



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

May 25, 2016

Stryker Orthopaedics
Ms. Margaret Klippel
Principal Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K153345

Trade/Device Name: Stryker Orthopaedics Total Hip Systems Labeling Update
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis.
Regulatory Class: Class II
Product Code: LPH, KWZ, LZO, MAY, MEH, JDI, KWL, LWJ, KWY, HWC, MBL
Dated: April 20, 2016
Received: April 22, 2016

Dear Ms. Klippel:

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 Parts 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 Industry and Consumer Education 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mark N. Melkerson -S

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): K153345

Device Name: Stryker Orthopaedics Total Hip System Labeling Update

Trident PSL Shell, Trident Tritanium Shell, Trident Hemispherical Shell

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, posttraumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

The Trident shells are intended for cementless fixation within the prepared acetabulum.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K153345

Device Name: Stryker Orthopaedics Total Hip System Labeling Update

Tritanium Acetabular Shell System

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, posttraumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

The Tritanium Acetabular Shell System is intended for cementless use only.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

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NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K153345

Device Name: Stryker Orthopaedics Total Hip System Labeling Update

Accolade II Femoral Stem, Secur-Fit Advanced Femoral Stem, Anato Femoral Stem

The indications for use for total hip arthroplasty with stems include:

- noninflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- rheumatoid arthritis;
- correction of functional deformity;
- revision procedures where other treatments or devices have failed; and,
- nonunions, femoral neck fractures, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Additional indication specific to use of the Femoral Stem with compatible Howmedica Osteonics Constrained Liners:

- When the stem is to be used with compatible Howmedica Osteonics Constrained Liners, the device is intended for use in primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability.

Accolade II, Secur-Fit Advanced and Anato Femoral Stems are intended for cementless use only and are intended for total and hemiarthroplasty.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K153345

Device Name: Stryker Orthopaedics Total Hip System Labeling Update

Exeter[®] V40[™] Hip System (includes Orthinox V40 Femoral heads)

The Exeter[®] V40[™] Hip System is intended for use in total hip replacement. It is intended for cemented use only.

The Exeter[®] Hip is indicated for:

- noninflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- rheumatoid arthritis;
- correction of functional deformity;
- revision procedures where other treatments or devices have failed; and,
- treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

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NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K153345

Device Name: Stryker Orthopaedics Total Hip System Labeling Update

Restoration Anatomic Shell

Indications for Use

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, posttraumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

When used with MDM Liners

- Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.
- Dislocation risks

When used with Constrained Liner:

- The Trident Constrained Acetabular Insert is indicated for use in primary and revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease, or intraoperative instability.

The Restoration® Anatomic Shell is indicated for cementless use only.

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

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NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K153345

Device Name: Stryker Orthopaedics Total Hip System Labeling Update

Omnifit HFX Femoral Stems

Indications:

For use as a Bipolar Hip Replacement:

- Femoral head/neck fractures or non-unions.
- Aseptic necrosis of the femoral head.
- Osteo-, rheumatoid, and post-traumatic arthritis of the hip with minimal acetabular involvement or distortion.

Other Considerations:

- Pathological conditions or age considerations which indicate a more conservative acetabular procedure and an avoidance of the use of bone cement in the acetabulum.
- Salvage of failed total hip arthroplasty.
- Femoral neck fractures.

For use as a Total Hip Replacement:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Clinical circumstances which require an altered femoral resection level due to a proximal fracture, bone loss or calcar lysis.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

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NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K153345

Device Name: Stryker Orthopaedics Total Hip System Labeling Update

Omnifit EON Cemented Femoral Stems

Indications

For use as a Bipolar Hip Replacement:

- Femoral head/neck fractures or non-unions.
- Aseptic necrosis of the femoral head.
- Osteo-, rheumatoid, and post-traumatic arthritis of the hip with minimal acetabular involvement or distortion.

Other Considerations:

- Pathological conditions or age considerations which indicate a more conservative acetabular procedure and an avoidance of the use of bone cement in the acetabulum.
- Salvage of failed total hip arthroplasty.

For use as a Total Hip Replacement:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K153345

Device Name: Stryker Orthopaedics Total Hip System Labeling Update

Secur-Fit Max and Secur-Fit Max Plus Hip Stems

Secur-Fit Max and Secur-Fit Max Plus Hip stems are single use devices and are intended for cementless fixation within the prepared femoral canals of patients requiring hip arthroplasty.

