Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 26 1994

Ms. Patricia Sandborn Beres
Director, Regulatory Affairs
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: (b)(4) Non-cemented Porous Coated Hip Prostheses
Dated: June 23, 1994
Received: June 30, 1994

Dear Ms Beres:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed the review of your Required Postmarket Surveillance (RPS) protocol for the above-referenced devices.

Your protocol listed above is conditionally approved. This approval is being granted on the condition that, within 45 days from the date of this letter, you submit to CDRH a summary response and a revised protocol that responds to the following (b)(4) deficiencies:

(b)(4)

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

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

(b)(4)

[redacted]

You do not need to resubmit the extensive photocopies of the scientific literature that you provided in Appendix I. We will refer to the previous submission as necessary.

Failure to submit a revised protocol that corrects all of the deficiencies listed above within 45 days from the date of this letter renders this conditional approval void. At that point,

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

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

FDA may pursue further regulatory actions since your failure to comply with any requirement under section 522 of the Federal, Food, Drug, and Cosmetic Act is a violation of the act as set forth below.

Future reports and other correspondence pertaining to this protocol, should be identified as protocol supplements, and should include the protocol reference number. Note that any changes to the protocol or Principal Investigator must be submitted as a protocol supplement for approval by the FDA. As your protocol provides, you must submit interim reports annually.

Please submit five copies of future reports and other supplements, and address all submissions to:

Center for Devices and Radiological Health
Postmarket Surveillance Studies Document Center
Room 3083(HFZ-544)
1350 Piccard Drive
Rockville, Maryland 20850

Failure of a manufacturer to conduct a RPS study according to an approved protocol, or to submit reports for these studies in a timely manner may be considered a failure or refusal to comply with section 522 of the Federal Food, Drug, and Cosmetic Act (the act). Under the act, failure of a manufacturer to meet its obligations under section 522 is a prohibited act under section 301(q)(1)(C) of the act (21 U.S.C. 331(q)(1)(C). Further, under section 502(t)(3) of the act (21 U.S.C. 352(t)(3)), a device is misbranded if there is a failure or refusal to comply with any requirement under section 522 of the act. Violations of sections 301 or 502 may lead to regulatory actions including seizure of your product, injunction, prosecution, or civil money penalties. Please note, you must continue to collect and report data needed to maintain compliance with postapproval requirements (21 CFR 814.80-814.84) and Medical Device Reporting regulations (21 CFR 803).

If you have any procedural or policy questions concerning postmarket surveillance study requirements, please contact Raymond O'Neill of the Postmarket Surveillance Studies Branch at 301-594-0639.

Sincerely yours,

Mary K Barrick

for Janet Arrowsmith-Lowe, M.D.
Acting Director
Office of Surveillance and Biometrics
Center for Devices and Radiological Health

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

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bcc:

HFZ-544
HFZ-543
HFZ-543 (R. O'Neill)
HFZ-150 (M. Bernier)
HFZ-541 (M. Torrence)
✓HFZ-404 (Re. K921181, K921224, K921225, K921274, K921277, K921301, K923452)
HFZ-410 (T. Stevens)
HFZ-300 (H. Pellerite)
HFR-MW240 (J. Dempster)
Board File
HFZ-500 (J. Arrowsmith-Lowe)

p:\pssb\biomet.app by RRO on 8/17/94 (RRO, RDS, MAM, MXT, and TRS reviews)
revised by RRO on 8/23/94 (MXT, MAM comments)
f/t:nsp:8/23/94:594-0639

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

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1350 Piccard Drive
Rockville MD 20850

Ms. Patricia Sandborn Beres
Senior Regulatory Specialist
Biomet, Inc.
P.O. Box 587
Warsaw, IN 46581-0587

JUN 16 1999

Re: RPS940005/S9
Non-Cemented Plasma Sprayed Porous Coated Hip Prostheses
Dated: April 27, 2000
Received: May 2, 2000

Dear Ms. Sandboron Beres

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your request for reconsideration of the postmarket surveillance orders for the hip prosthesis components identified above. The postmarket surveillance orders were issued in the substantial equivalence letters for premarket notification numbers K921181, K921224, K921225, K921274, K921277, K921301 and K923452.

Your request for reconsideration provides all of the information called for by our **Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements**. Based on our review of your request for reconsideration, CDRH believes that the plasma spray coating on the above hip prosthesis components has mechanical properties equal to, or better than, those of sintered or diffusion bonded porous coatings. CDRH believes that the information in your request answers the concerns that originally prompted our orders for postmarket surveillance of these devices. Therefore, CDRH is withdrawing the orders requiring you to conduct postmarket surveillance of the:

Mallory/Head Total Hip System
Bimetric Total Hip System
Integrel Total Hip System
Metallic Total Hip System
Ranawat/Burstein Total Hip System
Taperloc Femoral Hip Stem & Universal Acetabular Component
PMI Hip Femoral Stem

You may discontinue your postmarket surveillance efforts.

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

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

If you have any procedural or policy questions concerning the withdrawal of your postmarket surveillance orders, please contact the Issues Management Staff at (301) 594-3060.

Sincerely yours,

Larry G. Kessler, Sc. D
Director
Office of Surveillance and Biometrics
Center for Devices and Radiological Health

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

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

DO NOT REMOVE THIS ROUTE SLIP!!!!

7/15/92

TRS

K-92-1277

FROM: BIOMET ATTN: PATRICIA BERES P.O. BOX 587 WARSAW, IN 46581 SHORT NAME: BIOMET	LETTER DATE 03/12/92 LOGIN DATE 03/17/92 TYPE OF DOCUMENT: 510 (k) PHONE NO: 219-267-6639 ESTABLISHMENT NO: 1825034	DUE DATE 10/12/92 CONTROL # K921277 SU FA
TO: ODE/DMC	CONT. CONF.: N STATUS : R REV PANEL : OR PAN/PROD CODE(S): OR/ / X /	

SUBJECT:
RANAWAT/BURSTEIN TOTAL HIP SYSTEM

CPH

DECISION: DECISION DATE: / /	RQST INFO DATE: 06/12/92 DATE: / / DATE: / / DATE: / / DATE: / / DATE: / /	INFO DUE DATE: 07/12/92 DATE: / / DATE: / / DATE: / / DATE: / / DATE: / /

ORDB

NO

SUPPLEMENT: 01 LTR DATE: 920710 LOGIN DATE: 920714

FEB 16

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

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

K961277

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAR 8 1996

Ms. Patricia Sandborn Beres
Director, Regulatory Affairs
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: RPS940005/S2
Non-Cemented Plasma Sprayed Porous Coated Hip Systems
Dated: July 28, 1995
Received: August 1, 1995

Dear Ms. Beres:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your protocol for a Required Postmarket Surveillance (RPS) study of the above referenced device. This process included the review of a letter, dated August 3, 1995, from Dane Miller, Ph. D., of Biomet, Inc., and a meeting between you and other representatives of Biomet, Inc., and representatives of CDRH. As you know, the meeting requested in the August 3rd letter took place on November 7, 1995. Even though many of the issues contained in Dr. Miller's letter derive from this RPS study protocol, a separate response addressing the August 3rd letter will be sent directly to Dr. Miller.

At the November 7, 1995, meeting CDRH staff conveyed to you and the other Biomet, Inc., representatives CDRH's views on several issues. Among these was CDRH's view that RPS study of prosthetic hip systems fixed by biological ingrowth into plasma sprayed porous coatings remains necessary. As support for this opinion, CDRH staff presented a summary of clinical data previously provided by Biomet, Inc., i.e., the temporal pattern of device failures for several Biomet, Inc., plasma sprayed porous coated (PSPC) hip systems. CDRH believes that the total number and temporal pattern of device failures reported by this data supports the requirement for an RPS study of these devices. However, CDRH also believes that the data may indicate that during the first 5 years of implantation the failures of Biomet, Inc., PSPC hip systems are principally accounted for by the failure of the system's acetabular components. If early revision rates are accounted for by the failure of the acetabular components, then CDRH believes that its current requirements for the design of Biomet, Inc.'s, RPS study may be in error. Up to now CDRH has required that Biomet, Inc., conduct a study of each design of PSPC femoral stem. Because Biomet, Inc., has clearance to market 8 PSPC femoral stems this results in the study of 8 patient populations for a total study size of 2408 patients. If the conclusions suggested by the clinical data submitted thus far can be confirmed, then CDRH would accept altering the design of Biomet, Inc.'s RPS study to one based upon acetabular components. This would result in a study

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

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based on an adequate number of patients receiving each acetabular component. Patients within each acetabular cup design group could receive any of the 8 PSPC femoral stems sold by Biomet, Inc. The design of the femoral stem received by each patient in the study would still be recorded but the study's total sample size would be controlled by the number of different designs of acetabular components Biomet, Inc., intends to market for use with its PSPC stems rather than by the number of femoral stem designs.

At the conclusion of the November 7th meeting, CDRH representatives asked that Biomet, Inc., provide additional information to RPS940005. This information is needed to permit CDRH to accurately determine the revision rates for the various femoral stems, acetabular cups, and stem/cup combinations subject to the RPS requirement. If the revision rates bear out the conclusions suggested by the data examined thus far then CDRH could determine if a change in the study design was in order.

Therefore, your protocol remains conditionally approved on the condition that within 45 days of the date of this letter you submit a summary response and a revised protocol that correct the following deficiencies:

(b)(4)

[redacted]

Your revised protocol, all future reports, and other correspondence pertaining to this protocol must be identified as protocol supplements and addressed to the above identified RPS protocol number. Any future changes in the protocol or changes in Principal Investigator must be submitted as a protocol supplement and receive FDA approval prior to implementation. You must notify FDA in writing of the date of initiation of your study and provide interim and final reports including annual reports describing the progress of this study and every third year a full statistical analysis comparing the survivorship of each patient subgroup with that of the literature controls.

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

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

Please submit 5 copies of your supplement and address all submissions to:

Center for Devices and Radiological Health
Postmarket Surveillance Studies Document Center
Suite 330 DD (HFZ-544)
1350 Piccard Drive
Rockville, Maryland 20850

Failure to submit a summary and a revised protocol that correct the deficiencies listed above renders this conditional approval void and will be taken as a refusal to conduct a RPS study. Failure by a manufacturer to conduct a RPS study, failure to conduct such a study according to an FDA approved protocol, or failure to submit reports of such a study in a timely manner maybe considered as failures or refusals to comply with requirements under section 522 of the Food, Drug, and Cosmetic Act (the act). The failure or refusal to comply with requirements under section 522 is a prohibited act under section 301(q)(1)(C) of the act (21 U.S.C. 331(q)(1)(C)). Furthermore, under section 502(t)(3) of the act (21 U.S.C. 352(t)(3)) a device is misbranded if there is a failure or refusal by its manufacturer to comply with any requirement applied under section 522. Violations of sections 301(q)(1)(C) or 502(t)(3) may lead to regulatory actions including product seizure, injunction, prosecution, or civil money penalties.

CDRH acknowledges receipt of the written comments to the proposed guidance document for the testing of plasma sprayed porous coatings prepared by Richard Luedemann, Ph. D., of Biomet, Inc. We are still considering Dr. Luedemann's remarks and thank you for submitting comments to the proposed guidance document. CDRH is still reviewing the package of published literature you delivered at the November 7, 1995, meeting. If we determine that any of the literature articles you supplied has an impact on your RPS study we will inform you in writing.

If you have any procedural or policy questions concerning postmarket surveillance study requirements or require clarification of the above deficiencies, please contact Mr. Daniel S. McGunagle of the Postmarket Surveillance Studies Branch at (301) 594-0643.

Sincerely yours,

Larry G. Kessler, Sc.D.
Director
Office of Surveillance and Biometrics
Center for Devices and
Radiological Health

3

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

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bcc: HFZ-543
HFZ-544
HFZ-300 (H. Pellerite)
HFZ-404 (K921181, K921224, K91225, K921274, K921277, K921301, K923452)
HFZ-410 (T.Stevens)
HFZ-541 (R.Alderfer)
HFZ-150 (S.Brown)
HFZ-520 (T. Gross)
Board File
DO

DISK:PSSB Boilerplates
revised:DMcGunagle:3/27/95
:DMcGunagle:5/15/95
:NPignone:5/15/95
:DMcGunagle:8/4/95
:DMcGunagle:8/11/95
c:\wp51\rps\letters\940005s2
DMcGunagle:12/19/95
ARayner:1/31/96dMcGunagle:1/31/96
final type:jau:2/1/96
Tgross:2/26/96dMcGunagle2/27/96
jau:2/28/96

4

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

FEB 16 1994

Ms. Patricia S. Beres
Research Manager
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K921277
Ranawat/Burstein Total Hip System
Regulatory Class: II
Dated: July 10, 1992
Received: July 14, 1992

Dear Ms. Beres:

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 to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. This decision is based upon consideration of the specific designs of stem, porous coating characteristics and intended use detailed in this application, and upon data provided for the reclassified Biolox Ball manufactured by Cerasiv GmbH (formerly Feldmuehle Aktiengesellschaft). You may, therefore, market the device, subject to the general controls and to certain of the special controls provisions of the Federal Food, Drug, and Cosmetic Act (Act), and the following limitations:

1. Your device may only be labeled for noncemented use when intended for use in skeletally mature individuals undergoing primary surgery for rehabilitating hips damaged as a result of noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

2. The hip stems with Type II taper may only be labeled for use with the following Morgan Matroc Zirconia Hip Joint Balls:

Model Number	
RD-105492	28mm, -5mm Neck

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

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

RD-105493	28mm, Standard Neck
RD-105494	28mm, +2.5mm Neck
RD-105495	28mm, -3mm Neck
RD-105496	32mm, Standard Neck
RD-105497	32mm, -5mm Neck
RD-105498	32mm, -3mm Neck
RD-105499	32mm, +2.5mm Neck

The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

Under Section 522(a)(1) of the Act, FDA has determined that in order to provide for long-term safety and effectiveness data for these devices, you must conduct postmarket surveillance of your devices. Under Section 522(b) of the Act, you shall submit a protocol for the required surveillance within 30 days of the first introduction or delivery for introduction of your device into interstate commerce.

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. In addition, the Food and Drug Administration (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 the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-326) at (301) 427-4639. Other general information on your responsibilities under the Act, may be obtained from the

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

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

for Paul R. Beninger, M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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

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Ms. Patricia S. Beres
Research Manager
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K921277
Ranawat/Burstein Total Hip System
Regulatory Class: II
Dated: July 10, 1992
Received: July 14, 1992

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1. Your device may only be labeled for noncemented use when intended for use in skeletally mature individuals undergoing primary surgery for rehabilitating hips damaged as a result of noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

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RD-105494	28mm, +2.5mm Neck
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RD-105497	32mm, -5mm Neck
RD-105498	32mm, -3mm Neck
RD-105499	32mm, +2.5mm Neck

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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. In addition, the Food and Drug Administration (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 the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-326) at (301) 427-4639. Other general information on your responsibilities under the Act, may be obtained from the

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

for Paul R. Beninger, M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
410	Hebwingle	2/15/94						
410	Blackwell	2/16/94						

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

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bcc: HFZ-401 DMC
HFZ-403 RChissler
HFZ-410 DGRD
D.O.
d/t:TRS:cla:2/15/94
f/t:HFZ-410:

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

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

I N T E R O F F I C E M E M O R A N D U M

Date: 05-Nov-1993 01:03pm EST
From: Mary K. Barrick
MKB
Dept: OST-DBS
Tel No: 594-2812

TO: Susan Alpert (SXA)

CC: Anita M. Rayner (ARB)
CC: Richard P. Chiacchierini (RPC)
CC: Janet Arrowsmith-Lowe (JAL)

Subject: RE: Porous-Coated Hips

Susan,

As we discussed, here is the note from Anita which lays out our approach. I would suggest that, if he is agreeable, Paul or the appropriate folks on his staff contact Anita to start working on the rationale, letter language and guidance. Leslie will also want to be included when it comes to the appropriate language in the notification letters.

I appreciate your assurance that OSB will be included in future re-classifying discussions in order to work out appropriate postmarket requirements and mechanisms ahead of time.

Kay

RA - Copy to DGRD Thanks SA 11/18/93 DSM

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

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

I N T E R O F F I C E M E M O R A N D U M

Date: 03-Nov-1993 04:02pm EST
From: Anita M. Rayner
ARB
Dept: OST-DBS-PSSB
Tel No: 594-0639

TO: Mary K. Barrick (MKB)

CC: Janet Arrowsmith-Lowe (JAL)
CC: Richard P. Chiacchierini (RPC)

Subject: Porous-Coated Hips

Kay -

(b)(4)

[redacted]

Anita

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

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

INTEROFFICE MEMORANDUM

Date: 30-Sep-1993 07:42am DST
From: Mary Donoghue
MVD
Dept: ODE-POS
Tel No: 427-1190

TO: Daniel S. McGunagle (DSM)

CC: Robert I. Chissler (RIC)
CC: Heather S. Rosecrans (HSR)
CC: Nirmal K. Mishra (NKM)
CC: Paul Beninger (PRB)

Subject: DPS and Hips

Dan,

I received three porous coated hip 510(k)s back from OSB, each accompanied with a note from Kay Barrick. For your tracking, the 510(k)s are: K920955, K921277, and K921301. Each note reads:

"OSB can't sign off on this. DPS has not been authorized for hips. A proposal for ordering DPS may be considered by the Center committee now being formed. However, language ordering the DPS study should be removed from this letter."

(b)(4)

[redacted]

10

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

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

I N T E R O F F I C E M E M O R A N D U M

Date: 22-Sep-1993 08:05am DST
From: Daniel S. McGunagle
DSM
Dept: ODE-DGRD
Tel No: 594-2036

TO: Mary K. Barrick (MKB)

Subject: RE: Decisions

Kay,

(b)(4)

[redacted]

Daniel S. McGunagle

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

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

I N T E R O F F I C E M E M O R A N D U M

Date: 21-Sep-1993 01:40pm DST
From: Mary K. Barrick
MKB
Dept: OST-DBS
Tel No: 594-3060

TO: Daniel S. McGunagle (DSM)

Subject: RE: Decisions

Dan,

Each 510(k) package coming back carries a route slip from me to Heather sta that DPS cannot be ordered at this time. If that is not sufficient, let me know what you need.

Kay

12

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

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

I N T E R O F F I C E M E M O R A N D U M

Date: 21-Sep-1993 11:47am DST
From: Daniel S. McGunagle
DSM
Dept: ODE-DGRD
Tel No: 427-1036

TO: Mary K. Barrick (MKB)

Subject: RE: DPS and Hips

Kay,

(b)(4)

[redacted]

Daniel S. McGunagle

13

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

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

I N T E R O F F I C E M E M O R A N D U M

Date: 21-Sep-1993 07:05am DST
From: Mary K. Barrick
MKB
Dept: OST-DBS
Tel No: 594-3060

TO: Daniel S. McGunagle (DSM)

Subject: RE: DPS and Hips

Dan,

(b)(4)

[redacted]

Kay

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

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

ROUTING AND TRANSMITTAL SLIP

Date 9/20/93

TO: (Name, office symbol, room number, building, Agency/Post)	Initials	Date
1. Bill O'Connell	WOC	9/22/93
2. re: K921181		
3. HFZ-300		
4.		
5.		

	Action		File		Note and Return
	Approval		For Clearance		Per Conversation
	As Requested		For Correction		Prepare Reply
	Circulate		For Your Information		See Me
	Comment		Investigate	✓	Signature
	Coordination		Justify		

REMARKS

Please return to me. Thank you.

See comments used among (language used 522(b)(1)) and not 522(b)(2)

DO NOT use this form as a RECORD of approvals, concurrences, disposals, clearances, and similar actions

FROM: (Name, org. symbol, Agency/Post)

M. Donoghue

Room No.—Bldg. 280D

Phone No. 4190

5041-102

☆ U.S. G.P.O. 1992 312-070/60009

OPTIONAL FORM 41 (Rev. 7-76)
Prescribed by GSA
FPMR (41 CFR) 101-11.206

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

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

ROUTING AND TRANSMITTAL SLIP

Date 9/20/93

TO: (Name, office symbol, room number, building, Agency/Post)	Initials	Date
1. Bill O'Connell	WOC	9/20/93
2. re: K921225		
3. HFR-300		
4. See Comments		
5.		

	Action		File		Note and Return
	Approval		For Clearance		Per Conversation
	As Requested		For Correction		Prepare Reply
	Circulate		For Your Information		See Me
	Comment		Investigate	✓	Signature
	Coordination		Justify		

REMARKS

(b)(4)

[redacted]

clearances, and similar actions

FROM: (Name, org. symbol, Agency/Post)
M. Donoghue

Room No.—Bldg. 280D

Phone No. 4190

5041-102
☆ U.S. G.P.O. 1992 312-070/60009

OPTIONAL FORM 41 (Rev. 7-76)
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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

ROUTING AND TRANSMITTAL SLIP

Date 9/16/93

TO: (Name, office symbol, room number, building, Agency/Post)	Initials	Date
1. Heather Rosenau		
2.		
3.		
4.		
5.		

	Action		File		Note and Return
	Approval		For Clearance		Per Conversation
	As Requested		For Correction		Prepare Reply
	Circulate		For Your Information		See Me
	Comment		Investigate		Signature
	Coordination		Justify		

REMARKS

(b)(4)

[redacted]

DO NOT use this form as a RECORD of approvals, concurrences, disposals, clearances, and similar actions

FROM: (Name, org. symbol, Agency/Post)
Kay Barnett

Room No.—Bldg.
PICARD 300B

Phone No.
4-3060

5041-102

OPTIONAL FORM 41 (Rev. 7-76)
Prescribed by GSA
FPMR (41 CFR) 101-11.206

* U.S. GPO: 1988 — 241-174

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

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

ROUTING AND TRANSMITTAL SLIP

Date: 9/16/93

TO: (Name, office symbol, room number, building, Agency/Post)	Initials	Date
1. Heather Rosenrow		
2.		
3.		
4.		
5.		

	Action		File		Note and Return
	Approval		For Clearance		Per Conversation
	As Requested		For Correction		Prepare Reply
	Circulate		For Your Information		See Me
	Comment		Investigate		Signature
	Coordination		Justify		

REMARKS

(b)(4)

[redacted]

FROM: (Name, org. symbol, Agency/Post)
Kay Barrick.

Room No.—Bldg. 300A PICARD

Phone No. 4-3060

5041-102

OPTIONAL FORM 41 (Rev. 7-76)
Prescribed by GSA
FPMR (41 CFR) 101-11.206

★ U.S. GPO: 1988 — 241-174

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

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

ROUTING AND TRANSMITTAL SLIP

Date 9/16/93

TO: (Name, office symbol, room number, building, Agency/Post)	Initials	Date
1. Heather Rosenrans		
2.		
3.		
4.		
5.		

Action		File		Note and Return	
Approval		For Clearance		Per Conversation	
As Requested		For Correction		Prepare Reply	
Circulate		For Your Information		See Me	
Comment		Investigate		Signature	
Coordination		Justify			

REMARKS

(b)(4)

[redacted]

DO NOT use this form as a RECORD of approvals, concurrences, disposals, clearances, and similar actions

FROM: (Name, org. symbol, Agency/Post)
Kay Barrick

Room No.—Bldg.
PICARD 300M

Phone No.
4-3060

5041-102

OPTIONAL FORM 41 (Rev. 7-76)
Prescribed by GSA
FPMR (41 CFR) 101-11.206

★ U.S. GPO: 1988 — 241-174

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

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

ROUTING AND TRANSMITTAL SLIP

Date 9/13/93

TO: (Name, office symbol, room number, building, Agency/Post)	Initials	Date
*3. Bill O'Connell (OC)		
*4. Kay Barrick (OSB)		
*1. Dan MacGunagle		
*2. Mary Donoghue		
5.		

	Action		File		Note and Return
	Approval		For Clearance		Per Conversation
	As Requested		For Correction		Prepare Reply
	Circulate		For Your Information		See Me
	Comment		Investigate		Signature
	Coordination		Justify		

REMARKS

Hyjs —
K921224
K921225

DPS? SE letter

Dan — For resolution of DPS issue
MD 10/4/93

DO NOT use this form as a RECORD of approvals, concurrences, disposals, clearances, and similar actions

FROM: (Name, org. symbol, Agency/Post)
Mary Donoghue

Room No.—Bldg. 280D
Phone No. 41190

5041-102
☆ U.S. G.P.O. 1993 342-198/60012

OPTIONAL FORM 41 (Rev. 7-76)
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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

ROUTING AND TRANSMITTAL SLIP

Date 9/10/93

TO: (Name, office symbol, room number, building, Agency/Post)	Initials	Date
1. Dan		
2. Re: K921181		
3.		
4.		
5.		

	Action		File		Note and Return
	Approval		For Clearance		Per Conversation
	As Requested		For Correction		Prepare Reply
	Circulate		For Your Information		See Me
	Comment		Investigate		Signature
	Coordination		Justify		

REMARKS

One more time — S.E letter

Please ① reference the supportive documentation for requiring PMS from another 510(k) OR just copy what you had in the original 510(k) pkg that required PMS. THANK YOU!

② also need PB signature in letter ③ PP sig block on letter

DO NOT use this form as a RECORD of approvals, concurrences, disposals, clearances, and similar actions

FROM: (Name, org. symbol, Agency/Post) Mary Donoghue

Room No.—Bldg. 280D

Phone No. 41190

5041-102

☆ U.S. G.P.O. 1993 342-198/60012

OPTIONAL FORM 41 (Rev. 7-76)
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FPMR (41 CFR) 101-11.206

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

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

ROUTING AND TRANSMITTAL SLIP

Date 8/13/93

TO: (Name, office symbol, room number, building, Agency/Post)	Initials	Date
1. OSB/ Kay Barrick		
2.		
3.		
4.		
5.		

	Action		File		Note and Return
	Approval		For Clearance		Per Conversation
	As Requested		For Correction		Prepare Reply
	Circulate		For Your Information		See Me
	Comment		Investigate		Signature
	Coordination		Justify		

REMARKS

Please sign-off on the attached three letters of substantial equivalence. We are requesting your (OSB) sign-off due to our condition of discretionary PMS. Thank you,

DO NOT use this form as a RECORD of approvals, concurrences, disposals, clearances, and similar actions

FROM: (Name, org. symbol, Agency/Post)

Heather Rowcroft

Room No.—Bldg. 280 Price

Phone No. 7-1180

5041-102
☆ U.S. G.P.O. 1992 312-070/60009

OPTIONAL FORM 41 (Rev. 7-76)
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FPMR (41 CFR) 101-11.206

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

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

ROUTING AND TRANSMITTAL SLIP Date 8-12-93

TO: (Name, office symbol, room number, building, Agency/Post)	Initials	Date
1. McDermott	MMD	8-13-93
2. McGunagle	DSM	8/13/93
3. Mishka		
4. Benunger	MB	8/13/93
5. 510 K		

X	Action		File		Note and Return
	Approval		For Clearance		Per Conversation
	As Requested		For Correction		Prepare Reply
	Circulate		For Your Information		See Me
	Comment		Investigate	X	Signature
	Coordination		Justify		

REMARKS

6. Dave West no problem with the content

9/13 just new sig block - PJP

Final K-921225

Paul please check this two 510(k) [illegible] with panel. Does [illegible] or do we [illegible] need to change NM

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FROM: (Name, org. symbol, Agency/Post) Room No.—Bldg.

Phone No.

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GPO: 1990 — 262-080

23

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

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9

ROUTING AND TRANSMITTAL SLIP

Date 8/8/93

TO: (Name, office symbol, room number, building, Agency/Post)	Initials	Date
1. OC / Bill O'Connell	WPC	8/10/93
2.		
3. K920955		
4. K921272		
5. K921301		

	Action		File		Note and Return
	Approval	✓	For Clearance		Per Conversation
	As Requested		For Correction		Prepare Reply
	Circulate		For Your Information		See Me
	Comment		Investigate		Signature
	Coordination		Justify		

REMARKS

Please sign-off on the attached documents. Please return to me in 250 or call at 4-1190 & I will pick them up.

Thank you,
Heather R.

DO NOT use this form as a RECORD of approvals, concurrences, disposals, clearances, and similar actions

FROM: (Name, org. symbol, Agency/Post)

Room No.—Bldg.

Phone No.

5041-102
☆ U.S. G.P.O. 1992 312-070/60009

OPTIONAL FORM 41 (Rev. 7-76)
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4

2

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

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

ROUTING AND TRANSMITTAL SLIP Date 8-2-93

TO: (Name, office symbol, room number, building, Agency/Post)	Initials	Date
1. Dwd / Dan McGuinagle		
2.		
3. K920955		
4. K921272		
5. K921301		

Action		File		Note and Return	
Approval		For Clearance		Per Conversation	
As Requested		For Correction		Prepare Reply	
Circulate		For Your Information		See Me	
Comment		Investigate		Signature	
Coordination		Justify			

REMARKS

Please obtain DW Director sign-off on the attached 3 510(k)s and on the review memo in the front of the file (on his desk) — thanks — Heather

DO NOT use this form as a RECORD of approvals, concurrences, disposals, clearances, and similar actions

FROM: (Name, org. symbol, Agency/Post)

Room No.—Bldg.

Phone No.

5041-102
U.S. G.P.O. 1992 312-070/60009

OPTIONAL FORM 41 (Rev. 7-76)
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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

Ms. Patricia S. Beres
Research Manager
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 45681-0587

Re: K921277
Ranawat/Burstein Total Hip System
Dated: July 10, 1992
Received: July 14, 1992

Dear Ms. Beres:

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 to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. This decision is based upon consideration of the specific designs of stem, porous coating characteristics and intended use detailed in this application, and upon data provided for the reclassified Biolox Ball manufactured by Cerasiv GmbH (formerly Feldmuehle Aktiengesellschaft). You may, therefore, market the device, subject to the general controls and to certain of the special controls provisions of the Federal Food, Drug, and Cosmetic Act (Act), and the following limitations:

1. Your device may only be labeled for noncemented use when intended for use in skeletally mature individuals undergoing primary surgery for rehabilitating hips damaged as a result of noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

2. The hip stems may only be labeled for use with the following Metoxit/Precomp Zirconia Hip Joint Balls:

Model Number	
RD-105492	28mm, -5mm Neck
RD-105493	28mm, Standard Neck
RD-105494	28mm, +2.5mm Neck
RD-105495	28mm, -3mm Neck
RD-105496	32mm, Standard Neck
RD-105497	32mm, -5mm Neck
RD-105498	32mm, -3mm Neck
RD-105499	32mm, +2.5mm Neck

The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practice and labeling, and prohibitions against misbranding and adulteration.

Under Section 522(a)(2) of the Act, FDA has determined that in order to provide for long-term safety and effectiveness data for these devices, you must conduct postmarket surveillance of your devices. Under Section 522(b) of the Act, you shall submit a protocol for the required surveillance within 30 days of the first introduction or delivery for introduction of your device into interstate commerce.

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

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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. In addition, the Food and Drug Administration (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 the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being labeling for your device please contact the Division of Compliance Operations, Device Labeling Compliance Branch (HFZ-326) at (301) 427-1165. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll number (800) 638-2041 or (301) 443-6597.

Sincerely yours,

David L. West, Ph.D.
Deputy Director
Office of Device Evaluation
Center for Devices and
Radiological Health

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
410	Stevens	7/19/93	410	[illegible]	8/6/93	300	[illegible]	8/10/93
410	Mobunay/E	7/19/93	404	[illegible]	7/26/93			
410	Misha	7/21/93			7/29/93			

☆ U.S. GOVERNMENT PRINTING OFFICE 1991-519-771

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

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bcc: HFZ-401 DMC
HFZ-403 RChissler
HFZ-410 DGRD
D.O.
d/t:
f/t:HFZ-410:TStevens/DBS/7-7-93

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

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

ate

From — REVIEWER(S) - NAME(S) T. Stevens

Subject — 510(k) NOTIFICATION K921277/A

To — THE RECORD

It is my recommendation that the subject 510(k) Notification:

✓ (A) Is substantially equivalent to marketed devices. Some incl.

____ (B) Requires premarket approval. NOT substantially equivalent to marketed devices.

____ (C) Requires more data.

____ (D) Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Additional Comments:

Is this device subject to Postmarket Surveillance? Yes ☒ No ☐

This 510(k) contains: (check appropriate box(es))

☒ A 510(k) summary of safety and effectiveness, or Exhibit ~~VIII~~

☐ A 510(k) statement that safety and effectiveness information will be made available

☐ The required certification and summary for class III devices

The submitter requests under 21 CFR 807.95:*

____ No Confidentiality

____ Confidentiality for 90 days

____ Continued Confidentiality exceeding 90 days

Predicate Product Code w/panel and class:

~~87~~ LPH II

Additional Product Code(s) w/Panel (optional):

87 LZO II

REVIEW: Daniel S. McGarraghy (BRANCH CHIEF) — ODB (BRANCH CODE) — 7/6/93 (DATE)

FINAL REVIEW: (DIVISION DIRECTOR) — 8/3/93 (DATE)

2/16/94

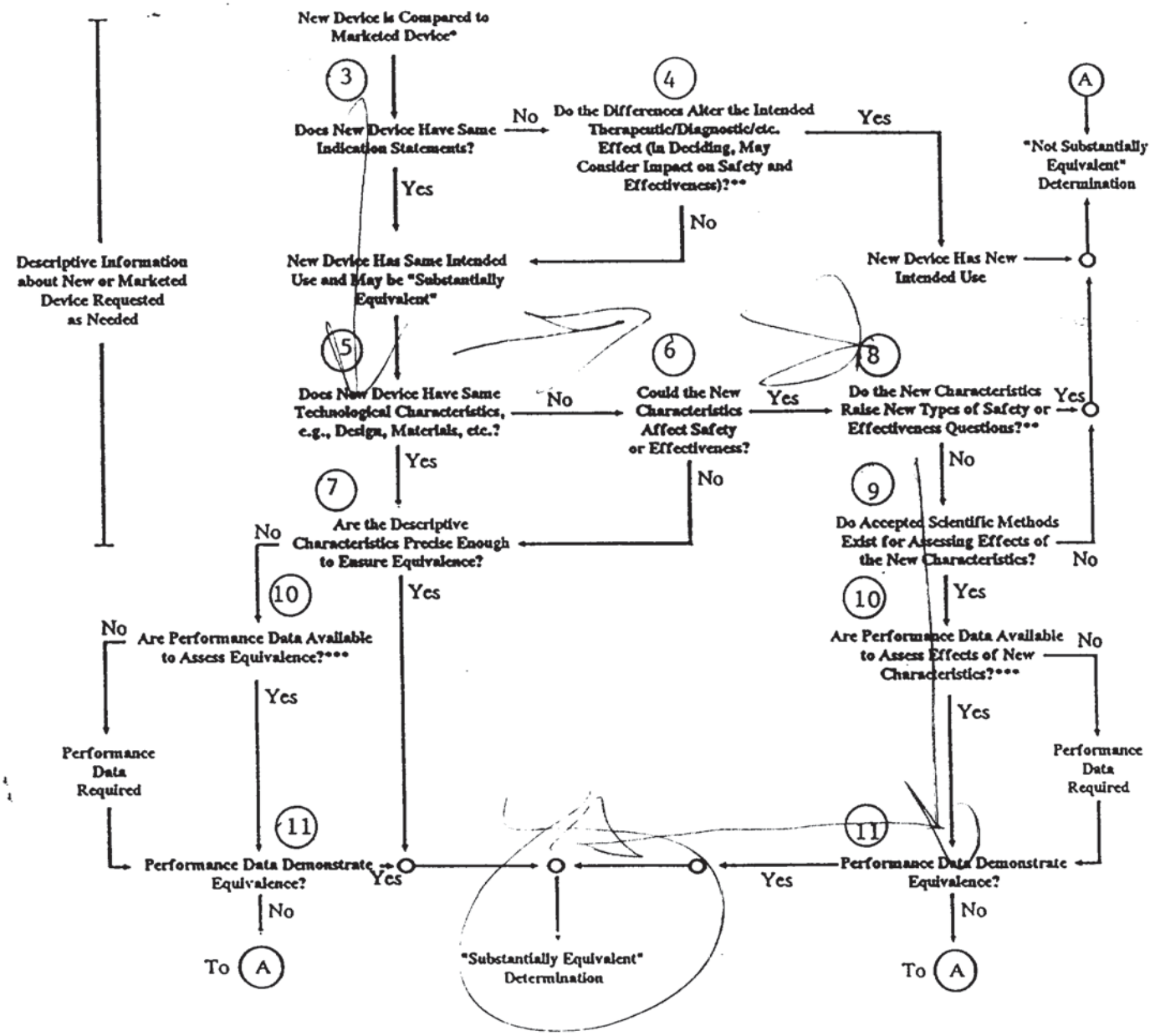
*DOES NOT APPLY TO ANY "SE" DECISIONS

Revised 11/18/91

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

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

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



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

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

MEMO

TO: Paul R. Beninger, M.D., Dir. DGRD, HFZ-410
The File; K920955, K921272, K921301

FROM: Branch Chief, ORDB/DGRD, HFZ-410

SUBJECT: Division Director Signature On The Above 510(k)s

DATE: August 3, 1993

(b)(4)

[redacted]

Could you please sign the yellow copies and return the documents to me ?

Daniel S. McGunagle

Daniel S. McGunagle

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

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

ROUTING AND TRANSMITTAL SLIP

Date 8-2-93

TO: (Name, office symbol, room number, building, Agency/Post)	Initials	Date
1. Deb / Dan McGuraghe		
2.		
3. K920955		
4. K921277		
5. K921301		

	Action		File		Note and Return
	Approval		For Clearance		Per Conversation
	As Requested		For Correction		Prepare Reply
	Circulate		For Your Information		See Me
	Comment		Investigate		Signature
	Coordination		Justify		

REMARKS

Please obtain Div Director sign-off on the attached 3 510(k)s and on the review memo in the front of the file (or his designee) - Thanks - Heather

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FROM: (Name, org. symbol, Agency/Post)

Room No.—Bldg.

Phone No.

5041-102
☆ U.S. G.P.O. 1992 312-070/60009

OPTIONAL FORM 41 (Rev. 7-76)
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32

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

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ROUTING AND TRANSMITTAL SLIP Date 7-7-93

TO: (Name, office symbol, room number, building, Agency/Post)	Initials	Date
1. Ted Stevens		7/8
2. DAN	DSM	7/19/93
3.		
4.		
5.		

	Action		File		Note and Return
	Approval		For Clearance		Per Conversation
	As Requested		For Correction		Prepare Reply
	Circulate		For Your Information		See Me
	Comment		Investigate	X	Signature
	Coordination		Justify		

REMARKS

K 921277 — FINAL

Needs yellow copy

DO NOT use this form as a RECORD of approvals, concurrences, disposals, clearances, and similar actions

FROM: (Name, org. symbol, Agency/Post)	Room No.—Bldg.
Dianne Smith	Phone No.

5041-102

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Prescribed by GSA
FPMR (41 CFR) 101-11.206

* U.S. GPO: 1990 — 262-080

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

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

MEMO RECORD

DATE: June 24, 1993

FROM: Theodore R. Stevens, Biomedical Engineer, HFZ-410
TO: The Record, K921277/A
SUBJECT: Ranawat/Burstein Hip for noncemented use

Biomet has responded to the remaining concerns on their plasma-sprayed hips for noncemented use. Based on the information contained in those responses and in the original 510(k), I recommend that the Ranawat/Burstein Femoral Stem be found substantially equivalent to legally marketed predicate devices when intended for cementless primary total hip arthroplasty to rehabilitate hips damaged as a result of NIDJD.

Background: The Ranawat/Burstein Porous Total Hip Femoral Component was previously cleared under K911685 for use with bone cement only. Biomet has provided mechanical testing and clinical data for devices with the same porous coating as the Ranawat/Burstein.

The Ranawat/Burstein hip is of an anatomic design. Four major variables are altered to provide an extensive line of components. The basic dimensions are: proximal cone thickness (4 available), proximal cone height (4 sizes), stem diameter (11-17.5 mm), and side (15.6° proximal bow, left or right). A total of 40 different stems are currently designed. The implantation of this system is somewhat different from that of many, because the surgeon "builds a femoral envelope from rasps for stem diameter, cone height, and cone thickness.

The femoral component uses modular CoCrMo (ASTM F-75) heads which are installed at the time of surgery. The included angle of the taper is 4°, the roughness of the inner bore is 34 µinches, and a the articulating surface has an R_A value of 5.6.

(b)(4)

[redacted]

Comparison to predicates: The Ranawat/Burstein stem is similar in design to the Howmedica PCA, Zimmer Anatomic stem, and Implant technology LSF stem. Each of these is of an

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anatomic geometry, with left and bowed configurations. All have a porous coating, and are cleared for use with bone cement only. The primary difference is that the Ranawat/Burstein stem is available in many more sizes, 40 versus 7 to 9 for the predicates.

