U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(lab)
FOLDER:	K042841 - 365 pages
COMPANY:	BIOMET, INC. (BIOMET)
PRODUCT:	PROSTHESIS, HIP, SEMI-CONSTRAINED (METAL CEMENTED ACETABULAR COMPONENT) (JDL)
SUMMARY:	Product: M2A/C2A ACETABULAR SYSTEM
DATE REQUESTED:	Aug 11, 2014
DATE PRINTED:	Aug 11, 2014
Note:	Printed

K042841 1/2

DEC 21 2004

BIOMET

510(k) Summary

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Patricia Sandborn Beres
Senior Regulatory Specialist

Proprietary Name: M²a™/C²a™ Acetabular System

Common Name: Metallic Acetabular System

Classification Name:

1. Hip joint metal/metal semi-constrained, with an uncemented acetabular component prosthesis (21 CFR 888.3330)
2. Hip joint metal/metal semi-constrained, with a cemented acetabular component prosthesis (21 CFR 888.3320)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed: Biomet devices:

K993438 - Metal on Metal Acetabular System
K003363 - M²a™ 32mm Taper System
K861114 - Mallory/Head PF Acetabular Component

Device Description: The M²a™/C²a™ Acetabular System consists of a titanium outer acetabular shell with a cobalt alloy metallic liner for metal on metal articulation.

The acetabular shells are hemispherical in shape to closely match the natural acetabulum. Two screw holes in the dome allow for additional fixation by the use of screws. The outer surface of the shells are covered with Biomet's plasma sprayed coating.

The metallic cobalt alloy bearing liner fits into the outer shell by means of a taper similar to the taper used for the attachment of a modular head to a femoral stem. The metallic liners articulate with cobalt alloy modular heads.

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SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

OFFICE
574.267.6639

FAX
574.267.8137

E-MAIL
biomet@biomet.com

Intended Use: The M²a™/C²a™ Acetabular System is intended for cemented or non-cemented use in cases of:

1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
2) Rheumatoid arthritis
3) Correction of functional deformity
4) Revision procedures where other treatment or devices have been unsuccessful
5) Treatment of non-union, femoral neck fracture, trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques

Summary of Technologies: The technological characteristics of the new device are similar of identical to the predicates.

Non-Clinical Testing: None provided

Clinical Testing: None provided.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 21 2004

Ms. Patricia S. Andborn Beres
Senior Regulatory Specialist
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46582

Re: K042841
Trade/Device Name: M^2a / C^2a™ Acetabular System
Regulation Number: 888.3330; 888.3320
Regulation Name: Hip joint metal/semi constrained, with uncemented acetabular component prosthesis; Hip joint metal / metal semi-constrained acetabular component prosthesis
Regulatory Class: III
Product Code: KWA, JDL
Dated: November 26, 2004
Received: November 29, 2004

Dear Ms. Andborn Beres:

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

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

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0210. 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 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/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042841

Device Name: M^2a™/C^2a™ Acetabular System

Indications For Use:

The M^2a™/C^2a™ Acetabular System is intended for cemented or non-cemented use in cases of:

1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
2) Rheumatoid arthritis
3) Correction of functional deformity
4) Revision procedures where other treatment or devices have been unsuccessful
5) Treatment of non-union, femoral neck fracture, trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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510(k) Number K042841

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 21 2004

Ms. Patricia S. Andborn Beres
Senior Regulatory Specialist
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46582

Re: K042841
Trade/Device Name: M^2a / C^2a™ Acetabular System
Regulation Number: 888.3330; 888.3320
Regulation Name: Hip joint metal/semi constrained, with uncemented acetabular component prosthesis; Hip joint metal / metal semi-constrained acetabular component prosthesis
Regulatory Class: III
Product Code: KWA, JDL
Dated: November 26, 2004
Received: November 29, 2004

Dear Ms. Andborn Beres:

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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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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.

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Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042841

Device Name: M^2a™/C^2a™ Acetabular System

Indications For Use:

The M^2a™/C^2a™ Acetabular System is intended for cemented or non-cemented use in cases of:

1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
2) Rheumatoid arthritis
3) Correction of functional deformity
4) Revision procedures where other treatment or devices have been unsuccessful
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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Page 1 of 1

510(k) Number K042841

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

October 14, 2004

BIOMET, INC.
56 EAST BELL DR.
P.O. BOX 587
WARSAW, IN 46582
ATTN: PATRICIA S. ANDBORN BERES

510(k) Number: K042841
Received: 14-OCT-2004
Product: M2A/C2A ACETABULAR SYSTEM

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

K042841

BIOMET

October 13, 2004

FDA/CDRH/OSE/DMD
2004 OCT 14 P 4:30

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

RE: M²a™/C²a™ Acetabular System
510(k) Premarket Notification
Payment ID Number: 014934-956733

Dear Sir or Madam:

Enclosed is a 510(k) notification for the M²a™/C²a™ Acetabular System. We believe this device is substantially equivalent* to other acetabular replacement devices on the market.

Please note, the C²a™ terminology in the title of this device refers to the C²a™-Taper Acetabular System that is the subject of a Modular Premarket Approval Application (PMA), M040011, submitted on September 29, 2004. The same acetabular shells are used for both the PMA ceramic-on-ceramic system and the metal-on-metal system which is the subject of this 510(k).

The sponsor of this 510(k) considers the existence of this notification confidential until a determination of substantial equivalence is made. Permission to fax or e-mail information related to this submission is granted by the Sponsor.

Sincerely,

Patricia S Beres

Patricia Sandborn Beres
Senior Regulatory Specialist
Biomet Manufacturing Corp.

*Any statement made in conjunction with this submission regarding and/or a determination of substantial equivalence to any other product is intended only to relate to whether the product can be lawfully marketed without pre-market approval or reclassification and is not intended to be interpreted as an admission or any other type of evidence in patent infringement litigation. [Establishment Registration and Premarket Notification Procedures, Final Regulation, Preamble, August 23, 1977, 42 FR 42520 (Docket No. 76N-0355)]

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19

5K-24
OR
II

Table of Contents

Form Approved:OMB No. 0910-0511 Expiration Date: August 31, 2006. See instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBE (b) (4)
Write the Payment Identification Num

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 submit the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include a 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. Louis, 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 transfers.
6. Include a copy of the completed 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)	2. CONTACT NAME
BIOMET MANUFACTURING CORP 56 EAST BELL DRIVE P.O. BOX 587 WARSAW, IN 46581-0578	PATRICIA BERES 2.1 E-MAIL ADDRESS patty.beres@biometmail.com 2.2 TELEPHONE NUMBER (Include Area Code) 574-267-6639
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) 352074037	2.3 FACSIMILE (FAX) NUMBER (Include Area Code) 574-372-1683

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:

- ☑ Premarket notification (510(k)); except for third party reviews
- ☐ 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:

- ☑ 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
- ☑ NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

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
- ☐ The sole purpose of the application is to support conditions of use for a pediatric population
- ☐ This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
- ☐ 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 ☑ NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2004)

(b) (4)

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
(As Required by 21 CFR 807.87(j))

I certify, in my capacity as a Development Engineer of Biomet Manufacturing Corp., 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.

W. Jason Slone
Signature

W. Jason Slone
Typed Name

9/29/2004
Date

M²a™/C²a™ Acetabular System
Device

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
(As Required by 21 CFR 807.87(j))

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

Signature

Robert E. Durgin
Typed Name

12 OCT 04
Date

M²a™/C²a™ Acetabular System
Device

Indications for Use

510(k) Number (if known):_____

Device Name: M^2a™/C^2a™ Acetabular System

Indications For Use:

The M^2a™/C^2a™ Acetabular System is intended for cemented or non-cemented use in cases of:

1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
2) Rheumatoid arthritis
3) Correction of functional deformity
4) Revision procedures where other treatment or devices have been unsuccessful
5) Treatment of non-union, femoral neck fracture, trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Notification

A. ADMINISTRATIVE INFORMATION

Applicant or Sponsor: Biomet Manufacturing Corp.
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587

Contact Person: Patricia Sandborn Beres
Senior Regulatory Specialist
Biomet Manufacturing Corp.
P.O. Box 587
Warsaw, Indiana 46581-0587
Phone: (574) 267-6639
FAX: (574) 372-1683
E-Mail: patty.beres@biometmail.com

Manufacturing Site(s):
Specification holder:

Biomet Manufacturing Corp.
56 East Bell Drive
Warsaw, Indiana 46582
Establishment Registration Number: 1825034

Manufacturer/Contract Manufacturer:

Biomet Manufacturing Corp.
56 East Bell Drive
Warsaw, Indiana 46582
Establishment Registration Number: 1825034

Contract Sterilizer(s):

(b) (4)

[redacted]

B. DEVICE IDENTIFICATION

Proprietary Name: M²a™/C²a™ Acetabular System

Common or Usual Name: Metallic Acetabular System

Classification Name:

1. Hip joint metal/metal semi-constrained, with an uncemented acetabular component prosthesis (21 CFR 888.3330)
2. Hip joint metal/metal semi-constrained, with a cemented acetabular component prosthesis (21 CFR 888.3320)

Device Classification:

1. Preamendment Class III
2. Preadmendment Class III

A Class III Certification and Summary may be found in Appendix 1 including the Medical Device Reports tabular summary and copies of the MAUDE Database reports. Class III literature review and copies of the abstracts are located in Appendix 2.

Device Product Code:

1. 87 KWA
2. 87 JDL

Performance Standards/Guidance Documents: No performance standards have been developed for this type of device.

Previous FDA Status: Components of this system were previously cleared through 510(k) K993438 - Metal on Metal Acetabular System and K003363 - M²a™ 32mm Taper System for non-cemented application only. The shell of this system is currently the subject of a PMA application for ceramic-on-ceramic articulation (M040011).

C. DEVICE DESCRIPTIVE INFORMATION

Intended Use: The M²a™/C²a™ Acetabular System is intended for cemented or uncemented use in cases of:

1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
2) Rheumatoid arthritis
3) Correction of functional deformity
4) Revision procedures where other treatment or devices have been unsuccessful
5) Treatment of non-union, femoral neck fracture, trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques

Device Description: The M²a™/C²a™ Acetabular System consists of a titanium outer acetabular shell with a cobalt alloy metallic liner for metal on metal articulation. A cobalt alloy modular head completes the system.

The acetabular shells are hemispherical in shape to closely match the natural acetabulum. The shells are available in outer diameters of 48mm to 70mm in 2 mm increments. The shell features eight radial fins to aid in the prevention of rotation. Two screw holes in the dome allow for additional fixation by the use of 6.5mm screws. The outer surface of the shells are covered with Biomet's plasma spray coating.

The metallic liners contained in this submission are identical to those previously cleared in 510(k) K993438 - Metal on Metal Acetabular System and K003363 - M²a™ 32mm Taper System. The taper locking mechanism of the shells is also identical to that of the shells cleared in these two 510(k)s.

The metallic, cobalt alloy bearing liner fits into the outer shell by means of a taper similar to the taper used for the attachment of a modular head to a femoral stem. The locking mechanism consists of an 18°55' taper. (b) (4) (b) (4) (b) (4) This is less than half the allowable deviation set forth in the ISO standard for modular head sphericity (ISO 7206-2).

The metallic liners articulate with cobalt alloy modular heads identical to those cleared through 510(k) K993438 - Metal on Metal Acetabular System and K003363 - M²a™ 32mm Taper System. (b) (4) (b) (4) Both 28mm and 32mm cobalt alloy modular heads are available in seven neck lengths ranging from -6mm to +12mm. Each modular head has Biomet's Type I Taper and will mate with any Biomet Type I Taper femoral component.

A part number listing and engineering drawings can be found in **Exhibit 1**. In addition, there are manual surgical instruments listed that are used with the device.

Materials: The acetabular shell is manufactured from titanium alloy (Ti-6Al-4V) conforming to ASTM F-136 or F-1472. The outer surface of the shell is plasma spray coated with Ti-6Al-4V powder conforming to ASTM F-1580. Please see the sample engineering drawings contained in **Exhibit 1** for the location of the coating. A full characterization of this coating may be found in Master File MAF-153. A table summarizing this information is contained in **Exhibit 2**. This coating is identical to the coatings cleared in 510(k) K993438 - Metal on Metal Acetabular System and K003363 - M²a™ 32mm Taper System.

The metallic acetabular liner and metallic modular heads are manufactured from cobalt alloy (Co-Cr-Mo) conforming to ASTM F-1537.

Labeling: Copies of the package label, package insert, surgical technique may be found in **Exhibit 3**.

Sterility Information: Devices are provided sterile by radiation methods as follows:

Radiation Type: Gamma
Radiation Source: Cobalt 60
Minimum Dosage: 25 kGy
Maximum Dosage: 40 kGy
Sterility Assurance Level: 10^{-6}
Sterility Validation Method: AMMI/ISO 11137, Method 1
Pyrogen-Free: no claims will be made
Labeling: All packages will display a yellow to red chemical indication dot along with a statement that the device has been sterilized by gamma irradiation, 2.5 Mrads.
Sterilization Site:

(b) (4)

[redacted]

A summary of Biomet's sterilization methods is presented in Biomet's Masterfile MAF-153. Sample bioburden audits and pyrogen testing is also included. Both of these tests are done on a periodic basis for all Biomet devices.

Packaging Description: Each component is supplied in an individual sterile package. They are then placed in an inner blister pack sealed with a Tyvek® lid which fits into an outer blister pack also sealed with a Tyvek® lid. The entire unit is placed in a cardboard box, shrink wrapped for protection.

Substantial Equivalence: Exhibit 4 contains a table comparing the M²a™/C²a™ Acetabular System to several of Biomet's cleared devices. These devices are:

K993438 - Metal on Metal Acetabular System
K003363 - M2a 32mm Taper System
K861114 - Mallory/Head PF Acetabular Component

Indications for Use
The M²a™/C²a™ Acetabular System has indications for use similar to the predicates. Predicate Mallory/Head acetabular shells have been cleared for both cemented and non-cemented applications.

Technological Characteristics
The acetabular shell diameters and overall geometry are identical to the Mallory/Head shells cleared in 510(k)s K993438 and K003363. The only difference is the addition of 2 screw holes to the Mallory/Head configuration. Besides the Mallory/Head style shells, the predicate 510(k)s contained the Universal style acetabular shell with 2 screw holes in the dome.

The shells inner taper angle that provides fixation of the metallic liner is identical to the predicates. Slight dimensional changes have been made to the inner shell geometry to insure proper seating of the liner in the shell even when the tolerances are at their limits. The surface roughness of the shell's inner taper has been increased over the predicate. In order to confirm that the locking strength of the components has not been altered from the predicates, testing has been conducted. **Exhibit 5** contains the test report and a discussion to the relevance of this testing to the current device.

The metallic liners are identical to those cleared in 510(k) s K993438 and K003363.

Summary

In summary, the M²a™/C²a™ Acetabular System is substantially equivalent to the predicate device in that:

- They have similar indications for use
- The acetabular shells are identical in overall design with no new features
- The taper locking mechanism for the metal liner is identical

D. 510(k) SUMMARY

A summary of information pertaining to the safety and effectiveness of this type of device is contained in Exhibit 6.

DEVICE LISTING

Liner Component Listing

Part Number	Description
15-105000	28mm I.D./37 Taper
15-105002	28mm I.D./41 Taper
15-105004	32mm I.D./41 Taper

28mm Modular Head Component Listing

Part Number	Description
11-163660	Metal on Metal 28mm -6mm Modular Head
11-163661	Metal on Metal 28mm -3mm Modular Head
11-163662	Metal on Metal 28mm std. Modular Head
11-163663	Metal on Metal 28mm +3mm Modular Head
11-163664	Metal on Metal 28mm +6mm Modular Head
11-163665	Metal on Metal 28mm +9mm Modular Head
11-163666	Metal on Metal 28mm +12mm Modular Head

32mm Modular Head Component Listing

Part Number	Description
11-163667	M²a™ 32mm Modular Head –6mm
11-163668	M²a™ 32mm Modular Head –3mm
11-163669	M²a™ 32mm Modular Head std
11-163670	M²a™ 32mm Modular Head +3mm
11-163671	M²a™ 32mm Modular Head +6mm
11-163672	M²a™ 32mm Modular Head +9mm skirt
11-163673	M²a™ 32mm Modular Head +12mm skirt

Acetabular Shell Component Listing

Part Number	Description
10-111148	37mm x 48mm Mallory-Head® Radial 2-Hole Shells
10-111150	37mm x 50mm Mallory-Head® Radial 2-Hole Shells
10-111152	41mm x 52mm Mallory-Head® Radial 2-Hole Shells
10-111154	41mm x 54mm Mallory-Head® Radial 2-Hole Shells
10-111156	41mm x 56mm Mallory-Head® Radial 2-Hole Shells
10-111158	41mm x 58mm Mallory-Head® Radial 2-Hole Shells
10-111160	41mm x 60mm Mallory-Head® Radial 2-Hole Shells
10-111162	41mm x 62mm Mallory-Head® Radial 2-Hole Shells
10-111164	41mm x 64mm Mallory-Head® Radial 2-Hole Shells
10-111166	41mm x 66mm Mallory-Head® Radial 2-Hole Shells
10-111168	41mm x 68mm Mallory-Head® Radial 2-Hole Shells
10-111170	41mm x 70mm Mallory-Head® Radial 2-Hole Shells

Screw Component Listing

Part Number	Description
103530	Titanium Acetabular Screw 6.5 x 15mm
103531	Titanium Acetabular Screw 6.5 x 20mm
103532	Titanium Acetabular Screw 6.5 x 25mm
103533	Titanium Acetabular Screw 6.5 x 30mm
103534	Titanium Acetabular Screw 6.5 x 35mm
103535	Titanium Acetabular Screw 6.5 x 40mm
103536	Titanium Acetabular Screw 6.5 x 45mm
103537	Titanium Acetabular Screw 6.5 x 50mm
103538	Titanium Acetabular Screw 6.5 x 60mm
103539	Titanium Acetabular Screw 6.5 x 70mm

Specialized Instrumentation

"Orthopedic manual surgical instruments are class I exempt per 21 CFR Part 888, section 888.4550.

Part Number	Description
31-103628	M²a™ Trial Liner 41/32mm
31-103629	M²a™ Trial Liner 41/28mm
31-103633	M²a™ Taper Liner Impactor 28mm
31-131004	M²a™ Taper Liner Impactor 32mm
31-103634	M²a™ Liner Extractor 37 Taper
31-103635	M²a™ Liner Extractor 41 Taper
31-434540	M²a™ Ringloc® Cup Inserter
31-434545	Dial-a-Version
31-434543	Dial-a-Version Locking Mechnism

(b) (4) Engineering Drawings

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(b) (4) Engineering Drawings

(b) (4) Engineering Drawings

(b) (4) Engineering Drawings

(b) (4) Engineering Specifications

Sample Labels

REF 10-111148 LOT 123123

C2A(TM) / M2A(TM) SYSTEM W/PLUG
48MM O.D. SHELL
SIZE 37MM I.D. TAPER

TI 6AL 4V ALLOY/POROUS COATED
WARNING! USE ONLY WITH
37MM O.D. TAPERED LINERS

LOT 123123 QTY. 1

BIOMET ORTHOPEDICS, INC.
56 EAST BELL DRIVE
P.O. BOX 587
WARSAW, IN 46581 USA
STERILE R
2004-08
EXPIRY DATE:
2014-08

REF 15-105000 LOT 123121

M2A(TM) TAPER LINER
28 MM I.D.
SIZE 37 MM O.D. TAPER

CO-CR-MO ALLOY
USE 11-163660/66
M2A(TM) MODULAR HEADS ONLY

LOT 123121 QTY. 1

CE 0086

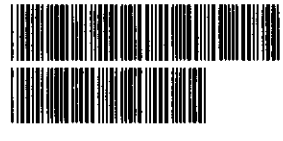
BIOMET ORTHOPEDICS, INC.
56 EAST BELL DRIVE
P.O. BOX 587
WARSAW, IN 46581 USA
STERILE R
2004-08
EXPIRY DATE:
2014-08

REF 11-163660 LOT 123123

M2A MODULAR HEAD COMPONENT
28 MM HEAD DIAMETER
MINUS 6 MM NECK

TYPE I TAPER/METAL ON METAL
CO-CR-MO ALLOY

LOT 123123 QTY. 1



CE 0086

BIOMET ORTHOPEDICS, INC.
56 EAST BELL DRIVE
P.O. BOX 587
WARSAW, IN 46581 USA
STERILE R
2004-08
EXPIRY DATE:
2014-08

64

Biomet Orthopedics, Inc.
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581 USA

01-50-0959
Date: 10/04

Biomet® M²a™ – Taper Prostheses

Attention Operating Surgeon

DESCRIPTION

The Biomet Metal on Metal Hip Joint Replacement Prosthesis is intended for cemented or uncemented use in primary and revision hip joint replacement procedures. The metal liners are intended for use with specific metal on metal femoral articulating heads. The specialized femoral heads and metal on metal liners are to be used with Biomet primary and revision femoral components.

Materials	
Femoral Heads	CoCrMo Alloy
Acetabular Shells	Titanium Alloy
Acetabular Liners	CoCrMo Alloy
Porous Coating	Titanium Alloy

INDICATIONS

1) Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2) Rheumatoid arthritis
3) Correction of functional deformity.
4) Revision procedures where other treatment or devices have been unsuccessful.
5) Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.

Patient selection factors to be considered include: 1) need to obtain pain relief and improve function, 2) ability and willingness of the patient to follow instructions, including control of weight and activity level, 3) a good nutritional state of the patient, and 4) the patient must have reached full skeletal maturity.

CONTRAINDICATIONS

Absolute contraindications include: infection, sepsis, and osteomyelitis. Relative contraindications include: 1) uncooperative patient or patient with neurologic disorders who are incapable of following directions, 2) osteoporosis, 3) metabolic disorders which may impair bone formation, 4) osteomalacia, 5) distant foci of infections which may spread to the implant site, 6) rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram, 7) vascular insufficiency, muscular atrophy, or neuromuscular disease.

WARNINGS

Improper selection, placement, positioning, alignment and fixation of the implant components may result in unusual stress conditions which may lead to subsequent reduction in the service life of the prosthetic components. Malalignment of the components or inaccurate implantation can lead to excessive wear and/or failure of the implant or procedure. Inadequate preclosure cleaning (removal of surgical debris) can lead to excessive wear. Improper preoperative or intraoperative implant handling or damage (scratches, dents, etc.) can lead to crevice corrosion, fretting, fatigue fracture and/or excessive wear. Do not modify implants. The surgeon is to be thoroughly familiar with the implants and instruments, prior to performing surgery.

1) Use Biomet metal on metal acetabular liners with specified Biomet metal on metal femoral heads.
2) Do not use a metallic impactor or punch against the tapered flange of the Titanium shell. Damage to the taper can cause the locking mechanism to malfunction.

65

3) When inserting the final metal liner, do not scratch the outer taper of the metal liner or the inner taper of the metal shell.
4) Firmly seat modular head components to prevent dissociation. Thoroughly clean and dry taper prior to attachment of the modular head component to avoid crevice corrosion and improper seating.
5) Use only low profile acetabular dome screws with the metal on metal acetabular shells. Acetabular screws are to be fully seated to assure stable fixation and to avoid interference with the metal liner component.
6) Prior to seating the liner into the shell component, all surgical debris (tissue fragments, etc.) must be removed from the interior of the shell component, as debris may inhibit the locking mechanism from engaging and securing the liner into the shell component.
7) Perforation entirely through the pelvic bone with dome fixation screws or rim screws is to be completely avoided. Caution is to be used when determining and selecting the length of screws to be used, as perforation through the pelvic bone with screws that are too long can cause damage to body structures (blood vessels, etc.) located on the interior side of the pelvis.
8) Tight fixation of all non-cemented components at the time of surgery is critical to the success of the procedure. Each component must properly press fit into the host bone which necessitates precise operative technique and the use of specified instruments. Bone stock of adequate quality must be present and appraised at the time of surgery.
9) Complete preclosure cleaning and removal of surgical debris at the implant site is critical to minimize wear of the implant articular surfaces.

Biomet joint replacement prostheses provide the surgeon with a means of reducing pain and restoring function for many patients. While these devices are generally successful in attaining these goals they cannot be expected to withstand the activity levels and loads of normal healthy bone and joint tissue.

Accepted practices in postoperative care are important. Failure of the patient to follow postoperative care instructions involving rehabilitation can compromise the success of the procedure. The patient is to be advised of the limitation of the reconstruction and the need for protection of the implants from full load bearing until adequate fixation and healing have occurred. Excessive activity, trauma and weight gain have been implicated with premature failure of the implant by loosening, fracture, and/or wear. Loosening of the implants can result in increased production of wear particles, as well as accelerate damage to bone making successful revision surgery more difficult. The patient is to be made aware and warned of general surgical risks, possible adverse effects as listed, and to follow the instructions of the treating physician including follow-up visits.

PRECAUTIONS

Specialized instruments are designed for Biomet joint replacement systems to aid in the accurate implantation of the prosthetic components. The use of instruments or implant components from other systems can result in inaccurate fit, sizing, excessive wear and device failure. Intraoperative fracture or breaking of instruments has been reported. Surgical instruments are subject to wear with normal usage. Instruments, which have experienced extensive use or excessive force, are susceptible to fracture. Surgical instruments should only be used for their intended purpose. Biomet recommends that all instruments be regularly inspected for wear and disfigurement.

Do not reuse implants. While an implant may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant. Do not treat patients with implants that have been, even momentarily, placed in a different patient.

POSSIBLE ADVERSE EFFECTS

1) Material sensitivity reactions. Implantation of foreign material in tissues can result in histological reactions involving various sizes of macrophages and fibroblasts. The clinical significance of this effect is uncertain, as similar changes may occur as a precursor to or during the healing process. Particulate wear debris and discoloration from metallic and polyethylene components of joint implants may be present in adjacent tissue or fluid. It has been reported that wear debris may

initiate a cellular response resulting in osteolysis or osteolysis may be a result of loosening of the implant.

2) Early or late postoperative, infection, and allergic reaction.
3) Intraoperative bone perforation or fracture may occur, particularly in the presence of poor bone stock caused by osteoporosis, bone defects from previous surgery, bone resorption, or while inserting the device.
4) Loosening or migration of the implants can occur due to loss of fixation, trauma, malalignment, bone resorption, excessive activity.
5) Periarticular calcification or ossification, with or without impediment of joint mobility.
6) Inadequate range of motion due to improper selection or positioning of components.
7) Undesirable shortening of limb.
8) Dislocation and subluxation due to inadequate fixation and improper positioning. Muscle and fibrous tissue laxity can also contribute to these conditions.
9) Fatigue fracture of components can occur as a result of loss of fixation, strenuous activity, malalignment, trauma, non-union, or excessive weight.
10) Fretting and crevice corrosion can occur at interfaces between components.
11) Wear and/or deformation of articulating surfaces.
12) Trochanteric avulsion or non-union as a result of excess muscular tension, early weight bearing, or inadequate reattachment.
13) Problems of the knee or ankle of the affected limb or contralateral limb aggravated by leg length discrepancy, too much femoral medialization or muscle deficiencies.
14) Postoperative bone fracture and pain.
15) Elevated metal ion levels have been reported with metal on metal articulating surfaces. Although mechanical testing demonstrates that metal on metal articulating surfaces produce a relatively low amount of particles, the total amount of particulate produced in vivo throughout the service life of the implants remains undetermined. The long-term biological effects of the particulate and metal ions are unknown.

STERILITY

Prosthetic components are sterilized by exposure to a minimum dose of 25kGy of gamma radiation. Do not resterilize. Do not use after expiration date.

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

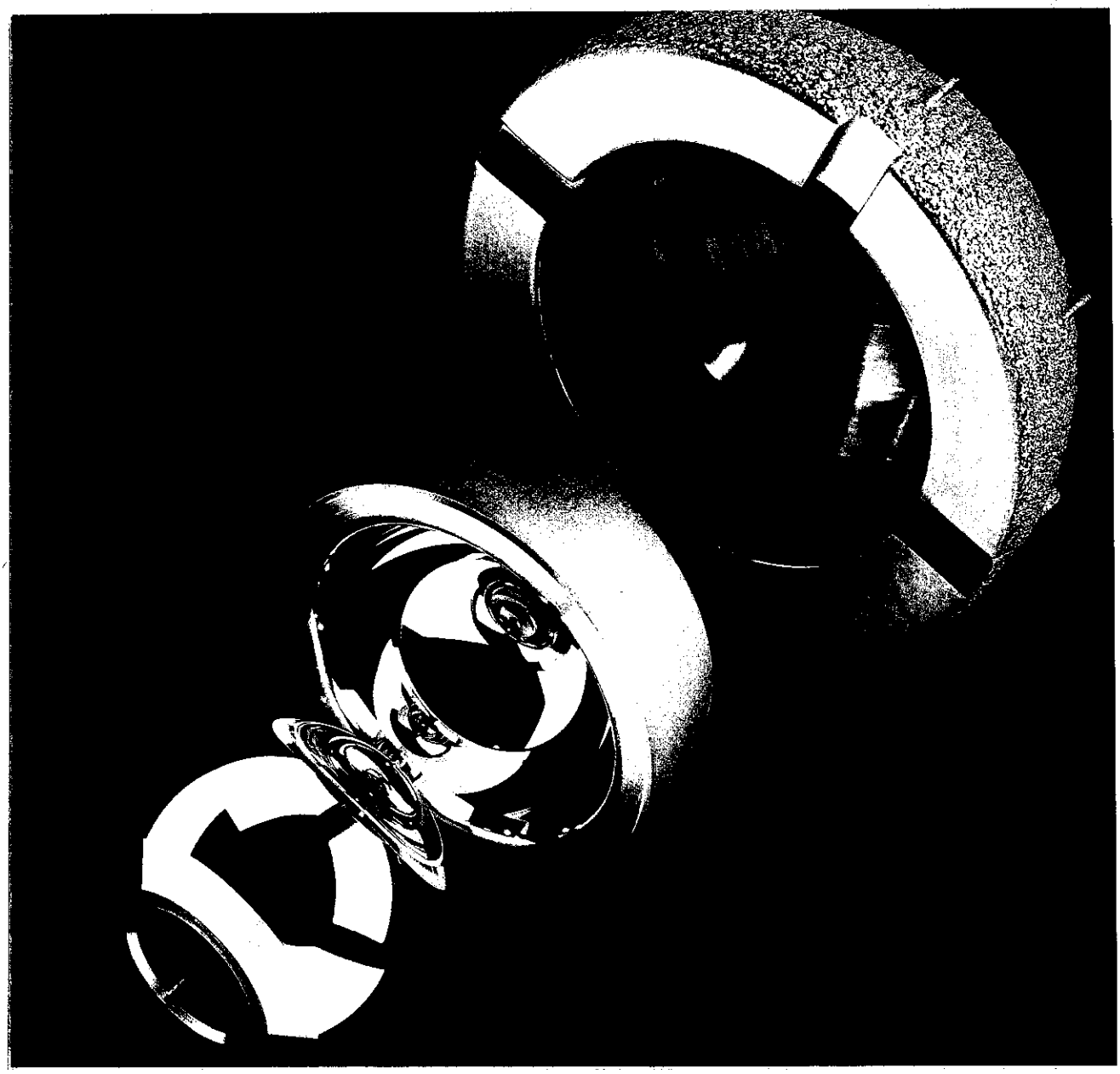
Comments regarding this device can be directed to Attn: Regulatory Dept., Biomet, P.O. Box 587, Warsaw, IN 46581 USA, Fax: 574-372-1683.

Authorized Representative: Biomet U.K. , Ltd.
Waterton Industrial Estates,
Bridgend, South Wales
CF31 3XA, U.K.

CE0086

Wright™ – Taper

metal-on-metal articulation



SURGICAL TECHNIQUE

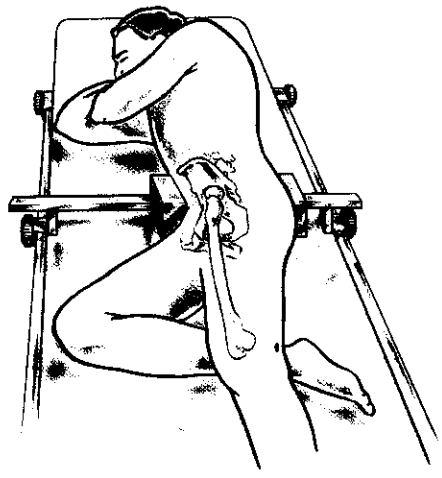


FIGURE 1

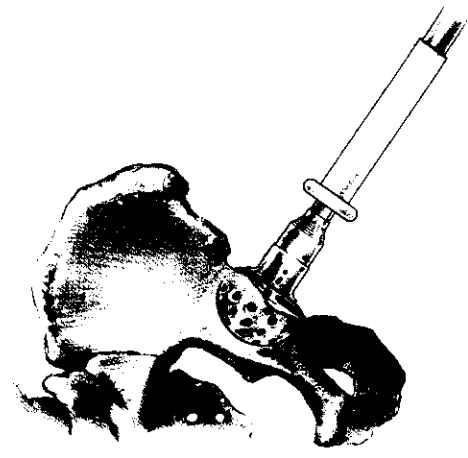


FIGURE 2

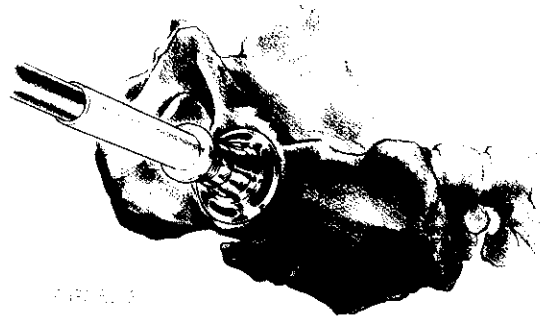
A small starter reamer prepares the acetabulum for subsequent reamers. A hemispherical reamer is utilized to reach the subchondral bone and attain proper sizing.

Preoperative Planning (Figure 1)

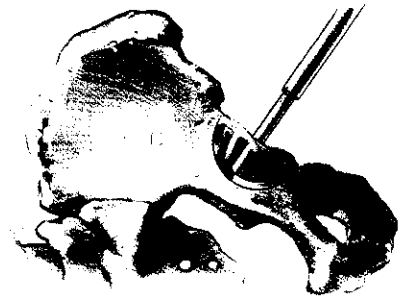
Accurate preoperative planning and acetabular templating are essential for obtaining a successful outcome. Estimate the acetabular size utilizing the RingLoc®, Mallory-Head® or Universal® templates along with the appropriate femoral templates in the A/P view. Mark the femoral head center, the neck resection level and the expected femoral stem size on the 14 x 17 A/P radiograph of the femur.

Incision and Surgical Exposure

The surgical approach is left to the surgeon's discretion. M²a™-Taper instrumentation is compatible with all routine hip exposures (Figure 1).



Progressive hemispherical reaming prepares the acetabulum for the final prosthesis.



A trial metal frame shell gauge is used to determine final shell diameter.

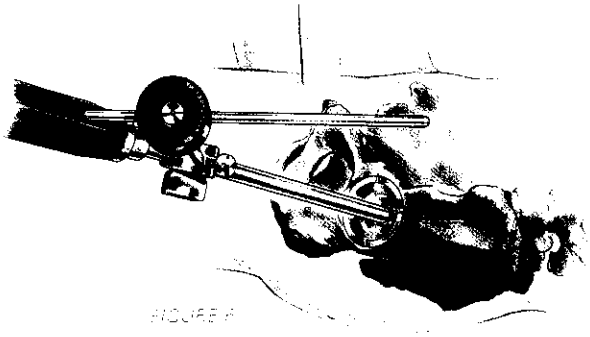
Acetabular Reaming

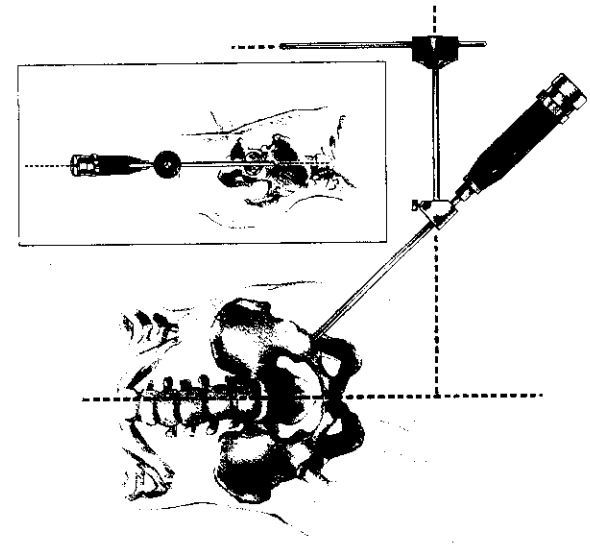
Circumferential exposure of the acetabulum should be obtained prior to beginning reaming. It is essential to remove peripheral soft tissue and any remaining acetabular cartilage, to create bleeding bone on the acetabular surface, and to preserve as much of the subchondral bone as possible.

Begin hemispherical reaming of the acetabulum with an acetabular reamer several sizes smaller than the templated diameter of the acetabulum (Figure 2). Progressive reaming is performed until "bleeding" bone, reaming "chatter," or desired template sizing is achieved. In general, the reaming should progress to the floor of the acetabular fossa; under-reaming by 1mm may enhance the fit of the final prosthesis, according to the surgeon's judgement of bone stock (Figure 3).

Acetabular trial gauges may be used throughout the reaming process and serve several purposes (Figure 4). The trial gauges determine both reaming accuracy and diameter of the final prosthesis. In addition, the acetabular trials allow judgement of the final position of the implant relative to the peripheral rim. A nerve hook may be inserted into the trial gauge to determine the apposition of the implant to the bone.

During the reaming process, it is important to maintain the structural integrity of the anterior and posterior columns of the acetabular rim. The thickness of the anterior and posterior columns should be monitored by the surgeon to avoid compromise of the bone stock.





Acetabular Component Insertion

The M²a™-Taper system utilizes two different acetabular shells. The Mallory-Head® Radial Shell is a solid porous coated acetabular shell with 8 radial fins that provide excellent rotational stability. The Universal® Shell is a hemispheric implant with two screw holes for additional screw fixation. A 17 degree rim flare provides excellent stability in the rim of the acetabulum.

The acetabular shell component is impacted utilizing the acetabular shell inserter. The shell inserter is threaded directly into the dome of the shell (Figure 5). In order to achieve correct positioning, the Dial-a-Version guide is positioned over the shaft of the acetabular inserter before threading the inserter into the shell and the appropriate anteversion is dialed into the alignment guide. In a lateral position, the inclination rod is perpendicular to the spine to obtain correct horizontal inclination of 45–50 degrees. The anteversion rod is parallel to the spine and should be at 10–15 degrees of anteversion (Figures 6 & 7).

