MAY 0 1 2013

P.O. Box 708
Warsaw, IN 46581-0708
574 267-6131

ZIMMER®

510(k) Summary of Safety and Effectiveness

Sponsor:	Zimmer GmbH Sulzer Allee 8 Winterthur, CH-8404, Switzerland
Contact Person:	Rebecca M. Brooks Sr. Specialist, Regulatory Affairs Telephone: (574) 371-8033 Fax: (574) 372-4605
Date:	April 30, 2013
Trade Name:	BIOLOX *delta* Ceramic Femoral Heads
Common Name:	Ceramic Femoral Head Prosthesis
Product Code / Device:	LZO - Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous, Uncemented
Regulation Number / Description:	21 CFR § 888.3353 – Hip joint metal/ceramic/ polymer semi-constrained cemented or nonporous uncemented prosthesis
Predicate Device:	BIOLOX *delta* Ceramic Femoral Heads, manufactured by Zimmer GmbH, K071535, cleared November 19, 2007 *Avenir* Müller Stem, manufactured by Zimmer GmbH, K123392, cleared March 4, 2013 Zimmer *Porolock* MIS Stem, manufactured by Zimmer GmbH, K071723, cleared March 7, 2008
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.

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:

No changes are being made to the designs of the subject BIOLOX *delta* Ceramic Femoral Heads. The proposed modification is limited to expanding the scope of compatible femoral stems. The BIOLOX *delta* Ceramic Femoral Heads are sterilized using equivalent materials and processes as their predicates. The subject devices also have the same intended use and performance characteristics as their predicates.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

Non-clinical testing as well as engineering and risk analyses were performed to demonstrate substantial equivalence of the subject femoral heads to the predicate devices. The specific non-clinical testing and analyses completed include pull-off testing and range of motion analyses. Additionally, a fatigue strength analysis was completed to ensure the new combination does not present a new worst case compared to other legally marketed combinations. This information and testing results formed the basis for a determination of substantial equivalence.

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
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 1, 2013

Zimmer GmbH
% Zimmer, Incorporated
Ms. Rebecca M. Brooks
Senior Specialist, Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581

Re: K130899
Trade/Device Name: BIOLOX® delta Ceramic Femoral Heads
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: March 29, 2013
Received: April 1, 2013

Dear Ms. Brooks:

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 contact 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. 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

Indications for Use

510(k) Number (if known): K130899 (pg 1/1)

Device Name:

BIOLOX® *delta* Ceramic Femoral Heads

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_ (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 if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 1, 2013

Zimmer GmbH
% Zimmer, Incorporated
Ms. Rebecca M. Brooks
Senior Specialist, Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581

Re: K130899
Trade/Device Name: BIOLOX® delta Ceramic Femoral Heads
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: March 29, 2013
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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.

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Sincerely yours,

Erin D. Keith

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

Enclosure

Concurrence & Template History Page
[THIS PAGE IS INCLUDED IN IMAGE COPY ONLY]

Full Submission Number:

For Office of Compliance Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=318

For Office of Surveillance and Biometrics Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=423

Digital Signature Concurrence Table	
Reviewer Sign-Off	Tara Shepherd
Branch Chief Sign-Off	Elizabeth Frank
Division Sign-Off	Erin I. Keith 2013.05.01 14:36:29 -04'00'

f/t:TNS:tmj:4/30/13:eaf:4/30/13
Template Name: K1(A) – SE after 1996

Template History:

Date of Update	By	Description of Update
7/27/09	Brandi Stuart	Added Updates to Boiler Table
8/7/09	Brandi Stuart	Updated HFZ Table
1/11/10	Diane Garcia	Liability/Warranty sentence added at bottom of 1st page
10/4/11	M. McCabe Janicki	Removed IFU sheet and placed in Forms
9/25/12	Edwena Jones	Added digital signature format
12/12/12	M. McCabe Janicki	Added an extra line between letter signature block and the word "Enclosure". Also, added a missing digit in 4-digit extension on letterhead zip code: "002" should be "0002".
4/2/2013	M. McCabe Janicki	Edited sentence that starts "If you desire specific advice for your

		device on our labeling regulation (21 CFR Part 801)…" Replaced broken Compliance link with general link to DSMICA.
4/12/2013	Margaret McCabe Janicki	Fixed a typo: Paragraph 1, final sentence, "We remind you, however; that device labeling must be truthful…" Replaced incorrect semicolon with a comma.

Indications for Use

510(k) Number (if known): K130899 (pg 1/1)

Device Name:

BIOLOX® *delta* Ceramic Femoral Heads

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)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices

K130899

P.O. Box 708
Warsaw, IN 46581-0708
(574) 267-6131

March 29, 2013

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Subject: Special 510(k): Device Modification – BIOLOX *delta* Ceramic Femoral Heads and *Avenir* Müller and *Fitmore* Femoral Stem Compatibility

Dear Sir or Madam:

As required by Section 510(k) of the Federal Food, Drug and Cosmetic Act, as amended by the Medical Device Amendments of 1976, the Safe Medical Devices Act of 1990, FDA Modernization Act of 1997 (FDAMA) and in accordance with Title 21 of the Code of Federal Regulations (CFR) Part 807, subpart E, the above noted premarket notification is hereby submitted to the Food and Drug Administration (FDA). As required by 21 CFR 807.90(c), this document is submitted in duplicate. One or more eCopies are included; the eCopy is an exact duplicate of the paper copy.

This Special 510(k) is being submitted for a modification to the BIOLOX *delta* Ceramic Femoral Heads, K071535, cleared November 19, 2007. This modification does not change the indications for use, intended use or fundamental scientific technology of the device.

If you require any additional information or have any questions, please contact me by telephone at (574) 371-8033, by e-mail at rebecca.brooks@zimmer.com, or fax at (574) 372-4605.

Sincerely,

Rebecca Brooks

Rebecca M. Brooks
Sr. Specialist, Regulatory Affairs

rmb/jm
Enclosure

17

Form Approved OMB No 0910 511 Expiration Date February 28, 2013 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)Trade
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)

ZIMMER INC
345 EAST MAIN STREET
WARSAW IN 46580
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
(b)(4)Trade S

2. CONTACT NAME
Rebecca Brooks
2.1 E MAIL ADDRESS
rebecca.brooks@zimmer.com
2.2 TELEPHONE NUMBER (include Area code)
574 371 8033
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)
06 Mar 2013

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. 0910 0120
Expiration Date: December 31, 2013
See PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
03/29/2013	MD 6067480-956733	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Request for Feedback
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-Submission
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Informational Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☒ Special	☐ Submision Issue Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Day 100 Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Agreement Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Determination Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Study Risk Determination
	☐ 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)*		
Zimmer GmbH	9613350		
Division Name *(if applicable)*	**Phone Number *(including area code)***		
N/A	+41 52 262 2930		
Street Address	**FAX Number *(including area code)***		
Sulzer Allee 8	+41 79 431 9485		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Winterthur	N/A	CH-8404	Switzerland
Contact Name			
Carol Vierling			
Contact Title	**Contact E-mail Address**		
Director, Regulatory Affairs	carol.vierling@zimmer.com		

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

Company / Institution Name			
Zimmer, Inc.			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
N/A	574-371-8033		
Street Address	**FAX Number *(including area code)***		
P.O. Box 708	574-372-4605		
City	**State / Province**	**ZIP Code**	**Country**
Warsaw	Indiana	46581-0708	USA
Contact Name			
Rebecca M. Brooks			
Contact Title	**Contact E-mail Address**		
Sr. Specialist, Regulatory Affairs	rebecca.brooks@zimmer.com		

PSC Publishing Services (301) 443 6740 EF

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):*

Addition of compatibility between BIOLOX delta ceramic femoral heads and both Fitmore and Avenir Mueller femoral stems.

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	LZO	2		3		4	
5		6		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	K071535	1	BIOLOX delta Ceramic Femoral Heads	1	Zimmer GmbH
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

LZO - Prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented

	Trade or Proprietary or Model Name for This Device		Model Number
1	BIOLOX delta Ceramic Femoral Heads	1	See Catalog Number Table
2		2	
3		3	
4		4	
5		5	

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

1 K071535	2 K123392	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	C.F.R. Section *(if applicable)*	Device Class
LZO	21 CFR 888.3353	☐ Class I ☒ Class II
Classification Panel		☐ Class III ☐ Unclassified
Orthopedics / 87		

Indications *(from labeling)*

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.

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

SECTION H	MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION	
☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☒ Repackager / Relabeler
Company / Institution Name Zimmer GmbH		Establishment Registration Number 9613350
Division Name *(if applicable)*		Phone Number *(including area code)* +41 52 262 2930
Street Address Sulzer Allee 8		FAX Number *(including area code)* +41 79 431 9485

City	State / Province	ZIP Code	Country
Winterthur	N/A	CH-8404	Switzerland

Contact Name	Contact Title	Contact E-mail Address
Carol Vierling	Director, Regulatory Affairs	carol.vierling@zimmer.com

(b)(4)Trade Secret Process

(b)(4)Trade Secret Process

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 *(Continued)*

(b)(4)Trade Secret Process

(b)(4)Trade Secret Process

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ 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	

FORM FDA 3514 (1/13) Add Continuation Page

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.					
	Standards No.	Standards Organization	Standards Title	Version	Date
1	21535	ISO	Non-active surgical implants -- Joint replacement implants -- Specific requirements for hip-joint replacement implants	2007	10/01/2007
	Standards No.	Standards Organization	Standards Title	Version	Date
2	F2009	ASTM	Standard Test Method for Determining the Axial Disassembly Force of Taper Connections of Modular Prostheses	2000	03/10/2000
	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					
Please include any additional standards to be cited on a separate page.					

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 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.

Acceptance Checklist

For Special 510(k)s

(should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.

510(k) Number: _____ **Date Received:** _____

Lead Reviewer Name: _____ **Branch:** _____ **Division:**_____**Office:** _____

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during RTA and that element will be assessed during substantive review.

Special 510(k) Criteria			
The submission should not be reviewed as a Special 510(k) if "No" is selected for any of the 4 criteria below. Complete the Refuse to Accept Checklist for a Traditional 510(k) if submission is converted.	**Yes**	**No**	**Page Number**
1. 510(k) is submitted to modify a legally marketed device (predicate) AND the Special 510(k) submission is submitted by the holder of the 510(k) for the predicate device.	**X**		**p. 19, 21**
Comments:			
2. Indications for Use of the proposed device are unchanged from the legally marketed device (predicate).	**X**		**p. 19, 37**
Comments:			
3. Fundamental technology of the proposed device is unchanged from the legally marketed device (predicate).	**X**		**p. 19, 22**
Comments:			
4. The submission includes only summary-level information (i.e., NO test reports with performance data. *Note that if performance data are provided and are conducted under design validation (21 CFR 820.30(g)), for example, to demonstrate continued conformance with a special control or recognized standard, then a Special 510(k) may be appropriate.*	**X**		**p. 148**
Comments:			

Does the submission meet all 4 criteria above?

☐ Yes, submission meets the criteria for a Special 510(k). Continue with the remainder of this checklist below.

☐ No, submission does not meet the criteria for a Special 510(k). Discontinue this RTA checklist; convert to a Traditional and apply the Traditional checklist.

Organizational Elements *Failure to include these items alone generally should not result in an RTA designation.*			
	Yes	**No**	**Page Number**
a. Submission contains Table of Contents	**X**	□	**p. 17**
b. Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.).	**X**	□	**N/A**
c. All pages of the submission are numbered. *All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2…).*	**X**	□	**All**
Comments:			

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed. **Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.**						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.		**Yes**	**N/A**	**No**	**Page Number**
A.	**Administrative**					
	1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.).	**X**		□	**N/A**
		Comments:				
	2.	Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or in 510(k) cover letter):	**X**		□	**p. 21, 35**
		a. Device trade name or proprietary name	**X**		□	**p. 21, 35**
		b. Device common name	**X**		□	**p. 21, 35**
		c. Device class and panel or classification regulation or statement that device has not been classified with rationale for that conclusion	**X**		□	**p. 35**
		Comments:				
	3.	Submission contains Indications for Use Statement with Rx and/or OTC designated (see also 801.109). *Submitter should use format appropriate for the reviewing Center/Office (CDRH/ODE, CDRH/OVID, CBER/OBRR, CEBER/OCTGT. If not provided in correct format, request the correct format during substantive review.*	**X**		□	**p. 38**
		Comments:				

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed.						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.		**Yes**	**N/A**	**No**	**Page Number**
	4.	Submission contains 510(k) Summary or 510(k) Statement *Either a) or b) must be answered "Yes" to be considered complete. Identify any missing element(s) as Comments.*	**X**		□	**p. 35**
		a. Summary contains all elements per 21 CFR 807.92 *See also 510(k) Summary Checklist*	**X**		□	**p. 35**
		b. Statement contains all elements per 21 CFR 807.93	□	**X**	□	
		Comments:				
	5.	Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k). *See recommended format. Select "Yes" if statement is present, and includes the text in the recommended format, and is signed by a responsible person of the firm (not consultant).*	**X**		□	**p. 33**
		Comments:				
	6.	Submission contains Class III Summary and Certification. *See recommended content.* *Form should be signed by a responsible person of the firm, not a consultant. Select "N/A" only if submission is not a Class III 510(k).*	□	**X**	□	
		Comments:				
	7.	If submission relies upon national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (FDA Form 3654) or includes detailed information about how and the extent to which the standard has been followed. *There should be a completed form for each referenced national or international standard.* *"N/A" only if submission does not reference any standards.*	**X**	□	□	**p. 154**
		Comments:				

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed.						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.		**Yes**	**N/A**	**No**	**Page Number**
	8.	The submission identifies prior submissions for the same device which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device. *This information may be included in the Cover Letter (i.e., as a statement that there were no prior submissions for the device or a listing of the number(s) of the prior submissions). Alternatively, a list of submission numbers may be found in Section F (prior related submissions section) of the CDRH Coversheet form (Form 3514) to address this criterion. Please be advised that if this section of the form is left blank, it should not be considered a statement that there were no prior submissions.*		**X**		□	**p. 4, 30**
		a.	If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. *To address this criterion, the submission may include a separate section with the prior submission number(s), a copy of the FDA feedback (e.g., letter, meeting minutes), and a statement of how or where in the submission this prior feedback was addressed. Note that the adequacy of how the feedback was addressed should be assessed during the substantive review.* For additional information regarding the Pre-Submission process, please refer to the Draft Guidance "Medical Devices: The Pre-Submission Program and Meetings with FDA Staff." (http://www fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm3 10375 htm). Once finalized, this guidance will represent the Agency's current thinking on this topic. *Select "N/A" if the submitter states there were no prior submissions in criterion above.*	**X**	□	□	**p. 30**
		Comments:				

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed.							
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.							
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**	**Page Number**
B.	**Device Description**						
	9.	a.	If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement. *Select "N/A" if there are no applicable requirements in a device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.*	**X**	□	□	**p. 22-23, 148-150**
		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	**X**	□	□	**p. 22-23, 148-150**
		Comments:					
	10.	Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:					
		a.	A description of the principle of operation and mechanism of action for achieving the intended effect.	**X**		□	**p. 22-26**
		b.	A description of proposed conditions of use such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	**X**		□	**p. 23-26**

				Yes	N/A	No	Page Number
Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed. **Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.** • Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.							
		c.	A list and description of each device for which clearance is requested. *Select "N/A" if there is only one device or model. "Device" may refer to models, part numbers, or various sizes, etc.*	**X**	□	□	**p. 145**
		Comments:					
	11.	A description of all device modification(s) including rationale for each modification.		**X**		□	**p. 30**
		Comments:					
	12.	Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions. *In lieu of drawings, schematics, etc. of each device to be marketed, "representative" drawings, etc. may be provided, where "representative" is intended to mean that the drawings, etc. provided capture the differences in design, size, and other important characteristics of the various models, sizes, or versions of the device(s) to be marketed.* *Select "N/A" if the sponsor provided a rationale for why the submission does not contain engineering drawings, schematics, etc. (e.g., device is a reagent and figures are not pertinent to describe the device).*		**X**	□	□	**p. 95**
		Comments:					
	13.	If device is intended to be marketed with multiple components, accessories, and/or as part of a system: *Select "N/A" if the device is not intended to be marketed with multiple components, accessories, and/or as part of a system.*			□		
		a.	Submission includes a list of all components and accessories to be marketed with the subject device.	**X**		□	**p. 23-29**
		b.	Submission includes a description (as detailed in item #10.a. and b. and 12 above) of each component or accessory. *Select "N/A" if the component(s)/accessory(ies) has been previously cleared, or is exempt, and the proposed indications for use are consistent with the cleared indications.*	**X**	□	□	**p. 23-29**

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed.							
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.							
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**	**Page Number**
		c.	A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance. *Select "N/A" if the submission states that component(s)/accessory(ies) does not have a prior 510(k) clearance or the components/accessory(ies) is 510(k) exempt.*	**X**	□	□	**p. 23-29**
		Comments:					
C.	**Substantial Equivalence Discussion**						
	14.	Submitter has identified a predicate(s) device.		**X**		□	**p. 21**
		a.	Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status* is *available online (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ComplianceActivities/ucm072746.htm).*	**X**		□	**p. 21**
		b.	The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary, if applicable and that used in comparative performance testing).	**X**		□	**p. 21, 35**
		Comments:					
	15.	Submission includes a comparison of the following for the predicate(s) and subject device:					
		a.	Indications for use	**X**		□	**p. 22**
		b.	Technology, including features, materials, and principles of operation	**X**		□	**p. 22**
		Comments: Submission is limited to expanded compatibility for legally marketed devices. No additional modifications are being made.					

