes 22, 28, 32mm) • Highly Crosslinked Vitamin E UHMWPE (ID sizes 28, 32, 36, **40mm**) Offset options: Neutral, +4mm offset, high wall, +4mm offset/10° elevated, and +4mm offset/high wall versions	Material Options: • Standard UHMWPE (ID sizes 22, 28, 32mm) • Highly Crosslinked Vitamin E UHMWPE (ID sizes 28, 32, 36mm) Offset options: Neutral, +4mm offset, high wall, +4mm offset/10° elevated, and +4mm offset/high wall versions
Bone Screws	Titanium alloy 6.5 mm diameter 15-60mm long	Titanium alloy 6.5 mm diameter 15-60mm long
Dome Hole Occluder	Titanium alloy	Titanium alloy

* Differences shown in bold

Reviewer Decision
The Comparison of the Technology to Predicate Devices is acceptable.

VI. Labeling

Labeling Review Needed?	Yes ☒	No ☐
Usability Consult Needed?	Yes ☐	No ☒

A General Labeling Requirements

General Labeling Requirements	Yes	No	N/A
Has the prescription statement been provided in accordance with 21 CFR 801.109(b)(1)) or "Rx only".	☐	☐	☐
Adequate instructions for OTC use? [1]	☐	☐	☒
The indications for use are consistent with the IFU page?	☐	☐	☐
Appropriate contraindications provided?	☐	☐	☐
Appropriate warnings provided?	☐	☐	☐
Appropriate cautions provided?	☐	☐	☐
Instructions are in accordance with the guidance (if applicable)?	☐	☐	☐
Appropriate labeling inside device? [2]	☐	☐	☐
Appropriate label/indicator outside device? [3]	☐	☐	☐
Appropriate Manual labeling? [4]	☐	☐	☐

Package Label:

The package label contains a brief device description, lot number (pictographic), catalogue number (pictographic), expiration date (pictographic), manufacturer's contact info (pictographic), device material, device quantity, Radiation/EtO sterile (pictographic), do not reuse (pictographic), see instructions for use (pictographic), keep dry (pictographic), do not use if package is damaged (pictographic), and Rx only. All symbols are defined on the label.

Package Insert:

Two package inserts are supplied, one for the PBP system and one for the ceramic heads. The PBP system package insert includes general description of components in a hips system, indications, contraindications, adverse reactions, warnings (including that no MR testing has been performed), precautions, and sterilization information. The ceramic ball insert contains all of the warning recommended in the ceramic ball guidance document. A package insert for the manual surgical instruments was also supplied, but was not reviewed.

Surgical Procedure:

A technique for both the femoral and acetabular components is supplied that include the indications for use.

Reviewer Decision
The Labeling is acceptable.

VII. Cleaning, Sterilization, Shelf Life and/or Reuse

Sterility Review Needed?	Yes ☒	No ☐

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Sterility Consult Needed?	Yes ☐	No ☒

Sterilization Information	Inadequate or Unknown
Identify the device(s)/component(s) that is sterilized All but XLVE liners	☐
Does the Manufacturer or User sterilize the device/component? Manufacturer	☐
Sterilization method description[1] Radiation	☐
Dose 25 - 40 kGy	☐
The standard(s) used for Validation ISO 11137-1:2006	☐
A description of the Validation Method for the sterilization cycle VDmax25 (for 25 kGy dose)	☐
Sterility Assurance Level (SAL) 10^-6	☐
Is it labeled "Pyrogen Free"? No	☐
A description of the packaging (not including package integrity test data) double PETG blisters with Tyvek Lids. Acetabular liners are also back-filled with nitrogen gas.	☐
Shelf Life 3 years	☐
Are there additional devices/components that are sterilized differently? Yes	☐
Identify the device(s)/component(s) that is sterilized XLVE liners	☐
Does the Manufacturer or User sterilize the device/component? Manufacturer	☐
Sterilization method description[1] Ethylene Oxide (EO, EtO)	☐
Sterilant residuals remaining on the device < 0.1 mg/day	☐
The standard(s) used for Validation ISO 11135	☐
A description of the Validation Method for the sterilization cycle Overkill Approach (e.g., Half-Cycle method)	☐
Sterility Assurance Level (SAL) 10^-6	☐
Is it labeled "Pyrogen Free"? No	☐
A description of the packaging (not including package integrity test data) LDPE mesh in double PETG blister with Tyvek lids	☐
Shelf Life 3 years	☐
Are there additional devices/components that are sterilized differently? Yes	☐
Identify the device(s)/component(s) that is sterilized reusable manual surgical instruments	☐
Does the Manufacturer or User sterilize the device/component? User	☐
Is 'Non-Sterile' prominent on the package labeling for it? Yes	☐
Sterilization method description[1] Steam (Moist Heat)	☐
Air Removal Method / Temperature / Exposure & Drying Time prevacumm/132C/4 min exposure 30 min drying	☐
The standard(s) used for Validation ISO 17665-1	☐
A description of the Validation Method for the sterilization cycle Overkill Approach (e.g., Half-Cycle method)	☐
Sterility Assurance Level (SAL) 10^-6	☐
Is it labeled "Pyrogen Free"? No	☐
A description of the packaging (not including package integrity test data) poly bags, sleeves, polyester tubes, and vinyl end caps	☐

Shelf Life N/A	☐
Are there additional devices/components that are sterilized differently? No	☐

Reviewer Decision
Sterilization, Shelf-Life and Reuse descriptions are unchanged from the predicate device and are acceptable.

VIII. Biocompatibility

Biocompatibility Review Needed?	Yes ☒	No ☐
Biocompatibility Consult Needed?	Yes ☐	No ☒

Reviewer Decision
The Biocompatibility is acceptable. Aside from hydroxyapatite, the device is made from the same materials as the predicate (CoCr, Ti alloy, cp Ti, UHMWPE, XLVE previously cleared in K112802). HA is a material common to hips and its biocompatibility is assessed via characterization. This data was reviewed by Limin Sun and found adequate.

IX. Software/Firmware

Software Review Needed?	Yes ☐	No ☒
Software Consult Needed?	Yes ☐	No ☒

Reviewer Decision
The Software is not applicable.

X. EMC & Electrical, Mechanical and Thermal Safety & Risk Analysis

Reviewer Decision
The EMC, EMT and Risk Analysis are not applicable

XI. Performance Testing

A Bench Testing

The submission includes all of the testing that was supplied in K112802 as ownership of the device is being transferred to Pipeline Biomedical Products LLC from Pipeline Orthopedics. For review of that testing please see K11802 memos. Only new testing is included here.

FDA Guidance Document Testing Report, (b)(4) [redacted], Report # (b)(4) [redacted], 11/3/11

HA characterization testing was reviewed by Dr. Sun, please see her attached consult. Initially, some tests were performed on a substrate that differs from the subject device in terms of porosity. In S1, the sponsor repeated static shear, static tensile, and dynamic shear testing on the appropriate substrate. Dr. Sun reviewed the new testing and determined it was adequate, please see her attached updated memo. This is adequate.

Hip Simulator Wear Resistance of Highly Crosslinked, Vitamin E Blended UHMWPE, Harris Orthopaedic Laboratory, 11/23/11

Wear testing was performed on the thinnest 28 and 40 mm ID liners that were aged per ASTM F2003 ([redacted]). 6 liners were tested and liners were used as a soak control. 5 Mc of loading (profile was per ISO 14242-1) was applied at 1 Hz. Lubricant was diluted bovine serum (18.5 g/L protein concentration) at 37C which was changed every 0.5 Mc. Gravimetric wear measurements were performed every 1 Mc after correction with a soak control. Wear particle analysis was performed on wear debris taken from the 4.0 – 4.5 Mc interval and analyzed via SEM. The wear results, as well as those from previous testing are summarized in the table below.

Device	Wear rate, mg/Mc
Subject (28 mm)	[redacted]
K112802 (36 mm)	[redacted]
Subject (40 mm)	[redacted]
K094035*	20.2
K111481*	1.84 ± 1.02

*Comparative data I have added from other XLVE submissions.

The figures below compare the particle size and inverse aspect ratio to the previously tested wear from the 36 mm liners.

[redacted]

Reviewer Comment: *Effect of size on wear has been adequately characterized and supports the use of new 40 mm liners. Particle size distribution and shape appears relatively independent of size. Although wear testing against ceramic heads has not been performed, testing of similar systems has shown that CoP systems generally produce less wear than MoP systems. Therefore additional testing is not required. The supplied testing is adequate.*

Range of Motion Study, Pipeline Uncemented System, Pipeline Orthopedics, TM110906, Joshua Weiss, Sept. 22, 2011

ROM was analyzed using SolidWorks 2011. When skirted heads were analyzed, no stems were included in the analysis as the ROM was limited by liner contacting the skirt, not the stem's neck. A table summarizing the testing can be seen below. The 22mm +0 heads were not affected by choice of stem (std or offset, size 2 or size 12, or choice of hi wall liner (hi wall or offset). This was not the case for 28 mm heads. The use of a hi wall liner does not affect the A/P direction.

Table 24: Range of Motion Analyses

Neutral, Elevated and +4 offset liners			
	Abduction/Adduction	Flexion/Extension	Internal/External Rotation
22+0	(b)(4)		
22+3.5			
28+10.5			
32+10.5			
36+10.5			
40+10.5			
Hi wall and +4 hi wall liners			
	Abduction/Adduction	Flexion/Extension	Internal/External Rotation
22+0	(b)(4)		
22+3.5			
28+10.5			
32+10.5			
36+10.5			
40+10.5			

Reviewer Comment: *The new 40 mm components have a greater ROM.*

Comparison of Values for Rotational Stability and Pulloff Forces for Biolox Delta and Biolox Forte Ball Heads on Different Taper Materials, CeramTec AG, Doc. 3799, June 7, 2008.

Pulloff and rotational testing was performed on Forte 28 mm 12/14 L heads on 3 stem materials. Testing was also performed on similarly sized delta head and on forte head with maximum contact area between taper and ball head. 5 samples were tested for each material/size. The test report includes engineering diagrams of the tapers that shows they are equivalent to the subject device. The results of the testing are summarized in the table below.

Head	Stem	Pulloff, N	Rotational Moment, Ncm
Forte 28 L mm	Ti alloy	(b)(4)	(b)(4)
Forte 28 L mm	SS	(b)(4)	(b)(4)
Forte 28 L mm	CoCr	(b)(4)	(b)
Delta 28 L mm	Ti alloy	(b)(4)	(b)(4)
Forte 32 S mm	Ti alloy	(b)(4)	(b)

Reviewer Comment: *The subject report adequately demonstrates the pulloff and rotational strength of the forte and delta heads. Only the delta heads are relevant to the subject device and testing was not performed on the subject tapers. However, this testing is not typically requested. Additionally, as the sponsor asserts that greatest clinical distraction loads are 250 N, there is a substantial safety margin. The supplied testing is not required.*

Influence of Diameter and Neck Length on Burst Strength of BIOLOX forte and BIOLOX delta ball heads with 12/14 Taper, CeramTec AG, Doc. 3300, Apr. 2, 2011

Testing per ISO 7206-10 at 2 mm/min was performed on various heads on a 12/14 taper. The effect of ceramic material (forte vs. delta), head diameter (28 – 44 mm), neck length (-4 - +4 mm), and neck material (Ti, SS, and CoCr) were investigated. The results show burst strength decreases with increasing neck length and decreasing head diameter. Delta is also stronger than forte, and head strength is reduced by the use of a CoCr neck (Ti alloy and SS are equivalent.)

Upon request (email dated 8/31), the sponsor has provided a side-by-side comparison of the subject device taper (all three stem systems have the same taper) and the taper tested in the CeramTec report.

	Pipeline taper	CeramTec test taper
Angle	(b)(4)	
Length		
Straightness		
Roundness		
Surface Roughness		
Gage diameter		
Ball/Cone Overlap*		
Ball Dia. Ball Size		
28mm L		
32mm L		
36mm XL		
40mm XL		

The following relevant heads were tested on Ti alloy stems in this test report

Material	Diameter, mm	Offset, mm	Burst Strength, kN
Delta	32	+7	(b)(4)
Delta	28	+3.5	

Reviewer Comment: *The provided testing includes testing of the two worst-case heads. However, testing was not performed on the subject stem. At this point in time, I have seen this test report in multiple submissions. The provided information demonstrates that the tested and subject tapers are adequately similar that a 50% reduction in burst strength is not expected. The provided testing is adequate.*

B Animal Testing

Not provided.

C Clinical Testing

Not provided.

Reviewer Decision

The Performance Testing is acceptable.

XII. Claims

In S1, the sponsor added the following claims to the submission.

Claim 1:
The highly-crosslinked Vitamin E Polyethylene material had an average wear rate 58% less than conventional gamma sterilized polyethylene in an abrasive environment, and 35% less than conventional gamma sterilized polyethylene in clean serum in bidirectional pin-on-disc wear testing.
Wear testing was performed on cylindrical test pins machined from vitamin E blended UHMWPE stock that was gamma irradiated and terminally EO sterilized (the highly crosslinked Vitamin E polyethylene) and from UHMWPE stock that was terminally gamma sterilized (conventional polyethylene). The bidirectional pin-on-disc wear tester approximates the crossing motion of the total hip.

The wear rates were measured for all test specimens articulating against polished cobalt chrome lubricated by bovine serum. For the abrasive phase of the study, third body particles (PMMA bone cement) were added to the bovine serum lubricant to create an adverse testing environment. Each test was conducted at 2 Hz; and included a bedding in period of at least 0.5×10^6 cycles. The test stopped at approximately every 0.157×10^6 cycles daily for gravimetric assessment of wear until a total of 1.128×10^6 cycles. The calculated average gravimetric linear wear rates under abrasive conditions were (b) [redacted] for the Highly Crosslinked Vitamin E Poly and (b)(4) [redacted] for the conventional polyethylene (58% less for the Highly Crosslinked Vitamin E Poly). The calculated average gravimetric linear wear rates under clean conditions were (b)(4) [redacted] for the Highly Crosslinked Vitamin E Poly and (b)(4) [redacted] the conventional polyethylene (35% less for the Highly Crosslinked Vitamin E Poly).
Bench testing is not necessarily indicative of clinical performance.
Reviewer Comment: *The claim above deals with POD testing and implies that improved POD wear implies improved wear performance of the device. However, wear performance is an extremely complicated multicomponent phenomena in which wear resistance, as measured by POD, is only a single factor. Therefore, the sponsor should demonstrate that POD wear leads to a clinical reduction in wear for the subject device. Otherwise, this claim should be removed. I called the sponsor on 12/4 regarding this claim and it was removed in an email dated 12/5.*

Claim 2:
The highly-crosslinked Vitamin E Polyethylene is more resistant to oxidation than conventional polyethylene per method ASTM F2102.
The highly-crosslinked Vitamin E Polyethylene is GUR 1020 blended with Vitamin E (GUR 1020-E) compression molded and then highly crosslinked by gamma irradiation at a dose of (b)(4) [redacted], which is machined to its final form and terminally sterilized via Ethylene Oxide. The highly crosslinked Vitamin E Polyethylene liners underwent oxidation analysis per ASTM F2102-06. The same analysis was also conducted on gamma-sterilized GUR 1020 (conventional polyethylene) reference material for comparison. As measured using ASTM F2102, the highly crosslinked Vitamin E poly had lower oxidation indices than the conventional polyethylene: mean surface oxidation index was 0.017 for Vitamin E and 0.097 for conventional poly; maximum oxidation index was 0.029 for Vitamin E and 0.248 for conventional poly; and bulk oxidation index was 0.009 for Vitamin E and 0.036 for conventional poly.
Bench testing is not necessarily indicative of clinical performance.
Reviewer Comment: *Data to support this claim was not provided. In addition, no standard accelerated aging was applied to the materials, making results difficult to interpret. I called the sponsor on 12/4 regarding this claim and it was removed in an email dated 12/5.*

XIII. Manufacturing Information

XIV. References

XV. Original Deficiencies

See original memo.

A1 Deficiencies

1. The Food and Drug Administration (FDA) has reviewed the information that you have provided to Pipeline Orthopedics for their 510(k) submission, i.e., Answers to FDA 510(k) Guidance Questions within (b)(4) [redacted] Mater File MAF-(b) [redacted], as well as the referenced Amendment 27 in the MAF-(b) [redacted]. Regarding your Answer #4, it appears that the test coupon used for the bonding tests is made of the same material as the Pipeline Orthopedics' device to be cleared, i.e., Ti6Al4V. However, the test coupon does not contain a porous surface as the subject device. It is not clear how the porous surface will affect the bonding strength of the HA coating. Therefore, please either provide the bonding strength tests using HA-coated test coupons with a

porous surface (the porous surface should be manufactured in the same way as the subject device), or provide rationales as to why the test results that you have provided are adequate for the HA-coated subject device.

Response: Static shear, static tensile, and dynamic shear testing was performed using the subject device's substrate material. This is adequate.

2. You have interactively supplied and updated 510(k) Summary with some, but not all, claims removed. Please remove/modify the following claims from the device description section. Alternatively, you may supply adequate information within the text of the claim to support it and give it adequate context.

   i. "Allowing the surgeon to optimize soft tissue tension and restore joint mechanics,"

   ii. "The porous structured surface's interconnected porosity provides a scaffold for bone ingrowth as shown in the transcortical implant canine model." You may state the coating allows for biological fixation as the subject coating meets FDA's definition of porous.

   iii. "For increased resistance to wear and oxidative degradation as compared with standard UHMWPE (demonstrated by comparative wear testing and comparative oxidation analyses summarized in section 8)."

   Response: Textual claims have been removed. 2 official claims have been added, but were removed at a later date.

3. Please provide a statement that no enhanced claims regarding your plasma sprayed coating will be made for this device. Enhanced claims such as osseointegration for example would be considered unsubstantiated and should be excluded in the submission.

   Response: No enhanced claims will be made.

4. Engineering drawings of the subject device are provided in Section xx of the submission. The engineering drawings doesn't seem to contain the HA coating information. Please reference the draft Guidance '510(k) Information Needed for Hydroxyapatite Coated Orthopedic Implants'

   (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080224.htm)

   for the total surface area of the implantable portion of the coated implant as recommended in #1 of the guidance, and provide updated engineering drawing in which the area or location of the HA coating on the subject device should be clearly depicted.

   Response: This information was contained in the submitted drawings.

   ADVISORY

5. For the plasma sprayed hydroxyapatite coating, please be advised that FDA recommends that you include all characterization parameters per the draft Guidance "510(k) Information Needed

for Hydroxyapatite Coated Orthopedic Implants" in your specifications on file as part of your design controls. All testing characterization should be performed on final, sterilized devices. Should you use alternative methods other than those provided in the guidance, FDA will review accordingly. Should you make any modifications to your coating, then FDA recommends that you provide the full characterization per the draft Guidance in a future 510(k) submission. Additionally, we recommend you have the shelf life data (see below) on file as part of your design controls.