Important: The position of the shell is crucial in the use of the M²a™-Taper Metal-on-Metal Articulation to reduce the risk for impingement.

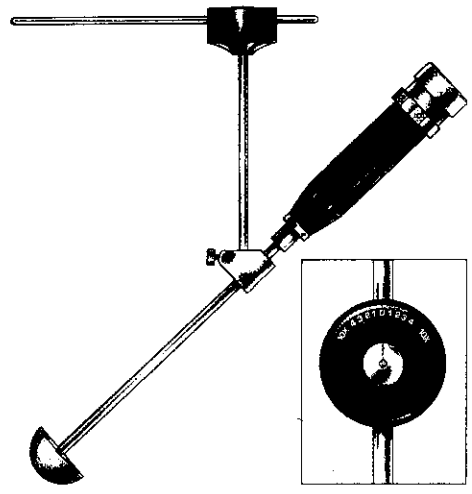
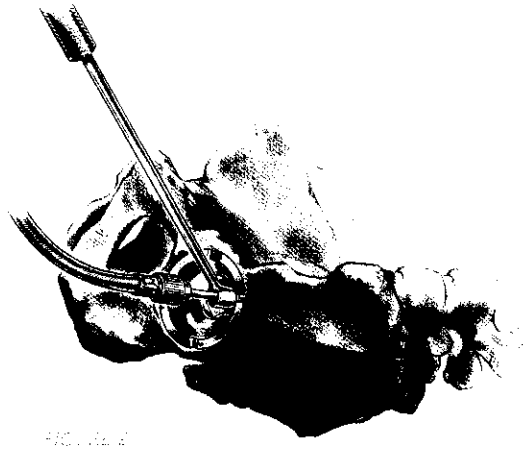


FIGURE 7

FIGURE 8

After the acetabular shell is fully seated, the shell should be checked again to ensure proper orientation. Stability of the bone-implant interface should be checked by applying moderate force to several areas of the rim of the prosthesis. Care must be used to avoid scratching the taper region of the interior of the implant. The acetabular implant should be firmly fixed within the acetabulum, with no gaps between the shell and the acetabulum (Figure 8). If the shell rotates within the acetabulum, a larger shell must be selected and the bone preparation process should be repeated by reaming to the larger size.

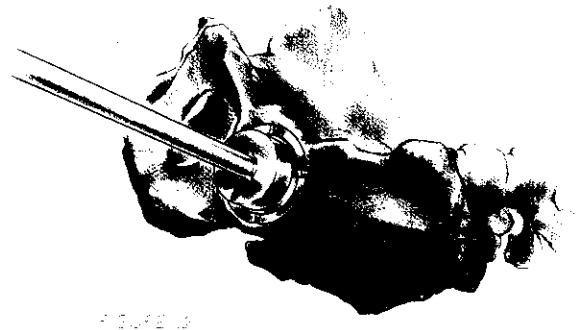
Important: If the surgeon desires a change in either the anteversion or inclination, an impactor or punch must not be used against the taper region of the titanium shell. This may damage the taper and cause the connection to malfunction. Avoid contacting the tapered flange with other instrumentation. If the tapered flange is scratched or damaged, the damaged implant should be removed and replaced with a new prosthesis.



Acetabular Screw Insertion

Low profile dome screws may be used for adjunctive fixation when utilizing the Universal® 2-Hole Acetabular component and when judged necessary by the surgeon. Screw placement must be chosen carefully to avoid injury to neurovascular structures (Figures 9 & 10). Care should also be exercised when supplement screw fixation is required to avoid damaging or scratching the taper.

Important: Only 6.5mm low profile dome screws may be used with the M²a™-Taper Universal® acetabular shells.



Acetabular Liner Insertion

Following the acetabular shell component insertion and fixation, a trial liner should now be inserted (Figure 11). The trial liner is easily inserted into and removed from the metal on metal shell. If preferred, a 3.5mm Hex screwdriver (part number 424496) can be used to tighten down the screw of the trial liner into the apical hole of the acetabular shell. The final liner should be inserted by hand and the surgeon should feel around the face of the shell with his finger to ensure that the liner is aligned properly. Several firm impactions of the acetabular liner are necessary utilizing the liner impactor to ensure stable seating of the device (Figure 12).

Important: When inserting the metal acetabular liner, the interior of the acetabular shell should be carefully cleaned and dried. The taper region of the metal acetabular liner should also be dry before insertion into the acetabular shell. Care should be taken not to scratch the taper surface of the metal liner or the inner taper of the metal shell.

FIGURE 13

Modular Head Selection and Impaction

With the acetabular trial or final liner in place, and upon completion of femoral reconstruction, a trial reduction should be performed to confirm restoration of limb length and stability of the hip in all planes.

Based on the chosen final trial head component, the corresponding modular head must now be selected. Only modular heads labeled for the M²a™-Taper articulation should be utilized. The precision tolerances of these femoral heads are necessary for optimum wear (Figure 13).

Important: Be sure taper surfaces are clean and dry before seating the modular head on the stem taper.

Impact the modular head onto the stem with several brisk mallet strikes using a plastic head impactor only. Metal impactors or any other metallic objects may scratch the modular head bearing surface or flatten out the radius in this region and, therefore, should not be used. If the modular head becomes scratched, it must be replaced.

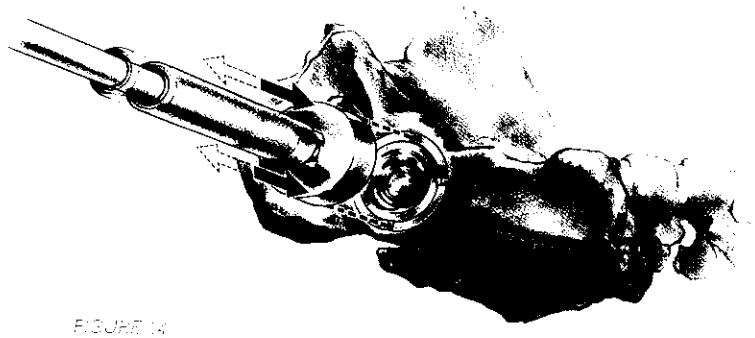


FIGURE 14

Above photo shows the retraction of the snap cylinder used to disassociate liner from shell.

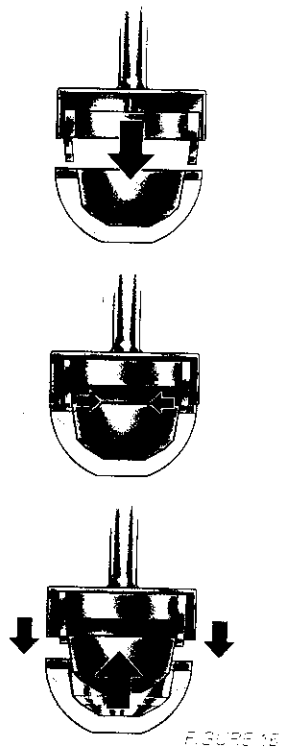


FIGURE 15

Separation of the Taper Junction

If the Metal-on-Metal Liner needs to be removed from the Metal-on-Metal Taper Acetabular Shell, the Metal-on-Metal Taper Liner Extractor is to be used. Turn the handle of the liner extractor to the left to expand the prongs and align with two opposing grooves on the acetabular shell (Figure 14). To ensure proper extension of the prongs, firmly tap the butt of the handle. Once the liner extractor is in contact with the shell, turn the handle to the right tightening the prongs around the liner. Once the outer hub is tightened against the acetabular shell, pull the snap cylinder on the liner extractor and release (Figure 14)* Remove the liner from the shell and turn the handle to the left to release the liner from the extractor (Figure 15).

***The vibration created from the impact of the snap cylinder will loosen the liner from the shell.**

Predicate Device Comparison Table

	New device	Metal on Metal Acetabular System	M²a™ 32mm Taper System	Mallory/Head PF Acetabular Component
Manufacturer	Biomet	Biomet	Biomet	Biomet
510(k) number	New	K993438	K003363	K861114
Indications for use	1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis 2) Rheumatoid arthritis 3) Correction of functional deformity 4) Revision procedures where other treatment or devices have been unsuccessful, 5) Treatment of non-union, femoral neck fracture, trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques	1) Non-inflammatory degenerative joint disease including avascular necrosis, diastrropic varient, fracture of the pelvis, fused hip, leg perthes, osteoarthritis, slipped capital epiphysis, subcapital fractures, and traumatic arthritis 2) Rheumatoid arthritis 3) Correction of functional deformity 4) Treatment of non-union, femoral neck fracture, trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques 5) Revision of previously failed total hip arthroplasty	1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis 2) Rheumatoid arthritis 3) Correction of functional deformity 4) Revision procedures where other treatment or devices have failed 5) Treatment of non-union, femoral neck fracture, trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques	None specified
Intended use	Cemented and Uncemented	Uncemented	Uncemented	Cemented

	New device	Metal on Metal Acetabular System		M2a 32mm Taper System		Mallory/Head PF Acetabular Component
510(k) number	New	K993438		K003363		K861114
Acetabular Liner						
Liner Material	Co-Cr-Mo	Co-Cr-Mo		Co-Cr-Mo		Not Applicable
Liner Internal Diameter	28mm & 32mm	28mm		32mm		
Liner Size Designation	37mm & 41mm	37mm		41mm		
Liner Locking Mechanism	Taper	Taper		Taper		
Acetabular Shell						
Shell Style	Mallory/Head	Mallory/Head	Universal	Mallory/Head	Universal	Mallory/Head
Shell Material	Ti-6Al-4V	Ti-6Al-4V	Ti-6Al-4V	Ti-6Al-4V	Ti-6Al-4V	Ti-6Al-4V
Liner Locking Mechanism	Taper	Taper	Taper	Taper	Taper	Hex-Loc
Shell Outer Diameters	48mm - 70mm by 2mm increments	52mm - 70mm by 2mm increments	48mm - 70mm by 2mm increments	52mm - 70mm by 2mm increments	52mm - 70mm by 2mm increments	46mm-70mm by 4mm increments
Shell Features	Radial Fins 2 Holes Plasma Spray Angled Cutouts	Radial Fins Solid Plasma Spray Straight Cutouts	2 Holes Plasma Spray Straight Cutouts	Radial Fins Solid Plasma Spray Straight Cutouts	2 Holes Plasma Spray Straight Cutouts	Fins Plasma Spray

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 8 2000

Ms. Michelle L. McKinley
Regulatory Specialist
Biomet, Inc.
Airport Industrial Park
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K993438/S1
Trade Name: Metal on Metal Acetabular Component
Regulatory Class: III
Product Code: KWA
Dated: February 18, 2000
Received: February 22, 2000

Dear Ms. McKinley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Whitten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number if Known: K993438
Device Name: Metal on Metal Acetabular System

The Metal on Metal Acetabular System is indicated for used in patients requiring total hip replacement due to the following:

a.) Non-inflammatory degenerative joint disease including avascular necrosis, diastrophic variant, fracture of the pelvis, fused hip, leg perthes, osteoarthritis, slipped capital epiphysis, subcapital fractures, and traumatic arthritis
b.) Rheumatoid arthritis
c.) Correction of functional deformity
d.) Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
e.) Revision of previously failed total hip arthroplasty.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over the Counter Use ____
(Per CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993438

000004

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 15 2000

Ms. Michelle L. Mckinley
Regulatory Specialist
Biomet, Inc.
P.O.Box 587
Warsaw, Indiana 46582

Re: K003363
Trade Name: M2A 32 MM Taper System
Regulatory Class: III
Product Code: KWA
Dated: December 6, 2000
Received: December 7, 2000

Dear Ms. Mckinley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003363

Device Name: M2a™ 32mm Taper System

Indications for Use:

The M2a™ 32mm Taper System is indicated for use in patients requiring total hip replacement due to the following:

1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis; 2) rheumatoid arthritis; 3) correction of functional deformity; 4) revision procedures where other treatment or devices have failed; 5) treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.

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

for Mark N Milham

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K003363

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

Ms. Judith Dermody
Clinical Research Assistant
Biomet Inc.
Corporate Headquarters
Airport Industrial Park
P.O. Box 587
Warsaw, Indiana 46580

APR 17 1986

Re: K861114
Mallory/Head - PF Acetabular Component

Dated: March 17, 1986
Received: March 25, 1986

Dear Ms. Dermody:

We have reviewed your Section 510(k) notification of intent to market the above device and we have determined the device to be substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) until such time as your device has been classified under Section 513. At that time, if your device is classified into either class II (Performance Standards) or class III (Premarket Approval), it would be subject to additional controls. Please note: This action does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or regulations.

General controls presently include regulations on annual registration, listing of devices, good manufacturing practice, labeling, and the misbranding and adulteration provisions of the Act. In the future, the scope of general controls may be broadened to include additional regulations.

All regulations and information on meetings of the device advisory committees, their recommendations, and the final decisions of the Food and Drug Administration (FDA) will be published in the Federal Register. We suggest you subscribe to this publication so you can convey your views to FDA if you desire and be notified of any additional requirements imposed on your device. Subscriptions may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Such information also may be reviewed in the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, Maryland 20857.

This letter does not in any way denote official FDA approval of your device or its labeling. Any representation that creates an impression of official approval of this device because of compliance with the premarket notification regulations is misleading and constitutes misbranding. If you desire advice on the labeling for your device or other information on your responsibilities under the Act, please contact the Office of Compliance, Division of Compliance Operations (HFZ-320), 8757 Georgia Avenue, Silver Spring, Maryland 20910.

Sincerely yours,

Carl A. Larson

Carl A. Larson, Ph.D.
Director
Division of Surgical
and Rehabilitation Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

85

Engineering Justification for M²a™/C²a™ Shells

9/27/2004

The M²a™/C²a™ Shells are substantially equivalent to our currently cleared M²a™ Shells (K003363). Both series of shells have the same dimensions for the locking cone interface. The size range is also equivalent in both series of shells. Both series of shells also accept the same Co-Cr-Mo metal bearing surface. The exterior geometry of the shells is identical.

The dimensions for the locking mechanism on the M²a™/C²a™ shells are both an 18°55'00" taper. The taper engagement length is also identical to the M²a™ Shells. The only difference in the locking mechanism is the surface finish of the female tapers. The M²a™ system has a smoother female taper surface finish, whereas the M²a™/C²a™ shells have a roughened female taper surface because the system is designed for future use with Biolox® Forte Alumina Inserts from CeramTec AG as well as the Co-Cr-Mo Inserts. The surface finish needed to be roughened in order to distribute the stress across the insert. This rougher surface acts like small peaks that can be conformed to the surface of the mating component actually increasing the locking strength of the interface as well as distributing the stress over more surface area. Ceramic Inserts were tested in a push-out (MT3045 and MT-3260) scenario with the smoother surface as well as the roughened surface. The smoother surface yielded an average push-out force of 180 lbs. The roughened surface yielded an average push-out force of 165lbs. Both of these values far exceed the requirements set by CeramTec AG for ceramic liner push-out which is only 45lbs.

Sizing for the M²a™/C²a™ shell system is 48mm to 70mm in increments of 2mm this is identical to the cleared M²a™ system. The exterior geometry of the system is based off of our Mallory/Head Radial® design with 8 evenly spaced fins. This geometry is also used in the M²a™ system. The metal insert the shells accept is also identical to the M²a™ System. The 48mm and 50mm shells accept a 28/37 tapered insert and the 54mm-70mm shells accept a 32/41 tapered insert.

Based on the previous comparison between the two shell systems I believe the M²a™/C²a™ shell system is substantially equivalent to the M²a™ system and no further testing is required.

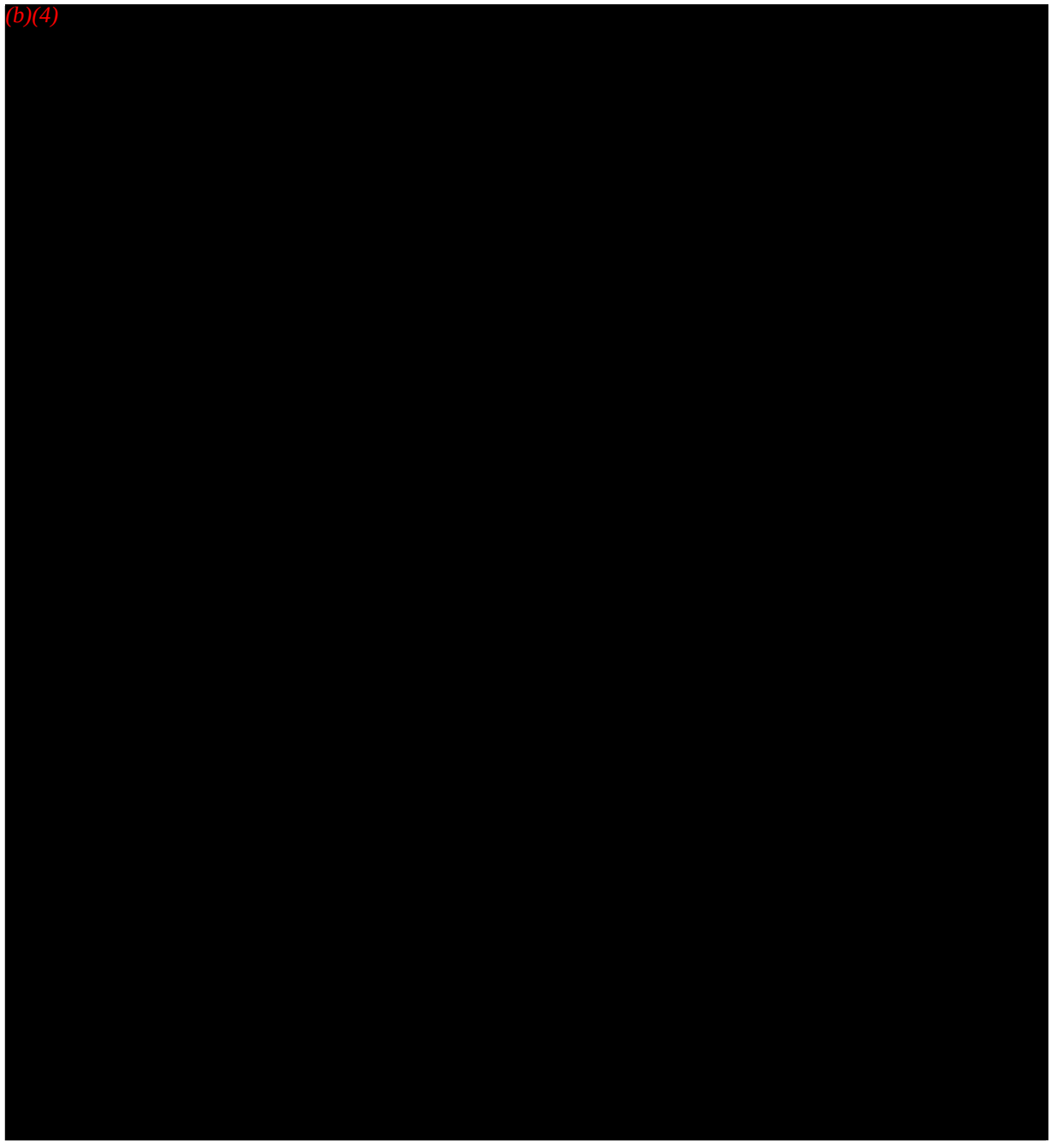
W. Jason Stone
9/30/2004

(b) (4) Test Reports and Results

(b) (4) Test Reports and Results

(b) (4) Test Reports and Results

(b)(4)



(b) (4) Test Reports and Results

(b) (4) Test Reports and Results

Conclusions

(b)(4)

[redacted]

References

(b)(4)

[redacted]

Appendix 1

Raw Data

(b) (4) Test Reports and Results

(b) (4) Test Reports and Results

(b) (4) Test Reports and Results

(b) (4) Test Reports and Results

Appendix 2

Biomet Laboratory Request

(b) (4) Test Reports and Results

(b) (4) Test Reports and Results

(b) (4) Test Reports and Results

(b) (4) Test Reports and Results

(b) (4) Test Reports and Results

(b) (4) Test Reports and Results

(b) (4) Test Reports and Results

Appendix 3

Drawings

(b) (4) Engineering Drawings

(b) (4) Engineering Drawings

(b) (4) Engineering Drawings

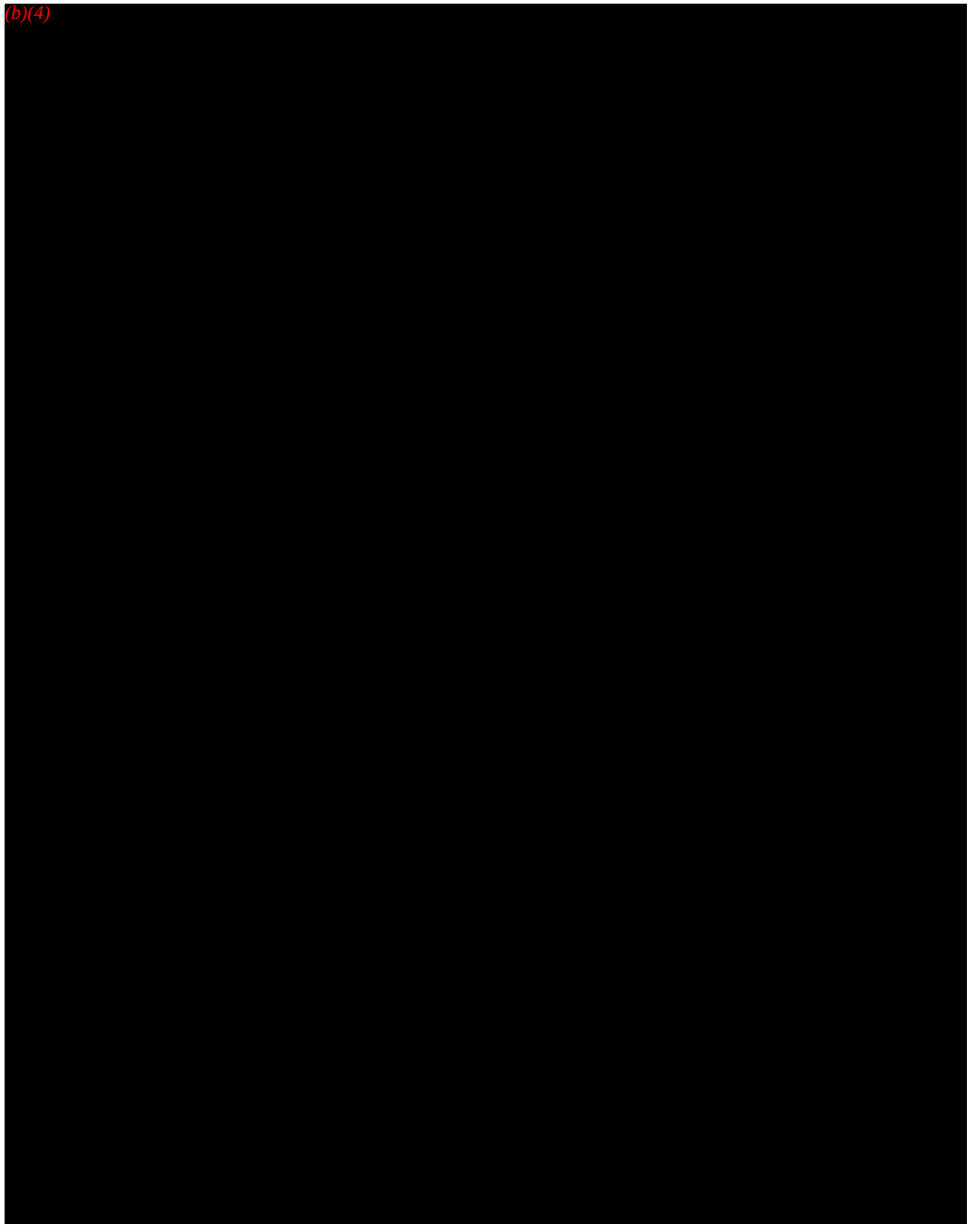
(b) (4) Engineering Drawings

(b) (4) Engineering Drawings

(b) (4) Engineering Drawings

(b) (4) Test Reports and Results

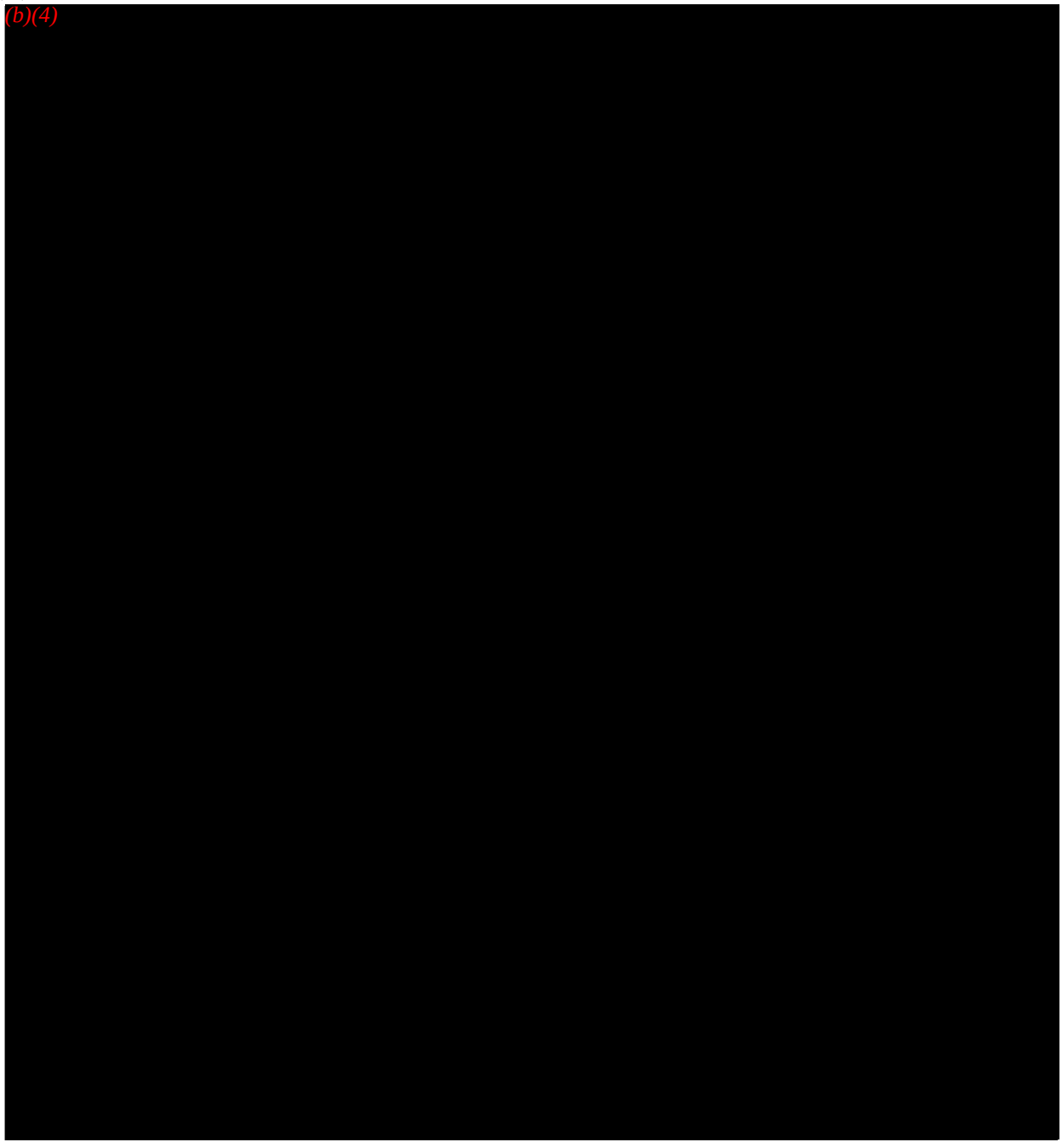
(b)(4)



(b) (4) Test Reports and Results / Materials

Results

(b)(4)



(b) (4) Test Reports and Results / Materials

Conclusions

(b)(4) [redacted]

References

(b)(4) [redacted]

Appendix 1

Raw Data

(b) (4) Raw Data Reports and Results

(b) (4) Raw Data Reports and Results

(b) (4) Raw Data Reports and Results

(b) (4) Raw Data Reports and Results

(b) (4) Raw Data Reports and Results

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Appendix 2

Biomet Laboratory Request

(b) (4) Raw Data Reports and Results

(b) (4) Raw Data Reports and Results

(b) (4) Raw Data Reports and Results

(b) (4) Raw Data Reports and Results

Appendix 3

Drawings

(b) (4) Engineering Drawings

(b) (4) Engineering Drawings

(b) (4) Engineering Drawings

(b) (4) Engineering Drawings

(b) (4) Engineering Drawings

(b) (4) Engineering Drawings

BIOMET

510(k) Summary

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Patricia Sandborn Beres
Senior Regulatory Specialist

Proprietary Name: M²a™/C²a™ Acetabular System

Common Name: Metallic Acetabular System

Classification Name:

1. Hip joint metal/metal semi-constrained, with an uncemented acetabular component prosthesis (21 CFR 888.3330)
2. Hip joint metal/metal semi-constrained, with a cemented acetabular component prosthesis (21 CFR 888.3320)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed: Biomet devices:

K993438 - Metal on Metal Acetabular System
K003363 - M²a™ 32mm Taper System
K861114 - Mallory/Head PF Acetabular Component

Device Description: The M²a™/C²a™ Acetabular System consists of a titanium outer acetabular shell with a cobalt alloy metallic liner for metal on metal articulation.

The acetabular shells are hemispherical in shape to closely match the natural acetabulum. Two screw holes in the dome allow for additional fixation by the use of screws. The outer surface of the shells are covered with Biomet's plasma sprayed coating.

The metallic cobalt alloy bearing liner fits into the outer shell by means of a taper similar to the taper used for the attachment of a modular head to a femoral stem. The metallic liners articulate with cobalt alloy modular heads.

MAILING ADDRESS
P.O. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

OFFICE
574.267.6639 ■ FAX
574.267.8137 ■ E-MAIL
biomet@biomet.com

Intended Use: The M²a™/C²a™ Acetabular System is intended for cemented or non-cemented use in cases of:

1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
2) Rheumatoid arthritis
3) Correction of functional deformity
4) Revision procedures where other treatment or devices have been unsuccessful
5) Treatment of non-union, femoral neck fracture, trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques

Summary of Technologies: The technological characteristics of the new device are similar of identical to the predicates.

Non-Clinical Testing: None provided

Clinical Testing: None provided.

Pages 127 through 243 are not included as part of this submission

M^2a™/C^2a™ Acetabular System
510(k) Premarket Notification
Biomet Manufacturing Corp.
October 13, 2004

Appendix 1 & 2

Class III Certification and Summary

[As required by 21 CFR 807.94]

I certify in my capacity as Senior Regulatory Specialist of Biomet Manufacturing Corp, that I have conducted a reasonable search of all information known or otherwise available about the types and causes of safety and effectiveness problems that have been reported for the metal on metal acetabular components. I further certify that I am aware of the types of problems to which the metal on metal acetabular components are susceptible and that, to the best of my knowledge, the following summary of the types and causes of safety and effectiveness problems about the metal on metal acetabular components is complete and accurate.

Patricia S Beres

Signature

Patricia Sandborn Beres

Typed Name

10/6/04

Date

Class III Device Summary

Metal on Metal Articulating Surfaces

I. **Medical Device Reports/Vigilance Reports:** Summary of MAUDE Medical Device Reports

A reasonable effort was made to find all adverse reports made for these devices under the Medical Device Reporting (MDR) regulations and under the vigilance-reporting requirement for medical devices under Article 10 of the European Medical Device Directive (MDD). A search of publicly available information yielded thirty-three (33) reports filed with the FDA for the metal/metal semi-constrained total hip prostheses. A summary of the reports is located on the next page, followed by MAUDE database reports of each incident listed.

SUMMARY OF ADVERSE EVENTS TABLE

Event Sequence	Device Manufacturer	Device 510K Number	Date of Report	Date FDA Received Notification	Adverse Event
1	Sulzer Orthopedic, Inc	K993569	4/24/2000	5/24/2000	Disassociation of anti-rotational pin from insert.
2	Sulzer Orthopedic, Inc	K674728	6/16/2000	7/5/2000	Deep infection resulting in explant of device.
3	Sulzer Orthopedic, Inc	K993569	7/21/2000	8/17/2000	Revision due to impingement between femoral stem and acetabular insert.
4	Sulzer Orthopedic, Inc	K993569	11/6/2000	12/1/2000	Pin insert came out after 1.5 years.
5	Sulzer Orthopedic, Inc	K993569	12/8/2000	1/5/2001	Multiple dislocations, patient revised 3 times.
6	Sulzer Orthopedic, Inc	K993569	1/23/2001	2/22/2001	Disassociation of Metasul insert from APRII shell. Patient also experienced two heavy falls previously.
7	Sulzer Orthopedic, Inc	K993569	5/10/2001	6/8/2001	Doctor impacted the insert into the shell but it did not seat. When he pulled the insert out to inspect, the locking pin was missing and located in one of the slots. Resulted in a 30-minute delay in surgery.
8	Sulzer Orthopedic, Inc	K974728	5/14/2001	6/13/2001	Patient complaining of hearing a "pop" and feeling a "pop" and thinks they have dislocated their hip. Physician notified.
9	Sulzer Orthopedic, Inc	K974728	6/8/2001	7/6/2001	Revision of femoral head at 7 weeks.
10	Sulzer Orthopedic, Inc	K993569	6/18/2001	7/18/2001	Metasul insert dislocated after 4 years implantation, significant metalosis. Severe pain.
11	Sulzer Orthopedic, Inc	K993569	8/23/2001	9/18/2001	APR Metasul insert disengaged nine months after surgery.
12	Sulzer Orthopedic, Inc	K993569	11/26/2001	12/18/2001	Disassociation of liner from cup.
13	Sulzer Orthopedic, Inc	K993569	12/12/2001	1/7/2002	Anti-rotational pin dislocated from the insert.
14	Encore Orthopedics, Inc	K003250	12/17/2001	1/9/2002	Surgery time extended due to failure to properly assemble acetabular liner into shell.
15	Sulzer Orthopedic, Inc	K993569	1/28/2002	2/6/2002	Doctor reported patient with pain, disassociation of liner from shell.
16	Sulzer Orthopedic, Inc	K993569	1/28/2002	2/27/2002	Disassociation of APR Metasul acetabular insert, size 59mm. Patient fell 2001.
17	Sulzer Orthopedic, Inc	K993569	2/27/2002	3/19/2002	APR Metasul acetabular liner disassociation, patient revised in 2002.

Last Update: 10/06/04

Event Sequence	Device Manufacturer	Device 510K Number	Date of Report	Date FDA Received Notification	Adverse Event
18	Sulzer Orthopedic, Inc	K993569	3/15/2002	4/12/2002	Disassociation of APR Metasul insert.
19	Sulzer Orthopedic, Inc	K993569	3/15/2002	4/12/2002	Reported pain and breakage of implant.
20	Sulzer Orthopedic, Inc	K993569	4/15/2002	5/1/2002	Disassociation of insert 2 years 9 months after initial surgery.
21	Sulzer Orthopedic, Inc	K974728	6/4/2002	6/26/2002	Patient was revised due to dislocation of the hip.
22	Biomet Inc.	K011110	11/8/2002	11/20/2002	Eleven total joint and/or revision procedures performed with five of these cases resulting in postoperative infection. Various implant components implanted. Concluded not to be related to implants because similar reports of infections have not been reported from other user facilities for any of the listed manufacturing lots.
23	Centerpulse Orthopedics, Inc	K974728	12/10/2002	12/17/2002	Second revision required because of instability of the hip. First revision was on a recall shell.
24	Biomet, Inc	K011110	12/9/2002	1/7/2003	Following total hip arthroplasty performed in 2002, patient continued to experience hip pain. Patient underwent additional surgery 1 month later, where osteophytes were removed and modular head component was exchanged.
25	DePuy International, LTD	K003523	1/10/2003	1/10/2003	The package was split – inner plastic portion.
26	DePuy International, LTD	K003523	3/27/2003	3/27/2003	The metal insert was locked into the shell off-axis. Insert could not be removed from acetabular shell.
27	Centerpulse Orthopedics, Inc	K993569	6/10/2003	6/25/2003	Patient felt pain due to dislocation. Patient was revised.
28	Centerpulse Orthopedics, Inc	K993569	6/19/2003	7/16/2003	Dislocation of APR Metasul insert.
29	Centerpulse Orthopedics, Inc	K993569	6/25/2003	7/17/2003	Patient had a dislocation and was revised.
30	Centerpulse Orthopedics, Inc	K974728	10/14/2003	10/14/2003	Delay in surgery.
31	Centerpulse Orthopedics, Inc	K993569	12/16/2003	12/16/2003	Patient was revised.
32	Centerpulse Orthopedics, Inc	K993569	12/17/2003	12/23/2003	Patient was revised in 2003.
33	DePuy Orthopaedics, Inc	K003523	12/19/2003	1/16/2004	Metal insert did not seat properly. Surgery was extended by 30 minutes due to the product problem.
34	DePuy Orthopedics	K924492	12/10/2003	1/09/2004	Ring broken, worn liner. Revised liner only to non-constrained.

Event Sequence	Device Manufacturer	Device 510K Number	Date of Report	Date FDA Received Notification	Adverse Event
35	DePuy-Raynham	K924492	2/10/2004	2/24/2004	Attorney reports this patient was revised due to premature polyethylene failure.
36	Centerpulse Orthopedics Ltd.	K003758	2/13/2003	2/28/2003	Revision
37	DePuy Orthopedics, Inc.	K924492	5/19/2004	5/25/2004	Surgeon claims polyethylene wear started to appear on x-rays 3 years after THA
38	Zimmer Austin, Inc.	K993569	6/24/2004	6/24/2004	Patient was revised in 2004

FDA U.S. Food and Drug Administration — Department of Health and Human Services

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Manufacturer and User Facility Device Experience (MAUDE) Database

Brand Name	ACET INS SZ 28X55 METASUL APR
Type of Device	HIP PROSTHESIS
Baseline Brand Name	ACET INS SZ 28X55 METASUL APR
Baseline Generic Name	HIP PROSTHESIS
Baseline Catalogue Number	4340-28-055
Baseline Device Family	NA
Baseline Device 510(K) Number	K993569
Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	12/01/1999
Manufacturer *(Section F)*	SULZER ORTHOPEDICS INC. 9900 Spectrum Austin TX 78717
Manufacturer *(Section D)*	SULZER ORTHOPEDICS INC. 9900 Spectrum Austin TX 78717
Manufacturer Contact	Randy Jasek, Supervisor 9900 Spectrum Dr Austin , TX 78717 (512) 432 -9611
Device Event Key	269992
MDR Report Key	278978
Event Key	261599
Report Number	2935620-2000-00012
Device Sequence Number	1
Product Code	KWA
Report Source	Manufacturer

Source Type	Company Representative
Event Type	Injury
Type of Report	Initial,Followup
Report Date	04/24/2000
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	05/24/2000
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	4340-28-055
Device LOT Number	1251199
Was Device Available For Evaluation?	Device Not Returned To Manufacturer
Date Returned to Manufacturer	04/24/2000
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Date Manufacturer Received	04/24/2000
Was Device Evaluated By Manufacturer?	Yes
Date Device Manufactured	08/01/1996
Is The Device Single Use?	Yes
Type of Device Usage	Initial
Patient Outcome	Hospitalization

Adverse Event or Product Problem Description
Report Date: 04/24/2000 MDR Text Key: 953779 Patient Sequence Number: 1
Allegedly the anti-rotation pin became dislodged from the polyethylene acetabular insert.