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed.						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**	**Page Number**
	16.	Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., do not constitute a new intended use, and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate) affect safety or effectiveness, or raise different questions of safety and effectiveness) (see section 513(i)(l)(A) of the FD&C Act) *If there is no difference between the subject and predicate(s with respect to the indications or technology), this should be explicitly stated, in which case "N/A" should be selected. Select "No" only if the submission does not include an analysis of differences as described above or a statement that there are no differences. Note that the adequacy of the analysis should be assessed during the substantive review; only the presence of such an analysis is required for acceptance.*		□	**X**	□	**p. 22, 30**
		Comments:					
D.	**Design Control Activities**						
	17.	Design Control Activities Summary includes all of the following:					
		a.	Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components AND the results of the analysis	**X**		□	**p. 30, 147-150**
		b.	Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria	**X**		□	**p. 147-150**
		c.	Declaration of conformity with design controls, including: *All 3 must be present to answer "Yes"*	**X**		□	**p. 147**
			i. Statement that all verification and validation activities were performed by designated individuals and results demonstrate that predetermined acceptance criteria were met.				
			ii. Statement that manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30.				
			iii. Statement is signed by the individual responsible for these activities.				
		Comments:					

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed.						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.		**Yes**	**N/A**	**No**	**Page Number**
E.	**Proposed Labeling (see also 21 CFR part 801)**					
	18.	Submission includes proposed labels, labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use.	**X**		□	**p. 40-92**
		a. All changes in proposed labeling resulting from device modification(s) are highlighted or prominently identified.	□	**X**	□	
		Comments:				
	19.	Statement that the intended use of the modified device, as described in the labeling, has not changed as a result of the modification(s).	**X**		□	**p. 22**
		Comments:				

Decision: **Accept**_____ **Refuse to Accept** _____

If Accept, notify applicant. If Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Team Leader Signature: _____ **Date:** _____

Supervisory Signature: _____ **Date:** _____

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P.O. Box 708
Warsaw, IN 46581-0708
(574) 267-6131

March 29, 2013

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Subject: Special 510(k): Device Modification – BIOLOX *delta* Ceramic Femoral Heads and *Avenir* Müller and *Fitmore* Femoral Stem Compatibility

Dear Sir or Madam:

As required by Section 510(k) of the Federal Food, Drug and Cosmetic Act, as amended by the Medical Device Amendments of 1976, the Safe Medical Devices Act of 1990, FDA Modernization Act of 1997 (FDAMA) and in accordance with Title 21 of the Code of Federal Regulations (CFR) Part 807, subpart E, the above noted premarket notification is hereby submitted to the Food and Drug Administration (FDA). As required by 21 CFR 807.90(c), this document is submitted in duplicate. One or more eCopies are included; the eCopy is an exact duplicate of the paper copy.

This Special 510(k) is being submitted for a modification to the BIOLOX *delta* Ceramic Femoral Heads, K071535, cleared November 19, 2007. This modification does not change the indications for use, intended use or fundamental scientific technology of the device.

If you require any additional information or have any questions, please contact me by telephone at (574) 371-8033, by e-mail at rebecca.brooks@zimmer.com, or fax at (574) 372-4605.

Sincerely,

Rebecca Brooks

Rebecca M. Brooks
Sr. Specialist, Regulatory Affairs

rmb/jm
Enclosure

BIOLOX® *delta* Femoral Heads

Compatibility with *Avenir*® Müller and *Fitmore*® Femoral Stems

Special 510(k) Premarket Notification

Zimmer, Inc.
P.O. Box 708
Warsaw, IN 46581-0708

x1. Pg. 32
x2. Pg. 34

Reason for Submission

The BIOLOX *delta* Ceramic Femoral Heads are legally marketed devices, previously cleared for use with various femoral stems utilizing a 12/14 taper. The subject submission is seeking clearance for expanded femoral head/stem compatibility within the United States, allowing for use with Zimmer's legally marketed *Avenir* Müller and *Fitmore* (formerly *Porolock* MIS) Femoral Stems. The modification (limited to head/stem compatibility) is not due to any adverse occurrences or corrective actions.

Truthful and Accurate Statement

The Truthful and Accurate Statement has been included as Exhibit A[x1].

Device Name

BIOLOX *delta* Ceramic Femoral Heads

Common Name

Ceramic Femoral Head Prosthesis

Section 514 Compliance

Section 514 of the Act does not apply to this type of device at this time.

Summary of Safety and Effectiveness

A summary of information regarding safety and effectiveness for the proposed device is presented in Exhibit B[x2].

Predicate Device Information

The predicate devices for the expanded compatibility of the BIOLOX *delta* Ceramic Femoral Heads are the following:

- BIOLOX *delta* Ceramic Femoral Heads, manufactured by Zimmer GmbH, K071535, cleared November 19, 2007
- *Avenir* Müller Stem, manufactured by Zimmer GmbH, K123392, cleared March 4, 2013
- Zimmer *Porolock* MIS Stem (now known as the *Fitmore* Stem), manufactured by Zimmer GmbH, K071723, cleared March 7, 2008

The proposed compatibility between the predicate devices does not modify any of the devices; the subject modification is limited to head/stem compatibility.

x1. Pg. 37
x2. Pg. 39
x3. Pg. 44

Substantial Equivalence

Except for the expanded head/stem compatibility described in this submission, the BIOLOX *delta* Ceramic Femoral Heads are identical to the predicate device. The modified compatibility does not change the indications for use, intended use or the fundamental scientific technology. Additionally, with the modified compatibility the devices still use the same operating principle, incorporate the same basic design and labeling and are manufactured and sterilized using the same materials and processes.

In summary, the BIOLOX *delta* Ceramic Femoral Heads described in this submission are, in our opinion, substantially equivalent to the predicate device.

Intended Use

The indications and usage for the modified device are identical to the predicate device and are provided as Exhibit C[x1].

Labeling

Representative package labels are provided in Exhibit D[x2]. Since the BIOLOX *delta* Femoral Heads were cleared prior to FDA's implementation of the requirement to provide English symbology definitions, symbol definitions have been added to the labels.

A draft package insert is also provided in Exhibit D[x3]. The package insert has been updated to include the precaution, "The BIOLOX *delta* Ceramic Femoral Heads have not been evaluated for safety and compatibility in the MR environment. The BIOLOX *delta* Ceramic Femoral Heads have not been tested for heating or migration in the MR environment." Additionally, the package insert has been updated to include a section titled, "General Instruction for Revision of Ceramic Components." This section was introduced as a result of Zimmer's global launches of the compatible BIOLOX *delta* Ceramic Liner (outside of the U.S.) and the subsequent reviews by Zimmer's EU Notified Body.

Device Description and Comparison

Overview

The BIOLOX *delta* Ceramic Femoral Heads are legally marketed femoral heads previously cleared for use with various 12/14 taper femoral stems under 510(k) K071535 (cleared November 19, 2007). The heads are purchased from (b)(4)Trade Secret and are marketed under the trade name BIOLOX *delta*. (b)(4)Trade Secret master file (b)(4)Trade Secret is available for review of any items pertinent to this submission. Exhibit E contains a letter authorizing FDA to access (b)(4)Trade Secret master file on behalf of Zimmer.

(b) (4)Trade fabricates the heads from the aluminum oxide matrix composite ceramic consisting of approximately (b) (4)Tr alumina (Al_2O_3), (b) (4)Tr zirconia (ZrO_2) and (b) (4) trace elements. Alumina provides the material's hardness and wear resistance while zirconia, together with other additives, provides the mechanical properties of high strength, high density, and small grain size of the alumina matrix. The pink color is due to the trace presence of chromium oxide (Cr_2O_3). A representative image is provided below (Figure 1).

Figure 1: Representative images of BIOLOX *delta* Femoral Heads

The legally marketed BIOLOX *delta* Femoral Heads are available in 28, 32, 36, and 40 mm diameters with a range of offsets to accommodate various patient anatomies. They serve as an alternative to both metal and alumina ceramic heads for use in total hip arthroplasty.

The BIOLOX *delta* Femoral Heads are designed to articulate upon a variety of ultra high molecular-weight polyethylene (UHMWPE) bearing surfaces of an acetabular component. The acetabular components which have previously been cleared for use with the BIOLOX *delta* Femoral Heads are listed in Table 1 below. Additionally, the heads were previously cleared for use with a variety of Zimmer 12/14 hip stems manufactured from Ti-6Al-4V, Ti-6Al-7Nb, and CoCrMo. The previously cleared compatible femoral stems are listed below in Table 2.

Table 1: Compatible Acetabular Components

Description	510(k) Number	Clearance Date
Müller Acetabular Cup	Preamendment Device	N/A
Zimmer Poly Cup (previous name TR-28 Acetabular Cup)	Preamendment Device	N/A
Harris/Galante Porous Total Hip System Acetabular Component	K840643	04/17/84
Non-Metal Backed All-Poly Acetabular Cup (previously manufactured by Astel)	K901240	03/26/90
BIAS Total Hip System Acetabular Component	K921557	02/22/94
HGP II Acetabular Shell and Liner	K921308	02/22/94
Trilogy Acetabular System	K934765 K953490 K954698	04/29/94 10/20/95 01/17/96
APR Acetabular System	K941617	10/06/94
CLS® Acetabular Component	K953688	11/29/95
Epsilon Polyethylene Inserts	K983509	02/03/99
Trilogy Acetabular System *Longevity* Crosslinked Polyethylene Liners	K990135	07/12/99
Trilogy Large Head Liners	K002960 K003478	12/11/00 02/05/01
Allofit Acetabular System	K003758 K013935	03/07/01 12/13/01
Converge Acetabular System	K012961 K012739	10/18/01 11/14/01
Trabecular Metal™ Modular Acetabular System	K021891	09/05/02
ZCA All Poly Acetabular Cup, Snap-In	K030153	04/01/03
ZCA All Poly Acetabular System	K901240	03/26/90
Trabecular Metal Revision Shell Liners	K051516	07/27/05
Continuum and *Trilogy* Integrated Taper (IT) Acetabular Systems-*Longevity* IT Neutral Liners	K091508	9/11/09
Continuum and *Trilogy* Integrated Taper (IT) Acetabular Systems-*Longevity* IT Elevated Liners	K093846 K101229	02/04/10 12/03/10
Longevity IT Offset and Oblique Liners	K103662	04/15/11
Vivacit-E Neutral and Elevated Liners	K120370	06/04/12

Table 2: Compatible Femoral Stems

Description	510(k) Number	Clearance Date
ALLOCLASSIC SL/SLL Femoral Stem	K030373	03/06/2003
ALLOCLASSIC VARIALL SL Offset	K033664	12/17/2003
Alpha System	K950312	05/17/1995
Anatomic II Hip Prosthesis	K041109	07/20/2004
APR II Hip System	K913634	12/16/1991
APR Fully Textured Hip Stem	K961589	07/09/1996
APR Oversized Hip Stem	K961921	08/05/1996
APR Porous HA Hip System	K973124	11/03/1997
Beta Hip Prosthesis	K953337	01/22/1996
CLS Brevius with *Kinectiv* Technology	K110836	10/07/2011
CLS Spotorno Stem	K042249	09/15/2004
CLS Stem	K953690	06/07/1996
CLS Stem, *Wagner* Revision Stem, *Alloclassic Zweymuller* Stem SL for use with Zirconia Ceramic Heads	K973837	01/06/1998
CLS Varus Stem/CLS 135 Stem	K010839	04/18/2001
CPT 12/14 Hip Prosthesis	K030265	03/04/2003
Delta Hip Prosthesis	K961378	10/08/1996
Epoch Hip Prosthesis	K014070	07/30/2002
Gamma System	K955473	02/161996
Heritage Hip System	K963109	01/09/1997
MAYO Conservative Hip Prosthesis	K030733	05/01/2003
MAYO Conservative Hip Prosthesis	K061461	12/20/2006
Modular Oncology System Technology (MOST)	K960626	04/18/1996
Natural Hip System Porous Stem- Collarless, Collared	K963266	10/15/1996
Natural Porous Hip System	K913060	10/11/1991
Natural Hip Porous Stem with Offset	K973675	12/19/1997
Natural Hip System Porous Stem with HA/CSTi	K970300	07/03/1997
Natural Hip System	K960258	07/12/1996
Precedent Revision Hip System with HA	K971523	10/01/1997
Precedent Revision Hip System	K972637	10/01/1997
Trabecular Metal Primary Hip Prosthesis	K051491	06/30/2005
VerSys Beaded FullCoat Bowed Revision Hip Prosthesis	K030079	02/05/2003
VerSys Beaded FullCoat Calcar Hip Prosthesis	K033034	11/05/2003
VerSys Hip System Beaded Hip Prosthesis	K973714	12/24/1997
VerSys Hip System Beaded MidCoat Low Head Center Hip Prosthesis	K042776	11/04/2004

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x2. Pg. 144

Description	510(k) Number	Clearance Date
VerSys Epoch FullCoat Hip Prosthesis	K052321 K073499	02/15/2006 08/07/2008
VerSys Fiber Metal MidCoat Low Head Center Hip Prosthesis *VerSys* Hip System- Fiber Metal Taper Hip Prosthesis	K061786 K964769	07/24/2006 02/13/1997
Wagner Cone Prosthesis	K032380 K113556	09/22/2003 02/17/2012
Wagner Revision Stem	K871347 K960588	07/01/1987 08/05/1996
Wagner SL Revision Stem Lateral	K043356	04/18/2005
Zimmer M/L Taper Hip Prosthesis	K032726 K042337 K060040 K063251	10/22/2003 11/04/2004 05/12/2006 01/24/2007
Zimmer M/L Taper Hip Prosthesis with *Kinectiv* Technology	K063251 K071856 K081007	01/24/2007 07/30/2007 05/06/2008
ZMR Hip System	K994286 K992667 K031572 K113296	03/10/2000 10/27/1999 06/24/2003 09/14/2012

Engineering Drawings

Engineering drawings for the legally marketed BIOLOX *delta* Ceramic Femoral Heads are included in Exhibit F[x1].

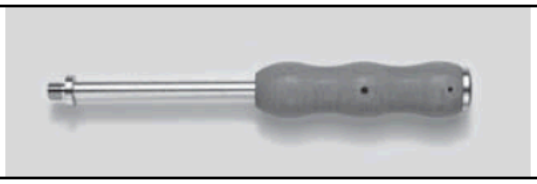
Catalog Numbers

All catalog numbers for the legally marketed BIOLOX *delta* Ceramic Femoral Heads are listed in Exhibit G[x2].

Surgical Instrumentation

The instrumentation that is utilized to implant the BIOLOX *delta* Ceramic Femoral Heads is listed below. These instruments are intended to be used with other currently marketed Zimmer implant systems. They are not unique to (are not accessories to) a single Zimmer device. Therefore, these instruments are Class I exempt. Additionally, the patient contacting materials utilized for the below instruments are identical to the materials utilized for and identified within the *Avenir* Müeller 510(k) submission (K123392).