Abrasion Testing: The test setup for the Biomet plasma spray consisted of a hardened block, which contacted a flat plasma-sprayed coupon with a convex half cylinder with radius 0.5 mm and length 25 mm. The half-cylinder was cycled back and forth over the plasma-sprayed surface for 10 cycles, with 5 tests at increasing loads. The abrasion of the coating was characterized by the percentage of the coating that was removed at the various loads. This was derived from the mass change of the specimens. From the graph on p. 438 of the Master File, there is a linear relationship between mass of coating removed and applied load. It appears that about 50% of the coating is removed with a load of 190 lb, and that detectable amounts of coating are abraded at much lower loads. These loads are significantly lower than those required to abrade sintered coatings such as Intermedics' CSTi (no detectable particles at 100 lb, 50% of coating removed at 625 lb). Despite the lower abrasion resistance, The clinical data for the Taperloc show no increased complications over cemented and sintered-bead stems at 2+ years.

Clinical Data for Taperloc (same plasma coating):

(b)(4)

[redacted]

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(b)(4)

Theodore R. Stevens

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K 921277 "SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

REVIEWER: Stevens DIVISION/BRANCH: DGRD/ORDB

TRADE NAME: Ranawat/Burnstein COMMON NAME: total hip prosthesis

PRODUCT TO WHICH COMPARED:
(510(k) NUMBER IF KNOWN)

	YES	NO	
1. IS PRODUCT A DEVICE?	✓		- IF NO STOP
2. 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?	✓		SE

NOTE: IN ADDITION TO COMPLETING PAGE TWO, "YES" RESPONSES TO QUESTIONS 4, 6, 8, AND 11, AND EVERY "NO" RESPONSE REQUIRES AN EXPLANATION ON PAGE THREE AND/OR FOUR

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NARRATIVE DEVICE DESCRIPTION

1. INTENDED USE: SEE INFRA

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. The following should be considered when preparing the summary of 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 for home use 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.

SUMMARY: SEE INFRA

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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: _____

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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

40

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BIOMET INC®

March 15, 1993

IDE Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
1390 Piccard Dr.
Rockville, Maryland 20850

RE: ~~MODULAR TOTAL HIP SYSTEM~~ Ranawat Burstein Total Hip System
~~K921274~~ K921277

Dear Sir or Madam:

Since response has not been received on the additional information submitted July 10, 1992 on the above referenced 510(k) notification, the sponsor wishes to supplement the document with the following information. This information was requested for similar 510(k)'s also pending FDA clearance.

(b)(4)

[redacted]

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(b)(4)

[redacted]

Sincerely,

Patricia S Beres

Patricia Sandborn Beres
Research Manager

PSB/vh

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(b)(4) Test Data

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(b)(4) Test Data

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2

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Designation: F 639 – 79 (Reapproved 1985)

An American National Standard

Standard Specification for Polyethylene Plastics for Medical Applications[1]

This standard is issued under the fixed designation F 639; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This specification covers polyethylene plastics (as defined in Definitions D 883) intended for use in medical device applications involving human tissue contact devices, short term indwellings of 30 days or less, and fluid transfer devices. The biocompatibility of these materials as a class has not been established. Biocompatibility tests must be conducted on the final product.

1.2 This specification is not applicable to ultra-high molecular weight polyethylenes (UHMWPE) plastics, such as those used in joint implants, etc.

2. Referenced Documents

2.1 *ASTM Standards:*

D 638 Test Method for Tensile Properties of Plastics[2]

D 671 Test Method for Flexural Fatigue of Plastics by Constant-Amplitude-of-Force[2]

D 695 Test Method for Compressive Properties of Rigid Plastics[2]

D 747 Test Method for Apparent Bending Modulus of Plastics by Means of a Cantilever Beam[2]

D 790 Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials[2]

D 883 Definitions of Terms Relating to Plastics[2]

D 1238 Test Method for Flow Rates of Thermoplastics by Extrusion Plastometer[2]

D 1248 Specification for Polyethylene Plastics Molding and Extrusion Materials[2]

D 1505 Test Method for Density of Plastics by the Density-Gradient Technique[2]

D 1898 Practice for Sampling of Plastics[3]

D 1928 Method for Preparation of Compression-Molded Test Sheets and Test Specimens[3]

D 2238 Test Methods for Absorbance of Polyethylene Due to Methyl Groups at 1378 cm^{-1} [3]

D 2576 Test Method for Metals in Water and Waste Water by Atomic Absorption Spectrophotometry[4]

3. Significance

3.1 This specification describes polyethylene plastics used in the manufacture of medical devices or components of medical devices. The properties listed should be considered in selecting material according to the specific end-use requirements.

4. Classification

4.1 Types of polyethylene plastics molding and extrusion material are described in Specification D 1248.

5. General Requirements

5.1 Polyethylene plastics consist of basic polymers made with ethylene as essentially the sole monomer (as defined in Definitions D 883).

5.2 Polyethylene for use in medical applications shall have a maximum extractable fraction, expressed as weight percent in polymer, in *n*-hexane of 5.5 % at 50°C (**1**).[5]

5.3 The formulated compound may contain optional adjuvant substances required in the production of the polymer or in the fabrication or intended use of the end product. The biocompatibility of these adjuvant substances shall be established on the finished compound (see Section 9).

5.4 The formulated compound shall yield a consistent infrared absorption spectrum characteristic of the established formulation.

5.5 Maximum levels and type of extractable metals shall be established in accordance with the intended use of the formulated resin (**2**) (see Appendix X1).

NOTE—Appendix X1 is a suggested method for determining extractable metals utilizing the current state-of-the-art methodology. Alternative methods with equal reliability may be used.

5.6 The physical properties of polyethylene plastics may be determined by the methods given in Section 7.

6. Sampling

6.1 The material should be sampled in accordance with standard sampling procedures such as those described in Recommended Practice D 1898.

7. Physical Methods

7.1 The following physical test procedures are suggested where applicable to the intended application:

7.1.1 *Density*—Test Method D 1505.

7.1.2 *Melt Flow*—Test Method D 1238.

7.1.3 *Tensile Properties*—Test Method D 638.

7.1.4 *Compressive Properties*—Test Method D 695.

7.1.5 *Stiffness*—Test Method D 747.

7.1.6 *Flexural Fatigue*—Test Method D 671.

7.1.7 *Flexural Properties*—Test Method D 790.

[1] This specification is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.02 on Resources.

Current edition approved Oct. 26, 1979. Published December 1979.

[2] *Annual Book of ASTM Standards*, Vol 08.01.

[3] *Annual Book of ASTM Standards*, Vol 08.02.

[4] Discontinued—See *1980 Annual Book of ASTM Standards*, Part 31.

[5] The boldface numbers in parentheses refer to the list of references at the end of this standard.

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8. Packaging and Labeling

8.1 The product shall be packaged in a suitable container to prevent contamination of contents.

8.2 The material shall be identified including lot or batch numbers and recommended method of storage.

9. Biocompatibility

9.1 The biological safety of each polyethylene plastic formulation shall be established. Specific biological tests shall be determined in accordance with the intended use. Formulated compounds used in these tests should include all colorants and other additives present in the final product.

9.2 The following types of biological tests are appropriate to determine biological safety and tissue reaction depending on the end use application. These tests should be conducted when indicated for specific applications.

9.2.1 *Extraction Tests* (3).
9.2.2 *Class I–VI Biological Tests* (3).
9.2.3 *Tissue Culture Test* (4, 5).
9.2.4 *Pyrogen Test* (6, 7).
9.2.5 *Hemolysis* (8, 9).

APPENDIX

X1. SUGGESTED PRACTICE FOR EXTRACTABLE METALS ANALYSIS OF PLASTIC BY ATOMIC ABSORPTION SPECTROSCOPY

X1.1 Scope

X1.1.1 This practice covers the analysis of extractable metals from plastics intended for use in medical device application.

X1.1.2 Formulated raw materials or finished products may be used.

X1.2 Referenced Documents

X1.2.1 *ASTM Standards:*

D 2576 Test Method for Metals in Water and Waste Water by Atomic Absorption Spectrophotometry[4]

E 117 Method for Spectrographic Analysis of Pig Lead by the Point-to-Plane Technique[6]

X1.3 Significance

X1.3.1 Concentrations of trace metals are measured as extracts in simulated body fluids. The metals concentration in extracts is based on the surface area of the plastic extracted from which the total amount of metal deliverable to the patient may be estimated.

X1.4 Preparation of Specimens

X1.4.1 Use suitable molded test strips of the formulated compound. The total surface area of the specimen to be exposed should be equivalent to 120 cm^2 when the specimen thickness is 0.5 mm or less or 60 cm^2 when the thickness is greater than 0.5 mm. Specimens may be separated from each other by suitable inert spacers to ensure contact with the extraction solvent.

X1.4.2 After the plastic sample has been prepared, extract the specimens using 20 ml of the desired solvent for 72 h at 50°C or 24 h at 70°C, as appropriate for the particular plastic. Then remove the plastic strips and analyze the extract for metals as described in Section X1.5.

X1.5 Preparation of Extract Solution

X1.5.1 Pipet 5.0 ml of the cottonseed oil (CSO) extract into a 10-ml volumetric flask and dilute to volume with hexane. Dilute the CSO atomic absorption standards and controls in the same manner.

X1.5.2 Run the saline eluate directly without dilution.

X1.6 Preparation of Atomic Absorption Standards

X1.6.1 Prepare certified aqueous standard solutions by diluting 1000 ppm of aqueous stock solutions with the 0.9 % saline solution used for extractions. Use the saline solution alone as the blank.

X1.6.2 Prepare the CSO standards by dissolving the appropriate organometallic compound in CSO to give intermediate solutions which are then diluted by volume 1+1 with hexane, giving final standard solutions of metal in the same matrix as the samples. Use a 1+1 dilution of CSO with hexane as the blank. Obtain the concentration analysis on organometallic standards from the manufacturer.

X1.7 Procedure

X1.7.1 Place the hollow cathode lamp for the element being tested in the instrument and set the instrument conditions for that element in accordance with the manufacturer's recommended procedure.

X1.7.2 When the lamp has warmed up, light the flame, adjust to the proper mixture, and allow to burn for 1 min to equilibrate the instrument. For the CSO-hexane mixtures, adjust the flame while aspirating the blank solution.

X1.7.3 Zero the instrument while aspirating the blank solution corresponding to the matrix to be analyzed.

X1.7.4 Aspirate a high standard and adjust the burner position and flame for the optimum signal and optimum signal-to-noise ratio.

X1.7.5 Rezero the instrument while aspirating blank solutions.

X1.7.6 Starting with the lowest, aspirate the standard solutions and record the absorbance corresponding to each. Between standards, aspirate the blank solution and check the zero.

X1.7.7 Aspirate the sample solutions and record the corresponding absorbance readings. Aspirate the blank solution and check the zero between samples.

X1.7.8 If there are many samples to be run, recheck the standards periodically during the analysis. In any case, rean-

[6] *Annual Book of ASTM Standards*, Vol 03.06.

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alyze the standards after all the samples have been run.

X1.8 Calculations

X1.8.1 Prepare a calibration chart by plotting absorbance versus concentration.

X1.8.2 Calculate the concentrations of metal in the sample extracts by reference to the standard curve.

X1.8.3 Calculate the total amount of metal extracted as follows:

$$\frac{\mu g \text{ metal}}{\text{ml extract}} \times \text{ml of extracts} = \text{total metal extracted, } \mu g$$

X1.8.4 Calculate the amount of metal extracted per square centimetre of sample, $\mu g/cm^2$:

$$\frac{\text{total metal extracted, } \mu g}{\text{surface area of film, } cm^2}$$

X1.9 Precision and Accuracy

X1.9.1 The precision and accuracy of this practice has not yet been determined. It is dependent upon several factors, such as, sample matrix, ionization interferences, sophistication of instrumentation, etc.

X1.9.2 Determine the precision for each test system in accordance with Method E 117.

NOTE—Pertinent data and other information regarding this suggested practice may be reported to Committee F-4 Staff Manager, ASTM Headquarters, 1916 Race St., Philadelphia, PA 19103. Comments and suggestions will be considered in future standards development activities.

REFERENCES

(1) *Federal Register*, Vol 21, Part 177.1520.

(2) *Accuracy in Trace Analysis*, NBS Special Publication No. 422, U.S. Government Printing Office, Washington, DC, Catalog No. C-13.10:422.

(3) *U.S. Pharmacopeia*, Vol XIX, 1975.

(4) Guess, W. L., et al., Journal of Pharmacological Science, Vol 54, 1965, p. 1545.

(5) Wilsnack, R. E., Meyer, F. J., and Smith, J. G., *Biomaterials Medical Device Art. Organization*, Vol 1, No. 3, 1973, pp. 543–562.

(6) Cooper, J. F., and Pearson, S. M., "The Detection of Endotoxins in Biological Products by Limulus Lystate Test," International Symposium on Pyrogenicity, Innocuity and Toxicity Test Systems for Biological Products, Budapest 1976, *Developments in Biological Standards*, Vol 34, 1977, p. 7.

(7) Basel, S. Karger, "Limulus Test Parenteral Drugs and Biological Products: An Approach," International Symposium on Pyrogenicity, Innocuity, and Toxicity Systems for Biological Products, Budapest 1976, *Developments in Biological Standards*, Vol 34, 1977, p. 97.

(8) Autian, John, "Toxicological Evaluation of Biomaterials: Primary Acute Toxicity Screening Program," *Journal of Artificial Organs*, Vol 1, No 1, 1977, p. 53.

(9) Autian, John, "The New Field of Plastics Toxicological Methods and Results," *CRC Critics Review in Toxicology*, 1973, p. 18.

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This standard is subject to revision at any time by the responsible technical committee and must be reviewed every five years and if not revised, either reapproved or withdrawn. Your comments are invited either for revision of this standard or for additional standards and should be addressed to ASTM Headquarters. Your comments will receive careful consideration at a meeting of the responsible technical committee, which you may attend. If you feel that your comments have not received a fair hearing you should make your views known to the ASTM Committee on Standards, 1916 Race St., Philadelphia, PA 19103.

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Designation: F 648 – 84

Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants[1]

This standard is issued under the fixed designation F 648; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This specification covers ultra-high molecular weight polyethylene powder (UHMWPE) intended for use in surgical implants.

1.2 The requirements of this specification apply to UHMWPE in two forms. One is virgin polymer powder (Section 4). The second is any form fabricated from this powder from which a finished product is subsequently produced (Section 5). This specification addresses material characteristics and does not apply to the packaged and sterilized finished implant.

1.3 The provisions of Specification D 4020 apply. Special requirements detailed in this specification are added to describe material which will be used in surgical implants.

1.4 The biological response to polyethylene in soft tissue and bone has been well-characterized by a history of clinical use **(1, 2, 3)**[2] and by laboratory studies **(4, 5, 6)**.

1.5 The following precautionary caveat pertains only to e test method portion, Section 7, of this specification: *This standard may involve hazardous materials, operations, and equipment. This standard does not purport to address all of the safety problems associated with its use. It is the responsibility of whoever uses this standard to consult and establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*

D 256 Test Methods for Impact Resistance of Plastics and Electrical Insulating Materials[3]

D 621 Test Methods for Deformation of Plastics Under Load[3]

D 638 Test Method for Tensile Properties of Plastics[3]

D 648 Test Method for Deflection Temperature of Plastics Under Flexural Load[3]

D 790 Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials[3]

D 1505 Test Method for Density of Plastics by the Density-Gradient Technique[3]

D 1898 Practice for Sampling of Plastics[4]

D 1921 Test Method for Particle Size (Sieve Analysis) of Plastic Materials[4]

D 2240 Test Method for Rubber Property—Durometer Hardness[5]

D 4020 Specification for Ultra-High Molecular Weight Polyethylene Molding and Extrusion Materials[6]

3. Description of Terms Specific To This Standard

3.1 *fabricated form*—any bulk shape of UHMWPE, fabricated from the virgin polymer powder, used during the process of fabricating surgical implants prior to packaging and sterilization.

3.1.1 *Discussion*—This form results from the application of heat and pressure to the virgin polymer powder, and the material characteristics of this form are subject to the applicable requirements of this specification. In present practice, this includes extruded bars or molded blocks from which the final product form is machined, or a molded shape which is subsequently trimmed.

3.2 *generic property*—that property which is determined solely by the chemical composition and structure of the virgin polymer.

3.3 *virgin polymer powder*—the form of UHMWPE as obtained from the manufacturer and prior to fabrication into a bulk shape.

4. Virgin UHMWPE Powder Requirements

4.1 *Generic Properties:*

4.1.1 The virgin polymer shall be a homopolymer of ethylene, as described in Specification D 4020.

NOTE 1—Information on the degree of branching, methyl group concentration, and vinylidene content would be useful. Presently, there is not a suitable method to determine these parameters.

4.1.2 Molecular weight of the polymer powder shall be indicated by determining the relative solution viscosity. The relative solution viscosity, when determined in accordance with the method given in Specification D 4020, shall be 2.30 or greater. The accuracy of the test results shall be determined by vendor-purchaser agreement.

NOTE 2—While the precise relationship between the bulk properties and wear resistance of implants and the molecular weight of the polyethylene used to fabricate them has not been established quantitatively, it has been demonstrated that UHMWPE is more suitable for such applications than are polyethylenes of lower molecular weight.

The relative solution viscosity of dilute solutions of UHMWPE powder may be used as adequate indicators that

[1] This specification is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.02 on Resources.

Current edition approved Sept. 28, 1984. Published February 1985.

[2] The boldface numbers in parentheses refer to the list of references at the end of this specification.

[3] *Annual Book of ASTM Standards*, Vol 08.01.

[4] *Annual Book of ASTM Standards*, Vol 08.02.

[5] *Annual Book of ASTM Standards*, Vol 09.01.

[6] *Annual Book of ASTM Standards*, Vol 08.03.

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some minimum value of molecular weight is attained. At present, there is some uncertainty regarding the extension of the solution viscosity/molecular weight relationship to the UHMWPE range.

Information on the molecular weight distribution would permit control of the weight fraction of low-molecular weight material. Presently, there is not a suitable method to determine the distribution.

4.2 *Nongeneric Properties:*

4.2.1 The polymer powder shall contain as little extraneous matter (such as dirt, lint, silica, and discoloring material) as possible. The purchaser and vendor shall agree on which of the following test methods will be used.

4.2.1.1 When a 400 cm^2 sample prepared in accordance with 7.1.2.1 is viewed, there shall be no particle whose largest dimension is greater than 300 µm, and there shall be no more than 10 particles whose largest dimension is 300 µm or less.

4.2.1.2 When a 300-g sample prepared in accordance with 7.1.2.2 is viewed, there shall be no more than 25 particles present.

4.2.2 The polymer powder shall contain as few trace elements as possible, and the level of those trace elements shall be as small as possible. To promote uniformity between different lots of polymer powder, the following maximum concentration limits for trace elements have been established.

Element	ppm, max
Al	100
Ti	300
Ca	100
Cl	120

4.2.2.1 Analyses for these and other elements shall be conducted by vendor-vendee agreement.

NOTE 3—There is no evidence that the concentration of trace elements affects the physical properties or the biological response of UHMWPE fabricated forms.

4.2.3 All powder shall pass a No. 16 (1.18-mm) sieve.

NOTE 4—A limitation on particle size stems from the possibility that excessively large particles of UHMWPE may not flow enough in subsequent "sintering" or molding operations to yield a sufficiently fused material. This could result in undesirable local inhomogeneity or a porous structure.

5. UHMWPE Fabricated Form Requirements

5.1 *Compositional Requirements:*

5.1.1 No stabilizers or processing aids are to be added to the virgin polymer powder during manufacture of a fabricated form.

5.1.2 The surface of a fabricated form shall contain as little extraneous matter as possible. When a 400-cm^2 sample prepared in accordance with 7.2.2 is viewed, there shall be no particle whose largest dimension is greater than 300 µm, and there shall be no more than 10 particles whose largest dimension is 300 µm or less.

5.2 *Physical Requirements:*

5.2.1 The surface of a fabricated form shall contain as few light patches (which would indicate unfused areas) as possible. When a 400-cm^2 sample prepared in accordance with 7.2.2 is viewed, there shall be no light patch whose largest dimension is greater than 300 µm.

5.2.2 The density of the fabricated form shall be between 0.930 and 0.944 g/cm^3.

5.3 *Mechanical Requirements:*

NOTE 5—The relationship between these mechanical properties and the *in vivo* performance of a fabricated form has not been determined. While trends are apparent, specific property-polymer structure relationships are not well-understood. These mechanical tests are frequently used to evaluate the reproducibility of a fabrication procedure and are applicable as quality control tests to determine lot to lot repeatability for a process of converting virgin polymer powder to a fabricated form. The mechanical properties are subject to variation as the fabrication process variables (such as temperature, pressure, and time) are changed.

5.3.1 UHMWPE in fabricated form from which implants shall be made shall meet the requirements listed in Table 1.

NOTE 6—The following mechanical tests may be conducted based on agreement between the vendor and purchaser:

(*1*) Deflection temperature; Test Method D 648 (1.8 MPa 264 psi)

(*2*) Flexural modulus; Test Methods D 790 (secant, 2 % offset)

6. Sampling

6.1 Where applicable, the requirements of this specification shall be determined for each lot of powder and fabricated form by sampling sizes and procedures according to Recommended Practice D 1898, or as agreed upon between the purchaser and seller.

7. Test Methods

7.1 *UHMWPE Powder:*

7.1.1 Determine the relative solution viscosity in accordance with the method given in Specification D 4020.

7.1.2 Determine the amount of extraneous matter by the following procedures as agreed by the vendor and purchaser.

7.1.2.1 Using a polished steel mold, press UHMWPE powder into sheets with a minimum surface area of 12 cm^2 and a maximum thickness of 6.0 mm, at 205 ± 10°C (400 ± 18°F) for 10 min. Examine a total surface area of 400 cm^2. Count the particles using optical microscopy within the translucent sheets.

7.1.2.2 A 300-g sample is divided into four 75-g samples. Place a 75-g sample in each of four 1000 mL Erlenmeyer flasks, add 400 mL isopropyl alcohol, shake 5 min, and let settle for 5 min. Count the total number of particles of extraneous matter in the four flasks.

7.1.3 Determine the trace element concentration by the following methods or by methods agreed upon by the vendor and purchaser:

Ti Atomic absorption or emission spectroscopy
Al Atomic absorbtion or emission spectroscopy
Ca Atomic absorption or emission spectroscopy
Cl Potentiometric methods or titration methods

7.1.4 Ensure that the particle size of the powder is correct by passing it through a No. 16 (1.18-mm) sieve in accordance with Method B of Test Method D 1921.

7.2 *UHMWPE Fabricated Form:*

7.2.1 The requirement that there will be no addition of any stabilizer or processing aid during fabrication of the fabricated form shall be met by certification of the fabricator.

7.2.2 Use optical microscopy to determine the size of the particles of extraneous matter and the size of light patches at the surface of the fabricated form. Examine a surface area of 400 cm^2 taken from locations within the fabricated form agreed upon by the vendor and the purchaser.

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TABLE 1 UHMWPE Fabricated Form Mechanical Requirements

Property	ASTM Test Method	Requirement minimum
Tensile Strength, 23°C	D 638 (Speed C)	
Ultimate		4000 psi (27 MPa)
Yield		2800 psi (19 MPa)
Elongation	D 638 (Speed C)	200 %
Izod Impact Strength	D 256 (15° notch A), double	1070 J/M (20 ft/lb)
Deformation under load	D 621 (A) (7 MPa (1000 psi) for 24 h)	2 % deformation after 90 min recovery
Hardness	D 2240 (Shore D)	60

7.2.3 Determine the density in accordance with Test Method D 1505.

7.2.4 Determine specific mechanical properties in accordance with the methods listed in Table 1. Mechanical test specimens shall be produced by methods that represent those used to produce surgical implants.

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(3) Mirra, J., Amstutz, H., Matos, M., Gold, R., "The Pathology of the Joint Tissues and Its Clinical Relevance in Prosthesis Failure," *Clincal Orthopaedics*, No. 117, June, 1976.

(4) Turner, J., Lawrence, W., Autian, J., "Subacute Toxicity Testing of Biomaterials Using Histopathologic Evaluation of Rabbit Muscle Tissue," *Journal of Biomedical Materials Research*, Vol 7, 1973.

(5) Laing, P., "Compatibility of Biomaterials," *Orthopedic Clinics of North America*, Vol 4, No. 2, April, 1973.

(6) Escalas, F., Galante, J., Rostoker, W., Biocompatibility of Materials for Total Joint Replacement," *Journal of Biomedical Materials Research*, Vol 10, No. 2, 1976.

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This standard is subject to revision at any time by the responsible technical committee and must be reviewed every five years and if not revised, either reapproved or withdrawn. Your comments are invited either for revision of this standard or for additional standards and should be addressed to ASTM Headquarters. Your comments will receive careful consideration at a meeting of the responsible technical committee, which you may attend. If you feel that your comments have not received a fair hearing you should make your views known to the ASTM Committee on Standards, 1916 Race St., Philadelphia, PA 19103.

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JULY 15, 1992

BIOMET
ATTN: PATRICIA BERES
P.O. BOX 587
WARSAW, IN 46581

510(k) Number: K921277
Received: 07-14-92
Product: RANAWAT/BURSTEIN TOTAL HIP SYSTEM

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (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. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

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

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

Robert I. Chissler
Chief, Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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K921277/A

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BIOMET INC®

July 10, 1992

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Re: Ranawat/Burstein Total Hip System
510(k) #921277

Dear Sir or Madame:

In response to your request for additional information regarding the above 510(k) submission, Biomet would like to direct you to it's Masterfile 153. This Masterfile has been amended to include the information required by the FDA newly developed Guidance Document for Metallic Surface Treated Orthopedic Implants Fixed by Tissue Ingrowth (May 1, 1992).

Also to comply with this guidance document, information regarding the broaches/rasps used in the implantation of this device is enclosed with this supplement.

The Ring-Loc Liners have been cleared under 510(k) #K920640 since the original submission of this 510(k).

We hope that the information presented on our porous coating will meet with your requirements.

Sincerely,

Patricia S Beres

Patricia Sandborn Beres
Research Manager

enc.

S4

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Ranawat/Burstein Total Hip System
Broaches/Rasps

A full surgical technique is included for clarification.

For non-cemented implantation of this device, the femoral broach/rasp sizes correspond directly to the implant size. An engineering drawing of the reamers and broaches which matches the stem drawing previously provided, is included.

(b)(4)

[redacted]

A full instrumentation listing is included.

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Grater-Type Reamers

31-476040	40mm Diameter
31-476041	41mm Diameter
31-476042	42mm Diameter
31-476043	43mm Diameter
31-476044	44mm Diameter
31-476045	45mm Diameter
31-476046	46mm Diameter
31-476047	47mm Diameter
31-476048	48mm Diameter
31-476049	49mm Diameter
31-476050	50mm Diameter
31-476051	51mm Diameter
31-476052	52mm Diameter
31-476053	53mm Diameter
31-476054	54mm Diameter
31-476055	55mm Diameter
31-476056	56mm Diameter
31-476057	57mm Diameter
31-476058	58mm Diameter
31-476059	59mm Diameter
31-476060	60mm Diameter
31-476061	61mm Diameter
31-476062	62mm Diameter
31-476063	63mm Diameter
31-476064	64mm Diameter
31-476065	65mm Diameter
31-476066	66mm Diameter
31-476067	67mm Diameter
31-476068	68mm Diameter
31-476069	69mm Diameter
31-476070	70mm Diameter
31-476000	Handle

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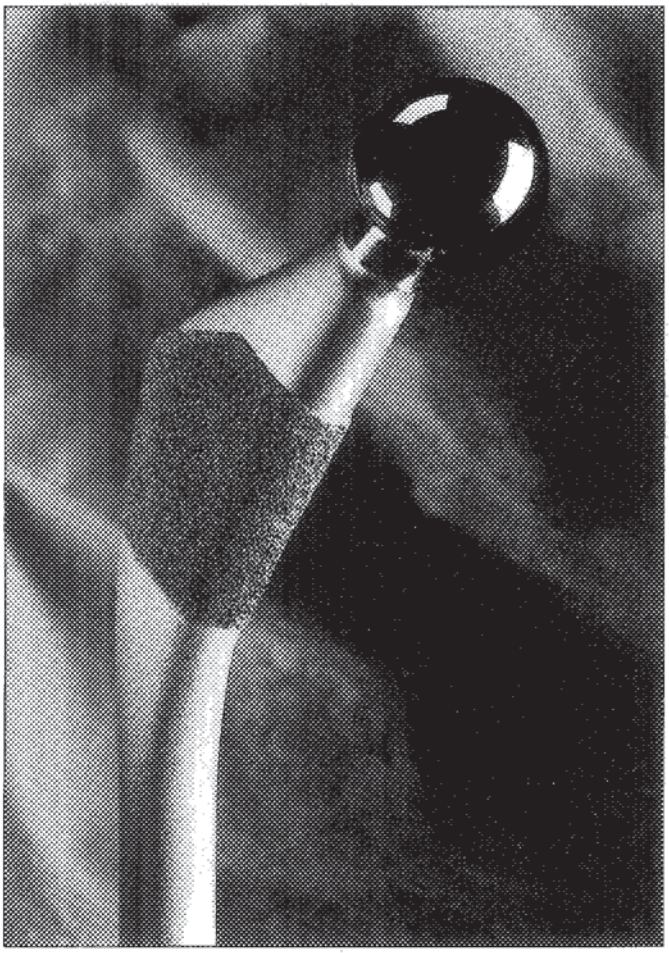
RANAWAT/BURSTEIN™
TOTAL HIP SYSTEM

The Metaphyseal/Diaphyseal Fit



Surgical Overview and Technique for the Porous Primary Series

BIOMET INC.®

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Pre-operative Planning

The purpose of hip reconstruction is to reproduce the anatomic geometry of the normal proximal femur as closely as possible.

Pre-operative planning can be done from a standard 20% magnified AP Pelvis radiograph. Specific magnification changes with the size of the patient, and this must be accounted for.

The AP film of the femur should be performed with the toes pointing vertically upwards, to project the neck shaft angle appropriately. From this film, the center of the femoral head should be identified. A line is then drawn perpendicular to the neck at a point 42mm (accounting for 20% magnification) distal to the center of the femoral head. This will give the level for the neck cut to be made during surgery which is 35mm distal to the center of the head. This distance is chosen because the standard neck length of **the M/D Fit prosthesis is 35mm FOR ALL SIZES.**

The template is then positioned from the reference point of the proposed neck cut along the medial calcar to see which height of the cone will fit a given bone - short, medium, long or extra long. Most patients measure medium or long.

The diaphyseal diameter of the femur should then be assessed by measuring the transverse inner cortical diameter approximately 10cm below the lesser trochanter. This should be done with a magnified ruler and template and will give you the size of the medullary canal. Thus, the surgeon should have a very good idea of which femoral component will be used as far as the distal diameter and height of the cone are concerned.

The width of the cone is represented by the numbers 1, 2, 3, 4 with 1 being the smallest and 4 the largest. This is judged at the time of surgery, or by CT scan templates (See reference chart, Fig. 1).

If a surgeon wishes to have off the shelf customization for the femoral component, the following steps should be taken. A CT scan of the proximal femur should be obtained with 1:1 magnification. The cuts should be through the neck to the lesser trochanter at 5mm intervals, with one cut 10cm distal to the lesser trochanter to access medullary diameter. One more cut may be performed through the knee, to determine anteversion. This is necessary only when the surgeon suspects an unusual degree of anteversion such as that seen in dysplastic hips.

Using the CT templates, the surgeon can assess the diaphyseal diameter and the width (1, 2, 3, 4) of the cone at the level of the cut. The AP pelvis radiograph is used to determine the height (S, M, L, XL) of the cone. Thus the size of the femoral component may be accurately predicted, such as "2" (height of cone), "L" (length of cone) and "14" (diameter of the stem in mm)

The CORTICAL INDEX (CI) may be easily calculated using the diaphyseal CT cut if desired. CI is equal to the outer diameter minus the inner diameter and divided by the outer diameter. (OD-ID/OD)

Using the CT templates, determine the distal diameter (11, 12.5, 14, 16, 17.5) and the metaphyseal size (1, 2, 3, 4). The AP pelvis radiograph is used to determine the height of the metaphyseal cone (S, M, L, XL), and the distal diameter if a CT scan is not utilized.

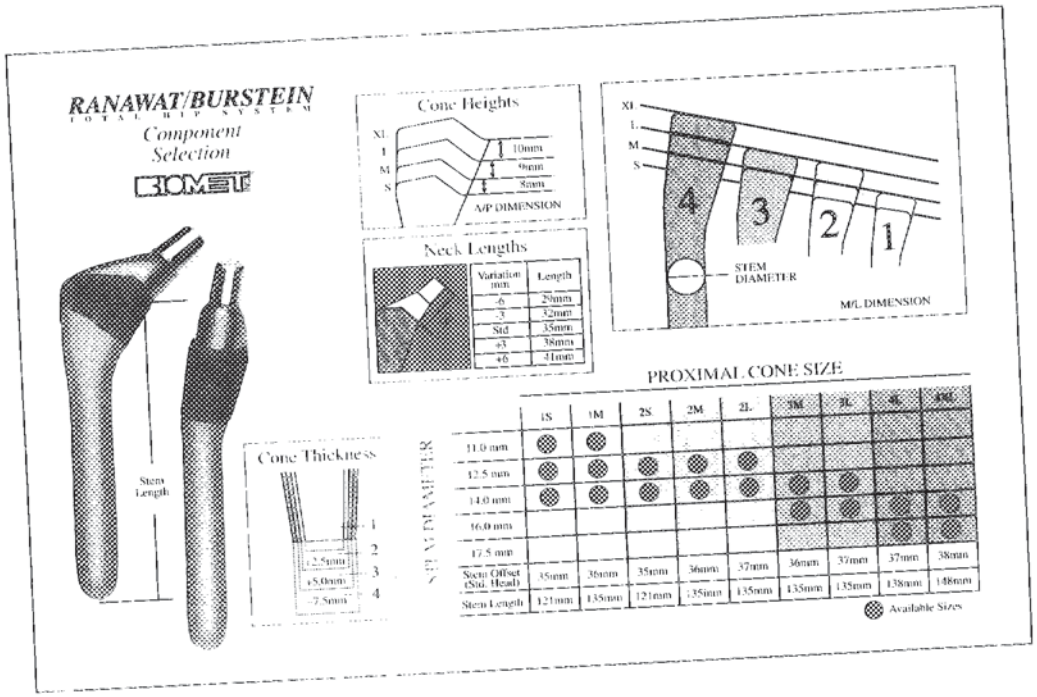

Figure 1

Reference chart for Ranawat/Burstein Porous Primary Components. Implants are sized in stem diameters, cone heights and cone thicknesses.

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Patient Positioning and Surgical Incision

After appropriate epidural anesthesia, the patient is placed in a lateral position. The hip region is prepped and draped free with triple Betadine application (Fig. 3).

The hip is approached with a long posterolateral incision (Fig. 2). After cutting the skin, superficial and deep fascia, the tensor fascia lata is incised along the line of incision. The gluteus maximus fibers are separated in the proximal part of the incision to expose the greater trochanter. Hemostasis is achieved with cautery. Two cotton lap pads soaked with antibiotic solution are applied to the skin margins. A self retaining Charnley Retractor is used to expose the greater trochanter. The external rotators starting from the pyriformis to the quadriceps along with the posterior capsule are detached from the trochanteric fossa and neck to expose the head and neck of the hip joint. The medial circumflex vessels are identified and coagulated. The gluteus maximus insertion from the femur is detached with the help of cautery. The first perforating vessels are coagulated. The inferior capsulotomy is then completed. The superior capsule is exposed and incised. The hip joint is dislocated with adduction, flexion and full internal rotation.

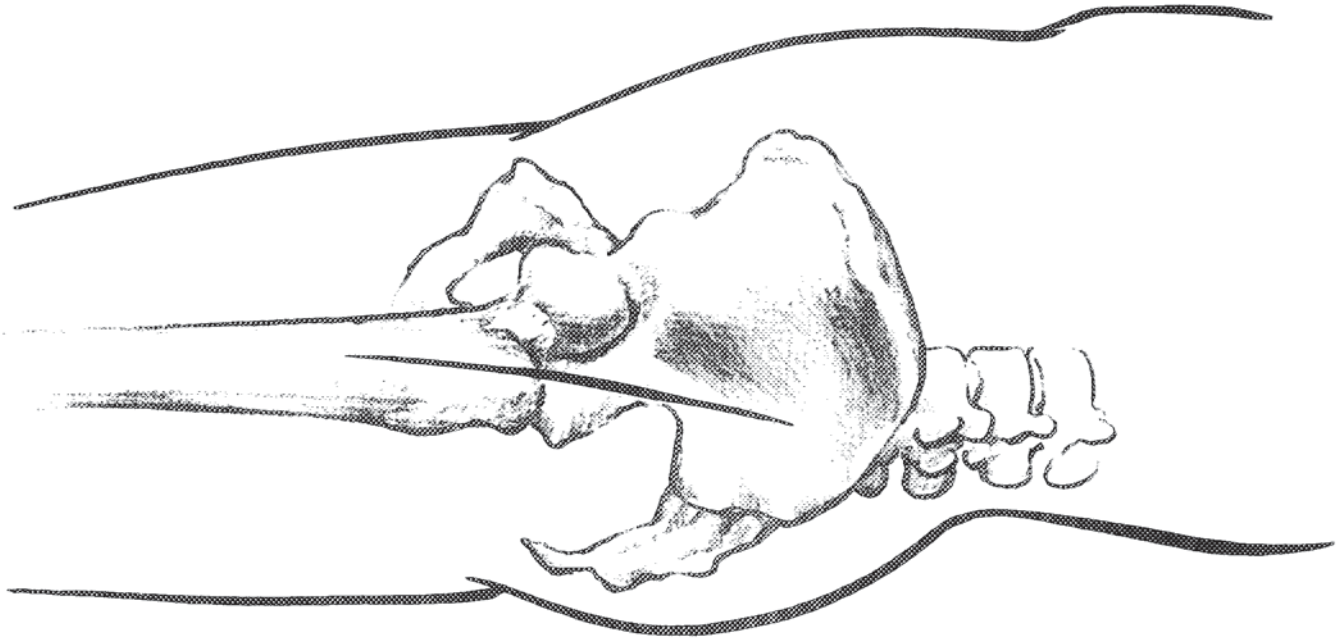

Figure 2

WARNING: The Ranawat/Burstein Hip prostheses are marketed for use with bone cement in the United States.

This brochure is presented to demonstrate the surgical technique utilized by Chitranjan Ranawat, M.D. Biomet, as the manufacturer of this device, does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and utilizing the appropriate techniques for implanting the prosthesis in each individual patient. Biomet is not responsible for selection of the appropriate surgical technique to be utilized for an individual patient.

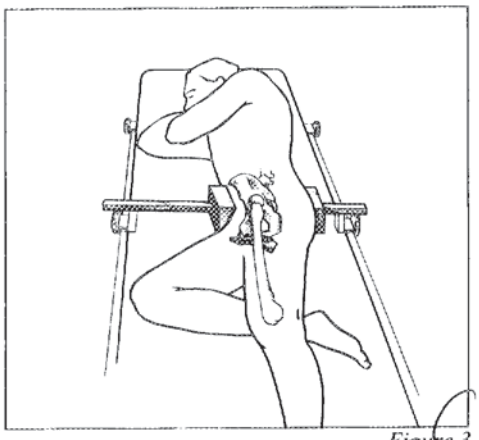

Figure 3

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Femoral Head Resection

Dislocation of the hip can now be easily carried out unless there are significant superior osteophytes. If this is the case, they can be easily removed.

The femoral head is amputated at 35mm from the center of the femoral head (Fig. 5). Before amputation of the femoral head the offset and the distance from the center of the head to the top of the lesser trochanter are measured. These measurements will be utilized to equalize the leg length and offset of the hip joint. The femur is retracted anteriorly with a C-retractor.

The hip is then dislocated. With the hip held in full external rotation, the leg is placed in line with the body for placement of retractors anteriorly, posteriorly and inferiorly around the acetabulum. The femoral head resection is then completed (Fig. 4).