Additional Manufacturer Narrative
Report Date: 04/24/2000 MDR Text Key: 1012481
H6 method reviewed mfg/inspection records with no form, fit or function discrepancies noted. H6 conclusions the cause of dissociation of the anti-rotation pin from the insert cannot be determined due to insufficient info provided.

Patient TREATMENT DATA

Date Received: 08/08/2000 Patient Sequence Number: 1

#	Treatment	Treatment Date
1	3442 28MM +4MM ALLOPRO BATORY FEM HD	01/01/1998
2	(LOT# B069262)(10/98).	01/01/1998

Database contains data received through March 30, 2004

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Center for Devices and Radiological Health / CDRH

Manufacturer and User Facility Device Experience (MAUDE) Database

Brand Name	SZ 28X57MM STD METASUL INS I-O
Type of Device	HIP PROSTHESIS
Baseline Brand Name	SZ 28X57MM STD METASUL INS I-O
Baseline Generic Name	HIP PROSTHESIS
Baseline Catalogue Number	4372-28-057
Baseline Device Family	NA
Baseline Device 510(K) Number	K974728
Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	08/03/1999
Manufacturer *(Section F)*	SULZER ORTHOPEDICS, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer *(Section D)*	SULZER ORTHOPEDICS, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer Contact	Randy Jasek, Supervisor 9900 Spectrum Dr Austin , TX 78717 (512) 432 -9611
Device Event Key	275284
MDR Report Key	284467
Event Key	266856
Report Number	2935620-2000-00022
Device Sequence Number	1
Product Code	KWA
Report Source	Manufacturer

Source Type	Company Representative
Event Type	Injury
Type of Report	Initial,Followup
Report Date	06/16/2000
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	07/05/2000
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	4372-28-057
Device LOT Number	1330653
Was Device Available For Evaluation?	Device Not Returned To Manufacturer
Date Returned to Manufacturer	06/19/2000
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Date Manufacturer Received	06/16/2000
Was Device Evaluated By Manufacturer?	Yes
Date Device Manufactured	10/01/1998
Is The Device Single Use?	Yes
Type of Device Usage	Initial
Patient Outcome	Required Intervention

Adverse Event or Product Problem Description
Report Date: 06/16/2000 MDR Text Key: 974574 Patient Sequence Number: 1
Pt weight bearing for only one week only then developed debilitating pain and returned to bed until deep infection was determined and explanted in 2000.

Additional Manufacturer Narrative
Report Date: 06/16/2000 MDR Text Key: 1026547
H6 method reviewed (other) reviewed mfr/inspection records, with no discrepancies noted. H6 conclusions (other) the revision surgery was due to deep septic infection, and was unrelated to sulzer orthopedics inc. Implants. H10 documentation provided from agent states "revision surgery was due to deep septic infection and was unrelated to zulzer orthopedics inc. Implants. ".

Patient TREATMENT DATA

Date Received: 08/24/2000 Patient Sequence Number: 1

#	Treatment	Treatment Date
1	7356-01-102 NATURAL HIP HA COLLARLESS SZ 2 LT	11/01/1999
2	(LOT # 1370384)(11/1999)	11/01/1999
3	7340-28-400 METASUL COCR HD 12/14 +4 NECK 28MM	11/01/1999
4	(LOT # 1340044)(11/1999).	11/01/1999

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Database contains data received through March 30, 2004

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New Search

Back To Search Results

Manufacturer and User Facility Device Experience (MAUDE) Database

Brand Name	ACET INS SZ 28X53 METASUL-APR
Type of Device	HIP PROSTHESIS
Baseline Brand Name	ACET INS SZ 28X53 METASUL-APR
Baseline Generic Name	HIP PROSTHESIS
Baseline Catalogue Number	4340-28-053
Baseline Device Family	NA
Baseline Device 510(K) Number	K993569
Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	12/01/1999
Manufacturer *(Section F)*	SULZER ORTHOPEDICS INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer *(Section D)*	SULZER ORTHOPEDICS INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer Contact	Randy Jasek, Supervisor 9900 Spectrum Dr Austin , TX 78717 (512) 432 -9611
Device Event Key	281298
MDR Report Key	290650
Event Key	272806
Report Number	2935620-2000-00030
Device Sequence Number	1
Product Code	KWA
Report Source	Manufacturer

Source Type	Company Representative
Event Type	Injury
Type of Report	Initial,Followup
Report Date	07/21/2000
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	08/17/2000
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	4340-28-053
Device LOT Number	1187760
Was Device Available For Evaluation?	Device Not Returned To Manufacturer
Date Returned to Manufacturer	08/09/2000
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Date Manufacturer Received	07/21/2000
Was Device Evaluated By Manufacturer?	No
Date Device Manufactured	09/01/1995
Is The Device Single Use?	Yes
Type of Device Usage	Initial
Patient Outcome	Hospitalization Required Intervention

Adverse Event or Product Problem Description
Report Date: 07/21/2000 MDR Text Key: 997321 Patient Sequence Number: 1
It was reported: revision hip surgery was performed due to impingement between the femoral stem and the acetabular insert.

Additional Manufacturer Narrative
Report Date: 07/21/2000 MDR Text Key: 1064198
Added section h6. Corrected section h3. H6: method: review of mfr/inspection records with no discrepancies noted. H6: results: indications are that early impingement was occurring, possibly with soft tissue or improperly positioned acetabular or femoral components. H6: results: possible surgical technique. H6: conclusions: the cause of occurrence could not be determined since x-ray and the femoral stem were not provided. Speculation is that the femoral stem impinged on the acetabular insert.

Patient TREATMENT DATA

Date Received: 10/05/2000 Patient Sequence Number: 1

#	Treatment	Treatment Date
1	1. 4310-02-053 APR II 12 SLOT SHELL 53MM (LOT#	01/01/2000
2	1195949)(11/2000).	01/01/2000
3	2. 7340-28-004 METASUL COCR HD 12/14-4 NECK 28MM	01/01/2000
4	(LOT#1181955)(11/2000)	01/01/2000

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5	3. 7354-01-203 NATURAL-HIP POR COLL STM LT SZ 3	01/01/2000
6	(LOT# 1213577)(11/2000).	01/01/2000

Database contains data received through March 30, 2004

FDA U.S. Food and Drug Administration — Department of Health and Human Services

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Manufacturer and User Facility Device Experience (MAUDE) Database

Brand Name	ACET INS SZ 28X49 METASUL-APR
Type of Device	HIP PROSTHESIS
Baseline Brand Name	ACET INS SZ 28X49 METASUL-APR
Baseline Generic Name	HIP PROSTHESIS
Baseline Catalogue Number	4340-28-049
Baseline Device Family	NA
Baseline Device 510(K) Number	K993569
Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	12/01/1999
Manufacturer *(Section F)*	SULZER ORTHOPEDICS, LTD. Grabenstrasse 25 Baar SWITZERLAND CH-6341
Manufacturer *(Section D)*	SULZER ORTHOPEDICS, LTD. Grabenstrasse 25 Baar SWITZERLAND CH-6341
Manufacturer Contact	Randy Jasek, Supervisor 9900 Spectrum Dr Austin , TX 78717 (512) 432 -9611
Device Event Key	296783
MDR Report Key	306697
Event Key	288203
Report Number	2935620-2000-00062
Device Sequence Number	1
Product Code	KWA

Report Source	Manufacturer
Event Type	Injury
Type of Report	Initial,Followup
Report Date	11/06/2000
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	12/01/2000
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	4340-28-049
Device LOT Number	1303668
Was Device Available For Evaluation?	Device Not Returned To Manufacturer
Date Returned to Manufacturer	11/13/2000
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Date Manufacturer Received	11/06/2000
Was Device Evaluated By Manufacturer?	Yes
Date Device Manufactured	09/01/1997
Is The Device Single Use?	Yes
Type of Device Usage	Initial
Patient Outcome	Required Intervention

Adverse Event or Product Problem Description
Report Date: 11/06/2000 MDR Text Key: 1055495 Patient Sequence Number: 1
It was reported: the pin in the metasul insert came out after 1. 5 years.

Additional Manufacturer Narrative
Report Date: 11/06/2000 MDR Text Key: 1156562
H6: method: reviewed mfr/inspection records, with no discrepancies noted. H6: conclusions: insufficient info was provided to determine the actual cause of this complaint.

Patient TREATMENT DATA

Date Received: 04/25/2001 Patient Sequence Number: 1

#	Treatment	Treatment Date
1	3461 AP BALL HEAD 28/14 (LOT# B285607)(2000).	01/01/2000

Database contains data received through March 30, 2004

Manufacturer and User Facility Device Experience (MAUDE) Database

Brand Name	ACET INS SZ 28X49 METASUL-APR
Type of Device	HIP PROSTHESIS
Baseline Brand Name	ACET INS SZ 28X49 METASUL-APR
Baseline Generic Name	HIP PROSTHESIS
Baseline Catalogue Number	4340-28-049
Baseline Device Family	NA
Baseline Device 510(K) Number	K993569
Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	12/01/1999
Manufacturer *(Section F)*	SULZER ORTHOPEDICS, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer *(Section D)*	SULZER ORTHOPEDICS, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer Contact	Randy Jasek, Supervisor 9900 Spectrum Dr Austin , TX 78717 (512) 432 -9611
Device Event Key	300804
MDR Report Key	310957
Event Key	292272
Report Number	2935620-2000-00075
Device Sequence Number	1
Product Code	KWA
Report Source	Manufacturer

Source Type	Company Representative
Event Type	Injury
Type of Report	Initial
Report Date	12/08/2000
1 **Device Was Involved in the Event**	
1 **Patient Was Involved in the Event**	
Date FDA Received	01/05/2001
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	4340-28-049
Was Device Available For Evaluation?	Device Not Returned To Manufacturer
Date Returned to Manufacturer	12/08/2000
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Date Manufacturer Received	12/08/2000
Was Device Evaluated By Manufacturer?	No
Is The Device Single Use?	Yes
Type of Device Usage	Initial
Patient Outcome	Required Intervention

Adverse Event or Product Problem Description
Report Date: 12/08/2000 MDR Text Key: 1071225 Patient Sequence Number: 1
It was reported: pt underwent total hip arthroplasty (tha) in 1998. Subsequently the pt was revised 3 times due to dislocations. Pt underwent the last tha in 2000 where the insert and ball head were replaced.

Patient TREATMENT DATA

Date Received: 01/05/2001 Patient Sequence Number: 1

#	Treatment	Treatment Date
1,3462 METASUL HEAD 29L/+4 12/14 (LOT#UNK) (11/2000),		

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Manufacturer and User Facility Device Experience (MAUDE) Database

Brand Name	ACET INS SZ 28X49 METASUL-APR
Type of Device	HIP PROSTHESIS
Baseline Brand Name	ACET INS SZ 28X49 METASUL-APR
Baseline Generic Name	HIP PROSTHESIS
Baseline Catalogue Number	4340-28-049
Baseline Device Family	NA
Baseline Device 510(K) Number	K993569
Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	12/01/1999
Manufacturer *(Section F)*	SULZER ORTHOPEDICS, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer *(Section D)*	SULZER ORTHOPEDICS, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer Contact	Randy Jasek, Supervisor 9900 Spectrum Dr Austin , TX 78717 (512) 432 -9611
Device Event Key	306464
MDR Report Key	316925
Event Key	297939
Report Number	2935620-2001-00003
Device Sequence Number	1
Product Code	KWA
Report Source	Manufacturer

Source Type	Company Representative
Event Type	Injury
Type of Report	Initial
Report Date	01/23/2001
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	02/22/2001
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	4340-28-049
Device LOT Number	1230114
Was Device Available For Evaluation?	Device Not Returned To Manufacturer
Date Returned to Manufacturer	01/25/2001
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Date Manufacturer Received	01/23/2001
Was Device Evaluated By Manufacturer?	No
Date Device Manufactured	03/01/1996
Is The Device Single Use?	Yes
Type of Device Usage	Initial
Patient Outcome	Hospitalization Required Intervention

Adverse Event or Product Problem Description
Report Date: 01/23/2001 MDR Text Key: 1092275 Patient Sequence Number: 1
It was reported: 11/13/2000: sudden "clunk" in hip-could not walk, x-ray in emergency dept: disassociation of metasul insert from the apr ii shell. Pt experienced two heavy falls, one onto their back in march 2000 and another fall forward in july 2000.

Patient TREATMENT DATA

Date Received: 02/22/2001 Patient Sequence Number: 1

#	Treatment	Treatment Date
1	19.28.06 METASUL HEAD 28MM (11/2000)	11/01/2000
2	(LOT# B154629).	11/01/2000

Database contains data received through March 30, 2004

Manufacturer and User Facility Device Experience (MAUDE) Database

Brand Name	ACET INS SZ 28X49 METASUL-APR
Type of Device	HIP PROSTHESIS
Baseline Brand Name	ACET INS SZ 28X49 METASUL-APR
Baseline Generic Name	HIP PROSTHESIS
Baseline Catalogue Number	4340-28-049
Baseline Device Family	NA
Baseline Device 510(K) Number	K993569
Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	12/01/1999
Manufacturer *(Section F)*	SULZER ORTHOPEDICS, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer *(Section D)*	SULZER ORTHOPEDICS, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer Contact	Randy Jasek, Qa Supervisor 9900 Spectrum Drive Austin , TX 78717 (512) 432 -9611
Device Event Key	325690
MDR Report Key	336384
Event Key	316615
Report Number	2935620-2001-01058
Device Sequence Number	1
Product Code	KWA
Report Source	Manufacturer

Source Type	Company Representative
Event Type	Injury
Type of Report	Initial
Report Date	05/10/2001
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	06/08/2001
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	4340-28-049
Device LOT Number	1427124
Was Device Available For Evaluation?	No
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Date Manufacturer Received	05/10/2001
Was Device Evaluated By Manufacturer?	Device Not Returned To Manufacturer
Date Device Manufactured	07/01/2000
Is The Device Single Use?	Yes
Type of Device Usage	Initial
Patient Outcome	Hospitalization

Adverse Event or Product Problem Description
Report Date: 05/10/2001 MDR Text Key: 1162660 Patient Sequence Number: 1
It was reported: the dr impacted the insert into the shell, but it did not seat. When he pulled the insert out to inspect, staff noticed the locking pin was missing and now in one of the slots. Resulted in a 30 minute delay in surgery. The patient was not at risk.

Database contains data received through March 30, 2004

Manufacturer and User Facility Device Experience (MAUDE) Database

Brand Name	SZ 28X55MM STD METASUL INS I-O
Type of Device	HIP PROSTHESIS
Baseline Brand Name	SZ 28 X 55MM STD METASUL INS I-O
Baseline Generic Name	HIP PROSTHESIS
Baseline Catalogue Number	4372-28-055
Baseline Device Family	NA
Baseline Device 510(K) Number	K974728
Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	08/03/1999
Manufacturer *(Section F)*	SULZER ORTHOPEDICS, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer *(Section D)*	SULZER ORTHOPEDICS, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer Contact	Randy Jasek, Supervisor 9900 Spectrum Drive Austin , TX 78717 (512) 432 -9611
Device Event Key	326311
MDR Report Key	337007
Event Key	317178
Report Number	2935620-2001-01060
Device Sequence Number	1
Product Code	KWA
Report Source	Manufacturer

Source Type	Health Professional
Event Type	Injury
Type of Report	Initial
Report Date	04/27/2001,05/14/2001
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	06/13/2001
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	4372-28-055
Device LOT Number	1417750
Was Device Available For Evaluation?	No
Is The Reporter A Health Professional?	Yes
Was the Report Sent to FDA?	No
Distributor Facility Aware Date	04/25/2001
Device Age	1 mo
Event Location	Hospital
Date Report TO Manufacturer	04/27/2001
Date Manufacturer Received	05/14/2001
Was Device Evaluated By Manufacturer?	Device Not Returned To Manufacturer
Date Device Manufactured	07/01/2000
Is The Device Single Use?	Yes
Type of Device Usage	Initial
Patient Outcome	Hospitalization Required Intervention

Adverse Event or Product Problem Description
Report Date: 04/27/2001 MDR Text Key: 1165142 Patient Sequence Number: 1
It was reported: pt has a left total hip replacement. After hanging up the phone pt complaining of hearing a "pop" and feeling a "pop". Pt stated "i think i dislocated my hip again. " physician was notified.

Database contains data received through March 30, 2004

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New Search

Back To Search Results

Manufacturer and User Facility Device Experience (MAUDE) Database

Brand Name	COCR HD 12/14 +4MM NECK 28MM METASUL
Type of Device	HIP PROSTHESIS
Baseline Brand Name	COCR HD 12/14 +4MM NECK 28MM METASUL
Baseline Generic Name	HIP PROSTHESIS
Baseline Catalogue Number	7340-28-400
Baseline Device Family	NA
Baseline Device 510(K) Number	K974728
Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	08/03/1999
Manufacturer *(Section F)*	SULZER ORTHOPEDICS, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer *(Section D)*	SULZER ORTHOPEDICS, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer Contact	Randy Jasek, Supervisor 9900 Spectrum Drive Austin , TX 78717 (512) 432 -9611
Device Event Key	329938
MDR Report Key	340619
Event Key	320719
Report Number	2935620-2001-01186
Device Sequence Number	1
Product Code	KWA
Report Source	Manufacturer

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Source Type	Company Representative
Event Type	Injury
Type of Report	Initial
Report Date	06/08/2001
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	07/06/2001
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	7340-28-400
Device LOT Number	1327368-F
Was Device Available For Evaluation?	No
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Date Manufacturer Received	06/08/2001
Was Device Evaluated By Manufacturer?	Device Not Returned To Manufacturer
Date Device Manufactured	10/01/1998
Is The Device Single Use?	Yes
Type of Device Usage	Initial
Patient Outcome	Hospitalization

Adverse Event or Product Problem Description
Report Date: 06/08/2001 MDR Text Key: 1178778 Patient Sequence Number: 1
It was reported: revision of femoral head 7 weeks later.

Database contains data received through March 30, 2004

Manufacturer and User Facility Device Experience (MAUDE) Database

Brand Name	ACET INS SZ 28X49 METASUL-APR
Type of Device	HIP PROSTHESIS
Baseline Brand Name	ACET INS SZ 28X49 METASUL-APR
Baseline Generic Name	HIP PROSTHESIS
Baseline Catalogue Number	4340-28-049
Baseline Device Family	NA
Baseline Device 510(K) Number	K993569
Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	12/01/1999
Manufacturer *(Section F)*	SULZER ORTHOPEDICS, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer *(Section D)*	SULZER ORTHOPEDICS, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer Contact	Randy Jasek, Supervisor 9900 Spectrum Drive Austin , TX 78717 (512) 432 -9611
Device Event Key	331904
MDR Report Key	342566
Event Key	322596
Report Number	2935620-2001-01162
Device Sequence Number	1
Product Code	KWA
Report Source	Manufacturer

Source Type	Company Representative
Event Type	Injury
Type of Report	Initial
Report Date	06/18/2001
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	07/18/2001
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	4340-28-049
Was Device Available For Evaluation?	Device Not Returned To Manufacturer
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Date Manufacturer Received	06/18/2001
Was Device Evaluated By Manufacturer?	No
Is The Device Single Use?	Yes
Type of Device Usage	Initial
Patient Outcome	Hospitalization Required Intervention

Adverse Event or Product Problem Description
Report Date: 06/18/2001 MDR Text Key: 1186749 Patient Sequence Number: 1
It was reported: metasul insert dislocation after 4 years implantation, significant metalosis. Severe pain.

Database contains data received through March 30, 2004

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New Search

Back To Search Results

Manufacturer and User Facility Device Experience (MAUDE) Database

Brand Name	ACET INS SZ 28X53 METASUL-APR
Type of Device	HIP PROSTHESIS
Baseline Brand Name	ACET INS SZ 28X53 METASUL-APR
Baseline Generic Name	HIP PROSTHESIS
Baseline Catalogue Number	4340-28-053
Baseline Device Family	NA
Baseline Device 510(K) Number	K993569
Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	12/01/1999
Manufacturer *(Section F)*	SULZER ORTHOPEDICS, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer *(Section D)*	SULZER ORTHOPEDICS, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer Contact	Randy Jasek, Supervisor 9900 Spectrum Drive Austin , TX 78717 (512) 432 -9611
Device Event Key	341161
MDR Report Key	351880
Event Key	331492
Report Number	2935620-2001-01531
Device Sequence Number	1
Product Code	KWA
Report Source	Manufacturer

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Source Type	Company Representative
Remedial Action	Replace
Event Type	No Answer Provided
Type of Report	Initial
Report Date	08/23/2001
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	09/18/2001
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	4340-28-053
Device LOT Number	1348667-B
Was Device Available For Evaluation?	No
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Date Manufacturer Received	08/23/2001
Was Device Evaluated By Manufacturer?	Device Not Returned To Manufacturer
Date Device Manufactured	08/01/2000
Is The Device Single Use?	Yes
Type of Device Usage	Initial
Patient Outcome	Hospitalization Required Intervention

Adverse Event or Product Problem Description
Report Date: 08/23/2001 MDR Text Key: 1221387 Patient Sequence Number: 1
It was reported: apr metasul insert disengaged [nine] months after surgery.

Database contains data received through March 30, 2004

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New Search

Back To Search Results

Manufacturer and User Facility Device Experience (MAUDE) Database

Brand Name	ACET INS SZ 28X53 METASUL-APR
Type of Device	HIP PROSTHESIS
Baseline Brand Name	ACET INS SZ 28X53 METASUL-APR
Baseline Generic Name	HIP PROSTHESIS
Baseline Catalogue Number	4340-28-053
Baseline Device Family	NA
Baseline Device 510(K) Number	K993569
Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	12/01/1999
Manufacturer *(Section F)*	SULZER ORTHOPEDICS, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer *(Section D)*	SULZER ORTHOPEDICS, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer Contact	Randy Jasek, Supervisor 9900 Spectrum Drive Austin , TX 78717 (512) 432 -9611
Device Event Key	355407
MDR Report Key	366284
Event Key	345365
Report Number	2935620-2001-01765
Device Sequence Number	1
Product Code	KWA
Report Source	Manufacturer

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Source Type	Company Representative
Remedial Action	Replace
Event Type	Injury
Type of Report	Initial
Report Date	11/26/2001
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	12/18/2001
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	4340-28-053
Was Device Available For Evaluation?	Device Not Returned To Manufacturer
Date Returned to Manufacturer	11/26/2001
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Date Manufacturer Received	11/06/2001
Was Device Evaluated By Manufacturer?	No
Is The Device Single Use?	Yes
Type of Device Usage	Initial
Patient Outcome	Hospitalization Required Intervention

Adverse Event or Product Problem Description
Report Date: 11/26/2001 MDR Text Key: 1272251 Patient Sequence Number: 1
It was reported: disassociation of liner from cup.

Database contains data received through March 30, 2004

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New Search Back To Search Results

Manufacturer and User Facility Device Experience (MAUDE) Database

Brand Name	ACET INS SZ 28X49 METASUL-APR
Type of Device	HIP PROSTHESIS
Baseline Brand Name	ACET INS SZ 28X49 METASUL-APR
Baseline Generic Name	HIP PROSTHESIS
Baseline Catalogue Number	4340-28-049
Baseline Device Family	NA
Baseline Device 510(K) Number	K993569
Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	12/01/1999
Manufacturer *(Section F)*	SULZER ORTHOPEDICS, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer *(Section D)*	SULZER ORTHOPEDICS, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer Contact	Randy Jasek, Supervisor 9900 Spectrum Drive Austin , TX 78717 (512) 432 -9611
Device Event Key	359226
MDR Report Key	370104
Event Key	349096
Report Number	2935620-2001-01806
Device Sequence Number	1
Product Code	KWA
Report Source	Manufacturer

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Source Type	Company Representative
Event Type	Injury
Type of Report	Initial
Report Date	12/12/2001
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	01/07/2002
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	4340-28-049
Device LOT Number	1302992
Was Device Available For Evaluation?	Device Not Returned To Manufacturer
Date Returned to Manufacturer	12/12/2001
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Date Manufacturer Received	12/12/2001
Was Device Evaluated By Manufacturer?	No
Date Device Manufactured	06/01/1997
Is The Device Single Use?	Yes
Type of Device Usage	Initial
Patient Outcome	Hospitalization Required Intervention

Adverse Event or Product Problem Description
Report Date: 12/12/2001 MDR Text Key: 1285891 Patient Sequence Number: 1
It was reported: the anti-rotation pin was dislocated from the insert.

Database contains data received through March 30, 2004

Manufacturer and User Facility Device Experience (MAUDE) Database

Brand Name	FMP ACETABULAR SYSTEM
Type of Device	ACETABULAR LINER
Baseline Brand Name	FMP ACETABULAR SYSTEM
Baseline Generic Name	ACETABULAR LINER
Baseline Catalogue Number	499-28-009
Baseline Device Family	METAL/METAL LINER
Baseline Device 510(K) Number	K003250
Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	01/01/2001
Manufacturer *(Section F)*	ENCORE ORTHOPEDICS, INC. 9800 Metric Blvd. Austin TX 78758
Manufacturer *(Section D)*	ENCORE ORTHOPEDICS, INC. 9800 Metric Blvd. Austin TX 78758
Manufacturer Contact	9800 Metric Blvd. Austin , TX 78758 (800) 456 -8696
Device Event Key	359915
MDR Report Key	370788
Event Key	349781
Report Number	1644408-2002-00001
Device Sequence Number	1
Product Code	KWA
Report Source	Manufacturer
Source Type	Health Professional

Event Type	Other
Type of Report	Initial
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	01/09/2002
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	499-28-009
Device LOT Number	770291
Was Device Available For Evaluation?	Yes
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Date Manufacturer Received	12/17/2001
Was Device Evaluated By Manufacturer?	Yes
Date Device Manufactured	10/01/2001
Is The Device Single Use?	Yes
Type of Device Usage	Initial
Patient Outcome	Other

Adverse Event or Product Problem Description
Report Date: 01/04/2001 MDR Text Key: 1288367 Patient Sequence Number: 1
Total hip replacement surgery extended due to failure to properly assemble acetabular liner into shell.

Additional Manufacturer Narrative
Report Date: 01/09/2002 MDR Text Key: 1288368
Evaluation determined that event was caused by swelling of the polyethylene due to improper handling prior to surgery.

Database contains data received through March 30, 2004

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New Search

Back To Search Results

Manufacturer and User Facility Device Experience (MAUDE) Database

Brand Name	ACET INS SZ 28X51 METASUL-APR
Type of Device	HIP PROSTHESIS
Baseline Brand Name	ACET INS SZ 28X51 METASUL-APR
Baseline Generic Name	HIP PROSTHESIS
Baseline Catalogue Number	4340-28-051
Baseline Device Family	NA
Baseline Device 510(K) Number	K993569
Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	12/01/1999
Manufacturer *(Section F)*	SULZER ORTHOPEDICS, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer *(Section D)*	SULZER ORTHOPEDICS, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer Contact	Randy Jasek, Supervisor 9900 Spectrum Drive Austin , TX 78717 (512) 432 -9611
Device Event Key	364616
MDR Report Key	375510
Event Key	354337
Report Number	2935620-2001-01841
Device Sequence Number	1
Product Code	KWA
Report Source	Manufacturer

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Source Type	Company Representative
Remedial Action	Replace
Event Type	Injury
Type of Report	Initial
Report Date	01/28/2002
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	02/06/2002
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	4340-28-051
Device LOT Number	1245308
Was Device Available For Evaluation?	Device Not Returned To Manufacturer
Date Returned to Manufacturer	01/28/2002
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Date Manufacturer Received	12/05/2001
Was Device Evaluated By Manufacturer?	No
Date Device Manufactured	06/01/1996
Is The Device Single Use?	Yes
Type of Device Usage	Initial
Patient Outcome	Hospitalization

Adverse Event or Product Problem Description
Report Date: 01/28/2002 MDR Text Key: 1305827 Patient Sequence Number: 1
It was reported: dr. Reported he had a patient with pain. Disassoclation of liner from shell.

Patient TREATMENT DATA

Date Received: 02/06/2002 Patient Sequence Number: 1

#	Treatment	Treatment Date
1	4311-00-051 APR II SCWLS SHELL 51MM (LOT#1295892)	01/01/2001
2,(2001)		
3442 ALLOPRO BATORY FEM HD 28MM +4 (2001),01/01/2001		

Database contains data received through March 30, 2004

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Manufacturer and User Facility Device Experience (MAUDE) Database

Brand Name	ACET INS SZ 28X59 METASUL-APR
Type of Device	HIP PROSTHESIS
Baseline Brand Name	ACET INS SZ 28X59 METASUL-APR
Baseline Generic Name	HIP PROSTHESIS
Baseline Catalogue Number	4340-28-059
Baseline Device Family	NA
Baseline Device 510(K) Number	K993569
Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	12/01/1999
Manufacturer *(Section F)*	SULZER ORTHOPEDICS, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer *(Section D)*	SULZER ORTHOPEDICS, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer Contact	Allyson Hein, Qa Supervisor 9900 Spectrum Drive Austin , TX 78717 (512) 432 -9285
Device Event Key	367942
MDR Report Key	378913
Event Key	357627
Report Number	2935620-2002-00026
Device Sequence Number	1
Product Code	KWA
Report Source	Manufacturer

Source Type	Health Professional
Remedial Action	Replace
Event Type	Injury
Type of Report	Initial
Report Date	01/28/2002
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	02/27/2002
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	4340-28-059
Device LOT Number	1230120
Was Device Available For Evaluation?	Device Not Returned To Manufacturer
Date Returned to Manufacturer	01/28/2002
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Date Manufacturer Received	01/28/2002
Was Device Evaluated By Manufacturer?	No
Date Device Manufactured	03/01/1996
Is The Device Single Use?	Yes
Type of Device Usage	Initial
Patient Outcome	Hospitalization Required Intervention

Adverse Event or Product Problem Description
Report Date: 01/28/2002 MDR Text Key: 1317161 Patient Sequence Number: 1
It was reported: disassociation of an apr metasul acetabular insert size 59mm. Patient fell in 2001.

Patient TREATMENT DATA

Date Received: 02/27/2002 Patient Sequence Number: 1

#	Treatment	Treatment Date
1	4311-00-059 APR II SHELL 59MM (LOT# 1298084)(2001)	01/01/2001
2	3461 AP BALL HD MED 28/14 (LOT# B023602)(2001).	01/01/2001

Database contains data received through March 30, 2004

Manufacturer and User Facility Device Experience (MAUDE) Database

Brand Name	ACET INS SZ 28X51 METASUL-APR
Type of Device	HIP PROSTHESIS
Baseline Brand Name	ACET INS SZ 28X51 METASUL-APR
Baseline Generic Name	HIP PROSTHESIS
Baseline Catalogue Number	4340-28-051
Baseline Device Family	NA
Baseline Device 510(K) Number	K993569
Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	12/01/1999
Manufacturer *(Section F)*	SULZER ORTHOPEDICS, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer *(Section D)*	SULZER ORTHOPEDICS, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer Contact	Allyson Hein, Supervisor 9900 Spectrum Drive Austin , TX 78717 (512) 432 -9285
Device Event Key	371588
MDR Report Key	382514
Event Key	361129
Report Number	2935620-2002-00069
Device Sequence Number	1
Product Code	KWA
Report Source	Manufacturer

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Source Type	Health Professional
Remedial Action	Replace
Event Type	Injury
Type of Report	Initial
Report Date	02/27/2002
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	03/19/2002
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	4340-28-051
Device LOT Number	1181946
Was Device Available For Evaluation?	No
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Was Device Evaluated By Manufacturer?	Device Not Returned To Manufacturer
Date Device Manufactured	09/01/1995
Is The Device Single Use?	Yes
Type of Device Usage	Initial
Patient Outcome	Hospitalization Required Intervention

Adverse Event or Product Problem Description
Report Date: 02/27/2002 MDR Text Key: 1329206 Patient Sequence Number: 1
It was reported: clinical advised on an apr metasul acetabular liner disassociation, patient was revised in 2002.

Database contains data received through March 30, 2004

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New Search

Back To Search Results

Manufacturer and User Facility Device Experience (MAUDE) Database

Brand Name	ACET INS SZ 28X57 METASUL-APR
Type of Device	HIP PROSTHESIS
Baseline Brand Name	ACET INS SZ 28 X 57 METASUL-APR
Baseline Generic Name	HIP PROSTHESIS
Baseline Catalogue Number	4340-28-057
Baseline Device Family	NA
Baseline Device 510(K) Number	K993569
Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	12/01/1999
Manufacturer *(Section F)*	SULZER ORTHOPEDICS, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer *(Section D)*	SULZER ORTHOPEDICS, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer Contact	Allyson Hein, Supervisor 9900 Spectrum Drive Austin , TX 78717 (512) 432 -9285
Device Event Key	376896
MDR Report Key	387867
Event Key	366275
Report Number	2935620-2002-00105
Device Sequence Number	1
Product Code	KWA
Report Source	Manufacturer

Source Type	Company Representative
Remedial Action	Replace
Event Type	Injury
Type of Report	Initial
Report Date	03/15/2002
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	04/12/2002
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	4340-28-057
Device LOT Number	1181949
Was Device Available For Evaluation?	Device Not Returned To Manufacturer
Date Returned to Manufacturer	03/28/2002
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Date Manufacturer Received	03/15/2002
Was Device Evaluated By Manufacturer?	No
Date Device Manufactured	09/01/1995
Is The Device Single Use?	Yes
Type of Device Usage	Initial
Patient Outcome	Hospitalization Required Intervention

Adverse Event or Product Problem Description
Report Date: 03/15/2002 MDR Text Key: 1346855 Patient Sequence Number: 1
It was reported: disassocation of an apr metasul insert.

Database contains data received through March 30, 2004

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New Search

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Manufacturer and User Facility Device Experience (MAUDE) Database

Brand Name	ACET INS SZ 28X51 METASUL-APR
Type of Device	HIP PROSTHESIS
Baseline Brand Name	ACET INS SZ 28X51 METASUL-APR
Baseline Generic Name	HIP PROSTHESIS
Baseline Catalogue Number	4340-28-051
Baseline Device Family	NA
Baseline Device 510(K) Number	K993569
Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	12/01/1999
Manufacturer *(Section F)*	SULZER ORTHOPEDICS, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer *(Section D)*	SULZER ORTHOPEDICS, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer Contact	Allyson Hein, Supervisor 9900 Spectrum Drive Austin , TX 78717 (512) 432 -9285
Device Event Key	376891
MDR Report Key	387862
Event Key	366270
Report Number	2935620-2002-00106
Device Sequence Number	1
Product Code	KWA
Report Source	Manufacturer

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Source Type	Company Representative
Remedial Action	Replace
Event Type	Injury
Type of Report	Initial
Report Date	03/15/2002
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	04/12/2002
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	4340-28-051
Device LOT Number	1245308
Was Device Available For Evaluation?	Device Not Returned To Manufacturer
Date Returned to Manufacturer	03/28/2002
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Date Manufacturer Received	03/15/2002
Was Device Evaluated By Manufacturer?	No
Date Device Manufactured	06/01/1996
Is The Device Single Use?	Yes
Type of Device Usage	Initial
Patient Outcome	Hospitalization Required Intervention

Adverse Event or Product Problem Description
Report Date: 03/15/2002 MDR Text Key: 1346839 Patient Sequence Number: 1
It was reported: pain and breakage of implant.

Patient TREATMENT DATA

Date Received: 04/12/2002 Patient Sequence Number: 1

#	Treatment	Treatment Date
1	3441 ALLPRO BATTROY HD 28MM NEU (LOT#96583972)2002	01/01/2002

Database contains data received through March 30, 2004

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New Search

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Manufacturer and User Facility Device Experience (MAUDE) Database

Brand Name	ACET INS SZ 28X49 METASUL-APR
Type of Device	HIP PROSTHESIS
Baseline Brand Name	ACET INS SZ 28X49 METASUL-APR
Baseline Generic Name	HIP PROSTHESIS
Baseline Catalogue Number	4340-28-049
Baseline Device Family	NA
Baseline Device 510(K) Number	K993569
Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	12/01/1999
Manufacturer *(Section F)*	SULZER ORTHOPEDICS, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer *(Section D)*	SULZER ORTHOPEDICS, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer Contact	Allyson Hein, Supervisor 9900 Spectrum Drive Austin , TX 78717 (512) 432 -9285
Device Event Key	380445
MDR Report Key	391396
Event Key	369693
Report Number	2935620-2002-00141
Device Sequence Number	1
Product Code	KWA
Report Source	Manufacturer

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Source Type	Company Representative
Remedial Action	Replace
Event Type	Injury
Type of Report	Initial
Report Date	04/15/2002
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	05/01/2002
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	4340-28-049
Device LOT Number	1322215
Was Device Available For Evaluation?	Device Not Returned To Manufacturer
Date Returned to Manufacturer	05/01/2002
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Date Manufacturer Received	04/15/2002
Was Device Evaluated By Manufacturer?	No
Is The Device Single Use?	Yes
Type of Device Usage	Initial
Patient Outcome	Hospitalization Required Intervention

Adverse Event or Product Problem Description
Report Date: 04/15/2002 MDR Text Key: 1359227 Patient Sequence Number: 1
It was reported: disassociation of insert 2 years 9 months after initial surgery.