Table 3: Surgical Instrumentation

Item Number	Product Description	Representative Instrument Graphic	Patient Contacting Material (Standard)
78.00.38	Ball Head Impactor Attachment		Polyphenylsulfone (ASTM F702) 1.4301 (304 SST) (ASTM F899)
75.11.00-02	Modular Repositioning Handle		1.4301 (304 SST) (ASTM F899)
00-7895-028-01	Femoral Head Provisional 28mm (-3.5)		Acetal Copolymer (ASTM F1855)
00-7895-028-02	Femoral Head Provisional 28mm(+0)		
00-7895-028-03	Femoral Head Provisional 28mm(+3.5)		
00-7895-032-01	Femoral Head Provisional 32mm(-3.5)		
00-7895-032-02	Femoral Head Provisional 32mm(+0)		
00-7895-032-03	Femoral Head Provisional 32mm(+3.5)		
00-7803-032-14	Femoral Head Provisional 32mm(+7)		
00-7895-036-01	Femoral Head Provisional 36mm(-3.5)		
00-7895-036-02	Femoral Head Provisional 36mm(+0)		
00-7895-036-03	Femoral Head Provisional 36mm(+3.5)		
00-7895-036-04	Femoral Head Provisional 36mm(+7)		

Item Number	Product Description	Representative Instrument Graphic	Patient Contacting Material (Standard)
00-7895-040-01	Femoral Head Provisional 40mm(-3.5)		Acetal Copolymer (ASTM F1855)
00-7895-040-02	Femoral Head Provisional 40mm(+0)		
00-7895-040-03	Femoral Head Provisional 40mm(+3.5)		
00-7895-040-04	Femoral Head Provisional 40mm(+7)		
00-7803-028-01	MIS Femoral Provisional Head 28mm (-3.5)		
00-7803-028-02	MIS Femoral Provisional Head 28mm (+0)		
00-7803-028-03	MIS Femoral Provisional Head 28mm (+3.5)		
00-7803-032-01	MIS Femoral Provisional Head 32mm (-3.5)		
00-7803-032-02	MIS Femoral Provisional Head 32mm (+0)		
00-7803-032-03	MIS Femoral Provisional Head 32mm (+3.5)		
00-7803-032-14	MIS Femoral Provisional Head 32mm (+7)		
00-7803-036-01	MIS Femoral Provisional Head 36mm (-3.5)		
00-7803-036-02	MIS Femoral Provisional Head 36mm (+0)		
00-7803-036-03	MIS Femoral Provisional Head 36mm (+3.5)		
00-7803-036-04	MIS Femoral Provisional Head 36mm (+7)		

Item Number	Product Description	Representative Instrument Graphic	Patient Contacting Material (Standard)
00-7803-040-01	MIS Femoral Provisional Head 40mm (-3.5)		Acetal Copolymer (ASTM F1855)
00-7803-040-02	MIS Femoral Provisional Head 40mm (+0)		
00-7803-040-03	MIS Femoral Provisional Head 40mm (+3.5)		
00-7803-040-04	MIS Femoral Provisional Head 40mm (+7)		

Materials

The BIOLOX *delta* Ceramic Femoral Head consists of an aluminum oxide matrix composite ceramic consisting of approximately (b) (4) alumina (Al_2O_3), (b) (4) zirconia (ZrO_2) and trace elements. The devices are sterilized utilizing gamma irradiation.

Minor Modifications to Device Since the Last 510(k) Clearance

There have been several minor modification(s) since the last 510(k) clearance for the BIOLOX *delta* Ceramic Femoral Heads (K071535). These minor changes resulted in no additional patient risk and no new submissions were required. All previous performance criteria remain valid. A summary of the changes is provided below.

The inner tray of the product packaging was changed from Polystyrene (PS) trays to Polyethylene Terephtalate Glycol (PETG) trays. Originally the heads were placed into an inner PS tray, fixed by a threaded retainer, heat sealed with a *Tyvek* lid, and the sealed tray was placed into an outer PETG tray that was heat sealed with a *Tyvek* lid, creating a double sterile barrier. The double sterile barrier system is still utilized with a final *Tyvek* sealed PETG tray, however the inner PS tray has been changed to be an inner PETG tray. The new packaging configuration meets the Sterility Assurance Level of 10^{-6} or better utilizing gamma irradiation and has been validated with the same method as the original packaging (ANSI/AAMI/ISO 11137, 1994, "Sterilization of Health Care Products - Requirements for Validation and Routine Control - Radiation Sterilization").

Additionally, the previously established five year shelf life has been extended to ten years. Testing was performed to confirm that the implant material, packaging, and sterility would perform as intended when subject to the extended shelf life.

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x2. Pg. 146
x3. Pg. 151

Modifications to the Device

The device modification that is the subject of this Special 510(k) Premarket Notification is modified femoral head/stem compatibility, allowing for use of Zimmer's BIOLOX *delta* Ceramic Femoral Heads with the legally marketed *Avenir* Müeller and *Fitmore* Femoral Stems. **There are no changes being made to the design of the heads or stems.**

(b)(4)Trade Secret Process

[redacted]

Zimmer has conducted additional pull-off testing between BIOLOX *delta* Ceramic Femoral Heads and the taper utilized for both the *Avenir* Müeller and *Fitmore* Femoral Stems and is now seeking clearance for compatibility in the United States.

Summary of Design Control Activities

The risk analysis method used to assess the impact of the modifications was a Failure Modes and Effects Analysis (FMEA). The design verification tests and analyses that were performed as a result of this risk analysis are listed in the Design Control Activities Summary, presented in Exhibit H[x1].

The signed Declaration of Conformity to Design Controls has also been included in Exhibit H[x2].

Class III Certification and Summary

This section is not applicable to this device.

Clinical Trial Certification of Compliance

A signed Certification of Compliance (Form FDA 3674) is included as Exhibit I[x3].

Standards Data Report for 510(k)s

Numerous national and international standards were utilized as part of the demonstration of substantial equivalence for the subject devices. A Standards Data Report (FDA 3654) is included for each of the following referenced standards, provided in Exhibit J[x1].

ISO 21535:2007 *Non-active surgical implants -- Joint replacement implants -- Specific requirements for hip-joint replacement implants*

ASTM F-2009 (2000) *Standard Test Method for Determining the Axial Disassembly Force of Taper Connections of Modular Prostheses*

Exhibit A

Truthful and Accurate Statement

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Senior Specialist, Regulatory Affairs of Zimmer, Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Rebecca Brooks
(Signature)

Rebecca M. Brooks
(Typed Name)

29-Mar-2013
(Date)

(Premarket Notification [510(k)] Number)

Exhibit B

Summary of Safety and Effectiveness

P.O. Box 708
Warsaw, IN 46581-0708
574 267-6131

Summary of Safety and Effectiveness

Sponsor:	Zimmer GmbH Sulzer Allee 8 Winterthur, CH-8404, Switzerland
Contact Person:	Rebecca M. Brooks Sr. Specialist, Regulatory Affairs Telephone: (574) 371-8033 Fax: (574) 372-4605
Date:	March 29, 2013
Trade Name:	BIOLOX *delta* Ceramic Femoral Heads
Common Name:	Ceramic Femoral Head Prosthesis
Product Code / Device:	LZO - Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous, Uncemented
Regulation Number / Description:	21 CFR § 888.3353 – Hip joint metal/ceramic/ polymer semi-constrained cemented or nonporous uncemented prosthesis
Predicate Device:	BIOLOX *delta* Ceramic Femoral Heads, manufactured by Zimmer GmbH, K071535, cleared November 19, 2007 *Avenir* Müller Stem, manufactured by Zimmer GmbH, K123392, cleared March 4, 2013 Zimmer *Porolock* MIS Stem, manufactured by Zimmer GmbH, K071723, cleared March 7, 2008
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.

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:	No changes are being made to the designs of the subject BIOLOX *delta* Ceramic Femoral Heads. The proposed modification is limited to expanding the scope of compatible femoral stems. The BIOLOX *delta* Ceramic Femoral Heads are sterilized using equivalent materials and processes as their predicates. The subject devices also have the same intended use and performance characteristics as their predicates.
Performance Data (Nonclinical and/or Clinical):	Non-Clinical Performance and Conclusions: Non-clinical testing as well as engineering and risk analyses were performed to demonstrate substantial equivalence of the subject femoral heads to the predicate devices. The specific non-clinical testing and analyses completed include pull-off testing and range of motion analyses. This information and testing results formed the basis for a determination of substantial equivalence. Clinical Performance and Conclusions: Clinical data and conclusions were not needed for this device.

Exhibit C

Indications for Use Statement

Indications for Use

510(k) Number (if known):

Device Name:

BIOLOX® *delta* Ceramic Femoral Heads

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)

(Please do not write below this line – Continue on another page if needed)

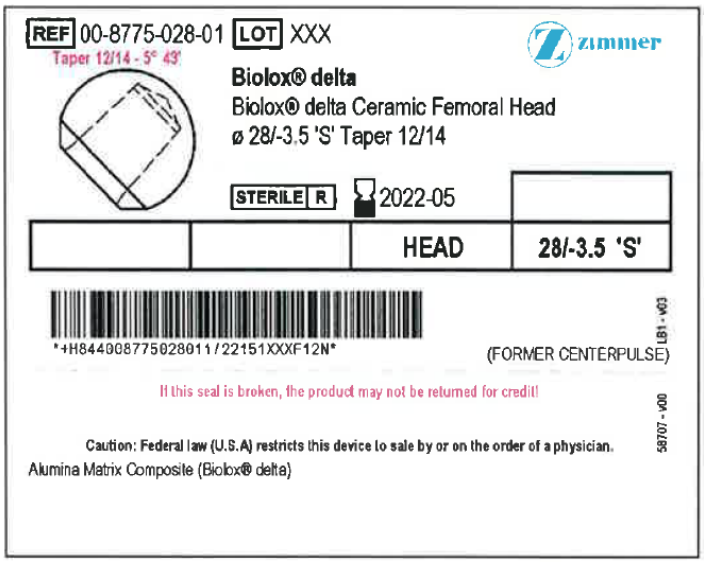
Concurrence of CDRH, Office of Device Evaluation (ODE)

Exhibit D

Labeling

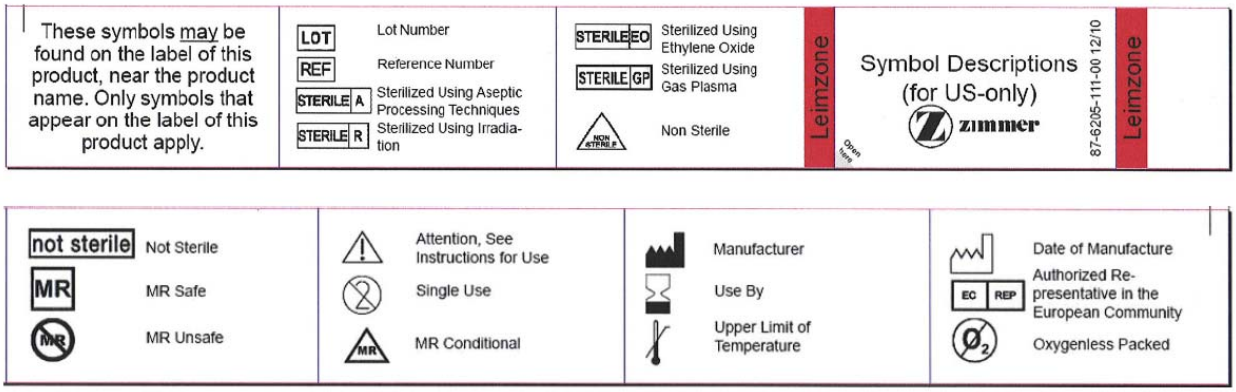
Representative 28mm BIOLOX *delta* Femoral Head Package Labels

Outer Box Labels

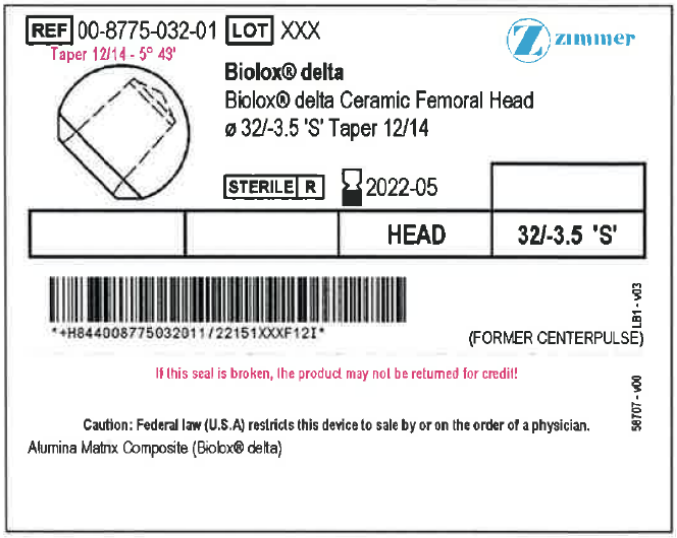


Patient Record Label

Package Outsert containing symbol definitions in English

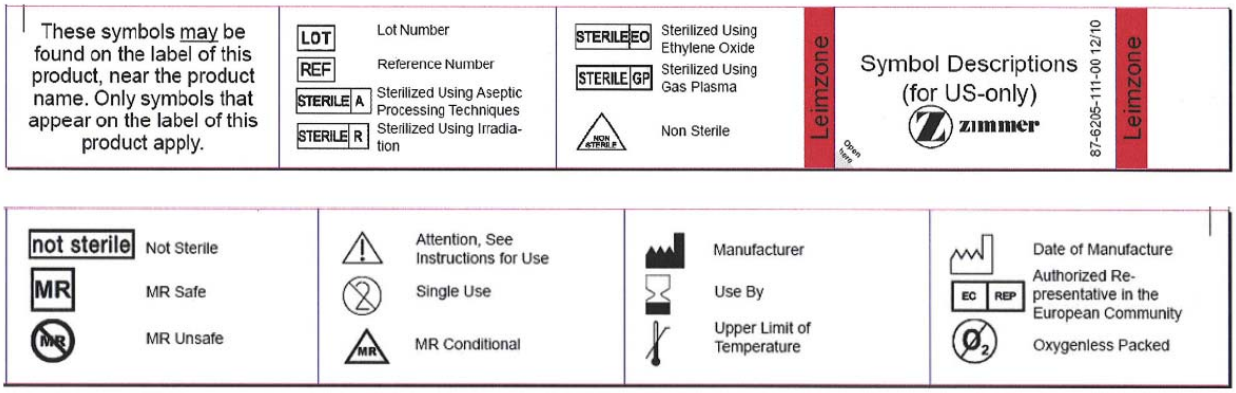


Representative 32mm BIOLOX *delta* Femoral Head Package Labels

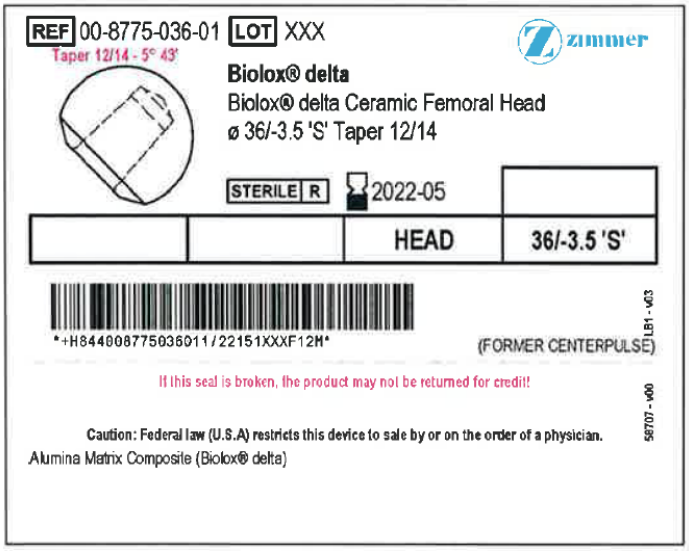


Patient Record Label

Package Outsert containing symbol definitions in English

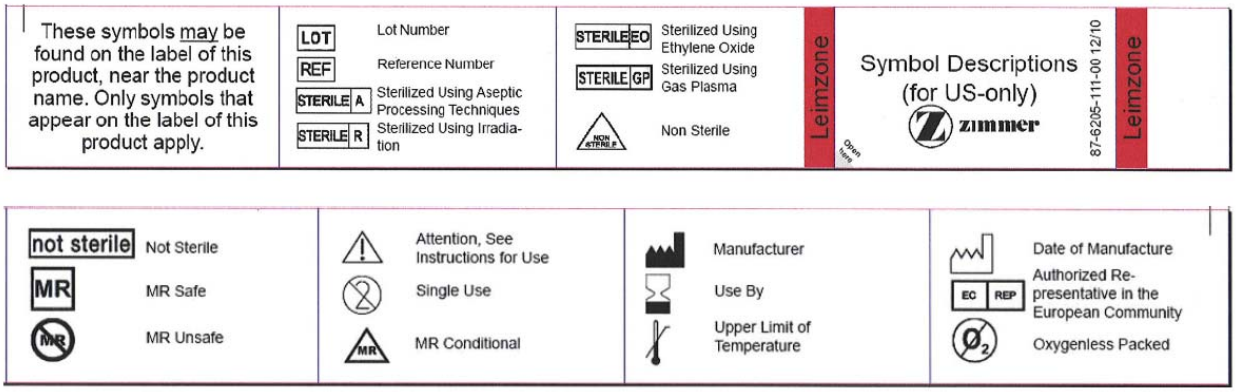


Representative 36mm BIOLOX *delta* Femoral Head Package Labels

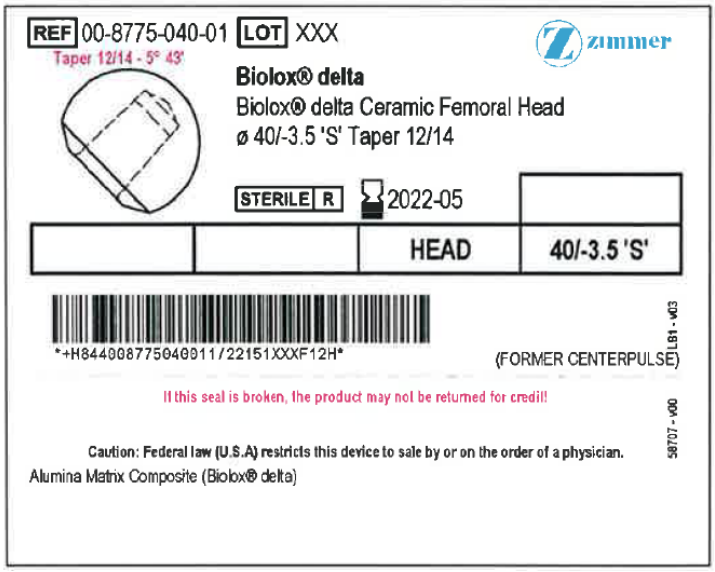


Patient Record Label

Package Outsert containing symbol definitions in English

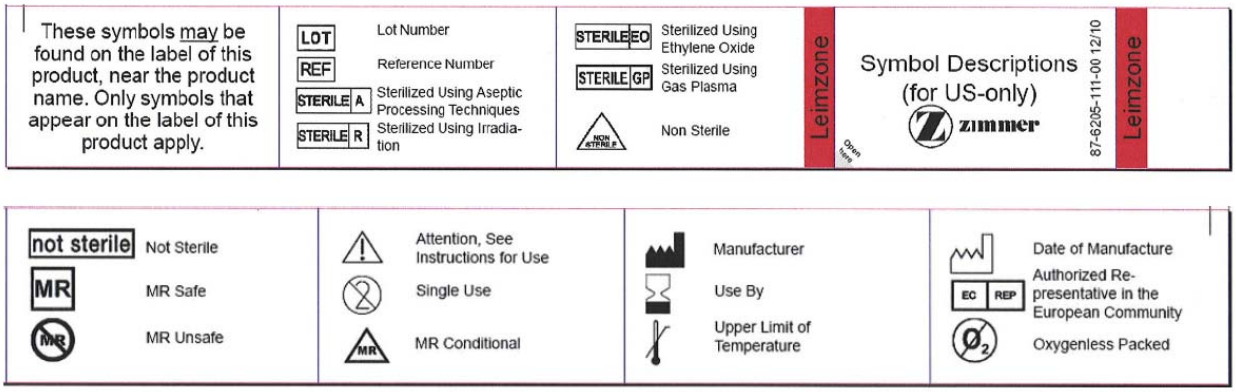


Representative 40mm BIOLOX *delta* Femoral Head Package Labels



Patient Record Label

Package Outsert containing symbol definitions in English



BIOLOX® delta Ceramic Femoral Head

CE 0086 (The CE mark is valid only if it is also printed on the product label)
Rx Only
Art. No. D011 500 245 - en/da/nl/fr/de/el/it/pt/es/sv - Ed. xx/xx