Some calcium phosphate coatings may be affected by aging in addition to shipping and storage conditions such as humidity, temperature extremes, mechanical forces, and packaging. Full characterizations per the "510(k) Information Needed for Hydroxyapatite Coated Orthopedic Implants" are recommended at the end of your requested shelf life, as well as at the beginning, unless there is reasonable evidence that the coating is relatively unaffected by the aging, shipping and storage conditions. Please provide the Ca/P ratio per wet chemistry methods and the solubility product on the coating at the initial time and at the proposed shelf life time (in addition to interim time points) exposed to humidity and temperature extremes. FDA recommends that the calcium phosphate coated products tested be in the same packaging that would be used for the marketed product and exposed to the appropriate test variables. We would entertain accelerated aging on devices with plasma sprayed calcium phosphate coatings. Please note that we are concerned about how the coated product in its packaging (sterile barrier) is affected by not only the shelf aging of the product but by the environmental conditions for which the coating would be exposed. For example, although the coating may be aged at ambient temperatures with low relative humidity at the manufacturer, the coated product may be exposed to different environmental conditions prior to being stored in a hospital facility. The coated product may encounter winter-like conditions and/or hot, humid conditions prior to hospital storage at ambient temperature. It is these fluctuations of the environmental conditions for which we are most concerned, and we recommend that you incorporate the worst case temperature and humidity fluctuations in addition to an aging process. Please note that depending on your information, additional information may be needed to support your shelf life.

For the solubility product information, we recommend an initial comparison with the National Institute of Standards & Technology (NIST) standard reference material (SRM), #2910 or #2910(a) – Calcium Hydroxyapatite. Alternatively, you may provide solubility product testing on your coating using the NIST method. The NIST method and/or SRM #2910 or #2910(a) standard reference material information are available at http://ts.nist.gov/srm. Please provide the solubility product, (Ksp) at 37°C. The pH changes of the solution should be recorded. The solubility product (Ksp) should be calculated based on the Ca5(PO4)3(OH) formula. Please note that the solubility product parameters should be provided for the coatings scraped from the implant and not coupons. If plasma spraying deposition techniques are used and solubility product testing is provided from the scrapings from a coupon or test component other than the implant, we request that you provide a rationale as to how the solubility product determined from scrapings from a coupon for example is appropriate for the subject implant. We recommend using your worst case coating thickness (e.g., thinnest thickness criterion) and comparing your Ca/P ratio and solubility product at the aged condition (which has been exposed to temperature and humidity extremes) to those at the initial time point. Should these values differ significantly, then your coating may not be considered stable or reliable. In this case, additional testing may be needed to determine the appropriate shelf-life, etc.

Finally, note that some calcium phosphate coating ISO standards reference a calcining heat treatment. Unless calcining is considered a post deposition heat treatment to a coating for which the coating will be shipped for clinical use, we recommend that you analyze the final, sterilized, non-calcined coating. We are willing to accept calcined samples for the analysis of the Ca/P ratio. Please acknowledge this advisory.

Response: Acknowledged.

XVI. Contact History

Date (MM/DD/YY)	Contact Method	Subject
08/22/12	Email	Interactive deficiencies sent to sponsor
08/31/12	Email	Ineractive response recieved

Lead Reviewer Sign-off:	Michael J. Kasser -S 2012.12.10 16:41:13 -05'00' Michael Kasser (ODE/DSORD/OJDB)	Date
Branch Level Sign-off:	Krishna R. Asundi 2012.12.10 16:57:45 -05'00' Branch Chief (Office Location)	Date
Division Level Sign-off:	Not required	Date

K122158/S001/MAF339 Consult Review Memorandum

TO: Michael Kasser, Reviewer, ODE/DOD/Joint and Fixation Two Branch

FROM: Limin Sun, Reviewer, ODE/DOD/Joint and Fixation Two Branch

DATE: November 29, 2012

SUBJECT: Coating Consult

SUBMISSION: K122158/S001 BPB Total Hip system

REFERENCE: Bio-Coat Device Master File MAF339

Limin Sun
2012.12.06 08:48:58
-05'00'

RECOMENDATION

I reviewed the sponsor's S001 response on HA coating characterization. The original deficiency is adequately address and there is no outstanding deficiency on coating characterization. The only update on memo is provided below the original deficiency at the end of the memo.

DEVICE DESCRIPTION

The PBP Total Hip System is an artificial hip replacement system comprised of femoral stems and mating metal heads; modular acetabular cups (acetabular shell and a mating acetabular liner), optional acetabular bone screws and optional acetabular dome hole occluders. The PBP Total Hip System subject of this 510(k) contains the same components as the predicate Pipeline Total Hip System (K112802), with the addition of a larger head size and associated acetabular liners, ceramic femoral heads and the addition of HA coated porous structured acetabular shells.

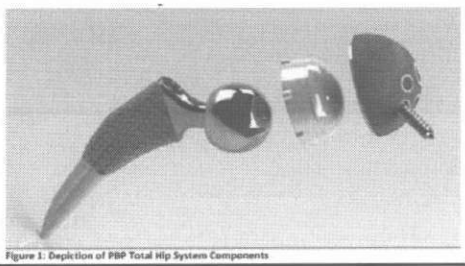

Figure 1: Depiction of PBP Total Hip System Components

The PBP Acetabular Shells (with the exception of the available HA coating option) are made entirely from Ti6Al4V alloy and both the shell substrate and the porous layer (Porous Structure Technology, PST) meet the chemical requirements of ASTM F-1472 and the applicable mechanical properties (tensile and yield strength). The shell's porous surface has a relatively large volumetric fully interconnected porosity that is integral with the shell body and hence not an applied coating. The HA PST surface for the subject PBP Acetabular Shell has the same surface as the predicate Pipeline Acetabular Shells (K112802) with the addition of a thin layer (b)(4)) of HA.

The HA coating is applied by Orchid Orthopedic Solutions. A letter of access to Orchids Master file is provided in Exhibit A-5. Additional information on the coating is provided according to FDA's guidance "510(k) Information Needed for Hydroxyapatite Coated Orthopedic Implants" revised on 2/20/1997 in Exhibit E-24: Orchid Orthopedics Answers to FDA 510(k) Guidance Questions within (b)(4) t Master file MAF-(b) . The report included in E-24 references the location of the data as outlined in FDA's guidance. References are made to the specific locations in the Master file and two additional reports that are provided in this submission as follows:

- E-28: Evaluation of Orchid Bio-coat HA Coating on Porous Rods Provided by Pipeline Orthopedics (TR-434: 3/12/2012); and

- E-29: Dissolution Testing for Pipeline Orthopedics Porous Rods Coated with Orchid Bio-Coat HA Coating (TR-435: 3/13/2012).

REVIEW

Guidance: "510(k) Information Needed for Hydroxyapatite Coated Orthopedic Implants" Prepared by Dr. Pei Sung and dated March 10, 1995 (revised 2/20/97) (Item #1-10).

Note to lead reviewer: The hydroxyapatite (HA) coating in MAF339 was previously cleared for K120739 Aequalis adjustable modular reverse shoulder system. While most of the characterization data are similar, the current review is focused on the items specific for the HA coating used in the subject device, including HA coating pore size and volume and total surface area (#1 in the guidance), thickness and cross section picture (#2), the bonding strength test (#4) and solubility(#5) and dissolution test (#6).

- Device/substrate: Ti6Al4V; the substrate is grit blasted to (b)(4) µm before coating.
- Deposition Process: Atmospheric Plasma Spray

1. The average porosity size, the overall pore volume and the total surface area of the implantable portion of the coated implant:

- Average Porosity Size:
  - Method: ASTM1854 (Amendment 27: TR-421, Page 2)
  - Result: (b)(4) (Amendment 27: TR-421, Page 4)

- Average% Porosity:
  - Method: ASTM1854 (Amendment 27: TR-421, Page 2)
  - Result: (b) (Amendment 27: TR-421, Page4)

Reviewer' comment: *The porosity is relative low (typical values are (b)(4)) implying a very dense coating. However, since there is no acceptance criterion for coating porosity, no additional information will be requested. Additionally, the above porosity and pore size were obtained on the coupon but not the subject device. Our current practice requires that all these characterizations be performed on final, sterilized devices as the geometry of the subject device (hip stem) is very different from that of the coupon (typically flat). The MAF holder provided the following rationale, which is accepted:*

An attempt was made to measure the pore size and porosity of (b)(4) HA coating on the pipeline orthopedics porous circular rod. Measurements were performed on the cross-section along the radius of the rod. Due to limitations of the ASTM 1854-09 measurement technique (see section 8.1.2.3) as well as the dimensions of the coating (b)(4) (b) thickness), it is not viable to measure the pore size and porosity of this coating not only on curved surface (hip cup or a rod with radius of curvature 44-68mm and 4mm respectively) but also on the flat solid surface. Thickness measurements have been recorded on the pipeline orthopedics porous rod (see #2 below).

High magnification SEM image provided in response to #2 below clearly show the integrity of the HA coating on the pipeline orthopedics circular porous rods. Given the porosity, pore size of the actual substrate material (b)(4) [redacted] and porosity measurements for the 15±10 µm HA coating would certainly be negligible.

Moreover the SEM picture of (b)(4) HA coating on the pipeline orthopedics porous circular rod represents the worst case scenario as the radius of curvature of the porous rod (4mm) is much smaller than the radius of curvature of the pipeline orthopedics hip cup (44-48mm). Hence the SEM images of the HA coated pipeline orthopedics hip cup were not obtained.

- Total surface area of the implantable portion of the coated implant: Implant Specific

Reviewer' comment: *Regarding the total surface area of the implantable portion of the coated implant, our current practice is to ask the sponsor to make sure that the area or location of the HA coating on the implant is clearly depicted in the engineering drawing. Therefore, please check if the engineering drawing is adequate; if not, a deficiency should be given to the sponsor, but not the MAF holder (see deficiency to the sponsor at the end of memo). Note to the leader reviewer*

2. SEM and cross-sectioned pictures of the metal particle - and the HA coated implant surfaces. Include coating thickness.

Orchid Bio-Coat evaluated the thickness of Orchid Bio-Coat HA coating on porous rods provided by pipeline orthopedics

- Thickness:
  - Method: ASTM1854 (TR434, Page 1; Exhibit E-28 of the submission)
  - Result: (b)(4) (TR434, Page 1)

- SEM surface and cross-sectional pictures are provided in TR434.

Reviewer's comment: *Although these data were not measured on the subject device, they are accepted based on the rationale provided in #1 above.*

4. Bonding strength between HA and titanium alloy or metal:

- Static Tensile Strength (64 samples)
  - Method: ASTM F1147 (Amendment 27: TR-311, Page 2)
  - Results: (b)(4) (Amendment 27: TR-311, Page 4)
  - Failure Areas: Adhesion/Glue (Amendment 27: TR-311, Page 4)

- Static Shear Strength (5 samples)
  - Method: ASTM F1044 (Amendment 27: TR-311, Page 2)
  - Results: (b)(4) (Amendment 27: TR-311, Page 5)
  - Failure Areas: Adhesion/Glue (Amendment 27: TR-311, Page 5)

- Shear Fatigue Strength (5 samples)
  - Method: ASTM F1160 (Amendment 27: TR-311, Page 3)
  - Results: (b)(4) (Amendment 27: TR-311, Page 6)
  - Failure Areas: Adhesion/Glue (Amendment 27:TR-311, Page 6 submitted to FDA on December 21, 2011)

Rationale: Bond strength measurements are performed on *50±10 µm HA coating which is the worst case for pipeline orthopedics since their parts are coated at* (b)(4) *Hence no separate measurements have been performed at* (b)(4).

Reviewer's comment: *The above tests were performed on 5 or more coupons and the results meet our acceptance criteria (if such criteria exist). However, although the coupon used for the bonding tests is made of the same material as the Pipeline Orthopedics' acetabular shell, i.e., Ti6Al4V, the coupon does not contain a porous (PST) surface as the subject device. It is not clear how the PST surface will affect the bonding strength of the HA coating. The sponsor will be asked to repeat the above tests using HA-coated test coupons with PST surface or provide rationales as to why the above test results are adequate for the HA coated subject device. MAF comment #1*

5. Solubility products of HA particles before and after coating:

Powder Form:

- Method: ADA Method using dilute phosphoric acid@ 37°C (Amendment 27: TR-313, Page 2)
- 24 Hours Results: pK_{sp} (HA) = (b)(4) $_{sp}$ (TCP) = (b)(4) (Amendment 27: TR-313, Page 3)
- 2 Weeks Results: pK_{sp} (HA) = (b)(4) (Amendment 27: TR-313, Page 3)
- (b)(4) (Amendment 27: TR-313, Appendix A Raw Data)
- (Amendment 27: TR-313, Appendix A Raw Data)

C

- Method: ADA Method using dilute phosphoric acid@ 37°C (Amendment 32: TR-447, Page 5, Table 3)
- 24 Hours Results: (b)(4) Page 5, Table 3)
- 2 Weeks Results: (b)(4) (Amendment 27: TR-313, Page 3)

(b)(4) (Amendment 32: TR-447, Page 102)
(Amendment 32: TR-447, Page 102)

Rationale: The coating thickness requirement for pipeline orthopedics hip cup implant is 15±10µm. Solubility testing requires scrapping off the coating from the substrate material. It is not only difficult to scrap off the coating but it is also hard to collect enough material that is required for the solubility measurements. Hence the solubility product measurements were carried out on a 25±10µm thick HA coating.

Reviewer's comment: *The above test method, test results and rationale are accepted.*

6. Dissolution rate of HA particles before and after coating:

Powder Form:

- Method: ADA Method using pH 4.65 @ 37°C (Amendment 27: TR-313, Page 2)
- Results: (b)(4) (Amendment 27: TR-313, Page 3)

(b)(4) mendment 27: TR-313, Raw data)
(Amendment 27: TR-313, Raw data)

Coating Form:

- Method: ASTM F1926 TRIS buffere solution (Amendment 27:TR-313, Page 2)
- Results: (b)(4)

(b)(4)

Reviewer's comment: *The above test methods and results are adequate.*

PROPOSED DEFICIENCIES AND ADVISORY TO THE SPONSOR:

Note to the leader reviewer: ***Please send the following two deficiencies to the sponsor as needed:***

1. Please provide a statement that no enhanced claims regarding your plasma sprayed coating will be made for this device. Enhanced claims such as osseointegration for example would be considered unsubstantiated and should be excluded in the submission.

2. Engineering drawings of the subject device are provided in Section xx of the submission. The engineering drawings doesn't seem to contain the HA coating information. Please reference the draft Guidance '510(k) Information Needed for Hydroxyapatite Coated Orthopedic Implants' (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080224.htm) for the total surface area of the implantable portion of the coated implant as recommended in #1 of the guidance, and provide updated engineering drawing in which the area or location of the HA coating on the subject device should be clearly depicted.

ADVISORY

1. For the plasma sprayed hydroxyapatite coating, please be advised that FDA recommends that you include all characterization parameters per the draft Guidance "510(k) Information Needed for Hydroxyapatite Coated Orthopedic Implants" in your specifications on file as part of your design controls. All testing characterization should be performed on final, sterilized devices. Should you use alternative methods other than those provided in the guidance, FDA will review accordingly. Should you make any modifications to your coating, then FDA recommends that you provide the full characterization per the draft Guidance in a future 510(k) submission.

Additionally, we recommend you have the shelf life data (see below) on file as part of your design controls.

Some calcium phosphate coatings may be affected by aging in addition to shipping and storage conditions such as humidity, temperature extremes, mechanical forces, and packaging. Full characterizations per the "510(k) Information Needed for Hydroxyapatite Coated Orthopedic Implants" are recommended at the end of your requested shelf life, as well as at the beginning, unless there is reasonable evidence that the coating is relatively unaffected by the aging, shipping and storage conditions. Please provide the Ca/P ratio per wet chemistry methods and the solubility product on the coating at the initial time and at the proposed shelf life time (in addition to interim time points) exposed to humidity and temperature extremes. FDA recommends that the calcium phosphate coated products tested be in the same packaging that would be used for the marketed product and exposed to the appropriate test variables. We would entertain accelerated aging on devices with plasma sprayed calcium phosphate coatings. Please note that we are concerned about how the coated product in its packaging (sterile barrier) is affected by not only the shelf aging of the product but by the environmental conditions for which the coating would be exposed. For example, although the coating may be aged at ambient temperatures with low relative humidity at the manufacturer, the coated product may be exposed to different environmental conditions prior to being stored in a hospital facility. The coated product may encounter winter-like conditions and/or hot, humid conditions prior to hospital storage at ambient temperature. It is these fluctuations of the environmental conditions for which we are most concerned, and we recommend that you incorporate the worst case temperature and humidity fluctuations in addition to an aging process. Please note that depending on your information, additional information may be needed to support your shelf life.

For the solubility product information, we recommend an initial comparison with the National Institute of Standards & Technology (NIST) standard reference material (SRM), #2910 or #2910(a) – Calcium Hydroxyapatite. Alternatively, you may provide solubility product testing on your coating using the NIST method. The NIST method and/or SRM #2910 or #2910(a) standard reference material information are available at http://ts.nist.gov/srm. Please provide the solubility product, (Ksp) at 37°C. The pH changes of the solution should be recorded. The solubility product (Ksp) should be calculated based on the $Ca_5(PO_4)_3(OH)$ formula. Please note that the solubility product parameters should be provided for the coatings scraped from the implant and not coupons. If plasma spraying deposition techniques are used and solubility product testing is provided from the scrapings from a coupon or test component other than the implant, we request that you provide a rationale as to how the solubility product determined from scrapings from a coupon for example is appropriate for the subject implant. We recommend using your worst case coating thickness (e.g., thinnest thickness criterion) and comparing your Ca/P ratio and solubility product at the aged condition (which has been exposed to temperature and humidity extremes) to those at the initial time point. Should these values differ significantly, then your coating may not be considered stable or reliable. In this case, additional testing may be needed to determine the appropriate shelf-life, etc.

Finally, note that some calcium phosphate coating ISO standards reference a calcining heat treatment. Unless calcining is considered a post deposition heat treatment to a coating for which the coating will be shipped for clinical use, we recommend that you analyze the final, sterilized, noncalcined coating. We are willing to accept calcined samples for the analysis of the Ca/P ratio. Please acknowledge this advisory.