Patient TREATMENT DATA

Date Received: 05/01/2002 Patient Sequence Number: 1

#	Treatment	Treatment Date
1	3460 METASUL BALL HD 28MM SZ S (LOT#B436274)(2002)	01/01/2002

Database contains data received through March 30, 2004

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New Search

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Manufacturer and User Facility Device Experience (MAUDE) Database

Brand Name	COCR HD 12/14 NECK NEU 28MM METASUL
Type of Device	HIP PROSTHESIS
Baseline Brand Name	COCR HD 12/14 NECK NEU 28MM METASUL
Baseline Generic Name	HIP PROSTHESIS
Baseline Catalogue Number	7340-28-000
Baseline Device Family	NA
Baseline Device 510(K) Number	K974728
Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	08/03/1999
Manufacturer *(Section F)*	SULZER ORTHOPEDICS, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer *(Section D)*	SULZER ORTHOPEDICS, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer Contact	Allyson Hein, Supervisor 9900 Spectrum Drive Austin , TX 78717 (512) 432 -9285
Device Event Key	390758
MDR Report Key	401722
Event Key	379644
Report Number	2935620-2002-00178
Device Sequence Number	1
Product Code	KWA
Report Source	Manufacturer

Source Type	Company Representative
Remedial Action	Replace
Event Type	Injury
Type of Report	Initial
Report Date	06/04/2002
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	06/26/2002
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	7340-28-000
Device LOT Number	1426357
Was Device Available For Evaluation?	No
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Date Manufacturer Received	06/04/2002
Was Device Evaluated By Manufacturer?	Device Not Returned To Manufacturer
Date Device Manufactured	07/01/2000
Is The Device Single Use?	Yes
Type of Device Usage	Initial
Patient Outcome	Hospitalization Required Intervention

Adverse Event or Product Problem Description
Report Date: 06/04/2002 MDR Text Key: 1395451 Patient Sequence Number: 1
It was reported: patient was revised due to dislocation of the hip.

Database contains data received through March 30, 2004

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New Search

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Manufacturer and User Facility Device Experience (MAUDE) Database

Brand Name	M2A MODULAR HEAD
Type of Device	PROSTHESIS, HIP, COMP.
Baseline Brand Name	M2A MODULAR HEAD
Baseline Generic Name	PROSTHESIS, HIP, COMP
Baseline Catalogue Number	11-173660
Baseline Device Family	M2A MODULAR HEAD
Baseline Device 510(K) Number	K011110
Baseline Shelf Life Information	Yes
Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	12
Date First Marketed	07/02/2001
Manufacturer *(Section F)*	BIOMET, INC. P.O. Box 587 Warsaw IN 46581 0587
Manufacturer *(Section D)*	BIOMET, INC. P.O. Box 587 Warsaw IN 46581 0587
Manufacturer Contact	Beth Albert, Correct Action As P.O. Box 587 Warsaw , IN 46581-0587 (574) 267 -6639
Device Event Key	417045
MDR Report Key	428854
Event Key	404930
Report Number	1825034-2002-00129
Device Sequence Number	1
Product Code	KWA

Report Source	Manufacturer
Source Type	User facility,Company Representative
Event Type	Injury
Type of Report	Initial
Report Date	11/08/2002
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	11/20/2002
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device EXPIRATION Date	07/01/2012
Device Catalogue Number	11-173660
Device LOT Number	698740
Was Device Available For Evaluation?	No
Date Manufacturer Received	11/08/2002
Was Device Evaluated By Manufacturer?	Device Not Returned To Manufacturer
Date Device Manufactured	07/01/2002
Is The Device Single Use?	Yes
Type of Device Usage	Initial
Patient Outcome	Hospitalization Required Intervention

Adverse Event or Product Problem Description
Report Date: 11/08/2002 MDR Text Key: 1488471 Patient Sequence Number: 1
Report rec'd from hospital stating that during the time period from event date to 11/2002, eleven total joint and/or revision procedures were performed, with five of these cases resulting in post operative infection. The procedures performed are comprised of various components being implanted. The co has no info that these incidents of infections are in any way related to the biomet device. The co is continuing to gather further info, but to date there is no common thread involving the device or its components that would lead biomet to conclude that the device caused any infection. Investigation continues at the hospital for non-device causes. Left "tha" performed in 2002, resulting in post-operative infection.

Additional Manufacturer Narrative
Report Date: 11/08/2002 MDR Text Key: 1488474
Biomet does not believe that the company's devices are implicated in these infections because similar reports of infection have not been rec'd from other user facilities for any of the listed mfg lots. Notwithstanding the fact that the company does not believe these events are related, the company is advising fda of these incidents under part 803 so that fda's files are complete. It is the co understanding that the institution has filed a medwatch form for these infections and biomet wants fda to know the status of its investigation.

Database contains data received through March 30, 2004

Center for Devices and Radiological Health / CDRH

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New Search

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Manufacturer and User Facility Device Experience (MAUDE) Database

Brand Name	COCR HD 12/14 +4MM NECK 28MM METASUL
Type of Device	HIP PROSTHESIS
Baseline Brand Name	COCR HD 12/14 +4MM NECK 28MM METASUL
Baseline Generic Name	HIP PROSTHESIS
Baseline Catalogue Number	7340-28-400
Baseline Device Family	NA
Baseline Device 510(K) Number	K974728
Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	08/03/1999
Manufacturer *(Section F)*	CENTERPULSE ORTHOPEDICS, INC 9900 Spectrum Dr. Austin TX 78717
Manufacturer *(Section D)*	CENTERPULSE ORTHOPEDICS, INC 9900 Spectrum Dr. Austin TX 78717
Manufacturer Contact	Ron Yarbrough, Supervisor 9900 Spectrum Dr Austin , TX 78717 (512) 432 -9437
Device Event Key	421879
MDR Report Key	432921
Event Key	409618
Report Number	2935620-2002-00393
Device Sequence Number	1
Product Code	KWA
Report Source	Manufacturer

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Source Type	Company Representative
Remedial Action	Replace
Event Type	Injury
Type of Report	Initial
Report Date	12/10/2002
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	12/17/2002
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	7340-28-400
Device LOT Number	1409774
Was Device Available For Evaluation?	No
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Date Manufacturer Received	12/10/2002
Was Device Evaluated By Manufacturer?	Device Not Returned To Manufacturer
Date Device Manufactured	10/01/1999
Is The Device Single Use?	Yes
Type of Device Usage	Initial
Patient Outcome	Hospitalization Required Intervention

Adverse Event or Product Problem Description
Report Date: 12/10/2002 MDR Text Key: 1502746 Patient Sequence Number: 1
It was reported: 2nd revision was required because of the instability of the hip, and was operated in 2001. This is apparent, given the fact that they converted to a hooded insert, as well as the fact that a +8 cocr head was used. Both of these changes will help to increase the stability of the hip. 1st rev. Of this patient is of a recall shell. P01-2916 (rm database).

Database contains data received through March 30, 2004

Manufacturer and User Facility Device Experience (MAUDE) Database

Brand Name	M2A MODULAR HEAD
Type of Device	PROSTHESIS, HIP, COMP.
Baseline Brand Name	M2A MODULAR HEAD
Baseline Generic Name	PROSTHESIS, HIP, COMP
Baseline Catalogue Number	11-173661
Baseline Device Family	M2A MODULAR HEAD
Baseline Device 510(K) Number	K011110
Baseline Shelf Life Information	Yes
Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	12
Date First Marketed	07/02/2001
Manufacturer *(Section F)*	BIOMET, INC. P.O. Box 587 Warsaw IN 46581 0587
Manufacturer *(Section D)*	BIOMET, INC. P.O. Box 587 Warsaw IN 46581 0587
Manufacturer Contact	Beth Albert,Correct Action Ast P.O. Box 587 Warsaw , IN 46581-0587 (574) 267 -6639
Device Event Key	425634
MDR Report Key	436691
Event Key	413272
Report Number	1825034-2003-00001
Device Sequence Number	1
Product Code	KWA

Report Source	Manufacturer
Source Type	Company Representative
Event Type	Injury
Type of Report	Initial
Report Date	01/07/2003,12/09/2002
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	01/07/2003
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device EXPIRATION Date	04/01/2012
Device Catalogue Number	11-173661
Device LOT Number	321210
Was Device Available For Evaluation?	Device Not Returned To Manufacturer
Date Returned to Manufacturer	12/09/2002
Is The Reporter A Health Professional?	Yes
Was the Report Sent to FDA?	No
Distributor Facility Aware Date	12/10/2002
Device Age	8 mo
Event Location	Hospital
Date Manufacturer Received	12/09/2002
Was Device Evaluated By Manufacturer?	Yes
Date Device Manufactured	04/01/2002
Is The Device Single Use?	Yes
Type of Device Usage	Initial
Patient Outcome	Hospitalization Required Intervention

Adverse Event or Product Problem Description
Report Date: 01/07/2003 MDR Text Key: 1515315 Patient Sequence Number: 1
Following total hip arthroplasty performed in 2002, pt continued to experience hip pain. Pt underwent add'l surgery 1 mo later, where osteophytes were removed and modular head component was exchanged.

Additional Manufacturer Narrative
Report Date: 01/07/2003 MDR Text Key: 1515318
There are warnings in the package insert that state that this type of event can occur. This type of event is not occurring at a rate above expected frequency. No remedial action will be taken. No further complications have been reported. Current info is insufficient to permit a valid conclusion as to the cause of the event.

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Database contains data received through March 30, 2004

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New Search

Back To Search Results

Manufacturer and User Facility Device Experience (MAUDE) Database

Brand Name	ULTAMET MOM INSRT 54ODX36ID
Type of Device	TOTAL HIP PROSTHESIS
Baseline Brand Name	ULTAMET MOM INSRT 54ODX36ID
Baseline Generic Name	PINNACLE METAL ON METAL ACETABULAR CUP
Baseline Catalogue Number	121887354
Baseline Device Family	ULTAMET MOM INSERT
Baseline Device 510(K) Number	K003523
Baseline Shelf Life Information	No
Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	12/13/2000
Manufacturer *(Section F)*	DEPUY INTERNATIONAL,LTD. St. Anthony's Rd Beeston, Leeds UNITED KINGDOM LS11 8DT
Manufacturer *(Section D)*	DEPUY INTERNATIONAL,LTD. St. Anthony's Rd Beeston, Leeds UNITED KINGDOM LS11 8DT
Manufacturer *(Section G)*	DEPUY ORTHOPAEDICS, INC. 700 Orthopaedic Drive Warsaw IN 46581 0988
Manufacturer Contact	Hans Kusserow, Mgr. 700 Orthopaedic Drive Warsaw , IN 46581-0988 (574) 372 -7416
Device Event Key	426244
MDR Report Key	437308
Event Key	413857

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Report Number	1818910-2003-00019
Device Sequence Number	1
Product Code	KWA
Report Source	Manufacturer
Source Type	Distributor
Remedial Action	Other
Event Type	Malfunction
Type of Report	Initial
Report Date	01/10/2003
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	01/10/2003
Is This An Adverse Event Report?	No
Is This A Product Problem Report?	Yes
Device Operator	Health Professional
Device Catalogue Number	121887354
Device LOT Number	YMD59
Was Device Available For Evaluation?	Yes
Date Returned to Manufacturer	12/13/2002
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Distributor Facility Aware Date	12/13/2002
Device Age	unknown
Event Location	Hospital
Date Manufacturer Received	12/11/2002
Was Device Evaluated By Manufacturer?	Yes
Date Device Manufactured	07/01/2002
Is The Device Single Use?	Yes
Type of Device Usage	Initial
Patient Outcome	Other

Adverse Event or Product Problem Description
Report Date: 01/10/2003 MDR Text Key: 1517381 Patient Sequence Number: 1
The package is split - inner plastic portion.

Additional Manufacturer Narrative
Report Date: 01/10/2003 MDR Text Key: 1517384
This complaint is still under investigation. Depuy will notify the fda of the results of this investigation once it has been completed.

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New Search

Back To Search Results

Manufacturer and User Facility Device Experience (MAUDE) Database

Brand Name	ULTAMET MOM INSRT 52ODX36ID
Type of Device	TOTAL HIP PROSTHESIS
Baseline Brand Name	ULTAMET MOM INSERT 52ODX36ID
Baseline Generic Name	PINNACLE METAL ON METAL ACETABULAR CUP
Baseline Catalogue Number	121887352
Baseline Device Family	ULTAMET MOM INSERT
Baseline Device 510(K) Number	K003523
Baseline Shelf Life Information	No
Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	12/13/2000
Manufacturer *(Section F)*	DEPUY INTERNATIONAL, LTD. St. Anthony's Road Leeds UNITED KINGDOM LS11 8DT
Manufacturer *(Section D)*	DEPUY INTERNATIONAL, LTD. St. Anthony's Road Leeds UNITED KINGDOM LS11 8DT
Manufacturer *(Section G)*	DEPUY ORTHOPAEDICS, INC. 700 Orthopaedic Drive Warsaw IN 46581 0988
Manufacturer Contact	Hans Kusserow, Mgr. 700 Orthopaedic Drive Warsaw , IN 46581-0988 (574) 372 -7416
Device Event Key	439175
MDR Report Key	450176
Event Key	426312

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Report Number	1818910-2003-00178
Device Sequence Number	1
Product Code	KWA
Report Source	Manufacturer
Source Type	Health Professional,Distributor
Remedial Action	Other
Event Type	Injury
Type of Report	Initial
Report Date	03/27/2003
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	03/27/2003
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	Yes
Device Operator	Health Professional
Device Catalogue Number	121887352
Device LOT Number	1070181
Was Device Available For Evaluation?	Yes
Date Returned to Manufacturer	03/03/2003
Is The Reporter A Health Professional?	Yes
Was the Report Sent to FDA?	No
Distributor Facility Aware Date	02/26/2003
Device Age	unknown
Event Location	Hospital
Date Manufacturer Received	02/26/2003
Was Device Evaluated By Manufacturer?	Yes
Is The Device Single Use?	Yes
Type of Device Usage	Initial
Patient Outcome	Required Intervention

Adverse Event or Product Problem Description
Report Date: 03/27/2003 MDR Text Key: 1562106 Patient Sequence Number: 1
The metal insert was locked into the shell off-axis. Insert could not be removed from acetabular shell.

Additional Manufacturer Narrative
Report Date: 03/27/2003 MDR Text Key: 1562109
This complaint is still under investigation. Depuy will notify the fda of the results of this investigation once it has been completed.

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Database contains data received through March 30, 2004

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New Search

Back To Search Results

Manufacturer and User Facility Device Experience (MAUDE) Database

Brand Name	ACET INS SZ 28X49 METASUL-APR
Type of Device	HIP PROSTHESIS
Baseline Brand Name	ACET INS SZ 28X49 METASUL-APR
Baseline Generic Name	HIP PROSTHESIS
Baseline Catalogue Number	4340-28-049
Baseline Device Family	NA
Baseline Device 510(K) Number	K993569
Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	12/01/1999
Manufacturer *(Section F)*	CENTERPULSE ORTHOPEDICS, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer *(Section D)*	CENTERPULSE ORTHOPEDICS, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer Contact	Jim Gonzales, Supervisor 9900 Spectrum Drive Austin , TX 78717 (512) 432 -9688
Device Event Key	456610
MDR Report Key	467685
Event Key	443229
Report Number	2935620-2003-00135
Device Sequence Number	1
Product Code	KWA
Report Source	Manufacturer

Source Type	Company Representative
Remedial Action	Replace
Event Type	Injury
Type of Report	Initial
Report Date	06/10/2003
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	06/25/2003
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	4340-28-049
Device LOT Number	1230114
Was Device Available For Evaluation?	Device Not Returned To Manufacturer
Date Returned to Manufacturer	06/13/2003
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Date Manufacturer Received	06/10/2003
Was Device Evaluated By Manufacturer?	No
Is The Device Single Use?	Yes
Type of Device Usage	Initial
Patient Outcome	Hospitalization

Adverse Event or Product Problem Description
Report Date: 06/10/2003 MDR Text Key: 1622790 Patient Sequence Number: 1
Pt felt pain, due to dislocation. Pt was revised.

Patient TREATMENT DATA

Date Received: 06/25/2003 Patient Sequence Number: 1

#	Treatment	Treatment Date
1	4310-02-049 APR 12 SLOT SHELL SZ49MM (LOT#1268548)	01/01/2003
2	3462 AP BALL HEAD LONG 28/14 (LOT#96547339).	01/01/2003

Database contains data received through March 30, 2004

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New Search

Back To Search Results

Manufacturer and User Facility Device Experience (MAUDE) Database

Brand Name	ACET INS SZ 28X51 METASUL-APR
Type of Device	HIP PROSTHESIS
Baseline Brand Name	ACET INS SZ 28X51 METASUL-APR
Baseline Generic Name	HIP PROSTHESIS
Baseline Catalogue Number	4340-28-051
Baseline Device Family	NA
Baseline Device 510(K) Number	K993569
Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	12/01/1999
Manufacturer *(Section F)*	CENTERPULSE ORTHOPEDICS, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer *(Section D)*	CENTERPULSE ORTHOPEDICS, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer *(Section G)*	CENTERPULSE ORTHOPEDICS, INC. 9900 Spectrum Drive Austin TX 78717
Manufacturer Contact	Jim Gonzales, Supervisor 9900 Spectrum Drive Austin , TX 78717 (512) 432 -9688
Device Event Key	460922
MDR Report Key	472071
Event Key	447449
Report Number	2935620-2003-00143
Device Sequence Number	1

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Product Code	KWA
Report Source	Manufacturer
Source Type	Company Representative
Remedial Action	Replace
Event Type	Injury
Type of Report	Initial
Report Date	06/19/2003
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	07/16/2003
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	4340-28-051
Device LOT Number	1303680
Was Device Available For Evaluation?	Device Not Returned To Manufacturer
Date Returned to Manufacturer	06/20/2003
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Date Manufacturer Received	06/19/2003
Was Device Evaluated By Manufacturer?	No
Date Device Manufactured	11/01/1997
Is The Device Single Use?	Yes
Type of Device Usage	Initial
Patient Outcome	Hospitalization

Adverse Event or Product Problem Description
Report Date: 06/19/2003 MDR Text Key: 1637251 Patient Sequence Number: 1
It was reported: dislocation of apr metasul insert.

Patient TREATMENT DATA

Date Received: 07/16/2003 Patient Sequence Number: 1

#	Treatment	Treatment Date
1	3461 AP BALL HEAD MED 28/14 (LOT#B525466)(2002).	01/01/2002

Database contains data received through March 30, 2004

Manufacturer and User Facility Device Experience (MAUDE) Database

Brand Name	ACET INS SZ 28X49 METASUL-APR
Type of Device	HIP PROSTHESIS
Baseline Brand Name	ACET INS SZ 28X49 METASUL-APR
Baseline Generic Name	HIP PROSTHESIS
Baseline Catalogue Number	4340-28-049
Baseline Device Family	NA
Baseline Device 510(K) Number	K993569
Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	12/01/1999
Manufacturer *(Section F)*	CENTERPULSE ORTHOPEDICS, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer *(Section D)*	CENTERPULSE ORTHOPEDICS, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer *(Section G)*	CENTERPULSE ORTHOPEDICS, INC. 9900 Spectrum Dr Austin TX 78717
Manufacturer Contact	Jim Gonzales, Supervisor 9900 Spectrum Drive Austin , TX 78717 (512) 432 -9688
Device Event Key	461150
MDR Report Key	472298
Event Key	447676
Report Number	2935620-2003-00142
Device Sequence Number	1

Product Code	KWA
Report Source	Manufacturer
Source Type	Company Representative
Remedial Action	Replace
Event Type	Injury
Type of Report	Initial
Report Date	06/25/2003
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	07/17/2003
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	4340-28-049
Device LOT Number	1322216
Was Device Available For Evaluation?	No
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Date Manufacturer Received	06/25/2003
Was Device Evaluated By Manufacturer?	Device Not Returned To Manufacturer
Date Device Manufactured	05/01/1998
Is The Device Single Use?	Yes
Type of Device Usage	Initial
Patient Outcome	Hospitalization

Adverse Event or Product Problem Description
Report Date: 06/25/2003 MDR Text Key: 1638072 Patient Sequence Number: 1
Pt had a dislocation and was revised.

Database contains data received through March 30, 2004

Manufacturer and User Facility Device Experience (MAUDE) Database

Brand Name	SZ 28X55MM STD METASUL INS I-O
Type of Device	HIP PROSTHESIS
Baseline Brand Name	SZ 28 X 55MM STD METASUL INS I-O
Baseline Generic Name	HIP PROSTHESIS
Baseline Catalogue Number	4372-28-055
Baseline Device Family	NA
Baseline Device 510(K) Number	K974728
Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	08/03/1999
Manufacturer *(Section F)*	CENTERPULSE ORTHOPEDICS, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer *(Section D)*	CENTERPULSE ORTHOPEDICS, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer *(Section G)*	CENTERPULSE ORTHOPEDICS, INC. 9900 Spectrum Dr Austin TX 78717
Manufacturer Contact	Jim Gonzales, Supervisor 9900 Spectrum Drive Austin , TX 78717 (512) 432 -9688
Device Event Key	478775
MDR Report Key	490033
Event Key	464565
Report Number	2935620-2003-00246
Device Sequence Number	1

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Product Code	KWA
Report Source	Manufacturer
Source Type	Company Representative
Remedial Action	Other
Event Type	Other
Type of Report	Initial
Report Date	10/14/2003
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	10/14/2003
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	4372-28-055
Device LOT Number	1426338-A
Was Device Available For Evaluation?	No
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Date Manufacturer Received	10/09/2003
Was Device Evaluated By Manufacturer?	No
Date Device Manufactured	08/01/2002
Is The Device Single Use?	Yes
Type of Device Usage	Initial
Patient Outcome	Hospitalization

Adverse Event or Product Problem Description
Report Date: 10/14/2003 MDR Text Key: 1696369 Patient Sequence Number: 1
Delay in surgery.

Database contains data received through March 30, 2004

Manufacturer and User Facility Device Experience (MAUDE) Database

Brand Name	ACET INS SZ 28X49 METASUL-APR
Type of Device	HIP PROSTHESIS
Baseline Brand Name	ACET INS SZ 28X49 METASUL-APR
Baseline Generic Name	HIP PROSTHESIS
Baseline Catalogue Number	4340-28-049
Baseline Device Family	NA
Baseline Device 510(K) Number	K993569
Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	12/01/1999
Manufacturer *(Section F)*	CENTERPULSE ORTHOPEDICS, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer *(Section D)*	CENTERPULSE ORTHOPEDICS, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer *(Section G)*	CENTERPULSE ORTHOPEDICS, INC. 9900 Spectrum Dr Austin TX 78717
Manufacturer Contact	Jim Gonzales, Supervisor 9900 Spectrum Drive Austin , TX 78717 (512) 432 -9688
Device Event Key	489867
MDR Report Key	501097
Event Key	475206
Report Number	2935620-2003-00279
Device Sequence Number	1

Product Code	KWA
Report Source	Manufacturer
Source Type	Company Representative
Remedial Action	Replace
Event Type	No Answer Provided
Type of Report	Initial
Report Date	12/16/2003
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	12/16/2003
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	4340-28-049
Device LOT Number	1230114
Was Device Available For Evaluation?	No
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Date Manufacturer Received	11/26/2003
Was Device Evaluated By Manufacturer?	Device Not Returned To Manufacturer
Date Device Manufactured	03/01/1996
Is The Device Single Use?	Yes
Type of Device Usage	Initial
Patient Outcome	Hospitalization

Adverse Event or Product Problem Description
Report Date: 12/16/2003 MDR Text Key: 1732417 Patient Sequence Number: 1
It was reported: pt was revised.

Database contains data received through March 30, 2004

Manufacturer and User Facility Device Experience (MAUDE) Database

Brand Name	ACET INS SZ 28X55 METASUL-APR
Type of Device	HIP PROSTHESIS
Baseline Brand Name	ACET INS SZ 28X55 METASUL APR
Baseline Generic Name	HIP PROSTHESIS
Baseline Catalogue Number	4340-28-055
Baseline Device Family	NA
Baseline Device 510(K) Number	K993569
Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	12/01/1999
Manufacturer *(Section F)*	CENTERPULSE ORTHOPEDICS, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer *(Section D)*	CENTERPULSE ORTHOPEDICS, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer *(Section G)*	CENTERPULSE ORTHOPEDICS, INC. 9900 Spectrum Drive Austin TX 78717
Manufacturer Contact	Jim Gonzales, Supervisor 9900 Spectrum Dr Austin , TX 78717 (512) 432 -9688
Device Event Key	491229
MDR Report Key	502457
Event Key	476487
Report Number	2935620-2003-00282
Device Sequence Number	1

Product Code	KWA
Report Source	Manufacturer
Source Type	Company Representative
Remedial Action	Replace
Event Type	Injury
Type of Report	Initial
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	12/23/2003
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	4340-28-055
Was Device Available For Evaluation?	Yes
Date Returned to Manufacturer	12/17/2003
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Date Manufacturer Received	12/17/2003
Was Device Evaluated By Manufacturer?	No
Is The Device Single Use?	Yes
Type of Device Usage	Initial
Patient Outcome	Hospitalization

Adverse Event or Product Problem Description
Report Date: 10/23/2003 MDR Text Key: 1737004 Patient Sequence Number: 1
It was reported: patient was revised in 2003.

Database contains data received through March 30, 2004

Manufacturer and User Facility Device Experience (MAUDE) Database

Brand Name	ULTAMET MOM INSRT 620DX36ID
Type of Device	TOTAL HIP REPLACEMENT
Baseline Brand Name	ULTAMET MOM INSERT 62ODX36ID
Baseline Generic Name	PINNACLE METAL ON METAL ACETABULAR CUP
Baseline Catalogue Number	121887362
Baseline Device Family	ULTAMET MOM INSERT
Baseline Device 510(K) Number	K003523
Baseline Shelf Life Information	No
Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	12/13/2000
Manufacturer *(Section F)*	DEPUY ORTHOPAEDICS, INC. 700 Orthopaedic Dr. P.O. Box 988 Warsaw IN 46581 0988
Manufacturer *(Section D)*	DEPUY ORTHOPAEDICS, INC. 700 Orthopaedic Dr. P.O. Box 988 Warsaw IN 46581 0988
Manufacturer *(Section G)*	DEPUY ORTHOPAEDICS, INC. 700 Prthopaedic Drive Warsaw IN 46581 0988
Manufacturer Contact	Hans Kusserow, Mgr. 700 Orthopaedic Drive Warsaw , IN 46581-0988 (574) 372 -7416
Device Event Key	495817
MDR Report Key	506895
Event Key	480781

Report Number	1818910-2004-00044
Device Sequence Number	1
Product Code	KWA
Report Source	Manufacturer
Source Type	Health Professional,Distributor
Remedial Action	Other
Event Type	Injury
Type of Report	Initial
Report Date	12/19/2003
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	01/16/2004
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	Yes
Device Operator	Health Professional
Device Catalogue Number	121887362
Device LOT Number	YHT84
Was Device Available For Evaluation?	Yes
Is The Reporter A Health Professional?	Yes
Was the Report Sent to FDA?	No
Event Location	Hospital
Date Manufacturer Received	12/19/2003
Was Device Evaluated By Manufacturer?	Yes
Date Device Manufactured	03/01/2002
Is The Device Single Use?	Yes
Type of Device Usage	Initial
Patient Outcome	Required Intervention

Adverse Event or Product Problem Description
Report Date: 12/19/2003 MDR Text Key: 1751674 Patient Sequence Number: 1
Metal insert did not seat properly. Surgery was extended by 30 minutes due to the product problem.

Additional Manufacturer Narrative
Report Date: 12/19/2003 MDR Text Key: 1751677
This complaint is still under investigation. Depuy will notify the fda of the results of this investigation once it has been completed.

Database contains data received through March 30, 2004

Center for Devices and Radiological Health / CDRH

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New Search Back To Search Results

Manufacturer and User Facility Device Experience (MAUDE) Database

Brand Name	SROM INS M28 10DEG 28MM C
Type of Device	TOTAL HIP PROSTHESIS
Baseline Brand Name	SROM INS M28 10DEG 28MM C
Baseline Generic Name	SROM INSERT
Baseline Catalogue Number	552710
Baseline Device Family	SROM INSERT 10 DEGREE
Baseline Device 510(K) Number	K924492
Baseline Shelf Life Information	No
Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	11/24/1992
Manufacturer *(Section F)*	DEPUY ORTHOPAEDICS, INC. 700 Orthopaedic Dr. Warsaw IN 46581 0988
Manufacturer *(Section D)*	DEPUY ORTHOPAEDICS, INC. 700 Orthopaedic Dr. Warsaw IN 46581 0988
Manufacturer *(Section G)*	DEPUY ORTHOPAEDICS, INC. 700 Orthopaedic Dr Warsaw IN 46581 0986
Manufacturer Contact	Hans Kusserow, Mgr. 700 Orthopaedic Drive Warsaw , IN 46581-0988 (574) 372 -7416
Device Event Key	494588

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MDR Report Key	505719
Event Key	479649
Report Number	1818910-2004-00050
Device Sequence Number	1
Product Code	KWA
Report Source	Manufacturer
Source Type	Health Professional,Distributor
Remedial Action	Other
Event Type	Injury
Type of Report	Initial
Report Date	12/10/2003
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	01/09/2004
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	Yes
Device Operator	Health Professional
Device Catalogue Number	552710
Was Device Available For Evaluation?	Yes
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Distributor Facility Aware Date	12/10/2003
Device Age	unknown
Event Location	Hospital
Date Manufacturer Received	12/10/2003
Was Device Evaluated By Manufacturer?	Yes
Is The Device Single Use?	Yes
Type of Device Usage	Initial
Patient Outcome	Required Intervention

Adverse Event or Product Problem Description
Report Date: 12/10/2003 MDR Text Key: 1747829 Patient Sequence Number: 1
Ring broken, worn liner. Revised liner only to non-constrained.

Additional Manufacturer Narrative
Report Date: 12/10/2003 MDR Text Key: 1747832
The investigation could not firmly establish a root cause for the event. Based on the investigation, this is the first reported complaint of wear or breakage against this

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product code, and as such, the need for corrective action has not been indicated. Should additional info related to this event be rec'd, the investigation will re-open. Depuy considers the investigation closed at this time.

Database contains data received through June 29, 2004

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New Search Back To Search Results

Manufacturer and User Facility Device Experience (MAUDE) Database

Brand Name	S-ROM INSERT L32, 10DEG., 32MM C
Type of Device	TOTAL HIP REPLACEMENT
Baseline Brand Name	S-ROM INSERT L32, 10 DEG., 32MM C
Baseline Generic Name	SROM INSERT
Baseline Catalogue Number	521632
Baseline Device Family	SROM INSERT
Baseline Device 510(K) Number	K924492
Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	11/24/1992
Manufacturer *(Section F)*	DEPUY-RAYNHAM A DIV OF DEPUY ORTHOPAEDICS, INC. 325 Paramount Dr Raynham MA 02767 0350
Manufacturer *(Section D)*	DEPUY-RAYNHAM A DIV OF DEPUY ORTHOPAEDICS, INC. 325 Paramount Dr Raynham MA 02767 0350
Manufacturer *(Section G)*	DEPUY ORTHOPAEDICS, INC. 325 Paramount Dr Raynham MA 02767 0350
Manufacturer Contact	Hans Kusserow, Mgr. 700 Orthopaedic Drive Warsaw , IN 46581-0988 (574) 372 -7416

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Device Event Key	501622
MDR Report Key	512613
Event Key	486353
Report Number	1818910-2004-00147
Device Sequence Number	1
Product Code	KWA
Report Source	Manufacturer
Source Type	Health Professional,Other
Remedial Action	Other
Event Type	Injury
Type of Report	Initial
Report Date	02/10/2004
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	02/24/2004
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	Yes
Device Operator	Health Professional
Device Catalogue Number	521632
Device LOT Number	SSC100739
Was Device Available For Evaluation?	No
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Distributor Facility Aware Date	02/10/2004
Device Age	7 yr
Event Location	Hospital
Date Manufacturer Received	02/10/2004
Was Device Evaluated By Manufacturer?	Device Not Returned To Manufacturer
Date Device Manufactured	04/01/1994
Is The Device Single Use?	Yes
Type of Device Usage	Initial

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Patient Outcome Required Intervention

Adverse Event or Product Problem Description
Report Date: 02/10/2004 MDR Text Key: 1770308 Patient Sequence Number: 1
Attorney reports this pt was revised due to premature polyethylene failure.

Additional Manufacturer Narrative
Report Date: 02/10/2004 MDR Text Key: 1770311
This complaint is still under investigation. Depuy will notify the fda of the results of this investigation once it has been completed.

Database contains data received through June 29, 2004

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New Search Back To Search Results

Manufacturer and User Facility Device Experience (MAUDE) Database

Brand Name	ALPHA MTSL 28 STD JJ/28
Type of Device	HIP PROSTHESIS
Baseline Brand Name	ALPHA MTSL 28 STD JJ/28
Baseline Generic Name	HIP PROSTHESIS
Baseline Catalogue Number	01.00010.410
Baseline Device Family	NA
Baseline Device 510(K) Number	K003758
Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	03/07/2001
Manufacturer *(Section F)*	CENTERPULSE ORTHOPEDICS LTD. Po Box Ch-8404 Winterthur SWITZERLAND
Manufacturer *(Section D)*	CENTERPULSE ORTHOPEDICS LTD. Po Box Ch-8404 Winterthur SWITZERLAND
Manufacturer Contact	Ron Yarbrough, Supervisor 9900 Spectrum Drive Austin , TX 78717 (512) 432 -9437
Device Event Key	434498

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MDR Report Key	445528
Event Key	421802
Report Number	9613350-2003-00003
Device Sequence Number	1
Product Code	KWA
Report Source	Manufacturer
Source Type	Company Representative
Remedial Action	Replace
Event Type	Injury
Type of Report	Initial
Report Date	02/13/2003
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	02/28/2003
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	01.00010.410
Device LOT Number	B661398
Was Device Available For Evaluation?	No
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Date Manufacturer Received	02/13/2003
Was Device Evaluated By Manufacturer?	Device Not Returned To Manufacturer
Is The Device Single Use?	Yes
Type of Device Usage	Initial
Patient Outcome	Hospitalization Required Intervention

Adverse Event or Product Problem Description
Report Date: 02/13/2003 MDR Text Key: 1545615 Patient Sequence Number: 1
Revision.

Additional Manufacturer Narrative
Report Date: 02/13/2003 MDR Text Key: 1545618
This investigation is considered closed. If any pertinent information becomes available this investigation will be reevaluated at that time.

Database contains data received through June 29, 2004

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New Search Back To Search Results

Manufacturer and User Facility Device Experience (MAUDE) Database

Brand Name	S-ROM INSERT M26, 15DEG, 26MM
Type of Device	TOTAL HIP REPLACEMENT
Baseline Brand Name	S-ROM INSERT M28, 15DEG, 26MM
Baseline Generic Name	S-ROM INSERT
Baseline Catalogue Number	551946
Baseline Device Family	S-ROM INSERT
Baseline Device 510(K) Number	K924492
Baseline Shelf Life Information	No
Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	11/24/1992
Manufacturer *(Section F)*	DEPUY ORTHOPAEDICS, INC. 700 Orthopaedic Dr. Warsaw IN 46581 0988
Manufacturer *(Section D)*	DEPUY ORTHOPAEDICS, INC. 700 Orthopaedic Dr. Warsaw IN 46581 0988
Manufacturer *(Section G)*	DEPUY ORTHOPAEDICS, INC. 700 Orthopaedics Drive Warsaw IN 46581 0988
Manufacturer Contact	Hans Kusserow, Mgr. 700 Orthopaedic Drive Warsaw , IN 46581-0988 (574) 372 -7416
Device Event Key	515787

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MDR Report Key	526619
Event Key	499874
Report Number	1818910-2004-00385
Device Sequence Number	1
Product Code	KWA
Report Source	Manufacturer
Source Type	Distributor
Remedial Action	Other
Event Type	Malfunction
Type of Report	Initial
Report Date	05/19/2004
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	05/25/2004
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	551946
Device LOT Number	SC104521
Was Device Available For Evaluation?	No
Is The Reporter A Health Professional?	No Answer Provided
Was the Report Sent to FDA?	No
Distributor Facility Aware Date	05/19/2004
Device Age	unknown
Event Location	Hospital
Date Manufacturer Received	05/19/2004
Was Device Evaluated By Manufacturer?	Device Not Returned To Manufacturer
Is The Device Single Use?	Yes
Type of Device Usage	Initial
Patient Outcome	Required Intervention

Adverse Event or Product Problem Description
Report Date: 05/19/2004 MDR Text Key: 1818260 Patient Sequence Number: 1
Surgeon claims polyethylene wear started to appear on x-rays 3 years after tha.

Additional Manufacturer Narrative
Report Date: 05/19/2004 MDR Text Key: 1818263
This complaint is still under investigation. Depuy will notify the fda of the results of

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this investigation once it has been completed. This complaint originated in japan. Therefore, we only have the hospital name.

Database contains data received through June 29, 2004

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New Search Back To Search Results

Manufacturer and User Facility Device Experience (MAUDE) Database

Brand Name	ACET INS SZ 28X49 METASUL-APR
Type of Device	HIP PROSTHESIS
Baseline Brand Name	ACET INS SZ 28X49 METASUL-APR
Baseline Generic Name	HIP PROSTHESIS
Baseline Catalogue Number	4340-28-049
Baseline Device Family	NA
Baseline Device 510(K) Number	K993569
Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	12/01/1999
Manufacturer *(Section F)*	ZIMMER AUSTIN, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer *(Section D)*	ZIMMER AUSTIN, INC. 9900 Spectrum Dr. Austin TX 78717
Manufacturer *(Section G)*	ZIMMER AUSTIN, INC. 9900 Spectrum Dr Austin TX 78717
Manufacturer Contact	Jim Gonzales, Supervisor 9900 Spectrum Dr Austin , TX 78717 (512) 432 -9688
Device Event Key	520393
MDR Report Key	531144

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Event Key	504236
Report Number	2935620-2004-00061
Device Sequence Number	1
Product Code	KWA
Report Source	Manufacturer
Source Type	Company Representative
Remedial Action	Replace
Event Type	Injury
Type of Report	Initial
Report Date	06/24/2004
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	06/24/2004
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	4340-28-049
Device LOT Number	11/87758
Was Device Available For Evaluation?	Device Not Returned To Manufacturer
Date Returned to Manufacturer	06/21/2004
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Date Manufacturer Received	06/21/2004
Was Device Evaluated By Manufacturer?	No
Date Device Manufactured	09/01/1995
Is The Device Single Use?	Yes
Type of Device Usage	Initial
Patient Outcome	Hospitalization

Adverse Event or Product Problem Description
Report Date: 06/24/2004 MDR Text Key: 1834094 Patient Sequence Number: 1
It was reported: pt was revised in 2004.

Patient TREATMENT DATA

Date Received: 06/24/2004 Patient Sequence Number: 1

#	Treatment	Treatment Date
1,4310-02-049 12 SLOT SHELL 49MM APR II(LOT#1202344),		

2,(2004),

3,3461 AP BALL HEAD MED 28/14(LOT#95336363),

4,(2004).,

Database contains data received through June 29, 2004

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Class III Device Summary

Metal on Metal Articulating Surfaces

II. Literature Review of Risks Associated with Metal on Metal Articulating Surfaces

The following is a list of types of safety and effectiveness concerns/issues associated with the metal on metal total hip arthroplasty reported in published literature. Refer to following pages for the Bibliography of Abstracts, followed by copies of the abstract.

