



U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (mac)

FOLDER: K053536 - 398 pages

COMPANY: ZIMMER GMBH (ZIMMERC)

PRODUCT: PROSTHESIS, HIP, SEMI-CONSTRAINED (METAL UNCEMENTED ACETABULAR COMPONENT) (KWA)

SUMMARY: Product: DUROM ACETABULAR COMPONENT AND METASUL LDH
LARGE DIAMETER HEADS

DATE REQUESTED: Jul 21, 2011

DATE PRINTED: Jul 21, 2011

Note: Printed





MAR 16 2006

Traditional 510(k) Premarket Notification

Summary of Safety and Effectiveness

Submitter Zimmer GmbH
Sulzer Allee 8
Winterthur, Switzerland CH-8404

Contact Person Laura D. Williams, RAC
Manager, Corporate Regulatory Affairs
Telephone: (574) 372-4523
Fax: (574) 372-4605

Date December 16, 2005

Trade Name *Durom*® Acetabular Component
Metasul® LDH™ Large Diameter Heads

Common Name Total hip prosthesis

Classification Name Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis

Classification Reference 21 CFR § 888.3330

Predicate Devices

- Biomet M²A Magnum System (K042037)
- Wright Metal Transcend Articular System (K021349)
- Centerpulse/Zimmer *Epsilon*™ *Metasul*® Acetabular Insert and *Metasul* Modular Femoral Head (K033634)

Device Description

The *Metasul LDH* large diameter head system consists of large diameter femoral heads, *Durom* acetabular components and neck adapters for neck length variation.

The *Metasul LDH* femoral heads are made of CoCrMo alloy, and are available in diameters ranging from 38 to 60mm. They are modular in design, and are for use with four head/neck length adaptors (-4 to +8mm), also manufactured from CoCrMo alloy. The femoral heads and neck adapters are compatible with 12/14 taper femoral stems.

The *Durom* Acetabular component is a metal monoblock CoCrMo alloy cup with a coating of titanium plasma spray. It is available in sizes from 44 to 66mm, and is intended for press-fit fixation in the acetabulum.

Intended Use

- Patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis.
- Those patients with failed previous surgery where pain, deformity, or dysfunction persists.
- Revision of previously failed hip arthroplasty.

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

Comparison to Predicate Device

The proposed device has the same intended use, has similar performance characteristics, is manufactured from similar materials using similar processes, and is similar in design to the predicate devices.

**Performance Data
(Nonclinical and/or
Clinical)**

The results of non-clinical analysis demonstrate that the device is safe and effective and substantially equivalent to the predicate device(s).



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 16 2006

Zimmer GmbH
c/o Ms. Laura D. Williams, RAC
Manager, Corporate Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K053536

Trade/Device Name: *Durom*[®] Acetabular Component and *Metasul*[®] LDH[®] Large Diameter Heads

Regulation Number: 21 CFR 888.3330

Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis

Regulatory Class: III

Product Codes: KWA

Dated: December 16, 2005

Received: December 19, 2005

Dear Ms. Williams:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

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

Sincerely yours,



for

Mark N. Melkerson
Acting Director
Division of General, Restorative and
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

K053536**Device Name:***Durom*® Acetabular Component
Metasul® *LDH*® Large Diameter Heads**Indications for Use:**

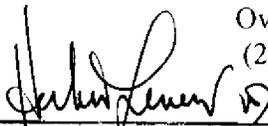
- Patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis.
- Those patients with failed previous surgery where pain, deformity, or dysfunction persists.
- Revision of previously failed hip arthroplasty.

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

Prescription Use X

(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)**(Division Sign-Off)**

(Please do not write below this line. Original to be filed on other page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE) &

**Division of General, Restorative
and Neurological Devices**

Page 1 of 1

510(k) Number K053536



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 16 2006

Zimmer GmbH
c/o Ms. Laura D. Williams, RAC
Manager, Corporate Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K053536

Trade/Device Name: *Durom*[®] Acetabular Component and *Metasul*[®] *LDH*[®] Large Diameter Heads

Regulation Number: 21 CFR 888.3330

Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis

Regulatory Class: III

Product Codes: KWA

Dated: December 16, 2005

Received: December 19, 2005

Dear Ms. Williams:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

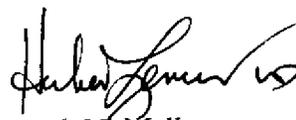
Page 2 - Ms. Laura D. Williams

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

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

Sincerely yours,



for
Mark N. Melkerson
Acting Director
Division of General, Restorative and
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

K053536

Device Name:

Durom® Acetabular Component
Metasul® LDH® Large Diameter Heads

Indications for Use:

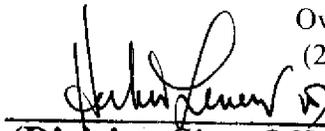
- Patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis.
- Those patients with failed previous surgery where pain, deformity, or dysfunction persists.
- Revision of previously failed hip arthroplasty.

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

Prescription Use X

(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)**(Division Sign-Off)**

(Please do not write below this line. Go to the other page if needed)

Concurrence of CDRE, Office of Device Evaluation (ODE)
**Division of General, Restorative
and Neurological Devices**

Page 1 of 1

510(k) Number K053536

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

December 19, 2005

ZIMMER GMBH
C/O ZIMMER, INC.
P.O. BOX 708
WARSAW, IN 46581
ATTN: LAURA D. WILLIAMS

510(k) Number: K053536
Received: 19-DEC-2005
Product: DUROM ACETABULAR
COMPONENT AND
METASUL LDH LARGE
DIAMETER HEADS

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

On May 21, 2004, FDA issued a Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. Please review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1567.html>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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

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

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer

64

K053536

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET	PAYMENT IDENTIFICATION NUMBER: MD6023419-956733 Write the Payment Identification number on your check.
A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:	
<ol style="list-style-type: none"> 1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent. 2. include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check. 3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (Note: In no case should payment be submitted with the application.) 4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.) 5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfer. 6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center. 	
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) ZIMMER INC P.O. Box 708 Warsaw IN 46581-0708 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) 810550219	2. CONTACT NAME Dalene Binkley 2.1 E-MAIL ADDRESS dalene.binkley@zimmer.com 2.2 TELEPHONE NUMBER (include Area code) 800-613-6131 14907 2.3 FACSIMILE (FAX) NUMBER (Include Area code) NO DATA
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/dc/mdufma)	
<u>Select an application type:</u> <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR)	3.1 <u>Select one of the types below</u> <input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:	
5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.	
<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially
6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)	
<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	
7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005) \$3,833.00	

65
 432
 FOR
 DT
 0001

CDRH Submission Cover Sheet

Date of Submission: **December 16, 2005** FDA Document Number:

Section A Type of Submission

PMA	PMA Supplement	PDP	510(k)	Meeting
<input type="checkbox"/> Original submission <input type="checkbox"/> Modular submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	<input type="checkbox"/> Regular <input type="checkbox"/> Special <input type="checkbox"/> Panel Track <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA Supplement	<input type="checkbox"/> Presubmission summary <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of intent to start clinical trials <input type="checkbox"/> Intention to submit Notice of Completion <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP <input type="checkbox"/> Report	<input checked="" type="checkbox"/> Original submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated <input type="checkbox"/> Additional Information: <input type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated	<input type="checkbox"/> Pre-IDE meeting <input type="checkbox"/> Pre-PMA meeting <input type="checkbox"/> Pre-PDP meeting <input type="checkbox"/> 180-day meeting <input type="checkbox"/> Other (specify):
IDE	Humanitarian Device Exemption	Class II Exemption	Evaluation of Automatic Class III Designation	Other Submission
<input type="checkbox"/> Original submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<input type="checkbox"/> Original submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report	<input type="checkbox"/> Original submission <input type="checkbox"/> Additional information	<input type="checkbox"/> Original submission <input type="checkbox"/> Additional information	Describe submission:

Section B Applicant or Sponsor

Company/Institution name: Zimmer GmbH		Establishment registration number: 9613350	
Division name (if applicable): N/A		Phone number (include area code): +41 52 262 6803	
Street address: Sulzer Allee 8		FAX number (include area code): +41 79 431 9485	
City: Winterthr	State/Province: N/A	Country: Switzerland	ZIP/Postal Code: CH-8404
Contact Name: Urs Volken			
Contact Title: Vice President, QA & Regulatory Affairs, Europe		Contact e-mail address: urs.volken@zimmer.com	

Section C Submission Correspondent (If Different from Above)

Company/Institution name: Zimmer, Inc.		Establishment registration number: 1822565	
Division name (if applicable): N/A		Phone number (include area code): 574-372-4523	
Street address: P.O. Box 708		FAX number (include area code): 574-372-4605	
City: Warsaw	State/Province: Indiana	Country: USA	ZIP/Postal Code: 46581-0708
Contact Name: Laura D. Williams, RAC			
Contact Title: Manager, Corporate Regulatory Affairs		Contact e-mail address: laura.williams@zimmer.com	

lwb

Section D1**Reason for Submission -- PMA, PDP, or HDE**

- | | | |
|--|--|--|
| <input type="checkbox"/> New device | <input type="checkbox"/> Change in design, component or specification: | <input type="checkbox"/> Location change: |
| <input type="checkbox"/> Withdrawal | <input type="checkbox"/> Software | <input type="checkbox"/> Manufacturer |
| <input type="checkbox"/> Additional or expanded indications | <input type="checkbox"/> Color Additive | <input type="checkbox"/> Sterilizer |
| <input type="checkbox"/> Licensing agreement | <input type="checkbox"/> Material | <input type="checkbox"/> Packager |
| | <input type="checkbox"/> Specifications | <input type="checkbox"/> Distributor |
| | <input type="checkbox"/> Other (specify below) | |
| <input type="checkbox"/> Process change: | <input type="checkbox"/> Labeling change: | <input type="checkbox"/> Report submission: |
| <input type="checkbox"/> Manufacturing | <input type="checkbox"/> Indications | <input type="checkbox"/> Annual or periodic |
| <input type="checkbox"/> Sterilization | <input type="checkbox"/> Instructions | <input type="checkbox"/> Post-approval study |
| <input type="checkbox"/> Packaging | <input type="checkbox"/> Performance Characteristics | <input type="checkbox"/> Adverse reaction |
| <input type="checkbox"/> Other (specify below) | <input type="checkbox"/> Shelf life | <input type="checkbox"/> Device defect |
| | <input type="checkbox"/> Trade name | <input type="checkbox"/> Amendment |
| <input type="checkbox"/> Reponse to FDA correspondence: | <input type="checkbox"/> Other (specify below) | |
| <input type="checkbox"/> Request for applicant hold | | <input type="checkbox"/> Change in ownership |
| <input type="checkbox"/> Request for removal of applicant hold | | <input type="checkbox"/> Change in correspondent |
| <input type="checkbox"/> Request for extension | | |
| <input type="checkbox"/> Request to remove or add manufacturing site | | |
| <input type="checkbox"/> Other reason (specify): | | |

Section D2**Reason for Submission -- IDE**

- | | | |
|--|--|--|
| <input type="checkbox"/> New device | <input type="checkbox"/> Change in: | <input type="checkbox"/> Response to FDA letter concerning: |
| <input type="checkbox"/> Addition of institution | <input type="checkbox"/> Correspondent | <input type="checkbox"/> Conditional approval |
| <input type="checkbox"/> Expansion / extension of study | <input type="checkbox"/> Design | <input type="checkbox"/> Deemed approved |
| <input type="checkbox"/> IRB certification | <input type="checkbox"/> Informed consent | <input type="checkbox"/> Deficient final report |
| <input type="checkbox"/> Request hearing | <input type="checkbox"/> Manufacturer | <input type="checkbox"/> Deficient progress report |
| <input type="checkbox"/> Request waiver | <input type="checkbox"/> Manufacturing process | <input type="checkbox"/> Deficient investigator report |
| <input type="checkbox"/> Termination of study | <input type="checkbox"/> Protocol - feasibility | <input type="checkbox"/> Disapproval |
| <input type="checkbox"/> Withdrawal of application | <input type="checkbox"/> Protocol - other | <input type="checkbox"/> Request extension of time to respond to FDA |
| <input type="checkbox"/> Unanticipated adverse effect | <input type="checkbox"/> Sponsor | <input type="checkbox"/> Request meeting |
| <input type="checkbox"/> Notification of emergency use | | |
| <input type="checkbox"/> Compassionate use request | <input type="checkbox"/> Report submission: | |
| <input type="checkbox"/> Treatment IDE | <input type="checkbox"/> Current investigator | |
| <input type="checkbox"/> Continuing availability request | <input type="checkbox"/> Annual progress | |
| | <input type="checkbox"/> Site waiver limit reached | |
| | <input type="checkbox"/> Final | |
| <input type="checkbox"/> Other reason (specify): | | |

Section D3**Reason for Submission -- 510(k)**

- | | | |
|---|---|--|
| <input checked="" type="checkbox"/> New device | <input type="checkbox"/> Change in technology | <input type="checkbox"/> Change in materials |
| <input type="checkbox"/> Additional or expanded indications | <input type="checkbox"/> Change in design | <input type="checkbox"/> Change in manufacturing process |
| <input type="checkbox"/> Other reason (specify): | | |

67

Section E Additional Information on 510(k) Submissions					
Product codes of devices to which substantial equivalence is claimed:					Summary of , or statement concerning safety and effectiveness data: <input checked="" type="checkbox"/> 510(k) summary attached <input type="checkbox"/> 510(k) statement
1	KWA	2		4	
5		6		8	
Information on devices to which substantial equivalence is claimed:					
510(k) Number	Trade or proprietary or model name				Manufacturer
1	K042037	1 M ² A Magnum System			1 Biomet
2	K021349	2 Metal Transcend Articular System			2 Wright Medical
3	K033634	3 Epsilon™ Metasul® Acetabular Insert and Metasul Modular Femoral Head			3 Centerpulse (Zimmer)
4		4			4
5		5			5
6		6			6
Section F Product Information – Applicable to All Applications					
Common or usual name or classification name:					
Trade or proprietary or model name					Model number
1	Metasul® LDH® Large Diameter Heads				1 01.00181 series
2	Durom® Acetabular Component				2 01.00214 series
3					3
4					4
5					5
6					6
FDA document numbers of all prior related submissions (regardless of outcome):					
1	2	3	4	5	6
7	8	9	10	11	12
Data included in submission: <input checked="" type="checkbox"/> Laboratory testing <input type="checkbox"/> Animal trials <input type="checkbox"/> Human trials					

Section G Product Classification – Applicable to All Applications		
Product code: KWA	C.F.R. Section 888.3330	Device class: <input type="checkbox"/> Class I <input type="checkbox"/> Class II <input checked="" type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification panel: Orthopedics/87		
Indications (from labeling):		
<ul style="list-style-type: none"> • Patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IID), e.g., rheumatoid arthritis. • Those patients with failed previous surgery where pain, deformity, or dysfunction persists. • Revision of previously failed hip arthroplasty. 		
Total hip replacements may be considered for younger patients if any unequivocal indication outweighs the risks associated with the age of the patient and modified demands regarding activity and hip joint loading are assured. This includes severely crippled patients with multiple joint involvement, for whom an immediate need of hip mobility leads to an expectation of significant improvement in the quality of their lives.		

68

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.

FDA Document Number:

Section H Manufacturing/Packaging/Sterilization Sites Relating to a Submission

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment registration number: 9613350		<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer		<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager/Relabeler	
Company/Institution name: Zimmer GmbH							
Division name (if applicable): N/A				Phone number (include area code): +41 52 262 6803			
Street address: Sulzer Allee 8				FAX number (include area code): +41 79 431 9485			
City: Winterthur		State/Province: N/A		Country: Switzerland		ZIP/Postal Code: CH-8404	
Contact name: Urs Volken							
Contact Title: Vice President, QA and Regulatory Affairs, Europe				Contact e-mail address: urs.volken@zimmer.com			
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment registration number: 8043792		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer		<input checked="" type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager/relabeler	
Company/Institution name: Studer AG/Werk Hard							
Division name (if applicable): N/A				Phone number (include area code): +41 62 188 9060			
Street address: Hogenweidstrasse 2				FAX number (include area code): +41 62 188 9070			
City: Daniken		State/Province:		Country: Switzerland		ZIP/Postal Code: 4658	
Contact name: Mr. Conrad Gunthard							
Contact Title:				Contact e-mail address:			

69

Traditional 510(k) Premarket Notification

Table of Contents

Cover Letter	10
Submission Title Page	11
Truthful and Accurate Statement	12
Device Name	12
Section 514 Compliance	12
Summary of Safety and Effectiveness	12
Device Description	12
Overview	12
Component Design	13
Metasul LDH Large Diameter Head and Head/Neck Adaptor	14
Durom Acetabular Component	14
Compatible Femoral Stems	16
Indications for Use	16
Predicate Device(s)	16
Substantial Equivalence Comparison	16
Catalog Numbers	17
Engineering Drawings/Dimensions	17
Materials	17
Method of Manufacturing	18

Traditional 510(k) Premarket Notification

Table of Contents

Packaging	18
Labeling	18
Sterilization	18
Color Additives	19
Software	19
Pyrogenicity	19
Latex	19
Performance Testing	20
Testing of Metallic Plasma Sprayed Coating	20
Compatibility of Metasul LDH Femoral Heads with Zimmer-Warsaw 12/14 Taper Stems	21
Experimental Investigation of the Connection Strength of the Ball Head Adapter	21
In-Vitro Friction and Wear Characteristics of Large Diameter Metal-on-Metal Articulations	21
Class III Certification and Summary	26
Exhibit A -- Truthful & Accurate Statement	27
Exhibit B -- Summary of Safety & Effectiveness	28
Exhibit C -- Compatible Femoral Stems	30
Exhibit D -- Indications for Use Enclosure	33
Exhibit E -- Predicate Device Information	34
K042037 -- Biomet M2A Magnum System	34

Traditional 510(k) Premarket Notification

Table of Contents

Promotional Material	38
K021349 -- Wright Metal Transcend System	51
Promotional Material	58
K033634 -- Centerpulse/Zimmer Epsilon Metasul System	85
Exhibit F -- Substantial Equivalence Comparison	90
Exhibit G -- Catalog Numbers	93
Exhibit H -- Engineering Drawings	95
Exhibit I -- Manufacturing Information	112
Durom Cup Manufacturing Flowchart	112
LDH Manufacturing Flowchart	113
Taper Adaptor Manufacturing Flowchart	114
Surface Roughness Inspection Specification	115
Exhibit J -- Packaging & Labeling	130
Package Inserts	130
Taper Adaptor	130
Durom Cup	137
LDH	145
Labels	150
Taper Adaptor	150
Durom Cup	151

Traditional 510(k) Premarket Notification

Table of Contents

LDH	152
Packaging & Sterilization Information	153
Draft Surgical Technique	158
Exhibit K -- Performance Testing	178
Morphological Properties of Ti-VPS Coating	178
Mechanical Properties of Ti-VPS Coating	193
Experimental Investigation of the Connection Strength of the Ball Head Adapter	214
Compatibility of Metasul LDH Femoral Heads with Zimmer Warsaw 12/14 Taper Stems	224
Durom Acetabular Component -- Stiffness Evaluation	233
In-Vitro Friction and Wear Characteristics of Large Diameter Metal-on-Metal Articulations	239
Exhibit L -- Class III Certification & Summary	255



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

December 16, 2005

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

Dear Sir or Madam:

Subject: Traditional 510(k) Premarket Notification – *Durom*® Acetabular Component and
Metasul® *LDH*™ Large Diameter Heads

As required by Section 510(k) of the Federal Food, Drug and Cosmetic Act, as amended by the Medical Device Amendments of 1976, the Safe Medical Devices Act of 1990, FDA Modernization Act of 1997 (FDAMA) and in accordance with Title 21 of the Code of Federal Regulations (CFR) Part 807, subpart E, the above noted premarket notification is hereby submitted to the Food and Drug Administration (FDA). As required by 21 CFR 807.90(c), this document is submitted in duplicate. A CD-ROM with identical content to the paper submission is also included for your convenience.

These devices have not been previously submitted to FDA for identical or different indications, are not currently being reviewed for different indications by the same or different branch within ODE, and have not been previously cleared by FDA for different indications.

If you require any additional information or have any questions, please contact me by telephone at (574) 372-4523, by e-mail at laura.williams@zimmer.com, or by fax at (574) 372-4605.

Sincerely,

Laura D. Williams, RAC
Manager, Corporate Regulatory Affairs

ldw
Enclosure

74

0010

Durom® and Metasul® LDH™ Large Diameter Heads

Traditional 510(k) Premarket Notification



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

75

0011

Truthful and Accurate Statement

The Truthful and Accurate Statement has been included in [Exhibit A](#).

Device Name

Durom® Acetabular Component
Metasul® LDH™ Large Diameter Heads

Section 514 Compliance

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

Summary of Safety and Effectiveness

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

Device Description

Overview

The *Metasul*® LDH™ Large Diameter Head System is intended to replace a trauma- or disease-damaged natural hip joint in total hip arthroplasty. It is intended to relieve pain, restore joint function, and replicate the natural joint anatomy while providing greater range of motion (ROM) than conventional total hip arthroplasty systems. The *Metasul* LDH System consists of a *Metasul* large diameter femoral head, a *Durom*® acetabular component and a neck adaptor (Figure 1).

The *Metasul* LDH System is designed to reduce the potential for postoperative impingement and dislocation. The large femoral head coupled with the reduced-hemisphere of the *Durom* cup naturally increases range of motion. By maximizing ROM and increasing the distance that must be overcome prior to dislocation, large diameter femoral head systems have been shown to increase the stability and decrease impingement of the replaced hip joint.^{1,2,3,4,5,6}

Like the predicates, the metal *Durom* acetabular component articulates with the *Metasul* femoral head, resulting in a metal-on-metal articulation. Metal-on-metal articulation, commonly utilized for total hip replacement since the early 1950s, has been shown in the literature to offer several benefits over conventional metal-on-polyethylene bearings, including reduced wear⁷. This results in a decreased likelihood of prosthesis failure due to third-body wear, a type of abrasive wear which occurs when wear particles (bone, polyethylene, metal, etc.) are present in the articular surfaces. It has also been reported that metal-on metal articulation with large diameter heads may produce decreased wear rates.⁸

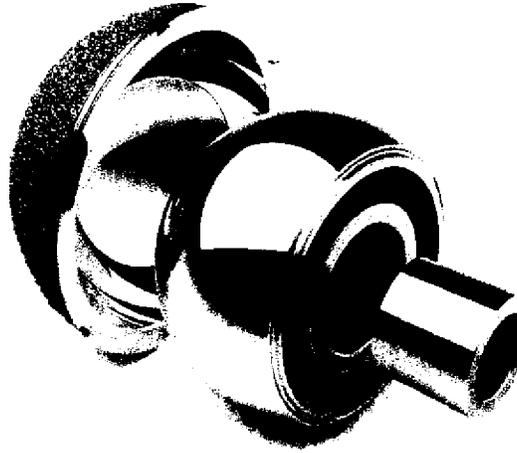


Figure 1: *Metasul LDH* and *Durom* Acetabular Cup System

Component Design

The components of the *Metasul LDH* System have been designed for optimum wear performance.

- **Material**

Chemical composition and material processing have a significant impact on the wear performance of metal-on-metal bearings. The articulating surfaces of the *LDH* femoral heads and the *Durom* acetabular cup are wrought, high-carbon alloys, which are recognized as having better wear resistance than lower-carbon alloys.⁹

- **Sphericity & Surface Finish**

Sphericity and surface roughness are also parameters which influence the wear behavior of metal-on-metal bearings. A high degree of sphericity in metal-on-metal articulation results in uniform clearance between the head and cup, while low surface roughness minimizes frictional torque and improves lubrication, resulting in lower wear.⁷ The *LDH* femoral head is precision-manufactured to tightly-controlled sphericity ($<10\mu\text{m}$) and surface finish ($R_a \leq 0.006\mu\text{m}$) specifications to minimize wear. An inspection specification (AAU Q.48.020 B) listing the maximum allowable surface roughness for femoral heads has been included in Exhibit I.

- **Diametral Clearance**

The clearance between the head and the cup – also a key parameter in metal-on-metal articulation – has been carefully chosen based on wear simulator testing. It has been shown that decreasing diametral clearance results in reduced contact stresses and wear; however, the clearance must be adequate to allow lubrication and avoid clamping – a condition in which equatorial loading of the head occurs as a result of deformation of the acetabular component. The diametral clearance between the *LDH* femoral heads and the *Durom* cup is size-dependent – the larger diameter bearing surfaces have larger clearances – and ranges from 120 to 250 microns.

Metasul LDH Large Diameter Head and Head/Neck Adaptor

The *Metasul LDH* large diameter head is modular (two-piece) in design, and consists of a large diameter femoral head and a head/neck adaptor. The head is manufactured from CoCrMo alloy (*Protasul*® 21 WF), and has an internal 18/20 taper which mates with the head/neck adaptor.

The head/neck adaptor is also manufactured from CoCrMo alloy (*Protasul*-20), and is available in four sizes to allow neck length variation from -4 to +8mm (see Figure 2). The inner taper of the head/neck adaptor is a standard 12/14 taper, and mates with any *Zimmer* femoral stem which incorporates a 12/14 taper (see [Exhibit C](#)).

The *Metasul LDH* head is an extended hemisphere which, in combination with the *Durom* acetabular component, allows a higher range of motion than smaller femoral heads. The large diameter head is available in 12 sizes with outer diameters (OD) ranging from 38 to 60mm. Head sizes 38mm to 48mm have a solid construction, while sizes 50mm to 60mm are partially hollowed out to reduce implant weight.

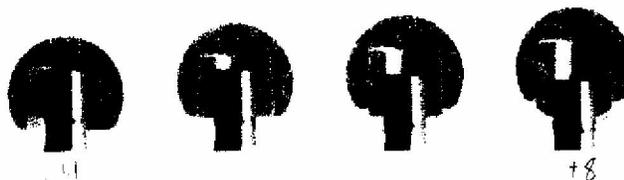


Figure 2. Head/Neck Adaptors

Durom Acetabular Component

Like the natural acetabulum, the *Durom* acetabular component is a reduced (165°) hemisphere, which promotes maximum range of motion and preservation of natural acetabular bone stock. It is monoblock in design – fabricated from a single piece of metal – and is available in 12 sizes, ranging from 44 to 66mm OD. The wall thickness of the acetabular component is

4mm for all sizes. This thickness allows for minimal bone removal while maintaining adequate implant strength.

The acetabular component is a high-carbon CoCrMo alloy (*Protasul 21 WF*) monoblock cup with a Titanium Vacuum Plasma Sprayed (*Porolock™ Ti VPS*) coating on the outer surface (Figure 3), ~~for biologic fixation~~. The articular surface is highly-polished for minimum wear, with a maximum surface roughness of .006 microns.

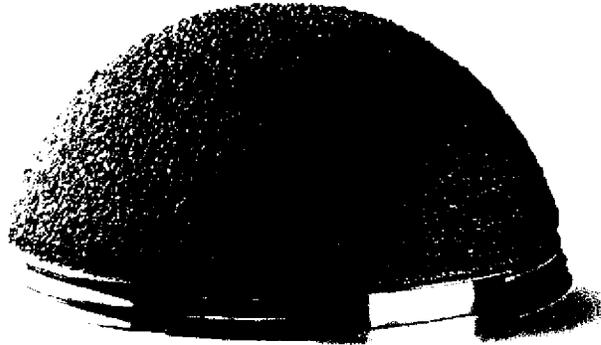


Figure 3: *Durom* acetabular component with Titanium VPS coating

The *Durom* acetabular component was designed to be implanted without cement. Primary fixation of the acetabular component is achieved via a 2mm press-fit, circumferential fins and high surface roughness. The surface roughness of the Ti VPS coating is 35 -50 microns, and the fins have a radial oversize of 0.5mm. Long-term secondary fixation is achieved by bone in-growth into the *Porolock Ti VPS porous coating* on the outer surface of the cup.

1. Smith, Thomas M et al, Metal-on-Metal Total Hip Arthroplasty with Large Heads May Prevent Early Dislocation. *Clin Orthop and Rel Res* Dec 2005; 441:137-142.
2. Crowninshield, Roy D et al, Biomechanics of Large Femoral Heads: What They Do and Don't Do. *Clinical Orth Rel Res* Dec 2004; 429:102-107
3. Cuckler, John M et al, Large versus small femoral heads in metal-on-metal total hip arthroplasty. *J Arth Dec* 2004; 19(8): 41-43.
4. Bader, R et al. The influence of head and neck geometry on stability of total hip replacement: a mechanical test study. *Acta Orthop Scand* Aug 2004; 75(4): 415-421
5. Beaulé PE et al., Jumbo femoral head for the treatment of recurrent dislocation following total hip replacement. *J Bone Joint Surg Am*, 2002 Feb; 84-A(2): 256-263
6. Amstutz, Harlan C et al, Prevention and Treatment of Dislocation after Total Hip Replacement using Large Diameter Balls. *Clin Orthop and Rel Res* Dec 2004; 429:108-116.
7. Chan, Frank W et al, Wear and Lubrication of Metal-on-Metal Hip Implants. *Clin Orthop* 1999; 369:10-24.
8. Smith, SL et al, The effect of femoral head diameter upon lubrication and wear of metal-on-metal total hip replacements. *Proc Instn Mech Engrs* 215(H): 161-170.
9. Tipper, JL et al, Quantitative analysis of the wear and wear debris from low and high carbon content cobalt chrome alloy used in metal on metal hip replacements. *J Mat Sci Mat Med* 1999; 10(6):353-362

Compatible Femoral Stems

The *Metasul LDH* femoral heads and neck adaptors are designed for use with any *Zimmer 12/14* taper femoral stem. A list of compatible femoral stems is included in [Exhibit C](#).

Indications for Use

See [Exhibit D](#) for the Indications for Use.

Predicate Device(s)

The predicates for this device are:

- Biomet M²A Magnum System, [K042037](#)
- Wright Metal Transcend System, [K021349](#)
- Centerpulse (Zimmer) *Epsilon Metasul* System, [K033634](#)

Predicate device information (clearance letters, promotional information) is presented in [Exhibit E](#).

Substantial Equivalence Comparison

See [Exhibit F](#) for a comparison table between the proposed device and the predicates. Information for competitive predicates has been taken from publicly available materials, including promotional material and 510(k) Summaries. The information presented demonstrates that the device has the same intended use and the same or similar technological characteristics as the predicates. Further, [performance testing](#) demonstrated that any minor technological differences do not raise new questions of safety and/or efficacy ([Exhibit K](#)).

- **Indications for Use**
The Indications for Use are the same as the predicates.
- **Sterility**
The proposed device, as the predicates, will be sold presterile.
- **Fixation Method (Acetabulum)**
The *Durom* cup is intended for press-fit fixation, as are the predicates.
- **Clearance**
The diametral clearance for the proposed device is within the range of the predicates.
- **Range of Motion**
The Range of Motion for the proposed device is similar to the predicates. The proposed device offers a slightly higher maximum ROM (168°) than the

predicates (167°). This difference does not raise new questions of safety or efficacy.

- **Acetabular Design Features**

The *Durom* acetabulum is equivalent to the predicates in design. The *Durom* cup is a metal monoblock design, as are two of the predicates. The range of sizes offered is the same as the Biomet predicate. The proposed *Durom* device is porous coated, as are the predicates. The materials of construction for the predicates and the proposed *Durom* device include CoCrMo alloy with titanium coating.

- **Femoral Head Design Features**

The fundamental design principles of the modular *LDH* femoral head are the same as the predicates. The Biomet predicate features a head and taper adapter for neck length adjustment, as does the proposed device. The range of diameters for the proposed device is within the range of those offered by the predicates. The proposed device connects to the femoral stem via a 12/14 taper, as do the predicates. The sphericity and surface finish are controlled to the same specifications as the Centerpulse (now Zimmer) predicate.

Catalog Numbers

All catalog numbers for the proposed device are listed in Exhibit G.

Engineering Drawings/Dimensions

Representative engineering drawings for the proposed device are included in Exhibit H.

Materials

The *Metasul LDH* System components are manufactured from materials with successful clinical histories of usage for orthopedic implant applications. Like the predicates, the material used for the metal-on-metal articulation is a high-carbon Cobalt-Chromium-Molybdenum (CoCrMo) Alloy. High-carbon alloys are generally considered to have better wear resistance when compared to lower-carbon alloys for metal-on-metal articulation.

Like the predicate *Epsilon Metasul* device (K033634), the articular surface of the *Durom* acetabular component is manufactured from *Protasul*®-21WF, a high-carbon CoCrMo alloy conforming to ISO 5832-12. The outer surface of the cup is porous-coated with titanium plasma spray (*Porolock* Ti VPS, commercially pure titanium) using an advanced vacuum plasma spray technology.

The large diameter femoral heads are also manufactured from *Protasul-21 WF* – the same material used for the predicate *Metasul femoral* heads cleared under K033634.

The head/neck adaptors are manufactured from *Protasul-20*, also a CoCrMo alloy conforming to ISO 5832-12. *Protasul-20* is currently used for other commercially available total hip arthroplasty components (K040947, *Durasul® Bipolar Shell*, cleared August 27, 2004).

The biocompatibility of CoCrMo alloys is well established through a long history of usage for orthopedic implant applications. *Protasul-20* and *Protasul 21WF* are both currently used in the manufacture of legally marketed Zimmer total hip components. The *Durom* cup is manufactured from *Protasul 21 WF* – identical the material used for the predicate Centerpulse (Zimmer) device – with the addition of a commercially pure Ti-VPS coating. Biocompatibility testing (short-term toxicity) for commercially pure titanium was conducted per AAMI/ANSI/ISO 10993-1 and is on file at Zimmer.

Method of Manufacturing

Manufacturing flowcharts for the implantable components are included in Exhibit I.

Packaging

A comprehensive description of the sterile packaging and packaging materials for these devices is located in Exhibit J.

Labeling

Sample labeling for each of the components is presented in Exhibit J. Also included is a draft surgical technique.

Sterilization

The subject devices are provided pre-sterile by gamma irradiation, as are the predicate devices.

Sterilization Method

Gamma Irradiation (Cobalt 60) at a contract sterilizer

Absorbed Radiation Dose

Minimum to maximum dose range is 25 - 40 kGy

Sterility Assurance Level

SAL greater than or equal to 10^{-6}

Sterilization Validation Method

The minimum sterilization dose was verified (method 1, dose setting validation) and the gamma radiation processing and dose mapping were conducted using ANSI/AAMI/ISO 11137-1994, "Sterilization of health care products – Requirements for validation and routine control - Radiation Sterilization."

Resterilization

Resterilization information is included in the package inserts provided with the Durom cups and Metasul femoral heads. These package inserts are included in Exhibit J.

AAMI TIR 12 was used as the reference document for steam, ethylene oxide, and STERRAD gas plasma resterilization studies. An SAL greater than or equal to 10^{-6} was verified for each.

Color Additives

This device does not have any color additives. No additional biocompatibility testing is required.

Software

This is an orthopaedic implant and has no associated software.

Pyrogenicity

This device is not labeled as nonpyrogenic. Per USP XXVII, requirements for specified endotoxin levels do not apply to orthopaedic implants.

Latex

There is no natural latex rubber in this product or its packaging.

Performance Testing

The following performance testing was conducted and is submitted in support of this product:

Testing of Metallic Plasma Sprayed Coating

- Mechanical Properties of Ti-VPS Coating on US Durom Cup (ZPR WI 0043 05), in accordance with FDA's *Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements*, dated February 2, 2000.

The results, which demonstrate the coating is safe and effective, are as follows:

- The static tensile strength is (b)(4)
- The static shear strength is (b)(4)
- The estimated fatigue shear strength is (b)(4)
- A cumulative mass loss of (b)(4) was observed

A complete test report is included in Exhibit K.

- Morphological Properties of Ti-VPS Coating on US Durom Cup (ZRR WI 0040 05) in accordance with FDA's *Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements*, dated February 2, 2000.

The results, which demonstrate that the coating is safe and effective, are as follows:

- Average surface roughness R_z of the coating is (b)(4)
- The average coating thickness is (b)(4)
- The average coating porosity is (b)(4)
- The average pore size is (b)(4)
- SEM pictures were taken and confirm the uniform and rough appearance of the surface
- The chemical composition of the coating powders is corresponds to ISO 5832-2 and ASTM F67 grade 4 commercially pure titanium (cp-Ti).
- The chemical composition of the coating was verified by EDX analysis to be pure Titanium

A complete test report is included in Exhibit K.

Compatibility of Metasul LDH Femoral Heads with Zimmer-Warsaw 12/14 Taper Stems

Metasul LDH large diameter femoral heads were mated with *Zimmer-Warsaw* 12/14 taper femoral hip stems to evaluate anatomic fatigue performance, post-fatigue interface distraction strength, and fretting fatigue characteristics.

All samples completed 10M fatigue cycles with no fractures at (b)(4) peak loading. The average distraction force of the head and head/neck adaptor from the stem was (b)(4). No fretting debris was observed. This test demonstrates that the *Metasul LDH* femoral heads and head/neck adaptors are compatible with *Zimmer-Warsaw* 12/14 taper femoral stems.

A complete test report (TM1488.05) is included in Exhibit K.

Experimental Investigation of the Connection Strength of the Ball Head Adapter

This testing was conducted to investigate the strength of the connection between the femoral head and the head/neck adaptor. The pull-off and torque-off values were compared to those for the head/stem connection of the legally marketed predicate (K033634), and were found to be acceptable.

A complete test report (BM1160R) is included in Exhibit K.

In-Vitro Friction and Wear Characteristics of Large Diameter Metal-on-Metal Articulations

In-vitro testing was conducted to demonstrate that the technological characteristics of the *Metasul LDH* system do not affect safety and effectiveness as compared to the predicate devices.

The clearance effect on wear of 38 – 56 mm metal-on-metal articulations was evaluated using two existing (b)(4) designs and a *Durom* prototype. The *Durom* prototype cup had a CoCr wall thickness of (b)(4) mm. The CoCr wall thickness of (b)(4) respectively, was thinner than the *Durom* prototype. Hence, a worst case scenario regarding the potential cup deformation interfering with clearance was included in this study, although the combination of Wagner and Artek cups with titanium shells might have improved the overall rigidity of the construct to some extent. In the wear study, diametral clearances from (b)(4) were tested on an AMTI (Advanced Mechanical Technology Inc., Watertown, MA) hip simulator for 5 million cycles for 38 mm, 50 mm, 54 mm and 56 mm components. The wear results are shown in Figure 2 below. For all clearances and diameters evaluated, a

running-in wear was observed. After the running-in wear, no measurable wear was observed. There was good correlation (b)(4) between the clearance and the amount of running-in wear. In addition, there was good correlation (b)(4) between the clearance and the number of cycles required to reach the steady-state wear, i.e., lower clearances required less cycles to reach steady-state wear. In contrast, neither the diameter nor the cup thickness appeared to have an influence on wear. These wear results suggested that clearance had the dominant effect on wear, i.e., a lower clearance resulted in lower wear.

Figure 3 shows the wear simulator results compared to the data from existing *Metasul* retrievals (K033634). The comparison suggested that a diametral clearance of less than (b)(4) was desirable.

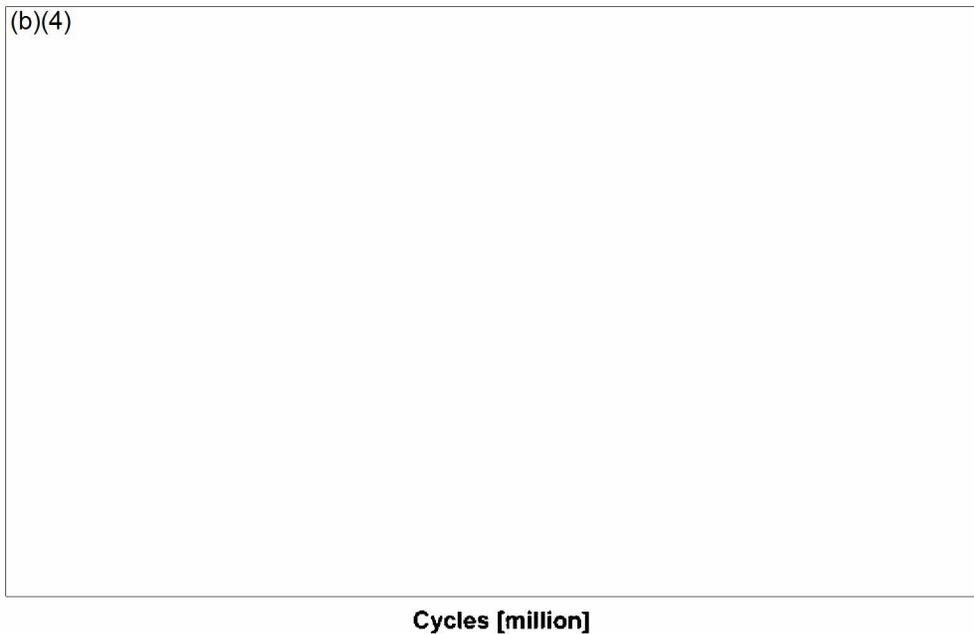


Figure 2: Linear wear results of the AMTI hip simulator testing



Time (year)

Figure 3: Wear comparison between large diameter metal-on-metal in-vitro data and Metasul retrievals (ZRR by Shen)

Clinical Retrievals of (b)(4)



found that a lower clearance resulted in less linear wear in the first year in-vivo, presumably still in running-in wear phase while under sub-optimal clinical conditions (Figure 4). These results supported the findings from the AMTI hip simulator testing.

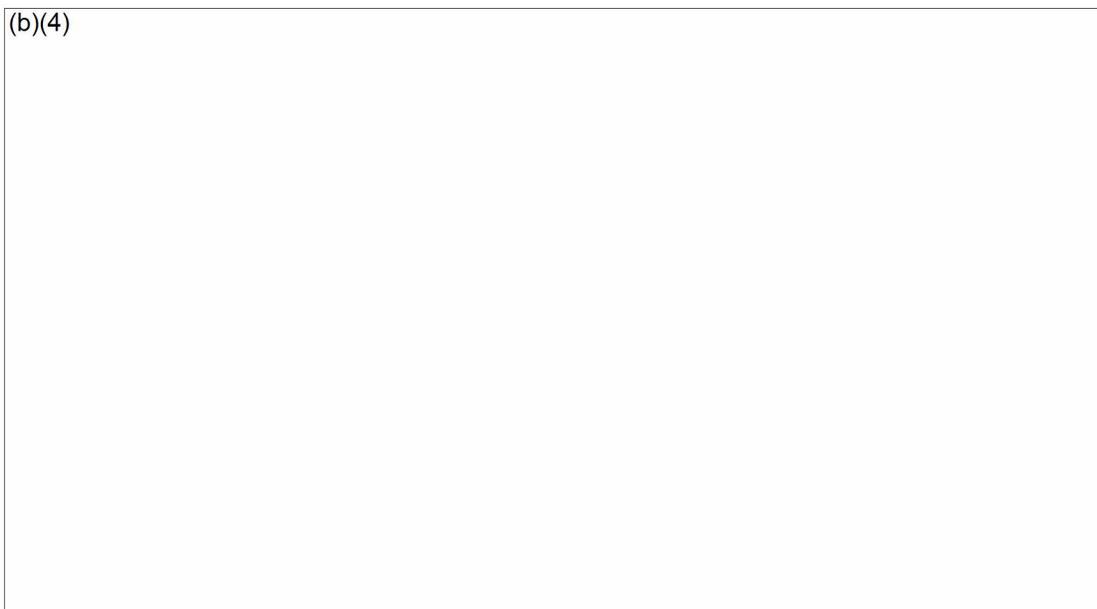
**Clearance [μm]**

Figure 4: Linear wear rate of 5 retrieved (b)(4) components (9 – 12 months in-vivo)

Design Improvement

Following the (b)(4) hip wear simulation and (b)(4) results; a lower clearance range was determined necessary, and the following design modifications were made to the *Durom* prototype:

- The manufacturing technique has since improved the sphericity of the femoral heads from (b)(4) down to 10 μm . An improvement in the sphericity will improve wear performance; therefore, the tested prototype represents a worst case component.
- The CoCr wall thickness of the *Durom* cup was increased by 1 mm to further reduce the cup deformation. With these changes, the new clearance range could be reduced to (b)(4).
- The coating on the outer surface of the *Durom* cup was modified to comply with the requirements in the U.S. FDA Guidance document.
- Additionally, two diameters, 58 mm and 60 mm, were included in the final design of the *Durom* cup. Due to the diameter increase in these two sizes, an additional FE analysis was performed to estimate the amounts of clearance increase required. An (b)(4) increase in the cup deformation was obtained. This data was incorporated in the diametral clearances in the final *Durom* cup design (Table 3), where the same safety factor (b)(4) was applied in all diameters.

(b)(4)

Table 2: Minimal allowable clearance for the current *Durom* design (b)(4)
 (b)(4) **clearance)**

Diameter (mm)	Diametral Clearance (µm)
38 – 56	(b)(4)
58	
60	

Table 3: Diametral clearances in the final design of *Durom* cup – *Metasul LDH* head pairing

2. Evaluation of Frictional Torque Characteristics

Frictional Torque Measurement by the Pendulum Apparatus

A pendulum apparatus was employed to verify the frictional torque characteristics of the final version of *Durom* cup, paired with *Metasul LDH* head, with diameters of 38 to 54 mm and clearances ranging from (b)(4) µm (ZRR report by Shen). The frictional torque results were compared to data collected from METASUL Alpha 32 mm system (Figure 5). The comparison suggested that no significantly higher frictional torque was associated with the pair, *Durom* cup – *LDH Metasul* head.



Figure 5: Frictional torque characteristics as a function of diameters (ZRR by Shen)

Complete test reports (ZRR_WI_0012_05, ZRR_WI_0079_05) are included in Exhibit K.

Class III Certification and Summary

In accordance with 21 CFR 807.94 and 807.87(j), a Class III Certification and Summary is included in Exhibit L. In order to fulfill the requirements of this part, Zimmer conducted a review of international complaints received for the *Durom* Acetabular Cup and the *Metasul LDH* Large Diameter Heads, which have been sold outside the U.S. since September 2003.