Zimmer GmbH
Sulzer-Allee 8
CH-8404 Winterthur, Switzerland
Telephone +41/ (0)52 262 60 70
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www.zimmer.com

Representative in the USA:
Zimmer, Inc.
1800 West Center Street
Warsaw, Indiana, 46580, USA

ENGLISH

The CE mark is valid only if it is also printed on the product label.

BIOLOX® delta Ceramic Femoral Head
Important information for the Operating Surgeon

Before using a product placed on the market by Zimmer, the operating surgeon should study carefully the following recommendations, warnings and instructions, as well as the available product-specific information (e.g., product literature, written surgical technique). Zimmer is not liable for complications arising from the use of the device outside of its indicated uses, surgical technique or judgment, product selection, and similar matters outside the control of Zimmer.

Due to the acquisition of pre-existing product lines, Zimmer has initiated a testing program to evaluate the compatibility of these devices with implants and components made or distributed by all Zimmer orthopaedic companies, which include Zimmer GmbH (previously Centerpulse Orthopedics Ltd.), Zimmer, Inc., Zimmer Trabecular Metal Technology, Inc. (previously Implex Corp.), Zimmer U.K. Ltd., and Zimmer Austin, Inc. (previously Centerpulse Orthopedics, Inc.). Only authorized combinations must be used. To determine whether these devices have been authorized for use in a proposed combination, please contact your Zimmer sales representative or visit the Zimmer website: www.productcompatibility.zimmer.com. A printout of the website information can also be obtained by calling Zimmer, Inc. Customer Service, 1-800-348-2759 (U.S.) or the local international access code +1-574-372-4999 (outside the U.S.). Former Centerpulse and Implex products that are now packaged in Zimmer boxes, and for which compatibility could be an issue, have been labeled “former Centerpulse” and “former Implex” to provide clarification for the user.

DESCRIPTION

- The *BIOLOX delta* Ceramic Femoral Head is used in conjunction with compatible acetabular and femoral stem components in total hip arthroplasty. A variety of sizes and neck lengths are

available for various patient anatomies and adjustment of the tension of the ligaments and reconstruction of the center of the natural head of the femur.

- A taper is incorporated in the design of the head to interlock it with the femoral stem.
- The ceramic head features a 12/14 bore for mating with femoral stems with corresponding tapers.
- The *BIOLOX delta* Ceramic Femoral Head may only be used in combination with highly cross-linked or conventional polyethylene (PE) or metal-back polyethylene liners, or authorized ceramics, where available. Ceramic liners articulating with *BIOLOX delta* heads are not approved for use in the U.S. **Wear couples with other manufacturer's ceramics or with metal liners are prohibited.**
- To determine whether these devices have been authorized for use in a proposed combination, please contact your Zimmer sales representative or visit the Zimmer website: www.productcompatibility.zimmer.com.
- **BIOLOX *delta* Femoral Heads are to be used only with femoral stems labeled "May be used with Ceramic Femoral Head." The package insert for the stem should be consulted to determine the compatibility of the stem and the ceramic head.**
- ***BIOLOX delta*** The *BIOLOX delta* Ceramic Femoral Head consists of the material *BIOLOX delta*, an aluminum oxide matrix composite ceramic consisting of approx. 75% alumina (Al_2O_3), 24% zirconia (ZrO_2) and trace elements. The pink color is due to Cr_2O_3.

INDICATIONS

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.

CONTRAINDICATIONS

- Patient's physical conditions that would eliminate or tend to eliminate adequate implant support or prevent the use of an appropriately sized implant, e.g. previous surgery, insufficient quality or quantity of bone resulting from conditions such as cancer or congenital dislocation, metabolic bone disease of the upper femur or pelvis, femoral osteotomy revision, girdlestone revision, osteoporosis, osteomyelitis, neuromuscular compromise or vascular deficiency in the affected limb in sufficient degree to render the procedure unjustifiable (e.g. absence of musculoligamentous supporting structures, joint neuropathy) or other conditions that may lead to inadequate skeletal fixation.
- Active infection of the hip, old or remote infection. This may be an absolute or relative contraindication.
- Allergy to the implanted material, above all to metal (e.g. cobalt, chromium, nickel etc.).
- Local bone tumours and/or cysts
- Pregnancy

GENERAL INSTRUCTION FOR REVISION OF CERAMIC COMPONENTS:

Revision of **undamaged** ceramic femoral heads:

BIOLOX delta Ceramic Femoral Heads may only be mounted on brand-new femoral stem taper. Intraoperative replacement of a femoral head must be carried out using a metal femoral head (e.g., *Metasul*®, *Protasul*®-S30, CoCr, *Tribosul*™) provided no damage to the femoral stem taper is visible. If the femoral stem taper is damaged, the femoral stem must also be replaced. **The only exception is *BIOLOX OPTION* Head System.** For instructions relating to the revisability of the femoral head components, please refer to the device-specific package inserts.

Revision of a **damaged** ceramic-only insert*:
For instructions relating to the revisability of acetabular components, please refer to the device specific package inserts..

Revision after **breakage** of one or both ceramic components:

- In these cases, all the ceramic particles must be removed and the wound thoroughly irrigated.
- The basic rule is: **"Once ceramic – always ceramic".**
- Because of the risk of ceramic particles remaining in the tissue, a metal femoral head may no longer be used since there would be a risk of increased wear due to third-body abrasion. Once again, therefore, a ceramic/ceramic* or a ceramic/polyethylene combination must be used.
- If the ceramic femoral head has failed, revision of the femoral stem is absolutely essential. **The only exception is *BIOLOX OPTION* Head System.**

Following the **breakage** of a ceramic insert*, but only if the ceramic femoral head is intact, it is possible:

- To leave the ceramic femoral head in place, but under no circumstances remove it from the stem.
- If the operating surgeon decides, for serious medical reasons, to replace a damaged femoral stem and/or outer shell, the possibility of loosening, fretting corrosion or fracture has to be taken into account even if a new ceramic component is used. When a metal head component is used, loosening, fretting corrosion and third-body wear must also be considered.
- For instructions relating to the revisability of acetabular components, please refer to the device-specific package inserts

*Note: Ceramic inserts articulating with *BIOLOX delta* heads are not approved for use in the United States.

WARNINGS

- Implants are for single use only. Do not reuse.
- Reuse of a single use device that has come into contact with blood, bone, tissue or other body fluids may lead to patient or user injury. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure and transmission of infectious agents.
- Do not use any component if damage is found or caused during setup or insertion.
- Do not use another manufacturer's femoral components with *BIOLOX delta* Ceramic Femoral Heads. The ceramic heads are designed and intended to be used with Zimmer modular femoral stems that have a corresponding 12/14 proximal neck taper.
- Do not use the *BIOLOX delta* Ceramic Femoral Head in revision surgery unless the femoral stem is also being revised
- Using a stem not tested for compatibility with these heads may increase the risk that the head will fracture.
- Do not use the femoral heads for trial reductions. Provisional (trial) implants are available for this purpose.
- Do not use a seating instrument with a metal face to seat the *BIOLOX delta* Ceramic Femoral Head - use a femoral head driver with a plastic face. Contact between ceramic components and any metal instrument may compromise the integrity of the device.
- Do not attempt removal of a head from the tapered neck femoral stem with any instrument other than the specifically designed (12/14) distraction instrument.
- Use only instruments and provisionals specifically designed for use with these devices to help ensure accurate surgical implantation and evaluation of joint function.
- Generally femoral heads with longer neck length may impose higher stresses on the implant or the interfaces (implant-bone for example). Therefore some head stem combination may not be permitted. The package labeling must be checked for warning labels regarding specific restrictions in the use of certain ball heads with particular stems.

- The load-bearing capacity of the implant can be compromised by notching, scratching, or striking the prosthesis, repeated assembly/disassembly of the modular components, or failing to provide metaphyseal support to the implant.
- Improper selection, placement, positioning, and fixation of the implant components may result in unusual stress conditions reducing the service life of the prosthetic implants.
- Do not use this product for other than labeled indications (off-label use).

PRECAUTIONS

- Continued surveillance for new or recurrent sources of infection should be continued as long as the device is in place.
- Do not assemble the mating components without ensuring that the surfaces are free of blood or debris. Failure to ensure that mating surfaces are clean and dry could result in inadequate seating of one component upon the other and subsequent disassembly of the mated components or fracture of the implant.
- Repeated assembly and disassembly of modular components could compromise the critical locking action of the Morse-type tapers. Use the provisional components during trial reductions. Change the components only when clinically necessary.
- Handle heads of femoral hip prostheses with care. Remove the protective covers only prior to implantation.
- Implants must not be machined or altered in any way, unless this is expressly envisaged in the design and in the surgical technique.
- The *BIOLOX delta* Ceramic Femoral Heads have not been evaluated for safety and compatibility in the MR environment. The *BIOLOX delta* Ceramic Femoral Heads have not been tested for heating or migration in the MR environment.

ADVERSE EFFECTS

The following adverse effects have been reported:

- Disassembly of modular components
- Wear
- Inflammatory reactions and osteolysis
- Loosening
- Fracture of the ceramic head
- Noise (ceramic pairings only)

STERILIZATION

- Gamma irradiation is indicated by the “Sterile-R” symbol on the labeling. These devices remain sterile as long as the package integrity has not been violated.
- Inspect each package prior to use and do not use the component if any seal or cavity is damaged or breached or if the expiration date has been exceeded.
- Once opened, the component must be used immediately or discarded.
- If the packaging is damaged or the sterility expiration date has been reached, the implants must be returned to the manufacturer. (Not applicable for the USA.)

BIOLOX delta **Ceramic Femoral Heads should not be resterilized by any method.**

STORAGE AND HANDLING

- Implants must be stored unopened in their original packaging.
- Protective caps or other protective devices must not be removed until immediately before use.
- Implants, implant parts and instruments that can no longer be used may be returned to the manufacturer for proper disposal free of charge. (Not applicable for the USA).

PATIENT COUNSELING INFORMATION

Complications and/or failure of prosthetic implants are more likely to occur in patients with unrealistic functional expectations, heavy patients, physically active patients, and/or with patients who fail to follow through with the required rehabilitation program. Physical activity can result in

loosening, wear, and/or fracture of the implant. The prospective implant patient must be counseled about the capabilities of the implant and the impact it will have on his or her lifestyle. The patient must be instructed about all postoperative restrictions, particularly those related to occupational and sports activities and about the possibility that the implant or its components may wear out, fail or need to be replaced. The implant may not last the rest of the patient's life, or any particular length of time. Because prosthetic implants are not as strong, reliable, or durable as natural, healthy tissues/bones, all such devices may need to be replaced at some point.

Avenir® Müller Stem

Surgical Technique

zimmer

Personal Fit. Restored Life.™

Avenir Müller Stem Surgical Technique

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Indications and Contraindications

The wide product range of the *Avenir* stem in its standard and lateralized version allows a large number of indications to be covered.

The *Avenir* Müller stem can be used in almost all cases where there are no contraindications to an uncemented stem.

Indications

- Advanced wear of the joint due to degenerative, post-traumatic or rheumatic diseases.
- Failed previous hip surgery including joint reconstruction (osteotomy),arthrodesis, hemi-arthroplasty or total hip prosthesis (THR)
- Acute traumatic fracture of the femoral head or neck
- Avascular necrosis of the femoral head.

Avenir Müller Stems are for cementless use only.

Contraindications

- Acute, chronic local or systemic infections.
- Severe muscular, neural or vascular diseases that endanger the limbs involved.
- Lack of bony structures proximal or distal to the joint, so that good anchorage of the implant is unlikely or impossible.
- Total or partial absence of the muscular or ligamentous apparatus.
- Any concomitant diseases that can jeopardize the functioning and the success of the implant.
- Allergy to the implanted material, above all to metal (e.g., cobalt, chromium, nickel, etc.).
- Local bone tumours and/or cysts.
- Pregnancy
- Skeletal Immaturity

Templating the Femur

To determine any leg length discrepancy on the x-ray a line should be drawn across the bottom of the ischium (Fig. 1). The distance should then be measured from the lesser trochanter to the drawn reference line.
The measured difference between the two measured sides is the radiographic leg length. As an alternate reference point, the tip of the greater trochanter to the drawn reference line may also be measured.

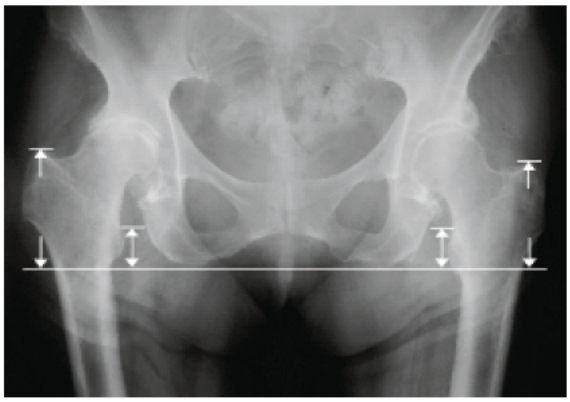


Fig. 1

On the AP X-ray (Fig. 2), select the femoral template size that will best:
1. restore the correct offset
2. equalize the leg length
3. fit the femur.

The femoral template should be in line with the long axis of the femur and in a neutral position. The proximal tip of the prosthesis and the tip of the greater trochanter are suitable reference points for determining the height of the final implant.

