Records processed under FOIA Request # 2016-1518; Released by CDRH on 05-23-2016

K050937
page 1 of 2

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

The Trabecular Metal Acetabular Revision Shells

Submitter Name:	Zimmer Trabecular Metal Technology, Inc.
Submitter Address:	80 Commerce Drive Allendale, New Jersey 07401-1600
Contact Person:	Marci Halevi
Phone Number:	(201) 818-1800 ext. 507
Fax Number:	(973) 879-0825
Date Prepared:	April 11, 2005
Device Trade Name:	The Trabecular Metal Acetabular Revision Shell
Device Common Name:	Acetabular revision shells or cages
Classification Number:	21 CFR § 888.3358 and 21 CFR § 888.3350

Substantial Equivalence: **The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without premarket approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.**

Device Description: The Trabecular Metal Acetabular Revision Shell is a modular acetabular reconstructive device (polyethylene liner is cemented to shell) intended for use in primary or revision reconstructive procedures of the acetabulum. The subject Trabecular Metal Acetabular Revision Shell is manufactured from Trabecular Metal porous tantalum. The TM Revision Shell has a Ti-6A1-4V instrument interface ring (ASTM F-136) along its outer perimeter that provides a rigid contact area for the impaction instrument used to implant the device. The Revision Shells are intended for either cementless or cemented fixation to the acetabulum with that allow for optional ancillary fixation to the acetebulum. The screwholes mate with commercially available Zimmer 6.5mm titanium alloy bone screws.

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

510(k) Summary (Continued)

Indications for Use: The Indications for Use of the Trabecular Metal Acetabular Revision Shells are:

- For cemented or cementless use.
- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problem where arthrodesis or alternative reconstruction 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.

Conclusion: The Trabecular Metal Acetabular Revision Shells are substantially equivalent to the identified predicate devices.

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 11 2005

Ms. Marci Halevi
Manager of Regulatory Affairs
Zimmer Trabecular Metal Technology
80 Commerce Drive
Allendale, New Jersey 07401-1600

Re: K050937
Trade/Device Name: Trabecular Metal Acetabular Revision Shells
Regulation Number: 21 CFR 888.3358, 888.3350
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis, Hip joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: LPH, JDI
Dated: April 11, 2005
Received: April 14, 2005

Dear Ms. Halevi:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

Records processed under FOIA Request # 2016-1518; Released by CDRH on 05-23-2016

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

for Miriam Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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

Records processed under FOIA Request # 2016-1518; Released by CDRH on 05-23-2016

510(k) Number (if known): K050937

Device Name: Trabecular Metal Acetabular Revision Shells

Indications For Use:

The Indications for Use of the Trabecular Metal Acetabular Revision Shells are:

- For cemented or cementless use.
- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problem where arthrodesis or alternative reconstruction 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 (Per 21 CFR 801 Subpart D) Yes

AND/OR...

Over-The-Counter Use No

(21 CFR 801 Subpart C)
(Optional Format 09-2004)

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

Concurrence of CDRH; Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K050937

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

Records processed under FOIA Request # 2016-1518; Released by CDRH on 05-23-2016

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 11 2005

Ms. Marci Halevi
Manager of Regulatory Affairs
Zimmer Trabecular Metal Technology
80 Commerce Drive
Allendale, New Jersey 07401-1600

Re: K050937
Trade/Device Name: Trabecular Metal Acetabular Revision Shells
Regulation Number: 21 CFR 888.3358, 888.3350
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis, Hip joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: LPH, JDI
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If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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

Records processed under FOIA Request # 2016-1518; Released by CDRH on 05-23-2016

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Miriam Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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

Records processed under FOIA Request # 2016-1518; Released by CDRH on 05-23-2016

510(k) Number (if known): K050937

Device Name: Trabecular Metal Acetabular Revision Shells

Indications For Use:

The Indications for Use of the Trabecular Metal Acetabular Revision Shells are:

- For cemented or cementless use.
- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problem where arthrodesis or alternative reconstruction 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 (Per 21 CFR 801 Subpart D) Yes AND/OR... Over-The-Counter Use No

(21 CFR 801 Subpart C)
(Optional Format 09-2004)

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

Concurrence of CDRH; Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K050937

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

Records processed under FOIA Request # 2016-1518; Released by CDRH on 05-23-2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

April 14, 2005

ZIMMER TRABECULAR
METAL TECHNOLOGY, INC.
80 COMMERCE DR.
ALLENDALE, NJ 07401
ATTN: MARCI HALEVI

510(k) Number: K050937
Received: 14-APR-2005
Product: TRABECULAR METAL ACETABULAR REVISION SHELLS

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

On May 21, 2004, FDA issued a Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. Please review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

You should be familiar with the regulatory requirements for medical device available at Device Advice http://www.fda.gov/cdrh/devadvice/". If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301)594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

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

Records processed under FOIA Request # 2016-1518; Released by CDRH on 05-23-2016

K050637

zimmer

80 Commerce Drive
Allendale, NJ 07401-1600
201 818-1800

FDA/CDRH/OCE/PMO

2005 APR 14 A 11: 39

Delivered via Fed-ex

April 11, 2005

RECEIVED

Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

Attention: Division of Orthopedic Devices, Office of Device Evaluation

Re: Special 510(k) Premarket Notification: Trabecular Metal Acetabular Revision Shells

To Whom It May Concern:

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (the Act), as amended, and in conformance with Title 21 of the Code of Federal Regulations, Part 807, Subpart E, this 510(k) Premarket Notification is being submitted to advise the Food and Drug Administration (FDA) of intent to commercially distribute the following medical devices: Trabecular Metal Acetabular Revision Shells.

The subject of this 510(k) Premarket Notification is a line extension and two minor modifications to the cleared Revision Shells/Cages. There are no changes to the Indications for Use, Intended Use or Fundamental Technology of cited predicated devices.

A Premarket Submission Cover Sheet has been included, and was prepared according to the Center for Devices and Radiological Health's Instructions for the Cover Sheet.

The Medical Device User Fee Cover Sheet is attached to this letter. The Payment Identification Number for this submission is (b)(4) [redacted].

The descriptions and information contained in this 510(k) Premarket Notification constitute confidential commercial information. We request that the FDA regard the contents of this submission as subject to protection from public disclosure to the extent permitted by the provisions of 21 CFR § 20.61.

We understand that the submission to the United States Government of false information is prohibited by Title 18 of the United States Code (USC) Part 1001, and Title 21 of the USC Part 331(q).

5/C33

OR II

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

Records processed under FOIA Request # 2016-1518; Released by CDRH on 05-23-2016

80 Commerce Drive
Allendale, NJ 07401-1600
201 818-1800

Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

April 11, 2005

Continued . . .

Please note that all trademarks, registered trademarks, and product names used within this 510(k) Premarket Notification are the property of their respective owners.

We hope that the information provided in this 510(k) Premarket Notification will support a determination of substantial equivalence to the other cited acetabular augments that have also received marketing clearance from the FDA.

If you have any questions or require additional information, please contact me at your convenience.

Sincerely,

Marci Halevi

Marci Halevi
Manager of Regulatory Affairs
Zimmer Trabecular Metal Technology

Enclosures: 510(k) Premarket Notification (submitted in duplicate)

cc: Robert Cohen

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

Records processed under FOIA Request # 2016-1518; Released by CDRH on 05-23-2016

Form Approved: OMB No. 0910-511 Expiration Date: August 31, 2005. 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) [redacted]
Write the Payment Identification number on your check.

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louise, MO 63195-6733. (*Note: In no case should payment be submitted with the application.*)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfer.
6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

-->

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

ZIMMER TRABECULAR METAL TECHNOLOGY
80 COMMERCE DRIVE
ALLENDALE NJ 07401
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
223116090

2. CONTACT NAME
Marci Halevi

2.1 E-MAIL ADDRESS
marci.halevi@zimmer.com

2.2 TELEPHONE NUMBER (include Area code)
201-818-1800 507

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
201-818-1800 507

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/dc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)

3.1 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: null

5. 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, parents, and partner firms
[ ] This biologics application is submitted under secion 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

6. 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

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005)
(b)(4) [redacted] 31-Mar-2005

14

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

Records processed under FOIA Request # 2016-1518; Released by CDRH on 05-23-2016

SPECIAL 510(k) PREMARKET NOTIFICATION

TRABECULAR METAL™ ACETABULAR REVISION SHELLS

Submitted by:
Zimmer Trabecular Metal Technology, Inc.
80 Commerce Drive
Allendale, New Jersey 07401-1600

Date Prepared: April 11, 2005

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

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510(k) Premarket Notification from Zimmer Trabecular Metal Technology, Inc.

Trabecular Metal Acetabular Revision Shells

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

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510(k) Premarket Notification from Zimmer Trabecular Metal Technology

Trabecular Metal Acetabular Augment System

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Appendix B	***Surgical Protocol***
Appendix C	***Engineering Drawings***
Appendix D	***Table of Contents for Master File*** (b)(4)

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

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SECTION 1

GENERAL INFORMATION

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

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SECTION 1.1

PREMARKET SUBMISSION COVER SHEET

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

Records processed under FOIA Request # 2016-1518; Released by CDRH on 05-23-2016

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
Premarket Submission Cover Sheet

Date of Submission: 04/11/2005

FDA Document Number:

Section A **Type of Submission**

- [x] 510(k) - Special
- [ ] 510(k) Add'l Information
- [ ] IDE
- [ ] IDE Amendment
- [ ] IDE Supplement
- [ ] IDE Report
- [ ] PMA
- [ ] PMA Amendment
- [ ] PMA Report
- [ ] PMA Supplement - Regular
- [ ] PMA Supplement - Special
- [ ] PMA Supplement - 30 day
- [ ] PMA Supplement - Panel Track

Section B1 **Reason for Submission - 510(k)s Only**

- [ ] New device
- [ ] Additional or *expanded* Indications
- [ ] Change in technology, *design*, materials, or manufacturing process
- [x] Other reason (specify): Line Extension to cleared Trabecular Metal Revision Shells

Section B2 **Reason for Submission - PMAs Only**

- [ ] New device
- [ ] Withdrawal
- [ ] Additional or expanded indications
- [ ] Licensing agreement
- [ ] Change in design, component, or specification:
  - [ ] Software
  - [ ] Color Additive
  - [ ] Other (specify below)
- [ ] Location change:
  - [ ] Manufacturer
  - [ ] Sterilizer
  - [ ] Packager
  - [ ] Distributor
- [ ] Labeling change:
  - [ ] Indications
  - [ ] Instructions
  - [ ] Performance Characteristics
  - [ ] Shelf life
  - [ ] Trade name
  - [ ] Other (specify below)
- [ ] Process change:
  - [ ] Manufacturer
  - [ ] Sterilizer
  - [ ] Packager
- [ ] Report submission:
  - [ ] Annual or periodic
  - [ ] Post-approval study
  - [ ] Adverse reaction
  - [ ] Device defect
  - [ ] Amendment
- [ ] Change in ownership
- [ ] Change in correspondent
- [ ] Response to FDA correspondence (specify below)
  - [ ] Request for applicant hold
  - [ ] Request for removal of applicant hold
  - [ ] Request for extension
  - [ ] Request to remove or add manufacturing site
- [ ] Other reason (specify):

Section B3 **Reason for Submission - IDEs Only**

- [ ] New device
- [ ] Addition of institution
- [ ] Expansion / extension of study
- [ ] IRB certification
- [ ] Request hearing
- [ ] Request waiver
- [ ] Termination of study
- [ ] Withdrawal of application
- [ ] Unanticipated adverse effect
- [ ] Change in:
  - [ ] Correspondent
  - [ ] Design
  - [ ] Informed consent
  - [ ] Manufacturer
  - [ ] Manufacturing
  - [ ] Protocol - feasibility
  - [ ] Protocol - other
  - [ ] Sponsor
- [ ] 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
- [ ] Emergency use:
  - [ ] Notification of emergency use
  - [ ] Additional information
- [ ] Report submission:
  - [ ] Current investigator
  - [ ] Annual progress
  - [ ] Site waiver limit reached
  - [ ] Final
- [ ] IOL submissions only:
  - [ ] Change in IOL style
  - [ ] Request for protocol waiver
- [ ] Other reason (specify):

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

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	FDA Document Number:

Section C **Product Classification**

Product code: LPH & JDI	CFR Section: 21 CFR § 888.3350/3358	Device class:
Classification panel: Orthopedic Devices		☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Section D **Information on 510(k) Submissions**

Product codes of devices to which substantial equivalence is claimed:

1. LPH	2. JDI	3.	4.	5.	6.
7.	8.	9.	10.	11.	12.

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

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1. K983837	1. The Hedrocel Acetabular Cage System	1. Zimmer TMT - former Implex Corp.
2. K001759	2. Implex Hedrocel Revision Cup	2. Zimmer TMT - former Implex Corp.
3.	3.	3.
4.	4.	4.
5.	5.	5.
6.	6.	6.

Section E **Product Information - Applicable to All Applications**

Common or usual name or classification name: Acetabular Cages

Trade or proprietary or model name	Model number
1 *Trabecular Metal Acetabular Revision Shells*	1 7000-XX-20 (Zimmer) 02-210-00XX3 (former Implex)
2	2
3	3

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

K983837	K001759				

Data included in submission: ☐ Laboratory testing ☐ Animal trials ☐ Human trials

Indications (from labeling): The Indications for Use of the Trabecular Metal Acetabular Revision Shells are:

- For cemented or cementless use.
- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problem where arthrodesis or alternative reconstruction 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.

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

		FDA Document Number:	
Section F	**Manufacturing / Packaging / Sterilization Sites**		
☒ Original ☐ Add ☐ Delete	FDA establishment registration number: 2247737	☒ Manufacturer ☐ Contract sterilizer ☐ Contract manufacturer ☐ Repackager / relabeler	
Company / Institution name: Zimmer			
Division name (if applicable): N/A		Phone number (include area code): (201) 818-1800	
Street address: 80 Commerce Drive		FAX number (include area code): (201) 995-9722	
City: Allendale	State / Province: New Jersey	Country: USA	ZIP / Postal Code: 07401-1600
Contact name: Marci Halevi			
Contact title: Manager of Regulatory Affairs			
☒ Original	FDA establishment registration	☐ Manufacturer	☒ Contract sterilizer

(b)(4)

[redacted]

☐ Original ☐ Add ☐ Delete	FDA establishment registration number:	☐ Manufacturer ☐ Contract sterilizer ☐ Contract manufacturer ☐ Repackager / relabeler	
Company / Institution name:			
Division name (if applicable):		Phone number (include area code):	
Street address:		FAX number (include area code):	
City:	State / Province:	Country:	ZIP / Postal Code:
Contact name:			
Contact title:			

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

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		FDA Document Number:	
Section G		**Applicant or Sponsor**	
Company / Institution name: Zimmer Trabecular Metal Technology, Inc.			FDA establishment registration number: 2247737
Division name (if applicable): N/A			Phone number (include area code): (201) 818-1800
Street address: 80 Commerce Drive			FAX number (include area code): (201) 995-9722
City: Allendale	State / Province: New Jersey	Country: USA	ZIP / Postal Code: 07401-1600
Signature: Marci Halevi			
Name: Marci Halevi			
Title: Manager of Regulatory Affairs			
Section H		**Submission correspondent (if different from above)**	
Company / Institution name:			
Division name (if applicable):			Phone number (include area code):
Street address:			FAX number (include area code):
City:	State / Province:	Country:	ZIP / Postal Code:
Contact name:			
Contact title:			

Your voluntary completion of this Premarket Submission Cover Sheet will not affect any FDA decision concerning your submission, but will help FDA's Center for Devices and Radiological Health process your submission more efficiently. The information you provide should apply *only* to a single accompanying submission. Please do not send cover sheets for any previous submissions. See the instructions for additional information on completing the cover sheet. If you have a question concerning completion of the cover sheet, please contact the Division of Small Manufacturers Assistance at (800) 638-2041 or (301) 443-6597.

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

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SECTION 1.2

PREMARKET NOTIFICATION [510(k)] CHECKLIST FOR ACCEPTANCE DECISION

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

Records processed under FOIA Request # 2016-1518; Released by CDRH on 05-23-2016

Premarket Notification [510(k)] Checklist for Acceptance Decision

Date DMC Received _____

Device Trade or Proprietary Name: Trabecular Metal Acetabular Revision Shells

Device Common or Usual Name: Acetabular Revision Shells

Reason for 510(k): Line Extension and minor modifications

Device Classification Name: Hip Joint/Polymer/Metal Semi Constrained Porous Coated, Uncemented Prostheses

Division/Branch: Orthopedic Devices

CFR Section: 21 CFR § 888.3358

Classification Panel: Orthopedic Devices

Class of Device: Class II

Product Code: LPH and JDI

	Yes Present Omission Justified	No Inadequate Omitted	Not Applicable
I. Critical Elements:			
A. Is the product a device?	☒	☐	☐
B. Is the device exempt from 510(k) by regulation or policy?	☐	☒	☐
C. Is device subject to review by CDRH?	☒	☐	☐
D. (i) Are you aware that this device has been the subject of a previous NSE decision?	☐	☒	☐
(ii) If yes, does this new 510(k) address the NSE issue(s) (e.g., performance data)?	☐	☐	☒
E. (i) Are you aware of the submitter being the subject of an integrity investigation? If yes, consult the ODE Integrity Officer.	☐	☒	☐
(ii) Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N- 0332, September 10, 1991.)	☐	☐	☒
F. Does the submission contain the information required under Sections 510(k), 513(f), and 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) and Subpart E of Part 807 in Title 21 of the Code of Federal Regulations?	☒	☐	☐
• Device trade or proprietary name	☒	☐	☐
• Device common or usual name or classification name	☒	☐	☐

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

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Premarket Notification [510(k)] Checklist for Acceptance Decision, Continued

	Yes Present Omission Justified	No Inadequate Omitted	Not Applicable
• Establishment registration number (only applies if establishment is registered)	☒	☐	☐
• Class into which the device is classified under (21 CFR Parts 862 to 892)	☒	☐	☐
• Classification Panel	☒	☐	☐
• Action taken to comply with Section 514 of the Act	☒	☐	☐
• Proposed labels, labeling and advertisements (if available) that describe the device, its intended use, and directions for use (Blue Book Memo #G91-1)	☒	☐	☐
• A 510(k) summary of safety and effectiveness or a 510(k) statement that safety and effectiveness information will be made available to any person upon request	☒	☐	☐
• For class III devices only, a class III certification and a class III summary	☐	☐	☒
• Photographs of the device	☒	☐	☐
• Engineering drawings for the device with dimensions and tolerances	☒	☐	☐
• The marketed device to which equivalence is claimed including labeling and description of the device	☒	☐	☐
• Statement of similarities and/or differences with marketed device	☒	☐	☐
• Data to show consequences and effects of a modified device	☐	☐	☒

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

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Premarket Notification [510(k)] Checklist for Acceptance Decision, Continued

	Yes Present Omission Justified	No Inadequate Omitted	Not Applicable
II. Additional Information that is necessary under 21 CFR 807.87(h):			
A. Submitter's name and address	☒	☐	☐
B. Contact person, telephone number and fax number	☒	☐	☐
C. Representative/Consultant, if applicable	☐	☐	☒
D. Table of Contents with pagination	☒	☐	☐
E. Address of manufacturing facility/facilities and, if appropriate, sterilization site(s)	☒	☐	☐
III. Additional Information that may be necessary under 21 CFR 807.87(h):			
A. Comparison table of the new device to marketed device	☒	☐	☐
B. Action taken to comply with voluntary standards	☒	☐	☐
C. Performance data			
marketed device			
bench testing	☐	☐	☒
animal testing	☐	☐	☒
clinical data	☐	☐	☒
new device			
bench testing	☐	☐	☒
animal testing	☐	☐	☒
clinical data	☐	☐	☒

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

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		Yes Present Omission Justified	No Inadequate Omitted	Not Applicable
D.	Sterilization information	☒	☐	☐
E.	Software information	☐	☐	☒
F.	Hardware information	☐	☐	☒
G.	Is this device subject to issues that have been addressed in specific guidance document(s)?	☐	☐	☒
	If yes, continue review with checklist from any appropriate guidance documents. A Checklist has been omitted because there is no change in device materials, technology, performance, intended use, or manufacturing processes	☐	☐	☒
	If no, is 510(k) sufficiently complete to allow substantive review?	☐	☐	☒
H.	Other (specify)	☐	☐	☒

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

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SECTION 1.3

DECLARATION OF CONFORMITY

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

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SPECIAL 510(K) PREMARKET NOTIFICATION

DECLARATION OF CONFORMITY

I, Marci Halevi, Manager of Regulatory Affairs, certify that the development of the Trabecular Metal Acetabular Revision Shells has been conducted in accordance with 21 CFR 820.30.

Accordingly, all verification and validation activities were determined and performed by the designated individual(s), and the results demonstrated that the predetermined acceptance criteria were met. The Device Risk Analysis is included within this 510(k) application.

Also, the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.230.

Finally, I certify that such records will be made available to the Food and Drug Administration for review as required.

Marci Halevi

Marci Halevi
Manager of Regulatory Affairs

April, 11, 2005

Date

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

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SECTION 1.4

MANUFACTURERS' CERTIFICATION

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

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MANUFACTURERS' CERTIFICATION

I, Marci Halevi, in my capacity Manager of Regulatory Affairs at Zimmer Trabecular Metal Technology, Inc. certify the following:

- That Zimmer will evaluate any product modification that may significantly affect the safety or efficacy of an orthopaedic system comprised of Zimmer Trabecular Metal Technology components.

- That Zimmer will not implement a modification to a device without prior review by Zimmer's Research & Development and Regulatory Affairs Departments.

- That Zimmer will evaluate the effect of such changes on safety and efficacy in accordance with FDA Office of Device Evaluation Memorandum 510(k) Memorandum #K97-1, Deciding When to Submit a 510(k) for a Change to an Existing Device, and will obtain marketing clearance, if appropriate, prior to marketing the modified device.

Marci Halevi

Marci Halevi
Manager of Regulatory Affairs

April 11, 2005
Date

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

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SECTION 1.5

DESCRIPTION OF CHANGES AND VALIDATION/VERIFICATION ACTIVITIES

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

The changes to the cleared Trabecular Metal Acetabular Shells are as follows:

Change	Risk	Verification Activity	Acceptance Criteria	Results of Verification
(b)(4) [redacted]				

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

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SECTION 1.6

RISK ANALYSIS

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 35

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IMPLANT RISK ANALYSIS

Trabecular Metal Acetabular Revision Shell

(b)(4) Rev (b)(4)

Product Catalog Numbers and Description:

Catalog Number	Description
02-210-00404	TM Revision Shell, 40mm
02-210-00424	TM Revision Shell, 42mm
02-210-00444	TM Revision Shell, 44mm
02-210-00464	TM Revision Shell, 46mm
02-210-00484	TM Revision Shell, 48mm
02-210-00504	TM Revision Shell, 50mm
02-210-00524	TM Revision Shell, 52mm
02-210-00544	TM Revision Shell, 54mm
02-210-00564	TM Revision Shell, 56mm
02-210-00584	TM Revision Shell, 58mm
02-210-00604	TM Revision Shell, 60mm
02-210-00624	TM Revision Shell, 62mm
02-210-00644	TM Revision Shell, 64mm
02-210-00664	TM Revision Shell, 66mm
02-210-00684	TM Revision Shell, 68mm
02-210-00704	TM Revision Shell, 70mm
02-210-00724	TM Revision Shell, 72mm
02-210-00744	TM Revision Shell, 74mm
02-210-00764	TM Revision Shell, 76mm
02-210-00784	TM Revision Shell, 78mm
02-210-00804	TM Revision Shell, 80mm
	DRAFT

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IMPLANT RISK ANALYSIS

Trabecular Metal Acetabular Revision Shell

(b)(4) Rev (b)(4)

1.0 Device Intended Use

a) General Description

Reference Design Input DI-200501001 – Trabecular Metal Acetabular Revision Shell

b) Is The Device Intended To Contact The Patient Or Other Persons?

- ☑ Implanted In Patient
- ☑ Touching Tissue inside Patient Wound
- ☑ Touching Tissue outside Patient Wound
- ☑ Touching Operating Room Staff Gloves
- ☐ Other _____

c) Is The Device Intended For Single Use Or Re-Use?

☑ Single Use ☐ Re-use

d) Where Intended For Single Use What Is The Probability That The Device May Be Reused?

The chance of Re-use is highly unlikely. The device would likely be damaged during retrieval.

e) Is Intra-Operative Modification To Device Allowed?

No

f) Are Instructions Provided For This Modification?

Not allowed

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 37

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IMPLANT RISK ANALYSIS

Trabecular Metal Acetabular Revision Shell

(b)(4) Rev (b)(4)

g) Identify All Other Components That Interface With the Device?

02-210 Acetabular Shell with:

Version Guide (b)(4) (b)(4) Material (b)(4) (b)(4)	☐ Assemble ☐ Contact ☐ Threaded ☐ Taper Lock ☐ Articulating ☐ Quick Connect ☐ Prepares fit ☐ Trials ☑ Other evaluates position	(b)(4)

DEVICE	INTERFACE	DESCRIPTION OF INTERFACE
Acetabular Rim Impactor (b)(4) Material: (b)(4) (b)	☐ Assemble ☐ Contact ☐ Threaded ☐ Taper Lock ☐ Articulating ☐ Quick Connect ☐ Prepares fit ☐ Trials ☑ Other	(b)(4)

DEVICE	INTERFACE	DESCRIPTION OF INTERFACE
TM Shell Rim Impactor (b)(4) (b) Material: (b)(4) (b)	☐ Assemble ☐ Contact ☐ Threaded ☐ Taper Lock ☐ Articulating ☑ Quick Connect ☐ Prepares fit ☐ Trials ☐ Other	(b)(4)

DEVICE	INTERFACE	DESCRIPTION OF INTERFACE
Spherical Reamers (b)(4) Material: (b)(4) (b)	☐ Assemble ☐ Contact ☐ Threaded ☐ Taper Lock ☐ Articulating ☐ Quick Connect ☑ Prepares fit ☐ Trials ☐ Other	(b)(4)

DEVICE	INTERFACE	DESCRIPTION OF INTERFACE
Acet Trial Shells (b)(4) Material: (b)(4) (b)(4)	☐ Assemble ☐ Contact ☐ Threaded ☐ Taper Lock ☐ Articulating ☐ Quick Connect ☐ Prepares fit ☑ Trials ☐ Other	(b)(4)

DEVICE	INTERFACE	DESCRIPTION OF INTERFACE
Cemented Revision Liner (b)(4) Material: (b)(4)	☑ Assemble ☐ Contact ☐ Threaded ☐ Taper Lock ☐ Articulating ☐ Quick Connect ☐ Prepares fit ☐ Trials ☐ Other	(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 38

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IMPLANT RISK ANALYSIS

Trabecular Metal Acetabular Revision Shell

(b)(4) Rev (b)(4)

DEVICE	INTERFACE	DESCRIPTION OF INTERFACE
Revision Liner Trials (b)(4) Material: (b)(4) (b)(4)	☐ Assemble ☐ Contact ☐ Threaded ☐ Taper Lock ☐ Articulating ☐ Quick Connect ☐ Prepares fit ☑ Trials ☐ Other	(b)(4)

DEVICE	INTERFACE	DESCRIPTION OF INTERFACE
Drill Guide (b)(4) Material: (b)(4) (b)	☐ Assemble ☑ Contact ☐ Threaded ☐ Taper Lock ☐ Articulating ☐ Quick Connect ☐ Prepares fit ☐ Trials ☐ Other	(b)(4)

DEVICE	INTERFACE	DESCRIPTION OF INTERFACE
Depth Gage (b)(4) Material: (b)(4) (b)(4)	☐ Assemble ☑ Contact ☐ Threaded ☐ Taper Lock ☐ Articulating ☐ Quick Connect ☐ Prepares fit ☐ Trials ☐ Other	(b)(4)

DEVICE	INTERFACE	DESCRIPTION OF INTERFACE
Bone Screw (b)(4) Material: (b)(4) (b)	☐ Assemble ☑ Contact ☐ Threaded ☐ Taper Lock ☐ Articulating ☐ Quick Connect ☐ Prepares fit ☐ Trials ☐ Other	(b)(4)

DEVICE	INTERFACE	DESCRIPTION OF INTERFACE
TM Acetabular Augments (b)(4) Material: (b)(4)	☑ Assemble ☐ Contact ☐ Threaded ☐ Taper Lock ☐ Articulating ☐ Quick Connect ☐ Prepares fit ☐ Trials ☐ Other	(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 39

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IMPLANT RISK ANALYSIS

Trabecular Metal Acetabular Revision Shell

(b)(4) Rev (b)(4)

2.0 Specifications

2.1 Material Specifications

a) Standards Or Specifications Referenced (ASTM Number):

Standard Specification Unalloyed Tantalum for Surgical Implant Applications (ASTM F-560)
Titanium Alloy Ti6Al4V ELI for Surgical Implants per ASTM F-136

b) Zimmer TMT Internal Specification (IMS Number):

(b)(4)

c) Material Biocompatibility Published Standards:

ASTM F-136 Section 1.2

If There Are No Standards What Testing Was Done?

Zimmer TMT Technical Report (b)(4)
Zimmer TMT Technical Report
Zimmer TMT Technical Report
Zimmer TMT Technical Report
Zimmer TMT Technical Report
Zimmer TMT Technical Report
Zimmer TMT Technical Report
Zimmer TMT Technical Report

2.2 Design Specifications:

a) Identify Design Specification. (i.e. Drawing Numbers)

(b)(4)

b) What Product Design Standards Were Used In Specifying The Design? (i.e. T-20 Torx 1/4-20 UNC-2B Thread, 12/14 Taper)

None identified

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

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IMPLANT RISK ANALYSIS

Trabecular Metal Acetabular Revision Shell

(b)(4) Rev (b)(4)

c) What Special Surface Finish Specifications Were Used? (i.e. Roughness Or Polish).

(b)(4)

d) Where Are The Weakest Points On The Device?

The thinnest sections of the Trabecular Metal (b)

e) What Type Of Loads Are Seen?

(b)(4)

(b)(4)

f) How Was Implant Sized?

(b)(4)

g) How Were Sizes Developed?

The sizes provided are proven industry standards.

h) Identify Device Maintenance Requirements.

No maintenance of device required.

i) Identify Device Calibration Requirements.

No calibration of device required.

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

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IMPLANT RISK ANALYSIS

Trabecular Metal Acetabular Revision Shell

(b)(4) Rev (b)(4)

2.3 Marking Specifications

a) What Type Of Marking Is Being Used On The Implant?

☐ Engraving ☑ Laser-mark ☐ Electro-Chemical
☐ Other _____

b) Is Marking In A Readable Location That Does Not Affect The Strength Function Or Stability Of The Device?

Yes, the shell has marking on the (b) 4) ring on the face of the shell.

c) What Information Is Marked On The Device?

☑ Zimmer Logo ☑ Catalog Number ☑ Trace Code
☑ Material Type ☐ Left/Right ☑ Size
☐ Other _____

d) Reason For Omission Of Aforementioned?

Left/Right information omitted because the implant is universal (it may be used for either left or right applications). Aforementioned information is easily read on the device outer label.

2.4 Packaging Specifications

a) How Is Device Packaged (identify sterile or non-sterile)?

☑ **Sterile** ☐ **Non-Sterile**

(b)(4) [redacted]

b) Which Packaging Components Are Used (check all that apply)?

(b)(4) [redacted]

c) How Are Related Components Packaged (check all that apply)?

☑ Separately ☐ Separate Bag Within Inner Sterile Pkg.
☐ Other __

d) General Description Of Package?

Reference Packaging Drawing (b)(4) [redacted]

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

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IMPLANT RISK ANALYSIS

Trabecular Metal Acetabular Revision Shell

(b)(4) Rev (b)(4)

2.5 Sterilization Specifications

a) Which Sterilization Method Is Used?

(b)(4) [redacted]

b) Who Performs Sterilization?

☐ Zimmer TMT ☐ User ☑ Vendor
☐ Other _____

c) Can The Device Be Re-Sterilized? Identify Limitations On The Number Of Resterilizations Or Sterilization Methods.

Resterilization is not recommended by the user. The device may be resterilized by TMT up to 3 times.

2.6 Labeling Specifications

a) Specify Regulatory Label Requirements Including Location (i.e. Pkg. Label, Pkg. Insert, Surgical Protocol)?

No device specific labeling requirements identified through 510K FDA review process. Reference made to labeling regulations within Code of Federal Regulations (21 CFR Part 801)

b) Identify Warnings, Indications and Contra-Indications Including Location (i.e. Pkg. Label, Pkg. Insert, Surgical Protocol)?

Reference Package Insert PI-001.

c) Which Labels Are Provided In Each Package (check all that apply)?

☑ Package Insert ☑ Patient Label ☑ Outer Label
☐ Surgical Protocol ☐ Other _____

d) What Information Is Provided On The Device Outer Package Label/Box (check all that apply)?

☑	Catalog Number	☑	Trace Code	☐	Serial Number
☑	Description	☑	Material Type	☑	Size
☑	Phone Number	☑	Address	☑	Zimmer Logo
☐	Sterility Date	☐	Left/Right	☐	Color Coding
☑	Shelf Life	☐	Other _____		

d) What Information Is Provide On The Device Inner Patient Label (check all that apply)?

☑	Catalog Number	☑	Trace Code	☐	Serial Number
☑	Description	☑	Material Type	☑	Size
☑	Phone Number	☑	Address	☑	Zimmer Logo
☐	Sterility Date	☐	Left/Right	☐	Other _____

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

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IMPLANT RISK ANALYSIS

Trabecular Metal Acetabular Revision Shell

(b)(4) Rev (b)(4)

3.0 Identify Other Device Characteristics Where Applicable Including But Not Limited To The Following:

a) Energy or Substance Delivered/Extracted.

☑ None identified ☐ Reference Below

b) Does The Device Control Or Interact With Other (Non-Zimmer TMT) Devices Or Drugs?