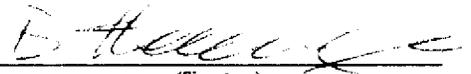
An estimated (b)(4) units have been sold internationally. (b)(4) complaints have been (b)(4)

Also submitted is information excerpted from the Metal-on-Metal Hip Reclassification petition submitted to FDA by the Orthopedic Surgical Manufacturer's Association (OSMA) in September 2005. This information includes a Summary of Published and Unpublished Clinical Results, and Medical Device Reports and Adverse Events from the Literature.

**PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT**

[As Required by 21 CFR 807.87(k)]

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



(Signature)

Bernad Henningsen
~~Sven Hoffman~~

(Typed Name)

16 12 05

(Date)

(Premarket Notification [510(k)] Number)

Summary of Safety and Effectiveness

Submitter	Zimmer GmbH Sulzer Allee 8 Winterthur, Switzerland CH-8404
Contact Person	Laura D. Williams, RAC Manager, Corporate Regulatory Affairs Telephone: (574) 372-4523 Fax: (574) 372-4605
Date	December 16, 2005
Trade Name	<i>Durom</i> ® Acetabular Component <i>Metasul</i> ® <i>LDH</i> ™ Large Diameter Heads
Common Name	Total hip prosthesis
Classification Name	Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
Classification Reference	21 CFR § 888.3330
Predicate Devices	<ul style="list-style-type: none">• Biomet M²A Magnum System (K042037)• Wright Metal Transcend Articular System (K021349)• Centerpulse/Zimmer <i>Epsilon</i>™ <i>Metasul</i>® Acetabular Insert and <i>Metasul</i> Modular Femoral Head (K033634)
Device Description	<p>The <i>Metasul LDH</i> large diameter head system consists of large diameter femoral heads, <i>Durom</i> acetabular components and neck adapters for neck length variation.</p> <p>The <i>Metasul LDH</i> femoral heads are made of CoCrMo alloy, and are available in diameters ranging from 38 to 60mm. They are modular in design, and are for use with four head/neck length adaptors (-4 to +8mm), also manufactured from CoCrMo alloy. The femoral heads and neck adapters are compatible with 12/14 taper femoral stems.</p> <p>The <i>Durom</i> Acetabular component is a metal monoblock CoCrMo alloy cup with a porous coating of titanium plasma spray. It is available in sizes from 44 to 66mm, and is intended for press-fit fixation in the acetabulum.</p>

Intended Use

- Patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis.
- Those patients with failed previous surgery where pain, deformity, or dysfunction persists.
- Revision of previously failed hip arthroplasty.

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

Comparison to Predicate Device

The proposed device has the same intended use, has similar performance characteristics, is manufactured from similar materials using similar processes, and is similar in design to the predicate devices.

Performance Data (Nonclinical and/or Clinical)

The results of non-clinical analysis demonstrate that the device is safe and effective and substantially equivalent to the predicate device(s).

Compatible *Zimmer* Femoral Stems

Femoral Stem	510(k) No.
EPOCH Porous Stem	K014070
VerSys Beaded FullCoat Low Head Center	K042776
VerSys Beaded FullCoat 10 and 20mm Calcar, Straight & Bowed	K033034, K030079
VerSys Cemented and CT Cemented	K950312
VerSys Heritage	K963109
VerSys Enhanced Taper Stem	K961378
VerSys Fiber Metal Taper	K964769
M/L Taper Stems	K032726, K042337
VerSys Revision Calcar Stem	K913649
Mayo 12/14 Stems	K030733
CPT 12/14 Stems	K960658, K030265
ZMR XL	K031572
ZMR Porous Revision System	K994286
Anatomic II Hip Stem	K041109
Trabecular Metal Hip	K051491
APR II Non-Porous Hip Stem	K913208
APR II Femoral Component	K890450, K920955
Modified APR II Femoral Component	K913634, K920955
APR Collared Revision Femoral Component	K885192, K920955
APR I & II Press Fit Femoral Components with Calcitite Coating	K905781

Femoral Stem	510(k) No.
APR Porous HA Hip System	K954800
APR Fully Textured Hip Stem	K961589
APR Oversized Hip Stem	K961921
APR Porous Stem with HA	K973124
Apollo Hip System	K933203
InterMoore Fracture Hip Stem	K954854, K963155
Premier Total Femoral Component	K873999, K894051
Premier Total Femoral Component with Calcitite Coating	K910755
DRG Femoral Component	K920003
Natural-Hip Porous Hip System	K913060, K920955
Natural-Hip Porous Stem with Short Neck	K963266
Natural-Hip Porous HA Hip Stem	K970300
Natural-Hip Calcar Replacement Stem	K945516, K961727
Natural CoCr DRG Hip Stems	K960258, K961799
Natural CoCr Hip Stem with Short Neck	K964357
Natural CoCr Revision Hip Stem	K970166
Precedent Revision Hip Stem with HA	K971523
Precedent Revision Hip Stem	K972637
Modular Options for Severe Bone Loss and Trauma (MOST) System	K960626, K964350, K973087
Natural-Hip CoCr Offset Stem	K973681
Natural-Hip Porous Ti Offset Stem	K973675
Wagner Revision Stem	K953689, K960588

Femoral Stem	510(k) No.
Alloclassic (Zweymuller) Stem	K033664, K030372, K962101
LD Stem	K001320
CLS Femoral Stem	K010839, K953690
Wagner Cone Prosthesis	K032380
MS-30 Femoral Stem	K040803, K020713, K001078, K993043

Indications for Use

510(k) Number (if known):

Device Name:

Durom® Acetabular Component
Metasul® LDH® Large Diameter Heads

Indications for Use:

- Patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis.
- Those patients with failed previous surgery where pain, deformity, or dysfunction persists.
- Revision of previously failed hip arthroplasty.

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

Prescription Use X

(Part 21 CFR 801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

97

0033

OCT 1 - 2004

K04 2037



510(k) Summary of Safety and Effectiveness

Applicant/Sponsor: Biomet Manufacturing Corp.
Contact Person: Kacy Arnold
Regulatory Specialist
Proprietary Name: M²a™ Magnum™ System
Common Name: Metallic Acetabular Articulation
Classification Name: Hip joint metal/metal semi-constrained, with uncemented acetabular component prosthesis (888.3330)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

The M²a™ Magnum™ System is substantially equivalent to:

- K011110 M2a™ Acetabular System 38mm (*Biomet*)
- K984028 Bio-Moore Endo Heads (*Biomet*)
- K002106 New Bio-Moore Endo Head, Taper Adapter (*Biomet*)
- K031963 Conserve® Plus Spiked Shell and Conserve® Total 56mm Femoral Head (*Wright Medical*)
- K021249 Metal Transcend® Articulation System (*Wright Medical*)

Device Description:

The M²a™ Magnum™ System consists of a CoCrMo monolithic acetabular cup, which articulates with a CoCrMo modular head. The smaller femoral heads, sizes 38mm and 40mm, are a one-piece design with neck length variations ranging from -6mm to +12mm. The larger femoral heads, sizes 42mm to 60mm, are a modular design with neck length variations ranging from -6mm to +9mm, achieved through the use of a titanium adapter assembled with the modular head component at the time of surgery. The femoral heads may be used in conjunction with any of Biomet's commercially available Type I taper femoral component.

Summary of Technologies: The M²a™ Magnum™ Hip System technological characteristics (material and design) are similar to predicate devices.

Non-Clinical Testing: Mechanical testing was performed to establish substantial equivalence to the predicate devices.

Clinical Testing: Clinical testing was not used to establish substantial equivalence to predicate devices.

All trademarks are property of Biomet, Inc.



OCT 1 - 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Kacy Arnold, RN, MBA
Biomet Manufacturing Corp.
P.O. Box 587
Warsaw, IN 46581-0587

Re: K042037

Trade Name: M²a™ Magnum™ System

Regulation Number: 21 CFR 888.3330

Regulation Name: Hip joint metal/metal semi-constrained, with uncemented acetabular component prosthesis

Regulatory Class: III

Product Code: KWA

Dated: July 28, 2004

Received: July 29, 2004

Dear Ms. Arnold:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

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

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

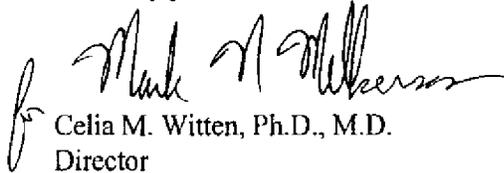
99

Page 2 – Ms. Kacy Arnold

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a large initial "C" and "W".

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

Enclosure

100

0036

Indications for Use

510(k) Number (if known): K042037

Device Name: M²a™ Magnum™ Hip System

Indications For Use:

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

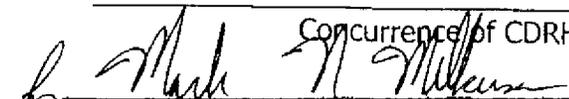
- Non-inflammatory degenerative joint disease including avascular necrosis, diastrophic variant, fracture of the pelvis, fused hip, Legg Perthes, osteoarthritis, slipped capital epiphysis, subcapital fractures and traumatic arthritis.
- Rheumatoid arthritis
- Correction of functional deformity
- Treatment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

Prescription Use
 (Part 21 CFR 801 Subpart D)

AND/OR

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

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

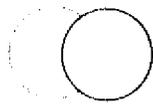

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-Off)
**Division of General, Restorative,
and Neurological Devices**

Page 1 of 1

2

510(k) Number K042037

101
0037



Surgical
Technique

ILLUSTRATION

Accurate preoperative planning and templating are essential for obtaining a successful outcome. Estimate the acetabular size utilizing the M²a-Magnum™ templates along with the appropriate femoral templates in the A/P view (Figure 1).

The surgical approach, head resection, and acetabular exposure are left to the surgeon's discretion. M²a-Magnum™ instrumentation is compatible with all routine hip exposures (Figure 2).

This brochure is presented to demonstrate the surgical technique of John M. Cuckler, M.D., of Birmingham, Alabama. 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 procedure is responsible for determining and utilizing the appropriate techniques for such procedure for each individual patient.

Preoperative Planning

Incision and Surgical Exposure

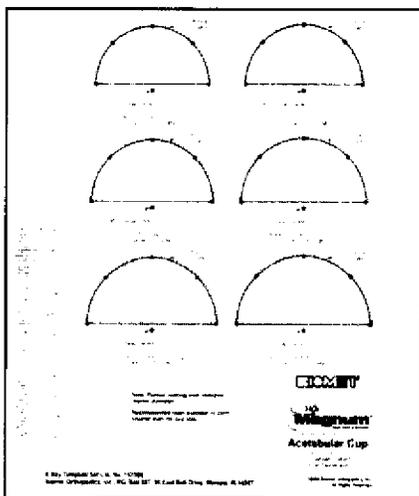


Figure 1

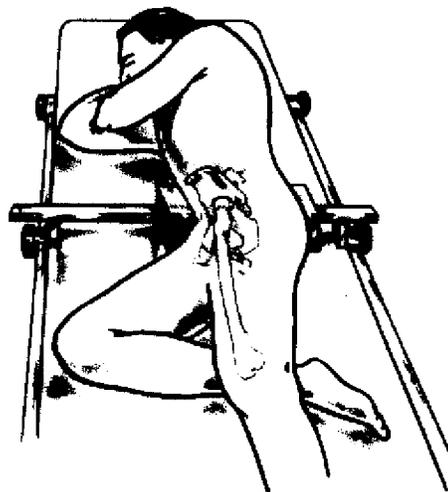


Figure 2

The M²a-Magnum™ cup's hemispherical design is intended to achieve stable fixation with a 2mm under ream (i.e. ream to 54mm, implant a 56mm cup) (Figure 3).

M²a-Magnum™ acetabular trials should be used throughout the reaming process to help determine the accuracy of the reaming process, and the size and position of the final prosthesis (Figure 4).

Acetabular Reaming Cup Trialing

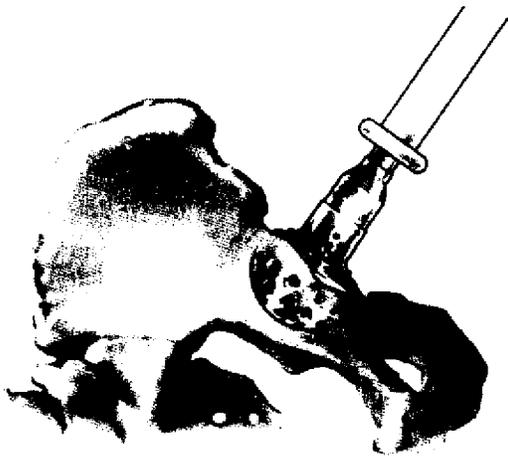


Figure 3



Figure 4

A standard cup inserter handle is threaded into the locking inserter plate. If using the optional locking sleeve, slide the locking sleeve onto the inserter handle and place the anti-rotation barb into the hole on top of the inserter plate prior to securing the inserter to the plate (Figure 5). Once the plate is secured to the handle, verify the plate is in the "open" position by rotating the handle counter-clockwise 45 degrees. Attach the plate by placing the three prongs into three of the four recessed slots around the outer rim of the cup and close the plate by rotating the handle clockwise 45 degrees (Figure 6). A click may be felt or heard when the plate is fully locked. The optional locking sleeve may now be pushed downward locking the plate in the closed position.

Note: The prongs are meant to be oriented in the anterior, superior, and posterior positions of the cup. The inferior region of the cup is sunk deeply into hard bone with proper cup abduction, thus the prong is purposely missing in this area as to avoid hang-ups when removing the faceplate.

Acetabular Cup Orientation and Insertion

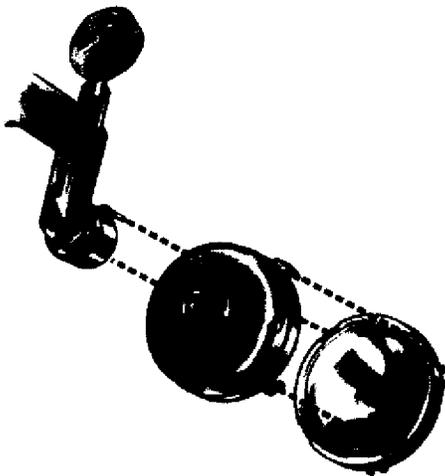


Figure 5



Figure 6

In order to establish correct positioning, the Dial-A-Version guide can be used with the inserter handle. Placing the cup at 40–45 degrees of abduction and 15–20 degrees of anteversion will provide optimal range of motion (Figure 7). Once appropriate shell positioning is achieved, the version guide can be easily removed.

In some patients with hard bone, a two-stage insertion and impaction process is recommended for the M^a-Magnum™ cup. First, use the locking inserter plate to obtain proper orientation and start the cup impaction. Once satisfied with the cup position, stop impaction prior to seating the upper edge of the cup into the rim of the acetabulum. Remove the locking inserter plate by rotating the inserter handle counterclockwise 45 degrees and lifting the plate off the face of the cup (Figures 8 & 9). Removing the locking inserter plate at this stage will avoid crimping the fingers in the hard bone on the acetabular rim.

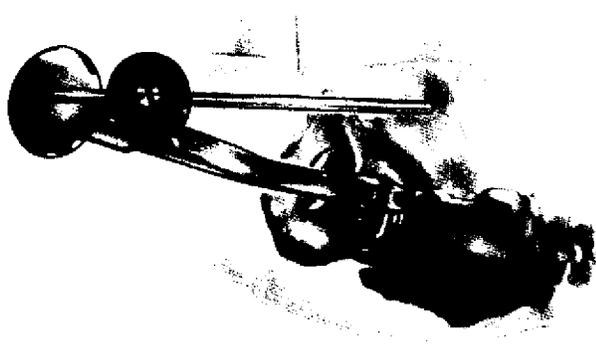


Figure 7

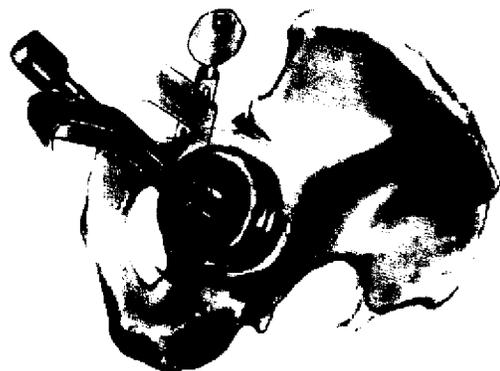


Figure 8

Second, use the appropriately sized ball impactor for final seating of the component (Figure 10).

Should it be determined that changes need to be made to either the anteversion or inclination angles once the cup has been impacted, **an impactor or punch should not be used on the rim of the cup to avoid damage to the bearing surface.** Rather, utilize one of the optional face plates (Part Nos. 31-157844–66) to protect the inner diameter of the cup and tap on the edge of the plate to gradually change cup position.

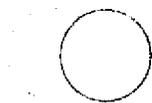


Figure 9



Figure 10

107⁰⁰⁴³

The M^a-Magnum™ head trials are available in 12 sizes from 38mm–60mm. The head size selected is determined by the M^a-Magnum™ cup implanted. The inner diameter of the M^a-Magnum™ cup is always 6mm smaller than the outer diameter of the cup (i.e. a 44mm cup uses a 38mm head and a 66mm cup uses a 60mm head).

The M^a-Magnum™ trial necks are available in six sizes (-6, -3, Std., +3, +6, +9mm) (Figure 11). These head and neck trials can be used in conjunction with both the acetabular trials and the final metal cup implants to determine joint stability and proper cup placement. With the acetabular cup in place, and upon completion of femoral reconstruction, a trial reduction should be performed to confirm restoration of leg length and stability of the hip in all planes.

Modular Head Selection, Assembly and Impaction



Figure 11

Based on the chosen trial head component and the estimated trial neck length, the corresponding M²a-Magnum™ modular head and taper insert implants must now be selected and joined together by hand (Figure 12).

The precision tolerances of these femoral heads are designed for optimum wear.* The taper surfaces must be clean and dry before impacting the M²a-Magnum™ taper insert inside the M²a-Magnum™ head and before seating the assembled head onto the taper of the femoral stem. Impact the assembled M²a-Magnum™ head and taper insert onto the femoral stem with three brisk taps of a mallet using the M²a-Magnum™ plastic head impactor (Figure 13).**

* **Note: Only modular heads labeled for M²a™ Metal-on-Metal articulations can be used.**
** Surfaces other than plastic may scratch the modular head disrupting fluid lubrication and wear. If the modular head becomes scratched or damaged in any way, it must be replaced.

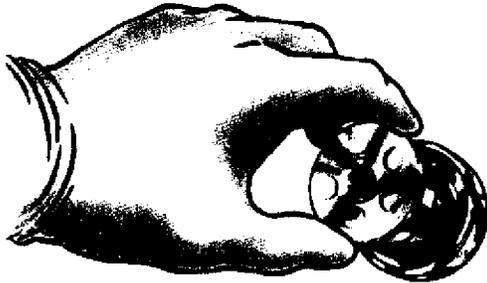


Figure 12

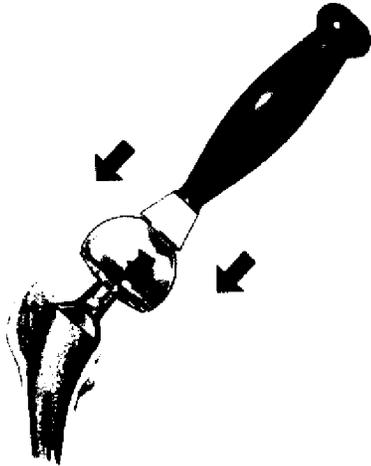


Figure 13

The modular head and cup may now be reduced (Figure 14). Special care should be taken when reducing the head into the cup, so as not to scratch the head on the edge of the cup. At this time, joint stability and range of motion may be confirmed, and customary repair of the hip capsule and wound may commence.

In the event the M²a-Magnum™ head and taper insert need to be removed from the femoral stem, the offset punch will need to be used. Align the tip of the offset punch inside one of the recessed flats on the taper insert and drive the head off the stem with a mallet (Figure 15).

An instrument is available to separate the taper insert from the sleeve of the M²a-Magnum™ head (Part No.31-139250). However, it is recommended that new taper inserts and heads be used anytime parts are replaced as unseen damage to the taper junction or head tolerances can negatively affect the implant's performance.

Final Reduction Head Removal



Figure 14



Figure 15

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

01-50-0960
Date: 10/04

Biomet M^a
ATTENTION OPERATING SURGEON

Description

The Biomet metal on metal Hip Joint Replacement Prosthesis is intended for use in primary and revision hip joint replacement procedures. The metal liners are intended for use with specific metal on metal femoral articulating heads. The specialized femoral heads and metal on metal liners are to be used with Biomet primary and revision femoral components. Specialized components such as taper adapters are available.

Materials

Femoral Heads	CoCrMo Alloy
One Piece Cup	CoCrMo Alloy
Porous Coating	Titanium Alloy
Taper Adapter	Titanium Alloy

Indications

- 1) Noninflammatory degenerative joint disease including avascular necrosis, diastrophic variant, fracture of the pelvis, fused hip, leg perthes, slipped capital epiphysis, subcapital fractures, and traumatic arthritis
- 2) Rheumatoid arthritis
- 3) Correction of functional deformity
- 4) Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques
- 5) Revision of previously failed total hip arthroplasty

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

Porous coated devices are marketed for non-cemented use in the United States for skeletally mature patients undergoing primary hip replacement surgery as a result of non-inflammatory degenerative joint disease.

Contraindications

Absolute contraindications include: infection, sepsis, and osteomyelitis.

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

Warnings

Improper selection, placement, positioning, alignment and fixation of the implant components may result in unusual stress conditions which may lead to subsequent reduction in the service life of the prosthetic components. Malalignment of the components or inaccurate implantation may lead to excessive wear and/or failure of the implant or procedure. Inadequate preclosure cleaning (removal of surgical debris) may lead to excessive wear. Use clean gloves when handling implants. Laboratory testing indicates that implants subjected to body fluids, surgical debris, or fatty tissue have lower adhesion strength to cement than implants handled with clean gloves. Improper preoperative or intraoperative implant handling or damage (scratches, dents, etc.) may lead to crevice corrosion, fretting, fatigue fracture, and/or excessive wear. Do not modify implants.

The surgeon is to be thoroughly familiar with the implants and instruments, prior to performing surgery.

1. Use Biomet femoral and modular head component with appropriate matching "Type I Taper," "Type II Taper," or "T2/T4 Taper."
2. Use Biomet metal on metal acetabular liners with specified Biomet metal on metal femoral heads.
3. Firmly seat modular head components to prevent dislocation. Thoroughly clean and dry taper prior to attachment of the modular head component to avoid crevice corrosion and improper seating.
4. Tight fixation of all non-cemented components at the time of surgery is critical to the success of the procedure. Each component must properly press fit into the host bone which necessitates precise operative technique and the use of specified instruments. Bone stock of adequate quality must be present and appraised at the time of surgery.
5. Perforation entirely through the pelvic bone with rim screws is to be completely avoided. Caution is to be used when determining and selecting the length of screws to be used, as perforation through the pelvic bone with screws that are too long may cause damage to body structures (blood vessels, etc.) located on the interior side of the pelvis.
6. Complete preclosure cleaning and removal of surgical debris at the implant site is critical to minimize wear of the implant articular surfaces.

The information contained in this package insert was current on the date this brochure was printed. However, the package insert may have been revised after that date. To obtain a current package insert, please contact Biomet at the contact information provided herein.

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

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

Precautions

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

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

Possible Adverse Effects

1. Material sensitivity reactions. Implantation of foreign material in tissues may result in histological reactions involving various sizes of macrophages and fibroblasts. The clinical significance of this effect is uncertain, as similar changes may occur as a precursor to or during the healing process. Particulate wear debris and discoloredation from metallic and polyethylene components of joint implants may be present in adjacent tissue or fluid. It has been reported that wear debris may initiate a cellular response resulting in osteolysis or osteolysis may be a result of loosening of the implant.
2. Early or late postoperative, infection, and allergic reaction.
3. Intraoperative bone perforation or fracture may occur, particularly in the presence of poor bone stock caused by osteoporosis, bone defects from previous surgery, bone resorption, or while inserting the device.
4. Loosening or migration of the implants may occur due to loss of fixation, trauma, malalignment, bone resorption, excessive activity.
5. Periparticular calcification or ossification, with or without impediment of joint mobility.
6. Inadequate range of motion due to improper selection or positioning of components.
7. Undesirable shortening of limb.
8. Dislocation and subluxation due to inadequate fixation and improper positioning. Muscle and fibrous tissue laxity may also contribute to these conditions.
9. Fatigue fracture of component may occur as a result of loss of fixation strenuous activity, malalignment, trauma, non-union, or excessive weight.
10. Fretting and crevice corrosion may occur at interfaces between components.
11. Wear and/or deformation of articulating surfaces.
12. Trochanteric avulsion or non-union as a result of excess muscular tension, early weight bearing, or inadequate reattachment.
13. Problems of the knee or ankle of the affected limb or contralateral limb aggravated by leg length discrepancy, too much femoral medialization or muscle deficiencies.
14. Intraoperative or postoperative bone fracture and/or postoperative pain.
15. Elevated metal ion levels have been reported with metal on metal articulating surfaces. Although mechanical testing demonstrates that metal on metal articulating surfaces produce a relatively low amount of particles, the total amount of particulate produced in vivo throughout the service life of the implants remains undetermined. The long-term biological effects of the particulate and metal ions are unknown.

Sterility

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

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

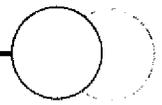
Comments regarding this device can be directed to Attn: Regulatory Dept., Biomet, P.O. Box 587, Warsaw, IN 46581 USA, Fax: 574-372-1683.

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

CE0086

111

Ordering Information



M'a-38™ Solid CoCr Modular Heads		
Implant	Head Trial	Description
11-173660	31-173738	-6 Neck
11-173661	31-173738	-3 Neck
11-173662	31-173738	Std. Neck
11-173663	31-173738	+3 Neck
11-173664	31-173738	+6 Neck
11-173665	31-173738	+9 Neck
11-173666	31-173738	+12 Neck

Selex™/M'a-Magnum™ Solid CoCr 40mm Modular Heads		
Implant	Head Trial	Description
S061140	31-173740	-6 Neck
S031140	31-173740	-3 Neck
S001140	31-173740	Std. Neck
S331140	31-173740	+3 Neck
S661140	31-173740	+6 Neck
S991140	31-173740	+9 Neck
S121140	31-173740	+12 Neck

M'a-Magnum™ Modular Heads		
Implant	Head Trial	Description
157442	31-173742	42mm
157444	31-173744	44mm
157446	31-173746	46mm
157448	31-173748	48mm
157450	31-173750	50mm
157452	31-173752	52mm
157454	31-173754	54mm
157456	31-173756	56mm
157458	31-173758	58mm
157460	31-173760	60mm

M'a-Magnum™ 42-50mm Taper Inserts	
Implant	Description
139252	-6 Neck
139254	-3 Neck
139256	Std. Neck
139258	+3 Neck
139260	+6 Neck
139262	+9 Neck

M'a-Magnum™ 52-60mm Taper Inserts	
Implant	Description
139264	-6 Neck
139266	-3 Neck
139268	Std. Neck
139270	+3 Neck
139272	+6 Neck
139274	+9 Neck

M'a-Magnum™ Threaded Neck Trials	
Part No.	Description
31-482590	-6 Neck
31-482591	-3 Neck
31-482592	Std. Neck
31-482593	+3 Neck
31-482594	+6 Neck
31-482595	+9 Neck

M'a-Magnum™ Press-Fit Cups		
Implant	Cup Trial	Description
US157844	31-167844	44 O.D. x 38 I.D.
US157846	31-167846	46 O.D. x 40 I.D.
US157848	31-167848	48 O.D. x 42 I.D.
US157850	31-167850	50 O.D. x 44 I.D.
US157852	31-167852	52 O.D. x 46 I.D.
US157854	31-167854	54 O.D. x 48 I.D.
US157856	31-167856	56 O.D. x 50 I.D.
US157858	31-167858	58 O.D. x 52 I.D.
US157860	31-167860	60 O.D. x 54 I.D.
US157862	31-167862	62 O.D. x 56 I.D.
US157864	31-167864	64 O.D. x 58 I.D.
US157866	31-167866	66 O.D. x 60 I.D.

Ordering Information

INSTRUMENTATION

Acetabular Cup Locking Inserters

31-157944	44 O.D. x 38 I.D.
31-157946	46 O.D. x 40 I.D.
31-157948	48 O.D. x 42 I.D.
31-157950	50 O.D. x 44 I.D.
31-157952	52 O.D. x 46 I.D.
31-157954	54 O.D. x 48 I.D.
31-157956	56 O.D. x 50 I.D.
31-157958	58 O.D. x 52 I.D.
31-157960	60 O.D. x 54 I.D.
31-157962	62 O.D. x 56 I.D.
31-157964	64 O.D. x 58 I.D.
31-157966	66 O.D. x 60 I.D.

Ball Impactors

31-131038	38mm
31-131040	40mm
31-131042	42mm
31-131044	44mm
31-131046	46mm
31-131048	48mm
31-131050	50mm
31-131052	52mm
31-131054	54mm
31-131056	56mm
31-131058	58mm
31-131060	60mm

M'a-Magnum™ Inserter Plate Locking Device

31-157157

M'a-Magnum™ Inserter Plate Bushing Adaptor

31-157257

Exact™ Offset Punch

X31-400058

RingLoc™ Inserter

31-434540

Head Impactor

31-476948

M'a-Magnum™ Taper Insert Removal Tool

31-139250

M'a-Magnum™ Templates

157500

For product information, including indications, contraindications, warnings, precautions, and potential adverse effects, see the package insert and Biomet's website.

This material is intended for the sole use and benefit of the Biomet sales force and physicians. It is not to be redistributed, duplicated or disclosed without the express written consent of Biomet.

M'a-Magnum, RingLoc and Exact are trademarks of Biomet Manufacturing Corp.

BIOMET®

ORTHOPEDICS, INC.

DrivenByEngineering

P.O. Box 587, Warsaw, IN 46581-0587 • 800.348.9500 (ext. 1501)
©2004 Biomet Orthopedics, Inc. All Rights Reserved • www.biomet.com
Form No. Y-BMT-911/121504/M

113 0049



Advanced science for real living.

Medical Professionals Products Hips

Primary Acetabular Components

Bio-Clad™ Polyethylene Acetabular Component

Full Hemisphere Solid Acetabular Component

M2a - Ringloc™ Liner

M2a - Taper™ Acetabular Hip System

M2a-38™ Metal-on-Metal Acetabular Hip System

M2a-Magnum™ Large Metal Articulation

Mallory/Head® Radial Acetabular Shell

Max-Rom™ Acetabular Liners

QSAC™ Quadrant Sparing Acetabular Component

Ranawat/Burstein® Polyethylene Acetabular Component

Ringloc® Acetabular Components

Ringloc® Acetabular Liners

RingLoc® Bi-Polar Articulating Hip System

Rx 90® Low Profile Acetabular Component

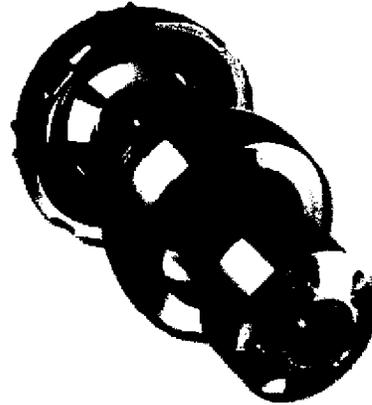
Rx 90® Polyethylene Acetabular Component

Tri-Spike™ Acetabular Component

Universal® Acetabular Component

M2a-Magnum™ Large Metal Articulation

Metal-on-metal articulations date back to the 1950s and offer a significant wear reduction compared with metal or ceramic-on-polyethylene while offering potentially higher stability and range of motion. The M2a-Magnum™ is an ultra-high performance metal-on-metal articulation offering superior joint mechanic restoration and full compatibility with Biomet's clinically proven hip stems. Unlike ceramic-on-ceramic or traditional metal-on-polyethylene bearings, the M2a-Magnum™ Hip System offers the stability and ROM of a big ball (>38mm) in acetabulums as small as 44mm.



- 162 Degrees Range of Motion (ROM)
- 2.2 Centimeter Average "Hop Height" (Dislocation Resistance)
- 6 Neck Length Offsets (-6 through +9mm)
- Porous Plasma Spray (PPS(r)) Surface Coating
- Full Hemisphere Geometry w/8 Fins
- Shell Sizes 44mm-66mm (2mm Increments)

Additional Information

M2a - Magnum™ Large Metal Articulation Surgical Technique	PDF File 621 KB	Brochure/Surgical Technique
01-50-0960 — Biomet® M2a™		Precautionary Statement

Contact a Biomet Distributor near you:

Select State

Customized On-Demand Literature

for Orthopedic Surgeons



Quick, Easy, Affordable.

Click to learn more



WRIGHT
MEDICAL TECHNOLOGY, INC.
5677 AIRLINE ROAD
ARLINGTON, TN 38002
901-867-9971

**510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS**

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this information serves as a Summary of Safety and Effectiveness for the use of the Metal TRANSCEND® Articulation System.

Submitted By:	Wright Medical Technology, Inc.
Date:	April 26, 2002
Contact Person:	Ehab M. Esmail Manager Regulatory Affairs
Proprietary Name:	Metal TRANSCEND® Articulation System (LARGER SIZES)
Common Name:	TOTAL HIP SYSTEM
Classification Name and Reference:	21 CFR 888.3320 Hip joint metal/ metal semi-constrained, with a cemented acetabular component prosthesis – Class III 21 CFR 888.3330 Hip joint metal/ metal semi-constrained, with an uncemented acetabular component prosthesis – Class III
Device Product Code and Panel Code:	Orthopedics/87/KWA

DEVICE INFORMATION

A. INTENDED USES/ INDICATIONS

The Metal TRANSCEND® Articulation System is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;



3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed

The Metal TRANSCEND® Articulation System components are for single use only.

B. DEVICE DESCRIPTION

The previously submitted and cleared Metal TRANSCEND® Articulation System (Exhibit 1: 510(k) K004043) is composed of two pieces, a metal shell and a metal liner that mates to the shell by the use of a taper locking mechanism. This two piece design limits the size of the femoral heads. The use of a monoblock superfinished shell allows larger head sizes to be used. The new Metal TRANSCEND® Articulation System (larger sizes) should increase the range of motion and decrease the risk of dislocation as compared to the current TRANSCEND® (510(k) K004043) Metal on Metal bearing couple.

The Metal TRANSCEND® Articulation System (larger sizes) consists of the following components that are substantially equivalent to the previously cleared components submitted under the Metal TRANSCEND® Articulation System (510(k): K004043): metal monoblock acetabular shells, and metal femoral heads.

Design features of the Metal TRANSCEND® Articulation Monoblock Shell (larger sizes) are summarized below:

- Manufactured from cast cobalt-chromium-molybdenum conforming to ASTM F75
- Porous coated with CoCrMo (ASTM F75) Sintered beads
- Available sizes: ranging from 46mm to 64mm (outer diameter) in 2mm increments (The inner diameter of each shell is 10mm smaller than the outer diameter)
- The articulating surface of the implants will be superfinished (1 microinch Ra maximum) to insure form tolerance and a fine surface finish
- A one-piece acetabular shell allows the surgeon to reconstruct the acetabulum while removing very little bone to accommodate a larger Femoral Head.

Design features of the Metal TRANSCEND® Femoral Head (larger sizes) are summarized below:

- Manufactured from cast cobalt-chromium-molybdenum conforming to ASTM F75
- Available sizes: 38mm, 40mm, 42mm, 44mm, 46mm, 48mm, 50mm, 52mm, 54mm
- Available neck lengths: -3.5, 0, +3.5
- The articulating surface of the implants will be superfinished (1 microinch Ra maximum) to insure form tolerance and a fine surface finish
- The taper connection for the Metal TRANSCEND® Femoral Heads (larger sizes) will be identical to the Metal TRANSCEND® Femoral Heads (510(k):K004043) and is intended to be used with our existing femoral stems manufactured with WMT12/14 taper.



C. MATERIALS

The materials used for the Metal TRANSCEND® Articulation System (larger sizes) are substantially equivalent to competitive devices previously cleared for market.

Monoblock Acetabular Shells

- Cast Cobalt-Chromium-Molybdenum CoCrMo (ASTM F75)
- Porous coated with CoCrMo (ASTM F75) Sintered beads

Femoral Head

- Cast Cobalt-Chromium-Molybdenum CoCrMo (ASTM F75)

D. CLINICAL DATA

The intended use, material, design features, type of interface, and reported wear rates of the Metal TRANSCEND® Articulation System (larger heads) are substantially equivalent to the previously submitted and cleared Metal TRANSCEND® Articulation System (510(k): K004043).

Therefore, Clinical success similar to that of the previously cleared components submitted under the Metal TRANSCEND® Articulation System (510(k) K004043) is expected. The clinical data (TRANSCEND® Metal Articulation System Controlled Clinical Trial in support of 510(k) Statistical Analysis Report Version 8.0 December 23, 2000– Volume 1 & 2) was previously submitted under the Metal TRANSCEND® Articulation System (510(k) K004043). The data was collected prospectively from multi-sites. After excluding a single site with significantly poorer survival than all other sites that was identified as having problems with surgical technique, 2-year cumulative survival was found to be clinically equivalent to (no worse than) the Dobbs metal on metal cohort. Nearly 90% of procedures resulted in “at least good results” at 1 and 2 years as determined by the Harris Hip Score, results that compared favorably with literature-based cohorts of THR. There was more than a 50% increase in the SF-12 physical function component score. Complications and adverse events were rare. Radiolucencies >2mm were rare. There were no findings of subsidence of the stem or migration of the cup >2mm.

In conclusion, this controlled clinical trial provides substantial evidence that the Metal TRANSCEND™ Articulation System (larger sizes) is as safe and effective as approved predicate devices with clinically equivalent patient outcomes relative to such devices, thus supporting a 510(k) claim.



E. SUBSTANTIAL EQUIVALENCE INFORMATION

The intended use, material, type of interface, and design features of the Metal TRANSCEND® Articulation System are substantially equivalent to the competitive devices. The safety and effectiveness of the Metal TRANSCEND® Articulation System are adequately supported by the substantial equivalence information, materials data, testing results, and clinical data provided within this Premarket Notification.





Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 2002

Mr. Ehab M. Esmail
Manager Regulatory Affairs
Wright Medical Technology
5677 Airline Road
Arlington, Tennessee 38002

Re: K021349

Trade Name: Metal TRANSCEND® Articular System (Larger Sizes)

Regulation Number: 21 CFR 888.3320 and 888.3330

Regulation Name: Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis; and

Hip joint metal/ metal semi-constrained, with an uncemented acetabular component, prosthesis

Regulatory Class: Class III

Product Code: KWA

Dated: April 26, 2002

Received: April 29, 2002

Dear Mr. Esmail:

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

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

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

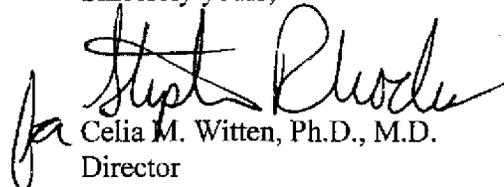
119 0055

Page 2 – Mr. Ehab M. Esmail

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,


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

Enclosure

K021349



WRIGHT
MEDICAL TECHNOLOGY, INC.
5677 AIRLINE ROAD
ARLINGTON, TN 38002
901-867-9971

Metal TRANSCEND® Articulation System

INDICATIONS STATEMENT

Indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

- 1) non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
- 2) inflammatory degenerative joint disease such as rheumatoid arthritis;
- 3) correction of functional deformity; and,
- 4) revision procedures where other treatments or devices have failed.

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

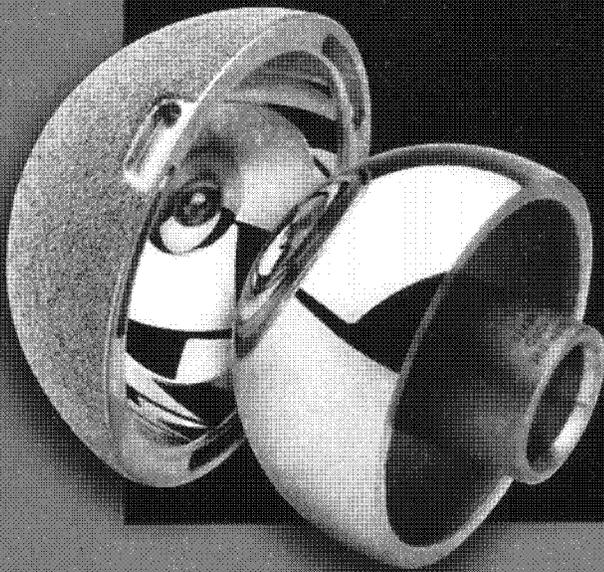
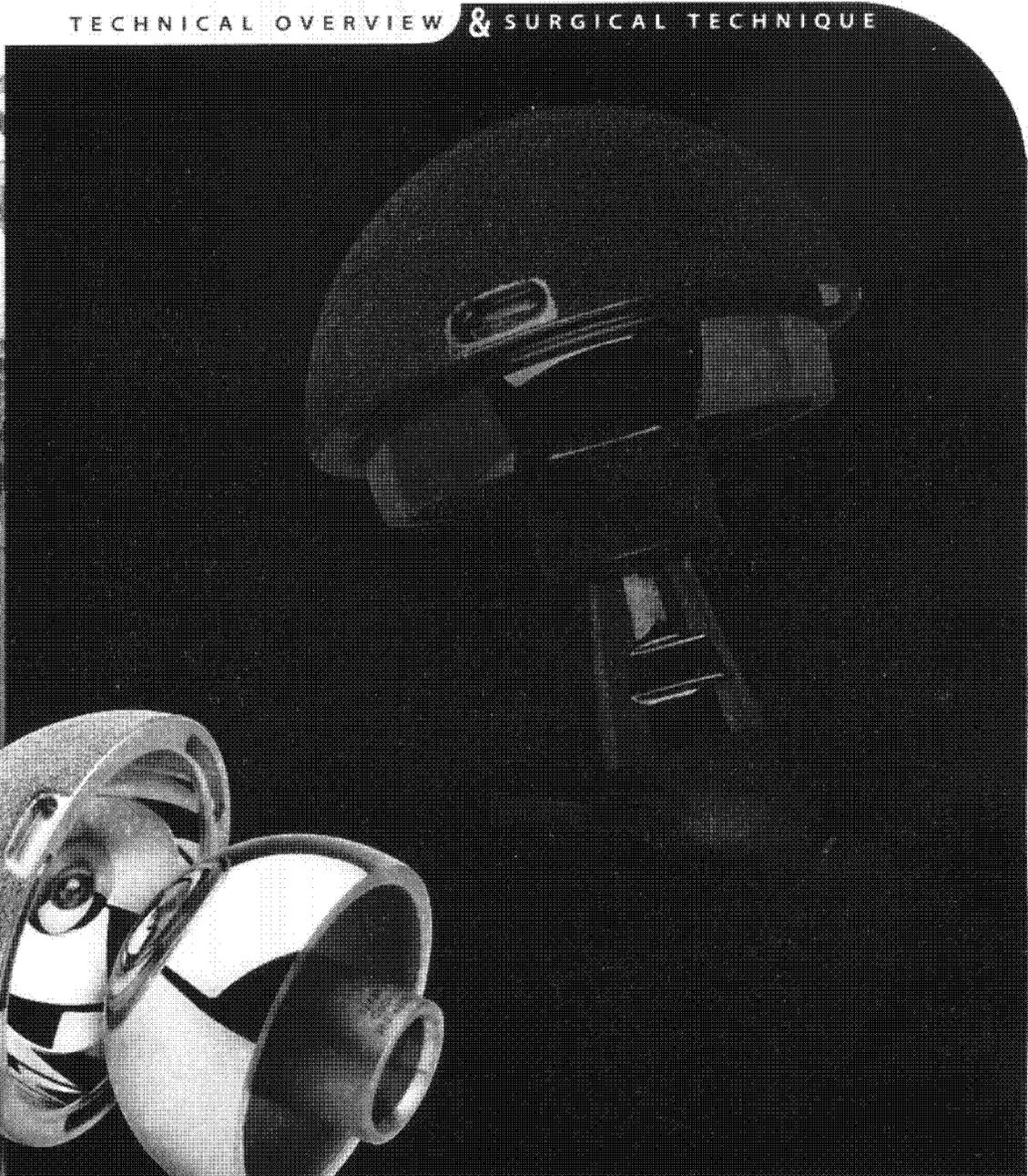
510(k) Number K021349



CONSERVE[®] Total

HIP SYSTEM with BFH[™] TECHNOLOGY

TECHNICAL OVERVIEW & SURGICAL TECHNIQUE



MAXIMIZING RANGE
OF MOTION.

WRIGHT.



Introducing The
CONSERVE® Total
 HIP SYSTEM with BFH™ TECHNOLOGY

WHAT IS CONSERVE® TOTAL HIP SYSTEM WITH BFH™ TECHNOLOGY?

In a normal, healthy adult, the femoral head is quite large in size. Traditionally, total hip replacement has replaced that large femoral head with a head much smaller than the original. The new CONSERVE® Total Hip System has been designed to mimic the natural kinematics of the hip by replacing the body's natural head with a large diameter femoral head implant. The CONSERVE® Total Hip System incorporates a liner-less super-finished cobalt chrome cup, with a large diameter super-finished cobalt chrome femoral head anchored by your choice of press-fit or cemented stems. This design concept gives patients a low-wear metal on metal articulation coupled with large diameter heads.

WHY BIG HEADS?