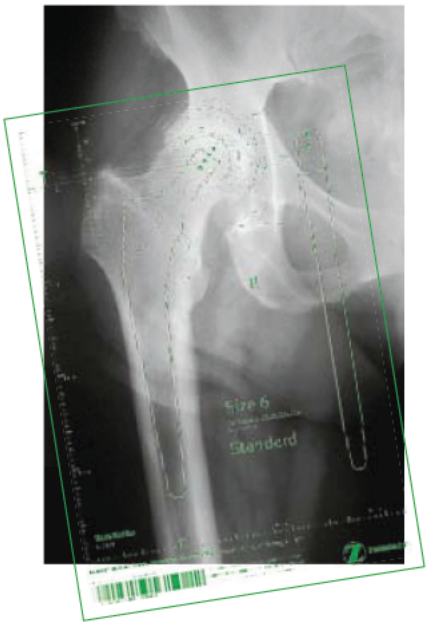
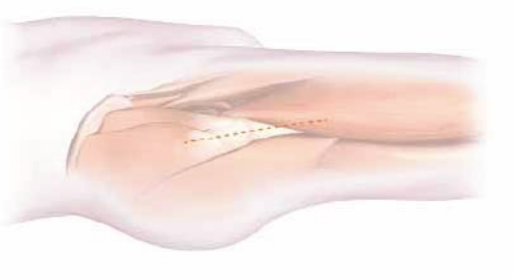


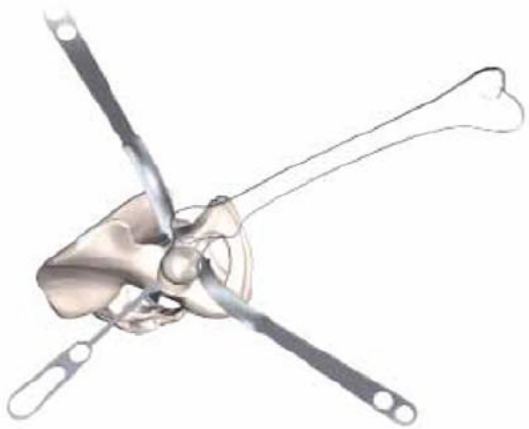
Fig. 2

Surgical Technique

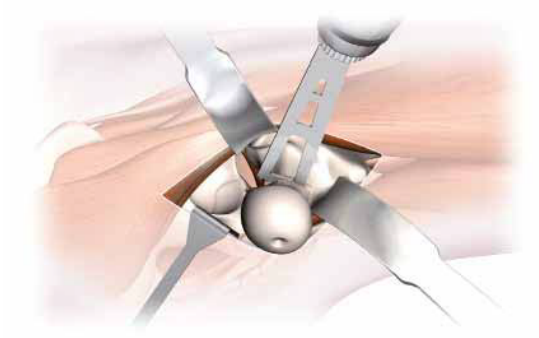
The *Avenir* Müller stem can be implanted via all operative approaches. The individual surgical steps shown below are for a conventional postero-lateral approach with the patient in lateral position (lateral decubitus). However, all technical details can be adapted to other kinds of approaches, including MIS™.



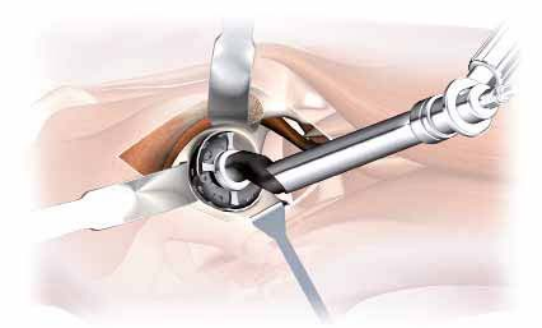
1. The patient is in lateral decubitus.
Incision of the fascia lata and partial dissociation of the femoral insertion of the gluteus maximus.
Insertion of a Hohmann lever under the gluteus medius on the level of the femoral neck.
Exposure and division of the outer rotators and of the dorsal articular capsule.



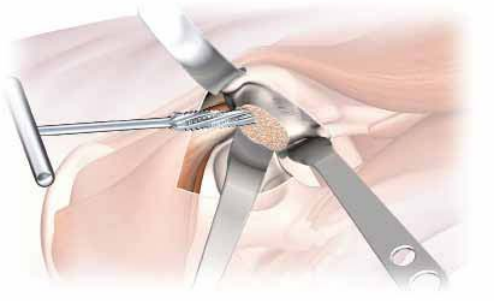
2. Dislocation of the hip by a combined movement with internal rotation, flexion and adduction. Resection of the residual capsule and osteotomy of the femoral neck according to the pre-operative planning. Removal of the femoral head.



3. Insertion of the Hohmann levers and exposure of the acetabulum. Preparation of the acetabulum and implantation of the cup.



4. Preparation of the femoral canal: the medial section of the greater trochanter is carefully prepared with the boxed chisel and the Luer Rongeur. Opening of the medullary cavity using the T-handle awl. In order to avoid varus positioning, the awl should be positioned close to the tip of the greater trochanter.



5. Insertion of the smallest rasp taking into account the correct anteversion and effectively rasping the greater trochanter (without ever touching the cancellous bone in the femoral calcar). Start with the smallest rasp and progress to the predetermined size. The handle must be adapted to the selected approach (e.g. a straight handle for the posterior lateral approach).

6. Once a satisfactory stability is obtained with the rasp that usually matches the planned size, the handle is removed from the rasp.

7. The modular rasp serves as a test prosthesis. The trial neck is positioned onto the rasp either by hand or using the trial neck-holder. The trial head is mounted on the neck.

8. Trial reduction and checking of the leg length, the muscle tension, the range of motion and the stability of the joint. Any differences in length are examined, the head and the trial neck are then removed, the handle is reconnected to the rasp and used for its removal, making space for the insertion of the final implant.

9. The stem is driven into the femur by an impactor until the edge of the hydroxyapatite coating corresponds to the insertion depth of the rasp. Special attention on the anteversion is necessary during the first few centimeters of insertion only, as subsequently the implant positions itself in the implant bed.

Postoperative Treatment

The postoperative treatment depends on the patient and the bone quality. Immediate weight bearing can be allowed in agreement with the orthopedic surgeon and mobilization may be started on the first postoperative day depending on the individual rehabilitation protocol. Crutches should be used until the patient is able to walk safely without limping.

Implants

Avenir® Müller Stem – Standard

Size	REF
1	01.06010.001
2	01.06010.002
3	01.06010.003
4	01.06010.004
5	01.06010.005
6	01.06010.006
7	01.06010.007
8	01.06010.008
9	01.06010.009

Avenir® Müller Stem – Lateral

Size	REF
1	01.06010.101
2	01.06010.102
3	01.06010.103
4	01.06010.104
5	01.06010.105
6	01.06010.106
7	01.06010.107
8	01.06010.108
9	01.06010.109

The range covers 9 standard and 9 lateralized sizes.

The difference beween two sizes (frontal view) varies by 0.9 mm for sizes 1 and 2 and by 2.3 mm for sizes 8 and 9.

This choice of size increments allows a precise insertion of the small sizes which often represent the difficult cases in uncemented hip replacement.

Materials

Stem:
Protasul®-64WF Forged Titanium, aluminum 6 and vanadium 4 alloy ISO 5832-3

Coating:
Layer made of nonalloyed titanium ISO 5832-2 and hydroxyapatite Ca5(OH)(PO4)3 – ISO 13779-2

Avenir Müller Stem – Standard

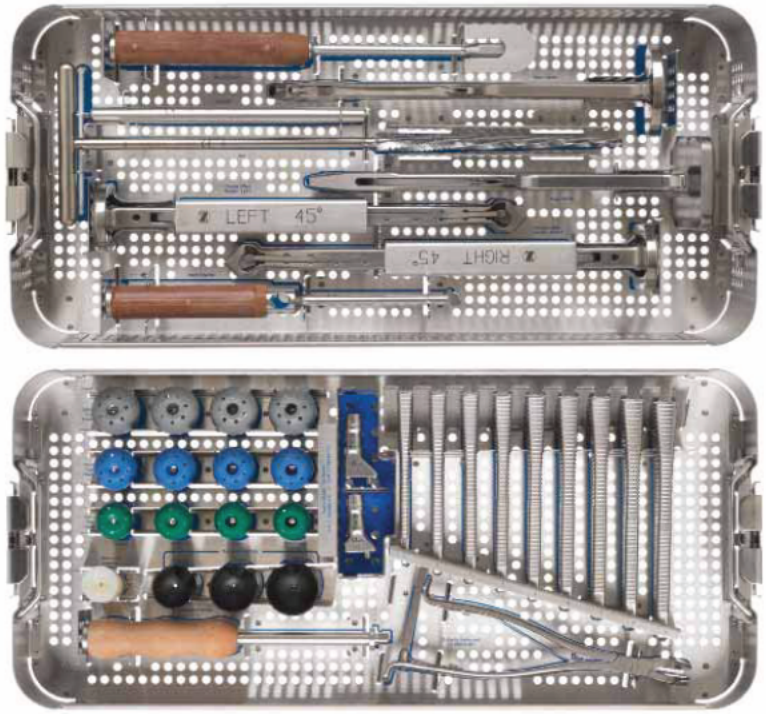
Size	Length neck (mm)	Offset (mm)	Length of the stem (mm)
1	54.79	38.74	129
2	55.40	39.17	135
3	56.11	39.68	141
4	56.88	40.22	147
5	57.85	40.91	153
6	58.91	41.66	159
7	60.18	42.55	165
8	61.75	43.66	171
9	62.99	44.54	177

Avenir Müller Stem – Lateral

Size	Length neck (mm)	Offset (mm)	Length of the stem (mm)
1	63.28	44.75	129
2	63.88	45.17	135
3	64.59	45.67	141
4	65.37	46.22	147
5	66.33	46.90	153
6	67.39	47.65	159
7	68.66	48.55	165
8	70.23	49.66	171
9	71.48	50.54	177

OUTSIDE USA

Instruments with Trunnion connection

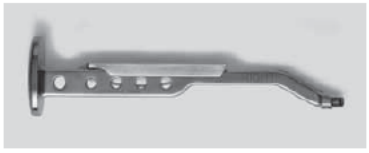


Avenir® Müller instrument tray (complete)
REF
ZS01.06010.903

Avenir® Müller base instrument tray (empty)
REF
00-6300-004-00

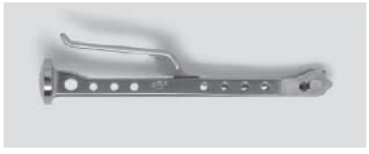
Avenir® Müller insert tray for instruments with Trunnion connection (empty)
REF
00-6300-005-00

Standard tray cover
REF
00-5900-099-00

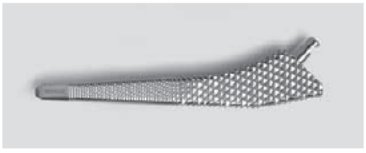


MIS Double Offset Rasp Handle

	REF
Left	00-7712-035-01
Right	00-7712-035-02



Straight Rasp Handle 45°
REF
00-7712-050-60



Avenir® Müller modular rasp

Size	REF
1	01.06620.001
2	01.06620.002
3	01.06620.003
4	01.06620.004
5	01.06620.005
6	01.06620.006
7	01.06620.007
8	01.06620.008
9	01.06620.009

Avenir® Müller MIS modular trial neck, standard
REF
01.06520.000

Avenir® Müller MIS modular trial neck, lateral
REF
01.06520.100

Upon request

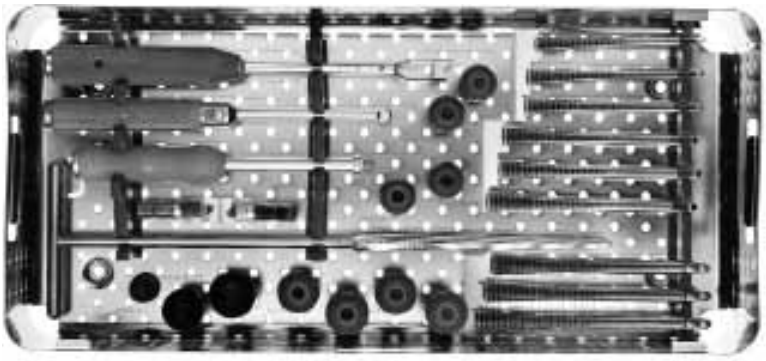
MIS A/S Double Offset Rasp Handle 45°

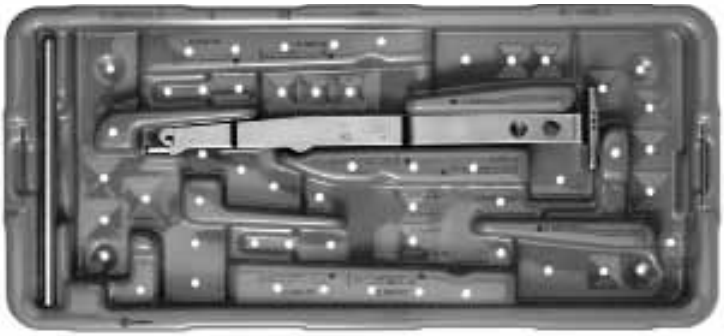
	REF
Left	00-7808-035-01
Right	00-7808-035-02

Trial head 12/14

∅ mm	Size	REF
28	S	6896
28	M	6897
28	L	6898
28	XL	01.01519.808
32	S	6836
32	M	6837
32	L	6838
32	XL	01.01519.208
36	S	01.01519.635
36	M	01.01519.636
36	L	01.01519.637
36	XL	01.01519.638

Instruments with Alloclassic® Zweymüller®/CLS® Spotorno® connection type



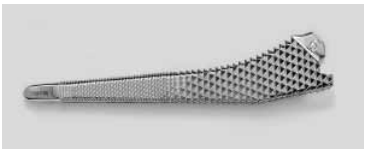


Avenir® Müller instrument tray (complete)
REF ZS01.06010.902

Avenir® Müller tray base (empty)
REF 01.06010.910

Avenir® Müller instrument tray for MIS handles (empty)
REF 01.06010.911

Standard tray cover
REF 01.00029.031



Avenir® Müller modular rasp

Size	REF
1	01.06610.001
2	01.06610.002
3	01.06610.003
4	01.06610.004
5	01.06610.005
6	01.06610.006
7	01.06610.007
8	01.06610.008
9	01.06610.009

Avenir® Müller MIS modular trial neck, standard
REF 01.06510.000

Avenir® Müller modular trial neck, lateral
REF 01.06510.100

Straight handle for modular rasps
REF 01.00001.001

Upon request

MIS Double offset rasp handle with strike plate right
REF 01.00001.002

MIS Double offset rasp handle with strike plate left
REF 01.00001.003

General instruments (available with both instruments connection types)

Long bar

REF
70.00.01

Stem impactor

REF
01.06310.004

Repositioning lever

REF
75.11.00-02

Repositioning top

∅ mm	REF
28	78.00.38-28
32	78.00.38-32
36	78.00.38-36

Ball-Head Impactor Attachment

REF
78.00.38

Trial head 12/14

∅ mm	Größe	REF
28	S	01.01559.128
28	M	01.01559.228
28	L	01.01559.328
28	XL	01.01559.428

Trial head 12/14

∅ mm	Größe	REF
32	S	01.01559.132
32	M	01.01559.232
32	L	01.01559.332
32	XL	01.01559.432

Trial head 12/14

∅ mm	Größe	REF
36	S	01.01559.136
36	M	01.01559.236
36	L	01.01559.336
36	XL	01.01559.436

Extended awl

REF
70.08.89

Boxed chisel

REF
72.13.02-10

Upon request

Extractor with small sliding hammer

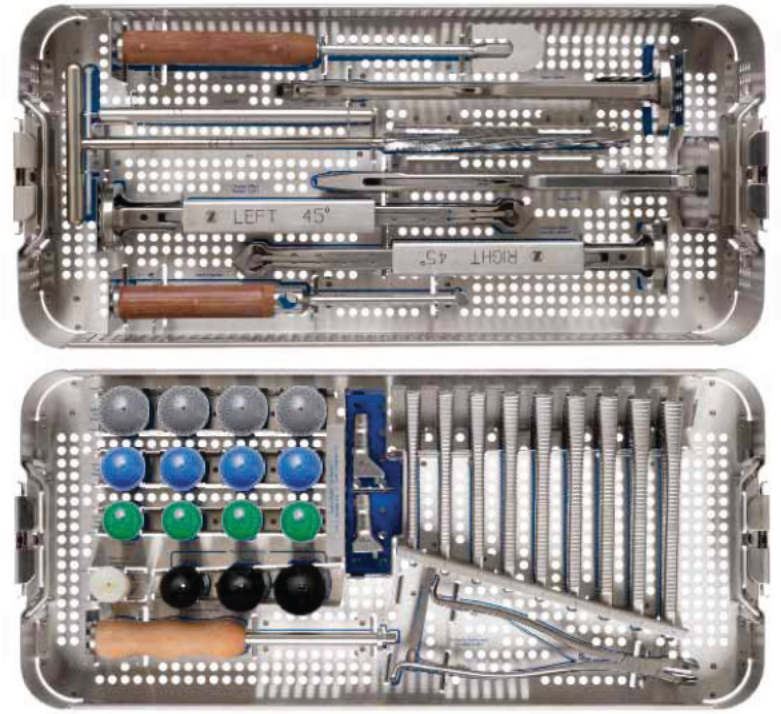
REF
01.06808.300

Trial neck holder

REF
01.06510.001

FOR US MARKET ONLY

Instruments



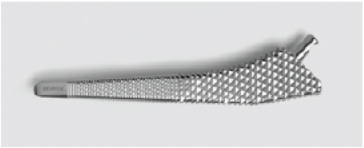
Avenir® Müller instrument tray (complete)
REF
KT-AVNR-0903

Avenir® Müller base instrument tray (empty)
REF
00-6300-004-00

Avenir® Müller insert tray for instruments with Trunnion connection (empty)
REF
00-6300-005-00

Standard tray cover
REF
00-5900-099-00

Straight Rasp Handle 45°
REF
00-7712-050-60



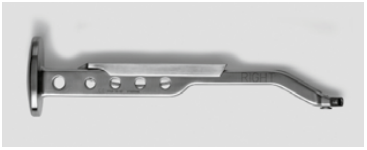
Avenir® Müller modular rasp

Size	REF
1	01.06620.001
2	01.06620.002
3	01.06620.003
4	01.06620.004
5	01.06620.005
6	01.06620.006
7	01.06620.007
8	01.06620.008
9	01.06620.009

Avenir® Müller MIS modular trial neck, standard
REF
01.06520.000

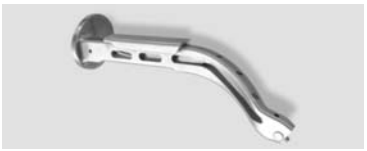
Avenir® Müller MIS modular trial neck, lateral
REF
01.06520.100

Upon request



MIS Double Offset Rasp Handle

	REF
Left	00-7712-035-01
Right	00-7712-035-02



MIS A/S Double Offset Rasp Handle 45°

	REF
Left	00-7808-035-01
Right	00-7808-035-02

General instruments

Long bar

REF
70.00.01

Stem impactor

REF
01.06310.004

Repositioning lever

REF
75.11.00-02

Repositioning top

∅ mm	REF
28	78.00.38-28
32	78.00.38-32
36	78.00.38-36

Ball-Head Impactor Attachment

REF
78.00.38

Femoral head provisionals

Size	Quantity	REF
28 mm (–3.5)	1	00-7895-028-01
28 mm (+0)	1	00-7895-028-02
28 mm (+3.5)	1	00-7895-028-03
28 mm (+7.0)	1	00-7803-028-14
28 mm (+10.5)	1	00-7895-028-05
32 mm (–3.5)	1	00-7895-032-01
32 mm (+0)	1	00-7895-032-02
32 mm (+3.5)	1	00-7895-032-03
32 mm (+7.0)	1	00-7803-032-14
32 mm (+10.5)	1	00-7895-032-05
36 mm (–3.5)	1	00-7895-036-01
36 mm (+0)	1	00-7895-036-02
36 mm (+3.5)	1	00-7895-036-03
36 mm (+7.0)	1	00-7895-036-04
36 mm (+10.5)	1	00-7895-036-05

Extended awl

REF
70.08.89

Boxed chisel

REF
72.13.02-10

Upon request

Extractor with small sliding hammer

REF
01.06808.300

Trial neck holder

REF
01.06510.001

Disclaimer

This documentation is intended exclusively for physicians and is not intended for laypersons.
Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part.