☐ None identified ☑ Reference Below

Zimmer Warsaw HG II acetabular bone screws, PMMA bone cement, Zimmer Warsaw reamers, trial shells, drill, drill guide, and trial inserts.

c) Biological Material Processed For Subsequent Re-Use.

☑ None identified ☐ Reference Below

d) Modifications To The Patient's Environment?

☑ None identified ☐ Reference Below

e) Does The Device Perform Interpretative Functions?

☑ None identified ☐ Reference Below

f) Does The Device Contain Software?

☑ None identified ☐ Reference Below

g) Unwanted Outputs Of Energy?

☑ None identified ☐ Reference Below

h) Essential Consumables Associated With The Device.

☑ None identified ☐ Reference Below

i) Does The Device Have A Measuring Function?

☑ None identified ☐ Reference Below

j) Is Maintenance Or Calibration Required?

☑ None identified ☐ Reference Below

k) Other

☑ None identified ☐ Reference Below

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

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IMPLANT RISK ANALYSIS

Trabecular Metal Acetabular Revision Shell

(b)(4) Rev (b)(4)

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8710

(b)(4) Implant Risk Analysis

(b)(4) Implant Risk Analysis

(b)(4) Implant Risk Analysis

(b)(4) Implant Risk Analysis

(b)(4) Implant Risk Analysis

(b)(4) Implant Risk Analysis

(b)(4) Implant Risk Analysis

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SECTION 2

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT

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

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PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

[As required by 21 CFR § 807.87 (j)]

I certify that, in my capacity as Manager of Regulatory Affairs at Zimmer Trabecular Metal Technology, 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.

Marci Halevi
(Signature)

Marci Halevi
(Typed Name)

April 11, 2005
(Dated)

_____
*(Premarket Notification [510(k)] Number)

*For a new submission, do not fill in the 510(k) Number blank.

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

Records processed under FOIA Request # 2016-1518; Released by CDRH on 05-23-2016

SECTION 3

DEVICE IDENTIFICATION AND CLASSIFICATION

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

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DEVICE IDENTIFICATION AND CLASSIFICATION

3.1 Device Identification

Device Trade Name: Trabecular Metal Acetabular Revision Shells

Intended Use: The Indications for Use of the Trabecular Metal Acetabular Revision Shells are:

- For cemented or cementless use.
- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problem where arthrodesis or alternative reconstruction 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.

3.2 Device Classification

Classification: Class II

Classification Name: Prosthesis, Hip, Acetabular Component, Non-Cemented

Reference: 21 CFR § 888.3358

Classification Panel: Orthopedic Devices

3.3 Predicate Device Information

Manufacturer: Zimmer TMT - former Implex Corp.

Device Trade Name: The Hedrocel Acetabular Cage System

Intended Use: The Indications for Use of the Implex Hedrocel® Acetabular Cage are:

- For cemented or cementless use.
- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problem where arthrodesis or alternative reconstruction techniques are less likely

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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.

510(k) Reference: K983837

Date Cleared: July 1, 1999

Manufacturer: **Zimmer TMT - former Implex Corp.**

Device Trade Name: The Hedrocel Revision Cup

Intended Use: The Indications for Use of the Hedrocel Revision Cup are as follows:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problem where arthrodesis or alternative reconstruction 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.

510(k) Reference: K001759

Date Cleared: August 24, 2000

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

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SECTION 4

INDICATIONS FOR USE

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

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510(k) Number (if known): _____

Device Name: Trabecular Metal Acetabular Revision Shells

Indications For Use:

The Indications for Use of the Trabecular Metal Acetabular Revision Shells are:

- For cemented or cementless use.
- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problem where arthrodesis or alternative reconstruction 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 _____ (Per 21 CFR 801 Subpart D)

AND/OR...

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(Optional Format 09-2004)

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

_____ _____ _____ _____ _____ _____

Concurrence of CDRH; Office of Device Evaluation (ODE)

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

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SECTION 5

RATIONALE FOR SUBSTANTIAL EQUIVALENCE AND SUPPORTING DATA

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 60

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RATIONALE FOR SUBSTANTIAL EQUIVALENCE AND SUPPORTING DATA

5.1 Overview

The subject of this 510(k) Premarket Notification is a line extension and two minor modifications to the cleared Trabecular Metal (formerly called Hedrocel) Acetabular Cage System/Revision Cup (K983837 and K001759). K983837 cleared sizes 52mm – 70mm shells and K001759 cleared sizes 40mm – 50mm shells. The purpose of this 510(k) application is to clear new larger sizes of shells and to allow for two minor design modifications. The larger sizes range from 72mm – 80mm (in 2mm increments) and the modifications are: (1) a modified instrument interface face ring that allows use with a new impaction instrument for all sizes (from 40mm – 80mm) and (2) a change in screw hole pattern within the shells for all sizes (40 – 80 mm).

5.2 Principal Device Description:

The Trabecular Metal Acetabular Revision Shell is a modular acetabular reconstructive device (polyethylene liners are cemented into the shell) intended for use in cases of primary or revision THR. The subject Trabecular Metal Acetabular Revision Shell (previously called Hedrocel Revision Cage or Revision Cup) is manufactured from Trabecular Metal porous tantalum. The subject device has an integral Ti-6Al-4V ring (ASTM F-136) on the face of the shell's perimeter that provides a rigid contact area for the impaction instrument used to implant the device. These Revision Shells are intended for either cementless or cemented fixation to the acetabulum, and in the event that the surgeon determines additional stability is required, there are screwholes that allow for optional ancillary fixation to the acetebulum. These screwholes are designed and cleared for use with commercially available Zimmer 6.5mm titanium alloy bone screws.

After implantation of the Trabecular Metal Revision Shell, a commercially available Zimmer TMT (former-Implex) polyethylene cup/liner is cemented to the inner surface of the Trabecular Metal Shell (cup/liner cleared in K926323). The insert articulates with legally marketed standard Zimmer and Zimmer TMT femoral head components.

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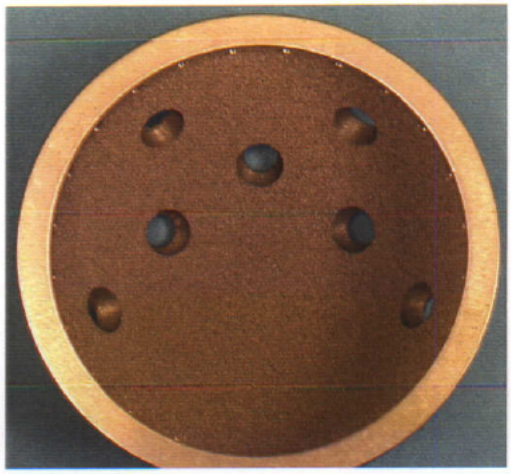

Photographs of the subject device (80 mm size)

Mechanical testing: (b)(4) [redacted]

(b)(4) [redacted]

The method of manufacture of the subject and predicate devices are the same. MAF (b)(4) contains the technical data and manufacturing information for Trabecular Metal porous tantalum. The complete size range that the subject device will be offered can be found in Appendix A, with the previously cleared and current sizes noted.

5.3 Predicate Device Description

The predicate Implex Corp. Hedrocel® Acetabular Cage System is intended for use in cases of revision of the acetabulum in the presence of poor bone stock and segmental defects. Almost identical to the subject device, this predicate is also a modular acetabular reconstructive system that consists of Trabecular Metal (previously called Hedrocel®) Cages that have been cleared in both K983837 for sizes 52mm – 70mm and K001759 for sizes 40mm – 50mm. The

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predicate Hedrocel/Trabecular Metal Cage is cleared for either cementless or cemented fixation to the adjacent acetabulum. As noted previously, the material used for the predicate shells, namely Trabecular Metal, has been extensively characterized in MAF (b)(4)

Similar to the subject devices, the predicate revision shells have a peripheral titanium alloy ring that provides a rigid surface for interfacing with the impaction instrument and for instrument attachment. One of the minor differences included in this 510k relates to the design of the ring; the predicate ring has flanges for instrument attachment while the rings of the subject devices (sizes from 40mm – 80mm) are flat. An updated surgical protocol is located in Appendix B.

The second minor difference between the predicate and subject device relates to the location of the screwholes in the shells. The screwholes provide the option for ancillary fixation and better initial stability upon implantation; this change in screwhole pattern better matches surgeon preference & use and has no effect on the strength or integrity of the shells.

The photo on page 28 shows the updated screwhole pattern and flat impaction ring.

The bone screws intended for use with these predicate systems are Zimmer 6.5mm titanium alloy screws that are commercially available.

The polyethylene cup/liner cleared in K926323 is used as a liner for both the predicate devices and the subject device. As such, the femoral heads that articulate with these cleared liners are all Zimmer and Zimmer TMT legally marketed devices.

Comparison of subject and predicate devices:

1. The subject 510(k) clears a line extension to the Trabecular Metal Revision Cages/Cups to include sizes 72mm – 80mm, providing the surgeon with larger size implant options. The predicate Trabecular Metal Revision Cages/Cups were cleared for sizes 40mm to 70mm (K983837 and K001759).

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2. The pattern of screw holes of the subject device was changed. This change was determined to have no adverse impact on strength of the device or intended use.

3. The Ti-6Al-4V instrument face ring does not have the same design as the predicate device (for all sizes). This change has no effect on the strength or integrity of the device, and the surgical protocol was modified to describe the technique with the current impaction ring.

Manufacturing, Packaging and Sterilization

Reference the original 510(k) Premarket Notifications and MAF (b)(4) for details regarding the manufacturing processes for Trabecular Metal. Zimmer will be clearly noted as the manufacturer on the outer label and/or box. Prior to sterilization, the Trabecular Metal Acetabular Revision Shell is packaged in a double (b)(4) pouch.

The packaged and labeled Trabecular Metal Acetabular Revision Shell is subjected to sterilization by means of (b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 64

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THE TRABECULAR METAL TECHNOLOGY (TMT) REVISION SHELL ORGANIZATION CHART

Zimmer TMT Catalog Numbers	Zimmer Catalog Numbers	Description	Modifications to cleared devices
02-210-00404	00-7000-040-70	TM Revision Shell, 40mm	Sizes cleared in K001759; current submission covers minor modification to screw hole pattern and to impaction ring.
02-210-00424	00-7000-042-70	TM Revision Shell, 42mm	
02-210-00444	00-7000-044-70	TM Revision Shell, 44mm	
02-210-00464	00-7000-046-70	TM Revision Shell, 46mm	
02-210-00484	00-7000-048-70	TM Revision Shell, 48mm	
02-210-00504	00-7000-050-70	TM Revision Shell, 50mm	
02-210-00524	00-7000-052-70	TM Revision Shell, 52mm	Sizes cleared in K983837; current submission covers minor modification to screw hole pattern and to impaction ring..
02-210-00544	00-7000-054-70	TM Revision Shell, 54mm	
02-210-00564	00-7000-056-70	TM Revision Shell, 56mm	
02-210-00584	00-7000-058-70	TM Revision Shell, 58mm	
02-210-00604	00-7000-060-70	TM Revision Shell, 60mm	
02-210-00624	00-7000-062-70	TM Revision Shell, 62mm	
02-210-00644	00-7000-064-70	TM Revision Shell, 64mm	
02-210-00664	00-7000-066-70	TM Revision Shell, 66mm	
02-210-00684	00-7000-068-70	TM Revision Shell, 68mm	
02-210-00704	00-7000-070-70	TM Revision Shell, 70mm	
02-210-00724	00-7000-072-70	TM Revision Shell, 72mm	Current submission; line extension to smaller sizes listed above and includes minor change to screw hole pattern and impaction ring.
02-210-00744	00-7000-074-70	TM Revision Shell, 74mm	
02-210-00764	00-7000-076-70	TM Revision Shell, 76mm	
02-210-00784	00-7000-078-70	TM Revision Shell, 78mm	
02-210-00804	00-7000-080-70	TM Revision Shell, 80mm	

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

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

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5.4 TABLE 1: COMPARISON OF PRINCIPAL AND PREDICATE DEVICES

Characteristic	Subject: Trabecular Metal Acetabular Revision Shell	Predicate: Hedrocel Acetabular Cage System (K983837)	Predicate: Hedrocel Revision Cup (K001759)
Indications for Use:	The Indications for Use of the Trabecular Metal Revision Cup are as follows: ▪ Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis or late stage avascular necrosis. ▪ Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure. ▪ Clinical management problem where arthrodesis or alternative reconstruction 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 Indications for Use of the Hedrocel Revision Cup are as follows: ▪ Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis or late stage avascular necrosis. ▪ Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure. ▪ Clinical management problem where arthrodesis or alternative reconstruction 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 Indications for Use of the Hedrocel Revision Cup are as follows: ▪ Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis or late stage avascular necrosis. ▪ Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure. ▪ Clinical management problem where arthrodesis or alternative reconstruction 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.
Materials?	Trabecular Metal Porous Tantalum and Titanium Alloy	Trabecular Metal Porous Tantalum and Titanium Alloy	Trabecular Metal Porous Tantalum and Titanium Alloy
TM Shell/Cage for THR surgery?	Yes	Yes	Yes
Poly insert cemented to Acetabular Shell?	Yes	Yes	Yes
Has screwholes for fixation?	Yes	Yes	Yes
Has titanium ring for impaction?	Yes	Yes	Yes
Shell/Cage similar in design?	Yes	Yes	Yes
Cemented or cementless use?	Yes	Yes	Yes
Size Range?	40mm – 80mm	52mm – 70mm	40mm – 50mm
Sterile?	Yes	Yes	Yes

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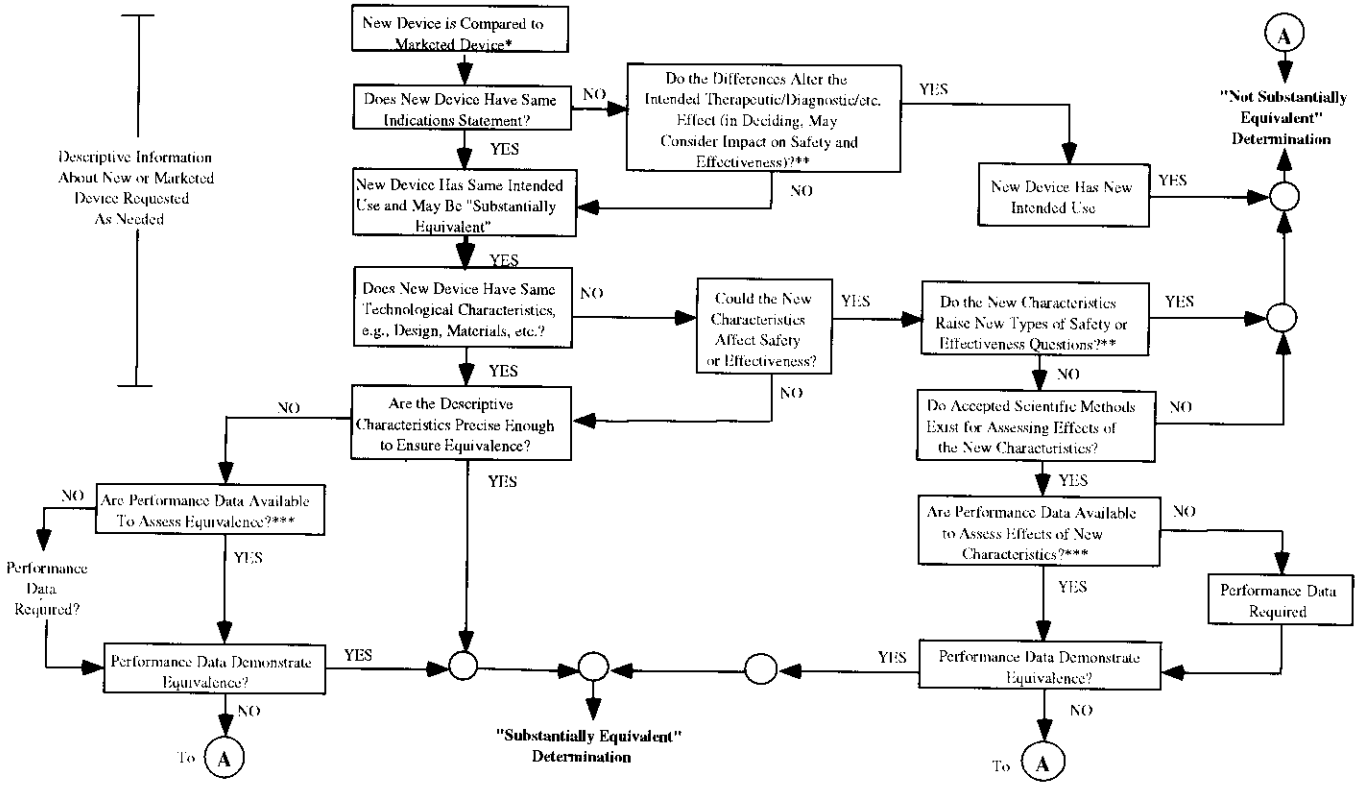
5.5 SUBSTANTIAL EQUIVALENCE DECISION-MAKING PROCESS

The conclusion that The Trabecular Metal Acetabular Revision Shells are substantially equivalent to the identified predicate devices is reached through the requirements of the substantial equivalence decision-making process. These requirements are set forth in the CDRH document entitled, *Guidance on the Center for Devices and Radiological Health's Premarket Notification Review Program.* The document includes a flow chart entitled, *510(k) Substantial Equivalence Decision-Making Process (Detailed)* which illustrates the requirements. A reproduction of the flow chart follows.

510(k) Substantial Equivalence Decision-Making Process



* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information if the Relationship Between Marketed and "Predicate" (Pre-Amendments or Reclassified Post-Amendments) Device is Unclear.
** This Decision is Normally Based on Descriptive Information Alone, But Limited Testing Information is Sometimes Required.
*** Data May Be in the 510(k), Other 510(k)s, the Center's Classification File, or the Literature.

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

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Does New Device Have Same Indications Statement?

Yes. The indications for use are identical to the cleared indications for use.

New Device Has Same Intended Use and May Be "Substantially Equivalent"?

Yes. The modified Trabecular Metal Acetabular Revision Shells have the same intended use as the claimed predicate devices.

Does New Device Have Same Technological Characteristics, e.g., Design, Materials, etc.?

Yes. The Trabecular Metal Acetabular Revision Shells are manufactured from the same materials and have the same technological characteristics as the predicate device.

Are the Descriptive Characteristics Precise Enough to Ensure Equivalence?

Yes. A comparison of device characteristics, Table 1, demonstrates that the Trabecular Metal Acetabular Revision Shells are substantially equivalent to the cleared Hedrocel Acetabular Cage/Revision Cup System (K983837 and K001759).

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

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5.6 CONCLUSIONS

The subject devices of this premarket notification are the Trabecular Metal Acetabular Revision Shells. The purpose of this 510(k) is to notify the FDA of a line extension and two minor modifications to these implants. The cleared line of Revision Shells (previously called Cages and Revision Cups) encompassed sizes 40mm – 70mm Shells; this 510k adds sizes 72mm – 80mm. The changes to the predicate devices are all minor and do not adversely affect or change the intended use, technology, performance, strength or function of the device. In conclusion, the modifications to the predicate device are minor and thus the current augments are substantially equivalent to the predicate devices.

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

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SECTION 6

LABELS AND LABELING

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 70

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LABELS AND LABELING

Overview

Labeling includes the primary package labels, package insert, patient record/reorder labels, and outer package labels. The labeling may include the quantity per package, catalog number, product description, Zimmer company name, address, symbols and pictorials, and notification of the contents of the package.

Labeling Scheme

Two (2) primary package labels are affixed to the outer carton of the package. Patient reorder labels are affixed to the exterior of the outer package. A package insert is included inside the outer carton. The prescription legend stating "CAUTION: Federal law restricts this device to sale by or on the order of a physician." is found on the outside of the outer container (i.e. printed directly on outer carton). Details regarding the labeling follow below.

Outer Package Labels: Patient Record Labels and Reorder Labels

Patient record and reorder labels are attached to the outside of the sterile outer package, but inside the primary package (box). The intent of the patient record and reorder labels is to provide the identity of the product for use on hospital records and to provide the operating room staff with the means to identify the implanted product so that replenishment of inventory may reliably occur. The information on the patient record and reorder label includes the component catalog number, the product size, and the product's unique identifier code number. The record of the product, therefore, can be traced back from the patient follow-up records to the dates of implantation and manufacture. The information found on the record and reorder label may also be used to reorder the replacement product from the manufacturer. Draft samples of the patient record and reorder labels are provided in section 6.3.

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

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Package Insert

The Package Insert content is provided in Section 6.1.

Primary Package Labeling

The primary package label is found on two sides of the primary package, and includes various information that is standard to the product such as manufacturer name, address, and corporate logo. Draft primary package labels and contents are provided in Section 6.2.

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

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SECTION 6.1

PACKAGE INSERT

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

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Implex Hip Systems English

87620389901

80 Commerce Drive
Allendale, NJ 07401
www.Implex.com (201) 818-1800

DESCRIPTION

Implex Hip System components consist of:

- **Modular Femoral Hip Stems, Cementless: Hydroxylapatite (HA) and Porous**
  The HA coated Stem is manufactured from titanium alloy and is coated in its proximal section with hydroxylapatite of high purity, density and crystallinity. The porous coated stem is made from cobalt chromium alloy with cobalt chromium alloy beads forming the porous surface.
- **Cemented Femoral Hip Stems, Modular, and Fixed Bearing Head with Cement Spacers**
  The cemented femoral stems are manufactured from either cast cobalt chromium alloy or wrought cobalt chromium alloy. Cemented stems incorporate a roughened surface proximally or a satin finish.

  Polymethylmethacrylate (PMMA) bone cement spacers are available for all stems.
- **Modular Bearing Heads, 22mm, 26mm, 28mm, and 32mm**
  Modular bearing heads are manufactured from wrought cobalt chromium alloy with Nitrogen ion bombarded or non ion bombarded surface options, alumina ceramic and zirconia ceramic. The modular bearing heads have a taper for assembly to the modular femoral stems, and are available in various neck offset lengths. The metal heads are available in two tapers. A head with a specific taper should correspond to the taper on femoral hip stem. The ceramic heads are only available in 12/14 taper and should only be used on a femoral stem with a 12/14 taper.
- **Monoblock Trabecular Metal Acetabular Cups With and Without Screwholes**
  The Monoblock Trabecular Metal Acetabular Cups are manufactured from Trabecular Metal (tantalum deposited upon a vitreous carbon skeleton) and a titanium alloy face ring with UHMWPE directly compression molded into the Trabecular Metal. The Trabecular Metal Acetabular Cup has an elliptical geometry. The Trabecular Metal Acetabular Cups are available in various face angles and inner diameters. The Monoblock Acetabular Cups are available in cup sizes from 40mm to 70mm. The Monoblock Trabecular Metal Acetabular Cups are available in cross linked enhanced options in OD sizes 52mm to 70mm.
- **Monoblock Porous Coated and HA-Coated Acetabular Cups**
  The Porous Coated Acetabular Cup has a CP titanium porous beaded coating and a factory assembled all polyethylene liner. The HA-Coated Acetabulars Cup has a hydroxyapatite coating and a factory assembled liner. The acetabular cups are available in various face angles and each face angle is available in various inner diameters. The cups are available in cup sized from 40mm to 70mm.
- **Modular Acetabular Cup/Shells**
  The modular elliptical acetabular cup/shells are manufactured from either trabecular metal with a titanium alloy inner surface or with a CP titanium beaded outer surface. The locking ring and the dome hole plugs are made from titanium alloy. The modular cup is available in cup sizes from 40mm to 70mm.
- **Modular UHMWPE Liners 0°, 10°, and 20°**
  The Modular UHMWPE Liners are available in three face angles, and each face angle is available in various inner diameters. The modular liners have scallops on the outer rim that allow the surgeons to dial in the face angle intra-operatively.
- **Cemented All Polyethylene Acetabular Cups**
  The All Polyethylene Acetabular Cups are manufactured from Ultra-High Molecular Weight Polyethylene and have a radiographic marker ring manufactured from cobalt chromium alloy. The All Polyethylene Acetabular Cups are available in OD sizes 40-70mm in 2mm increments. The All-Polyethylene Acetabular Cups are available in two face angles (0° and 10°) and each face angle is available in various inner diameters.
- **Trabecular Metal Revision Acetabular Shells, Augments and Restrictors**
  The Trabecular Metal Acetabular Augments and Restrictors are manufactured wholly from trabecular metal (Tantalum deposited upon a vitreous carbon skeleton). The Trabecular Metal Acetabular Augment is affixed to the porous acetabular cup using bone cement. The porous Acetabular Augment/Cup construct is intended for cemented and cementless use. The Trabecular Metal Acetabular Restrictors are intended for the restriction of effusion of bone cement, allograft bone, and/or autograft bone into the pelvis if defects in the acetabulum are encountered.

  The Trabecular Metal Revision Acetabular Shell has an elliptical geometry and is manufactured from trabecular metal with a titanium alloy face ring. The Trabecular Metal Revision Acetabular Shell is available with or without dome screwholes. The Trabecular Metal Revision Acetabular Shell is intended for use with cemented Replacement UHMWPE liner. The Trabecular Metal Revision Acetabular Shell is available in cup sizes from 40mm to 80mm.

  Continuum Bone Screws (6.5mm and 5.0mm) or Zimmer *Trilogy*® Acetabular System or HGP II Bone Screws (6.5mm), all manufactured from titanium alloy, are used when adjunct fixation is required.
- **Replacement UHMWPE Liners**
  The Replacement Liner is manufactured from UHMWPE and is compatible with all acetabular cups and shells manufactured from trabecular metal. The HA and Porous Cup Replacement Liner is comprised of UHMWPE with a titanium locking ring. All Replacement Liners are marked to coincide with the Implex cup sizes.
- **Bone Screws**
  Implex Bone Screws are manufactured from titanium alloy and are available in 5.0mm and 6.5mm diameters with various lengths.
- **Cement Plug**
  The Cement Plug is manufactured from low-density polyethylene.

Note: Trabecular metal (tantalum deposited upon a vitreous carbon skeleton) is manufactured by Implex Corp. Under the Implex label, the trabecular metal biomaterial is also marketed under the trade name Hedrocel®.

All Implex femoral stems and bearing head components are intended to function as total hip components when articulated with Implex acetabular components. Variations in patient size and shape may be accommodated by choice of implant size. The system is to be used with specifically designed instrumentation. Implex Acetabular components are intended for use with Implex femoral heads or femoral heads manufactured or distributed by Zimmer, Inc.

INDICATIONS

The use of the Implex Hip System is indicated for:

a) Severely disabled joints as a result of degenerative arthritis or avascular necrosis.
b) Secondary revision of a previously unsuccessful femoral component or total hip replacement.
c) Other hip problems where clinical experience has shown that alternative modes of treatment are less likely to achieve satisfactory results.
d) Fracture dislocation of the hip or irreducible fractures in which adequate fixation cannot be obtained.
e) Non-union or femoral neck or head fractures.
f) Salvage of a failed primary or secondary total or hemi hip.

CONTRA-INDICATIONS

a) Active or latent infection in or about the hip joint are absolute contra-indications which should be ruled out in patients who exhibit:
   1. fever and/or local inflammation
   2. rapid joint destruction or bone absorption as seen on X-ray
   3. elevation of sedimentation rate otherwise unexplained, elevation of white blood cell count or a significant shift in differential count.
b) Mental or neuromuscular disorders which would create an unacceptable risk of joint instability, component fixation, post-operative complications, or component structural failure.
e) Hos hyperaktive eller tunge patienter er muligheden for struktursvigt af komponenterne foræget. Der skal gøres en stor indsats for at begrænse aktivitetsniveauer og reducere patienternes vægt efter implantation.
f) Implex hoftesystemkomponenter (omfatter ikke trabekulære acetabulum metalkomponenter) må ikke bruges sammen med en komponent fra en anden producent pga. variationer i størrelse, tolerancer eller andre behandlingspraksiser. Implex trabekulære acetabulum metalkomponenter kan anvendes med Implex femurhoveder eller femurhoveder, der udelukkende er fremstillet eller distribueret af Zimmer, og må ikke anvendes sammen med en komponent fra en anden producent pga. variationer i størrelse, tolerancer eller andre behandlingspraksiser.

   I de tilfælde hvor det er nødvendigt at blande komponenter fra forskellige producenter, skal kompatibiliteten mellem komponenterne sikres med hensyn til størrelse, tolerancer eller materialer.
g) Implantater må aldrig ændres, bøjes eller på anden måde behandles efter levering af producenten.
h) Det zirkoniumkeramiske hoved består af et nyt keramisk materiale med begrænset klinisk historie. Selv om mekanisk afprøvning viser, at den delvist stabiliserede zirkoniumkugle producerer en relativ lille partikelmængde, når den bruges sammen med acetabulum skåler af polyetylen, er den totale partikelmængde ikke fastslået. På grund af den begrænsede kliniske og prækliniske erfaring er de biologiske langtidsvirkninger af partiklerne ukendte.
i) Implex knogleskruer er ikke godkendt til skruefastgøring eller -fiksering til de posteriore elementer (pedikler) i den cervikale, torakale eller lumbale rygsøjle.

FORHOLDSREGLER

a) Mentale eller neuromuskulære sygdomme, der ville skabe en unacceptabel risiko for ledinstabilitet, komponentfiksering, postoperative komplikationer eller komponentstruktursvigt.
b) Kirurgen skal være fuldt bekendt med komponenterne og den kirurgiske teknik, der vedrører Implex hoftesystemet. En brochure om hofteteknik udleveres til disse formål.
c) Når komponenten først er implanteret, må den aldrig genbruges.
d) Implex keramiske femurhoveder må kun anvendes sammen med titanlegeringen eller kobolt-kromlegeringen til hoftestem med en 12/14 konustap fra Implex Corp.
e) Når en Implex acetabulum komponent sættes sammen med et femurhoved, der er fremstillet eller distribueret af Zimmer, skal brugeren være fuldt bekendt med Zimmer komponenter og kirurgiske teknikker og informeret om implantaternes beregnede brug og risici. Se Advarsler, Forholdsregler og Uønskede bivirkninger på indlægssedlen, der følger med Zimmer indsatsen. Læs også den relevante kirurgiske Zimmer teknik.

INSTRUMENTPLEJE - SÆRLIGE FORHOLDSREGLER

Korrekt håndtering, dekontaminering herunder forskylning, vask, skylning og sterilisering, opbevaring og anvendelse er vigtige for alle kirurgiske instrumenters og prøvekomponenters lange og funktionelle levetid. Selv ved korrekt brug, pleje og vedligeholdelse kan de ikke forventes at vare evigt. Dette gælder i særlig grad for skæreinstrumenter (f.eks. borehoveder, reamere, raspe, hulmejsler, styreskinner og mejsler), drivinstrumenter (f.eks. drev, hammere, stødere, pinde, ekstraktere og indbankere) og prøvekomponenter. Disse instrumenter er ofte udsat for store belastninger og/eller stødkræfter. Under sådanne forhold kan der opstå brud, især når instrumentet er tæret, beskadiget, skåret eller ridset.

Efterse omhyggeligt alle instrumenter og prøvekomponenter før hver brug. Anvend ikke et drivinstrument, der er alvorligt ødelagt og slidt, eller et skæreinstrument med sløve skær. Sløve instrumenter skal altid returneres til Implex, så det kan afgøres, om genskærpning er mulig.

Bemærk: at på et tidspunkt opslides instrumenter og skal udskiftes. Kontakt Implex Corp. angående retningslinjer, der er relateret til pleje og håndtering af kirurgiske instrumenter.

UØNSKEDE BIVIRKNINGER

a) Postoperativ dislokation af hofteleddet er rapporteret.
b) Tidlig eller sen løsning af komponenten er rapporteret.
c) Metale sensitive reaktioner er rapporteret. Betydningen af sådanne reaktioner afventer en yderligere undersøgelse
d) Ektopisk knogledannelse og perifere neuropatier kan forekomme.
e) Træthedsfrakturer af totale hoftekomponenter forekommer sjældent. Komponentfraktur eller -slid forekommer hyppigere hos tunge eller hyperaktive patienter. Et kontralateralt led eller en invalideret ekstremitet kan belaste komponenterne uforholdsmæssigt meget.
f) En ny operation er undertiden nødvendig for at korrigere en uønsket bivirkning. I sjældne tilfælde kan kliniske komplikationer kræve arthrodesis af leddet eller amputation af ekstremiteten.

ANVENDELSE OG IMPLANTATION

Der medfølger et komplet instrumenteringssæt, der kræves til implantation af komponenterne. Røntgenologiske skabeloner hjælper kirurgen med at vurdere størrelsen eller størrelsesintervallet, der skal bruges.

De medfølgende reamere, skrabere og prøvekomponenter i instrumentsættet er de endelige afgørende faktorer for den protesestørrelse, der skal bruges. Anvendelse af prøvekomponenterne for at bekræfte størrelsesvalget og ledstabiliteten bevarer implantaternes integritet og sterilitet.

Passende placering af komponenterne er med til at undgå, at de belastes utilsigtet og kan forlænge implantaternes funktionelle levetid. Brochurer, der omhandler Implex hofteteknik, kan udleveres for at give yderligere detaljerede oplysninger om den anbefalede procedure.

STERILITET

Komponenterne i Implex hoftesystem er steriliseret ved ^{60}Co gammabestråling med en minimumdosis på 25 kGy. Komponentens steriliseringsdato eller udløbsdato er trykt på den udvendige pakkeetiket. Resterilisering af komponenterne anbefales ikke specifikt. Alle polyetylenkomponenter er pakket i nitrogengas. Både forseglingen på udvendige og indvendige emballage (den indvendige emballage indeholder komponenten) skal grundigt efterses for defekter eller utætheder, før implantatet anvendes.

Prøve-/foreløbige komponenter og andre instrumenter anvendes til at bestemme størrelsen, før den sterile emballage skal åbnes. Prøve-/foreløbige komponenter og instrumenter skal steriliseres ifølge institutionens steriliseringsprotokoller og -procedurer. Desuden skal alle steriliseringsmetoder være i overensstemmelse med relevante AAMI/ANSI/ISO retningslinjer og standarder, og der skal opnås et sterilitetssikkerhedsniveau på 10⁻⁶. Instrumentsterilisering er valideret for indpakkede instrumentkasser. Indpakkede instrumentkasser kan dampsteriliseres ved en steriliseringstemperatur på 134 °C i 20 minutter med en tørretid på 30 minutter. Instrumenter skal rengøres ifølge institutionens protokoller og procedurer.