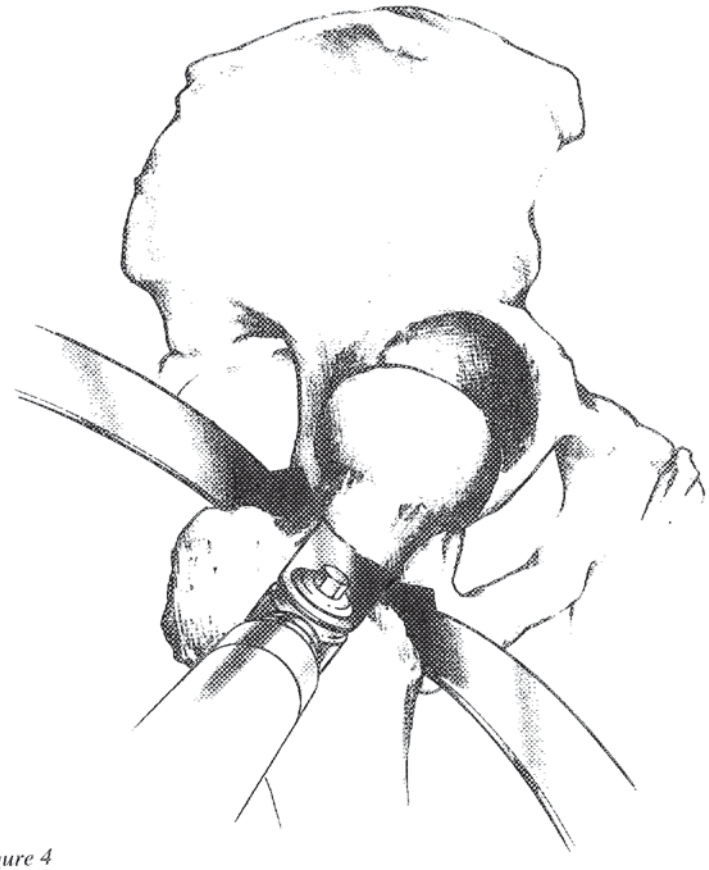

Figure 4

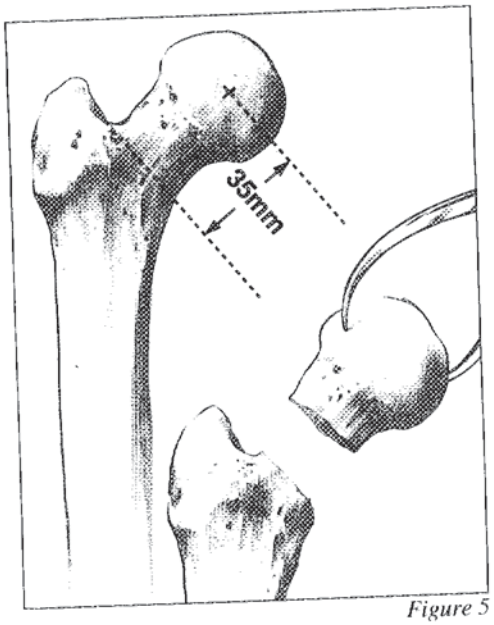

Figure 5

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Acetabular Reaming

The acetabulum is exposed by applying a Steinmann Pin in the ilium to retract the gluteus medius and minimus muscle. A bent medium sized Hohmann Retractor is applied posteriorly to retract the posterior capsule. An Aufranc Retractor is inserted inferior to the transverse ligament to expose the acetabulum completely. The excision of the labrum is performed. The fovea is cleaned of its soft tissue. **Care should be taken at the rim to clear away all soft tissue.**

The socket is reamed progressively with reamers starting medially and then proximally to a depth to preserve superior hard subchondral bone and medially to the outer table of the floor of the acetabulum. This will effectively center the eventual position of the cup by reaming in a concentric manner from both the anterior and posterior walls of the acetabulum (Fig. 6). Any superior deformation of the acetabulum will be taken into account as the reaming progresses. Reaming continues sequentially until subchondral bone is reached and appropriate sizing is obtained (Fig. 7).

It is usually possible to obtain a corticocancellous base in most of the reamed portion of the acetabulum, with elimination of the inferior horseshoe, so that the medial wall becomes an integral part of the reamed surface. The cortical plate of the medial wall should be left intact.

Acetabular trial gauges are used to determine reaming accuracy and final diameter of the shell to be used. The trial gauges also measure how well the shell will sit on the peripheral rim (Fig. 7). The trial gauge corresponding to the last reamer used is placed on the gauge handle and inserted into the acetabulum. If the trial seats fully into the acetabulum but still moves freely, the next larger size trial should be chosen. One should only have to lightly impact the trial gauge into a fully seated position and not be able to significantly toggle it, to assure a good fit of the corresponding acetabular shell. Once the appropriate size reamer/trial gauge is obtained, **cup selections will be 2mm larger than the last reamer or trial gauge is used.**

It is important to note that the rim of the acetabulum must be completely free of any soft tissue and osteophytes, and that a clean and complete view of the acetabular rim is obtained (Fig. 9). This is extremely important to ensure that the liner will seat firmly into the acetabular shell.

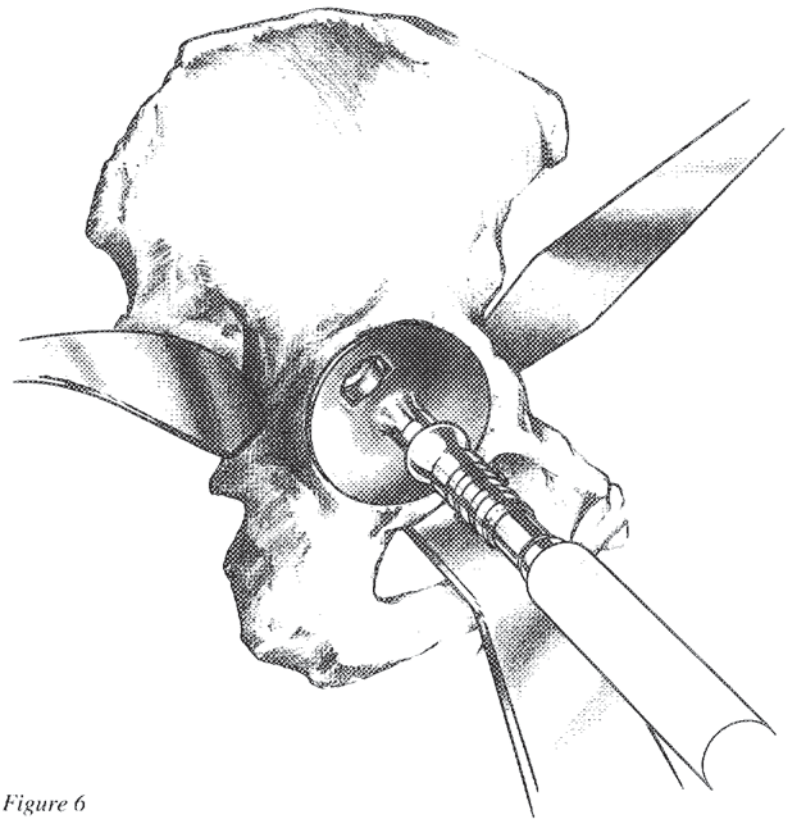

Figure 6

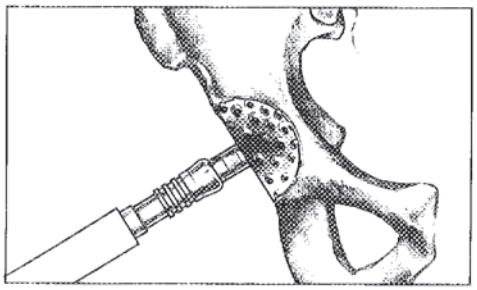

Figure 7

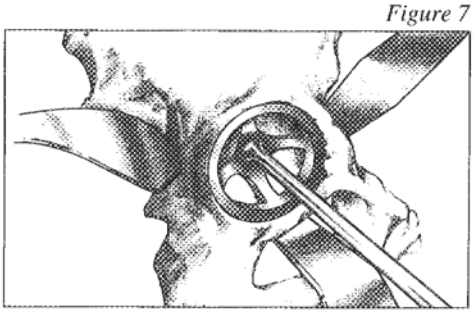

Figure 8

Figure 9

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The Ranawat/Burstein cup is attached to the inserter. The cup is then held in the correct horizontal position and properly anteverted (Fig. 10). The long handle should lie 45 degrees off the vertical axis from the center of the patient's trunk. The acetabular component should be medialized to the medial pelvic wall, but should not penetrate the medial bone. The superior/inferior placement should be such that the inferior margin of the socket is approximately 5mm lateral and superior to the inferior margin of the teardrop.

The lateral opening of the socket should be approximately 45 degrees, with 10 to 15 degrees of anteversion (Fig. 11). The shell should be fully contained within the bony structure whenever possible. Acetabular cysts, when present, should be curetted and filled with cancellous bone from the femoral head. Components with less than 50mm outer diameter should be considered for a 22mm insert to preserve maximum thickness of the polyethylene. Remember, the long handle of the inserter should also lie with 10-15 degrees of anteversion to the patient's trunk (Fig. 11).

With the acetabular inserter screwed down snugly on the acetabular component, align the shell over the rim of the acetabulum. The acetabular shell should be inserted with the area of screw holes placed superiorly.

Prior to final shell impaction, the optional rim punch can be used to slightly adjust the position of the component in the acetabulum, independently of the acetabular inserter, which is screwed into the dome of the shell.

Slowly tap the component into place, taking care to check for correct positioning as the shell advances into the pelvis. If orientation is acceptable, solidly impact the inserter and fully seat the component (Fig. 12). The inserter is then carefully removed to avoid any torquing of the cup.

Inspection of the cup should reveal that it is well seated. Use a depth gauge or hemostat placed through the holes in the cup to confirm a position against the acetabular walls.

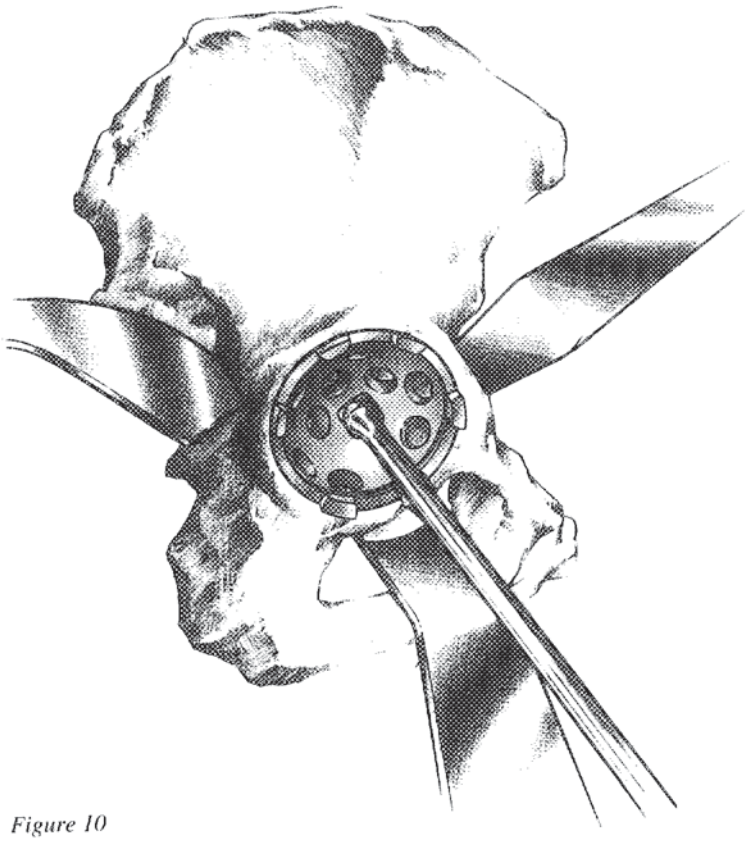

Figure 10

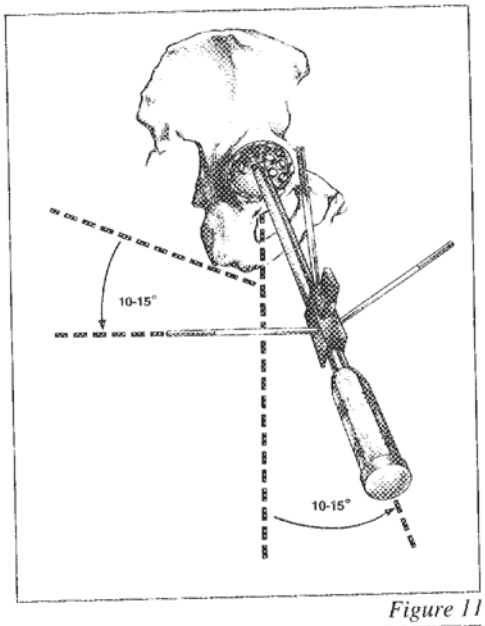

Figure 11

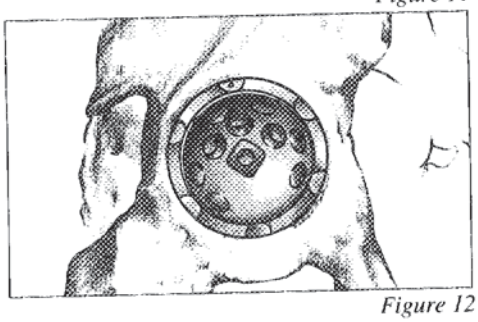

Figure 12

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The most superior and middle screw hole is then selected for primary insertion. Drilling is carried out with a flexible drill shaft and a 2.8mm x 20mm drill bit. If the bone is very sclerotic, a 3.2mm drill may be selected. A drill guide is also used to allow for centering of the drill bit in the screw hole (Fig. 13). Drilling should be carried out in this superior hole to allow for bicortical fixation. Always begin using the 20mm length drill bit when preparing the screw holes in the acetabulum. This enables the surgeon to angle the drill hole in the proper orientation for screw placement. The use of 30mm and 40mm drill bits may be required in larger acetabula.

Palpation of the notch area can be done with the index finger placed over the posterosuperior aspect of the acetabulum. When drilling any of the posterosuperior screw holes, the pillar should be palpated. The superior and anterior screw holes usually will be bicortical as well.

As the second cortex is approached, drilling should be done carefully to avoid plunging. Once the second cortex has been drilled, a depth gauge can be used to assess the screw length (Fig. 14). A hemostat is used to clamp or mark the depth gauge (Fig. 15). Final screw length can be determined by verifying the previously drilled hole. This is a safe zone, but careful measuring should be carried out to avoid excessive screw threads beyond the far cortex.

Note: When assessing screw length, the length of the drill bit exiting the standard drill guide is equal to the screw length (Fig. 16).

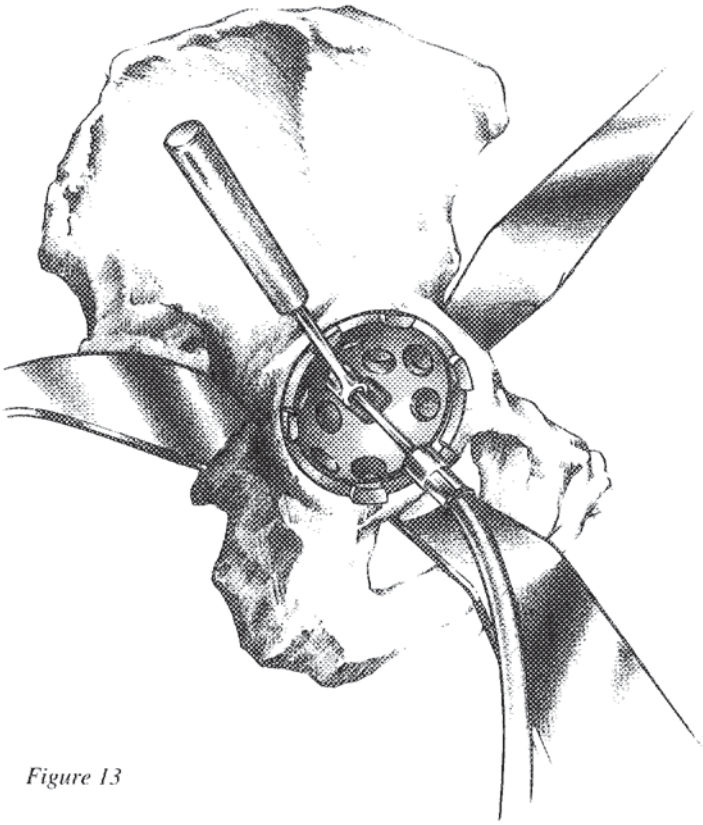

Figure 13

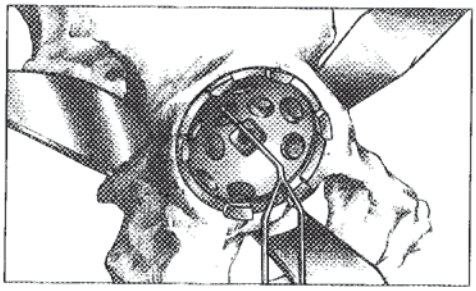

Figure 14

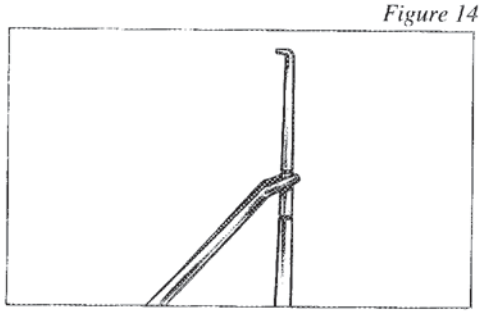

Figure 15

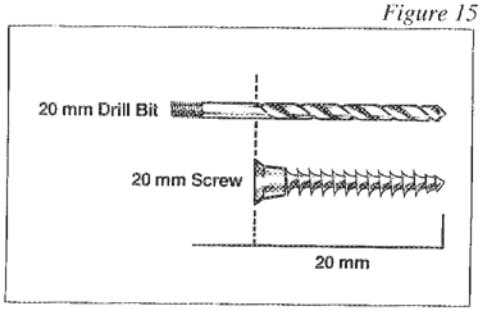

Figure 16

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Screw Placement and Insertion

The screw is inserted using a universal screwdriver (Fig. 17). Optional screw forceps may be used for additional stability when inserting screws. A straight screwdriver can also be used to firmly seat the screw. With the initial screw being placed, the remaining superior screw holes are filled as appropriate.

If difficulty is encountered in seating any of the screws a universal tap is available. The use of a 3.2mm drill bit has also proven to be successful in facilitating difficult screw placement, particularly when encountering hard, sclerotic bone.

With these screws in place, usually numbering between 2 and 3, good superior fixation of the acetabular cup is obtained. Low profile bone screws should always be used with this acetabular shell.

Once this step is accomplished and the outer edges of the cup have been thoroughly cleaned, the trial liner may now be inserted.

Each Ring Loc shell comes with a specific Ring Loc band that has been pre-inserted into the inner shell diameter. This titanium metal band is the locking mechanism for the acetabular liner (Fig. 18A). In addition to the Ring Loc feature, each shell has from 6-8 rim tabs that provide rotational stability for the liner. The trial liner is slightly undersized so it can be easily taken in and out of the acetabular shell. The final liner, however, is matched specifically to the shell and features a locking groove to engage the Ring Loc band around the rim of the inner shell diameter (Fig. 18B).

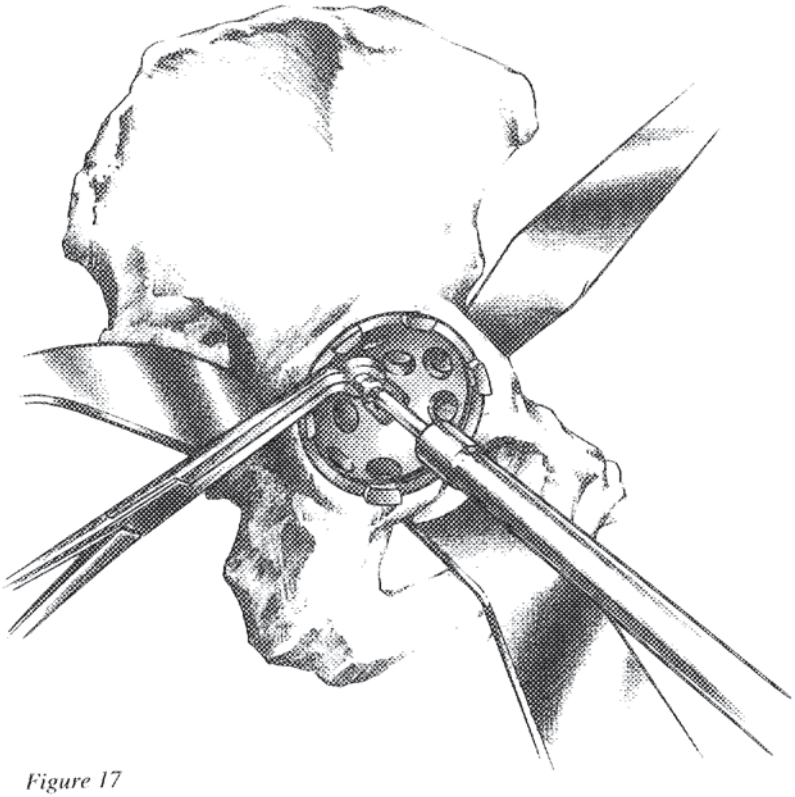

Figure 17

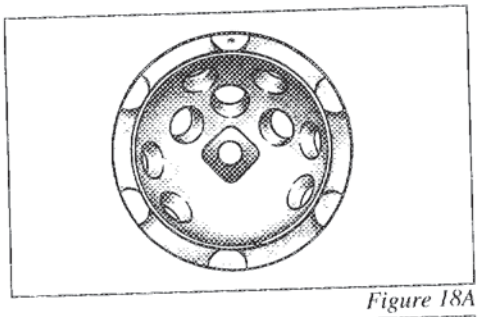

Figure 18A

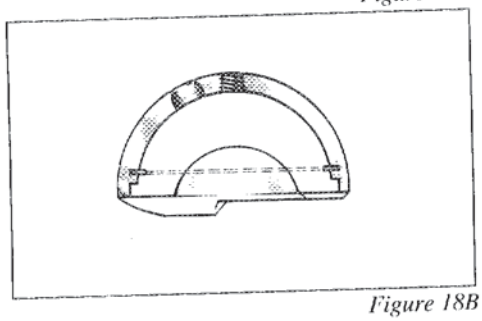

Figure 18B

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

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After the acetabulum has been inserted, a moist lap pad is placed in the cup, and a posterior retractor placed under the cut femoral neck, with the leg internally rotated and knee flexed so that the tibia is perpendicular to the floor. Any excess soft tissue is cleaned from the neck. Using either a box osteotome or a power tool, the remnants of the lateral cut neck should be removed.

The canal finder is used to make the starter hole (Fig. 19). The axial reaming is begun with a 9.0mm reamer, progressing in 0.5mm increments until the desired diameter is reached (Fig. 20): either as judged by CT template or by the feel and resistance encountered at the time of reaming. Each diaphyseal reamer has 3 reference bands that illustrate the various cone heights available with this prosthesis (Fig. 21). The most proximal band refers to an extra large cone height (XL), the middle band refers to the large or medium cone height (M and L stems with these cone heights are approximately the same length) and the distal band refers to the small cone height.

The reamer should be taken to a depth equal to or one size greater than planned prosthesis. For example, if a 2L14 prosthesis is templated, the reaming would be carried up to 14mm, with the depth equal to "L". The diaphyseal reamers should be taken down the canal until the desired reference band (S, M/L, XL) is in line with the resected medial bone. Excessive cortical reaming is not recommended. Sufficient lateralization of the reamers should be maintained in order to avoid a varus implant position.

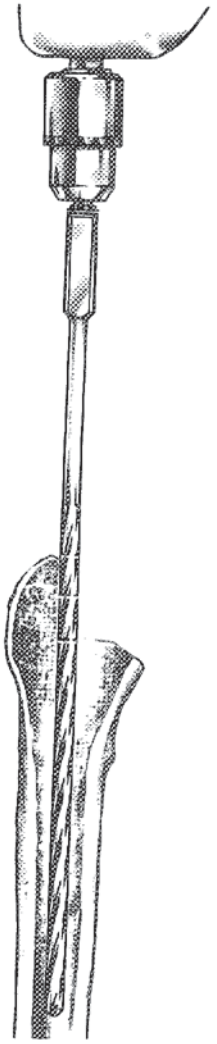

Figure 19

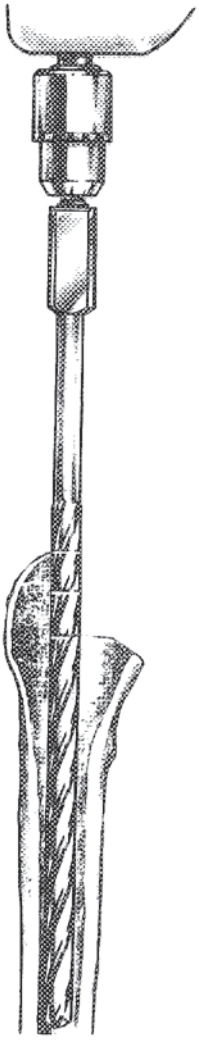

Figure 20

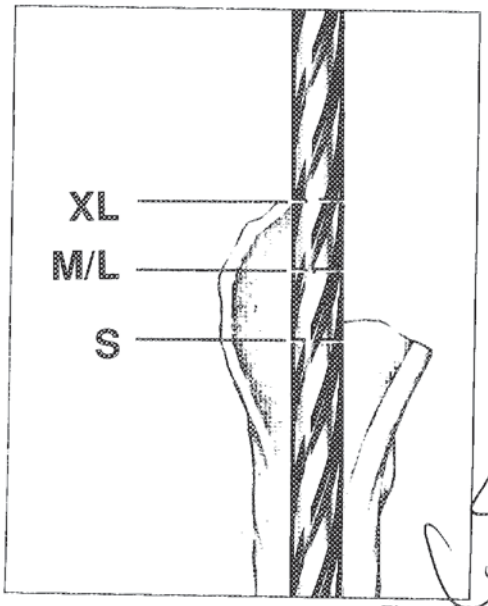

Figure 21

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The appropriate size distal broach bullet tip (Fig. 24) which matches the final distal reaming diameter is now screwed onto the alignment rod (Fig. 22), and manually inserted down the canal until it stops - do not impact this with a mallet.

Now, beginning with the #0 broach, metaphyseal broaching is begun using the slide hammer (Fig. 23A). Please note that the broaches can be assembled for either LEFT or RIGHT femurs (Fig. 23B).

Impact the #0 broach until a tight, stable position is achieved, making sure to keep lateral pressure to avoid a varus position. Note the depth of the rasp, as measured by the inscribed lines (S, M/L, XL) - this will give you the height of the metaphyseal cone for the reamed femur (Fig.25). Each broach from #0 through #4 has identical lines on both sides to indicate cone heights. The difference in each broach is its A/P thickness.

Now withdraw the #0 broach and insert broach #1 each successive broach (1, 2, 3, 4) will increase in AP diameter. Continue to progress until you have good contact all around the broach, and the next larger broach will be too big (Fig. 26). In this example, #2 is the correct size (CT templating is usually quite accurate in determining the size).

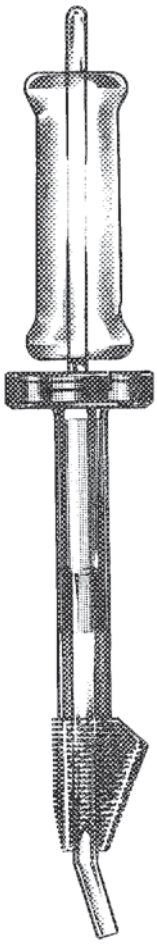

Figure 22

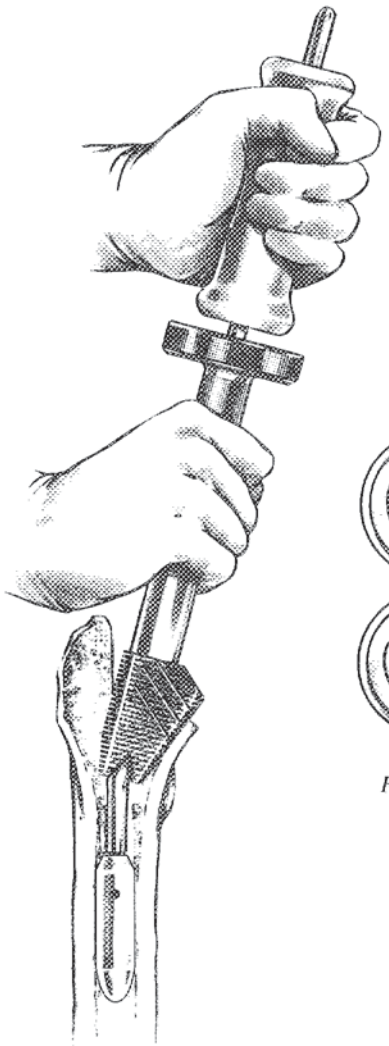

Figure 23A

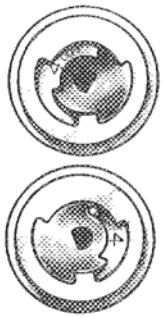

Figure 23B

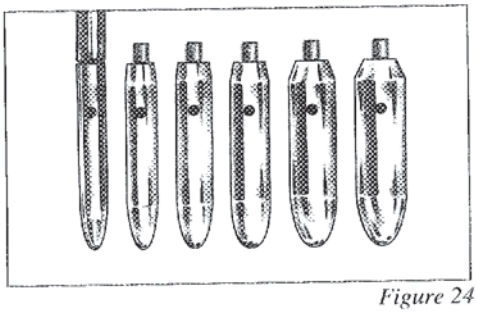

Figure 24

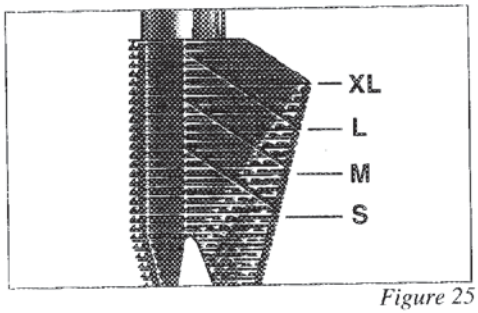

Figure 25

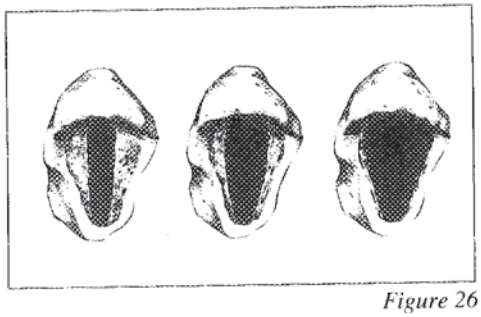

Figure 26

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Once proximal broaching is complete, assemble the desired transitional broach with the proper distal tip (Fig. 28). Again, each distal tip refers to the previously reamed diaphysis but is 0.5mm undersized to allow a line-to-line fit with the final implant.

The correct transitional rasp/provisional is determined by the final broaching assembly. For example: Suppose if the last proximal broach used was a size #2 (cone thickness), L (cone height), 14 (diaphyseal diameter bullet tip) or 2Lx14.0mm. The appropriate transitional rasp would be a "2L" left or right and the 14.0mm bullet tip would be threaded onto this modular rasp/provisional.

The rasp/provisional assembly is then impacted down the canal using a rasp handle that attaches to the neck and securely locks in place. The rasp is taken down until the line markings on the rasp match the neck cut (Fig. 27). Remember, the prior diaphyseal reaming and proximal broaching have prepared the basic canal envelope. The transitional rasp simply prepares the transition area between these two zones and allows a means to do a trial reduction before final component insertion.

Once the modular rasp/provisional is fully seated, making sure contact is satisfactory, the rasp handle is removed and a trial modular head is placed on the neck for an initial trial reduction (Fig. 29).

Using the trial modular head, the rasp assembly is checked for appropriate length and offsets as compared to the previously measured intact femur (Fig. 30).

If length and offsets are satisfactory, the leg is reduced and range of motion is measured.

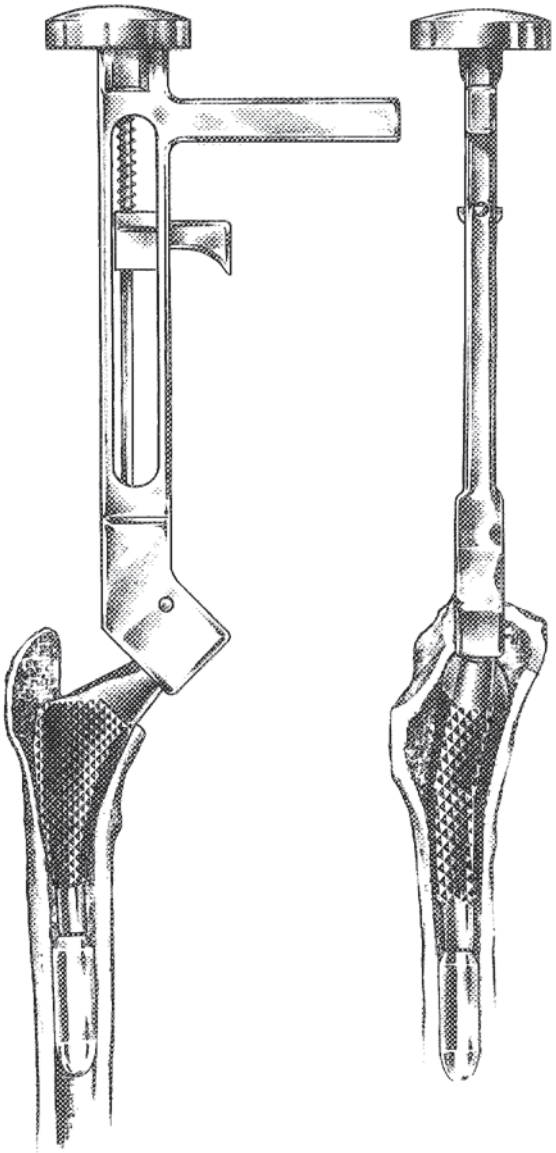

Figure 27

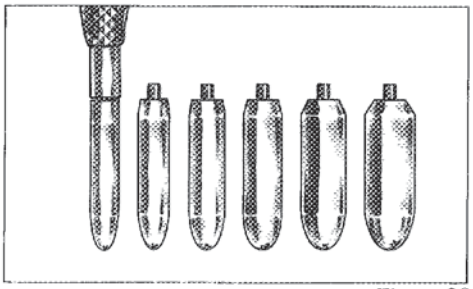

Figure 28

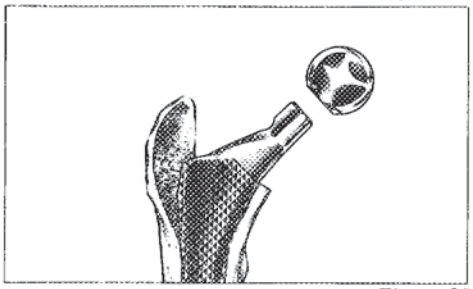

Figure 29

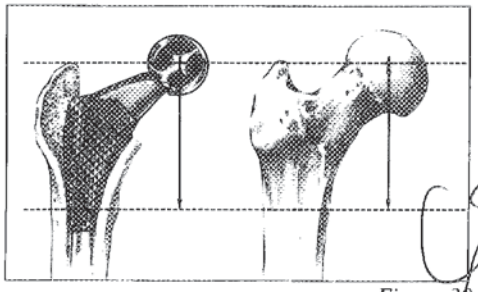

Figure 30

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

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If all is satisfactory, open the actual femoral component. Irrigate it briefly, and insert it BY HAND into the canal. Using hand pressure, the prosthesis should be able to be seated so that about 50% of the porous coating is still visible. If none of the porous coating is engaged, DO NOT impact the prosthesis with a mallet because it may not seat fully. If the component sits too far proximally, use the axial reamer corresponding to the distal diameter chosen, and ream the metaphyseal-diaphyseal transition area slightly. (This area corresponds to the anterior bend area in the prosthesis).

Once the component is satisfactorily inserted by hand, impact it into position using the impactor and a mallet (Fig. 31). If you have not already done so, impact the modular head into position, and reduce the hip (Fig. 32).

The Ranawat/Burstein porous implant has 15 degrees of anteversion built into the prosthesis. Because of the very tight fit you will achieve, you will not be able to change the anteversion of the femur unless you use an undersized component or plan for this at the time of proximal broaching (Fig. 33). Please take this into account when positioning the cup, especially if there is any reason to suspect that the patient has increased femoral anteversion.

The wound is irrigated and closed in layers. The external rotators and posterior capsule are attached to the trochanter with the help of polyester sutures passed through the holes in the trochanter. The gluteus maximus insertion is reattached with Tevdek. Two Redi-Vacette drains are inserted in the hip joint superiorly and tensor fascialata is closed with synthetic absorbable interrupted sutures. The subcutaneous tissue is closed with synthetic interrupted sutures. The skin is closed with running 3-0 nylon. A light compression dressing is applied and held with ACE Bandage Spica.

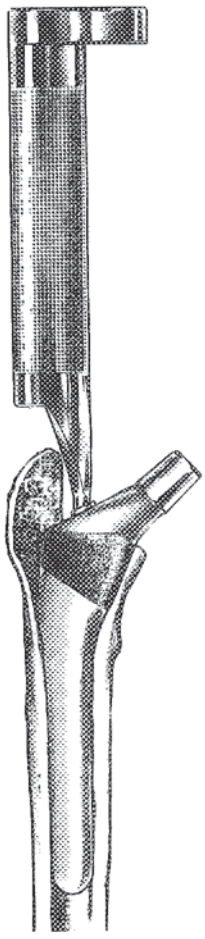

Figure 31

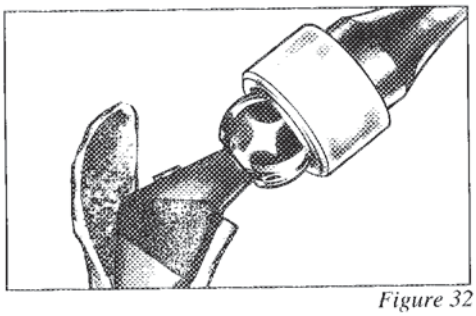

Figure 32

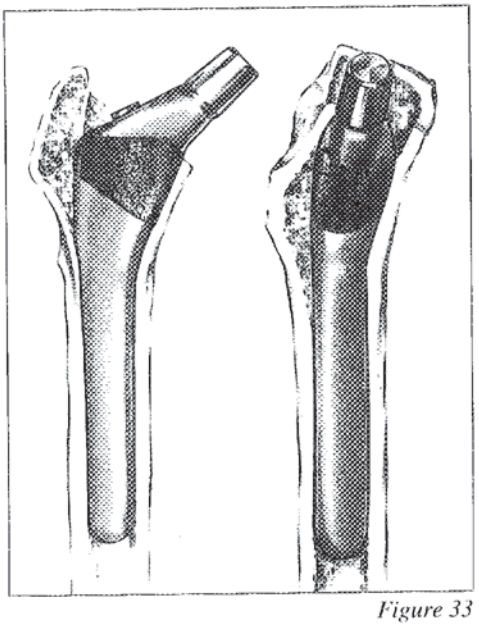

Figure 33

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

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The trial liner and the final liner usually are inserted with the Hi-Wall or 10-degree face positioned to protect from posterosuperior dislocation. The polyethylene Hi-Wall offers an extended articulating surface to prevent dislocation (Fig. 35). The 10-degree face allows correction of orientation in the event of shell malalignment (Fig. 36). Due to the configuration of the liner, there are between twelve and sixteen possible locations for the insertion (Fig. 37).

With the acetabular trial liner in place, and femoral reconstruction completed, a trial reduction can be carried out to determine if the correct neck length has been chosen for the femoral component. A full range of motion is then checked, particularly extension, adduction, external rotation (E.A.E.) and flexion, adduction, internal rotation (F.A.I.) (Fig. 34).

The wound is irrigated and closed in layers. The external rotators and posterior capsule are attached to the trochanter with the help of polyester sutures passed through the holes in the trochanter. The gluteus maximus insertion is reattached with Tevdek. Two Redi-Vacette drains are inserted in the hip joint superiorly and tensor fascialata is closed with synthetic absorbable interrupted sutures. The subcutaneous tissue is closed with synthetic interrupted sutures. The skin is closed with running 3-0 nylon. A light compression dressing is applied and held with ACE Bandage Spica.