Dislocation following primary and revision total hip arthroplasty continues to be one of the primary factors of early implant failure. Despite improvements in surgical technique, joint alignment and implant design, early dislocation still remains a significant problem with reported occurrence ranging from 1% to 10% for primary replacement and 10% to 20% for revision arthroplasty.^{1-4,9} The introduction of these large diameter femoral heads increases range of motion. This reduces the chance for impingement and subsequent dislocation. Additionally, the CONSERVE® Total Hip System has no skirts thus creating better range of motion. All of these factors coupled with the low wear metal on metal articulation make the CONSERVE® Total Hip System a great choice for today's orthopaedic surgeon.

HOW DOES BFH™ TECHNOLOGY ADDRESS DISLOCATION?

ANATOMIC SIZE FEMORAL HEADS

Forget worrying about reaching the largest acetabular size possible just to reach a 36mm femoral head. With the CONSERVE® Total Hip System, anatomically-sized femoral heads are available for every acetabular size. Femoral heads range from 36-54mm in the CONSERVE® Total Hip System.

***There is always a 10mm difference between the head and cup.**

Size Range

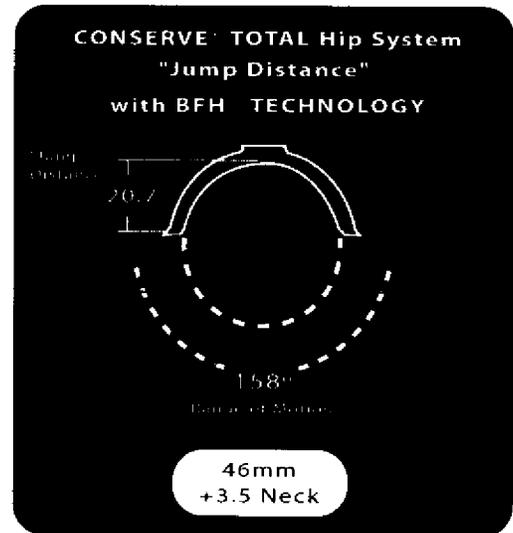
36 OD	46 OD	29%
38 OD	48 OD	36%
40 OD	50 OD	43%
42 OD	52 OD	50%
44 OD	54 OD	57%
46 OD	56 OD	64%
48 OD	58 OD	72%
50 OD	60 OD	79%
52 OD	62 OD	86%
54 OD	64 OD	92%

JUMP DISTANCE

The result of this increased femoral head diameter, is an anatomically-sized femoral head with a significantly larger dislocation height. With BFH™ Technology, dislocation "jump distance" reaches 24mm as compared to 16mm for more traditional size femoral heads.⁵

CONSERVE® Total Hip System "Jump Distance" and Range of Motion (ROM) with PERFECTA® Slim Neck Stem (3904-1050)

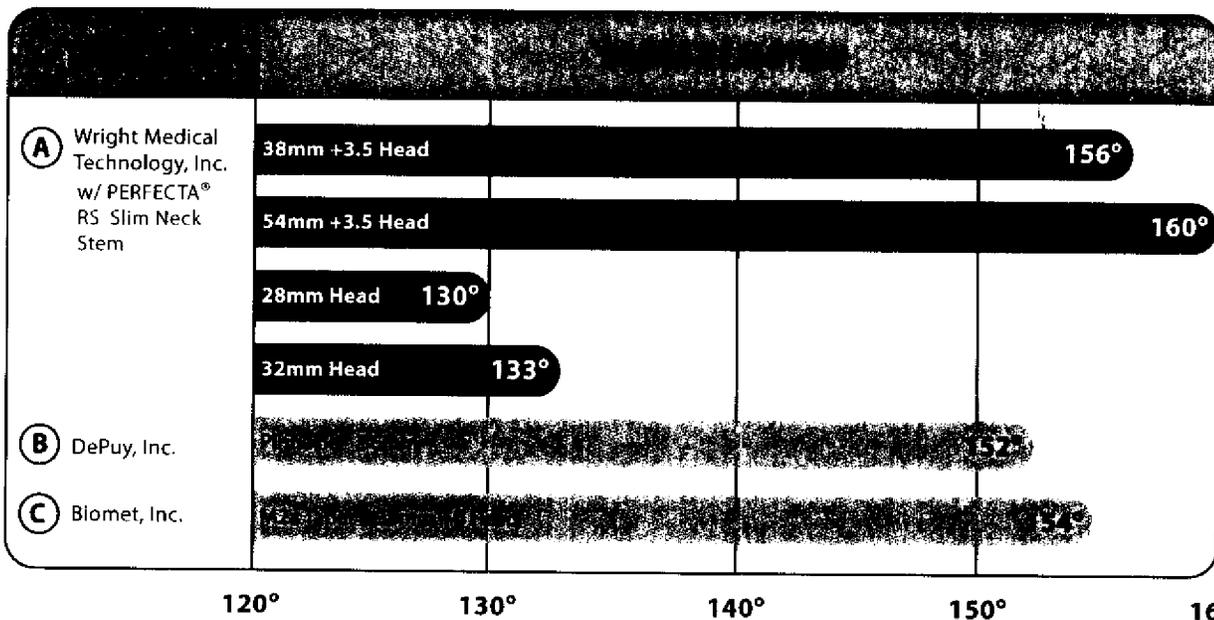
36 mm	16.0 mm	147°	151°	155°
38 mm	17.0 mm	148°	152°	156°
40 mm	17.9 mm	150°	153°	157°
42 mm	18.8 mm	151°	154°	157°
44 mm	19.7 mm	152°	155°	155°
46 mm	20.7 mm	154°	156°	158°
48 mm	21.6 mm	157°	156°	159°
50 mm	22.5 mm	161°	157°	159°
52 mm	23.4 mm	164°	158°	160°
54 mm	24.4 mm	167°	159°	160°



MAXIMUM RANGE OF MOTION

Contemporary systems promote increased range of motion (ROM) through availability of 32mm and 36mm heads along with narrowed stem neck geometries. Despite these improvements, impingement due to limited ROM still exists. With the large femoral head sizes of the CONSERVE® Total Hip System, ROM has been maximized up to 167°, significantly reducing the opportunity for impingement.⁶

Comparison of Competitive Range of Motion

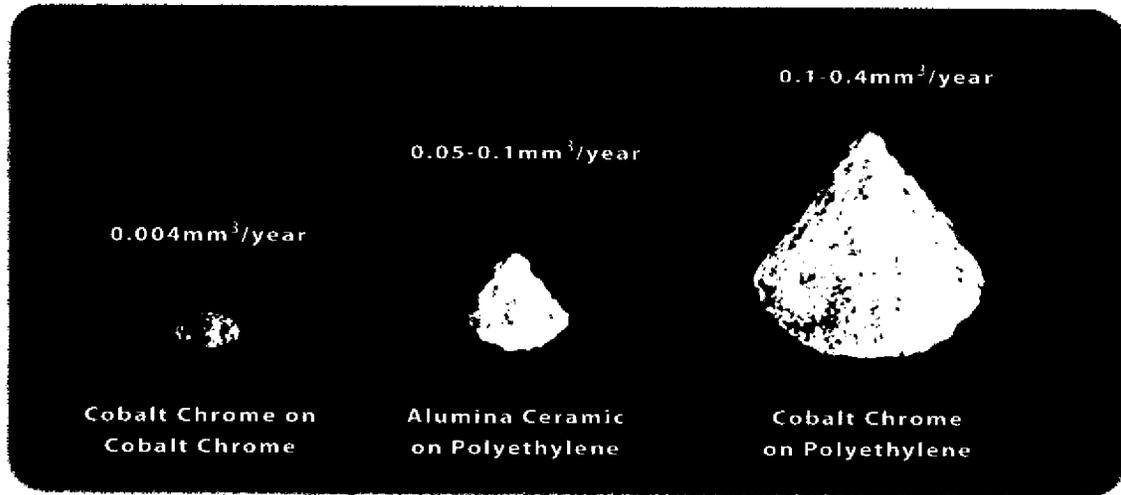


124

WHAT ABOUT WEAR?

Despite improvements in the manufacturing, processing and sterilization of polyethylene, wear related problems still exist in modern THA.⁷ To address this problem, the CONSERVE[®] Total Hip System has eliminated the problem of polyethylene, by removing it from the design altogether. The result is a two-piece, highly superfinished metal-metal hip design, which provides significantly less wear than a conventional total hip replacement.

VOLUMETRIC WEAR (annual basis)⁸ Metal - Metal Implants (mm³/million cycles)



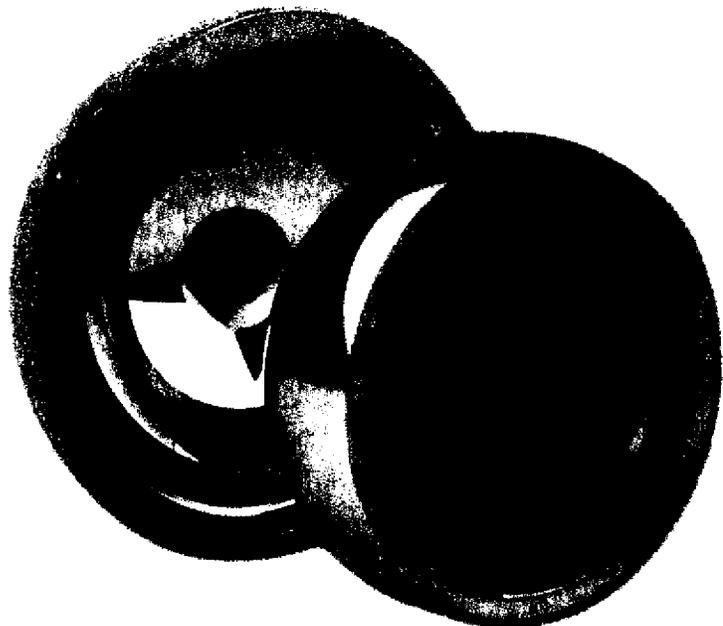
SUMMARY

Whether it is prevention of post-operative dislocation, increased patient function through maximum ROM, or decreased wear, the CONSERVE[®] Total Hip System with BFH[™] Technology provides a solution for today's orthopaedic surgeon. By simply adding large diameter heads to the total hip replacement procedure we hope to mimic the body's natural kinematics and restore a more natural gait.

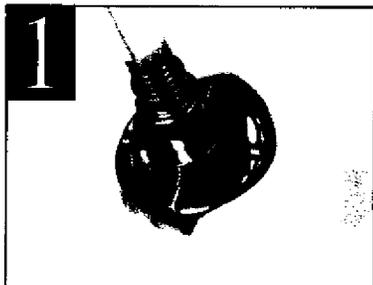
(A) Data on file at Wright Medical Technology, Inc.

(B) DePuy information can be found at:
<http://www.depuy.com>

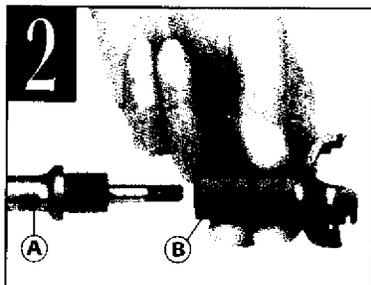
(C) Biomet information can be found at:
<http://www.biomet.com/>



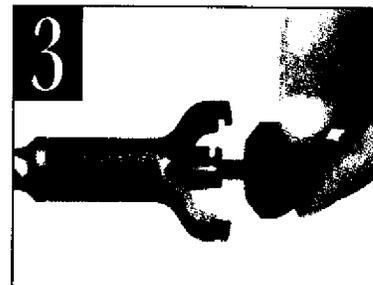
Proper surgical procedures and techniques are the responsibility of the medical professional. The following guidelines are furnished for informational purposes only. Each surgeon must evaluate the appropriateness of the procedures based on his or her personal medical training and experience.



Begin by reaming the acetabulum to the appropriate size based on preoperative templating and intraoperative assessment. With the CONSERVE® Total Hip System it is recommended to ream 1mm less than the chosen shell size for a 1mm circumferential press-fit. For example, ream to a 57mm diameter and implant a 58mm shell.



Assemble the appropriate size bayonet impactor that matches the chosen implant size. To properly assemble the shell impactor, thread the handle (A) to the appropriate size bayonet (B).



To complete the assembly, thread the plastic head to the handle/bayonet combination.



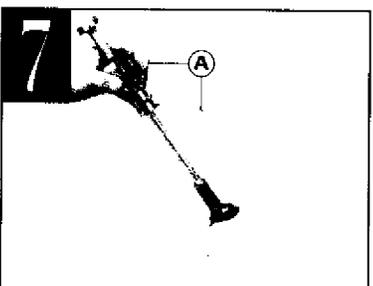
With the bayonet impactor completely assembled, attach the correct size final shell implant to the impactor by aligning the three arms of the bayonet with the three slots in the shell implant (A).



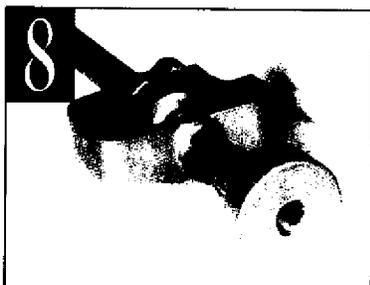
Complete the assembly by inserting the arms of the bayonet into the shell and turning the impactor in a clockwise manner (A).



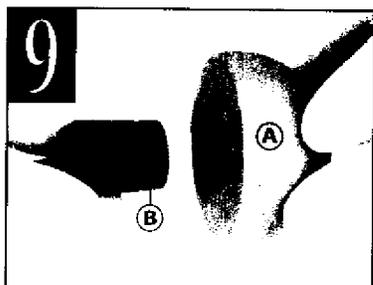
Tighten the final locking screw counter-clockwise until the plastic head bottoms out in the shell.



Align the shell and impactor to the acetabulum using standard positioning techniques. Secondary guidepins are available with the impactor handle to confirm correct placement of the acetabular shell (A). The alignment pins should be facing both parallel and perpendicular to the patient to ensure a 45° position with 15° of anteversion.



Once the shell is impacted turn the locking screw clockwise to retract the plastic head. Then turn entire handle counterclockwise to disengage the bayonets.



With the shell in place, trial the femoral head component using the appropriate size head trial (A) and sleeve trial (B). Trial head sizes range from 36mm to 54mm in diameter and sleeves are provided in -3.5, +0, and +3.5mm neck increments.

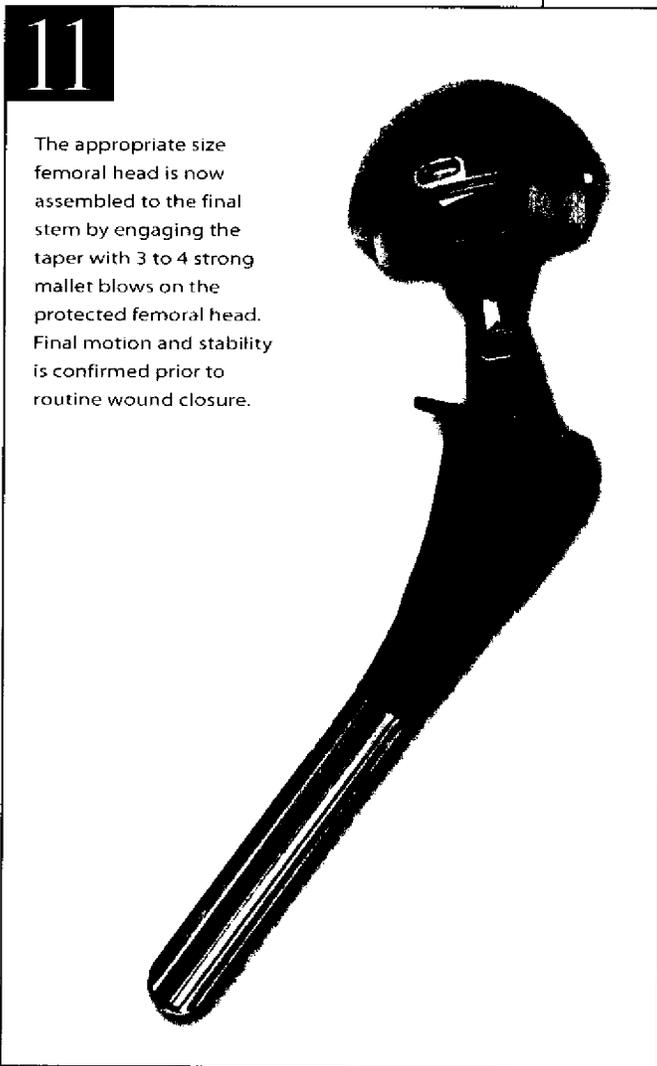
IMPORTANT NOTE | Always use a femoral head size 10mm smaller than the chosen shell size. For example, a 48mm femoral head should be used with a 58mm acetabular shell.



Attach the assembled trial head/sleeve combination to the appropriate size trial neck and complete a full trial reduction to confirm excellent range of motion, joint tension and stability. A final trial reduction may also be performed with the actual stem implant and trial head/sleeve assembly to confirm proper joint tension and stability.

REFERENCES

1. Von Knoch, Marius MD, Berry, Daniel MD, et al, Late Dislocation after Total Hip Arthroplasty. *JBSJ* Vol. 84-A, Number 11, p. 1949-1953, November 2002
2. Aliberton, Gregory et al, Dislocation after Revision Total Hip Arthroplasty. Volume 84-A, Number 10, pp. 1788-1791 *JBSJ*, October 2002.
3. Johnston, Richard C MD, Callaghan, John J MD et al, Dislocation after Total Hip Arthroplasty: A Single Surgeon's Experience. *Orthopedic Clinics of North America* Vol. 32 No. 4 October 2001
4. Beaulé, Paul MD, Scemmalzried, Thomas MD, Arnstutz, Harlan MD, Jumbo Femoral Head for the Treatment of Recurrent Dislocation Following THR. *JBSJ* Vol. 84-A, Number 2 pp. 256-263, February 2002.
5. Data on file at Wright Medical Technology, Inc
6. Data on file at Wright Medical Technology, Inc
7. Harris WH: The problem is osteolysis. *Clin Orthop* 311:46-53, 1995.
8. Data on file at Wright Medical Technology, Inc
9. Grigoris, Peter MD, Grecula, Michael MD, Arnstutz, Harlan MD, Tripolar Hip Replacement for Recurrent Prosthetic Dislocation. *Clinical and Orthopedic Related Research* #304 pp. 148-155 1994



The appropriate size femoral head is now assembled to the final stem by engaging the taper with 3 to 4 strong mallet blows on the protected femoral head. Final motion and stability is confirmed prior to routine wound closure.

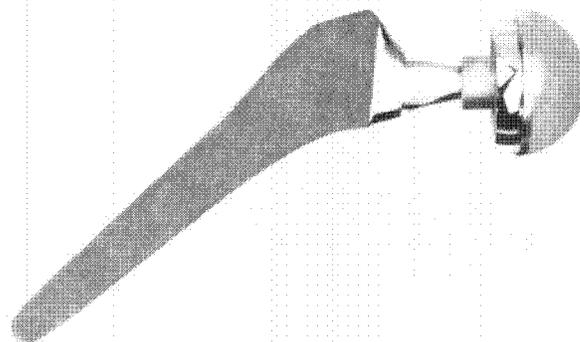


Wright Medical Technology, Inc.
 5677 Airline Road
 Arlington, TN 38002
 901.867.9971 phone
 800.238.7188 toll-free
 www.wmt.com

Wright Cremascoli Ortho SA
 Zone Industrielle la Farlede
 Rue Pasteur BP 222
 83089 Toulon Cedex 09
 France
 011.33.49.408.7788 phone

PINNACLE is a registered trademark of Depuy, Inc., M2a TAPER is a registered trademark of Biomet, Inc. All others are ® Registered marks or ™ Trademarks of Wright Medical Technology, Inc. Patents Pending © 2003 Wright Medical Technology, Inc. All Rights Reserved.

Metal-on-Metal Articulation and Wear



FREQUENTLY ASKED QUESTIONS

WRIGHT

frequently asked **QUESTIONS**

METAL-ON-METAL ARTICULATION AND WEAR

Irina Timmerman and Harlan Amstutz, MD



FIGURE 1 | McKee-Lamar (left), Huggler (middle), and Miller (right) non-hip prostheses (1950s and 1960s)

HOW LONG HAS METAL-ON-METAL ARTICULATION BEEN IN USE?

George McKee of Norwich, England was the first to use metal-on-metal with modified Thompson stems and a one-piece cobalt chrome socket combination in THR in 1953 | **FIGURE 1**. The design was primitive but many lasted for more than 7 years. Although metal wear was detected in devices that were revised, McKee did not observe any undesirable effects of that debris on the soft tissues or the bone¹. The early history of M/M devices, including the Dr. Amstutz' experience with the McKee device in New York, has been previously published^{2,3,4}.

WHAT IS THE OPTIMUM MATERIAL FOR METAL-ON-METAL ARTICULATION?

Metal-on-metal articulation is typically associated with the cobalt chromium molybdenum alloy. Typically these alloys are divided into two categories: high carbon, where the C content is above 0.20%; and low carbon, where the C content is less than 0.05%. Several studies comparing both groups have been conducted | **FIGURE 2**. Earlier studies presented inconclusive results⁵. By comparison, later studies isolated the contribution of factors such as surface finish, clearance, sphericity and carbon content. There is now general consensus in the industry that the high carbon alloy has much better wear resistance than the low carbon type⁶.

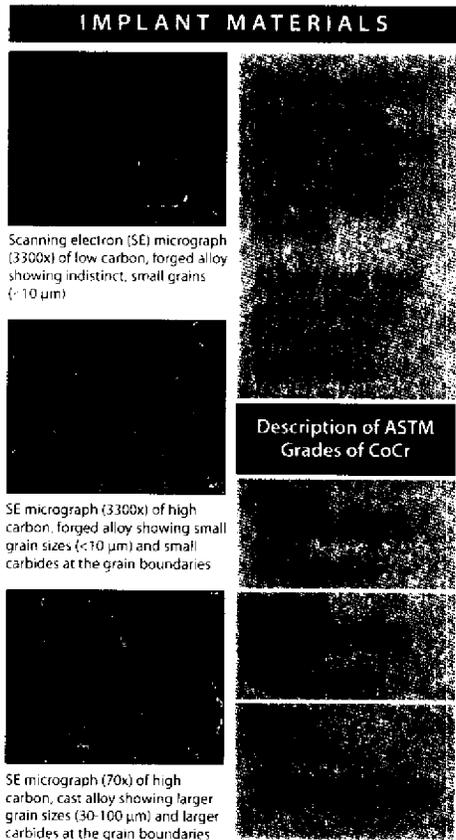
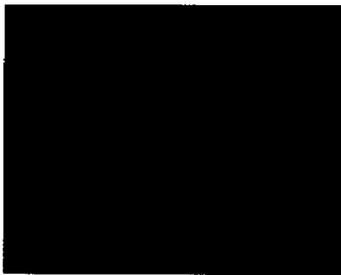


FIGURE 2 | Implant Materials



CoCr Forged 200X



CoCr Cast 50X

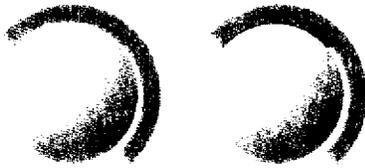
FIGURE 3 | Grain Size Comparison

In addition, there are two types of processes used in manufacturing the cobalt chrome molybdenum components. One method is casting the components (used by Wright for the CONSERVE[®] Plus and CONSERVE[®] Total implants) and the other is forging the material. Although the chemical composition can be exactly the same between the two materials, there is a structural difference. The grain size of the forged alloy is typically less than 10 microns, whereas the grain size for the cast material ranges from 30 to 1000 microns | **FIGURE 3**. There is also a marked difference in the appearance of the carbides, in that the carbide regions tend to be smaller in the forged material. Metal liners and femoral heads have been produced at Wright with both types of material. A limited number of couples were tested in a hip wear simulator. The test showed less wear with cast high carbon alloy than the forged alloy. Due to the limited number of samples, the difference had low statistical reliability.⁷ **This study was the basis for Wright’s decision for choosing case cobalt chrome alloy as the material of choice for their metal-on-metal components.**

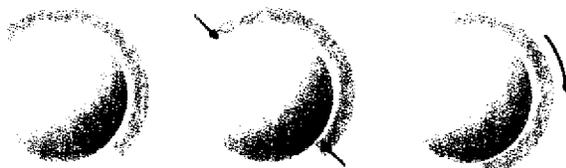
DOES THE CLEARANCE BETWEEN ARTICULATING COMPONENTS PLAY A ROLE IN WEAR DEBRIS GENERATION?

Absolutely! This is probably the most influential factor in wear behavior.

The proper clearance is essential for entrapping the synovial fluid between the articulating surfaces. This fluid is largely responsible for separating the surfaces while the joint is in motion and, thereby, reducing wear. If the gap between components is too small or too large you will see a sharp increase in wear rates⁸ | **FIGURE 4**.



Clearance too large: spot contact.



Clearance too small: wedging

FIGURE 4 | Effects of Improper Clearance

A study conducted by Isaac, Dowson and others (DePuy International, Leeds, UK) compared wrought and as-cast components with various clearances between those two groups. The results of the hip simulator study strongly indicated that clearance plays a major role in wear rates, and that “wear appears to be relatively insensitive to changes in materials that have similar chemical compositions but different microstructures.”¹⁶

DOES THE CONSERVE® PLUS ACETABULAR SHELL WITH THE BIG FEMORAL HEAD USE THE SAME CLEARANCE FOR ALL SIZES?

No. The clearance between components is size-dependent. The larger the diameter, the larger the gap between the components. The range for the entire family of sizes is from 90 to 200 microns of diametral clearance, each bearing size having an optimized gap for maximum fluid film thickness | **FIGURE 5.**

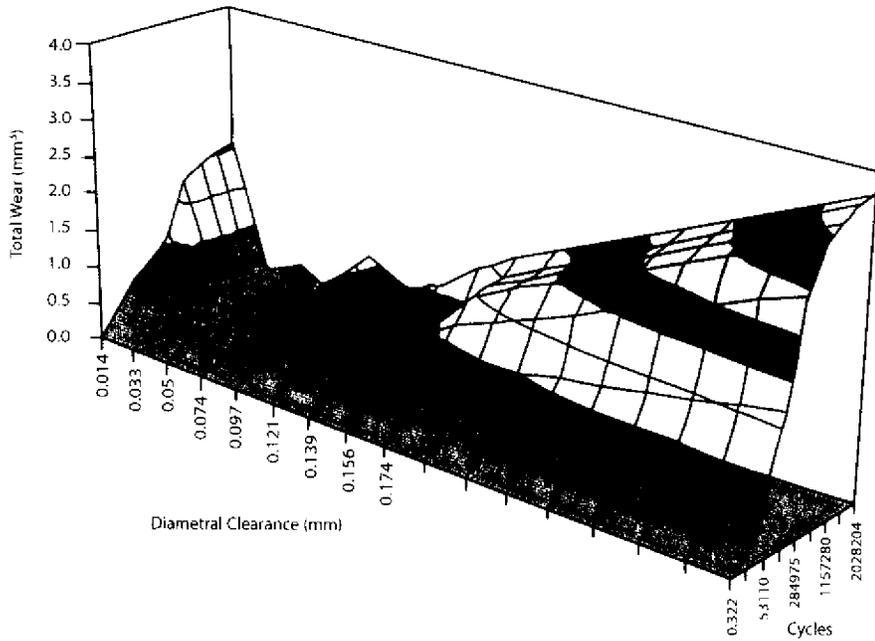


FIGURE 5 | Head Diameter Wear Results



FIGURE 6 | CoCr HIPed 50x

I'VE HEARD A LOT ABOUT HEAT-TREATED COBALT CHROME COMPONENTS VERSUS "AS CAST" COMPONENTS. WHAT ARE THEY TALKING ABOUT AND IS THERE A DIFFERENCE?

Cobalt Chrome Molybdenum components that are cast usually go through the hot isostatic pressing (HIP) and solution annealing processes to remove microporosities often found in castings, and to improve the ductility and homogeneity of the material. The microstructure of this type of heat-treated material looks different from that of the original casting. It is important to note that even though heat treated material looks different it doesn't affect wear | **FIGURE 6.**

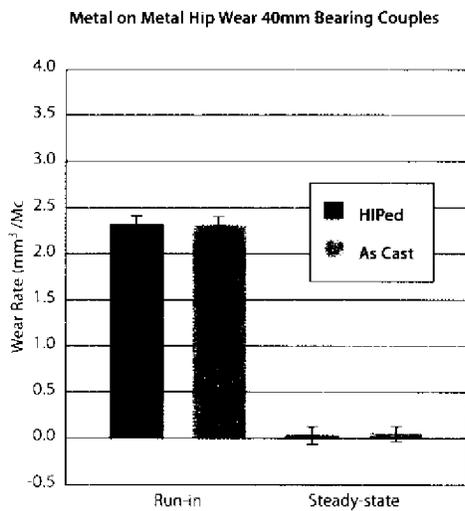


FIGURE 7 | Corin Data from Bowsher JG, Shelton JL: Influence of Heat Treatments on Large Diameter Metal Metal Hip Joint Wear. Trans 18th Ann Symposium Int Soc for Tech in Arthroplasty. 184 2002.

Two global metal-on-metal resurfacing manufacturers use the heat-treated process for the castings (Corin, LTD. and WMI, Inc.). Midland Medical, the producer of the Birmingham Hip Resurfacing (BHR) implant, leaves the castings untreated. The BHR product champion, Derek McMinn, MD claims that heat treatment can lead to carbide depletion and, in turn, it can adversely affect wear rates. One "pin on disk" type test suggests that "as cast" material wears slightly less than "HIP" cast material, however, the data shows so much scatter that the results are inconclusive¹⁰. In addition, the linear tracking motion of the type of "pin-on-disk" used in that study is very different from the actual hip motion. A linear tracking pin-on-disk test is conducted by sliding the cylinder on the flat surface back and forth along one axis. The actual movement of the femoral head inside the socket produces crossing path motion. Studies in hip simulators are more relevant since they more closely resemble the actual hip function by reproducing this crossing path motion. It has been shown that a linear tracking pin-on-disk test under-estimates UHMWPE wear rates by 10 to 100 times, and over-estimates metal-on-metal wear rates as compared to hip simulators and retrieval studies¹¹. Midland Medical has not published any data from a hip simulator to support their claim. Also, zero clinical studies have been conducted which suggest BHR components create less wear than heat treated components.

Bowsher, et al conducted a hip simulator wear study in which 40mm diameter metal-on-metal bearings, either "as cast" or heat treated, were compared side-by-side⁸. Wear rates were compared for the running-in state (first 1 million cycles), steady state, and also fast jogging | **FIGURE 7.** In all three conditions, there was no difference between wear rates of the two forms of the alloy. The authors concluded that HIPing and solution annealing do not adversely affect the wear rates of large diameter metal-on-metal articulations Furthermore, one additional study was presented at the recent June, 2003 Conference on Metal-on-Metal Devices in Montreal that corroborate the Bowsher study¹⁵.

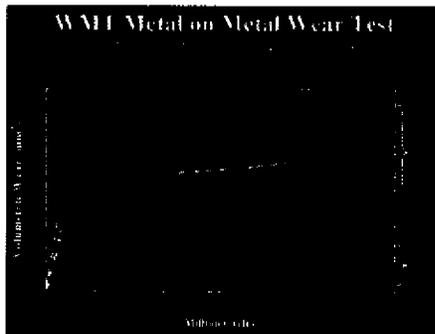


FIGURE 8 | Al Kellop UG, "Wear of Wright Medical 11 Millimeter Metal on Metal Hip Prostheses" August 23, 2006. The Vernon Luck Orthopaedic Research Center, Orthopaedic Hospital, Los Angeles.

WHAT IS THE "STEADY-STATE" WEAR?

Typically, metal-on-metal couples in the hip simulators go through the "run-in" or "wear-in" period where the weight loss due to wear increases linearly. At some point, usually between 500,000 and 1 million cycles, the wear increase drops dramatically or stops altogether. It is then said that the metal-on-metal couple reached the "steady-state" of wear. Both "wear-in" and "steady-state" are demonstrated in | **FIGURE 8**.

DOES THE SURFACE FINISH AFFECT WEAR RATES?

Surface finish has a definite effect on wear rates. The rougher the surface finish, the higher the peaks of material that eventually will be removed. Typical surface finish for the CONSERVE[®] resurfacing components is 0.008 microns (micrometers). This is an order-of-magnitude smoother than the finish on typical metal femoral heads articulating with polyethylene inserts used for THR.

DO LARGER HEADS WEAR LESS THAN SMALLER HEADS?

Theoretically, if the metal couple is dry, larger heads should wear more than smaller heads due to their longer sliding distance per step. However, in the presence of the fluid the opposite is true, larger diameter heads should wear less because of their greater sliding velocity. Calculations show that larger diameter wear couples can form a thicker synovial fluid film between components⁷.

$$H_{\min} = 1.64D(\dot{U}/ED)^{0.65}(W/ED^2)^{-0.21}$$

- WHERE:** H_{\min} is the minimum film thickness
 D is the head diameter
 \dot{U} is the entraining velocity

According to the formula above, the larger the articulating diameter, the larger the H_{\min} value. A thicker fluid film means less contact between hard surfaces during motion and, presumably, less wear. Does this theory prove itself? The study cited above compared 22mm, 26mm, and 35mm diameter metal-on-metal articulations and found no difference between the three. Isaac compared 16mm, 22mm, 28mm, 36mm, and 54.5mm diameter couples¹⁵ and, for diameters 28mm and larger, it was determined that wear decreases with increasing head diameter.

In the study of the 54mm articulating couple (the largest size currently available in the BFH[®] product line) conducted at WMT, the wear rates were found to be very similar to the wear rates for the 44mm CONSERVE[®] Plus articulating couple performed at another institution | **FIGURE 9**.

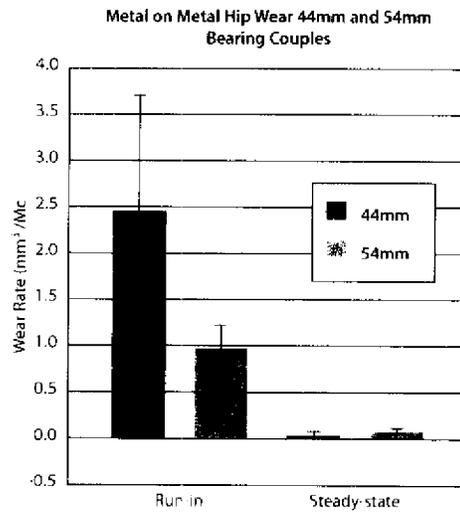


FIGURE 9 | M. Kelley II, Amstutz H, Lu B, Tomkinson J, Carroll M. A Hip Simulator Study of the Wear of Large Diameter Metal-on-Metal Hip Surface Replacements. Trans 27th Ann Meeting Soc for Biomedical p. 337, 2001

These numbers are in agreement with other experimental data obtained with hip simulators.

Source	Couple Size (mm ³ /Mc)	Run-in Wear Rate (mm ³ /Mc)	Steady-State Wear Rate	Sponsored By

a. M. Kelley et al., 2001 Society for Biomedical, 27th Annual Meeting Transactions, 139
 b. On file at Wright Medical Technology, ETR0-0049.
 c. www.centerpulse.com, Metasul, Tribological Results, August 18, 2003.
 d. www.bionet.com, M2a, Laper, and M2c, 38, product information, August 19, 2003.
 e. Bowler et al., 1993 Annual Meeting of the Orthopaedic Research Society, Poster #1398.

TABLE 1 | Hip Simulator Data

WHAT DO THEY MEAN WHEN THEY SAY THAT COBALT CHROME IS "SELF-HEALING"

A cobalt chrome articulation has the ability to polish out the scratches from abrasive damage such as third-body wear. In retrieval studies, the deep scratches have often been partially or entirely polished out of the main contact zones.

WHAT IS THE AVERAGE PARTICLE SIZE FOR METAL WEAR DEBRIS?

In one study, the cobalt chrome particles from a McKee-Farrar metal-on-metal articulation were in the range of 6 to 744 nm (nanometers), with an average size of 42 nm¹¹. By comparison, polyethylene particles range from 0.05 to 5 micrometers (50 to 5000 nm).

CAN A METAL-ON-METAL ARTICULATION PREVENT OSTEOLYSIS?

Since a metal-on-metal articulation does not eliminate wear entirely, there is always the potential for an osteolytic reaction. There are reports of isolated cases of osteolysis with metal-on-metal joints¹². However, these are mostly limited to the first-generation metal-on-metal components. Those were implanted with acrylic cement, which can fragment and generate third-body abrasive particles. It is believed that the metal debris is too small, in comparison to the polyethylene particles, to initiate an osteolytic reaction. A study of several metal-on-metal components (Metasul™ total hip replacements and McMinn surface replacements) investigated the bone and tissue reactions to the metal debris¹³. It was noted that metallosis (a grey-black appearance of the soft tissue) was present with the surface replacements and the total hip replacements. Macrophages filled with metallic particles were found in all tissues, but in larger amounts in those with metallosis. Giant cells and small areas of histiocytic granulomas were also present. The authors noted that there were fewer macrophages and giant cells than typically seen in tissues around metal-polyethylene joints, and although an inflammatory response to the metal particles was present, this was not as severe as the response to the cement particles. The authors concluded that the long-term response to these very small CoCr particles should be monitored. There has been no observed occurrence of metallosis in connection with CONSERVE Plus or CONSERVE Total implants.

WHAT ABOUT METAL ION RELEASE?

Metal ions find their way into the tissues through wear particles or through corrosion mechanisms. These ions then travel into the blood stream and eventually expel in the urine. The topic of metal ion release will be discussed in greater detail in a separate technical monograph.

CONCLUSIONS:

Many factors affect metal-on-metal wear behavior. Some of them are more significant than others. Surface finish, appropriate radial clearance and high carbon content have been shown to play the greatest role in reducing wear rates.

The microstructure of the alloy does not play a key role in wear behavior. While "as cast" and heat treated alloys were directly compared in hip simulators by the scientists from Corin, DePuy, Centerpulse, and in some independent laboratories, proponents of "no heat treatment" regimes have not provided us with laboratory or clinical data to date. McMinn's claim of better metallurgy with the "as cast" components is based primarily on "pin-on-disk" type testing. The "pin-on-plate" or "pin-on-disk" type experiment can compare the wear of different materials as a flat surface, but the mechanism of these tests has nothing in common with the motion of the hip joint.

Hip simulators offer the most reliable way to assess wear in the laboratory, but keep in mind that the outcome greatly depends on the method, testing equipment, and measuring equipment. Since we are dealing with tiny amounts of debris, test results may vary greatly from one hip simulator study to another. Take that into account when comparing data between two tests conducted by different people and with different equipment.

And finally, the best proof of a good design is in the clinical outcome. To date, there have been no published reports of the clinical performance of the BHR device. The CONSERVE[®] Plus metal-on-metal articulation has a good clinical history with over 6 years and over 600 patients. The paper presenting the clinical results of the first 400 CONSERVE[®] Plus hip resurfacing cases performed at the JRI has been accepted for publication by the Journal of Bone and Joint Surgery.

REFERENCES

1. McKee, G. K., and Watson-Farrar, J: Replacement of arthritic hips by the McKee-Farrar prosthesis. *J Bone Joint Surg.* 48B:245-259, 1966.
2. Wilson, P. D.; Amstutz, H. C.; Czerniecki, A.; Salvati, F. A.; and Mendes, D. G.: Total hip replacement with fixation by acrylic cement. A preliminary study of 101 consecutive McKee-Farrar prosthetic replacements. *J Bone Joint Surg. Am.*, 54A:207-236, 1972.
3. Amstutz, H. C., and Grigoris, P.: Metal-on-metal bearings in hip arthroplasty. *Clin Orthop* 329:511-54, 1996.
4. McKellop, H.; Park, S.-H.; Chiesa, R.; Doorn, P.; Lu, B.; Normand, B.; Grigoris, P.; and Amstutz, H.: In vivo wear of three types of metal-on-metal hip prostheses during two decades of use. *Clin Orthop*, 329 Suppl:5128-140, 1996.
5. Chan F.W, Bobyn JD, Medley JB, Kryzner JI: Comparison of Alloys and designs in a hip simulator study of metal-on-metal implants. *CORR*, Vol. 39 148-159, 1996.
6. Chan F.W, Bobyn JD, Medley JB, Kryzner JI, Tanzer M: Wear and lubrication of metal-on-metal hip implants. *CORR*, No. 369, pp.10-24, 1996.
7. Nolan FJ, Farrar R, Schmidt MB, Phillips H, Tucker JK: Effect of head size and diastraical clearance on wear production of a new metal-on-metal hip prosthesis. 42th Annual Meeting of the Orthopaedic Research Society, Poster #71, 1997.
8. Bowsker JG, Nevelos J, Dickard J, Shelton JC: Do heat treatments influence the wear of large diameter metal-on-metal hip joints? An in-vitro study under normal and adverse gait conditions. 49th Annual Meeting of the Orthopaedic Research Society, Poster #1398, 2003.
9. Schmalzried TP: Metal-on-metal: historical perspectives and lessons learned through retrieval studies. *Seminars in Arthroplasty*, Vol.9, No.2 pp 133-142, 1998.
10. Varano R, Bobyn JD, Medley JB, Yue S: Does alloy heat treatment influence metal-on-metal wear? 59th Annual Meeting of The Orthopaedic Research Society Poster #1399, 2003.
11. Doorn PF, Campbell PA, Worrall J, Benya PJ, McKellop HA, Amstutz HC: Metal wear particle characterization from metal on metal total hip replacements. transmission electron microscopy study of periprosthetic tissues and isolated particles. *Journal of Biomedical Material Research* 1998 Oct;42(1):103-11.
12. Kleppereich C, Graham J, Prout L, Rice MD: Failure of a metal-on-metal total hip arthroplasty from progressive osteolysis. *Journal of Arthroplasty* Vol.19 No.7, 1999, pp 877-881.
13. Campbell P, McKellop H, Allan R, Mirra J, Nait S, Dorr L, Amstutz HC: Metal-on-metal hip replacements: wear performance and cellular response to wear particles. *ASTM STP1365*, 1999, pp 193-209.
14. McKellop HA: Testing Issues in Metal-Metal Tribology. Second International Conference on Metal-Metal Hip Prostheses, Jun22 2003, Montreal.
15. Isaac G, Hardaker C, Tlett M, Dowson D: Factors Affecting Wear in Metal-Metal Hips. An Overview of Simulator Testing. Second International Conference on Metal-Metal Hip Prostheses, Jun22 2003, Montreal.



Wright Medical Technology, Inc.

5677 Airline Road
Arlington, TN 38002
901.867.9971 phone
800.238.7188 toll-free
www.wmt.com

Wright Cremascoli Ortho SA

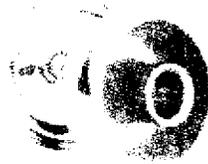
Zone Industrielle la Farlecle
Rue Pasteur BP 222
83089 Toulon Cedex 09
France
011.33.49.408.7788 phone

*Trademarks and *Registered marks of Wright Medical Technology, Inc.
©2005 Wright Medical Technology, Inc. All Rights Reserved.

MH 258-1003
Rev. 0405

138

0074



• Home

• Patients
• Physicians
Learn About BFH™ Technology

- Advantages
- Cost of Dislocation
- BFH™ Where to go
- Risks of BFH™
- Medical History
- Warranted Satisfaction
- US Hospital Accredited
- FAQ
- Testimonials
- Certification
- Product Literature

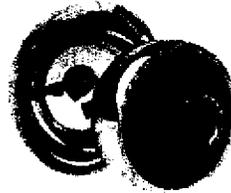
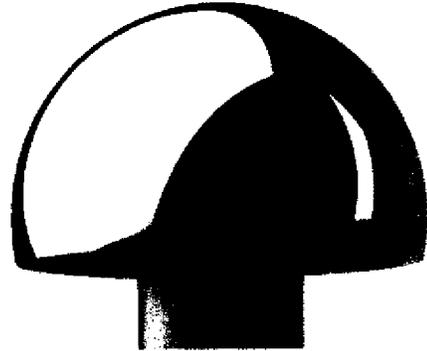
- Prescribing Information
- WMT Home
- Contact Us

Learn about BFH™ Technology

What is the CONSERVE® Total Hip with BFH™ Technology?

The femoral head of a normal, healthy adult is quite large in size. Traditionally, total hip replacement has replaced the large femoral head with a head much smaller than the original. The new CONSERVE® Total Hip system has been designed to mimic the natural kinematics of the hip by replacing the body's natural head with a large diameter femoral head implant. The CONSERVE® Total Hip system incorporates a liner-less, high carbon, cast cobalt chrome cup, with a large diameter high carbon, cast cobalt chrome femoral head anchored by either press-fit or cemented stems. This provides a low-wear metal on metal articulation coupled with large diameter heads.

Big Femoral Head



WRIGHT MEDICAL TECHNOLOGY

© 2005 Wright Medical Technology, Inc. All rights reserved.
 Please see **Site Disclaimers** for complete information regarding contents, correspondence, advertising, product information, and links to other web sites.



• Home

• Patients

• Physicians

Learn About BFH™ Technology

Advantages

Consistent Results

BFH™ With Total

Head of Acetabulum

Metals on Metals

Surgeon's Choice

A 5 Year Clinical Study

WMT

Wright

Wright

Wright

• Prescribing Information

• WMT Home

• Contact Us

Advantages

Why Big Heads?

Dislocation following primary and revision total hip arthroplasty continues to be one of the primary factors of early implant failure. Early dislocation still remains a significant problem despite improvements in surgical technique, joint alignment, and implant design. Reported occurrence ranges from 2% to 10% for primary replacement and 10% to 20% for revision arthroplasty.^{1-4, 8} The introduction of the large diameter CONSERVE® Total Hip femoral heads increases range of motion. This reduces the chance for impingement and subsequent dislocation. Additionally, the CONSERVE® Total Hip system has no skirts thus creating better range of motion. All of these factors coupled with the low wear metal on metal articulation make CONSERVE® Total Hip a great choice for today's orthopaedic surgeon.