Amerikanske patentnumre:
5,593,451/5,443,519/5,549,698/5,571,200/5,571,201/5,282,861/5,702,487/5,486,181/6,087,553/6,063,442

Implex Corp., 2003 Alle rettigheder forbeholdt

Implex, Continuum og Hedrocel er registrerede varemærker, der tilhører Implex Corp

Zimmer og Trilogy er registrerede varemærker, der tilhører Zimmer, Inc, Warsaw, IN

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

c) Insufficient bone stock so as to make the bone unable to support and fix the component.

d) Implex Ceramic Femoral Heads are contra-indicated for use with any other than an UHMWPE cup or a metal backed UHMWPE Cup.

WARNINGS

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a) Sites of infection or potential infection distant from the hip may spread to the hip hematogenously and should be treated prior to surgery.

b) The surgeon should be fully familiar with the components and the surgical technique regarding the Implex Hip System. Implex Hip Technique brochures are supplied for such purposes.

c) Post-operative dislocation is a serious complication of total hip surgery. Patients should be treated in such a way to reduce the likelihood of dislocation until soft tissue can provide necessary stability to the joint.

d) Once implanted, the component must never be reused.

e) In overly active or heavy patients, the possibility of structural failure of the components is increased. Every effort should be taken to limit activity levels and reduce the weight of the patients following implantation.

f) Implex Hip System components (not including Trabecular Metal Acetabular Components) should not be used in conjunction with a component of another manufacturer because of variances in sizing, tolerances, or other processing practices. Implex Trabecular Metal Acetabular Components may be used with Implex femoral heads or femoral heads manufactured or distributed by Zimmer only and should not be used in conjunction with a component of another manufacturer because of variances in sizing, tolerances, or other processing practices.

Under the circumstances necessitating mixing components of different manufacturers, compatibility between components with regard to sizing, tolerances, or materials must be ascertained.

g) Implants must never be modified, bent or otherwise processed after shipping by the manufacturer.

h) The Zirconia Ceramic Head is composed of a new ceramic material with limited clinical history. Although mechanical testing demonstrates that when used with polyethylene acetabular cups, the partially stabilized zirconium ball produces relatively low amount of particulates, the total amount of particulate remains undetermined. Because of the limited clinical and preclinical experience, the long term biological effects of the particulates are unknown.

i) Implex bone screws are not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

PRECAUTIONS

a) Mental or neuromuscular disorders which would create an unacceptable risk of joint instability, component fixation, postoperative complications, or component structural failure.

b) The surgeon should be fully familiar with the components and the surgical technique regarding the Implex Hip System. A Hip Technique brochure is supplied for such purposes.

c) Once implanted, the component must never be reused.

d) Implex Ceramic Femoral Heads must be used with Implex Corp. titanium alloy or cobalt chromium alloy hip stems with a 12/14 taper trunnion only.

e) When interfacing an Implex acetabular component with a femoral head manufactured or distributed by Zimmer, the user should be fully familiar with Zimmer components and surgical techniques and informed of the implants' intended use and risks. Refer to the Zimmer Package Insert for Warnings, Precautions and Adverse Effects. Refer also to the appropriate Zimmer Surgical Technique.

INSTRUMENT CARE-SPECIAL PRECAUTIONS

Proper handling, decontamination, including prerinsing, washing, rinsing and sterilization; storage and utilization are important for the long and useful life of all surgical instruments and provisionals even with correct use, care and maintenance, they should not be expected to last indefinitely. This is especially true for cutting instruments (e.g., drill bits, reamers, rasps, gauges, guides, and chisels), driving instruments (e.g., drivers, mallets, tamps, pins, extractors, and impactors) and provisionals. These items are often subjected to high loads and/or impact forces. Under such conditions, breakage can occur, particularly when the item is corroded, damaged, nicked or scratched.

Before each use, carefully inspect all instruments and provisionals. Do not use a driving instrument that is severely marred and worn or a cutting instrument with dull edges. Dull instruments should always be returned to Implex to determine if reshorpening is possible.

Note: That at some point in time, instruments wear out and should be replaced. For guidelines related to care and handling of surgical instruments contact Implex Corp.

ADVERSE EFFECTS

a) Post-operative dislocation of the hip joint has been reported.

b) Early or late loosening of the component has been reported.

c) Metal sensitivity reactions have been reported. The significance of such reactions awaits further study.

d) Heterotopic bone formation and peripheral neuropathies may occur.

e) Fatigue fractures of total hip components have rarely occurred. Component fracture or wear is more likely in heavy or overly active patients. Contralateral joint or extremity disability may place a disproportionate load on the components.

f) Re-operation is sometimes necessary to correct an adverse effect. On rare occasions, clinical complications may require orthrodesis of the joint or amputation of the limb.

UTILIZATION AND IMPLANTATION

A complete set of instrumentation necessary for the implantation of the components is supplied. Radiographic templates assist the surgeon in estimating the size or size range to be used.

The reamers, shavers, and trials provided in the set of instruments are the final determinants of the prosthetic size to be used. Use of the trials to confirm size selection and joint stability preserves the integrity and sterility of the implants.

Appropriate placement of the components helps to avoid unintended loading of the components and may improve service life of the implants. Implex Hip Technique brochures are available to provide additional detailed information regarding the recommended procedure.

STERILITY

Implex Hip System components are sterilized by means of ^{60}Co gamma irradiation at a minimum dose of 25 kGy. The date of the component sterilization or expiration is printed on the outer package label. Resterilization of components is specifically not recommended. All polyethylene components are Nitrogen gas packaged. Both outer and inner package (inner contains the component) seals should be thoroughly inspected for defects of leaks before using the implant.

Trials/Provisionals and other instruments are used to determine sizing before the sterile package needs to be opened. Trials/Provisionals and instruments should be sterilized in accordance with institution sterilization protocols and procedures. Further, all sterilization methods must comply with the appropriate AAMI/ANSI/ISO guidance's and standards, and a sterility level of 10^{-6} should be achieved. Instrumentation sterilization has been validated for wrapped instrument cases. The wrapped instrument case may be steam sterilized at a sterilization temperature of 273° F (134° C) for 20 minutes, with a drying time of 30 minutes. Instruments should be cleaned in accordance with institution protocols and procedures.

Implex Heupsystemen

Dutch

OMSCHRIJVING

De componenten van Implex heupsystemen zijn:

- **Modulaire femur-heupstelen, cementvrij: Hydroxylapatiet (HA) en poreus**
  De met HA gecoate steel is vervaardigd van titaniumlegering en het proximale gedeelte is gecoat met hydroxylapatiet met een hoge graad van zuiverheid, dichtheid en kristalvormigheid. De poreus gecoate steel is vervaardigd van kobalt-chroomlegering, waarbij het poreuze oppervlak wordt gevormd door een parelstructuur van kobalt-chroomlegering.
- **Femur-heupstelen voor gecementeerd gebruik , modulair, voorzien van kop met vaste draagvlakken en cementspacers**
  De femurstelen voor gecementeerd gebruik worden vervaardigd van gegoten of gesmede kobalt-chroomlegering. Voor het gecementeerd gebruik van stelen is een opgerowd proximaal oppervlak of een zijdeglansafwerking benodigd.
  Voor alle stelen zijn botcementspacers van polymethylmethacrylaat (PMMA) verkrijgbaar.
- **Koppen met modulair draagvlak, 22 mm, 26 mm, 28 mm en 32 mm**
  Koppen met modulair draagvlak worden vervaardigd van gesmede kobalt-chroomlegering, met naar keuze een wel of niet met stikstofionen gebombardeerd oppervlak van keramisch aluminiumoxide of zirconium. De koppen met modulair draagvlak zijn voorzien van een conus voor het samenvoegen met de modulaire femurstelen, en zij zijn verkrijgbaar in uiteenlopende halsoffsetlengtes. De metalen koppen zijn met twee conustypes verkrijgbaar. Een kop met een bepaalde conus moet overeenstemmen met de conus op de femur-heupsteel. De keramische koppen zijn alleen met 12/14 conus verkrijgbaar en kunnen uitsluitend bij femurstelen met 12/14 conus worden gebruikt.
- **Monoblock Trabecular Metal (poreus tantaal) acetabulumcups met en zonder schroefgaten**
  Monoblock Trabecular Metal acetabulumcups worden vervaardigd van Trabecular Metal (tantaal afgezet op een skelet van vitreuze koolstof) en een kraagring van titaanlegering, waarin, rechtstreeks in het Trabecular Metal, UHMWPE is geperst. De acetabulumcup van Trabecular Metal is elliptisch van vorm. Er zijn acetabulumcups van Trabecular Metal verkrijgbaar in diverse vlakhoeken en binnendiametermaten. Monoblock acetabulumcups zijn verkrijgbaar in cupmaten van 40 mm tot 70 mm. Ook zijn de monoblock acetabulumcups van Trabecular Metal beschikbaar in kruiselings versterkte uitvoering, in buitendiametermaten van 52 mm tot 70 mm.
- **Monoblock poreus gecoate en HA-gecoate acetabulumcups**
  De poreus gecoate acetabulumcup is voorzien van een parelcoating van titaan van zuivere handelskwaliteit en een bij fabricage gemonteerde voering van 100% polyethyleen. De HA-gecoate acetabulumcup heeft een coating van hydroxylapatiet en een bij fabricage gemonteerde voering. Er zijn acetabulumcups verkrijgbaar in diverse vlakhoeken, en elke vlakhoek wordt geleverd in diverse binnendiametermaten. De cups zijn verkrijgbaar in cupmaten van 40 mm tot 70 mm.
- **Modulaire acetabulumcup/omhulsels**
  De modulaire, elliptisch gevormde acetabulumcup/omhulsels worden vervaardigd van trabeculair metaal uitgerust met een binnenoppervlak van titaanlegering of met een buitenoppervlak van zuiver titaan van handelskwaliteit in parelstructuur. De vergrendeling en de plugs voor de gewelfgaten zijn gemaakt van titaanlegering. De modulaire cup is verkrijgbaar in cupmaten van 40 mm tot 70 mm.
- **Modulaire 0°-, 10°- en 20°-voeringen van UHMWPE**
  Er zijn modulaire UHMWPE voeringen verkrijgbaar in drie vlakhoeken, en elke vlakhoek wordt geleverd in diverse binnendiametermaten. De modulaire voeringen zijn voorzien van schelpvormige schalen op de buitenrand. Hierdoor wordt het chirurgen mogelijk gemaakt, de vlakhoek intraoperatief in te draaien.
- **Acetabulumcups van 100% polyethyleen voor gecementeerd gebruik**
  De acetabulumcups van 100% polyethyleen zijn vervaardigd van polyethyleen met een ultrahoog molecuiair gewicht (UHMWPE) en zijn voorzien van een ring van kobalt-chroomlegering voor röntgenmarkering. Er zijn acetabulumcups van 100% polyethyleen verkrijgbaar in buitendiametermaten van 40 mm tot 70 mm, in toenemestappen van 2 mm. De acetabulumcups van 100% polyethyleen zijn verkrijgbaar in twee vlakhoeken (0° en 10°), en beide vlakhoeken worden geleverd in diverse binnendiametermaten.
- **Trabeculaire metalen acetabulum-omhulsels voor revisie, augmentatiestukken en restrictor**
  Trabeculaire metalen acetabulum-augmentatiestukken worden geheel vervaardigd van trabeculair metaal (tantaal afgezet op een skelet van vitreuze koolstof). Het trabeculair metalen acetabulum-augmentatiestuk wordt met behulp van botcement aan de poreuze acetabulumcup gehecht. De constructie van poreus acetabulum-augmentatiestuk en acetabulum is zowel voor gecementeerd als voor ongecementeerd gebruik bedoeld.Het trabeculair metalen acetabulum-omhulsel voor revisie is elliptisch van vorm en is vervaardigd van trabeculair metaal met een kraagring van titaanlegering. De trabeculaire metalen revisie-acetabulumcup is verkrijgbaar met gewelfschroefgaten. Het trabeculair metalen acetabulum-omhulsel voor revisie is bestemd voor gebruik met een gecementeerde vervangingsvoering van UHMWPE. Het trabeculair metalen acetabulum-omhulsel voor revisie is verkrijgbaar in cupmaten van 40 mm tot 80 mm.
  Continuum botschroeven (6,5 mm en 5,0 mm), met botschroeven behorend tot het Zimmer *Trilogy*® acetabulumsysteem of met HGPII botschroeven (6,5 mm). Deze producten zijn alle vervaardigd van titaanlegering en worden gebruikt als aanvullende fixatie vereist is.
- **Vervangingsvoeringen van UHMWPE**
  De vervangingsvoering wordt vervaardigd van UHMWPE en is compatibel met alle acetabulumcups en -omhulsels die van trabeculair metaal zijn gemaakt. De vervangingsvoering voor HA-gecoate en poreuze cups is van UHMWPE en is voorzien van een vergrendeling van titaan. Alle vervangingsvoeringen zijn geëtiketteerd in overeenstemming met de door Implex gevoerde cupmaten.
- **Botschroeven**
  Implex botschroeven worden gemaakt van titaanlegering. De schroeven zijn verkrijgbaar in diametermaten van 5,0 mm en 6,5 mm en in uiteenlopende lengtematen.
- **Cementplug**
  De cementplug is vervaardigd van polyethyleen met een lage dichtheid.

Opmerking: Trabeculair metaal (tantaal afgezet op een skelet van vitreuze koolstof) wordt gefabriceerd door Implex Corp. Onder het Implex handelsmerk wordt het biomateriaal van trabeculair metaal ook op de markt gebracht onder de handelsnaam Hedrocel®

INDICATIES

Het gebruik van het Implex heupsysteem is geïndiceerd voor:

a) Gewrichten die als gevolg van degeneratieve artritis of avasculaire necrose ernstig verminkt zijn.

b) Secondaire revisie van een eerder mislukte femurcomponentimplantatie of totale heupartroplastiek.

c) Overige heupklachten waarbij klinische ervaring heeft aangetoond dat andere behandelmethodieken een geringere kans op bevredigende resultaten bieden.

d) Fractuurdislocatie van de heup of niet-reponeerbare fracturen waarbij geen adequate fixatie kan worden verkregen.

e) Pseudo-artrose van femurhals- of -kopfracturen.

f) Herstelbehandeling van een mislukte primaire of secundaire totale of hemi-heupartroplastiek.

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CONTRA-INDICATIES

a) Actieve of latente infecties in of bij het heupgewricht zijn absolute contra-indicaties. Deze dienen te worden uitgesloten bij patiënten met de volgende symptomen:

1. koorts en/of lokale inflammatie

Implex hoftesystemer

Danish

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BESKRIVELSE

Implex hoftesystemkomponenter består af:

- **Modulære femurhoftestem, cementfri: HA (hydroxylapatit) og porøse**
  Det HA-belagte stem er fremstillet af en titanlegering og er belagt med hydroxylapatit med en høj grad af renhed, tæthed og krystalindhold i den proksimale del. Det porøse belagte stem er produceret af en kobolt-kromlegering med kobolt-kromlegeringsbobler, der danner den porøse overflade.
- **Cementerede femurhoftestem, modulære og fikserede støttehoveder med cementmellemstykker**
  De cementerede femurstem er fremstillet af enten en støbt kobolt-kromlegering eller en svejset kobolt-kromlegering. Cementerede stem er udstyret med enten en grov overflade proksimalt eller en atlaskoverflade. Mellemstykker af PMMA (polymetylmetakrylat) -knoglecement kan fås til alle stem.
- **Modulære støttehoveder, 22 mm, 26 mm, 28 mm og 32 mm**
  Modulære støttehoveder er fremstillet af en svejset kobolt-kromlegering med og uden nitrogenionbombarderet overflade, aluminakeramik og zirkoniumkeramik. De modulære støttehoveder er udstyret med en konus til montering til de modulære femurstem og leveres med forskellige halsforskydningslængder. Metalhovederne fås med to konusser. Et hoved med en specifik konus skal svare til konussen på den femoral hoftestem. De keramiske hoveder fås kun med 12/14 konus og må kun anvendes på en femoral stem med 12/14 konus.
- **Acetabulumcupper af monoblok trabekulært metal med og uden skruehuller**
  Acetabulumcupperne af monoblok trabekulært metal er fremstillet af trabekulært metal (tantal aflejret på et glashårdt kulstofskelet) og en ring med titanlegeringsflade med UHMWPE direkte formpresset i det trabekulære metal. Acetabulumcuppen af trabekulært metal har en elliptisk geometri. Acetabulumcupperne af trabekulært metal leveres i forskellige kantvinkler og indvendige diametre. Acetabulum monoblokcupperne leveres i cupstørrelser fra 40 til 70 mm. Acetabulum monoblokcupperne af trabekulært metal leveres i tværforbundne forbedrede udgaver med udvendige diameterstørrelser på 52 til 70 mm.
- **Porøst belagte og HA-belagte acetabulumcupper**
  Den porøst belagte acetabulumcup har en kemisk ren, porøs, perleagtig titanbelægning og en fabriksmonteret indsats kun bestående af polyetylen. Den Ha-belagte acetabulumcup har en hydroxyapatitbelægning og en fabriksmonteret indsats. Acetabulumcupperne leveres i forskellige kantvinkler, og hver kantvinkel leveres i forskellige indvendige diametre. Cupperne leveres i cupstørrelser fra 40 til 70 mm.
- **Modulære acetabulum skåler/skaller**
  De modulære elliptiske acetabulum skåler/skaller er fremstillet af enten trabekulært metal med en indvendig overflade af en titanlegering eller med en kemisk ren bobbelformet udvendig titanoverflade. Låseringen og tophulspropperne er fremstillet af titanlegering. Den modulære skålleveres i størrelser fra 40 til 70 mm.
- **Modulære UHMWPE-indsatser 0°, 10° og 20°**
  De modulære UHMWPE-indsatser leveres i forskellige kantvinkler, og hver kantvinkel leveres i forskellige indvendige diametre. De modulære indsatser har tunger på den udvendige kant, der gør det muligt for kirurgen at indstille kantvinklen peroperativt.
- **Cementerede acetabulumcupper fremstillet udelukkende af polyetylen**
  Acetabulumcupperne er udelukkende fremstillet af polyetylen med ultrahøj molekylærvægt og er udstyret med en røntgenologisk markørring, der er fremstillet af en kobolt-kromlegering. Acetabulumcupperne fremstillet udelukkende af polyetylen leveres i udvendige diameterstørrelser på 40 - 70 mm med 2 mm intervaller. Acetabulumcupperne af polyetylen leveres med to kantvinkler (0° og 10°), og hver kantvinkel leveres med forskellige indvendige diametre.
- **Trabekulære acetabulum metalrevisionsskaller, forstærkninger og begrænsning**
  De trabekulære acetabulum metalforstærkninger er fremstillet udelukkende af trabekulært metal (tantal anbragt på et glashårdt kulstofskelet). Den trabekulære acetabulum metalforstærkning er fastgjort til den porøse acetabulum skål vha. knoglecement. Den porøse acetabulum forstærkning/acetabulum konstruktion er beregnet til brug med og uden cement. Den trabekulære acetabulum metalrevisionsskal har en elliptisk geometri og er fremstillet af trabekulært metal med en ring med en titanlegeringsflade. Den trabekulære acetabulum metalrevisionsskål leveres med topskruehuller. Den trabekulære acetabulum metalrevisionsskal er beregnet til brug med en cementeret UHMWPE-reserveindsats. Den trabekulære acetabulum metalskal leveres i skålstørrelser fra 40 til 80 mm.

  Continuum knogleskruer (6,5 mm og 5,0 mm) eller Zimmer *Trilogy*® acetabulum system eller HGPII knogleskruer (6,5 mm), alle fremstillet af titanlegering bruges når supplerende fiksering er nødvendig.
- **UHMWPE-reserveindsatser**
  Reserveindsatsen er fremstillet af UHMWPE og er kompatibel med alle acetabulum skåler og skaller, der er fremstillet af trabekulært metal. HA-skålreserveindsatsen og den porøse skålreserveindsats består af UHMWPE med en titanlåsering. Det er markeret på alle reserveindsatser, at de passer sammen med Implex skålstørrelserne.
- **Knogleskruer**
  Implex knogleskruer er fremstillet af en titanlegering og leveres i 5,0 mm og 6,5 mm diametre med forskellige længder.
- **Cementprop**
  Cementproppen er fremstillet af polyetylen med en lav tæthedsgrad.

Bemærk: Trabekulært metal (tantal anbragt på et glashårdt kulstofskelet) er fremstillet af Implex Corp. Under Implex etiketten er biomaterialet trabekulært metal også markedsført under varemærket Hedrocel®.

INDIKATIONER

Brugen af Implex hoftesystemet indiceres til:

a) Svært invaliderede led som et resultat af degenerativ arthritis eller karfri nekrose.

b) Sekundær revision af en tidligere svigtet femurkomponent eller en total hoftesubstitution.

c) Andre hofteproblemer, hvor klinisk erfaring har vist, at det er mindre sandsynligt, at der opnås tilfredsstillende resultater vha. alternative behandlingsmåder

d) Frakturdislokation af hoften eller irreponible frakturer, hvor der ikke kan opnås tilstrækkelig fiksering.

e) Manglende heling eller frakturer i femurhals eller -hoved.

f) Bevarelse af en svigtet primær eller sekundær total eller halv hofte

KONTRAINDIKATIONER

a) Aktiv eller latent infektion i eller omkring hofteleddet er absolutte kontraindikationer, som skal udelukkes hos patienter, som viser
   1. feber og/eller lokal betændelse
   2. hurtig leddestruktion eller knogleresorption som vist på røntgenbilleder
   3. ellers uforklaret forhøjelse af sænkningshastigheden, forhøjelse af det hvide blodbillede eller et tydeligt skift i differentialtællingen.

b) Mentale eller neuromuskulære sygdomme, der ville skabe en unacceptabel risiko for ledinstabilitet, komponentfiksering, postoperative komplikationer eller komponentstruktursvigt.

c) Utilstrækkelig knoglestamme til at gøre knoglen i stand til at støtte og fiksere komponenten.

d) Implex keramiske femurhoveder kontraindiceres til brug med andre komponenter end en UHMWPE-skål eller en metalstøttet UHMWPE-skål.

ADVARSLER

a) Infektionssteder eller potentiel infektion fjernt fra hoften kan forårsage hæmatogen metastasering til hoften og skal behandles inden indgrebet.

b) Kirurgen skal være fuldt bekendt med komponenterne og den kirurgiske teknik, der vedrører Implex hoftesystemet. Brochurer, der omhandler Implex hofteteknikken, leveres af Implex til disse formål.

c) Postoperativ dislokation er en betænkelig komplikation ved total hofteoperation. Patienter skal behandles, så risikoen for dislokation reduceres, indtil bløddele kan give den nødvendige stabilitet til leddet.

d) Når komponenten først er implanteret, må den aldrig genbruges.

1. koorts en/of lokale inflammatie
2. versnelde gewrichtsdestructie of botabsorptie die op röntgen-opnamen waarneembaar zijn
3. een verhoogde bloedbezinking waarvoor geen andere verklaring kan worden gegeven, een verhoogde leukocytentelling of een significante verandering in de differentiële leukocytentelling

b) Mentale of neuromusculaire stoornissen waardoor een onaanvaardbaar risico van gewrichtsinstabiliteit zou ontstaan, fixatie van componenten, postoperatieve complicaties of structurele malfunctie van componenten.

c) Insufficiëntie van botmassa, waardoor het bot onvoldoende ondersteuning biedt om de component te fixeren.

d) De keramische femurkoppen van Implex zijn gecontra-indiceerd voor toepassing met andere cups dan een UHMWPE cup of een met metaal beklede UHMWPE cup.

WAARSCHUWINGEN

a) Op afstand van de heup gelegen (potentiële) infectiehaarden kunnen zich via de bloedbaan naar de heup uitbreiden en dienen vóór de chirurgische procedure te worden behandeld.

b) De chirurg dient zich volledig vertrouwd te hebben gemaakt met de componenten en de chirurgische technieken samenhangend met het Implex heupsysteem. Daartoe worden door Implex brochures over de Implex heuptechnieken ter beschikking gesteld.

c) Postoperatieve dislocatie is een ernstige complicatie van totale heupchirurgie. Patiënten dienen op een zodanige wijze te worden behandeld dat het risico van dislocatie wordt verminderd, totdat er zich voldoende zacht weefsel vormt om het gewricht de nodige stabiliteit te geven.

d) Een component mag nooit worden hergebruikt nadat deze eenmaal geïmplanteerd is geweest.

e) Bij overmatig actieve of zwaarlijvige patiënten bestaat een vergroot risico van falen van de componentenconstructie. Na een implantatie dient de behandeling nadrukkelijk gericht te zijn op beperking van de fysieke activiteit en op vermindering van het lichaamsgewicht van de patiënt.

f) Men dient de componenten van het Implex heupsysteem (waarbij niet inbegrepen de trabeculaire metalen acetabulumcomponenten) niet te gebruiken in combinatie met componenten van andere fabrikanten, omdat de maattoleranties of andere procesgegevens kunnen afwijken. De trabeculaire metalen acetabulumcomponenten van Implex kunnen uitsluitend worden gebruikt in combinatie met Implex femurkoppen of met femurkoppen gefabriceerd of verhandeld door Zimmer; de trabeculaire componenten dienen niet te worden gebruikt met componenten van andere fabrikanten, omdat de maattoleranties of andere procesgegevens kunnen afwijken.

   Indien de omstandigheden het gemengd gebruik van componenten van verschillende fabrikanten noodzakelijk maken, dient men zich te vergewissen van de onderlinge compatibiliteit van de componenten ten aanzien van maatvoering, toleranties en materialen.

g) Implantaten mogen na verzending door de fabrikant nooit worden aangepast, gebogen of anderszins bewerkt.

h) De Zirconia keramische kop is gemaakt van een nieuw keramisch materiaal —zirconium—met een beperkte klinische bestaansgeschiedenis. Hoewel door mechanisch testen is aangetoond dat de gedeeltelijk gestabiliseerde zirconium kogel bij het gebruik in combinatie met polyethyleen acetabulumcups een relatief geringe hoeveelheid losse deeltjes afgeeft, is het totale quantum aan partikeltjes nog niet vastgesteld. Vanwege de beperkte klinische en preklinische ervaringsopbouw zijn de biologische uitwerkingen van de partikels op langere termijn nog niet bekend.

i) Botschroeven van Implex zijn niet goedgekeurd voor schroefbevestiging of fixatie aan de posterieure elementen (pediculus) van de cervicale, thoracale en lumbale wervels.

VOORZORGSMAATREGELEN

a) Mentale of neuromusculaire stoornissen waardoor een onaanvaardbaar risico van gewrichtsinstabiliteit zou ontstaan, fixatie van componenten, postoperatieve complicaties of structurele malfunctie van componenten.

b) De chirurg dient zich volledig vertrouwd te hebben gemaakt met de componenten en de chirurgische technieken samenhangend met het Implex heupsysteem. Daartoe wordt een brochure over heuptechnieken ter beschikking gesteld.

c) Een component mag nooit worden hergebruikt nadat deze eenmaal geïmplanteerd is geweest.

d) De keramische femurkoppen van Implex kunnen uitsluitend worden gebruikt in combinatie met heupstelen van titaan- of kobalt-chroomlegering, geleverd door Implex Corp. en voorzien van een 12/14 conische draaitap.

e) Indien men een Implex acetabulumcomponent koppelt met een femurkop gefabriceerd of verhandeld door Zimmer, moet de gebruiker zich volledig vertrouwd hebben gemaakt met de Zimmer-componenten en de daaraan gerelateerde chirurgische technieken, en moet hij of zij zich op de hoogte hebben gesteld van de gebruiksbestemmingen en risico's van de implantaten. Raadpleeg de verpakkingsbijsluiter van Zimmer om kennis te nemen van de waarschuwingen, voorzorgsmaatregelen en bijwerkingen. Raadpleeg eveneens de relevante chirurgische techniek van Zimmer.

SPECIALE VOORZORGEN M.B.T. INSTRUMENTVERZORGING

Voor een lange en nuttige gebruiksduur van alle chirurgische instrumenten en proefcomponenten zijn een doelmatige behandeling, ontsmetting (waaronder voorspoelen, wassen, spoelen en sterilisatie), opslag en gebruik belangrijke factoren. Zelfs bij smetteloos gebruik, verzorging en onderhoud mag echter geen onbeperkte levensduur worden verwacht. Dit geldt in het bijzonder voor de snij-instrumenten (b.v. boorbits, ruimers, raspen, gutsen, geleiders en beitels), impactie-instrumenten (b.v. draaiers, hamers, stampers, pinnen, extractors en impactors) en proefcomponenten. Deze artikelen worden dikwijls blootgesteld aan zware belastingen en/of impactiekrachten. Onder zulke omstandigheden kan breuk optreden, vooral wanneer het gereedschap is gecorrodeerd, beschadigd, gekerfd of bekrast.

Inspecteer alle instrumenten en proefcomponenten zorgvuldig vóór elk gebruik. Maak geen gebruik van impactie-instrumenten die ernstig zijn ontsierd en versleten of snij-instrumenten met botte snijranden. Botte instrumenten dienen altijd naar Implex te worden geretourneerd, zodat kan worden beoordeeld of slijpen mogelijk is.

Opmerking: Vroeger of later verslijten alle instrumenten en moeten zij worden vervangen. Neem voor richtlijnen over de verzorging en behandeling van chirurgische instrumenten contact op met Implex Corp.

BIJWERKINGEN

a) Er zijn meldingen gedaan van postoperatieve dislocatie van de heup.

b) Ook is losraken van de component in een vroeger of later stadium gemeld.

c) Er zijn meldingen van metaalovergevoeligheidsreacties. Ten aanzien van de significantie van dergelijke reacties wordt nog nader onderzoek verricht.

d) Heterotope botvorming en perifere neuropathieën kunnen voorkomen.

e) Sporadisch is fractuur door metaalmoeheid van componenten bij totale heupvervanging voorgekomen. Zwaarlijvige of overmatig actieve patiënten lopen meer risico van fractuur of slijtage van componenten. Een contralateraal gewricht of invaliditeit van een ledemaat kan de oorzaak zijn van een onevenredige belasting van de componenten.

f) Soms is herhaling van de ingreep noodzakelijk om een bijwerking te corrigeren. In zeldzame gevallen kan door klinische complicaties de noodzaak ontstaan van artrodese van het gewricht of amputatie van het lichaamsdeel.

GEBRUIK EN IMPLANTATIE

Een volledige set instrumenten benodigd voor implantatie van de componenten wordt bijgeleverd. Röntgensjablonen bieden de chirurg hulp bij het schatten van de maat of het maatbereik dat moet worden gebruikt.

De ruimers, schaven en proefcomponenten die van de instrumentenset deel uitmaken geven uiteindelijk de doorslag ten aanzien van de prothesemaat die moet worden gebruikt. Door gebruikmaking van de proefcomponenten voor het bevestigen van de maatkeuze en gewrichtsstabiliteit blijven de implantaten en hun steriliteit onaangetast.

Door componenten in een juiste passing te plaatsen vermijdt men het onnodig inbrengen van componenten en kan de nuttige gebruiksduur van een implantaat worden verlengd. Er zijn brochures over de Implex heuptechnieken beschikbaar, die aanvullende detailinformatie bevatten over de aanbevolen procedure.

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

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STERILITEIT

De componenten van het Implex heupsysteem worden gesteriliseerd door blootstelling aan ^{60}Co gammastraling met een minimumdosis van 25 kGy. De sterilisatiedatum of de uiterste gebruiksdatum van een component staat op het etiket van de buitenverpakking gedrukt. Hersterilisatie van componenten wordt uitdrukkelijk afgeraden. Alle componenten van polyethyleen zijn in stikstofgas verpakt. De sluitingen van de buiten- en binnenverpakking (de binnenverpakking bevat de component) moeten grondig worden geïnspecteerd op defecten of lekken voordat men het implantaat gebruikt.

Voordat de steriele verpakking wordt geopend, moet met behulp van proefcomponenten en andere instrumenten de juiste passing van het implantaat worden bepaald. Proefcomponenten en instrumenten moeten worden gesteriliseerd overeenkomstig de sterilisatieprotocollen en -procedures van het ziekenhuis. Bovendien moeten alle sterilisatiemethoden voldoen aan de relevante ANSI/AAMI/ISO-richtlijnen en -normen, en moet er een steriliteitsgraad van 10^{-6} worden bereikt. De sterilisatie van instrumenten is gevalideerd voor in sterilisatiedoek gewikkelde instrumentencassettes. De in sterilisatiedoek gewikkelde instrumentencassette mag gedurende 20 minuten met stoom worden gesteriliseerd bij een sterilisatietemperatuur van 134 °C en moet 30 minuten drogen. De instrumenten moeten worden gereinigd overeenkomstig de protocollen en procedures van het ziekenhuis.