PROPOSED COMMENTS TO MAF HOLDER (NOT SPONSOR)

1. The Food and Drug Administration (FDA) has reviewed the information that you have provided to Pipeline Orthopedics for their 510(k) submission, i.e., Answers to FDA 510(k) Guidance Questions within Orchid Bio-Coat Mater File MAF(b) , as well as the referenced Amendment 27 in the MAF-(b) . Regarding your Answer #4, it appears that the test coupon used for the bonding tests is made of the same material as the Pipeline Orthopedics' device to be cleared, i.e., Ti6Al4V. However, the test coupon does not contain a porous surface as the subject device. It is not clear how the porous surface will affect the bonding strength of the HA coating. Therefore, please either provide the bonding strength tests using HA-coated test coupons with a porous surface (the porous surface should be manufactured in the same way as the subject device), or provide rationales as to why the test results that you have provided are adequate for the HA-coated subject device.

S002 Reviewer's comment: In S001, Pipeline has conducted the requested bond strength testing using HA-coated test coupons with a porous surface (with the porous surface manufactured the same way as the subject

device). The rest results are provided in Exhibit 1 and summarized below:

- Static Shear Test Results (ASTM F1044): Six samples were tested. The average peak tensile load was [redacted] (b) [redacted], which exceeds the 20 MPa minimum given in the FDA Guidance Document. The failure mode was 100% adhesive for all samples.

- Static Tensile Test Results (ASTM F1147): Six samples were tested. The average peak tensile load was [redacted] (b) [redacted], which exceeds the 20 MPa minimum given in the FDA Guidance Document. The failure mode was 100% adhesive for all samples.

- Dynamic Shear Test Results (ASTM F1160): Ten shear fatigue specimens were tested to establish an SN curve. [redacted] (b)(4) [redacted] (b)(4) [redacted].

The above test methods and results are adequate. Although not stated in the submission, from the images provided in the test report, the thickness of the HA coating in the test sample appears to be same or thicker than the HA coating to be applied on the subject device, which is [redacted] (b)(4) *; therefore the test sample is the worst case for the subject device.*

Kasser, Michael

rom: Terry Sheridan Powell <tpowell@msquaredassociates.com>
ent: Wednesday, December 05, 2012 12:20 PM
To: Kasser, Michael
Subject: K122158 - 510k Summary 12-05-2012
Attachments: K122158 - 510k Summary 12-05-2012.pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Hi Dr. Kasser,

We have removed the section for Claims (previously section 10) from the 510k Summary, and the revised document, dated today, is attached.

We understand that claim language will not be included in future 510(k) Summaries, because it does not accord with the requirements for 510k content and format given in CFR Sec. 807.92 ("Content and format of a 510(k) summary").

Thank you for your assistance, and please let me know if you require any further changes.

-Terry

erry Sheridan Powell
enior Project Manager
M Squared Associates, Inc.
901 King Street, Suite 102
Alexandria, VA 22314
(T) 703-562-9800 x252
(F) 703-562-9797
tpowell@msquaredassociates.com

510(k) Summary: K122158

The following 510k Summary is provided in accordance with the requirements of 21 CFR 807.92.

1. Device Name and Classification

Device Trade Name:	PBP Total Hip System
Device:	Artificial Total Hip Replacement
Regulation Number and Description:	888.3358 - Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis 888.3350 - Hip joint metal/polymer semi-constrained cemented prosthesis) 888.3353 – Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Device Class:	II
Product Codes:	LPH - prosthesis, hip, semi-constrained, metal/polymer, porous uncemented JDI - prosthesis, hip, semi-constrained, metal/polymer, cemented OQG - hip prosthesis, semi-constrained, cemented, metal/polymer, + additive, porous, uncemented OQH - hip, semi-constrained, cemented, metal/polymer + additive, cemented MEH (hip, semi-constrained, uncemented, metal/polymer, non-porous, calcium-phosphate) LZO (Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis) OQI - hip, semi-constrained, cemented, metal/ceramic/polymer + additive, porous uncemented
Advisory Panel:	Orthopedic

2. Address and Registration

Submitter's Name:	Pipeline Biomedical Products, LLC
Address:	3 Wing Drive Suite 102 Cedar Knolls, NJ 07927
Contact Person:	Robert C. Cohen
Telephone Number:	(973) 267-8800
Fax Number:	(973) 267-8810

Date Summary Prepared: December 5, 2012
Establishment Registration Number: Not yet registered

3. Purpose of Submission

The purpose of this submission is to obtain 510k clearance for the PBP Total Hip System, a new device system for Pipeline Biomedical Products, LLC.

4. Identification of Legally Marketed Device to which Submitter Claims Equivalence

The subject PBP Total Hip System by Pipeline Biomedical Products is substantially equivalent to the predicate devices as outlined in the following table.

Table 1: Predicate Devices

Device Name	Company	510(k) Number	Clearance Date
Pipeline Total Hip System	Pipeline Orthopedics	K112802	3/9/2012
Tritanium® Peri-Apatite Acetabular Shell System	Howmedica Osteonics	K101072 K971206	4/11/2011 2/11/1998
Biolox *delta* Ceramic Femoral Head	Zimmer	K071535	11/19/2007

5. Device Description

The PBP Total Hip System is an artificial hip replacement system. The system includes femoral stems, femoral heads, acetabular shells, acetabular liners, acetabular bone screws and dome hole covers (occluders) for the holes in the acetabular shells.

The PBP Femoral Stems are forged titanium alloy and feature a proximal roughened surface (plasma-sprayed CP Titanium), a polished tapered neck, a flat tapered geometry with reduced A/P width (wedge design), and a contoured distal tip and reduced lateral shoulder. The PBP Femoral Stems come in a range of sizes, and are offered in two offset neck options per size.

The PBP Femoral Heads are available in a polished cobalt chromium alloy or a high purity alumina oxide ceramic compound (Biolox® *delta*). The heads come in a range of diameters and extension options. The variety of head and stem sizes and offsets accommodates differences in patient anatomy.

The PBP PST™ (Porous Structured Technology) Acetabular Shells are manufactured from titanium alloy and feature a porous structured surface or an HA porous structured surface. The shells feature a dome hole, are available with or without a cluster screw hole pattern for supplemental bone screw fixation, and come in a range of outer diameter sizes. The porous structured surface provides biologic fixation.

The PBP Acetabular Liners are manufactured from standard UHMWPE, or from highly crosslinked Vitamin E UHMWPE (XLVE™). The liners are mechanically assembled to the mating shells via engagement of the tightly toleranced liner taper and shell bore. The liners are available in a range of sizes and in neutral, high wall, and offset versions.

Optional components include a threaded acetabular dome hole occluder and acetabular bone screws, all manufactured from titanium alloy.

6. Intended Use

The PBP Total Hip System is indicated for use in skeletally mature individuals undergoing surgery for total hip replacement due to:

- A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis, or congenital hip dysplasia;
- Acute traumatic fracture of the femoral head or neck;
- Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty or total hip replacement.

The PBP Total Hip System hip stems and porous structured acetabular shells are intended for cementless or cemented fixation. The porous structured surface provides biological fixation when used in a cementless application.

The PBP Total Hip System HA porous structured acetabular shells are intended for cementless fixation. The HA porous structured surface provides biological fixation.

7. Comparison of Technological Characteristics

The PBP Total Hip System is manufactured from the same materials as the predicate device systems. In addition, the components are packaged, and sterilized using similar processes. The subject Total Hip System is substantially equivalent to the predicates based on comparisons of intended use, design features and technological characteristics.

8. Performance Testing

The following performance tests were provided to demonstrate substantial equivalence:

- Biocompatibility testing for the highly crosslinked Vitamin E Polyethylene:
  - Cytotoxicity, 10993-5
  - Maximization/Sensitization, 10993-10
  - Intracutaneous, 10993-10
  - Acute Systemic Toxicity, 10993-11
  - Sub-acute/Subchronic Systemic Toxicity, 10993-11
  - Genotoxicity, 10993-3
  - Muscle Implantation, 10993-6.
- Wear testing:
  - Testing was conducted on 28 mm, 36mm and 40mm inner diameter highly crosslinked Vitamin E poly liners, that had been EO-sterilized and accelerated aged in

accordance with ASTM F2003, and subject to wear testing in accordance with ISO 14242, using a standard walking gait cycle as specified by ISO 14242-1.
  - Bidirectional pin-on-disc abrasive wear testing was also conducted to compare the wear rates of the highly-crosslinked Vitamin E poly material to conventional (standard) gamma sterilized poly under clean and abrasive conditions. The wear reduction for the Vitamin E poly over conventional poly is 35% (7.7 vs 5 mg/Mc) in clean serum and 58% (8.3 vs 3.5 mg/Mc) in an abrasive environment.
- Wear particle characterization was conducted.
- The highly-crosslinked Vitamin E Polyethylene underwent exhaustive extraction testing using both polar and non-polar solvents, with GCMS and LCMS analysis to determine all volatile, semi-volatile, and non-volatile extracts. The results were compared to a predicate material to demonstrate that no new radiation degradation products are released by the material.
- Highly-crosslinked Vitamin E Polyethylene liners underwent oxidation analysis per ASTM F2102-06 after accelerated aging per ASTM F2003, wear testing, and exhaustive extraction. The analysis was also conducted on gamma-sterilized GUR 1020 (standard poly) reference material for comparison. The highly crosslinked Vitamin E poly exhibited lower oxidation indices than the standard poly, demonstrating higher resistance to oxidation: mean surface oxidation index was 0.017 for Vitamin E and 0.097 for standard poly; maximum oxidation index was 0.029 for Vitamin E and 0.248 for standard poly; and bulk oxidation index was 0.009 for Vitamin E and 0.036 for standard poly.
- Highly-crosslinked Vitamin E Polyethylene liners were evaluated by polarized light microscopy and SEM analysis of freeze fractured surfaces, after accelerated aging per ASTM F2003 and wear testing, to demonstrate that the subject material has equivalent consolidation to a predicate material.
- Liner Assembly/Disassembly Testing: Testing of the worst case size Pipeline Hip System highly crosslinked Vitamin E poly acetabular liner and worst case size conventional poly liner were tested for push-out, lever out torque, and axial torque.
- Hip Stem Fatigue Testing was conducted for the worst case (smallest) hip stem according to the method described in ISO 7206-4:2010, Implants for surgery-Partial and total hip joint prostheses, Determination of Endurance Properties and Performance of Stemmed Femoral Components.
- Stem Neck Fatigue Testing of the worst-case size was conducted according to the methods described in ISO 7206-6:1992 Implants for surgery-Partial and total hip joint prostheses-Part 6 and ASTM F2068-03 Standard Specification for Femoral Prostheses – Metallic Implants.
- Pull off testing was conducted on the metal and ceramic femoral heads.
- Burst Strength testing was conducted on Biolox *delta* Femoral Heads according to ISO 7206-10.
- An analysis was conducted of the typical and worst case ranges of motion permitted by the designs of various liner size/style, head size/style, and stem size/style combinations. The ROM was reported for flexion/extension, abduction/adduction, and internal/external rotation per ISO 21535.

- Bone screw testing was conducted in accordance with ASTM F543-07, Standard Specification and Test Methods for Metallic Medical Bone Screws, for torsion (torque to failure) and screw pull-out (pull-out to failure).
- Characterization in accordance with relevant aspects of "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement," was completed for: 1) Acetabular Shell – PST Surface; 2) Acetabular Shell – HA PST Surface; 3) Hip Stem – Plasma-Spray Titanium Coating.
- Characterization in accordance with relevant aspects of "Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball HIP Systems" was completed for the ceramic femoral heads.
- The porous structured surface was evaluated in a transcortical canine model to assess the biological response, using histological and mechanical evaluations, at intervals up to 12 weeks.

9. Conclusions

The subject PBP Total Hip System shares the same indications for use as the predicate hip system, and a comparison of technological characteristics supported by performance testing demonstrates the Substantial Equivalence of the PBP Total Hip System to the predicate hip systems.

Kasser, Michael

rom: Terry Sheridan Powell <tpowell@msquaredassociates.com>
ent: Friday, December 07, 2012 3:57 PM
To: Kasser, Michael
Subject: RE: K122158 - 510k Summary 12-05-2012
Attachments: Indications for Use Statement.docx

Follow Up Flag: Follow up
Flag Status: Flagged

Please see attached. -Terry

From: Kasser, Michael [mailto:Michael.Kasser@fda.hhs.gov]
Sent: Friday, December 07, 2012 11:51 AM
To: Terry Sheridan Powell
Subject: RE: K122158 - 510k Summary 12-05-2012

Could you please email me a word version of the indications for use page?

Thanks!

From: Terry Sheridan Powell [mailto:tpowell@msquaredassociates.com]
Sent: Wednesday, December 05, 2012 12:20 PM
o: Kasser, Michael
ubject: K122158 - 510k Summary 12-05-2012

Hi Dr. Kasser,

We have removed the section for Claims (previously section 10) from the 510k Summary, and the revised document, dated today, is attached.

We understand that claim language will not be included in future 510(k) Summaries, because it does not accord with the requirements for 510k content and format given in CFR Sec. 807.92 ("Content and format of a 510(k) summary").

Thank you for your assistance, and please let me know if you require any further changes.

-Terry

Terry Sheridan Powell
Senior Project Manager
M Squared Associates, Inc.
901 King Street, Suite 102
Alexandria, VA 22314
(T) 703-562-9800 x252
(F) 703-562-9797
powell@msquaredassociates.com

K122158/S001

K11

K122158: PBP Total Hip System
Response to 9/7/2012 AI request

November 14, 2012

Dear Dr. Kasser,

The following information is provided in response to FDA's AI request dated September 7, 2012. Each of FDA's requests is reproduced below, and is followed by Pipeline's response.

We are providing an electronic copy of the response, which is an exact copy of the paper response.

If you require any further information, please contact the undersigned. Thank you for your assistance with this submission.

Sincerely,

Terry Sheridan Powell,
M Squared Associates, Inc., Consultants to Pipeline Orthopedics
901 King Street, Suite 102
Alexandria, VA 22314
(T) 703-562-9800 x 252
(F) 703-562-9898
(E) tpowell@msquaredassociates.com

TRADITIONAL PREMARKET NOTIFICATION [510(K)]

PBP TOTAL HIP SYSTEM
K122158

(RESPONSE TO ADDITIONAL INFORMATION REQUEST DATED SEPTEMBER 7, 2012)

PIPELINE BIOMEDICAL PRODUCTS, LLC
3 WING DRIVE, SUITE 102
CEDAR KNOLLS, NJ 07927

NOVEMBER 14, 2012

- CONFIDENTIAL -

K122158: PBP Total Hip System
Response to 9/7/2012 AI request

November 14, 2012

Dear Dr. Kasser,

The following information is provided in response to FDA's AI request dated September 7, 2012. Each of FDA's requests is reproduced below, and is followed by Pipeline's response.

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If you require any further information, please contact the undersigned. Thank you for your assistance with this submission.

Sincerely,

Terry Sheridan Powell,
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1. **The Food and Drug Administration (FDA) has reviewed the information that you have provided to Pipeline Orthopedics for their 510(k) submission, i.e., Answers to FDA 510(k) Guidance Questions within (b)(4) Mater File MAF-(b) as well as the referenced Amendment 27 in the MAF-(b). Regarding your Answer #4, it appears that the test coupon used for the bonding tests is made of the same material as the Pipeline Orthopedics' device to be cleared, i.e., Ti6Al4V. However, the test coupon does not contain a porous surface as the subject device. It is not clear how the porous surface will affect the bonding strength of the HA coating. Therefore, please either provide the bonding strength tests using HA-coated test coupons with a porous surface (the porous surface should be manufactured in the same way as the subject device), or provide rationales as to why the test results that you have provided are adequate for the HA-coated subject device.**

Pipeline has conducted the requested bond strength testing using HA-coated test coupons with a porous surface (with the porous surface manufactured the same way as the subject device). Please see Exhibit 1 for the test report: J1209POI-372 Pipeline Porous Structure Technology with Hydroxyapatite Coating Testing Final Report.

Static Shear Test Results (ASTM F1044): Six samples were tested. The average peak tensile load (b)(4) and the average peak shear stress was (b)(4) (b)(4), which exceeds the 20 MPa minimum given in the FDA Guidance Document for Testing Orthopedic Implants With Modified Metallic Surfaces Apposing Bone Or Bone Cement. The failure mode was 100% adhesive for all samples.

Static Tensile Test Results (ASTM F1147): Six samples were tested. The average peak tensile (b)(4)), and the average peak tensile stress was (b)(4). (b)(4)), which exceeds the 20 MPa minimum given in the FDA Guidance Document for Testing Orthopedic Implants With Modified Metallic Surfaces Apposing Bone Or Bone Cement. The failure mode was 100% adhesive for all samples.

Dynamic Shear Test Results (ASTM F1160): Ten shear fatigue specimens were tested to establish an SN curve. Five specimens completed runout testing to ten million cycles. The approximate shear fatigue strength was determined to be (b)(4). See Figure 1, below.

(b)(4)

2. You have interactively supplied and updated 510(k) Summary with some, but not all, claims removed. Please remove/modify the following claims from the device description section. Alternatively, you may supply adequate information within the text of the claim to support it and give it adequate context.

i. "Allowing the surgeon to optimize soft tissue tension and restore joint mechanics,"

We have removed this language from the 510(k) Summary. See Exhibit 2.

ii. "The porous structured surface's interconnected porosity provides a scaffold for bone ingrowth as shown in the transcortical implant canine model." You may state the coating allows for biological fixation as the subject coating meets FDA's definition of porous.

We have removed the statement and replaced it with a statement that the coating provides biologic fixation. See Exhibit 2.

iii. "For increased resistance to wear and oxidative degradation as compared with standard UHMWPE (demonstrated by comparative wear testing and comparative oxidation analyses summarized in section 8)."

We have removed this statement and have instead added two claims to the 510k Summary. See Exhibit 2.

Claim 1 relates to the reduction in wear rate for the highly crosslinked Vitamin E UHMWPE as compared with standard UHMWPE demonstrated in side-by-side wear testing. The claim language is similar to a claim (claim #4) cleared by FDA for the competitive DJO Surgical device (Highly Cross-linked Vitamin E UHMWPE Tibial Innsert), 510k #K103223 (Exhibit 3).

Claim 2 relates to the improved resistance to oxidation for the highly crosslinked Vitamin E UHMWPE as compared with standard UHMWPE demonstrated in comparative testing per ASTM F2101. The claim language is similar to a claim (claim #1) cleared by FDA for the competitive Stelkast EXp Acetabular Liners, 510k #K094035 (Exhibit 4).

3. Please provide a statement that no enhanced claims regarding your plasma sprayed coating will be made for this device. Enhanced claims such as osseointegration for example would be considered unsubstantiated and should be excluded in the submission.

The plasma sprayed CP Ti coating on the PBP Total Hip System hip stems is the same coating cleared via K112802. Pipeline refers to the plasma-sprayed coating on the hip stems as a roughened surface, and not a porous surface, and does not intend to make enhanced claims (such as osseointegration) for the plasma sprayed coating.