1. Radiological changes
2. Fretting corrosion
3. Aseptic loosening
4. Elevated serum levels of Cobalt and/or Chromium (significance unknown)
5. Pain
6. Dislocation
7. Revision
8. Septic loosening
9. Periarticular ossification
10. Elevated erythrocytes and urine metal ions
11. Early loosening
12. Infection
13. Calcar resorption
14. Artifact arising from metal hardware
15. Ectopic ossification
16. Progressive cement/bone interface radiolucencies
17. Cancer risk (increased risk not established)
18. Metal sensitivity
19. Metal wear debris

METAL ON METAL TOTAL HIP ARTHROPLASTY
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1: Ann Chim. 2003 Jan-Feb;93(1-2):1-10.

Cobalt blood levels after total hip replacement (THR): a new follow-up study in Trieste (Italy).

Adami G, Smarrelli D, Martinelli B, Acquavita A, Reisenhofer E.

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Cobalt and chromium release in patients undergone a metal-on-metal total hip replacement (THR) is a matter recently discussed and whose we do not have enough information about it yet. In literature there is little data and not completely indicative, in the biological fluids and organs the amounts of released metals are different. This is also due to the fact that cobalt and chromium blood levels can change depending on physical and working activity, individual feeding and metabolism. The results obtained confirm the presence of an increase of cobalt inthe blood of patients after total hip replacement, while the chromium levels are almost alike: average values in patients operated are 4.1 +/- 1.5 microg/L for cobalt (0.3 +/- 0.1 microg/L in the control group) and 4.5 +/- 2.9 microg/L for chromium (4.7 +/- 2.4 microg/L in the control group). In spite of the cobalt values stand below the concentration generally considered dangerous, the difference between the two examined groups points out that a risk exists for the health of these patients. These results must be confirmed by further studies, providing better information and more reliable and biocompatible materials.

PMID: 12650568 [PubMed - indexed for MEDLINE]

1: Clin Orthop. 1996 Aug;(329 Suppl):S297-303.

Metal on metal total hip replacement workshop consensus document.

Amstutz HC, Campbell P, McKellop H, Schmalzreid TP, Gillespie WJ, Howie D, Jacobs J, Medley J, Merritt K.

Joint Replacement Institute, Los Angeles, CA, USA.

The objective of this workshop was to provide a forum to discuss the reintroduction of metal on metal bearings for clinical use in total hip arthroplasty. Approximately 100 researchers clinicians, and industry representatives presented the state of the art interpretation of the metal on metal total hip replacement's past performance, and the clinical, tribologic, and biologic considerations of all metal bearings. Based on the scientific presentations at the symposium, the extant literature, the clinical experience of the panelists, and the current regulatory, legal, and economic environment, consensus statements were developed.

PMID: 8769344 [PubMed - indexed for MEDLINE]

1: Clin Orthop. 1996 Aug;(329 Suppl):S11-34.

Comment in:
- Clin Orthop. 1997 Jul;(340):283-4.

Metal on metal bearings in hip arthroplasty.

Amstutz HC, Grigoris P.

Joint Replacement Institute, Orthopaedic Hospital, Los Angeles, CA, USA.

Periprosthetic osteolysis caused by wear debris released from the bearing surface of polyethylene components is the major problem in contemporary hip arthroplasty. Several types of metal on metal prostheses were developed in the 1960s, but by the mid 1970s they were completely displaced by polyethylene bearings. There have been several generations of all metal components with significant variation in design, tolerances, and bearing surface quality. A number of these hips have survived for more than 25 years because of low wear rates and minimal osteolysis. Identification of the characteristics that contributed to long term function is important. The historical development and clinical results of metal on metal hip arthroplasties are presented. Factors that led to the abandonment of the metal on metal bearings are related to: (1) the early success of the Charnley prosthesis; (2) the frictional torque issue; (3) carcinogenesis concerns; (4) metal sensitivity concerns; (5) high infection rates; and (6) increased strain rates in periprosthetic bone and fatigue fractures of the acetabular floor. The accumulated experience to date enables one to evaluate all the factors with a different perspective and makes the use of newer metal on metal bearings a viable option in younger patients.

Publication Types:
- Review
- Review, Multicase

PMID: 8769320 [PubMed - indexed for MEDLINE]

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1: Clin Orthop. 1985 Dec;(201):111-22.

Long-term review of ring total hip arthroplasty.

Andrew TA, Berridge D, Thomas A, Duke RN.

In a five- to 12-year follow-up survey of 179 sequential cementless Ring metal-on-metal total hip arthroplasties, 55 (31%) of the patients were found to have died as a result of nonorthopedic conditions. Analysis of the records demonstrated that 20% of these patients had had poor results attributable to pain. Of the remaining 124 patients, 116 (94%) attended for full clinical and radiologic review yielding a total of 154 hips. Using Ring's classification, 75 hips were judged to have excellent or good results. Forty-one hips were graded as fair or poor as a result of pain, and an additional 15 hips were revised for symptomatic loosening. There were five cases of Brooker Grade IV periarticular ossification, four cases of gross metal reaction requiring prosthetic removal, and two cases of infection. There was considerable variation in the radiographic appearance of the hips, and at times radiographic changes were inconsistent with clinical symptoms. Eleven of the revised hips were converted to longer and larger-diameter uncemented Ring femoral components. Nine of these yielded only fair or poor results at the time of review, whereas both cases in which the femoral component was cemented were associated with good results.

PMID: 4064395 [PubMed - indexed for MEDLINE]

1: Acta Orthop Scand. 1999 Dec;70(6):578-82.

Metal-on-metal bearing in hip prosthesis generates 100-fold less wear debris than metal-on-polyethylene.

Anissian HL, Stark A, Gustafson A, Good V, Clarke IC.

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Aseptic loosening due to osteolysis in total hip replacement has been related to wear debris released from prosthetic components. Retrospective longterm observations of patients with the metal-on-metal prosthesis has shown long-term survivorship and good mechanical performance. Thus, the new and modified metal-on-metal prosthesis has been introduced on the market. Historical clinical data from the 1st generation metal-on-metal hip prosthesis may not be relevant for the 2nd generation of metal-on-metal hip prosthesis. Therefore, preclinical testing of the prosthesis must be conducted before clinical evaluation. We assessed the tribological performance of the metal-on-metal prosthesis versus the metal-on-polyethylene prosthesis introduced on the market as Metasul and Protasul, respectively. In a 12-channel joint simulator, 6 metal-on-metal bearing and 3 metal on polyethylene prostheses were tested, with the same number of corresponding soak controls. The wear was assessed gravimetrically. The "steady-state" wear-rates from the metal-on-metal prosthesis were almost 100 times less than that from the metal-on-polyethylene prosthesis. The tribological wear performance of the metal-on-metal hip prosthetic system is promising.

PMID: 10665722 [PubMed - indexed for MEDLINE]

1: Clin Orthop. 2000 Oct;(379):12-21.

LWWonline Lippincott Williams & Wilkins

Alternate bearing surfaces in total joint arthroplasty: biologic considerations.

Archibeck MJ, Jacobs JJ, Black J.

Department of Orthopaedic Surgery, Rush-Presbyterian-St Luke's Medical Center, Chicago, IL 60612, USA.

The problem of periprosthetic osteolysis is currently the major limiting factor in joint arthroplasty longevity. Because this process has been shown to be primarily a biologic response to wear particles, corrosion products, or both, efforts to reduce particle generation are being undertaken. These efforts include the development of modified polyethylene and alternative articulating surfaces. These alternate bearing surfaces currently include ceramic-on-polyethylene, ceramic-on-ceramic, and metal-on-metal. Although these alternate bearings diminish or eliminate the generation of polyethylene particles, ceramic and metal particles are produced. The purpose of the current review is to discuss the literature that addresses the biologic response to these particles, locally and systemically.

Publication Types:
- Review
- Review, Academic

PMID: 11039787 [PubMed - indexed for MEDLINE]

Display Abstract Show: 20 Sort Send to Text

1: J Bone Joint Surg Br. 1986 Aug;68(4):520-7.

The McKee-Farrar hip arthroplasty. A long-term study.

August AC, Aldam CH, Pynsent PB.

Between 1965 and 1973 a total of 808 McKee-Farrar metal-on-metal cemented total hip arthroplasties were performed in the Norfolk and Norwich Hospital. Of these, 230 surviving arthroplasties have been reviewed at average follow-up of 13.9 years. There were good or excellent results in 49% of the arthroplasties as judged by the Harris hip score with 78% of these having little or no pain. A comprehensive radiographic analysis was undertaken and a survivorship study of 81% of the total number of prostheses is presented.

PMID: 3733823 [PubMed - indexed for MEDLINE]

Display Abstract Show: 20 Sort Send to Text

1: Clin Orthop. 2004 Jan;(418):87-93.

LWWonline Lippincott Williams & Wilkins

Risk factors affecting outcome of metal-on-metal surface arthroplasty of the hip.

Beaule PE, Dorey FJ, LeDuff M, Gruen T, Amstutz HC.

David Geffen School of Medicine at UCLA, Joint Replacement Institute at Orthopaedic Hospital, Los Angeles, CA 90007, USA. pbeaule@mednet.ucla.edu

We evaluated radiologic and clinical features affecting the outcome of hybrid metal-on-metal surface arthroplasty of the hip in 119 hips in patients 40 years and younger. Only the hips that had either failed or had minimum 2-year followup were reviewed. Ninety-four hips in 83 patients with a mean age of 34.2 years (range, 15-40 years) were reviewed. Seventy-one percent of the patients were males and 29% of the patients were females; 14% had previous surgery. The Chandler index and surface arthroplasty risk index were calculated. The mean followup at 3 years (range, 2-5 years) showed that three hips were converted to a total hip replacement at a mean of 27 months (range, 2-50 months) after the original surgery, and 10 hips had significant radiologic changes. The mean surface arthroplasty risk index for these 13 problematic hips versus the remaining hips was significantly higher, 4.7 and 2.6, respectively. The mean angle between the prosthesis stem and femoral shaft in the problematic group was significantly smaller than in the remaining hips: 133 degrees and 139 degrees, respectively. With a surface arthroplasty risk index score greater than 3 the relative risk of early problems is 12 times greater than if surface arthroplasty risk index less than or equal to 3.

PMID: 15043098 [PubMed - in process]

Display Abstract Show: 20 Sort Send to Text

Related Articles, Links

1: Br Med J. 1975 Nov 15;4(5993):374-5.

Metal sensitivity in patients with joint replacement arthroplasties.

Benson MK, Goodwin PG, Brostoff J.

A high incidence of unexpected metal sensitivity was found in patients with metal-to-metal (McKee) hip arthroplasties. Patients with metal-to-plastic (Charnley) prostheses had no greater incidence of metal sensitivity than a control group awaiting operation. If metal sensitivity does occur loosening of the prosthesis may be a complication.

PMID: 1192078 [PubMed - indexed for MEDLINE]

Display Abstract Show: 20 Sort Send to Text

1: Proc Inst Mech Eng [H]. 2001;215(6):543-8.

Contact mechanics of a novel metal-on-metal total hip replacement.

Besong AA, Lee R, Farrar R, Jin ZM.

Department of Mechanical and Medical Engineering, University of Bradford, UK.

The contact mechanics of a novel metal-on-metal total hip replacement (THR) were investigated in this study. The metal-on-metal prosthesis considered consists of a cobalt-chrome acetabular insert connected to a titanium shell through a taper contact, articulating against a cobalt-chrome femoral head. Both the experimental measurement of the displacement of the acetabular insert and the contact area between the two bearing surfaces, and the corresponding numerical predictions using the finite element method have been conducted. Excellent agreement has been demonstrated between the experimental measurement and the finite element prediction under various loads up to 3 kN. The maximum contact pressure at the articulating surfaces has been predicted to be about 31 MPa from a simple axisymmetric finite element model, significantly lower than that of a similar cup but with a monoblock construct. This has been mainly attributed to the flexibility of the insert, leading to an increase in the conformity between the femoral head and the acetabular insert. In addition, the predicted maximum contact pressure is only slightly increased to 37 MPa, from a more realistic three-dimensional anatomical finite element model. The design features on metal-on-metal THRs have been shown to reduce contact stresses and may improve tribological performances of these hard-on-hard bearing couples.

PMID: 11848386 [PubMed - indexed for MEDLINE]

1: Clin Orthop. 1996 Aug;(329 Suppl):S244-55.

Metal on metal bearings. A practical alternative to metal on polyethylene total joints?

Black J.

IMN Biomaterials, King of Prussia, PA, USA.

Metal on metal articulation is proposed as an alternative to metal on polymer in total hip replacement arthroplasty as a technical means of reducing wear debris production and subsequent osteolysis leading to the need for surgical revision. The question of whether metal on metal articulation is a practical alternative to current practice is essentially that of whether it is as safe as, and more effective than, metal on polymer articulations in use for more than 20 years. Unfortunately, the metal on metal articulation introduces additional biologic risks associated with production of increased metallic corrosion and wear products. The clinical longevity and success of metal on polymer articulation in total hip replacements, as embodied in the Charnley type, is such that it may prove humanly impossible to determine that metal on metal articulations are more effective, even if that is objectively the case. Therefore, it is suggested that, consistent with modern technical and ethical standards, it cannot be concluded that metal on metal articulation is a practical alternative to current metal on polymer designs. It is suggested that future improvement in total hip replacement arthroplasty outcome is more likely to be through evolutionary than revolutionary designs.

PMID: 8769338 [PubMed - indexed for MEDLINE]

1: Acta Orthop Belg. 1997;63 Suppl 1:96-7.

Experiences with metal on metal components in THR.

Boehler N.

It can be stated that polyethylene wear can be shown as a problem in long term joint replacement. Metal-on-metal bearings are solving this problem as long term clinical and experimental investigations can demonstrate. To avoid the problem of high friction that was found to be a problem in older series, a new technique called Metasul with smaller diameter was invented. Intermediate results of Weber and our own data are showing promising results giving us the hope to solve the wear induced problem in hip replacement.

PMID: 9532860 [PubMed - indexed for MEDLINE]

1: J Bone Joint Surg Br. 2002 Jan;84(1):128-36.

Adverse tissue reactions to wear particles from Co-alloy articulations, increased by alumina-blasting particle contamination from cementless Ti-based total hip implants. A report of seven revisions with early failure.

Bohler M, Kanz F, Schwarz B, Steffan I, Walter A, Plenk H Jr, Knahr K.

Institute for Histology and Embryology, Vienna, Austria.

We revised seven alumina-blasted cementless hip prostheses (Ti-alloy stems, cp Ti threaded sockets) with low- or high-carbon Co-alloy bearings at a mean of 20.1 months after implantation because of pain and loosening. Histological examination of the retrieved periprosthetic tissues from two cases in which the implant was stable and three in which the socket was loose showed macrophages with basophilic granules containing metal and alumina wear particles and lymph-cell infiltrates. In one of the two cases of stem loosening the thickened neocapsule also contained definite lymphatic follicles and gross lymphocyte/plasma-cell infiltrates. Spectrometric determination of the concentration of elements in periprosthetic tissues from six cases was compared with that of joint capsules from five control patients undergoing primary hip surgery. In the revisions the mean concentration of implant-relevant elements was 693.85 microg/g dry tissue. In addition to Cr (15.2%), Co (4.3%), and Ti (10.3%), Al was predominant (68.1%) and all concentrations were significantly higher ($p < 0.001$) than those in the control tissues. The annual rates of linear wear were calculated for six implants. The mean value was 11.1 microm (heads 6.25 microm, inserts 4.82 microm). SEM/EDXA showed numerous fine scratches and deep furrows containing alumina particles in loosened sockets, and stems showed contamination with adhering or impacted alumina particles of between 2 and 50 microm in size.

PMID: 11837818 [PubMed - indexed for MEDLINE]

1: Orthopedics. 1995 Sep;18(9):879-80.

Metal/metal articulating interfaces.

Bohler N.

Allg Offentl Krankenhaus, Stadt Linz Orthopaedische Abteilung, Austria.

Polyethylene wear can be shown as a problem in long-term joint replacement. Metal-on-metal bearing is solving this problem, as long-term clinical and experimental investigations demonstrate. To avoid the problem of high friction found in old series, a new Metasul called technique with a smaller diameter was invented. Intermediate results of Weber and our own data show promising outlook for a solution to the wear-induced problem in hip replacement.

PMID: 8570496 [PubMed - indexed for MEDLINE]

1: J Bone Joint Surg Am. 2003 Nov;85-A(11):2168-73.

Serum cobalt levels after metal-on-metal total hip arthroplasty.

Brodner W, Bitzan P, Meisinger V, Kaider A, Gottsauner-Wolf F, Kotz R.

Department of Orthopaedics, Vienna General Hospital, University of Vienna, Austria. wolfram.brodner@akh-wien.ac.at

BACKGROUND: Systemic cobalt dissemination from the Metasul Co-28Cr-6Mo-0.2C metal-on-metal total hip prosthesis has been demonstrated in the first year after implantation. The aim of this prospective study was to monitor the serum cobalt concentrations in patients during the first five years after total hip arthroplasty with a metal-on-metal articulation. METHODS: A total hip arthroplasty was performed without cement in 100 consecutive patients who had either unilateral osteoarthritis or unilateral osteonecrosis. Fifty patients were randomized to be treated with a metal-on-metal articulation, and fifty patients, with a ceramic-on-polyethylene bearing. The femoral stem was made of a Ti-6Al-7Nb alloy, and the threaded acetabular cup was made of commercially pure titanium. Blood samples were taken before the operation and at multiple time-points for five years after the operation. Serum cobalt concentrations were measured with use of atomic absorption spectrometry. RESULTS: In the metal-on-metal group, the median serum cobalt concentration was 1 micro g/L at one year after surgery and 0.7 micro g/L at five years. The median of the serum cobalt concentrations measured from three to twelve months did not differ from the median of subsequent measurements, with the numbers available. The median serum cobalt level in the control group of patients treated with the ceramic-on-polyethylene articulation was below the detection limit at all time-points. CONCLUSIONS: Systemic cobalt release from Metasul metal-on-metal articulations was demonstrated throughout the five-year study period. The median serum cobalt concentrations were found to be slightly above the detection limit and remained in a constant range. The serum cobalt concentrations did not reflect a so-called run-in wear period of the metal-on-metal articulations.

Publication Types:
- Clinical Trial
- Randomized Controlled Trial

PMID: 14630848 [PubMed - indexed for MEDLINE]

1: J Bone Joint Surg Br. 1997 Mar;79(2):316-21.

Erratum in:
- J Bone Joint Surg Br 1997 Sep;79(5):885.

Elevated serum cobalt with metal-on-metal articulating surfaces.

Brodner W, Bitzan P, Meisinger V, Kaider A, Gottsauner-Wolf F, Kotz R.

Department of Occupational Medicine, University of Vienna, Austria.

We determined serum cobalt levels in 55 patients by atomic absorption spectrophotometry before and after implantation of uncemented total hip arthroplasties. In a randomised, prospective trial 27 wrought Co-28Cr-6Mo-0.2C metal-on-metal articulations were compared with 28 ceramic-on-polyethylene hips which did not contain cobalt. Other sources of iatrogenic cobalt loading were excluded. The metal-on-metal group produced detectable serum cobalt levels (median 1.1 microg/l after one year) which were significantly different ($p < 0.0001$) from those of the ceramic-on-polyethylene control group (median below detection limit of 0.3 microg/l after one year). Our findings indicate that metal-on-metal bearings generate some systemic release of cobalt.

Publication Types:
- Clinical Trial
- Randomized Controlled Trial

PMID: 9119865 [PubMed - indexed for MEDLINE]

1: Z Orthop Ihre Grenzgeb. 2000 Sep-Oct;138(5):425-9.

[Serum cobalt and serum chromium level in 2 patients with chronic renal failure after total hip prosthesis implantation with metal-metal gliding contact]

[Article in German]

Brodner W, Grohs JG, Bitzan P, Meisinger V, Kovarik J, Kotz R.

Universitatsklinik fur Orthopadie, AKH Wien. wolfram.brodner@akh-wien.ac.at

PURPOSE: The influence of chronic renal failure on serum cobalt and serum chromium in two patients with metal-on-metal bearing (Metasul) and cementless total hip arthroplasty (Alloclassic) is investigated. METHODS: Serum cobalt and serum chronium levels were determined in the postoperative course using atomic absorption spectrometry. RESULTS: Maximum values are found to be more than 100-fold elevated when compared to the reported median serum cobalt concentrations in patients with the same prosthesis type and no known renal disease. CONCLUSION: Chronic renal failure seems to be responsible for the marked elevation of serum cobalt and serum chromium. CLINICAL RELEVANCE: Despite evidence of adverse health reactions, a possible effect of long-term cobalt and chromium loading cannot be neglected. In our opinion, metal-on-metal bearings in THA should not be inserted in patients with chronic renal failure. Follow-up investigations (serum cobalt, serum chromium, serum creatinine, BUN, echocardiography) should be performed at short intervals.

PMID: 11084743 [PubMed - indexed for MEDLINE]

1: Biomaterials. 2000 Feb;21(4):385-92.

ELSEVIER FULL-TEXT ARTICLE

Effect of mechanical surface pretreatment on metal ion release.

Browne M, Gregson PJ.

School of Engineering Sciences, Materials Group, University of Southampton, UK.

The degree of metal ion dissolution from Ti-6Al-4V alloy hip replacement stems subjected to various mechanical and chemical surface pretreatments was analysed in vitro. High-dissolution rates were observed for nitric acid passivated samples that had been mechanically surface treated to increase the implant surface area. Significantly lower ion release levels were observed for mechanically treated samples which had been aged in de-ionised water. The application of an hydroxyapatite coating decreased the metal ion release from the nitric acid passivated samples (compared to the uncoated sample) and increased the metal ion dissolution from the aged samples. The dissolution behaviour of the samples is explained in terms of the diffusion processes occurring at the stem/solution interface and the morphological and chemical characteristics of the surface treated stems.

PMID: 10656320 [PubMed - indexed for MEDLINE]

1: J Arthroplasty. 1991;6 Suppl:S5-10.

Survivorship analysis of the Ring hip arthroplasty.

Bryant MJ, Mollan RA, Nixon JR.

Department of Orthopaedic Surgery, Musgrave Park Hospital, Belfast, Northern Ireland.

Two hundred fifty-three Ring mark 2 metal-on-metal hip arthroplasties performed between 1968 and 1974 were evaluated using survivorship analysis. Using revision as the criterion for failure, the authors found a cumulative survival rate of 60.4% after 21 years. The results are compared with data from previous studies that used survivorship analysis for metal-on-metal hip arthroplasties, and it is shown that the Ring hip arthroplasty performed as well as the McKee-Farrar prosthesis and better than the Stanmore prosthesis.

PMID: 1774571 [PubMed - indexed for MEDLINE]

1: Acta Orthop Scand. 2002 Oct;73(5):506-12.

Positive cytokine production in failed metal-on-metal total hip replacements.

Campbell PA, Wang M, Amstutz HC, Goodman SB.

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Tissues surrounding failed conventional total hips have been shown to produce inflammatory cytokines that can induce osteoclastic bone resorption. We evaluated the cytokine profiles of tissues from 5 failed metal-on-metal total hip replacements. Serial frozen sections were stained using immunohistochemical and in situ hybridization techniques. Inflammatory and osteoclast-stimulating cytokines were noted in the tissues. As compared to a group of 5 metal-polyethylene hip tissues, we found fewer CD68 positive macrophages, and lower levels of TGF-beta and TNF-alpha, but no differences in CD3 positive lymphocytes, IL-1beta, IL-6 and PDGF-alpha in the metal-on-metal tissues. This may be due, in part to the presence of wear particles from sources other than the bearing surfaces. Thus, cytokines associated with bone resorption and implant loosening may occur in total hips despite the use of alternative bearing materials.

PMID: 12440492 [PubMed - indexed for MEDLINE]

1: Clin Orthop. 1996 Dec;(333):96-107.

Engineering issues and wear performance of metal on metal hip implants.

Chan FW, Bobyn JD, Medley JB, Krygier JJ, Yue S, Tanzer M.

Jo Miller Orthopaedic Research Laboratory, Montreal General Hospital and McGill University, Quebec, Canada.

A major concern in total hip arthroplasty is the generation of polyethylene wear particles at the articulating surfaces and resulting macrophage mediated periimplant osteolysis. There is renewed interest in metal on metal bearings as a solution to this problem in view of their potential for greatly improved wear performance. Using a commercially available hip simulator, the wear performance of metal on metal femoral head and acetabular cup combinations was evaluated and various parameters affecting metal on metal implant wear were identified. Nine implants custom manufactured from 2 medical grades of CoCrMo alloy (ASTM F1537-95 and F75-92) were tested within bovine serum as the lubricant to 3 million cycles (equivalent to approximately 3 years of service in vivo). The progressive wear of the components was determined by gravimetric methods at approximately every 300,000 cycles. The wear rates were characterized by an initial period of accelerated wear after which a lower steady state wear rate was observed for subsequent cycles. The presence of calcium phosphate films on the component surfaces, the microstructure of the lower carbon, wrought alloy, and increased effective radii (decreased diametral clearances) were identified as factors that may be favorable to improved wear performance. The extent of the effect on wear of each parameter, however, cannot be discerned at this point and necessitates a study in which parametric changes are more tightly controlled. The present study suggests that the use of metal on metal articulating surfaces may mitigate the problem of osteolysis by offering improved wear performance.

PMID: 8981885 [PubMed - indexed for MEDLINE]

1: J Bone Joint Surg Br. 2003 Aug;85(6):913-7.

Levels of metal ions after small- and large-diameter metal-on-metal hip arthroplasty.

Clarke MT, Lee PT, Arora A, Villar RN.

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Metal-on-metal (MOM) bearings for hip arthroplasty are increasing in popularity. Concern remains, however, regarding the potential toxicological effects of the metal ions which these bearings release. The serum levels of cobalt and chromium in 22 patients who had undergone MOM resurfacing arthroplasty were compared with a matched group of 22 patients who had undergone 28 mm MOM total hip arthroplasty (THA). At a median of 16 months (7 to 56) after resurfacing arthroplasty, we found the median serum levels of cobalt and chromium to be 38 nmol/l (14 to 44) and 53 nmol/l (23 to 165) respectively. These were significantly greater than the levels after 28 mm MOM THA which were 22 nmol/l (15 to 87, $p = 0.021$) and 19 nmol/l (2 to 58, $p < 0.001$) respectively. Since the upper limit for normal patients without implants is typically 5 nmol/l, both groups had significantly raised levels of metal ions. MOM bearings of large diameter, however, result in a greater systemic exposure of cobalt and chromium ions than bearings of small diameter. This may be of relevance for potential long-term side-effects. It is not known to what extent this difference is due to corrosion of the surfaces of the component or of the wear particles produced.

PMID: 12931818 [PubMed - indexed for MEDLINE]

1: J Bone Joint Surg Br. 2003 Jul;85(5):650-4.

Dislocation after total hip replacement in relation to metal-on-metal bearing surfaces.

Clarke MT, Lee PT, Villar RN.

BUPA Cambridge Lea Hospital, Impington, England, UK.

Metal-on-metal (MOM) is a commonly used bearing notable for its 'suction fit' when lubricated. In this study, we examined the capacity for MOM bearings to protect against dislocation after total hip replacement (THR). We undertook a clinical investigation to compare the rate of dislocation of MOM bearings with those of ceramic-on-polyethylene (COP) bearings and found that one MOM bearing dislocated in a series of 109 hips (0.9%) compared with nine of 145 hips (6.2%) in the COP group ($p = 0.02$). We also performed an in vitro investigation comparing the peak forces generated during forced separation of the two bearings of the same dimensions at velocities from 1 to 50 cm/s. This revealed that the MOM bearing generated significant resistance to separation at all velocities (maximum mean 24 N), whereas the COP did not (maximum mean 1.9 N, $p < 0.001$). We conclude that MOM bearings are more stable to dislocation than COP bearings as a result of the interfacial forces provided by a thin, lubricating fluid.

PMID: 12892184 [PubMed - indexed for MEDLINE]

1: Ann Clin Lab Sci. 1996 Mar-Apr;26(2):139-46.

Cancer risk from orthopedic prostheses.

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Permanent replacement of joints damaged by fracture or arthritis has become common over the last 50 years. Vigilance over possible long-term adverse effects of metal prostheses is required. Some of the metal components are potentially carcinogenic. Prolonged contact of metal alloys with body fluids results in gradual corrosion of even the most inert metals. Three cohost studies of persons with a hip prosthesis have been reported; they provide direct, quantitative observations of cancer risk in a human population with hip prosthesis. The design and the results of these studies are similar. Combining the results sharpens the precision of risk estimates. Collectively, the studies examined cancer risk in 40,945 patients followed up for a mean 8.5 years after hip replacement. Overall, the relative risk of cancer was 1.02 (95 percent CI 1.00 to 1.05). There was an 8 percent excess of haemopoietic malignancy (leukaemia and lymphoma), with a total of 347 cases observed (RR 1.08, 95 percent CI 0.97 to 1.20). Significant deficits of cancers of the breast and large bowel were seen in the two smaller studies, but combined results from all three studies suggest the relative risk is close to unity. Cancer risk in the first 10 years after hip replacement was not different from that expected, but there was an excess of borderline statistical significance 10 or more years after surgery, with a relative risk of 1.08 (95 percent CI 1.00 to 1.13) based on 1,005 cases. All three studies were well-designed and executed. Their results are not alarming, but give no cause for complacency, since the number of patients with a prosthesis and the length of time they live with the prosthesis will increase. A register of malignancy complicating joint prosthesis would not help quantify any risk. Instead, a large cohort study of patients with joint prostheses is needed, including information on the type and composition of the prosthesis and on potential confounding exposures for each patient. Measures of corrosion in cancer cases and of tissue levels of relevant metal ions in cases and controls (prosthesis but no cancer) matched for age, sex, and time since insertion would be valuable. Such a study could be done internationally, using orthopedic units with good clinical records for 10 to 15 years in areas with long-term cancer registration.

PMID: 8852423 [PubMed - indexed for MEDLINE]

278

1: J Bone Joint Surg Br. 2004 Mar;86(2):177-84.

Metal-on-metal resurfacing of the hip in patients under the age of 55 years with osteoarthritis.

Daniel J, Pynsent PB, McMinn DJ.

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The results of conventional hip replacement in young patients with osteoarthritis have not been encouraging even with improvements in the techniques of fixation and in the bearing surfaces. Modern metal-on-metal hip resurfacing was introduced as a less invasive method of joint reconstruction for this particular group. This is a series of 446 hip resurfacings (384 patients) performed by one of the authors (DJWM) using cemented femoral components and hydroxyapatite-coated uncemented acetabular components with a maximum follow-up of 8.2 years (mean 3.3). Their survival rate, Oxford hip scores and activity levels are reviewed. Six patients died due to unrelated causes. There was one revision (0.02%) out of 440 hips. The mean Oxford score of the surviving 439 hips is 13.5. None of the patients were told to change their activities at work or leisure; 31% of the men with unilateral resurfacings and 28% with bilateral resurfacings were involved in jobs that they considered heavy or moderately heavy; 92% of men with unilateral hip resurfacings and 87% of the whole group participate in leisure-time sporting activity. The extremely low rate of failure in spite of the resumption of high level occupational and leisure activities provides early evidence of the suitability of this procedure for young and active patients with arthritis.

PMID: 15046429 [PubMed - indexed for MEDLINE]

1: Arch Orthop Trauma Surg. 1986;105(3):158-62.

Total hip replacement comparison between the McKee-Farrar and Charnley prostheses in a 5-year follow-up study.

Djerf K, Wahlstrom O.

In a prospective study, 177 patients who underwent total hip replacement by the McKee-Farrar or Charnley techniques were followed up for 5 years with yearly clinical examinations, walking tests, and X-rays. The findings concerning pain, walking ability, and complications were satisfactory and similar to the inventors' own 5-year results. Comparison between the two techniques disclosed no major differences. Over 90% of the patients were free from pain; the infection rate was 3.4% and the loosening rate 6%. A walking test showed marked increase in speed over the first few years and a slight decrease after the third year. Our findings do not support the hypothesis that the metal-on-metal prosthesis is clinically inferior to the metal-on-polyethylene prosthesis.

PMID: 3741069 [PubMed - indexed for MEDLINE]

1: Clin Orthop. 1996 Aug;(329 Suppl):S206-16.

Metal versus polyethylene wear particles in total hip replacements. A review.

Doorn PF, Campbell PA, Amstutz HC.

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Research has recently been focused on the development of hip replacements with alternative bearing surfaces with cobalt chrome alloy, to avoid the production of polyethylene wear particles in hip replacements and polyethylene wear debris mediated bone lysis. Cobalt chrome on cobalt chrome bearing surfaces are being reevaluated. Characterization of wear particles and studies on the reaction of the body to these particles, have played an important role in the determination of the factors that cause aseptic loosening and will therefore play an important role in the comparison of metal on polyethylene and metal on metal hip prostheses. In this paper, a comparison between the different aspects of metal and polyethylene wear particles is made using data from the literature and the authors' experience. The authors conclude that techniques need to be optimized to isolate and characterize individual metal wear particles from periprosthetic tissues and they advocate the performance of in vitro studies with these in vivo generated wear particles or comparable particles.

Publication Types:
- Review
- Review, Tutorial

PMID: 8769335 [PubMed - indexed for MEDLINE]

1: J Biomed Mater Res. 1998 Oct;42(1):103-11.

Metal wear particle characterization from metal on metal total hip replacements: transmission electron microscopy study of periprosthetic tissues and isolated particles.

Doorn PF, Campbell PA, Worrall J, Benya PD, McKellop HA, Amstutz HC.

Joint Replacement Institute at Orthopaedic Hospital, Los Angeles, California 90007, USA.

The less intense tissue reaction around metal on metal total hip replacements (THRs) compared to metal on polyethylene (PE) THRs may be explained by the differences in the characteristics of metal wear particles. In this study, transmission electron microscopy was used to study metal wear particles that were either in situ in cells or had been extracted from the cells by a new technique based on enzymatic tissue digestion. The tissues were obtained from 13 patients undergoing revision of metal on metal THRs with cobalt-chromium-molybdenum (CoCrMo) bearing couples. Most of the CoCrMo wear particles were smaller than 50 nm (range 6-834 nm) and round to oval in shape with irregular boundaries. This size range is considerably smaller than that reported for PE particles. While even a small volume of metal wear will produce high numbers of particles, the apparently less severe local tissue reaction to metal particles may be due to the possibility that corrosion, dissolution, and dissemination of metal particles may result in fewer local biological effects than the long-term retention of PE particles in the periprosthetic tissues.

PMID: 9740012 [PubMed - indexed for MEDLINE]

1: Clin Orthop. 1996 Aug;(329 Suppl):S187-205.

Tissue reaction to metal on metal total hip prostheses.

Doorn PF, Mirra JM, Campbell PA, Amstutz HC.

Joint Replacement Institute, Los Angeles, CA, USA.

The periprosthetic tissue reaction to polyethylene wear debris in metal on polyethylene total hip replacements is strongly implicated as the cause of osteolysis. This has led to a renewed interest in metal on metal total hip replacements. However, little is known about the role of wear debris in failures of these prostheses. Capsular and interface tissues from 9 long and short term metal on metal total hip replacement retrievals were studied to assess the tissue reaction around these prostheses. As compared with metal on polyethylene cases, the extent of the granulomatous inflammatory reaction and the presence of foreign body type giant cells was much less intense in metal on metal cases, likely because of the lower numbers and overall smaller size of metal wear debris particles. This may lead to a better transport of the particles from the joint tissues and a lower incidence of periprosthetic osteolysis around metal on metal hip replacement.

PMID: 8769334 [PubMed - indexed for MEDLINE]

1: Clin Orthop. 1996 Dec;(333):108-17.

Modern metal on metal articulation for total hip replacements.

Dorr LD, Hilton KR, Wan Z, Markovich GD, Bloebaum R.

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Between 1991 and 1994, 70 patients received total hip replacements with metal on metal articulation. The results of 54 of these patients with 54 hips who have a 2- to 4-year (2.7-year average) followup are reported. Patients were prospectively evaluated using the Harris hip score, a patient self assessment form, and radiographs. Hip aspiration was performed preoperatively and 6 to 24 months postoperatively in 24 hips with metal on metal articulations. Implant retrieval was obtained from 2 patients. Harris hip score averages increased from 49 to 93. No patient had revision surgery for loosening, but 1 had revision surgery for dislocation. Patient self assessment forms showed 51 of 54 patients scored their results as good or excellent. Serial radiographs did not show loosening or osteolysis. Wear could not be measured radiographically. Synovial fluid samples had metal particles of 1 to 10 microm in 10 hips. Twenty patients had bilateral total hip replacements with 1 hip metal on polyethylene articulation, and patients could not determine any difference between the hips. Compared with historic results of previous metal on metal prostheses, the modern metal on metal articulation investigated in this study did not have early acetabular loosening or clinical symptoms of component impaction. Retrieval implants and synovial fluid analysis suggest early wear was minimal.

PMID: 8981886 [PubMed - indexed for MEDLINE]

1: J Bone Joint Surg Am. 2000 Jun;82(6):789-98.

Comment in:
- J Bone Joint Surg Am. 2001 May;83-A(5):783-5.

Total hip arthroplasty with use of the Metasul metal-on-metal articulation. Four to seven-year results.

Dorr LD, Wan Z, Longjohn DB, Dubois B, Murken R.

Weber Institute, St. Gallen, Switzerland.

BACKGROUND: Total hip replacements with a metal-on-metal articulation were commonly used until the mid-1970s; most were then abandoned in favor of hip replacement with a metal-on-polyethylene articulation. The reason for this change was primarily early cup loosening, which was more prevalent with these metal-on-metal designs than it was with metal-on-polyethylene designs. In the late 1980s, a metal-on-metal design with improved clearance (adequate space between the femoral head and the acetabular articulation surface to allow fluid film lubrication and clearance of any debris from within this joint), metal hardness, and reproducible surfaces was introduced by Sulzer Orthopedics in Switzerland. Orthopaedic surgeons were interested in this Metasul articulation because the contribution of polyethylene wear particles to the failure of total hip replacements had become evident. This study was undertaken to review the clinical performance of this implant and to determine if early acetabular loosening or revision and wear and osteolysis were prevalent. METHODS: Between 1991 and 1994, seventy patients (seventy hips) had a total hip replacement with the Metasul metal-on-metal articulation and a cemented Weber cup. Nine patients died less than four years after the replacement; none of these deaths were related to the operation. Five patients were not available for radiographic evaluation, but they were contacted and it was known that the hip was not painful and had not been revised. Fifty-six patients (fifty-six hips) had complete clinical and radiographic data four to 6.8 years after the operation, and they made up the study group. The patients were evaluated with use of the Harris hip score, a patient-self-assessment form, and radiographs. RESULTS: At an average of 5.2 years (range, four to 6.8 years) after the operation, the average total Harris hip score for the fifty-three patients who did not have a revision was 89.6 points (range, 62 to 100 points). The average Harris pain score was 41.0 points (range, 30 to 44 points), and the average Harris limp score was 9.4 points (range, 5 to 11 points). One patient had revision of a loose cup, but there were no other loose acetabular components in the series. Two patients had revision of the acetabular component because of dislocation. No patient had a loose or revised femoral component. Therefore, the mechanical failure rate was one (2 percent) of fifty-six patients. Thirty-six of forty-seven patients who completed the patient-self-assessment form rated their result as excellent; seven, as very good; two, as good; one, as fair; and one, as poor. Wear could not be measured on radiographs because of the metal-on-metal articulation. No hip had radiographic evidence of acetabular osteolysis and two

hips had calcar resorption, but there was no other radiographic evidence of focal osteolysis. CONCLUSIONS: Our four to seven-year experience with this articulation surface indicates that the clinical results are similar to those of total hip replacements with a metal-on-polyethylene articulation. We believe that the Metasul articulation may have a role in reducing the wear that occurs with total hip replacement. The Metasul articulation appears to be particularly indicated for more active patients. A historical comparison with the reports in the literature of which we are aware indicated that the hips in our study had a lower rate of acetabular revision and loosening than did those with previous metal-on-metal designs and that they had no more acetabular loosening or osteolysis than did those with metal-on-polyethylene articulations followed for an average of five years.