US Patent Nrs.
5,593,451/5,443,519/5,549,698/5,571,200/5,571,201/5,282,861/5,702,487/5,486,181/6,087,553/6,063,442

Implex Corp., 2003 Alle rechten voorbehouden
Implex, Continuum en Hedrocel zijn gedeponeerde handelsmerken van Implex Corp.
Zimmer en Trilogy zijn gedeponeerde handelsmerken van Zimmer, Inc., Warsaw, IN

French

Systèmes de hanche Implex

DESCRIPTION

Les éléments du système de hanche Implex sont les suivants :

- **Tiges de hanche fémorales modulaires non cimentées : hydroxyapatite (HA) et poreuses**
  La tige revêtue HA est fabriquée à partir d'un alliage de titane et sa section proximale est revêtue d'hydroxylapatite de haute pureté, densité et cristallinité. La tige à revêtement poreux est fabriquée à partir d'un alliage chrome cobalt, les gouttelettes d'alliage chrome cobalt formant la surface poreuse.
- **Tiges de hanche fémorales cimentées, tête à palier modulaire et fixe avec pièces d'espacement en ciment**
  Les tiges de hanche fémorales cimentées sont fabriquées à partir d'un alliage chrome cobalt moulé ou d'un alliage chrome cobalt corroyé. Les tiges cimentées présentent en leur partie proximale une surface rugosifiée ou une finition satinée. Les pièces d'espacement osseux en ciment de méthacrylate de polyméthyle (PMMA) sont disponibles pour toutes les tiges.
- **Têtes à palier modulaire, 22 mm, 26 mm, 28 mm et 32 mm**
  Les têtes à palier modulaire sont fabriquées en alliage chrome cobalt corroyé avec des options de surface avec bombardement ionique d'azote ou sans bombardement ionique, en céramique aluminée et en céramique zirconée. Les têtes à palier modulaire sont équipées d'un cône pour l'assemblage aux tiges fémorales modulaires et sont proposées en différentes longueurs de décolage du col. Les têtes de métal sont disponibles en deux cônes. Une tête avec un cône spécifique devrait correspondre au cône sur la tige de hanche fémorale. Les têtes de céramique sont uniquement disponibles en cônes 12/14 et devraient uniquement être utilisées sur une tige fémorale avec un cône 12/14.
- **Cupules acétabulaires monobloc en métal trabéculaire avec et sans trous de vis**
  Les cupules acétabulaires monobloc en métal trabéculaire sont fabriquées en métal trabéculaire (tantale déposé sur un squelette de carbone vitreux) avec une bague de face en alliage de titane avec UHMWPE moulé directement par compression dans le métal trabéculaire. Les cupules acétabulaires en métal trabéculaire ont une géométrie elliptique. Les cupules acétabulaires en métal trabéculaire sont disponibles en divers angles de face et diamètres intérieurs. Elles existent pour des tailles de cupules de 40 à 70 mm. Les cupules acétabulaires monobloc en métal trabéculaire sont disponibles en option réticulée avec des diamètres extérieurs variant de 52 à 70mm.
- **Cupules acétabulaires à revêtement poreux et à revêtement HA monobloc**
  Les cupules acétabulaires à revêtement poreux sont recouvertes d'un revêtement de gouttelettes de titane poreux et possèdent une garniture tout polyéthylène montée d'origine. Les cupules acétabulaires à revêtement HA sont recouvertes d'un revêtement d'hydroxyapatite et possèdent une garniture montée d'origine. Les cupules acétabulaires sont proposées en différents angles de face et chaque angle de face existe en différents diamètres intérieurs. Elles existent pour des tailles de cupules de 40 à 70 mm.
- **Cupules/coques acétabulaires modulaires**
  Les cupules/coques acétabulaires modulaires sont fabriquées soit en métal trabéculaire avec une surface intérieure en alliage de titane, soit en titane avec des gouttelettes de titane formant un revêtement externe poreux. La bague de fermeture et le bouchon de coupole sont fabriqués en alliage de titane. Les cupules modulaires existent pour des tailles de cupules de 40 à 70 mm.
- **Garnitures modulaires UHMWPE 0°, 10° et 20°**
  Les garnitures UHMWPE modulaires sont proposées en trois angles de face et chaque angle de face existe en différents diamètres intérieurs. Les garnitures modulaires présentent des festons sur le bord externe pour permettre aux chirurgiens d'accéder à l'angle de face au cours de l'intervention.
- **Cupules acétabulaires tout polyéthylène cimentées**
  Les cupules acétabulaires tout polyéthylène sont fabriquées en polyéthylène à très haut poids moléculaire et possèdent un anneau de marquage radiographique en alliage chrome cobalt. Les cupules acétabulaires tout polyéthylène sont disponibles avec des diamètres extérieurs variant de 40 à 70 mm par incréments de 2 mm. Les cupules acétabulaires tout polyéthylène sont proposées en deux angles de face (0 ° et 10 °) et chaque angle de face existe en différents diamètres intérieurs.
- **Coques acétabulaires de révision, augmentateurs et réducteurs en métal trabéculaire**
  L'augmentateur acétabulaire en métal trabéculaire est entièrement fabriqué en métal trabéculaire (tantale déposé sur un squelette de carbone vitreux). L'augmentateur acétabulaire en métal trabéculaire est fixé sur la cupule acétabulaire poreuse à l'aide de ciment à os. Le système acétabulaire/augmentateur acétabulaire poreux est conçu pour des usages avec et sans ciment.
  Les coques acétabulaires de révision en métal trabéculaire ont une géométrie elliptique et sont fabriquées en métal trabéculaire avec une bague de face en alliage de titane. Les coques acétabulaires de révision en métal trabéculaire existent avec des trous de vis pour coupole. La coque acétabulaire de révision en métal trabéculaire est destinée à être utilisée avec la garniture de remplacement cimentée UHMWPE. Elle existe pour des tailles de cupules de 40 à 80 mm.
  Il convient d'utilisre les vis à os Continuum (6,5 mm et 5,0 mm), le système acétabulaire Zimmer *Trilogy*® ou les vis à os HGPII (6,5 mm), tous fabriqués en alliage de titane, lorsqu'une fixation supplémentaire est requise.
- **Garnitures de remplacement UHMWPE**
  La garniture de remplacement est fabriquée en UHMWPE et est compatible avec toutes les cupules et coques acétabulaires en métal trabéculaire. La garniture de remplacement HA et poreuse est fabriquée en UHMWPE et comporte une bague de fermeture en titane. Toutes les garnitures de remplacement sont marquées pour correspondre aux dimensions des cupules

- **Modulare UHMWPE Einsätze 0°, 10° und 20°**
  Die modularen UHMWPE Einsätze stehen mit drei verschiedenen Vorderseitenwinkeln zur Verfügung, wobei jeder Vorderseitenwinkel mit verschiedenen Innendurchmessern erhältlich ist. Die modularen Einlagen haben Zacken am äußeren Rand, damit der Chirurg intraoperativ den Vorderseitenwinkel einstellen kann.
- **Zementierte Ganzpolyäthylen-Acetabullumschalen**
  Die Ganzpolyäthylen-Acetabullumschalen werden aus Polyäthylen mit ultrahohem Molekulargewicht hergestellt und haben einen Röntgenmarkierungsring, der aus Kobalt-Chrom-Legierung hergestellt wird. Die Ganzpolyäthylen-Acetabullumschalen stehen in Aussendurchmessergrößen von 40 mm bis 70 mm, in 2 mm Schritten, zur Verfügung. Die Ganzpolyäthylen-Acetabullumschalen stehen mit zwei verschiedenen Vorderseitenwinkeln ((0° und 10°) zur Verfügung, wobei jeder Vorderseitenwinkel mit verschiedenen Innendurchmessern erhältlich ist.
- **Trabekulär-Metall-Revision-Acetabullumschalen, Verstärkungen und Restriktor**
  Die Acetabullumverstärkungen aus trabekulärem Metall und Restriktoren werden vollständig aus trabekulärem Metall (Tantal, das auf einem glasartigen Kohlenstoffskelett abgelagert wird) hergestellt. Die Acetabullumverstärkung aus trabekulärem Metall wird mit Knochenzement an der porösen Acetabullumschale befestigt. Die poröse Acetabullumverstärkung/Acetabullumkonstruktion kann sowohl mit Zement als auch zementfrei verwendet werden.
  Die Trabekulär-Metall-Revision-Acetabullumschale hat eine ovale Geometrie und wird aus trabekulärem Metall mit einem Auflagering aus Titanlegierung hergestellt. Die Trabekulär-Metall-Revision-Acetabullumschale ist mit Schraubenlöchern in der Kuppel erhältlich. Die Trabekulär-Metall-Revision-Acetabullumschale ist nur zur Verwendung mit einer zementierten UHMWPE-Austauscheinlage gedacht. Die Trabekulär-Metall-Acetabullumschale steht in Schalengrößen von 40 mm bis 80 mm zur Verfügung.
  Continuum Knochenschrauben (6,5 mm und 20 5,0 mm) oder dem Zimmer *Trilogy*® Acetabullumsystem oder mit HGPII Knochenschrauben (6,5 mm), alle aus Titanlegierung hergestellt, werden verwendet, wenn zusätzliche Fixierung erforderlich ist.
- **UHMWPE Austauscheinsätze**
  Die Austauscheinlagen bestehen aus UHMWPE und sind mit allen Acetabullumschalen und -hülsen aus trabekulärem Metall kompatibel. Der HA- und die poröse Schalenaustauscheinlage besteht aus UHMWPE mit einem Titanverschlußring. Alle Austauscheinlagen sind markiert, um mit den Größen der Implex Schalen zusammenzupassen.
- **Knochenschrauben**
  Die Implex Knochenschrauben werden aus Titanlegierung hergestellt und stehen in den Durchmessern 5,0 mm und 6,5 mm verschiedenen Längen zur Verfügung.
- **Zementdocht**
  Der Zementdocht ist aus Polyäthylen niedriger Dichte hergestellt.

Hinweis: Trabekuläres Metall (Tantal, das auf ein glasartiges Kohlenstoffskelett aufgebracht wird) wird von Implex Corp. hergestellt. Unter dem Namen Implex wird trabekuläres Metall auch unter dem Markennamen Hedrocel™ vermarktet.

INDIKATIONEN

Die Verwendung des Implex Hüftsystems ist indiziert bei:

a) Schwerbehinderten Gelenken als Folge von degenerativer Arthritis oder aseptischer avaskuläre Nekrose.
b) Sekundären Revision eines zuvor nicht erfolgreichen Einsatzes einer femoralen Komponente oder einer Hüftendoprothese.
c) Anderen Hüftproblemen, bei denen die klinische Erfahrung gezeigt hat, daß alternative Behandlungsmethoden mit geringerer Wahrscheinlichkeit zu befriedigenden Ergebnissen führen.
d) Luxationsbrüchen der Hüfte oder nicht reponierbare Brüche, bei denen eine adäquate Fixierung nicht erreicht werden kann.
e) Nichtheilen oder Schenkelhals- oder Hüftkopffrakturen.
f) Rettung einer primär oder sekundär nicht erfolgreichen Hüfttotal- oder teilprothese.

KONTRAINDIKATIONEN

a) Aktive oder latente Infektionen in oder um das Hüftgelenk sind absolute Kontraindikationen, die bei Patienten mit den folgenden Symptomen unbedingt ausgeschlossen werden sollten:
   1. Fieber und/oder lokale Entzündung
   2. rasante Gelenkszerstörung oder Knochenabsorption, röntgenologisch darstellbar
   3. erhöhte Blutsenkungsgeschwindigkeit, anderweitig nichterklärbare Erhöhung der weißen Blutkörperchen oder eine Verschiebung im Differentialblutbild.
b) Geistige oder neuromuskuläre Störungen, die zu einem nicht akzeptablen Risiko in Bezug auf die Gelenkstabilität oder Komponentenbefestigung, bzw. zu postoperativen Komplikationen oder Materialversagen der Komponenten führen würden.
c) Ungenügende Knochenmasse, durch die es dem Knochen unmöglich wird, die Komponente zu stützen und zu halten.
d) Implex keramische Femurköpfe sind für die Verwendung mit einer anderen Schale als mit einer UHMWPE-Schale oder mit einer metallhinterlegten UHMWPE-Schale kontraindiziert.

WARNHINWEISE

a) Infektionsherde oder mögliche Infektionsherde, die weit von der Hüfte entfernt liegen, können sich eventuell hämatogen bis zur Hüfte ausbreiten und sollten vor der Operation behandelt werden.
b) Der Chirurg sollte mit den Komponenten und der OP-Technik in Bezug auf das Implex Hüftsystem vertraut sein. Implex stellt dafür die Implex Hüftbroschüren zur Verfügung.
c) Postoperative Luxation ist eine ernste Komplikation der Hüfttotalendoprothese. Die Patienten sollten so behandelt werden, daß die Wahrscheinlichkeit einer Luxation verringert wird, bis die Weichteile dem Gelenk die notwendige Stabilität geben können.
d) Eine einmal implantierte Komponente sollte niemals wieder verwendet werden.
e) Bei übermäßig aktiven oder schweren Patienten ist das Risiko eines Materialversagens der Komponenten erhöht. Nach der Implantation sollte alles unternommen werden, um den Aktivitätsgrad zu begrenzen und das Gewicht der Patienten zu reduzieren.
f) Implex Hüftsystemkomponenten (ausschließlich der Trabekulär-Metall-Acetabullumkomponenten) sollten nicht zusammen mit einer Komponente eines anderen Herstellers verwendet werden, da es Unterschiede in der Größe, den Toleranzen oder anderen Verarbeitungsverfahren gibt. Implex Trabekulär-Metall-Acetabullumkomponenten dürfen nur zusammen mit Implex Femurköpfen oder mit von Zimmer hergestellten oder vertriebenen Femurköpfen verwendet werden und sollten nicht zusammen mit einer Komponente eines anderen Herstellers verwendet werden, da es Unterschiede in der Größe, den Toleranzen oder anderen Verarbeitungsverfahren gibt.
   Falls es Umstände erfordern, Komponenten verschiedener Hersteller zu mischen, muß die Kompatibilität zwischen den Komponenten in Bezug auf Größe, Toleranzen und Materialien sichergestellt werden.
g) Implantate dürfen niemals verändert, gebogen oder sonst irgendwie bearbeitet werden, nachdem sie vom Hersteller ausgeliefert worden sind.
h) Die Zirkoniumkeramikköpfe werden aus einem neuen keramischen Material hergestellt, für das bisher nur begrenzte klinische Erfahrungen vorliegen. Obwohl mechanische Tests gezeigt haben, daß der teilweise stabilisierte Zirkoniumball bei Verwendung zusammen mit Polyäthylen-Acetabullumschalen relativ wenig Partikel erzeugt, so ist die Gesamtmenge der Partikel noch unbestimmt. Wegen der begrenzten klinischen und vorklinischen Erfahrungen sind die biologischen Langzeiteffekte der Partikel unbekannt.
i) Implex Knochenschrauben sind nicht zur Verschraubung/Schraubbefestigungen an den posterioren Elementen (Pediculi) der Hals- Brust- oder Lendenwirbelsäule gedacht.

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WARNHINWEISE

a) Geistige oder neuromuskuläre Störungen, die zu einem nicht akzeptablen Risiko in Bezug auf die Gelenkstabilität oder Komponentenbefestigung, bzw. zu postoperativen Komplikationen oder Materialversagen der Komponenten führen würden.
b) Der Chirurg sollte mit den Komponenten und der OP-Technik in Bezug auf das Implex Hüftsystem vertraut sein. Dafür steht eine Broschüre Hüft-Technik zur Verfügung.

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

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- **Vis à os**
  Les vis à os Implex sont fabriquées en alliage de [illegible] 6,5 mm de diamètre et en différentes longueurs.
- **Bouchon de ciment**
  Le bouchon de ciment est réalisé en polyéthylène à faible densité.

Remarque : Le métal trabéculaire (tantale déposé sur un squelette de carbone vitreux) est fabriqué par Implex Corp. Lorsqu'il porte la marque Implex, le matériel biologique en métal trabéculaire est également commercialisé sous l'appellation déposée Hedrocel®.

INDICATIONS

L'emploi du système de hanche Implex est indiqué dans les cas suivants :

a) Articulations sévèrement compromises à la suite d'ostéoarthrite dégénérative ou de nécrose avasculaire.
b) Révision secondaire après remplacement d'un élément fémoral ou arthroplastie totale de la hanche non réussis.
c) Autres problèmes de hanche pour lesquels l'expérience clinique a démontré que des alternatives de traitement ont moins de chances de donner des résultats satisfaisants.
d) Fracture de la hanche avec dislocation ou fractures irréductibles dans lesquelles une contention suffisante ne peut être obtenue.
e) Fractures sans consolidation ou fractures du col ou de la tête du fémur.
f) Réparation d'arthroplastie totale ou partielle de la hanche, primaire ou secondaire, n'ayant pas abouti.

CONTRE-INDICATIONS

a) Une infection active ou latente dans l'articulation de la hanche ou à proximité de celle-ci constitue une contre-indication absolue. Cette intervention ne pourra être envisagée pour les patients présentant les symptômes suivants :
   1. fièvre et/ou inflammation localisée ;
   2. absorption ou destruction osseuse rapide déterminée par radiographie ;
   3. élévation inexpliquée du taux de sédimentation, élévation de la leucocytose ou altération notable de la formule leucocytaire.
b) Troubles mentaux ou neuromusculaires qui créeraient un risque inacceptable d'instabilité d'articulation, de fixation du composant, de complications post-opératoires ou de défaillance structurelle du composant.
c) Insuffisance de matériau osseux à un degré tel que l'on serait incapable de soutenir et de fixer le composant.
d) Les têtes fémorales en céramique Implex sont contre-indiquées pour l'utilisation avec des cupules autres qu'une cupule en UHMWPE ou une cupule en UHMWPE doublée de métal.

MISES EN GARDE

a) Des sites d'infection ou d'infection potentielle éloignés de la hanche peuvent s'étendre à la hanche par voie hématogène et il conviendra de les traiter avant l'opération.
b) Le chirurgien devra s'être entièrement familiarisé avec les composants et avec la technique chirurgicale relative au système de hanche Implex. Des brochures portant sur les techniques d'intervention sur les hanches sont fournies par Implex à cet effet.
c) Une dislocation post-opératoire constitue une complication grave à une intervention d'arthroplastie totale de la hanche. Il conviendra de traiter les patients de façon à réduire la possibilité de dislocation jusqu'à ce que le tissu mou puisse assurer la stabilité nécessaire à l'articulation.
d) Une fois implanté, le composant ne doit jamais être réutilisé.
e) Chez les patients d'un poids excessif ou extrêmement actifs, la possibilité de défaillance structurelle du composant est accrue. Tous les efforts possibles devront être entrepris pour limiter les niveaux d'activité des patients et leur faire perdre du poids après l'implantation.
f) Les éléments du système de hanche Implex (à l'exclusion des éléments acétabulaires en métal trabéculaire) ne doivent pas être employés en conjonction avec un composant provenant d'un autre fabricant, du fait de variations dans le dimensionnement, les tolérances ou autres pratiques de traitement. Les éléments acétabulaires en métal trabéculaire Implex ne peuvent être utilisés qu'avec les têtes fémorales Implex ou avec les têtes fémorales fabriquées ou distribuées par Zimmer et ne doivent pas être employés en conjonction avec un composant provenant d'un autre fabricant, du fait de variations dans le dimensionnement, les tolérances ou autres pratiques de traitement.
   Dans les circonstances nécessitant le mélange de composants de différents fabricants, il conviendra de s'assurer de la compatibilité entre les composants eu égard au dimensionnement, aux tolérances ou aux matériaux.
g) Les implants ne devront jamais être modifiés, déformés ou altérés de toute autre manière après leur expédition par le fabricant.
h) La tête en céramique zirconée est constituée d'un nouveau matériau à base de céramique pour lequel on ne dispose que de données cliniques limitées. Bien que les tests mécaniques aient démontré que, lorsqu'elle est utilisée avec des cupules acétabulaires en polyéthylène, la tête en zircon partiellement stabilisée ne produit qu'une quantité relativement faible de particules, la quantité totale de particules demeure indéterminée. En raison de l'expérience clinique et préclinique limitée, les effets biologiques à long terme des particules sont inconnus.
i) Les vis à os Implex ne sont pas homologuées pour la fixation par vis ni pour la fixation aux éléments postérieurs (pédicules) de la colonne vertébrale cervicale, thoracique ou lombaire.

PRÉCAUTIONS

a) Troubles mentaux ou neuromusculaires qui créeraient un risque inacceptable d'instabilité d'articulation, de fixation du composant, de complications post-opératoires ou de défaillance structurelle du composant.
b) Le chirurgien devra s'être entièrement familiarisé avec les composants et avec la technique chirurgicale relative au système de hanche Implex. Une brochure portant sur les techniques d'intervention sur les hanches est fournie à cet effet.
c) Une fois implanté, le composant ne doit jamais être réutilisé.
d) Les têtes fémorales en céramique Implex doivent impérativement être utilisées avec les tiges de hanche en alliage de titane ou en alliage chrome-cobalt Implex Corp. avec un pivot de raccord 12/14 uniquement.
e) Lors de l'utilisation conjointe d'un élément acétabulaire Implex et d'une tête fémorale fabriquée ou distribuée par Zimmer, l'utilisateur devra s'être entièrement familiarisé avec les composants et avec les techniques chirurgicales relatives aux composants Zimmer et s'être informé sur l'usage prévu des implants et les risques qui y sont associés. Se référer à la notice jointe à l'emballage Zimmer pour les avertissements, précautions et effets secondaires. Se référer également à la technique chirurgicale Zimmer appropriée.

ENTRETIEN DES INSTRUMENTS - PRÉCAUTIONS PARTICULIÈRES

Une manipulation et une décontamination adéquates, y compris en ce qui concerne le prérinçage, le lavage, le rinçage et la stérilisation, ainsi qu'un stockage et une utilisation appropriés, sont importants pour prolonger la durée de vie des instruments et accessoires provisoires chirurgicaux ; même s'ils sont correctement utilisés et entretenus, on ne doit pas s'attendre à ce que ceux-ci aient une durée de vie illimitée. Ceci est particulièrement vrai dans le cas des instruments tranchants (par ex. forets, alésoirs, râpes, gouges, guides et burins), des instruments d'entraînement (par ex. moteurs d'entraînement, maillets, tasseurs, broches, extracteurs et impacteurs) et des accessoires provisoires. Ces accessoires sont souvent soumis à des charges et/ou à des forces d'impact importantes. Dans ces conditions, une rupture est possible, en particulier si l'accessoire est corrodé, endommagé, rayé ou entaillé.

Avant chaque utilisation, inspecter attentivement tous les instruments et accessoires provisoires. Ne pas utiliser un instrument d'entraînement fortement rayé et usé ou un instrument au tranchant émoussé. Les instruments émoussés seront toujours renvoyés chez Implex afin de déterminer s'il est possible de les aiguiser.

Remarque: A un moment donné, les instruments s'usent et doivent être remplacés. Pour des instructions relatives à l'entretien et à la manipulation des instruments chirurgicaux, contacter Implex Corp.

RÉACTIONS INDÉSIRABLES

a) Des dislocations post-opératoires de la hanche ont été signalées.
b) Des détachements précoces ou tardifs des composants ont été signalés.
c) Des réactions de sensibilité au métal ont été signalées. La signification de ces réactions requiert des études supplémentaires.
d) Une formation osseuse hétérotopique [illegible]

c) Eine einmal implantierte Komponente sollte niemals wieder verwendet werden.
d) Implex keramische Femurköpfen dürfen nur mit Implex Corp Stielen aus Titanlegierung oder Kobalt-Chrom-Legierung mit einem 12/14 Konustragzapfen verwendet werden.
e) Beim Zusammensetzen einer Implex Acetabulumkomponenten mit einem von Zimmer hergestellten oder vertriebenen Femurkopf sollte der Benutzer vollständig mit den Zimmerkomponenten und den chirurgischen Techniken vertraut und über den Verwendungszweck und die Risiken des Implantats informiert sein. Für Warnungen, Vorsichtsmaßnahmen und unerwünschte Ereignisse den Zimmer Beipackzettel beachten. Die entsprechende Zimmer Broschüre OP-Technik beachten.

PFLEGE DER INSTRUMENTE - BESONDERE VORSICHTSMASSNAHMEN

Richtige Handhabung, Dekontamination, einschließlich Vorspülen, Waschen, Abspülen sowie Sterilisieren, Lagerung und Verwendung sind für die lange Nutzungsdauer aller chirurgischen Instrumente wichtig. Selbst bei richtiger Verwendung, Pflege und Wartung kann keine unbegrenzte Nutzungsdauer erwartet werden. Dies gilt ganz besonders für schneidende Instrumente (z.B. Bohreinsätze, Fräsen, Feilen, Hohlbeitel, Führer und Meißel), treibenden Instrumenten (z.B. Treiber, Hammer, Stampfer, Stifte, Abzieher und Stößel) sowie Hilfsmittel. Diese Gegenstände werden oft sehr großen Belastungen und/oder Stoßkräften ausgesetzt. Unter solchen Bedingungen, kann es zu Bruch kommen, besonders wenn der Gegenstand korrodiert, beschädigt, angeschlagen oder zerkratzt ist.

Vor jeder Verwendung alle Instrumente und Hilfsmittel genau inspizieren. Keine treibenden Instrumente, die ernsthaft beschädigt und abgenutzt sind, verwenden. Keine Schneidinstrumente mit stumpfen Klingen verwenden. Stumpfe Instrumente sollten immer an Implex eingeschickt werden, um die Möglichkeit eines erneuten Schärfens zu prüfen.

Hinweis: Instruments sind zu irgendeinem Zeitpunkt abgenutzt und müssen ausgetauscht werden. Richtlinien zur Pflege und Handhabung von chirurgischen Instrumente sind bei Implex Corp. erhältlich.

UNERWÜNSCHTE EREIGNISSE

a) Postoperative Luxationen des Hüftgelenks wurden berichtet.
b) Frühe oder späte Lockerung der Komponenten wurden berichtet.
c) Metallüberempfindlichkeitsreaktionen wurden berichtet. Die Signifikanz solcher Reaktionen bedarf noch weiterer Untersuchungen.
d) Heterotrope Knochenbildung und periphere Neuropathien können auftreten.
e) Ermüdungsbrüche der Komponenten der Hüfttotalprothese sind selten vorgekommen. Komponentenbrüche und -abnutzung sind bei schweren oder übermäßig aktiven Patienten wahrscheinlicher. Durch beidseitige Gelenk- oder Extremitätenbehinderung können die Komponenten einer unverhältnismäßigen Belastung ausgesetzt werden.
f) Zur Korrektur eines unerwünschten Ergebnisses ist manchmal eine Reoperation erforderlich. In seltenen Fällen können klinische Komplikationen eine Arthrodese des Gelenks oder eine Amputation der Gliedmaße erforderlich machen.

VERWENDUNG UND IMPLANTATION

Ein Set mit dem kompletten Instrumentarium, das für die Implantation der Komponenten benötigt wird, wird mitgeliefert. Röntgenvorlagen helfen dem Chirurgen beim Abschätzen der zu verwendenden Größe bzw. Größenbereichs.

Die Fräsen, Schaber und Proben, die mit dem Instrumentariumssatz geliefert werden, sind letztendlich entscheidend für die zu verwendende Prothesengröße. Die Verwendung der Proben zur Bestätigung der Größenwahl und der Gelenkstabilität erhält die Unversehrtheit und Sterilität des Implantats.

Geeignete Plazierung der Komponenten hilft, unabsichtliche Belastung der Komponenten zu verhindern und kann die nutzbare Lebensdauer der Implantate verlängern. Implex Hüfttechnikbroschüren, die zusätzliche detaillierte Informationen zur empfohlenen Technik geben, stehen zur Verfügung.

STERILITÄT

Die Implex Hüftsystemkomponenten werden mit ^{60}Co-Gammastrahlung mit mindestens 25 kGy sterilisiert. Das Datum der Komponentensterilisation oder das Verfallsdatum wird auf das Etikett auf der äußeren Packung aufgedruckt. Eine Resterilisierung der Komponenten wird ausdrücklich NICHT empfohlen. Alle Polyethylenkomponenten sind unter Stickstoff verpackt. Vor der Verwendung des Implantats sollte die Versiegelung der äußeren und inneren Packung (die innere Packung enthält die Komponenten) auf defekte und undichte Stellen hin untersucht werden.

Proben/Provisorien und andere Instrumente werden zur Größenbestimmung verwendet, bevor die sterilen Packungen geöffnet werden müssen. Proben/Provisorien und Instrumente sollten entsprechend den üblichen Protokollen und Verfahren des Krankenhauses sterilisiert werden. Außerdem müssen alle Sterilisationsmethoden den entsprechenden AAMI/ANSI/ISO-Richtlinien bzw. Normen entsprechen, und es sollte ein Sterilitätsgrad von 10^{6} erreicht werden. Die Instrumentensterilisation wurde für verpackte Instrumentencontainer validiert. Die verpackten Instrumentencontainer können bei einer Temperatur von 134° C (273° F) 20 Minuten lang und mit 30 Minuten Trockenzeit dampfsterilisiert werden. Instrumente sollten entsprechend den üblichen Protokollen und Verfahren des Krankenhauses gereinigt werden.

USA Patentnummern:
5,593,451/5,443,519/5,549,698/5,571,200/5,571,201/5,282,861/5,702,487/5,486,181/6,087,553/6,063,442

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e) Des fractures de tangue de composants pour arthroplastie totale de la hanche se sont rarement produites. Les chances de fracture ou d'usure de composant sont plus grandes chez les patients d'un poids excessif ou extrêmement actifs. Un handicap de l'articulation ou de l'extrémité controlatérale peuvent engendrer une charge disproportionnée sur les composants.

f) Une seconde intervention est parfois nécessaire pour rectifier les réactions indésirables. Des complications cliniques rares peuvent nécessiter l'arthrodèse de l'articulation ou l'amputation du membre.

UTILISATION ET IMPLANTATION

Un jeu complet d'instruments nécessaires à l'implantation des composants est fourni. Des modèles radiographiques aideront le chirurgien à estimer la dimension ou la plage de dimensions à utiliser.

Ce sont les alésoirs, rasoirs et dispositifs d'essai fournis dans le jeu d'instruments qui détermineront définitivement la taille de prothèse à employer. L'emploi de ces dispositifs d'essai pour confirmer le choix de taille et la stabilité de l'articulation préserve l'intégrité et la stérilité des implants.

Le bon placement des composants contribue à éviter une charge non intentionnelle des composants et permet d'améliorer la durée de vie des implants. Des brochures Implex consacrées aux techniques d'intervention sur les hanches sont disponibles pour fournir des informations supplémentaires détaillées concernant la procédure recommandée.

STÉRILITÉ

Les composants du système de la hanche Implex sont stérilisés par irradiation aux rayons gamma ^{60}Co à une dose minimale de 25 KGy. La date de stérilisation ou de péremption des composants est imprimée sur l'étiquette apposée sur l'emballage extérieur. La restérilisation des composants est spécifiquement déconseillée. Tous les composants en polyéthylène sont emballés sous atmosphère d'azote. Il convient d'examiner soigneusement les fermetures des emballages extérieurs et intérieurs (l'emballage intérieur contient le composant) pour vérifier l'absence de défaut ou de fuite avant d'utiliser l'implant.

Des dispositifs d'essai et d'autres instruments seront employés pour déterminer le dimensionnement avant l'ouverture de l'emballage stérile. Les dispositifs d'essai ou provisoires et les instruments doivent être stérilisés conformément aux protocoles et procédures de stérilisation de l'établissement. Toutes les méthodes de stérilisation devront de plus se conformer aux conseils et normes AAMI/ANSI/ISO pertinentes et un niveau de stérilité de 10^{-6} devra être atteint. La stérilisation des instruments a été validée pour des trousses d'instruments emballées. Les trousses d'instruments emballées peuvent être stérilisées à la vapeur à 134°C (273°F) pendant 20 minutes, avec un temps de séchage de 30 minutes. Les instruments doivent être nettoyés conformément aux protocoles et procédures de l'établissement.

N° de brevets américains :
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Zimmer et Trilogy sont des marques déposées de Zimmer, Inc, Warsaw, IN, Etats-Unis

Implex Hüftsysteme

German

BESCHREIBUNG

Implex Hüftsystemkomponenten bestehen aus:

- **Modulare femorale Hüftstiele, zementfrei: Hydroxylapatit (HA) und porös**
  Der HA-beschichtete Stiel ist aus Titanlegierung hergestellt und sein proximaler Abschnitt ist mit Hydroxylapatit von hohem Reinheitsgrad, Dichte und Kristallinität beschichtet. Der porös beschichtete Stiel wird aus einer Kobalt-Chrom-Legierung hergestellt, wobei Kobalt-Chrom-Perlen die poröse Oberfläche bilden.
- **Zementierte femorale Hüftstiele, modular, und fester Auflagekopf mit Zementdistanzstücken**
  Die zementierten Femurstiele werden entweder aus Kobalt-Chrom-Guß oder aus Kobalt-Chrom-Knetlegierung hergestellt. Zementierte Stiele haben proximal entweder eine aufgerauhte oder eine seidenmatte Oberfläche.
  Polymethylmethacrylat (PMMA) Knochenzementdistanzstücke stehen für alle Stiele zur Verfügung.
- **Modulare Auflageköpfe, 22 mm, 26 mm, 28 mm, und 32 mm**
  Die modularen Auflageköpfe werden entweder aus einer mit Stickstoffionen beschossenen Kobalt-Chrom-Knetlegierung oder als nicht mit Stickstoffionen beschossene Oberflächenoptionen, aus Aluminiumkeramik oder Zirkoniumkeramik hergestellt. Die modularen Auflageköpfe haben einen Konus zur Montage an den modularen Femurstielen, und stehen mit verschiedenen Halsversatzlängen zur Verfügung. Die Metallköpfe stehen in zwei Konusausführungen zur Verfügung: Ein Kopf mit einem bestimmten Konus sollte mit dem Konus an femoralen Hüftstielen übereinstimmen. Die Keramikköpfe stehen nur mit 12/14 Konus zur Verfügung und sollten nur an femoralen Stielen mit einem 12/14 Konus verwendet werden.
- **Trabekulär-Metall-Acetabullumschalen aus einem Guss mit und ohne Schraubenlöchern**
  Die Trabekulär-Metall-Acetabullumschalen aus einem Guss werden aus Trabekulär-Metall (Tantal, das auf einem glasartigen Kohlenstoffskelett aufgebracht wird) hergestellt und haben einen Auflagering aus Titanlegierung mit UHMWPE, der direkt in das Trabekulär-Metall warmgepresst ist. Die Trabekulär-Metall-Acetabullumschale hat eine ovale Geometrie. Die Trabekulär-Metall-Acetabullumschalen stehen mit verschiedenen Vorderseitenwinkeln und Innendurchmessern zur Verfügung. Die Acetabullumschalen aus einem Guss stehen in Schalengrößen von 40 mm bis 70 mm zur Verfügung. Die Trabekulär-Metall-Acetabullumschalen aus einem Guss stehen in verbesserten vernetzten Optionen mit Aussendurchmessern von 52 mm bis 70mm zur Verfügung.
- **Porös-beschichtete und HA-beschichtete Acetabullumschalen aus einem Guss**
  Die porös beschichtete Acetabullumschale hat eine poröse Beschichtung aus CP Titanperlen und eine fabrikseitig zusammengebaute Ganzpolyäthyleneinlage. Die HA-beschichtete Acetabullumschale hat eine Hydroxylapatitbeschichtung und eine fabrikseitig zusammengebaute Einlage. Die Acetabullumschalen stehen mit verschiedenen Vorderseitenwinkeln zur Verfügung, wobei jeder Vorderseitenwinkel mit verschiedenen Innendurchmessern erhältlich ist. Die Schalen stehen in Schalengrößen von 40 mm bis 70 mm zur Verfügung.
- **Modulare Acetabullumschalen/-hülsen**
  DDie modularen ovalen Acetabullumschalen/-hülsen werden entweder aus trabekulärem Metall mit einem Innenfläche aus Titanlegierung oder mit einer Außenfläche aus CP Titanperlen hergestellt. Der Verschlußring und die Dochte für das Kuppelloch werden aus Titanlegierung hergestellt. Die modularen Schalen stehen in Schalengrößen von 40 mm bis 70 mm zur Verfügung.