Indications for use as a Total Hip Replacement include:

- noninflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- rheumatoid arthritis;
- correction of functional deformity;
- revision procedures where other treatments or devices have failed; and,
- treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

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NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K153345

Device Name: Stryker Orthopaedics Total Hip System Labeling Update

Accolade C Femoral Stems

The Accolade C Femoral Stems are single-use devices intended for cemented fixation.

Indications for use as a Total Hip Replacement include:

- noninflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- rheumatoid arthritis;
- correction of functional deformity;
- revision procedures where other treatments or devices have failed; and,
- treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K153345

Device Name: Stryker Orthopaedics Total Hip System Labeling Update

Accolade HFx Femoral Stems

- noninflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- rheumatoid arthritis;
- correction of functional deformity;
- revision procedures where other treatments or devices have failed; and,
- treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

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

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NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K153345

Device Name: Stryker Orthopaedics Total Hip System Labeling Update

Accolade TMZF and Accolade TMZF Plus Femoral Stems

The subject hip stem is a single-use device intended for use in total hip replacement. It is intended for the reconstruction of the head and neck of the femoral joint. This hip stem is intended for primary reconstruction of the proximal femur or revision total hip arthroplasty. This device is intended for use with any currently available Howmedica Osteonics acetabular component and V40™ femoral heads that can be mated with a TMZF 5° 40' trunnion.

Indications:

- Cementless primary hip surgery in cases of non-inflammatory degenerative joint disease including osteoarthritis, avascular necrosis, rheumatoid arthritis, and correction of functional deformity.
- Treatment of nonunion, and femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.
- Revision procedures where other treatments or devices have failed.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K153345

Device Name: Stryker Orthopaedics Total Hip System Labeling Update

Restoration Acetabular Wedge Augments

Indications for Use:

The indications for use of the Restoration Acetabular Wedge Augments:

General Indications for Total Hip Replacement Components:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

Indications Specific to the Acetabular Wedges:

- As an alternative to structural allograft in cases of superior and superior/posterior segmental acetabular deficiencies.

Acetabular Augments are intended for cementless use only to the bone interface, and are affixed to the mating cup using bone cement

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K153345

Device Name: Stryker Orthopaedics Total Hip System Labeling Update

Trident AD Acetabular shells

Indications for Use:

The Trident AD Acetabular shells are single use devices. The shell is intended for cemented or cementless fixation within the prepared acetabulum. The Trident AD Acetabular Component System is compatible with any appropriately selected Howmedica Osteonics hip stem/femoral head combination.

Indications:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

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NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K153345

Device Name: Stryker Orthopaedics Total Hip System Labeling Update

Trident T Acetabular shells

Indications for Use:

The Trident Acetabular shells are single-use devices intended for cementless fixation within the prepared acetabulum. They are compatible with Trident polyethylene acetabular bearing insert. If additional fixation is desired, the dome screw holes, if present, have been designed to accept Stryker Orthopaedics 6.5mm or 5.5mm bone screws.

General Indications for Total Hip Replacement Components:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K153345

Device Name: Stryker Orthopaedics Total Hip System Labeling Update

Restoration ADM System, Modular Dual Mobility (MDM) Liner and X3 Acetabular Insert

Indications for Use:

The indications for use of the total hip arthroplasty prostheses include:

- Noninflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;
- Revision procedures where other treatments or devices have failed;
- Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.
- Dislocation risks.

These devices are intended for cementless use only

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 OF
 NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K153345

Device Name: Stryker Orthopaedics Total Hip System Labeling Update

Acetabular Dome Hole Plug

The Dome Hole Plug is an optional device which is available to seal the Howmedica Osteonics Acetabular Shell components during cemented or cementless applications of the acetabular cup. The Howmedica Osteonics Dome Hole Plug is threaded into the dome hole of the shell.

Indications

- In cemented or cementless hip arthroplasty, when an acetabular shell plug is thought to be advantageous.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K153345

Device Name: Stryker Orthopaedics Total Hip System Labeling Update

Trident X3, Trident Crossfire, Trident N2Vac and Trident X3/Crossfire Elevated Rim Acetabular Liners

Indications for Use:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K153345

Device Name: Stryker Orthopaedics Total Hip System Labeling Update

Trident® Constrained Acetabular Insert

Indications for Use:

The Trident® Constrained Acetabular Insert is intended for use as a component of a total hip prosthesis in primary or revision patients at a high risk of hip dislocation due to a history of dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease or intraoperative instability.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K153345

Device Name: Stryker Orthopaedics Total Hip System Labeling Update

BIOLOX Delta Ceramic Heads (C-Taper, Universal Taper, V40 to Universal Taper Adapter Sleeve, and C-Taper to Universal Taper Adapter Sleeve)

The femoral heads are intended for mechanical fixation to their mating hip stems, and can be used in cemented or cementless hip arthroplasty procedures.