4. **Engineering drawings of the subject device are provided in Section xx (sic) of the submission. The engineering drawings doesn't seem to contain the HA coating information. Please reference the draft Guidance '510(k) Information Needed for Hydroxyapatite Coated Orthopedic Implants'**

Please see the following two engineering drawings, provided as Exhibit 5 of this response (and in Appendix C of the original 510k):

- Drawing number SK-00756, Rev A (POROUS STRUCTURE ACETABULARSHELL, NO HOLE, WITH HA): Page 1 of the drawing shows "Note 15 (see sheet 2)". Note 15, appearing on sheet 2 of the drawing, states, "HA COAT POROUS SURFACE, (b)(4) MICRONS THICK PER ASTM F1185." Thus, the HA coating is applied to the outer shell over the entire area of the porous structured surface (which is depicted on the drawing as the speckled/shaded area).
- Drawing number SK-00757, Rev A (RESTORIS PST ACETABULAR SHELL, CLUSTER HOLE WITH HA): Page 1 of the drawing shows "Note 1". Note 1, appearing on sheet 1 of the drawing, states, "HA COAT POROUS SURFACE, (b)(4) MICRONS THICK PER ASTM F1185." Thus, the HA coating is applied to the outer shell over the entire area of the porous structured surface (which is depicted on the drawing as the speckled/shaded area).

FDA also provided the following advisory, reproduced below.

ADVISORY

5. **For the plasma sprayed hydroxyapatite coating, please be advised that FDA recommends that you include all characterization parameters per the draft Guidance "510(k) Information Needed for Hydroxyapatite Coated Orthopedic Implants" in your specifications on file as part of your design controls. All testing characterization should be performed on final, sterilized devices. Should you use alternative methods other than those provided in the guidance, FDA will review accordingly. Should you make any modifications to your coating, then FDA recommends that you provide the full characterization per the draft Guidance in a future 510(k) submission. Additionally, we recommend you have the shelf life data (see below) on file as part of your design controls.**

   Some calcium phosphate coatings may be affected by aging in addition to shipping and storage conditions such as humidity, temperature extremes, mechanical forces, and packaging. Full characterizations per the "510(k) Information Needed for Hydroxyapatite Coated Orthopedic Implants" are recommended at the end of your requested shelf life, as well as at the beginning, unless there is reasonable evidence that the coating is relatively unaffected by the aging, shipping and storage conditions. Please provide the Ca/P ratio per wet chemistry methods and the solubility product on the coating at the initial time and at the proposed shelf life time (in addition to interim time points) exposed to humidity and temperature extremes. FDA recommends that the calcium phosphate coated products tested be in the same packaging that would be used for the marketed product and exposed to the appropriate test variables. We would entertain accelerated aging on devices with plasma sprayed calcium phosphate coatings. Please note that we are concerned about how the coated product in its packaging (sterile barrier) is affected by not only the shelf aging of the product but by the environmental conditions for which the coating would be exposed. For example, although the coating may be aged at ambient temperatures with low relative humidity at the manufacturer, the coated product may be exposed to different environmental conditions prior to being stored in a hospital facility. The coated product may encounter winter-like conditions and/or hot, humid conditions prior to hospital storage at ambient temperature. It is these fluctuations of the environmental conditions for which we are most concerned, and we recommend that you incorporate the worst case temperature and humidity fluctuations in addition to an aging process. Please note that depending on your information, additional information may be needed to support your shelf life.

   For the solubility product information, we recommend an initial comparison with the National Institute of Standards & Technology (NIST) standard reference material (SRM), #2910 or #2910(a) – Calcium Hydroxyapatite. Alternatively, you may provide solubility product testing on your coating using the NIST method. The NIST method and/or SRM #2910 or #2910(a) standard reference material information are available at

http://ts.nist.gov/srm. Please provide the solubility product, (Ksp) at 37°C. The pH changes of the solution should be recorded. The solubility product (Ksp) should be calculated based on the Ca5(PO4)3(OH) formula. Please note that the solubility product parameters should be provided for the coatings scraped from the implant and not coupons. If plasma spraying deposition techniques are used and solubility product testing is provided from the scrapings from a coupon or test component other than the implant, we request that you provide a rationale as to how the solubility product determined from scrapings from a coupon for example is appropriate for the subject implant. We recommend using your worst case coating thickness (e.g., thinnest thickness criterion) and comparing your Ca/P ratio and solubility product at the aged condition (which has been exposed to temperature and humidity extremes) to those at the initial time point. Should these values differ significantly, then your coating may not be considered stable or reliable. In this case, additional testing may be needed to determine the appropriate shelf-life, etc.

Finally, note that some calcium phosphate coating ISO standards reference a calcining heat treatment. Unless calcining is considered a post deposition heat treatment to a coating for which the coating will be shipped for clinical use, we recommend that you analyze the final, sterilized, non-calcined coating. We are willing to accept calcined samples for the analysis of the Ca/P ratio.

Please acknowledge this advisory.

Pipeline acknowledges the advisory and plans to address the specified shelf life issues related to the HA coating, and to include the testing (or incorporate reference to vendor testing) that addresses the issues noted by FDA as part of Pipeline's design controls.

Exhibit 1: J1209POI-372 Pipeline Porous Structure Technology with Hydroxyapatite Coating Testing Final Report

Exhibit 2: Revised 510k Summary

510(k) Summary

The following 510k Summary is provided in accordance with the requirements of 21 CFR 807.92.

1. Device Name and Classification

Device Trade Name:	PBP Total Hip System
Device:	Artificial Total Hip Replacement
Regulation Number and Description:	888.3358 - Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis 888.3350 - Hip joint metal/polymer semi-constrained cemented prosthesis) 888.3353 – Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Device Class:	II
Product Codes:	LPH - prosthesis, hip, semi-constrained, metal/polymer, porous uncemented JDI - prosthesis, hip, semi-constrained, metal/polymer, cemented OQG - hip prosthesis, semi-constrained, cemented, metal/polymer, + additive, porous, uncemented OQH - hip, semi-constrained, cemented, metal/polymer + additive, cemented MEH (hip, semi-constrained, uncemented, metal/polymer, non-porous, calcium-phosphate) LZO (Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis) OQI - hip, semi-constrained, cemented, metal/ceramic/polymer + additive, porous uncemented
Advisory Panel:	Orthopedic

2. Address and Registration

Submitter's Name:	Pipeline Biomedical Products, LLC
Address:	3 Wing Drive Suite 102 Cedar Knolls, NJ 07927
Contact Person:	Robert C. Cohen
Telephone Number:	(973) 267-8800
Fax Number:	(973) 267-8810

Date Summary Prepared: November 16, 2012
Establishment Registration Number: Not yet registered

3. Purpose of Submission

The purpose of this submission is to obtain 510k clearance for the PBP Total Hip System, a new device system for Pipeline Biomedical Products, LLC.

4. Identification of Legally Marketed Device to which Submitter Claims Equivalence

The subject PBP Total Hip System by Pipeline Biomedical Products is substantially equivalent to the predicate devices as outlined in the following table.

Table 1: Predicate Devices

Device Name	Company	510(k) Number	Clearance Date
Pipeline Total Hip System	Pipeline Orthopedics	K112802	3/9/2012
Tritanium® Peri-Apatite Acetabular Shell System	Howmedica Osteonics	K101072 K971206	4/11/2011 2/11/1998
Biolox *delta* Ceramic Femoral Head	Zimmer	K071535	11/19/2007

5. Device Description

The PBP Total Hip System is an artificial hip replacement system. The system includes femoral stems, femoral heads, acetabular shells, acetabular liners, acetabular bone screws and dome hole covers (occluders) for the holes in the acetabular shells.

The PBP Femoral Stems are forged titanium alloy and feature a proximal roughened surface (plasma-sprayed CP Titanium), a polished tapered neck, a flat tapered geometry with reduced A/P width (wedge design), and a contoured distal tip and reduced lateral shoulder. The PBP Femoral Stems come in a range of sizes, and are offered in two offset neck options per size.

The PBP Femoral Heads are available in a polished cobalt chromium alloy or a high purity alumina oxide ceramic compound (Biolox® *delta*). The heads come in a range of diameters and extension options. The variety of head and stem sizes and offsets accommodates differences in patient anatomy.

The PBP PST™ (Porous Structured Technology) Acetabular Shells are manufactured from titanium alloy and feature a porous structured surface or an HA porous structured surface. The shells feature a dome hole, are available with or without a cluster screw hole pattern for supplemental bone screw fixation, and come in a range of outer diameter sizes. The porous structured surface provides biologic fixation.

The PBP Acetabular Liners are manufactured from standard UHMWPE, or from highly crosslinked Vitamin E UHMWPE (XLVE™). The liners are mechanically assembled to the mating shells via engagement of the tightly toleranced liner taper and shell bore. The liners are available in a range of sizes and in neutral, high wall, and offset versions.

Optional components include a threaded acetabular dome hole occluder and acetabular bone screws, all manufactured from titanium alloy.

6. Intended Use

The PBP Total Hip System is indicated for use in skeletally mature individuals undergoing surgery for total hip replacement due to:

- A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis, or congenital hip dysplasia;
- Acute traumatic fracture of the femoral head or neck;
- Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty or total hip replacement.

The PBP Total Hip System hip stems and porous structured acetabular shells are intended for cementless or cemented fixation. The porous structured surface provides biological fixation when used in a cementless application.

The PBP Total Hip System HA porous structured acetabular shells are intended for cementless fixation. The HA porous structured surface provides biological fixation.

7. Comparison of Technological Characteristics

The PBP Total Hip System is manufactured from the same materials as the predicate device systems. In addition, the components are packaged, and sterilized using similar processes. The subject Total Hip System is substantially equivalent to the predicates based on comparisons of intended use, design features and technological characteristics.

8. Performance Testing

The following performance tests were provided to demonstrate substantial equivalence:

- Biocompatibility testing for the highly crosslinked Vitamin E Polyethylene:
  - Cytotoxicity, 10993-5
  - Maximization/Sensitization, 10993-10
  - Intracutaneous, 10993-10
  - Acute Systemic Toxicity, 10993-11
  - Sub-acute/Subchronic Systemic Toxicity, 10993-11
  - Genotoxicity, 10993-3
  - Muscle Implantation, 10993-6.
- Wear testing:

  - Testing was conducted on 28 mm, 36mm and 40mm inner diameter highly crosslinked Vitamin E poly liners, that had been EO-sterilized and accelerated aged in accordance with ASTM F2003, and subject to wear testing in accordance with ISO 14242, using a standard walking gait cycle as specified by ISO 14242-1.
  - Bidirectional pin-on-disc abrasive wear testing was also conducted to compare the wear rates of the highly-crosslinked Vitamin E poly material to conventional (standard) gamma sterilized poly under clean and abrasive conditions. The wear reduction for the Vitamin E poly over conventional poly is 35% (7.7 vs 5 mg/Mc) in clean serum and 58% (8.3 vs 3.5 mg/Mc) in an abrasive environment.
- Wear particle characterization was conducted.
- The highly-crosslinked Vitamin E Polyethylene underwent exhaustive extraction testing using both polar and non-polar solvents, with GCMS and LCMS analysis to determine all volatile, semi-volatile, and non-volatile extracts. The results were compared to a predicate material to demonstrate that no new radiation degradation products are released by the material.
- Highly-crosslinked Vitamin E Polyethylene liners underwent oxidation analysis per ASTM F2102-06 after accelerated aging per ASTM F2003, wear testing, and exhaustive extraction. The analysis was also conducted on gamma-sterilized GUR 1020 (standard poly) reference material for comparison. The highly crosslinked Vitamin E poly exhibited lower oxidation indices than the standard poly, demonstrating higher resistance to oxidation: mean surface oxidation index was 0.017 for Vitamin E and 0.097 for standard poly; maximum oxidation index was 0.029 for Vitamin E and 0.248 for standard poly; and bulk oxidation index was 0.009 for Vitamin E and 0.036 for standard poly.
- Highly-crosslinked Vitamin E Polyethylene liners were evaluated by polarized light microscopy and SEM analysis of freeze fractured surfaces, after accelerated aging per ASTM F2003 and wear testing, to demonstrate that the subject material has equivalent consolidation to a predicate material.
- Liner Assembly/Disassembly Testing: Testing of the worst case size Pipeline Hip System highly crosslinked Vitamin E poly acetabular liner and worst case size conventional poly liner were tested for push-out, lever out torque, and axial torque.
- Hip Stem Fatigue Testing was conducted for the worst case (smallest) hip stem according to the method described in ISO 7206-4:2010, Implants for surgery-Partial and total hip joint prostheses, Determination of Endurance Properties and Performance of Stemmed Femoral Components.
- Stem Neck Fatigue Testing of the worst-case size was conducted according to the methods described in ISO 7206-6:1992 Implants for surgery-Partial and total hip joint prostheses-Part 6 and ASTM F2068-03 Standard Specification for Femoral Prostheses – Metallic Implants.
- Pull off testing was conducted on the metal and ceramic femoral heads.
- Burst Strength testing was conducted on Biolox *delta* Femoral Heads according to ISO 7206-10.
- An analysis was conducted of the typical and worst case ranges of motion permitted by the designs of various liner size/style, head size/style, and stem size/style combinations.

The ROM was reported for flexion/extension, abduction/adduction, and internal/external rotation per ISO 21535.

- Bone screw testing was conducted in accordance with ASTM F543-07, Standard Specification and Test Methods for Metallic Medical Bone Screws, for torsion (torque to failure) and screw pull-out (pull-out to failure).
- Characterization in accordance with relevant aspects of "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement," was completed for: 1) Acetabular Shell – PST Surface; 2) Acetabular Shell – HA PST Surface; 3) Hip Stem – Plasma-Spray Titanium Coating.
- Characterization in accordance with relevant aspects of "Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball HIP Systems" was completed for the ceramic femoral heads.
- The porous structured surface was evaluated in a transcortical canine model to assess the biological response, using histological and mechanical evaluations, at intervals up to 12 weeks.

9. Conclusions

The subject PBP Total Hip System shares the same indications for use as the predicate hip system, and a comparison of technological characteristics supported by performance testing demonstrates the Substantial Equivalence of the PBP Total Hip System to the predicate hip systems.

10. Claims

Claim 1:

The highly-crosslinked Vitamin E Polyethylene material had an average wear rate 58% less than conventional gamma sterilized polyethylene in an abrasive environment, and 35% less than conventional gamma sterilized polyethylene in clean serum in bidirectional pin-on-disc wear testing .

Wear testing was performed on cylindrical test pins machined from vitamin E blended UHMWPE stock that was gamma irradiated and terminally EO sterilized (the highly crosslinked Vitamin E polyethylene) and from UHMWPE stock that was terminally gamma sterilized (conventional polyethylene). The bidirectional pin-on-disc wear tester approximates the crossing motion of the total hip.

The wear rates were measured for all test specimens articulating against polished cobalt-chrome lubricated by bovine serum. For the abrasive phase of the study, third body particles (PMMA bone cement) were added to the bovine serum lubricant to create an adverse testing environment. Each test was conducted at 2 Hz; and included a bedding in period of at least 0.5×10^6 cycles. The test stopped at approximately every 0.157×10^6 cycles daily for gravimetric assessment of wear until a total of 1.128×10^6 cycles. The calculated average gravimetric linear

wear rates under abrasive conditions were 3.5 ± 0.2 mg/MC for the Highly Crosslinked Vitamin E Poly and 8.3 ± 1.3 mg/MC for the conventional polyethylene (58% less for the Highly Crosslinked Vitamin E Poly). The calculated average gravimetric linear wear rates under clean conditions were 5.0 ± 0.5 mg/MC for the Highly Crosslinked Vitamin E Poly and 7.7 ± 1.5 mg/MC for the conventional polyethylene (35% less for the Highly Crosslinked Vitamin E Poly).

Bench testing is not necessarily indicative of clinical performance.

Claim 2:
The highly-crosslinked Vitamin E Polyethylene is more resistant to oxidation than conventional polyethylene per method ASTM F2102.

The highly-crosslinked Vitamin E Polyethylene is GUR 1020 blended with Vitamin E (GUR 1020-E) compression molded and then highly crosslinked by gamma irradiation at a dose of 100 ± 10 kGy, which is machined to its final form and terminally sterilized via Ethylene Oxide. The highly-crosslinked Vitamin E Polyethylene liners underwent oxidation analysis per ASTM F2102-06. The same analysis was also conducted on gamma-sterilized GUR 1020 (conventional polyethylene) reference material for comparison. As measured using ASTM F2102, the highly crosslinked Vitamin E poly had lower oxidation indices than the conventional polyethylene: mean surface oxidation index was 0.017 for Vitamin E and 0.097 for conventional poly; maximum oxidation index was 0.029 for Vitamin E and 0.248 for conventional poly; and bulk oxidation index was 0.009 for Vitamin E and 0.036 for conventional poly.