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

US Patent No. 5,593,451/5,443,519/5,549,698/5,571,200/5,571,201/5,282,861/5,702,487/5,486,181/6,087,553/6,063,442

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11/03
Cat. # PI001 Rev. 0

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

Records processed under FOIA Request # 2016-1518; Released by CDRH on 05-23-2016

Συστήματα Ισχίου Implex

ΠΕΡΙΓΡΑΦΗ

Τα εξαρτήματα του Συστήματος Ισχίου Implex αποτελούνται από τα παρακάτω:

- **Ρυθμιζόμενα Μηριαία Στελέχη Ισχίου, Χωρίς Τσιμέντο: Υδροξυλαπατίτης (HA) και Πορώδες**
  Το Στέλεχος με επικάλυψη HA κατασκευάζεται από κράμα τιτανίου και το κεντρικό του τμήμα έχει επικάλυψη Υδροξυλαπατίτη υψηλής καθαρότητας, πυκνότητας και κρυσταλλότητας. Το πορώδες επικαλυμμένο στέλεχος είναι κατασκευασμένο από κράμα κοβαλτίου χρωμίου με σφαιρίδια κράματος κοβαλτίου χρωμίου τα οποία σχηματίζουν την πορώδη επιφάνεια.
- **Μηριαία Στελέχη Ισχίου με Τσιμέντο, και Σταθερό Έδρανο Κεφαλής με Διαχωριστικά Τσιμέντου**
  Τα μηριαία στελέχη με τσιμέντο κατασκευάζονται από γύψο κοβαλτίου χρωμίου ή κράμα επεξεργασμένου κοβαλτίου χρωμίου. Τα στελέχη με τσιμέντο ενσωματώνουν ακατέργαστη επιφάνεια ή σατινέ φινίρισμα.

  Για όλα τα στελέχη διατίθενται διαχωριστικά τσιμέντου των οστών από Πολυμεθυλμεθακρυλάτη (PMMA).
- **Ρυθμιζόμενα Έδρανα Κεφαλών , 22mm, 26mm, 28mm, και 32mm**
  Τα ρυθμιζόμενα έδρανα κεφαλών κατασκευάζονται από κράμα επεξεργασμένου κοβαλτίου χρωμίου με δυνατότητα επιλογής επιφάνειας βομβαρδισμένη με ιόντα Αζώτου ή μη βομβαρδισμένη με ιόντα, κεραμικό οξείδιο αργυλλίου ή κεραμικό οξείδιο ζιρκονίου. Τα ρυθμιζόμενα έδρανα κεφαλών συναρμολογούνται στον κώνο των ρυθμιζόμενων μηριαίων στελεχών και διατίθενται σε διάφορα μήκη αντιστάθμισης. Οι μεταλλικές κεφαλές διατίθενται σε δύο τύπους κώνου. Μια κεφαλή με έναν ειδικό κώνο πρέπει να αντιστοιχεί στον κώνο του στελέχους του μηριαίου ισχίου. Οι κεραμικές κεφαλές διατίθενται μόνο με κώνο 12/14 και θα πρέπει να χρησιμοποιούνται μόνο σε μηριαίο στέλεχος με κώνο 12/14.
- **Συμπαγή Κοτυλιαία Κυάθια Δοκιδωτού Μετάλλου με ή χωρίς οπές Βίδας**
  Τα Συμπαγή Κοτυλιαία Κυάθια Δοκιδωτού Μετάλλου κατασκευάζονται από Δοκιδωτό Μέταλλο (στρώμα τανταλίου επάνω σε υαλώδη σκελετό από άνθρακα) και δακτύλιο με επιφάνεια από κράμα τιτανίου με UHMWPE καλουπωμένο κατευθείαν στο Δοκιδωτό Μέταλλο. Το Κοτυλιαίο Κυάθιο Δοκιδωτού Μετάλλου έχει ελλειπτικό σχήμα. Τα Κοτυλιαία Κυάθια Δοκιδωτού Μετάλλου διατίθενται σε διαφορετικές γωνίες επιφάνειας και εσωτερικές διαμέτρους. Τα Συμπαγή Κοτυλιαία Κυάθια διατίθενται σε μεγέθη κυαθίων από 40mm έως 70mm. Τα Συμπαγή Κοτυλιαία Κυάθια Δοκιδωτού Μετάλλου διατίθενται με επιλογές ενισχυμένων σταυροειδών συνδέσεων σε μεγέθη εξωτερικής διαμέτρου 52mm έως 70mm.
- **Συμπαγή Κοτυλιαία Κυάθια Πορώδους Επικάλυψης και Επικάλυψης HA**
  Το Κοτυλιαίο Κυάθιο με Πορώδη Επικάλυψη διαθέτει πορώδη επικάλυψη σφαιριδίων τιτανίου CP και εσωτερικό χιτώνιο πολυαιθυλενίου εργοστασιακής τοποθέτησης. Το Κοτυλιαίο Κυάθιο με επικάλυψη HA, διαθέτει επικάλυψη υδροξυλαπατίτη και εσωτερικό χιτώνιο εργοστασιακής τοποθέτησης. Τα κοτυλιαία κυάθια διατίθενται σε διάφορες γωνίες επιφάνειας και κάθε γωνία επιφάνειας διατίθεται σε διάφορα μεγέθη εσωτερικής διαμέτρου. Τα κυάθια διατίθενται σε μεγέθη από 40mm έως 70mm.
- **Ρυθμιζόμενο Κοτυλιαίο Κυάθιο/ Περιβλήματα**
  Τα ελλειπτικά ρυθμιζόμενα κοτυλιαία κυάθια/ περιβλήματα κατασκευάζονται από δοκιδωτό μέταλλο με εσωτερική επιφάνεια κράματος τιτανίου ή με εξωτερική επιφάνεια σφαιριδίων Τιτανίου CP. Ο δακτύλιος ασφαλείας και τα θολωτά βύσματα κατασκευάζονται από κράμα τιτανίου. Το ρυθμιζόμενο κυάθιο διατίθεται σε μεγέθη κυαθίου από 40mm έως 70mm.
- **Ρυθμιζόμενα Χιτώνια UHMWPE 0 , 10 , και 20**
  Τα ρυθμιζόμενα χιτώνια UHMWPE διατίθενται σε τρεις γωνίες επιφάνειας και κάθε γωνία επιφάνειας διατίθεται σε διάφορα μεγέθη εσωτερικής διαμέτρου. Τα ρυθμιζόμενα χιτώνια διαθέτουν χτένια στην εξωτερική στεφάνη που επιτρέπουν στον χειρουργό ενδοχειρουργική μέτρηση της γωνίας επιφάνειας.
- **Κοτυλιαία Κυάθια Πολυαιθυλενίου με Τσιμέντο**
  Τα Κοτυλιαία Κυάθια Πολυαιθυλενίου κατασκευάζονται από Πολυαιθυλένιο εξαιρετικά υψηλού μοριακού βάρους και διαθέτουν ακτινογραφικό δακτύλιο δείκτη που κατασκευάζεται από κράμα κοβαλτίου χρωμίου. Τα Κοτυλιαία Κυάθια Πολυαιθυλενίου διατίθενται σε μεγέθη εξωτερικής διαμέτρου 40-70mm με διαβάθμιση 2mm. Τα Κοτυλιαία Κυάθια Πολυαιθυλενίου διατίθενται σε δύο γωνίες επιφάνειας (0° και 10°) και κάθε γωνία επιφάνειας διατίθεται σε διάφορα μεγέθη εσωτερικής διαμέτρου.
- **Επανορθωτικά Κοτυλιαία Περιβλήματα Δοκιδωτού Μετάλλου, Προσθετικά και Σφιγκτήρας**
  Τα Κοτυλιαία Προσθετικά Δοκιδωτού Μετάλλου κατασκευάζονται αποκλειστικά από δοκιδωτό μέταλλο (στρώμα τανταλίου επάνω σε υαλώδη σκελετό από άνθρακα). Το Κοτυλιαίο Προσθετικό Δοκιδωτού Μετάλλου επισυνάπτεται στο πορώδες κοτυλιαίο κυάθιο με τσιμέντο οστών. Το πορώδες Κοτυλιαίο Προσθετικό / Κοτυλιαία κατασκευή έχει σχεδιαστεί για χρήση με ή χωρίς τσιμέντο.

  Το Επανορθωτικό Κοτυλιαίο Περίβλημα Δοκιδωτού Μετάλλου έχει ελλειπτικό σχήμα και κατασκευάζεται από δοκιδωτό μέταλλο με δακτύλιο επιφάνειας από κράμα τιτανίου. Το Επανορθωτικό Κοτυλιαίο Κυάθιο Δοκιδωτού Μετάλλου διατίθεται με θολωτές οπές Βίδας. Το Επανορθωτικό Κοτυλιαίο Περίβλημα Δοκιδωτού Μετάλλου έχει σχεδιαστεί για χρήση με χιτώνα Αντικατάστασης UHMWPE με Τσιμέντο. Το Επανορθωτικό Κοτυλιαίο Περίβλημα Δοκιδωτού Μετάλλου διατίθεται σε μεγέθη κυαθίου από 40mm έως 80mm.

  Όταν απαιτείται πρόσθετη σταθεροποίηση χρησιμοποιούνται Βίδες Οστών Continuum (6,5mm και 5,0mm) ή το Κοτυλιαίο Σύστημα Zimmer Trilogy® ή Βίδες Οστών HGPII (6,5mm), τα οποία κατασκευάζονται από κράμα τιτανίου..
- **Χιτώνια Αντικατάστασης UHMWPE**
  Το Χιτώνιο Αντικατάστασης κατασκευάζεται από UHMWPE και είναι συμβατό με όλα τα κοτυλιαία Κυάθια και περιβλήματα που κατασκευάζονται από δοκιδωτό μέταλλο. Το Χιτώνιο Αντικατάστασης Πορώδους και HA του Κυαθίου αποτελείται από UHMWPE με δακτύλιο ασφαλείας τιτανίου. Όλα τα Χιτώνια Αντικατάστασης φέρουν ένδειξη που συνταυτίζεται με τα μεγέθη κυαθίων Implex.
- **Βίδες Οστών**
  Οι Βίδες Οστών Implex κατασκευάζονται από κράμα τιτανίου και διατίθενται σε μεγέθη διαμέτρου 5,0mm και 6,5mm καθώς και σε διάφορα μήκη
- **Επιστόμιο Τσιμέντου**
  Το Επιστόμιο Τσιμέντου κατασκευάζεται από χαμηλής πυκνότητας πολυαιθυλένιο.

Σημείωση: Το δοκιδωτό μέταλλο (στρώμα τανταλίου επάνω σε υαλώδη σκελετό από άνθρακα) κατασκευάζεται από την Implex Corp. Το βιολογικό υλικό δοκιδωτό μέταλλο διανέμεται με την ετικέτα της Implex και με την εμπορική ονομασία Hedrocel®.

ΕΝΔΕΙΞΕΙΣ

Η χρήση του Συστήματος Αρθροπλαστικής Ισχίου Implex ενδείκνυται για τα ακόλουθα περιστατικά::

α) Σοβαρή αναπηρία αρθρώσεων, αποτέλεσμα εκφυλιστικής αρθρίτιδας ή οστεονέκρωσης.

β) Δευτερεύουσα διόρθωση προηγούμενου ανεπιτυχούς μηριαίου εξαρτήματος ή ολική αντικατάσταση ισχίου.

γ) Άλλα προβλήματα ισχίου, όπου η κλινική εμπειρία έχει δείξει ότι εναλλακτικές μέθοδοι θεραπείας έχουν λιγότερες πιθανότητες να επιτύχουν ικανοποιητικά αποτελέσματα..

δ) Κάταγμα, εξάρθρωση του ισχίου ή κατάγματα που δεν δύναται να μειωθούν και στα οποία δεν μπορεί να επιτευχθεί επαρκής στερέωση.

ε) Κατάγματα του μηριαίου αυχένα ή της κεφαλής ή μη επουλώσιμα κατάγματα.

στ) [illegible] προηγούμενης πρωτεύουσας ή δευτερεύουσας ολικής ή ημι-αρθροπλαστικής

con una ghiera frontale in lega di titanio. La coppa acetabolare da revisione in metallo trabecolare è disponibile con fori per viti per la cupola; La corazza acetabolare da revisione in metallo trabecolare è destinata all'uso con guscio cementato da sostituzione in UHMWPE. La corazza acetabolare in metallo trabecolare è disponibile in misure di coppa da 40 mm a 80 mm.

Le viti ossee Continuum (6,5 mm e 5,0 mm), il sistema acetabolare *Trilogy*® della Zimmer o le viti ossee HGPII (6,5 mm), tutte in lega di titanio, si impiegano quando il caso richiede un fissaggio aggiuntivo.

- **Gusci da sostituzione in UHMWPE**
  Il guscio da sostituzione è realizzato in UHMWPE ed è compatibile con tutte le coppe e corazze acetabolari in metallo trabecolare. Il guscio da sostituzione coppa rivestito con HA e materiale poroso è composto da UHMWPE con un anello di bloccaggio in titanio. Tutti i gusci da sostituzione sono contrassegnati in modo da coincidere con le misure delle coppe Implex.
- **Viti ossee**
  Le viti ossee Implex sono realizzate in lega di titanio e sono disponibili in diametri da 5,0 mm e 6,5 mm con varie lunghezze.
- **Tappo di cemento**
  Il tappo di cemento è realizzato in polietilene a bassa densità.

Nota: Il metallo trabecolare (tantalio depositato su una struttura di carbonio vetroso) è prodotto da Implex Corp. Il biomateriale metallo trabecolare viene commercializzato inoltre con il marchio Hedrocel® di Implex.

INDICAZIONI

L'uso del sistema protesico d'anca Implex è indicato per:

a) Articolazioni gravemente compromesse in seguito ad artrite degenerativa o necrosi avascolare.

b) Revisione secondaria di una precedente sostituzione di un componente femorale o sostituzione totale dell'anca con esito negativo.

c) Altre problematiche legate all'anca per le quali l'esperienza clinica ha mostrato che metodiche di trattamento alternative hanno minori probabilità di raggiungere risultati soddisfacenti.

d) Frattura-lussazione dell'anca o fratture irriducibili in cui non è possibile ottenere una fissazione adeguata.

e) Mancata giunzione o fratture del collo o della testa femorale.

f) Recupero di una sostituzione primaria o secondaria totale o parziale d'anca con esito negativo.

CONTROINDICAZIONI

a) L'infezione attiva o latente interna o adiacente l'articolazione dell'anca rappresenta una controindicazione assoluta che dovrà essere esclusa in pazienti che presentano:

1. febbre e/o infiammazione locale;
2. rapida distruzione dell'articolazione o riassorbimento osseo evidenziati dall'esame radiografico
3. aumento della velocità di sedimentazione non spiegabile altrimenti, aumento della conta leucocitaria o variazione significativa nella conta differenziale.

b) Disturbi mentali o neuromuscolari che creerebbero un rischio inaccettabile di instabilità dell'articolazione, complicazioni post-operatorie o collasso strutturale del componente.

c) Sostanza ossea insufficiente che non consente all'osso di sostenere e fissare il componente.

d) Le teste femorali ceramiche Implex sono controindicate per l'uso con componenti diversi da coppe in UHMWPE o coppe in UHMWPE rinforzate in metallo.

AVVERTENZE

a) I siti di infezione o una potenziale infezione distante dall'anca possono estendersi all'anca per via ematica e devono essere trattati prima dell'intervento chirurgico.

b) Il chirurgo dovrà avere completa familiarità con i componenti e con la tecnica chirurgica relativa al sistema protesico d'anca Implex. A tale scopo, Implex fornisce brochure sulla Tecnica di protesizzazione d'anca Implex.

c) La lussazione post-operatoria rappresenta una seria complicazione dell'artroplastica totale dell'anca. I pazienti devono essere trattati in modo tale da ridurre la possibilità di lussazione fino a quando i tessuti molli non sono in grado di fornire la stabilità necessaria all'articolazione.

d) Una volta impiantato, il componente non deve essere mai riutilizzato.

e) In pazienti particolarmente attivi o in sovrappeso, la possibilità di collasso strutturale dei componenti è superiore. Adottare ogni misura per limitare i livelli di attività e ridurre il peso dei pazienti successivamente all'impianto.

f) I componenti del sistema protesico d'anca Implex (esclusi i componenti acetabolari in metallo trabecolare) non devono mai essere utilizzati in combinazione con componenti di altri produttori, a causa delle differenze di misura, tolleranza o delle diverse tecniche di lavorazione. I componenti acetabolari in metallo trabecolare Implex possono essere utilizzati esclusivamente con teste femorali Implex o con teste femorali prodotte o distribuite dalla Zimmer e non devono mai essere utilizzati in combinazione con componenti di altri produttori, a causa delle differenze di misura, tolleranza o delle diverse tecniche di lavorazione.

Qualora le circostanze richiedano l'uso combinato di componenti di produttori diversi, accertare preventivamente il grado di compatibilità tra i componenti in merito a misura, tolleranza o materiali.

g) Non modificare, piegare o altrimenti manipolare in nessun caso gli impianti dopo la spedizione da parte del produttore.

h) La testa ceramica all'ossido di zirconio è realizzata con un nuovo materiale ceramico con storia clinica limitata. Sebbene test meccanici abbiano dimostrato che, quando utilizzata con coppe acetabolari in polietilene, la sfera di zirconio parzialmente stabilizzata produce una quantità di particelle relativamente bassa, la quantità totale di particelle resta incerta. A causa della limitata esperienza clinica e pre-clinica, gli effetti biologici a lungo termine delle particelle sono sconosciuti.

i) Le viti ossee Implex non sono approvate per il fissaggio con vite o il fissaggio agli elementi posteriori (peduncoli) al tratto cervicale, toracico o lombare della colonna vertebrale.

PRECAUZIONI

a) Disturbi mentali o neuromuscolari che creerebbero un rischio inaccettabile di instabilità dell'articolazione, complicazioni post-operatorie o collasso strutturale del componente.

b) Il chirurgo dovrà avere completa familiarità con i componenti e con la tecnica chirurgica relativa al sistema protesico d'anca Implex. A tale scopo, Implex fornisce una brochure sulla Tecnica di protesizzazione d'anca.

c) Una volta impiantato, il componente non deve essere mai riutilizzato.

d) Le teste femorali ceramiche Implex devono essere utilizzate esclusivamente con steli d'anca in lega di titanio o in lega cromo-cobalto prodotti da Implex Corp., con perno di articolazione rastremato 12/14.

e) Durante l'interfacciamento di un componente acetabolare Implex con una testa femorale prodotta o distribuita dalla Zimmer, il chirurgo dovrà avere completa familiarità con i componenti e con le tecniche chirurgiche Zimmer ed essere informato sull'uso designato e sui rischi degli impianti. Consultare il foglio illustrativo all'interno della confezione del prodotto Zimmer per avvertenze, precauzioni ed effetti indesiderati. Fare riferimento inoltre alla tecnica chirurgica Zimmer appropriata.

CURA DEGLI STRUMENTI – PRECAUZIONI SPECIALI

Procedure corrette di manipolazione, decontaminazione - incluso risciacquo preliminare, lavaggio, risciacquo e sterilizzazione -, immagazzinamento e utilizzo sono importanti per garantire una lunga durata di tutti gli strumenti chirurgici e dei provvisori. Anche dopo un uso, cura e manutenzione corretti, tali strumenti non potranno necessariamente durare a tempo indeterminato. Ciò vale in particolare per gli strumenti di taglio (ad es., punte di trapano, alesatori, raspe, sgorbie, guide e scalpelli), gli strumenti di inserzione (ad es., introduttori, martelli, pestelli, perni, estrattori e dispositivi d'urto) e i provvisori. Questi componenti sono spesso soggetti ad elevati carichi e/o forze d'urto. In tali condizioni, possono verificarsi rotture, specie nel caso in cui il componente sia corroso, danneggiato, scalfito o graffiato.

Prima di ciascun impiego, ispezionare attentamente tutti gli strumenti e i provvisori. Non usare strumenti di inserzione gravemente danneggiati e usurati o strumenti di taglio con bordi non affilati. Eventuali strumenti non affilati dovranno essere sempre restituiti alla Implex per determinare la possibilità di riaffilarli.

Nota: Col tempo, gli strumenti si usurano e dovranno essere sostituiti. Contattare Implex Corp. per indicazioni sulle procedure

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

στ) Διάσωση αποτυχημένης πρωτεύουσας ή δευτερεύουσας ολικής ή ημι-αρθροπλαστικής

ΑΝΤΕΝΔΕΙΞΕΙΣ

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α) Ενεργή ή λανθάνουσα λοίμωξη μέσα ή περί της άρθρωσης του ισχίου αντενδείκνυται κατηγορηματικά, και θα πρέπει να αποκλείονται ασθενείς που παρουσιάζουν
   1. Πυρετό και / ή τοπική φλεγμονή
   2. Ραγδαία καταστροφή των αρθρώσεων ή οστική απορρόφηση σύμφωνα με την ακτινογραφία
   3. Ανεξήγητη αύξηση του ρυθμού καθίζησης, αύξηση των λευκών αιμοσφαιρίων ή σημαντική απόκλιση της διαφορικής μέτρησης των λευκών αιμοσφαιρίων

β) Διανοητικές ή νευρομυϊκές διαταραχές, οι οποίες θα δημιουργούσαν ανεπιθύμητο κίνδυνο αρθρικής αστάθειας, σταθεροποίησης των εξαρτημάτων, μετεγχειρητικές επιπλοκές ή κατασκευαστική ανεπάρκεια εξαρτημάτων.

γ) Ανεπαρκή οστικό όγκο που δεν θα επιτρέπει στο οστό να υποστηρίξει και να σταθεροποιήσει το εξάρτημα.

δ) Οι Κεραμικές Μηριαίες Κεφαλές Implex αντενδείκνυνται για χρήση με οποιοδήποτε άλλο κυάθιο πλην κυαθίου UHMWPE ή Κυάθιο UHMWPE με μεταλλική στήριξη.

ΠΡΟΕΙΔΟΠΟΙΗΣΕΙΣ

α) Λοιμώδεις ή δυνητικά λοιμώδεις περιοχές που βρίσκονται μακριά από το ισχίο μπορεί να μεταδώσουν τη λοίμωξη σε αυτό μέσω του αίματος και θα πρέπει να αντιμετωπίζονται πριν από τη χειρουργική επέμβαση.

β) Ο χειρουργός θα πρέπει να είναι απόλυτα εξοικειωμένος με τα εξαρτήματα, καθώς και τη χειρουργική τεχνική που αφορά στο Σύστημα Αρθροπλαστικής Ισχίου της Implex. Για αυτό το λόγο η Implex παρέχει φυλλάδια της Τεχνικής Αρθροπλαστικής Ισχίου της Implex.

γ) Η μετεγχειρητική εξάρθρωση αποτελεί σοβαρή επιπλοκή της ολικής αρθροπλαστικής ισχίου. Οι ασθενείς θα πρέπει να κάνουν θεραπεία τέτοια, ώστε να μειώνεται η πιθανότητα εξάρθρωσης μέχρι ο μαλακός ιστός να είναι σε θέση να παράσχει την απαραίτητη σταθερότητα στην άρθρωση

δ) Μετά την εμφύτευση, το εμφύτευμα δεν πρέπει σε καμία περίπτωση να ξαναχρησιμοποιηθεί.

ε) Η πιθανότητα κατασκευαστικής ανεπάρκειας των εμφυτευμάτων αυξάνεται σε πολύ δραστήριους ή παχύς ασθενείς. Πρέπει να γίνεται κάθε προσπάθεια περιορισμού του επιπέδου δραστηριότητας και μείωσης του βάρους των ασθενών μετά την εμφύτευση

στ) Τα εξαρτήματα του συστήματος αρθροπλαστικής ισχίου Implex (εξαιρουμένων των κοτυλιαίων εξαρτημάτων Δοκιδωτού Μετάλλου) δεν πρέπει να χρησιμοποιούνται σε συνδυασμό με εξαρτήματα άλλου κατασκευαστή λόγω των αποκλίσεων των μεγεθών, ανοχών και άλλων διαδικαστικών πρακτικών. Τα Κοτυλιαία Εξαρτήματα Δοκιδωτού Μετάλλου της Implex μπορούν να χρησιμοποιηθούν με τις μηριαίες κεφαλές της Implex ή μόνο με μηριαίες κεφαλές που κατασκευάζονται ή διατίθενται από τη Zimmer και θα δεν θα πρέπει να χρησιμοποιούνται σε συνδυασμό με εξάρτημα άλλου κατασκευαστή λόγω αποκλίσεων στα μεγέθη, τις ανοχές και σε άλλες διαδικαστικές πρακτικές. Υπό συνθήκες που υπαγορεύουν την ανάμιξη εξαρτημάτων διαφορετικών κατασκευαστών, πρέπει να διαβεβαιώνεται η συμβατότητα μεταξύ των εξαρτημάτων όσον αφορά στα μεγέθη, τις ανοχές ή τα υλικά κατασκευής

ζ) Τα εμφυτεύματα δεν πρέπει σε καμία περίπτωση να τροποποιούνται, να κάμπτονται, ή να υποβάλλονται σε επεξεργασία μετά την αποστολή τους από τον κατασκευαστή.

η) Η Κεφαλή Οξειδίου Ζιρκονίου κατασκευάζεται από ένα νέο κεραμικό υλικό με περιορισμένο κλινικό ιστορικό. Παρόλο που οι μηχανικές δοκιμές δείχνουν ότι όταν χρησιμοποιείται με κοτυλιαία κυάθια πολυαιθυλενίου, η μερικώς σταθεροποιημένη σφαίρα ζιρκονίου παράγει σχετικά χαμηλή ποσότητα σωματιδίων, η συνολική ποσότητα σωματιδιακών υπολειμμάτων δεν έχει προσδιοριστεί. Λόγω της περιορισμένης κλινικής και προ-κλινικής εμπειρίας, είναι άγνωστα τα μακροπρόθεσμα βιολογικά αποτελέσματα των σωματιδίων

θ) Οι βίδες οστών της Implex δεν είναι εγκεκριμένες για χρήση σύνδεσης με βίδα ή σταθεροποίηση σε οπίσθια μέρη (αυχένας τόξου σπονδύλων) της αυχενικής, θωρακικής και οσφυϊκής χώρας της σπονδυλικής στήλης

ΠΡΟΦΥΛΑΞΕΙΣ

α) Διανοητικές και νευρομυϊκές διαταραχές, οι οποίες μπορεί να δημιουργήσουν ανεπιθύμητους κινδύνους αρθρικής αστάθειας, σταθεροποίησης εμφυτεύματος, μετεγχειρητικές επιπλοκές ή κατασκευαστική ανεπάρκεια του εμφυτεύματος.

β) Ο χειρουργός θα πρέπει να είναι απόλυτα εξοικειωμένος με τα εξαρτήματα καθώς και τη χειρουργική τεχνική του Συστήματος Αρθροπλαστικής Ισχίου Implex. Για αυτό το λόγο η Implex παρέχει ειδικό φυλλάδιο Χειρουργικής Τεχνικής Αρθροπλαστικής Ισχίου.

γ) Μετά την εμφύτευση, το εξάρτημα δεν πρέπει να ξαναχρησιμοποιηθεί σε καμία περίπτωση.

δ) Οι Κεραμικές Μηριαίες Κεφαλές Implex πρέπει να χρησιμοποιούνται με Στελέχη Ισχίου κράματος τιτανίου ή κράματος κοβαλτίου χρωμίου της Implex Corp. μόνο με σημείο στήριξης κώνου 12/14.

ε) Όταν διασυνδέεται ένα κοτυλιαίο εξάρτημα Implex με μηριαία κεφαλή που κατασκευάζεται ή διανέμεται από την Zimmer, ο χρήστης πρέπει να είναι πλήρως εξοικειωμένος με τα εξαρτήματα και τις χειρουργικές τεχνικές και να γνωρίζει την προτεινόμενη χρήση και τους κινδύνους των εμφυτευμάτων. Ανατρέξατε στη Συσκευασία Χιτωνίου της Zimmer για τις Προειδοποιήσεις, Προφυλάξεις και Ανεπιθύμητα Αποτελέσματα. Ανατρέξατε επίσης στο κατάλληλο φυλλάδιο Χειρουργικής Τεχνικής της Zimmer

ΚΑΘΑΡΙΣΜΟΣ ΟΡΓΑΝΩΝ - ΕΙΔΙΚΕΣ ΠΡΟΦΥΛΑΞΕΙΣ

Ο σωστός χειρισμός, η απολύμανση, συμπεριλαμβανομένης της πλύσης πριν από τη χρήση, τον καθαρισμό, την πλύση και αποστείρωση, καθώς και η φύλαξη και χρήση αποτελούν σημαντικούς παράγοντες για την μεγαλύτερη διάρκεια χρήσης όλων των χειρουργικών και αναλώσιμων οργάνων, αλλά ακόμη και με σωστή χρήση, περιποίηση και συντήρηση δεν είναι δυνατόν να διατηρηθούν επ αόριστον. Αυτό ισχύει ιδιαίτερα για τα όργανα εκτομής (π.χ. τεμαχίδια τρυπάνου, αποξυστικά, ράσπες, σμίλες, οδηγοί και γλυφίδες), τα όργανα οδήγησης (π.χ. οδηγοί, σφύρες, έμβολα πίεσης, ακίδες, εξαγωγείς, και εισαγωγείς) και αναλώσιμα όργανα. Τα όργανα αυτά συχνά υποβάλλονται σε μεγάλες πιέσεις και/ ή δυνάμεις πρόσκρουσης. Υπό αυτές τις συνθήκες μπορεί να επέλθουν βλάβες, ιδιαίτερα όταν το όργανο είναι διαβρωμένο, έχει υποστεί βλάβες, εγκοπές ή αμυχές.

Πριν από κάθε χρήση, ελέγξτε προσεκτικά όλα τα όργανα και αναλώσιμα. Μη χρησιμοποιείτε όργανο οδήγησης που είναι πολύ κατεστραμμένο ή έχει φθαρεί ή όργανο εκτομής με αμβλεία κόψη. Τα αμβλεία όργανα θα πρέπει πάντα να επιστρέφονται στην Implex προκειμένου να προσδιοριστεί εάν είναι δυνατόν να ακονιστούν εκ νέου.

Σημείωση: Σε κάποια χρονική στιγμή τα όργανα φθείρονται και θα πρέπει να αντικαθίστανται. Για οδηγίες σχετικά με την περιποίηση και χειρισμό χειρουργικών οργάνων επικοινωνήστε με την Implex Corp.

ΑΝΕΠΙΘΥΜΗΤΑ ΑΠΟΤΕΛΕΣΜΑΤΑ

α) Έχει αναφερθεί μετεγχειρητική εξάρθρωση του ισχίου.

β) Έχει αναφερθεί πρώιμη ή όψιμη χαλάρωση του εμφυτεύματος.

γ) Έχουν παρατηρηθεί αντιδράσεις υπερευαισθησίας στο μέταλλο. Η σημασία των αντιδράσεων αυτών απαιτεί περαιτέρω μελέτη.

δ) Μπορεί να εμφανιστεί ετερότοπος οστεοποίηση και περιφερικές νευροπάθειες.

ε) Σπανίως αναφέρονται και κατάγματα λόγω υπερκόπωσης των εξαρτημάτων ολικής αρθροπλαστικής ισχίου. Το κάταγμα των εμφυτευμάτων ή η φθορά τους είναι πιθανότερη σε πολύ δραστήριους ή παχύς ασθενείς. Η ετερόπλευρη αναπηρία της άρθρωσης ή του άκρου μπορεί να εφαρμόσει δυσανάλογο βάρος στα εξαρτήματα.

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

στ) Σε ορισμένες περιπτώσεις [illegible] ανεπιθύμητων αποτελεσμάτων. Σε σπάνιες περιπτώσεις, οι κλινικές επιπλοκές μπορεί να καταστήσουν απαραίτητη την αρθροδεσία ή τον ακρωτηριασμό.

di cura e manipolazione degli strumenti chirurgici.

EFFETTI INDESIDERATI

a) È stata riferita lussazione post-operatoria dell'articolazione dell'anca.

b) È stato riferito allentamento prematuro o ritardato del componente.

c) Sono state riferite reazioni di sensibilità al metallo. L'effetto di tali reazioni è in attesa di ulteriore ricerca.

d) Possono verificarsi ossificazione ectopica e neuropatie periferiche.

e) In rari casi si sono verificate fratture da affaticamento dei componenti della protesi totale d'anca. La rottura o l'usura del componente è più probabile in pazienti particolarmente attivi o in sovrappeso. L'invalidità dell'articolazione controlaterale o dell'estremità può sottoporre i componenti ad un carico sproporzionato.

f) In alcuni casi si rende necessario eseguire nuovamente l'intervento per correggere un effetto indesiderato. In rare occasioni, le complicazioni cliniche possono richiedere interventi di artrodesi dell'articolazione o amputazione dell'arto.