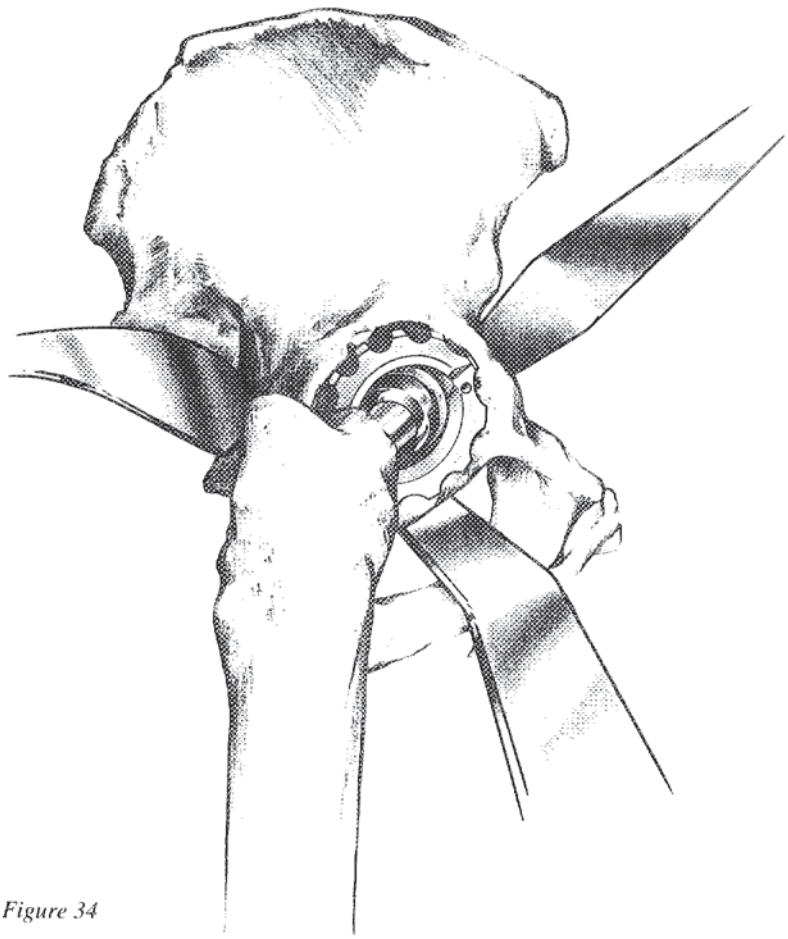
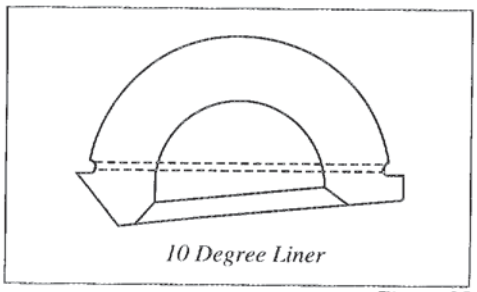
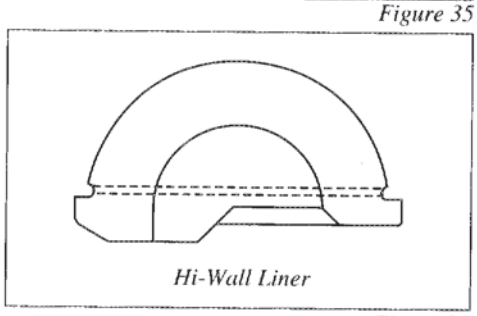


Figure 34



10 Degree Liner

Figure 35



Hi-Wall Liner

Figure 36

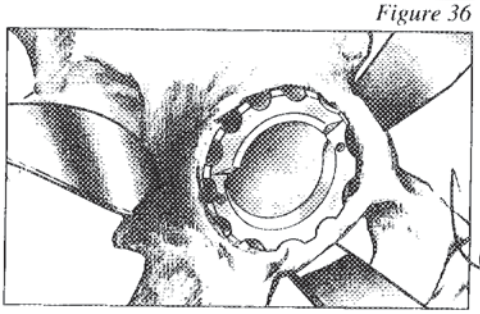


Figure 37

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

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Femoral Ordering Information

Size 1 Porous CoCr Femoral Component			
Part No.		Size	Side
Small	Medium		
105701	105707	11mm	Right
105702	105708	11mm	Left
105703	105709	12.5mm	Right
105704	105710	12.5mm	Left
105705	105711	14mm	Right
105706	105712	14mm	Left

Size 1 Transition Rasp/Provisional		
Part No.		Side
Small	Medium	
428001	428003	Right
428002	428004	Left

Size 2 Porous CoCr Femoral Component				
Part No.			Size	Side
Small	Medium	Large		
105727	105733	105739	12.5mm	Right
105728	105734	105740	12.5mm	Left
105729	105735	105741	14mm	Right
105730	105736	105742	14mm	Left

Size 2 Transition Rasp/Provisional			
Part No.			Side
Small	Medium	Large	
428009	428011	428013	Right
428010	428012	428014	Left

Size 3 Porous CoCr Femoral Component			
Part No.		Size	Side
Medium	Large		
105757	105763	14mm	Right
105758	105764	14mm	Left
105759	105765	16mm	Right
105760	105766	16mm	Left

Size 3 Transition Rasp/Provisional		
Part No.		Side
Medium	Large	
428019	428021	Right
428020	428022	Left

Size 4 Porous CoCr Femoral Component			
Part No.		Size	Side
Large	X-Large		
105787	105793	16mm	Right
105788	105794	16mm	Left
105789	105795	17.5mm	Right
105790	105796	17.5mm	Left

Size 4 Transition Rasp/Provisional		
Part No.		Side
Large	X-Large	
428029	428031	Right
428030	428032	Left

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CoCr and Zirconia Ceramic Modular Heads - Taper Type II						
Part No. 28mm CoCr	Part No. 28mm Zirconia	Part No. 28mm Provisionals	Part No. 32mm CoCr	Part No. 32mm Zirconia	Part No. 32mm Provisionals	Neck Length
163700		31-473476	163705		31-473481	-6mm (29mm)
	163120	31-473448		163125	31-473449	-5mm (30mm)
163701		31-473477	163706		31-473482	-3mm (32mm)
	163121	31-473400		163126	31-473401	-2.5 mm (32.5mm)
163702	163122	31-473478	163707	163127	31-473483	Std (35mm)
	163123	31-473406		163128	31-473407	+2.5mm (37.5mm)
163703		31-473479	163708		31-473484	+3mm (38mm)
	163124	31-473446		163129	31-473447	+5mm (40mm)
163704		31-473480	163709		31-473485	+6mm (41mm)

Femoral Instrumentation

Canal Reamers

428159 9.0mm Starter
428160 9.5mm
428161 10.0mm
428162 10.5mm
428163 11.0mm
428164 11.5mm
428165 12.0mm
428166 12.5mm
428167 13.0mm
428168 13.5mm
428169 14.0mm
428170 14.5mm
428171 15.0mm
428172 15.5mm
428173 16.0mm
428174 16.5mm
428175 17.0mm
428176 17.5mm
428177 18.0mm

T-Handle

31-473620

Broach Alignment Rod

428070

Slide Hammer

428072

Modular Bullets
(for Alignment Rod 428070)

428061 11.0mm
428062 12.5mm
428064 14.0mm
428066 16.0mm
428067 17.5mm

Proximal Broaches

428040 Size 0
428041 Size 1
428042 Size 2
428043 Size 3
428044 Size 4

Rasp Handle w/ Outrigger

428033

Modular Bullets
(for Transitional Rasps/Provisionals 428001-428032)

428121 1 x 11.0mm
428122 1 and 2 x 12.5mm
428124 1 and 2 x 14.0mm
428134 3 x 14.0mm
428136 3 x 16.0mm
428146 4 x 16.0mm
428147 4 x 17.5mm

Align Rod Cross Pin

428071

Stem Impactor

428074

Delrin Extractor Collet

428081

Stem Extractor

428080

Stem Extractor Rod

428082

Large Slide Hammer

428083

X-ray Templates

428035

Sterilization Trays

592161 Transitional Rasps/Bullets
592162 Prox.Broaches/Rods/Bullets
592163 Canal Reamers-Complete Set 1/2
592164 Canal Reamers-Complete Set 2/2
592165 Canal Reamers-Basic Set
592166 General Instrumentation

21

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Acetabular Ordering Information

Ranawat/Burstein Acetabular Shell

Implant Part No.	Shell Diameter	Liner Size
106044	44mm Diameter	Size 21
106046	46mm Diameter	Size 22
106048	48mm Diameter	Size 22
106050	50mm Diameter	Size 23
106052	52mm Diameter	Size 23
106054	54mm Diameter	Size 24
106056	56mm Diameter	Size 24
106058	58mm Diameter	Size 25
106060	60mm Diameter	Size 25
106062	62mm Diameter	Size 26
106064	64mm Diameter	Size 26
106066	66mm Diameter	Size 27
106068	68mm Diameter	Size 27
106070	70mm Diameter	Size 28

Low Profile Acetabular Bone Screws

Implant Part No.	Self-Tapping Cancellous	Length mm	Length in.
103530	6.5mm	15	0.6
103531	6.5mm	20	0.8
103532	6.5mm	25	1.0
103533	6.5mm	30	1.2
103534	6.5mm	35	1.4
103535	6.5mm	40	1.6
103536	6.5mm	45	1.8
103537	6.5mm	50	2.0
103538	6.5mm	60	2.4
103539	6.5mm	70	2.8

Ring Loc Acetabular Liners

Hi-Wall Liner				10 Degree Liner				Liner Size
28mm Diameter		32mm Diameter		28mm Diameter		32mm Diameter		
Implant Part No.	Provisional Part No.	Implant Part No.	Provisional Part No.	Implant Part No.	Provisional Part No.	Implant Part No.	Provisional Part No.	
105901	423701			105911	423711			Size 21
105902	423702			105912	423712			Size 22
105903	423703	105923	423723	105913	423713	105933	423733	Size 23
105904	423704	105924	423724	105914	423714	105934	423734	Size 24
105905	423705	105925	423725	105915	423715	105935	423735	Size 25
103906	423706	105926	423726	105916	423716	105936	423736	Size 26
103907	423707	105927	423727	105917	423717	105937	423737	Size 27
105908	423708	105928	423728	105918	423718	105938	423738	Size 28

Acetabular Instrumentation

Acetabular Shell Inserter
423609

Angle Guide
424486

Ring Loc Liner Remover
423619

Rim Punch
423611

Drill Guides
424412 2.8mm Std
424427 2.8mm Long
424404 3.2mm Std
424405 3.2mm Long

Flexible Drill Shaft
424399

Drill/Threaded Shank (Fits 424399)
424409 2.8 x 20mm
424410 2.8 x 30mm
424411 2.8 x 40mm
424501 3.2 x 20mm
424502 3.2 x 30mm
424503 3.2 x 40mm

Calibrated Flexible Depth Gauge
424492

Acetabular Template Set
106001

Sterilization Case
592146 General Acet. Tray 1
592147 General Acet. Tray 2
592148 Acet. Shell Gauge Tray
592149 Acet. Trial Tray

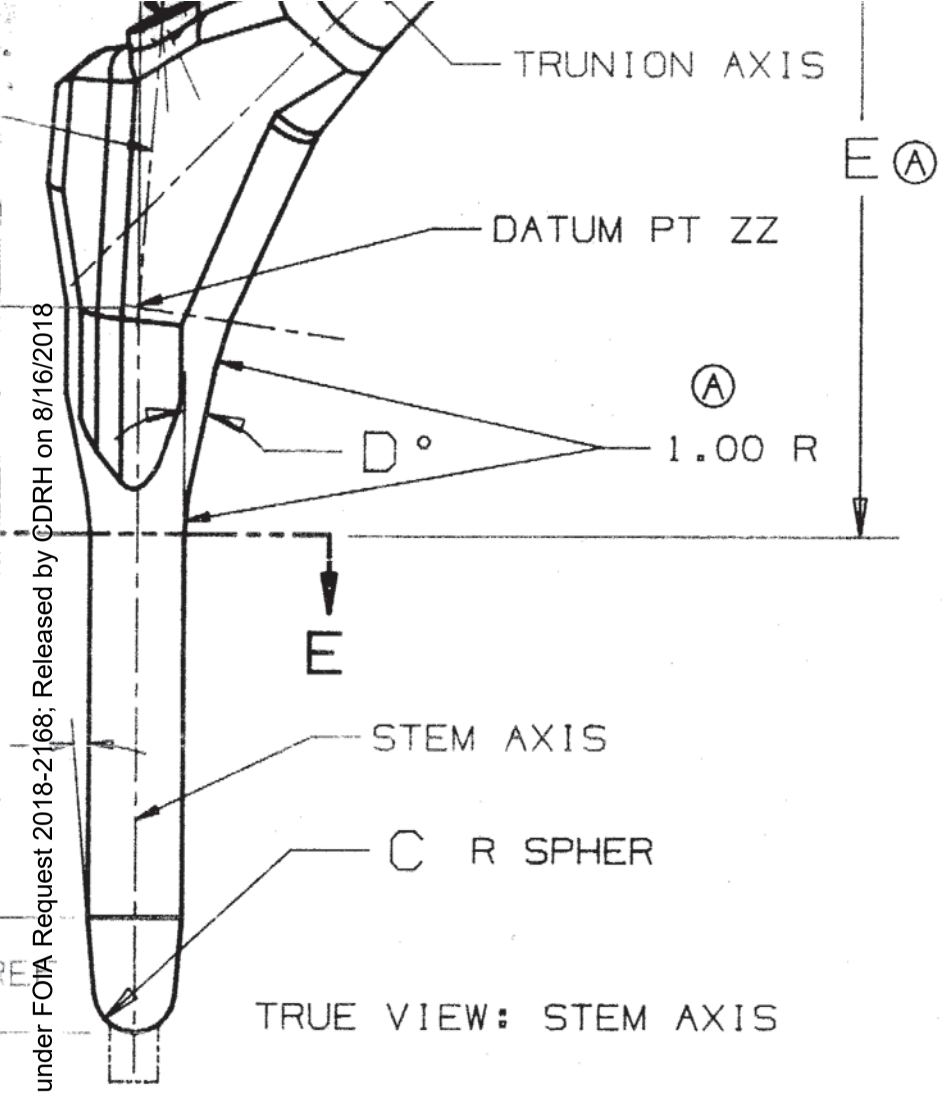
Metal Frame Shell Gauges
423740 40mm
423742 42mm
423744 44mm
423746 46mm
423748 48mm
423750 50mm
423752 52mm
423754 54mm
423756 56mm
423758 58mm
423760 60mm
423762 62mm
423764 64mm
423766 66mm
423768 68mm
423770 70mm

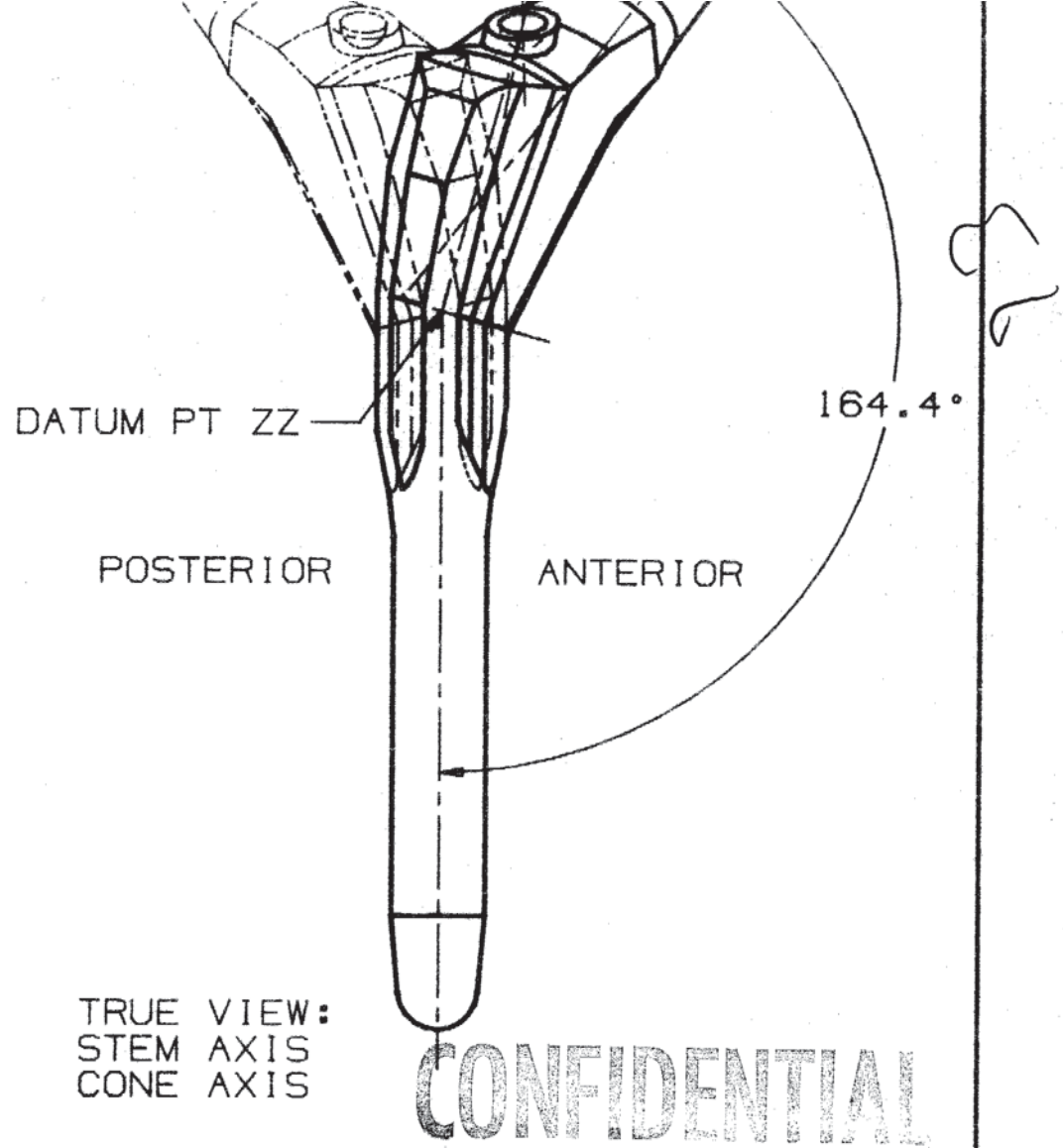
Metal Frame Gauge Handle
423598

BIOMET INC.

Biomet, Inc., Warsaw, Indiana 46581-0587 (219) 267-6639 ©1992 Biomet, Inc. All Rights Reserved
Biomet Ltd., Waterton Industrial Estate, Bridgend, South Glamorgan CF31 3YN, U.K.
Form No. Y-BMT-228/021592
Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018





CONFIDENTIAL

PER REQUEST	10-11-91	MH	
REVISED FROM	DATE	BY	CK

THIS DRAWING OWNED BY BIOMET INC., WARSAW, IN IS CONDITIONALLY LOANED AND IS DISCLOSED TO THE RECIPIENT IN CONFIDENCE. IN RECEIVING IT, THE RECIPIENT AGREES NOT TO REPRODUCE OR COPY IT IN WHOLE OR IN PART OR TO FURNISH INFORMATION FROM IT TO OTHERS AND TO RETURN IT IMMEDIATELY UPON REQUEST.

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1. REMOVE BURRS AND SHARP CORNERS.
2. DO NOT SCALE DRAWING.
3. TOLERANCE:

DECIMAL ±
.X .04
.XX .02
.XXX .010

ANGLES ± .5°

BIOMET WARSAW, IN 46580

TITLE: HSS POROUS FEMORAL			FINISH: POLISH
PART NAME: SEE TABLE			AMT PER UNIT: 1
MATL: 01-04-3100 RIGHT 01-04-3101 LEFT			DRAWING NO. 1057-01/06-01
DATE: 1-31-91	DR: JB	CK:	SCALE: NTS

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

(b)(4) Device Engineering Drawing

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

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

(b)(4) Device Engineering Drawing

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

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

(b)(4) Device Engineering Drawing

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

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

(b)(4) Device Engineering Drawing

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

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

(b)(4) Device Engineering Drawing

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

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

(b)(4) Device Engineering Drawing

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

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

(b)(4) Device Engineering Drawing

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

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

(b)(4) Device Engineering Drawing

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

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

(b)(4) Device Engineering Drawing

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

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

(b)(4) Device Engineering Drawing

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

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

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Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

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

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

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

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

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)
1390 Piccard Drive
Rockville, Maryland 20850

JUNE 12, 1992

BIOMET
ATTN: PATRICIA BERES
P.O. BOX 587
WARSAW, IN 46581

510(k) Number: K921277
Product: RANAWAT/BURSTEIN
TOTAL HIP SYSTEM

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST be sent in duplicate to the Document Mail Center (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. Because of equipment and personnel limitations, we cannot accept telefax material as part of your official premarket notification submission unless specifically requested of you by an FDA official.

If after 30 days the requested information is not received, we will discontinue review of your submission and proceed to delete your file from our review system. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

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

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

Robert I. Chissler
Chief, Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

DO NOT REMOVE THIS ROUTE SLIP!!!!

K-92-1277

6/12/92

FROM:	LETTER DATE	LOGIN DATE	DUE DATE
BIOMET ATTN: PATRICIA BERES P.O. BOX 587 WARSAW, IN 46581	03/12/92	03/17/92	06/15/92
	TYPE OF DOCUMENT: 510 (k)		CONTROL # K921277
SHORT NAME: BIOMET	PHONE NO: 219-267-6639 ESTABLISHMENT NO: 1825034		

TO:	
ODE/DMC	CONT. CONF.: N STATUS : H REV PANEL : OR PAN/PROD CODE(S): OR/ / /

SUBJECT:
RANAWAT/BURSTEIN TOTAL HIP SYSTEM

DECISION:	RQST INFO	INFO DUE
DECISION DATE: / /	DATE: 06/12/92	DATE: 07/12/92
	DATE: / /	DATE: / /
	DATE: / /	DATE: / /
	DATE: / /	DATE: / /
	DATE: / /	DATE: / /
	DATE: / /	DATE: / /

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

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

Date

From REVIEWER(S) - NAME(S) T. Stevens

Subject 510(k) NOTIFICATION K921277

To THE RECORD

It is my recommendation that the subject 510(k) Notification:

_____ (A) Is substantially equivalent to marketed devices.

_____ (B) Requires premarket approval. NOT substantially equivalent to marketed devices.

X (C) Requires more data. Waiting for abrasion data (had been on desk hold)

_____ (D) Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Additional Comments:

Is this device subject to Postmarket Surveillance? Yes ☐ No ☐

This 510(k) contains: (check appropriate box(es))

☐ A 510(k) summary of safety and effectiveness, or

☐ A 510(k) statement that safety and effectiveness information will be made available

☐ The required certification and summary for class III devices

The submitter requests under 21 CFR 807.95:*

_____ No Confidentiality

_____ Confidentiality for 90 days

_____ Continued Confidentiality exceeding 90 days

Predicate Product Code w/panel and class:

_____

Additional Product Code(s) w/Panel (optional):

_____

REVIEW: Mark N. Melkerson (BRANCH CHIEF) ORDB BRANCH CODE 6/12/92 (DATE)

Acting

FINAL REVIEW: _____ (DIVISION DIRECTOR) (DATE)

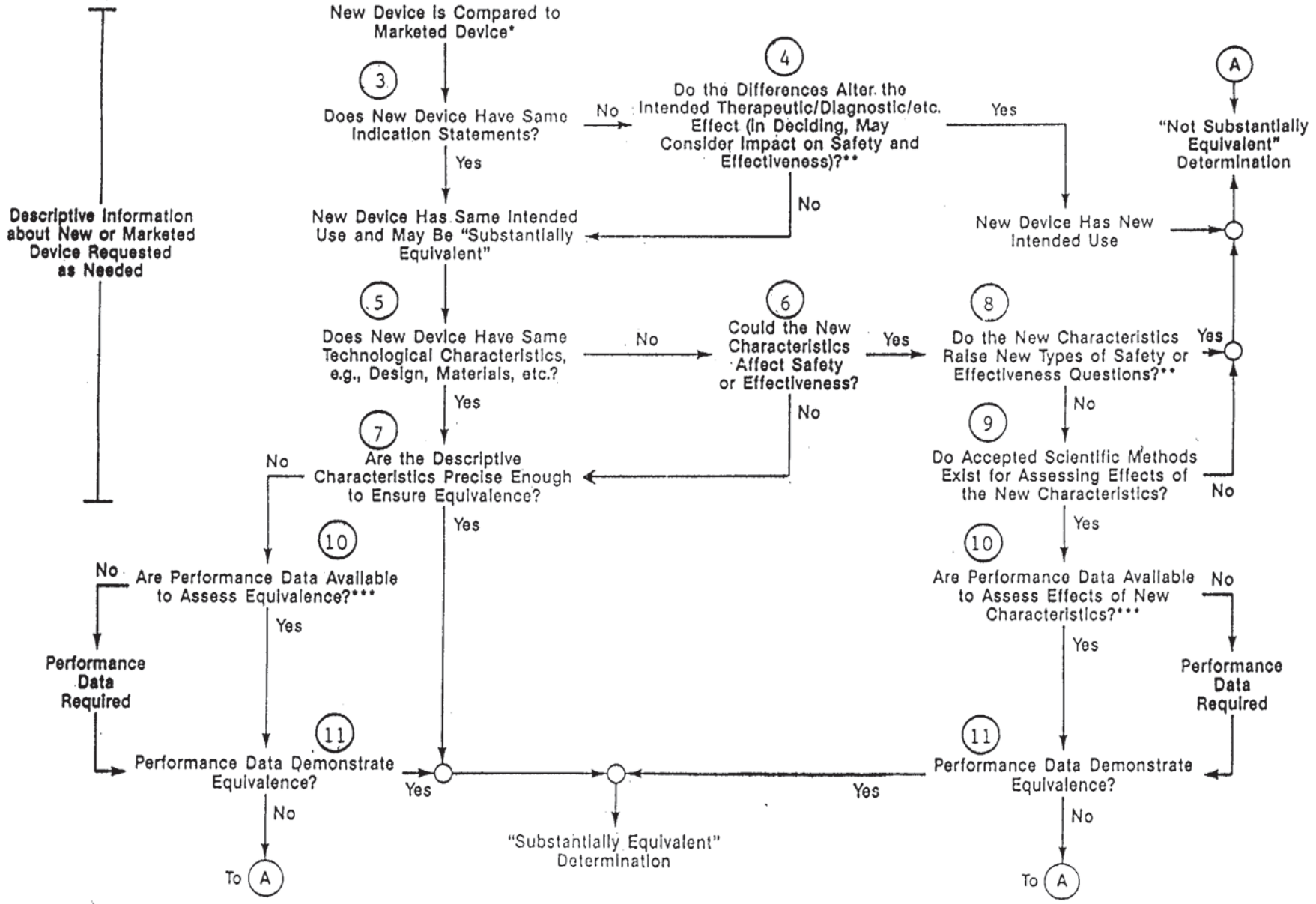
Revised 11/18/91

*DOES NOT APPLY TO ANY "SE" DECISIONS

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

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



* 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.

** Decision is Normally Based on Descriptive Information Alone, But Limited Testing Information is Sometimes Required.

*** Data May Be in the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

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

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

MEMO RECORD

DATE: June 12, 1992

FROM: Theodore R. Stevens, Biomedical Engineer, HFZ-410
TO: The Record, K921274, K921277, K921301
SUBJECT: Biomet plasma srayed hips for uncemented use

The subjects of these 510(k)'s are the Modular Hip sytem, Ranawat/Burnstein and Taperloc systems. Each was previously cleared for cemented use only.

I previously requested reports of testing of the plasma sprayed coating, which is essentially the same for all of the devices. Ms. Sandborn indicated that it would be available shortly, so the documents were held at my desk.

On 6/12/92, with the 90th review day approaching, and no sign of the incoming information, I again called Ms. Sandborn and requested the information, this time stating that the documents were to be put on hold. She said that it would be another week or so until the information was available, and that it was fine if they went on hold.

INFORMATION REQUESTED: Testing reports in accordance with draft metallic coating guidance document, for each coating and substrate.

Theodore R. Stevens

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

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

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)
1390 Piccard Drive
Rockville, Maryland 20850

MARCH 20, 1992

BIOMET
ATTN: PATRICIA BERES
P.O. BOX 587
WARSAW, IN 46581

510(k) Number: K921277
Received: 03-17-92
Product: RANAWAT/BURSTEIN
TOTAL HIP SYSTEM

We have 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.

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

In addition, the SMDA requires all persons submitting a premarket notification submission to include either (1) a summary of the safety and effectiveness information in the premarket notification submission upon which an equivalence determination could be based (510(k) summary), OR (2) a statement that safety and effectiveness information will be made available to interested persons upon request (510(k) statement). Safety and effectiveness information refers to information in the premarket notification submission, including adverse safety and effectiveness information, that is relevant to an assessment of substantial equivalence. The information could be descriptive information about the new and predicate device(s), or performance or clinical testing information. We cannot issue a final decision on your 510(k) unless you comply with this requirement.

Although FDA acknowledges that the law provides the 510(k) submitter an alternative, FDA encourages manufacturers to provide a 510(k) statement to FDA and to make their safety and effectiveness information available to the public, excluding confidential manufacturing process information, in lieu of submitting a 510(k) summary to the agency until FDA promulgates a regulation on the content and format of 510(k) summaries. Since the law

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

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

:equires that FDA must make the 510(k) summary, or the source of information referred to in the 510(k) statement, publicly available within 30 days of making a substantial equivalence determination, we advise you that we may no longer honor any request for extended confidentiality under 21 CFR 807.95.

Additionally, the new legislation also requires any person who asserts that a device is substantially equivalent to a class III device to (1) certify that he or she has conducted a reasonable search of all information known, or otherwise available, about the generic type of device, AND (2) provide a summary description of the types of safety and effectiveness problems associated with the type of device and a citation to the literature, or other sources of information, upon which they have based the description (class III summary and certification). The description should be sufficiently comprehensive to demonstrate that an applicant is fully aware of the types of problems to which the device is susceptible. If you have not provided this class III summary and certification in your premarket notification, please provide it as soon as possible. We cannot complete the review of your submission until you do so.

Furthermore, the new legislation, section 522(a)(1), of the Act, states that if your device is a permanent implant the failure of which may cause death, you may be subject to required postmarket surveillance. If the premarket notification for your device was originally received on or after November 8, 1991, is subsequently found to be substantially equivalent to an Aneurysm Clip, Annuloplasty Ring, Artificial Embolization Device, Automatic Implanted Cardioverter Defibrillator System, Cardiovascular Intravascular Filter, Cardiovascular Permanent Pacemaker Electrode (Lead), Central Nervous System Fluid Shunt, Coronary Vascular Stent, Implantable Pacemaker Pulse Generator, Implanted Diaphragmatic/Phrenic Nerve Stimulator, Intracardiac Patch or Pledget, Intravascular Occluding Catheter, Replacement Heart Valve, Total Artificial Heart, Tracheal Prosthesis, Vascular Graft Prosthesis (less than 6 mm diameter), Vascular Graft Prosthesis (6 mm or greater diameter), Vena Cava Clip, or Ventricular Assist Device - Implant, you will be subject to the required postmarket surveillance and so notified of this determination in your substantially equivalent letter. (Some of the above listed types of devices may require a premarket approval application). This list is subject to change without notification. If you have any questions as to whether or not your device may be subject to postmarket surveillance or about this program, please contact Ms. Anita Rayner at (301) 443-7120.

Please note that the SMDA may have additional requirements affecting your device. You will be informed of these requirements as they become effective.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

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

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

Robert I. Chissler
Chief, Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

K921277

Corporate
Headquarters

Mailing Address:
P.O. Box 587
Warsaw, IN 46581-0587

Shipping Address:
Airport Industrial Park
Warsaw, IN 46580

(219) 267-6639 Office
(219) 267-8137 FAX

March 12, 1992

IDE Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
1390 Piccard Dr.
Rockville, Maryland 20850

RECEIVED
17 Mar 92 12 49
FDA/CDRH/ODE/DMC

RE: RANAWAT/BURSTEIN TOTAL HIP SYSTEM

Dear Sir or Madame:

Please find the enclosed 510(k) Notification for the non-cemented use of the Ranawat/Burstein Total Hip System. This submission is based on the recent decision to reclassify uncemented metallic hip systems into Class II.

We hope you will find this submission in meeting with your requirements.

Sincerely,

Patricia S Beres

Patricia Sandborn Beres
Research Manager

PSB/vh

94

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

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

510(k) Notification

A. Classification Name: Hip Joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis for biological fixation.

Common or Usual Name: Metallic total hip system.

Proprietary Name: Ranawat/Burstein Total Hip System

B. Establishment Registration: 1825034

C. Device Classification: Effective February 21, 1992, uncemented metallic hip systems were reclassified into Class II based on a petition filed by Richards Medical Company and Intermedics Orthopaedics, Inc.

D. Performance Standards: No Performance Standards have been developed at this time.

E. Labeling and Promotional Materials: No promotional materials specific to non-cemented uses have been developed at this time. Samples of proposed labeling may be found in Exhibit I.

(b)(4)

[redacted]

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

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

(b)(4)

[redacted]

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

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

(b)(4)

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

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

(b)(4)

[redacted]

H. Summary of Safety and Effectiveness: A summary of the safety and effectiveness of this type of device is contained in Exhibit VIII.

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

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

Table 1

Device	Ranawat/Burstein	AML	Bias
Substrate Metal	(b)(4) [redacted]		
Porous Surface Metal			
Porous Surface Composition			
Average Pore Size (range)			
Pore Volume			
Porous Surface Thickness			
Method of Application			

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

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

EXHIBIT I

12

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

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

Exhibit I

Labeling and Packaging

The final product will be supplied in individual sterile packages. 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. The sterility assurance level for Biomet products is 10^{-6} verified by AMMI methods. Sterilization is performed by either RSI (Schaumburg, IL) or Isomedix, Inc. (Morton Grove, IL).

Each component is placed within a plastic bag or scabbard. 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.

Sample Label

Biomet No.: XXXXXX
Ranawat/Burstein Porous
Femoral Hip Stem
<size>
Co-Cr-Mo\Ti-6Al-4V
Lot No.: XXXXXXX Qty 1

Biomet No.: XXXXXX
Ranawat/Burstein Porous
Acetabular Shell
<size>
Ti-6Al-4V
Lot No.: XXXXXXX Qty 1

Contents of this package
sterile if unopened

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

Biomet No.: XXXXXX
Ranawat/Burstein All
Polyethylene Acetabular Cup
<size>
UHMWPE
Lot No.: XXXXXXX Qty 1

Advertisements and Promotional Literature

Advertisements and promotional literature have not been developed for non-cemented use of this device.