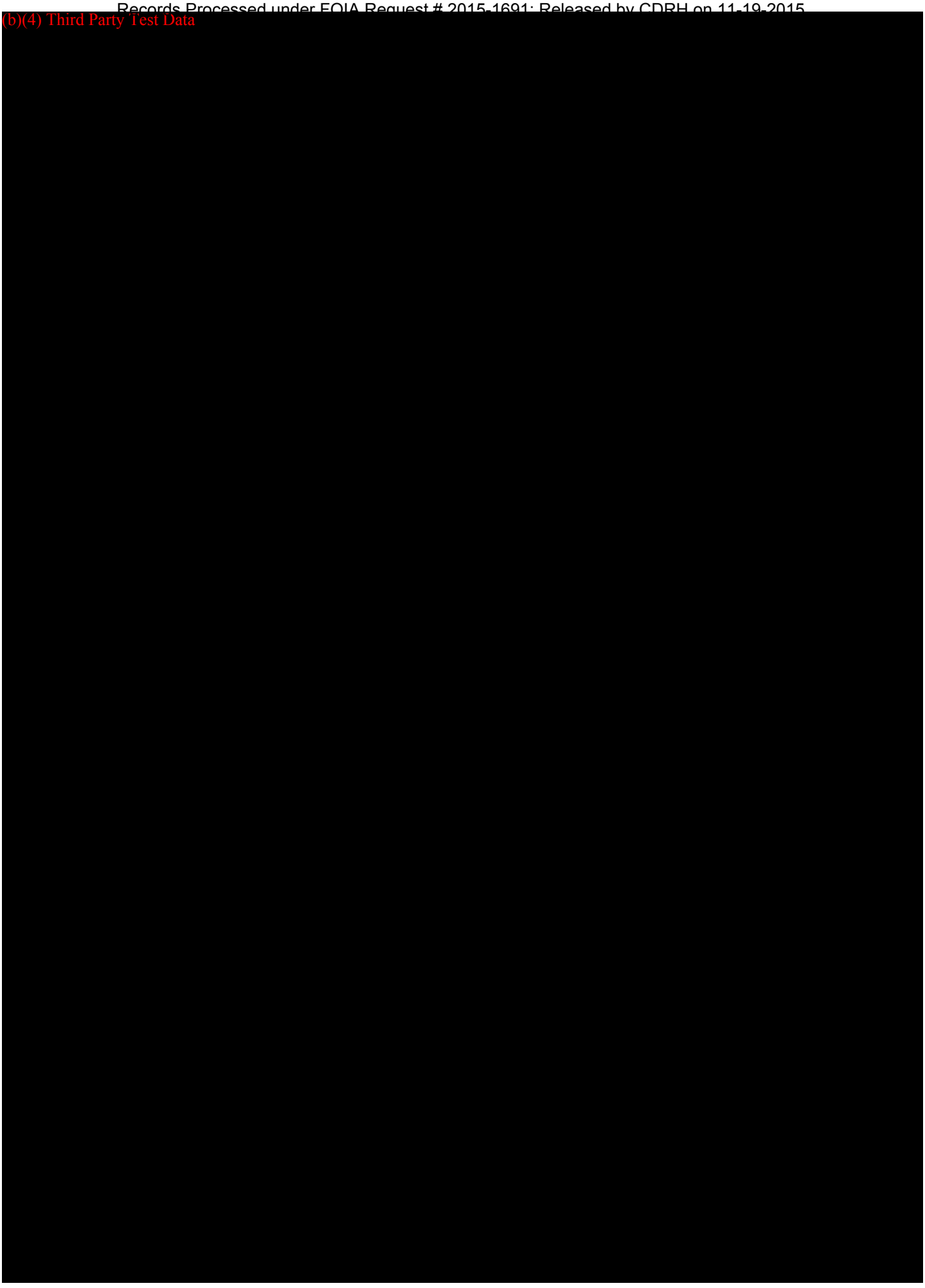
Bench testing is not necessarily indicative of clinical performance.

Exhibit 3: K103223 DJO Surgical - Highly Crosslinked Vitamin E UHMWPE Tibial Inserts

Exhibit 4: K094035 StelKast – EXp Acetabular Liners

Exhibit 5: Engineering Drawings for the Pipeline Acetabular Shells with HA-PST surface, showing location of HA coating

(b)(4) Third Party Test Data



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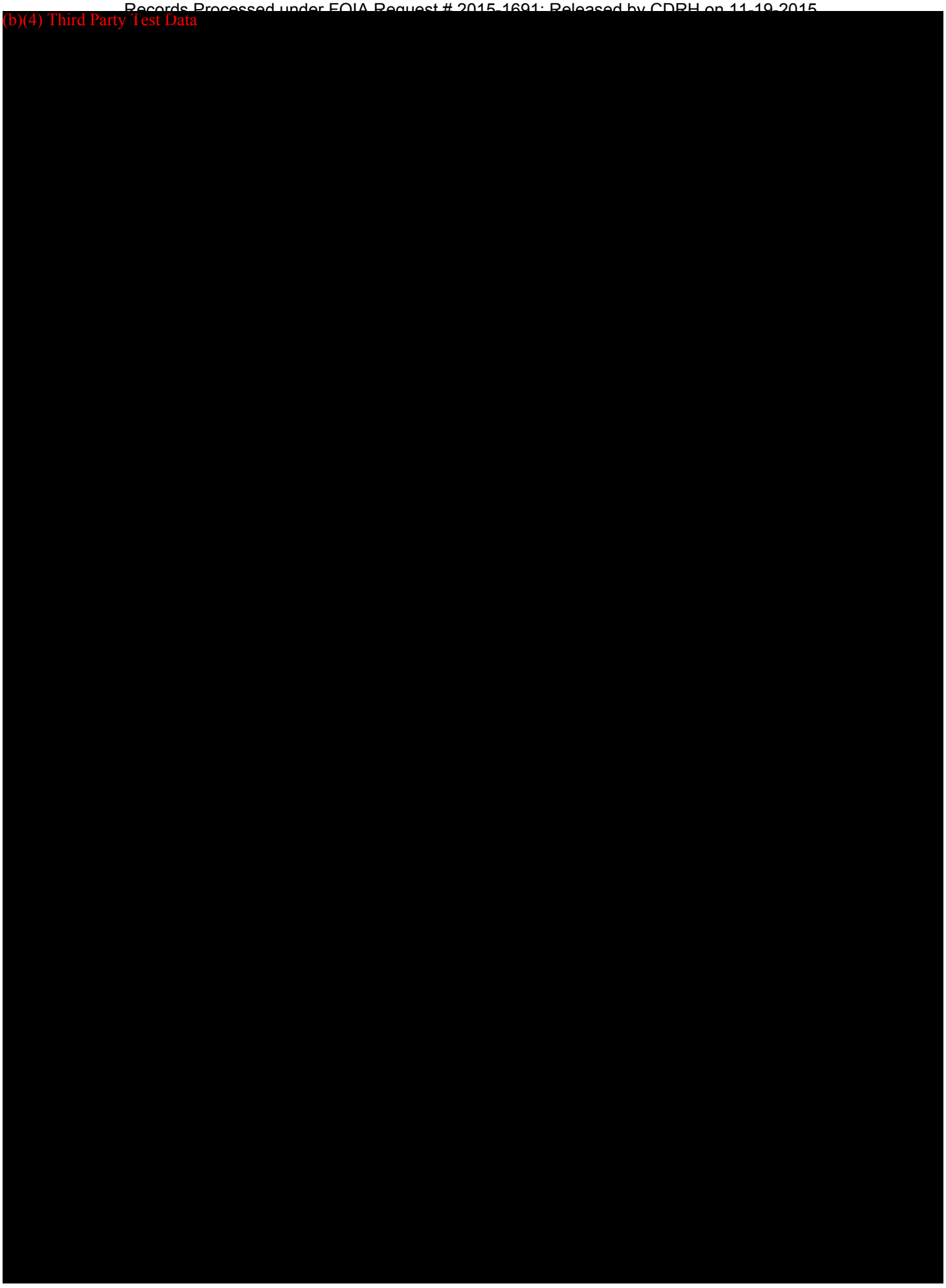

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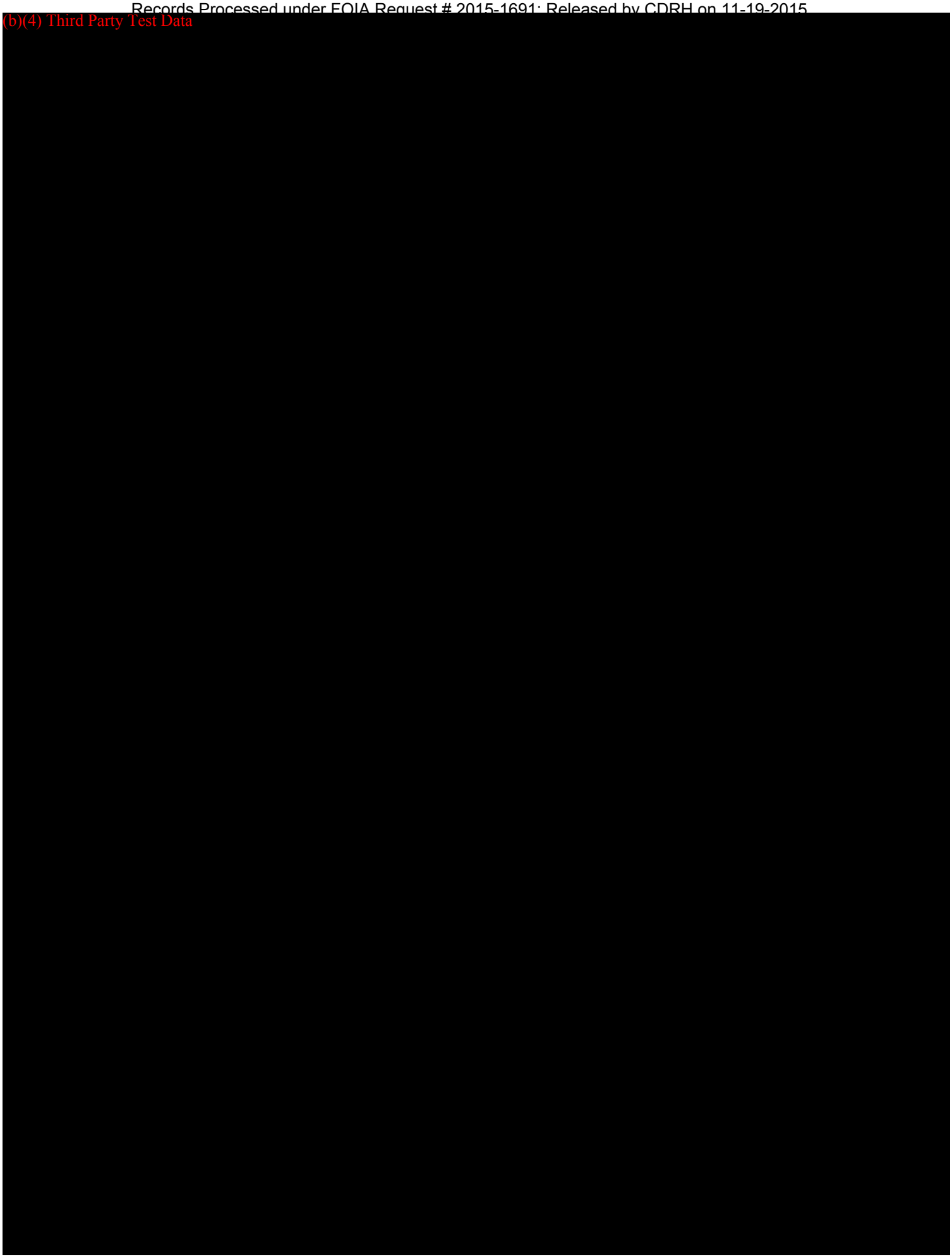

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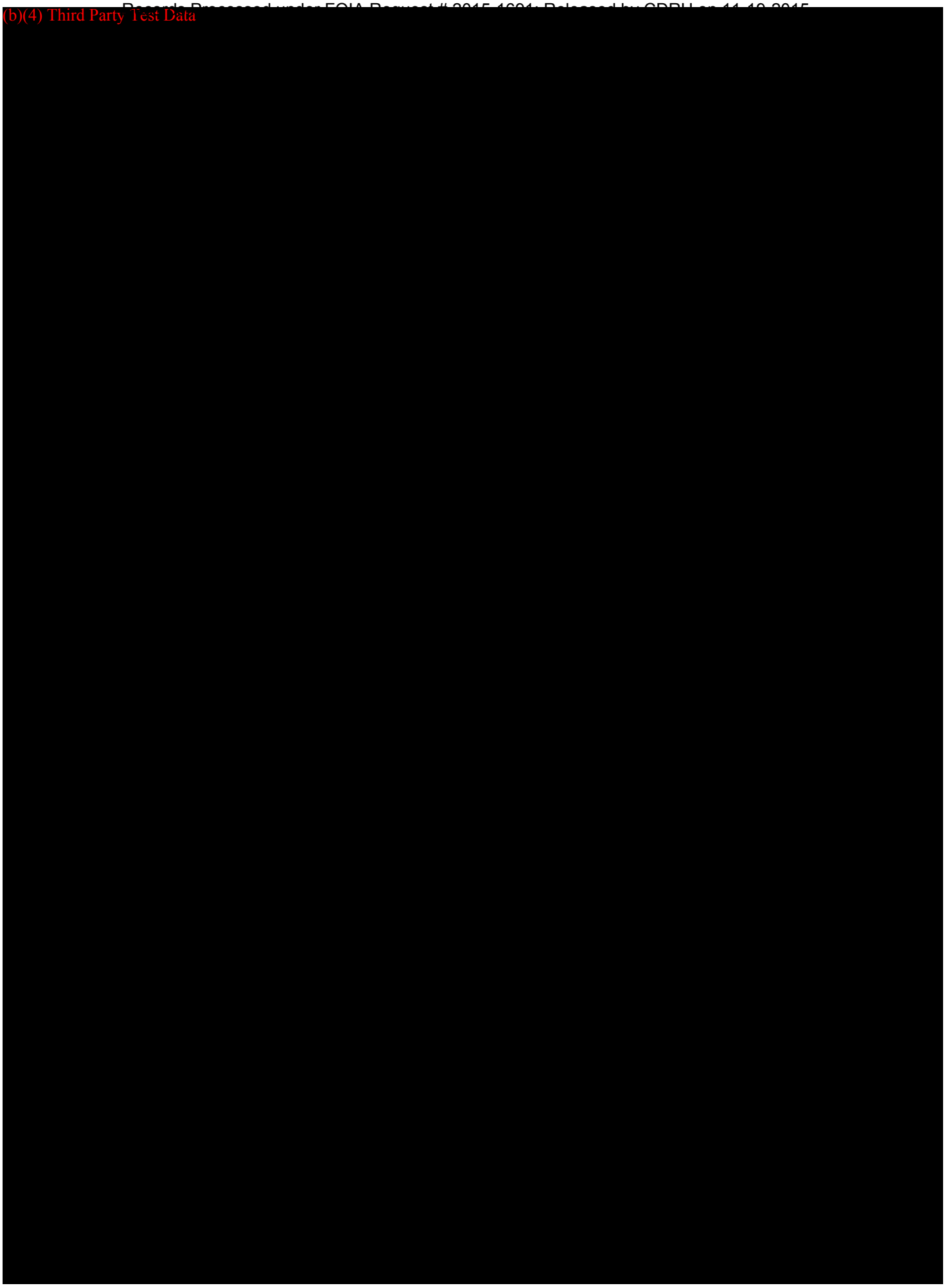
(b)(4) Third Party Test Data



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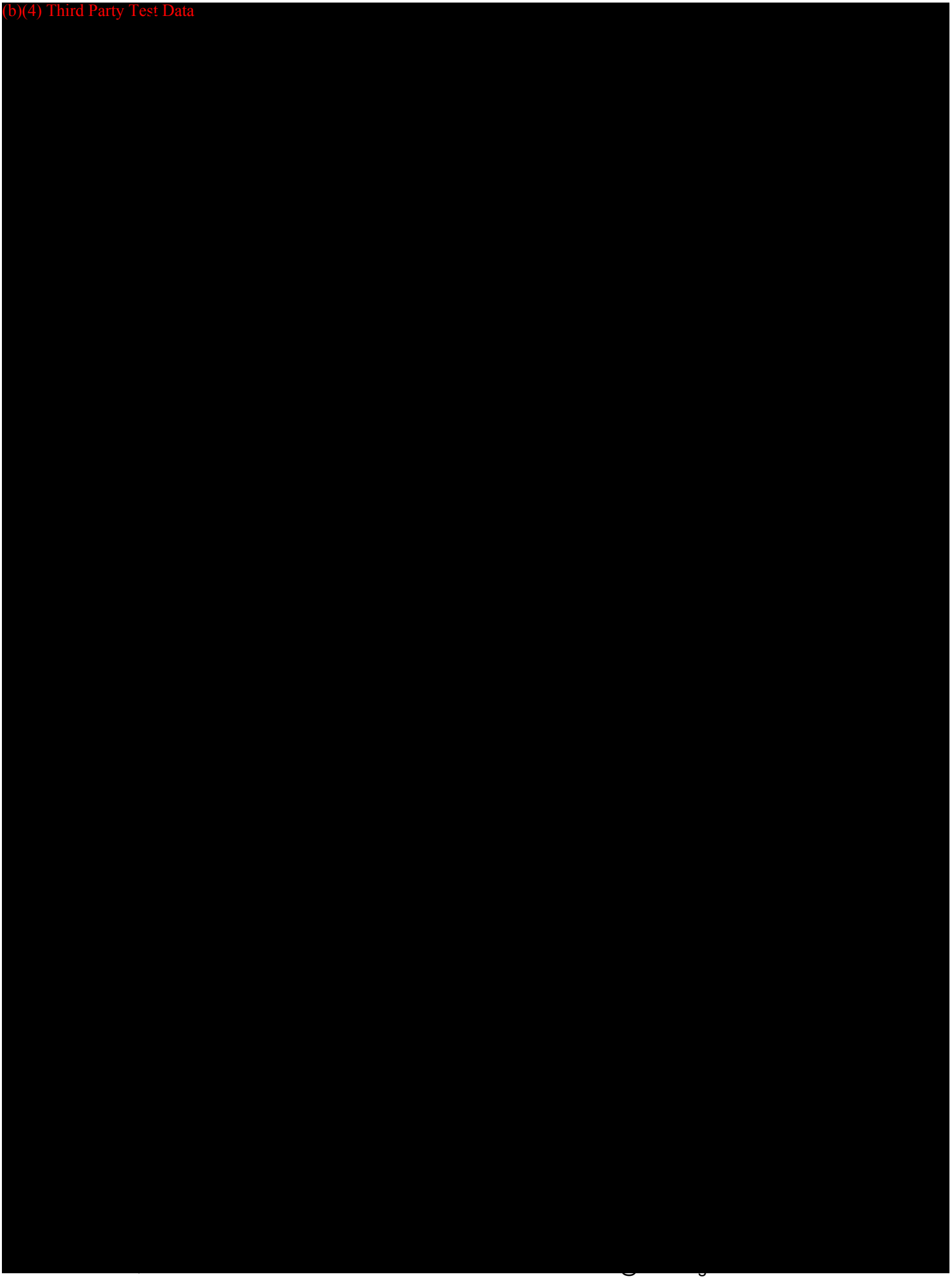
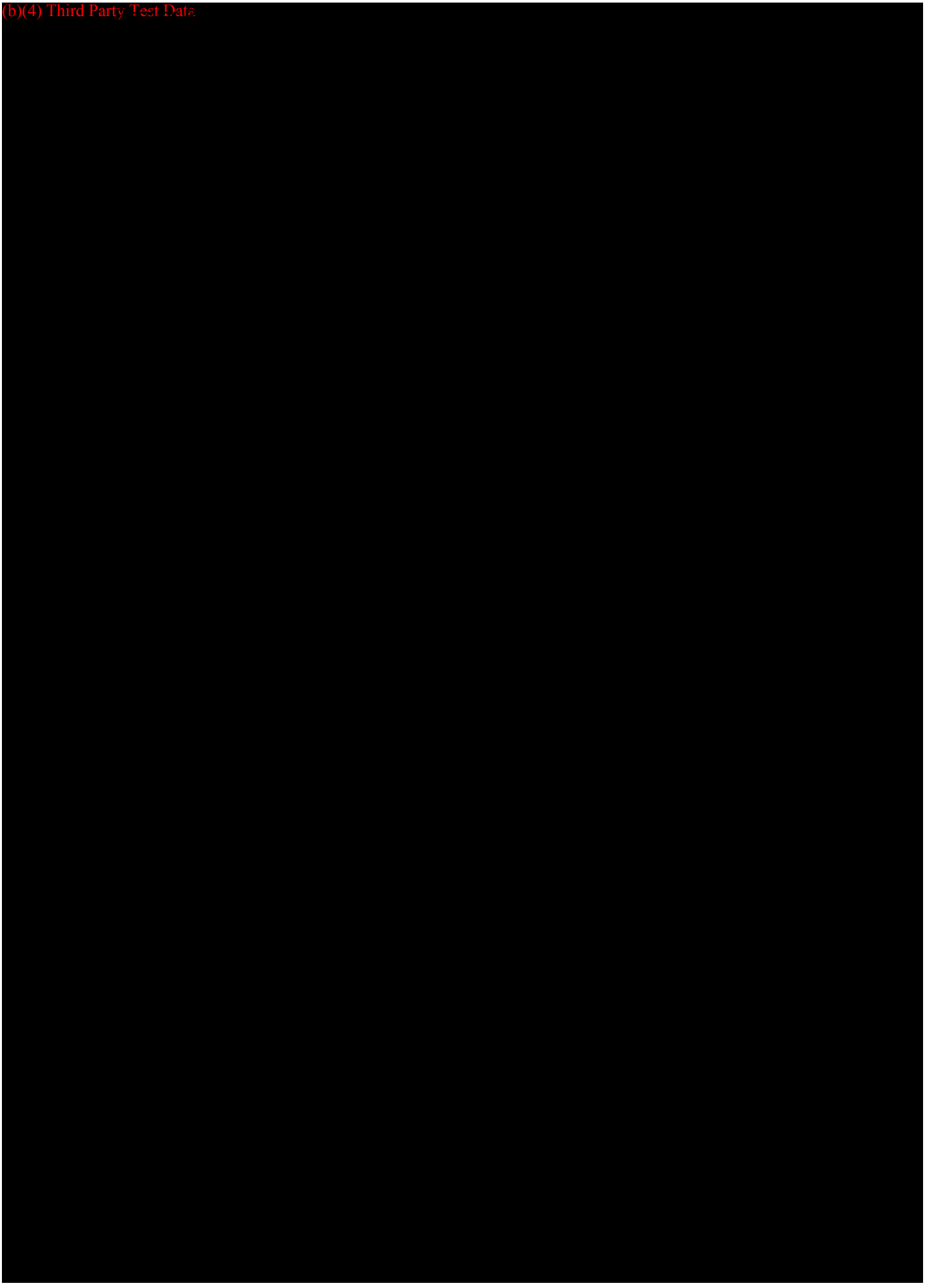