UTILIZZO ED ESECUZIONE DELL'IMPIANTO

Viene fornito un set completo di strumenti necessario per l'impianto dei componenti. Alcuni modelli radiografici assistono il chirurgo nella valutazione della misura o dell'intervallo di misure da impiegare.

Gli alesatori, i raschietti e i campioni forniti con il set di strumenti sono i componenti che determinano la misura definitiva della protesi da impiegare. L'uso dei campioni per confermare la misura scelta e la stabilità dell'articolazione preserva l'integrità e la sterilità degli impianti.

Il corretto posizionamento dei componenti consente di evitare il carico involontario dei componenti e può prolungare la durata utile degli impianti. Sono disponibili brochure sulla Tecnica di protesizzazione d'anca Implex per ulteriori informazioni dettagliate sulla procedura raccomandata.

STERILIZZAZIONE

Componenti del sistema protesico d'anca Implex sono sterilizzati per esposizione a radiazioni gamma emesse da ^{60}Co a una dose minima di 25 KGy. La data di sterilizzazione o di scadenza del componente è stampata sull'etichetta della confezione esterna. La risterilizzazione dei componenti è specificamente sconsigliata. Tutti i componenti in polietilene sono confezionati con gas di azoto. Prima di usare l'impianto, ispezionare accuratamente le chiusure ermetiche sia della confezione interna che di quella esterna (la confezione interna contiene il componente) per verificare la presenza di eventuali difetti o aperture.

Per determinare le dimensioni corrette prima di aprire la confezione sterile si utilizzano componenti di prova e strumenti provvisori. I componenti di prova e gli strumenti provvisori devono essere sterilizzati in conformità ai protocolli e alle procedure di sterilizzazione del proprio istituto. Inoltre, tutti i metodi di sterilizzazione devono essere conformi alle relative indicazioni e agli standard ANSI/AAMI/ISO, assicurando un livello di sterilità pari a 10^{-6}. La sterilizzazione degli strumenti è stata convalidata per i vassoi di strumenti con involucro. I vassoi di strumenti con involucro possono essere sterilizzati a vapore ad una temperatura di 134°C (273°F) per 20 minuti, quindi lasciati asciugare per 30 minuti. Gli strumenti devono essere puliti in conformità ai protocolli e alle procedure di sterilizzazione del proprio istituto.

Brevetti USA N°
5,593,451/5,443,519/5,549,698/5,571,200/5,571,201/5,282,861/5,702,487/5,486,181/6,087,553/6,063,442

Implex Corp., 2003 Tutti i diritti riservati
Implex, Continuum e Hedrocel sono marchi registrati di Implex Corp.
Zimmer e Trilogy sono marchi registrati di Zimmer, Inc, Warsaw, IN (USA)

Portuguese

Sistema para a Bacia da Implex

DESCRIÇÃO

Os componentes do sistema para a bacia da Implex consistem em:

- **Suporte modular para a bacia femoral, sem cimento: Hydroxylapatite (HA) e Poroso**
  O suporte revestido de HA é fabricado de alumínio de titânio e revestido em sua seção proximal com Hydroxylapatite de alta pureza, densidade e cristanilidade. O suporte poroso revestido é feito de alumínio de cromo de cobalto, com o alumínio de cromo de cobalto formando a superfície porosa.
- **Suporte para a bacia femoral cimentado e cabeças de rolamentos fixos com espaçadores cimentados**
  Os suportes cimentados do femoral são fabricados com alumínio de croma de cobalto fundido ou alumínio de cromo de cobalto forjado. Os suportes cimentados incorporam um superfície proximal rugosa ou um acabamento de acetinado.
  Os espaçadores cimentados ósseos Polymethylmethacrylate (PMMA) estão disponíveis para todos os suportes.
- **Cabeças de rolamentos modulares, 22mm, 26mm, 28mm e 32mm**
  As cabeças de rolamentos modulares são fabricadas em liga de crómio/cobalto forjado, com as opções de superfícies bombardeadas ou não com ião de nitrogênio, óxido de alumínio cerâmica ou zircônio cerâmico. As cabeças de rolamentos modulares têm um adaptador cônico para a montagem nos suportes modulares femorais e estão disponíveis em diversos comprimentos de deslocamento do pescoço. As cabeças metálicas estão disponíveis em dois adaptadores cônicos. Uma cabeça com um adaptador cónico específico deve corresponder ao adaptador cônico no suporte femoral da bacia. As cabeças cerâmicas só estão disponíveis em adaptador cônico 12/14 e só devem ser usadas num suporte femoral com um adaptador cônico 12/14.
- **Ventosa do monobloco de cavidade cotilóide de Metal Trabecular com ou sem buracos para parafusos**
  As ventosas do monobloco de cavidade cotolóide são fabricadas em Metal Trabecular (tântalo depositado em uma estrutura de carbono vítreo) e um anel de face de liga de titânio com UHMWPE diretamente compresso moldado no Metal Trabecular. A ventosa de cavidade cotiláide de Metal Trabecular tem uma geometria elíptica. As ventosas de cavidade catilóide de Metal Trabecular estão disponíveis em vários ângulos faciais e diâmetros internos. As Ventosas de monobloco de cavidade cotilóide estão disponíveis em tamanhos de 40mm a 70mm. As ventosas de monobloco de cavidade cotilóide de Metal Trabecular estão disponíveis em opções aprimoradas de ligação cruzada em tamanhos OD de 52mm a 70mm.
- **Ventosas de monobloco de cavidade cotilóide com Revestimento Poroso e com Revestimento HA**
  A ventosa de cavidade cotilóide com revestimento poroso tem um revestimento assentado em titânio poroso CP e um alinhador todo de polietileno montado na fábrica. A ventosa de cavidade cotilóide revestida com HA tem um revestimento de hidroxilapatite e um alinhador montado na fábrica. As ventosas cotilóides estão disponíveis em vários ângulos faciais e cada ângulo facial está disponível em vários diâmetros internos. As ventosas estão disponíveis em tamanhos de 40mm a 70mm.
- **Enxerto/Revestimento de cavidade de cotilóide modular**
  Os enxertos/revestimentos de cavidade cotilóide elíptica modular são fabricados de metal trabecular com uma superfície interna de alumínio de titânio ou com uma superfície externa assentada em titânio CP. O anel de travamento e os pinos com cabeça de furos são feitos de alumínio de titânio. Os enxertos modulares estão disponíveis em tamanhos de 40mm a 70mm.
- **Alinhadores modulares UHMWPE 0°, 10° e 20°**
  [illegible] estão disponíveis em três ângulos faciais e cada ângulo facial está disponível em vários [illegible]

Records processed under FOIA Request # 2016-1518; Released by CDRH on 05-23-2016

Οι ακτινογραφίες επίσης αποτελούν βοήθημα για τον χειρουργό στην εκτίμηση του μεγέθους ή της κλίμακας μεγεθών που θα πρέπει να χρησιμοποιηθούν.

Τα όργανα διάνοιξης, οι ξυριστικές συσκευές και τα δοκιμαστικά παρέχονται στο σετ οργάνων και αποτελούν τα όργανα τελικού προσδιορισμού του μεγέθους των προσθετικών που θα χρησιμοποιηθούν. Με τη χρήση των δοκιμαστικών, προς επιβεβαίωση της επιλογής του σωστού μεγέθους και της σταθερότητας της άρθρωσης, διατηρούνται ακέραια και αποστειρωμένα τα εμφυτεύματα.

Η σωστή τοποθέτηση των εξαρτημάτων βοηθά στην αποφυγή υπερβολικής τους φόρτισης και μπορεί να παρατείνει τη διάρκεια ζωής των εμφυτευμάτων. Η Implex διαθέτει ειδικά φυλλάδια της Τεχνικής Χειρουργικής Αρθροπλαστικής Ισχίου ώστε να παρέχονται πρόσθετες πληροφορίες σχετικά με την προτεινόμενη διαδικασία.

ΑΠΟΣΤΕΙΡΩΣΗ

Τα εξαρτήματα του Συστήματος Αρθροπλαστικής Ισχίου της Implex αποστειρώνονται με ακτινοβολία γ ^{60}Co με ελάχιστη δόση 25 kGy.

Η ημερομηνία αποστείρωσης ή λήξης των εξαρτημάτων αναγράφεται στην ετικέτα της εξωτερικής συσκευασίας. Συνιστάται ρητώς η αποφυγή επαναποστείρωσης των εξαρτημάτων. Όλα τα εξαρτήματα πολυαιθυλενίου συσκευάζονται με χρήση αζώτου. Πριν από τη χρήση του εμφυτεύματος θα πρέπει να ελέγχονται προσεκτικά για ατέλειες ή διαρροές οι σφραγίδες ασφαλείας στις εξωτερικές καθώς και εσωτερικές συσκευασίες (η εσωτερική συσκευασία περιέχει το εξάρτημα).

Για τον προσδιορισμό του μεγέθους χρησιμοποιούνται δοκιμαστικά/ αναλώσιμα και άλλα εργαλεία προτού ανοιχθεί το αποστειρωμένο πακέτο. Τα δοκιμαστικά/αναλώσιμα εξαρτήματα και όργανα θα πρέπει να αποστειρώνονται σύμφωνα με τους τύπους και διαδικασίες αποστείρωσης του εκάστοτε νοσηλευτικού ιδρύματος. Επιπλέον, όλες οι μέθοδοι αποστείρωσης πρέπει να συμφωνούν με τις αντίστοιχες οδηγίες και πρότυπα των AAMI/ANSI/ISO, και θα πρέπει να επιτυγχάνεται αποστείρωση επιπέδου 10^{-6}. Η αποστείρωση των οργάνων πιστοποιείται για τις συσκευασμένες κασετίνες. Η συσκευασμένη κασετίνα δύναται να αποστειρωθεί δι' ατμού σε θερμοκρασία 273° F (134° C) για χρονική διάρκεια 20 λεπτών, με αποξήρανση διάρκειας 30 λεπτών. Τα εξαρτήματα θα πρέπει να καθαρίζονται σύμφωνα με τους τύπους και διαδικασίες του εκάστοτε νοσηλευτικού ιδρύματος.

Italian

Sistemi protesici d'anca Implex

DESCRIZIONE

I componenti dei sistemi protesici d'anca Implex sono composti da:

- **Steli d'anca femorali modulari, non cementati: rivestimento in idrossiapatite (HA) e poroso**
  La stelo rivestito con HA è realizzato in lega di titanio ed è rivestito in corrispondenza della sezione prossimale con idrossiapatite ad elevata purezza, densità e cristallinità. Lo stelo rivestito in materiale poroso è realizzato in lega cromo-cobalto con microsfere in lega cromo-cobalto che formano la superficie porosa.
- **Steli d'anca femorali cementati modulari e testina di sostegno fissa con spessori in cemento**
  Gli steli femorali cementati sono realizzati in lega cromo-cobalto da getto oppure in lega cromo-cobalto da lavorazione plastica. Gli steli cementati sono dotati di superficie ruvida a livello prossimale o di finitura satinata.
  Per tutti gli steli sono disponibili spessori di cemento osseo in polimetilmetacrilato (PMMA).
- **Teste di sostegno modulari da 22 mm, 26 mm 28 mm e 32 mm**
  Le teste di sostegno modulari sono realizzate in lega cromo-cobalto forgiato. Le superfici sono disponibili nelle versioni bombardate agli ioni di azoto oppure non bombardate agli ioni, ceramica all'ossido di alluminio e ceramica all'ossido di zirconio. Le teste di sostegno modulari hanno sezione rastremata per il montaggio agli steli femorali modulari e sono disponibili in varie lunghezze di offset del collo femorale. Le teste metalliche sono disponibili in due sezioni rastremate. La rastrematura di una determinata testa deve corrispondere a quella dello stelo d'anca femorale associato. Le teste ceramiche sono disponibili solo in rastrematura da 12/14 e devono essere utilizzate solo con steli femorali della stessa misura.
- **Coppe acetabolari monoblocco in metallo trabecolare con e senza fori per viti**
  Le coppe acetabolari monoblocco in metallo trabecolare sono realizzate in metallo trabecolare (tantalio depositato su una struttura di carbonio vetroso) ed una ghiera frontale in lega di titanio con UHMWPE stampato a compressione direttamente nel metallo trabecolare. La coppa acetabolare in metallo trabecolare ha una geometria ellittica. Le coppe acetabolari in metallo trabecolare sono disponibili in varie angolazioni frontali e diametri interni. Le coppe acetabolari monoblocco sono disponibili in misure da 40 mm a 70 mm. Le coppe acetabolari monoblocco in metallo trabecolare sono disponibili con opzioni reticolate di diametro esterno da 52 mm a 70mm.
- **Coppe acetabolari monoblocco con rivestimento poroso e rivestimento in HA**
  La coppa acetabolare con rivestimento poroso presenta un rivestimento in microsfere di titanio commercialmente puro ed un inserto interamente in polietilene assemblato in fabbrica. La coppa acetabolare con rivestimento in HA presenta un rivestimento in idrossiapatite ed un inserto assemblato in fabbrica. Le coppe acetabolari sono disponibili in varie angolazioni frontali, ciascuna disponibile in vari diametri interni. Le coppe sono disponibili in misure da 40 mm a 70 mm.
- **Coppa/corazze acetabolari modulari**
  La coppa/corazze acetabolari ellittiche modulari sono realizzate in metallo trabecolare con una superficie interna in lega di titanio oppure con una superficie esterna in microsfere di titanio commercialmente puro. L'anello di bloccaggio e il tappo per il foro della cupola sono realizzati in lega di titanio. La coppa modulare è disponibile in misure da 40 mm a 70 mm.
- **Inserti modulari in UHMWPE da 0°, 10° e 20°**
  Gli inserti UHMWPE modulari sono disponibili in tre angolazioni frontali, ciascuna disponibile in vari diametri interni. Gli inserti modulari presentano dentellature sul bordo esterno che consentono al chirurgo di selezionare l'angolazione frontale durante l'intervento operatorio.
- **Coppe acetabolari cementate interamente in polietilene**
  Le coppe acetabolari interamente in polietilene sono realizzate in polietilene ad altissimo peso molecolare e sono dotate di anello marker radiografico realizzato in lega cromo-cobalto. Le coppe acetabolari interamente in polietilene sono disponibili in misure di diametro esterno da 40-70 mm con incrementi di 2 mm. Le coppe acetabolari interamente in polietilene sono disponibili in due angolazioni frontali (0° e 10°), ciascuna disponibile in vari diametri interni.
- **Corazze, estensioni e limitatori acetabolari da revisione in metallo trabecolare**
  Le estensioni acetabolari in metallo trabecolare sono realizzate interamente in metallo trabecolare (tantalio depositato su una struttura di carbonio vetroso). L'estensione acetabolare in metallo trabecolare viene applicata alla coppa acetabolare porosa mediante cemento osseo. Il gruppo estensione acetabolare poroso/struttura acetabolare è destinato alla fissazione cementata e non cementata.
  La corazza acetabolare da revisione in metallo trabecolare ha una geometria ellittica ed è realizzata in metallo trabecolare

todem no ângulo facial, a nível intra-operativo.

- **Ventosas de cavidade cotilóide cimentadas todas em polietileno**
  As ventosas de cavidade cotilóide todas em polietileno são fabricadas com polietileno de peso molecular ultra-elevado e têm um anel de marcação radiográfica fabricado em liga de crómio/cobalto. As ventosas de cavidade cotilóide todas em polietileno estão disponíveis nos tamanhos OD de 40-70mm em incrementos de 2mm. As ventosas de cavidade cotilóide todas em polietileno estão disponíveis em dois ângulos faciais (0° e 10°) e cada ângulo facial está disponível em vários diâmetros internos.
- **Revestimentos de cavidade cotilóide de revisão Metal Trabecular, Enxertos e Limitador**
  Os enxertos e limitadores de metal trabecular de cavidade cotilóide são fabricados totalmente com metal trabecular (tântalo depositado sobre um estrutura de carbono vítreo). O enxerto de cavidade cotilóide de metal trabecular é afixado ao enxerto poroso de cavidade cotilóide usando cimento ósseo. O desenho do enxerto de cavidade cotilóide/cavidade cotilóide é para uso com ou sem cimento. O revestimento de cavidade cotilóide de revisão metal trabecular tem uma geometria elíptica e é fabricado com metal trabecular com um anel de face de alumínio de titânio. O revestimento de cavidade cotilóide de revisão metal trabecular está disponível com parafusos com cabeça. O revestimento de cavidade cotilóide de revisão metal trabecular é para ser usado com o alinhador cimentado UHMWPE de substituição. Os enxertos de cavidade cotilóide de metal trabecular estão disponíveis em tamanhos de 40mm a 80mm.
  Os parafusos ósseos Continuum Bone (6.5mm e 5.0mm) ou com o Sistema de Cavidade Cotilóide Zimmer *Trilogy*™ ou com os parafusos ósseos HGPII (6.5mm), todos fabricados com alumínio de titânio, são usados quando a fixação adjunta for requerida.
- **Alinhadores UHMWPE de Reposição**
  Os Alinhadores de Reposição é fabricado de UHMWPE e são compatíveis com todos os enxertos e revestimentos de cavidade cotilóide fabricados com metal trabecular. O Alinhador de Reposição de Enxerto Poroso e HA é composto de UHMWPE com um anel de travamento de titânio. Todos os Alinhadores de Reposição são marcados para coincidirem com os tamanhos de enxertos da Implex.
- **Parafusos Ósseos**
  Os Parafusos Ósseos da Implex são fabricados com alumínio de titânio e estão disponíveis nos diâmetros de 5.0mm e 6.5mm com diversos comprimentos.
- **Pino de Cimento**
  O Pino de Cimento é fabricado com polietileno de baixa densidade.

Observação: metal trabecular (tântalo depositado sobre uma estrutura de carbono vítreo) é fabricado pela Implex Corp. Sob a marca Implex, o biomaterial metal trabecular também é comercializado sob a marca registrada Hedrocel®

INDICAÇÕES

O uso do Sistema de Bacia da Implex é indicado para:

a) Juntas severamente doentes como resultado de artrite degenerativa ou necrose vascular.
b) Revisão secundária de uma prévia substituição de componente femoral ou de toda a bacia.
c) Outros problemas da bacia onde a experiência clínica mostrou que os modos alternativos de tratamento têm menor chance de atingir os resultados satisfatórios.
d) Deslocamento da fratura da bacia ou fraturas não reduzíveis, no qual a fixação adequada não pode ser obtida.
e) Não junção ou fraturas da cabeça ou pescoço femoral.
f) Recuperação de uma falha primária ou secundária do total ou parte da bacia.

CONTRA-INDICAÇÕES

a) Infecção ativa ou latente na ou em torno da junta da bacia são contra-indicações absolutas e o procedimento não deve ser aplicado nos pacientes que as apresentem:
   1. febre e/ou inflamação local
   2. destruição rápida da junta ou absorção óssea vistas no Raio X
   3. elevação ou taxa de sedimentação não explicável, elevação da contagem de células brancas sangüíneas ou uma significativa mudança na contagem diferencial.
b) As desordens mentais ou neuromuscular que possam criar um risco inaceitável da instabilidade da junta, fixação do componente, complicações pós operatórias ou falha estrutural do componente.
c) Quantidade insuficiente de osso que possa causar ao osso não ser capaz de suportar e fixar o componente.
d) As Cabeças Cerâmicas do femoral da Implex são contra-indicadas para uso com qualquer outro enxerto diferente da UHMWPE ou com um Enxerto Metálico UHMWPE.

ADVERTÊNCIAS

a) Locais de infecção ou potenciais para a infecção distantes da bacia podem espalhar-se sob a forma de hematomas para bacia e devem ser tratados antes da cirurgia.
b) O cirurgião deve estar totalmente familiarizado com os componentes e a técnica cirúrgica do Sistema de Bacia da Implex. Folhetos de Técnicas da Bacia da Implex são fornecidos pela Implex para estes propósitos.
c) O deslocamento pós operatório é uma complicação séria da cirurgia total da bacia. Os pacientes devem ser tratados de uma maneira para reduzir a possibilidade do deslocamento, até que o tecido mole possa fornecer a estabilidade necessária para a junta.
d) Uma vez implantado, o componente nunca deve ser reusado.
e) Em pacientes muito ativos ou com muito peso, a possibilidade de falha estrutural dos componentes é maior. Todos os esforços devem ser envidados para limitar os níveis de atividade e reduzir o peso dos pacientes submetidos ao implante.
f) Os componentes do Sistema de Bacia da Implex (não incluindo os componentes de cavidade cotilóide de Metal Trabecular) não devem ser usados em conjunto com um componente de outro fabricante devido as variações de tamanho, tolerâncias ou outras práticas de processamento. Os componentes de Cavidade Cotilóide de Metal Trabecular da Implex podem e devem somente ser usadas com as cabeças do femoral da Implex ou as fabricadas ou distribuídas pela Zimmer e não devem ser usados em conjunto com um componente de outro fabricante devido as variações de tamanho, tolerâncias ou outras práticas de processamento.
   Nas circunstâncias em que for necessário misturar componentes de diferentes fabricantes, a compatibilidade entre os componentes em relação ao tamanho, tolerâncias ou materiais deve ser assegurada.
g) Os implantes nunca devem ser modificados, dobrados ou processados de outra forma, após o envio pelo fabricante.
h) A Cabeça de Cerâmica de Zircônio é composta de um novo material cerâmico com história clínica limitada. Embora os testes mecânicos demonstram que quando usadas com enxertos de cavidade cotilóide de polietileno, a esfera de zircônio parcialmente estabilizada produz uma quantidade relativamente pequena de partículas; a quantidade total de partículas permanece indeterminada. Devido a limitada experiência clínica e pré clínica, os efeitos biológicos de longo prazo das partículas são desconhecidos.
i) Os parafusos ósseos da Implex não são aprovados para a colocação ou fixação de parafusos para os elementos posteriores (pedículos) da coluna cervical, toráxica ou lombar.

PRECAUÇÕES

a) As desordens mentais ou neuromusculares que possam criar um risco inaceitável da instabilidade da junta, fixação do componente, complicações pós operatórias ou falha estrutural do componente.
b) O cirurgião deve estar totalmente familiarizado com os componentes e a técnica cirúrgica do Sistema de Bacia da Implex. Um folheto de Técnica de Bacia é fornecido para este propósito.
c) Uma vez implantado, o componente nunca deve ser reusado.
d) As Cabeças Cerâmicas da Femoral da Implex devem somente ser usadas com Suportes de Bacia de alumínio de titânio ou alumínio de cromo de cobalto da Implex Corp., com um adaptador cônico de 12/14.
e) Ao efetuar a interface de um componente de cavidade cotilóide da Implex com uma cabeça do femoral fabricada ou distribuída pela Zimmer, o usuário deve estar totalmente familiarizado com os componentes e técnicas cirúrgicas da Zimmer e informado da intenção de uso e riscos do implante. Consulte a Embalagem do Alinhador da Zimmer para conhecer as Advertências, Precauções e Efeitos Adversos. Consulte também a Técnica Cirúrgica apropriada da Zimmer.

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

Records processed under FOIA Request # 2

PRECAUÇÕES ESPECIAIS DE CUIDADOS COM OS INSTRUMENTOS

O uso e descontaminação apropriado, incluindo a pré lavagem, rinsagem e esterilização, armazenamento e utilização, são importantes para a longa vida útil dos instrumentos cirúrgicos e mesmo com o uso correto, cuidado e manutenção, não se deve prever que irão durar indefinidamente. Isto é especialmente verdadeiro para os instrumentos de corte (como brocas, espaçadores, raspadores, goivas, guias e formão), instrumentos de guia (e.g., guias, malhos, calços, pinos, extratores e impactadores) e outros. Estes itens são com freqüência sujeitos a altas cargas e/ou forças de impacto. Sob tais condições, pode ocorrer a quebra, particularmente quando o item estiver desgastado, danificado, com ranhuras ou riscado.

Antes de cada uso, inspecione com cuidado os instrumentos e itens. Não use um instrumento de guia que esteja severamente desfigurado ou desgastado ou um instrumento de corte com bordas cegas. Instrumentos com bordas cegas devem sempre ser retornados para a Implex para determinar se podem ser afiados.

Observação: Após certo tempo os instrumentos se desgastam e devem ser substituídos. Para obter as diretrizes relativas ao cuidado e uso de instrumentos cirúrgicos contate a Implex Corp.

EFEITOS ADVERSOS

a) Foi reportado o deslocamento pós operatória da junta da bacia.
b) Foi reportado o afrouxamento adiantado ou tardio do componente.
c) Foi reportado reação de sensibilidade ao metal. A significância de tais reações aguardam estudos adicionais.
d) Podem ocorrer a formação de osso heteratópico e neuropatias periféricas.
e) Ocorreu com raridade a fratura por fadiga dos componentes totais da bacia. A fratura ou desgaste tem maior possibilidade de ocorrer em pacientes pesados ou muito ativos. Uma junta contralateral ou extrema invalidez pode colocar uma carga desproporcional nos componentes.
f) Algumas vezes é necessário uma nova operação para corrigir o efeito adverso. Em raras ocasiões, complicações clínicas podem requerer a artródose da junta ou amputação do membro.

UTILIZAÇÃO E IMPLANTE

É fornecido um conjunto completo de instrumentos necessário para o implante dos componentes. Modelos de radiografia ajudam ao cirurgião a estimar o tamanho ou faixa de tamanho a ser usado.

Os espaçadores, raspadores e testes fornecidos no conjunto de instrumentos são os determinantes finais do tamanho da prótese a ser usada. O uso de testes para confirmar a seleção do tamanho e a estabilidade da junta preserva a integridade e esterilidade dos implantes.

A colocação correta dos componentes ajudam a evitar a carga não prevista dos componentes e podem aprimorar a vida útil dos implantes. Folhetos de Técnica da Bacia da Implex estão disponíveis para fornecer informações detalhadas adicionais com relação ao procedimento recomendado.

ESTERILIDADE

Os componentes do Sistema da Bacia da Implex são esterilizados por irradiação de gama de ^{60}Co, com uma dosagem mínima de 25 KGy. A data da esterilização ou expiração do componente está impressa no rótulo da embalagem exterior. Especificamente, não é recomendada a resterilização dos componentes. Todos os componentes de polietileno são embalados em azoto gasoso. Os selos das embalagens internas e externas (a embalagem interna contém o componente) devem ser bem inspecionados para localizar defeitos ou vazamentos antes de usar o implante.

São usados testes/provisórios e outros instrumentos para determinar o tamanho antes de ser necessário abrir o pacote esterilizado. Os testes/provisórios e instrumentos devem ser esterilizados de acordo com os protocolos e procedimentos de esterilização da instituição. Além disso, todos os métodos de esterilização devem obedecer às orientações e normas adequadas de AAMI/ANSI/ISO, devendo atingir um nível de esterilidade de 10^{6}. A esterilização dos instrumentos foi validada para caixas de instrumentos embalados. A caixa de instrumentos embalada podem ser esterilizadas a vapor com uma temperatura de 273ºF (134ºC) por 20 minutos, com um tempo de secagem de 30 minutos. Os instrumentos devem ser limpos de acordo com os protocolos e procedimentos da instituição.

Nºs. de Patente nos EUA:
5,593,451/5,443,519/5,549,698/5,571,200/5,571,201/5,282,861/5,702,487/5,486,181/6,087,553/6,063,442

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Implex, Continuum e Hedrocel são marcas registradas da Implex Corp.
Zimmer e Trilogy são marcas registradas da Zimmer, Inc, Warsaw, IN

Spanish

Sistemas de cadera de Implex

DESCRIPCIÓN

Los componentes del sistema de cadera Implex consisten en:

- **Vástagos femorales modulares no cementados: recubrimiento de hidroxiapatita (HA) y poroso**
  El vástago recubierto de HA está fabricado con una aleación de titania y recubierto en su sección proximal con hidroxiapatita de alta pureza, densidad y cristalinidad. El vástago recubierto poroso está fabricado con una aleación de cobalto cromo con una superficie porosa formada por partículas de aleación de cobalto cromo.
- **Vástagos femorales modulares cementados y cabeza fija con cojinetes y espaciadores de cemento**
  Los vástagos femorales cementados están fabricados con una aleación de cobalto cromo en pilares o de cobalto cromo labrada. Los vástagos cementados incorporan una superficie rugosa en su extremo proximal o un acabado satinado.
  Se dispone de espaciadores de cemento óseo de polimetilmetacrilato (PMMA) para todos los vástagos.
- **Cabezas modulares con cojinetes de 22 mm, 26 mm, 28 mm y 32 mm**
  Las cabezas modulares con cojinetes están fabricadas con una aleación de cobalto cromo labrada con opciones de superficie bombardeada o no bombardeada con iones de nitrógeno, con aluminio cerámico y circonio cerámico. Las cabezas modulares con cojinetes tienen una conificación para ensamblaje con los vástagos femorales modulares, y están disponibles en varias longitudes de distancia de cuello. Las cabezas de metal están disponibles en dos conificaciones distintas. La conificación específica de la cabeza debe corresponderse con la conificación del vástago femoral. Las cabezas de material cerámico sólo están disponibles con conificación 12/14, y sólo deben utilizarse en vástagos femorales con conificación 12/14.
- **Copas acetabulares de metal trabecular monobloque con y sin orificios para tornillos**
  Las copas acetabulares de metal trabecular monobloque están fabricadas con metal trabecular (tantalio depositado sobre un esqueleto de carbono vítreo) y un anillo con superficie de aleación de titanio con UHMWPE moldeado directamente por compresión en el metal trabecular. La copa acetabular de metal trabecular tiene una forma elíptica. Las copas acetabulares de metal trabecular están disponibles en diversos ángulos de superficie y diámetros internos. Las copas acetabulares de metal trabecular monobloque están disponibles en tamaños de copa de 40 mm a 70 mm. Las copas acetabulares de metal trabecular monobloque están disponibles en opciones potenciadas con enlaces cruzados en tamaños de diámetro externo de 52 mm a 70 mm.
- **Copas acetabulares recubiertas porosas y recubiertas con HA monobloque**
  La copa acetabular [illegible] tiene un recubrimiento poroso de partículas de titanio CP y un disco integramente de polietileno montado en fábrica. La copa acetabular recubierta con HA tiene un recubrimiento de hidroxiapatita y un disco [illegible] montado en fábrica. Las copas acetabulares están disponibles en diversos ángulos de superficie, y cada ángulo de superficie

Swedish

Implex höftsystem

BESKRIVNING

Implex höftsystemkomponenter består av:

- **Modulära femorala höftstammar, cementfria: Hydroxiapatit (HA) samt porös beläggning**
  Den HA-belagda stammen är tillverkad av titanlegering med beläggning av HA av hög renhetsgrad och kristallinisering på dess proximala del. Stammen med porös beläggning är tillverkad av koboltkromlegering med koboltkrompärlor för att bilda den porösa ytan.
- **Cementerade femorala höftstammar, modulära och fixerade lagerhuvuden med cementmellanlägg**
  De cementerade femorala stammarna är tillverkade antingen av gjuten koboltkromlegering eller smidd koboltkromlegering. Cementerade stammar har antingen en skrovlig yta proximalt, eller en blank yta.
  Bencementmellanlägg av polymetylmetakrylat (PMMA) finns för alla stammar.
- **Modulära lagerhuvuden, 22 mm, 26 mm, 28 mm och 32 mm**
  Modulära lagerhuvuden är tillverkade av smidd koboltkromlegering med ett val av ytbehandling med eller utan kvävejonbombardemang, aluminiumoxidkeramik eller zirkoniumkeramik. De modulära lagerhuvudena har en kona för montering vid de modulära femorala stammarna och de finns tillgängliga med olika halsförskjutningslängder. Metallhuvudena finns med två koningar. Ett huvud med en specifik koning ska passa på koningen på den femorala höftstammen. De keramiska huvudena finns bara med 12/14 koning och får endast användas till en femoral stam med en 12/14 koning.
- **Monoblock acetabulär trabekulär metallcup med eller utan skruvhål**
  Monoblock acetabulär trabekulär metallcup är tillverkad av trabekulär metall (tantaldeponering på ett glasartat kolskelett) samt en ytring av titanlegering med UHMWPE kompressionsgjutet direkt i den trabekulära metallen. Den acetabulära trabekulära metallcupen har en elliptisk geometri. Acetabulär trabekulär metallcup finns med olika ytvinklar och innerdiametrar. Monoblock acetabulär cup finns med cupstorlekar mellan 40 mm och 70 mm. Monoblock acetabulär trabekulär metallcup finns i korslänkade utökade alternativ med ytterdiametrar mellan 52 mm och 70mm.
- **Monoblock acetabulär cup med porös beläggning eller HA-beläggning**
  Den acetabulära cupen med porös beläggning ar en beläggning av CP titanpärlor och en på fabriken monterad insats helt av polyeten. Den acetabulära cupen med HA-beläggning har en beläggning av hydroxiapatit och en på fabriken monterad insats. Acetabulär cup finns med olika ytvinklar och varje ytvinkel finns med olika innerdiametrar. Cupen finns i storlekar mellan 40 mm och 70 mm.
- **Modulär acetabulär skål/skal**
  Modulär acetabulär skål/skal tillverkas antingen av trabekulär metall med en inneryta av titanlegering eller med en utsida med CP titanpärlor Låsringen och kupolhålpluggarna är tillverkade av titanlegering. Den modulära skålen finns i skålstorlekar mellan 40 mm och 70 mm.
- **Modulära UHMWPE-insatser - 0°, 10° och 20°**
  Modulär UHMWPE-insatser finns med tre ytvinklar, och varje ytvinkel finns med olika innerdiametrar. De modulära insatserna har uddar på den yttre kanten som möjliggör för kirurgen att vrida in ytvinkeln under operationen.
- **Cementerad acetabulär cup helt av polyeten**
  Acetabulär cup helt av polyeten är tillverkad av polyeten med ultrahög molekylvikt (UHMWP) med en röntgenmarkeringsring av koboltkromlegering. Acetabulär cup helt av polyeten finns med en ytterdiameter mellan 40 mm och 70 mm i intervaller på 2 mm. Acetabulär cup helt av polyeten finns med två ytvinklar (0° and 10°) och varje ytvinkel finns med olika innerdiametrar.
- **Acetabulära trabekulära metallskal för revision, förstärkning och begränsare**
  Acetabulära trabekulära metallskal för revision har en elliptisk geometri och är tillverkade av trabekulär metall med en ytring av titanlegering. Acetabulär trabekulär metallskal för revision tillhandahålls med eller utan kupolskruvhål. Acetabulärt trabekulärt metallskal för revision är avsett att användas med cementerad UHMWPE-insats för utbyte. Acetabulärt trabekulärt metallskal finns i cupstorlekar mellan 40 mm och 80 mm.
  Acetabulärt trabekulärt metallskal för revision är avsett att användas tillsammans med Continuum benskruvar (6,5 mm och 5,0 mm) eller Zimmer *Trilogy*® acetabulärt system eller HGP II benskruvar (6,5mm). Alla är tillverkade av titanlegering.
- **UHMWPE-insatser för utbyte**
  Utbytesinsatsen är tillverkad av UHMWPE och är kompatibel med alla acetabulära skålar och skal som är tillverkade av trabekulär metall. Utbytesinsatsen för HA- och porös skål består av UHMWPE med en låsring av titan. Alla utbytesinsatser är markerade för att överensstämma med Implex skålstorlekar.
- **Benskruvar**
  Implex benskruvar är tillverkade av titanlegering och finns i diametrar på 5, 0 mm och 6,5 mm och i olika längder.
- **Cementplugg**
  Cementpluggen är tillverkad av polyetylen av låg densitet.