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

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

EXHIBIT II

2

1004

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

Records processed under FOIA Request 2018-2168; Released by CDRH on 8/16/2018

Ranawat/Burstein Total Hip System
Component Listing

Part#	Description	Cone Width	Height	Size	Side
105701	Porous Femoral Component	1	Small	11mm	Right
105702	Porous Femoral Component	1	Small	11mm	Left
105703	Porous Femoral Component	1	Small	12.5mm	Right
105704	Porous Femoral Component	1	Small	12.5mm	Left
105705	Porous Femoral Component	1	Small	14mm	Right
105706	Porous Femoral Component	1	Small	14mm	Left
105707	Porous Femoral Component	1	Medium	11mm	Right
105708	Porous Femoral Component	1	Medium	11mm	Left
105709	Porous Femoral Component	1	Medium	12.5mm	Right
105710	Porous Femoral Component	1	Medium	12.5mm	Left
105711	Porous Femoral Component	1	Medium	14mm	Right
105712	Porous Femoral Component	1	Medium	14mm	Left
105727	Porous Femoral Component	2	Small	12.5mm	Right
105728	Porous Femoral Component	2	Small	12.5mm	Left
105729	Porous Femoral Component	2	Small	14mm	Right
105730	Porous Femoral Component	2	Small	14mm	Left
105733	Porous Femoral Component	2	Medium	12.5mm	Right
105734	Porous Femoral Component	2	Medium	12.5mm	Left
105735	Porous Femoral Component	2	Medium	14mm	Right
105736	Porous Femoral Component	2	Medium	14mm	Left
105739	Porous Femoral Component	2	Large	12.5mm	Right
105740	Porous Femoral Component	2	Large	12.5mm	Left
105741	Porous Femoral Component	2	Large	14mm	Right
105742	Porous Femoral Component	2	Large	14mm	Left
105757	Porous Femoral Component	3	Medium	14mm	Right
105758	Porous Femoral Component	3	Medium	14mm	Left
105559	Porous Femoral Component	3	Medium	16mm	Right
105760	Porous Femoral Component	3	Medium	16mm	Left
105763	Porous Femoral Component	3	Large	14mm	Right
105764	Porous Femoral Component	3	Large	14mm	Left
105765	Porous Femoral Component	3	Large	16mm	Right
105766	Porous Femoral Component	3	Large	16mm	Left
105787	Porous Femoral Component	4	Large	16mm	Right
105788	Porous Femoral Component	4	Large	16mm	Left
105789	Porous Femoral Component	4	Large	17.5mm	Right
105790	Porous Femoral Component	4	Large	17.5mm	Left

105

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105793	Porous Femoral Component	4	X-Large	16mm	Right
105794	Porous Femoral Component	4	X-Large	16mm	Left
105795	Porous Femoral Component	4	X-Large	17.5mm	Right
105796	Porous Femoral Component	4	X-Large	17.5mm	Left
106040	Porous Acetabular Shell			40mm	
106042	Porous Acetabular Shell			42mm	
106044	Porous Acetabular Shell			44mm	
106046	Porous Acetabular Shell			46mm	
106048	Porous Acetabular Shell			48mm	
106050	Porous Acetabular Shell			50mm	
106052	Porous Acetabular Shell			52mm	
106054	Porous Acetabular Shell			54mm	
106056	Porous Acetabular Shell			56mm	
106058	Porous Acetabular Shell			58mm	
106060	Porous Acetabular Shell			60mm	
106062	Porous Acetabular Shell			62mm	
106064	Porous Acetabular Shell			64mm	
106066	Porous Acetabular Shell			66mm	
106068	Porous Acetabular Shell			68mm	
106070	Porous Acetabular Shell			70mm	
105842	All Polyethylene Cup			22x42mm	
105844	All Polyethylene Cup			22x44mm	
105846	All Polyethylene Cup			22x46mm	
105848	All Polyethylene Cup			22x48mm	
105849	All Polyethylene Cup			28x48mm	
105850	All Polyethylene Cup			28x50mm	
105852	All Polyethylene Cup			28x52mm	
105854	All Polyethylene Cup			28x54mm	
105856	All Polyethylene Cup			28x56mm	
105858	All Polyethylene Cup			28x58mm	

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Ring-Loc Liners
Component Listing
510(k) K920640 (pending)

Part #	Description	Type	Size
105901	Ringloc Acetabular Liner	28mm Hi-wall	21
105902	Ringloc Acetabular Liner	28mm Hi-wall	22
105903	Ringloc Acetabular Liner	28mm Hi-wall	23
105904	Ringloc Acetabular Liner	28mm Hi-wall	24
105905	Ringloc Acetabular Liner	28mm Hi-wall	25
105906	Ringloc Acetabular Liner	28mm Hi-wall	26
105907	Ringloc Acetabular Liner	28mm Hi-wall	27
105908	Ringloc Acetabular Liner	28mm Hi-wall	28
105911	Ringloc Acetabular Liner	28mm 10 degree	21
105912	Ringloc Acetabular Liner	28mm 10 degree	22
105913	Ringloc Acetabular Liner	28mm 10 degree	23
105914	Ringloc Acetabular Liner	28mm 10 degree	24
105915	Ringloc Acetabular Liner	28mm 10 degree	25
105916	Ringloc Acetabular Liner	28mm 10 degree	26
105917	Ringloc Acetabular Liner	28mm 10 degree	27
105918	Ringloc Acetabular Liner	28mm 10 degree	28
105923	Ringloc Acetabular Liner	32mm Hi-wall	23
105924	Ringloc Acetabular Liner	32mm Hi-wall	24
105925	Ringloc Acetabular Liner	32mm Hi-wall	25
105926	Ringloc Acetabular Liner	32mm Hi-wall	26
105927	Ringloc Acetabular Liner	32mm Hi-wall	27
105928	Ringloc Acetabular Liner	32mm Hi-wall	28
105933	Ringloc Acetabular Liner	32mm 10 degree	23
105934	Ringloc Acetabular Liner	32mm 10 degree	24
105935	Ringloc Acetabular Liner	32mm 10 degree	25
105936	Ringloc Acetabular Liner	32mm 10 degree	26
105937	Ringloc Acetabular Liner	32mm 10 degree	27
105938	Ringloc Acetabular Liner	32mm 10 degree	28
105980	Ringloc Acetabular Liner	22.2mm Hi-wall	20
105981	Ringloc Acetabular Liner	22.2mm Hi-wall	21
105982	Ringloc Acetabular Liner	22.2mm Hi-wall	22
105983	Ringloc Acetabular Liner	22.2mm Hi-wall	23

Ring-Loc Acetabular Component

Part #	Description	Size
105440	"Size" R Lock Ring	20
105444	"Size" R Lock Ring	21
105446	"Size" R Lock Ring	22
105450	"Size" R Lock Ring	23
105454	"Size" R Lock Ring	24
105458	"Size" R Lock Ring	25
105462	"SIze" R Lock Ring	26
105466	"Size" R Lock Ring	27
105470	"Size" R Lock Ring	28

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

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RANAWAT/BURSTEIN™
TOTAL HIP SYSTEM

Component Selection

BIOMET INC®

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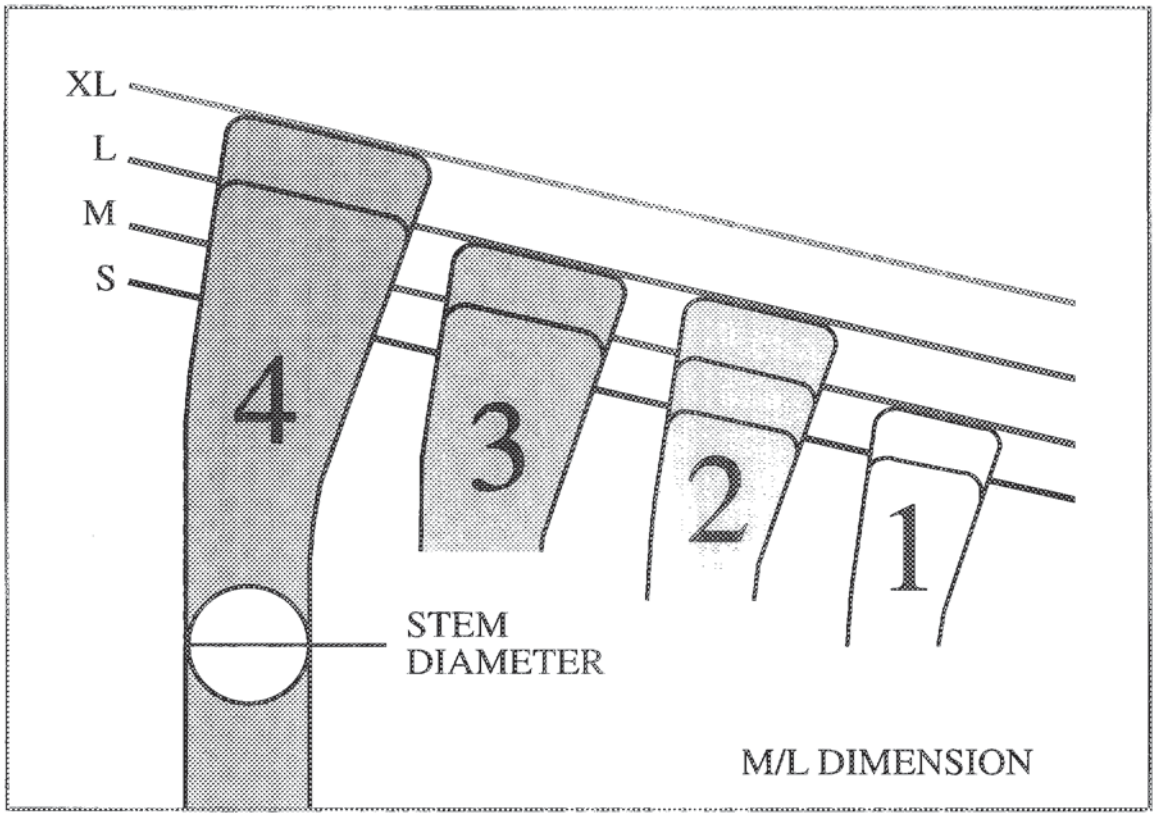
nm
nm
nm
NSION

Length
29mm
32mm
35mm
38mm
41mm



PROXIMAL CONE SIZE

1S	1M	2S	2M	2L	3M	3L	4L	4XL
●	●							
●	●	●	●	●				
●	●	●	●	●	●	●		
					●	●	●	●
							●	●
mm	36mm	35mm	36mm	37mm	36mm	37mm	37mm	38mm
1mm	135mm	121mm	135mm	135mm	135mm	135mm	138mm	148mm

● Available Sizes

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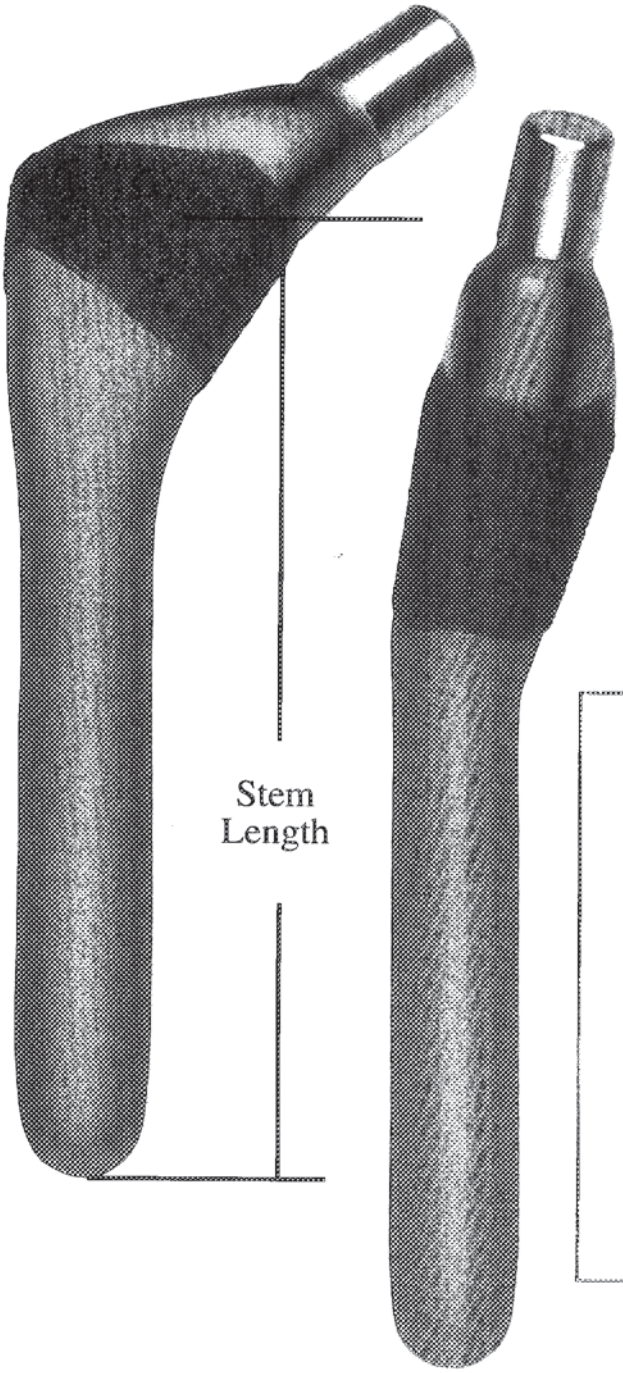
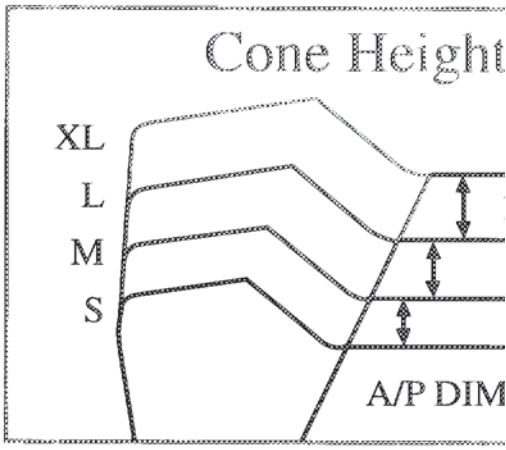
BIOMET

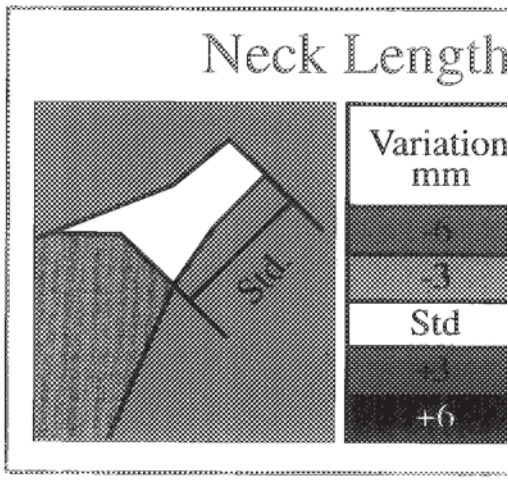
RANAWAT/BURSTEIN™
TOTAL HIP SYSTEM

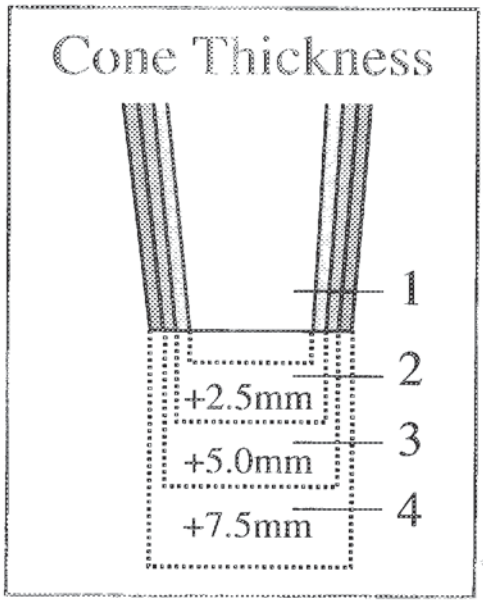
Component Selection

WARNING: The Ranawat/Burstein Hip System prostheses are marketed for use with bone cement in the United States.









STEM DIAMETER

11.0 mm
12.5 mm
14.0 mm
16.0 mm
17.5 mm
Stem Offset (Std. Head)
Stem Length

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

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Type II Taper Modular Heads
Component Listing

Part #	Description	Size
163700	Co-Cr Modular Head	28 mm -6 mm
163701	Co-Cr Modular Head	28 mm -3 mm
163702	Co-Cr Modular Head	28 mm Std
163703	Co-Cr Modular Head	28 mm +3 mm
163704	Co-Cr Modular Head	28 mm +6 mm
163705	Co-Cr Modular Head	32 mm -6 mm
163706	Co-Cr Modular Head	32 mm -3 mm
163707	Co-Cr Modular Head	32 mm Std
163708	Co-Cr Modular Head	32 mm +3 mm
163709	Co-Cr Modular Head	32 mm +6 mm
RD-105492	Zirconia Ceramic Modular Head	28 mm -5 mm
RD-105493	Zirconia Ceramic Modular Head	28 mm Std
RD-105494	Zirconia Ceramic Modular Head	28 mm +3 mm
RD-105495	Zirconia Ceramic Modular Head	28 mm -3 mm
RD-105496	Zirconia Ceramic Modular Head	28 mm Std
RD-105497	Zirconia Ceramic Modular Head	28 mm -5 mm
RD-105498	Zirconia Ceramic Modular Head	28 mm -3 mm
RD-105499	Zirconia Ceramic Modular Head	28 mm +2.5mm

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RING-LOC LINER STABILITY TESTING

(b)(4)

[redacted]

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PERFORMANCE CHARACTERISTICS OF TWO PIECE ACETABULAR CUPS

The Orthopaedic Research Laboratory
Mt. Sinai Medical Center
Cleveland, Ohio 44106

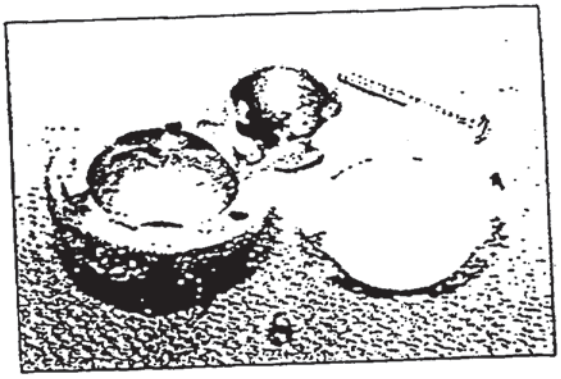
Steven Tradonsky, M.D.
Paul D. Postak, B.S.
Avrum I. Froimson, M.D.
A. Seth Greenwald, D. Phil. (Oxon)

INTRODUCTION

Two piece acetabular cup designs have gained a wide degree of clinical popularity in THA. Their advantages lie in an ability to maximize appositional contact between the cup and pelvic bony bed often facilitated by the use of graft and screw fixation. Secondarily, polyethylene liners can offer variable head coverage as well as the potential for replacement in situations of clinical difficulty and material failure.

These modular constructs are however not without short term problems. Liner separation as well as polyethylene fracture, in the absence of normal wear, have been reported.

One year retrieval from a 50 year old female who underwent THA for degenerative arthritis. This patient experienced left hip pain for two months prior to revision surgery. Liner separation and polyethylene fracture are observed along with significant galling of the cup interface.

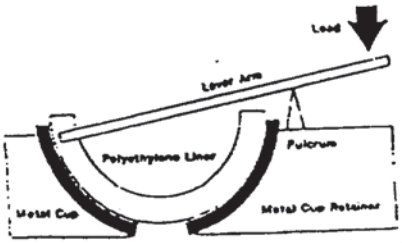


This study investigates, a) the integrity of the locking mechanisms, b) the degree of cup/liner congruity, and c) the practice of liner reinsertion at surgery, for eight contemporary two piece acetabular cup designs.

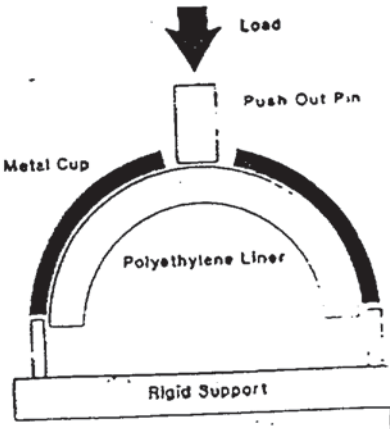
EVALUATION

Locking mechanism integrity was evaluated by measuring the forces required to fully seat and then push out or lever out a 32mm. polyethylene liner. Three liners were tested in each mode with insertion and removal being repeated on the final liner. The test setups depicted were mounted in an Instron Testing Machine utilizing a loading rate of 0.2 in./min.

Cup/liner congruence was demonstrated by fully seating a liner into a cup filled with a blue contrast, liquid acrylic. After curing each assembly was sectioned using a diamond wire saw.



LEVER OUT TEST ASSEMBLY



PUSH OUT TEST ASSEMBLY

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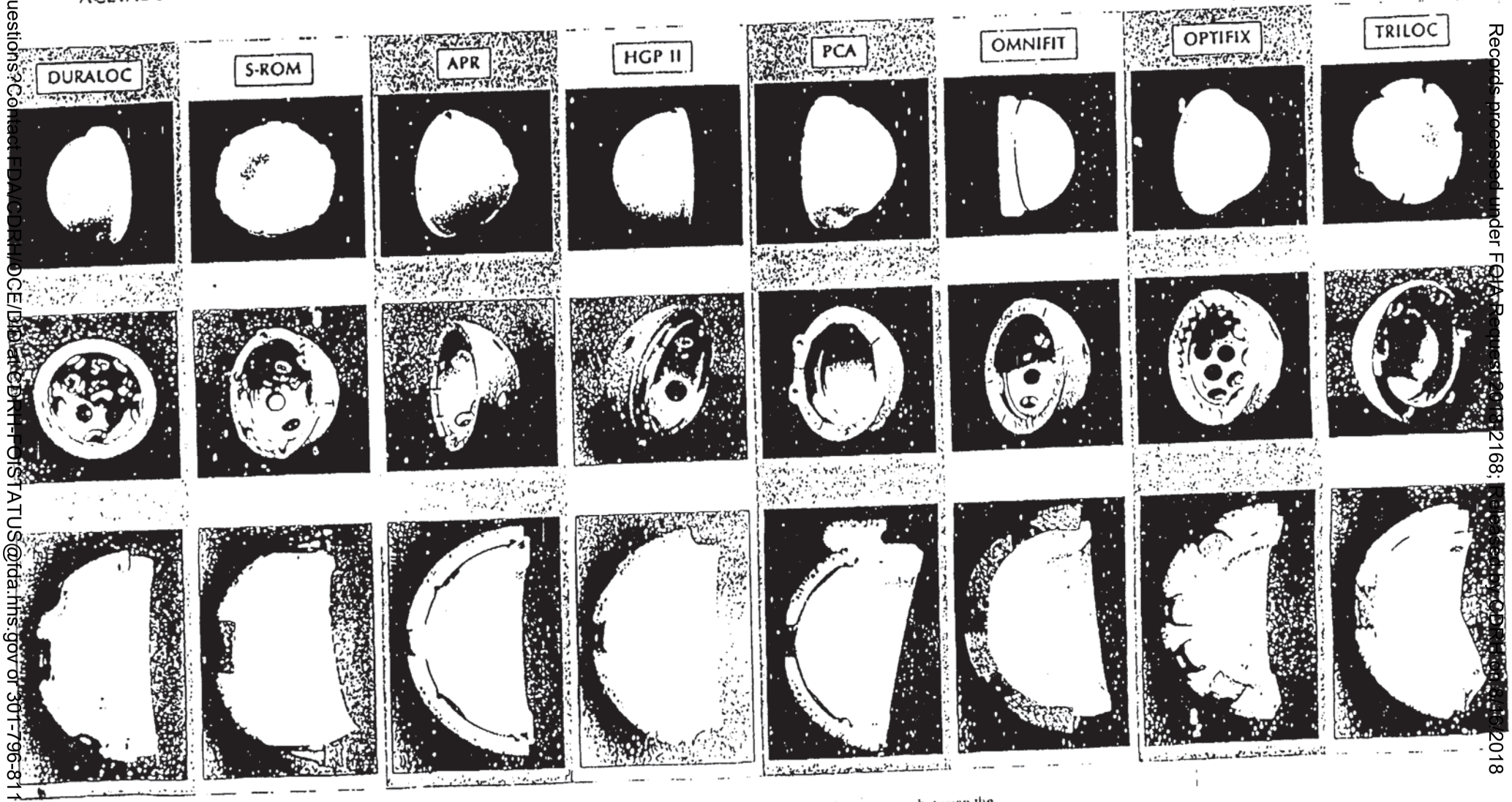
ACETABULAR CUP DESIGNS



SECTION ANALYSIS

The sectioned cup/liner assemblies were visually inspected to determine the degree of congruence between the two components. It is noted that *all* systems exhibit some degree of incongruence, which may be attributed to component design, material behavior, and manufacturing tolerance. Additionally, in systems with multiple screw holes there are significant areas of unsupported polyethylene.

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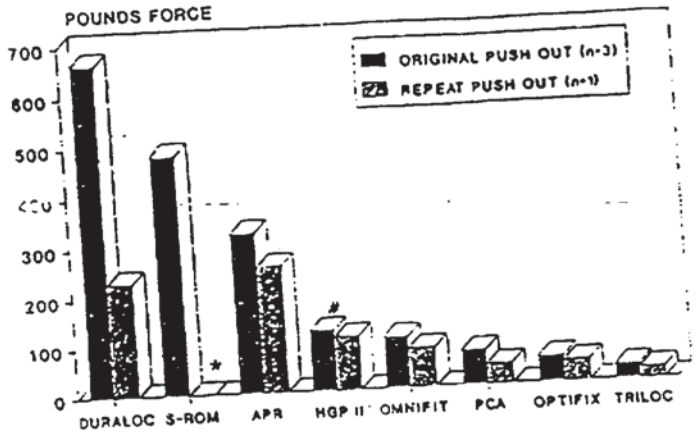
RESULTS

bar graphs depict, initial and repeat, forces and torques required to dislodge each liner. For some systems it was not possible to perform the repeat test, because of significant damage to the polyethylene. For the HGP II, the metal cup itself was deformed during initial testing, allowing only one test on each cup.

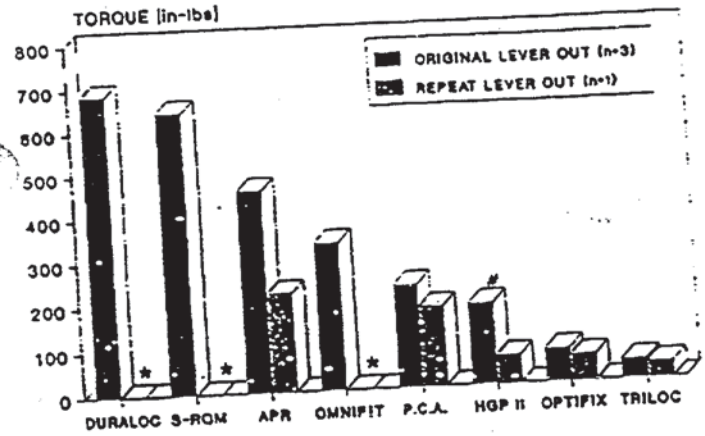
PUSH OUT TEST



★ SIGNIFICANT DAMAGE

n=1

LEVER OUT TEST



★ SIGNIFICANT DAMAGE

n=1

These results, shown in descending order, are interpreted as a measure of the efficacy of the particular retention mechanism provided by each cup design. As the in vivo loading of these systems is complex and the mechanism of liner dislocation not fully understood, the results do not infer the clinical advantage of any one design, but rather provide a basis for comparison of retention mechanisms.

The repeat push out and lever out tests for all systems indicate a reduction in retention strength, ($p<0.05$), reflective of a degradation of polyethylene material integrity. A conclusion drawn; *it is not an advisable clinical practice to reseat cup liners at the time of surgery for any reason.*

IMPLICATIONS

Two piece acetabular cup designs enjoy increasing use for cementless and hybrid THA application. However, problems of short term liner separation and polyethylene fracture in the absence of normal wear have lead to one systems recall and a more careful scrutiny of two piece cup performance.

It is not known how much force a cup-liner assembly should be able to tolerate to prevent separation, but it seems logical that the higher the resistance to dislocation the higher the degree of safety. While it is unlikely that pure push out forces represent a component of in vivo hip loading they do by comparison provide a measure of system integrity. This is better appreciated when a statistically significant correlation is drawn with the lever out tests which could arise in a varus or valgus anatomical orientation, ($p<0.05$).

The section analysis points to cup-liner incongruity of varying amount for all systems studied. Additionally, the presence of multiple screw holes in some systems results in further areas of unsupported polyethylene. This suggests that implant loading is not uniformly transferred to all cup surfaces.

Non-uniform loading results in excessive local stresses in the polyethylene, predisposing the liner *to deformation* and early fracture and may also contribute to accelerated polymer wear. Maximizing congruity between cup and liner provides a better distribution of forces and decreases the possibility of these types of failure.

This study suggests that factors of cup-liner locking mechanism and congruity may play an important role in insuring the in vivo integrity of two piece acetabular cups.

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1/0

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DATE: 1-25-91

SUBJECT: Tension Testing of Plasma Sprayed Buttons

(b)(4)

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CORROSION AT THE INTERFACE OF COBALT ALLOY HEADS ON TITANIUM ALLOY STEMS

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Introduction

In the early 1980's the desire for reduced femoral hip stem stiffness lead to the increasing use of titanium alloys in place of the stiffer cobalt-chrome materials. The first generation titanium alloy femoral hip components with integral heads were seen to suffer scratching, burnishing, and loss of head sphericity to a greater degree than their cobalt alloy counterparts. Therefore, in the mid-1980's the trend towards modular prostheses which permitted variable neck lengths through separate heads and stems which could be mated at the time of surgery provided manufacturers the opportunity to combine dissimilar metals.

The appearance of corrosion along and around the machined tapered neck of the titanium alloy femoral component and inside the matching tapered recess of the cobalt alloy femoral head of more than 50% of 18 components examined in our laboratory leads to the dual concerns that significant metal ion release is ongoing, and that the mechanical integrity of the lock of the femoral head on the titanium stem is in jeopardy.

Methods

Seventy-six porous-coated femoral hip prostheses with heads sent to our lab for histological examination of the porous coating/host interface were examined for corrosion of the head/tapered neck interface. Forty-nine of these prostheses were provided with cobalt alloy heads on cobalt alloy stems. Nine prostheses combined titanium alloy heads with titanium alloy stems. Eighteen prostheses matched cobalt alloy heads with titanium stems. In each case a detailed examination using a high-powered dissecting microscope was carried out on the surface of both the tapered neck of the femoral component and the matching tapered recess of the femoral head. Some surfaces were examined using a Scanning Electron Microscope. In all cases where there appeared to be any evidence of corrosion, the femoral head was sectioned using a thin ceramic bladed saw so that the location and extent of corrosion could be accurately mapped.

Results

None of the 49 matched cobalt alloy heads on cobalt alloy stems were found to demonstrate any evidence of corrosion at the interface. None of the titanium alloy heads mated to titanium alloy stems provided any evidence of corrosion, although all of the titanium heads showed evidence of wear of the articulating surface as evidenced by scratching, burnishing, and loss of sphericity. Ten of eighteen cobalt alloy head/titanium alloy stem components presented evidence of significant corrosion along the matching tapers.

A statistical analysis of the eighteen retrieved multi-alloy prostheses was attempted to determine whether a correlation between the presence of corrosion and duration, patient age, weight, or sex could be determined. Only post-operative duration provided positive correlation with a P of less than .005. Mean duration for corroded components was 39.4 months; mean duration for non-corroded samples was 9.9 months.

Discussion

The corrosion that occurs within crevices and other shielded areas on metal surfaces exposed to corrosives (body fluids) is crevice corrosion[1]. The potential for the corrosion which occurs at the interface between a titanium alloy stem and a cobalt alloy head is galvanic in nature and occurs when the passive oxide layer on the titanium is breached during fixation of the femoral head to the titanium component. Metals or alloys which depend on oxide films or passive layers for corrosion resistance are particularly susceptible to crevice corrosion.[2, 3] The result of breakdown of the passive layer is an increase in the galvanic corrosion potential from approximately -100mv to approximately 500mv as measured using a microvoltmeter in our lab, using a standard corrosion cell with saline solution as the electrolyte. The breakdown potential for crevice corrosion of the cobalt/titanium alloy couples is less than 400mv[4]. The initiation of crevice corrosion requires, in addition to a breakdown of the passive film on the titanium, the presence of an aqueous environment which occurs as body fluids seep into the interface between the two components. The ramifications are that fluid from inside the taper with a high metal ion content of the constituents of both the cobalt alloy and titanium alloys will be released into the host.

Conclusions

There is the potential for significant corrosion at the interface between cobalt alloy heads and titanium alloy stems of hip components. This corrosion appears to begin in the early post-operative months and was first visible under the dissecting microscope in this study at 12.9 months. The corrosion appears to continue over time and those prostheses received at periods longer than 20 months post-operatively all demonstrated significant corrosion at the interface. The presence of corrosion at the interface is evidence that there must be paths for fluid transfer between the interface and the host, therefore, significant metal ion release is occuring with these prostheses. A continuation of the crevice corrosion leads to the potential of loss of the mechanical bond between the head and stem, possibly resulting in separation. The use of dissimilar metals separated by crevices containing body fluids is not recommended.

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Acknowledgments

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EXCISION OF TUMOURS OF HUMERUS AND FEMUR, WITH RESTORATION BY INTERNAL PROSTHESES

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A personal experience is recounted of operations in cases of tumour involving the humerus or femur with restoration by endoprostheses. Twenty-four patients were treated in this way from 1950 to 1969 inclusive and have been followed up for between four and twenty-four years. The patients selected for treatment have presented chondrosarcoma (ten), so-called benign giant-cell tumour of bone, usually recurrent (nine), angiomatous osteolysis (two), seemingly single thyroid or renal metastasis (two), and ununited pathological fracture after irradiation of a tumour (one). Development of the prostheses from early beginnings is outlined. Some points in surgical management are referred to. The complications and results are recorded.

In 1949 Seddon and Scales reported a case, not in this series, in which a limb rendered useless by monomelic fibrous dysplasia was amputated through the thigh at K. I. Nissen's suggestion and the stump of the femur replaced in polyethylene.[1] We repeated the procedure twice, once with an acrylic prosthesis in a similar case and once with a hollow metallic implant in a case of angiomatous osteolysis (Case 7). These three patients have been using their artificial limbs effectively for twenty-four, twenty-two and eighteen years. One stump required trimming because the lower end of the prosthesis, unwisely prong-shaped, came to the surface. We were naturally stimulated to attempt restoration in continuity by permanent fixation of the prosthesis to bone, which at that time presented mechanical and biological problems now largely overcome.

Endoprosthetic work was known to the Incas (Gurdjian 1973) and was developed in Europe in the nineteenth and early twentieth centuries. In 1940 Austin Moore and Bohlman (1943) replaced some 30 centimetres of the upper part of the femur for a recurrent giant-cell tumour, using a Vitallium prosthesis with side members bolted to the bone; the patient had good function before his death from myocardial failure twenty months later. Moore and Lunceford (1960) have illustrated replacement of the upper part of the femur by a stemmed prosthesis in carcinoma. Bingold (1972), anticipating our Case 2 by seven months, replaced the upper end of a femur by an acrylic prosthesis in 1951; with one renewal, satisfactory function has continued.

One of us (Burrows 1968) has already described work with Scales on major replacement of parts of the femur and humerus by endoprostheses in various selected conditions, with special attention to the lessons that we had learnt by that time. We now recount an extended experience in the more restricted field of tumours. This excludes several replacements in fibrous dysplasia and one in hydatid cyst in which Sir Herbert Seddon paved the way to successful replacement of the knee and lower end of the femur. The follow-up is from four to twenty-four years. Today much of our early work seems primitive.

Initially our implants were of polyethylene or acrylic resin (Table I). When their unsuitability became evident we resorted to cobalt-chromium-molybdenum[2] (CCM) and, later, to titanium[3] and an alloy of titanium[4] except for bearing surfaces of joints. For the latter we used CCM fitted into prostheses of titanium, itself unsuitable for both surfaces of a bearing. We have had no evident trouble from combining these metals in the body, which accords with the work of Gross and Gold (1957), Mears (1965) and Down (1966).

When both surfaces of the joint have been replaced, CCM on CCM has been used. This is discouraged in engineering practice. Although the frictional torque of CCM on CCM is about three times that of CCM on RCH 1000 polyethylene, we have not encountered loosening of the components of total joint replacements. The rate of wear of CCM on CCM in laboratory tests is about one-twentieth of that of CCM on RCH 1000

[1] Alkathene: trade name of low-molecular-weight polyethylene made by Imperial Chemical Industries.
[2] Vinertia: trade name of cobalt-chromium-molybdenum alloy, complying with A.S.T.M. 75, 1967, and B.S. 3531, 1968; made by Deloro Stellite (U.K.) Ltd, Stratton St Margaret, Swindon, England.
[3] Titanium 160: commercially pure titanium; made by Imperial Metal Industries, Birmingham, England.
[4] Titanium 318: alloy of titanium containing 6 per cent aluminium and 4 per cent vanadium; made by Imperial Metal Industries.

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TABLE I

PARTICULARS OF IMPLANTS

Case number	Implant	Basic[1] length in mm	Fixation device	Materials: Body	Materials: Fixation device	Materials: Bearings	Materials: Cement Simplex C or P
1	Humerus, upper part	229	Plates (Sherman)	Polyethylene	Stainless steel	—	—
2	Femur, upper part	255	Plates (Eggers)	Acrylic	CCM	—	—
3	Femur, lower part and knee	220	Plates (slotted)	CCM	CCM	CCM	—
4	Humerus, upper part	150	Plates (slotted)	Polyethylene	CCM	—	—
		237	Fishtail stem	Ti 160	Ti 160	—	P
5	Humerus, upper part	140	Plates (slotted)	Polyethylene	CCM	—	—
6	Femur, upper part	220	Plates (slotted)	CCM	CCM	—	—
7	Femur, upper part. Fenestrated with pyriform distal end. Terylene bobbin net cover	306	—	CCM	—	—	—
8	Femur, upper part	152	Integral plates (slotted)	CCM	CCM	—	—
		143	Medullary stem	Ti 160	Ti 160	—	C
9	Femur, upper part	184	Plates (slotted)	CCM	CCM	—	—
10	Humerus, upper part and shaft	245	Fishtail stem	Ti 160	Ti 160	—	P
11	Femur, upper part and acetabulum	159	Medullary stem	CCM	CCM	CCM	C (stem) (Acetabulum nailed)
		210	Medullary stem	Acetabulum and head, etc., CCM. Rest Ti 160	Ti 160	CCM	C (stem) P (acetabulum)
12	Femur, upper part	182	Medullary stem	CCM, hollow welded	CCM	—	C
13	Femur, lower part.	127	Medullary stem	Ti 160, hollow welded	Ti 160	CCM	C
14	Humerus, upper part	208	Medullary stem	Ti 160, hollow welded	Ti 160	—	C
15	Femur, lower part and knee	208	Medullary stem	Ti 160, hollow welded	Ti 160	CCM	C
16	Femur, upper part and acetabulum	267	Medullary stem	Acetabulum and head, etc., CCM. Rest Ti 160	Ti 160	CCM	C (Acetabulum nailed)
17	Femur, upper part and acetabulum	210	Medullary stem	Acetabulum and head, etc., CCM. Rest Ti 160	Ti 160	CCM	C (stem) P (acetabulum)
18	Femur, lower part and knee	160	Medullary stems	Acetabulum and head, etc., CCM. Rest Ti 160	Ti 160	CCM	C (stem) P (acetabulum)
19	Humerus, upper part	102	Medullary stem	Ti 160, hollow welded	Ti 160	—	C
20	Femur, upper part and acetabulum	235	Medullary stem	Acetabulum and head, etc., CCM. Rest Ti 160	Ti 160	CCM	C (stem) P (acetabulum)
21	Femur, lower part and knee	152	Medullary stems	Ti 160, hollow welded	Ti 160	CCM	C (femur) P (tibia)
22	Humerus, upper part	160	Medullary stem	Ti 160	Ti 160	—	C
23	Femur, upper part and acetabulum	237	Medullary stem	Acetabulum and head, etc., CCM. Rest Ti 160	Ti 160	CCM	C (stem) P (acetabulum)
24	Femur, upper part and acetabulum	184	Medullary stem	Acetabulum and head, etc., CCM. Rest Ti 160	Ti 160	CCM	C (stem) P (acetabulum)

[1] The basic length is exclusive of the fixing device, e.g., medullary stem. It includes the acetabulum in total hip prostheses and the tibial plateau in knee prostheses. It represents approximately the length of resection.

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(Scales and Lowe 1971). Wear products have not so far produced any undesirable tissue reaction.

Doubting that a simple uncemented medullary rod could be relied upon to control rotation lastingly, we fixed our earlier prostheses to bone by paired plates secured by bolts and nuts. In the main these were mechanically satisfactory, as witness Case 3, that of a patient operated upon twenty years ago (Figs. 1 and 2). However, they added greatly to the extent of an already testing operation, and in certain circumstances indicated later were biologically unsatisfactory because application of the plates prejudiced the blood supply of the host bone.

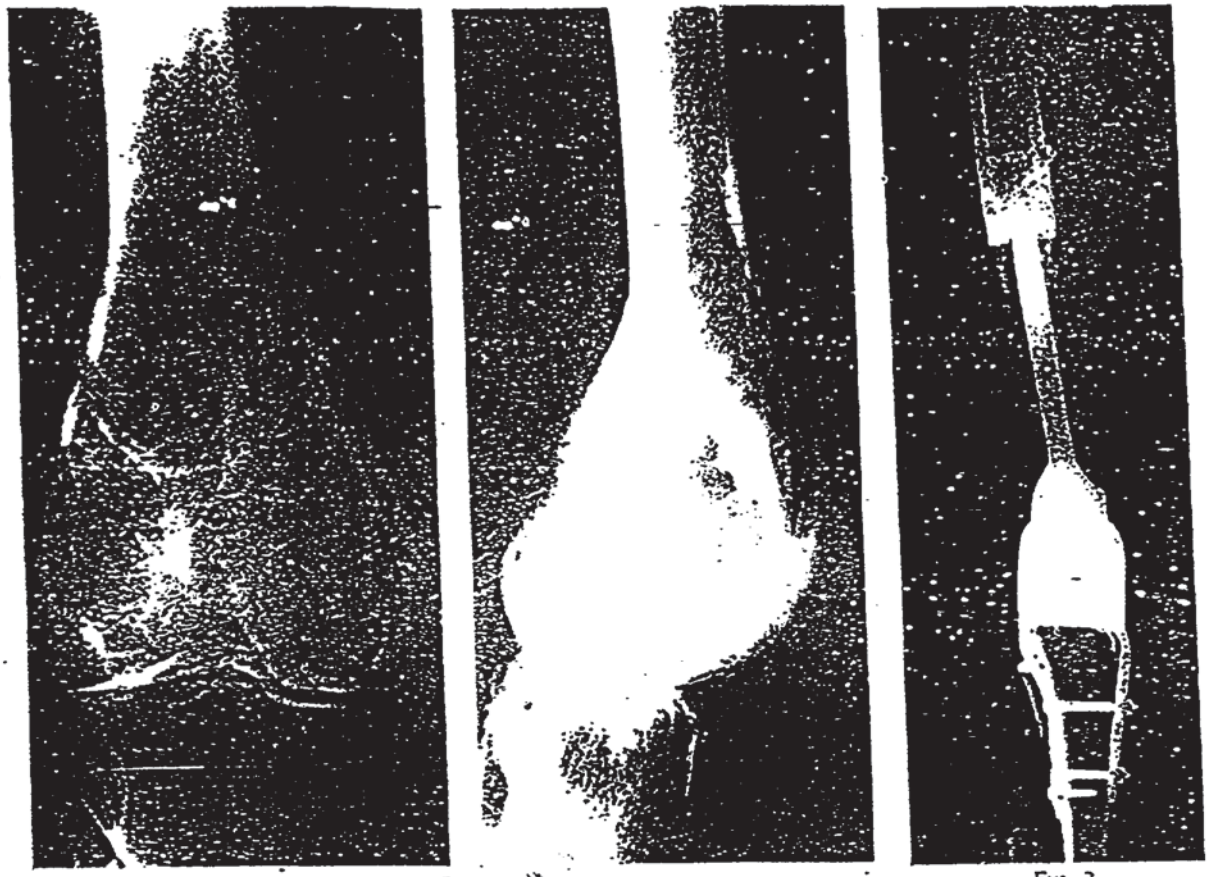

FIG. 1 FIG. 2

Case 3. Figure 1—The radiographic appearances of the recurrent giant-cell tumour before operation. Figure 2—A radiograph showing firm fixation of the endoprosthesis after eighteen years. It remains so after twenty years.

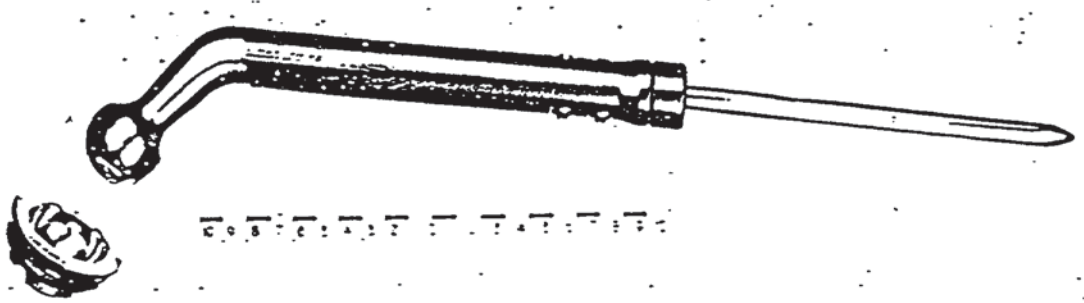

FIG. 3

The present Stanmore model of upper femoral prosthesis. The part comprising the head, neck and trochanteric region is made of CCM[1] and is riveted to the rest of the body, which is of titanium 160. This is attached to the medullary stem with hollow bolts which are expanded at operation to retain the nuts. The acetabular cup in this instance is of CCM but alternatively may be of high density polyethylene.[2]

[1] Alivium: trade name for vacuum-melt, vacuum-cast CCM: supplied by Zimmer Great Britain, London, U.K., complying with A.S.T.M. 75, 1967, and B.S. 3531, 1968.
[2] RCH 1000: trade name: made by Ruhrchemie, Oberhausen-Holten, West Germany.