(b)(4) Third Party Test Data

[redacted]

(b)(4) Third Party Test Data



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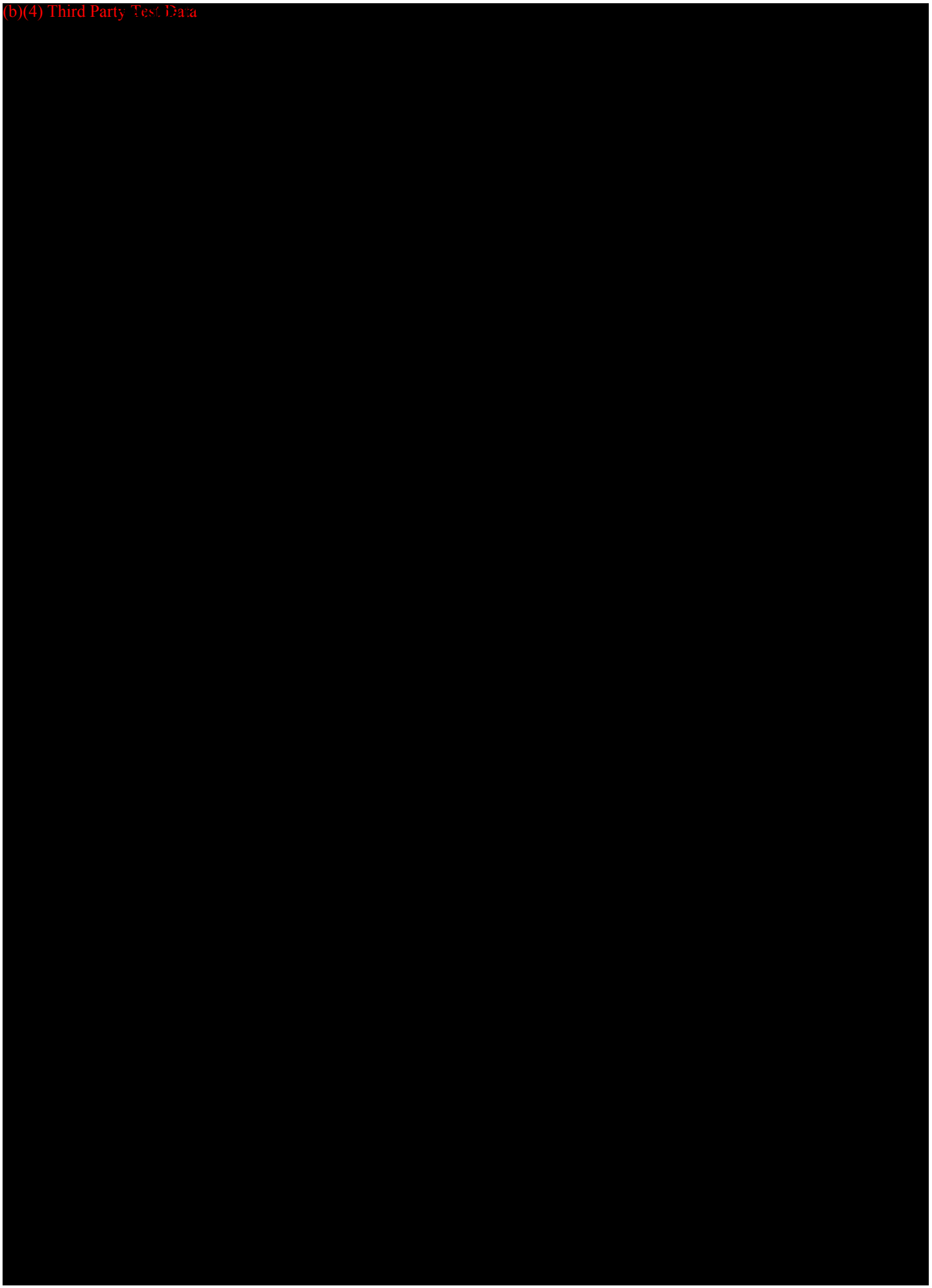
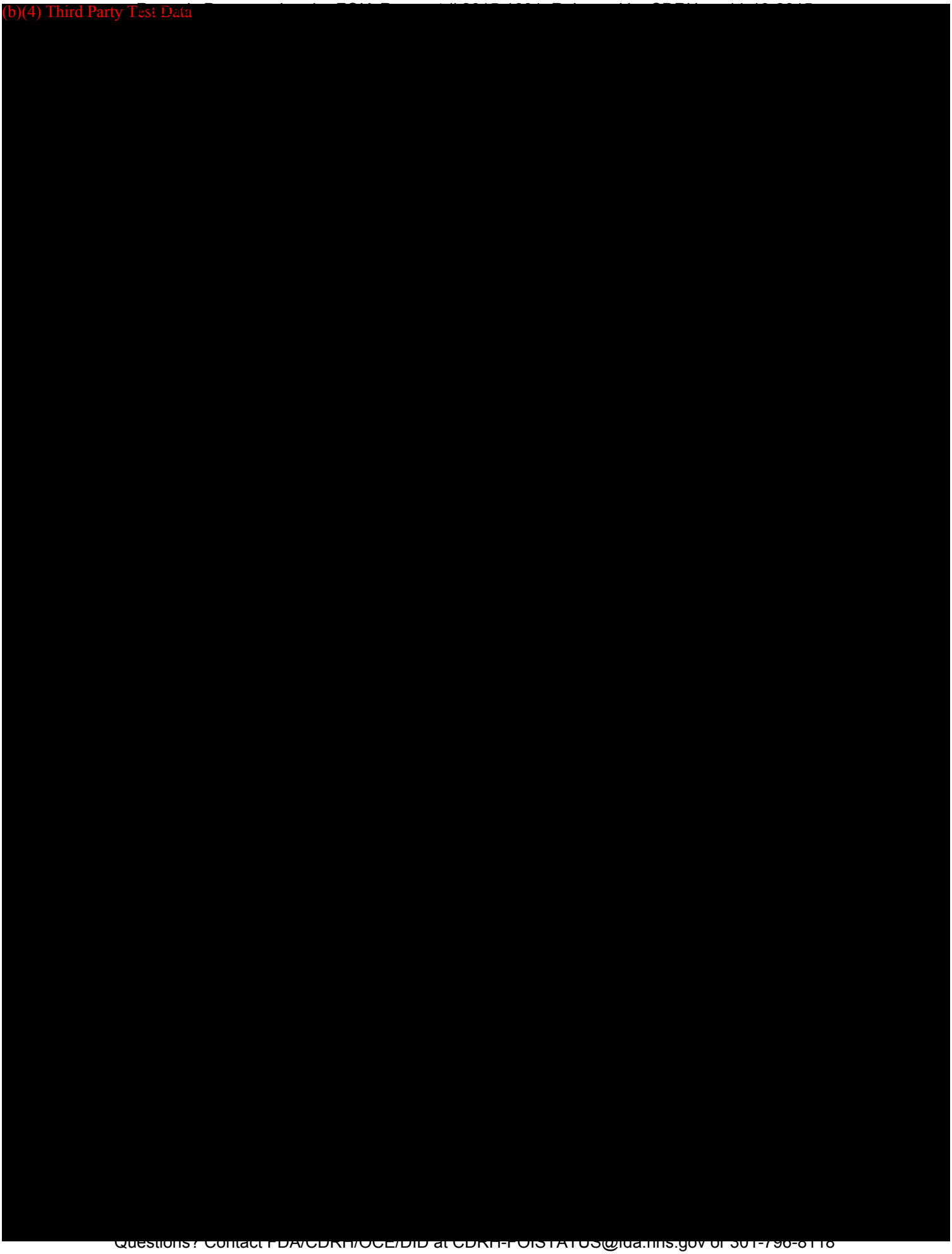


(b)(4) Third Party Test Data



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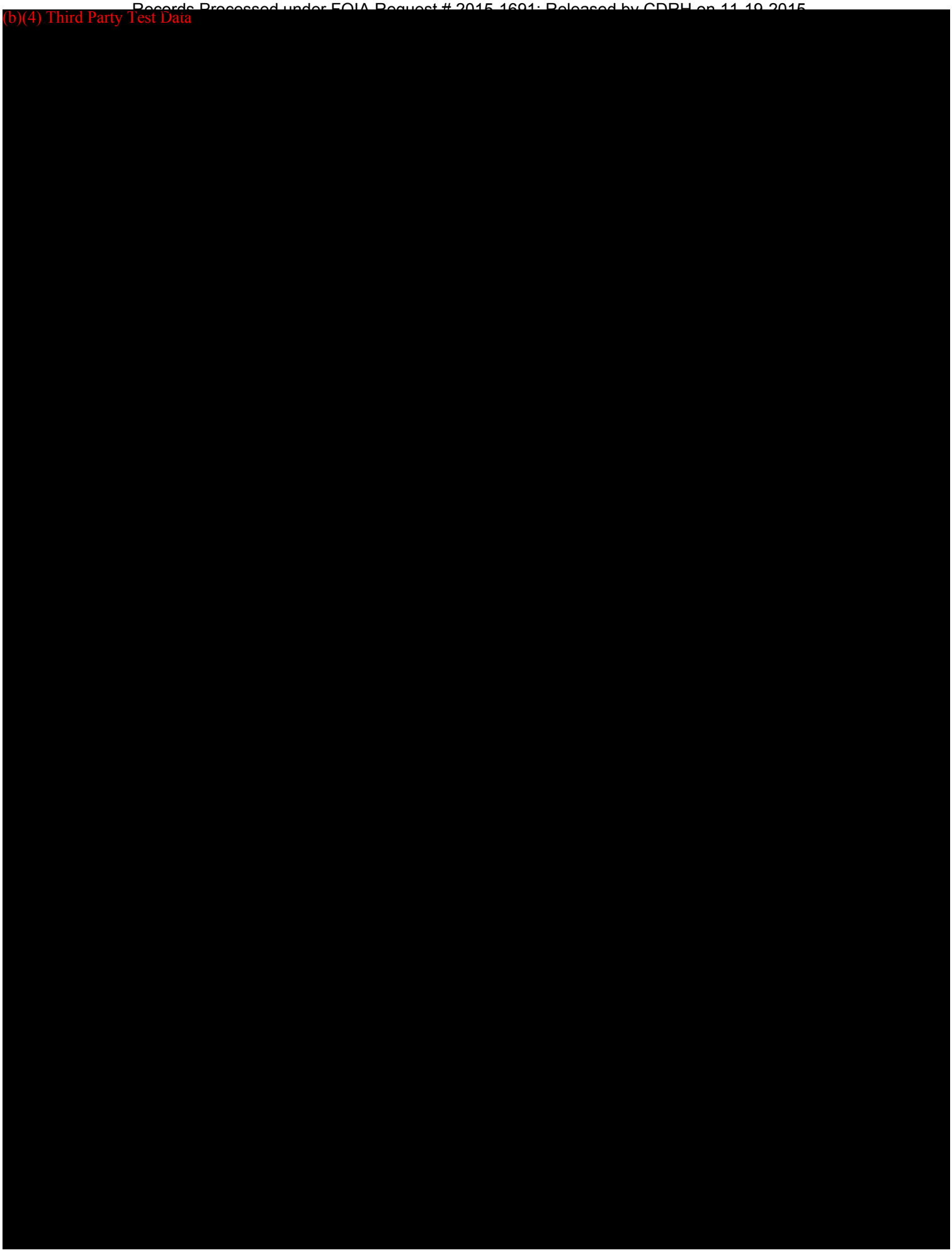

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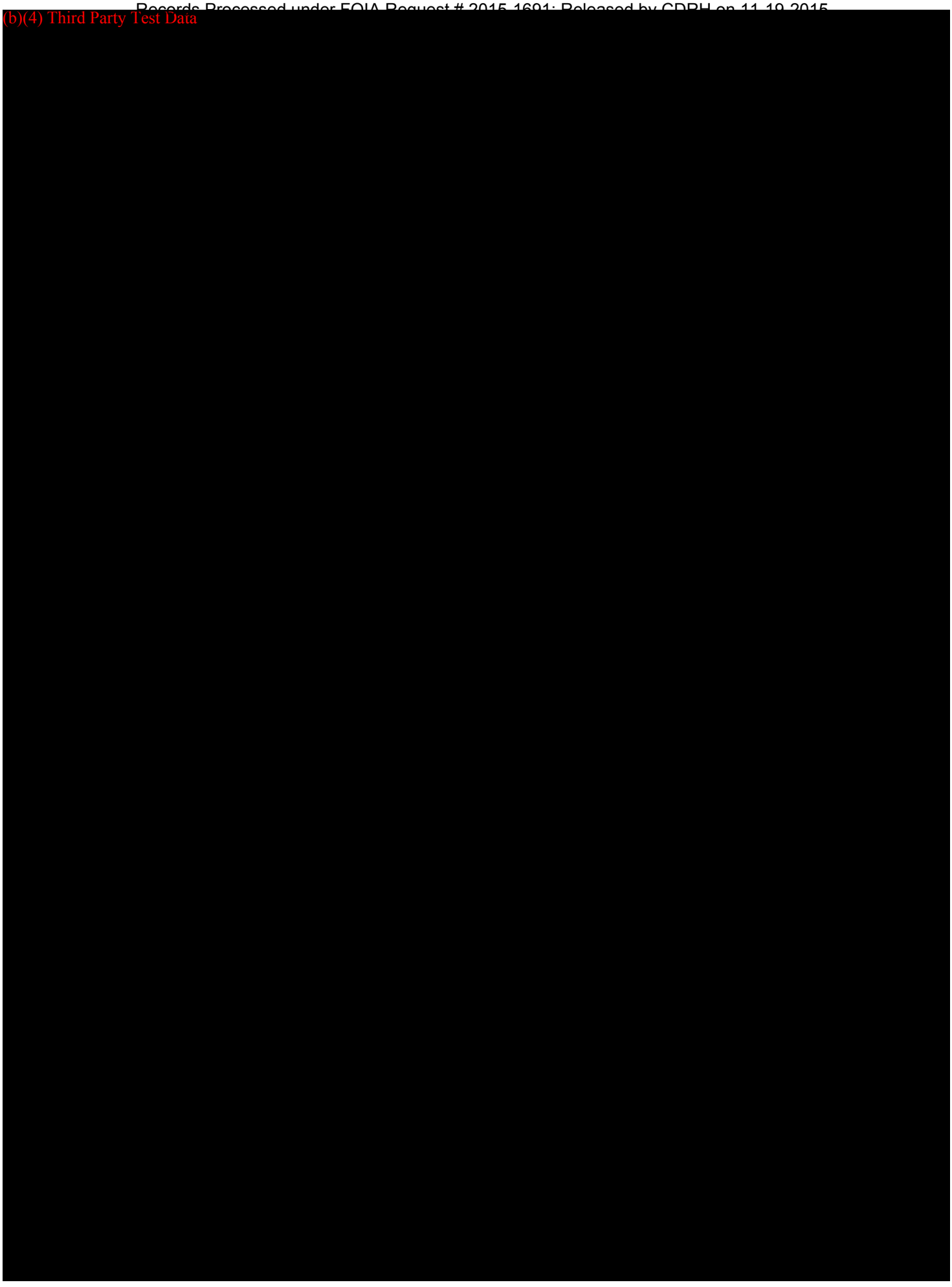