DESIGN RATIONALE

The CONSERVE® Total Hip System with BFH™ Technology is designed to eliminate dislocation. Because the human femoral head is large in nature, it therefore makes sense to implant a large, anatomic replacement. This was not possible in the past due to the necessity for polyethylene liners, which decreased the viability of large, anatomic femoral heads. However, with the introduction of metal-on-metal articulation we can now eliminate liners. This not only eliminates the metal liner/metal cup interface, but it allows surgeons to utilize large femoral heads. In fact, the BFH&trade system has heads ranging from 36-54mm in diameter.

The largest head (54mm) coupled with a -3.5mm head length actually produces 167° range of motion. Along with this incredible range of motion, the CONSERVE® Total Hip System has a theoretical jumping distance of up to 24mm. This means that the femoral head must travel 24mm before it will dislocate, once it impinges.

The BFH&trade femoral head design gives surgeons the benefits of both large head sizes and low wear implants.

ANATOMIC SIZE FEMORAL HEADS

Forget worrying about reaching the largest acetabular size possible just to reach a 36mm femoral head. With the CONSERVE® Total Hip, anatomically sized femoral heads are available for every acetabular size. Femoral heads range from 36-54mm in the CONSERVE® Total Hip system.

SIZE RANGES

HEAD Outside Diameter	CUP Outside Diameter	% INCREASE IN HEAD SIZE vs. 28MM
36mm	46mm	28 %
38mm	48mm	36 %
40mm	50mm	43 %

42mm	52mm	50 %
44mm	54mm	57 %
46mm	56mm	64 %
48mm	58mm	72 %
50mm	60mm	79 %
52mm	62mm	86 %
54mm	64mm	92 %

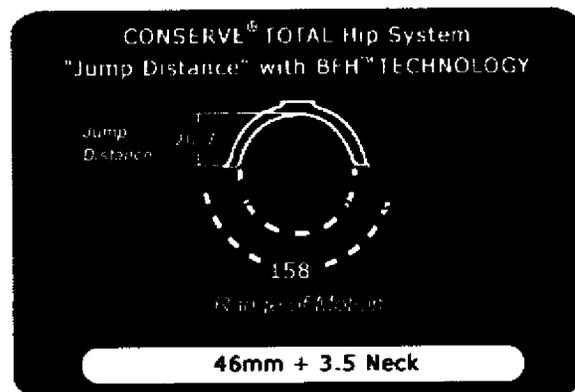
There is always a 10mm difference between the head and cup.

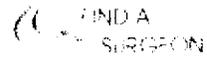
JUMP DISTANCE

The result of this increased femoral head diameter is an anatomically sized femoral head with a significantly larger dislocation height. With BFH™ Technology, dislocation "jump height" reaches 24mm as compared to 16mm for more traditional size femoral heads.⁵

CONSERVE® Total Hip System "Jump Distance" and Range of Motion (ROM) with PERFECTA® Slim Neck Stem (3904-1050)

HEAD DIAMETER	JUMP DISTANCE	-3.5 mm NECK ROM	+0 mm NECK ROM	+3.5 mm NECK ROM
36mm	16.0mm	147	151	155
38mm	17.0mm	148	152	156
40mm	17.9mm	150	153	157
42mm	18.8mm	151	154	157
44mm	19.7mm	152	155	158
46mm	20.7mm	154	156	158
48mm	21.6mm	157	156	159
50mm	22.5mm	161	157	159
52mm	23.4mm	164	158	160
54mm	24.4mm	167	159	160





Copyright © 2005 Wright Medical Technology, Inc. All rights reserved.
Please see **Site Disclaimers** for complete information regarding contents, correspondence, surgical procedures, product information, and links to other web sites.



• Home

• Patients

• Physicians

Learn About BFHT

Technology

Advantages

Cost of Dislocation

BFHT - What's New?

Range of Motion

Material Matters

Surrounding Muscles

• Surgeons' Perspective

• Age

• Lifestyle

• Research

• Total Hip

• Prescribing Information

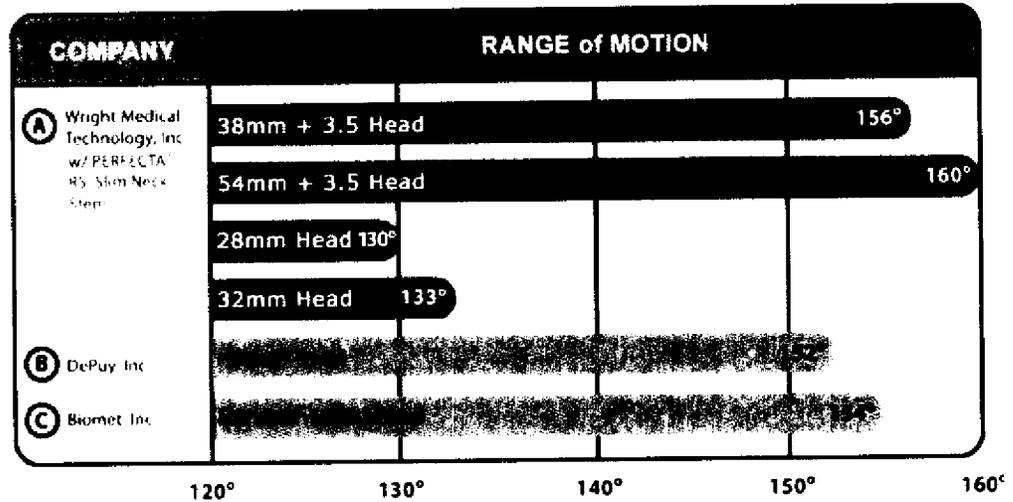
• WMT Home

• Contact Us

Range of Motion

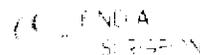
MAXIMUM RANGE OF MOTION

Contemporary systems promote increased range of motion (ROM) through availability of 32mm and 36mm heads along with narrowed stem neck geometries. Despite these improvements, impingement due to limited ROM still exists. With the large femoral head sizes of the CONSERVE® Total Hip, ROM has been maximized up to 167°, significantly reducing the opportunity for impingement.⁶



Beyond providing a solution for impingement, the increased ROM and noticeable stability also provide patients with a more anatomically functioning total hip that can return them to a more active lifestyle.

Click here for references



Copyright © 2005 Wright Medical Technology, Inc. All rights reserved. Please see **Site Disclaimers** for complete information regarding contents, correspondence, surgical procedures, product information, and links to other web sites.



• Home

Metal on Metal

• Patients

• Physicians

Learn About BPH

Technology

Advantages

Cost of Dislocation

BPH - Wear Data

Range of Motion

Metal on Metal

Surgical Technique

A Surgeon's Perspective

FAQ's

References

Referrals

Find a Surgeon

• Prescribing Information

• WMT Home

• Contact Us

Shell Features

- Low profile, 170 degree cup
- One piece cup (liner-less)
- High Carbon Cast Cobalt Chrome
- No rim flare
- Super-finished for tight tolerances and low-wear
- Beaded porous coating for excellent bone growth
- Easy Instrumentation
- Sizes 46-64mm
- Accepts heads from 36-54mm in diameter



Head Features

- Large Diameter heads- 36-54mm in diameter (2mm increments)
- Superfinished for extreme wear resistance
- High Carbon Cast Cobalt Chrome
- No skirts
- 12/14 SLT taper
- Biggest Heads in the Industry



Articles of Interest: Total Hip Dislocation

It is widely held that dislocation occurs in 2-10% of all primary total hip replacements and as much as 20% in revision procedures. This summary highlights several articles written over the last 10 years about hip dislocation and its effects.

BEAULE, PAUL MD, SCHMALZRIED, THOMAS MD, AMSTUTZ, HARLAN MD, Jumbo Femoral Head for the Treatment of Recurrent Dislocation Following THR, JBJS Vol.84-A, Number 2, pp.256-263, February 2002.

- Joint Replacement Institute investigation of 12 hips in 12 patients
- Patients had recurrent instability in their hips and underwent revisions utilizing jumbo femoral heads with an average size of 44mm
- 12 patients had an average of 4 previous operations
- 10 patients received bipolar or fixed heads and 2 patients received unipolar or modular heads
- Average post-op follow-up was 6.5 years
- 1 patient died, but was stable up until time of death, 10 of the remaining 11 had no additional episodes of instability
- 1 hip did dislocate again, the cup was then repositioned and the patient was still stable 7.6 years later
- A larger femoral head must travel a greater distance before subluxing or dislocating, and a greater range of motion is allowed before the femoral neck impinges

- In a previous study of 850 surface replacements, with head sizes ranging from 38-51mm, the dislocation rate was 0.3%, thus supporting the use of jumbo heads in the treatment of dislocations

VON KNOCH, MARIUS MD, BERRY, DANIEL MD, et al ,
Late Dislocation after Total Hip Arthroplasty, *JBJS* Vol.84-A, Number 11,
pp.1949-1953, November 2002.

- Mayo Clinic investigation of 19,680 THRs between 1965-1995
- Purpose of this study was to determine the prevalence of late dislocation in THR (greater than 5 years)
- The investigators also characterize demographics and other factors
- 513 hips dislocated (2.6%) with 32% dislocating 5 or more years after surgery
- Late dislocation was more frequent in women and younger patients
- Late dislocation occurred often in association with poly wear of more than 2mm
- The authors concluded that late dislocations were much more common than previously thought

ALBERTON, GREGORY, et al ,
Dislocation after Revision Total Hip Arthroplasty, *JBJS* Volume 84-A, Number 10,
pp.1788-1791, October 2002.

- Mayo Clinic investigation of 1,548 revisions in 1,405 patients (minimum 2 year follow-up)
- Dislocation is the leading cause of failure in revision total hip arthroplasty
- 115 or 7.4% of the patients dislocated
- Revisions with 28 and 32mm heads were significantly more stable than with 22mm heads
- Overall 36% of the hips remained unstable
- 7.5% had anterolateral approach, 7.8% had lateral approach with trochanteric osteotomy, and 6.1% had posterior approach (no statistical significance in approach was recorded)
- Trochanteric non-union was a dominant risk factor for dislocation (7 of 9 non-unions dislocated)

LACHIEWICZ, PAUL F, KELLY, SCOTT ,
The Use of Constrained Components in Total Hip Arthroplasty, *JAAOS* Volume 10,
No.4, pp.233-238, August 2002.

- Constrained components are often used as a surgical treatment for recurrent dislocation
- They usually include a locking mechanism incorporated into the poly liner to keep the femoral head in place
- Depuy and SHO designs were looked at in this study
- This study showed component failure rates of 4-29% at a relatively short term follow-up
- Failure occurs in four ways: loosening of cup, disassociation of the constrained liner from the shell, material failure (breakage), and disengagement of the constraining ring
- Acetabular liner thinning and head and neck separation were also seen
- With a failure rate exceeding 20%, in many cases it appears that constrained liners should not be used prophylactically based on these results

JOLLES, B.M. MD, et al ,
Factors Predisposing to Dislocation after Primary THR: A Multivariate

Analysis, *The Journal of Arthroplasty*, Vol.17, No.3, 2002.

- Investigation of 2,023 THAs performed between 1991 and 1998 at the Orthopedic Hospital de la Suisse Romande, Lausanne, Switzerland
- Many patient related factors have been implicated in dislocations including but not limited to: age, gender, alcohol abuse, diagnosis of OA, lack of compliance, and muscle weakness in the joint
- Technical factors are also prevalent causes of dislocation including inappropriate cup or stem position, posterior approach, thick implant necks, small femoral heads, and limited surgeon experience
- 21 patients who had at least one dislocation were compared to 21 patients without dislocations
- Implant position, seniority of the surgeon, American Society of Anesthesiologists (ASA) scores, and diminished motor coordination were recorded
- Dislocations rates were 6.9 times higher if total anteversion was not between 40 and 60 degrees and 10 times higher in patients with high ASA scores
- Patients >80 years of age had a dislocation rate of 9%, three times higher than the rest of the group
- Surgeons should pay particular attention to anteversion and use the ASA score as a preoperative assessment of dislocation risk

JOHNSTON, RICHARD C MD, CALLAGHAN, JOHN J MD, et al,
Dislocation after Total Hip Arthroplasty: A Single Surgeon's Experience,
Orthopedic Clinics of North America, Vol.32, No.4, October 2001.

- Study of 4,967 THR (4,164 primaries, 803 revisions) performed by Richard Johnston between 1970 and 1996 at the University of Iowa
- Surgeon used the Charnley 22mm components between 1970-79, Iowa 28mm monolithic between 1982-88, modular 22mm components between 1992-93 and other combinations between 1980-81 and 1994-96
- During the 26 year period 7.2% of primary and 11.2% of revision procedures dislocated
- The most startling fact was that the surgeon returned to 22mm heads in 1992 and had a 13.4% dislocation rate in primaries and 10% in revisions
- Another key fact was that the surgeon found that more than 25% of the patients dislocated 2 or more years after the procedure (normally, most dislocate in the first 3 months)
- The final takeaway was that the authors used constrained components in many revisions for dislocation with a 3.3% recurrent dislocation rate as opposed to a 33% recurrent dislocation rate without these constrained components

BARTZ, REED MD, et al,
The Effect of Femoral Component Head Size on Posterior Dislocation of the Artificial Hip Joint, *JBJS* Vol.82-A, No.9, September 2000.

- 6 cadaveric bones were implanted with uncemented hips and mechanically tested
- Range of motion and impingement were tested for 22, 26, 28 and 32mm heads
- The results showed that by increasing the head size from 22 to 28mm, range of flexion increased by 5.6 ° and by 7.6 ° prior to posterior dislocation
- Increasing the head size from 28 to 32mm did not provide more significant improvement
- Increasing the head size increases ROM and decreases impingement and subsequent dislocation

END A
SECTION

Copyright © 2005 Wright Medical Technology, Inc. All rights reserved.
Please see **Site Disclaimers** for complete information regarding contents, correspondence,
surgical procedures, product information, and links to other web sites.



- Home

- Patients

- Physicians

Learn About BPH™

Technology

Advantages

Cost of BPH System

SPH™ White Label

Range of Motion

Material Used

Surgeon Technique

A Surgeon's Statement

FAQ's

For Patients

For Physicians

For Surgeons

- Prescribing Information

- WMT Home

- Contact Us

Frequently Asked Questions:

1. **Do Big Heads wear more or less than smaller heads?**

Several studies have been done which have shown that head size diameter does not adversely affect the rate of wear. In fact, there's theoretically less wear with larger heads.

2. **What is jump distance?**

Jump distance is the distance from the dome of the cup to the rim. It is the overall distance that the femoral head must travel in order to dislocate once the stem has impinged on the edge of the cup. The range of jump distance for the CONSERVE® Total Hip with BFH™ Technology is 16-24.4mm. The average jump distance for 28mm heads is 15mm.

3. **Why does Wright superfinish the Big Heads and Cups?**

Superfinishing is a proprietary grinding and polishing process maintaining ultra high tolerances related to the overall size and roundness. We measure this process in tolerances down to 0.000001in (one millionth of an inch). In addition to smooth rotation, this superfinishing also allows for optimum fluid lubrication of components which in turn reduces wear.

4. **What is the maximum range of motion?**

The 54mm head coupled with the PERFECTA® Slim Neck design has a range of motion of 167°.

5. **Is the CONSERVE® Total Hip System cup a true hemisphere?**

No, the CONSERVE® PLUS Hip cup is a low-profile cup with 170° of spherical geometry compared to 180° of a true hemispherical design.

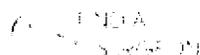
6. **Does the CONSERVE® Total Hip System cup have a rim flare?**

No, the cup has no rim flare. It does not feature built-in press-fit like the LINEAGE® Hip Cup System. Therefore, Wright recommends that the surgeon under ream by 1mm for a proper press fit.

7. **How do I locate a surgeon in my area that performs a CONSERVE® Total with BFH™ Technology total hip replacement?**

Click the link below to find a surgeon near you.

<http://www.wmt.com/PhysLocator/PhysLoc.asp>



Copyright © 2005 Wright Medical Technology, Inc. All rights reserved.
Please see **Site Disclaimers** for complete information regarding contents, correspondence, surgical procedures, product information, and links to other web sites.

SEP 15 2004

K033634

510(k) Premarket Notification
32mm Epsilon Metasul Acetabular Insert and 32mm Metasul Femoral Head, as amended

000014

510(k) SUMMARY

SPONSOR NAME: Centerpulse Orthopedics, Inc., a division of Zimmer
9900 Spectrum Drive
Austin, TX 78717

CONTACT: Audrey Swearingen
Phone: (512) 432-9255
E-Mail: Audrey.Swearingen@Zimmer.com

TRADE NAME: Epsilon™ Metasul® Acetabular Insert and Metasul Modular
Femoral Head

COMMON NAME: Total hip replacement system acetabular insert and head

CLASSIFICATION: CFR §888.3330 (KWA) - Hip joint metal/metal
semiconstrained, with an uncemented acetabular
component, prosthesis, reviewed by the Orthopedic Devices
panel. Metal-on-metal hip prostheses are Preamendment
Class III devices.

PREDICATE DEVICES:

- Centerpulse Orthopedics Epsilon Metasul Acetabular Insert, 28mm Standard (K974728) and Hooded (K001526)
- Centerpulse Metasul® Modular Femoral Head (K974728)
- Biomet M2a™ Ringloc® Acetabular Liner (K002379)
- Biomet M2a -Taper™ Acetabular System (K003363, K993438, unknown)
- J&J DePuy Ultamet Femoral Heads (K980513)

DEVICE DESCRIPTION:

The Epsilon Metasul 32mm Acetabular Insert is a hemispherically shaped design, composed of an outer component manufactured from polyethylene (UHMWPE) (in compliance with ASTM F648) which is thermo-mechanically bonded to a wrought hot-forged CoCr alloy metallic inlay (in compliance with ISO 5832-12). The Epsilon Metasul Acetabular Insert is designed for use only with a Metasul femoral head component, as a metal-on-metal system. The body's natural synovial fluid lubricates the metal surfaces. The Epsilon Metasul 32mm Acetabular Insert, both standard and hooded, is available in sizes designed to mate with Converge® Acetabular Shells, sizes 53mm to 81mm (in 2mm increments).

The Epsilon Metasul 32mm Insert has what is commonly referred to as a "poly-sandwich" design. The inner diameter, which forms the bearing surface of the insert, features a metallic Metasul inlay that is polished to a mirror-finish and thermo-mechanically bonded into the polyethylene liner, which is then locked into the Converge acetabular shell via the proven snap mechanism. On the hooded inserts, the face of the polyethylene outer diameter incorporates a 20° overhang of polyethylene extending superiorly from the midpoint of the insert face. This hood feature is designed to provide additional resistance to subluxation and instability.

The 32mm Metasul® Modular Femoral Head is manufactured from Protasul-21WF

149 0085

(wrought forged CoCrMo, in compliance with ISO 5832-12). The design incorporates a 12/14 Morse-type female taper and a beveled face that allows for easier reduction of the hip intraoperatively. This femoral head component is offered in both a standard and an eccentric version, and is designed specifically to articulate with Centerpulse Orthopedics acetabular inserts having a Metasul[®] Inlay.

INTENDED USE:

The 32mm Epsilon Metasul Acetabular Insert and Metasul Femoral Head are intended for use in total hip arthroplasty for treatment of the following:

- patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis;
- those patients with failed previous surgery where pain, deformity, or dysfunction persists;
- revision of previously failed hip arthroplasty.

BASIS OF SUBSTANTIAL EQUIVALENCE:

Performance tests, design comparisons, indications for use and labeling of the 32mm Epsilon Metasul Acetabular Insert and Metasul Femoral Head demonstrate that they are substantially equivalent in terms of design features, materials, and indications for use to the predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 15 2004

Ms. Audrey Swearingen
Manager, Regulatory Affairs
Zimmer Inc.
9900 Spectrum Drive
Austin, Texas 78717

Re: K033634
Trade/Device Name: Epsilon™ Metasul® Acetabular 32mm Insert/Femoral Head
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
Regulatory Class: III
Product Code: KWA
Dated: August 23, 2004
Received: August 24, 2004

Dear Ms. Swearingen:

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

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

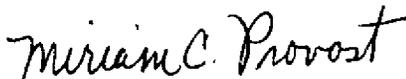
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

Page 2 – Ms. Audrey Swearingen

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



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

Enclosure

Indications for Use

510(k) Number (if known): K033634

Device Name: Epsilon™ Metasul® 32mm Acetabular Insert

Indications for Use:

The Epsilon™ Metasul® Acetabular Insert is intended for use in total hip arthroplasty for treatment of the following:

- patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g., osteoarthritis, post-traumatic arthritis or avascular necrosis and inflammatory joint disease (IJD), e.g., rheumatoid arthritis;
- those patients with failed previous surgery where pain, deformity, or dysfunction persists;
- revision of previously failed hip arthroplasty.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K033634

Page ___ of ___

(Posted November 13, 2003)



Substantial Equivalence Comparison between the Proposed Device and the Predicates

Property or Characteristic	Proposed Device <i>Durom</i> Acetabular Component and <i>Metasul</i> L.DH	Predicate #1 Biomet M ² A Magnum System K042037	Predicate #2 Wright Metal Transcend K021349	Predicate #3 Centerpulse <i>Epsilon</i> <i>Metasul</i> System K033634
Indications for Use	<ul style="list-style-type: none"> • Patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis. • Those patients with failed previous surgery where pain, deformity, or dysfunction persists. • Revision of previously failed hip arthroplasty. 	<p>1. Noninflammatory degenerative joint disease including avascular necrosis, diastrophic variant, fracture of the pelvis, fused hip, leg perthes, slipped capital epiphysis, subcapital fractures, and traumatic arthritis.</p> <p>2. Rheumatoid arthritis.</p> <p>3. Correction of functional deformity.</p> <p>4. Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.</p> <p>5. Revision of previously failed total hip arthroplasty.</p>	<p>The Metal TRANSCEND Articulation System is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:</p> <ol style="list-style-type: none"> 1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia; 2. inflammatory degenerative joint disease such as rheumatoid arthritis; 3. correction of functional deformity; and, 4. revision procedures where other treatments or devices have failed 	<p>Same as proposed device</p>
Sterility	<p>Devices provided sterile by exposure to gamma irradiation</p>	<p>Devices provided sterile by exposure to gamma irradiation</p>	<p>Devices provided sterile by exposure to gamma irradiation</p>	<p>Devices provided sterile by exposure to gamma irradiation</p>
Fixation Method (Acetabulum)	<p>Press-fit</p>	<p>Press-fit</p>	<p>Press-fit</p>	<p>Press-fit (<i>Epsilon</i> <i>Metasul</i> Liner used with <i>Converge</i> Acetabular Shell K012739, K012961)</p>



Traditional 510(k) Premarket Notification

Property or Characteristic		Proposed Device <i>Durom</i> Acetabular Component and <i>Metasul</i> /LDH	Predicate #1 Biomet M ² A Magnum System K042037	Predicate #2 Wright Metal Transcend K021349	Predicate #3 Centerpulse <i>Epsilon</i> <i>Metasul</i> System K033634
Diametral Clearance		120-250µm	150 to 300µm	90-200µm	70-170µm
Range of Motion		144-168°	151.74 to 162.82°	167° maximum	126° maximum
General Design		Metal Monoblock design	Metal Monoblock design	Metal Monoblock design	Poly-sandwich design (UHMWPE insert with metallic inlay)
Geometry		Reduced hemisphere (165°) with fins	Full Hemisphere with fins	Reduced hemisphere (170°)	Hemispherical
Sizes (O.D.)		Available in sizes from 44mm to 66mm in 2mm increments	Available in sizes from 44mm to 66mm in 2mm increments	Available in sizes from 46mm to 64mm in 2mm increments	<i>Epsilon</i> <i>Metasul</i> Liner mates with <i>Converge</i> Acetabular Shell in sizes ranging from 53 to 81mm in 2mm increments
Acetabular Design Features		Porous plasma spray surface coating	Porous plasma spray surface coating	Porous coated with CoCrMo sintered beads	<i>Epsilon</i> <i>Metasul</i> liner mates with <i>Converge</i> shell which is porous coated with Cancellous Structured titanium (CSTi)
Surface		<ul style="list-style-type: none"> • <i>Protasul</i>® 21WF CoCrMo Alloy • Commercially pure titanium (porous coating) 	<ul style="list-style-type: none"> • CoCrMo Alloy • Titanium Alloy (porous coating) 	<ul style="list-style-type: none"> • CoCrMo Alloy • CoCrMo Sintered Beads (porous coating) 	<ul style="list-style-type: none"> • <i>Protasul</i>® 21WF CoCrMo Alloy (inlay) • UHMWPE • Titanium Alloy (<i>Converge</i> Acetabular Shell)
Material		<ul style="list-style-type: none"> • <i>Protasul</i>® 21WF CoCrMo Alloy • Commercially pure titanium (porous coating) 	<ul style="list-style-type: none"> • CoCrMo Alloy • Titanium Alloy (porous coating) 	<ul style="list-style-type: none"> • CoCrMo Alloy • CoCrMo Sintered Beads (porous coating) 	<ul style="list-style-type: none"> • <i>Protasul</i>® 21WF CoCrMo Alloy (inlay) • UHMWPE • Titanium Alloy (<i>Converge</i> Acetabular Shell)



Property or Characteristic		Proposed Device <i>Darom</i> Acetabular Component and <i>Metasul</i> EDH	Predicate #1 Biomet MFA Magnum System K042037	Predicate #2 Wright Metal Transcend K021349	Predicate #3 Centerpulse <i>Epsilon</i> <i>Metasul</i> System K033634
Femoral Head Design Features	General Design	Modular -- head and taper adapter	<ul style="list-style-type: none"> Modular (sizes 42-60mm) One-piece (sizes 38-40mm) 	One-piece	One-piece
	Material	<ul style="list-style-type: none"> <i>Protasul</i>® 21WF CoCrMo Alloy (high carbon) <i>Protasul</i>® -20 CoCrMo Alloy (taper adapter) 	<ul style="list-style-type: none"> CoCrMo Alloy Titanium Alloy (taper adapter) 	High carbon CoCr	<i>Protasul</i> ® 21WF CoCrMo Alloy (high carbon)
	Diameter	38mm to 60mm in 2mm increments	42mm to 60mm in 2mm increments	36 to 54mm in 2mm increments	28 and 32mm Neck lengths from -4 to +8mm
	Neck Length	-4 to +8mm	<ul style="list-style-type: none"> -6 to +9mm (for modular heads) -6 to +12mm (for one-piece heads) 	-3.5 to +3.5mm	<ul style="list-style-type: none"> -4 to +4mm (28mm) -4 to +8mm (32mm)
	Taper	12/14	Biomet Type I Taper	12/14	12/14
	Sphericity	<10µm	<5µm	Unknown	<10µm
	Surface Finish	.006 µm	.005 µm	Unknown	.006 µm

***Durom Acetabular Component and Metasul LDH Large Diameter Heads
Implant Catalog Numbers***

Durom Acetabular Components

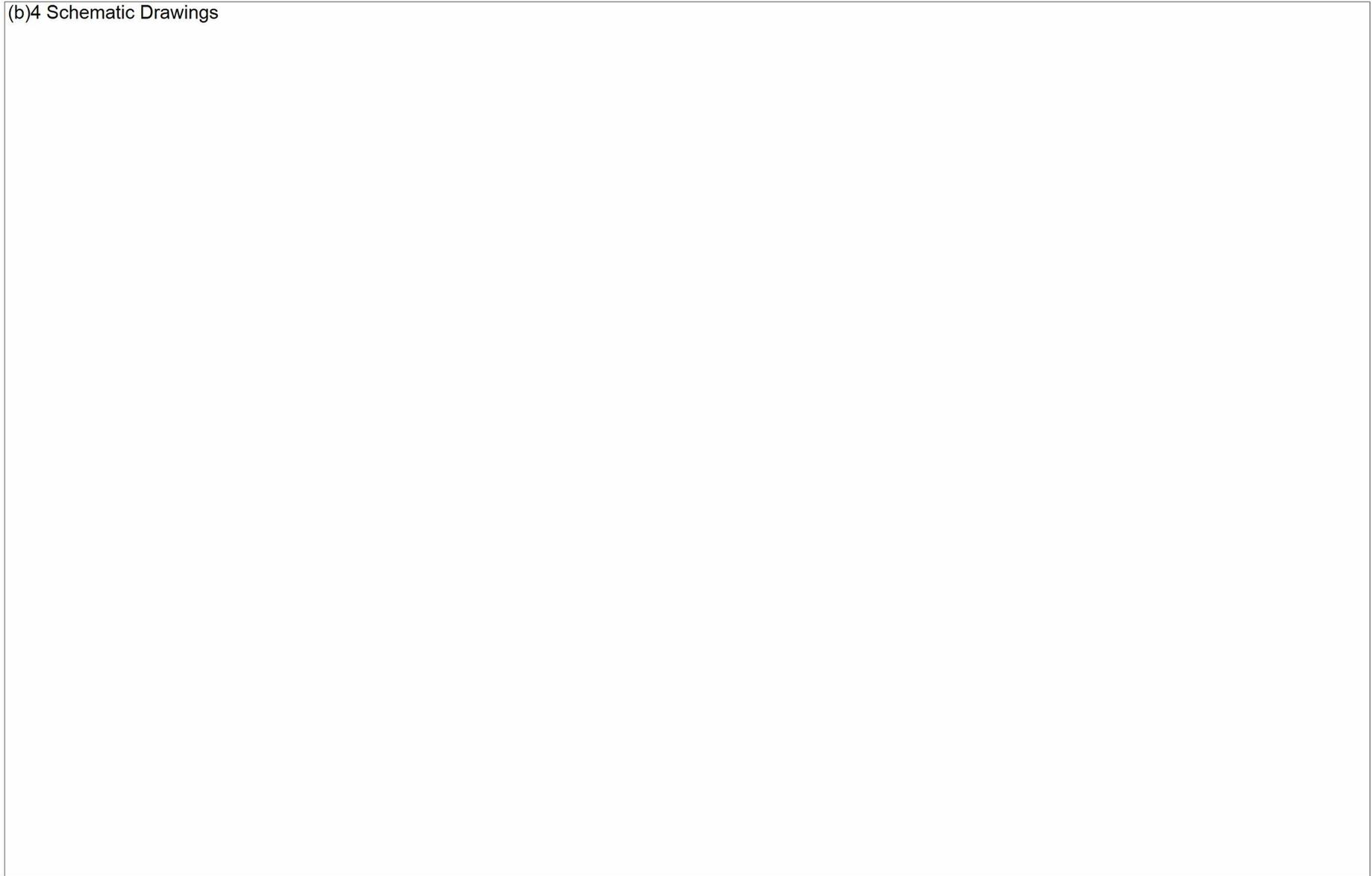
Catalog Number	Description
01.00214.144	DUROM US Acetabular Component 44/38 D
01.00214.146	DUROM US Acetabular Component 46/40 F
01.00214.148	DUROM US Acetabular Component 48/42 H
01.00214.150	DUROM US Acetabular Component 50/44 J
01.00214.152	DUROM US Acetabular Component 52/46 L
01.00214.154	DUROM US Acetabular Component 54/48 N
01.00214.156	DUROM US Acetabular Component 56/50 P
01.00214.158	DUROM US Acetabular Component 58/52 R
01.00214.160	DUROM US Acetabular Component 60/54 T
01.00214.162	DUROM US Acetabular Component 62/56 V
01.00214.164	DUROM US Acetabular Component 64/58 X
01.00214.166	DUROM US Acetabular Component 66/60 Z

Metasul LDH Large Diameter Heads & Adapters

Catalog Number	Description
01.00181.380	Metasul Large Diameter Head Ø 38 code D
01.00181.400	Metasul Large Diameter Head Ø 40 code F
01.00181.420	Metasul Large Diameter Head Ø 42 code H
01.00181.440	Metasul Large Diameter Head Ø 44 code J
01.00181.460	Metasul Large Diameter Head Ø 46 code L

Catalog Number	Description
01.00181.480	Metasul Large Diameter Head Ø 48 code N
01.00181.500	Metasul Large Diameter Head Ø 50 code P
01.00181.520	Metasul Large Diameter Head Ø 52 code R
01.00181.540	Metasul Large Diameter Head Ø 54 code T
01.00181.560	Metasul Large Diameter Head Ø 56 code V
01.00181.580	Metasul Large Diameter Head Ø 58 code X
01.00181.600	Metasul Large Diameter Head Ø 60 code Z
01.00185.145	Head adapter S, 12/14
01.00185.146	Head adapter M, 12/14
01.00185.147	Head adapter L, 12/14
01.00185.148	Head adapter XL, 12/14