For Use as a Total Hip Replacement:

- Painful disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous cup arthroplasty or other procedures
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies in the acetabulum.

For Use as a Bipolar Hip Replacement

- Femoral head/neck fractures or non-unions.
- Aseptic necrosis of the femoral head.
- Osteo-, rheumatoid, and post traumatic arthritis of the hip with minimal acetabular involvement or distortion.
- Pathological considerations or age considerations which indicate a more conservative acetabular procedure and an avoidance of the use of bone cement in the acetabulum.
- Salvage of failed total hip arthroplasty

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K153345

Device Name: Stryker Orthopaedics Total Hip System Labeling Update

V40 BIOLOX Delta Ceramic Heads

The femoral heads are intended for mechanical fixation to their mating hip stems, and can be used in cemented or cementless hip arthroplasty procedures.

For Use as a Total Hip Replacement:

- Painful disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous cup arthroplasty or other procedures
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

For Use as a Bipolar Hip Replacement

- Femoral head/neck fractures or non-unions.
- Aseptic necrosis of the femoral head.
- Osteo-, rheumatoid, and post traumatic arthritis of the hip with minimal acetabular involvement or distortion.

Other considerations:

- Pathological considerations or age considerations which indicate a more conservative acetabular procedure and an avoidance of the use of bone cement in the acetabulum.
- Salvage of failed total hip arthroplasty

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K153345

Device Name: Stryker Orthopaedics Total Hip System Labeling Update

Alumina C-Taper Ceramic Heads

For Use as a Total Hip Replacement:

- Painful disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage vascular necrosis.
- Revision of previous cup arthroplasty or other procedures
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

For Use as a Bipolar Hip Replacement

- Femoral head/neck fractures or non-unions.
- Aseptic necrosis of the femoral head.
- Osteo-, rheumatoid, and post traumatic arthritis of the hip with minimal acetabular involvement or distortion.

Other Considerations:

- Pathological considerations or age considerations which indicate a more conservative acetabular procedure and an avoidance of the use of bone cement in the acetabulum.
- Salvage of failed total hip arthroplasty

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K153345

Device Name: Stryker Orthopaedics Total Hip System Labeling Update

Alumina V40 Ceramic Heads

Indications:

- Painful, disabling joint disease of the hip resulting from: Non-inflammatory degenerative arthritis (osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, pelvic fracture, failed fracture fixation, or diastrophic variant);
- Rheumatoid arthritis
- Correction of functional deformity
- Where bone stock is of poor quality or inadequate for other reconstructive techniques as indicated by the deficiencies of the acetabulum;
- Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques;
- Revision procedures where other treatments or devices have failed.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K153345

Device Name: Stryker Orthopaedics Total Hip System Labeling Update

C-Taper CoCr Femoral Heads (LFIT and non-LFIT)

For use as a Bipolar Hip Replacement:

1. Femoral head/neck fractures or non-unions
2. Aseptic necrosis of the femoral head.
3. Osteo-, rheumatoid, and post-traumatic arthritis of the hip with minimal acetabular involvement or distortion.

Other Considerations:

1. Pathological conditions or age considerations which indicate a more conservative approach to the acetabulum and the avoidance of the use of bone cement in the acetabulum.
2. Salvage of failed total hip arthroplasty.

Indications for use as part of a Total Hip Replacement include:

1. Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
2. Revision of previous unsuccessful femoral head replacement, cup arthroplasty, or other procedure.
3. Clinical management situations where arthrodesis or alternate reconstructive techniques are less likely to achieve satisfactory results.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

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NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K153345

Device Name: Stryker Orthopaedics Total Hip System Labeling Update

V40 CoCr Femoral Heads (LFIT and non-LFIT)

Indications for Use:

- Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis
- Correction of functional deformity
- Revision procedures where other treatments or devices have failed
- Nonunions, femoral neck fractures, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K153345

Device Name: Stryker Orthopaedics Total Hip System Labeling Update

Unitrax Endoprosthesis, Unitrax V40 Adapter Sleeve, Unitrax C-Taper Adapter Sleeve