PMID: 10859098 [PubMed - indexed for MEDLINE]

National Library of Medicine

☐ 1: J Bone Joint Surg Br. 1974 Nov;56-B(4):626-42. Related Articles, Links

Metal sensitivity as a cause of bone necrosis and loosening of the prosthesis in total joint replacement.

Evans EM.

PMID: 4452710 [PubMed - indexed for MEDLINE]

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1: J Bone Joint Surg Br. 1988 Aug;70(4):539-42.

Erratum in:
- J Bone Joint Surg [Br] 1996 Jul;78(4):680.

The incidence of cancer following total hip replacement.

Gillespie WJ, Frampton CM, Henderson RJ, Ryan PM.

Christchurch Hospital, Christchurch School of Medicine, University of Otago, New Zealand.

We have studied the incidence of tumours at remote sites following total hip replacement: 1,358 individuals have been followed up for 14,286 person-years after operation. In the decade following implantation the incidence of tumours of the lymphatic and haemopoietic systems was significantly greater, and that of cancer of the breast, colon, and rectum, significantly less than expected. Whilst the association might be due in part to an effect of the prosthetic implants, other mechanisms, particularly drug therapy, require consideration.

PMID: 3403594 [PubMed - indexed for MEDLINE]

1: Rev Chir Orthop Reparatrice Appar Mot. 1999 Jun;85(3):217-25.

[Value and limits of determining serum cobalt levels in patients with metal on metal articulating prostheses]

[Article in French]

Gleizes V, Poupon J, Lazennec JY, Chamberlin B, Saillant G.

Service de Chirurgie Orthopedique, Traumatologique et Reparatrice de l'Appareil Locomoteur, CHU Pitie-Salpetriere, Universite Paris VI.

PURPOSE OF THE STUDY: The purpose of this study was to measure the serum cobalt levels and their correlation with clinical and radiological findings in patients with metal on metal hip articulating surfaces. METHOD: Forty-one patients with metal on metal hip arthroplasty were reviewed retrospectively at mean follow-up of 12.9 months. Serum cobalt levels were determined for each patient by atomic absorption spectrometry at the maximal follow-up and were compared to a control group (19 patients). Two patients and one control subjects also performed exercise on a treadmill in order to appreciate the influence of physical activity on serum cobalt levels. RESULTS: The metal on metal group presented higher serum cobalt levels than those of the control group ($p < 0.0001$). There was no correlation between serum cobalt and clinical and radiological findings at the exception of patient age ($n = 40$, $r = 0.37$). However, when the follow-up was greater than 18 months, mean serum cobalt was significantly higher compared to a follow-up less than 18 months. The physical exercise test led to a moderate elevation (around 10 p. 100) of cobalt in the two patients but not in the control subject. DISCUSSION AND CONCLUSION: The interpretation of an elevated cobalt serum level is difficult. Cobalt-containing drugs, other implants, excess of activity and diseases (renal failure) may influence serum cobalt level. In this study, the high serum cobalt levels seem not linked to a failure of the implant, mainly because of the short follow-up. They could rather be attributed to an increase of the patient activity beginning 18 months after the surgery. Because potential long-term cobalt toxicity and carcinogenicity is not well known, careful medical follow-up should be emphasized specially in young patients.

PMID: 10422126 [PubMed - indexed for MEDLINE]

1: Proc Inst Mech Eng [H]. 2000;214(1):39-47.

A comparative joint simulator study of the wear of metal-on-metal and alternative material combinations in hip replacements.

Goldsmith AA, Dowson D, Isaac GH, Lancaster JG.

DePuy International, A Johnson and Johnson Company, Leeds, UK.

While total hip replacement represents the major success story in orthopaedic surgery in the twentieth century, there is much interest in extending even further, early in the twenty first century, the life of implants. Osteolysis has been identified as a major factor limiting the life of prostheses, with indications that fine polyethylene wear debris, generated primarily at the interface between the femoral head and the acetabular cup, promotes the process. There is therefore considerable interest in the introduction of alternative wear resistant systems to limit the deleterious effects of wear. These alternatives include ceramic-on-ceramic and metal-on-metal configurations and the present paper is primarily concerned with the latter. Some six pairs of new metal-on-metal implants of 36 mm diameter and four pairs of existing metal-on-metal implants of 28 mm diameter were tested in a ten-station hip joint simulator in the presence of a 25 per cent bovine serum solution. The implants were tested in the anatomical position to 5 x 10(6) cycles. The new heads and cups were manufactured from CoCrMo alloy with careful attention being paid to sphericity and surface finish of both components. The wear performance of the new and existing metal-on-metal total hip replacements have been evaluated and compared. The overall wear rates have then been compared with previously reported wear rates for a zirconia-on-polyethylene prosthesis of 22 mm diameter tested on the same simulator. The comparison is taken further by recalling published penetration data for metal-on-polyethylene implants of 22 and 28 mm diameter and converting these to volumetric wear rates. It was found that the heads and cups in metal-on-metal joints wore by almost equal amounts and that the opposing surfaces converged to similar surface roughness as the testing time increased. Steady state wear rates were generally achieved after 1-2 x 10(6) cycles. The mean long-term wear rates for the metal-on-metal prostheses were very low, being 0.36 mm3/10(6) cycles and 0.45 mm3/10(6) cycles for the new implants of 36 mm diameter and established implants of 28 mm diameter respectively. These wear rates compare with 6.3 mm3/10(6) cycles for zirconia-on-ultra-high molecular weight polyethylene tested on the same simulator and representative clinical values for metal-on-polyethylene of 36 mm3/year for heads of 22 mm diameter and a reported range of 60-180 mm3/year for 28 mm heads. These values do not translate directly into numbers of particles, since the metallic debris from metal-on-metal joints is very fine. The number of metallic particles may exceed the number of polyethylene wear particles from an otherwise similar metal-on-polyethylene joint by a factor of 10(3). A detailed discussion of the size and morphology of wear debris and tissue reaction to various forms of debris is beyond the scope of this paper, but the biological response to polymeric, metallic and ceramic wear

debris forms a major subject for further study. The present investigation nevertheless confirms the potential of carefully designed and manufactured metal-on-metal total replacement joints for the treatment of diseased and damaged hips.

PMID: 10718049 [PubMed - indexed for MEDLINE]

1: J Bone Joint Surg Am. 2001 Mar;83-A(3):428-36.

Metal sensitivity in patients with orthopaedic implants.

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All metals in contact with biological systems undergo corrosion. This electrochemical process leads to the formation of metal ions, which may activate the immune system by forming complexes with endogenous proteins. Implant degradation products have been shown to be associated with dermatitis, urticaria, and vasculitis. If cutaneous signs of an allergic response appear after implantation of a metal device, metal sensitivity should be considered. Currently, there is no generally accepted test for the clinical determination of metal hypersensitivity to implanted devices. The prevalence of dermal sensitivity in patients with a joint replacement device, particularly those with a failed implant, is substantially higher than that in the general population. Until the roles of delayed hypersensitivity and humoral immune responses to metallic orthopaedic implants are more clearly defined, the risk to patients may be considered minimal. It is currently unclear whether metal sensitivity is a contributing factor to implant failure.

Publication Types:
- Review
- Review, Tutorial

PMID: 11263649 [PubMed - indexed for MEDLINE]

1: J Orthop Res. 2004 Mar;22(2):250-9.

Related Articles, Links

ELSEVIER FULL-TEXT ARTICLE

Differences in the fretting corrosion of metal-metal and ceramic-metal modular junctions of total hip replacements.

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The use of modular interlocking components is a central design feature of total joint replacements. In this investigation we hypothesized that clinically available ceramic-metal modular connections used in total hip arthroplasty release more metal through fretting corrosion than traditional metal-metal modular connections. This was investigated using an in vitro comparison of ceramic (zirconia, ZrO2) and metal (Co-alloy) femoral-head fretting upon Co-alloy stem components. In vitro fretting corrosion testing consisted of potentiodynamic monitoring and analysis of metal release from zirconia and Co-alloy 28 mm femoral heads with similar surface roughnesses (Ra=0.46 microm) on identical Co-alloy stems at 2.2 kN for 1x10(6) cycles at 2 Hz. In contrast to our original hypothesis, we found greater metal release (approximately 11-fold increase in Co and 3-fold increase in Cr) and potentiodynamic fretting of metal-metal modular junctions when compared to ceramic-metal. Potentiodynamic testing demonstrated that lower initial voltages (-266<153 mV), greater maximum voltage changes (116>56 mV, $p<0.05$, t-test) and voltage variability (3>0.5 mV, $p<0.05$, t-test) were associated with the open circuit potentials of Co-alloy on Co-alloy junctions when compared to zirconia on Co-alloy junctions. In this study of a single total hip replacement stem and head design, zirconia heads mated with Co-alloy stems produced less fretting than Co-alloy heads mated with Co-alloy stems. Although further studies are necessary with a variety of implant designs and under different experimental conditions, the evidence presented here should, in part, alleviate concerns of increases in fretting corrosion at modular junctions of ceramic-metal coupled components.

PMID: 15013082 [PubMed - indexed for MEDLINE]

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1: J Biomed Mater Res. 2000 Sep;53(5):480-9.

A triple assay technique for the evaluation of metal-induced, delayed-type hypersensitivity responses in patients with or receiving total joint arthroplasty.

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Department of Orthopedic Surgery, Rush-Presbyterian-St. Luke's Medical Center, Chicago, IL 60612, USA. nhallab@rush.edu

The determination of biocompatibility has been dominated historically by the characterization of candidate materials based upon the observation of adverse host responses. However, some adverse responses are subtle in clinical settings and continue to foster debate and investigation. One of these responses is "metal allergy" or hypersensitivity to metallic biomaterials. Current methods used to diagnose hypersensitivity reactions, such as dermal patch testing and migration inhibition assays, are not well accepted in orthopedic practice as a means for the characterization of hypersensitivity to metallic joint-replacement components. An increasing need to resolve whether metal sensitivity may be a significant and/or predisposing factor for eliciting an over-aggressive immune response in patients with metallic implant components requires improved and standardized widespread study. Here we present three in vitro methodologies: (1) a proliferation assay, (2) cytokine analysis using ELISA, and (3) a migration inhibition assay. When in conjunction with one another, these assays may be used to more comprehensively quantify metal-induced hypersensitivity responses. Therefore, these methodologies are detailed with the intent of facilitating multi-center large-scale studies. In the following cases, a multi-assay approach for measuring the prevalence of delayed-type hypersensitivity in orthopedic patients shows the propensity to yield a more comprehensive and, therefore, more conclusive determination than currently employed patch testing or single assay techniques.

PMID: 10984695 [PubMed - indexed for MEDLINE]

1: Mol Cell Biochem. 2001 Jun;222(1-2):127-36.

Orthopaedic implant related metal toxicity in terms of human lymphocyte reactivity to metal-protein complexes produced from cobalt-base and titanium-base implant alloy degradation.

Hallab NJ, Mikecz K, Vermes C, Skipor A, Jacobs JJ.

Department of Orthopedic Surgery, Rush-Presbyterian-St. Lukes Medical Center, Chicago, IL, USA.

Metal toxicity from sources such as orthopaedic implants was investigated in terms of immune system hyper-reactivity to metal implant alloy degradation products. Lymphocyte response to serum protein complexed with metal from implant alloy degradation was investigated in this in vitro study using primary human lymphocytes from healthy volunteers (n = 10). Cobalt chromium molybdenum alloy (Co-Cr-Mo, ASTM F-75) and titanium alloy (Ti-6Al-4V, ASTM F-136) beads (70 microm) were incubated in agitated human serum at 37 degrees Celsius to simulate naturally occurring metal implant alloy degradation processes. Particulate free serum samples, which were incubated with metal, were then separated into molecular weight based fractions. The amounts of soluble Cr and Ti within each serum fraction were measured and correlated with lymphocyte proliferation response to the individual serum fractions. Lymphocytes from each subject were cultured with 11 autologous molecular weight based serum fractions either with or without added metal. Two molecular weight ranges of human serum proteins were associated with the binding of Cr and Ti from Co-Cr-Mo and Ti implant alloy degradation (at < 30 and 180-330 kDa). High molecular weight serum proteins (approximately 180 kDa) demonstrated greater lymphocyte reactivity when complexed with metal released from Co-Cr-Mo alloy and Ti alloy than with low (5-30 kDa) and midrange (30-77 kDa) serum proteins. When the amount of lymphocyte stimulation was normalized to both the moles of metal and the moles of protein within each fraction (Metal-Protein Complex Reactivity Index, MPCRI), Cr from Co-Cr-Mo alloy degradation demonstrated approximately 10 fold greater reactivity than Ti in the higher molecular weight serum proteins (approximately 180-250 kDa). This in vitro study demonstrated a lymphocyte proliferative response to both Co-Cr-Mo and Ti alloy metalloprotein degradation products. This response was greatest when the metals were complexed with high molecular weight proteins, and with

1: J Biomed Mater Res. 2001 Sep 5;56(3):427-36.

Differential lymphocyte reactivity to serum-derived metal-protein complexes produced from cobalt-based and titanium-based implant alloy degradation.

Hallab NJ, Mikecz K, Vermes C, Skipor A, Jacobs JJ.

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The lymphocyte response to serum protein complexed with metal from implant alloy degradation was investigated in this in vitro study using primary human lymphocytes from healthy volunteers (n = 10). Cobalt chromium molybdenum alloy (Co-Cr-Mo, ASTM F-75) and titanium alloy (Ti-6Al-4V, ASTM F-136) beads (70 microm) were incubated in agitated human serum at 37 degrees C to simulate naturally occurring metal implant alloy degradation processes. Particulate free serum samples that had been incubated with metal were then separated into molecular weight based fractions. The amounts of soluble Cr and Ti within each serum fraction were measured and correlated with lymphocyte proliferation response to the individual serum fractions. Lymphocytes from each subject were cultured with 11 autologous molecular weight based serum fractions either with or without added metal. Two molecular weight ranges of human serum proteins were associated with the binding of Cr and Ti from Co-Cr-Mo and Ti implant alloy degradation (at <30 and 180-250 kDa). High molecular weight serum proteins (approximately 180 kDa) demonstrated greater lymphocyte reactivity when complexed with Cr alloy and Ti alloy than low (5-30 kDa) and midrange (30-77 kDa) serum proteins. When the amount of lymphocyte stimulation was normalized to both the moles of metal and the moles of protein within each fraction (metal-protein complex reactivity index), Cr from Co-Cr-Mo alloy degradation demonstrated approximately 10-fold greater reactivity than Ti in the higher molecular weight serum proteins (approximately 180 kDa). This in vitro study demonstrated a lymphocyte proliferative response to both Co-Cr-Mo and Ti alloy metalloprotein degradation products. This response was greatest when the metals were complexed with high molecular weight proteins, and with metal-protein complexes formed from Co-Cr-Mo alloy degradation.

1: J Biomed Mater Res. 2002 Jun 5;60(3):420-33.

Concentration- and composition-dependent effects of metal ions on human MG-63 osteoblasts.

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Metal debris from implants has been shown to alter the function of osteoblasts in cell cultures. Its remains unclear, however, if specific forms of released ionic metals are involved in the pathogenesis of periprosthetic osteolysis. We evaluated the relative effects of ionic forms of implant metals by treating human osteoblast-like MG-63 osteosarcoma cells with eight concentrations (0.001-10.0 mM) of Cr(+3), Mo(+5), Al(+3), Ta(+5), Co (+2), Ni(+2), Fe(+3), Cu(+2), Mn(+2), Mg(+2), Na(+2), and V(+3) chloride solutions. The results demonstrated that the metal ions differentially affected osteoblast proliferation, viability, type-I collagen gene expression, and cytokine release. The metal ions were ranked in order from least to most toxic (based on a 50% reduction in viability) as follows: Na < Cr < Mg < Mo < Al < Ta < Co < Ni < Fe < Cu < Mn < V. Metal-induced decreases in osteoblast proliferation were similar in ranking. Nontoxic concentrations of metals had no effect on procollagen alpha1[I] gene expression; only at toxic concentrations did metals produce a decrease in gene expression. The most toxic metals (V, Mn, Fe, and Ni) were also the only metals found to induce IL-6 secretion on a per cell basis (of the cytokines tested, interleukin 6 (IL-6), interleukin beta 1 (IL-1beta), transforming growth factor beta 1 (TGF-beta1), and tumor necrosis factor alpha (TNF-alpha), only IL-6 was detectable in the culture medium after 48 h for any metal at any concentration). Less toxic metals (e.g., Co and Cr) had little effect on IL-6 release, even at high concentrations. In general, metal ions reduced osteoblast function (i.e., proliferation and collagen gene expression) in proportion to the degree of toxicity. These results support the hypothesis that adverse local cellular responses (particularly necrotic responses) associated with metal debris from implanted metallic devices may be due in part to metal ions released from implants or from particulate debris.

PMID: 11920666 [PubMed - indexed for MEDLINE]

1: J Bone Joint Surg Br. 2004 Jan;86(1):27-30.

Pain in the well-fixed, aseptic titanium hip replacement. The role of corrosion.

Hallam P, Haddad F, Cobb J.

University College London Hospitals, England, UK.

We have investigated nine patients with cemented Furlong (JRI, London, UK) titanium hip replacements who presented with early pain despite a well-fixed, aseptic prosthesis. All were followed up clinically and radiologically at regular intervals. Pain was located in the thigh and was worse at night. Radiographs showed cortical hypertrophy of the femur around the tip of the stem. Eight of the nine patients subsequently required single-stage revision using an uncemented prosthesis, which relieved the pain. At revision, the pH of the tip of the stem was found to be highly acidic with macroscopic evidence of corrosion consisting of multiple layers of titanium oxides when studied by X-ray dispersive analysis. Cemented titanium implants have a potential for crevice corrosion leading to cortical hypertrophy and intractable pain.

PMID: 14765860 [PubMed - indexed for MEDLINE]

1: J Arthroplasty. 2002 Oct;17(7):893-5.

ELSEVIER FULL-TEXT ARTICLE

Serum levels of cobalt and chromium in a complex modular total hip arthroplasty system.

Harding I, Bonomo A, Crawford R, Psychoyios V, Delves T, Murray D, McLardy-Smith P.

Nuffield Orthopaedic Centre, Headington, Oxford, United Kingdom.
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There is concern that modularity in a total hip arthroplasty system increases serum cobalt and chromium ion levels. This study measures the serum cobalt and chromium levels in patients with an Oxford Universal Hip (Corin, Cirencester, United Kingdom), which has a modular sliding mechanism; patients with a similarly manufactured hip with no sliding mechanism; and a control group. Loosening was excluded clinically and radiologically. Arthroplasty patients had statistically higher levels of serum cobalt and chromium than controls, but there was no significant difference in levels between the implanted groups. Copyright 2002, Elsevier Science (USA)

PMID: 12375249 [PubMed - indexed for MEDLINE]

1: J Trace Elem Electrolytes Health Dis. 1992 Dec;6(4):239-43.

Nickel-, chrom- and cobalt-concentrations in human tissue and body fluids of hip prosthesis patients.

Hennig FF, Raithel HJ, Schaller KH, Dohler JR.

Department of Accidental Surgery, University of Erlangen-Nurnberg, Fed. Rep. of Germany.

The world-wide experience with millions of metallic implantations suggests the biocompatibility of modern alloys, commonly made of cobalt, chromium and nickel. There is, however, little information available on the internal metal exposure resulting from implants. In this study we assessed the metal concentrations in body fluids and tissue samples (muscle, bone) of patients who had undergone total hip replacement. Our patients were divided up into two groups. One group had firmly fixed implants two years after surgery. The other group had loose implants of the same Co-Cr-Mo alloy. Urine analyses revealed an increased renal elimination of nickel, chromium and cobalt. Cobalt and nickel exceeded the upper normal value. In serum the concentrations of nickel and chromium were normal or slightly elevated, the cobalt concentrations were significantly elevated. In some cases tissues adjacent to the implant showed extremely high concentrations of chromium and cobalt. This finding was also obtained in tissues that had no direct contact with the arthroplasty. The findings suggest that alloys of prostheses can undergo corrosion and release metal ions.

PMID: 1304233 [PubMed - indexed for MEDLINE]

1: Arch Orthop Trauma Surg. 1997;116(3):121-4.

Metal-on-metal CoCrMo McKee-Farrar total hip arthroplasty: characteristics from a long-term follow-up study.

Higuchi F, Inoue A, Semlitsch M.

Department of Orthopaedic Surgery, Kurume University School of Medicine, Japan.

A total of 38 cemented metal-on-metal CoCrMo McKee-Farrar total hip arthroplasties (THAs) were clinically and radiographically evaluated over a long-term follow-up. No osteolysis and no granuloma were found more than 20 years after the operation. The main radiological findings were bone erosion and migration of the acetabular component, seen in 17 hips (44.7%). The direction of the migration correlated with the setting position of the acetabular component at operation. At revision surgery, metallosis was observed in unstable THA, and no metallosis was observed in stable THA. Using a micrometer, no wear of the sockets was found. Therefore, the loosening was thought to be due to the equatorial bearing rather than to metallosis. The mean survival of the THA to data was 14.6 years in those patients 60 years old or younger at operation and was significantly less (11.9 years) in those 61 years old or older at operation ($P < 0.03$). The mean survival time was 13.8 years.

Publication Types:
- Case Reports

PMID: 9061164 [PubMed - indexed for MEDLINE]

1: Clin Orthop. 1996 Aug;(329 Suppl):S99-105.

Contemporary total hip replacement with metal on metal articulation.

Hilton KR, Dorr LD, Wan Z, McPherson EJ.

Center for Arthritis and Joint Implant Surgery, USC University Hospital, Los Angeles, CA, USA.

Between 1991 and 1994, 74 patients received total hip replacements with metal on metal articulation. The results of these patients with 74 hips who had a 6-month to 4-year (average, 2.2 years average) followup are reported. Patients were prospectively evaluated by the Harris hip score, a patient self assessment form, and radiographs. The average postoperative Harris hip score was 91. Patient self assessment forms showed that 95% of the patients scored their results as excellent or good. No patient had revision for loosening, but 1 underwent revision surgery for recurrent dislocation. Serial radiographs have not revealed loosening or osteolysis. Wear could not be measured radiographically. Twenty-seven of the patients had bilateral total hip replacements with 1 hip being metal on polyethylene; the patients could not detect any difference between the 2 hips. The satisfactory short term results from the contemporary metal on metal articulation investigated in this study are encouraging and warrant continued study.

PMID: 8769327 [PubMed - indexed for MEDLINE]

1: Clin Orthop. 1996 Aug;(329 Suppl):S217-32.

Biologic effects of cobalt chrome in cell and animal models.

Howie DW, Rogers SD, McGee MA, Haynes DR.

Department of Orthopaedics and Trauma, Royal Adelaide Hospital, Australia.

The literature on animal and cellular models used to study the response to cobalt chrome alloy implants and wear and corrosion products is reviewed. Animal studies show that in solid form cobalt chrome alloy is relatively well tolerated. Injections of large numbers of particles in a single bolus lead to acute inflammation and necrosis, followed by a chronic inflammatory response. Macrophages are the predominant cell type and may persist in the tissues for years. Long term studies have failed to confirm the induction of tumors. In vitro studies confirm the toxic effects of cobalt chrome alloy corrosion products and wear particles, especially cobalt, and show that intracellular corrosion is an important mechanism for early release of cobalt ions. In vitro studies show that cobalt chrome alloy particles induce the release of inflammatory mediators from macrophages before causing cell death. These mediators have significant effects on osteoblastlike cells, as well as inducing bone resorption. Variations in the cell types, implantation site, and characteristics of the particles used in experimental models make interpretation of the results difficult. Standardized methods to control for size, shape, and number of particles for testing are proposed. It is important that in vitro and in vivo findings not be taken in isolation, but be compared with the results of human studies.

PMID: 8769336 [PubMed - indexed for MEDLINE]

Display Abstract Show: 20 Sort Send to Text

1: J South Orthop Assoc. 2003 Summer;12(2):106-11. Related Articles, Links

Alternative bearing surfaces in total hip arthroplasty.

Inzerillo VC, Garino JP.

University of Pennsylvania School of Medicine, Philadelphia, PA, USA.

Polyethylene wear and extension of indications of total hip arthroplasty into younger and younger age groups have pushed manufacturers to develop more durable bearing surfaces. Standard polyethylene, the plastic used for the first 3 decades of hip replacement, virtually ceases to exist in its original form. Modifications of the processing, including sterlization in an inert environment and cross-linking, have demonstrated some improvements in wear. Hard-on-hard bearings such as ceramic-on-ceramic and metal-on-metal also have demonstrated extremely low wear. This article reviews the pros and cons of the alternative bearing options available to assist in the proper bearing selection for a particular patient.

PMID: 12882250 [PubMed - indexed for MEDLINE]

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1: J Bone Joint Surg Am. 1991 Dec;73(10):1475-86.

Related Articles, Links

Comment in:

- J Bone Joint Surg Am. 1992 Oct;74(9):1431-2.

Release and excretion of metal in patients who have a total hip-replacement component made of titanium-base alloy.

Jacobs JJ, Skipor AK, Black J, Urban R, Galante JO.

Department of Orthopedic Surgery, Rush-Presbyterian-St. Luke's Medical Center, Chicago, Illinois 60612.

Serum concentration and urinary excretion of titanium, aluminum, and vanadium were measured for patients who had a well functioning cementless primary total hip replacement of one of two different designs, for patients who had a loose total hip replacement that was to be revised, and for control subjects who had no implant. Serum concentrations of titanium were elevated approximately twofold in the patients who had a loose implant, compared with the values for the control subjects. No major differences in terms of urine concentration of titanium, serum concentration of aluminum, or urine concentration of aluminum were observed among any of the groups that were studied. Concentrations of vanadium were uniformly low in all groups.

PMID: 1844129 [PubMed - indexed for MEDLINE]

Display Abstract Show: 20 Sort Send to Text

1: Clin Orthop. 1996 Aug;(329 Suppl):S256-63.

Cobalt and chromium concentrations in patients with metal on metal total hip replacements.

Jacobs JJ, Skipor AK, Doorn PF, Campbell P, Schmalzried TP, Black J, Amstutz HC.

Department of Orthopedic Surgery, Rush Arthritis and Orthopedics Institute, Chicago, IL, USA.

There has been a resurgence of interest in the use of metal on metal bearings in total hip arthroplasty. Although the use of metal on metal bearing couples would eliminate or substantially reduce particulate polyethylene generation (depending on the presence or absence of polyethylene in the implant system), there is concern about the potential for increased particulate and ionic metal generation in comparison with polyethylene on metal bearings.These metallic degradation products may be transported away from the implant site and distributed systemically. Chromium concentrations in the serum and urine and cobalt concentrations in the serum were measured in subjects with cobalt chromium alloy metal on metal total hip replacements and in controls without implants. Eight subjects with long term (> 20 years) McKee-Farrar total hip replacements had 9-fold elevations in serum chromium, 35-fold elevations in urine chromium, and at least 3-fold elevations in serum cobalt concentrations in comparison with controls. Six subjects with short term (< 2 years) metal on metal surface replacement arthroplasties had 3-fold elevations in serum chromium, 4-fold elevations in urine chromium, and 4-fold elevations in serum cobalt concentrations in comparison with subjects with McKee-Farrar implants. Although the toxicologic importance of these trace metal elevations has not been established, serum and urine metal concentrations may be useful markers for the tribologic performance of metal on metal bearings.

PMID: 8769339 [PubMed - indexed for MEDLINE]

1: J Bone Joint Surg Am. 1998 Oct;80(10):1447-58.

Metal release in patients who have had a primary total hip arthroplasty. A prospective, controlled, longitudinal study.

Jacobs JJ, Skipor AK, Patterson LM, Hallab NJ, Paprosky WG, Black J, Galante JO.

Department of Orthopedic Surgery, Rush Arthritis and Orthopedics Institute, Rush Medical College, Rush-Presbyterian-St. Luke's Medical Center, Chicago, Illinois 60612, USA. jacobs@ortho4.pro.rpslmc.edu

There is an increasing recognition that, in the long term, total joint replacement may be associated with adverse local and remote tissue responses that are mediated by the degradation products of prosthetic materials. Particular interest has centered on the metal-degradation products of total joint replacements because of the known toxicities of the metal elements that make up the alloys used in the implants. We measured the concentrations of titanium, aluminum, cobalt, and chromium in the serum and the concentration of chromium in the urine of seventy-five patients during a three-year prospective, longitudinal study. Twenty patients had had a so-called hybrid total hip replacement (insertion of a modular cobalt-alloy femoral stem and head with cement and a titanium acetabular cup without cement), fifteen had had insertion of an extensively porous-coated cobalt-alloy stem with a cobalt-alloy head and a titanium-alloy socket without cement, and twenty had had insertion of a proximally porous-coated titanium-alloy stem with a cobalt-alloy head and a titanium socket without cement. The remaining twenty patients did not have an implant and served as controls. The results of our study showed that, thirty-six months postoperatively, patients who have a well functioning prosthesis with components containing titanium have as much as a threefold increase in the concentration of titanium in the serum and those who have a well functioning prosthesis with cobalt-alloy components have as much as a fivefold and an eightfold increase in the concentrations of chromium in the serum and urine, respectively. The predominant source of the disseminated chromium-degradation products is probably the modular head-neck junction and may be a function of the geometry of the coupling. Passive dissolution of extensively porous-coated cobalt-alloy stems was not found to be a dominant mode of metal release. CLINICAL RELEVANCE: Increased concentrations of circulating metal-degradation products derived from orthopaedic implants may have deleterious biological effects over the long term that warrant investigation. This is a particularly timely concern because of recent clinical trends, including the reintroduction of metal-on-metal bearing surfaces and the increasing popularity of extensively porous-coated devices with large surface areas of exposed metal. Accurate monitoring of the concentrations of metal in the serum and urine after total hip replacement also can provide insights into the mechanisms of metal release. Our findings suggest that fretting corrosion at the head-neck coupling is an important source of metal release that can lead to increased concentrations of chromium in the serum. Determinations of the concentrations of metal in the serum and

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urine may be useful in the diagnosis of patients who are symptomatic after a total joint replacement as increased levels are indicative of at least one mode of mechanical dysfunction (for example, fretting corrosion) of the device.

PMID: 9801213 [PubMed - indexed for MEDLINE]

1: Clin Orthop. 1996 Aug;(329 Suppl):S60-8.

Twenty-year results of McKee-Farrar versus Charnley prosthesis.

Jacobsson SA, Djerf K, Wahlstrom O.

Department of Orthopaedics, University Hospital, Linkoping, Sweden.

The results of 107 consecutive McKee-Farrar and 70 Charnley total hip arthroplasties performed in 169 patients between 1975 and 1976 are reviewed. At an average followup of 20 years (range, 19-21 years), 29 patients with 20 McKee-Farrar and 11 Charnley prostheses were available for clinical and radiologic evaluation; 102 patients (107 hips) had died, 3 patients were lost to followup, and 5 patients (6 hips) were unavailable for review because of medical problems. There were 5 revisions for sepsis and 1 Girdlestone procedure for recurrent dislocation. Sixteen McKee-Farrar and 8 Charnley prostheses were revised for aseptic loosening, giving a 20-year aseptic probability of survival of 77% and 73%, respectively. Radiographic signs of loosening were present in 52% of the surviving prostheses. Clinical scores showed weak correlation with the radiographic loosening in both groups, and 18 McKee-Farrar and 8 Charnley prostheses were still considered satisfactory by the patients. The mean annual linear polyethylene wear was 0.12 mm. Osteolytic lesions were observed in association with 2 McKee-Farrar and 5 Charnley prostheses in surviving hips. The long term results of the McKee-Farrar prosthesis are comparable with those of the low friction arthroplasty in this series. Wear of the polyethylene bearing and accumulation of polyethylene particles in the periprosthetic tissue may become an increasing problem. Second generation all metal implants seem to be worth considering in patients with long life expectancy.

PMID: 8769323 [PubMed - indexed for MEDLINE]

1: Am J Orthop. 1998 Apr;27(4):283-92.

Hard bearing surfaces in total hip arthroplasty.

Jazrawi LM, Kummer FJ, Di Cesare PE.

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Periprosthetic osteolysis and aseptic loosening are serious problems affecting the outcome of total joint replacement. Polyethylene particulate debris generated from metal-on-polyethylene bearing surfaces and the resulting biologic response to this debris are thought to be largely responsible. As a result, there has been a renewal of interest in hard bearing surfaces for total joint arthroplasty, including both metal-on-metal and ceramic-on-ceramic components. The new-generation all-ceramic and all-metal prostheses have demonstrated, both clinically and in the laboratory, lower friction and wear rates than metal-on-polyethylene bearing surfaces. Theoretically, lower wear rates result in less particulate debris and decreased inflammatory response. Despite excellent tribologic (lubrication, friction, wear) properties, metal-on-metal bearings raise associated issues of metal sensitivity and toxicity. For ceramic-on-ceramic bearing surfaces, issues of ceramic quality and the possibility of brittle fracture must be considered.

Publication Types:
- Review
- Review, Tutorial

PMID: 9586727 [PubMed - indexed for MEDLINE]

1: J Am Acad Orthop Surg. 1998 Jul-Aug;6(4):198-203.

Alternative bearing surfaces for total joint arthroplasty.

Jazrawi LM, Kummer FJ, DiCesare PE.

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The biologic response to polyethylene particulate debris generated from metal-on-polyethylene bearing surfaces is thought to be largely responsible for periprosthetic osteolysis and aseptic loosening in total joint arthroplasty. As a result, there has been an interest in developing polyethylene with improved wear characteristics, as well as a renewed interest in alternative bearing surfaces for total joint arthroplasty, including ceramic-polyethylene, metal-metal, and ceramic-ceramic articulations. These alternative surfaces have demonstrated less friction and lower wear rates than metal-on-polyethylene bearing surfaces in both clinical and laboratory experiments. Clinical results, although only short- to mid-term, have been encouraging. Alternative bearing surfaces, with lower wear rates and less particulate debris formation, may have the potential to improve total joint arthroplasty survivorship by decreasing periprosthetic osteolysis, especially in younger, high-demand patients.

Publication Types:
- Review
- Review, Tutorial

PMID: 9682082 [PubMed - indexed for MEDLINE]

1: Arch Orthop Trauma Surg. 2003 Feb;123(1):5-11. Epub 2002 Dec 19. Related Articles, Links

SpringerLink FULL-TEXT ARTICLE

Zweymueller with metal-on-metal articulation: clinical, radiological and histological analysis of short-term results.

Korovessis P, Petsinis G, Repanti M.

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BACKGROUND: This is a prospective study. METHOD:. A total of 266 consecutive patients, who received 350 third-generation Zweymueller-SL total hip arthroplasties with metal-on-metal articulation for primary or secondary osteoarthritis, was followed and evaluated clinically, radiologically and histologically. The age of the patients at the time of surgery was 55+/-9 years, (range 25-70 years). Seven (3%) patients did not return for their last follow-up evaluation for reasons unrelated to their hip operation. RESULTS: The mean follow-up was 52 months (range 37-92 months). The preoperative Harris hip score was 45+/-19 and increased to 96+/-4 postoperatively. The invalidity of the patients was significantly improved postoperatively ($p<0.001$). In all, 97% of the patients were satisfied or very satisfied with the result of the operation. There was no aseptic loosening noted in this series. Revision was done in 6 (1.8%) hips because of septic loosening (n=5, 1.5%) or technical error (n=1, 0.3%) during implantation. Dislocation of the prosthesis occurred in the early postoperative period in 2 (0.6%) hips. Periarticular ossification was observed in 30% of the hips (5% Brooker grades III and IV), but without associated disability. During revision surgery, no macroscopic metalosis could be identified in the newly formed hip joint membrane; however microscopic evidence for metalosis (Mirra grades 1 and 2) was seen in all revised hips. The survival for Zweymueller screw socket and stem 7.6 years after implantation was 99.4% and 96.8%, respectively. CONCLUSIONS: This study showed that the short-term results of Zweymueller total hip arthroplasty with metal-on-metal articulation were just as satisfactory as those of a conventional polyethylene on ceramic articulation, while the metal-on-metal articulation does not seem to give rise to new problems or complications.

PMID: 12582789 [PubMed - indexed for MEDLINE]

1: Clin Orthop. 1991 Feb;(263):263-71.

Periprosthetic chronic inflammation characterized through the measurement of superoxide anion production by synovial-derived macrophages.

Kossovsky N, Liao K, Millett D, Feng D, Campbell PA, Amstutz HC, Finerman GA, Thomas BJ, Kilgus DJ, Cracchiolo A, et al.

Department of Pathology and Laboratory Medicine, UCLA Medical Center 90024-1732.

Periprosthetic macrophages were isolated from the synovium of primary and revision arthroplasty patients. Inflammatory activity was determined by the level of superoxide (O2-) production de novo and in response to phorbol myristate acetate (PMA) stimulation. Nonstimulated primary arthroplasty-derived macrophages produced 2.54 +/- 2.04 pmoles of O2-/minute/10(5) cells. When identical reaction tubes were stimulated with PMA, O2- levels increased to 5.76 +/- 3.77 pmol of O2-/minute/10(5) cells. Nonstimulated revision arthroplasty-derived macrophages produced 3.26 +/- 2.02 pmol of O2-/minute/10(5) cells during this ten-minute time period. When identical reaction tubes were stimulated with PMA, O2- levels increased to 3.98 +/- 2.52 pmol of O2-/minute/10(5) cells. The difference in the ratio of O2- production in response to stimulation between primary and revision groups was statistically significant. The observation of a chronic moderate level of activation and the lack of responsiveness to a potent stimulator suggests that macrophage inflammatory activity is down-regulated in periprosthetic synovium.