(b)4 Schematic Drawings

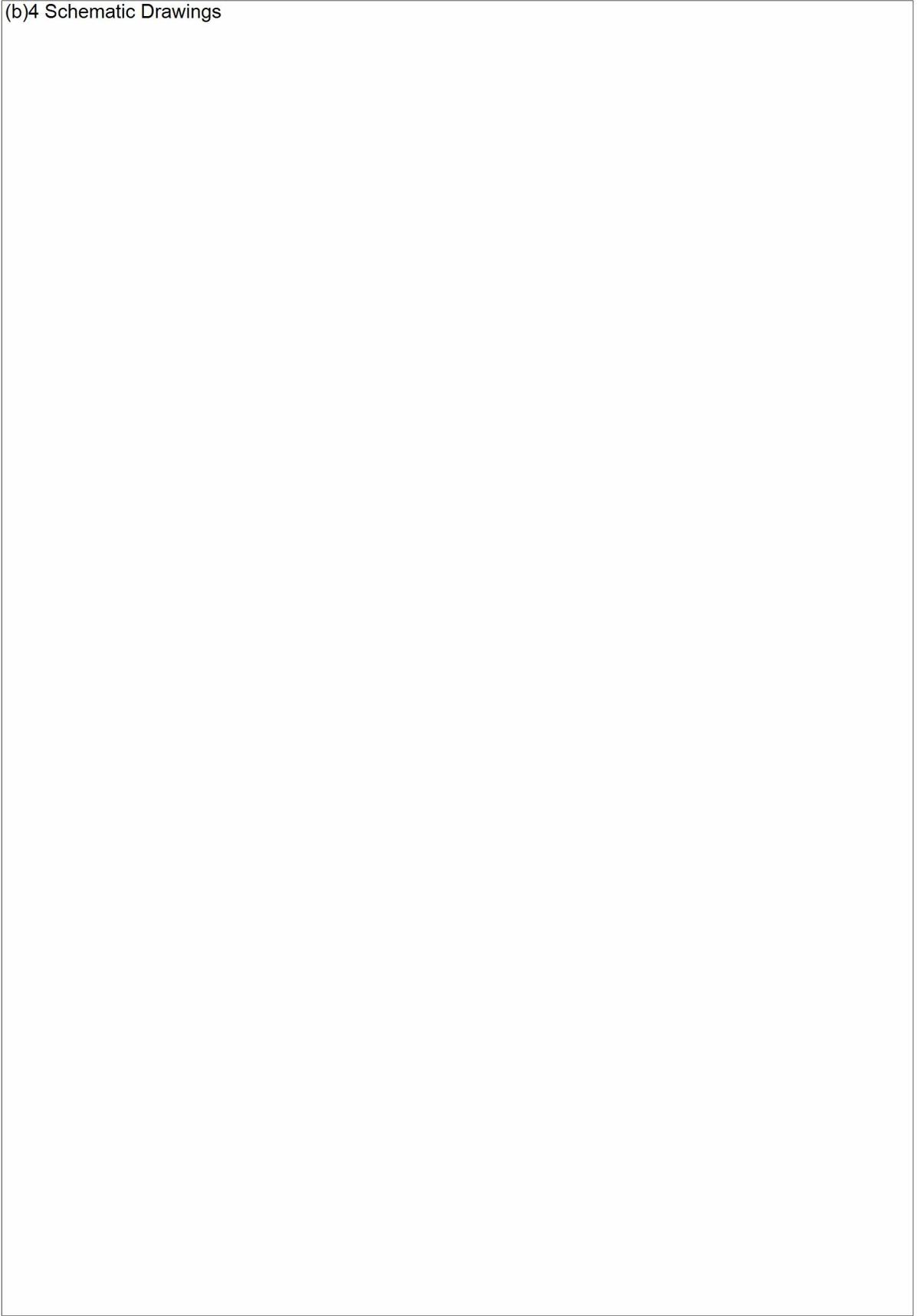


159

**CONFIDENTIAL AND PROPRIETARY INFORMATION
EXEMPT FROM DISCLOSURE UNDER FOI**

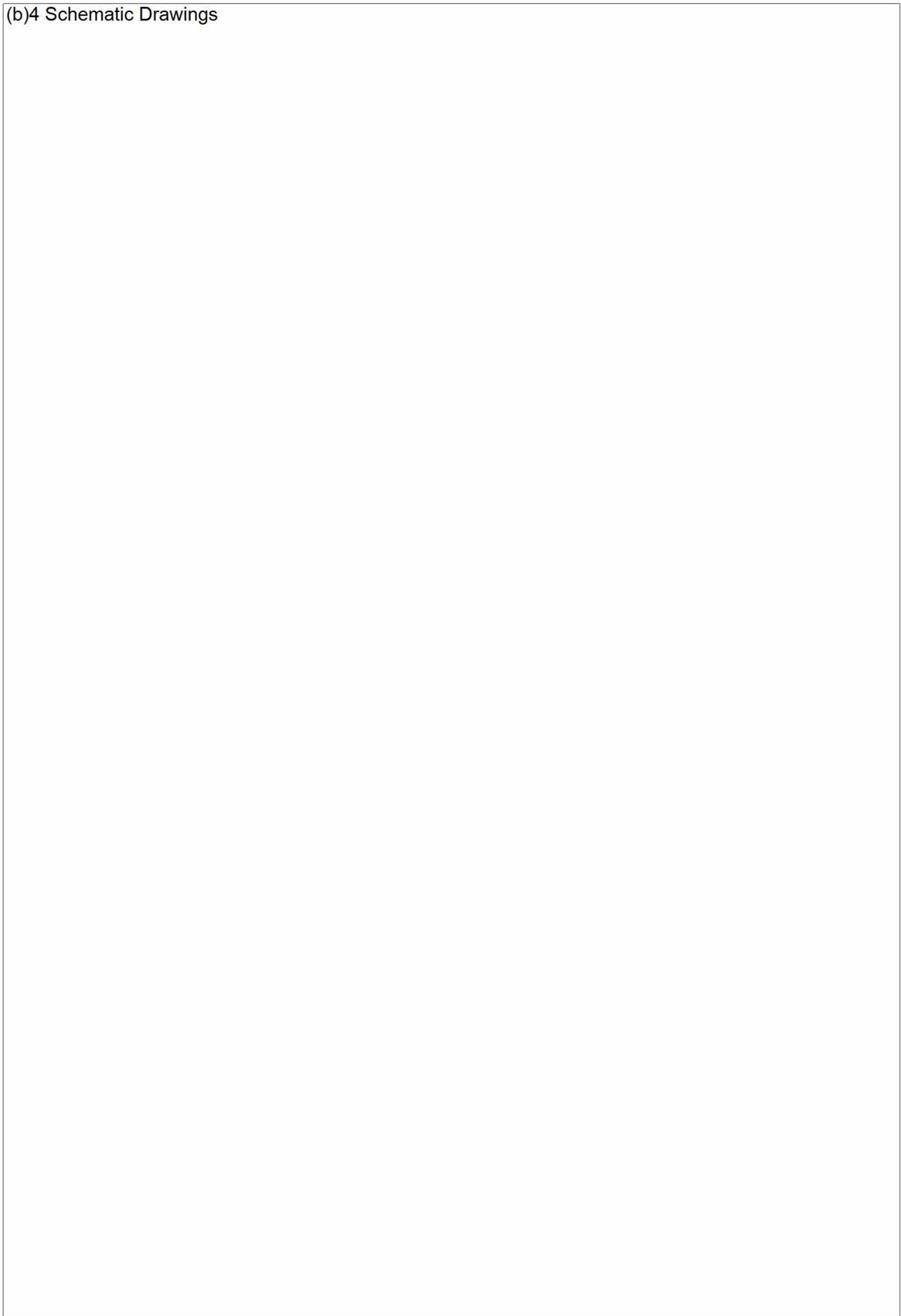


(b)4 Schematic Drawings





(b)4 Schematic Drawings





(b)4 Schematic Drawings



162



(b)4 Schematic Drawings



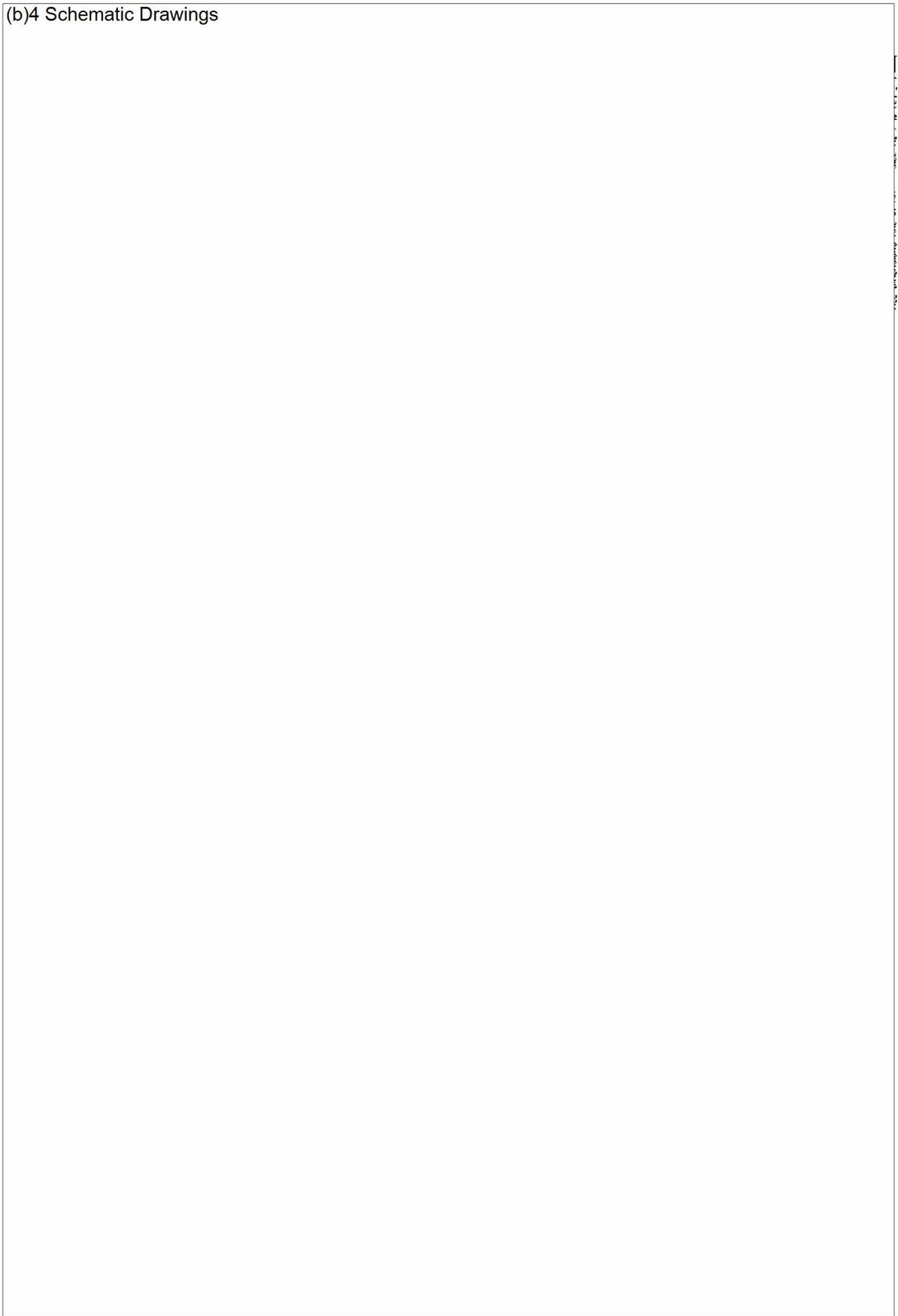


(b)4 Schematic Drawings





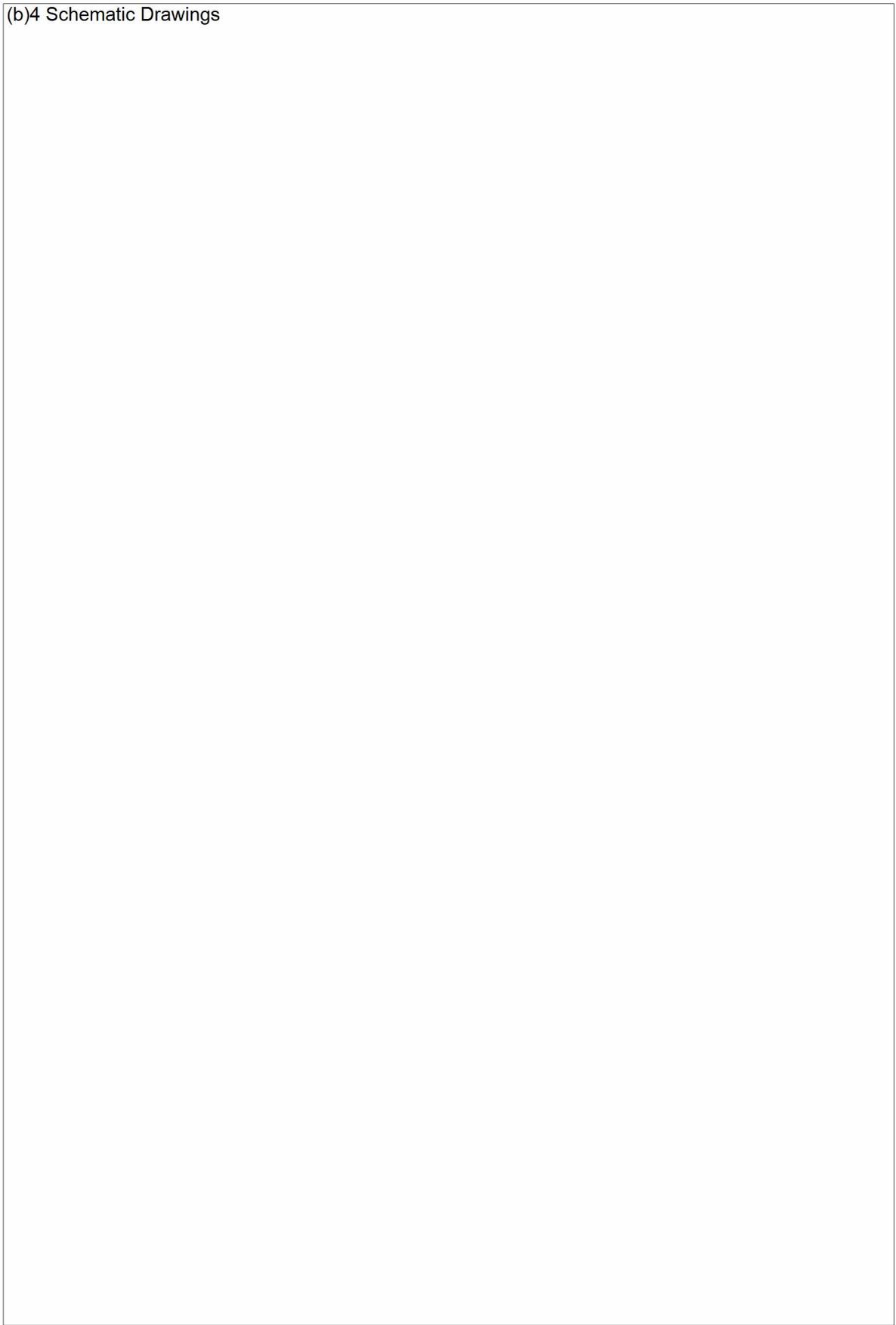
(b)4 Schematic Drawings



165



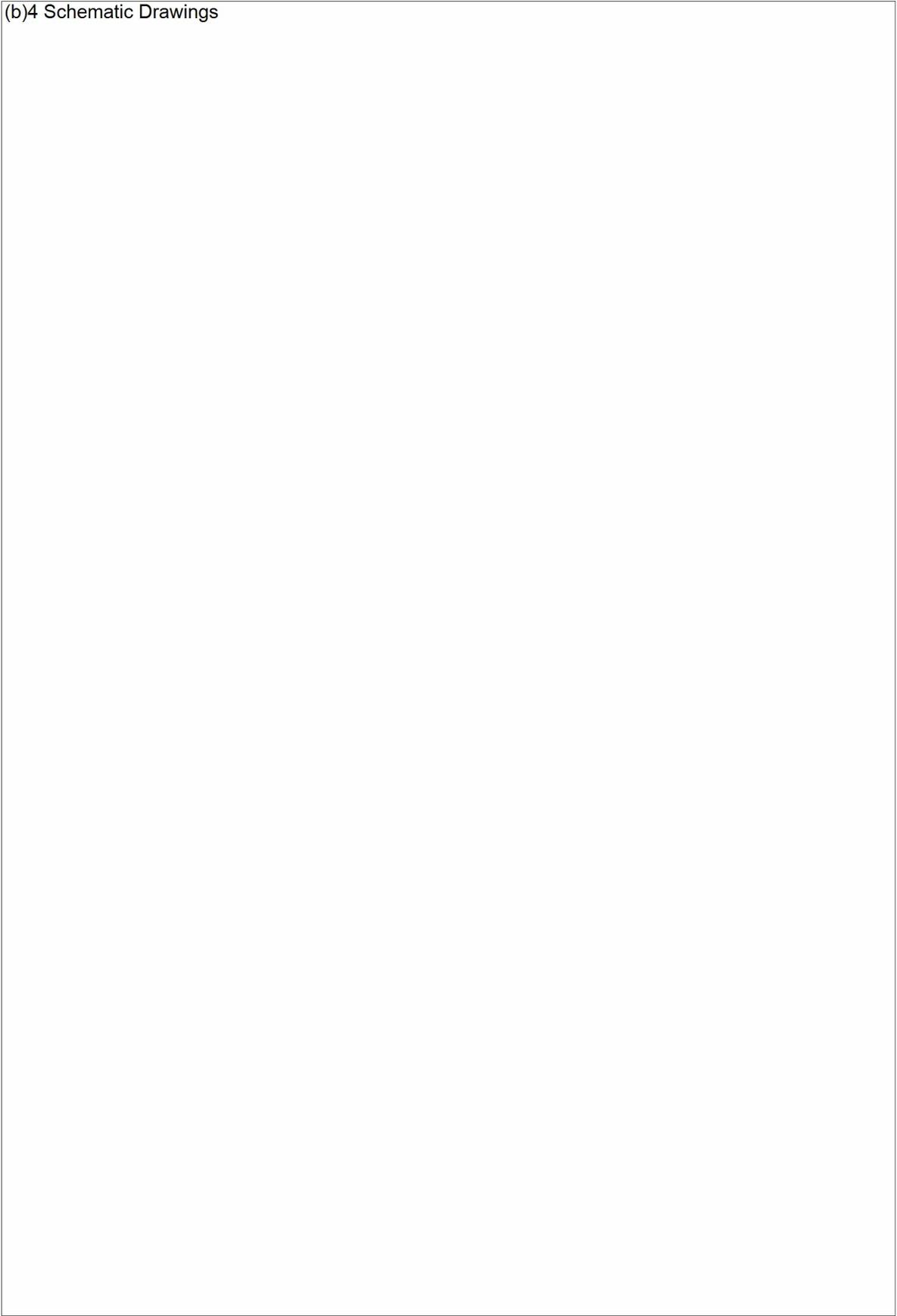
(b)4 Schematic Drawings



146



(b)4 Schematic Drawings

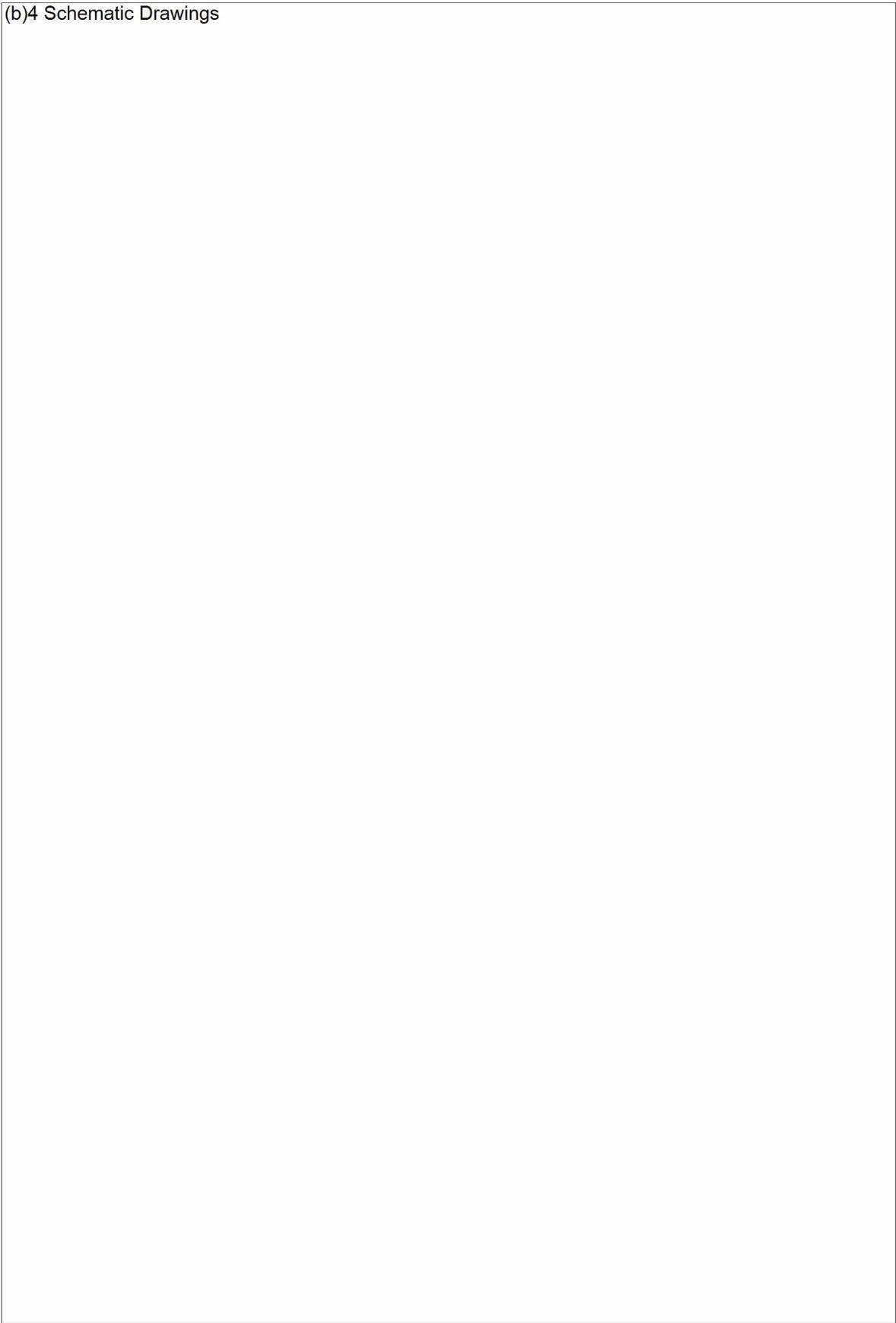


167

CONFIDENTIAL AND PROPRIETARY INFORMATION
EXEMPT FROM DISCLOSURE UNDER FOI



(b)4 Schematic Drawings



168

CONFIDENTIAL AND PROPRIETARY INFORMATION
EXEMPT FROM DISCLOSURE UNDER FOI



(b)4 Schematic Drawings



169

CONFIDENTIAL AND PROPRIETARY INFORMATION
EXEMPT FROM DISCLOSURE UNDER FOI



(b)4 Schematic Drawings



170



(b)4 Schematic Drawings

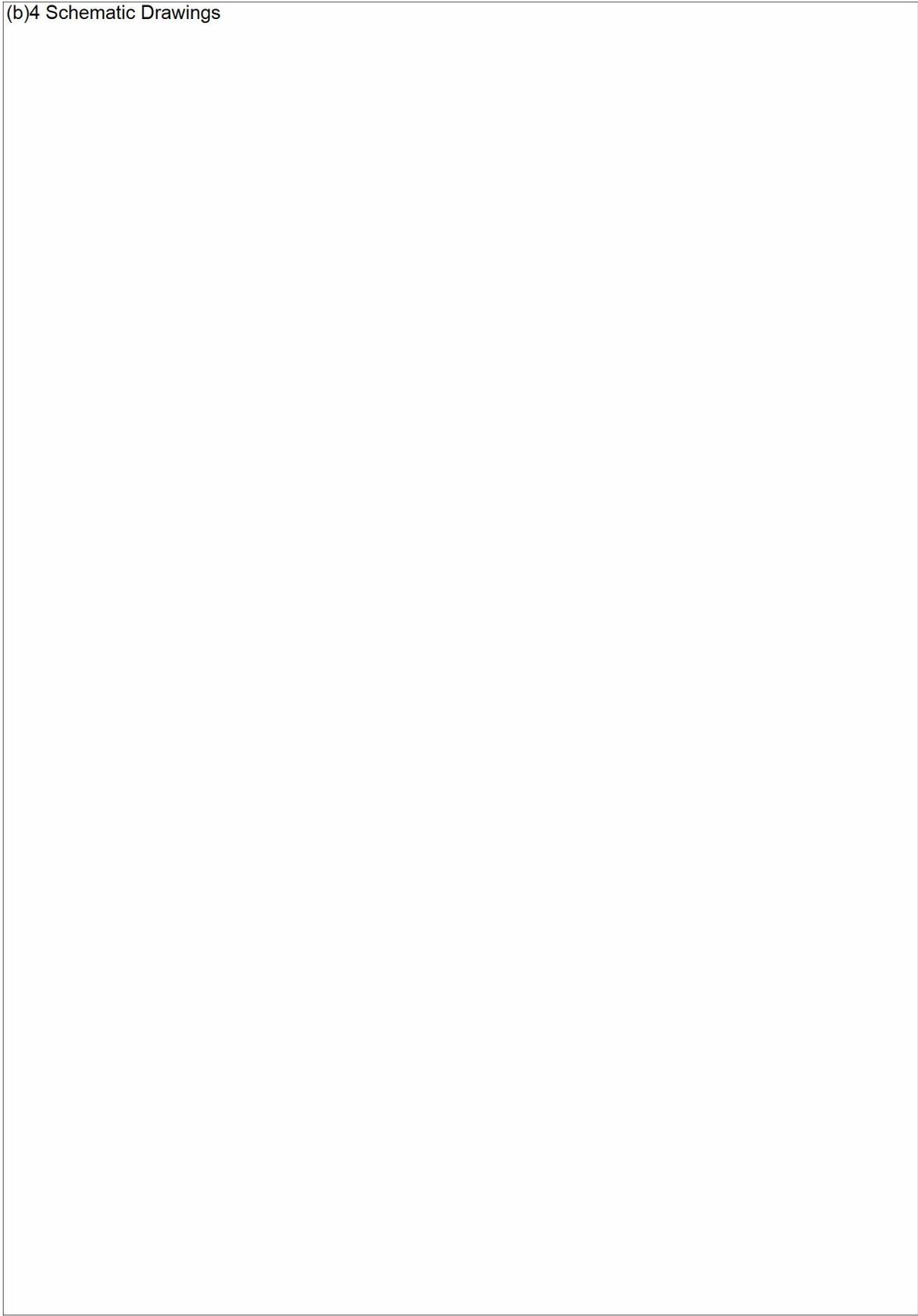


171

CONFIDENTIAL AND PROPRIETARY INFORMATION
EXEMPT FROM DISCLOSURE UNDER FOI



(b)4 Schematic Drawings



CONFIDENTIAL AND PROPRIETARY INFORMATION
EXEMPT FROM DISCLOSURE UNDER FOI



(b)4 Schematic Drawings

CONFIDENTIAL AND PROPRIETARY INFORMATION
EXEMPT FROM DISCLOSURE UNDER FOI

173



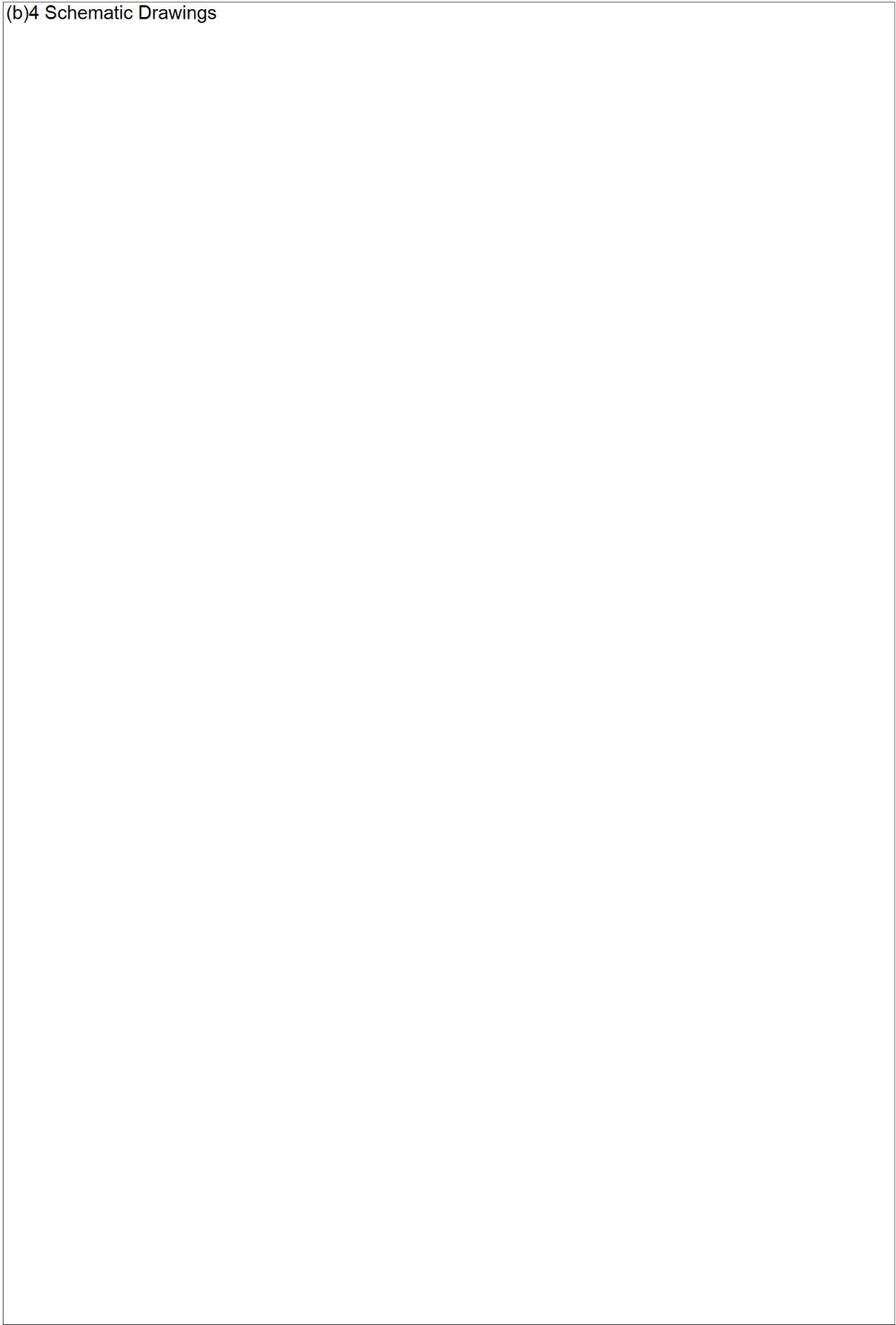
(b)4 Schematic Drawings



5/14/15



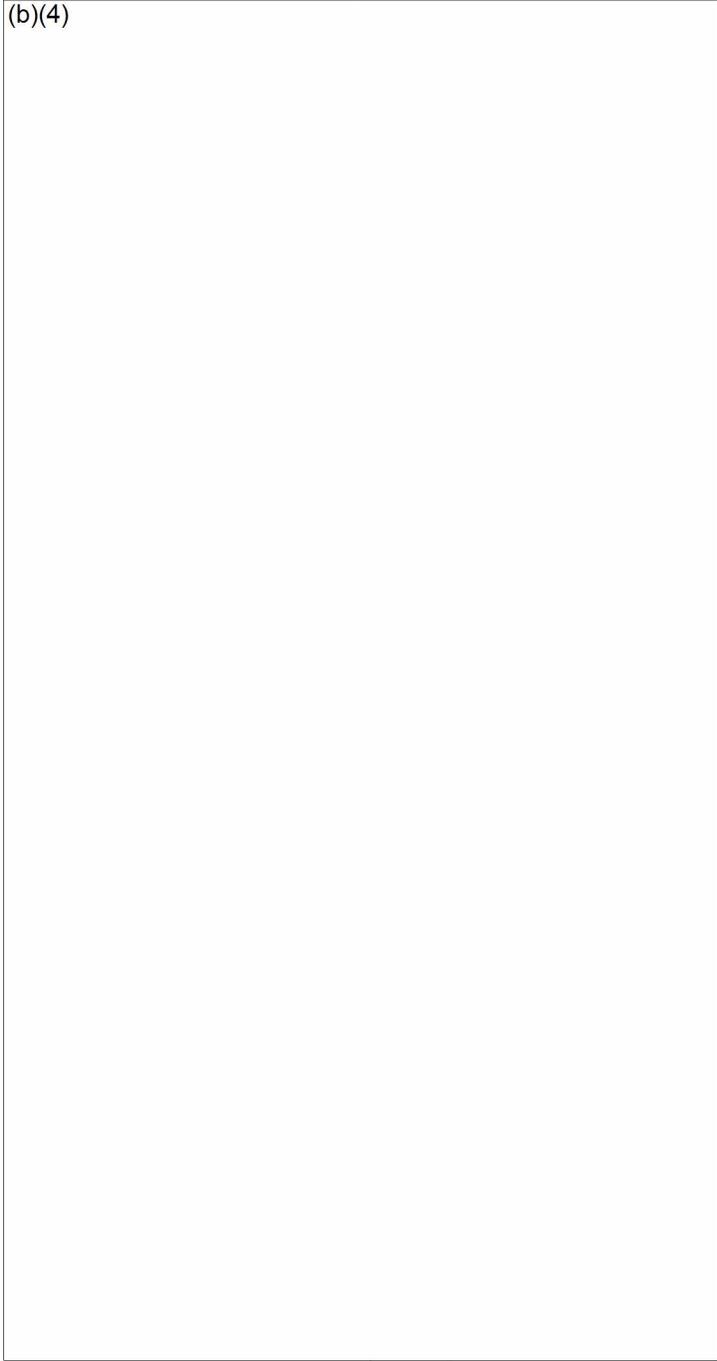
(b)4 Schematic Drawings



Manufacture of Durom Acetabular Components

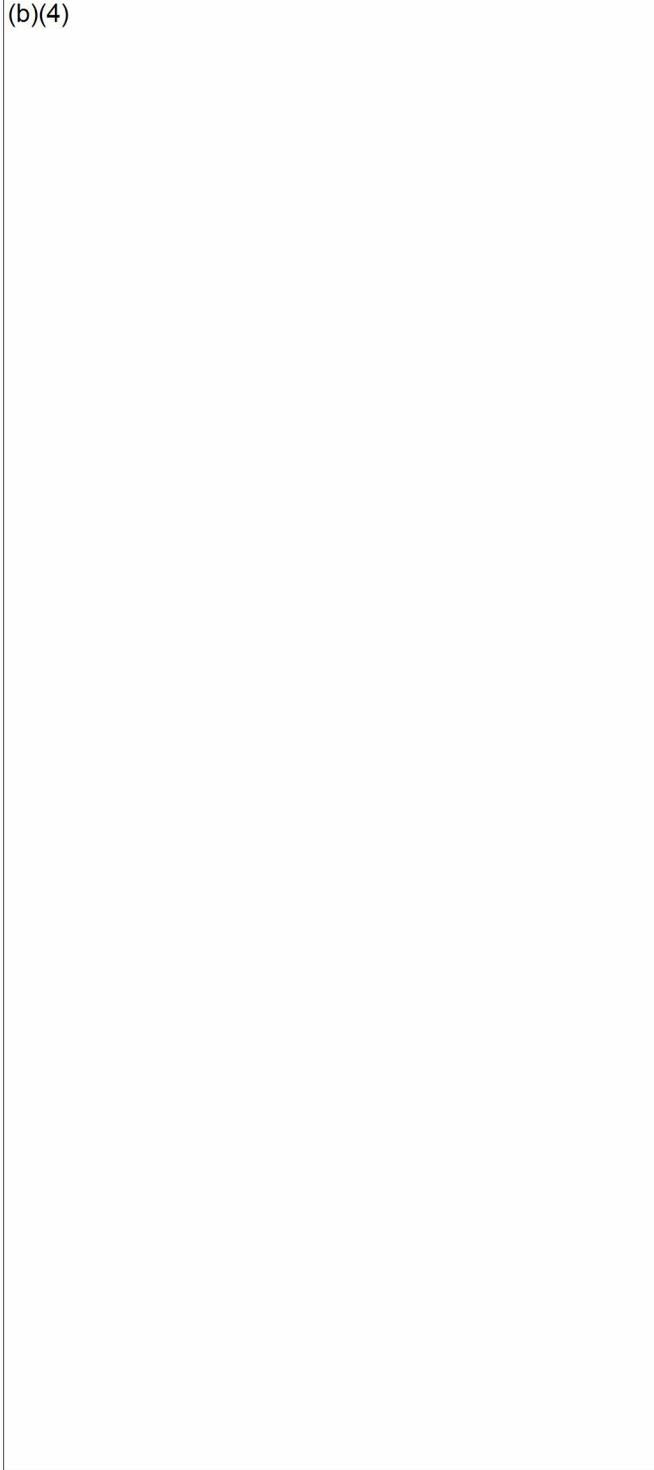
All Durom Acetabular Components are manufactured and inspected in accordance with the certified ISO 13485 Quality Assurance System of Zimmer GmbH.

(b)(4)



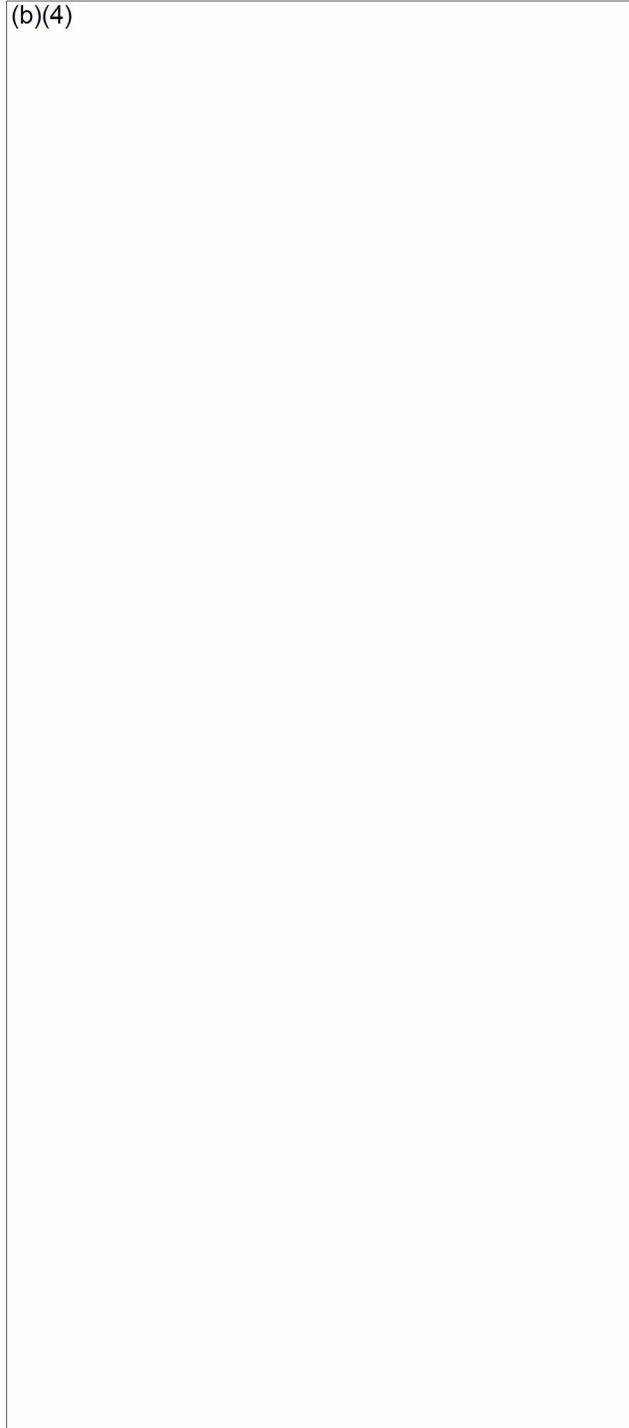
Manufacturing Flowchart of the Large Diameter Head

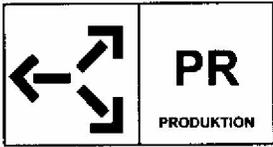
(b)(4)



Manufacturing Flowchart of the LDH Adapter

(b)(4)





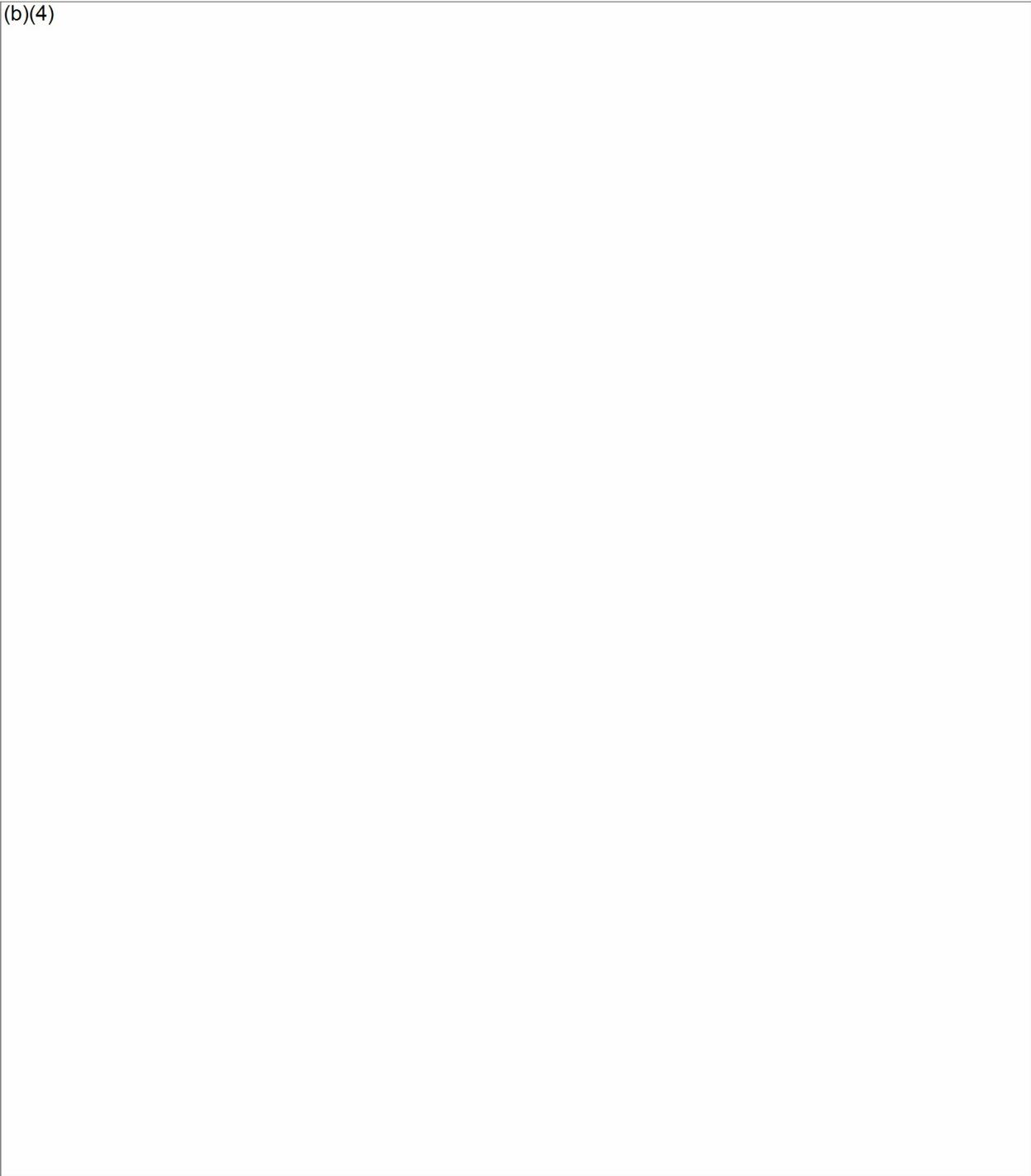
A
A
U



Beil. 1 zu AAU Q.48.020
Seite 1 von 1
Rev. B
Datum 2004-10-04

KOLLERH 12.12.2005 12:00:42

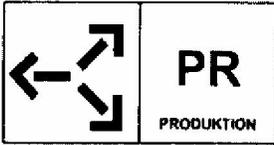
(b)(4)



QV1 / Q.48.020 / B / DB1 02 / freigegeben

CONFIDENTIAL AND PROPRIETARY INFORMATION
EXEMPT FROM DISCLOSURE UNDER FOI

0115
179



AAU



Beif. 1 zu AAU Q.48.020

Datum 3.10.02

COLLERH 12.12.2005 12:00:42

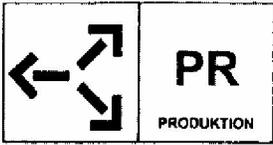
(b)(4)



CONFIDENTIAL AND PROPRIETARY INFORMATION
EXEMPT FROM DISCLOSURE UNDER FOI

QV1

0116
180



A
A
U



Beil. 1 zu AAU Q.48.020

Datum 3.10.03

KOLLERH 12.12.2005 12:00:42

(b)(4)



QV1 / Q.48.020 / B / DB1 02 / freigegeben

CONFIDENTIAL AND PROPRIETARY INFORMATION
EXEMPT FROM DISCLOSURE UNDER FOI

0117
181

(b)(4)



Beil. 1 zu AAU Q.48.020

Datum 3.10.03

KOLLERH 12.12.2005 12:00:42

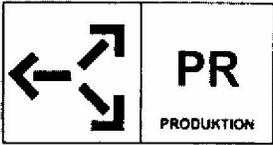
(b)(4)



QV1 / Q.48.020 / B / DB1 02 / freigegeben

**CONFIDENTIAL AND PROPRIETARY INFORMATION
EXEMPT FROM DISCLOSURE UNDER FOI**

0118
182



AAU

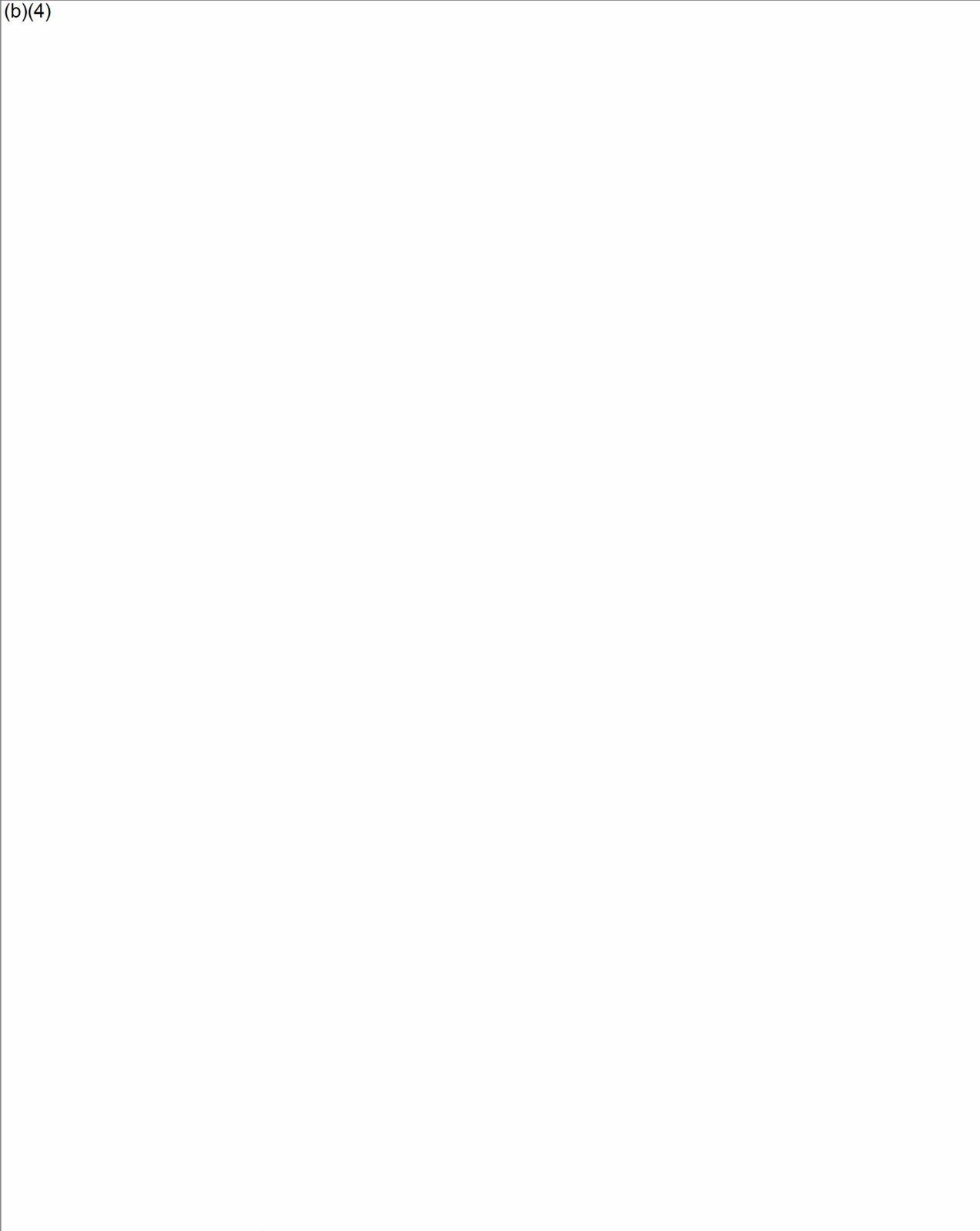


Beil. 1 zu AAU Q.48.020

Datum 3.10.03

KOLLERH 12.12.2005 12:00:42

(b)(4)

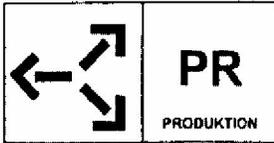


QV1 / Q.48.020 / B1 / DB1 02 / Freigegeben

CONFIDENTIAL AND PROPRIETARY INFORMATION
EXEMPT FROM DISCLOSURE UNDER FOI

183

0119



AAU



Beil. 1 zu AAU Q.48.020

Datum 3.10.03

OLLERH 12.12.2005 12:00:42

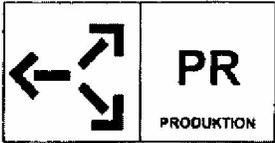
(b)(4)



CONFIDENTIAL AND PROPRIETARY INFORMATION
EXEMPT FROM DISCLOSURE UNDER FOI

184

0120



AAU

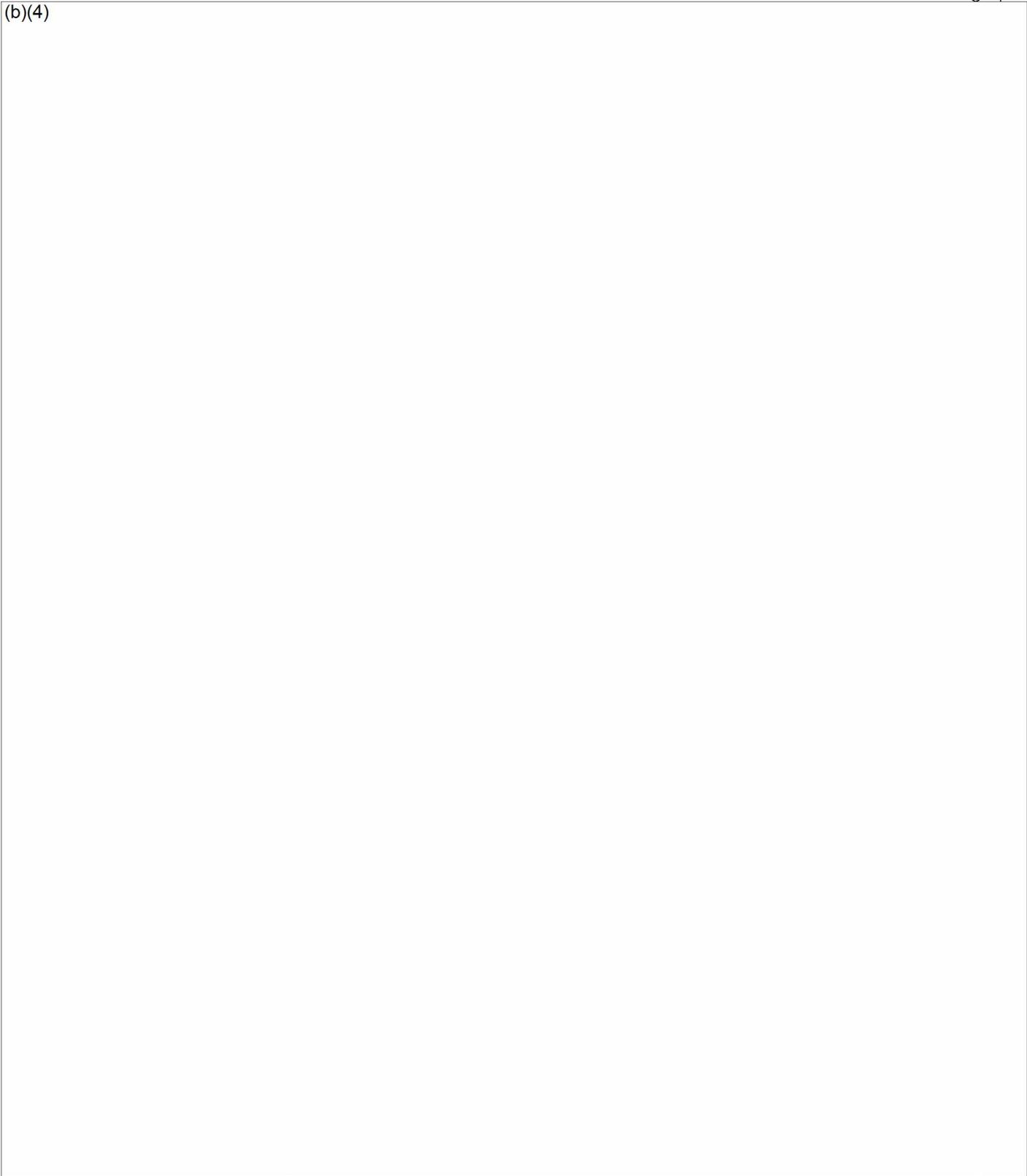


Beil. 1 zu AAU Q.48.020

Datum 3.10.03

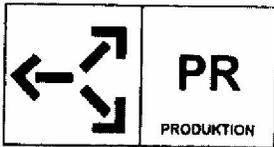
COLLERH 12.12.2005 12:00:42

(b)(4)



CONFIDENTIAL AND PROPRIETARY INFORMATION
EXEMPT FROM DISCLOSURE UNDER FOI

185 ov



A
A
U



Beil. 1 zu AAU Q.48.020

Datum 3.10.03

LLERH 12.12.2005 12:00:42

(b)(4)

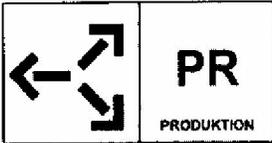


CONFIDENTIAL AND PROPRIETARY INFORMATION
EXEMPT FROM DISCLOSURE UNDER FOI

186

QV1

0122



AAU



Beil. 1 zu AAU Q.48.020

Datum 3.10.03

LLERH 12.12.2005 12:00:42

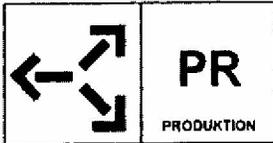
(b)(4)



CONFIDENTIAL AND PROPRIETARY INFORMATION
EXEMPT FROM DISCLOSURE UNDER FOI

187 QV1

0123



AAU



Beil. 1 zu AAU Q.48.020

Datum 3.10.03

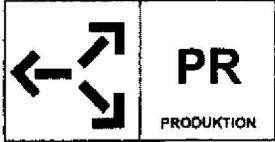
OLLERH 12.12.2005 12:00:42

(b)(4)



CONFIDENTIAL AND PROPRIETARY INFORMATION
EXEMPT FROM DISCLOSURE UNDER FOI

188 QV1



AAU



Beil. 1 zu AAU Q.48.020

Datum 5.11.03

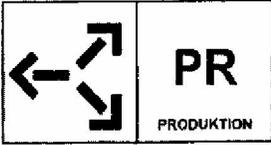
LEHR 12.12.2005 12:00:42

(b)(4)



CONFIDENTIAL AND PROPRIETARY INFORMATION
EXEMPT FROM DISCLOSURE UNDER FOI

189 QV1/Q



AAU

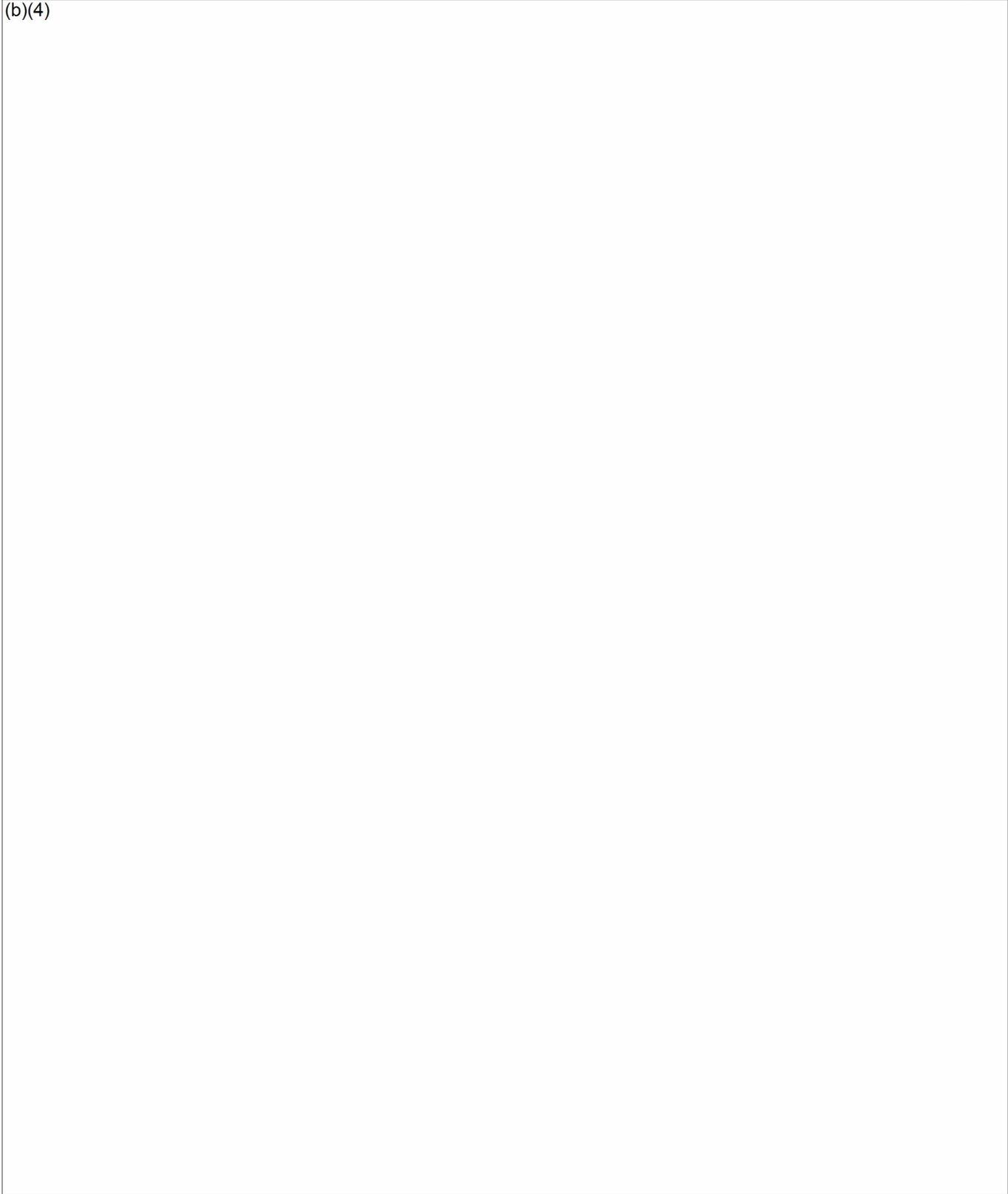


Beil. 1 zu AAU Q.48.020

Datum 5.11.03

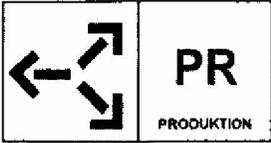
LERH 12.12.2005 12:00:42

(b)(4)



CONFIDENTIAL AND PROPRIETARY INFORMATION
EXEMPT FROM DISCLOSURE UNDER FOI

190



A
A
U



Beil. 1 zu AAU Q.48.020

Datum 5.11.03

LLERH 12.12.2005 12:00:42

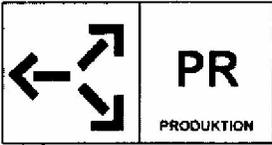
(b)(4)



CONFIDENTIAL AND PROPRIETARY INFORMATION
EXEMPT FROM DISCLOSURE UNDER FOI

0170

0127
191



AAU



Beil. 1 zu AAU Q.48.020

Datum 5.11.03

RH 12.12.2005 12:00:42

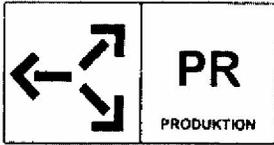
(b)(4)



CONFIDENTIAL AND PROPRIETARY INFORMATION
EXEMPT FROM DISCLOSURE UNDER FOI

CV1

0128
192



A
A
U



Beil. 1 zu AAU Q.48.020

Datum 9.3.04

ERH 12.12.2005 12:00:42

(b)(4)

CONFIDENTIAL AND PROPRIETARY INFORMATION
EXEMPT FROM DISCLOSURE UNDER FOI

0V1

0129
193

Femoral Stems for Total Hip Arthroplasty



Important information for the operating surgeon

CE 0123 (The CE mark is valid only if it is also printed on the product label)

Zimmer GmbH
P.O. Box
CH-8404 Winterthur, Switzerland
Telephone +41/ (0)52 262 60 70
Fax +41/ (0)52 262 01 39
www.zimmer.com

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

Manufacturer:	Representative in the USA:
Zimmer GmbH	Zimmer Austin, Inc.
Sulzer-Allee 8	9900 Spectrum Drive
CH-8404 Winterthur, Switzerland	Austin, Texas 78717, USA

Art. No. D 011 500 211 - e/d/f/i/sp/sw - Ed. 10/05

1. Instructions for use

Before using a product placed on the market by Zimmer, the operating surgeon should study carefully the following recommendations, warnings and instructions, as well as the product-specific information (technical product description, description of the surgical technique, catalogue sheet, etc.). Additional product information can be found in the description of the surgical technique, in the technical description of the product or on the appropriate catalogue sheet. Zimmer also recommends attending the appropriate user-training courses. The aforementioned documents and details of the training courses may be obtained from the appropriate representatives in the various countries.