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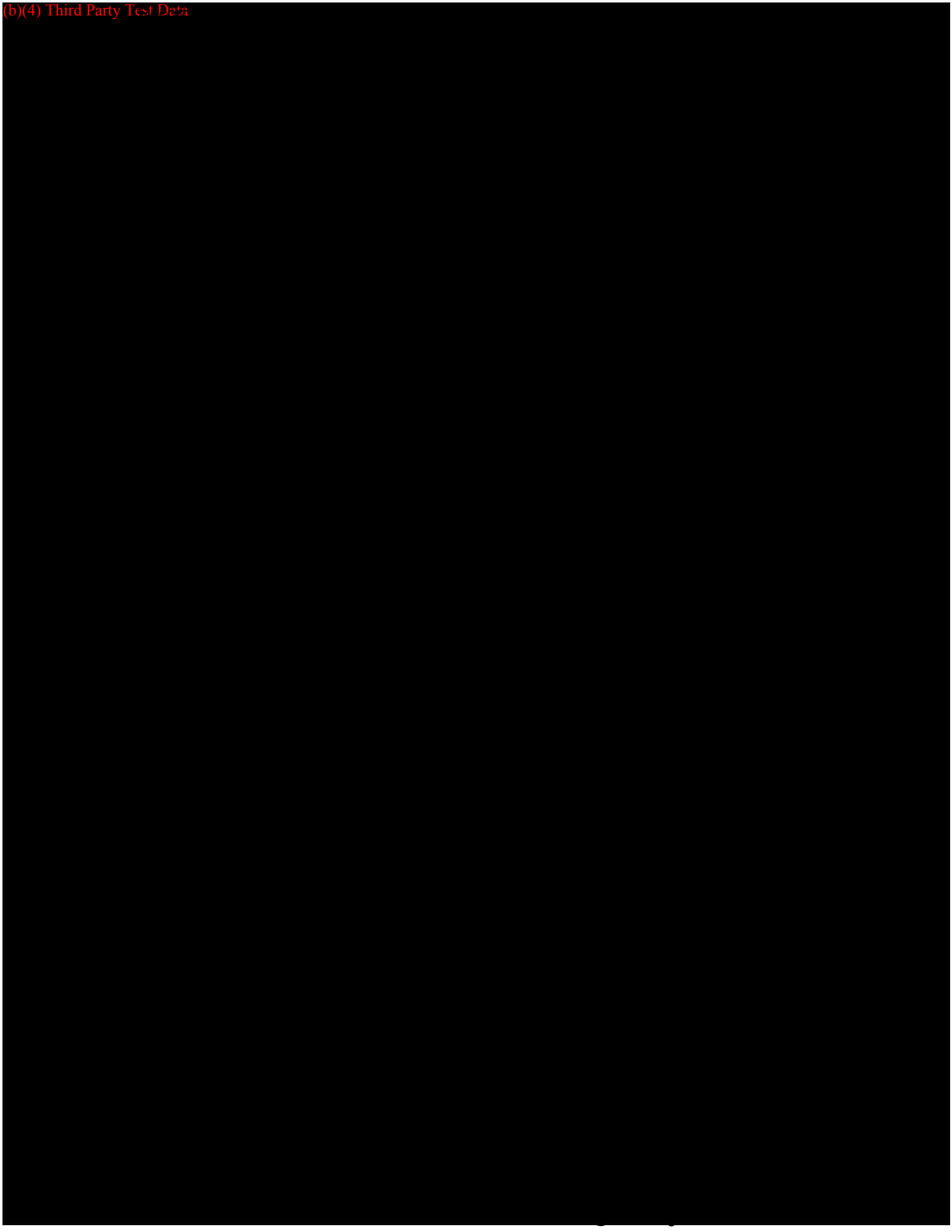

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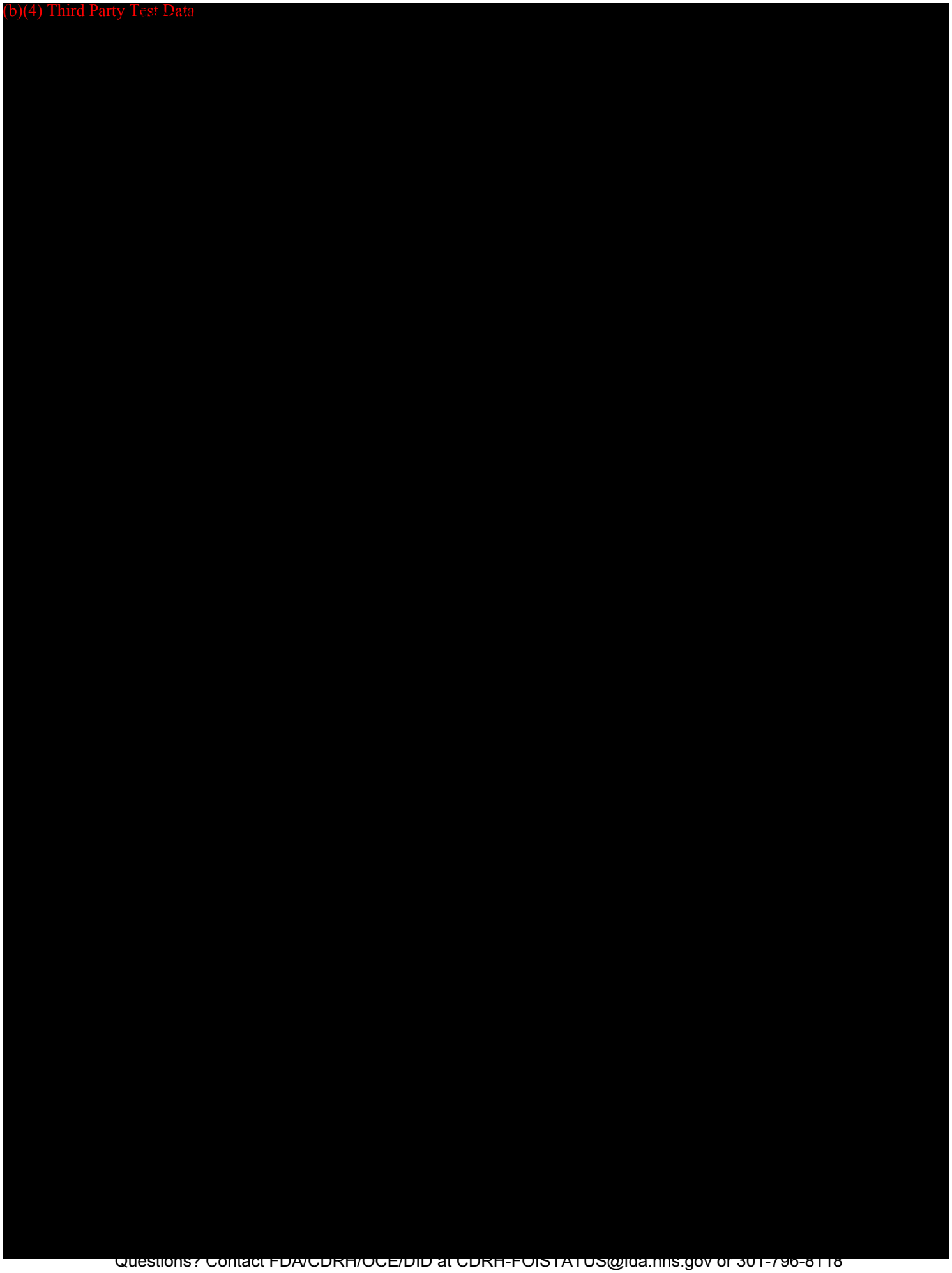
(b)(4) Third Party Test Data



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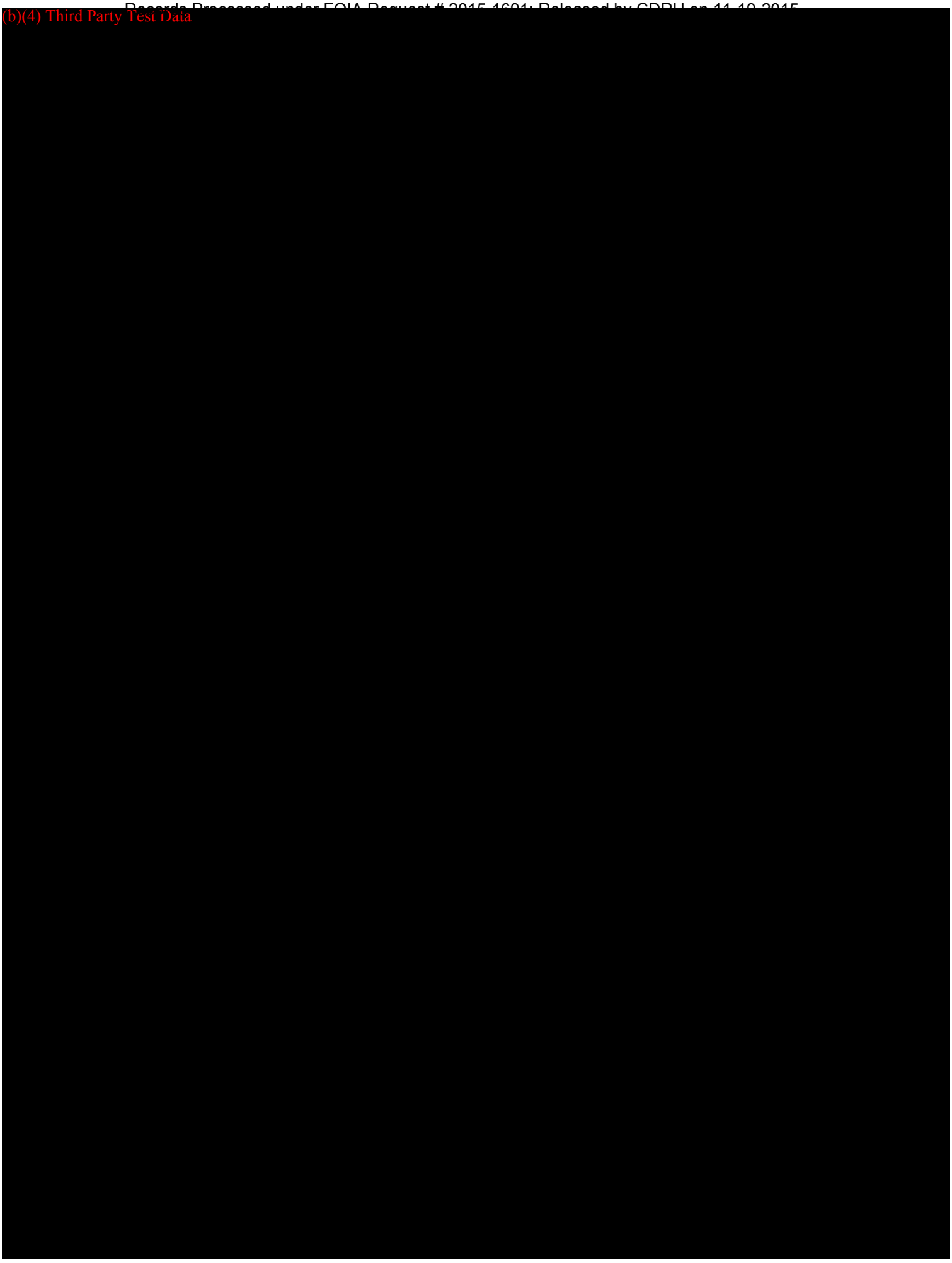

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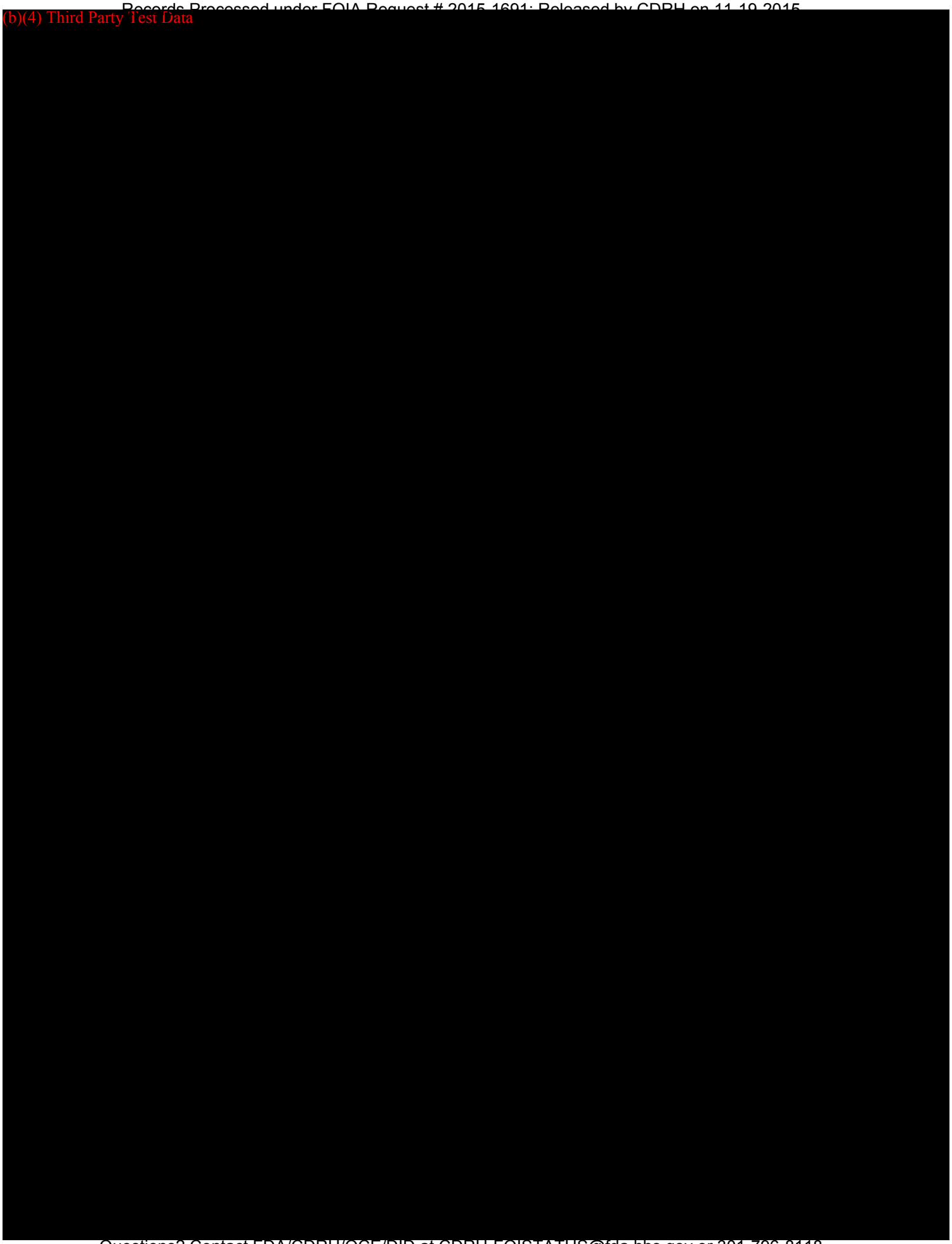

Summary of Safety and Effectiveness

DEC 2 1 2010

Preparation Date: December 17, 2010

Applicant/Sponsor: Encore Medical (d.b.a. DJO Surgical)
9800 Metric Blvd
Austin, TX 78758

Contact Person: William Garzon
Regulatory Affairs Technician

Device Name: Highly Cross-Linked Vitamin E UHMWPE Tibial Insert

Classification Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis (888.3560), OIY, JWH, MBH

Legally Marketed Devices to Which Substantial Equivalence is Claimed:
Encore Medical L.P. - Highly Cross-Linked Vitamin E UHMWPE Tibial Insert, K091956

Device Description:
Subject of this Traditional 510(k) Premarket Notification is a request for labeling claims for the DJO Surgical 3DKnee HXL VE Tibial Insert. The *in vitro* wear claim will be made for the use of the 3DKnee femoral component coupled with a 3DKnee HXL VE Insert. It is important to note that there are no new total knee components being introduced as a result of this Traditional 510(k) premarket notification.

Indications for Use:
Total joint replacement is indicated for patients suffering from disability due to:

- degenerative, post-traumatic or rheumatoid arthritis;
- avascular necrosis of the femoral condyle;
- post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy;
- moderate valgus, varus or flexion deformities;
- Treatment of fractures that are unmanageable using other techniques

This device may also be indicated in the salvage of previously failed surgical attempts. This device is intended to be used with the 3DKnee System for cemented or uncemented applications.

Intended Use:
DJO Surgical knee devices are intended for treatment of patients who are candidates for knee arthroplasty per the indications for use. While total knee replacements are not intended to withstand activity levels and loads of normal healthy bone, they are a means of restoring mobility and reducing pain for many patients.

Comparable Features to Predicate Device(s):

- similar product claims
- have the same indicated use,
- incorporate the same design,
- incorporate the same materials,
- have the same shelf life, and
- packaged and sterilized using the same materials and processes

Claims:

The following is a summary of the claims submitted for clearance:

Claim 1:
DJO Surgical HXL VEK showed no measurable oxidation during accelerated age testing per ASTM-2003

FTIR analysis was performed on samples of HXL VEK tibial inserts at three different time points: non- aged, two weeks aged, and four weeks aged. Accelerated aging was performed per ASTM F2003 (oxygen environment at 5 atmospheres at 70°C for 14 and 28 days). The oxidation index was calculated using the method described in ASTM F2102. All three time points showed no detectable oxidation (oxidation indices < 0.1). Oxidation indices were 0.04±0.02, 0.04±0.00, and 0.03±0.02 respectively. As a comparison, oxidation index for Compression Molded UHMWPE (CM) at two weeks aged is 0.73±0.12.

Izod Impact testing was performed on HXL VEK test specimens per ASTM D256 in both pre and post aged material. Impact testing can indicate the relative brittleness of a material; a consequence of oxidation. Accelerated aging was performed per ASTM F2003 (oxygen environment at 5 atmospheres at 70°C for 14 days). CM was used as a control group for comparative purposes. The average impact resistance for CM before and after accelerated aging was 93.5±7.2 KJ/m^2 and 25.1±7.0 KJ/m^2 respectively while the average impact resistance for HXL VEK before and after accelerated aging was 96.2±12.3 KJ/m^2 and 102.3±13.3 KJ/m^2 respectively.

HXL VEK showed no reduction in impact resistance after accelerated aging whereas CM showed marked degradation in impact resistance after accelerated aging.

CM bar stock is machined into a final part and then inspected, cleaned, packaged with nitrogen flush, and sterilized via gamma irradiation.

HXL VEK is UHMWPE powder that is blended with pure liquid pharmaceutical grade alpha-tocopheral (Vitamin E), compression molded, and machined into bar stock. HXL VEK bar stock is then gamma irradiated to cross link the material. The HXL VEK bar stock is then machined into a final part and then inspected, cleaned, pre-packaged, sterilized via gas plasma, and final packaged.

Bench testing is not necessarily indicative of clinical performance.

Claim 2:
DJO Surgical HXL VEK maintains the mechanical strength of conventional compression molded UHMWPE (CM) during mechanical testing.