The marriage of prosthesis to bone was revolutionized by the suggestion of Sven Kiaer (1953), supported by the experimental work of Henrichsen, Jansen and Krogh-Poulsen (1952), that self-polymerizing plastics might be

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used for the purpose. This was put into clinical practice by Haboush (1953), but little noticed here until the advocacy of Charnley (1960). This technique largely overcame the shortcomings of the medullary rod, and we adopted the method in 1964. The prostheses have become increasingly simple, without excrescences for the attachment of muscles (Fig. 3). All have been made individually from engineering drawings based on corrected radiographic measurements.

SELECTION OF CASES

Strict selection has made our series small. Apart from limiting consideration to humerus and femur, we have almost confined ourselves to what may be called, for want of a better nomenclature, locally malignant growths. By this we mean tumours that extend relentlessly, usually slowly and without infiltration, but disseminate late if at all. An exception is so-called angiomatous osteolysis or disappearing bone, for which the angiomatous tissue is not excised, but bone, which succumbs to osteoclasts, is replaced by metal. These criteria have practically confined our selection of tumours to: 1) low-grade endosteal chondrosarcoma; 2) the misnamed "benign giant-cell tumour" or "osteoclastoma" if either neglected or recurrent, for which amputation would often be the alternative; 3) angiomatous osteolysis; and 4) the occasional seemingly isolated thyroid or renal secondary neoplasm. We have included, without strict relevance, a case of radio-necrosis with pathological fracture after irradiation of a round-cell tumour twenty years before.

Two cases outside our criteria are excluded. They were in men of sixty-three and fifty-seven with an aggressive pleomorphic chondrofibrosarcoma and an osteosarcoma of the upper part of the femur. Both had had unsuccessful radiotherapy; both received prosthetic replacements; both had local recurrence within six weeks and died of metastases within six months. Local excision in such cases can discredit the procedure, though there may be an occasional, as yet undefined, case for it in palliation.

Endosteal chondrosarcoma—A chondromatous tumour that starts growing in an adult is potentially malignant and must be removed. Evidence of growth may be the onset of pain, a pathological fracture (Case 4, Fig. 4), or in serial radiographs extension of the lesion or disappearance of previous calcification. Before pain is confidently ascribed to growth of a demonstrated cartilaginous tumour other sources should be considered. In one patient (Case 5) a histological diagnosis of enchondroma was made after excision of the upper end of the humerus for supposed chondrosarcoma: in retrospect the pain probably had another origin. Unfortunately the biopsy of a chondromatous growth may be inconclusive or misleading.

Giant-cell tumour or osteoclastoma—This ill-named tumour, distinguished from the so-called "giant-cell

FIG. 4
Case 4—Radiograph showing an endosteal low-grade chondrosarcoma with a pathological fracture.

variants", must almost invariably be treated initially by thorough curettage, with or without chemical or heat treatment and usually with grafting. The operation gives naked-eye and histological confirmation of the diagnosis. Often it cures, but sometimes there is local recurrence. For the occasional neglected case (for example, Case 15, Fig. 5), and much more commonly for recurrence, excision is indicated, though this itself can be followed by recurrence (Case 13, Fig. 11). We believe that amputation is too often resorted to when excision with some form of restoration of continuity would be possible. Radiotherapy is discredited, not because of the misleading transitory appearance of deterioration that ensues and must be ignored, but because an adequate dose has sometimes caused an irradiation sarcoma independent of the original tumour after some twenty to twenty-five years (Fig. 6).

Angiomatous osteolysis—The logical course is to replace the eroded bone by a material resistant to the osteoclast—Case 7, femur (Aston 1958), and Case 10, humerus (Poirier 1968). Although destruction can spread beyond the initial region, this has fortunately not happened in our two cases after seventeen and ten years.

Isolated secondary tumours—A single metastasis of thyroid or kidney may persist for many years but nevertheless call for removal. We have carried out local excision with prosthetic replacement in one case of a seemingly single thyroid metastasis in the femur, evident for three years, twice irradiated and with a pathological fracture (Case 6), and in one case (Case 19) of a seemingly single metastasis of a clear-cell renal carcinoma (hypernephroma) in the humerus.

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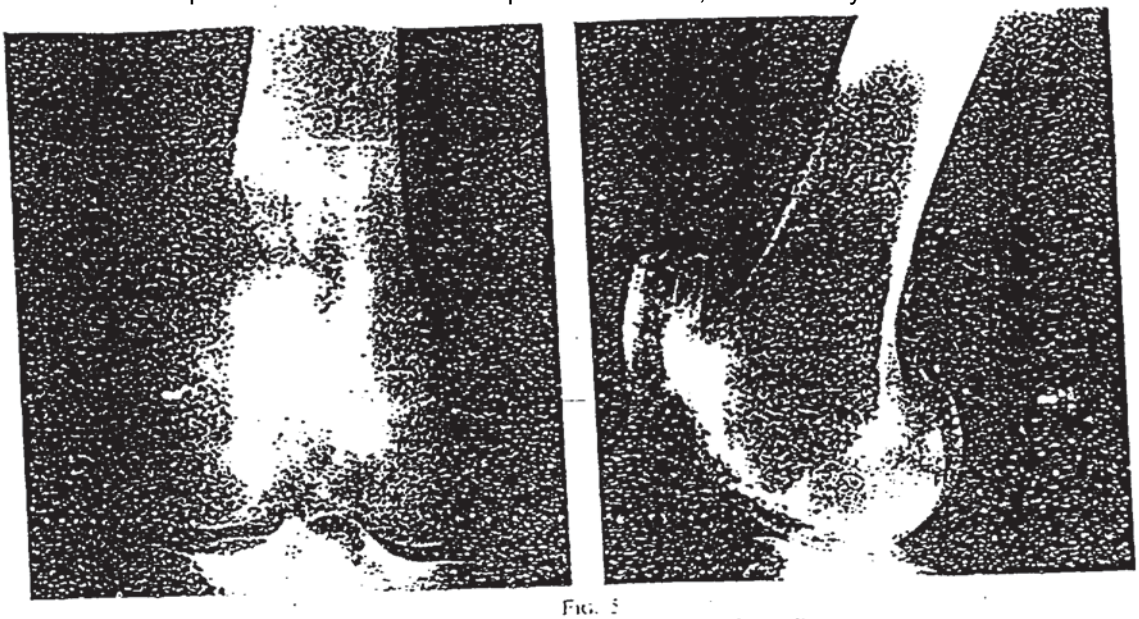

FIG. 5
Case 15—Radiographs showing the overlooked giant-cell tumour.

NOTES ON SURGICAL MANAGEMENT

Alternatives to internal prosthetic replacement—Endoprosthetic replacement must always be measured against other methods of treatment: amputation, autogenous bone grafting, re-implantation of killed excised tissue, radiotherapy. All our replacements have involved a joint. It is in such cases that internal prostheses offer the greatest advantage over other implants, for example, grafts. We have been unhappy about the appearance after successful restoration of a major part of the humerus with a fibular graft (Lettin 1964). Joints cannot as yet be transplanted with reasonable expectation of success.

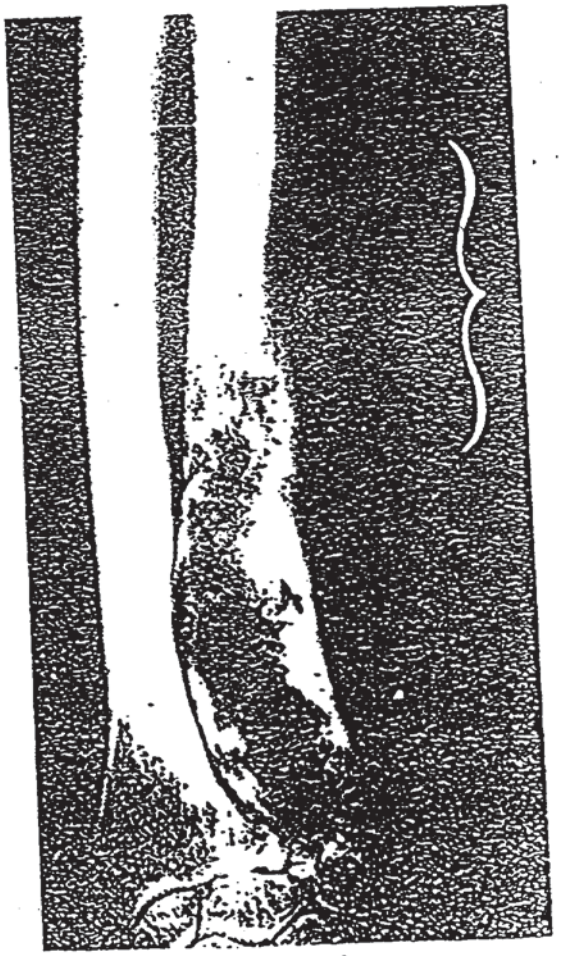

FIG. 6
Radiograph showing an independent pleomorphic sarcoma twenty-two years after the irradiation of a giant-cell tumour of the ulna

Pre-operative assessment—A searching assessment of operability is imperative. Radiology is especially important, involving routine radiographs of the lungs, usually a skeletal survey, and often unorthodox projections, varying penetration and tomography. We have no assessment of other scanning methods. Our limited experience of angiography has been disappointing, both as a diagnostic aid and for identifying recurrence; if done, it must precede biopsy, not follow it. Limited tissue damage from previous radiotherapy has not prevented successful operation (Case 17).

Phasing of operation: one stage or two—The two major phases, namely excision and replacement, may be combined or performed separately. We have invariably operated in one stage. The advantages are a ready-made bed for the prosthesis, one less operation for the patient, and prompt restoration of form and function. The disadvantages are the more severe operation, the delay while the prosthesis is being made, the indirect means of measurement for the latter, and sometimes the discarding of a prosthesis because circumstances revealed at operation forbid its use. Slight delay is unimportant in cases suitable for the present type of treatment. Occasional wastage of a prosthesis prepared at considerable effort and cost must be accepted.

Technique before, during and after operation. Details cannot be given here but are available from the authors. Several points, however, need special emphasis.

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Consent—The surgeon must have authority to carry out an alternative procedure, notably amputation.

Control of haemorrhage—We have seldom used hypotensive drugs. A snare has been applied to the common iliac vessels or to the subclavian vessels by a vascular surgeon. It is tightened as the risk of haemorrhage approaches and is released before closure. Local haemostasis is strict, and blood loss is measured.

Incision—This must be planned: 1) to include excision of the route of previous biopsy; 2) to allow early estimation of the extent of the tumour and the feasibility of effective local excision; and 3) not to compromise possible amputation.

Removal of the tumour—This is carried out without transgressing the overlying tissue and always extraperiosteally. The part to be removed is freed gradually: when dissection at one place becomes difficult the surgeon moves temporarily to another. Usually, but not always, we have found it easiest to divide the soft structures of the joint and dislocate it before completing the dissection and dividing the bone. Great care is necessary not to strip periosteum from the retained bone, because it needs a blood supply.

Insertion of the prosthesis—The prosthesis is disarticulated so that the components can be fixed separately. Each is tested in its seating before being fixed by grouting with cold-curing acrylic cement,[3] usually injected under pressure with a pneumatic gun. Rotational orientation needs special care.

Closure—The snare on the main vessels is removed and that incision is closed. The main wound is closed over a suction drain. The muscles and fascial layers are restored without (nowadays) attaching muscles to the prosthesis. In the case of the lower limb, gentle skin traction is applied; the upper limb is bound to the side.

Treatment after operation—Despite careful haemostasis: an important amount of blood may drain from the large area of dissection and is a factor in deciding the replacement needed. Suction is continued until drainage ceases. The patient sits up and starts exercising as soon as possible. Commonly, the wound is left alone till the stitches are removed after twelve to fourteen days. Restraint of the limb is now discontinued and re-education becomes progressive.

COMPLICATIONS AND RESULTS

We have followed all the patients till death or till the present time except one who returned to Nigeria after seven years and has been untraced since (Case 13). The remainder have been seen personally, except two who have kept in touch from Egypt and Bangladesh (Cases 9 and 18). The duration of observation is shown in Table II.

Sepsis—We have had one case (Case 9), in an Egyptian medical student aged twenty-one with a particularly large giant-cell tumour of the upper end of the femur (Fig. 7). The infection proved uncontrollable because pus inside the hollow implant likened this to an involucrum, and

FIG. 7
Case 9—Radiograph showing the giant-cell tumour of the upper end of the femur.

amputation through the hip became unavoidable. Eleven years after the original operation he remains alive and well, now qualified and practising. We learnt that a hollow implant must be sealed.

Loosening of prosthesis—In some of our early cases of plate fixation—Cases 1, 4 and 5 in the humerus and Case 2 in the femur—absorption of adjacent host bone led to loosening. Division of the bone had deprived it of its endosteal blood supply and fixation of the plates had embarrassed the periosteal supply, as shown diagrammatically in Figure 8. It did not occur with plate fixation when the endosteal supply could be preserved (Cases 3 and 8). Only two prostheses with medullary stems loosened, and in these instances mechanical fixation had been difficult on account of the smallness of the remaining bone (Cases 10 and 14). With destruction of the endosteal supply by a medullary stem we have been careful to preserve the periosteum of the retained bone right up to the point of division. In the upper limb, loosening was compatible with surprisingly fair function, allowing for instance nearly all household chores. In the lower limb, the one patient treated thus, a simple and wayward man

[3] Surgical Simplex: trade name of acrylic bone cement made by North Hill Plastics Ltd, London, in three varieties: Simplex P, non-radio-opaque; and radio-opaque; and C, more liquid and suitable for injection through a medullary cannula.

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TABLE II

CLINICAL FEATURES

Case number	Sex	Age at operation (years)	Diagnosis	Site	Years ago	Surgeon	Follow-up and comments
1	Female	37	Endosteal chondrosarcoma	Humerus, upper part	24	H. J. B.	Broken prosthesis, but good general function except for the shoulder. Died after 15 years. Necropsy: generalised spindle-cell neoplasm of obscure source; no local recurrence. (See text)
2	Male	46	Endosteal chondrosarcoma	Femur, upper part	23	H. J. B.	Bone absorption between plates; loosening. Died after 22 years without recurrence. (See text)
3	Female	20	Recurrent giant-cell tumour	Femur, lower part	20	H. J. B.	3 cm shortening; limp; no pain; range of flexion of knee 70 degrees. 16 years later, fractured patella repaired; regained 45 degrees knee flexion. Married; two sons; full housework; walks 6 miles daily. (See text)
4	Female	41	Endosteal chondrosarcoma, pathological fracture	Humerus, upper part	19 11	H. J. B. H. J. B.	At first operation, upward subluxation at shoulder, but otherwise good function. Bone absorption between plates; loosening. After second operation, no dislocation, no loosening. (See text)
5	Female	54	Endosteal chondroma	Humerus, upper part	19	H. J. B.	No evidence of malignancy in specimen; pain presumably of extraneous origin. Bone absorption between plates; loosening. (See text)
6	Female	52	Isolated thyroid metastasis	Femur, shaft	17	H. J. B.	Replacement included upper end. Good function. Death 6 months later from old rheumatic carditis. (See text)
7	Female	24	Angiomatous osteolysis	Femur, whole shaft	17	H. J. B.	Erosion of whole shaft, much being absent. Amputation through thigh and endoprosthetic replacement of femoral stump (Aston 1958). Hip initially mobile but stiffened. No complaints. (See text)
8	Female	55	Endosteal chondrosarcoma	Femur, upper part	15 9	H. J. B. H. J. B.	Femoral head and neck excised elsewhere for atypical chondrosarcoma 5 years before; since then enlargement of the residue, filling greater trochanter. Excision of upper part of shaft and replacement of whole upper end of femur was followed after 5½ years by breakage of the incorporated plates; replaced by stemmed prosthesis. A similar growth occurred in the opposite ilium; died 6 years ago from multiple metastases. (See text).
9	Male	21	Recurrent giant-cell tumour	Femur, upper part	11	H. J. B.	Sepsis. Hip disarticulation after 15 months. Now medically qualified, married with three sons. (See text)
10	Male	37	Angiomatous osteolysis	Humerus, shaft	10	H. J. B.	Nigerian. Humerus replaced except for lower end (Poirier 1968). Some loosening from the small distal remnant, but useful function. No extension of lysis. Formerly a factory hand, now an office worker.
11	Male	34	Recurrent giant-cell tumour	Femur, upper part	10 6	H. J. B. J. N. W.	Car accident after 4 years; broken stem; replacement. No trouble since. Very slight roll, but negative Trendelenburg; full movements. Male nurse. (See text)
12	Female	34	Recurrent giant-cell tumour with pathological fracture	Femur, upper part	20	H. J. B.	Hip stiff in slight adduction. Upward migration of head within the acetabulum; no protrusion; no pain.
13	Female	24	Recurrent giant-cell tumour	Femur, lower part	10	H. J. B.	Nigerian. History of 14 months; curettage and grafting, sepsis, sequestrectomy, and 6 months later, supracondylar fracture. At excision for replacement, friable bone and extension into knee. Recurrence after 21 months; good initial response to deep x-rays. 7 years later fell, fracturing femur and prosthesis; radiographs revealed large recurrence (Fig. 11). Amputation advised, but returned to Nigeria and is untraced. (See text)

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TABLE II—*continued*

CLINICAL FEATURES

Case number	Sex	Age at operation (*years*)	Diagnosis	Site	Years ago	Surgeon	Follow-up and comments
14	Male	61	Chondrosarcoma	Humerus, upper part	10	H. J. B.	Pain in shoulder not wholly relieved by replacement. Formerly a labourer, he became a bookmaker and was able to garden and fish. Died of unknown cause in a geriatric unit 8 years later.
15	Male	40	Giant-cell tumour	Femur, lower part	9	H. J. B. and J. N. W.	Returned to tennis, golf and cricket. 22 months later broken axle replaced. 3 years ago, after a twisting strain, discomfort and instability; fracture of stem; amputation through thigh. Returned to work of engineering manager. (See text)
16	Male	20	Recurrent giant-cell tumour	Femur, upper part	8	H. J. B. and J. N. W.	No complaints. Slight limp from 2·5 cm shortening; negative Trendelenburg; almost full movements. Has returned to work as a quantity surveyor.
17	Male	38	Radio-necrosis with pathological fracture	Femur, upper part	7	H. J. B.	20 years before, a histologically malignant round-cell tumour had been heavily irradiated. No recurrence but a painful ununited fracture. No complaints, but a limp from shortening of 5 cm: Trendelenburg negative. Virtually full movements. Full work in own business.
18	Male	27	Recurrent giant-cell tumour	Femur, lower part	7	H. J. B. and J. N. W.	Pakistani general practitioner from Dacca. 3 months after operation, no pain, good gait and flexion range 45 degrees. Returned to Bangladesh and is alive and well.
19	Female	57	Metastasis from clear-cell renal carcinoma (hypernephroma)	Humerus, upper part	7	J. N. W.	Biopsy of 9 months old lesion: hypernephroma. Non-functioning kidney removed: hypernephroma. Died of pulmonary metastases 18 months after excision and replacement. (See text)
20	Male	57	Endosteal chondrosarcoma	Femur, upper part	7	J. N. W.	2 years of pain. Biopsy before excision and replacement. Now no pain; positive Trendelenburg but no stick; virtually full movements. Has resumed former work as motor mechanic (Wilson 1971).
21	Female	25	Recurrent giant-cell tumour	Femur, lower part	6	J. N. W.	Regained full extension and 80 degrees flexion of knee (Wilson 1971). 3½ years later, twisted and fell; subtrochanteric fracture at tip of medullary rod. (See text and Fig. 12.) Full recovery with conservative treatment except for 3·5 cm of shortening. Normal domestic duties.
22	Male	41	Chondrosarcoma	Humerus, upper part	5	J. N. W.	2 years before, painful swelling of right arm; biopsy and local excision of cartilage-capped exostosis; no evidence of malignancy. Recurrence in 12 months; excision with replacement of upper end of humerus; chondrosarcoma. Further recurrence after 18 months; forequarter amputation. Since then no recurrence.
23	Female	29	Recurrent chondrosarcoma	Femur, upper part	4	J. N. W.	8 years of pain in thigh; biopsy after 2 years, low-grade chondrosarcoma, but curettage only; recurrence with increasing pain. 3 weeks after resection and prosthetic replacement, a dislocation was reduced manually; plaster spica. Still indefinite discomfort but no evident recurrence. Almost full movements. Uses a stick out of doors.
24	Female	30	Recurrent chondrosarcoma	Femur, upper part	4	J. N. W.	6 years before, chondrosarcoma of femoral head; excision and Thompson prosthesis. Recurrence; major resection and prosthesis. Now has full hip movements; Trendelenburg just positive; uses a stick out of doors. No evident recurrence.

(Case 2), declined an appliance or further intervention and took to crutches six years after operation. Recently he became bedridden at another hospital with severe rheumatoid disease, an iatrogenic leucopenia of 300/m³, and finally ulceration over a plate of the prosthesis. Removal of all the metal was followed two days later

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by death from gas gangrene, twenty-two years after our operation.

Breakage of prosthesis—Of the plastic prostheses, one humeral prosthesis broke; of the metallic prostheses, four broke, all femoral.

The first fracture was of the plates of a CCM upper femoral prosthesis cast in one piece, probably from a fatigue fracture precipitated by a casting defect. It occurred five and a half years after insertion. The prosthesis was replaced by a stemmed prosthesis without difficulty (Case 8).

Three medullary stems have broken. A male nurse (Case 11) had a CCM acetabular and upper femoral prosthesis with an integrally cast stem and was very active for four years. He then had a head-on car collision; there was no evident serious damage, but six weeks later he turned suddenly and felt severe pain in the thigh; a radiograph revealed a proximal fracture of the stem. At operation 2·5 centimetres of the proximal end of the remaining portion of the femur was excised; the broken stem was driven distally to crack the cement and was then removed; and a new prosthesis made of CCM with a titanium 160 stem was cemented in. He now has a very slight limp, a negative Trendelenburg test and full movements. He is on full duty and includes mountain walking in his holidays.

An exceptionally athletic patient (Case 15) had the distal end of his femur and knee joint replaced, and he returned to tennis and other games. He broke the 4-millimetre Barr-type bolt holding together the components of the CCM axle; the bolt was readily replaced and the bearing gave no further trouble; the design is no longer used. Six years from the original operation the medullary stem of titanium 160 broke at the run-out of grooves intended to favour firm grouting (Fig. 9). At operation efforts to remove the stem were unavailing and the limb was amputated through the thigh. Other solutions are conceivable, for instance replacement of the whole femur achieved in 1952 and again in 1964 by Buchman (1965).

The case of a patient with further recurrence of a giant-cell tumour of the lower end of the femur whose prosthesis broke at a similar site is described later (Case 13, Fig. 11).

We hope to prevent broken stems by our present practice of omitting the retention grooves and by using titanium alloy 318. In composite units we have had no failure of fabrication by welding (which is tested radiographically), by riveting or by bolting with locking nuts.

Breakage of bone—Persisting rarefaction may have contributed to two fractures. In Case 21 a subtrochanteric fracture occurred just distal to the tip of the stem of a

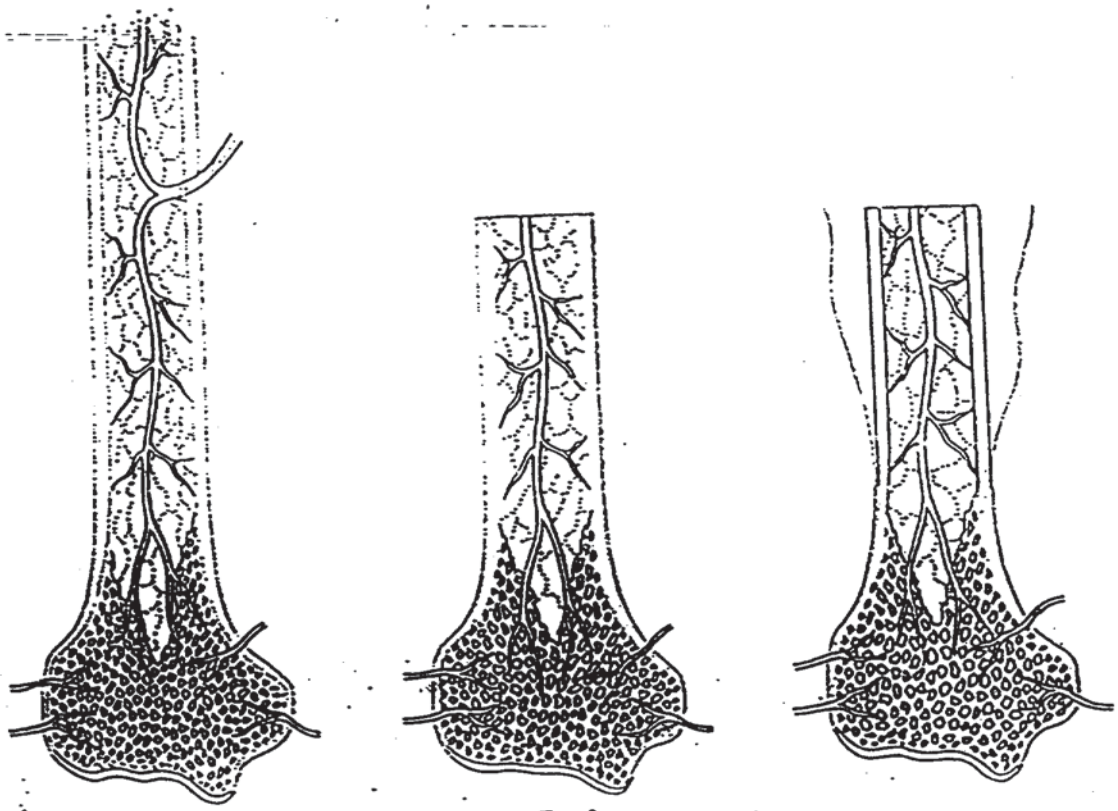

FIG. 8

A diagrammatic representation of the normal blood supply of the shaft of a long bone, its partial interruption by transection, and further interruption by periosteal stripping.

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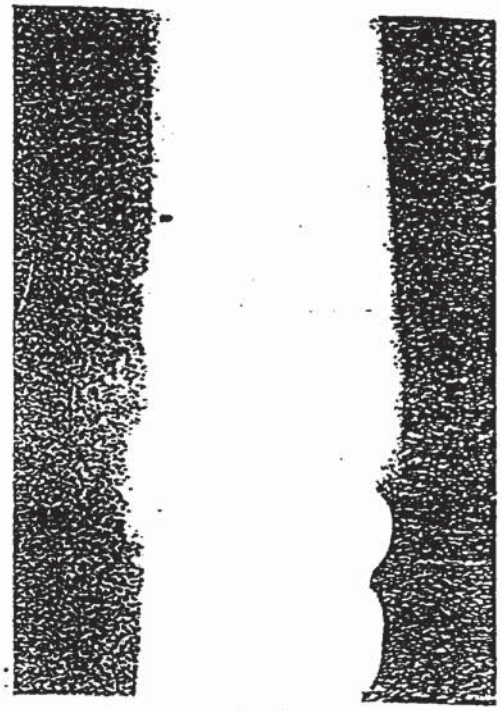

FIG. 9
Case 15—Radiograph showing the broken stem of the prosthesis.

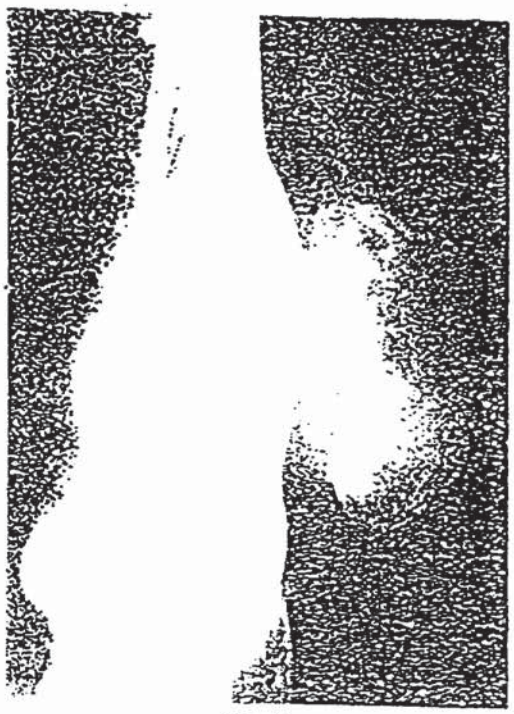

FIG. 10
Case 3—Radiograph showing a fracture of the patella from direct violence.

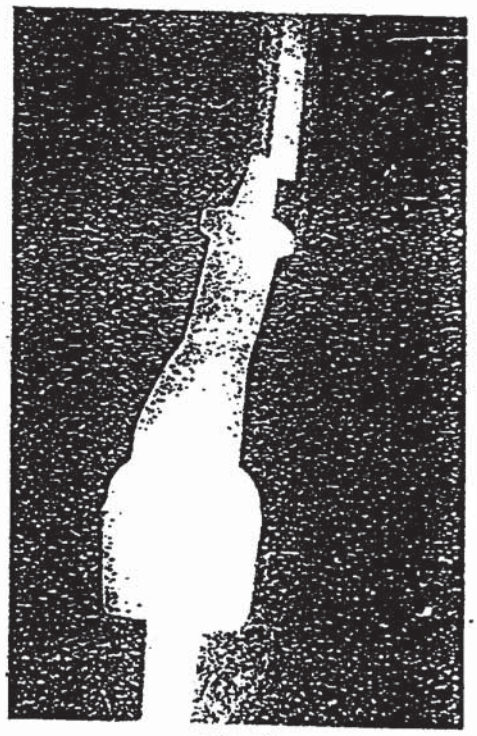

FIG. 11
Case 13—Radiograph showing fracture of prosthesis seven years after excision of an advanced giant-cell tumour, and also revealing a recurrence.

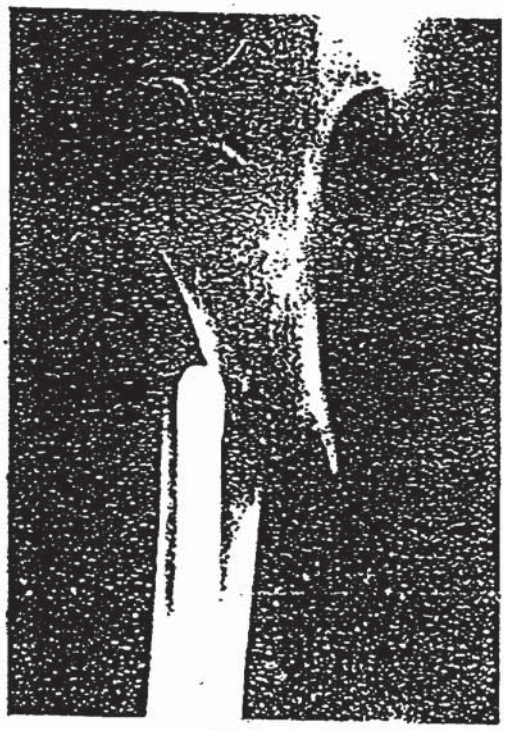

FIG. 12
Case 21—Radiograph showing a fracture through non-neoplastic porotic bone from a twisting injury.

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lower femoral prosthesis from a twist and fall three and a half years after insertion. Figure 12 shows the cortical rarefaction, which was not neoplastic.

The first patient in whom we replaced the lower part of the femur and the knee (Case 3) tripped sixteen years later and sustained a Y-shaped fracture of the patella (Fig. 10). This was sutured by Mr E. L. Trickey. Although radiologically slightly rarefied, the patella appeared of normal consistency at operation. The patella is an important separator of implant from subcutaneous tissue, and we fully endorse its retention. The patient recovered fully from the fracture except for slight aching in the knee: she is married, does all her own housework and continues to walk nearly six miles daily on school journeys with her two sons.

Trouble with joints. *Lack of active control of the shoulder joint*—In excision of the upper end of the humerus we have resected much of the rotator cuff, which has prevented repair of the supraspinatus and active elevation of the limb. In one instance, on this account but most unwisely, we splinted the shoulder in abduction at the end of the operation (Case 4). It became subluxed and remained so for eight years. Eleven years ago we replaced the prosthesis, which has remained fully reduced.

Dislocation—We have had two instances of dislocation of an upper femoral prosthesis within a week of operation; both dislocations were reduced manually. In another instance, only recognised after eighteen days, open reduction was necessary. In spite of rotational precision in fixing the prosthesis, careful handling of the anaesthetised patient and good control of traction, it is wise to check during early convalescence for dislocation, to which these wide resections predispose.

Stiffening—A hip, in which a hollow CCM prosthesis replaced the upper end of the femur to provide an amputation stump (Case 7), achieved good movement and then stiffened many months after operation, possibly because of fibrosis induced by a cover of four-ply Terylene bobbin net intended to encourage adhesion of muscles. Nevertheless the patient uses an artificial limb fully, has married and has brought up two children.

Protrusio acetabuli—We had one case before including the acetabulum in our replacements.

Mechanical defects—Joints have been free from these except for the defective axle bolt already mentioned.

Toxic reactions—A very active patient with a CCM knee joint was found after four years to have a symptomless excess of cobalt and chromium in hair, blood and urine (Case 11). Similar changes have been observed by one of us (J. T. S.) after ordinary total hip replacements made of this alloy. Sludge about the joint is taken up by macrophages, particularly around capillaries (Scales and Lowe 1971; Coleman, Herrington and Scales 1973). There has been no clinical evidence of allergy to these elements or to nickel (McKenzie, Aitken and Ridsdill-Smith 1967), nor any sudden drop of blood pressure or cardiac arrest during or after operation.

Local recurrence—A Nigerian housewife (Case 13) had a recurrent giant-cell tumour of the femur already complicated by grafting and sequestrectomy and by transgression of the knee joint itself. During excision there was inevitable disintegration and spilling. Twenty-one months later there were small recurrences in the femur adjacent to the prosthesis and in the scar. There was a good initial response to deep radiation (6 240–7 200 r) given by Dr G. Piciotto and she returned to Nigeria, where she suffered a fracture of the prosthesis seven years after the operation; radiographs revealed a large popliteal recurrence (Fig. 11). Amputation was advised, but further follow-up has failed.

A Sikh (Case 22) had had local excision of what was presumed to be a cartilage-capped exostosis of the upper part of the humerus two years before, with recurrence within a year. Five years ago a chondrosarcoma and the upper part of the humerus were removed and replaced by an endoprosthesis. Eighteen months later, recurrence was observed and a forequarter amputation was carried out. There has been no evident further recurrence.

Deaths—Two patients have died from multiple growths. One concerned our first excision of an endosteal chondrosarcoma of the humerus performed twenty-four years ago in a woman of thirty-seven (Case 1) who died fifteen years later of a generalised spindle-cell neoplasm of uncertain origin. Necropsy revealed no local recurrence.

Another patient, a woman of fifty-five (Case 8), had had incomplete removal elsewhere of an atypical endosteal chondrosarcoma by excision of the head and neck of the femur; the residue extended to fill the greater trochanter. We excised the upper end of the femur, replacing it with a prosthesis. Six years afterwards she presented with a rapidly-growing similar growth of the opposite ilium, where there had been no radiographic defect before, and soon died of pulmonary metastases.

A woman of fifty-seven (Case 19) who had a right kidney and the upper 10 centimetres of the left humerus removed for hypernephroma died of pulmonary metastases, without evident local recurrence, eighteen months after the humeral resection; there was no necropsy.

A woman of fifty-two (Case 6) had had a solitary thyroid metastasis in the femur for three years, twice treated by deep x-rays, and had now a pathological fracture. Six months after upper femoral replacement she died of cardiac failure. At necropsy this was ascribed to old rheumatic carditis with mitral stenosis.

One patient (Case 14) with a chondrosarcoma of the upper end of the humerus died in a geriatric unit at the age of sixty-nine, eight years after excision and replacement. Little clinical information and no necropsy were available, but metastases were not ruled out.

Reference has already been made to a patient (Case 2) with loosening of a femoral prosthesis and severe rheumatoid disease who died twenty-two years after excision of a chondrosarcoma.

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This work has been made possible by the establishment of a Department of Biomedical Engineering within the clinical environment of one centre, and by the generosity of those who have referred patients to take advantage of this.

We owe much to Professor Sir Herbert Seddon for his encouragement and example; Dr G. K. T. Roche, anaesthetist; Mr M. A. Birnstingl, vascular surgeon; Professor H. A. Sissons and Dr Paul Byers, morbid anatomists; Professor Charles H. Lack, microbiologist; Dr E. H. Allen and Dr R. O. Murray, radiologists; Miss J. Nichol, theatre sister, and her staff; Mr Ron Ansell, chief technician and draughtsman in the Department of Biomedical Engineering; Mr Robert Child, who has made many of the implants; Mr A. Heron and his colleagues of Trucast, Farnham Royal, and Mr S. Medcraft and colleagues, formerly of Deloro Stellite, now of Metallo Medical, Swindon, all concerned in the development of cobalt-chrome-molybdenum components; to Mr C. Davenport, librarian; Mr R. J. Whitley, medical photographer; Mr Frank B. Price, medical artist; Miss Mary Lang, records clerk; and Miss Patricia Chambers, medical secretary. We gratefully acknowledge the support of basic relevant work by the Department of Health and Social Security.

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H. S. Dobbs,[1] *and J. T. Scales*[1]

Behavior of Commercially Pure Titanium and Ti-318 (Ti-6Al-4V) in Orthopedic Implants

REFERENCE: Dobbs, H. S. and Scales, J. T., "Behavior of Commercially Pure Titanium and Ti-318 (Ti-6Al-4V) in Orthopedic Implants," *Titanium Alloys in Surgical Implants, ASTM STP 796*, H. A. Luckey and Fred Kubli, Jr., Eds., American Society for Testing and Materials, 1983, pp. 173–186.

ABSTRACT: At the Royal National Orthopaedic Hospital major replacement of long bones began in 1949, and the first titanium-containing endoprosthesis was inserted in 1954. By now over 250 titanium-containing endoprostheses of various kinds have been inserted. Most of these components were made on a modular basis and included sections of cast cobalt-chromium-molybdenum alloy. In 1972 titanium alloy 318 (Ti-318)(Ti-6Al-4V) was introduced, and this alloy largely replaced the previously used commercially pure titanium.

This paper presents our experiences with these endoprostheses, with titanium total hip replacements, and with other titanium devices. Using standard statistical methods, survival curves for the nonremoval of the component were obtained. These curves demonstrated that the performance of upper femoral, lower femoral, and upper tibial endoprostheses was slightly worse than that of standard total hip replacements. This worse performance was a result of five intramedullary stem fractures, but we now think that this problem has been overcome by the introduction of Ti-318. These and other fractures emphasize the importance of good design, good surface finish, and optimum stem or section size. There was no evidence that the combination within a single implant of cobalt-chromium-molybdenum and titanium, commercially pure or alloy, caused corrosion or clinically significant problems. Although blackening of adjacent tissue has been observed, there was no evidence that this was associated with an undesirable tissue response.

KEY WORDS: titanium, implants, fracture, corrosion, biocompatibility, implant materials

In the United Kingdom the use of titanium in orthopedic implants began in the mid-1950s when Down Bros. and Zimmer GB carried out clinical trials. Shortly thereafter these companies began marketing titanium products. The products included nails, plates, screws, and Austin Moore and Thompson prostheses. Commercially pure titanium was used, namely, titanium 160

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(Ti-160) and other grades. By the early 1970s these companies were selling at least 6000 prostheses each. In 1972 titanium alloy 318 (Ti-318)(Ti-6Al-4V) was introduced, and this replaced Ti-160 for most applications. In certain applications where extra hardness was required, titanium alloys 550 (Ti-550) and 680 (Ti-680), both of which contained tin, molybdenum, aluminum, and silicon, were used.

In 1962 the British Standard Institute issued British Standard (BS) 3531, entitled "Metal Surgical Implants, Drills and Screwdrivers Used for Bone Surgery." This standard, updated in 1968, included the various grades of commercially pure titanium but did not include titanium alloy Ti-318. In the early 1970s, Ti-318 for implant use was supplied against an aerospace standard such as BS TA 13, since it was not included in BS 3531 until the 1980 revision. Both the aerospace standard and this revision permit a higher level of interstitials, especially oxygen, than does the ASTM Specification for Titanium 6Al-4V ELI Alloy for Surgical Implant Applications (F 136-79). This difference remains a matter of interest because of the supposed superiority of the "extra-low interstitial" material.