The manufacturer, the importer and the suppliers of Zimmer products are not liable for complications or other effects that might occur for reasons such as incorrect indications or surgical technique, unsuitable choice of material or handling thereof, unsuitable use or handling of the instruments, asepsis and so on.

Patient Counseling Information

Complications and/or failure of total hip prostheses are more likely to occur in patients with unrealistic functional expectations, heavy patients, physically active patients, and/or patients that fail to follow through with the required rehabilitation program. Patients should be cautioned that these devices do not have the strength, elasticity, and/or durability characteristics of healthy bone. The patient must be instructed about all postoperative restrictions, particularly those related to occupational and sports activities, and about the possibility that the implant or its components may wear out, fail, or need to be removed and/or replaced.

1.1 General instructions

- Products of Zimmer may be implanted only by operating surgeons who are familiar with the general problems of joint replacement and who master the product-specific surgical techniques. The surgical techniques for Zimmer implants may be learned by attending courses held at hospitals that have experience with these implants.
- Implantation is to take place in accordance with the instructions for the recommended surgical procedure.
- Zimmer has not tested the safety or effectiveness of these devices for use in combination with non-Zimmer products or components. If surgeons elect to assemble and implant a construct that includes components not manufactured or distributed by Zimmer, they do so in reliance on their own clinical judgment and should so inform their patients.
- Due to the acquisition of pre-existing product lines, Zimmer has initiated a testing program to evaluate the **compatibility of these devices** with implants and components made or distributed by other Zimmer companies, including those of Zimmer GmbH (previously Centerpulse Orthopedics Ltd.), Zimmer, Inc., Zimmer Trabecular Metal Technology, Inc. (previously Implex Corp.), Zimmer U.K. Ltd., and Zimmer Austin, Inc. (previously Centerpulse Orthopedics, Inc.). Only authorized combinations should be used. To determine whether these devices have been authorized for use in a proposed combination, please contact your Zimmer sales representative or visit the Zimmer website: www.productcompatibility.zimmer.com. A printout of the website information can also be obtained by calling Zimmer, Inc. Customer Service, 1-800-348-2759 (U.S.) or the local international access code +1-574-372-4999 (outside the U.S.). Former Centerpulse and Implex products that are now packaged in Zimmer boxes, and for which compatibility could be an issue, have been labeled "former Centerpulse" and "former Implex" to provide clarification for the user.
- Product marking, especially size and taper specific information, should be checked to ensure correspondence with the product labeling. The taper size is indicated on the product label and – if possible – on the implant itself. **It is critical that the user ensure taper compatibility.**

- Before use, implants and corresponding instrumentation must be checked for damage. Implants or implant parts that are contaminated, unsterile, damaged, scratched or have been improperly handled or altered without authorization must not be implanted under any circumstances. Use of damaged or altered stems or surgical instruments may lead to early failure of the implant.
- Implants must not be machined or altered in any way, unless this is expressly envisaged in the design and in the surgical technique.
- Before putting the femoral head onto the stem, the taper of the stem must be cleaned and dried. The femoral head has to be inserted on to the stem taper with a rotary motion until it is immovable. For fixation of the femoral head, the plastic impactor should be struck with a mallet in an axial direction as necessary.
- Do not impact the stem into the femoral canal after the head component is assembled. Further impaction could damage the head component or the taper attachment.
- Reliable seating of the femoral head on the stem taper is only possible when both mating surfaces are completely intact. If the stem taper is damaged in any way, the stem must not be used and should be replaced. **It is absolutely essential that the taper of the femoral stem fit perfectly with the taper of the head.**
- Femoral heads with greater neck lengths may be accompanied by a higher risk e.g. breakage or earlier loosening of the hip stem. The smaller the stem, the greater is this danger. Therefore, a +7 or an XL (+8) ball head should not be combined with the smallest stem sizes.
- With revision stems,
 - the longer the stem,
 - the smaller its diameter and
 - the more distal its point of anchorage, the greater the danger of a fracture of the stem.
- Implants are intended for single use only.
- Functioning of implants is of limited duration (see also Point 1.3 and 2.4).
- If a Zimmer product is passed on to a third party, the party who passes it on must ensure that the relevant batch-tracking is possible at any time (traceability).

1.2 Product description and implant materials

A femoral stem component is used in conjunction with a femoral head component for replacement of the proximal femur in total hip arthroplasty. Femoral stems are available in different designs, materials, sizes, neck lengths and taper sizes. A taper is incorporated in the design of the stem to interlock it with the femoral head.

Femoral Stems for Total Hip Arthroplasty

This Physicians Insert is valid for the following femoral stems:

MS-30 Stem, Standard and Lateral version (Protasul-S30 [ISO 5832-9])

A highly polished stainless steel stem with optional distal centralizers. Intended for cemented use only.

Alloclassic Zweymüller-Stem (Protasul-100 [ISO 5832-11])

A rectangular, grit blasted titanium alloy stem intended for press-fit fixation only.

CLS-Spotorno Stem (Protasul-100 [ISO 5832-11])

A proximally fluted, grit blasted titanium alloy stem intended for press-fit fixation only.

Wagner Cone Protheses Stem (Protasul-100 [ISO 5832-11])

Wagner-Revision Stem (Protasul-100 [ISO 5832-11])

A circular, fully fluted grit blasted titanium alloy stem intended for press-fit fixation only.

Head Adapter (Protasul-20 [ISO 5832-12])

Intended for use as adapter between Metasul[®] LDH[™] Large Diameter Heads with standard Zimmer stem cones 12/14 and allows to adjust the neck length

Attention: These stems are not compatible for use with the VerSys +10.5 CoCrMo Head.

Information about the chemical composition and the mechanical properties of the materials used can be found in the appropriate sheets of the materials catalogue or in the appropriate product information documents.

1.3 General information on indications, contraindications and risk factors

- Indications and contraindications for the use of these components may be relative or absolute and must be carefully weighed against the patient's entire evaluation and the prognosis for possible alternative procedures.
- Patient selection should be largely dependent on patient's age, general health, conditions of available bone stock, prior surgery and anticipated further surgeries. An implantation is generally only indicated for patients who have reached skeletal maturity.

A. Indications

- Patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis.
- Those patients with failed previous surgery where pain, deformity, or dysfunction persists.
- Revision of previously failed hip arthroplasty.
- Total hip replacements may be considered for younger patients if any unequivocal indication outweighs the risks associated with the age of the patient and modified demands regarding activity and hip joint loading are assured. This includes severely crippled patients with multiple joint involvement, for whom an immediate need of hip mobility leads to an expectation of significant improvement in the quality of their lives.

B. Contraindications

- Patient's physical conditions that would eliminate or tend to eliminate adequate implant support or prevent the use of an appropriately sized implant, e.g., previous surgery, insufficient quality or quantity of bone resulting from conditions such as cancer or congenital dislocation, metabolic bone disease of the upper femur or pelvis, femoral osteotomy revision, girdlestone revision, osteoporosis, osteomyelitis, neuromuscular compromise or vascular deficiency in the affected limb in sufficient degree to render the procedure unjustifiable (e.g., absence of musculoligamentous supporting structures, joint neuropathy) or other conditions that may lead to inadequate skeletal fixation.
- Active infection of the hip, old or remote infection. This may be an absolute or relative contraindication. Every effort should be undertaken to rule out preoperative infection in a patient with suspicious symptoms, such as a history of, or when there are signs of, local inflammation, abscesses, fever, increased blood sedimentation rate, evidence of rapid joint destruction or bone resorption.
- Allergy to the implanted material, above all to metal (e.g. cobalt, chromium, nickel etc.).
- Local bone tumours and/or cysts.
- Pregnancy.

C. Risk factors

Risk factors can influence the success of the operation.

- Charcot's joints
- Muscle deficiencies
- Multiple joint disabilities
- Refusal to modify postoperative physical activities
- Heavy patients, obesity (especially over 220 pounds (100 kg)).
- Small-boned patients.
- Heavy labor
- Active sports
- History of falls
- General neurological abnormalities or neurological conditions including mental conditions (e.g., mental illness, senility, drug use, alcoholism) that tend to pre-empt the patient's ability or willingness to follow the surgeon's postoperative instructions.
- Marked osteoporosis, osteomalacia
- Systemic and metabolic disorders leading to progressive deterioration of bone, (e.g., cortisone therapies, immunosuppressive therapies)
- Patient's resistance generally weakened (HIV, tumor, infection).
- Suspected allergic reactions to implant materials
- Other joint disability (i.e., knees or ankles)
- Severe deformity leading to impaired anchorage or improper positioning of implants.

2. Warnings**2.1 Preoperative**

- Preoperative planning and the surgical technique for an implantation are based on principles that provide the foundations for sound surgical handling. Complete familiarity with the surgical technique is essential. The use of specific surgical instruments is recommended for each operation.
- Patients receiving hip joint replacements should be advised that the longevity of the implant may depend on their weight and level of activity.
- The doctor must explain the risks of inserting an implant to the patient, including the possible impact of the factors mentioned under Point 1.3 on the success of the operation and the possible negative effects mentioned under Point 2.4. The patient should also be informed as to what steps he/she can take in order to reduce the possible effects of these factors.
- If an implantation is taken into consideration, in particular for young and active patients, the operating surgeon should discuss all aspects of the operation and of the implant with the patient before surgery. This includes the

limits of joint restoration, the specific limitations for the patients, the possible consequences that could result from these limitations and the need, therefore, to follow the doctor's preoperative instructions.

- Allergies and other reactions to implant materials, although rare, should be considered and ruled out preoperatively.
- X-ray templates should be used to estimate implant sizes, placement and joint alignment. An adequate inventory of implant sizes as well as the corresponding instruments should be available at the time of surgery, including sizes larger and smaller than those expected to be used. Extra implant components are recommended.
- Re-use of an implant that was already implanted in the patient's body is strictly forbidden. Re-using an implant that has come into contact with the body fluids or tissues of a third party is also forbidden.
- Polymethylmethacrylate (PMMA) bone cement is used for securing, supporting and stabilizing devices intended for cemented fixation in bone, but it neither replaces the support function of sound bone nor eliminates the need for additional support during healing. In using cement for implant fixation, care should be used to ensure complete cement support on all parts of the device embedded in the bone cement to help prevent possible stress concentrations that may lead to failure.
- The safety and effectiveness of the use of this device in bilateral applications have not been established.

Failure to carry out proper preoperative planning can lead to errors (e.g. with regard to incorrect positioning and the choice and size of the implant).

2.2 Intraoperative

- The correct selection of the implant is extremely important. Selection of the implant refers to the appropriate type and size for each patient with consideration of the anatomical and biomechanical factors involved. Such factors include patient age, activity level, weight, bone and muscle conditions.
- Prior to closure, the surgical site should be thoroughly cleansed of bone chips, ectopic bone, bone cement, etc. Foreign particles at the metal/plastic articular interface may cause excessive wear and/or friction. Ectopic bone and/or bone spurs may lead to dislocation or painful and restricted motion. Range of motion should be thoroughly checked for early contact or instability.
- The largest cross-section component that allows for adequate bone support to be maintained is recommended. Failure to use the optimum size may result in loosening, bending, cracking, or fracture of the component, bone, or cement (if cement used).
- Stem and cup positioning and neck length are of critical importance. Subluxation, dislocation, and/or fracture of components may result due to muscle looseness and/or malpositioning of components.

2.3 Postoperative

- Early postoperative care should be carefully structured to maintain range of motion, and to prevent dislocation or thromboembolism. The patient should be instructed on the limitations of this device and should be cautioned regarding the load-bearing, range of motion, and activity levels permissible. Early load-bearing should be carefully controlled. A prosthesis-bearer's card should also be completed for the patient.
- Postoperative therapies, patient handling, and patient activities should be structured to prevent excessive loading of the operated limb. Surgical procedure chosen, patient's age and/or bone quality may necessitate extending the period of limited weight bearing.
- Periodic X-rays are recommended for close comparison with immediate postoperative X-rays to detect long-term evidence or progressive changes in implant position or loosening, or evidence of bending, cracking of component or cement, and/or disassembly of components.
- The patient should be encouraged to promptly report any unusual changes in the operative extremity to his physician.

2.4 Side effects

The potential adverse effects occurring with any total hip replacement may commonly include:

- Changing position of the implant (bending, fracture and/or disassembly of components or cement) with or without loosening or clinical symptoms.
- Perforation, fissure of the acetabulum, femur or trochanter, and/or trochanter avulsion.
- Subluxation, dislocation, decreased range of motion, and shortening or lengthening of the extremity.
- Fractures of the femur resulting from stress, bone defects resulting from earlier surgical procedures, deformity and/or osteoporosis.
- Ectopic ossification.
- Early or late infection.
- Cardiovascular disorders, including damage to blood vessels (iliac obturator, and femoral arteries), wound hematoma, venous thrombosis, pulmonary embolism, and myocardial infarction.
- Temporary or permanent neuropathies involving the femoral, sciatic, peroneal or obturator nerves.
- Pulmonary disorders including pneumonia and atelectasis.
- Aggravated conditions in other joints or back due to intraoperative trauma, leg length discrepancy, femoral medialization, or muscular deficiencies.
- Excessive wear of the acetabular component from damage to mating wear surfaces or debris particles.

- Tissue reactions and allergies to corrosion or wear products and cement particles.
- Urological complications, especially urinary retention and infection.
- Aseptic loosening.
- Possible detachment of coatings could be associated with increased debris.
- Other complications associated with general surgery, drugs, or ancillary devices used, blood, etc.
- Pain.

2.5 Sterilization

Implants have been sterilized by a minimum of 25 KGy (2.5 Mrad) of gamma irradiation.

2.6 Resterilization

Contact with substances containing chlorine, phosphorus, fluorine or detergents containing fats must be avoided.

These sterilization instructions are consistent with AORN and ANSI/AAMI/ISO guidelines. They should be used for items supplied non-sterile, for reprocessing reusable devices, or for sterile items that were opened but unused.

Recommended Sterilization/Resterilization Specifications:

Solid Metal Implants, and PMMA-Coated Metal Implants and Provisionals

Steam Sterilization			
Type	Minimum Temperature	Minimum Exposure Time	Dry Time
Gravity Displacement	121°C (250°F)	30 minutes	Varies by load configuration and sterilizer type
Gravity Displacement	132°C (270°F)	15 minutes	
Pre-vacuum	132°C (270°F)	4 minutes	

All Reusable Instruments and Provisionals

Steam Sterilization			
Type	Minimum Temperature	Minimum Exposure Time	Dry Time
Pre-vacuum	132°C (270°F)	4 minutes	Varies by load configuration and sterilizer type

Follow the sterilizer manufacturer's instructions for loading patterns and selection of sterilization parameters. Drying times vary according to load size and should be increased for larger loads.

Note: Where there is a concern about TSE/vCJD contamination, decontaminate using a prevacuum autoclave cycle at a minimum of 134 °C (273 °F) for at least 18 minutes or use a gravity autoclave cycle at a minimum of 121°C (250 °F) for at least 60 minutes. World Health Organization (WHO/CDS/CSR/APH 200 3, "WHO Infection Control Guidelines for TSE," March 1999).

UHMWPE Implants, PMMA Implants and Metal/Polymer Combination Implants

100% Ethylene Oxide (EO) Sterilization			
Gas Concentration	Temperature	Exposure Time	Relative Humidity
725 mg/L EO	55°C (131°F)	60 minutes	70%

The recommended aeration period for EO is a minimum of 12 hours at 130 °F (54°C) in a heated mechanical aerator.

UHMWPE Implants, PMMA Implants

STERRAD Gas Plasma Sterilization		
Gas Concentration	Temperature	Exposure Time
6 mg/L (5% hydrogen peroxide)	45°C (113°F)	65 minutes

Do not reuse instruments or devices labeled for single use only.

Do not resterilize single use only components that have been contaminated with body fluids or debris or previously implanted.

Do not use the original plastic cavities or lids for resterilization. Single devices may use a standard Tyvek pouch. Ensure that the pouch is large enough to contain the device without stressing the seals or tearing the pouch.

Do not expose polyethylene or polymethyl methacrylate (PMMA) components to steam sterilization (including flash sterilization). The high temperatures may cause softening, warping, cracking, or dimensional and material property changes.

Rinse porous, PMMA or PMMA-coated components to remove lint or debris (using USP purified water) and enclose in a lint-free sterilization wrap but do not allow any PMMA surface to contact the wrap or tray. During sterilization the coating softens and may be damaged by contact. Cool naturally and do not force cooling by immersion in room temperature water or saline. Any fine lines in the coating that develop during sterilization will not affect bonding of the PMMA.

Modular implant components must be sterilized separately to minimize potential bioburden buildup in the dead space and expansion/contraction stresses.

Implants made from plastic materials and components with plastic parts cannot be re-sterilized and reprocessed industrially, as this can lead to deterioration of the material.

If a Zimmer product is sterilized or re-sterilized by the user, a note should be made of this in the appropriate patient documentation (e.g surgical report), and the relevant certification kept as evidence.

Validation of the cleaning, disinfecting and sterilizing or re-sterilising procedures and especially the correct settings of the relevant equipment should be verified regularly.

Once the "Use By" date of a product has been reached, it should not be repacked and re-sterilized by a third-party firm, since in this case there would no longer be any guarantee of traceability.

The recommendations given here are provided for information purposes only. No liability can be accepted with regard to the sterility of implants or instruments cleaned and sterilized by purchasers or users or to those that are re-sterilized.

3. Storage and Handling

- Implants must be stored unopened in their original packaging.
- Before sterile implants are removed from their packaging, the protective wrapping must be examined for possible damage as this could jeopardize their sterility. If an expiration date for sterility of the product is indicated, this must be observed. If the packaging is damaged or the sterility expiration date has been reached, the implants must be returned to the manufacturer.
- Protective caps or other protective devices must not be removed until immediately before use.
- Implants, implant parts and instruments that can no longer be used may be returned to the manufacturer for proper disposal free of charge.
- Implants are extremely sensitive to damage. Even small scratches or marks left by impacts on the surfaces will cause excessive wear and may give rise to complications. Extremely careful handling is therefore strongly recommended.
- Instruments are subject to a certain degree of wear and therefore have to be considered non-durable materials. They must be checked for correct functioning before use and, if necessary, they must be returned to the appropriate local representative for repair.
- Any additional instructions (e.g. adhesive instruction labels on the packaging) are to be followed.

3.1 Color Coding for products of joint replacement

Left	Red
Right	Green
Cemented	Yellow
Uncemented	Blue
Metasul	Magenta
Ceramic	Grey

4. Pictograms



Symbol for «Follow the Instructions for Use»



Symbol for «Not to be re-used »



Symbol for «To be used by... » (Year, Month)



Symbol for «By Prescription Only»



Symbol for «Manufacture Date»



Symbol for «Manufacturer»



Symbol for «Contents packed without sterilization»

STERILE R[!]

Symbol for «Sterile» and «Sterilization by radiation»

5. Trademarks

PROTASUL®, METASUL®, DURASUL®, MS-30®, ALLOCLASSIC®, ZWEYMÜLLER®, CLS™, SPOTORNO™ and WAGNER™ are trademarks of Zimmer.

Acetabular cups

Important information for the operating surgeon

CE 0123 (The CE mark is valid only if it is also printed on the product label)

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

Manufacturer: Zimmer GmbH Sulzer-Allee 8 CH-8404 Winterthur, Switzerland	Representative in the USA: Zimmer Austin, Inc. 9900 Spectrum Drive Austin, Texas 78717, USA	Art. No. D011 500 213 - e/d/f/i/sp/sw - Ed. 08/05
---	--	---



Zimmer GmbH
P.O. Box
CH-8404 Winterthur, Switzerland
Telephone +41/ (0)52 262 60 70
Fax +41/ (0)52 262 01 39
www.zimmer.com

1. Instructions for use

Before using a product placed on the market by Zimmer, the operating surgeon should study carefully the following recommendations, warnings and instructions, as well as the product-specific information (technical product description, description of the surgical technique, catalogue sheet, etc.). Additional product information can be found in the description of the surgical technique, in the technical description of the product or on the appropriate catalogue sheet. Zimmer also recommends attending the appropriate user-training courses. The aforementioned documents and details of the training courses may be obtained from the appropriate representatives in the various countries.

The manufacturer, the importer and the suppliers of Zimmer products are not liable for complications or other effects that might occur for reasons such as incorrect indications or surgical technique, unsuitable choice of material or handling thereof, unsuitable use or handling of the instruments, asepsis and so on.

Patient Counseling Information

Complications and/or failure of total hip prostheses are more likely to occur in patients with unrealistic functional expectations, heavy patients, physically active patients, and/or patients that fail to follow through with the required rehabilitation program. Patients should be cautioned that these devices do not have the strength, elasticity, and/or durability characteristics of healthy bone. The patient must be instructed about all postoperative restrictions, particularly those related to occupational and sports activities, and about the possibility that the implant or its components may wear out, fail, or need to be removed and/or replaced.

1.1 General instructions

- Zimmer products may be implanted only by operating surgeons who are familiar with the general problems of joint replacement and who are able to master the product-specific surgical techniques. The surgical techniques for Zimmer implants may be learned by attending courses held at hospitals that have experience with these implants.
- Implantation is to take place in accordance with the instructions for the recommended surgical procedure.
- Zimmer has not tested the safety or effectiveness of these devices for use in combination with non-Zimmer products or components. If surgeons elect to assemble and implant a construct that includes components not manufactured or distributed by Zimmer, they do so in reliance on their own clinical judgment and should so inform their patients.
- Due to the acquisition of pre-existing product lines, Zimmer has initiated a testing program to evaluate the **compatibility of these devices** with implants and components made or distributed by other Zimmer companies, including those of Zimmer GmbH (previously Centerpulse Orthopedics Ltd.), Zimmer, Inc., Zimmer Trabecular Metal Technology, Inc. (previously Implex Corp.), Zimmer U.K. Ltd., and Zimmer Austin, Inc. (previously Centerpulse Orthopedics, Inc.). Only authorized combinations should be used. To determine whether these devices have been authorized for use in a proposed combination, please contact your Zimmer sales representative or visit the Zimmer website: www.productcompatibility.zimmer.com. A printout of the website information can also be obtained by calling Zimmer, Inc. Customer Service, 1-800-348-2759 (U.S.) or the local international access code +1-574-372-4999 (outside the U.S.). Former Centerpulse and Implex products that are now packaged in Zimmer boxes, and for which

compatibility could be an issue, have been labeled «former Centerpulse» and «former Implex» to provide clarification for the user.

- Product marking, especially size and taper specific information, should be checked to ensure correspondence with the product labeling. The taper size is indicated on the product label and – if possible – on the implant itself. **It is critical that the user ensures taper compatibility.**
- Implants and the corresponding instrumentation should be carefully checked before they are used or implanted. Implants or implant parts that are contaminated, not sterile, damaged or scratched or that have been improperly handled or processed without authorization may not be implanted or used under any circumstances. The use of damaged implants or instruments that have been processed without authorization in any way may lead to premature failure.
- Implants must not be machined or altered in any way, unless this is expressly shown in the design and in the surgical technique.
- Before attaching mating components such as the acetabular insert/shell or femoral head/stem taper, each surface must be cleaned and dried.
- Reliable seating of the femoral head on the acetabular cup is only possible when both mating surfaces are completely intact. If the femoral head or the acetabular cup is damaged in any way, the head and the cup must not be used and should be replaced. **It is absolutely essential that the size of the head fit with the size of the cup.**
- *Cup components should be implanted according to the surgical technique. Generally, this implantation is with an inclination of between 40 and 45° and an anteversion of between 10 and 20°. Outside these limits, the range of motion is diminished and this may lead to subluxation and/or dislocation of the head out of the cup.*
- Implants are intended for single use only.
- Functioning of implants is of limited duration (see also Points 1.3 and 2.4).
- If a Zimmer product is passed on to a third party, the party who passes it on must ensure that the relevant batch-tracking is possible at any time (traceability).

Important information for the users of Zimmer hip systems with METASUL metal pairings:

Hard Metasul metal-metal pairings consist of two articulating joint surfaces featuring a precisely defined geometry and a precisely defined material.

Cup systems intended for Metasul pairings may only be paired with the corresponding Metasul ball heads provided for this purpose. The operating surgeon must always make sure that the chosen cup and ball head match each other in accordance with this requirement.

1.2 Product description and implant materials

An acetabular cup component is used in conjunction with a femoral head component for replacement of resurfacing of the acetabulum during total hip arthroplasty.

Acetabular cup components are available in different designs, materials and sizes.

Acetabular cup components for Total Hip Arthroplasty

This Physicians Insert is valid for the following acetabular cup components:

INTENDED ONLY FOR USE WITH BONE CEMENT:

Low Profile Acetabular Cup (UHMW Polyethylene Sulene-PE [ISO 5834-1/-2])

Cemented, all-polyethylene components for use with reinforcement rings and cages.

Full Profile Acetabular Cup (UHMW Polyethylene Sulene-PE [ISO 5834-1/-2])

Cemented, all-polyethylene components for use with reinforcement rings and cages.

Acetabular Roof Reinforcement Rings and Cages; Burch-Schneider Cage, Müller Ring, Ganz Ring (Protasul-Ti [ISO 5832-2 Grade 1])

Metallic, plate-like, flanged/hooked acetabular components with multiple screwholes for acetabular deficiencies/reconstruction.

INTENDED ONLY FOR USE WITHOUT BONE CEMENT:

Alloclassic Zweymüller Acetabular Cup (Protasul-Ti [ISO 5832-2 Grade 1/-4A] / Protasul-100 [ISO 5832-11])

Threaded acetabular shell system.

CLS Spotorno Acetabular Cup (Protasul-100 [ISO 5832-11])

Flattened, hemispherical shell with sharp, toothed expansion lobes for fixation.

Allotit Acetabular Cup (Protasul-Ti [ISO 5832-2 Grade 1/-4A])

Flattened, hemispherical shell with toothlike circumferential macrotexture for fixation.

Durom Acetabular Component (Protasul-21WF [ISO 5832-12], Porolock™ (Ti-VPS) [ISO 5832-2])

Uncemented, monobloc acetabular component with Ti-VPS coating for biological fixation and circumferential fins for additional primary fixation

Information about the chemical composition and the mechanical properties of the materials used can be found in the appropriate sheets of the materials catalogue or in the appropriate product information documents.

1.3 General information on indications, contraindications and risk factors

- An implantation may only be considered if all other therapeutic possibilities have been carefully weighed and found unsuitable or inappropriate.
- Every implant is subject to unavoidable wear and aging. In the course of time, an implant initially implanted in a stable manner can loosen or its functionality can become impaired. Wear, aging and loosening of an implant can lead to the need for re-operation.
- An infection in the region of an implant will have negative consequences for the patient in most cases, because it will usually necessitate removal of the implant.
- Indications and contraindications for the use of artificial hip joints may be relative or absolute, and must be carefully weighed, taking the overall condition of the patient into account including other alternative procedures, e.g. non-surgical treatment, arthrodesis.
- The selection of patients depends to a great extent on age, his/her general state of health, the condition of the existing bone, previous operations and anticipated further surgery. Normally speaking, an implantation is only indicated for patients whose skeleton is fully developed.

A. Indications

- Patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis.
- Those patients with failed previous surgery where pain, deformity, or dysfunction persists.
- Revision of previously failed hip arthroplasty.
- Total hip replacements may be considered for younger patients if any unequivocal indication outweighs the risks associated with the age of the patient and modified demands regarding activity and hip joint loading are assured. This includes severely crippled patients with multiple joint involvement, for whom an immediate need of hip mobility leads to an expectation of significant improvement in the quality of their lives.

B. Contraindications

- Patient's physical conditions that would eliminate or tend to eliminate adequate implant support or prevent the use of an appropriately sized implant, e.g., previous surgery, insufficient quality or quantity of bone resulting from conditions such as cancer or congenital dislocation, metabolic bone disease of the upper femur or pelvis, femoral osteotomy revision, girdlestone revision, osteoporosis, osteomyelitis, neuromuscular compromise or vascular deficiency in the affected limb in sufficient degree to render the procedure unjustifiable (e.g., absence of musculoligamentous supporting structures, joint neuropathy) or other conditions that may lead to inadequate skeletal fixation.
- Active infection of the hip, old or remote infection. This may be an absolute or relative contraindication. Every effort should be undertaken to rule out preoperative infection in a patient with suspicious symptoms, such as a history of, or when there are signs of, local inflammation, abscesses, fever, increased blood sedimentation rate, evidence of rapid joint destruction or bone resorption.
- Allergy to the implanted material, above all to metal (e.g. cobalt, chromium, nickel etc.).
- Kidney insufficiency: In spite of the fact that there is no currently known causal relationship with increased serum cobalt and serum chromium levels, it is not possible to exclude completely any impairments of health due to low long-term additional loading. In the presence of chronic kidney insufficiency, however, a Metasul metal / metal pair should not be used or should only be used subject to close monitoring of progress (serum cobalt, serum chromium, serum creatine, BUN, echocardiography) in order to avoid increased serum cobalt and serum chromium levels and after carefully weighing the therapeutic benefits against the risks.
- Local bone tumours and/or cysts.
- Pregnancy.

C. Risk factors

Risk factors can influence the success of the operation.

- Charcot's joints.
- Muscle deficiencies.
- Multiple joint disabilities.
- Refusal to modify postoperative physical activities.
- Heavy patients, obesity (especially over 220 pounds (100 kg)).
- Small-boned patients.
- Heavy labor.
- Active sports.
- History of falls.
- General neurological abnormalities or neurological conditions including mental conditions (e.g., mental illness, senility, drug use, alcoholism) that tend to pre-empt the patient's ability or willingness to follow the surgeon's postoperative instructions.
- Marked osteoporosis, osteomalacia.
- Systemic and metabolic disorders leading to progressive deterioration of bone, (e.g., cortisone therapies, immunosuppressive therapies).
- Patient's resistance generally weakened (HIV, tumor, infection).
- Suspected allergic reactions to implant materials.
- Other joint disability (i.e., knees or ankles).
- Severe deformity leading to impaired anchorage or improper positioning of implants.

2. Warnings

2.1 Preoperative

- The preoperative planning and surgical technique for an implantation represent principles that are basic to sound surgical management in total hip replacement. Thorough familiarity with the surgical technique is essential. The use of certain surgical instruments is suggested in the performance of every surgery.
- Patients receiving hip joint replacements should be advised that the longevity of the implant may depend on their weight and level of activity.
- The doctor must explain the risks of inserting an implant to the patient, including the possible impact of the factors mentioned under Point 1.3 on the success of the operation and the possible negative effects mentioned under Point 2.4. The patient should also be informed as to what steps he/she can take in order to reduce the possible effects of these factors.
- When an implantation is being considered, particularly for the young and the active patient, the surgeon should discuss all aspects of the surgery and the implant with the patient before surgery. The discussion should include the limitations of joint reconstruction, limitations particular to the patient, the possible consequences resulting from these limitations and, therefore, the necessity of following the doctor's preoperative instructions.
- Allergies and other reactions to implant materials, although rare, should be considered and ruled out preoperatively.
- X-ray templates should be used for evaluating the implant size, position and alignment of the joint. A full inventory of implant sizes should be at disposal for the operation.
- Re-use of an implant that was already implanted in the patient's body is strictly forbidden. Re-using an implant that has come into contact with the body fluids or tissues of a third party is also forbidden.
- The use of polymethylmethacrylate (PMMA) bone cement can be useful in securing, supporting and stabilizing those devices intended for cemented fixation in bone, but it neither replaces the support function of sound bone nor eliminates the need for additional support during healing. In using cement for implant fixation, care should be used to ensure complete cement support on all parts of the device embedded in the bone cement to help prevent possible stress concentrations that may lead to failure.
- The safety and effectiveness of the use of this device in bilateral applications have not been established.

Failure to carry out proper preoperative planning can lead to errors (e.g. with regard to incorrect positioning and the choice and size of the implant).

2.2 Intraoperative

- The correct selection of the implant is extremely important. Selection of the implant refers to the appropriate type and size for each patient with consideration of the anatomical and biomechanical factors involved. Such factors include patient age, activity level, weight, bone and muscle conditions.

- Prior to closure, the surgical site should be thoroughly cleansed of bone chips, ectopic bone, bone cement, etc. Foreign particles at the articular interface may cause excessive wear and/or friction. Ectopic bone and/or bone spurs may lead to dislocation or painful and restricted motion. Range of motion should be thoroughly checked for early contact or instability.
- The largest cross-section component that allows for adequate bone support to be maintained is recommended. Failure to use the optimum size may result in loosening, bending, cracking, or fracture of the component, bone, or cement (if cement used).
- Stem and cup positioning and neck length are of critical importance. Subluxation, dislocation, and/or fracture of components may result due to muscle looseness and/or malpositioning of components.
- The rules of asepsis are to be observed during the implantation.

2.3 Postoperative

- Immediate postoperative care must be carefully planned in order to retain mobility and to prevent dislocation and thromboembolism. The patient must be instructed as to the limits of the implant as well as its lower loadability, the range of motion and the permissible level of activity. Early weight-bearing must be carefully controlled. A prosthesis-bearer's card should also be completed for the patient.
- Postoperative treatment, care of the patient and his/her activity must be planned in such a way as to avoid excess loading of the operated limb. Depending on the type of operation chosen, the age of the patient and his/her bone quality, it may be necessary to spare the joint for a long period by limiting weight-bearing.
- Regular X-ray checks are recommended in order to detect any changes in the position of the implant, cracking of component or cement, and signs of loosening or breakage of components.
- The patient should be urged to inform his doctor immediately of any unusual changes to the operated limb.
- The patient must be told that implants can affect the results of computer tomography (CT) or magnetic resonance imaging (MRI) scans.

2.4 Side effects

The general risks involved in endoprosthetics are allergic reactions to the implant material used, loosening, wear, corrosion, incorrect positioning, dislocation, aging, deterioration and fracture of the implant or implant parts and revision or reoperation.

Possible consequences of a total hip replacement:

- Implants, implant parts and instruments can fracture, become loose or undergo excessive wear, or their functioning may be impaired if they are subjected to excessive loading, are damaged or have been implanted incorrectly or handled improperly.
- Changing position of the implant (bending, fracture and/or disassembly of components or cement) with or without loosening or clinical symptoms.
- Perforation, fissure of the acetabulum, femur or trochanter, and/or trochanter avulsion.
- Fractures of the femur resulting from stress, bone defects resulting from earlier surgical procedures, deformity and/or osteoporosis.
- Early or late infections.
- Dislocation, subluxation, insufficient range of movement, undesirable shortening or lengthening of the limb involved due to less than optimal positioning of the implant.
- Wound haematoma and slow wound healing.
- Restricted freedom of movement.
- Circulatory disorders, including injury of blood vessels (iliac artery, obturator artery and femoral arteries), venous thrombosis, pulmonary embolism and myocardial infarction.
- Temporary or permanent nerve diseases involving the femoral, sciatic, peroneal or obturator nerves.
- Lung diseases, including pneumonia and atelectasis.
- Aggravation of conditions involving other joints or the back due to intraoperative trauma, differences in leg lengths, femoral medialisation or weakening of the muscles.
- Excessive wear of the acetabular component from damage to mating wear surfaces or debris particles.
- Tissue reactions and allergies to the products of corrosion or wear and cement particles.
- Urological complications, in particular urinary retention and infections.
- Aseptic loosening.
- Other complications associated with surgery in general, with medication, with other instruments used, with blood, anesthesia and so on.
- Ectopic ossification.
- Pain.

2.5 Sterilization

Metallic acetabular shell components, Metasul acetabular inserts and polyethylene (Sulene) acetabular inserts are sterilized by a minimum of 25 KGy (2.5 Mrad) of gamma irradiation.

Durasul acetabular inserts are sterilized using ethylene oxide gas.

2.6 Re-sterilization

Implants and instruments may not come into contact with substances containing chlorine, phosphorus or fluorine or with detergents containing fats.

These sterilization instructions are consistent with AORN and ANSI/AAMI/ISO guidelines. They should be used for items supplied non-sterile, for reprocessing reusable devices, or for sterile items that were opened but unused.

Recommended Sterilization/Resterilization Specifications:

Solid Metal Implants, and PMMA-Coated Metal Implants and Provisionals

Steam Sterilization			
Type	Minimum Temperature	Minimum Exposure Time	Dry Time
Gravity Displacement	121°C (250°F)	30 minutes	Varies by load configuration and sterilizer type
Gravity Displacement	132°C (270°F)	15 minutes	
Pre-vacuum	132°C (270°F)	4 minutes	

All Reusable Instruments and Provisionals

Steam Sterilization			
Type	Minimum Temperature	Minimum Exposure Time	Dry Time
Pre-vacuum	132°C (270°F)	4 minutes	Varies by load configuration and sterilizer type

Follow the sterilizer manufacturer's instructions for loading patterns and selection of sterilization parameters. Drying times vary according to load size and should be increased for larger loads.

Note: Where there is a concern about TSE/CJD contamination, decontaminate using a prevacuum autoclave cycle at a minimum of 134 °C (273 °F) for at least 18 minutes or use a gravity autoclave cycle at a minimum of 121 °C (250 °F) for at least 60 minutes. World Health Organization (WHO/CDS/CSR/APH 200.3: "WHO Infection Control Guidelines for TSE," March 1999).

UHMWPE Implants, PMMA Implants and Metal/Polymer Combination Implants

100% Ethylene Oxide (EO) Sterilization			
Gas Concentration	Temperature	Exposure Time	Relative Humidity
725 mg/L EO	55°C (131°F)	60 minutes	70%

The recommended aeration period for EO is a minimum of 12 hours at 130 °F (54°C) in a heated mechanical aerator

UHMWPE Implants, PMMA Implants

STERRAD Gas Plasma Sterilization		
Gas Concentration	Temperature	Exposure Time
6 mg/L (59% hydrogen peroxide)	45°C (113°F)	65 minutes

Do not reuse instruments or devices labeled for single use only.

Do not resterilize single use only components that have been contaminated with body fluids or debris or previously implanted.

Do not use the original plastic cavities or lids for resterilization. Single devices may use a standard Tyvek pouch. Ensure that the pouch is large enough to contain the device without stressing the seals or tearing the pouch.

Do not expose polyethylene or polymethyl methacrylate (PMMA) components to steam sterilization (including flash sterilization). The high temperatures may cause softening, warping, cracking, or dimensional and material property changes.

Rinse porous, PMMA or PMMA-coated components to remove lint or debris (using USP purified water) and enclose in a lint-free sterilization wrap but do not allow any PMMA surface to contact the wrap or tray. During sterilization the coating softens and may be damaged by contact. Cool naturally and do not force cooling by immersion in room temperature water or saline. Any fine lines in the coating that develop during sterilization will not affect bonding of the PMMA.

Modular implant components must be sterilized separately to minimize potential bioburden buildup in the dead space and expansion/contraction stresses.

Implants made of synthetic materials and components with synthetic parts may not be re-sterilized or industrially processed for re-use, as this can cause deterioration of the material.

If a Zimmer product is sterilized or re-sterilized by the user, this should be indicated in the corresponding patient documentation (i.e. in the Operation Report), and the relevant documents kept on file.

Validation of the cleaning, disinfecting and sterilizing or re-sterilizing procedures and especially the correct settings of the relevant equipment should be verified regularly.

Products past their «Use By» dates may not be repacked and re-sterilized by third-party firms, since this would mean that traceability would no longer be guaranteed.

The recommendations set forth under this point are provided for informational purposes only. No liability is accepted regarding sterility for implants or instruments that are cleaned and sterilized or re-sterilized by the purchaser or the user.

3. Storage and Handling

- Implants must be stored unopened in their original packaging.
- Before sterile implants are removed from their packaging, the protective wrapping must be examined for possible damage as this could jeopardize their sterility. If an expiration date for sterility of the product is indicated, this must be observed. If the packaging is damaged or the sterility expiration date has been reached, the implants must be returned to the manufacturer.
- Protective caps or other protective devices must not be removed until immediately before use.
- Implants are extremely sensitive to damage. Even small scratches or marks left by impacts on the surfaces will cause excessive wear and may give rise to complications. Extremely careful handling is therefore strongly recommended.
- Instruments are subject to a certain degree of wear and therefore have to be considered non-durable materials. They must be checked for correct functioning before use and, if necessary, they must be returned to the appropriate local representative for repair.
- Any additional instructions (e.g. adhesive instruction labels on the packaging) are to be followed.

3.1 Color Coding for products of joint replacement

Left	Red
Right	Green
Cemented	Yellow
Uncemented	Blue
Metasul	Magenta
Ceramic	Grey

4. Pictograms



Symbol for «Follow the Instructions for Use»



Symbol for «Not to be re-used »



Symbol for «To be used by... » (Year, Month)

not sterile

Symbol for «Contents packed without sterilization»

STERILE R

Symbol for «Sterile» and «Sterilization by radiation»

STERILE EO

Symbol for «Sterile» and «Sterilization with ethylene oxide gas»

5. Trademarks

PROTASUL®, METASUL®, DURASUL®, SULENE®, ALLOCLASSIC®, ZWEYMÜLLER®,
CLST™, SPOTORNO™ and ALLOFIT™ are trademarks of the manufacturer.

Modular Femoral Heads

Important information for the operating surgeon

Zimmer GmbH
P.O. Box
CH-8404 Winterthur
Switzerland
Telephone +41/ (0)52 262 60
70
Fax +41/ (0)52 262 01 39
www.zimmer.com

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

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

Manufacturer:
Zimmer GmbH
Sulzer-Allee 8
CH-8404 Winterthur,
Switzerland

Representative in the
USA:
Zimmer Austin, Inc.
9900 Spectrum Drive
Austin, Texas 78717,
USA

Art. No. D011 500 111 -
e/d/ffi/sp/sw - Ed. 08/05

1. Instructions for use

Before using a product placed on the market by Zimmer, the operating surgeon should study carefully the following recommendations, warnings and instructions, as well as the product-specific information (technical product description, description of the surgical technique, catalogue sheet, etc.). Additional product information can be found in the description of the surgical technique, in the technical description of the product or on the appropriate catalogue sheet. Zimmer also recommends attending the appropriate user-training courses. The aforementioned documents and details of the training courses may be obtained from the appropriate representatives in the various countries.