The Howmedica Osteonics Unitrax Endoprosthesis, and the Unitrax V40 Modular Adaptor sleeves are used as a hemiarthroplasty device for the following indications: femoral neck fractures, idiopathic avascular necrosis, and non-unions. The Unitrax C-taper sleeves are intended for use as a Hemi-Hip Replacement with the following indications: femoral head/neck fractures or non-unions, aseptic necrosis of the femoral head/neck and osteo- and post traumatic arthritis. The patient's acetabular bone stock must be adequate to support articulation with the head of the endoprosthesis.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K153345

Device Name: Stryker Orthopaedics Total Hip System Labeling Update

Universal Distal Spacer

Howmedica Osteonics Corp.'s accessory products for cemented arthroplasty are optional devices intended to assist in the preparation, implantation and/or positioning of a femoral implant intended for cemented application.

Indications

For cement spacers, mid-shaft restrictors and Cement Plugs:

- In cemented hip arthroplasty, when the cement spacer, restrictor and/or plug is thought to be advantageous.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K153345

Device Name: Stryker Orthopaedics Total Hip System Labeling Update

Torx Screws, GAP Plate Screws and Osteolock Bone Screws

- Howmedica Osteonics Torx Cancellous Bone Screws are intended for supplemental fixation of associated Howmedica Osteonics cementless Acetabular Shells or Howmedica Osteonics Tibial Tray components.
- Howmedica Osteonics Osteolock Bone Screws are intended for supplemental fixation of associated cementless Trident Tritanium Multihole Acetabular shells, Restoration Acetabular Augments, and Restoration Anatomic Shell.
- Howmedica Osteonics Restoration GAP Plate Screws are intended only for fixation of the dome and iliac plates of the associated Howmedica Osteonics Restoration GAP Acetabular Shells, Trident Tritanium Hemispherical Multihole Acetabular Shells, Restoration Acetabular Augments and Restoration Anatomic Shell.

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 OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K153345

Device Name: Stryker Orthopaedics Total Hip System Labeling Update

V40 to C-Taper Adapter Sleeve

For Use as a Total Hip Replacement

- Painful disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage vascular necrosis.
- Revision of previous cup arthroplasty or other procedures.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

For Use as a Bipolar Hip Replacement

- Femoral head/neck fractures or non-unions.
- Aseptic necrosis of the femoral head.
- Osteo-, rheumatoid, and post traumatic arthritis of the hip with minimal acetabular involvement or distortion.

Other Considerations:

- Pathological considerations or age considerations which indicate a more conservative acetabular procedure and an avoidance of the use of bone cement in the acetabulum.
- Salvage of failed total hip arthroplasty.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

Sponsor Stryker Orthopaedics
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Date Prepared: May 24, 2016

Proprietary Name: Stryker Orthopaedics Total Hip Systems Labeling Update

Common Name: Artificial Hip Replacement Components –Acetabular and Femoral

**Classification Name:
And References:** Hip joint metal/polymer/metal semi-constrained
porous-coated uncemented prosthesis 21 CFR §888.3358

Hip joint metal/polymer constrained cemented
or uncemented prosthesis 21 CFR §888.3310

Hip joint metal/ceramic/polymer semi-constrained cemented or
nonporous uncemented prosthesis 21 CFR §888.3353

Hip joint metal/polymer semi-constrained cemented prosthesis 21
CFR §888.3350

Hip joint femoral (hemi-hip) metallic cemented or uncemented
prosthesis 21 CFR §888.3360

Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis 21 CFR §888.3390

Smooth or threaded metallic bone fixation fastener 21 CFR §888.3040

Product Codes:

LPH - prosthesis, hip, semi-constrained, metal/polymer, porous uncemented

KWZ - prosthesis, hip, constrained, cemented or uncemented, metal/polymer

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

MEH - prosthesis, hip, semi-constrained, uncemented, metal/polymer, non-porous

JDI - prosthesis, hip, semi-constrained, metal/polymer, cemented

LWJ - prosthesis, hip, semi-constrained, metal/polymer, uncemented

KWL - prosthesis, hip, hemi-, femoral, metal

KWY - prosthesis, hip, hemi-, femoral, metal/polymer, cemented or uncemented

MAY - prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous cemented, osteophilic finish

MBL-prosthesis, hip, semi-constrained, uncemented, metal/polymer, porous

HWC - screw, fixation, bone

Legally Marketed Device to Which Substantial Equivalence is Claimed:

Femoral Stems	
Exeter Femoral Stems (V40 taper – includes Orthinox femoral heads)	K011623, K031730, K110290, K121308
SecurFit Max Femoral Stems SecurFit Max Plus Femoral Stems	K041170, K051738
Accolade C Femoral Stems	K022555, K121308
Accolade TMZF Femoral Stems Accolade TMZF Plus Femoral Stem	K994366, K020572 K994366, K023102
Accolade HFX Femoral Stem	K051741, K121308
Accolade II Femoral Stems	K103479, K120578, K143085
SecurFit Advanced Femoral Stems	K122853, K143085
Anato Femoral Stems	K123604, K143085
OmniFit HFX Femoral Stems	K031744
OmniFit EON Femoral Stems	K983226
Acetabular Shells/Augments/Plug	
Trident Hemispherical Shells (multiple configurations)	K013676, K143085
Titanium Shells (multiple styles)	K081171, K143085

Restoration Anatomic Acetabular Shell	K142462, K151264
Tritanium Multi-Hole Shell	K010170, K143085
Trident AD Acetabular Shell (multiple styles)	K983502
Trident HA PSL Shell (multiple styles)	K983382, K143085
Trident T Shell	K040412
Restoration ADM Acetabular Shell	K072020
Restoration Acetabular Augments	K102019
Acetabular Dome Hole Plug	K920868 K942809
Acetabular Liners	
MDM Liners	K103233
ADM/MDM X3 inserts	K093644
ADM/MDM Duration Inserts, OD 42mm-52mm	K072020
Trident X3 Liners (multiple sizes)	K033716 K061434 K062419
Trident Crossfire Liners (multiple sizes)	K983502 K991952 K021911 K020497
Trident Constrained Liner Trident All Polyethylene Constrained Liner	K061654
Trident 10 degree Constrained Liner	P960047
Trident Liners N2/Vac(multiple sizes)	K983502
Femoral heads and Adapter Sleeves	
BIOLOX Delta Heads (Various sizes, styles)	K052718 K070885 K041940 K051588
Co Cr Heads (various styles/sizes)	K993601 K010757, K022077, K061434 K900836, K993601, K021310 K910988, K061434 K121308
Alumina C-Taper and V40 Heads (various sizes)	K023901, K971409 K003391, K991952
Unitrax Endo Head (38, 40-56, 58, 61) Unitrax V40 Adapter Sleeve Unitrax C-Taper Adapter Sleeve	K902365, K014226 K954077, K992570 K121308
Adapter Sleeves (various styles)	K003379 K051737 K070885
Bone Screws and Distal Spacer	
Torx Screws	K894124

GAP Plate Screws	K943549
Osteolock Bone Screws	K903362
Universal Distal Spacer	K914406

Device Description:

All of the subject devices have been found substantially equivalent in previous premarket indications. The purpose of this submission is to modify the labeling to add MR compatibility to the labeling for the devices indicated above, and to remove a contraindication for selected devices. There have been no changes made to the devices requiring 510(k) clearance – only the labeling is being modified.

Intended Use:

In general, these devices are intended for use in primary or revision hip arthroplasty. Specific indications appear below:

Trident PSL Shell, Trident Titanium Shell, Trident Hemispherical Shell

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, posttraumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

The Trident shells are intended for cementless fixation within the prepared acetabulum.

Titanium Acetabular Shell System

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, posttraumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

The Titanium Acetabular Shell System is intended for cementless use only.

Accolade II Femoral Stem, Secur-Fit Advanced Femoral Stem, Anato Femoral Stem

The indications for use for total hip arthroplasty with stems include:

- noninflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- rheumatoid arthritis;
- correction of functional deformity;
- revision procedures where other treatments or devices have failed; and,

- nonunions, femoral neck fractures, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Additional indication specific to use of the Femoral Stem with compatible Howmedica Osteonics Constrained Liners:

- When the stem is to be used with compatible Howmedica Osteonics Constrained Liners, the device is intended for use in primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability.

Accolade II, Secur-Fit Advanced and Anato Femoral Stems are intended for cementless use only and are intended for total and hemiarthroplasty.

Exeter® V40™ Hip System (includes Orthinox V40 Femoral heads)

The Exeter® V40™ Hip System is intended for use in total hip replacement. It is intended for cemented use only.