Please refer to the package inserts for important product information, including, but not limited to, contraindications, warnings, precautions, and adverse effects.

Contact your Zimmer representative or visit us at www.zimmer.com

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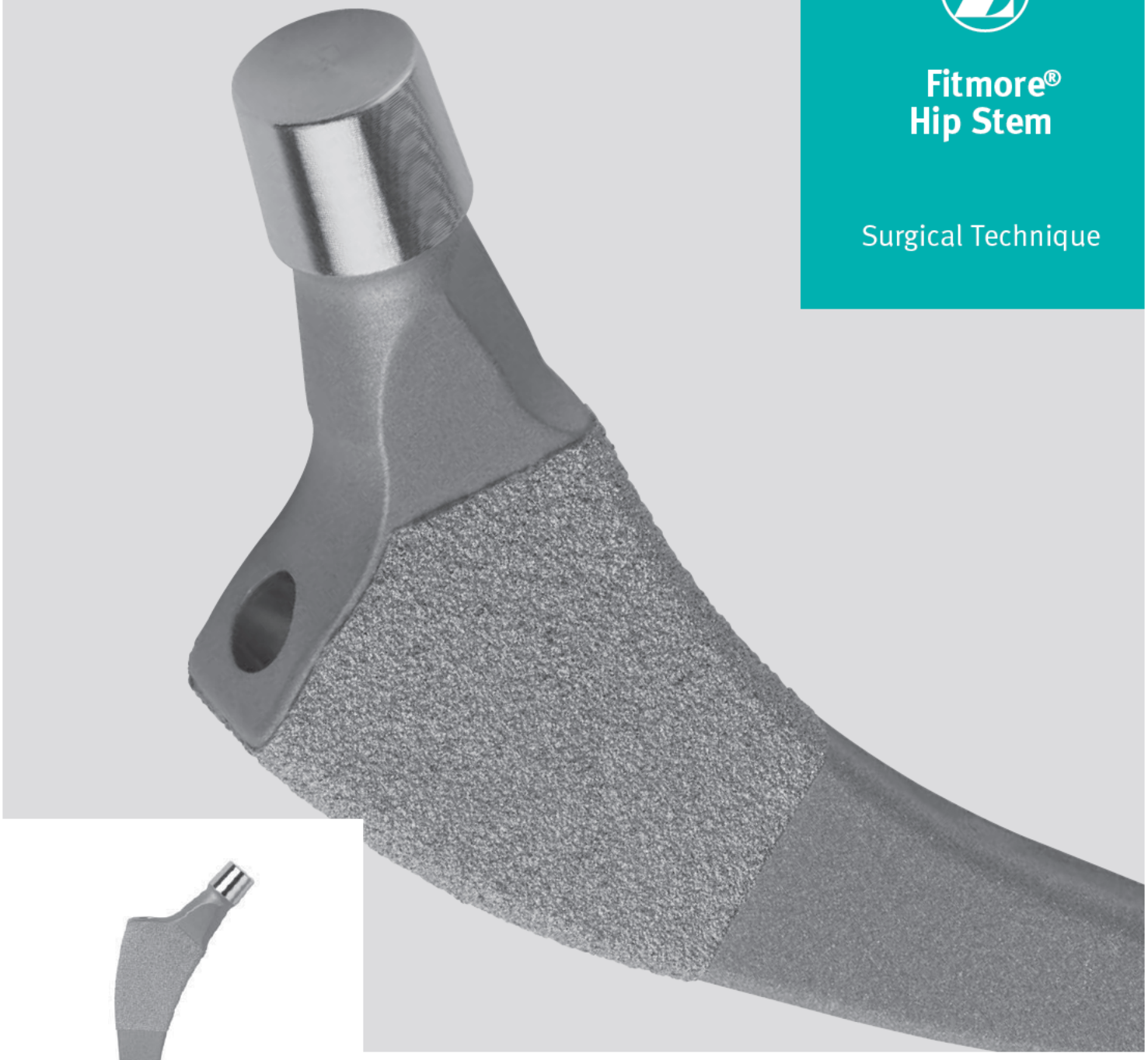
Personal Fit. Renewed Life.™

Lit. No. 06.01340.012 – Ed. 2012-Rev ZHUB

DRAFT

Fitmore® Hip Stem

Surgical Technique



zimmer

Surgical Technique Fitmore Hip Stem

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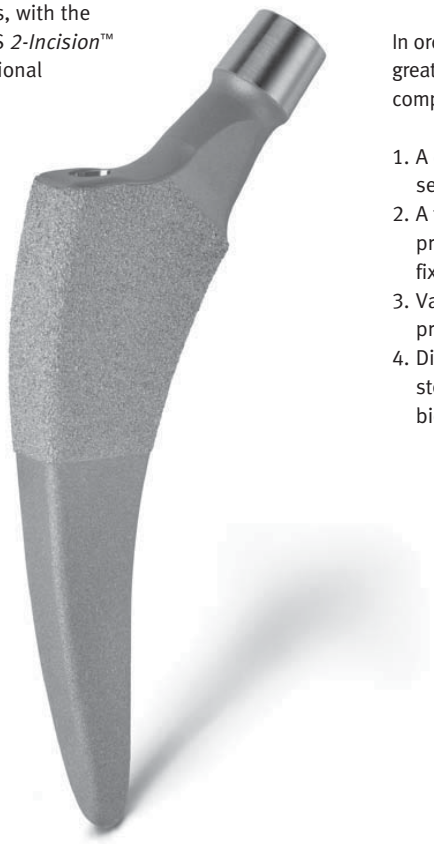
Introduction

The *Fitmore* Hip Stem is a curved uncemented stem with a trapezoidal cross-section, which is coated proximally with Ti-VPS (Titanium Vacuum Plasma Spray) and rough-blasted distally.

The stem system is comprised of 3 stem families A, B and C (family B with two offsets), in order to cover different anatomies.

The anchorage is mainly metaphyseal, in the intertrochanteric region. The rasps and the corresponding implants are not inserted straight into the femoral canal, but rather along the calcar, so that the area of the greater trochanter and, therefore, the insertion of the gluteal muscles can be preserved.

The *Fitmore* Hip Stem is compatible with all *Zimmer*® MIS approaches, with the exception of the *Zimmer* MIS *2-Incision*™ approach, and with all traditional approaches.



The Offset Options

The *Fitmore* Hip Stem offers a wide range of offset options to address a variety of anatomic offsets among individuals. Biomechanical characteristics such as the femoral offset and the leg length can be restored while achieving soft tissue balance around the hip joint.

The same surgical technique is used for implantation of the *Fitmore* Hip Stem family A, family B, family B-Extended and family C.

In most cases, the B families will be the appropriate choice because they fit in most femora and offer the possibility to accommodate a bigger offset (B and B-Extended options). The A family might be more suitable for hips with a small offset, whereas varus hips with long necks may be better treated with C family stems.

In order to preserve bone stock of the greater trochanter and to be MIS compatible the *Fitmore* Hip Stem offers:

1. A curved shape and trapezoidal cross-section for maximum rotational stability
2. A three-dimensional wedge shape and proximal Ti-VPS coating for press-fit fixation
3. Various medial curves to optimize proximal fit
4. Different offsets independent from stem size to accurately restore joint biomechanics

Indications

- This femoral stem is for total or hemi hip arthroplasty and is indicated for the following conditions: Patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis and inflammatory degenerative joint disease (IJD), e.g., rheumatoid arthritis; those patients with failed previous surgery where pain, deformity, or dysfunction persists; revision of previously failed hip arthroplasty

- Total hip replacements may be considered for younger patients if any unequivocal indiction outweighs the risks associated with the age of the patient and modified demands regarding activity and hip joint loading are assured. This includes severely crippled patients with multiple joint involvement, for whom an immediate need of hip mobility leads to an expectation of significant improvement in the quality of their lives

- This stem is for uncemented use

Contraindications

- Patient's physical conditions that would eliminate or tend to eliminate adequate implant support or prevent the use of an appropriately sized implant, e. g., previous surgery, insufficient quality or quantity of bone resulting from conditions such as cancer or congenital dislocation, metabolic bone disease of the upper femur or pelvis, femoral osteotomy revision, girdlestone revision, osteoporosis, osteomyelitis, neuromuscular compromise or vascular deficiency in the affected limb in sufficient degree to render the procedure unjustifiable (e. g., absence of musculoligamentous supporting structures, joint neuropathy) or other conditions that may lead to inadequate skeletal fixation

- Active infection of the hip, old or remote infection. This may be an absolute or relative contraindication. Every effort should be undertaken to rule out preoperative infection in a patient with suspicious symptoms, such as a history of, or when there are signs of, local inflammation, abscesses, fever, increased blood sedimentation rate, evidence of rapid joint destruction or bone resorption

- Allergy to the implanted material, above all to metal (e. g. cobalt, chromium, nickel, etc.)

- Local bone tumors and/or cysts

- Pregnancy

Preoperative Planning

It is important that the preoperative planning is made with the necessary accuracy and that the individual steps of the operation are followed exactly.

Although X-ray quality may vary, a carefully planned total hip replacement helps to minimize intraoperative complications.

The Primary Objectives of Preoperative Planning are to

1. Determine preoperative leg length
2. Determine acetabular component size and position
3. Choose the family of the *Fitmore* Hip Stem by restoring offset, center of rotation and by matching the medial contour of the stem with the calcar arch
4. Determine femoral component size, position and fit

In addition, preoperative planning will assist in identifying bone deformities and potential problems that might require special instrumentation during surgery. In the event that adverse bone conditions are present, it is recommended to have a C-arm ready in the operating room in order to assess the implant position intraoperatively.

Positioning for X-rays

For the AP X-ray of the pelvis, both femurs should be rotated internally until both patellae point straight anteriorly, to be able to assess the femoral neck length and offset. An axial view may also be helpful in determining implant size and version of the femur.

Considerations

- In a proper X-ray, it is possible to draw a continuous line from the femoral neck to the greater trochanter
- In external rotation contracture, it may be helpful to use the contralateral hip for planning

Templating

There are four basic steps

- Determination of the position and orientation of the acetabular component
- Choice of the right family of the *Fitmore* hip stem
- Restoration of the leg length
- Choice the right size of the *Fitmore* Hip Stem

Templating the Acetabulum

The primary objective of templating the acetabulum is to estimate the size of the acetabular component. Preoperative determination of the correct acetabular component size requires an X-ray of the affected hip in both AP and lateral views. The initial templating should start with the AP X-ray. Furthermore, component position with respect to inclination and anteversion of the cup is planned while achieving sufficient bony cup coverage. Finally, the amount of osteophytes necessary to remove to avoid impingement is estimated.

Templating the Femur

The primary objective of templating the femur is to choose the appropriate family and size of the stem. It requires an X-ray of the entire pelvis, which includes the proximal third of the femur.

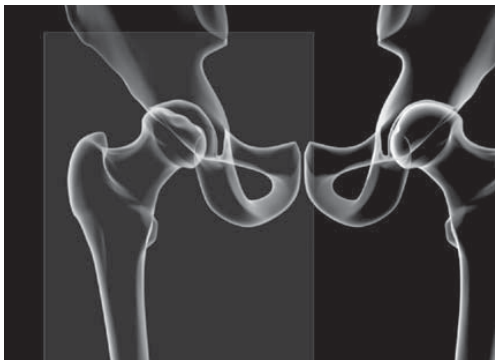
Choice of the appropriate family and size of the stem: Three different families (A, B, C) of the *Fitmore* Hip Stem are shown on the overview template. With this template the most suitable family is determined by restoring anatomical offset and by confirming that the medial curve of this stem follows closely the inner line of the cortex in the calcar region when the stem is in axis with the femoral canal. After choosing the correct stem family with the help of the overview template, the appropriate size is selected using the family-specific templates. The width of the medullary canal determines the body size.

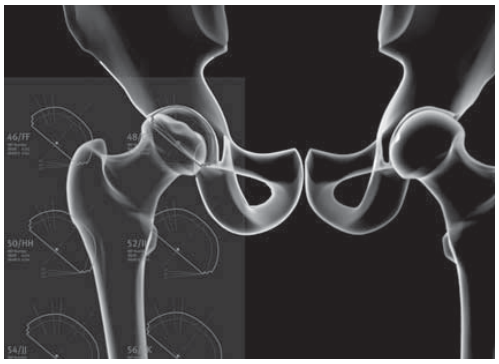
Planning Steps

The preoperative planning determines the correct position and size of the acetabular and femoral component. The correct positioning of the acetabular and femoral components is mandatory in order to ensure optimal component fixation and restore hip biomechanics.

Acetabular Component

The cup templates are placed on the X-ray with the acetabular component in approximately 40 to 45 degrees of inclination. Several sizes are assessed to determine which acetabular component will provide the optimal fit with maximum coverage. The anatomical center of rotation of the femoral head should be reproduced by the position of the acetabular component. The component that meets these requirements is selected. The tracing paper is placed on the X-ray and the template. The contour of the hemipelvis and the chosen cup are drawn on the tracing paper. Then the paper is removed.

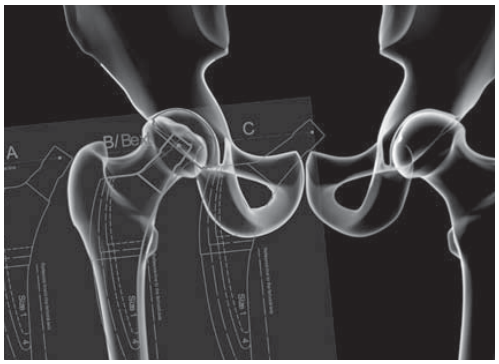


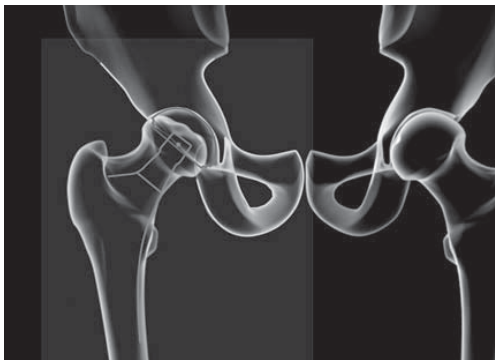


Determination of the Stem Family

Place the overview template on the pelvis X-ray. In the overview template, the three stem families are displayed with their smallest and biggest sizes. The correct family is chosen primarily based on the correct offset.