PMID: 1847099 [PubMed - indexed for MEDLINE]

1: J Bone Joint Surg Br. 1996 Jan;78(1):18-21.

Systemic release of cobalt and chromium after uncemented total hip replacement.

Kreibich DN, Moran CG, Delves HT, Owen TD, Pinder IM.

Freeman Hospital, Newcastle upon Tyne and Southampton General Hospital, England.

We measured the levels of cobalt and chromium in the serum in three groups of patients after uncemented porous-coated arthroplasty. Group 1 consisted of 14 consecutive patients undergoing revision for aseptic loosening. Group 2 comprised 14 matched patients in whom the arthroplasty was stable and group 3 was 14 similarly matched patients with arthritis awaiting hip replacement. Specimens were analysed using atomic absorption spectrophotometry. Aseptic loosening of a component resulted in a significant elevation of serum cobalt ($p < 0.05$), but not of serum chromium. The relative risk of a component being loose, if the patient had a serum cobalt greater than 9.0 nmol/l, was 2.8.

PMID: 8898120 [PubMed - indexed for MEDLINE]

1: J Bone Joint Surg Br. 1992 Nov;74(6):831-9.

Systemic distribution of wear debris after hip replacement. A cause for concern?

Langkamer VG, Case CP, Heap P, Taylor A, Collins C, Pearse M, Solomon L.

Bristol Royal Infirmary, England.

The production of particulate wear debris is a recognised complication of joint arthroplasty, but interest has concentrated on local tissue reactions and a possible association with implant loosening. The fate of wear products in the body remains unknown, although some of the metals used in the construction of orthopaedic implants are known to have toxic and oncogenic properties. We report histological and electron-microscopic evidence from two cases which shows that metallic debris can be identified in the lymphoreticular tissues of the body distant from the hip some years after joint replacement. The increase in the use of total arthroplasty in younger patients, the development of new alloys and the use of porous coatings must raise concern for the long-term effects of the accumulation of wear debris in the body.

Publication Types:
- Case Reports

PMID: 1447243 [PubMed - indexed for MEDLINE]

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1: J Orthop Res. 1997 Jan;15(1):40-9.

Human monocyte/macrophage response to cobalt-chromium corrosion products and titanium particles in patients with total joint replacements.

Lee SH, Brennan FR, Jacobs JJ, Urban RM, Ragasa DR, Glant TT.

Department of Orthopedic Surgery, Rush Arthritis and Orthopedics Institute, Rush Medical College, Rush-Presbyterian-St. Luke's Medical Center, Chicago, IL 60612, USA.

The responses of human peripheral blood monocytes of 10 normal volunteers and 14 patients with total hip replacements to particles of commercially pure titanium and chromium orthophosphate (a corrosion product from cobalt-chromium alloy implants) were studied. In addition, these phagocytosable particles were added to cultured mononuclear cells isolated from the interfacial membrane of 14 patients with failed implants. Peripheral blood monocytes from patients who had had a total hip replacement produced significantly higher levels of interleukin-1 (both interleukin-1 alpha and interleukin-1 beta) and prostaglandin E2 following particulate stimulation than those from normal volunteers. Supernatants from both titanium and chromium orthophosphate-stimulated peripheral blood monocytes from the volunteers and patients with total hip replacement induced bone resorption (assayed in organ cultures of newborn mouse calvariae) and the proliferation of human fibroblasts. The levels of bone resorption were significantly higher ($p < 0.05$) in patients with implants than in normal volunteers. There were no significant differences in the responses of cells between patients with focal osteolysis and those without osteolysis. Interfacial membrane mononuclear cells also produced high levels of interleukin-1 alpha, interleukin-1 beta, and prostaglandin E2 and expressed bone resorptive activities following stimulation with either titanium or chromium orthophosphate. More importantly, interfacial membrane mononuclear cells "spontaneously" produced high levels of prostaglandin E2 that were comparable with the response of peripheral blood monocytes stimulated with particulate wear debris. The clinical relevance of this study is 2-fold. First, mononuclear cells from patients with total hip replacement were some-how "sensitized" to metal particles in comparison with mononuclear cells from individuals without an implant. Second, the chromium orthophosphate corrosion product was a potent macrophage/monocyte activator and may contribute to macrophage-mediated osteolysis and aseptic loosening.

PMID: 9066525 [PubMed - indexed for MEDLINE]

1: J Orthop Res. 2003 Mar;21(2):189-95.

ELSEVIER FULL-TEXT ARTICLE

Four-year study of cobalt and chromium blood levels in patients managed with two different metal-on-metal total hip replacements.

Lhotka C, Szekeres T, Steffan I, Zhuber K, Zweymuller K.

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BACKGROUND: Metal-on-metal total hip prostheses will produce a certain amount of wear debris. This results in increased whole-blood metal levels, which may cause adverse effects. It is not known to what extent the problem has been overcome by advances in alloy technology. METHODS: In 259 patients who with total hip replacement, blood cobalt and chromium concentrations were measured with atomic absorption spectrophotometry over a period of four years after arthroplasty. Of the patients enrolled in the study, 131 had been managed with a METASUL cobalt-chromium alloy metal-on-metal bearing combination, while 128 had been given a SIKOMET-SM21 cobalt-chromium alloy metal-on-metal combination. The control group consisted of 31 age- and gender-matched subjects. RESULTS: Compared with the controls, all the patients had higher cobalt and chromium levels. Cobalt concentrations were up to 50 times higher, while chromium concentrations were up to 100 times higher. CONCLUSIONS: Both systems showed evidence, in the whole-blood samples, of wear debris production by the implants. Therefore, patients managed with metal-on-metal bearing combinations should be carefully monitored in order to ensure that any local or systemic complications are detected early on.

PMID: 12568948 [PubMed - indexed for MEDLINE]

1: Arch Orthop Trauma Surg. 1986;105(5):263-7.

Development of heterotopic ossification around the hip. A long-term follow-up of patients who underwent surgery with two different types of endoprostheses.

Lindholm TS, Viljakka T, Vankka E, Popov L, Lindholm TC.

Heterotopic ossification has been reported in many pathological situations, most important clinically as a sequel to hip arthroplasty and spinal trauma. The etiology of heterotopic ossification is yet not clear, but the disease is supposed to be connected with trauma. Heterotopic bone was found in 53% (1.2% with the severe form) of 623 patients operated on at the Orthopaedic Hospital of the Invalid Foundation, Helsinki, Finland; the operations included 849 arthroplasties. The rate of heterotopic ossification was higher after revision arthroplasty, following operation of the contralateral side, in men, and in primary coxarthrosis, and the incidence was higher with the Brunswik (metal-on-plastic) endoprosthesis than in the McKee-Farrar type (metal-on-metal). Heterotopic bone formation generally seemed to increase and to be more manifest during long-term observation.

PMID: 3778160 [PubMed - indexed for MEDLINE]

1: J Arthroplasty. 2001 Dec;16(8 Suppl 1):122-8.

ELSEVIER FULL-TEXT ARTICLE

Short-term results of the M2a-taper metal-on-metal articulation.

Lombardi AV Jr, Mallory TH, Alexiades MM, Cuckler JM, Faris PM, Jaffe KA, Keating EM, Nelson CL Jr, Ranawat CS, Williams J, Wixson R, Hartman JF, Capps SG, Kefauver CA.

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A polyethylene-free, metal-on-metal acetabular system (M2a-taper [Biomet, Inc., Warsaw, IN]) was designed in an effort to improve total hip arthroplasty (THA) longevity. Minimum 2-year follow-up results involving 72 polyethylene liner THAs and 78 metal liner THAs from a multicenter, randomized, controlled, investigational device exemption study are reported. Mean Harris hip scores of 95.54 (polyethylene liner group) and 95.23 (metal liner group) were reported at mean follow-up intervals of 3.29 and 3.23 years. Radiographic evaluation revealed no evidence of early failure. No acetabular components have been revised or are pending revision. No statistically significant differences in the data were calculated between liner types except for the immediate postoperative (P=.0415) and minimum 2-year follow-up (P=.0341) angles of inclination. The M2a-taper metal-on-metal articulation may represent a viable alternative for THA in younger, higher demand patients.

Publication Types:
- Clinical Trial
- Randomized Controlled Trial

PMID: 11742463 [PubMed - indexed for MEDLINE]

1: J Arthroplasty. 2004 Feb;19(2):260.

ELSEVIER SCIENCE
FULL-TEXT ARTICLE

Mid-term results of a polyethylene-free metal on metal articulation.

Lombardi AV, Mallory TH, Alexiades MM, Cuckler JM, Faris PM, Jaffe KA, Keating EM, Nelson CL Jr, Ranawat CS, Williams J, Wixson R, Berend KR, Dodds KL, Adams JB.

PMID: 14973915 [PubMed - in process]

1: Clin Orthop. 2003 Jan;(406):282-96.

LWWonline

Metal-on-metal versus polyethylene in hip arthroplasty: a randomized clinical trial.

MacDonald SJ, McCalden RW, Chess DG, Bourne RB, Rorabeck CH, Cleland D, Leung F.

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A prospective, randomized, blinded clinical trial was done to evaluate polyethylene versus metal bearing surfaces in total hip replacement. Forty-one patients were randomized to receive either a metal (23 patients) or a polyethylene (18 patients) insert. The femoral and acetabular components were identical with the acetabular insert the only variable. Patients were assessed preoperatively and postoperatively using radiographs, multiple outcome measures (Western Ontario MacMaster University Score, Harris hip score, Short Form-12), erythrocyte metal ion analysis (cobalt, chromium, titanium), and urine metal ion analysis (cobalt, chromium, titanium). Patients were followed up for a minimum of 2 years (mean 3.2 years; range, 2.2-3.9 years). There were no differences in radiographic outcomes or outcome measurement tools between patients. Patients receiving a metal-on-metal articulation had significantly elevated erythrocyte and urine metal ions compared with patients receiving a polyethylene insert. Patients who had metal-on-metal inserts had on average a 7.9-fold increase in erythrocyte cobalt, a 2.3-fold increase in erythrocyte chromium, a 1.7-fold increase in erythrocyte titanium, a 35.1-fold increase in urine cobalt, a 17.4-fold increase in urine chromium, and a 2.6-fold increase in urine titanium at 2 years followup. Patients receiving a polyethylene insert had no change in erythrocyte titanium, urine cobalt, or urine chromium and a 1.5-fold increase in erythrocyte cobalt, a 2.2-fold increase in erythrocyte chromium, and a 4.2-fold increase in urine titanium. Forty-one percent of patients receiving metal-on-metal articulations had increasing metal ion levels at the latest followup.

Publication Types:
- Clinical Trial
- Randomized Controlled Trial

PMID: 12579029 [PubMed - indexed for MEDLINE]

1: J Bone Joint Surg Br. 1995 May;77(3):345-50.

Total hip replacement and cancer. A cohort study.

Mathiesen EB, Ahlbom A, Bermann G, Lindgren JU.

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The incidence of cancer after hip replacement was studied in the 1.6 million inhabitants of Stockholm County, Sweden. A cohort of 10,785 individuals who had had hip replacement between 1974 and 1988 was followed from the date of operation to the first malignant tumour, to death, or to the end of 1989. The follow-up was based on 58,437 person-years at risk as calculated from information obtained by record-linkage with the National Cancer Registry and the National Cause-of-Death Register. The Standardised Morbidity Ratio (SMR) for all cancer sites, disregarding the length of follow-up, was 0.96 (95% CI 0.90 to 1.03). For lymphoma and leukaemia the corresponding SMR was 0.89 (0.68 to 1.14). Our results do not support previous suggestions of an increased incidence of leukaemia and lymphoma after total hip replacement.

PMID: 7744912 [PubMed - indexed for MEDLINE]

1: Clin Orthop. 1996 Aug;(329 Suppl):S128-40.

In vivo wear of three types of metal on metal hip prostheses during two decades of use.

McKellop H, Park SH, Chiesa R, Doorn P, Lu B, Normand P, Grigoris P, Amstutz H.

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Wear was analyzed on 21 metal on metal hip replacements, including McKee-Farrar, Muller, and Ring, that were retrieved from patients after as many as 25 years. Light and scanning electron microscopy indicated that early wear included substantial third body abrasion, possibly from particles generated while scratches from the original polishing were being eradicated and from dislodged surface carbides. However, the main contact zones were eventually worn smoother than the original surfaces. Wear was quantified by digitizing the shapes of the components on a coordinate measuring machine and identifying those areas that deviated from the original spheric surface. On the femoral heads, wear was typically concentrated in the superomedial region, that is, on the load axis. Three cases also had substantial wear inferiorly, but there were no cases with circumferential (equatorial) wear. The long term wear rates averaged approximately 6 micrometers per year or less and produced an average of approximately 6 mm3 of metallic wear debris per year or less. Wear rate tended to increase as clearance increased over the range of 127 to 386 micrometers, and a McKee-Farrar prosthesis with the extreme clearance of 1.7 mm wore approximately 16 times faster than the average, but there was no apparent relationship between clearance and time to revision. Larger McKee-Farrar balls had less volumetric wear, on average, than smaller balls, and the Muller balls had the greatest wear, which may have been due to contact with the edges of recesses machined into the bearing zones of the Muller cups.

PMID: 8769330 [PubMed - indexed for MEDLINE]

1: Clin Orthop. 1996 Aug;(329 Suppl):S89-98.

Metal on metal surface replacement of the hip. Experience of the McMinn prothesis.

McMinn D, Treacy R, Lin K, Pynsent P.

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The historical failure of surface replacement has been due to the production of wear debris with subsequent bone resorption, loosening, and failure. To avoid these problems, a surface replacement using a metal on metal bearing allowing thin components and femoral design and instrumentation to avoid varus alignment has been designed. Two hundred thirty-five joints have been resurfaced with this prosthesis in almost 5 years. There have been no femoral neck fractures and no dislocations. There have been 4 designs differing in the method of fixation. In the press fit group, 6 of 70 hips had to be revised for aseptic loosening. In the cemented group, debonding of the cup occurred in 3 of 43 cases. Six patients had hydroxyapatite coated components and have had excellent clinical outcomes. The current design uses a peripherally expanded hydroxyapatite coated cup and a cemented metal head; 116 of this design have been implanted during a 19-month period with excellent outcome. Despite short followup the authors are hopeful that the combination of a polar metal on metal bearing with appropriate fixation will yield a method of preserving bone stock in the younger patient requiring arthroplasty.

PMID: 8769326 [PubMed - indexed for MEDLINE]

1: Clin Orthop. 1996 Aug;(329 Suppl):S233-43.

Distribution of cobalt chromium wear and corrosion products and biologic reactions.

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Replacement hip arthroplasty with the use of ultrahigh molecular weight polyethylene for the cup articulating with a metal head has provided a low friction arthroplasty with years of success. However, the search for improved materials and designs for articulating surfaces continues. The use of metallic heads articulating with metallic cups is now being reconsidered for total hip replacements. Success will be enhanced if wear and corrosion of the articulating surfaces can be kept below that of the metal on ultrahigh molecular weight polyethylene couple. Concern has been raised about the release, and biologic fate, of metal species from corrosion and wear. Titanium alloys have been shown to have limitations as an articulating surface showing significant wear, and the alloy per se should not be considered for wear couples in total hip replacements. The cobalt chromium alloys are known to have reasonable wear and corrosion properties and continue to be evaluated. The issue of cobalt chromium wear and corrosion products and how this relates to the biologic performance of total hip replacement devices is reviewed. Under the condition of wear as currently experienced at the articulating surfaces of cobalt chromium alloys and ultrahigh molecular weight polyethylene, the amount of metallic products transferred to the tissues is sufficiently low to be well tolerated by the biologic system. Nickel and cobalt ions arc, rapidly transported from the implant site and eliminated in the urine. Chromium is stored in the tissue and eliminated more slowly. The issue of host hypersensitivity to these elements remains of concern. All 3 elements, in ionic form, are known to cause contact dermatitis. Untoward biologic reactions, including hypersensitivity, should be minimized if wear and corrosion phenomena are minimized.

Publication Types:
- Review
- Review, Tutorial

PMID: 8769337 [PubMed - indexed for MEDLINE]

1: Clin Orthop. 1996 May;(326):71-9.

Immune response to synthetic materials. Sensitization of patients receiving orthopaedic implants.

Merritt K, Rodrigo JJ.

Metallic orthopaedic devices are composed of elements that are known to be skin sensitizers in the general population. There is concern about the possibility of sensitivity reactions in patients bearing these implants. Blood samples were drawn from 22 patients having primary total joint replacement and who had no known prior metal allergies or exposure. Repeat blood samples were drawn 3 months to 1 year later. All preoperative blood samples showed no immune reactions against titanium, cobalt, chromium, or nickel ion solutions in a leukocyte migration inhibition test. Thirty two percent (7 of 22) of the patients developed sensitivity to at least 1 of the antigens, but only 5 percent (1 of 22) developed a severe reaction. Review of the literature and these studies has indicated that such reactions can occur. However, the incidence seems to be very low.

PMID: 8620661 [PubMed - indexed for MEDLINE]

1: J Natl Cancer Inst. 1995 Jan 4;87(1):28-33.

Cancer risk after hip replacement with metal implants: a population-based cohort study in Sweden.

Nyren O, McLaughlin JK, Gridley G, Ekbom A, Johnell O, Fraumeni JF Jr, Adami HO.

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BACKGROUND: Joint replacement with metal implants has been the standard procedure for surgical treatment of irreversible degeneration of hip and knee joints for more than two decades. However, reports of local malignancy after joint replacement and experimental studies that suggest a carcinogenic action of metal ions and polymethylmethacrylate (an acrylic compound used to stabilize the implant in the host) have raised concern about the possible long-term risks associated with metal implants. PURPOSE: Our aim was to study cancer risk in a Swedish cohort of patients who had hip replacement surgery during the period 1965 through 1983. METHODS: We studied the risk of cancer in a cohort of 39 154 patients (14 869 men and 24 285 women), identified in the nationwide Swedish Inpatient Register with at least one hip replacement during the period 1965 through 1983. The patients were followed through 1989 by means of record linkage to the Swedish Cancer Register. The cohort contributed a total of 327 922 person-years at risk. Standardized incidence ratios (SIRs) were computed using age-, sex-, and period-specific incidence rates derived from the entire Swedish population. RESULTS: The overall relative risk of cancer was increased by only 3%. Bone cancer--the focus of previous concerns--occurred in six cases versus 4.3 expected, and connective tissue cancer occurred in 28 cases versus 25.9 expected. Increased risks were observed for kidney cancer (SIR = 1.31; 95% confidence interval [CI] = 1.13-1.51), prostate cancer (SIR = 1.13; 95% CI = 1.04-1.22), and melanoma (SIR = 1.23; 95% CI = 1.00-1.50). The relative risk of gastric cancer steadily declined with increasing follow-up time, in both men and women (SIR = 0.58; 95% CI = 0.39-0.84 more than 10 years after hip replacement). CONCLUSION: In this study, the largest study to date to evaluate hip replacement and subsequent cancer risk, the overall cancer risk appears to be negligible from a public health perspective, and our results have not produced any strong evidence against the continued use of these devices. Nevertheless, the small but statistically significant increases in kidney and prostate cancers and the decrease in gastric cancer deserve further study.

PMID: 7666459 [PubMed - indexed for MEDLINE]

1: Radiographics. 2000 May-Jun;20(3):699-712.

Metal artifact reduction sequence: early clinical applications.

Olsen RV, Munk PL, Lee MJ, Janzen DL, MacKay AL, Xiang QS, Masri B.

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Artifact arising from metal hardware remains a significant problem in orthopedic magnetic resonance imaging. The metal artifact reduction sequence (MARS) reduces the size and intensity of susceptibility artifacts from magnetic field distortion. The sequence, which is based on view angle tilting in combination with increased gradient strength, can be conveniently used in conjunction with any spin-echo sequence and requires no additional imaging time. In patients with persistent pain after femoral neck fracture, the MARS technique allows visualization of marrow adjacent to hip screws, thus enabling diagnosis or exclusion of avascular necrosis. Other applications in the hip include assessment of periprosthetic soft tissues after hip joint replacement surgery, postoperative assessment after resection of bone tumors and reconstruction, and localization of unopacified methyl methacrylate cement prior to hip arthroplasty revision surgery. In the knee, the MARS technique allows visualization of structures adjacent to implanted metal staples, pins, or screws. The technique can significantly improve visualization of periprosthetic bone and soft-tissue structures even in patients who have undergone total knee arthroplasty. In patients with spinal fixation hardware, the MARS technique frequently allows visualization of the vertebral bodies and spinal canal contents. The technique can be helpful after wrist fusion or screw fixation of scaphoid fractures.

PMID: 10835123 [PubMed - indexed for MEDLINE]

1: J Arthroplasty. 1999 Apr;14(3):272-80.

Erratum in:

- J Arthroplasty 2000 Jan;15(1):136-7.

J Arthroplasty

Cancer incidence in Finnish hip replacement patients from 1980 to 1995: a nationwide cohort study involving 31,651 patients.

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Nationwide, computer-based reporting of all arthroplasties performed in Finland was started in January 1980. Using data from these records, a cohort of 31,651 polyethylene-on-metal total hip arthroplasty (THA) patients was followed up for cancer, using Finnish Cancer Registry data, from 1980 to 1995. During follow-up, 2,367 cancers were observed. There were statistically significantly fewer cancers among the THA patients (standardized incidence ratio [SIR], 0.90; 95% confidence interval [CI], 0.87-0.93). SIRs for cancers of the lung (0.69) and stomach (0.77) were significantly below unity. There was no significantly increased risk at any site. The SIR for cancer overall in male THA patients was below unity during the first 3 years after THA but returned to unity thereafter. The low SIR among men during the first 3 years was largely because the lung cancer SIR was 0.47 (95% CI, 0.35-0.62). In women, the SIR remained around 0.93 throughout follow-up. The SIR for stomach cancer was below unity only in women (SIR, 0.67; 95% CI, 0.51-0.86). For cancer of the urinary bladder, the SIR during the first 3 years after THA was below unity but later slightly above it (SIR, 1.24 in relation to > or =3 years of follow-up; 95% CI, 0.99-1.52). For myeloma and leukemia, SIRs were greater than unity only for THA patients followed up for 3 to 9 years. The study findings, in contrast to previously reported findings, do not indicate that there is any increased risk of hematopoietic cancers after THA using polyethylene-on-metal prostheses. SIRs relating to soft tissue cancers and bone sarcomas did not differ significantly from unity. No sarcoma was observed at the site of a prosthesis. THA seems to play no major role in cancer causation.

PMID: 10220179 [PubMed - indexed for MEDLINE]

1: Acta Orthop Scand. 1986 Oct;57(5):415-8.

Metal ions in body fluids after arthroplasty.

Pazzaglia UE, Minoia C, Gualtieri G, Gualtieri I, Riccardi C, Ceciliani L.

We measured levels of metal ions in urine and plasma of 17 patients 7-15 years after they had a Co-Cr-Mo alloy total hip replacement. They had higher levels of cobalt and chromium than controls. No case of skin sensitivity to the investigated metals was observed. The values of cobalt and chromium in plasma and urine were considerably lower than in professionally exposed groups and do not represent a toxic hazard for the patients.

PMID: 3811884 [PubMed - indexed for MEDLINE]

1: Aust N Z J Surg. 1997 Sep;67(9):634-6.

Metal-on-metal articulation in total hip arthroplasty: preliminary results in 57 cases.

Randle R, Gordiev K.

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BACKGROUND: Aseptic loosening of hip prostheses may lead to implant failure and necessitate revision surgery. Metal-on-metal hip articulation has characteristics that may minimize prosthesis loosening when compared with other forms of hip articulation. The purpose of the present prospective study was to identify early problems that may contraindicate the use of the 'prosthesis femorale modulaire' (PFM) metal-on-metal prosthesis. METHODS: The preliminary results of 57 metal-on-metal total hip arthroplasties performed by one surgeon (RR) from 1994 to 1996 in Lismore, New South Wales, are presented here. Data were obtained using patient questionnaires, physical examination and by examination of radiographs. RESULTS: A total of 87.6% of patients had an excellent or good outcome, according to the Harris rating system, at the latest review. The two patients with poor results had obvious alternative causes for their continuing symptoms. There was no radiological evidence of bone or prosthesis failure during the period of follow-up. CONCLUSIONS: The preliminary results are comparable with those of other authors who have examined the early results of metal-on-metal total hip arthroplasty.

PMID: 9322702 [PubMed - indexed for MEDLINE]

1: Rev Chir Orthop Reparatrice Appar Mot. 1996;82(1):85-89.

[15 years survival of the Mac-Kee Farrar metal hip prosthesis. Apropos of 58 cases and 4 explanted cups]

[Article in French]

Ray A.

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PURPOSE OF THE STUDY: Despite a high percentage of loosening (femoral, iliac or both), many surgeons have been surprised by some excellents results of Mac Kee Farrar prosthesis after 15, or even 20 years follow-up. MATERIALS AND METHODS: 37 patients (on 58) were reviewed with a follow-up of more than 15 years (48 hips). Among 17 cases followed for more than 20 years, with very good results (clinical and radiological), only one femoral loosening was observed. A part, 4 paired explanted implants (loosening at 18 years for 3 and at 21 years for one) were examined for a dimensional and metallurgic study. RESULTS: The results showed: no wear, very good bearing surface statement and sphericity, We never observed agressive granulomatous lesions with metallic particles (metallosis), nor wear concerning the cup. CONCLUSION: The peripheric design appears able to give a very good pressure repartition from cup to bone, allowing a homogeneous coat of cement with an equal thickness, and avoids loosening. Finally, we think that the progressive polar cavity in the cup, could have a great importance on lubrification, as an hydrokinetic reserve and micropump for synovial fluid.

PMID: 8762995 [PubMed - indexed for MEDLINE]

1: Proc Inst Mech Eng [H]. 2001;215(2):153-60.

In vitro comparison of the two hard-hard articulations for total hip replacements.

Rieker C, Konrad R, Schon R.

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Polyethylene particle disease is one of the major causes of late aseptic loosening of total hip replacement. Two hard-hard articulations (alumina-on-alumina and metal-on-metal) have been developed in Europe as an alternative to the ultra-high molecular weight polyethylene (UHMWPE) articulations. Even though these hard-hard articulations are on the market and numerous reports have been published about them, only a very limited number of studies allowing a direct in vitro comparison of the two articulations have been published so far. This paper compares in vitro these two types of articulation (alumina-on-alumina and metal-on-metal), which have been tested with a hip simulator for their tribological behaviour using exactly the same experimental methodology. This comparison shows that these two types of hard-hard articulation have very similar abrasive wear behaviour with four main features: 1. A running-in wear period (1 x 10(6) cycles) gives a cumulative wear of about 20 microns with head diameters of 28 mm. 2. After the running-in wear, there is a stabilization of the linear wear behaviour with a low linear wear rate/10(6) cycles for both types of articulation. 3. The volumetric wear rate of both articulations (< 2.0 mm3/year for head diameters of 28 mm) is significantly lower than that observed for metal-on-polyethylene or ceramic-on-polyethylene articulations having the same head diameter. 4. Abrasive wear is readily apparent (indicating a mixed lubrication regime) with both types of articulation. The extremely low wear performance of these articulations is confirmed and they constitute a low-wear alternative to the UHMWPE articulations currently used.

PMID: 11382074 [PubMed - indexed for MEDLINE]

1: Biomaterials. 2003 Mar;24(6):1081-91.

Related Articles, Links

ELSEVIER FULL-TEXT ARTICLE

Retrieval study of uncemented metal-metal hip prostheses revised for early loosening.

Reinisch G, Judmann KP, Lhotka C, Lintner F, Zweymuller KA.

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A tribologic assessment was performed on 22 metal-metal hip prostheses from a single manufacturer, following removal for early aseptic loosening after a mean service life of 32 months (range, 12-59 months). The mean linear wear rate was 7.6 microm/year (range, 2.9-12.8 microm/year). This was below the rates previously observed in other modern metal-metal combinations. A novel contour analysis technique using a coordinate measuring machine showed the mean volumetric wear rate to be 2.02 mm (3)/year (range, 0.55-3.74 mm(3)/year), which corresponds to a mean gravimetric wear rate of 16.9 mg/year (range, 4.6-31.4 mg/year). The mean clearance of 39.8 microm (range, 30-50 microm) was within the optimal range for hard-hard bearing combinations. Evidence of abrasive, adhesive, and third-body wear was found on all bearing surfaces. The tribologic assessment did not indicate manufacturing defects as a cause of early loosening. Equally, third-body wear was too low to be considered a causative factor for early loosening.

PMID: 12504531 [PubMed - indexed for MEDLINE]

1: J Med Eng Technol. 1994 Nov-Dec;18(6):208-17.

Effect of implant material properties on the performance of a hip joint replacement.

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A composite material implant prosthesis for hip replacement has been developed. The design of the prosthesis substructure was based on investigation of the stress and strain fields that were developed in the human femur at the proximal end when a prosthesis stem had been inserted into it. The prosthesis stem structure was of unidirectional fibrous composite material core (graphite fibres in polysulfone matrix), wrapped with four layers of the same material but orientated at different angles. The orthotropic moduli of the outer layer are very close to the moduli of a human cortical bone in the vertical and circumferential directions. The moduli increased gradually from the outer layer to the inner core. A three-dimensional finite element model of the prosthesis and the bone has been constructed and loaded with the range of forces that might appear upon operation. The behaviour of the composite prosthesis and the femur was then compared with the intact femur and three other types of prosthesis materials, namely stainless steel, titanium, an isoelastic material and a hypothetical one with moduli identical to the cortical bone. The titanium has modulus of elasticity that is only half of the stainless steel. It was found that the composite prosthesis gave the best performance for most of the categories that were examined.

PMID: 7595934 [PubMed - indexed for MEDLINE]

1: Acta Orthop Scand. 2003 Aug;74(4):380-8.

Alternative materials to improve total hip replacement tribology.

Santavirta S, Bohler M, Harris WH, Konttinen YT, Lappalainen R, Muratoglu O, Rieker C, Salzer M.

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An improvement in tribology of bearing surfaces is an effective means of increasing the longevity of total hip replacement (THR). Currently, 3 approaches are available to achieve this aim: first, use of highly cross-linked UHMWPE; second, aluminum oxide ceramic bearings, and third, metal-on-metal bearings. Cross-linking reduces the wear resistance of UHMWPE markedly without impairment of other significant properties of the material. Simulator studies and some clinical long-term (10-22 years) follow-up surveys suggest an almost immeasurable wear of the highly cross-linked UHMWPE-based acetabular components during an expected clinical life span. Bioinert alumina ceramic (aluminum oxide) was introduced 3 decades ago for THR-bearing surfaces to improve performance and longevity. Alumina ceramic is entirely biostable and bioinert and has good mechanical properties. For correctly positioned alumina-on-alumina bearings, the annual linear wear rate has been reported to be 3.9 microm. Alumina heads have been successfully used in combination with polyethylene sockets, but as regards wear, the best results have been obtained with alumina-on-alumina bearings. In ceramic THR bearings, precise manufacture and contact surface geometry, including optimal clearance, are most important. For the currently available products, the component fracture risk is almost nonexistent (less than 1 per 1000). Metal-on-metal bearings were used in the early stage of THR surgery, although not all old designs were successful. More recent analyses of the early series have shown the advantages of metal-on-metal to be better and have led to a renaissance of this articulation. Initially, stainless steel was used because it was easy to manufacture and polish. Current metal-on-metal bearings are based on cobalt-chromium-molybdenum alloys with varying carbon contents. Such bearings are self-polishing. Linear wear rates remain at the level of a few microm a year. An improvement in technology has increased the life span of the above three THR-bearing systems. Although the technical solutions differ considerably, they all seem to improve clearly the tribology and longevity of the THR. Each of these bearing concepts will probably permit the use of larger head sizes, to reduce the risk of impingement and luxations.

Publication Types:
- Review
- Review, Tutorial

PMID: 14521286 [PubMed - indexed for MEDLINE]

1: J Biomed Mater Res. 2003 Sep 1;66A(3):450-6.

Ion release in stable hip arthroplasties using metal-on-metal articulating surfaces: a comparison between short- and medium-term results.

Savarino L, Granchi D, Ciapetti G, Cenni E, Greco M, Rotini R, Veronesi CA, Baldini N, Giunti A.

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The use of metallic heads articulating with metallic cups could solve the problem of polyethylene (PE) wear in total hip replacement (THR) with metal-on-PE bearings. A conspicuous release of metal ions from new models of metal-on-metal bearings has been found in the short-term, but it is yet unclear whether the medium-term corrosion rate is high or, on the contrary, it becomes negligible, because of the continuous surface finishing. Our purpose was to compare the serum ion values (nanograms per milliliter) in 15 patients with metal-on-metal stable prosthesis (Group A), in the short-term (subgroup A(1); mean follow-up: 24 mo) and medium-term (subgroup A(2); mean follow-up: 52 mo), in order to determine whether the ion release decreased with time of implant. Chromium (Cr), cobalt (Co), molybdenum (Mo) and aluminum (Al) were analyzed. Twenty-two presurgical patients were used for comparison (Group B). The reference range was obtained from a population of 27 healthy subjects (Group C). Co and Cr levels in the medium-term (subgroup A(2)) were not decreased in comparison with the short-term values (subgroup A(1)) and were significantly higher ($p < 0.001$) than presurgical and reference values. Otherwise, Mo and Al concentrations were not significantly increased in comparison with reference values. In conclusion, despite the apparent advantage of metal-on-metal coupling, especially in younger patient populations, there is a major concern about the extent and duration of the relevant "internal" exposure to Cr and Co ions. This exposure should be carefully monitored, in order to clarify the biologic effects of ion dissemination and, consequently, to identify risks concerning long-term toxicity of metals. Copyright 2003 Wiley Periodicals, Inc. J Biomed Mater Res 66A: 450-456, 2003

PMID: 12918026 [PubMed - in process]

1: J Biomed Mater Res. 2002;63(5):467-74.

Ion release in patients with metal-on-metal hip bearings in total joint replacement: a comparison with metal-on-polyethylene bearings.

Savarino L, Granchi D, Ciapetti G, Cenni E, Nardi Pantoli A, Rotini R, Veronesi CA, Baldini N, Giunti A.

Laboratorio di Fisiopatologia degli Impianti Ortopedici, Istituti Ortopedici Rizzoli, Bologna, Italy. lucia.savarino@ior.it

Polyethylene (PE) wear has been shown to be a problem in long-term joint replacement using metal-on-PE bearing. The use of metallic heads articulating with metallic cups could solve this problem: success will be enhanced if wear and corrosion of the articulating surfaces are maintained at a low level. New models with metal-on-metal bearing have been proposed, to be used mainly for young subjects: such coupling seems to have a reduced release, but it is unclear yet if the medium-term corrosion rate is really negligible or, on the contrary, it is significantly higher than in the metal-on-PE bearing. Aim of our study was the comparison of ion release in the serum of two groups of patients who had the same type of stable cementless prosthesis, but different bearing: twenty-six patients with metal-on-metal (Group A) and fifteen patients with metal-on-PE bearing (Group B) were examined. The follow-up was 14-38 months for group A and 18-34 months for group B. The serum concentration of chromium (Cr), cobalt (Co) and molybdenum (Mo) was measured. Twenty-two patients before surgery were used for comparison (Group C). The reference values were obtained from a population of twenty-two healthy subjects (Group D). Our findings indicate that metal-on-metal bearings produce a significantly higher systemic release of cobalt and chromium (ng/ml) when compared with levels found in metal-on-PE, pre-surgery and reference groups. Such a high release should induce to improve the bearing materials or, at least, to study the biologic fate of metal ions and consequently their long-term effects. In such a way a risk-to-benefit ratio for the patient could be established.
 J Biomed Mater Res (Appl Biomater) 63: 467-474, 2002

PMID: 12209889 [PubMed - indexed for MEDLINE]

1: J Toxicol Clin Toxicol. 1999;37(7):839-44.

Increased blood cobalt and chromium after total hip replacement.

Schaffer AW, Pilger A, Engelhardt C, Zweymueller K, Ruediger HW.

Department of Occupational Medicine, University of Vienna, Austria.
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OBJECTIVE: To determine metal concentrations in blood and urine of patients who received cobalt-chromium-alloy metal on metal hip implants. METHODS: Cobalt and chromium were determined in blood and urine of 76 patients and 26 controls by electrothermal atomic absorption spectroscopy. RESULTS: A significant postoperative elevation of the metal concentrations was observed for total hip replacement patients in contrast to the control group. Twenty-nine patients exceeded the EKA (Expositionaquivalente fur Krebserzeugende Arbeitsstoffe) threshold limits for cobalt in blood and for cobalt and chromium in urine. We obtained a significant correlation between cobalt in blood and cobalt in urine ($r = 0.79$; $p < 0.005$), chromium in blood and chromium in urine ($r = 0.79$; $p < 0.005$), cobalt in blood and chromium in blood ($r = 0.69$; $p = 0.008$), and cobalt in urine and chromium in urine ($r = 0.95$; $p = 0.004$). CONCLUSION: Our findings suggest that in total hip replacements using metal-metal pairings, metal ions of the alloys are released. This release may lead to significantly elevated metal concentrations in biological fluids. Long-term studies are needed to determine the risk of metal-metal implants as a potential cause of cobalt and chromium toxicity.

Publication Types:
- Clinical Trial

PMID: 10630267 [PubMed - indexed for MEDLINE]

1: Clin Orthop. 1996 Aug;(329 Suppl):S48-59.

Factors correlating with long term survival of McKee-Farrar total hip prostheses.

Schmalzried TP, Szuszczewicz ES, Akizuki KH, Petersen TD, Amstutz HC.

Joint Replacement Institute at Orthopaedic Hospital, Los Angeles, CA, USA.

Clinical and radiographic evaluations of 15 McKee-Farrar hip replacements in 13 patients with followup of 21 to 26 years were performed. The average Harris hip score was 86 with no patients having a poor result. These patients outscored the age matched controls in all categories of the SF-36 health survey. All patients were community ambulators with qualitative activity levels exceeding the average for their age. Quantitative activity assessment with a pedometer in 3 patients indicated a current average of approximately 900,000 cycles per year. This represents more than 21 million cycles when extrapolated during the life of the implants. None of the femoral components were radiographically loose. One acetabular component may be loose. Osteolysis developed in 3 apparently well fixed femurs and in 1 acetabulum. There were several features of these cases that may have contributed to the long survival: (1) relatively small stature of the patients who averaged 160.5 cm (5 feet 5 inches) in height and 66.9 kg (147 lbs) in weight; (2) favorable biomechanics of the reconstruction with the hip center of rotation being medialized by an average of 6.4 mm and the femoral offset increased by an average of 4.9 mm; (3) decreased potential for neck socket impingement with an average lateral acetabular opening of 54 degrees and all components were anteverted; (4) radiolucent cement in 13 of 15 hips; and (5) no radiographically measurable wear. Previous analyses and comparisons of the clinical performance of the McKee-Farrar implant have focused on the metal on metal bearing. As has been recognized with the many variations of total hip replacement using metal on plastic hearings, there are a myriad of variables that contribute to clinical outcome. The results of this study suggest that patient selection and technical factors may contribute to the long term survival, and conversely to the failure, of McKee-Farrar implants.