The manufacturer, the importer and the suppliers of Zimmer products are not liable for complications or other effects that might occur for reasons such as incorrect indications or surgical technique, unsuitable choice of material or handling thereof, unsuitable use or handling of the instruments, asepsis and so on.

Patient Counseling Information

Complications and/or failure of total hip prostheses are more likely to occur in patients with unrealistic functional expectations, heavy patients, physically active patients, and/or patients that fail to follow through with the required rehabilitation program. Patients should be cautioned that these devices do not have the strength, elasticity, and/or durability characteristics of healthy bone. The patient must be instructed about all postoperative restrictions, particularly those related to occupational and sports activities, and about the possibility that the implant or its components may wear out, fail, or need to be removed and/or replaced.

1.1 General instructions

- Zimmer products may be implanted only by operating surgeons who are familiar with the general problems of joint replacement and who are able to master the product-specific surgical techniques. The surgical techniques for Zimmer implants may be learned at courses held at hospitals that have experience with these implants.
- Implantation is to take place in accordance with the instructions for the recommended surgical procedure.
- Zimmer has not tested the safety or effectiveness of these devices for use in combination with non-Zimmer products or components. If surgeons elect to assemble and implant a construct that includes components not manufactured or distributed by Zimmer, they do so in reliance on their own clinical judgment and should so inform their patients.
- Due to the acquisition of pre-existing product lines, Zimmer has initiated a testing program to evaluate the **compatibility of these devices** with implants and components made or distributed by other Zimmer companies, including those of Zimmer GmbH (previously Centerpulse Orthopedics Ltd.), Zimmer, Inc., Zimmer Trabecular Metal Technology, Inc. (previously Implex Corp.), Zimmer U.K. Ltd., and Zimmer Austin, Inc. (previously Centerpulse Orthopedics, Inc.). Only authorized combinations should be used. To determine whether these devices have been authorized for use in a proposed combination, please contact your Zimmer sales representative or visit the Zimmer website: www.productcompatibility.zimmer.com. A printout of the website information can also be obtained by calling Zimmer, Inc. Customer Service, 1-800-348-2759 (U.S.) or the local international access code +1-574-372-4999 (outside the U.S.). Former Centerpulse and Implex products that are now packaged in Zimmer boxes, and for which compatibility could be an issue, have been labeled «former Centerpulse» and «former Implex» to provide clarification for the user.
- Product marking, especially size and taper specific information, should be checked to ensure correspondence with the product labeling. The taper size is indicated on the product label and – if possible – on the implant itself. **It is critical that the user ensures taper compatibility.**
- Implants and the relevant instruments should be carefully checked before they are used or implanted. Implants or implant parts that are contaminated, not sterile, damaged or scratched or that have been improperly handled or processed without authorization may not be implanted or used under any circumstances. The use of damaged joint implants or instruments that have been processed without authorization in any way may lead to premature failure.
- Implants must not be machined or altered in any way, unless this is expressly envisaged in the design and in the surgical technique.
- Before putting the femoral head onto the stem, the taper of the stem must be cleaned and dried. The femoral head has to be inserted on to the stem taper with a rotary motion until it is immovable. For fixation of the femoral head, the plastic impactor should be struck with a mallet in an axial direction as necessary.
- Do not impact the stem into the femoral canal after the head component is assembled. Further impaction could damage the head component or the taper attachment.
- Reliable seating of the femoral head on the stem taper is only possible when both mating surfaces are completely intact. If the corresponding stem taper is damaged in any way, the stem must be replaced. **It is absolutely essential that the taper of the femoral stem fit perfectly with the taper of the head.**
- Femoral heads with greater neck lengths may be accompanied by a higher risk e.g. breakage or earlier loosening of the hip stem. The smaller the stem, the greater is this danger. Therefore, a +7 or an XL (+8) ball head should not be combined with the smallest stem sizes.
- Implants are intended for single use only.
- Functioning of implants is of limited duration (see also Point 1.3).
- If a Zimmer product is passed on to a third party, the party who passes it on must ensure that the relevant batch-tracking is possible at any time (traceability).

1.2 Product description and implant materials

A modular head component is used in conjunction with a femoral stem component for replacement of the proximal femur in total hip arthroplasty. Femoral heads are available in different materials, sizes, neck lengths and taper sizes.

A taper is incorporated in the design of the head to interlock it with the femoral stem.

The different neck-lengths can facilitate, for example, adjustment of the tension of the ligaments and reconstruction of the center of the natural head of the femur.

Modular Femoral Heads for Total Hip Arthroplasty

Modular femoral heads are designed for use in total hip arthroplasty with an acetabular component with an inner articulating surface. The size of the femoral head used must match the inner diameter of the articulating surface.

This insert is valid for following modular femoral heads:

Durasul CoCr Femoral Heads (Protasul-20 [ISO 5832-12])

CoCr Femoral Heads (Protasul-20 [ISO 5832-12])

May only be used in combination with Durasul or conventional polyethylene (PE).

Metasul Femoral Heads (Protasul-21WF [ISO 5832-12])

May only be used in combination with Metasul or conventional polyethylene (PE).

As a metal/metal combination, the Metasul Femoral Head must only be used in combination with a Metasul cup inlay. Metasul Femoral Heads are also marked with a groove in the area of the taper which is evident on x-rays.

Protasul S30 Femoral Heads (ISO 5832-9)

May only be used in combination with conventional polyethylene (PE).

Information about the chemical composition and the mechanical properties of the materials used can be found in the appropriate sheets of the materials catalogue or in the appropriate product information documents.

1.3 Indications, contraindications and risk factors

Modular femoral heads are intended for use in total hip arthroplasty in combination with compatible femoral stems and acetabular components.

For information for the patient, instruction and information on specific indications, contraindications, risk factors, adverse effects and factors that can jeopardize the success of the operation, Zimmer refers to the package insert which is enclosed with the hip stem.

2. Warnings

Do not use *Zimmer* femoral heads with *Zimmer* femoral stems using a different taper. Heads using the 6-degree or 12/14 bore must only be mated with stems that have a corresponding 6-degree or 12/14 neck taper.

Do not mate the cobalt-chrome alloy femoral head with stainless steel. Do not mate the stainless steel head with cobalt-chrome or titanium alloys. Galvanic corrosion may develop with these combinations.

Do not use the femoral head for trial reductions. Provisional (trial) devices are available for this purpose.

Do not attempt removal of the head from the tapered neck of the femoral stem with any instrument other than the specifically designed distraction instruments.

2.1 Sterilization

Implants have been sterilized by a minimum of 25 KGy (2.5 Mrad) of gamma irradiation.

2.2 Resterilization

Implants and instruments may not come into contact with substances containing chlorine, phosphorus or fluorine or with detergents containing fats.

These sterilization instructions are consistent with AORN and ANSI/AAMI/ISO guidelines. They should be used for items supplied non-sterile, for reprocessing reusable devices, or for sterile items that were opened but unused.

Recommended Sterilization/Resterilization Specifications:

Solid Metal Implants, and PMMA-Coated Metal Implants and Provisionals

Steam Sterilization			
Type	Minimum Temperature	Minimum Exposure Time	Dry Time
Gravity Displacement	121°C (250°F)	30 minutes	Varies by load configuration and sterilizer type
Gravity Displacement	132°C (270°F)	15 minutes	
Pre-vacuum	132°C (270°F)	4 minutes	

Do not reuse instruments or devices labeled for single use only.

Do not resterilize single use only components that have been contaminated with body fluids or debris or previously implanted.

Do not use the original plastic cavities or lids for resterilization. Single devices may use a standard Tyvek pouch. Ensure that the pouch is large enough to contain the device without stressing the seals or tearing the pouch.

For hip prostheses, leave the knitted femoral head covers on during resterilization. Remove just prior to implantation.

Modular implant components must be sterilized separately to minimize potential bioburden buildup in the dead space and expansion/contraction stresses.

Implants made of synthetic materials and components with synthetic parts may not be resterilized or industrially processed for re-use, as this can cause deterioration of the material.

If a Zimmer product is sterilized or re-sterilized by the user, this should be indicated in the corresponding patient documentation (i.e. in the Operation Report), and the relevant documents kept on file.

Validation of the cleaning, disinfecting and sterilizing or re-sterilizing procedures and especially the correct settings of the relevant equipment should be checked regularly.

Products past their «Use By » dates may not be repacked and re-sterilized by third-party firms, since this would mean that traceability would no longer be guaranteed.

The recommendations set forth under this point are provided for informational purposes. No liability is accepted regarding sterility for implants or instruments that are cleaned and sterilized or re-sterilized by the purchaser or the user.

3. Storage and Handling

- Implants must be stored unopened in their original packaging.
- Before sterile implants are removed from their packaging, the protective wrapping must be examined for possible damage as this could jeopardize their sterility. If an expiration date for sterility of the product is indicated, this must be observed. If the packaging is damaged or the

- sterility expiration date has been reached, the implants must be returned to the manufacturer.
- Protective caps or other protective devices must not be removed until immediately before use.
 - Implants are extremely sensitive to damage. Even small scratches or marks left by impacts on the surfaces will cause excessive wear and may give rise to complications. Extremely careful handling is therefore strongly recommended.
 - Instruments are subject to a certain degree of wear and therefore have to be considered non-durable materials. They must be checked for correct functioning before use and, if necessary, they must be returned to the appropriate local representative for repair.
 - Any additional instructions (e.g. adhesive instruction labels on the packaging) are to be followed.

3.1 Color Coding for products of joint replacement

Left Red
Right Green
Cemented Yellow
Uncemented Blue
Metasul Magenta
Ceramic Grey

4. Pictograms

- Symbol for «Follow the Instructions for Use»
- Symbol for «Not to be re-used »
- Symbol for «To be used by... » (Year, Month)
- Symbol for «Contents packed without sterilization»
- Symbol for «Sterile» and «Sterilization by radiation»

5. Trademarks

PROTASUL®, METASUL® and DURASUL® are trademarks of the manufacturer.

Summary for REF: 01.00185.145 Version: 00
 Printed: scaccorn at BAAD301A on 12.12.05 - 11:51 AM

Product Label

CoC/No: (Protasu®-20) ISO 5832-12

Caution: Federal law (U.S.A) restricts this device to sale by or on the order of a physician.
 If this seal is broken, the product may not be returned for credit!

REF: 01.00185.145 EDI: 0100185145
 Taper 12/14 - 18/20 LDH™

LDH™ Head Adapter 'S' -4
 Taper 12/14 - 18/20

STERILE R 2010-06

		ADAPTER	'S' / -4
--	--	---------	----------

***H844010018514517*0181XXXG050* (FORMER CENTERPULSE)

Bar Code Label

REF: 01.00185.145 EDI: 0100185145
 LOT: XXX Qty: 001

LDH™ Head Adapter 'S' -4 Taper 12/14 - 18/20

LDH™ Kopf Adapter 'S' -4 Konus 12/14 - 18/20
 LDH™ Adaptateur pour tête 'S' -4 Cône 12/14 - 18/20
 LDH™ Adattatore per testa 'S' -4 Cono 12/14 - 18/20
 LDH™ Adaptador para cabeza 'S' -4 Cono 12/14 - 18/20

STERILE R 2010-06 2005-07

Zimmer GmbH, CH-8484 Winterthur, Switzerland | www.zimmer.com (FORMER CENTERPULSE)

Translation Label

! Xn CE R only STERILE R 2010-06 2005-07

Zimmer GmbH, CH-8484 Winterthur, Switzerland | www.zimmer.com

REF: 01.00185.145 EDI: 0100185145
 LOT: XXX Qty: 001

LDH™ Kopf Adapter 'S' -4
 Konus 12/14 - 18/20

LDH™ Adaptateur pour tête 'S' -4
 Cône 12/14 - 18/20

LDH™ Adattatore per testa 'S' -4
 Cono 12/14 - 18/20

LDH™ Adaptador para cabeza 'S' -4
 Cono 12/14 - 18/20

Patient Chart Sticker

REF: 01.00185.145 EDI: 0100185145
 LOT: XXX Exp: 2010-06

LDH™ Head Adapter 'S' -4 Taper 12/14 - 18/20
 CoC/No: (Protasu®-20) ISO 5832-12

Taper 12/14 18/20

Zimmer GmbH, CH-8484 Winterthur, Switzerland | www.zimmer.com

Warning Label

No label defined

Notice Label

No label defined

Additional Label

No label defined

Colour Definitions:

Left Red	Right Green	Cemented Yellow	Uncemented Blue	Metasul Magenta
----------	-------------	-----------------	-----------------	-----------------

Summary for REF: 01.00214.146 Version: 00
 Printed: scacom at BAAD301A on 07.11.05 - 03:52 PM

Product Label

CoCrMo (Proxalus®-21WF) ISO 5832-12
 C.P. Titanium (Proxalus®-Ti) ISO 5832-2

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

If this seal is broken, the product may not be returned for credit!

REF 01.00214.146 EDI: 0100214146
Durom®
 Metasul® Durom® Acetabular Component
 uncemented 46/ ø40 Code F

STERILE R 2010-10 METASUL

UNCEMENTED ACETABULUM 46/ø40 F

FORMER CENTERPULSE

Bar Code Label

REF 01.00214.146 EDI: 0100214146
 LOT XXX Qty: 001

Metasul® Durom® Acetabular Component uncemented 46/ ø40 Code F

Metasul® Durom® Acetabulum Komponente uncementiert 46/ ø40 Code F
 Metasul® Durom® Composant acetabulaire sans ciment 46/ ø40 Code F
 Metasul® Durom® Componente acetabolare non cementata 46/ ø40 Code F
 Metasul® Durom® Componente acetabular no cementada 46/ ø40 Code F

STERILE R 2010-10 2005-11

Zimmer GmbH, CH-8404 Winterthur, Switzerland | www.zimmer.com

FORMER CENTERPULSE

Translation Label

STERILE R 2010-10 2005-11

Zimmer GmbH, CH-8404 Winterthur, Switzerland | www.zimmer.com

REF 01.00214.146 EDI: 0100214146
 LOT XXX Qty: 001

Metasul® Durom® Acetabulum Komponente
 unzementiert 46/ ø40 Code F

Metasul® Durom® Composant acetabulaire
 sans ciment 46/ ø40 Code F

Metasul® Durom® Componente acetabolare
 non cementata 46/ ø40 Code F

Metasul® Durom® Componente acetabular no
 cementada 46/ ø40 Code F

Patient Chart Sticker

REF 01.00214.146 EDI: 0100214146
 LOT XXX Exp: 2010-10

Metasul® Durom® Acetabular Component uncemented 46/ ø40 Code F

CoCrMo (Proxalus®-21WF) ISO 5832-12
 C.P. Titanium (Proxalus®-Ti) ISO 5832-2

Zimmer GmbH, CH-8404 Winterthur, Switzerland | www.zimmer.com

Warning Label

Metasul®

MUST be used for
Metasul® pairing

810 97 c

Notice Label

No label defined

Additional Label

No label defined

Colour Definitions:

Left Red Right Green Cemented Yellow Uncemented Blue Metasul Magenta

Product Label

CoCrMo (Protasul®-21WF) ISO 5832-12

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

If this seal is broken, the product may not be returned for credit.

REF 01.00181.380 EDI: 0100181380
Taper 18/20 5 38 LDH™
Metasul® LDH™ Head 38 Code D
Taper 18/20

STERILE R 2010-10 METASUL

HEAD 38 / D

2585V01-01

(FORMER CENTERPULSE)

Bar Code Label

REF 01.00181.380 EDI: 0100181380
LOT XXX Qty: 001

Metasul® LDH™ Head 38 Code D Taper 18/20

Metasul® LDH™ Kopf 38 Code D Konus 18/20
Metasul® LDH™ Tête 38 Code D Cône 18/20
Metasul® LDH™ Testa 38 Code D Cono 18/20
Metasul® LDH™ Cabeza 38 Code D Cono 18/20

STERILE R 2010-10 2005-11

Zimmer GmbH, CH-8484 Winterthur, Switzerland | www.zimmer.com

(FORMER CENTERPULSE) 2585V01-LB1V00

Translation Label

STERILE R 2010-10 2005-11

Zimmer GmbH, CH-8484 Winterthur, Switzerland | www.zimmer.com

REF 01.00181.380 EDI: 0100181380
LOT XXX Qty: 001
Metasul® LDH™ Kopf 38 Code D
Konus 18/20
Metasul® LDH™ Tête 38 Code D
Cône 18/20
Metasul® LDH™ Testa 38 Code D
Cono 18/20
Metasul® LDH™ Cabeza 38 Code D
Cono 18/20

2585V01-LB1V00

Patient Chart Sticker

REF 01.00181.380 EDI: 0100181380
LOT XXX Exp: 2010-10

Metasul® LDH™ Head 38 Code D Taper 18/20
CoCrMo (Protasul®-21WF) ISO 5832-12

Taper 18/20 - 5° 38'

Zimmer GmbH, CH-8484 Winterthur, Switzerland | www.zimmer.com

2585V01-LB1V00

Warning Label

No label defined

Notice Label

No label defined

Additional Label

No label defined

Colour Definitions:

Left Red Right Green Cemented Yellow Uncemented Blue Metasul Magenta Cement Grey



Zimmer GmbH
 P.O.Box
 CH-8404 Winterthur
 Phone +41 (0)52 262 60 70
 Fax +41 (0)52 262 01 39
 www.zimmer.com

Statement to Packaging and Sterilization Revision A

1) Packaging and Labeling

Zimmers's Packaging and Finishing Departments are responsible for the product packaging and labeling of all of Zimmer products. Packaging consists of a box, trays, plastic pouches, physician inserts and labeling. All inserts and labeling are printed in five to six different languages.

After final packaging, all components are sterilized.

Packaging must provide a sterile and biocompatible environment for the orthopedic device. In addition, it must be cost-efficient to manufacture, meet all regulatory labeling requirements and from an end-user's perspective, be easy to open.

Packaging for new Zimmer products is evaluated early in the development phase. If existing package designs cannot be used, Packaging and Finishing will co-develop new packaging with a third party manufacturer. Packaging, like the implant it protects, must go through a risk analysis and validation process, culminating in a declaration of conformity with the MDD (Medical Device Directive). Packaging changes may occur during a product's life cycle for a variety of reasons, including a change in company name, the addition of regulatory information (e.g. CE mark) or in order to decrease costs.

1.1) Packaging Components

Knee, Hip, Upper Ex. and Trauma components, Gamma sterilized (Except ball heads and conventional Sulene-PE parts and Durasul components)

Component	Description	Material
peelable pouch (evacuated)	primary packaging component. A peelable, transparent pouch.	OPA-PE / 15-60 (Oriented Polyamide-Polyethylene)
peelable pouch (evacuated)	secondary packaging component. A peelable, transparent pouch.	OPA-PE / 15-60 (Oriented Polyamide -Polyethylene)
protective pouch (evacuated)	tertiary packaging component. A non peelable, dust and puncture resistant protective pouch.	PA-PE / 20-70 (Polyamide -Polyethylene)
Barcode Label	printed label for barcode and other legally required information. Same label uses as barcode label on the shelf container and the patient chart labels (in the protective pouch)	Material: Thermfilm Select 21944E PA 50g/m2 (Polyamide) Adhesive: modified acrylic
Physician Insert	Physician Insert to be enclosed with each single product.	Z-Pharma white / 40g/m2

Shelf Container	The shelf container consists of two elements. The "drawer" and the "sleeve". The drawer is designed to absorb all mechanical influences, the sleeve has to close (tamper evidence) and to bear printed information. The labels are adhered to the shelf container (one product label and one barcode label)	"Drawer": corrugated "micro" paper board or paperboard, 350-400 g/m2. "Sleeve": paperboard, 150 g/m2
Product Label	printed label for product identification.	Material: Cast Cote 80g/m2 / Paper Adhesive: 170 ST modified acrylic
Barcode Label	printed label for barcode and other legally required information. Same label uses as barcode label on the shelf container and the patient chart labels (in the protective pouch)	Material: Thermfilm Select 21944E PA 50g/m2 (Polyamide) Adhesive: modified acrylic

Ball Heads, Gamma sterilized

Component	Description	Material
Inner Tray	primary packaging component. A rigid, transparent injection molded tray.	K-resin KR01 (Butadien/Styrol-Polymer)
Inner Lid	primary packaging component. A soft, tissue like, coated lid which is sealed against the inner tray to provide sterile barrier. Sealed system is peelable.	Tyvek 1073 B = PE, spun bonded (Polyethylene) coated with SBP 2000 (sealing media / hot melt)
Outer Tray	secondary packaging component. A rigid, transparent thermoformed tray.	PETG (PolyethyleneTerephthalatGlycol)
Outer Lid	secondary packaging component. A soft, tissue like, coated lid which is sealed against the inner tray to provide sterile barrier. Sealed system is peelable.	Tyvek 1073 B = PE, spun bonded (Polyethylene) coated with SBP 2000 (sealing media / hot melt)
<i>protective pouch (evacuated)</i>	<i>Not used</i>	<i>PA-PE / 20-70 (Polyamide -Polyethylene)</i>
Barcode Label	printed label for barcode and other legally required information. Same label uses as barcode label on the shelf container and the patient chart labels (in the protective pouch)	Material: Thermfilm Select 21944E PA 50g/m2 (Polyamide) Adhesive: modified acrylic
Physician Insert	Physician Insert to be enclosed with each single product.	Z-Pharma white / 40g/m2
Shelf Container	The shelf container consists of two elements. The "drawer" and the "sleeve". The drawer is designed to absorb all mechanical influences, the sleeve has to close (tamper evidence) and to bear printed information. The labels are adhered to the shelf container (one product label and one barcode label)	"Drawer": corrugated "micro" paper board or paperboard, 350-400 g/m2. "Sleeve": paperboard, 150 g/m2
Product Label	printed label for product identification.	Material: Cast Cote 80g/m2 / Paper Adhesive: 170 ST modified acrylic

Barcode Label	printed label for barcode and other legally required information. Same label uses as barcode label on the shelf container and the patient chart labels (in the protective pouch)	Material: Thermfilm Select 21944E PA 50g/m2 (Polyamide) Adhesive: modified acrylic
---------------	--	--

Conventional Sulene-PE parts: Gamma sterilized

Component	Description	Material
peelable pouch (Nitrogen purged and evacuated)	primary packaging component. A peelable, transparent pouch.	OPA-SiOx-PE / 15-75 (Oriented Polyamide –Silicium Oxyde - Polyethylene)
peelable pouch (Nitrogen purged and evacuated)	secondary packaging component. A peelable, transparent pouch.	OPA-SiOx-PE / 15-75 (Oriented Polyamide –Silicium Oxyde - Polyethylene)
protective pouch (evacuated)	tertiary packaging component. A non peelable, dust and puncture resistant protective pouch.	PA-PE / 20-70 (Polyamide -Polyethylene)
Barcode Label	printed label for barcode and other legally required information. Same label uses as barcode label on the shelf container and the patient chart labels (in the protective pouch)	Material: Thermfilm Select 21944E PA 50g/m2 (Polyamide) Adhesive: modified acrylic
Physician Insert	Physician Insert to be enclosed with each single product.	Z-Pharma white / 40g/m2
Shelf Container	The shelf container consists of two elements. The "drawer" and the "sleeve". The drawer is designed to absorb all mechanical influences, the sleeve has to close (tamper evidence) and to bear printed information. The labels are adhered to the shelf container (one product label and one barcode label)	"Drawer": corrugated "micro" paper board or paperboard, 350-400 g/m2. "Sleeve": paperboard, 150 g/m2
Product Label	printed label for product identification.	Material: Cast Cote 80g/m2 / Paper Adhesive: 170 ST modified acrylic
Barcode Label	printed label for barcode and other legally required information. Same label uses as barcode label on the shelf container and the patient chart labels (in the protective pouch)	Material: Thermfilm Select 21944E PA 50g/m2 (Polyamide) Adhesive: modified acrylic

Durasul components, ETO sterilized

Component	Description	Material
peelable pouch	primary packaging component. A peelable, one face transparent pouch.	Tyvek 1073 B = PE, spun bonded (Polyethylene) coated with SBP 2000 (sealing media / hot melt)
peelable pouch	secondary packaging component. A peelable, one face transparent pouch.	Tyvek 1073 B = PE, spun bonded (Polyethylene) coated with SBP 2000

		(sealing media / hot melt)
Barcode Label	printed label for barcode and other legally required information. Same label uses as barcode label on the shelf container and the patient chart labels (in the protective pouch)	Material: Thermfilm Select 21944E PA 50g/m2 (Polyamide) Adhesive: modified acrylic
Physician Insert	Physician Insert to be enclosed with each single product.	Z-Pharma white / 40g/m2
Shelf Container	The shelf container consists of two elements. The "drawer" and the "sleeve". The drawer is designed to absorb all mechanical influences, the sleeve has to close (tamper evidence) and to bear printed information. The labels are adhered to the shelf container (one product label and one barcode label)	"Drawer": corrugated "micro" paper board or paperboard, 350-400 g/m2. "Sleeve": paperboard, 150 g/m2
Product Label	printed label for product identification.	Material: Cast Cote 80g/m2 / Paper Adhesive: 170 ST modified acrylic
Barcode Label	printed label for barcode and other legally required information. Same label uses as barcode label on the shelf container and the patient chart labels (in the protective pouch)	Material: Thermfilm Select 21944E PA 50g/m2 (Polyamide) Adhesive: modified acrylic

2) Sterilization methods

2.1) Gamma sterilized devices

Standard metal, ceramic and conventional poly products are gamma radiation sterilized. The minimal dose is 25 kGy, the maximum dose is 40 kGy. The applicable standard is EN 552.

Conventional poly products are nitrogen purged and evacuated prior irradiation.

2.2) ETO sterilized devices

Polyethylene implants with the trade name Durasul™ are sterilized with ETO (ethylene oxide gas). Since ethylene-oxide gas is highly toxic, for the protection of the staff and the environment, this type of sterilisation must only be used when other sterilisation procedures are not possible. With sterilisation with ethylene-oxide or formaldehyde gas, the products can take up the gas and in the case of insufficient degassing (desorption), gas can remain in the material. Before they are used, products that have been sterilised with ethylene-oxide gas require adequate degassing. The degassing procedure depends on the material being sterilised and the ventilation that is available and can be accelerated by the use of an aerator. The applicable standard is EN 550.

2.3) General

Implants in sterile packing must be left in their protective packing, unopened, until the time of the implantation. Before the implant is used, the expiry date for sterility, indicated on the bar code or on the expiry label, has to be noted and the protective packing and the sterile packing must be checked for damage.

3) Testing

(b)(4)

The ZIMMER Packaging components are tested and validated according a Standard Operation Procedure. The purpose of this Standard Operating Procedure is to specify the Package Seal Integrity Validation Program that is used to validate Zimmer GmbH sterile medical device packages.

Reference documentation

ASTM F 88	Seal Strength of Flexible Barrier Materials
ASTM D 903	Peel or Stripping Strength of Adhesive Bonds
ASTM F 1140	Failure Resistance of Unrestrained and Nonrigid Packages for Medical Applications
ISO 11607	Packaging for terminally sterilized medical devices
ISTA Project 1A / 2A	Performance test for individual packaged product
ASTM F 1980	Standard Guide for Accelerated Aging of Sterile Medical Device Packages
ASTM D 4332	Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing

Validation program:

(b)(4)



**Metasul® LDH™
Large Diameter
Head**

Surgical Technique



Large heads. Large benefits.



zimmer
Confidence in your hands®

0158

222

General description of the implant	3
Overview of the entire range of implants	6
Patient selection	7
Preoperative planning	8
Preparation of the acetabular component	9
Assembly of the <i>Metasul LDH</i> large diameter head with its head adapter	12
Implants	17
Instruments	18

This document is intended exclusively for experts in the field, i.e. physicians in particular, and is expressly not for the information of laypersons.

The information on the products and/or procedures contained in this document is of a general nature and does not represent medical advice or recommendations. Since this information does not constitute any diagnostic or therapeutic statement with regard to any individual medical case, individual examination and advising of the respective patient are absolutely necessary and are not replaced by this document in whole or in part.

The information contained in this document was gathered and compiled by medical experts and qualified Zimmer employees to the best of their knowledge. The greatest care was taken to ensure the accuracy and ease of understanding of the information used and presented. Zimmer does not assume any liability, however, for the up-to-dateness, accuracy, completeness or quality of the information and excludes any liability for tangible or intangible losses that may be caused by the use of this information.

General description of the implant

The combination of a very large range of motion and excellent articular stability along with proven clinical results on the metal/metal articulations make the *Metasul LDH* large diameter head concept an ideal solution for numerous patients.

The *Metasul* articulation presents great resistance to wear. It has been implanted on more than 250,000 patients since 1988. No other metal/metal combination has obtained better clinical results.

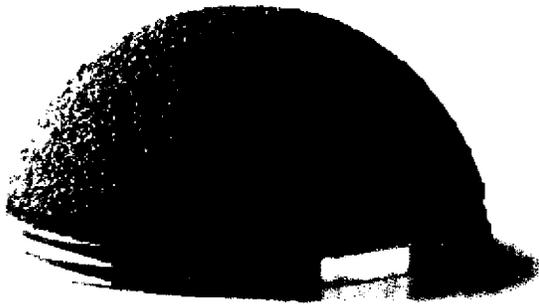
This experience forms the basis of the last generation of metal/metal articulations, the *Metasul LDH* large diameter head.

Like the acetabulum, the *Durom* acetabular component was designed to preserve maximum bone stock. The wall thickness of the acetabular component is reduced to a strict minimum, and the cup subtends an angle of 165 degrees, comparable to that of the acetabulum.



Depending on the size of the acetabular component and on the design of large diameter heads, the prosthetic range of motion of 144 to 160° is incomparable. Range of motion is essential in hip replacements in order to obtain unrestricted walking and optimized functioning of the hip, while reducing the risks of prosthetic impingement. The *Metasul LDH* large diameter heads are available from 38 to 60 mm and must be used in combination with the *Durom* acetabular component.

Porolock™ Ti VPS surface coating of the *Durom* acetabular component is pure titanium deposited by vacuum plasma spray technology. This microporous coating promotes reliable osteointegration ensuring durable secondary fixation. The process of vacuum plasma spray technology, carefully controlled, makes it possible to obtain very high adhesive strength between the chrome cobalt substrate and the *Porolock* Ti VPS coating, thus reducing the risk of the generation of titanium 3rd-wear particles.



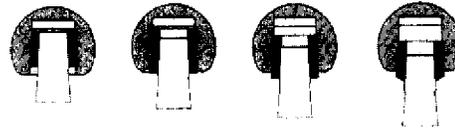
*Durom** acetabular component



Porolock Ti VPS

* U.S. Patent No. 6, 126, 695

To offer a wide choice in the adaptation of the size for the neck length as primary line as well as for revision, the system *Metasul LDH* large diameter head has been developed with 4 neck lengths (S, M, L and XL) for the 12/14 taper. The design and use of this adapter system correspond to a proven concept.



Adaptation of the neck length

Range of sizes

Taper	Neck length (mm)			
	S	M	L	XL
12/14	4	0	+4	+8

The range of heads covers over 12 sizes from 38 to 60 mm. From size 38 to size 48, the heads are monoblock, while from size 50 to 60 mm, they are partially hollowed out, in order to reduce the overall weight of the implant.

Head size – approximate weight



Head size, mm	38	40	42	44	46	48
Approx. weight, g	146	174	206	240	276	316



Head size, mm	50	52	54	56	58	60
Approx. weight, g	254	277	299	326	351	382

Overview of the entire range of implants

A *Durom* acetabular component is combined with a *Metasul LDH* large diameter head of 6 mm smaller. A letter code confirms the appropriate combination, for example: a 54/N *Durom* acetabular component must be used with a 48/N *Metasul LDH* large diameter head.

- The acetabular component has been designed to be implanted without cement. The *Metasul LDH* large diameter heads may be used with the wide range of Zimmer hip stems.
- The actual equatorial diameter of an acetabular component is greater than its nominal diameter by 2 mm; for example an acetabular component of size 54N has an actual equatorial diameter of 56 mm. If the last reamer used is of 54 mm, the 54 mm trial implant (the trial implant is line to line with the reamer), the size of the acetabular implant is 54/N. As a result, there is a hemispheric press-fit effect of 2 mm.

Durom acetabular component combined with Metasul head

<i>Durom</i> acetabular component			<i>Metasul LDH</i> large diameter head		
Nominal diameter (mm)	Inner diameter (mm)	Code	Nominal diameter (mm)	Actual diameter (mm)	Code
Ø 44	38	D	Ø 38	38	D
Ø 46	40	F	Ø 40	40	F
Ø 48	42	H	Ø 42	42	H
Ø 50	44	J	Ø 44	44	J
Ø 52	46	L	Ø 46	46	L
Ø 54	48	N	Ø 48	48	N
Ø 56	50	P	Ø 50	50	P
Ø 58	52	R	Ø 52	52	R
Ø 60	54	T	Ø 54	54	T
Ø 62	56	V	Ø 56	56	V
Ø 64	58	X	Ø 58	58	X
Ø 66	60	Z	Ø 60	60	Z

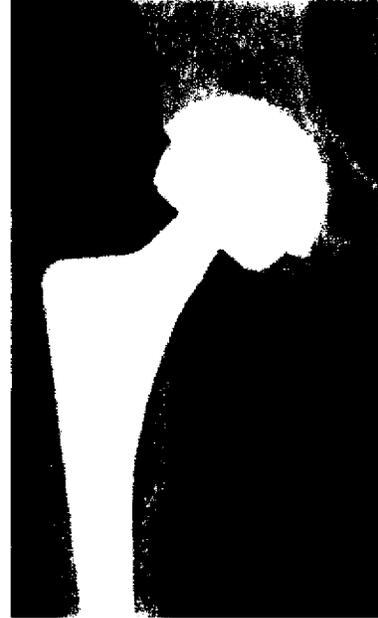
Patient selection

The *Durom* acetabular component without cement may be used for a wide variety of indications. For example, it is adapted for primary and secondary coxarthroses, subject to a slightly deformed or complete acetabulum. All the cases for which the quality of the acetabulum bone is insufficient to guarantee primary stability are contraindicated.

Osteoarthropathy in a 56-year-old patient



Preoperative



One month postoperative

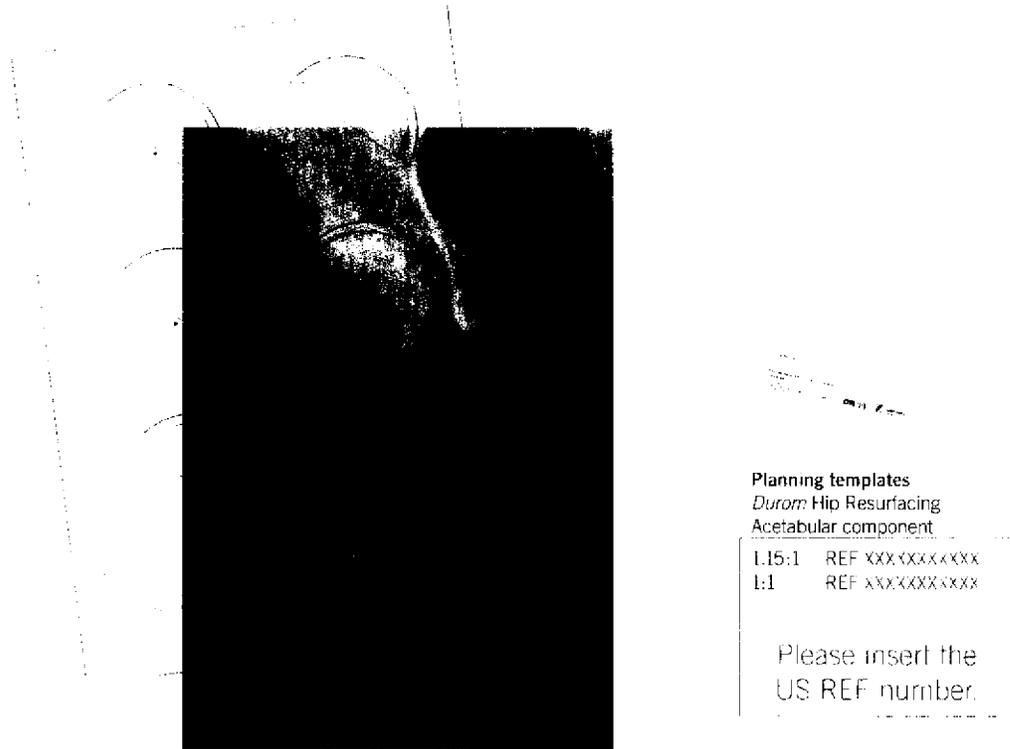
Preoperative planning

Templates of the *Durom* acetabular component are available for preoperative planning. They are available in 115% magnification for conventional radiographs and 100% magnification for digital x-rays.

Magnification is greater in obese patients and less in thinner patients. It is necessary to combine these templates with that of the stem used by making the centers of rotation correspond. The final size of the prosthesis is determined during the surgical procedure.

With the *Durom* acetabular component templates, it is possible to determine the most important parameters for planning the procedure:

- the physiological center of rotation (from the opposite side)
- the ideal position of the acetabular component, in particular its depth, as well as its inclination which must be ideally located between 40 and 45°
- the approximate size of the implant



Durom acetabular template

Preparation of the acetabular component

Every approach of hip articulation and prosthetic replacement is usable for positioning the *Durom* acetabular components. It will be chosen according to the surgeon's preferences.

1. Acetabular preparation

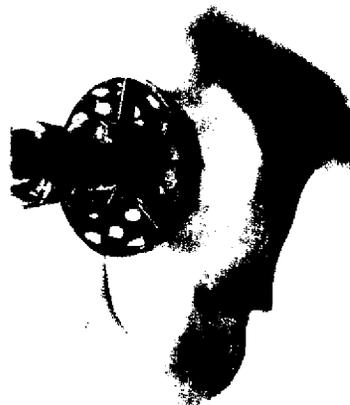
The acetabular labrum is excised and significant peripheral osteophytes are removed. The stump of the ligamentum teres is excised and the true floor of the acetabulum identified.

2. Reaming

Sequential reaming is carried out with the dedicated acetabular reamers. The *Durom* acetabular component subtend is 165° . It is, therefore, not necessary to overdeepen the acetabulum. In hard bone, it is advisable to use reamers in 1 mm increments when approaching the definitive acetabular size.

Assuming that a near hemispherical cavity has been created and adequate cancellous bone has been exposed, the reaming is stopped. In case of sclerotic acetabular bone, a 1 mm press-fit should allow the acetabular component to sit properly with sufficient primary stability.

Important: During the acetabular preparation, one must be particularly careful in order to prevent excessive reaming of the bone and maintain a hemispherical cavity.



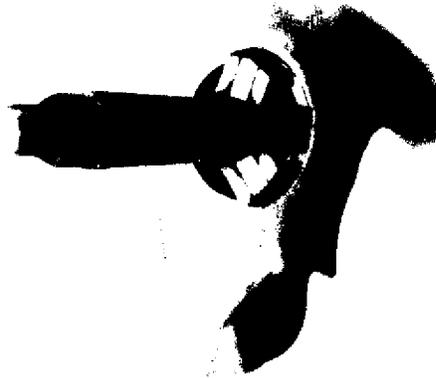
3. Positioning of the trial acetabular implant

The accuracy of the reaming is checked using an acetabular trial of the same size as the last reamer used. Any remaining protruding rim osteophytes are removed and acetabular cysts are grafted appropriately.

The acetabular trials have the same dimensions as the reamers. They are not used to test stability, but the quality of acetabular preparation. The nominal size of the *Durom* acetabular component is the same as that of the acetabular trial: e.g. 54 mm acetabular trial component, implant size 54/N the diameter of the implanted acetabular component is 2 mm larger than the acetabular trial.

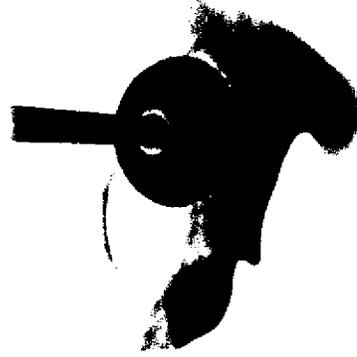
4. Impaction of the acetabular component

The definitive acetabular component is mounted on the appropriate cup inserter and the threaded rod is tightened securely with the large tightening bar. The impactor head is then screwed on to the cup-coupling handle. The acetabular component is impacted into the prepared acetabulum in approximately 10 to 15° of anteversion and a lateral opening of 45°.



5. Final impaction of the acetabular component

When the acetabular component is fully seated, the cup inserter is removed by unscrewing the impactor head and loosening the threaded rod. If necessary, the appropriately sized cup impactor can be used to complete the insertion of the acetabular component.



Assembly of the Metasul LDH large diameter head with its head adapter

Use of the trial head with its head adapter

The appropriately sized trial head adapter is mounted onto the femoral stem, ensuring that the latter is sitting flush on the femoral stem taper.

The femoral trial head corresponding to the inner diameter of the *Durom* acetabular component is then attached to the adapter.

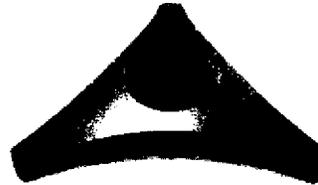
The hip is then reduced, the length of the neck, the ligament tension and the range of motion are checked. If the results are insufficient, the same procedure must be repeated with different sizes of head adapters.



Assembly of the head adapter

Assembly of the head adapter on the *Metasul LDH* large diameter head is done outside the operative field after having carried out the reduction trial with the large trial head attached to the trial head adapter.

The metal base plate and its plastic assembly inlay are positioned on a stable support. Make sure the inlay sits firmly within the base plate.



Position the femoral head on the inlay as shown in the illustration.



Place the appropriately sized head adapter into the female taper of the femoral head.



Attention: properly check the position of the taper according to the head before impacting it, as well as the size of the taper 12/14.

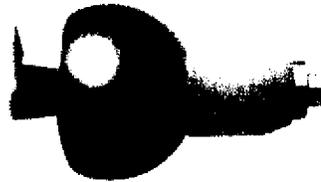


With the impactor handle and its 12/14 assembly attachment, the head adapter is impacted into the femoral head by means of a firm and strong impact with a heavy mallet, preferably heavier than 500 g.

Clean and dry the stem taper, removing any residues.

Position the femoral head while carrying out a slight rotation movement on the stem taper.

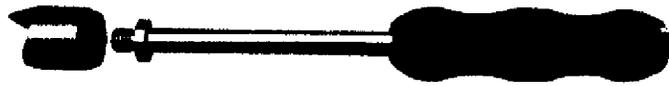
With a soft impact into the impactor with the plastic impactor attachment, the *Metasul LDH* large diameter head is then mounted on the femoral stem.



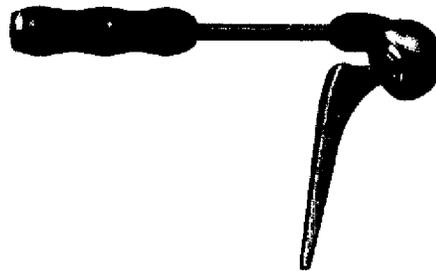
in situ extraction of the head

In some cases where the large diameter head must be removed, the following procedure is recommended:

Mount the head disassembly attachment on the impactor handle and position the instrument on the lower edge of the femoral head with a slight incidence towards the latter.

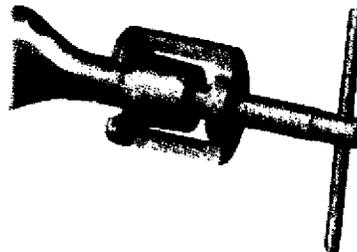
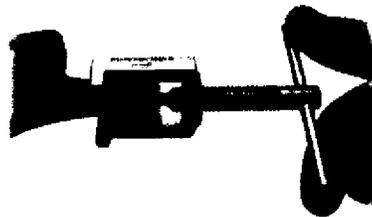


Loosening of the head and the stem taper is done with small successive blows. The use of this device prevents unintended stem taper damages of the in situ abiding stem.



NB: To separate the head from the taper intraoperatively, use the plastic disassembly attachment. For revision cases, use the metal disassembly attachment.

In the case where the head comes off of the stem taper without the head adapter, the latter must be removed from the stem separately. Carefully slide the adapter extractor under the neck of the stem and turn the threaded crank at the same time to pull the head adapter out of the taper. The taper should not be damaged by this manipulation.

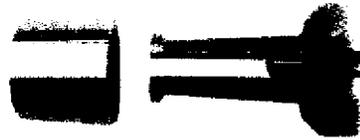


**Disassembly of the head adapter
and the large diameter head**

In the case where the head adapter cannot be extracted and remains attached to the head, please use the adapter extractor for 12/14 taper (ref. 01.00189.151) and proceed as follows:



Slide the sleeve into the head adapter until you feel or hear that its end is completely docked.



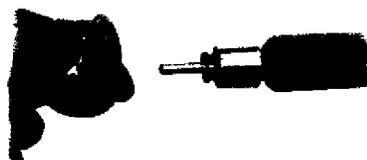
Push the handle through the sleeve and screw in.



After several turns, the handle reaches the bottom of the female taper of the large diameter head; you will notice an increase in resistance. Continue to turn and the handle will then separate the adapter from the head.



Carefully remove the head adapter while preventing the head from falling.