Since the early report of Leventhal in 1951 [*1*],[2] clinical and laboratory experience has demonstrated the suitability of titanium for implant use, specifically, because of its excellent strength [*2,3*], corrosion resistance [*4,5*], and biocompatibility [*6,7*]. However, a few problems were encountered. In 1973 Scales et al [*8*] reported on their experience with Ti-160 after examining 74 multicomponent devices removed from patients. Although there was no evidence of simple corrosion, 40 percent of the implants used in weight-bearing situations (that is, in the lower limbs) exhibited "interface attack," or fretting, and 2.6 percent fractured in the patient. In 1972 Hughes and Jordan reported a fracture of a commercially pure titanium prosthesis, which had initiated at a surface stress concentration [*9*]. The following year Meachim and Williams [*10,11*] reported on their study of tissue adjacent to commercially pure titanium implants. They found no adverse tissue reactions of any kind, but noted the presence of detectable quantities of titanium in the tissues as a result of possible wear or diffusion, or both. Meanwhile, some laboratory tests suggested that the wear of titanium against polyethylene was greater than that of either cobalt-chromium-molybdenum alloy or stainless steel against polyethylene; however, other tests indicated that the wear rates were comparable [*12,13*]. In 1978 Trent and later McKellop et al [*14*] demonstrated that the addition of acrylic bone cement to the joint fluid increased the wear rate and produced scoring of the titanium component with a characteristic blackening of the fluid. In 1979 Rae [*15*] tested a Stanmore Ti-318 metal-on-plastic total hip replacement in his wear simulator in physiological fluid. After 3×10^5 cycles, the fluid was examined using atomic absorption spectrophotometry. No soluble titanium or aluminum was detected, the detection limits having

[2] The italic numbers in brackets refer to the list of references appended to this paper.

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been 330 and 2.5 ng ml^{-1}, respectively. On the other hand, particulate titanium wear debris was produced, but when primary monolayer cultures of human synovial fibroblasts were exposed to the debris for up to ten days, no gross morphological changes were observed. To our knowledge there are no reports which suggest that metal sensitivity or adverse reactions of any kind are associated with titanium implants.

At the Royal National Orthopaedic Hospital (RNOH) major prosthetic replacement of long bones began in 1949. Subsequently, over 250 major bone and joint endoprostheses containing titanium have been made by the Department of Biomedical Engineering and inserted at the RNOH and elsewhere. These replacements were of various types and were used in the treatment of a variety of conditions: (1) nonmalignant tumors, (2) malignant tumors, (3) metastases, and (4) salvage procedures as a result of a failed previous treatment. In addition to these endoprostheses, over 220 titanium total hip replacements have been inserted at the RNOH since 1972. This article is concerned with the performance of these components, but especially with that of upper femoral, lower femoral, and upper tibial replacements. The article also describes the failures that have occurred.

Use and Design of Components

Table 1 gives details of the titanium-containing endoprostheses. The heading "160" implies that the only titanium used in the component was Ti-160. The heading "318" implies that Ti-318 was used in the component, either alone or in conjunction with Ti-160. Components containing Ti-318 had an intramedullary stem of this alloy. As of April 1981 there had been a total implantation time of 289 years for Ti-160 and 447 years for Ti-318.

Figures 1 through 3 show three types of endoprosthesis, namely, upper femoral replacement with hip joint, lower femoral replacement with knee joint, and upper tibial replacement with knee joint. In a short paper such as this it is not possible to describe the design of these components in detail. Suffice it to say that most of these components were made on a modular basis and made use of existing cobalt-chromium-molybdenum castings. Thus, a typical upper femoral replacement consisted of a cobalt-chromium-molybdenum head and neck attached by shrink-fit and riveted to a titanium shaft bolted or riveted to a titanium intramedullary stem. Similarly, a typical lower femoral or upper tibial replacement consisted of a modified cobalt-chromium-molybdenum hinged knee joint attached using acrylic bone cement to a titanium shaft bolted or riveted to a titanium alloy intramedullary stem. Each component was custom-made, the necessary measurements being taken from the patient's radiographs. Fixation to bone was by means of acrylic cement. Further details of the design, materials selection, surgical techniques, and so on have been described in previous reports [*16*].

Table 2 gives details of Ti-318 total hip replacements inserted at the RNOH.

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TABLE 1—*Use of titanium 160 and 318 in endoprostheses.*

Type	Alloy	Date of First Insertion	No. Inserted as of [illegible]	Average Duration, years	No. of Insertions Implanted >5 Years
Upper femur	160	1.64	[illegible]	9.05	13
	318	5.72	[illegible]	2.25	6
Lower femur	160	10.64	[illegible]	7.57	5
	318	3.72	[illegible]	1.87	4
Total femur	160	4.75	[illegible]	4.42	1
	318	6.78	[illegible]	1.23	0
Upper tibia	318	4.76	[illegible]	0.99	0
Upper humerus	160	11.63	[illegible]	8.18	4
	318	2.72	29	2.12	4
Lower humerus[a]	160	9.70	[illegible]	5.29	1
	318	11.72	[illegible]	1.99	2
Other[b]	160	9.71	1	9.08	1
	318	11.76	[illegible]	1.47	0
All	160	1.64	[illegible]	7.99	21
All	318	2.72	[illegible]	1.96	16
All	160 + 318	1.64	263	2.80	41

[a] Includes one total humerus.
[b] Includes one ankle, two wrists, three pelvises, three extending and one femoral midshaft.

Except for the special prostheses, which were custom made, these components were of the standard Stanmore design. At present the total implantation time for these components is 282 years.

Materials Specification

Table 3 gives the composition and heat treatment of typical batches of Ti-160 and Ti-318, the data being from the manufacturer's test certificates. Both were supplied by IMI Ltd. in rod form of various diameters, and both complied with BS 3531. The cobalt-chromium-molybdenum-components also complied with BS 3531 and were supplied by Deloro Stellite Ltd., and later by Zimmer GB, now OEC Orthopaedic Ltd. The acrylic bone cement was Simplex, manufactured by North Hill Plastics Ltd. The polyethylene cups were RCH 1000 manufactured by Ruhrchemie.

Before insertion, all titanium components were passivated in a nitric acid solution in accordance with BS 3531 (1962 and 1968), and some were anodized in a solution of orthophosphoric and sulfuric acids at 70 V. Metal components were steam sterilized or gamma-irradiated at 2.5 Mrad. Plastic components were gamma-irradiated.

Survival of Implants

Two studies of replacement survival were undertaken, one of upper femoral replacements and the other of lower femoral and upper tibial replacements. In the first study there were 105 cases; 16 replacements were of Ti-160, and of

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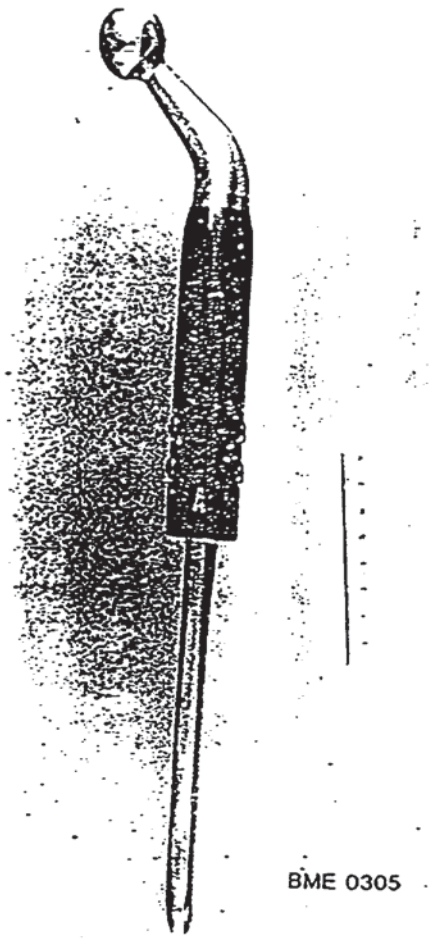

FIG. 1—*Upper femoral replacement with plastic acetabular cup.*

these one had a polyethylene acetabular cup, 13 a metal cup, and two no cup at all. The remaining cases were Ti-318; 69 had a polyethylene cup and 20 a metal cup. In the second study there were 95 cases; 6 were of Ti-160 and 89 of Ti-318.

The survival of the components was determined using standard statistical methods [17]. The failure criterion was taken to be removal of the component, but removals due to recurrence of the disease were disregarded, thereby enabling the results to be compared with those obtained for standard replacements in patients not suffering from malignant disease. Survival was measured from the date of prosthesis insertion. For each patient the actual length

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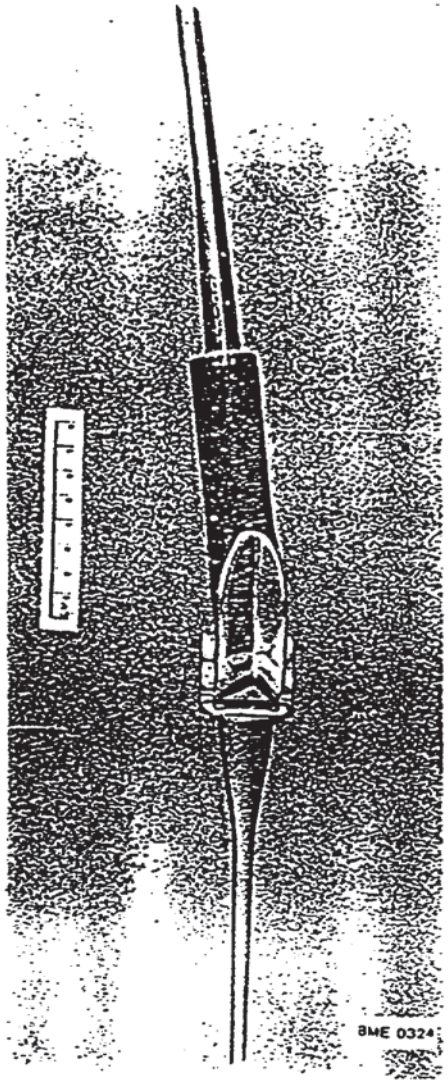

FIG. 2—*Lower femoral replacement with knee joint.*

of the follow-up was determined. Absence of follow-up (only five) and death were not regarded as failures. Survival curves were plotted, showing the overall probability of survival as a function of time.

Results

Figure 4 shows the survival curves for upper femoral replacements with hip joints and for lower femoral and upper tibial replacements with knee joints.

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Type
Special
Standard (all Ti)
Ceramic head
Co-Cr-Mo head

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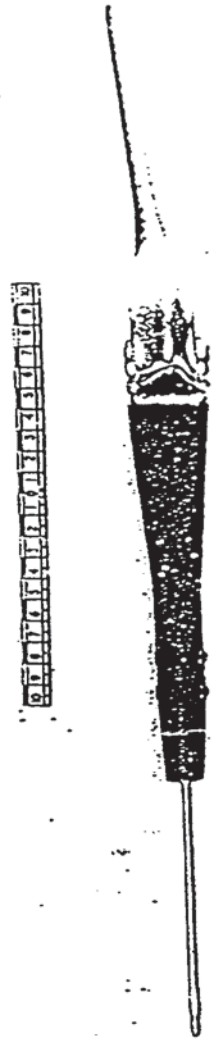

FIG. 3—*Upper tibial replacement with knee joint.*

TABLE 2—*Use of titanium 318 alloy in total hip replacements.*

Type	Date of First Insertion	No. Inserted as of April 1981	Average Duration, years	No. of Insertions Implanted >5 Years
Special	4.72	39	2.65	6
Standard (all Ti)	1.73	22	3.38	5
Ceramic head	7.78	25	0.68	0
Co-Cr-Mo head	7.79	135	0.85	0

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TABLE 3—*Details of typical batches of Ti-160 and Ti-318.*

	Ti-160	Ti-318
Composition, %	0.30 O_2, 0.01 N_2, 0.02 C, 0.04 Fe, 0.05 each Al, Cr, Mn, Ni, V, 0.02 each Cu, Si, Sn, Balance Ti	0.15 to 0.22 Fe, 6.24 to 6.52 Al, 4.14 to 4.46 V, 0.15 to 0.20 O_2, <0.01 N_2, 0.01 to 0.03 C, Balance Ti
Heat treatment	1 h at 700°C, AC[a]	1 h at 700°C, AC

[a] AC = air cooled.

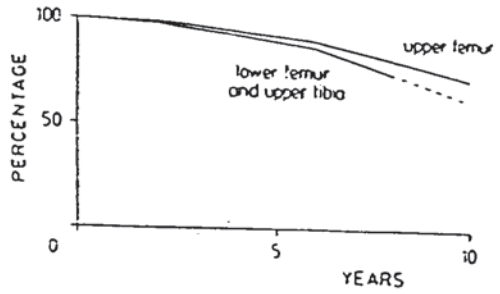

FIG. 4—*Survival curves for upper femoral replacements with hip joint, and for lower femoral and upper tibial replacements with knee joint. The curves show the probability of survival (nonremoval) as a percentage versus the time since the insertion in years.*

After ten years the probability of survival for upper femoral replacements was 72 percent, and approximately 62 percent for lower femoral and upper tibial replacements.

Table 4 gives the cause of removals. These were five stem fractures, five cases of infection, and two cases of loosening. The incidence of infection over the 2.8-year average implantation period was 1.9 percent, which is not abnormally high. For upper femoral replacements alone there were two stem fractures, both of Ti-160, three cases of infection, and two cases of loosening (one of a cobalt-chromium-molybdenum cup). For lower femoral replacements alone there were three stem fractures, two of Ti-160 and one of Ti-318. For upper tibial replacements there were no stem fractures and one case of infection.

Table 5 shows the incidence of intramedullary stem fracture for the upper and lower femoral replacements. The average annual incidence can be used as a means of comparison, and on this basis Ti-318 appears better than Ti-160. Unfortunately, it is still too soon to be certain about the superiority of Ti-318; although there has only been one fracture, the average duration has been relatively short, and fewer than ten Ti-318 stems have been in service for the length of time that it took the Ti-160 stems to break, that is, six years on average. The one Ti-318 fracture occurred after less than a year, but this was certainly the result of a design fault.

Figure 5 (*left*) shows a typical intramedullary stem fracture, and the photo-

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TABLE 4—*Cause of removal of endoprosthesis of all types.*

Alloy	Fracture, No.	Infection, No.	Loosening, No.	Others, No.[a]	All, No.
160	4	1	1	2	8
318	1	4	1	14	20
160 + 318	5	5	2	16	28[b]

[a] Including recurrence of the disease (14) and dislocation (2).
[b] In addition to these removals, there were 34 deaths, in most cases due to spread of the disease.

TABLE 5—*Incidence of intramedullary stem fracture for upper and lower femoral replacements.*

Alloy	Fractured, No.	Inserted, No.	Average Duration, years	Average Annual Incidence, %	No. Insertions Implanted >5 Years
160	4	22	8.65	2.10	18
318	1	164	2.08	0.29	10

graph on the right shows the fracture surface. Recently, we have examined nine fractured devices, the five already mentioned and four plates, one of which was of Ti-318. In our opinion, most of these failures were fatigue fractures, which initiated at surface stress concentrations, a result of either poor design or poor surface finish.

Figure 6 shows a Ti-550 McIntosh tibial plateau removed after two years because of pain. This component was inserted in the left knee of a 67-year-old patient suffering from rheumatoid arthritis. The figure shows that the component has worn as a result of contact with the femoral condyle.

A recently examined Ti-318 total hip replacement removed after two and a half years also exhibited wear. In this case the anodized head which had been in combination with a polyethylene cup was yellow in the worn region at the apex and blue elsewhere. This change in color suggests that a few tenths of a micrometre of material had been removed.

Figure 7 shows the fibrous capsule surrounding the titanium tibial plateau shown in Fig. 6. This capsule contained macrophages which had engulfed wear particles in the vicinity of blood vessels. Giant cells were not a feature. There was very little inflammatory response to these particles. Tissue from a total of 27 removed titanium implants of various types has been examined, and in no case was there a significant tissue reaction.

Blackening of tissue adjacent to titanium implants was observed in many cases, but the degree of blackening varied considerably. Even in cases in which there was very little movement between tissue and implant and no obvious wear

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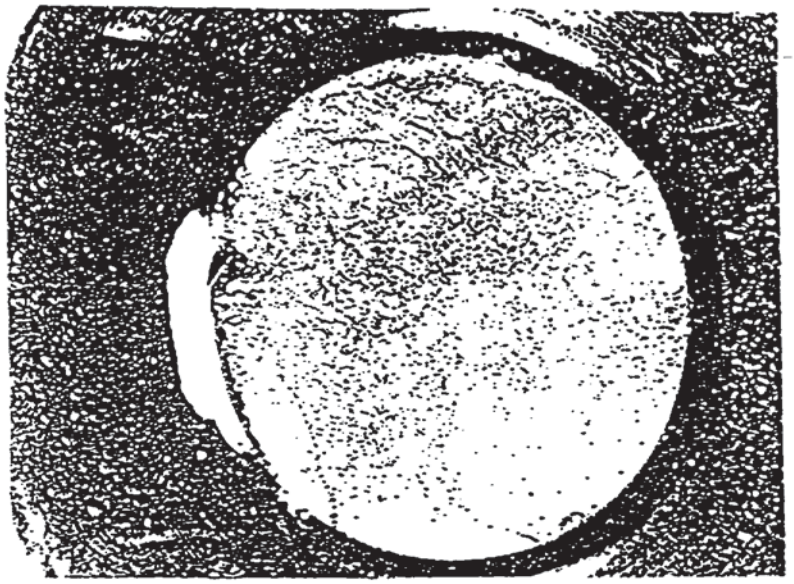

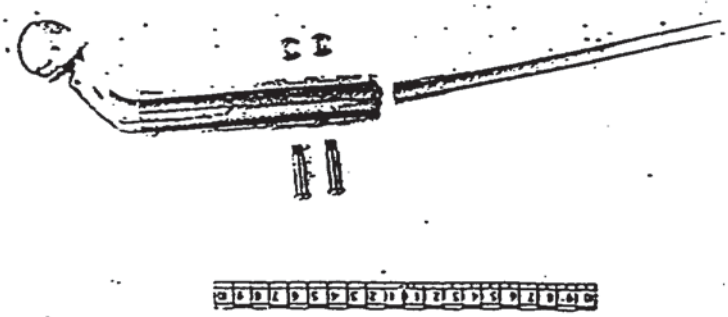

FIG. 5—(Left) Fracture of intramedullary stem; (right) appearance of fracture surface.

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FIG. 6—*Ti-550 McIntosh tibial plateau showing wear.*

FIG. 5—(Left) *Fracture of intramed. stem;* (right) *appearance of fracture surface.*

or abrasion, blackening occurred. In no case was blackening associated with an adverse tissue response. Nor did any of our patients exhibit a dermatological reaction or metal sensitivity to titanium when patch tested before insertion.

Discussion

A previous study of the survival of cobalt-chromium-molybdenum total hip replacements obtained a ten-year survival value of 80 percent for metal-on-plastic prostheses [*18,19*]. The value obtained for titanium-containing upper femoral replacements was 72 percent, and, for lower femoral and upper tibial replacements it was 62 percent. These values are worse than that obtained for the total hip replacements; however, if the problem of intramedullary stem fracture could be overcome (as we think it has been), then a ten-year survival value in excess of 80 percent could be expected. This is especially so, since loosening is a less important problem with endoprostheses than with total hip replacements.

Although our results do not yet demonstrate the unequivocal superiority of Ti-318 over Ti-160, the materials data strongly suggest that better results can be expected with Ti-318. In addition, the importance of good design, good surface finish, and optimum stem size is now recognized, and this should help

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FIG. 7.—Fibrous capsule surrounding the titanium tibial plateau shown in Fig. 6 (Ehrlich hematoxylin and eosin). The scale marker indicates 10 μm.

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to reduce mechanical stress and minimize the likelihood of stem fracture. We have no evidence to suggest that "extralow interstitial" Ti-6Al-4V would give better results than Ti-318, but we do think, as indicated by Dobbs and Robertson [20], that other titanium alloys may offer significant advantages.

There was no evidence that the combination within a single implant of cobalt-chromium-molybdenum and titanium, commercially pure metal, or alloy Ti-318, caused corrosion or clinically significant problems. Furthermore, as mentioned earlier, the survival rate was comparable to that for cobalt-chromium-molybdenum total hip replacements. These observations suggest that the chosen metallic combinations were suitable for implant use, a result which is consistent with the view of Mears that dissimilar metals can be used in the body provided they are themselves of a passive nature [21]. A similar result was obtained recently by Rüedi et al, who found that titanium and stainless steel could be used satisfactorily in combination [22]. A similar result was also obtained in laboratory tests [23,24].

Our preliminary observations of titanium wear, histology of adjacent tissue, and tissue blackening do not suggest that these considerations need be a source of concern in the future. Nevertheless where titanium is to be used as a bearing surface in combinations with polyethylene, it should be used with care, and contact with acrylic cement should be avoided. Alternatively, the use of a substitute bearing surface such as in the Stanmore composite total hip replacement can be recommended.

Perhaps the least understood aspect of the use of titanium concerns the release of its ions into the tissues. Is the release mechanism wear, corrosion, or diffusion? Do the ions remain local to the implant or are they widely distributed within the body, and if so what levels occur? Are aluminum, which is possibly toxic, and vanadium also released? These are important questions which are as yet unanswered.

Acknowledgments

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The Use of Dissimilar Metals in Surgery

D. C. MEARS, *Department of Orthopaedic Surgery, University of Pittsburgh, Children's Hospital of Pittsburgh, Pittsburgh, Pennsylvania 15213*

Summary

Previously, the use of dissimilar metals for the construction of surgical implants has been strongly discouraged because the combination of metals was likely to provoke more rapid corrosion of one metal. With the passive alloys that are in present and future application, however, a reconsideration of the use of dissimilar metals is required. Presently available electrochemical tests allow accurate prediction of safe and unsafe combinations of metals. The use of dissimilar metals would permit selection of the alloy of appropriate mechanical properties for each part of an implant and would allow improved corrosion resistance that certain alloys can convey to other alloys with which they are in contact.

INTRODUCTION

Until 30 years ago, there was no alloy available for construction of orthopedic surgical tools and implants which had sufficient inertness and appropriate mechanical properties. Then, certain austenitic stainless steels and cobalt-chromium alloys were introduced, and more recently titanium and nickel alloys were used successfully. Most surgical tools and implants have been manufactured from a single alloy of homogenous mechanical properties. There are many situations, however, where different parts of a single surgical tool or implant require different mechanical properties. Just as different tissues of the body such as bone, muscle and tendon show widely different and, indeed, contrasting mechanical properties of strength, hardness, elasticity and plasticity, so different portions of a tool or implant may have different needs. For examples, surgical scissors require hard wear-resistant cutting edges. While the cutting edges can be prepared from tungsten carbide, the remainder of the intricately shaped blades and handles requires a more ductile and less brittle material such as certain stainless steel alloys. Metal implants for replacement of human joints require hard wear-resistant articulating surfaces of low coefficient of friction while the remainder of the implant requires inert ductile materials. More complex implants are in various stages of design which require components of widely differing mechanical properties where combinations of different

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metals as well as combinations of metals with nonmetallic substances seem essential.

Over 100 years ago, workers observed that two different metals such as zinc and iron in contact in a solution such a nitric acid might provoke more rapid dissolution of one metal than would occur when either was isolated in the same environment. Galvanic corrosion of dissimilar metals has been widely described in surgical literature. Indeed, past workers have strongly recommended that dissimilar metals should never be used in the human body. In view of the present and future need to combine different alloys to fashion a single implant, the present article reviews the mechanisms of dissolution of combinations of metals. Electrochemical methods for study of combinations of alloys are reviewed to determine whether safe combinations of alloys can be selected for implantation.

Electrochemical Principles of Corrosion and Passivation of Metals

Corrosion refers to a kind of metallic deterioration in which metal leaves the metallic state by anodic dissolution to form aqueous cations in solutions or by anodic conversion to solid compound. This is accompanied by an equivalent cathodic reduction of some constituent in the aqueous electrolyte. The corrosion rate is faradaically equivalent to the current flowing between the anodes and cathodes. On corroding metals, these may be a few centimeters or a few atoms apart, or anodic and cathodic reactions may occur at the same atomic point on the metal surface; but the net passage of positive charge from metal to environment at the anode is always equal to the net passage of negative charge from metal to environment at the cathode. The basic reaction in corrosion is the removal of metal positive ions from their positions in the metal crystal lattice, where they are stablized electrically by the metal negative electrons, to positions in the environment where they are stabilized by negative anions. This is an anodic reaction and must be accompanied by

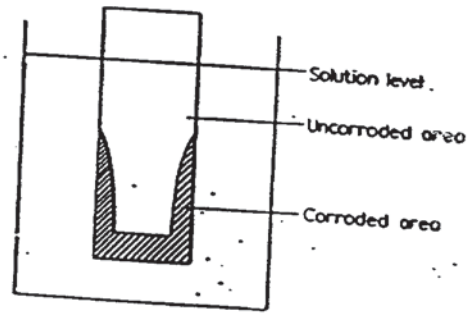

Fig. 1. Distribution of corrosion on an iron plate immersed in sodium chloride solution.

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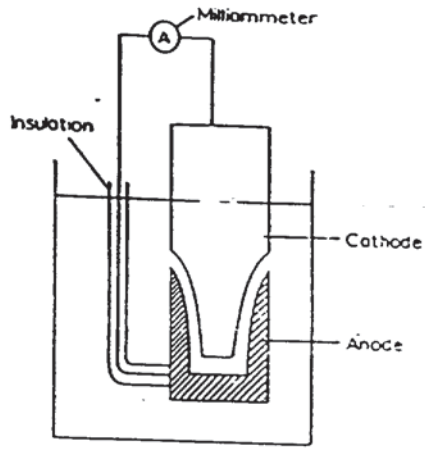

Fig. 2. Measurement of the current flowing between anodic and cathodic areas on iron partly immersed in sodium chloride solution.

a corresponding cathodic reaction in which the metal electrons thus freed, remove cations from the environment or create anions. Thus, for iron corroding in neutral aerated saline solution the overall anode reaction is:

$$Fe_{metal} - 2e^-_{metal} \rightarrow Fe^{2+}_{aqueous}$$

and the overall cathode reaction is:

$$\tfrac{1}{2} O_2 + H_2O + 2e^-_{metal} \rightarrow 2OH^-_{aqueous}$$

The latter represents reduction of dissolved oxygen in solution. The electric current flows equivalent to the amount of metal that dissolves at the anode. Hence, corrosion is an electrochemical deterioration of metals that obeys Faraday's laws. This was confirmed by early workers who studied the corrosion of iron plates partly immersed in stagnant saline solutions [1], [2]. The corrosion distribution was found as shown in Figure 1. Attack began at the edges, spread inwards, and then ceased to spread, while alkali was formed at and near the waterline. Next, the plates were cut along the zone of demarcation, as shown in Figure 2, and the pieces were joined through a milliammeter to measure current flow between corrosion sites and unattacked metal. In more complex experiments the electrode potential at the anodic and cathodic zones on corroding metal was measured by means of capillaries leading to a standard half cell electrode. The current corresponding to any particular potential was measured by applying a variable external electromotive force between separated anodes and cathodes. The resulting polarization curve (Fig. 3) allowed potential measurements to be used to estimate corrosion currents

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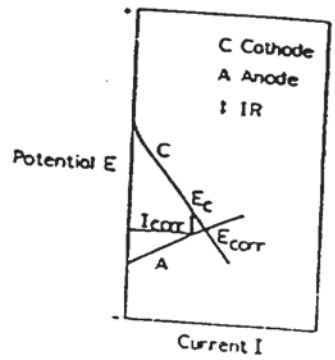

Fig. 3. Polarization of the anodic and cathodic reactions in a corrosion cell [2]. When anodic and cathodic reactions occur on the same piece of corroding metal they mutually polarize one another. The more positive cathode tends to pull the more negative anode in the positive direction in the electropotential scale and the anode tends to pull the cathode in the negative direction. Polarization to the values E_c and E_a thus occurs where $E_c - E_a =$ IR is the working electromotive force sufficient to drive the current I through the circuit of resistance R. For low-resistance metal and electrolyte paths (anode and cathode are near together) R is sometimes small enough for E_c to approximate E_a to within 1 mV and each may be identified with E_{corr}, the corrosion potential.

on metals carrying both anode and cathode thereby to deduce the corrosion rate.

Anodic Reactions of Metals in Passivity and Corrosion

When the presently used implant alloys are immersed in an aqueous buffered solution of pH 7 they become passivated immediately through the formation of a compact solid film of hydroxide, $M(OH)_2$, or the corresponding oxide. Usually, however, before exposure to the solution, the metal is covered with an air-formed oxide film and exposure serves to provide a thickened film and better barrier to prevent the egress of metal into solution.

In strongly acid solutions, the same metals may show different behavior [3]. Upon exposure the air-formed oxide film dissolves and subsequently the bare metal dissolves with the formation of aqueous metallic cations in solution. If the anode potential is made more positive (Fig. 4) by application of the potentiostatic technique, then the anodic current and rate of metallic dissolution increase. With further polarization, and increase of potential beyond point B, the anodic formation of $M(OH)_2$ or MO becomes thermodynamically possible and may well be kinetically easier than that of dissolved M^{2+} ions: if the hydroxide or oxide forms as a compact and adherent film on the metal surface, it provides a barrier to

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the further outward passage of M^{2+} ions. The anode current density falls (BC on Fig. 4) to a very small value and the metal is passive. Further rise of anode potential leads to an increase (CD on Fig. 4) of the very small anode current density or rate of conversion of solid metal to hydroxide film although this falls with passage of time since the thickening solid film becomes an improved barrier. Still further rise of anode potential

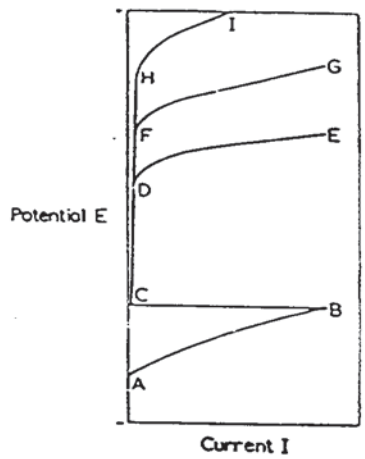

Fig. 4. Schematic diagram of an anodic polarization curve for a passive metal.

AB active dissolution; this is the portion of the anodic curve shown in Figure 3 where the classic "bare" metal dissolution is described.
BC passivating; rapid decrease in rate of metallic dissolution.
CD passive; slow rate of metallic dissolution through a protective "passive" film.
DE transpassive; oxidation of the passive film to a soluble form so that rapid metallic dissolution ensues. Pure chromium exhibits this behavior in sulphuric acid solution.
FG oxygen gas evolution; the metal remains passive.
HI chloride breakdown; resumption of rapid metallic dissolution occurs with the formation of brightened hemispherical pits.

The anodic polarization curve shows the relationship between current flow and the potential of a metal. Other observations are required to determine the nature of the electrochemical reaction and the rate of metallic dissolution. Two or more anodic reactions may occur simultaneously on a metal surface. If the potential of the metal is lowered to point A, the corrosion rate is 0. This can be accomplished by cathodic protection. Alternatively by combination of the metal with an appropriate cathodic material, the potential of the metal can be regulated between CD so that the metal is passive (anodic protection). For satisfactory application of anodic protection to surgical alloys, conditions for repassivation are required in addition to maintenance of passivity. For fulfillment of this criterion, either an efficient cathode is needed which can provide adequate current to raise the potential past point B, or the "active loop", ABC, must be small enough so that the magnitude of current B for repassivation approximates the current of passive dissolution, CD.

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can lead to one of several phenomena: 1) the film may be oxidized to a soluble product whereupon the metal resumes rapid dissolution (DE on Fig. 4) in the transpassive state; 2) a substance in the solution, such as hydroxyl ion, may become oxidized and oxygen gas is evolved (FG on Fig. 4), the metal remaining passive or; 3) in the presence of chloride-containing solutions passive metals are liable to a third mode of behavior [4]. Usually, passivation is greatly delayed or entirely prevented by the presence of chloride ions in solution. Often these are strongly adsorbed on metal surfaces and prevent contact with water or oxygen-bearing anions, which is essential for the easy formation of adherent compact oxide or hydroxide layers. Furthermore, chloride ions tend to break down passive oxide films and air-formed oxide films. Above a critical potential (HI on Fig. 4) chloride anion enters the passive film at singular points where the film is less regular than usual. The "contaminated" oxide so formed has a greatly increased ion conductivity that allows rapid egress of metal into solution. Hence, hemispherical pits form at these sites on the metal surface. Present electrochemical techniques [5] allow accurate prediction of the behavior that will be found if a previously untried alloy is exposed to body fluids for an indefinite length of time. As will be described shortly, these methods also allow estimation of how combinations of metals will behave in regard to corrosion or passivation in vivo. First, the cathodic reactions in corrosion will be described briefly.

Cathodic Reactions in Corrosion

As was previously emphasized whenever a metal dissolves as an anode, an equivalent cathodic reaction must transpire. If all cathodic reactants could be removed from the environment, then a metal could not dissolve electrochemically. The principal cathodic reaction in the corrosion of surgical implants is the reduction of dissolved oxygen to hydroxyl ion.

$$\tfrac{1}{2}\,O_2 + H_2O + 2e^-_{metal} \rightarrow 2OH^-_{aqueous}$$

At sites of low oxygen concentration, however, such as a crevice between two components of an implant or between cement and an implant, water reduction may supercede the oxygen reduction cathode.

$$2H_2O + 2e^-_{metal} \rightarrow H_2^{\uparrow} + 2OH^-_{aqueous}$$

It is possible that organic constituents of body fluids participate to a minor degree as cathodic reactants although, at present, little is known about their nature or significance.

The Behavior of Combinations of Metals

For over 100 years it has been known that combinations of dissimilar metals in solutions might show quite different rates of dissolution from

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the same metals when exposed singly to the same environment. The presence of one metal might provoke rapid dissolution of another metal as galvanic corrosion; or one metal might serve to protect the other metal and in turn, dissolve more rapidly; or, rarely, one metal might protect the other without enhancement of its own rate of dissolution. Considerable practical application this knowledge was made, notably by cathodic protection of copper sheathing of wooden ship hulls after the observations of Sir Humphrey Davy [6]. He suggested that the copper sheathing on wooden ships hulls could be protected from corrosion by placing blocks of iron or zinc in contact with the copper at various sites on the hull of the ship. Corrosion would be concentrated on the iron or zinc blocks; when these corroded away they could be replaced.

Upon certain occasions, however, unpredictable disasters occurred. Suddenly, one metal, seemingly protected by the presence of another metal would begin to dissolve far more rapidly than it would have done if immersed alone. For example, amphoteric metals, such as aluminium, might exhibit rapid dissolution upon excessive cathodic polarization. The disasters lent considerable skepticism in the value of application of dissimilar metals for corrosion protection of surgical implants. In view of recent knowledge, the disasters are now of historic interest and should not distract surgeons from the value of this method of corrosion protection. Hence, the behavior of dissimilar metals is reviewed.

Galvanic Corrosion

Galvanic corrosion is a mode of metallic deterioration whereby two metals in contact with one another are immersed in solution and one "base" or "reactive" metal, the anode, undergoes more rapid dissolution while the other "noble" metal, the cathode, undergoes less rapid dissolution than the isolated specimens would exhibit with similar immersion. Early workers [7] measured the rate of corrosion of iron when it was in contact with numerous other materials (Table I). The table shows that iron is protected by contact with a baser metal, whereas, it suffers serious corrosion by contact with a relatively noble metal. Such considerations were probably responsible for the widespread belief that the Table of Normal Potentials (Table II) could be used to determine dangerous or safe combinations of metals. It is well established that the electromotive force formed by two metals placed respectively in solutions that contain their salts at equivalent concentrations is obtained approximately by subtraction of the normal potential of the baser metal from that of the nobler metal. Under such conditions the further apart the two metals stand in the Table of Normal Potentials, the larger will be the electromotive force of the combination. Hence, the corrosion rate of the baser metal, the anode, might be expected to increase as the difference between the

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TABLE I

Bimetallic Corrosion of Iron and a Second Metal Immersed in 1% Sodium Chloride Solution[7]

Corrosion of Iron (milligrammes)	Second Metal	Corrosion of Second Metal (milligrammes)
183.1	copper	0.0
181.1	nickel	0.2
171.1	tin	2.5
183.2	lead	3.6
176.0	tungsten	5.2
153.1	antimony	13.8
9.3	aluminium	105.9
0.4	cadmium	307.9
0.4	zinc	688.0
0.0	magnesium	3104.3

two Normal Electrode Potentials becomes greater. However, as a practical guide for prediction of metallic dissolution rate of combinations of metals, the Table of Normal Potentials has proved of limited value. This is not surprising since each number in the Table refers to film-free metal placed in a solution with its ions at normal activity. No alloy in present or future use in surgery is film-free when immersed in body fluids. As will be described shortly, combinations of film-covered metals show quite different behavior. Furthermore, in physiologic conditions, normal activity of metallic ions would never be encountered.

Alternatively as a guide for behavior of combinations of metals, engineers adopted tables of potentials obtained empirically by measurements on combinations of metals placed in sea water. This environment was selected because most serious cases of galvanic corrosion were met in marine conditions. In view of the similarity of sea water to body fluids as a corrosive environment several workers have suggested that these tables are of application for selection of safe combinations of surgical alloys. The procedure of selection rests on the assumption that the working electromotive force of a bimetallic combination can be obtained by subtraction of the potential provided by one half-cell, consisting of one metal immersed in sea water in reference to a standard half-cell such as a calomel or silver chloride reference cell, from that provided by another half-cell consisting of the other metal and a reference half-cell immersed in sea water. This procedure is legitimate for reversible potentials as

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tabulated in Table II, but incorrect for irreversible potentials as obtained in sea water or body fluids. Furthermore, the magnitude of the electromotive force alone does not determine the current generated with metallic dissolution. The current and therefore the corrosion rate is largely determined by polarization considerations. Polarization is an electrochemical term that refers to changes in the potential of an electrochemical system that arise from: 1) differing concentrations of metallic ions in a corrosion system; 2) the activation energy of the several reactions in a corrosion system, and; 3) the ohmic potential drop through the electrolyte and through the metal-reaction product films that coat the surfaces of the electrodes. It must be emphasized that the corrosion rate will not necessarily be highest with those combinations that produce the greatest electromotive force. More recently with the advent of the potentiostatic technique [8] accurate methods of prediction of unsafe

TABLE II

Normal Potentials for a Metal in the Film-Free State in Equilibrium with a Solution that Contains its Own Ions at Normal Activity

Equilibrium	Volt (hydrogen scale)
$Au \rightleftharpoons Au^{+++} + 3e$	+ 1.50
$Ag \rightleftharpoons Ag^{+} + e$	+ 0.7991
$2Hg \rightleftharpoons Hg_2^{++} + 2e$	+ 0.789
$Cu \rightleftharpoons Cu^{++} + 2e$	+ 0.337
$Cu \rightleftharpoons Cu^{+} + e$ (unstable)	+ 0.522
$H_2 \rightleftharpoons 2H^{+} + 2e$	0.000 (arbitrary zero)
$Pb \rightleftharpoons Pb^{++} + 2e$	− 0.126
$Sn \rightleftharpoons Sn^{++} + 2e$	− 0.136
$Ni \rightleftharpoons Ni^{++} + 2e$	− 0.250
$Cd \rightleftharpoons Cd^{++} + 2e$	− 0.403
$Fe \rightleftharpoons Fe^{++} + 2e$	− 0.440
$Zn \rightleftharpoons Zn^{++} + 2e$	− 0.763
$Al \rightleftharpoons Al^{+++} + 3e$	− 1.66 [a]
$Mg \rightleftharpoons Mg^{++} + 2e$	− 2.37 [a]

[a] These equilibria are not usually realized in aqueous solution owing to film-formation. The numbers in such cases are calculated from thermodynamic data.

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combinations of metals have been discovered. With these methods one can rapidly screen combinations of metals and eliminate from consideration those pairs that would be liable to provoke rapid dissolution of one alloy.