Publication Types:
- Review
- Review, Tutorial

PMID: 8769322 [PubMed - indexed for MEDLINE]

1: Clin Orthop. 1996 Aug;(329 Suppl):S106-14.

Metal on metal surface replacement of the hip. Technique, fixation, and early results.

Schmalzried TP, Fowble VA, Ure KJ, Amstutz HC.

Joint Replacement Institute at Orthopaedic Hospital, Los Angeles, CA, USA.

High volumetric wear of polyethylene plays a central role in periprosthetic bone resorption and the failure of metal on polyethylene total hip resurfacing prostheses. An assessment of technique, initial fixation, and the early results of 21 hips in 19 patients implanted with a metal on metal bearing total hip resurfacing prosthesis, 4 all cementless Wagner prostheses and 17 all cemented McMinn prostheses, is presented. Pain relief was equal to conventional total hip replacement with a better functional result with an average followup of 16 months (range, 10-25 months). The femoral component position and fixation is satisfactory in all 21 hips and there were no femoral neck notches or fractures. All 4 cementless Wagner acetabular components appear to be osseointegrated with stable interfaces. The cemented McMinn acetabular components, however, have shown progressive cement bone interface radiolucencies in 12 hips. This preliminary experience underscores the importance of obtaining secure initial fixation. There have been no problems directly attributable to the metal on metal bearing but the authors will continue to follow these hips and evaluate their performance. The metal on metal hip surface replacement procedure is in evolution. This ongoing experience will help guide total hip surface replacement component design and implantation techniques.

Publication Types:
- Case Reports

PMID: 8769328 [PubMed - indexed for MEDLINE]

1: J Arthroplasty. 1996 Apr;11(3):322-31.

Long-duration metal-on-metal total hip arthroplasties with low wear of the articulating surfaces.

Schmalzried TP, Peters PC, Maurer BT, Bragdon CR, Harris WH.

Joint Replacement Institute at Orthopaedic Hospital, Los Angeles, CA 90007, USA.

The 20-year performance of metal-on-metal hip articulations has not been reported. Five McKee-Farrar total hip prostheses and one Sivash prosthesis were obtained at revision surgery after a mean implantation time of 21.3 years. A radiographic, histologic, implant, and wear analysis was performed on these total hip implants with cobalt-chrome metal-on-metal articulations. All cases were associated with femoral component loosening, but the bearing surfaces performed remarkably well. The worst case estimate of combined femoral and acetabular linear wear was 4.2 microns per year, about 25 times less than that typically seen with polyethylene. Metal particles and foreign-body inflammation were seen in all cases, but the volume of reactive tissue was small compared with what is generally seen at revision of hips with a polyethylene acetabular bearing. This may be due to a reduced particle burden or a decreased inflammatory reaction to particulate metal, or both. In addition to articular wear, other sources of metal particles included femoral neck impingement on the acetabular rim, stem burnishing, and corrosion. Prosthetic hip reconstructions can fail for many reasons, including suboptimal femoral stem and/or acetabular cup design and/or fixation. By today's standards, the McKee-Farrar and Sivash stem and acetabular component designs are suboptimal; however, after more than 20 years of use, the metal-on-metal bearing surfaces in these cases demonstrated low wear and do not appear to be the cause of failure. Recent advances in total hip arthroplasty, which include improved implant design, materials, manufacturing, and fixation, combined with a better understanding of the mechanisms of implant loosening and failure, suggest that the cobalt-chrome metal-on-metal bearing be reexamined as an alternative to polyethylene when exceptional durability is required.

Publication Types:
- Case Reports

PMID: 8713913 [PubMed - indexed for MEDLINE]

1: J Bone Joint Surg Br. 1999 Jan;81(1):46-50.

Analysis of 118 second-generation metal-on-metal retrieved hip implants.

Sieber HP, Rieker CB, Kottig P.

Regionalspital, Biel, Switzerland.

Osteolysis is due to particulate wear debris and is responsible for the long-term failure of total hip replacements. It has stimulated the development of alternative joint surfaces such as metal-on-metal or ceramic-on-ceramic implants. Since 1988 the second-generation metal-on-metal implant Metasul has been used in over 60 000 hips. Analysis of 118 retrieved specimens of the head or cup showed rates of wear of approximately 25 microm for the whole articulation per year in the first year, decreasing to about 5 microm per year after the third. Metal surfaces have a 'self-polishing' capacity. Scratches are worn out by further joint movement. Volumetric wear was decreased some 60-fold compared with that of metal-on-polyethylene implants, suggesting that second-generation metal-on-metal prostheses may considerably reduce osteolysis.

PMID: 10068001 [PubMed - indexed for MEDLINE]

1: Proc Inst Mech Eng [H]. 2001;215(2):161-70.

The effect of femoral head diameter upon lubrication and wear of metal-on-metal total hip replacements.

Smith SL, Dowson D, Goldsmith AA.

School of Mechanical Engineering, University of Leeds, UK.

It has been found that a remarkable reduction in the wear of metal-on-metal hip joints can be achieved by simply increasing the diameter of the joint. A tribological evaluation of metal-on-metal joints of 16, 22.225, 28 and 36 mm diameter was conducted in 25 per cent bovine serum using a hip joint simulator. The joints were subject to dynamic motion and loading cycles simulating walking for both lubrication and wear studies. For each size of joint in the lubrication study, an electrical resistivity technique was used to detect the extent of surface separation through a complete walking cycle. Wear of each size of joint was measured gravimetrically in wear tests of at least 2 x 10(6) cycles duration. Joints of 16 and 22.225 mm diameter showed no surface separation in the lubrication study. This suggested that wear would be proportional to the sliding distance and hence joint size in this boundary lubrication regime. A 28 mm diameter joint showed only limited evidence of surface separation suggesting that these joints were operating in a mixed lubrication regime. A 36 mm diameter joint showed surface separation for considerable parts of each walking cycle and hence evidence of the formation of a protective lubricating film. Wear testing of 16 and 22.225 mm diameter metal-on-metal joints gave mean wear rates of 4.85 and 6.30 mm3/10(6) cycles respectively. The ratio of these wear rates, 0.77, is approximately the same as the joint diameters ratio, 16/22.225 or 0.72, as expected from simple wear theory for dry or boundary lubrication conditions. No bedding-in was observed with these smaller diameter joints. For the 28 mm diameter joint, from 0 to 2 x 10(6) cycles, the mean wear rate was 1.62 mm3/10(6) cycles as the joints bedded-in. Following bedding-in, from 2.0 x 10(6) to 4.7 x 10(6) cycles, the wear rate was 0.54 mm3/10(6) cycles. As reported previously by Goldsmith et al. in 2000 [1], the mean steady state wear rate of the 36 mm diameter joints was lower than those of all the other diameters at 0.07 mm3/10(6) cycles. For a range of joints of various diameters, subjected to identical test conditions, mean wear rates differed by almost two orders of magnitude. This study has demonstrated that the application of sound tribological principles to prosthetic design can reduce the wear of metal-on-metal joints, using currently available materials, to a negligible level.

PMID: 11382075 [PubMed - indexed for MEDLINE]

1: J Biomed Mater Res. 2004 Jan 15;68B(1):1-14.

Wear evaluation of cobalt-chromium alloy for use in a metal-on-metal hip prosthesis.

St John KR, Zardiackas LD, Poggie RA.

Department of Orthopaedic Surgery and Rehabilitation, The University of Mississippi Medical Center, 2500 North State Street, Jackson, Mississippi 39216, USA. kstjohn@sod.umsmed.edu

Wear of the polyethylene in total joint prostheses has been a source of morbidity and early device failure, which has been extensively reported in the last 20 years. Although research continues to attempt to reduce the wear of polyethylene joint-bearing surfaces by modifications in polymer processing, there is a renewed interest in the use of metal-on-metal bearing couples for hip prostheses. Wear testing of total hip replacement systems involving the couple of metal or ceramic heads on polymeric acetabular components has been performed and reported, but, until recently, there has been little data published for pin-on-disk or hip-simulator wear studies involving the combination of a metallic femoral head component with an acetabular cup composed of the same or a dissimilar metal. This study investigated the in vitro wear resistance of two cobalt/chromium/molybdenum alloys, which differed primarily in the carbon content, as potential alloys for use in a metal-on-metal hip-bearing couple. The results of pin-on-disk testing showed that the alloy with the higher (0.25%) carbon content was more wear resistant, and this alloy was therefore chosen for testing in a hip-simulator system, which modeled the loads and motions that might be exerted clinically. Comparison of the results of metal-on-polyethylene samples to metal-on-metal samples showed that the volumetric wear of the metal-on-polyethylene bearing couple after 5,000,000 cycles was 110-180 times that for the metal-bearing couple. Polyethylene and metal particles retrieved from either the lubricant for pin-on-disk testing or hip simulator testing were characterized and compared with particles retrieved from periprosthetic tissues by other researchers, and found to be similar. Based upon the results of this study, metal-on-metal hip prostheses manufactured from the high carbon cobalt/chromium alloy that was investigated hold sufficient promise to justify human clinical trials. Copyright 2003 Wiley Periodicals, Inc.

PMID: 14689490 [PubMed - in process]

1: J Arthroplasty. 1998 Apr;13(3):343-5; discussion 345-6.

Comment on:

- J Arthroplasty. 1998 Apr;13(3):339-43; discussion 346-7.

Metal-on-metal articulation in total hip arthroplasty: the case for using metal-on-metal.

Streicher RM.

Stryker, Adliswil, Switzerland.

Publication Types:

- Comment

PMID: 9590647 [PubMed - indexed for MEDLINE]

Display Abstract Show: 20 Sort Send to Text

1: J Arthroplasty. 1997 Oct;12(7):819-24.

Progressive bilateral pelvic osteolysis in a patient with McKee-Farrar metal-metal total hip prostheses.

Szuszczewicz ES, Schmalzried TP, Petersen TD.

Harbor-UCLA Medical Center, Torrance, California, USA.

As accumulating evidence indicates that polyethylene plays a central role in periprosthetic osteolysis, there is a renewed interest in alternatives such as metal-metal bearings. Several long-term studies report encouraging results with the McKee-Farrar total hip arthroplasty, but there is a paucity of data on the incidence, severity, and pathogenesis of osteolysis in metal-metal bearing total hip arthroplasties. This study presents a patient who had progressive bilateral pelvic osteolysis associated with his McKee-Farrar metal-metal total hip prostheses. His left hip was revised after 13.5 years of service. The tissues revealed no gross metal staining and fewer inflammatory constituents than are typically found in metal-polyethylene bearing hips. His right hip was still functioning after 22.5 years of service, although the acetabular component was loose by that point. An arthrogram of this hip demonstrated communication of the joint with the iliac osteolysis. The development of osteolysis in both hips followed a pattern similar to that seen in metal-polyethylene total hip arthroplasties. Bearing wear could not be detected in either of the hips. Accumulating evidence indicates that particulate debris of appropriate size and number is capable of fueling periprosthetic inflammation. Specific to this study, consideration should be given to particles of cobalt-chromium alloy, polymethyl methacrylate bone-cement, and barium sulfate. Other factors that should be considered are increased joint fluid pressure, soluble inflammatory mediators, and the effective joint space. When bone becomes part of the effective joint space, it is exposed to particulate debris, soluble factors, and potentially increased joint fluid pressures, which may promote localized bone resorption. It must be kept in mind that the development of osteolysis is multifactorial. Although bearings with better wear characteristics are desirable, the elimination of polyethylene will not eliminate osteolysis.

Publication Types:
- Case Reports

PMID: 9355013 [PubMed - indexed for MEDLINE]

1: Orthopade. 1997 Feb;26(2):142-51.

[Changes in shape of the McKee-Farrar hip endoprosthesis]

[Article in German]

Tager G, Euler E, Plitz W.

Chirurgische Klinik und Poliklinik, Klinikum Innenstadt, Ludwig-Maximilians-Universitat Munchen.

The still unsolved problem of aseptic loosening in total hip arthroplasties with identification of polyethylene wear particles as one of its major causes, has led to reintroduction of metal-to-metal articulations, as indicated by a few good clinical long-term results with all-metal McKee-Farrar arthroplasties. In this paper, data on 145 patients from a population of more than 1400, all with implanted McKee-Farrars, who underwent revision surgery for aseptic loosening, are collected and analysed for dependence of duration to brands of the implants and position of the cups. The surface of each of 55 revised implants was measured using a 3-D device. The results showed no interdependence between time of loosening, brand inclination of the cup and deviation in shape of ball and cup. Additionally, the deviations in shape were slight.

PMID: 9157354 [PubMed - indexed for MEDLINE]

Display Abstract Show: 20 Sort Send to Text

1: J Bone Joint Surg Am. 2001 May;83-A(5):774-80. Related Articles, Links

Full text article at www.ejbjs.org

The risk of cancer following total hip or knee arthroplasty.

Tharani R, Dorey FJ, Schmalzried TP.

Joint Replacement Institute at Orthopaedic Hospital, Los Angeles, CA 90007, USA.

Publication Types:
- Review
- Review Literature

PMID: 11379749 [PubMed - indexed for MEDLINE]

Display Abstract Show: 20 Sort Send to Text

1: Health Technol Assess. 2002;6(15):1-109.

A systematic review of the effectiveness and cost-effectiveness of metal-on-metal hip resurfacing arthroplasty for treatment of hip disease.

Vale L, Wyness L, McCormack K, McKenzie L, Brazzelli M, Stearns SC.

Health Services Research Unit, Institute of Applied Health Sciences, University of Aberdeen, UK.

Publication Types:

- Review
- Review, Academic

PMID: 12137721 [PubMed - indexed for MEDLINE]

1: Orthopedics. 1991 Feb;14(2):137-42.

Cancer risk after Mckee-Farrar total hip replacement.

Visuri T, Koskenvuo M.

Department of Public Health, University of Helsinki, Finland.

Cancer incidence in 433 McKee-Farrar total hip replacement patients, operated on between 1967 and 1973, was examined for 5729 person-years, to the end of 1981. The expected number of natural deaths was slightly higher than observed, suggesting some selection of the operated patients. The risk of total cancer incidence did not increase, but the risk for site-specific cancer did because there were no cases of kidney or bladder cancer, or rare forms of cancer. The risk of leukemias and lymphomas increased, and the risk of breast cancer decreased; these results were surprisingly similar to those of a study from New Zealand. This study concluded that patients with total hip prostheses have a cancer morbidity differing from the general population. The role of chrome-cobalt-molybdenum alloy in carcinogenesis requires further investigation.

PMID: 2008381 [PubMed - indexed for MEDLINE]

1: Clin Orthop. 1996 Aug;(329 Suppl):S280-9.

Cancer risk after metal on metal and polyethylene on metal total hip arthroplasty.

Visuri T, Pukkala E, Paavolainen P, Pulkkinen P, Riska EB.

Central Military Hospital, Helsinki, Finland.

The incidence of cancer after metal on metal total hip arthroplasty (McKee-Farrar) and polyethylene on metal total hip arthroplasty (Brunswik, Lubinus) was compared with that of the general population in Finland. The mean followup time for the patients who had metal on metal total hip arthroplasty was 15.7 (9092 person years) and for the patients who had polyethylene on metal total hip arthroplasty it was 12.5 years (19,846 person years). One hundred thirteen malignant cancers were observed in patients who had metal on metal total hip arthroplasty and 212 were observed in patients who had polyethylene on metal total hip arthroplasty. The standardized incidence ratio for all cancers of the metal on metal arthroplasty group was 0.95 (95% confidence limits 0.79-1.13) and that of the polyethylene on metal arthroplasty group was 0.76 (95% confidence limits 0.68-0.86). The risk of total cancer in the patients who had metal on metal total hip arthroplasty was 1.23-fold compared with that of the patients who had polyethylene on metal total hip arthroplasty. Both groups had significantly less lung cancer than the general population: the leukemia incidence in the patients who had metal on metal total hip arthroplasty was slightly increased (observed to experienced 7/3.03, standardized incidence ratio 0.61; 95% confidence limits 0.17-1.56). The leukemia rate of the patients who had metal on metal total hip arthroplasty was 3.77-fold compared with that of the patients who had polyethylene on metal total hip arthroplasty, but this difference was not statistically significant. No sarcomas were observed at the site of the prosthesis. The incidence of the other forms of cancers did not differ significantly from those in the general population. The observed variation in the incidence of different cancers among patients who had total hip arthroplasty compared with the general population suggests that factors other than total hip arthroplasty play a major role in the origin of cancer.

Publication Types:
- Review
- Review, Tutorial

PMID: 8769342 [PubMed - indexed for MEDLINE]

1: Clin Orthop. 2000 Oct;(379):123-33.

Medium-term results of a modern metal-on-metal system in total hip replacement.

Wagner M, Wagner H.

Orthopaedic Department, Zeisigwaldkliniken Bethanien, Chemnitz, Germany.

Since 1988, metal-on-metal articulation from cobalt-chromium-molybdenum alloy was reintroduced into hip arthroplasty as an alternative to metal-on-polyethylene or ceramic-on-polyethylene components. Modular joint surfaces were developed for the second generation metal-on-metal articulation using newly introduced and proven prosthetic implants. Since 1990, 78 patients with 78 uncemented total hip replacements were followed up in a prospective study. The mean followup was 60 months. Three patients were lost to followup. The average age of the patients at the time of surgery was 48.8 years. Thirty-three patients had been operated on previously. No early infections occurred; one late infection occurred after 3 years. Dislocation of the prosthesis occurred in one patient who was lost to followup. In two patients ectopic ossifications were removed 17 and 27 months postoperatively. At revision surgery no metallosis could be identified. At the last followup examination, the Harris hip score was 96.8 points on average. There was no evidence that the metal-on-metal articulation gave rise to new problems or complications. Metal-on-metal articulation reduced wear considerably in the authors' previous experience. It is hoped that foreign body reactions are reduced significantly so that an alternative for total hip replacement in younger and active patients will be available.

PMID: 11039799 [PubMed - indexed for MEDLINE]

1: Clin Orthop. 1996 Aug;(329 Suppl):S78-88.

Preliminary results of uncemented metal on metal stemmed and resurfacing hip replacement arthroplasty.

Wagner M, Wagner H.

Orthopaedic Hospital, Wichernhaus, Schwarzenbruck, Nuremburg, Germany.

Seventy uncemented stemmed total hip replacements and 35 uncemented surface replacements with all metal Metasul articulating surfaces were followed up in a prospective study. There was no evidence that this metal on metal articulation causes new problems or complications that were not known already from other polyethylene-aluminum oxide ceramic articulating combinations. The results of 64 of 70 patients could be assessed as excellent and good. When tissue samples obtained during 2 reoperations for ectopic ossification were examined histologically, there was no light microscopic evidence of metal particles. In these cases, aseptic loosening seemed to be due to the lack of initial fixation with the original femoral component design, and was not related to the use of the Metasul bearing. The metal on metal articulation reduces the production of particles considerably according to experience to date. It is therefore hoped that foreign body reactions due to wear particles will be significantly reduced. The results support the continued investigation of metal on metal joint replacements for younger, active patients.

PMID: 8769325 [PubMed - indexed for MEDLINE]

1: Orthopade. 1989 Sep;18(5):370-6.

[Polyethylene wear and late loosening of a total prosthesis of the hip joint. New perspectives for metal/metal pairing of the capsule and head]

[Article in German]

Weber BG, Fiechter T.

Twenty-nine years' experience with total hip replacement surgery, including continuing quality control and follow-up studies, indicate that late loosening after 10-15 years is related to wear of the polyethylene cup. Metal-to-metal prostheses implanted 20 years ago and longer, on the other hand, show no signs of wear or loosening. In conclusion, polyethylene does not last long enough when compared to biocompatible precision-made artificial metal-metal hip joints.

PMID: 2812770 [PubMed - indexed for MEDLINE]

1: Nippon Seikeigeka Gakkai Zasshi. 1993 May;67(5):391-8.

Total hip joint replacement using a CoCrMo metal-metal sliding pairing.

Weber BG, Semlitsch MF, Streicher RM.

Orthopadie am Rosenberg, St. Gallen/Heiden, Switzerland.

Late loosening in total hip replacement is explained by a foreign body reaction of the connective tissue along the bone-implant interface due to polyethylene debris. In contrast, metal-metal prostheses of the McKee type implanted in the sixties, may still work perfectly today without any signs of osteolysis along the bone-cement interface, proving that metal-metal pairing is superior to prostheses with polyethylene cups and proving also that cement anchorage may be adequate for fixation. A new metal-metal total hip joint is presented, that has been implanted 90 times between 1988 and 1991.

PMID: 8336059 [PubMed - indexed for MEDLINE]

1: Clin Orthop. 1996 Aug;(329 Suppl):S69-77.

Experience with the Metasul total hip bearing system.

Weber BG.

Orthopadie am Rosenberg, Heiden, Switzerland.

The author and Sulzer Medical Technology Ltd, Switzerland, have developed a new generation of metal on metal bearing total hip joints. The design is different than the McKee type prostheses in that the cobalt chrome alloy heads and cups (Metasul) are of the highest precision with controlled loose fitting. These allow low friction and low wear of approximately 5 micrometers per year. It is anticipated that debris related late loosening will be avoided by the use of this design. Approximately 30,000 Metasul hearings have been produced. The first 110 Weber metal on metal hip implants have been analyzed. No adverse effects from the wear of the new metal on metal components have been noted in this series.

PMID: 8769324 [PubMed - indexed for MEDLINE]

1: Clin Orthop. 1996 Aug;(329 Suppl):S160-86.

Wear behavior and histopathology of classic cemented metal on metal hip endoprostheses.

Willert HG, Buchhorn GH, Gobel D, Koster G, Schaffner S, Schenk R, Semlitsch M.

Department for Orthopaedics, University of Gottingen, Germany.

The authors reviewed their collection of retrieved all metal hip joints (9 McKee-Farrar, 7 Muller, and 3 Huggler type prostheses) and tissues from the joint capsules and implant beds. The amount of wear was measured, and the total volume was calculated. The tissues were analyzed by atomic absorption spectral analysis or inductively coupled plasma mass spectrometry and examined by light and scanning electron microscopy. The size of particles was measured with a texture analysis system. The articulating surfaces showed many delicate scratches which represent normal wear. The calculated annual wear averaged approximately 5 mm3 per year, which is low compared with polyethylene. The cellular reaction to metal wear particles was regarded as mild. The cellular reaction to scattered and worn bone cement was always more pronounced than to metallic debris. Scanning electron microscopy confirmed the irregular shapes and mostly submicron size of the metal particles. The analytically detected metal content of the periarticular tissue was relatively low and in accordance with the wear measurements from the articulating surfaces. The excess of chromium in the tissues is discussed in the light of the elimination of cobalt as well as the relation between elements representing either corrosion products or elements still bound in wear particles.

PMID: 8769333 [PubMed - indexed for MEDLINE]

1: Clin Orthop. 1996 Dec;(333):4-14.

Tissue reactions to plastic and metallic wear products of joint endoprostheses.

Willert HG, Semlitsch M.

Publication Types:
- Biography
- Classical Article
- Historical Article

Personal Name as Subject:
- Willert HG
- Semlitsch M

PMID: 8981878 [PubMed - indexed for MEDLINE]

1: Clin Orthop. 1989 Sep;(246):39-47.

Experience with total hip arthroplasty in Greece, the first 20 years. A particular reference to long-term results with the McKee-Farrar technique.

Zaoussis AL, Patikas AF.

Asklepion Red Cross Orthopaedic Hospital, Athens, Greece.

Total hip arthroplasty was introduced early in Greece (1966-1967) and was initially performed in very small numbers. However, even after the difficult early period, statistics are low compared to other countries. An estimate brings the total number of operations during a 20-year period to 9000 with a rate in recent years of 1000 per year. An early series of 143 arthroplasties (122 patients), mainly of the McKee-Farrar metal-to-metal technique, was reviewed. A final group of 52 arthroplasties, all primary prostheses of the McKee-Farrar type, were assessed with a follow-up period ranging from 12 to 20 years postoperatively. In the surviving cases, 53% were pain-free, and, in 79%, useful motion was maintained. The roentgenographic results were less satisfying but a fair roentgenographic picture did not preclude a good or very good clinical and functional outcome. Although the metal-to-metal technique now appears to be more of historic value, long-term results with this type of implant offer grounds for comparison with current cemented techniques.

PMID: 2766621 [PubMed - indexed for MEDLINE]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Christopher Hack

Subject: 510(k) Number K042841

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) NCP

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 d

Predicate Product Code with class: KWA, JDL Class III

Additional Product Code(s) with panel (optional):

Review: (Branch Chief) for ORDB (Branch Code) 12/21/04 (Date)

Final Review: (Division Director) (Date) 12/21/04

Revised:4/2/03

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review? 2. Did we grant expedited review?		
3. Have you verified that the Document is labeled Class III for GMP purposes? 4. If, not, has POS been notified?		
5. Is the product a device? 6. Is the device exempt from 510(k) by regulation or policy? 7. Is the device subject to review by CDRH?		
8. Are you aware that this device has been the subject of a previous NSE decision? 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? 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 CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: K042841

The cover letter clearly identifies the type of 510(k) submission as (**Check the appropriate box**):

☐ Special 510(k) - Do Sections 1 and 2

☐ Abbreviated 510(k) - Do Sections 1, 3 and 4

☑ Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.	✓	
Table of Contents.	✓	
Truthful and Accurate Statement.	✓	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	✓	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	✓	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510)] Manual.	✓	
Statement of Indications for Use that is on a separate page in the premarket submission.	✓	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate.	✓	
510(k) Summary or 510(k) Statement.	✓	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	✓	
Identification of legally marketed predicate device. *	✓	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	✓	
Class III Certification and Summary. **	✓	
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]	✓	
510(k) Kit Certification ***		

* - May not be applicable for Special 510(k)s.
** - Required for Class III devices, only.
*** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.		
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
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 required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, **SEE Required Elements for a Declaration of Conformity to a Recognized Standard,** which is posted with the 510(k) boilers on the **H drive.**]		

For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, ~~which~~ relies on a non-recognized standard that has been historically accepted by ~~FDA~~, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has not been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:	✓	
b) Sterilization and expiration dating information:	✓	
i) sterilization process	✓	
ii) validation method of sterilization process		
iii) SAL	✓	
iv) packaging		
v) specify pyrogen free	✓	
vi) ETO residues	✓	
vii) radiation dose		
viii) Traditional Method or Non-Traditional Method	✓	
c) Software Documentation:	✓	

Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the "Missing or Inadequate" column must be submitted before substantive review of the document.

Passed Screening ✓ **Yes** ____ **No**
Reviewer: CDH
Concurrence by Review Branch:

Date:

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

REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K_____

Reviewer:_____

Division/Branch:_____

Device Name:_____

Product To Which Compared (510(K) Number If Known):_____

	YES	NO	
1. Is Product A Device			If **NO** = Stop
2. Is Device Subject To 510(k)?			If **NO** = Stop
3. Same Indication Statement?			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?			If **YES** = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 8
7. Descriptive Characteristics Precise Enough?			If **NO** = Go To 10 If **YES** = Stop **SE**
8. New Types Of Safety Or Effectiveness Questions?			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: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Intended Use:

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

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 performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

510(k) MEMORANDUM

Date: 12/20/04

Reviewer: Christopher Hack BSE, Biomedical Engineer
FDA/CDRH/ODE/DGRD/ORDB, HFZ-410

Document #: K042841

Date on Submission: 10/13/04

Review Initiated: 12/12/04

Received in ODE: 10/14/04
Document Received: 10/18/04

Due Date (60 Days):
Decision Date (75 Days): 12/28/04

RECOMMENDATION: SE

Sponsor and Official Contact:

Patricia S Andborn Beres
56 East Bell Dr.
P.O. Box 587
Warsaw, IN 46582

Establishment Registration Number

1825034

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.		

DECISION MAKING FLOWCHART FOR "SUBSTANTIAL EQUIVALENCE"

	YES	NO	
1. Is the product a device?	x		NO then Stop
2. Is the device subject to 510(k)?	x		NO then Stop
3. Is the indication statement the same?	x		YES then Go To 5
4. Do differences in the indication statement raise new issues of safety and effectiveness?			YES then NSE
5. Does the device have the same technological characteristics?		x	YES then Go To 7
6. Could the new characteristics affect safety and effectiveness?			YES then Go To 8
7. Are the descriptive characteristics precise enough?	x		NO then Go To 10 YES then SE
8. Are there new types of safety and effectiveness questions?			YES then NSE
9. Do accepted scientific methods exist to test the impact of the new characteristics?			NO then NSE
10. Is performance data available?			NO then Request Data
11. Does the performance data demonstrate substantial equivalence?			FINAL DECISION: SE

SUMMARY OF REVIEW

This is a metal on metal acetabular system. Only minor modifications were made in this submission. There is an addition of a slightly rougher surface for the liner cup interface, and there is the addition of two screw holes. Neither of these additions warranted addition testing information, however, the taper roughening was evaluated with push out testing to show that the taper was indeed strengthened by the slight surface roughening. The taper angles remained the same. I recommend that this device be found SE.

REQUIRED FORMS

Truthful & Accuracy Statement: √
Indications for Use Page (IFU): √
510k Summary: √

DEVICE IDENTIFICATION

Trade Name: M^2a / C^2a Acetabular system, metallic acetabular system
Regulation Number: 888.3330 – hip joint metal/semi constrained, with uncemented acetabular component prosthesis

888.3320 – hip joint metal / metal semi-constrained acetabular component prosthesis
Regulatory Class: Class III
Product Code: KWA, JDL

INTENDED USE AND INDICATIONS

The M^2a/ C^2a acetabular system us intended for cemented or non-cemented use in cases of:

1) non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
2) rheumatoid arthritis
3) correction of functional deformity
4) revision procedures where other treatment or devices have been unsuccessful
5) treatment of non-union, femoral neck fracture, trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques

DEVICE DESCRIPTION

The M^2a/C^2a Acetabular System consists of a titanium outer acetabular shell with a cobalt alloy metallic liner for metal on metal articulation. A cobalt alloy modular head completes the system. The acetabular shells are hemispherical in shape to closely match the natural acetabulum. The shells are available in out diameters of 48mm to 70 mm in 2mm increments. The shell features eight radial fins to aid in the prevention of rotation. Two screw holes in the dome allow for additional fixation by the use of 6.5mm screws. The outer surfaces of the shells are covered with Biomet's plasma spray coating.

The metallica liners contained in this submission are identical to those previously cleared in K993438- metal on metal acetabular system and K003363 – M^2a 32mm taper system. The taper locking mechanism of the shells is also identical to that of the shells cleared in these two 510(k)s.

The metallic cobalt alloy bearing liner fits into the outer shell by means of a taper similar to the taper used for attachment of a modular head to a femoral stem. The locking mechanism consists of an 18°55' taper. (b) (4) [redacted] his is less than half the allowable deviation set forth in the ISO standard for modular head sphericity (ISO 7206-2)

The metallic liners articulate with cobalt alloy modular heads identical to those cleared through K993438 an dK0033633- M^2a 32mm taper system. (b) (4) [redacted] Both 28mm and 32mm cobalt alloy modular heads are available in seven neck lengths ranging from -6mm to +12mm. Each modular head has Biomet's type 1 taper and will mate with any Biomet's type 1 taper femoral component.

The acetabular shell diameters and overall geometry are identical to the Mallory/ head shells cleared K993438 and K003363. The only difference is the addition of 2 screw holes to the Mallory/ head configuration. Besides the Mallory head style shells, the predicate 510(k)s contained the universal acetabular shell with 2 screw holes in the dome.

The shells inner taper angle that provides fixation of the metallic liner is identical to the predicates. Slight dimensional changes have been made to the inner shell geometry to insure proper seating of the liner in the shell even when the tolerances are at their limits. The surface roughness of the shell's inner taper has been increased over the predicate.

DEVICE MATERIALS

Acetabular shell is manufactured form ti-alloy (ti-6al-4v) conforming to ASTM F-136 or F-1472

The outer surface of the shell is spray coated with ti-alloy powered conforming to ASTM F-1580
The metallic liner and modular heads are manufactured for cobalt chrome alloy CoCrMo conforming to ASTM F-1537

Plasma spray characterization

(b) (4)

[redacted]

STERILIZATION

Radiation type : Gamma
Source: cobalt 60
Min dose ; 25Kgy
Max dose: 40kGy
Sal 10^{-6}
No pyrogen free claims

LABELING

Adequate

TESTING DETAILS

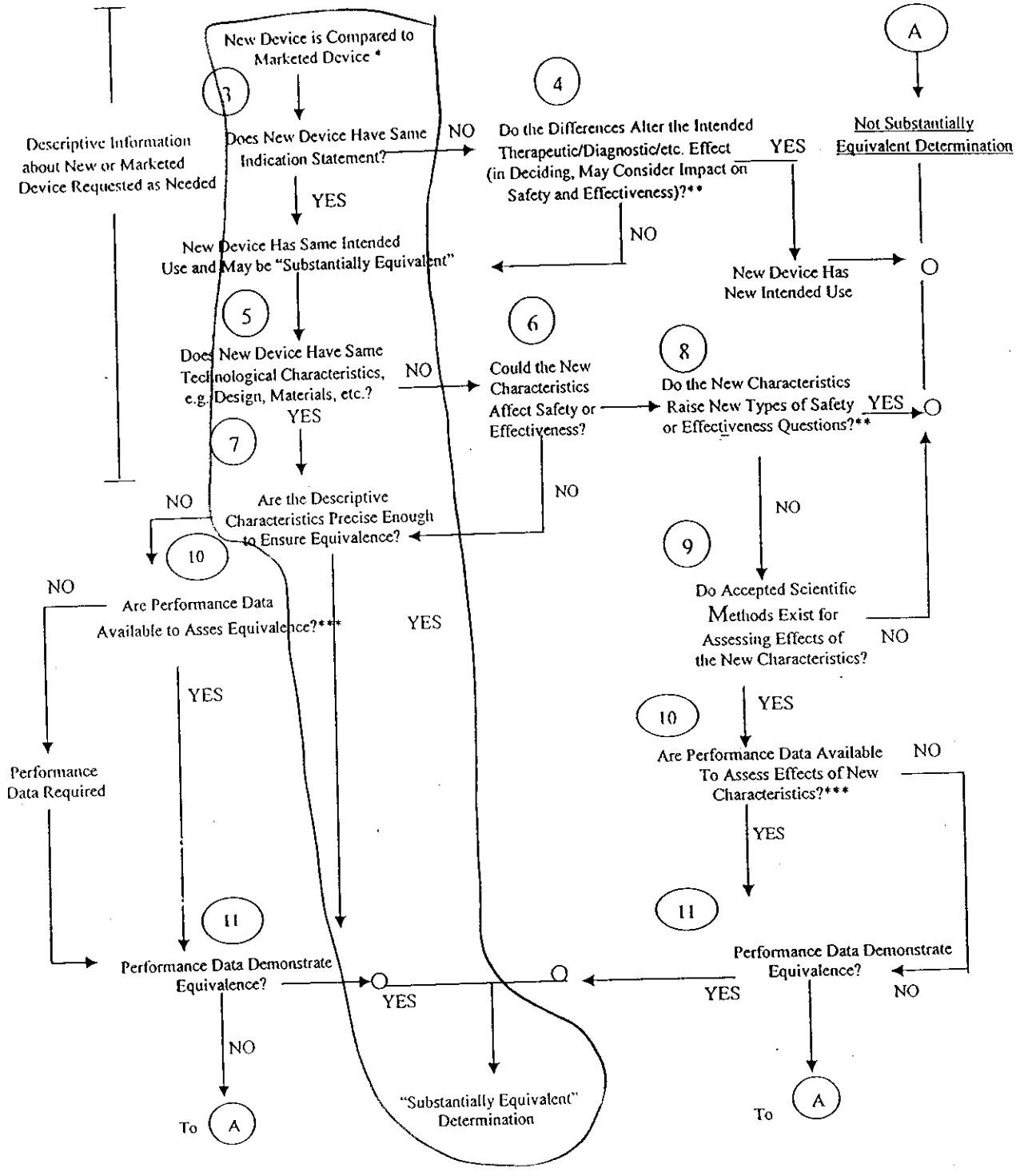
Liner locking mechanism: The only modifications the sponsor had made to the liner locking mechanism is by adding a roughened surface finish to the female taper of the Acetabular shell. The sponsor says this modification was done in order to be able to use the same shell with a future ceramic system. The sponsor has been able to show that the push –out strength with the ceramic liners in place was increased 15lbs from 165lbs to 180 lbs with the female taper roughening. The sponsor feels that the same result will be replicated with the metal liners.

Although the sponsor did not testing the roughening with the metal liners, the data from the ceramic liners with the roughened acetabular cup show that the taper is strengthened by the roughening. It does not however show by how much the taper is strengthened.

ADDITIONAL INFORMATION RELATING TO PREDICATE DEVICE

	New device	Metal on metal Acetabular system		M²a 32mm Taper System		Mallory Head PF Acetabular Component
Manufacture	Biomet	Biomet		Biomet		Biomet
K #	042841	K993438		K003363		K861114
Intended use	Cemented and uncemented	Uncemented		Uncemented		Cemented
Liners						
Liner material	Co-Cr-Mo	Co-Cr-Mo		Co-Cr-Mo		n/a
Liner internal diameter	28mm &32mm	28mm		32mm		n/a
Liner size designation	37mm &41mm	37mm		41mm		n/a
Liner locking mechanism	Taper	Taper		Taper		n/a
Acetabular Shell						
Shell style	Mallory/head	Mallory/ head	Universal	Mallory/ head	Universal	Mallory / head
Shell material	Ti-6Al-4V	Ti-6Al-4V	Ti-6Al-4V	Ti-6Al-4V	Ti-6Al-4V	Ti-6Al-4V
Liner locking mechanism	Taper	Taper	Taper	Taper	Taper	Hex-loc
Shell outer diameters	48mm-70mm by 2mm increments	52mm – 70 mm by 2mm increments	48mm-70mm by 2mm increments	52mm-70mm by 2mm increments	52mm-70mm by 2mm increments	46mm – 70mm by 4mm increments
Shell features	Radial fins 2 holes plasma spray angled cutouts	Radial fins solid plasma spray straight cut-outs	2 holes plasma spray straight cut outs	Radial fins solid plasma spray straight cut outs	2 holes plasma spray straight cut outs	Fins plasma spray

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.