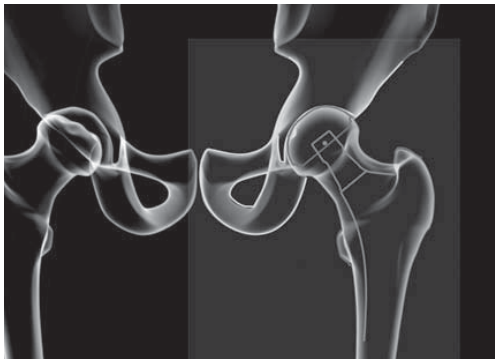
To choose the correct stem family, position the overview template of the family that seems most appropriate into the medullary canal so that the reference line of the femoral axis is parallel to the femur and that the medial contour of the prosthesis is aligned with the cortex. Now move the template up- or downward until the centers of rotation of the cup and the chosen stem family are in line (with the reference center line). If these centers overlap the selected stem family reproduces the offset correctly and you will continue your planning with this stem family. If the centers do not overlap, repeat the procedure with the other families until one family fits correctly representing the family of choice. Trace the medial outline of the selected stem family on the tracing paper.



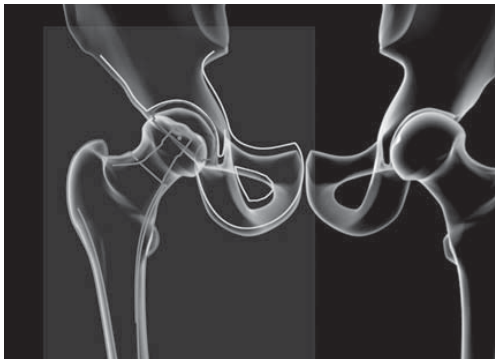


Equalizing Leg Length

Place the tracing paper on the opposite side with the cup and the medial contour of the stem aligned to the femur. The tips of the greater and lesser trochanters are drawn as reference for leg length.

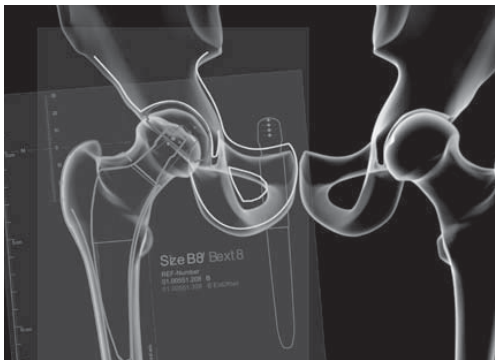


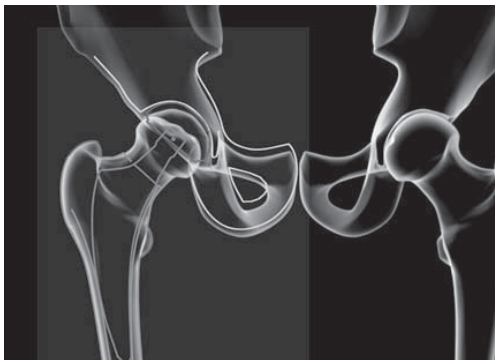
Place the tracing paper again on the side to be operated. The drawn trochanters are placed in line with the trochanters of the side to be operated which automatically equalizes leg length in the planning. Be aware that the positioning of the pelvis on the tracing paper will reflect changes in leg lenth and may not be aligned with the x-ray during the remaining steps. The inner and outer contours of the femur are outlined.



Determination of the Size

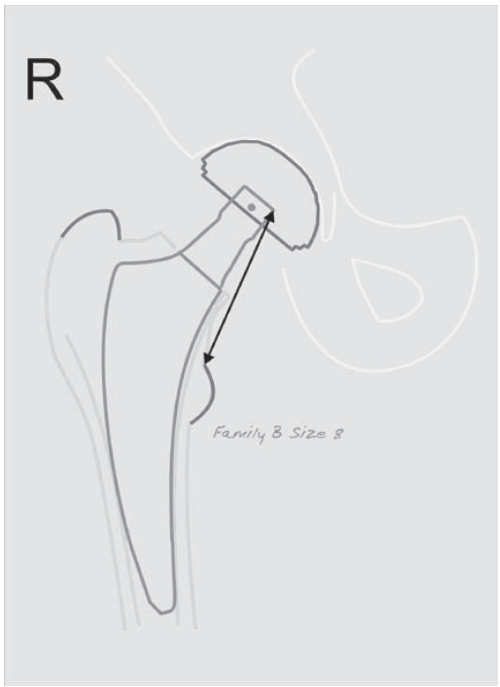
Take the sizing templates of the selected stem family, place its medial contour accurately on the previously drawn contour and increase the size starting with size one until the stem fills the medullary canal, i.e. the lateral side of the stem touches the lateral cortex. It is very important that the axis of the stem shown on the template is parallel to the femoral axis. The stem that fits best completes the drawing of the contour of the optimal stem on the tracing paper.





Final Result

The distance between the proximal end of the stem taper and the lesser trochanter is measured and written down. Other reference marks may be used depending on the individual technique and can be measured as well, for example the distance between the tip of the greater trochanter and the shoulder of the prosthesis. Finally, all necessary information about the patient and the prosthetic components is written down.

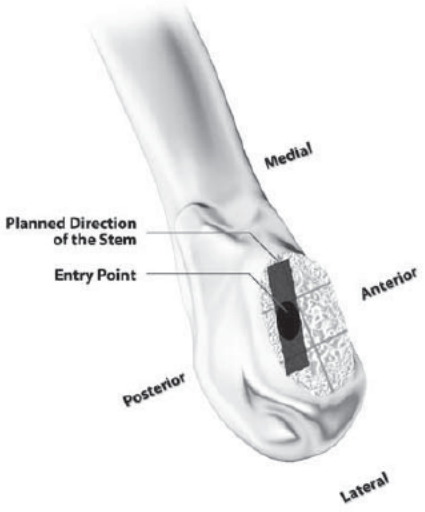


Surgical Technique

This surgical technique may be adapted to the surgeon's specific approach. The following description of the surgical technique starts with the osteotomy of the femoral neck.

Osteotomy of the Femoral Neck

The *Fitmore* Hip Stem instrument set simplifies the surgery and allows a well-targeted and efficient operating procedure. The osteotomy typically starts at the base of the femoral neck and is inclined by 45°. Depending on the planning and the individual anatomy the osteotomy may vary in height.



Preparation of the Femoral Canal

The femoral canal is entered by opening the medullary canal with a starter instrument (curved chisel or curved hand rasp) which enters into the resection surface on the posterior side, in the middle third, and should be in line with the axis of the femur.

It is recommended to direct the entry point towards the medullary canal following the axis of the femur. This will ensure the correct introduction of the starter instrument (curved hand rasp or curved chisel) and the subsequent starter rasp. The starter instrument should only be inserted and not twisted in the cancellous bone. Care must be taken to preserve as much bone as possible. **The use of an awl is not recommended.**

Prepare the femoral canal by first using the starter rasp to enter the medullary canal.

Start with the smallest rasp size of the stem family chosen in the preoperative planning. The insertion of the first rasp will determine the anteversion of the subsequent rasps and the final implant.

The femoral canal is prepared, using rasps of increasing size, until maximum stability is obtained usually with the preoperatively determined stem size. If the medial fit of the rasp is not adequate, i.e. there is no cortical contact in the calcar region, one should consider switching from stem family A to B or from stem family B to C. In this case it is recommended to start rasping two sizes smaller than the last rasp size used.

Example: If the last rasp used was A8, start again with rasp B6.

It must be taken into consideration that by changing the stem family the offset is also changed. Therefore, the new stem family and the preoperatively planned stem height (to the references chosen on the preoperative planning) need to be reassessed in order to avoid lengthening the leg. In most cases switching families means downsizing one to two sizes within the new stem family.

Tip
If, based on the X-rays, one is not certain which family is best, then start with family A. Then the offset could be increased gradually from stem family A to B and then from B to C, but not directly from A to C. It is only allowed to switch from a smaller offset prosthesis to a bigger, which means from family A to B, or B to C. But do not switch from family A directly to family C. The order A to B and B to C must always be maintained.

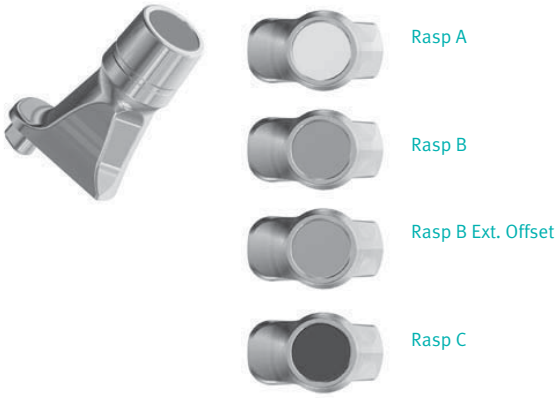
Warning
Never switch from C to B, or C to A, or B to A.

Trial Reduction

Remove the rasp handle and leave the rasp in the femoral canal. Choose the appropriate trial neck following the stem family concept, i.e. A, B, B-Ext. or C. The stem families are indicated on the top of the trial necks. Each rasp family has a specific design coding feature to prevent incorrect rasp body and trial neck mating. Please be aware that only stem family B has two different offset options (B and B-Ext.) on the same rasp body. Once the trial neck is inserted, check the distance between lesser trochanter and taper compared with your preoperative planning. If the distance is according to the preoperative planning the adequate trial head is used for trial reduction.

Joint stability and soft-tissue tension are assessed. This procedure is repeated as necessary, using trial heads of different lengths, until optimal offset, leg length and stability are achieved. A trial reduction should not allow significant push-pull of the joint in full extension. The range of motion is checked to avoid bony and implant impingement as well as instability.

Color Coding and Labeling



Design Coding

Insertion of the Fitmore Hip Stem

After removal of the rasp, the selected stem is inserted and driven in until cortical contact stabilizes the stem.

It is important to adjust the force of the mallet blows to the quality of the bone and to stop immediately when the dull sound (cancellous bone) changes to the sharp sound (cortical bone).

After driving in the stem, the taper protector is removed from the taper and a trial head may be mounted for a final trial head reduction. Once the final range of motion and “shuck” tests are completed, the taper is carefully cleaned and dried. The selected femoral head is mounted with a rotational movement and rotated further with axial force until it is firmly seated. The femoral head is seated with one light mallet blow on the head impactor in an axial direction. After reduction of the joint, the range of motion and the stability of the joint are reassessed throughout the whole range of motion.

Wound closure is carried out according to the specific technique and approach used.

Intraoperative Extraction of the Fitmore Hip Stem

If the stem needs to be removed intraoperatively, only the specific extraction instrument, which protects the taper of the stem, may be used. Slide the extraction instrument over the stem taper. Tighten the exchangeable plastic jaws by closing the lever. Make sure that the instrument is firmly fixed. Remove the stem by hammering back on the extraction instrument.

Important

The extraction instrument must be used exclusively for intraoperative stem extraction. It is not suitable for revision cases. The plastic jaws can be exchanged, if necessary. In case of intraoperative repositioning of the stem the surgeon must verify the integrity of the stem.

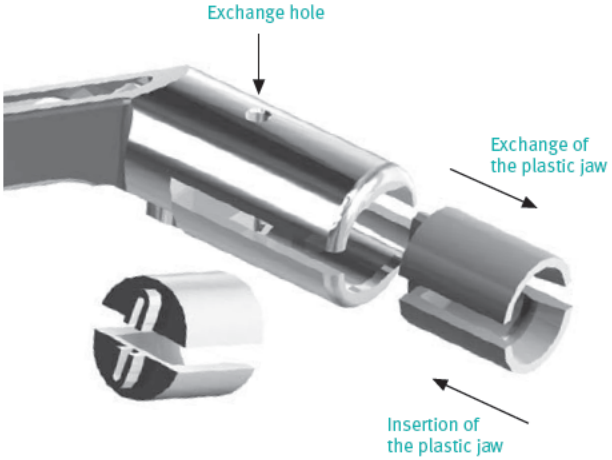
Exchangeable Plastic Jaws

Insertion of the Plastic Jaw

Each plastic jaw is aligned with the slot and snapped in place inside the housing.

Exchange of the Plastic Jaws

A pin is used through the hole to release the plastic jaws.



Postoperative Treatment

The postoperative treatment depends on the patient and the bone quality. Immediate weight bearing can be allowed in agreement with the orthopedic surgeon and mobilization may be started on the first postoperative day depending on the individual rehabilitation protocol. Crutches should be used until the patient is able to walk safely without limping.

Fitmore Hip Stem Implants

Fitmore Hip Stem A, 140°

Details: *Protasul*®-64 Alloy, Taper 12/14, uncemented, STERILE R

Dimensions	Offset	REF			
Size 2	31.50	01.00551.102	Size 9	35.50	01.00551.109
Size 3	32.00	01.00551.103	Size 10	36.25	01.00551.110
Size 4	32.50	01.00551.104	Size 11	37.00	01.00551.111
Size 5	33.00	01.00551.105	Size 12	37.75	01.00551.112
Size 6	33.62	01.00551.106	Size 13	38.50	01.00551.113**
Size 7	34.25	01.00551.107	Size 14	39.25	01.00551.114**
Size 8	34.88	01.00551.108			

Fitmore Hip Stem B, 137°

Details: *Protasul*-64 Alloy, Taper 12/14, uncemented, STERILE R

Dimensions	Offset	REF			
Size 1	37.00	01.00551.201	Size 8	40.88	01.00551.208
Size 2	37.50	01.00551.202	Size 9	41.50	01.00551.209
Size 3	38.00	01.00551.203	Size 10	42.25	01.00551.210
Size 4	38.50	01.00551.204	Size 11	43.00	01.00551.211
Size 5	39.00	01.00551.205	Size 12	43.75	01.00551.212
Size 6	39.62	01.00551.206	Size 13	44.50	01.00551.213**
Size 7	40.25	01.00551.207	Size 14	45.25	01.00551.214**

Fitmore B Ext. Offset, 129°

Details: *Protasul*-64 Alloy, Taper 12/14, uncemented, STERILE R

Dimensions	Offset	REF			
Size 1	44.00	01.00551.301	Size 8	47.88	01.00551.308
Size 2	44.50	01.00551.302	Size 9	48.50	01.00551.309
Size 3	45.00	01.00551.303	Size 10	49.25	01.00551.310
Size 4	45.50	01.00551.304	Size 11	50.00	01.00551.311
Size 5	46.00	01.00551.305	Size 12	50.75	01.00551.312
Size 6	46.62	01.00551.306	Size 13	51.50	01.00551.313**
Size 7	47.25	01.00551.307	Size 14	52.25	01.00551.314**

Fitmore Hip Stem C, 127°

Details: *Protasul*-64 Alloy, Taper 12/14, uncemented, STERILE R

Dimensions	Offset	REF			
Size 1	51.00	01.00551.401	Size 8	54.88	01.00551.408
Size 2	51.50	01.00551.402	Size 9	55.50	01.00551.409
Size 3	52.00	01.00551.403	Size 10	56.25	01.00551.410
Size 4	52.50	01.00551.404	Size 11	57.00	01.00551.411
Size 5	53.00	01.00551.405	Size 12	57.75	01.00551.412
Size 6	53.62	01.00551.406	Size 13	58.50	01.00551.413**
Size 7	54.25	01.00551.407	Size 14	59.25	01.00551.414**

**Available upon request

Fitmore Hip Stem Instruments

Fitmore Rasp Set A

Fitmore Rasp Set A
(complete set with all instruments)

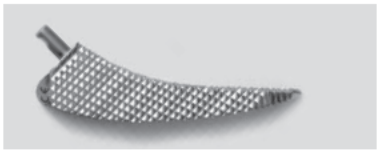
REF
KT-0055-910-01

Fitmore Rasp Tray A

REF
00-7895-061-00

Lid

REF
00-5900-099-00



Fitmore Rasp A

Description	Quantity	REF
Size 1	1	01.00559.101
Size 2	1	01.00559.102
Size 3	1	01.00559.103
Size 4	1	01.00559.104
Size 5	1	01.00559.105
Size 6	1	01.00559.106
Size 7	1	01.00559.107
Size 8	1	01.00559.108
Size 9	1	01.00559.109
Size 10	1	01.00559.110
Size 11	1	01.00559.111
Size 12	1	01.00559.112
Size 13	1	01.00559.113**
Size 14	1	01.00559.114**

Fitmore Trial Neck A, 140°

Quantity	REF
1	01.00559.150

Fitmore Rasp Set B

Fitmore Rasp Set B
(complete set with all instruments)

REF
KT-0055-910-02

Fitmore Rasp Tray B

REF
00-7895-063-00

Lid

REF
00-5900-099-00

Fitmore Rasp B

Description	Quantity	REF
Size 1	1	01.00559.201
Size 2	1	01.00559.202
Size 3	1	01.00559.203
Size 4	1	01.00559.204
Size 5	1	01.00559.205
Size 6	1	01.00559.206
Size 7	1	01.00559.207
Size 8	1	01.00559.208
Size 9	1	01.00559.209
Size 10	1	01.00559.210
Size 11	1	01.00559.211
Size 12	1	01.00559.212
Size 13	1	01.00559.213**
Size 14	1	01.00559.214**

Fitmore Trial Neck B, 137°

Quantity	REF
1	01.00559.250

Fitmore Trial Neck B Ext. Offset, 129°

Quantity	REF
1	01.00559.251

**Available upon request

Fitmore Rasp Set C

Fitmore Rasp Set C
(complete set with all instruments)