The Exeter® Hip is indicated for:

- noninflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- rheumatoid arthritis;
- correction of functional deformity;
- revision procedures where other treatments or devices have failed; and,
- treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Restoration Anatomic Shell

Indications for Use

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, posttraumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

When used with MDM Liners

- Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.
- Dislocation risks

When used with Constrained Liner:

- The Trident Constrained Acetabular Insert is indicated for use in primary and revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease, or intraoperative instability.

The Restoration® Anatomic Shell is indicated for cementless use only.

Omnifit HFX Femoral Stems

Indications:

For use as a Bipolar Hip Replacement:

- Femoral head/neck fractures or non-unions.
- Aseptic necrosis of the femoral head.
- Osteo-, rheumatoid, and post-traumatic arthritis of the hip with minimal acetabular involvement or distortion.

Other Considerations:

- Pathological conditions or age considerations which indicate a more conservative acetabular procedure and an avoidance of the use of bone cement in the acetabulum.
- Salvage of failed total hip arthroplasty.
- Femoral neck fractures.

For use as a Total Hip Replacement:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Clinical circumstances which require an altered femoral resection level due to a proximal fracture, bone loss or calcar lysis.

Omnifit EON Cemented Femoral Stems

Indications

For use as a Bipolar Hip Replacement:

- Femoral head/neck fractures or non-unions.
- Aseptic necrosis of the femoral head.
- Osteo-, rheumatoid, and post-traumatic arthritis of the hip with minimal acetabular involvement or distortion.

Other Considerations:

- Pathological conditions or age considerations which indicate a more conservative acetabular procedure and an avoidance of the use of bone cement in the acetabulum.
- Salvage of failed total hip arthroplasty.

For use as a Total Hip Replacement:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

Secur-Fit Max and Secur-Fit Max Plus Hip Stems

Secur-Fit Max and Secur-Fit Max Plus Hip stems are single use devices and are intended for cementless fixation within the prepared femoral canals of patients requiring hip arthroplasty.

Indications for use as a Total Hip Replacement include:

- noninflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- rheumatoid arthritis;
- correction of functional deformity;
- revision procedures where other treatments or devices have failed; and,
- treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Accolade C Femoral Stems

The Accolade C Femoral Stems are single-use devices intended for cemented fixation.

Indications for use as a Total Hip Replacement include:

- noninflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- rheumatoid arthritis;
- correction of functional deformity;
- revision procedures where other treatments or devices have failed; and,
- treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Accolade HFX Femoral Stems

- noninflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- rheumatoid arthritis;
- correction of functional deformity;
- revision procedures where other treatments or devices have failed; and,
- treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Accolade TMZF and Accolade TMZF Plus Femoral Stems

The subject hip stem is a single-use device intended for use in total hip replacement. It is intended for the reconstruction of the head and neck of the femoral joint. This hip stem is intended for primary reconstruction of the proximal femur or revision total hip arthroplasty. This device is intended for use with any currently available Howmedica Osteonics acetabular component and V40™ femoral heads that can be mated with a TMZF 5° 40' trunnion.

Indications:

- Cementless primary hip surgery in cases of non-inflammatory degenerative joint disease including osteoarthritis, avascular necrosis, rheumatoid arthritis, and correction of functional deformity.

- Treatment of nonunion, and femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.
- Revision procedures where other treatments or devices have failed.

Restoration Acetabular Wedge Augments

The indications for use of the Restoration Acetabular Wedge Augments:

General Indications for Total Hip Replacement Components:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

Indications Specific to the Acetabular Wedges:

- As an alternative to structural allograft in cases of superior and superior/posterior segmental acetabular deficiencies.

Acetabular Augments are intended for cementless use only to the bone interface, and are affixed to the mating cup using bone cement

Trident AD Acetabular shells

The Trident AD Acetabular shells are single use devices. The shell is intended for cemented or cementless fixation within the prepared acetabulum. The Trident AD Acetabular Component System is compatible with any appropriately selected Howmedica Osteonics hip stem/femoral head combination.

Indications:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

Trident T Acetabular shells

The Trident Acetabular shells are single-use devices intended for cementless fixation within the prepared acetabulum. They are compatible with Trident polyethylene acetabular bearing insert. If additional fixation is desired, the dome screw holes, if present, have been designed to accept Stryker Orthopaedics 6.5mm or 5.5mm bone screws.

General Indications for Total Hip Replacement Components:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

Restoration ADM System, Modular Dual Mobility (MDM) Liner and X3 Acetabular Insert

The indications for use of the total hip arthroplasty prostheses include:

- Noninflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;
- Revision procedures where other treatments or devices have failed;
- Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.
- Dislocation risks.