Tensile testing was performed per ASTM D638 on CM, Highly Cross-Linked (HXL), and HXL VEK material. All test specimens were accelerated aged per ASTM F2003 (oxygen environment at 5 atmospheres at 70°C for 14 days). Average yield strength for each material was 24.98±0.76 MPa, 21.96±0.63 MPa, and 25.09±0.72 MPa respectively. There was approximately a 12% drop off in yield strength for HXL as compared to CM. However, there was no drop off in yield strength for HXL VEK as compared to CM. Maintaining yield strength is a critical parameter for knee tibial insert performance.

 K103223
p 3/5

Tibial insert posterior peel-out testing was performed to determine the mechanical integrity of the tibial inserts relative to the metal baseplate. A snap feature is utilized to secure the poly inserts to the metal baseplates. Tibial insert test parts that employ identical snap features were manufactured at nominal conditions for both CM and HXL VEK material. Testing was performed to simulate a worst case peel-out phenomenon in which the thickest tibial insert is forced out of the baseplate by applying a load to the insert in the anterior direction. An acceptance criterion was that the HXL VEK inserts should exhibit at least the same amount of resistance to posterior peel-out force as CM inserts. The average resistance load to posterior peel-out for CM and HXL VEK were 169.67±18.18 lbs and 182.43±2.23 lbs respectively.

CM bar stock is machined into a final part and then inspected, cleaned, packaged with nitrogen flush, and sterilized via gamma irradiation.

HXL bar stock is CM bar stock that is gamma irradiated to cross link the material. The HXL bar stock is then machined into a final part and then inspected, cleaned, pre-packaged, sterilized via gas plasma, and final packaged.

HXL VEK is UHMWPE powder that is blended with pure liquid pharmaceutical grade alpha-tocopheral (Vitamin E), compression molded, and machined into bar stock. HXL VEK bar stock is then gamma irradiated to cross link the material. The HXL VEK bar stock is then machined into a final part and then inspected, cleaned, pre-packaged, sterilized via gas plasma, and final packaged.

Bench testing is not necessarily indicative of clinical performance.

Claim 3:
DJO Surgical HXL VEK maintains mechanical strength after accelerated aging.

Tensile, small punch, and Izod Impact testing were performed on HXL VEK before and after accelerated aging. There was no significant decrease in yield strength, ultimate load, or impact resistance after accelerated aging. Accelerated aging was performed per ASTM F2003 (oxygen environment at 5 atmospheres at 70°C for 14 days). Tensile testing was performed per ASTM D638. The average yield strength for HXL VEK before and after accelerated aging was 26.76±0.96 MPa and 25.09±0.72 MPa respectively. Small punch testing was performed per ASTM F2183. The average ultimate load for HXL VEK before and after accelerated aging was 80.80±4.56 N and 81.31±4.22 N respectively. Izod impact testing was performed per ASTM D256. The average impact resistance for HXL VEK before and after accelerated aging was 96.2±12.3 KJ/m^2 and 102.3±13.3 KJ/m^2 respectively.

HXL VEK is UHMWPE powder that is blended with pure liquid pharmaceutical grade alpha-tocopheral (Vitamin E), compression molded, and machined into bar stock. HXL VEK bar stock is then gamma irradiated to cross link the material. The HXL VEK bar stock is then machined into a final part and then inspected, cleaned, pre-packaged, sterilized via gas plasma, and final packaged.

Bench testing is not necessarily indicative of clinical performance.

Claim 4:
DJO Surgical HXL VEK tibial bearings had an average wear rate that was 57% less than that of a conventional direct compression molded UHMWPE (DCM) bearing of the same geometry in knee simulator wear testing.

Wear testing was performed on the 3D™ Knee system comparing DCM tibial inserts and machined HXL VEK tibial inserts. Each test was performed on a multi-axis, force driven knee simulator (Instron/Stanmore 4-Station Knee Simulator) per ISO 14243-1 for 5 million cycles in a 25% concentration of defined bovine calf serum. Both inserts were articulated against a 3D™ Knee CoCr femoral component of matching size. The HXL VEK inserts were aged for two weeks per ASTM F2003 (oxygen environment at 5 atmospheres at 70°C for 14 days) while the DCM inserts were not aged. Both sets of inserts employed soak controls (loaded and unloaded) to correct for fluid absorption of the polyethylene during wear testing. The test specimens were Size 6 Left Femoral Components, Size 6 Left 11mm Inserts, and Size 6 Left Tibial Baseplates. The average wear rate for the DCM and HXL VEK tibial inserts were 4.4±3.0

mg/million cycles and 1.9±1.9 mg/million cycles respectively which was statistically significant ($\rho<0.01$). Even though the HXL VEK inserts were machined and aged (vs. not aged for the DCM inserts), the HXL VEK inserts still showed superior wear properties over the DCM inserts.

Note, reduction in total polyethylene wear volume or wear rate alone may not result in an improved clinical outcome as wear particle size and morphology are also critical factors in the evaluation of the potential for wear mediated osteolysis and associated aseptic implant loosening. Particle size and morphology were not evaluated as part of this wear claim.

DCM parts are inspected, cleaned, packaged with nitrogen flush, and sterilized via gamma irradiation.

HXL VEK is UHMWPE powder that is blended with pure liquid pharmaceutical grade alpha-tocopheral (Vitamin E), compression molded, and machined into bar stock. HXL VEK bar stock is then gamma irradiated to cross link the material. The HXL VEK bar stock is then machined into a final part and then inspected, cleaned, pre-packaged, sterilized via gas plasma, and final packaged.

Bench testing is not necessarily indicative of clinical performance.

Claim 5:
DJO Surgical HXL VEK material was classified as a non-irritant as compared to the control under the conditions of the muscle implantation study.

Intramuscular implant testing was performed per ISO 10993 on three healthy adult New Zealand White rabbits. Compression molded UHMWPE (CM) material was used as the control article to compare to HXL VEK. Five HXL VEK sites and five CM sites were implanted for each rabbit. The surgical sites were closed, and the animals were observed daily for 13 weeks. After 13 weeks, the rabbits were euthanized and the HXL VEK and CM specimens were explanted at necropsy. All tissues were fixed in 10% neutral buffered formalin. Hematoxylin and eosin (H&E) stained sections of the test and control implant sites were prepared from all animals. A veterinary pathologist microscopically evaluated the H&E stained tissue sections of each implant site. There were no gross abnormalities. The average irritant scores for CM and HXL VEK were 5.7 and 5.1 respectively. The Irritant Ranking Score is defined as: Test Group Average – Control Group Average. In this case, 5.1 – 5.7 = -0.6. According to the interpretation of the Irritant Ranking Score, a non-irritant is classified as having a range of 0.0 – 2.9. Therefore, with an Irritant Ranking Score of -0.6, HXL VEK is classified as a non-irritant. Note, inflammatory response to device wear particles has not been evaluated.

CM bar stock is machined into a final part and then inspected, cleaned, packaged with nitrogen flush, and sterilized via gamma irradiation.

HXL VEK is UHMWPE powder that is blended with pure liquid pharmaceutical grade alpha-tocopheral (Vitamin E), compression molded, and machined into bar stock. HXL VEK bar stock is then gamma irradiated to cross link the material. The HXL VEK bar stock is then machined into a final part and then inspected, cleaned, pre-packaged, sterilized via gas plasma, and final packaged.

Per the ISO 10993-1 standard, all permanently implanted medical devices should be evaluated for irritation potential as part of the biocompatibility assessment.

Animal testing is not necessarily indicative of clinical performance.

Non-Clinical Testing:

The following non-clinical laboratory testing was performed to determine substantial equivalence: mechanical material characterization (Tensile, Small Punch, Izod Impact, and crack propagation), physical and chemical characterization (Oxidation Index, Compressive Modulus, Poisson's Ratio, Surface Roughness, Density, Onset Melting Temperature, Peak Melting Temperature, Delta H, Degree of Crystallinity, Crosslink Density, Swell Ratio, Molecular Weight, Polydispersity Index,

Lamallae Thickness, Free Radical Concentration, Vitamin E Concentration, Vitamin E Consolidation, Vitamin E Elution/Extraction, Trans-vinylene Index), tibial insert peel-out strength, wear testing, and biocompatibility. All testing has demonstrated the device is substantially equivalent to the predicate devices.

Clinical Testing:
None provided as a basis for substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Encore Medical, L.P.
% Mr. William Garzon
Regulatory Affairs Technician
9800 Metric Boulevard
Austin, Texas 78758

DEC 2 1 2010

Re: K103223
Trade/Device Name: Highly Cross-Linked Vitamin E UHMWPE Tibial Insert
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: OIY, JWH, MBH
Dated: October 29, 2010
Received: November 4. 2010

Dear Mr. Garzon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEC 2 1

510(k) Number (if known): K103223

Device Name: Highly Cross-Linked Vitamin E UHMWPE Tibial Insert DEC 2 1 2010

Indications for Use:

Joint replacement is indicated for patients suffering from disability due to:

- degenerative, post-traumatic or rheumatoid arthritis;
- avascular necrosis of the femoral condyle;
- post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy;
- moderate valgus, varus or flexion deformities;
- Treatment of fractures that are unmanageable using other techniques

This device may also be indicated in the salvage of previously failed surgical attempts. This device is intended to be used with the 3DKnee System for cemented or uncemented applications.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

for M Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103223

510(k) Summary

Manufacturer: StelKast, Inc.
200 Hidden Valley Road
McMurray, PA 15317

MAR 2 4 2011

Device Trade Name: EXp Acetabular Shell Liner

Contact: Mr. Donald A. Stevens
Vice Chairman
(888) 273-1583

Prepared by: Musculoskeletal Clinical Regulatory Advisers, LLC
1331 H Street, NW, 12th Floor
Washington, DC 20005
Phone: (202)552-5800

Date Prepared: March 14, 2011

Common Name: Acetabular Shell Liner

Classification: 21 CFR 888.3358, Hip joint metal/polymer/metal semiconstrained porous-coated uncemented prosthesis

Class: II

Product Codes: OQG, OQH, OQI, LPH, LWJ, JDI, MAY, LZO

Indications For Use:
The EXp Acetabular Shell Liner is intended for use in reconstruction of the articulating surface of the acetabular portion of the hip that is severely disabled and/or very painful resulting from:

1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Correction of functional deformity.
4. Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
5. Revision of previously failed total hip Arthroplasty.

Cemented and Uncemented Applications

Device Description:
The EXp Acetabular Shell Liner is made of polyethylene to which Vitamin E has been added. It is available in both hooded and non-hooded options. The liner is part of a complete total hip system and will be used in conjunction with an acetabular shell, femoral head and femoral stem in total hip arthroplasty. The femoral heads which are to be mated with the EXp Liner are made of Biolox *forte*, Biolox Delta, or CoCr alloy.

Predicate Devices:
Liners
Comparative information presented in the 510(k) supports the substantial equivalence of the EXp Acetabular Liner with respect to its indications for use, design, materials, and function.

This 510(k) demonstrates the substantial equivalence of the EXp Acetabular Liner to the following predicate devices: Acetabular Liners in the Stelkast Provident Hip System (K935484) and the Stelkast ProForm Hip System (K950827); Biomet RingLoc Acetabular Component with ArCom Polyethylene (K032396 and K970501). Previously cleared polyethylene acetabular liners to which Vitamin E has been added include the Biomet E-Poly (Vitamin E) Acetabular Liners (K050327).

All of these acetabular liners have the same intended use, have the same general design and available sizes, and are made of UHMWPE.

Non-clinical testing was performed on the EXp Acetabular Liner to determine tensile strength, impact strength, compressive strength, small punch strength, thermal properties, free radical concentration, oxidation resistance, swell ratio, hip simulator wear under normal and abrasive conditions, wear particle characterization, rim impingement, liner push-out, lever-out, and torque-out resistance, GCMS analysis of hexane extract post-wear testing, fusion defect characterization, fatigue crack propagation, trans-vinylene index, and biocompatibility (i.e., mutagenicity, irritation, sensitization, and cytotoxicity testing).

The results of the performed tests demonstrate that the EXp Acetabular Liner is substantially equivalent to legally marketed predicate devices.

Femoral Heads
The StelKast Biolox Delta Ceramic Femoral heads are substantially equivalent to previously cleared Biolox Delta Ceramic Femoral Heads: Smith & Nephew (K083762); Biomet (K073102); Zimmer (K071535); and Howmedica Osteonics (K051588). The StelKast Biolox *forte* Ceramic Femoral Heads were approved for use with StelKast femoral stems in P040051. The CoCr Femoral Heads were cleared for use with StelKast femoral stems in K934162.

Testing in support of the ceramic femoral heads includes static burst strength, fatigue, post-fatigue burst strength, pull-off, and rotational stability.

Claims for the EXp Liner

Oxidative Stability and Mechanical Performance of the EXp material

1) EXp is more resistant to oxidation than conventional UHMWPE and its ultimate load, as measured per ASTM F2183, does not decrease during oxidative aging per ASTM F2003. The EXp UHMWPE is a compression molded GUR 1020 blended with Vitamin E, crosslinked with gamma irradiation and terminally sterilized using ethylene oxide. For comparison, a well recognized industry standard material, conventional GUR 1050 material, sterilized using 25kGy in an inert environment was tested in parallel. The EXp UHMWPE demonstrated resistance to oxidation, as measured using ASTM F2102, after aging per ASTM F2003. Specifically, after four weeks of aging per ASTM F2003, the maximum ASTM F2102 oxidation index increased from 0.1 ± 0.02 to 0.2 ± 0.02 for the EXp material and from 0.1 ± 0.04 to 3.8 ± 0.2 for the conventional GUR1050 material.

   Consistent with the oxidation index data, the resulting mechanical performance of the materials, as determined using the ASTM F2183 small punch test, showed that the EXp material retained its mechanical performance while that of the 25kGy GUR 1050 material decreased. Specifically, the ultimate load for the EXp material remained relatively constant, 63.3 ± 8.9 N and 73.1 ± 5.2 N, for the non-aged and 4-week-aged material, respectively. The ultimate load for the conventional material decreased from 71.5 ± 3.0 N for the non-aged material to an embrittled condition in which no small punch sample could be machined. For reference, the ultimate load after two weeks of aging had reduced to 45.7 ± 5.9 N.

   All EXp samples were machined from GUR1020- E, which is blended by percentage weight with Vitamin E, compression molded, crosslinked with gamma irradiation, and subsequently ethylene oxide sterilized. All conventional samples were machined from GUR1050, ram extruded UHMWPE and subsequently gamma sterilized using 25-40 kGy in an inert environment. *Bench testing is not necessarily indicative of clinical performance.*

2) The morphology of the EXp UHMWPE is consistent with conventional UHMWPE. Material samples of both the EXp UHMWPE and 25kGy GUR 1050 material were subjected to freeze fracture analysis. Both materials demonstrated no consolidation defects or voids when imaged at high magnification under scanning electron microscopy.

   All EXp samples were machined from GUR1020- E, which is blended by percentage weight with Vitamin E, compression molded, crosslinked with gamma irradiation, and subsequently ethylene oxide sterilized. All conventional samples were machined from GUR1050, ram extruded UHMWPE and subsequently gamma sterilized using 25-40 kGy in an inert environment. *Bench testing is not necessarily indicative of clinical performance.*

3) The vitamin E blended into the EXp UHMWPE does not elute from the EXp material during hexane extraction or isopropanol (IPA) extraction. Gas chromatography-mass spectrometry (GC-MS) and liquid chromatography –mass spectrometry (LC-MS) analysis of hexane solvent used for extraction of the EXp material confirmed that no Vitamin E was extracted from the material when refluxed at 74°C for 24 hours. GC-MS and LC-MS analysis of IPA solvent used for extraction of the EXp material confirmed

that no Vitamin E was extracted from the material when soaked at room temperature for 18 hours. The GC-MS and LC-MS technique have detection limits of 50-250 ppb and 1000 ppm, respectively.

All EXp samples were machined from GUR1020- E, which is blended by percentage weight with Vitamin E, compression molded, crosslinked with gamma irradiation, and subsequently ethylene oxide sterilized. *Bench testing is not necessarily indicative of clinical performance.*

Oxidative Stability and Mechanical Performance of the EXp Liners

4) EXp remains resistant to oxidation after 5 million cycles of wear testing and artificial aging. Wear testing followed by accelerated aging provides a method to assess the possibility that repeated loading experienced during wear testing may change the distribution or content of the Vitamin E in the EXp material; leaving the material susceptible to oxidation. Testing was conducted per ISO 14242-1 using an AMTI hip simulator with 20g/L bovine serum lubricant to a total cycle count of 5.0 million cycles. All samples were tested in their final sterilized form. Following wear testing, the EXp Liners were aged in an oxidative environment per ASTM F2003 for 4 weeks. The EXp Liners demonstrated a resistance to oxidation, as measured using ASTM F2102. Specifically, the maximum oxidation index increased from 0.1 ± 0.02 for the non-aged EXp material to 0.2 ± 0.02 for the four-week-aged EXp material.

   EXp samples were machined from GUR1020- E, which is blended by percentage weight with Vitamin E, compression molded, crosslinked with gamma irradiation, and subsequently ethylene oxide sterilized. *Bench testing is not necessarily indicative of clinical performance.*

5) The EXp liners experienced no failures as a result of dynamic impingement testing. Dynamic impingement testing, per ASTM F2582, confirmed that artificially aged EXp liners demonstrated a resistance to rim fracture under fatigue loading conditions to 1.0MC. Specifically, three liners were loaded to engage the liner rim with the femoral neck at moments equal to 4.6 Nm (70% of the static peak dislocation moments). All three samples reached run-out equal to 1.0MC and no fractures of the liners were observed throughout testing nor did the locking mechanism fail.

   All EXp samples were machined from GUR1020- E, which is blended by percentage weight with Vitamin E, compression molded, crosslinked with gamma irradiation, and subsequently ethylene oxide sterilized. *Bench testing is not necessarily indicative of clinical performance.*

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

StelKast, Inc.
% Mr. Donald A. Stevens
Vice Chairman
200 Hidden Valley Road
McMurray, Pennsylvania 15317

MAR 24 2011

Re: K094035
Trade/Device Name: EXp Acetabular Shell Liner
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip Joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: OQG, OQH, OQI, LPH, LWJ, JDI, MAY, LZO
Dated: March 15, 2011
Received: March 17, 2011

Dear Mr. Stevens:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

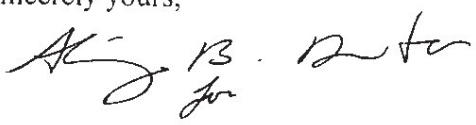
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K094035

Device Name: EXp Acetabular Liner

Indications for Use:

1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Correction of functional deformity.
4. Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
5. Revision of previously failed total hip Arthroplasty.

Cemented and Uncemented Applications

Prescription Use ___YES___ **(Part 21 CFR 801 Subpart D)** **AND/OR** **Over-The-Counter Use** ___NO___ **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K094035

(b)(4) Schematic Drawing

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