OBS! Trabekulär metall (tantaldeponering på ett glasartat kolskelett) tillverkas av Implex Corp. Biomaterialet trabekulär metall marknadsförs även under Implex varumärke med varunamnet Hedrocel®

INDIKATIONER

Användning av Implex höftsystem är indicerat vid:

a) Svårt invalidiserade leder, t.ex. vid degenerativ artrit eller avaskulär nekros.
b) Sekundär revision av en tidigare misslyckad femoral komponent eller total höftledsplastik.
c) Övriga höftledsproblem där kliniska erfarenheter har visat att alternativa behandlingsmetoder troligen inte kommer att uppnå tillfredsställande resultat.
d) Frakturluxation av höften eller icke-reducerbara frakturläkningar där adekvat fixering inte kan erhållas.
e) Utebliven frakturläkning eller fraktur på lårbenshals eller femoralhuvud.
f) Räddning av en havererad primär eller sekundär total eller hemi- höftledsplastik

KONTRAINDIKATIONER

a) Aktiv eller latent infektion i eller omkring höftleden utgör absoluta kontraindikationer och sådan infektion måste uteslutas hos patienter som uppvisar:
   1. feber och/eller lokal inflammation
   2. snabb leddestruktion eller benabsorbering enligt röntgen
   3. förhöjd sedimenteringstakt som inte kan förklaras på annat sätt, förhöjt leukocytvärde eller förhöjd differentialräkning av leukocyter
b) Mentala eller neuromuskulära sjukdomar som skulle medföra en oacceptabel risk för ledinstabilitet, komponentfixering, postoperativa komplikationer eller strukturellt komponenthaveri.
c) Otillräcklig benmassa som skulle göra skelettet oförmöget att stödja och fixera komponenten.
d) Implex keramiska femorala huvuden får endast användas tillsammans med en UHMWPE-skål eller en metallförstärkt UHMWPE-skål

VARNINGAR

a) Infektionsställen eller potentiella infektioner på avstånd från höften kan spridas via blodet till höften och bör därför behandlas före operationen.
b) Kirurgen skall vara väl förtrogen med komponenterna och den kirurgiska tekniken för Implex höftsystem. Broschyrer för Implex höftteknik kan beställas från Implex för detta ändamål.
c) Postoperativ luxation är en svår komplikation vid total höftledsplastik. Patienten bör behandlas på ett sådant sätt att risken för luxation är så liten som möjligt, tills de mjuka vävnaderna kan erbjuda tillräcklig stabilitet för leden.
d) Efter implantation får komponenten aldrig återanvändas.
e) [illegible] kraftigt överviktiga patienter är risken för komponenthaveri större. Vidtag alla åtgärder för att begränsa patientens [illegible] eller operation [illegible]

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está disponible en diversos diámetros internos. Las copas están disponibles en tamaños de copa de 40 mm a 70 mm.

- **Copa/cubiertas acetabulares modulares**
  Las copa/cubiertas acetabulares elípticas [illegible] fabricadas con metal trabecular con una superficie interna de aleación de titanio o con una superficie externa de partículas de titanio CP. El anillo de fijación y los tapones para los orificios de la cúpula están fabricados con una aleación de titanio. La copa modular está disponible en tamaños de copa de 40 mm a 70 mm.
- **Discos modulares de UHMWPE a 0°, 10° y 20°**
  Los discos modulares UHMWPE están disponibles en tres ángulos de superficie, y cada ángulo de superficie está disponible en diversos diámetros internos. Los discos modulares tienen escotaduras en el anillo externo que permiten al cirujano seleccionar el ángulo de superficie intraoperatoriamente.
- **Copas acetabulares cementadas íntegramente de polietileno**
  Las copas acetabulares íntegramente de polietileno están fabricadas con polietileno de peso molecular ultra alto (UHMWPE) y tienen un anillo marcador radiográfico fabricado con aleación de cobalto cromo. Las copas acetabulares íntegramente de polietileno están disponibles en tamaños de diámetro externo de 40 mm a 70 mm en incrementos de 2 mm. Las copas acetabulares íntegramente de polietileno están disponibles en dos ángulos de superficie (0° y 10°), y cada ángulo está disponible en diversos diámetros internos.
- **Limitador, cubiertas y aumentos acetabulares de revisión de metal trabecular**
  Los aumentos y limitadores se fabrican completamente de metal trabecular (tantalio depositado sobre un esqueleto de carbón vítreo). El aumento acetabular de metal trabecular está fijado a la copa acetabular porosa con cemento óseo. El aumento o constructo acetabular poroso es para uso con o sin cemento.

  La cubierta acetabular de revisión de metal trabecular tiene una forma elíptica y está fabricado con metal trabecular con un anillo de superficie de aleación de titanio. La copa acetabular de revisión de metal trabecular está disponible con orificios para tornillos en la cúpula. La cubierta acetabular de revisión de metal trabecular está diseñada para su uso con un disco de sustitución cementado de UHMWPE. La cubierta acetabular de metal trabecular está disponible en tamaños de copa de 40 mm a 80 mm.

  En los casos en que se requiere la fijación de los componentes, se utilizan tornillos para hueso Continuum (6,5 mm y 5,0 mm), con el sistema acetabular *Trilogy*™ de Zimmer o con tornillos para hueso HGPII (6,5 mm), todos ellos fabricados con una aleación de titanio.
- **Discos de UHMWPE de sustitución**
  El disco de sustitución está fabricado con UHMWPE y es compatible con todas las copas y cubiertas acetabulares fabricadas con metal trabecular. El disco de sustitución de copas de HA y porosas está fabricado con UHMWPE con un anillo de fijación de titanio. Todos los discos de sustitución están marcados para que coincidan con los tamaños de copa de Implex.
- **Tornillos para hueso**
  Los tornillos para hueso de Implex están fabricados con una aleación de titanio y están disponibles en diámetros de 5,0 mm y 6,5 mm con varias longitudes.
- **Tapón de cemento**
  El tapón de cemento está fabricado con polietileno de baja densidad.

Nota: El metal trabecular (tantalio depositado sobre un esqueleto de carbono vítreo) es fabricado por Implex Corp. Bajo la marca de Implex, el material biológico de metal trabecular también se comercializa con el nombre comercial Hedrocel®.

INDICACIONES

El uso del sistema de cadera de Implex está indicado en los siguientes casos:

a) Articulaciones gravemente discapacitadas como resultado de una artritis degenerativa o una necrosis avascular.
b) Revisión secundaria de un componente femoral o una sustitución total de cadera previamente no satisfactorios.
c) Otros problemas de cadera en los cuales la experiencia clínica ha demostrado que las posibilidades de éxito de los modos alternativos de tratamiento son menores.
d) Luxación por fractura de la cadera o fracturas irreducibles en las cuales no se puede conseguir una fijación adecuada.
e) Fracturas sin consolidar y fracturas del cuello o la cabeza femoral.
f) Rescate de una cadera total o semisustituida primaria o secundaria fracasada.

CONTRAINDICACIONES

a) La infección activa o latente en la articulación de la cadera o su entorno constituye una contraindicación absoluta que debe descartarse en los pacientes que presenten:
   1. Fiebre o inflamación local.
   2. Destrucción articular rápida o absorción ósea en las radiografías.
   3. Aumento de la velocidad de sedimentación que no se pueda explicar por otras causas, elevación del recuento de leucocitos o cambio significativo en la fórmula leucocitaria.
b) Determinados trastornos mentales o neuromusculares que suponen un riesgo inaceptable de inestabilidad articular, falta de fijación del componente, complicaciones postoperatorias o fracaso estructural del componente.
c) Reserva ósea insuficiente que incapacite al hueso para soportar y fijar el componente.
d) Las cabezas femorales de cerámica de Implex están contraindicadas con copas distintas a las copas de UHMWPE o a las copas de UHMWPE con respaldo metálico.

AVISOS

a) Las fuentes de infección o infección potencial a distancia de la cadera pueden diseminarse hasta ella por vía hematógena, por lo que deben ser tratadas antes de la cirugía.
b) El cirujano debe estar totalmente familiarizado con los componentes y la técnica quirúrgica relacionada con el sistema de cadera de Implex. A tal efecto, Implex dispone de manuales de técnicas quirúrgicas de cadera.
c) La luxación postoperatoria es una complicación grave de la cirugía total de cadera. Los pacientes deben recibir tratamiento para reducir la probabilidad de luxación hasta que el tejido blando pueda proporcionar la estabilidad necesaria a la articulación.
d) Una vez implantado, el componente no debe reutilizarse.
e) La posibilidad de fracaso estructural de los componentes aumenta en los pacientes demasiado activos u obesos. Se tomarán las medidas apropiadas para limitar los niveles de actividad y reducir el peso de los pacientes sometidos al implante.
f) Los componentes del sistema de cadera de Implex (excepto los componentes acetabulares de metal trabecular) no deben utilizarse con componentes de otros fabricantes debido a las variaciones de tamaño, tolerancia y otros procedimientos de procesamiento. Los componentes acetabulares de metal trabecular de Implex deben utilizarse exclusivamente con cabezas femorales de Implex o fabricadas o distribuidas por Zimmer, y no con componentes de otros fabricantes debido a las variaciones de tamaño, tolerancia y otros procedimientos de procesamiento.

   En aquellos casos en que sea necesario combinar componentes de distintos fabricantes, deberá confirmarse la compatibilidad en la forma, la tolerancia o los materiales de los componentes.
g) No se debe modificar, doblar o procesar en modo alguno el implante una vez enviado por el fabricante.
h) La cabeza de circonio cerámico está compuesta de un nuevo material de cerámica con una historia clínica limitada. Aunque las pruebas mecánicas demuestran que la esfera de circonio parcialmente estabilizada libera una cantidad relativamente escasa de macropartículas cuando se utiliza con copas acetabulares de polietileno, no se ha determinado la cantidad total de macropartículas. Debido a que la experiencia clínica y preclínica es limitada, no se conocen los efectos biológicos a largo plazo de estas macropartículas.
i) Los tornillos para hueso de Implex no están aprobados para la fijación o anclaje con tornillos a los elementos posteriores (pedículos) de la columna cervical, dorsal o lumbar.

PRECAUCIONES

a) Determinados trastornos mentales o neuromusculares suponen un riesgo inaceptable de inestabilidad articular, falta de fijación del componente, complicaciones postoperatorias o fracaso estructural del componente.
b) El cirujano debe estar totalmente familiarizado con los componentes y la técnica quirúrgica relacionada con el sistema de cadera de Implex. A tal fin se suministra un manual de técnicas quirúrgicas de cadera.
c) Una vez implantado, el componente no debe reutilizarse.
d) Las cabezas femorales de cerámica de Implex deben utilizarse exclusivamente con vástagos de cadera de aleación de titanio o de aleación cobalto cromo de Implex Corp. con un muñon conificado 12/14.

f) De komponenter som ingår i Implex höftsystem (ej medräknat acetabulära trabekulära metallkomponenter) får ej användas tillsammans med en komponent från en annan tillverkare på grund av variationer i storleksbestämning, toleransnivåer eller bearbetningsmetoder. Implex acetabulära trabekulära metallkomponenter kan användas med Implex femorala huvuden eller [illegible] som tillverkats eller distribuerats av Zimmer och får ej användas tillsammans med komponenter från någon annan tillverkare till följd av variationer i storlek, toleranser eller bearbetningsmetoder.

   Under omständigheter som kräver blandning av komponenter från olika tillverkare, måste kompatibiliteten mellan de olika komponenterna beträffande storleksbestämning, toleranser eller material fastställas
g) Implantaten får aldrig modifieras, böjas eller på annat vis bearbetas efter leverans från tillverkaren.
h) Keramiskt zirkoniumhuvud består av ett nytt keramiskt material med begränsad klinisk historik. Trots att mekaniska tester har visat att den partiellt stabiliserade zirkoniumkulan, då den används med en acetabulär polyetylenskål, producerar förhållandevis små partikelmängder, förblir den totala partikelmängden obestämd. På grund av begränsad klinisk och förklinisk erfarenhet, är de långsiktiga biologiska effekterna av partiklarna okända.
i) Implex benskruvar är ej godkända för inskruvning eller fixering vid de bakre elementen (pediklarna) i hals-, bröst- eller ländryggraden

FÖRSIKTIGHETSÅTGÄRDER

a) Mentala eller neuromuskulära sjukdomar som skulle medföra en oacceptabel risk för ledinstabilitet, komponentfixering, postoperativa komplikationer eller komponenthaveri.
b) Kirurgen skall vara väl förtrogen med komponenterna och den kirurgiska tekniken för Implex höftsystem. Broschyrer för Implex höftteknik kan beställas från Implex för detta ändamål.
c) Efter implantation får komponenten aldrig återanvändas.
d) Implex femorala keramiska huvuden får endast användas med höftstammar från Implex Corp av titanlegering eller koboltkromlegering med en 12/14 kontapp.
e) Vid koppling till en Implex acetabulär komponent med ett femoralt huvud som tillverkats eller distribuerats av Zimmer, skall användaren vara väl förtrogen med Zimmers komponenter och kirurgiska teknik och vara informerad om implantatens avsedda användning och risker. Läs i Zimmers förpackningsinlaga beträffande varningar, försiktighetsåtgärder och biverkningar. Läs också i aktuell kirurgisk teknik från Zimmer.

SÄRSKILDA HÄNSYN VID INSTRUMENTVÅRD

Korrekt hantering, dekontaminering, bl.a. försköljning, tvätt, sköljning och sterilisering; förvaring och användning är viktigt för lång och produktiv användning av alla kirurgiska instrument och provisorier. Även vid korrekt användning, vård och underhåll skall man inte förvänta sig att produkterna skall vara för evigt. Detta är i synnerhet sant beträffande skärinstrument (m.a.o. borrstycken, upprymmare, raspar, hålmejslar och mejslar), drivinstrument (m.a.o. drivhandtag, hammare, stampar, stift, utdragare och impaktorer) samt provisorier. Dessa produkter utsätts ofta för hög belastning och/eller slagkraft. Under sådana omständigheter kan brott uppstå på instrumenten, i synnerhet om produkten är korroderad skadad, hackad eller repad.

Undersök alla instrument och provisorier före varje användning. Använd inte ett drivinstrument som är svårt skadat och slitet eller ett skärinstrument med trubbig egg. Trubbiga instrument skall alltid skickas till Implex, för att fastställa huruvida slipning är möjligt.

OBS! Vid något tillfälle kommer instrumenten att slitas ut och vara tvungna att bytas ut. Kontakta Implex Corp, för riktlinjer angående vård och hantering av kirurgiska instrument.

BIVERKNINGAR

a) Postoperativ luxation av höftleden har rapporterats.
b) Tidig eller sen lossning av komponenterna har rapporterats.
c) Överkänslighet mot metall har rapporterats. Betydelsen av sådan reaktion skall undersökas
d) Heterotop benbildning och periferiska neuropatier kan uppstå.
e) Frakturer till följd av materialtrötthet i de totala höftledskomponenterna har sällan rapporterats. Det är större risk för komponentfraktur eller nedslitning hos överviktiga eller överaktiva patienter. Invalidisering av kontralateral led eller extremitet kan medföra en oproportionell belastning på komponenterna
f) Ny operation är i bland nödvändigt för att korrigera en biverkning. Kliniska komplikationer kan i sällsynta fall medföra behov av steloperation i leden eller amputation av benet.

ANVÄNDNING OCH IMPLANTATION

Det finns ett fullständigt instrumentarium som behövs för implantation av komponenterna. Röntgenmallar underlättar för kirurgen att beräkna den storlek eller det storleksomfång som krävs.

Upprymmare, hyvlar och försökskomponenter som ingår i instrumentariet bestämmer slutgiltigt storleken på den protes som skall användas. Genom att använda försökskomponenterna för att bekräfta val av storlek och ledstabilitet kan man bevara implantatens integritet och stabilitet.

Korrekt placering av komponenterna gör att man lättare kan undvika oavsiktlig belastning av komponenterna och implantatens livstid kan därmed förbättras. Implex höftteknikbroschyrer finns att tillgå för ytterligare detaljerad information angående den rekommenderade metoden.

STERILITET

Implex höftsystemkomponenter är steriliserade med hjälp av ^{60}Co gammastrålning med en minimidos på 25 kGy. Datum då komponenten steriliserades eller ej får användas längre anges på etiketten på den yttre förpackningen. Vi avråder bestämt från återsterilisering av komponenterna. Alla polyetenkomponenter är förpackade i kvävgas. Förseglingarna på såväl den inre som den yttre förpackningen (den inre förpackningen innehåller produkten) till komponenten skall undersökas för eventuella brister eller läckage innan implantatet används.

Prov och provisoriska komponenter samt andra instrument skall användas för att fastställa storleken innan den sterila förpackningen öppnas. Prov och provisoriska komponenter samt instrument skall steriliseras i enlighet med sjukhusets steriliseringsrutiner och metoder. Vidare måste all sterilisering uppfylla kraven i tillämplig AAMI/ANSI/ISO-standard och en sterilitetsnivå på 10^{-6} skall uppnås. Steriliseringen av instrumenteringen har validerats för inslagna instrumentfodral. Inslagna instrumentfodral kan steriliseras vid 134° C under 20 minuter, med en torktid på 30 minuter. Instrumenten skall rengöras i enlighet med sjukhusets steriliseringsrutiner och metoder.

US Patent nr.:
5,593,451/5,443,519/5,549,698/5,571,200/5,571,201/5,282,861/5,702,487/5,486,181/6,087,553/6,063,442

Implex Corp., 2003 Alla rättigheter förbehålles

Implex, Continuum och Hedrocel är registrerade varumärken som tillhör Implex Corp Zimmer och Trilogy är registrerade varumärken som tillhör Zimmer, Inc, Warsaw, IN

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e) Cuando se utilice un componente acetabular de Implex con una cabeza femoral fabricada o distribuida por Zimmer, el usuario debe estar totalmente familiarizado con las técnicas quirúrgicas y componentes de Zimmer e informado de los usos y riesgos previstos de los implantes. Consúlense las secciones de advertencias, precauciones y efectos adversos del prospecto del disco de Zimmer. Consúltese también la técnica quirúrgica apropiada de Zimmer.

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PRECAUCIONES ESPECIALES PARA EL CUIDADO DEL INSTRUMENTAL

Es importante aplicar procedimientos apropiados de manipulación, descontaminación, incluidos los procesos de preaclarado, lavado, aclarado y esterilización, conservación y uso para conseguir una vida útil prolongada de todo el instrumental y los materiales provisionales quirúrgicos; aunque las condiciones de uso, cuidado y mantenimiento sean apropiadas, no debe esperarse que tengan una duración indefinida. Esto es especialmente aplicable a los instrumentos cortantes (p. ej., brocas, escariadores, bisturíes, gubias, guías y escoplas), los instrumentos de introducción (p. ej., introductores, martillos, tamps, agujas, extractores e impactores) y materiales provisionales. Estos instrumentos a menudo están sometidos a cargas o fuerzas de impacto intensas. En estas condiciones puede producirse la rotura del instrumento, especialmente si está corroído, dañado, mellado o arañado.

Antes de cada uso deben inspeccionarse detenidamente todo el instrumental y materiales provisionales. No utilice instrumentos de introducción que estén claramente estropeados o desgastados ni instrumentos cortantes con bordes romos. Los instrumentos romos deben devolverse a Implex para determinar si es posible volver a afilarlos.

Nota: En algún momento, los instrumentos se desgastan y deben ser sustituidos. Si desea obtener instrucciones en relación con el cuidado y la manipulación del instrumental quirúrgico, póngase en contacto con Implex Corp.

ACONTECIMIENTOS ADVERSOS

a) Se ha descrito la luxación de la articulación de la cadera en el postoperatorio.

b) Se ha descrito el aflojamiento precoz o tardío del componente.

c) Se han descrito reacciones de sensibilidad a los metales. Es preciso realizar nuevos estudios para determinar la importancia de estas reacciones.

d) Se puede producir la formación de hueso heterotópico y neuropatías periféricas.

e) Se han producido en raras ocasiones fracturas por fatiga de los componentes de la prótesis total de cadera. La fractura o desgaste del componente es más probable en caso de pacientes obesos o demasiado activos. La discapacidad de la articulación o de la extremidad contralaterales puede generar una carga desproporcionada para los componentes.

f) En ocasiones es necesario una reintervención para corregir los acontecimientos adversos. Las complicaciones clínicas pueden requerir en raras ocasiones la artrodesis de la articulación o la amputación de la extremidad.

USO E IMPLANTACIÓN

Se suministra un juego completo del instrumental necesario para la implantación de los componentes. Las plantillas radiológicas ayudarán al cirujano a estimar el tamaño o intervalo de tamaños que debe utilizarse.

Los escariadores, fresas y materiales de prueba que se incluyen en el juego de instrumentos son los determinantes finales del tamaño de la prótesis utilizada. El uso de los materiales de prueba para confirmar la selección del tamaño y la estabilidad articular preserva la integridad y esterilidad de los implantes.

La colocación adecuada de los componentes evita la sobrecarga excesiva accidental de los componentes y puede mejorar la vida útil de los implantes. Están disponibles diversos manuales de técnicas quirúrgicas de cadera de Implex con información detallada adicional sobre el procedimiento recomendado.

ESTERILIDAD

Los componentes del sistema de cadera Implex se esterilizan mediante radiación gamma con ^{60}Co a una dosis mínima de 25 kGy. La fecha de esterilización o caducidad del componente está impresa en la etiqueta del envase externo. Específicamente no se recomienda la reesterilización de los componentes. Todos los componentes de polietileno se envasan con gas nitrógeno. Antes de utilizar el implante se inspeccionarán cuidadosamente los precintos de los envases interno y externo (el envase interno contiene el componente) en busca de defectos o fugas.

Antes de abrir el envase estéril debe determinarse el tamaño del implante utilizando los materiales de prueba/provisionales y otro instrumental. Los materiales de prueba/provisionales y el instrumental deben esterilizarse conforme a los protocolos y procedimientos de esterilización de cada centro. Además, todos los métodos de esterilización deben cumplir las correspondientes normas y estándares ANSI/AAMI/ISO, con un nivel de esterilidad de 10^{-6}. Se ha validado la esterilización de instrumental para cajas de instrumental envueltas. Las cajas de instrumental envueltas pueden esterilizarse por vapor a 134 °C durante 20 minutos, con un tiempo de secado de 30 minutos. El instrumental debe limpiarse conforme a los protocolos y procedimientos de cada centro.

Números de patente en Estados Unidos:
5,593,451/5,443,519/5,549,698/5,571,200/5,571,201/5,282,861/5,702,487/5,486,181/6,087,553/6,063,442

Implex Corp., 2003 Reservados todos los derechos

Implex, Continuum y Hedrocel son marcas registradas de Implex Corp.

Zimmer y Trilogy son marcas registradas de Zimmer, Inc, Warsaw, IN.

85

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

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SECTION 6.2

DRAFT PRIMARY PACKAGE LABELS

- **Patient Record Label**
- **Patient Reorder Label**

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Note:

- The prescription legend, address, and sterility graphic are printed directly on the box.
- The primary materials that comprise the implant are identified on the label.

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PACKAGING SET-UP SHEET

Records processed under FOIA Request # 2016-1518; Released by CDRH on 05-23-2016

LOT ZLOTNUBR CAT. NO. 7000-80-70
ACETABULAR REVISION SHELL
POROUS
80 MM CUP SIZE
TANTALUM/TITANIUM ALLOY STERILE QTY - 1
U.S. PATENTS: 5,443,519; 5,282,861; 5,571,200

+M21000700080701 3
+10120ZLOTNUBRD0538

CAT. NO. 02-210-00803
LOT LOTNUMBR
ZCN # ZLOTNUBR
I.D. # 50405920

CAT. NO. 7000-80-70
ACETABULAR REVISION SHELL
POROUS
80 MM CUP SIZE

STERILE R 2010-04

zimmer ALLENDALE, NJ 07401, U.S.A.

CE 0120

LOT ZLOTNUBR CAT. NO. 7000-80-70
ACETABULAR REVISION SHELL
POROUS
80 MM CUP SIZE
TANTALUM/TITANIUM ALLOY STERILE QTY - 1
zimmer ALLENDALE, NJ 07401, U.S.A.

LOT ZLOTNUBR CAT. NO. 7000-80-70
ACETABULAR REVISION SHELL
POROUS
80 MM CUP SIZE
TANTALUM/TITANIUM ALLOY STERILE QTY - 1
zimmer ALLENDALE, NJ 07401, U.S.A.

LOT ZLOTNUBR CAT. NO. 7000-80-70
ACETABULAR REVISION SHELL
POROUS
80 MM CUP SIZE
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zimmer ALLENDALE, NJ 07401, U.S.A.

LOT ZLOTNUBR CAT. NO. 7000-80-70
ACETABULAR REVISION SHELL
POROUS
80 MM CUP SIZE
TANTALUM/TITANIUM ALLOY STERILE QTY - 1
zimmer ALLENDALE, NJ 07401, U.S.A.

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

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SECTION 7

510(k) SUMMARY

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8119

Records processed under FOIA Request # 2016-1518; Released by CDRH on 05-23-2016

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

The Trabecular Metal Acetabular Revision Shells

Submitter Name:	Zimmer Trabecular Metal Technology, Inc.
Submitter Address:	80 Commerce Drive Allendale, New Jersey 07401-1600
Contact Person:	Marci Halevi
Phone Number:	(201) 818-1800 ext. 507
Fax Number:	(973) 879-0825
Date Prepared:	April 11, 2005
Device Trade Name:	The Trabecular Metal Acetabular Revision Shell
Device Common Name:	Acetabular revision shells or cages
Classification Number:	21 CFR § 888.3358 and 21 CFR § 888.3350

Substantial Equivalence: **The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without premarket approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.**

Device Description: The Trabecular Metal Acetabular Revision Shell is a modular acetabular reconstructive device (polyethylene liner is cemented to shell) intended for use in primary or revision reconstructive procedures of the acetabulum. The subject Trabecular Metal Acetabular Revision Shell is manufactured from Trabecular Metal porous tantalum. The TM Revision Shell has a Ti-6A1-4V instrument interface ring (ASTM F-136) along its outer perimeter that provides a rigid contact area for the impaction instrument used to implant the device. The Revision Shells are intended for either cementless or cemented fixation to the acetabulum with that allow for optional ancillary fixation to the acetebulum. The screwholes mate with commercially available Zimmer 6.5mm titanium alloy bone screws.

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

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510(k) Summary (Continued)

Indications for Use: The Indications for Use of the Trabecular Metal Acetabular Revision Shells are:

- For cemented or cementless use.
- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problem where arthrodesis or alternative reconstruction 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.

Conclusion: The Trabecular Metal Acetabular Revision Shells are substantially equivalent to the identified predicate devices.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 91

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APPENDIX A

PRODUCT DESCRIPTION ORGANIZATION CHART

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THE TRABECULAR METAL TECHNOLOGY (TMT) REVISION SHELL ORGANIZATION CHART

Zimmer TMT Catalog Numbers	Zimmer Catalog Numbers	Description	Modifications to cleared devices
02-210-00404	00-7000-040-30	TM Revision Shell, 40mm	Sizes cleared in K001759; current submission covers minor modification to screw hole pattern and to impaction ring.
02-210-00424	00-7000-042-30	TM Revision Shell, 42mm	
02-210-00444	00-7000-044-30	TM Revision Shell, 44mm	
02-210-00464	00-7000-046-30	TM Revision Shell, 46mm	
02-210-00484	00-7000-048-30	TM Revision Shell, 48mm	
02-210-00504	00-7000-050-30	TM Revision Shell, 50mm	
02-210-00524	00-7000-052-30	TM Revision Shell, 52mm	Sizes cleared in K983837; current submission covers minor modification to screw hole pattern and to impaction ring..
02-210-00544	00-7000-054-30	TM Revision Shell, 54mm	
02-210-00564	00-7000-056-30	TM Revision Shell, 56mm	
02-210-00584	00-7000-058-30	TM Revision Shell, 58mm	
02-210-00604	00-7000-060-30	TM Revision Shell, 60mm	
02-210-00624	00-7000-062-30	TM Revision Shell, 62mm	
02-210-00644	00-7000-064-30	TM Revision Shell, 64mm	
02-210-00664	00-7000-066-30	TM Revision Shell, 66mm	
02-210-00684	00-7000-068-30	TM Revision Shell, 68mm	
02-210-00704	00-7000-070-30	TM Revision Shell, 70mm	
02-210-00724	00-7000-072-30	TM Revision Shell, 72mm	Current submission; line extension to smaller sizes listed above and includes minor change to screw hole pattern and impaction ring.
02-210-00744	00-7000-074-30	TM Revision Shell, 74mm	
02-210-00764	00-7000-076-30	TM Revision Shell, 76mm	
02-210-00784	00-7000-078-30	TM Revision Shell, 78mm	
02-210-00804	00-7000-080-30	TM Revision Shell, 80mm	

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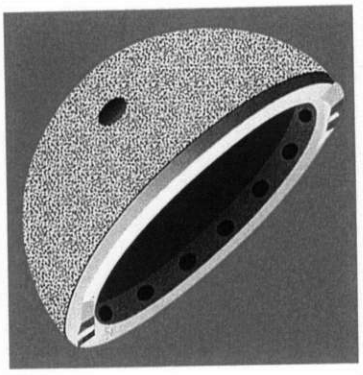
TRABECULAR METAL REVISION SHELL



Surgical Technique

zimmer

Confidence in your hands

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

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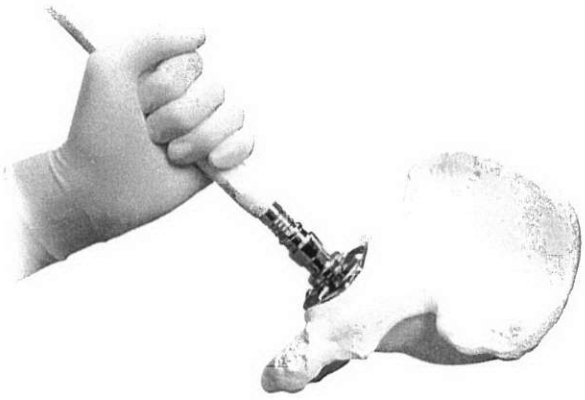
1 ACETABULAR PREPARATION

Use progressively larger reamers to prepare the acetabulum. Hold the reamer steady in the same position in which the shell will be implanted (approximately 45° of abduction and 15° of anteversion). Minimize the amount of bone reaming, performing only that necessary to achieve creation of an adequate hemispherical cavity for support of the Revision Shell.



2 SHELL SIZING AND POSITIONING

Provisional shell sizes match the outside dimensions of the acetabular reamers. The provisional shell has protruding 1mm teeth around the rim to stabilize it during trial reduction. It also has fenestrations so that shell seating within the acetabulum can be assessed. The elliptical Revision Shell implant provides 2mm of interference fit at its periphery.

Select the provisional shell that is the same size as the last even-numbered reamer used. Screw the Provisional Shell Impactor Handle onto the provisonal shell. Place the T-handled Version Guide into the slot on the Impactor Handle. When the Version Guide is perpendicular to the longitudinal axis of the patient, the provisional shell is properly positioned at 45° of abduction.

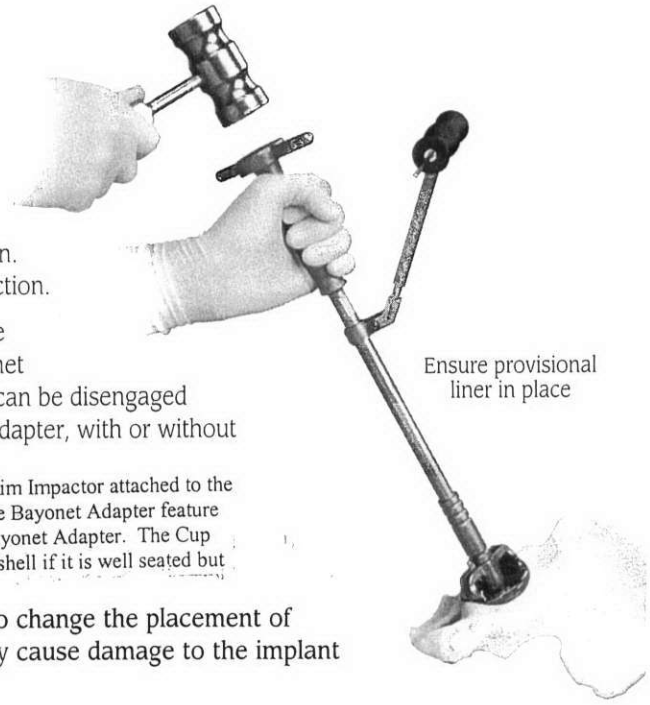
4 REVISION SHELL INSERTION

Orient the solid portion of the shell (devoid of screw holes) in an anterior-inferior position. Bring the Revision Shell to the appropriate version and inclination (approx. 45° of abduction and 15° of anteversion). Impact the Bayonet Handle to seat the shell in position.