These devices are intended for cementless use only

Acetabular Dome Hole Plug

The Dome Hole Plug is an optional device which is available to seal the Howmedica Osteonics Acetabular Shell components during cemented or cementless applications of the acetabular cup. The Howmedica Osteonics Done Hole Plug is threaded into the dome hole of the shell.

Indications

- In cemented or cementless hip arthroplasty, when an acetabular shell plug is thought to be advantageous.

Trident X3, Trident Crossfire, Trident N2Vac and Trident X3/Crossfire Elevated Rim Acetabular Liners

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

Trident® Constrained Acetabular Insert

The Trident® Constrained Acetabular Insert is intended for use as a component of a total hip prosthesis in primary or revision patients at a high risk of hip dislocation due to a history of dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease or intraoperative instability.

BIOLOX Delta Ceramic Heads (C-Taper, Universal Taper, V40 to Universal Taper Adapter Sleeve, and C-Taper to Universal Taper Adapter Sleeve)

The femoral heads are intended for mechanical fixation to their mating hip stems, and can be used in cemented or cementless hip arthroplasty procedures.

For Use as a Total Hip Replacement:

- Painful disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous cup arthroplasty or other procedures
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies in the acetabulum.

For Use as a Bipolar Hip Replacement

- Femoral head/neck fractures or non-unions.
- Aseptic necrosis of the femoral head.
- Osteo-, rheumatoid, and post traumatic arthritis of the hip with minimal acetabular involvement or distortion.
- Pathological considerations or age considerations which indicate a more conservative acetabular procedure and an avoidance of the use of bone cement in the acetabulum.
- Salvage of failed total hip arthroplasty

V40 BIOLOX Delta Ceramic Heads

The femoral heads are intended for mechanical fixation to their mating hip stems, and can be used in cemented or cementless hip arthroplasty procedures.

For Use as a Total Hip Replacement:

- Painful disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous cup arthroplasty or other procedures
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

For Use as a Bipolar Hip Replacement

- Femoral head/neck fractures or non-unions.
- Aseptic necrosis of the femoral head.
- Osteo-, rheumatoid, and post traumatic arthritis of the hip with minimal acetabular involvement or distortion.

Other considerations:

- Pathological considerations or age considerations which indicate a more conservative acetabular procedure and an avoidance of the use of bone cement in the acetabulum.
- Salvage of failed total hip arthroplasty

Alumina C-Taper Ceramic Heads

For Use as a Total Hip Replacement:

- Painful disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous cup arthroplasty or other procedures
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

For Use as a Bipolar Hip Replacement

- Femoral head/neck fractures or non-unions.
- Aseptic necrosis of the femoral head.
- Osteo-, rheumatoid, and post traumatic arthritis of the hip with minimal acetabular involvement or distortion.

Other Considerations:

- Pathological considerations or age considerations which indicate a more conservative acetabular procedure and an avoidance of the use of bone cement in the acetabulum.
- Salvage of failed total hip arthroplasty

Alumina V40 Ceramic Heads

- Painful, disabling joint disease of the hip resulting from: Non-inflammatory degenerative arthritis (osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, pelvic fracture, failed fracture fixation, or diastrophic variant);
- Rheumatoid arthritis
- Correction of functional deformity
- Where bone stock is of poor quality or inadequate for other reconstructive techniques as indicated by the deficiencies of the acetabulum;
- Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques;
- Revision procedures where other treatments or devices have failed.

C-Taper CoCr Femoral Heads (LFIT and non-LFIT)

For use as a Bipolar Hip Replacement:

1. Femoral head/neck fractures or non-unions
2. Aseptic necrosis of the femoral head.
3. Osteo-, rheumatoid, and post-traumatic arthritis of the hip with minimal acetabular involvement or distortion.

Other Considerations:

1. Pathological conditions or age considerations which indicate a more conservative approach to the acetabulum and the avoidance of the use of bone cement in the acetabulum.
2. Salvage of failed total hip arthroplasty.

Indications for use as part of a Total Hip Replacement include:

1. Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
2. Revision of previous unsuccessful femoral head replacement, cup arthroplasty, or other procedure.

3. Clinical management situations where arthrodesis or alternate reconstructive techniques are less likely to achieve satisfactory results.