REF
KT-0055-910-03

Fitmore Rasp Tray C

REF
00-7895-065-00

Lid

REF
00-5900-099-00

Fitmore Rasp C

Description	Quantity	REF
Size 1	1	01.00559.301
Size 2	1	01.00559.302
Size 3	1	01.00559.303
Size 4	1	01.00559.304
Size 5	1	01.00559.305
Size 6	1	01.00559.306
Size 7	1	01.00559.307
Size 8	1	01.00559.308
Size 9	1	01.00559.309
Size 10	1	01.00559.310
Size 11	1	01.00559.311
Size 12	1	01.00559.312
Size 13	1	01.00559.313**
Size 14	1	01.00559.314**

Fitmore Trial Neck C, 127°

Quantity	REF
1	01.00559.350

**Available upon request

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Fitmore General Instrument Set

Fitmore General Set (complete set with all instruments)

REF
KT-0055-910-00

Fitmore Base Tray General Instruments REF

00-7895-067-00

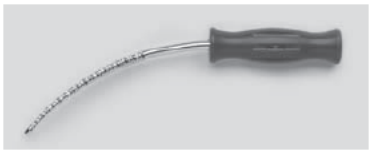
Fitmore Tray Insert General Instruments REF

00-7895-068-00

Lid

REF

00-5900-099-00



Fitmore Curved Hand Rasp

Quantity	REF
1	00-7942-020-00

Fitmore Curved Chisel

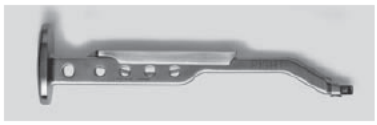
Quantity	REF
1	01.00559.630

Fitmore Starter Rasp

Quantity	REF
1	01.00559.610

Fitmore Intra-Operative Extraction Instrument

Quantity	REF
1	01.00559.620



MIS Double Offset Rasp Handle 45°

Quantity		REF
1	Left	00-7712-035-01
1	Right	00-7712-035-02

Straight Rasp Handle 45°

Quantity	REF
1	00-7712-050-60

Modular Repositioning Handle, short

Quantity	REF
1	75.11.00-02

Repositioning Top

Size	Quantity	REF
28 mm	1	78.00.38-28
32 mm	1	78.00.38-32
36 mm	1	78.00.38-36

Ball-Head Impactor Attachment

Quantity	REF
1	78.00.38

MIS Osteotomy Guide 45°

Quantity	REF
1	00-7806-009-45

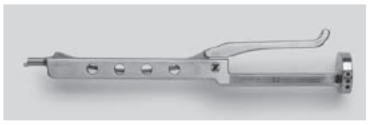
Femoral head provisionals

Size	Quantity	REF
28 mm (–3.5)	1	00-7895-028-01
28 mm (+0)	1	00-7895-028-02
28 mm (+3.5)	1	00-7895-028-03
28 mm (+7.0)	1	00-7803-028-14
28 mm (+10.5)	1	00-7895-028-05
32 mm (–3.5)	1	00-7895-032-01
32 mm (+0)	1	00-7895-032-02
32 mm (+3.5)	1	00-7895-032-03
32 mm (+7.0)	1	00-7803-032-14
32 mm (+10.5)	1	00-7895-032-05
36 mm (–3.5)	1	00-7895-036-01
36 mm (+0)	1	00-7895-036-02
36 mm (+3.5)	1	00-7895-036-03
36 mm (+7.0)	1	00-7895-036-04
36 mm (+10.5)	1	00-7895-036-05

Stem Driver (offset with teardrop-tip)

Quantity	REF
1	00-7712-057-10

Upon Request



Stem Driver (with locking mechanism)

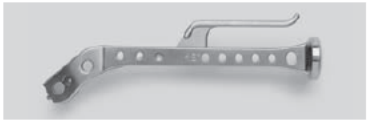
Quantity	REF
1	00-7712-056-00

Calcar Planer

Quantity	Size	REF
1	small	00-7942-023-00
1	large	00-7942-025-00

Stem Driver (straight with teardrop tip)

Quantity	REF
1	00-7712-057-00

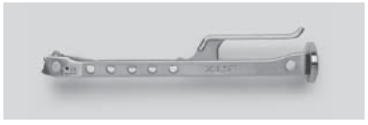


MIS Anterior Offset Rasp Handle 45°

Quantity	REF
1	00-7806-050-00

Plastic Jaws for REF 01.00559.620

Quantity	REF
1	01.00559.621* **



TM Primary Rasp Handle 23.5°

Quantity	REF
1	00-7865-035-20

Stem Driver (straight with round tip)

Quantity	REF
1	00-7712-064-00

* Reusable

**Available upon request

Please refer to package insert for complete product information, including contraindications, warnings, precautions, and adverse effects.

Contact your Zimmer representative or visit us at www.zimmer.com

zimmer

+H1249705510020 01/$081203E09$
97-0551-002-00 0810-H05 4.2ML Printed in USA ©2008 ,2009 Zimmer, Inc.

Exhibit E

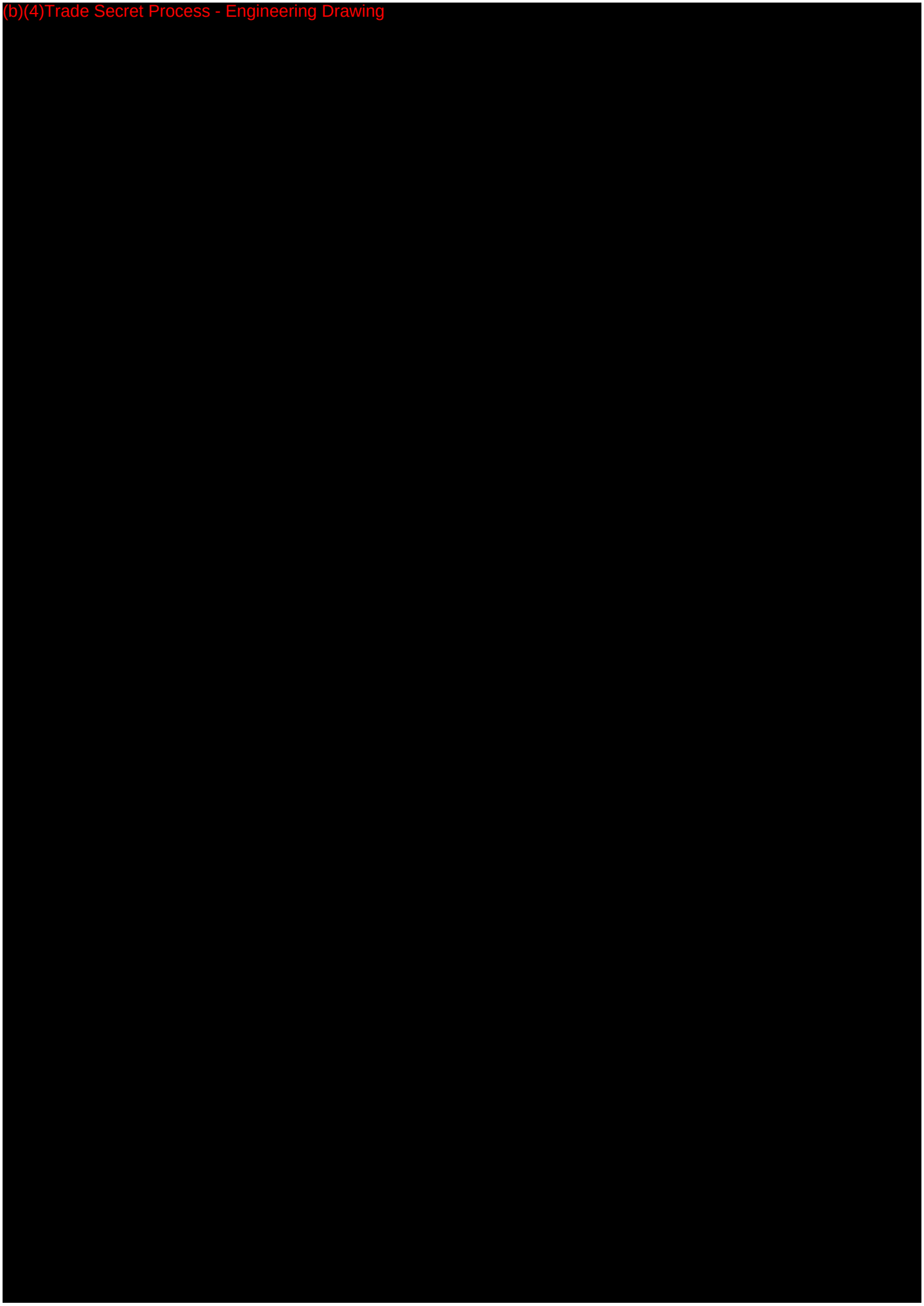
Master File Access

(b)(4)Trade Secret Process - Product Specs

Exhibit F

Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawing


(b)(4)Trade Secret Process - Engineering Drawing

(b)(4) Trade Secret Process - Engineering Drawing

(b)(4)Trade Secret Process - Engineering Drawing

(b)(4)Trade Secret Process - Engineering Drawing

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(b)(4)Trade Secret Process - Engineering Drawing

(b)(4)Trade Secret Process - Engineering Drawing

Exhibit G

Catalog Number Table

BIOLOX *delta* Ceramic Femoral Heads
Implant Catalog Numbers

Description	Catalog Numbers
BIOLOX *delta* Femoral Head, 12/14, 28 x -3.5	00-8775-028-01
BIOLOX *delta* Femoral Head, 12/14, 28 x 0	00-8775-028-02
BIOLOX *delta* Femoral Head, 12/14, 28 x +3.5	00-8775-028-03
BIOLOX *delta* Femoral Head, 12/14, 32 x -3.5	00-8775-032-01
BIOLOX *delta* Femoral Head, 12/14, 32 x 0	00-8775-032-02
BIOLOX *delta* Femoral Head, 12/14, 32 x +3.5	00-8775-032-03
BIOLOX *delta* Femoral Head, 12/14, 32 x +7	00-8775-032-04
BIOLOX *delta* Femoral Head, 12/14, 36 x -3.5	00-8775-036-01
BIOLOX *delta* Femoral Head, 12/14, 36 x 0	00-8775-036-02
BIOLOX *delta* Femoral Head, 12/14, 36 x +3.5	00-8775-036-03
BIOLOX *delta* Femoral Head, 12/14, 36 x +7	00-8775-036-04
BIOLOX *delta* Femoral Head, 12/14, 40 x -3.5	00-8775-040-01
BIOLOX *delta* Femoral Head, 12/14, 40 x 0	00-8775-040-02
BIOLOX *delta* Femoral Head, 12/14, 40 x +3.5	00-8775-040-03
BIOLOX *delta* Femoral Head, 12/14, 40 x +7	00-8775-040-04

Exhibit H

Design Controls

zimmer

Special 510(k)
Device Modification

Declaration of Conformity with Design Controls

BIOLOX® *delta* Ceramic Femoral Heads

To the best of my knowledge, all verification and validation activities, as required by the risk analysis (FMEA), were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.

The manufacturing facility, Zimmer, GmbH, is in conformance with the design control procedure requirements as specified in 21 CFR § 820.30 and the records are available for review.

Matthias Buerger
Vice President of Quality and Regulatory Affairs
Zimmer GmbH

27. Mai. 2013
Date

Design Control Activities Summary

Modification: Addition of BIOLOX *delta* Femoral Heads for use with *Avenir* Müller and *Fitmore (*formerly Zimmer *Porolock* MIS*)* Femoral Stems.

Risk	Verification Activity	Acceptance Criteria	Results of Verification
Insufficient range of motion.	(b)(4)Trade Secret Process		

Risk	Verification Activity	Acceptance Criteria	Results of Verification
	(b)(4)Trade Secret Process		
Unintended disassembly of the femoral head from the femoral stem.			

Risk	Verification Activity	Acceptance Criteria	Results of Verification
	(b)(4)Trade Secret Process		
New head/stem combination negatively impacts ceramic head burst strength.			
New head/stem combination negatively impacts ceramic head fatigue strength.			

Exhibit I

Clinical Trial Certification

See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616, Expiration Date: 2-28-2015

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
Zimmer GmbH

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
Mar 29, 2013

3. ADDRESS *(Number, Street, State, and ZIP Code)*
Sulzer Allee 8
Winterthur, Switzerland CH-8404

4. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) 574-371-8033
(Fax) 574-372-4605

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)

BIOLOX delta Ceramic Femoral Heads

LZO - Prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented

See Catalog Number Table for model numbers

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)
Rebecca Brooks

12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11
(Name) Rebecca M. Brooks
(Title) Sr. Specialist, Regulatory Affairs

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12)*
P.O. Box 708
Warsaw, IN 46581-0708

14. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) 574-371-8033
(Fax) 574-372-4605

15. DATE OF CERTIFICATION
Mar 29, 2013

PSC Publishing Services (301) 443-6740 EF

Exhibit J

Standards Data Report Forms

Form Approved: OMB No. 0910 0120; Expiration Date: 12/31/13

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]

ISO 21535:2007, Non active surgical implants Joint replacement implants Specification requirements for hip joint replacement

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 tests? 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 and 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 for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 21535:2007, Non active surgical implants Joint replacement implants Specification requirements for hip joint replacement

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4 and Annex A	4) Intended Performance	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
Evaluated the range of motion for the worst case constructs for the subject devices.

DESCRIPTION
(b)(4)Trade Secret Process

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

Public reporting burden for this collection of information is estimated to average 1 hour 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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 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.

Form Approved: OMB No. 0910 0120; Expiration Date: 12/31/13

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 F2009 00: Standard Test Method for Determining the Axial Disassembly Force of Taper Connection of Modular Prostheses

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 tests? 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: Draft Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems

[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 and 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 for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ASTM F2009 00: Standard Test Method for Determining the Axial Disassembly Force of Taper Connection of Modular Prostheses

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7.3	Section 7 Procedure	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
Section 7.3 allows for two different assembly methods; Constant Rate Assembly Method or Drop Weight Assembly Method. Assembly method 7.3.1 "Constant Rate Assembly Method" was utilized.

DESCRIPTION
Assembly method 7.3.1 "Constant Rate Assembly Method" was utilized.

JUSTIFICATION
Section 7.3 allows for two different assembly methods.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All other sections	Various All other sections	☒ 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

Public reporting burden for this collection of information is estimated to average 1 hour 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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 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.

* * * COMMUNICATION RESULT REPORT (MAY. 6. 2013 11:30AM) * * *

FAX HEADER 1:
FAX HEADER 2:

TRANSMITTED/STORED : MAY. 6. 2013 11:00AM FILE MODE	OPTION	ADDRESS	RESULT	PAGE
4830 MEMORY TX		915743724605	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 20993-0002

May 1, 2013

Zimmer GmbH
% Zimmer, Incorporated
Ms. Rebecca M. Brooks
Senior Specialist, Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581

Re: K130899
Trade/Device Name: BIOLOX® delta Ceramic Femoral Heads
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: March 29, 2013
Received: April 1, 2013

Dear Ms. Brooks:

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

COVER SHEET MEMORANDUM

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

From: Reviewer Name Tara N. Shepherd

Subject: 510(k) Number K130899

To: The Record

Please list CTS decision code: SE - Substantially Equivalent

☐ Refused to Accept (Note: this is considered the first review cycle. See screening checklist.)

☐ Hold (Additional Information or Telephone Hold)

☒ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.)

Please complete the following for a final clearance decision (i.e, SE, SE with Limitations, etc.)	YES	NO
Indications for Use Page *(Attach IFU)*	X	
510(k) Summary or 510(k) Statement *(Attach Summary or Statement)*	X	
Truthful and Accurate Statement *(Must be present for a Final Decision)*	X	
Is the device Class III?		X
Does firm reference standards? (If yes, please attach Form 3654.)	X	
Is this a combination product?		X
Is this a reprocessed single use device? (See Guidance for Industry and FDA Staff - MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices.)		X
Is this device intended for pediatric use only?		X
Is this a prescription device? (If both prescription & OTC, check both boxes.)	X	
Is clinical data necessary to support the review of this 510(k)?		X
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 was incomplete, then applicant must be contacted to obtain completed form.)		X
Does this device include an Animal Tissue Source?		X
All Pediatric Patients age <= 21		X
Neonate/Newborn (Birth to 28 days)		X
Infant (29 days to < 2 years)		X
Child (2 years to <12 years)		X
Adolescent (12 years to <18 years)		X
Transitional Adolescent A (18 years to <21 years); Special considerations are being given to this group, different from adults age >= 21 (different device design or tesating, different protocol procedures, etc.)		X
Transitional Adolescent B (18 years to <21 years); No special considerations compared to adults >= 21 years)		X

Nanotechnology		X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance)		X

Regulation Number:	888.3353
Class:	II
Product Code:	LZO
Additional Product Codes:	

Digital Signature Concurrence Table
(Not all signatures may be required)

Branch Chief Sign-Off	Elizabeth L. Frank -S 2013.04.30 16:14:23 -04'00'
Division Sign-Off	Erin I. Keith 2013.05.01 14:33:46 -04'00'