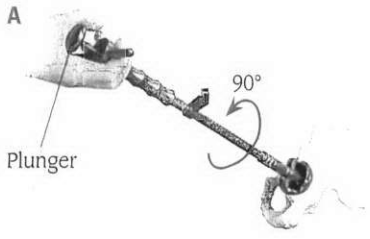
Note: Ensure that the Plunger is NOT in the Bayonet Handle during impaction.

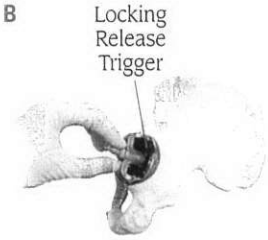
To release the Bayonet Adapter from the cup, slide the Plunger into the Bayonet Handle. Depress the Plunger until the key lifts out of the slot in the shell, then rotate the Bayonet Handle 90° to free it from the cup locking slot (A). Alternatively, the shell can be disengaged by pushing the Locking Release Trigger at the distal end of the Bayonet Adapter, with or without the Bayonet Handle in place (B). The provisional liner is then removed.

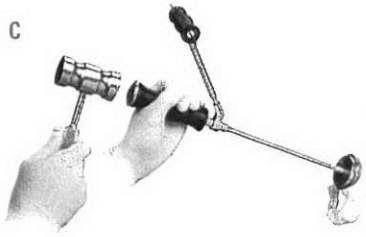
For shells which do not have the Bayonet Adapter feature on the rim, the sized-matched Rim Impactor attached to the Provisional Shell Handle should be used to impact the shell (C). For shells which have the Bayonet Adapter feature on the rim, the Rim Impactor can be used for additional impaction following use of the Bayonet Adapter. The Cup Rim Impactor from the General Instrument Set can be used to adjust the face angle of the shell if it is well seated but requires repositioning.



Warning: The Bayonet is for impaction only. Use of this instrument to change the placement of the shell after partial or full seating, or to remove a seated shell, may cause damage to the implant construct. Only direct axial impaction loads should be applied.







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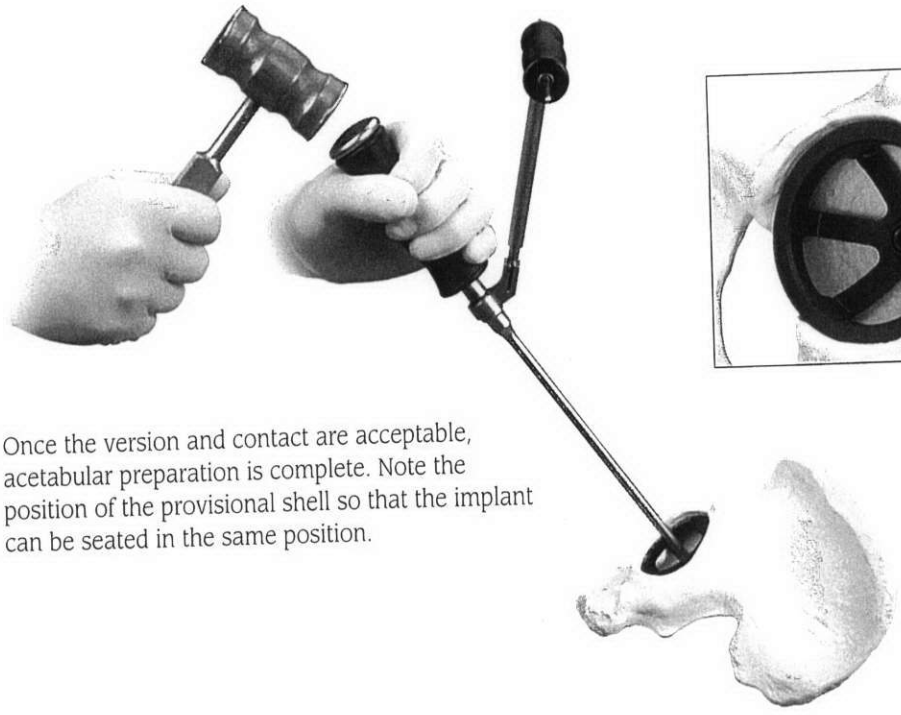
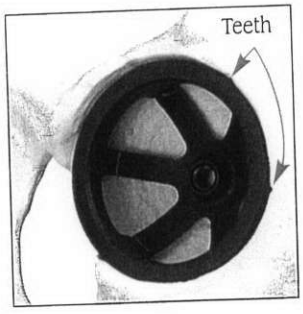
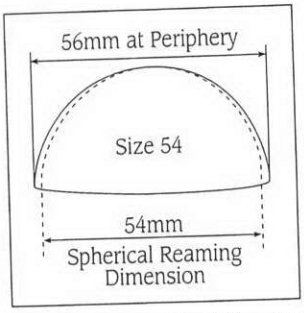


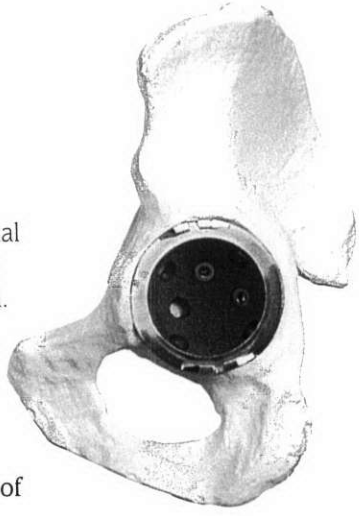
Once the version and contact are acceptable, acetabular preparation is complete. Note the position of the provisional shell so that the implant can be seated in the same position.





Elliptical geometry of the shell provides a 2mm interference fit at the periphery and implant-bone contact at the dome.

5 SCREW INSERTION (AS REQUIRED)

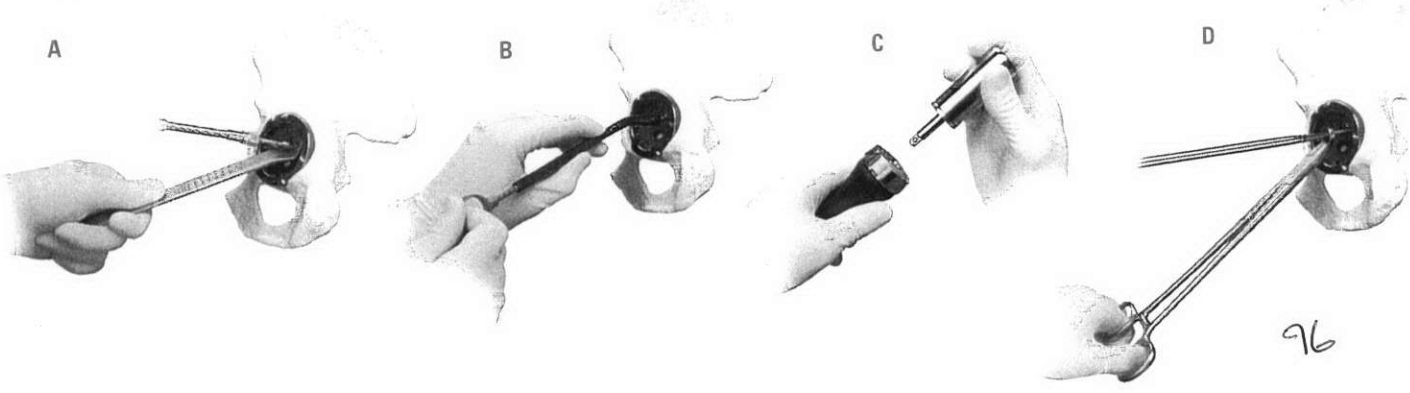


If screw placement is desired, drill a pilot hole by placing the drill through the Drill Guide in the desired screw hole (A). Measure the hole's depth with the Depth Gauge (B).

Attach the Torque Limiter to the Screwdriver (C). Avoid overtightening of screws and potential advancement through the shell screw hole. **Note**: The Torque Limiter does not eliminate the need for surgeon evaluation of bone quality, appropriate screw selection, and torque control.

Select the appropriate length 6.5mm screw and insert it in the hole with the Screwdriver/Torque Limiter construct (D). Place additional screws as necessary. **Note:** Unused screw holes may be plugged with bone wax or bone graft. Bone wax may be used to fill the screw heads. This may assist bone cement removal if future need arises.

Warning: Avoid screw placement through the shell into the anterior-inferior quadrant of the acetabulum to prevent injury to intrapelvic neurovascular structures.



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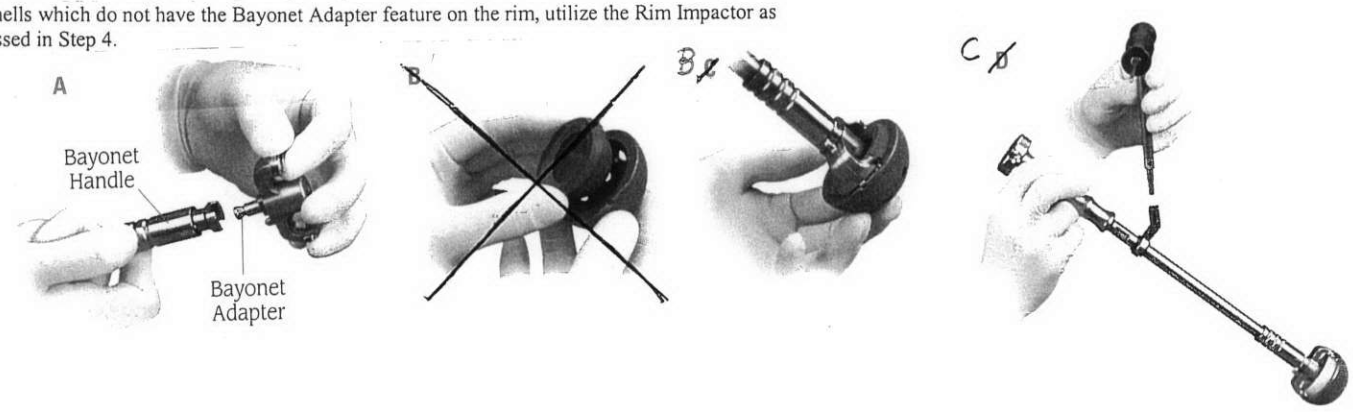
3 INSTRUMENT ASSEMBLY

For shells which have the Bayonet Adapter feature on the rim

Assemble the Bayonet Adapter, sized to match the implant, on the Bayonet Handle (A). The provisional liner aids in centering the Bayonet Adapter on the implant.

With the Bayonet Adapter positioned on the flat portion of the rim of the Revision Shell, turn the adapter until it locks into place (~~C~~ B). Place the Version Guide on the Bayonet Handle (~~D~~ C). During impaction, the Version Guide should be perpendicular to the longitudinal axis of the patient and parallel to the planar axis of the patient.

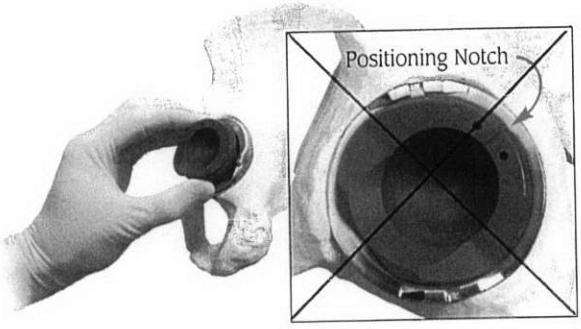
For shells which do not have the Bayonet Adapter feature on the rim, utilize the Rim Impactor as discussed in Step 4.



6 PROVISIONAL LINER AND TRIAL REDUCTION

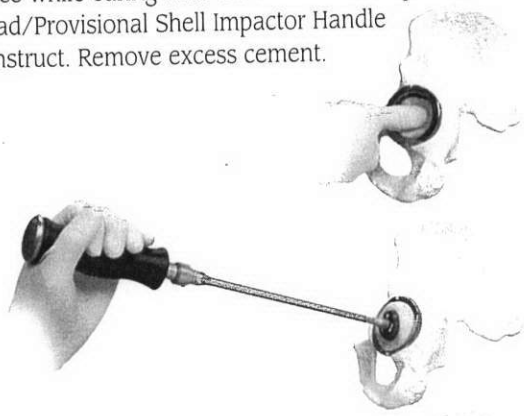
Select a Revision Shell provisional liner size that matches the shell. Provisional liners are used to assess joint stability and face-angle position. Adjust liner position to best fit the needs of the patient.

Perform a trial reduction with the femoral stem and trial femoral head in place.



7 LINER INSERTION AND PLACEMENT

Prepare *Osteobond*® Copolymer Bone Cement. Place cement in Revision Shell while in a doughy state. The Revision Shell Liner provides a nominal 2mm cement mantle between the shell and liner. Place the polyethylene liner into position and hold in place while curing with the Acetabular Impactor Head/Provisional Shell Impactor Handle construct. Remove excess cement.



With the Revision Shell implanted and the liner securely cemented in place, the construct is ready for final reduction with the femoral component.

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

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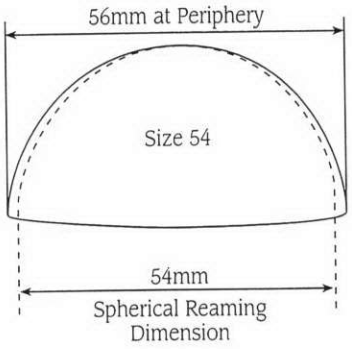
INITIAL AND LONG-TERM STABILITY

- Fully-interconnected trabecular structure with two to three times the porosity of other cups enables extensive tissue ingrowth and strong attachment.[1]
- High coefficient of friction[1] against bone provides great scratch-fit and initial stability.
- Low stiffness of *Trabecular Metal* can produce more normal physiological loading and reduce stress shielding.[2]
- One-piece construct, created by cementing the liner, eliminates concerns about backside wear.
- Elliptical geometry creates a 2mm interference fit at the periphery of the shell, maximizing bone contact for initial and long-term stability.



VERSATILE FIXATION AND POSITIONING

- Shell can be used in majority of primary and revision cases.
- Shell is placed in best position for maximum host bone contact, while liner can be oriented independently, allowing for best patient version.
- Dome screw holes allow for additional fixation into structural bone.
- Various liner configurations available to best meet patient need.

1 Bobyn JD, Hacking SA, Chan SP, et al. Characterization of a new porous tantalum biomaterial for reconstructive orthopaedics. Scientific Exhibit, Proc of AAOS, Anaheim, CA. 1999.

2 Pedersen DR, Brown TD, Poggie RA. Finite element analysis of peri-articular stress of cemented, metal-backed, and porous tantalum-backed acetabular components. 45th Annual Orthopaedic Research Society Meeting, Anaheim, CA. 1999.

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ORDER INFORMATION

REVISION SHELL

Cat. No.	Description
7000-48-20	48mm Cup Size
7000-50-20	50mm Cup Size
7000-52-20	52mm Cup Size
7000-54-20	54mm Cup Size
7000-56-20	56mm Cup Size
7000-58-20	58mm Cup Size
7000-60-20	60mm Cup Size
7000-62-20	62mm Cup Size
7000-64-20	64mm Cup Size
7000-66-20	66mm Cup Size
7000-68-20	68mm Cup Size
7000-70-20	70mm Cup Size

REVISION SHELL LINER – 20°

Cat. No.	Description
7020-48-28	28mm ID, 48mm Cup Size
7020-50-28	28mm ID, 50mm Cup Size
7020-52-28	28mm ID, 52mm Cup Size
7020-54-28	28mm ID, 54mm Cup Size
7020-56-28	28mm ID, 56mm Cup Size
7020-58-28	28mm ID, 58mm Cup Size
7020-60-28	28mm ID, 60mm Cup Size
7020-62-28	28mm ID, 62/64mm Cup Size
7020-66-28	28mm ID, 66/68/70mm Cup Size

REVISION SHELL LINER – 10°

Cat. No.	Description
7010-48-28	28mm ID, 48mm Cup Size
7010-50-28	28mm ID, 50mm Cup Size
7010-52-28	28mm ID, 52mm Cup Size
7010-54-28	28mm ID, 54mm Cup Size
7010-56-28	28mm ID, 56mm Cup Size
7010-58-28	28mm ID, 58mm Cup Size
7010-60-28	28mm ID, 60mm Cup Size
7010-62-28	28mm ID, 62/64mm Cup Size
7010-66-28	28mm ID, 66/68/70mm Cup Size

REVISION SHELL LINER – 0°

Cat. No.	Description
7005-48-28	28mm ID, 48mm Cup Size
7005-50-28	28mm ID, 50mm Cup Size
7005-52-28	28mm ID, 52mm Cup Size
7005-54-28	28mm ID, 54mm Cup Size
7005-56-28	28mm ID, 56mm Cup Size
7005-58-28	28mm ID, 58mm Cup Size
7005-60-28	28mm ID, 60mm Cup Size
7005-62-28	28mm ID, 62/64mm Cup Size
7005-66-28	28mm ID, 66/68/70mm Cup Size

CE 0120

INSTRUMENTS

Cat. No.	Description
7000-15	General Acetabular Instrument Set (Includes one each of all items listed below; portions of kit used for both Monoblock Cup and Revision Shell)
7050-76	Instrument Case Base w/Lid (Outer Case)
7050-77	Instrument Case Bottom Tray
7050-78	Instrument Case Top Tray

Provisional Shell

7040-40	40mm Cup Size
Through ↓	Through ↓
7040-70	70mm Cup Size

Available in 2mm increments.

Cup Adapter w/Bayonet

7045-40	40mm Cup Size
Through ↓	Through ↓
7045-70	70mm Cup Size

Available in 2mm increments.

General Instruments

7050-30	Cup Rim Impactor
7050-31	Cup Version Guide
7050-32	Provisional Liner Extractor (Monoblock Cup only)
7050-33	Bayonet Handle w/Hudson Adapter (Plunger included)
7050-34	Provisional Shell Impactor Handle
7050-35	Medial Cup Impactor (Monoblock Cup only)
7050-36	Acetabular Impactor Head, 28mm
7050-38	Acetabular Impactor Head, 22mm

Provisional Liner – 0° (Monoblock Cup Only)

7360-40-22	22mm ID, 40mm Cup Size
Through ↓	Through ↓
7360-46-22	22mm ID, 46mm Cup Size
7360-48-28	28mm ID, 48mm Cup Size
Through ↓	Through ↓
7360-70-28	28mm ID, 48mm Cup Size

Available in 2mm increments.

Provisional Liner – 10° (Monoblock Cup Only)

7361-40-22	22mm ID, 40mm Cup Size
Through ↓	Through ↓
7361-46-22	22mm ID, 46mm Cup Size
7361-48-28	28mm ID, 48mm Cup Size
Through ↓	Through ↓
7361-70-28	28mm ID, 70mm Cup Size

Available in 2mm increments.

7050-95	General Instrument Case Holds 0° or 10° Monoblock Provisional Liners
7050-33-01	Plunger (replacement ordered separately)

INSTRUMENTS - continued

Cat. No.	Description
7000-17	Revision Shell Instrument Set (Includes one each of all items listed below; used only for Revision Shell)

Revision Shell Provisional Liner – 20°

7320-48-28	28mm ID, 48mm Cup Size
7320-50-28	28mm ID, 50mm Cup Size
7320-52-28	28mm ID, 52mm Cup Size
7320-54-28	28mm ID, 54mm Cup Size
7320-56-28	28mm ID, 56mm Cup Size
7320-58-28	28mm ID, 58mm Cup Size
7320-60-28	28mm ID, 60mm Cup Size
7320-62-28	28mm ID, 62/64mm Cup Size
7320-66-28	28mm ID, 66/68/70mm Cup Size

Revision Shell Provisional Liner – 10°

7310-48-28	28mm ID, 48mm Cup Size
7310-50-28	28mm ID, 50mm Cup Size
7310-52-28	28mm ID, 52mm Cup Size
7310-54-28	28mm ID, 54mm Cup Size
7310-56-28	28mm ID, 56mm Cup Size
7310-58-28	28mm ID, 56mm Cup Size
7310-60-28	28mm ID, 60mm Cup Size
7310-62-28	28mm ID, 62/64mm Cup Size
7310-66-28	28mm ID, 66/68/70mm Cup Size

Revision Shell Rim Impactor

7330-48	Rev Shell Rim Impactor, Size 48
7330-50	Rev Shell Rim Impactor, Size 50
7330-52	Rev Shell Rim Impactor, Size 52
7330-54	Rev Shell Rim Impactor, Size 54
7330-56	Rev Shell Rim Impactor, Size 56
7330-58	Rev Shell Rim Impactor, Size 58
7330-60	Rev Shell Rim Impactor, Size 60
7330-62	Rev Shell Rim Impactor, Size 62/64
7330-66	Rev Shell Rim Impactor, Size 66/68/70
7050-81	Revision Shell Instrument Case holds 10° and 20° Provisional Liners and Rim Impactors

REVISION SHELL PROVISIONAL LINER – 0° (ORDERED SEPARATELY)

Cat. No.	Description
7005-17	Provisional Liner Kit, 0°
7305-48-28	28mm ID, 48mm Cup Size
7305-50-28	28mm ID, 50mm Cup Size
7305-52-28	28mm ID, 52mm Cup Size
7305-54-28	28mm ID, 54mm Cup Size
7305-56-28	28mm ID, 56mm Cup Size
7305-58-28	28mm ID, 58mm Cup Size
7305-60-28	28mm ID, 60mm Cup Size
7305-62-28	28mm ID, 62/64mm Cup Size
7305-66-28	28mm ID, 66/68/70mm Cup Size

BONE SCREWS

Cat. No.	Description
6250-65-15	6.5mm x 15mm
6250-65-20	6.5mm x 20mm
6250-65-25	6.5mm x 25mm
6250-65-30	6.5mm x 30mm
6250-65-35	6.5mm x 35mm
6250-65-40	6.5mm x 40mm
6250-65-50	6.5mm x 50mm
6250-65-60	6.5mm x 60mm

SCREW INSTRUMENTS

Cat. No.	Description
6260-99-02	*Trilogy*® Holed Instrument Set (Includes one of each of all items listed below)
6260-02	Flex Shaft w/Modular Connector
6260-03-01	Drill Bit, 15mm Length
6260-03-02	Drill Bit, 30mm Length
6260-03-03	Drill Bit, 45mm Length
6260-06	Drill Guide
6260-07-01	Tap, 4.5mm Diameter
6260-07-02	Tap, 6.5mm Diameter
6260-08-01	Tap Guide, 4.5mm Diameter
6260-08-02	Tap Guide, 6.5mm Diameter
6260-10	Tap Handle
6260-24	Straight Screwdriver
6260-25	Universal Screwdriver
6260-26	Modular Universal Handle
6260-13	Screw Holding Forceps, 15°
6260-14	Screw Holding Forceps, 45°
6611-98	Depth Gauge
6260-85-01	Case (including base and lid)

4215-200	Screwdriver Torque Limiter (ordered separately, not in kit)

Trabecular Metal Revision Shell system developed in cooperation with David G. Lewallen, MD, Orthopedic Surgeon, Mayo Clinic.

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.

Manufactured by

Distributed by

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

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APPENDIX B

SURGICAL PROTOCOL

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

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APPENDIX C

ENGINEERING DRAWINGS

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

(b)(4) Engineering Drawings

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APPENDIX D

MASTERFILE (b)(4) TABLE OF CONTENTS

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

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Device Master File for (b)(4) [redacted]

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[redacted]

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) P. Su

Subject: 510(k) Number K050937

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☒ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?	☐ YES	☒ NO
Is this device subject to the Tracking Regulation?	☐ YES	☒ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☒ NO
Is this a prescription device?	☒ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☒ NO
Special 510(k)?	☒ YES	☐ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☒ NO

Truthful and Accurate Statement ☐ Requested ☒ Enclosed

☒ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices

☒ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source ☐ YES ☒ NO Material of Biological Origin ☐ YES ☒ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☒ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: LPH/II

Additional Product Code(s) with panel (optional): JDI, II

Review: Glen Gregory (Branch Chief) ORDB (Branch Code) 5/10/05 (Date)

Final Review: Steph Phoebe (Division Director) 5/11/05 (Date)

Revised:4/2/03

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

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Re: K050937
Trade/Device Name: Trabecular Metal Acetabular Revision Shells
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
Dated: April 11, 2005
Received: April 14, 2005

5/10/05

Recommendation:

This subject Special 510(k) notification:

- [x] fulfills the requirements for a "Special" 510(k)
- [ ] requires more data.
- [ ] changes to traditional 510(k).

Type letter and wording suggested:

- [x] "SE" Letter Attached
- [ ] "SN" Letter Attached
- [ ] "AI" Letter Attached
- [ ] "AI" via Telephone and/or FAX

Summary:

This modified device is modified from K983837 and K001759.

The sponsor has stated on the front page (April 11, 2005 letter) that "There are no changes to the Indications for Use, Intended Use, or Fundamental Technology of cited predicated devices."

The purpose of this 510(k) application is to add new larger sizes of shells (72mm - 80mm in 2mm increments) and to allow two minor design modifications. The modifications are: (1) a modified instrument interface face ring that allows for use with a new impaction instrument for all sizes (from 40mm-80mm); and (2) a change in screw hole pattern within the shells for all sizes (40-80 mm).

This submission does contain information/data on modifications made to the submitter's own device and 510(k).

The sponsor has provided the necessary to fulfill the requirements for a Special 510(k). As part of a "Special" 510(k), the sponsor is not required to provide much of the information in the traditional 510(k). The "SE" decision is primarily based on an administrative review as the Special regulations were intended.

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

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This Special 510(k) Includes:

1. Coversheet identifying the application as "Special 510(k): Device Modification";
2. Name and 510(k) of device for which it is a modification;
3. Description of the device modifications;
4. Statement that intended use of modified device as described in its labeling have not changed;
5. Information that fundamental scientific technology of the modified device has not changed;
6. Design control activities summary:
   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;
   b) based on the risk analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied;
   c) Declaration of conformity with design; and
7. General information required for all 510(k) submissions.

510(k)# and Name of the Device Modified From:

K983837 and K001759, Trabecular Metal (formerly called Hedrocel) Acetabular Cage System/Revision Cup

Indications for Use:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problem where arthrodesis or alternative reconstruction 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 device is indicated for cemented or cementless use.

Type Modifications:

The device included in this subject 510(k) is a line extension to the cleared Trabecular Metal (formerly called Hedrocel) Acetabular Cage System/Revision Cup cleared via K983837 and K001759. K983837 cleared sizes 52mm-70mm shells and K001759 cleared sizes 40mm-50mm shells.

The purpose of this 510(k) application is to add new larger sizes range from 72mm - 80mm, in 2mm increments with two minor design modifications. The modifications include:

- a modified surgical instrument that allows use with a new impaction instrument for all shell sizes (from 40mm-80mm) and
- a change in screw hole pattern within the shells for all sizes (40-80 mm).

Description of changes and validation/verification activities are attached in Section 1.5 (pp. 16-17). Risk analysis is attached in Section 1.6 (from p.18).

Device comparison table is attached on p.31.

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

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Conclusion:
The sponsor has provided the necessary to fulfill the requirements for a Special 510(k).

Contact Person:
Marci Halevi
Manager of Regulatory Affairs
Zimmer Trabecular Metal Technology
80 Commerce Drive
Allendale, NJ 07401-1600
Phone: 201-818-1800

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

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Decision Making Documentation

Product to which compared: see review

	YES	NO	
1. Is Product A Device	x		If NO = Stop
2. Is Device Subject To 510(k)?	x		If NO = Stop
3. Same Indication Statement?	x		If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?	x		If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?	x		If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?			If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: "Yes" responses to questions 4,6,8,11, and every "No" response requires an explanation.

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performances data are needed:
11. Explain how the performance data demonstrate that the device is or is not substantially equivalent:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8113

Records processed under FOIA Request # 2016-1518; Released by CDRH on 05-23-2016

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		x
2. Did we grant expedited review?		x
3. Have you verified that the Document is labeled Class III for GMP purposes?	x	
4. If, not, has POS been notified?		
5. Is the product a device?	x	
6. Is the device exempt from 510(k) by regulation or policy?		x
7. Is the device subject to review by CDRH?	x	
8. Are you aware that this device has been the subject of a previous NSE decision?		x
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation?		x
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		

Screening Chicklist

2. GENERAL INFORMATION: REQUIRED IN SPECIAL 510(K) SUBMISSIONS							
Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i)	NA		YES		NO		
	SPECIALS		ABBREVIATED		TRADITIONAL		
	YES	NO	YES	NO	YES	NO	
a) trade name, classification name, establishment registration number, device class	x						
b) OR a statement that the device is not yet classified	FDA-may be a classification request; see coordinator						
c) identification of legally marketed equivalent device	NA						
d) compliance with Section 514 - performance standards	NA						
e) address of manufacturer	x						
f) Truthful and Accurate Statement	x						
g) Indications for Use enclosure	x						
h) SMDA Summary or Statement (FOR ALL DEVICE CLASSES)	x						
i) Class III Certification & Summary (FOR ALL CLASS III DEVICES)							
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals	x						
k) Proposed Labeling:	x						
l) Comparison Information (similarities and differences) to named legally marketed equivalent device	x						
m) If kit, kit certification							
3. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II , III OR RESERVED CLASS I DEVICE							
a) Name & 510(k) number of legally marketed (unmodified) predicate device	x						
b) STATEMENT - INTENDED USE AND INDICATIONS FOR USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED*	x		* If no - STOP not a special				
c) STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED*	x		* If no - STOP not a special				
d) Design Control Activities Summary	x						
i) 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						
ii) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied	x						
iii) A declaration of conformity with design controls.	x						

Passed Screening: Yes Reviewed by: Pei Sung Concurred by: [signature] 5/10/05

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

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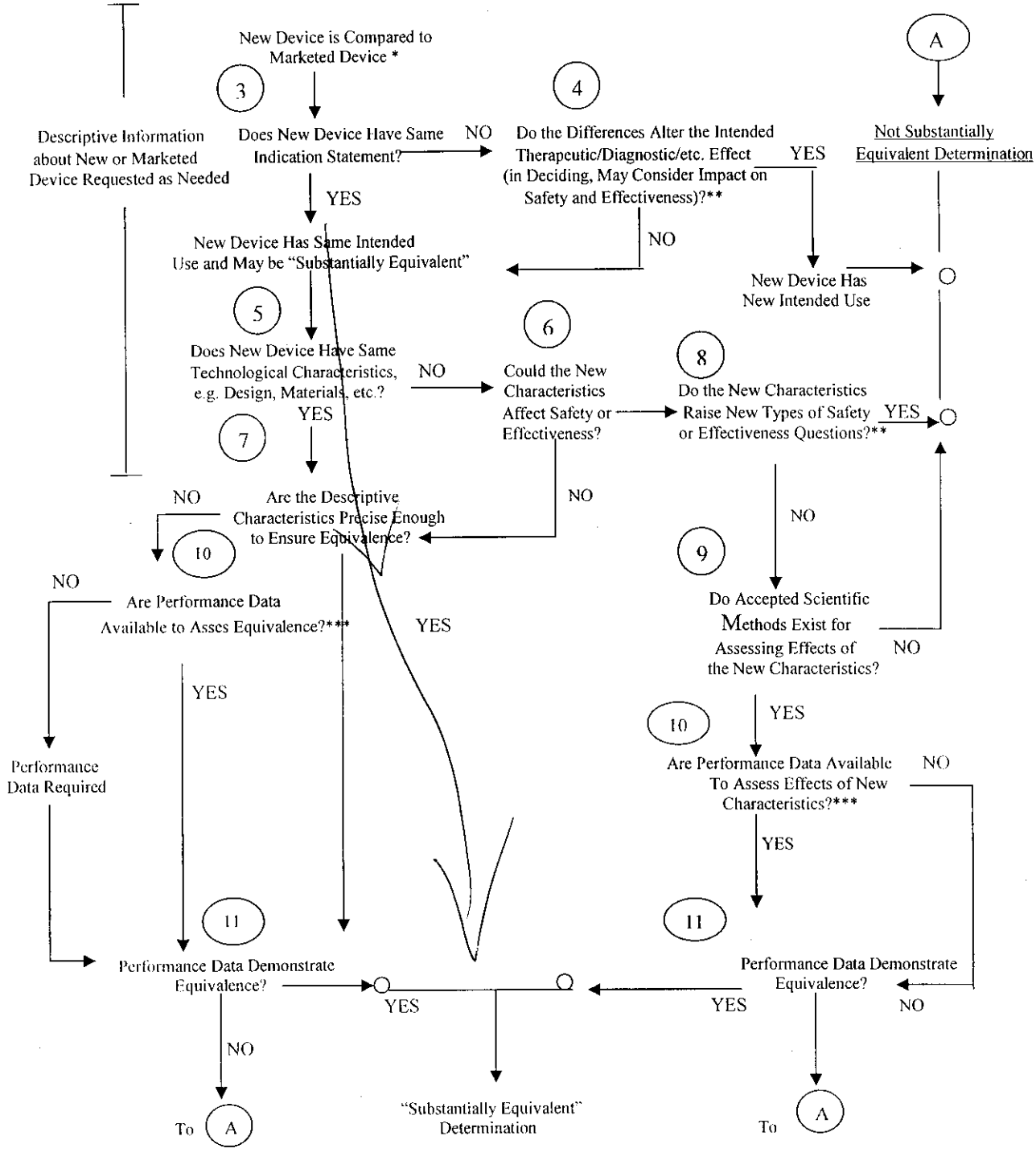
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



- ❖ 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- ❖❖ This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- ❖❖❖ Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

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