V40 CoCr Femoral Heads (LFIT and non-LFIT)

- Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis
- Correction of functional deformity
- Revision procedures where other treatments or devices have failed
- Nonunions, femoral neck fractures, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Unitrax Endoprosthesis, Unitrax V40 Adapter Sleeve, Unitrax C-Taper Adapter Sleeve

- The Howmedica Osteonics Unitrax Endoprosthesis, and the Unitrax V40 Modular Adaptor sleeves are used as a hemiarthroplasty device for the following indications: femoral neck fractures, idiopathic avascular necrosis, and non-unions. The Unitrax C-taper sleeves are intended for use as a Hemi-Hip Replacement with the following indications: femoral head/neck fractures or non-unions, aseptic necrosis of the femoral head/neck and osteo- and post traumatic arthritis. The patient's acetabular bone stock must be adequate to support articulation with the head of the endoprosthesis.

Universal Distal Spacer

Howmedica Osteonics Corp.'s accessory products for cemented arthroplasty are optional devices intended to assist in the preparation, implantation and/or positioning of a femoral implant intended for cemented application.

Indications

For cement spacers, mid-shaft restrictors and Cement Plugs:

- In cemented hip arthroplasty, when the cement spacer, restrictor and/or plug is thought to be advantageous.

Torx Screws, GAP Plate Screws and Osteolock Bone Screws

- Howmedica Osteonics Torx Cancellous Bone Screws are intended for supplemental fixation of associated Howmedica Osteonics cementless Acetabular Shells or Howmedica Osteonics Tibial Tray components.
- Howmedica Osteonics Osteolock Bone Screws are intended for supplemental fixation of associated cementless Trident Tritanium Multihole Acetabular shells, Restoration Acetabular Augments, and Restoration Anatomic Shell.
- Howmedica Osteonics Restoration GAP Plate Screws are intended only for fixation of the dome and iliac plates of the associated Howmedica Osteonics Restoration GAP Acetabular Shells, Trident Tritanium Hemispherical Multihole Acetabular Shells, Restoration Acetabular Augments and Restoration Anatomic Shell.

V40 to C-Taper Adapter Sleeve

For Use as a Total Hip Replacement

- Painful disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage vascular necrosis.
- Revision of previous cup arthroplasty or other procedures.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

For Use as a Bipolar Hip Replacement

- Femoral head/neck fractures or non-unions.
- Aseptic necrosis of the femoral head.
- Osteo-, rheumatoid, and post traumatic arthritis of the hip with minimal acetabular involvement or distortion.

Other Considerations:

- Pathological considerations or age considerations which indicate a more conservative acetabular procedure and an avoidance of the use of bone cement in the acetabulum.
- Salvage of failed total hip arthroplasty.

Summary of Technological Characteristics:

There have been no changes requiring 510(k) clearance to the technological characteristics of the Stryker Total Hip systems as a result of the revision to the labeling. The subject devices have the same design and are manufactured from the same materials as the predicate devices.

Non-Clinical Testing:

The following non-clinical laboratory testing was performed to determine substantial equivalence:

Non-clinical testing as outlined in the FDA guidance document “Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment – Guidance for Industry and FDA Staff”, dated December 11, 2014 was conducted to characterize the compatibility of Stryker Orthopaedics total hip passive implants in the MR environment. FDA draft guidance “Assessment of Radiofrequency-Induced Heating in the Magnetic Resonance (MR) Environment for Multi-Configuration Passive Medical Devices – Draft Guidance for Industry and FDA Staff”, dated June 29, 2015 was also consulted for the heating evaluations performed. Testing was performed according to the standards listed below:

- Magnetically Induced Displacement Force – performed per ASTM F2052-06 and ASTM F2052-14, Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the MR Environment
- Magnetically Induced Torque – performed per ASTM F2213-06 (Reapproved 2011), Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the MR Environment
- Image Artifact – performed per ASTM F2119-07 (Reapproved 2013), Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants

- Heating by RF Fields per ASTM F2182-11a, Standard Test Method for Measurement of Radio Frequency Induced Heating near Passive Implants during MR Imaging

The labeling has been modified to include the MR conditional symbol, and to provide the parameters under which a patient who has the device can be safely scanned. Additionally, for certain devices, a contraindication was removed.

Clinical Testing: Clinical testing was not required as a basis for substantial equivalence.

Conclusion: The Stryker Orthopaedics Hip System devices are substantially equivalent to the predicate devices identified in this premarket notification.

Device comparisons showed that the subject devices have the same intended use, and substantially equivalent design, materials and operational principles to the predicate devices.