There are other highly peculiar situations wherein a combination of dissimilar metals may arise and thereby provoke corrosion of one metal [9]. A metal specimen may be exposed to a liquid which contains reducible compounds of a more cathodic metal. In hydrochloric acid solution, zinc dissolves far more rapidly after the addition of a platinum salt. Similarly, Frankenthal and Pickering [10] have described the breakdown of stainless steel alloys after exposure to hydrochloric acid solutions that contain platinum salts. Addition of salts of other cathodic metals such as antimony or silver may also stimulate attack. Under these conditions, the cathodic metal salts are reduced and particles of the cathodic metal are deposited on the metal surface, thereby to create numerous minute galvanic cells. It is conceivable that dissolution of dental alloys could provoke similar galvanic corrosion of stainless steel implant alloys, although the author is not aware of any reported cases. Another unusual situation is when acceleration of corrosion of the less noble metal is accompanied by acceleration of corrosion of the more noble metal or alloy. This represents galvanic corrosion accompanied with cathodic corrosion. It only occurs when the more noble metal is amphoteric such as aluminium or magnesium, or when the more noble metal undergoes hydrogen embrittlement, another unusual form of cathodic corrosion. Within the range of passsive alloys presently in use for surgical implants, these modes of cathodic corrosion would not be encountered.

It should be emphasized that corrosion currents may be generated within a single alloy which lacks homogeneity because of the presence of grain boundaries, differential grain size or orientation, differential surface treatment or surface roughness, or differential mechanical strain. These factors will not be discussed.

Corrosion Protection by Combination of Alloys

Over a century ago, Schonbein and Faraday [11] studied the rates of dissolution and mechanisms of corrosion of bimetallic combinations. They observed that for iron in contact with platinum in a solution of dilute nitric acid, the platinum provoked rapid dissolution of the iron. Whereas, in concentrated nitric acid the platinum helped to maintain resistance of the iron to dissolution. We now know that the explanation for the altered behavior of iron in concentrated nitric acid is the formation of a passive film on the surface of the iron [12]. The platinum served to maintain the integrity of the film by regulation of the potential of the

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iron within the passive range (on Fig. 4 CD). In the past, the principal liability of anodic protection was that in practice the auxillary platinum or palladium electrode could provide adequate current to maintain passivity but it could not provide adequate current to produce passivity if generalized corrosion was ever provoked by some extraneous agent (Fig. 4). Now, certain stainless steel and titanium alloys are available that require such little current for passive film formation that anodic protection can be used to provide and to maintain passivity. For use in surgical alloys perhaps the greatest asset of this method of corrosion control is that the rate of dissolution of the cathodes is not increased by coupling with the anodic material. Titanium-palladium alloys have been tested extensively [5] for corrosion resistance in body fluids and the results of the tests indicate that they should perform well in the human body.

Cathodic Protection

Cathodic protection is an electrochemical method of corrosion resistance wherein a second metal is connected to the specimen of interest and is thereby used to lower the potential that drives the corrosion process in the specimen. Reference to Figure 4 will show that adequate depression of the potential of a metal anode could produce a wholly inert specimen with no dissolution. From this point of view, this method should be of great interest to surgeons for clinical application in implant corrosion protection. Furthermore, it holds even more promise for investigations on the effect of metals on tissues in a state of no metallic dissolution. For use in surgery, the principal liability is the accompanying dissolution of the auxillary or "sacrificial" anode. Even with the use of a metal whose metallic dissolution products are shown to be nontoxic by all available tests, surgeons, would be concerned that prolonged accumulation of the auxillary anode's dissolution products might provoke some deleterious toxic response. Alternatively, instead of a sacrificial anode, a battery and an inert electrode can be used as a source of electrons to protect the specimen. For widespread use in surgery the provision and replacement of batteries would present considerable practical problems. Hence, cathodic protection does not appear to be feasible for surgical implants.

Combination of Passive Alloys

There is one other situation in which certain alloys can be used in combination without liability of rapid dissolution of either metal. It is a highly peculiar situation which depends on a unique characteristic of some passive alloys. As Hoar and Mears described [5], it is thermody-

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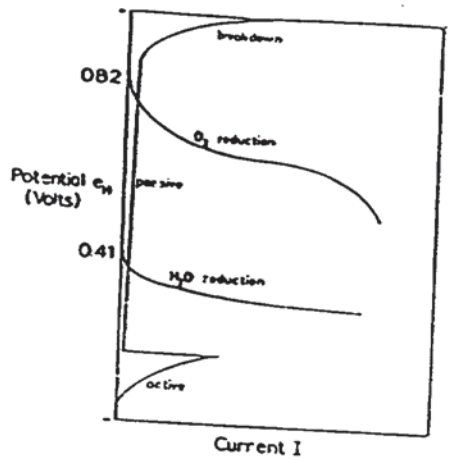

Fig. 5. Schematic polarization curve for alloys that show optimal behavior in body fluids. Such alloys show only passive dissolution in vivo. Combination of these alloys will not provoke more rapid dissolution of any constituent.

namically impossible for certain passive alloys immersed in body fluids to undergo breakdown of passivity. This criterion is met by those alloys tha conform to the polarization curve shown in Figure 5. Breakdown at high potential, with pitting and activity at low potential such as crevice corrosion, will both be avoided if the metal concerned has a breakdown potential more positive than the oxygen-reduction reversible potential and a passivation potential less positive than the water (or hydrogen ion)-reduction reversible potential. High-potential depassivation might equally be the transpassivity caused by anodic oxidation of passivating oxide to soluble products, not discussed here. At present, titanium and its alloys, and probably some materials based on zirconium, niobium, and tantalum appear to be the only alloys that can fulfill the condition in chloride media. These alloys may be combined with one another and they will continue to exhibit passive behavior. The slow rates of dissolution of all constituents of the combination will remain virtually unchanged.

One additional combination of passive alloys is of considerable practical importance in orthopedic surgery. This is the combination of one truly passive metal as defined in the previous section, with a less passive alloy, especially one that is liable to undergo crevice corrosion. From the corrosion point of view, a similar situation arises with the combination of two passive alloys that are both liable to crevice corrosion. The question is raised on the likelihood of enhanced crevice corrosion by the presence of the second material. In the past, many workers in corrosion would have suggested that the two metals should be considered as

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the two pieces of divided metal shown in Figure 2 wherein one, the truly passive metal, behaves as the cathode and the other, the less passive one, behaves as the dissolving anode so that the combination serves to accelerate the corrosion rate. In fact, for passive metals this portrayal is grossly in error. A passive metal that undergoes pitting exhibits two anodic dissolution processes that occur in parallel. Most of the metal surface shows an exceedingly slow rate of dissolution through the passive oxide film while a minute portion of the metal surface at the crevice shows rapid active dissolution. All of the metal surface apart from the minute crevice is apt to behave simultaneously as a cathode with oxygen reduction. Hence, addition of a second truly passive metal in combination with the former, merely serves to enlarge the surface of metal that shows passive dissolution of metal and cathodic reduction of oxygen. While the cathodic reaction on the truly passive metal might occur with much greater or lesser efficiency than occurs on the less passive alloy, within the range of alloys that are presently used for orthopedic surgical implants, this does not seem to be of practical significance. Hence, by combination of a titanium implant with a less inert stainless steel one, the liability and rate of crevice corrosion on the stainless steel are unlikely to be diminished but are extremely unlikely to be enhanced.

Past Experience on the Use of Dissimilar Metals in Orthopedic Surgery

Before the mid-nineteen thirties when many highly corrosive metals were used for surgical implants, numerous observations [13] were made by surgeons on the accelerated attack of one active metal such as mild steel when combined with a more noble one such as copper. Undoubtedly, these observations account for the extreme reluctance of surgeons to use mixed metals in surgery. It should be emphasized, however, that they are not comparable to the combination of presently used passive surgical alloys. Scales, Winter and Shirley [14], described large numbers of orthopedic implants after removal from human implantation. They reported the incidence of corrosion of metallic combinations of different austenitic stainless steel alloys (e.g., 18% chromium–8% nickel alloy with 18% chromium–8% nickel and 2.5% molybdenum) and of combinations of austenitic stainless steel alloys with a cobalt-chromium-molybdenum alloy. The alloys in combination did not show an enhanced incidence of corrosion compared to their behavior when used alone. Indeed, for combinations of stainless steel alloys, mutual protection seemed to be conferred by the combination. More recently, Cohen and Wulff [15], have reported observations on the corrosion of a combination of a wrought cobalt-chromium-tungsten-nickel alloy with a cast cobalt-chromium-molybdenum alloy. Crevice attack was observed on the

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former alloy but not on the latter material. Next they undertook laboratory tests in which teflon gaskets were applied to specimens of either cobalt-chromium alloy to form crevices between the metal and the tetrafluorethylene material. The specimens were immersed individually in solutions of sodium chloride. Potential-time studies and metallographic observations showed that the cobalt-chromium-tungsten-nickel alloy underwent crevice attack while the cobalt-chromium-molybdenum alloy did not undergo similar corrosion. The experiments confirm that crevice corrosion on passive metals is provoked by the presence of a crevice on a susceptible alloy and not by the presence of dissimilar passive alloys. Similar observations are required for other potentially useful combinations of dissimilar surgical alloys.

Effects of Galvanic Currents on Tissues and Cells

There has been widespread speculation on the effect of corrosion currents on tissues and cells, although few facts are available. Corrosion may alter cells in at least three ways: 1) the metallic dissolution products may affect cell metabolism; 2) corrosion may be accompanied by changes in the chemical environment of the cell such as the production of hydrogen ions or hydroxyl ions, or the evolution of a gas such as hydrogen, oxygen or chlorine, and; 3) the corrosion currents may effect cell behavior.

The first two factors are not discussed here as they are not peculiar to galvanic corrosion. At present, the effects of electric currents on cell behavior are under intense scrutiny. Observations on the effects of application of direct current to cell cultures include: induction of osteogenesis, alignment of randomly oriented collagen fibres and transformation of red cell precursor cells into fully differentiated red cells. It is possible that either deleterious or useful change in cell behavior may be induced by corrosion currents although this is unknown at present. The currents that would be produced by combinations of dissimilar passive alloys under consideration for use as implants are much smaller than the magnitude of current that is required to stimulate neuromuscular tissues. Hence, unwanted neuromuscular stimulation is unlikely to occur in vivo.

CONCLUSION

This paper attempts to show that the time honoured dogma: "thou shalt not mix the metals" is no longer of advantage for the best practice of orthopedic surgery. Admittedly, in the absence of expert knowledge of the properties of metals and alloys it is safe practice to avoid the use of dissimilar metals for surgical implantation. Knowledge has increased,

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[1] U. R. Evans, L.
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however, so that more sophisticated rules should replace this tradition. Combinations of passive alloys should be introduced into surgical practice so that materials of different mechanical properties including those in composite form, are used in conjunction with one another. Each metal would be selected for its peculiar mechanical attributes. Also, the combination could provide improved corrosion resistance for the less inert material. Electrochemical techniques are available to test combinations of passive alloys and to classify them into the following types: 1) combinations that do not appreciably alter the corrosion resistance of any consituent; 2) combinations where the presence of one alloy improves the corrosion resistance of the other alloy by anodic protection, without deterioration of its own corrosion resistance, and; 3) combinations where one alloy improves the corrosion resistance of another alloy and simultaneously provokes more rapid corrosion of itself. Such cathodic protection is unlikely to be considered useful for surgical implants. This paper does not recommend indiscriminant mixture of metals but rather it attempts to show that selected combinations of metals can be used safely with considerable advantage for all those who use surgical implants. The situation is analogous to the well-established simultaneous application of pharmacologic agents such as triple chemotherapy for tuberculosis with isoniazid, streptomycin and para aminosalycylic acid or digoxin, diuretics and hypotensive agents for severe hypertensive cardiac failure or nitrogen mustard, vincristine sulphate, procarbazine hydrochloride and prednisone for treatment of advanced Hodgkin's disease [16]. It requires a similar vigilance to avoid potentially adverse side effects just as may occur with combined chemotherapy such as the enhanced bleeding tendency when aspirin or barbituates are used with oral anticoagulants or the potentiation of monamine oxidase inhibitors by sympathomimetic agents that may result in hypertensive crises. Further observations are required to confirm whether, as in the author's opinion, the presently used alloys can be used in combination without enhanced rates of corrosion of any alloy. Some corroborative evidence will be published elsewhere [17].

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Evaluation of Couple/Crevice Corrosion by Prosthetic Alloys under *in Vivo* Conditions

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Summary

Alloys of cast Co-Cr-Mo, wrought Co-Cr-W, wrought Co-Ni-Cr-Mo (MP35N), Ti-6% Al-4% V, and graphite were incorporated in specimens which simulated both a couple and a crevice corrosion condition. These specimens were implanted in a dog for 30 months. Post-sacrifice examination showed no substantial evidence of corrosion activity on the surfaces of the metals except for a tarnish film on the titanium alloy specimens. The presence of the tarnish film is taken as some evidence of corrosion activity and this correlated with a thicker average fibrous membrane, cellular activity in and near the fibrous membrane, and some increased vascularity. These must be regarded as preliminary observations.

INTRODUCTION

It has been stated recently[1–3] that some of the corrosion-resistant alloys used in internal prostheses could be applied in composite configurations despite the proscription against the use of dissimilar metals and alloys. The existence of chemically resistant, structurally stable, high electrical resistivity films should keep corrosion currents to the level of those associated with the condition of passivity despite the existence of couple potentials. In practice a combined hazard of couple and crevice corrosion might be created at opposing interfaces by use of dissimilar passive alloys. In a preliminary evaluation[1] of the possibilities of accelerated corrosion by couple/crevice conditions in an *in vitro* experiment design, it was demonstrated that only stainless steel 316L exhibited significant accelerated corrosion response. Stainless steel is vulnerable to crevice corrosion whether or not a couple with another passive alloy exists. The cast Co-Cr, wrought Co-Cr, Ti-6% Al-4% V and the wrought Co-Ni-Cr (MP35N)

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alloys were shown not to develop corrosion pits. The present paper describes the results of a similar experimental approach adapted to *in vivo* conditions.

MATERIAL AND METHODS

Five materials were involved in selected couples: cast Co-Cr-Mo alloy (ASTM F75-67), wrought Co-Cr-W alloy (ASTM F90-68), Ti-6% Al-4% V ELI grade (ASTM B 367-69 grade CS), wrought Co-Ni-Cr-Mo alloy (Trade name MP35N), and a high-purity, petroleum-coke-derived graphite. A couple/crevice specimen was created in the following manner. Thin disks of specimen material about 12 mm diam × 3 mm thick with a 5-mm center hole were polished on one flat surface to a quality of finish appropriate for metallographic examination. These surfaces had a mirror-like quality free of pits but not necessarily free of shrinkage porosity. The polished surfaces of two materials were clamped opposite each other by means of an acrylic rivet through the center holes. By microscopic evaluation the separation between surfaces was about thirty microns, although in the practical limits of preserving flatness this must have been somewhat variable.

Four couple/crevice specimens of each of the following were prepared: cast Co-Cr-Mo/wrought Co-Cr-W; cast Co-Cr-Mo/MP35N; cast Co-Cr-Mo/graphite, and cast Co-Cr-Mo/Ti-6% Al-4% V. All sixteen specimens were implanted in the paravertebral muscles of a large dog. The dog was sacrificed 30 months later. The implants were all hosted in one animal because the primary purpose of the experiment was to look for corrosion evidences on metallic specimens in a single characteristic environment. The presence of multiple implants separated from each other could not have produced an interactive effect in the corrosion processes.

At sacrifice a block of soft tissue containing each implant was removed, fixed in 6% glutaraldehyde, and stored in 50% alcohol for 2 days until the implants were extracted. The tissue immediate to the implant was examined visually for gross changes and discoloration.

For histological examination, samples were embedded in paraffin, cut into 6-μ-thick sections, and stained with hematoxylin eosin. Six sections were obtained from each specimen.

The following features were evaluated by microscopic examination:

(a) the fibrous membrane—the thickness of this structure was

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measured using a Zeiss measuring eyepiece at four different points and the average values were calculated.

(b) the cellular pattern in the fibrous layer and surroundings, the presence of inflammatory cells, blood vessels, and polymorphonuclear cells were recorded

(c) screening for signs of degeneration, tissue necrosis, and signs of chronic inflammation.

A numerical system was used to grade the observation from 0 to 2 in increasing degree of severity.

The implants themselves were disassembled by dissolving the acrylic rivet with acetone and separating the two halves. After this process the previously polished surfaces possess a semiopaque film which disappeared after immersion in acetone overnight. Some white areas of film remained on a few specimens. These dissolved in 30% hydrogen peroxide during a 24-hr immersion; from this one may deduce that they were probably tissue ingrowths from the periphery of the crevice. The residual surfaces were examined without further treatment or preparation using a low-power stereoptic, light microscope and a scanning electron microscope (SEM) looking for pitting and other evidences of corrosion.

RESULTS

All surfaces of cast Co-Cr and wrought Co-Cr in apposition for 30 months were seen to be bright, free of tarnish films, and free of corrosion pits (as distinct from shrinkage porosity). All surfaces of cast Co-Cr and MP35N in apposition were also bright, free of tarnish films, and free of corrosion pits. The surfaces of the cast Co-Cr alloy in apposition to graphite was bright, free of tarnish and corrosion pits. The surfaces of cast Co-Cr specimens in apposition to the Ti-6% Al-4% V alloy were bright, free of tarnish and corrosion pits. However, the titanium alloy surfaces were lightly tarnished, as seen both by light optics and electron optics. The tarnish as viewed by SEM is illustrated in Figure 1.

At autopsy there were no macroscopic signs of infection or inflammation. In one sample of group I and in two samples of group II, slight rust coloration of the membrane was found (see Table I). In two samples of group IV, extensive-to-moderate rust color was found. One sample of group III showed blackening but this was attributed to the low abrasive resistance of graphite.

Microscopic examination showed a fibrous tissue layer adjacent

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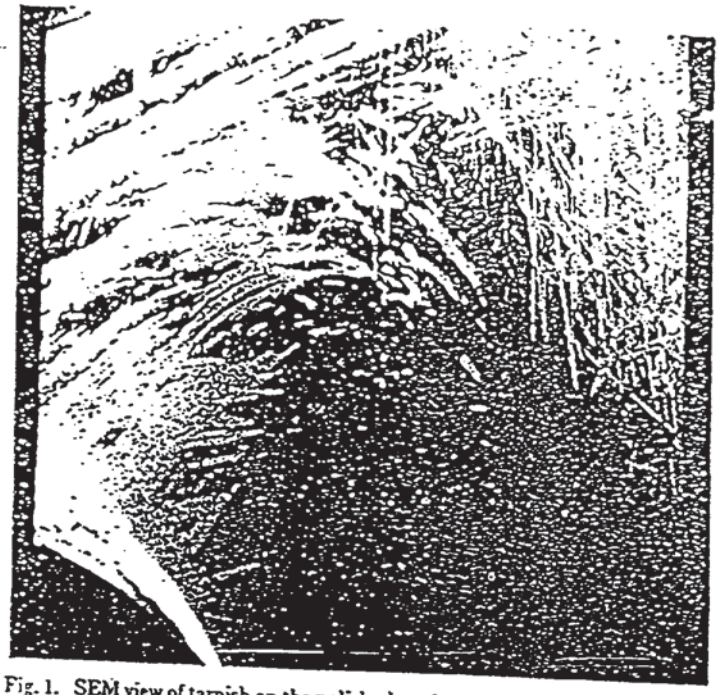

Fig. 1. SEM view of tarnish on the polished surface of a Ti-6% Al-4% V specimen. ×32.

to the implant. Thicknesses varied considerably (see Table I) with averages: 100 μ (group I), 203 μ (group II), 154 μ (group III), and 300 μ (group IV). Note that the most extensive pigmentation corresponds to the thickest fibrous tissue layer.

No signs of acute inflammation were seen in any of the samples but those of group IV did show increased vascularity. In two of these same samples of group IV, membrane cellularity was seen—a proliferation of macrophages and fibroblasts. These appearances are illustrated in Figure 2. There were no evidences of giant cells.

On examination of the organs, heart worms were found in the lungs. The lungs also gave evidence of bronchitis. There was also histological signs of hepatitis and elongated eosinophilic crystals (intranuclear inclusion bodies) in the liver. None of these indications are thought to be relevant to the generation of corrosion products.

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TABLE I
Observations on Tissue Immediate to the Implants

Group No.	Specimen No.	Macroscopic Discoloration	Thickness of Fibrous Layer Microns (Av.)	Membrane Cellularity	Inflammatory Response	Microscopic Pigmentation of Fibrous Layer
	1		50	0	0	
I Cast Co-Cr/	2		37	0	0	
wrought Co-Cr	3		126	1	0	
	4	+	120	1	0	
	5	+	178	1	1	+
II Cast Co-Cr/	6		135	0	0	+
MP35N	7	+	342	0	0	+
	8		155			
	9	+	24	0	0	
III Cast Co-Cr/	10		78	0	0	
graphite	11		148		0	
	12		148	1	1	
	13	+	360	0	2	+
IV Cast Co-Cr/	14		296	1	2	
Ti-6% Al-4% V	15		453	2	2	
	16	+	259	0	0	+

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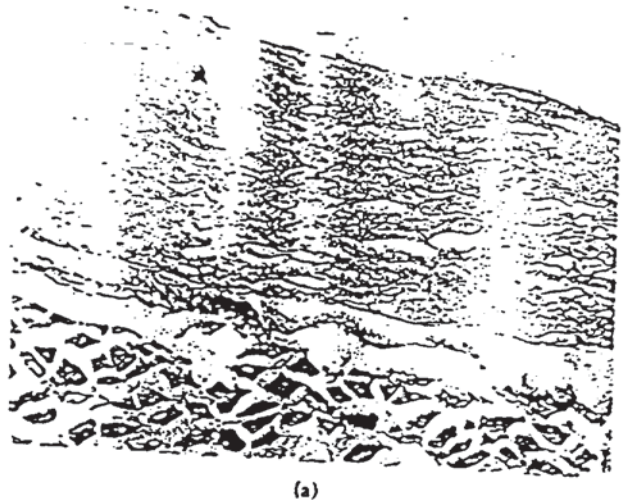

(a)

(b)

Fig. 2. (a) Normal fibrous membrane without cell invasion; (b) designated level 2 of membrane cellularity. Arrow indicates discoloration. Magnification: ×340. Specimen of tissue from group IV.

DISCUSSION AND SUMMARY

Cast cobalt-chromium, wrought cobalt-chromium alloys, and the Co-Ni-Cr-Mo (MP35N) alloy, when implanted for 30 months in the tissues of a living animal as part of certain couple/crevice configura-

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tions, showed no evidence of corrosion. These findings are in agreement with *in vitro* studies reported previously.[1]

The titanium alloy, Ti-6% Al-4% V, when coupled with the cast Co-Cr alloy, showed a tarnish film which was not observed by the *in vitro* experiments. The existence of the tarnish film, which indicates some level of corrosion activity, correlated with increased average fibrous membrane thickness, cellularity immediate to the membrane and minor indications of inflammation.

These indications suggest that a prosthetic device which is a composite of the cast Co-Cr and Ti-6% Al-4% V alloys may be inappropriate. This can only be a tentative conclusion because these experiments do not represent a full-scale biological assay with adequate reproducibility and controls. These reported observations also suggest that *in vitro* studies alone are not completely definitive.

This work was supported by the U.S. Army Medical Research and Development Command (Contract No. DADA-17-71-C-1102) and the National Institute of Arthritis, Metabolism and Digestive Diseases (Grant AM-16485).

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TRUNION TESTING
RANAWAT/BURSTEIN FEMORAL COMPONENT

(b)(4)

[redacted]

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(b)(4)

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EXHIBIT VII

7

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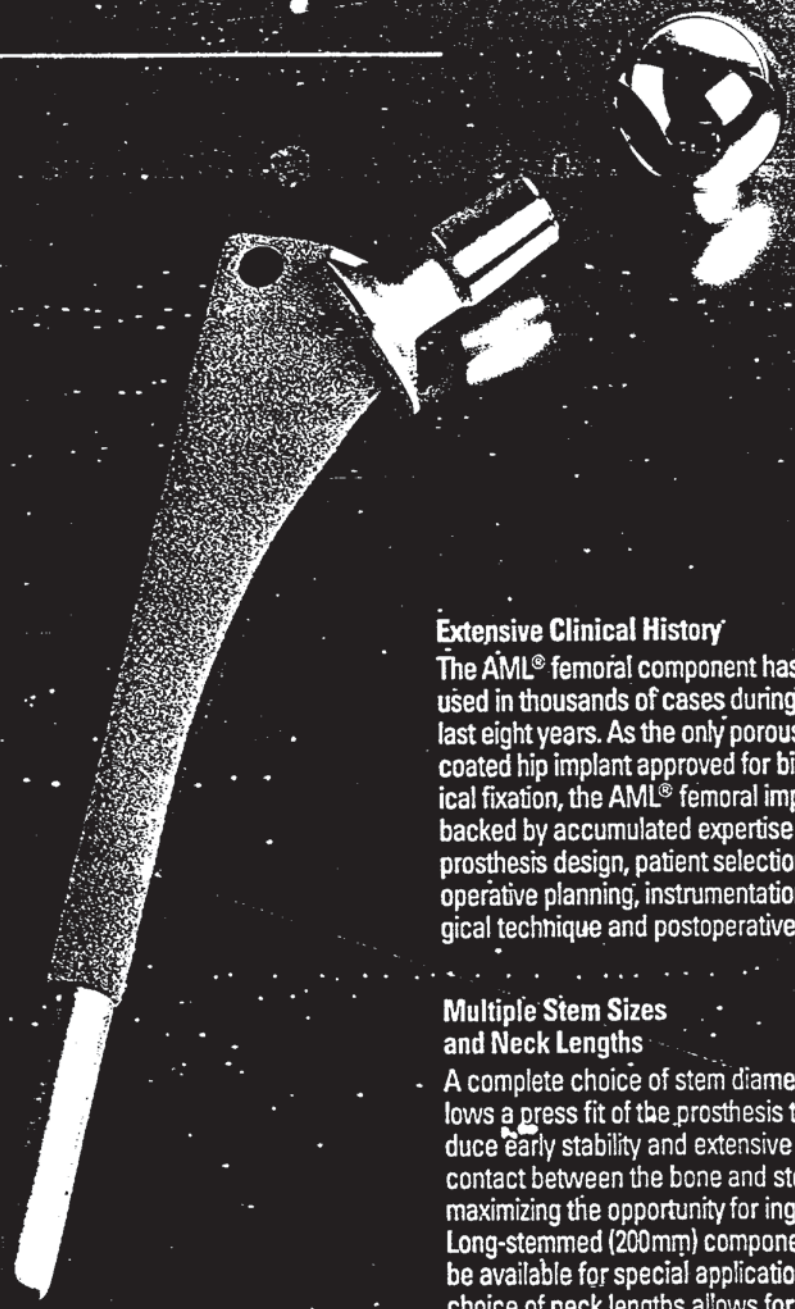
the AML® Modular Head Femoral Component

with Porocoat®

The only commercially available, porous-coated total hip for biological fixation.



Unique Design for Biological Fixation

A long, straight stem facilitates proper implant alignment, establishing uniform cancellous and cortical bone support. A proximal oval cross-section extends laterally into the intertrochanteric region to maximize cancellous bone contact and give rotational stability. The proportionally sized collar directly contacts cortical bone in the calcar region for additional stability and support. A circular cross-section distally fills the canal providing immediate stability. The AML® femoral component features the only commercially available porous coating to fall within the pore size range identified as optimal for biological fixation.

Extensive Clinical History

The AML® femoral component has been used in thousands of cases during the last eight years. As the only porous-coated hip implant approved for biological fixation, the AML® femoral implant is backed by accumulated expertise in prosthesis design, patient selection, preoperative planning, instrumentation, surgical technique and postoperative care.

Multiple Stem Sizes and Neck Lengths

A complete choice of stem diameters allows a press fit of the prosthesis to produce early stability and extensive surface contact between the bone and stem, thus maximizing the opportunity for ingrowth. Long-stemmed (200mm) components will be available for special applications. A choice of neck lengths allows for proper joint spacing and leg length adjustment.

Versatile, Cost-Efficient Modular System

A minimal inventory of modular heads and stems yields a wide selection of head/stem combinations. AML® modular heads and stems can be used with the 32mm inside diameter acetabular cup of choice. Reduced inventory limits costs without limiting size selection.

DePuy

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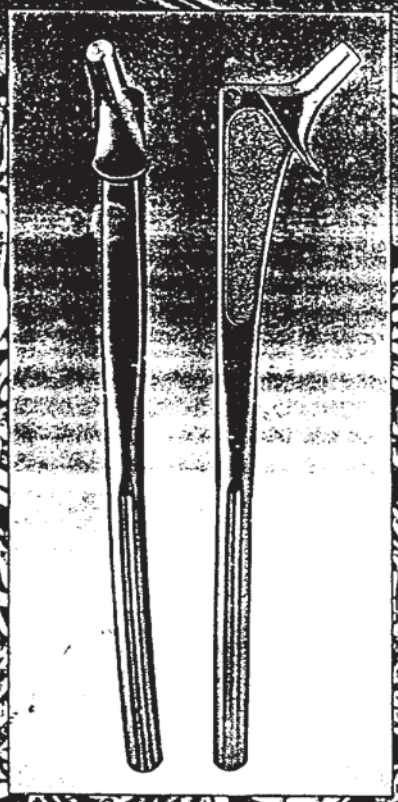
BIAS

Hip Prosthesis

A Proven Hip Prosthesis
Indicated For Use Without Bone Ce



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□ A rotational guide is inserted into the proximal portion of the prosthesis to provide antirotational stability during insertion.

□ The femoral neck has been anteverted 12 degrees to promote anatomical reconstruction.

□ A Morse-type taper provides the versatility of modular sizing with reduced inventory investments and storage requirements.

□ A medial collar provides optimal load transfer, yet allows for anterior and posterior access should removal be necessary.

■ Commercially pure titanium fiber-metal pads* provide enhanced fixation proximally.

□ Available in one-millimeter incremental sizing, the femur can be proportionally sized for optimal prosthesis-to-patient fit.

□ An anatomical, wedge-shaped proximal prosthesis duplicates the natural femur, both in the straight lateral and curved medial aspects.

□ The high-strength and outstanding biocompatibility of TIVANIUM Alloy.

□ The inclusion of an anterior bow in the intramedullary stem duplicates the natural bow of the femur and provides additional torsional stability, an important consideration when a longer stem length is required.

□ A longer, intramedullary rod-like stem provides initial stability while resisting bending forces and allows the bone itself to transmit compressive loads. Early full weight bearing.

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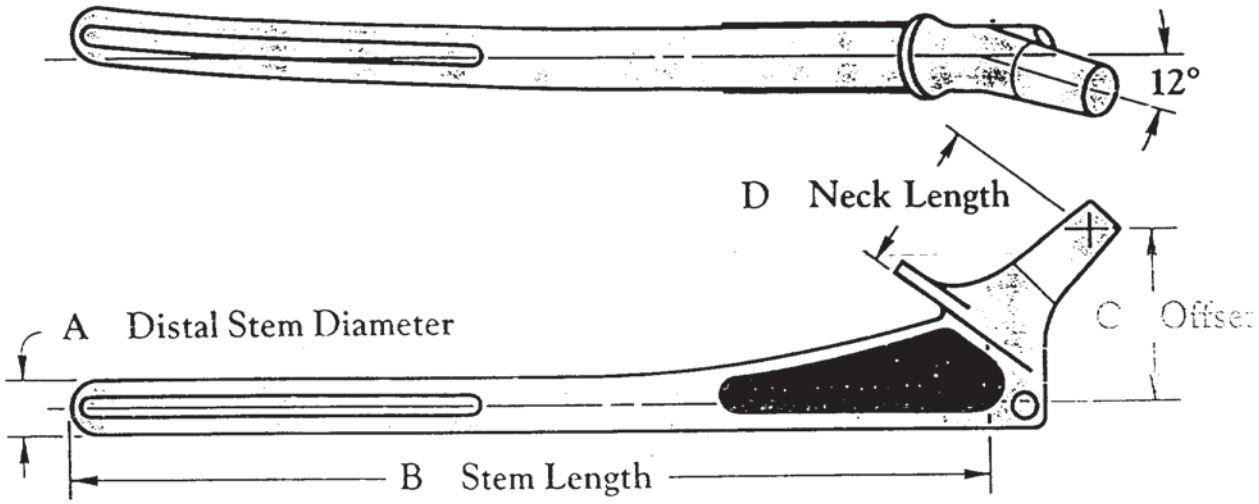
BIAS Hip Prosthesis



Product Number	Description	A Distal Stem Diameter (mm)	B Stem Length (mm)	C Offset (mm) Femoral Head Offset Prosthesis Selection Short	Medium	Long	C Offset (mm) Femoral Head Offset Prosthesis Selection Short	Medium	Long
6550-09-01† 6550-09-02†	9 mm Left 9 mm Right	9	176	35	40	45	30	37	44
6550-10-01 6550-10-02	10 mm Left 10 mm Right	10	186	35	40	45	30	37	44
6550-11-01 6550-11-02	11 mm Left 11 mm Right	11	196	35	40	45	30	37	44
6550-12-01 6550-12-02	12 mm Left 12 mm Right	12	206	35	40	45	30	37	44
6550-13-01 6550-13-02	13 mm Left 13 mm Right	13	216	35	40	45	30	37	44
6550-14-01 6550-14-02	14 mm Left 14 mm Right	14	226	35	40	45	30	37	44
6550-15-01 6550-15-02	15 mm Left 15 mm Right	15	236	35	40	45	30	37	44
6550-16-01 6550-16-02	16 mm Left 16 mm Right	16	241	40	45	50	37	44	51
6550-17-01 6550-17-02	17 mm Left 17 mm Right	17	241	40	45	50	37	44	51
6550-18-01 6550-18-02	18 mm Left 18 mm Right	18	241	40	45	50	37	44	51
6550-19-01 6550-19-02	19 mm Left 19 mm Right	19	241	40	45	50	37	44	51
6550-20-01 6550-20-02	20 mm Left 20 mm Right	20	241	40	45	50	37	44	51

†Available through Specialty Orthopaedic Products.

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WARNING AND PRECAUTIONS FOR BIOMET POROUS COATED FEMORAL HIP PROSTHESES FOR USE WITHOUT BONE CEMENT

ATTENTION OPERATING SURGEON

CAUTION: Use Biomet Femoral Components with Ceramic Modular Head Component or Metallic Modular Head Components with appropriate matching "Type I Taper" or "Type II Taper".

DESCRIPTION

Biomet Porous Coated Femoral Hip Prostheses are designed for cementless applications. Fixation is achieved through biological ingrowth into the porous surfaces located on the proximal portions of the stem. The porous surface in applied using a plasma spray technique which does not significantly alter the strength characteristics of the stem. The pore size average is 300 microns, with a range from 50 to 1,000 microns. Biomet Porous Coated Femoral Hip Prosthesis may be used with either a 28MM or 32MM Biomet Ceramic or Metallic Modular Head Component. The Porous Coated Femoral Hip Prostheses and Modular Head Components may be used with a variety of Biomet Acetabular Component designs. Porous Coated Femoral Hip Prostheses are made from Titanium 6Al 4V Alloy.

INDICATIONS

The indications for use of Biomet Porous Coated Femoral Hip Prostheses include: 1) noninflamatory 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 nonunions, femoral neck 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 of the patient to follow instructions, 3) a good nutritional state of the patient, and 4) the patient is to have reached full sketetal maturity.

CONTRAINDICATIONS

Infection, sepsis and osteomyelitis are absolute contraindications. Relative contraindications include: 1) uncooperative patients or patients with neurologic disorders who are incapable of or unwilling to follow instructions, 2) absence of adequate bone stock in the proximal femur which could compromise stability, 3) osteoporosis, 4) metabolic disorders which may impair bone formation, 5) osteomalacia, and 6) distant foci of infections which may spread to the implant site.

WARNINGS

Improper selection, placement, positioning, alignment, and fixation of the implant components may result in unusual stress conditions and a subsequent reduction in the service life of the prosthetic components by loosening, dislocation, disassociation, or wear. The surgeon is to be thoroughly familiar with the implants, instruments, and surgical procedure prior to performing surgery. For further imformation contact Biomet.

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Non-cemented application of the Biomet Porous Coated Femoral Prosthesis requires precise surgical technique and the use of specified instruments. (*See Surgical Technique*) A tight fit at the time of surgery is critical to the success of the procedure. The device must fress-fit into the prepared femoral canal and the porous surface is to be adjacent to bone. Do no use excessive force. The rasp/provisional and the porous coated stem should advance easily by tapping, using appropriate surgical instruments. If the device fails to advance as anticipated, do not apply excessive force. Forcing a rasp/provisional or a porous coated stem into the femoral canal can cause fracture of the femur. However, the porous coated stem should meet with at least some resistance. Failure to achieve a desirable tight fit with the porous surface adjacent to bone may cause or contribute to failure of the reconstruction. An adequate close or tight fit should be appraised at the time of implantation.

Bone stock of adequate quality to provide stability must be present and appraised at the time surgery.

The clinical safety and effectiveness of these devices has not been fully investigated for patients less than 40 year of age.

Accepted practices should be followed meticulously in postoperative care. Walking aids should be used during the initial stages of rehabilitation, and should continue for two to three months after surgery. The patient is to be advised of the limitations of the reconstruction and the need for protection of the implant from full weight bearing until adequate fixation and healing have occurred. Excessive physical activity and trauma have been implicated with premature failure of the reconstruction by loosening, fracture, subsidence, dislocation, disassociation, and/or wear of the components. The patient is to be cautioned to govern activities accordingly, protecting the replaced joint from unreasonable stresses.

The patient is to be warned of surgical risks, and made aware of the possible adverse effects. The patient is to be warned that the device does not replace normal healthy bone, and that the implant(s) can break or be damaged as a result of strenuous activity or trauma.

PRECAUTIONS

Specialized instruments are available to assist in the accurate implantation of the prosthetic components. In order to assist in preoperative planning, templates of various implant sizes are available.

An implant should never be reused. While it may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant.

While rare, intraoperative fracture or breaking of instruments has been reported. Instruments which have experienced extensive use or excessive force are susceptible to fracture. Biomet recommends that instruments be examined for wear and disfigurement prior to surgery.

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

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POSSIBLE ADVERSE EFFECTS

1) Peripheral neuropathies have been reported following total hoint surgery. Subclinical nerve damage occurs more frequently, possibly as a result of surgical trauma.
2) Sensitivity reactions in patients following joint replacement have been rarely reported. The significance and effects of sensitization await further clinical evaluation. Implantation of foriegn 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.
3) Dislocation and subluxation of implant components have been reported resulting from improper positioning of implant components. Muscle and fibrous tissue laxity can also contribute to these conditions.
4) Implants can loosen or migrate due to trauma or loss of fixation.
5) Infection can lead to failure of the joint replacement.
6) While rare, fatigue fracture of the implant can occur as a result of strenuous activity, malalignment, or trauma. Heavy, physically active patients with smaller size stems are at greater risk.
7) Fracture of the femur can occur while pressfitting (seating) the femoral component into the prepared femoral canal.

Intraoperative and early postoperative complications may include; 1) bone perforation or fracture, 2) femoral or acetabular fracture, 3) damage to blood vessles, 4) temporary or permanent nerve damage, 5) undesirable shortening of the limb, 6) traumatic arthrosis of the knee, 7) cardiovascular problems including venous thrombosis, pulmonary embolism, or myocardial infarction, 8) hematoma, 9) subsidence of the femoral stem, 10) delayed wound healing, and 11) infection.

Late postopertive complications can include; 1) throchanteric avulsion as a result of excess muscular tension, early weight bearing, or inadvertent intraoperative weakening, 2) trochanteric nonunion, 3) aggrivated problems of the knee or ankle of the affected limb or contralateral extremity by leg length discrepancy, too much femoral medialization or muscle deficiencies, 4) femoral fracture by trauma or excessive loading, particularly in the presence of poor bone stock, 5) bone resorption which may contribute to deteriorating fixation and loosening, 6) heterotopic bone formation, periarticular calcification, with or without impediment to joint mobility, and 7) inadequate range of motion due to improper selection and placement of components or ankylosis.

STERILITY

Prosthetic components are sterilized by exposure to a minimum dose of 2.5 Mrads of gamma irradiation. Metallic components may be resterilized using appropriate procedures for autoclaving. DO NOT resterilize Ultra High Molecular Weight Poluethylene components.

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

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Postmarket Surveillance Recommendation:

The clinical data and bench testing for the uncemented use of plasma-sprayed hips provides a reasonable assurance of the safety and effectiveness of the device. However, because the coating is relatively new, there is not much long-term data for these devices. Due to the nature of the plasma-sprayed coatings, there is a theoretical possibility of particle shedding over time, which could cause an increasing incidence of osteolysis and loosening. While these were not problems in the clinical study, with up to 4-year follow-up, there is a possibility of these problems occurring. In order to address these long-term concerns, it is necessary to obtain data, preferably in the form of postmarket surveillance. A simple survivorship analysis (i.e., the proportion of stems revised within each time period) should suffice to alert FDA to any long-term safety problems.

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