Implants



Durum[®] Acetabular Component



Metasul[®] LDH™ Head



Metasul[®] LDH™ Head

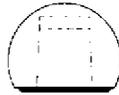


Head adapter

Protasul[®] Pi (VPS-Ti)
Protasul[®]-21 WF
uncemented



Protasul[®]-21 WF



Protasul[®]-21 WF



Protasul[®]-20



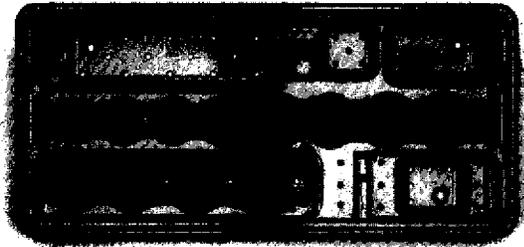
STERILE

Size	ID** mm	Code	REF	Size	Code	REF	Size	Type	REF	Size	Type	REF
44	38	D	01.00214.144	38	D	01.00181.380				S	12/14	01.00185.145
46	40	F	01.00214.146	40	F	01.00181.400	-			M	12/14	01.00185.146
48	42	H	01.00214.148	42	H	01.00181.420				L	12/14	01.00185.147
50	44	J	01.00214.150	44	J	01.00181.440	-			XL	12/14	01.00185.148
52	46	L	01.00214.152	46	L	01.00181.460						
54	48	N	01.00214.154	48	N	01.00181.480						
56	50	P	01.00214.156	-			50	P	01.00181.500			
58	52	R	01.00214.158	-			52	R	01.00181.520			
60	54	T	01.00214.160	-			54	T	01.00181.540			
62	56	V	01.00214.162	-			56	V	01.00181.560			
64	58	X	01.00214.164	-			58	X	01.00181.580			
66	60	Z	01.00214.166	-			60	Z	01.00181.600			

*U.S. Patent No. 6,126,695

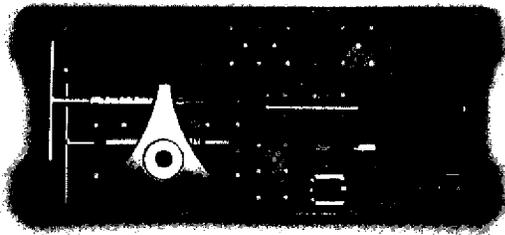
**ID = inner diameter

Instruments



Extractor

Taper REF
12/14 01.00189.151



Insert remover pusher

REF
75.10.01

Base tray (empty)
REF
01.00189.210

insert for tray (empty)
REF
01.00189.211

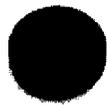
Standard container cover, gray
REF
01.00029.031

Sail head impactor attachment
REF
78.00.38



Handle reduction and impact attachment

REF
75 11 00-02



Assembly inlay

REF
01.00189.104



Large trial head

Size	REF
∅ 38 mm	01.00189.380
∅ 40 mm	01.00189.400
∅ 42 mm	01.00189.420
∅ 44 mm	01.00189.440
∅ 46 mm	01.00189.460
∅ 48 mm	01.00189.480
∅ 50 mm	01.00189.500
∅ 52 mm	01.00189.520
∅ 54 mm	01.00189.540
∅ 56 mm	01.00189.560
∅ 58 mm	01.00189.580
∅ 60 mm	01.00189.600



Assembly base plate

REF
01.00189.100



Adapter extractor

REF
01.00189.150



Assembly attachment

REF
12/14 01.00189.102



Head disassembly attachment metal

REF
01.00189.103



Trial adapter

Size	REF
S	12/14 01.00189.145
M	12/14 01.00189.146
L	12/14 01.00189.147
X	12/14 01.00189.148



Head disassembly attachment plastic

REF
01.00189.110

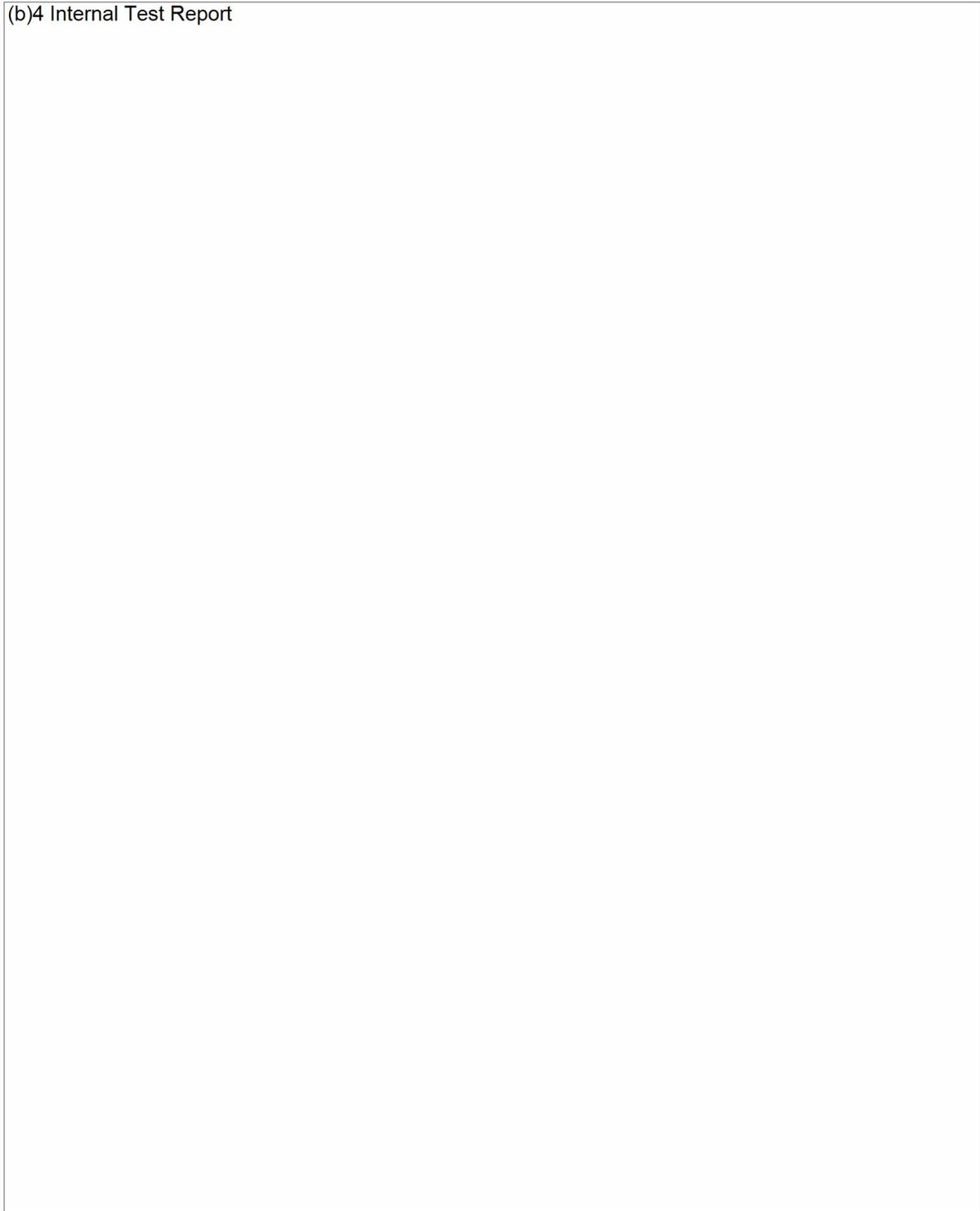
Please contact your Zimmer representative or consult our website www.zimmer.com



241

MORPHOLOGICAL PROPERTIES OF Ti-VPS COATING ON US DUROM CUP

(b)4 Internal Test Report



(b)4 Internal Test Report

243

0179

(b)4 Internal Test Report

(b)4 Internal Test Report

245

**CONFIDENTIAL AND PROPRIETARY INFORMATION
EXEMPT FROM DISCLOSURE UNDER FOI**

0181

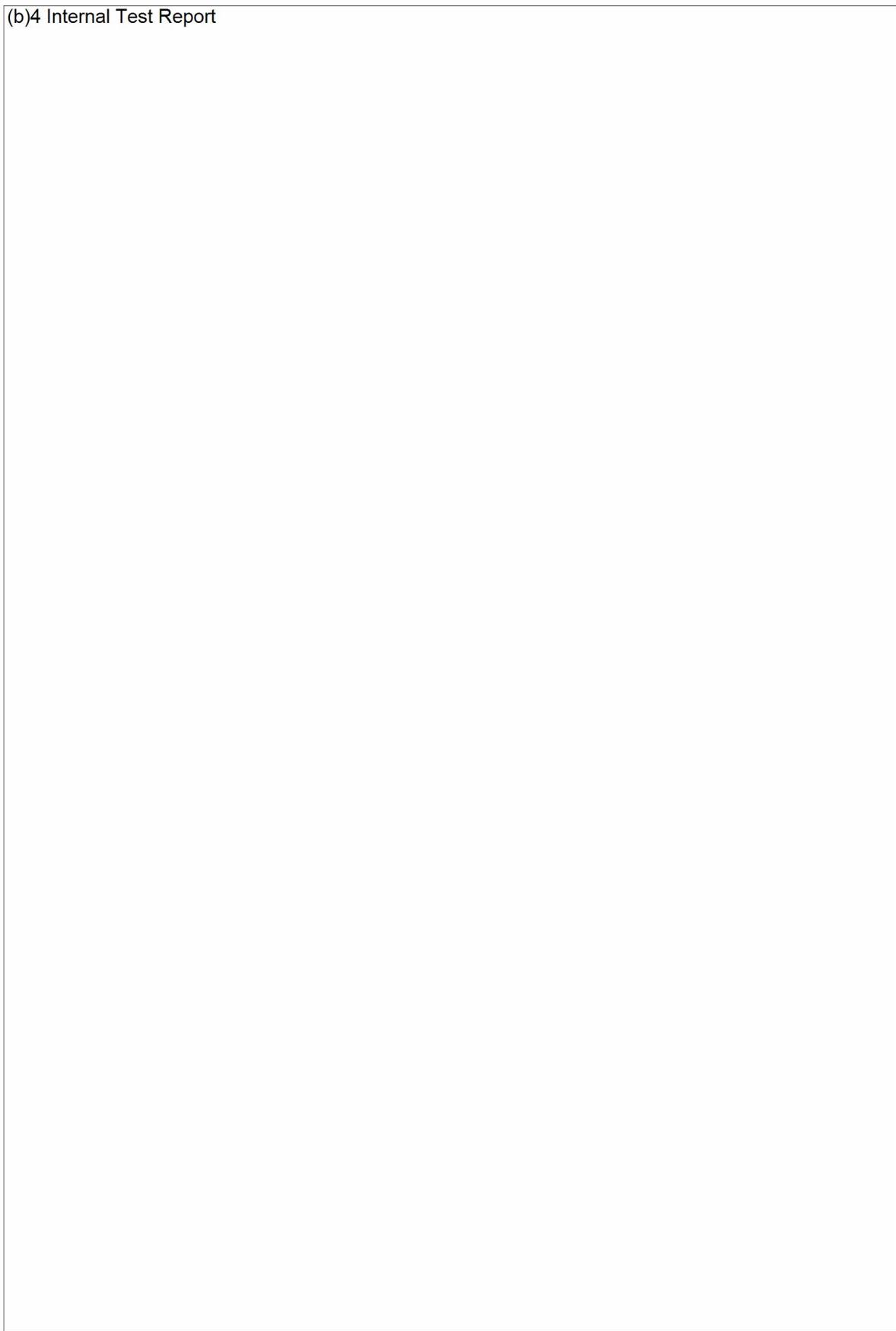
(b)4 Internal Test Report

**CONFIDENTIAL AND PROPRIETARY INFORMATION
EXEMPT FROM DISCLOSURE UNDER FOI**

246

0182

(b)4 Internal Test Report



(b)4 Internal Test Report



(b)4 Internal Test Report

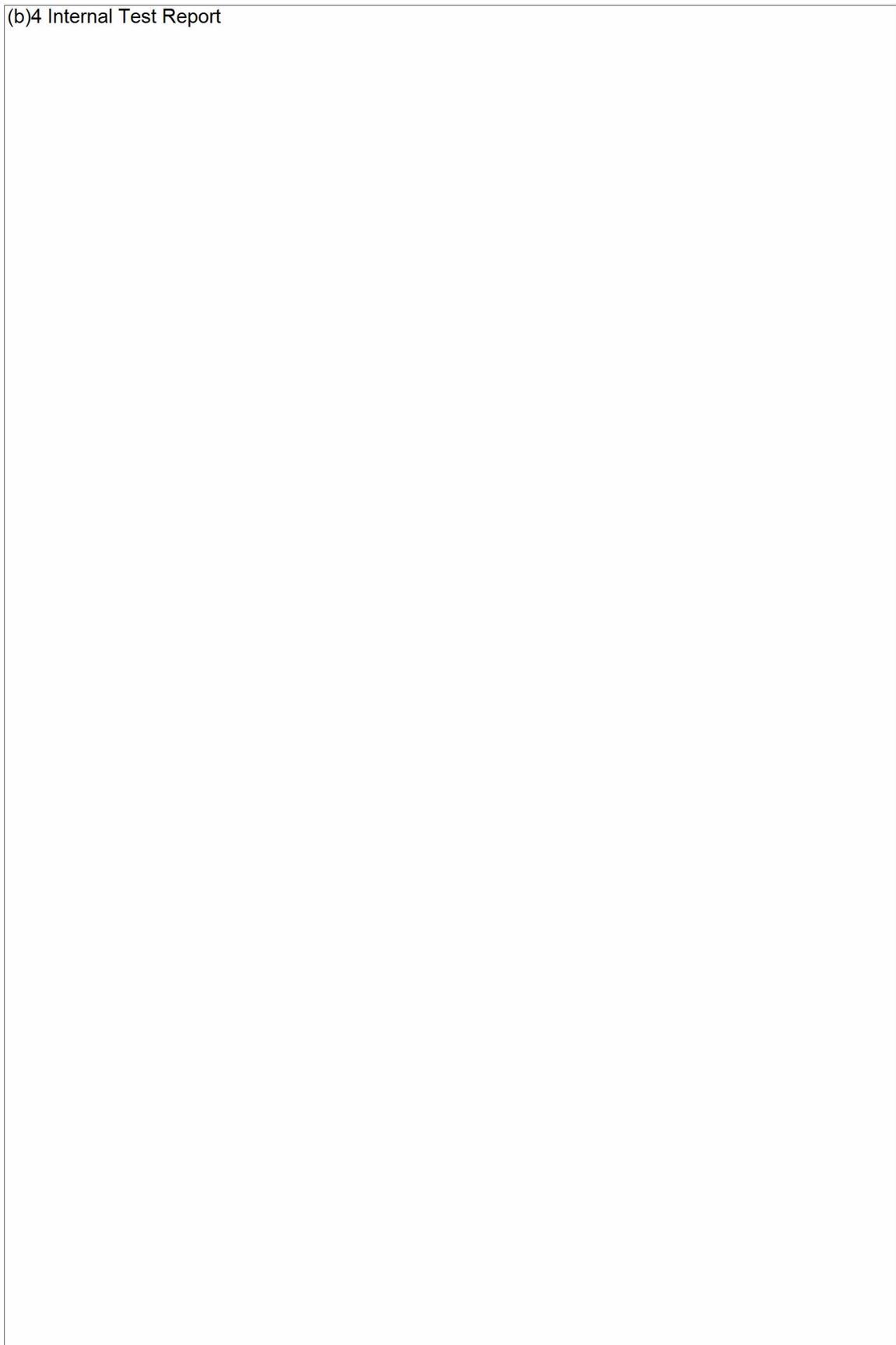


**CONFIDENTIAL AND PROPRIETARY INFORMATION
EXEMPT FROM DISCLOSURE UNDER FOI**

249

0185

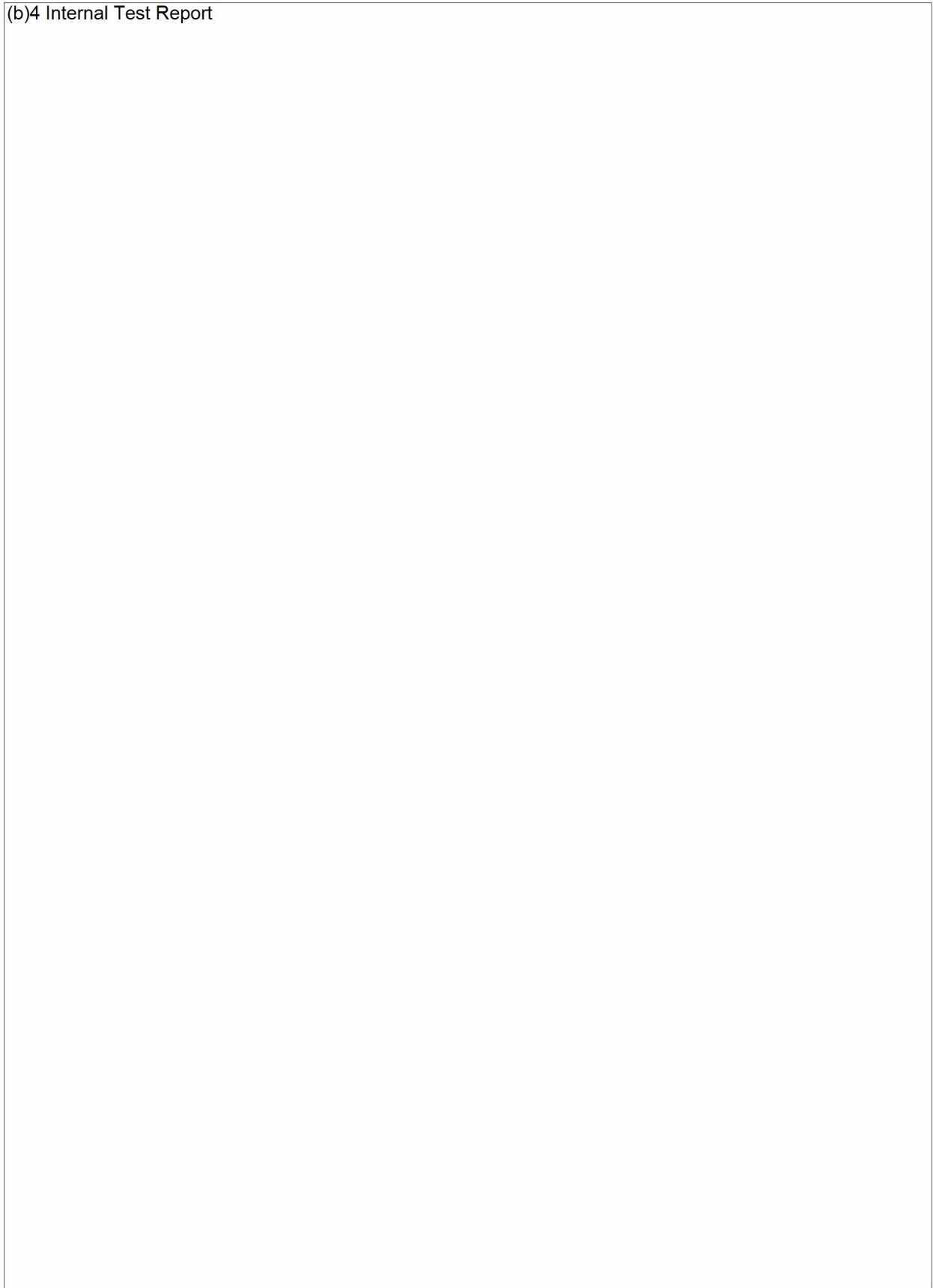
(b)4 Internal Test Report



(b)4 Internal Test Report



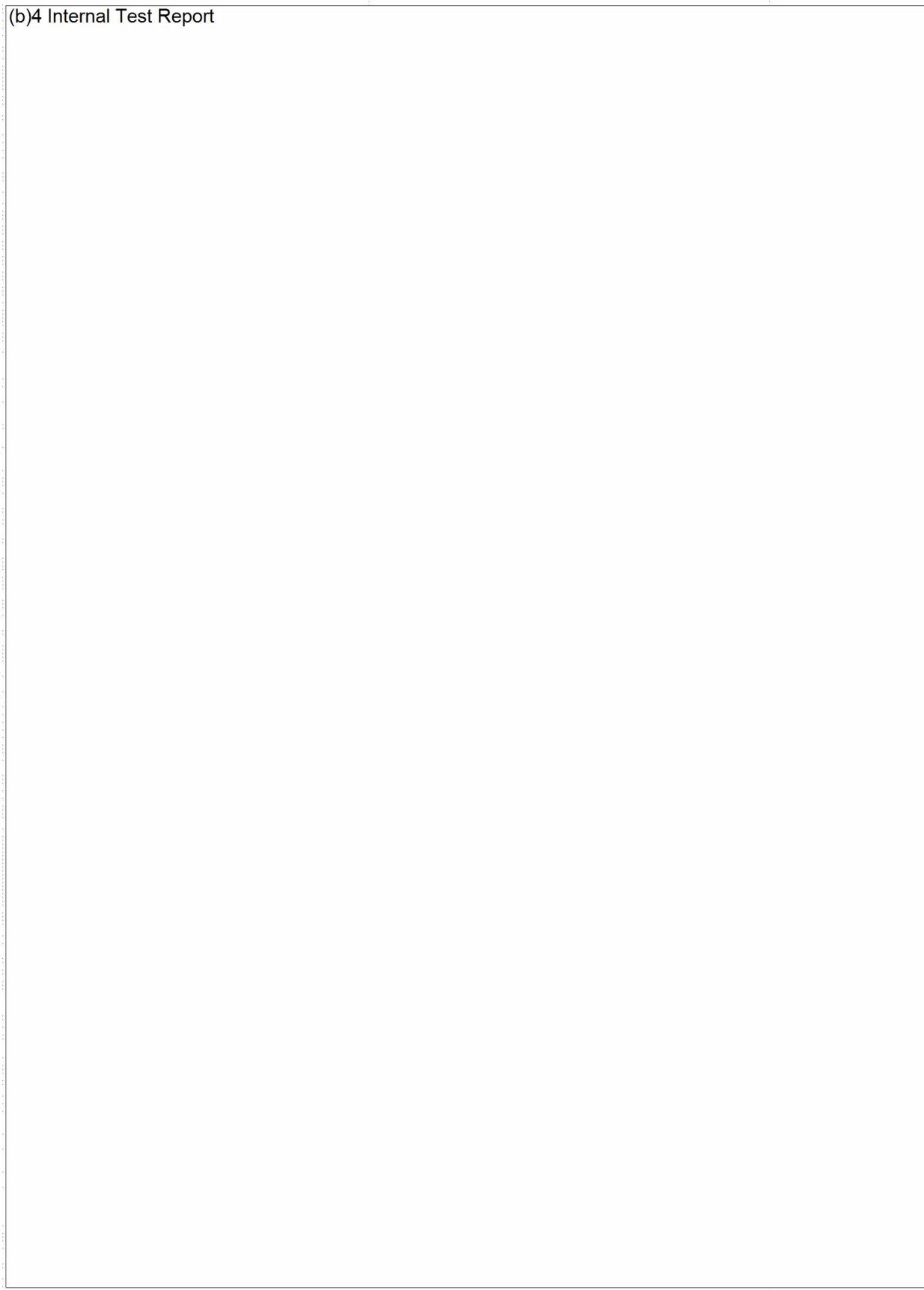
(b)4 Internal Test Report



(b)4 Internal Test Report



(b)4 Internal Test Report



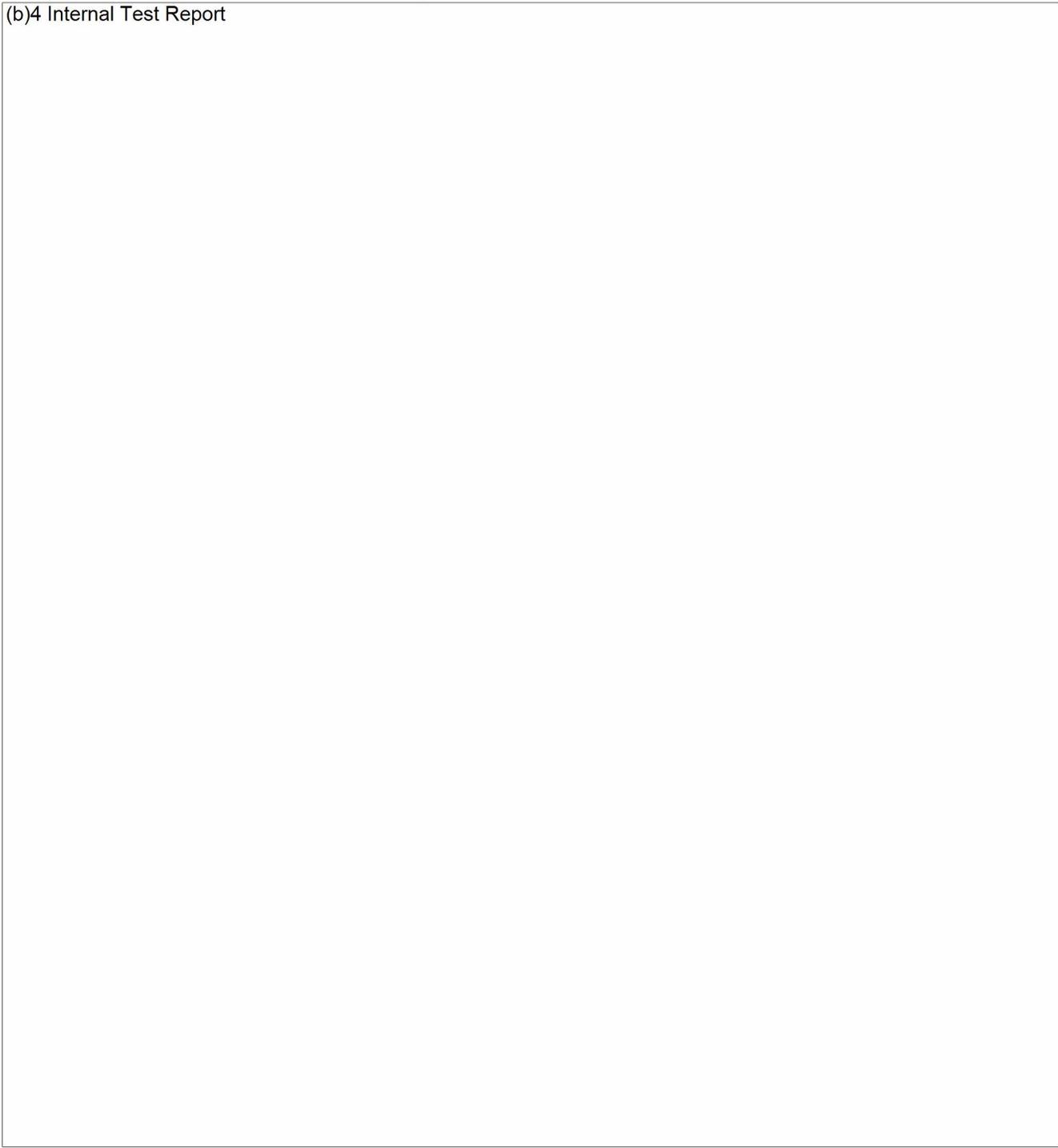
(b)4 Internal Test Report

CONFIDENTIAL AND PROPRIETARY INFORMATION
EXEMPT FROM DISCLOSURE UNDER FOI

255

0191

(b)4 Internal Test Report



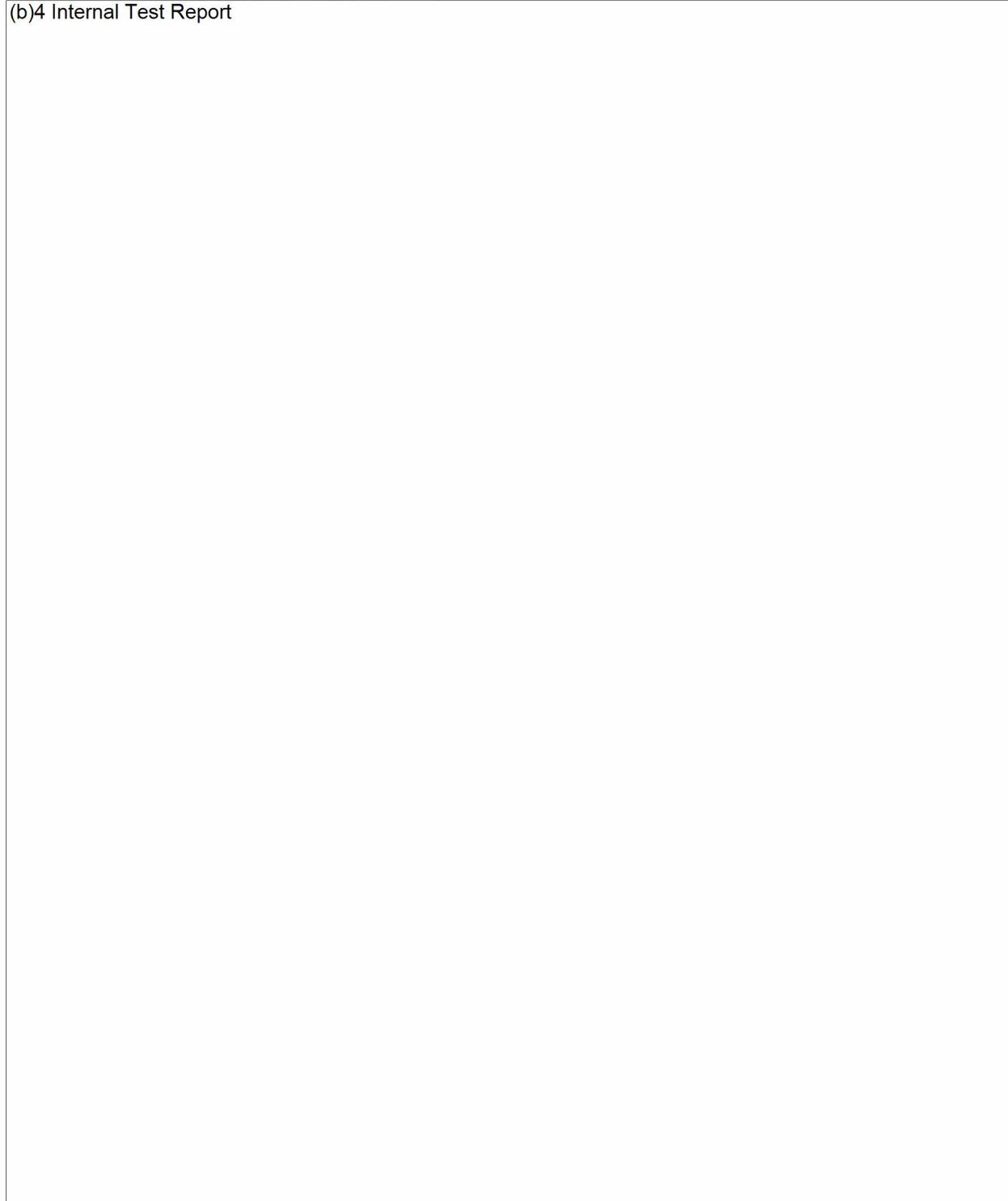
**CONFIDENTIAL AND PROPRIETARY INFORMATION
EXEMPT FROM DISCLOSURE UNDER FOI**

256

0192

MECHANICAL PROPERTIES OF TI-VPS COATING ON US DUROM CUP

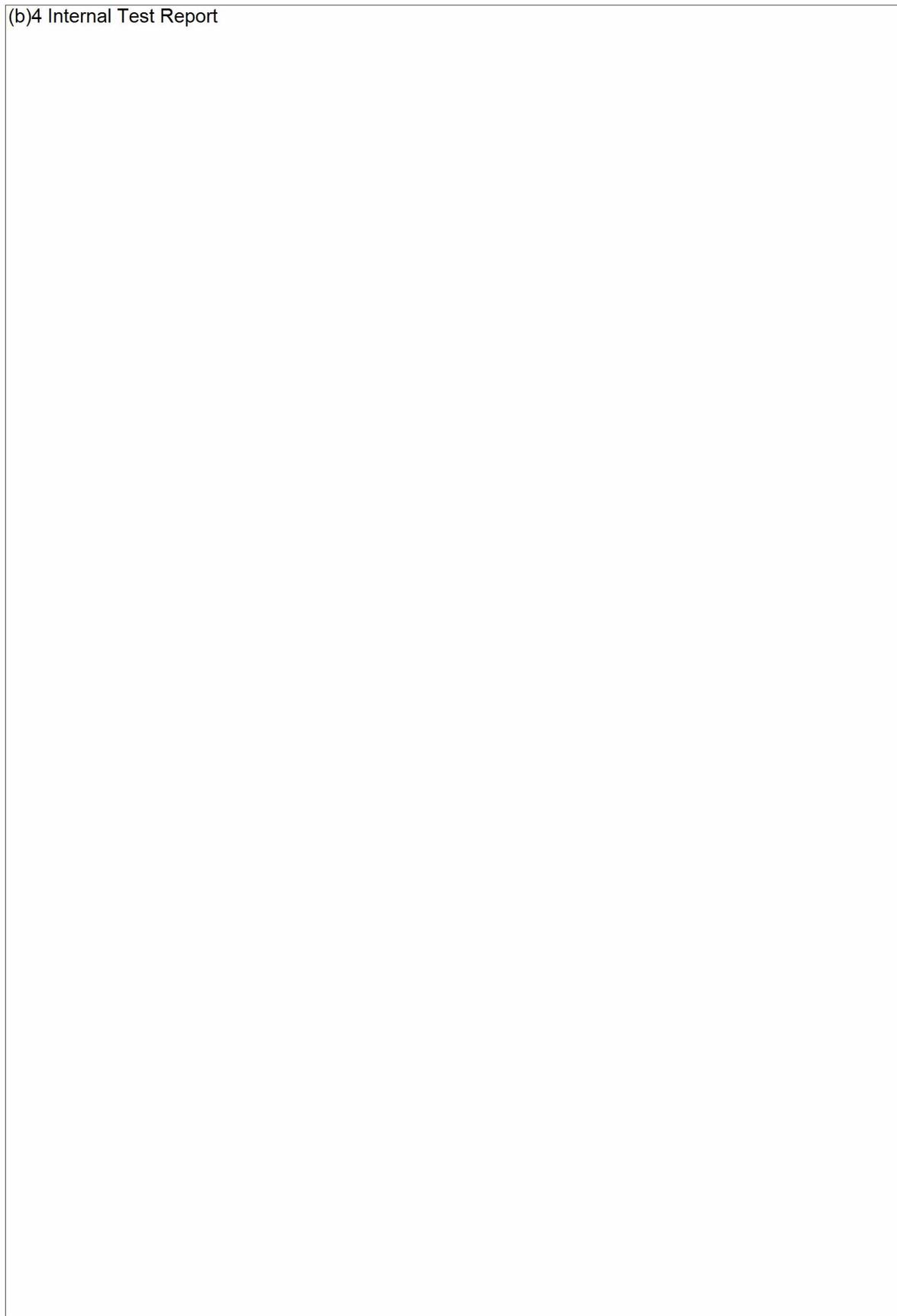
(b)4 Internal Test Report



(b)4 Internal Test Report



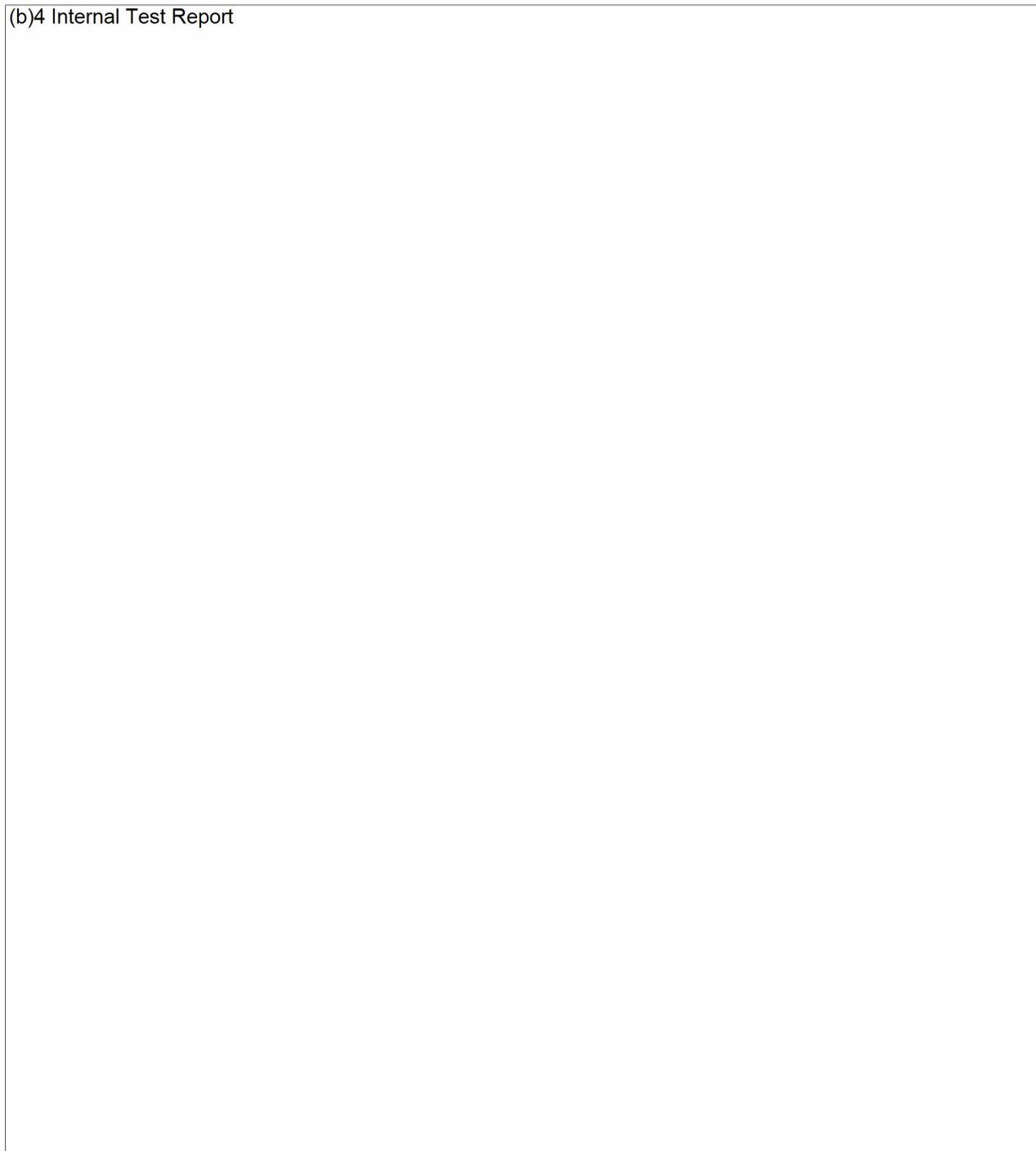
(b)4 Internal Test Report



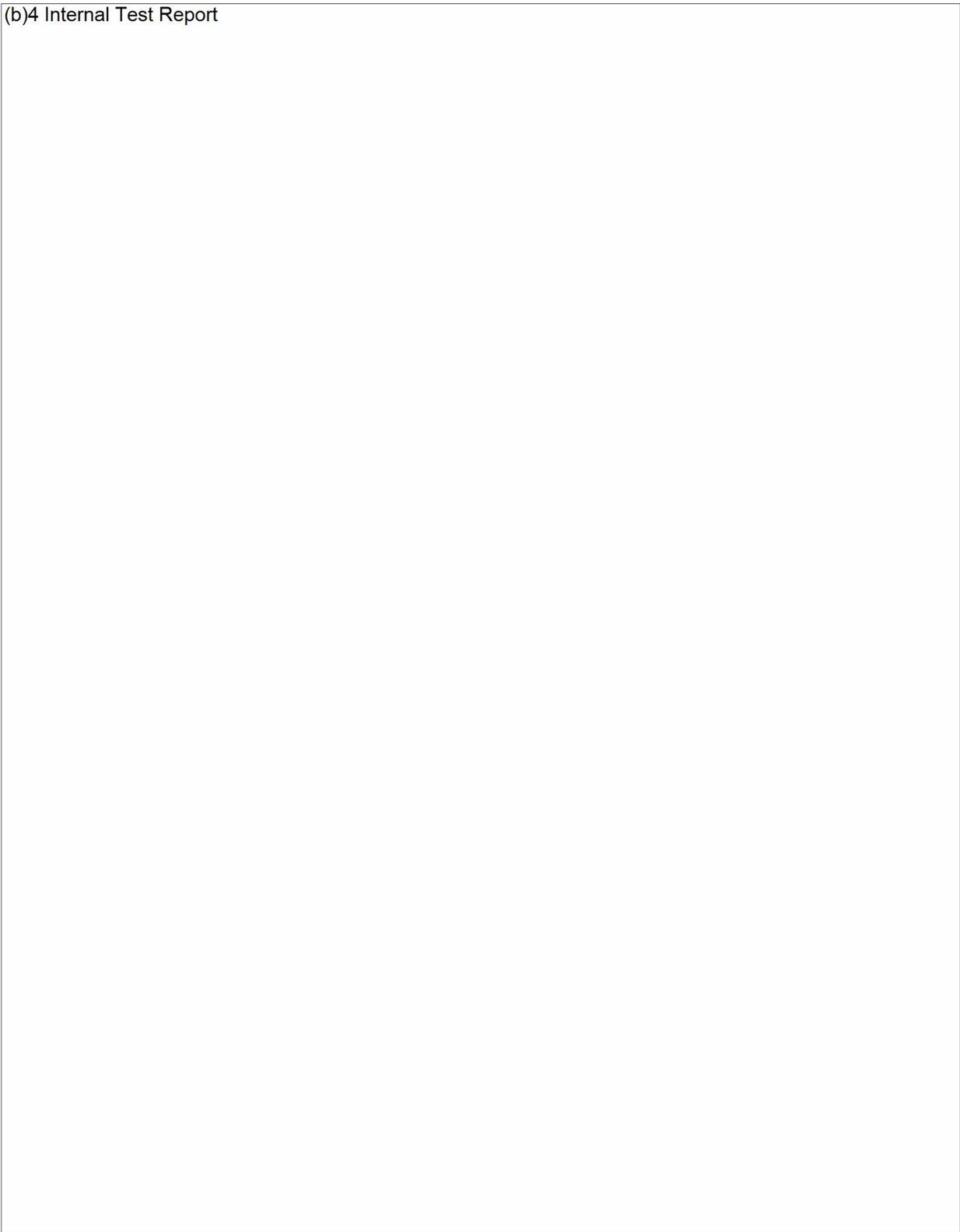
(b)4 Internal Test Report



(b)4 Internal Test Report



(b)4 Internal Test Report



(b)4 Internal Test Report

**CONFIDENTIAL AND PROPRIETARY INFORMATION
EXEMPT FROM DISCLOSURE UNDER FOI**

263

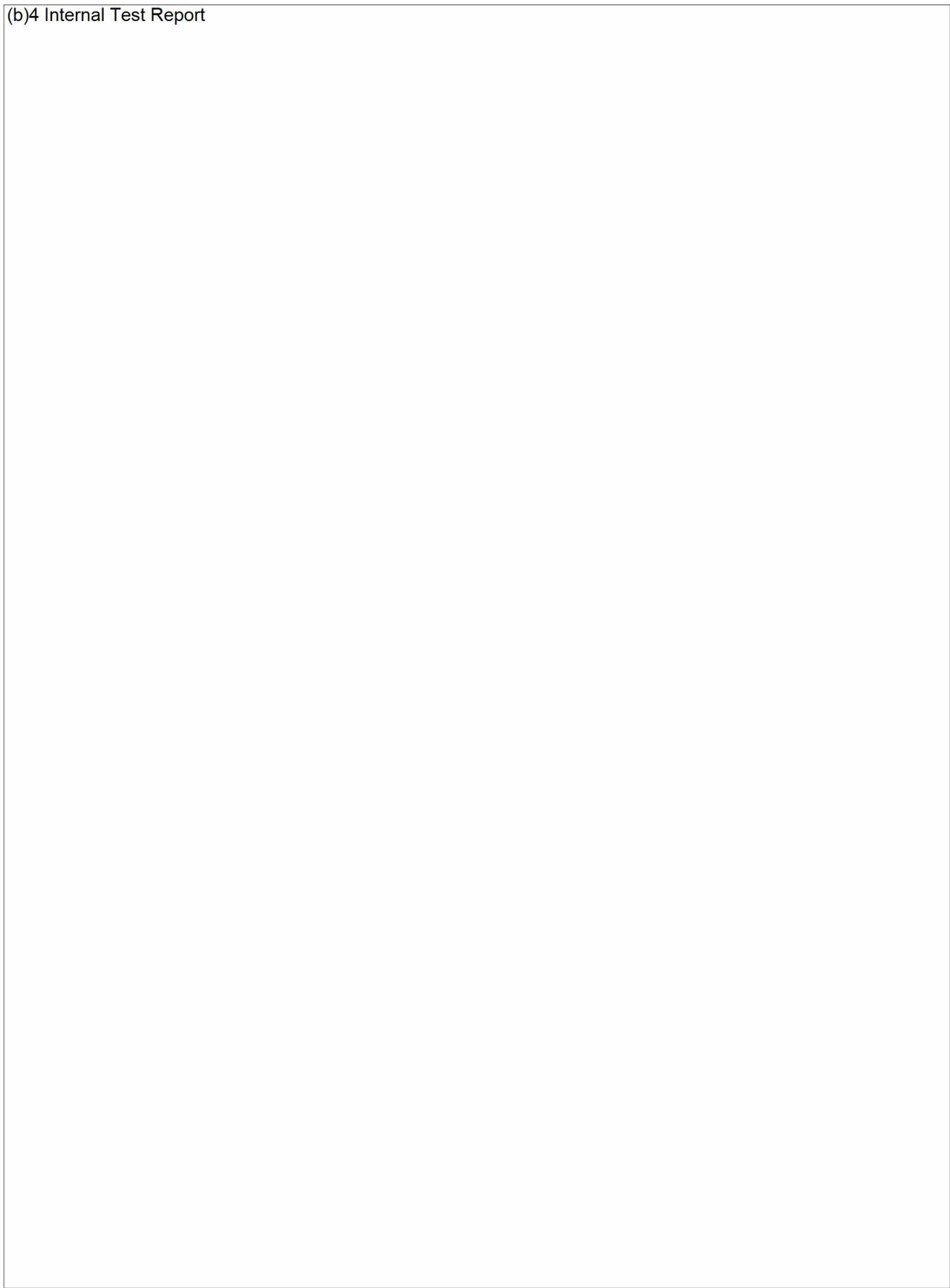
0199

(b)4 Internal Test Report



(b)4 Internal Test Report

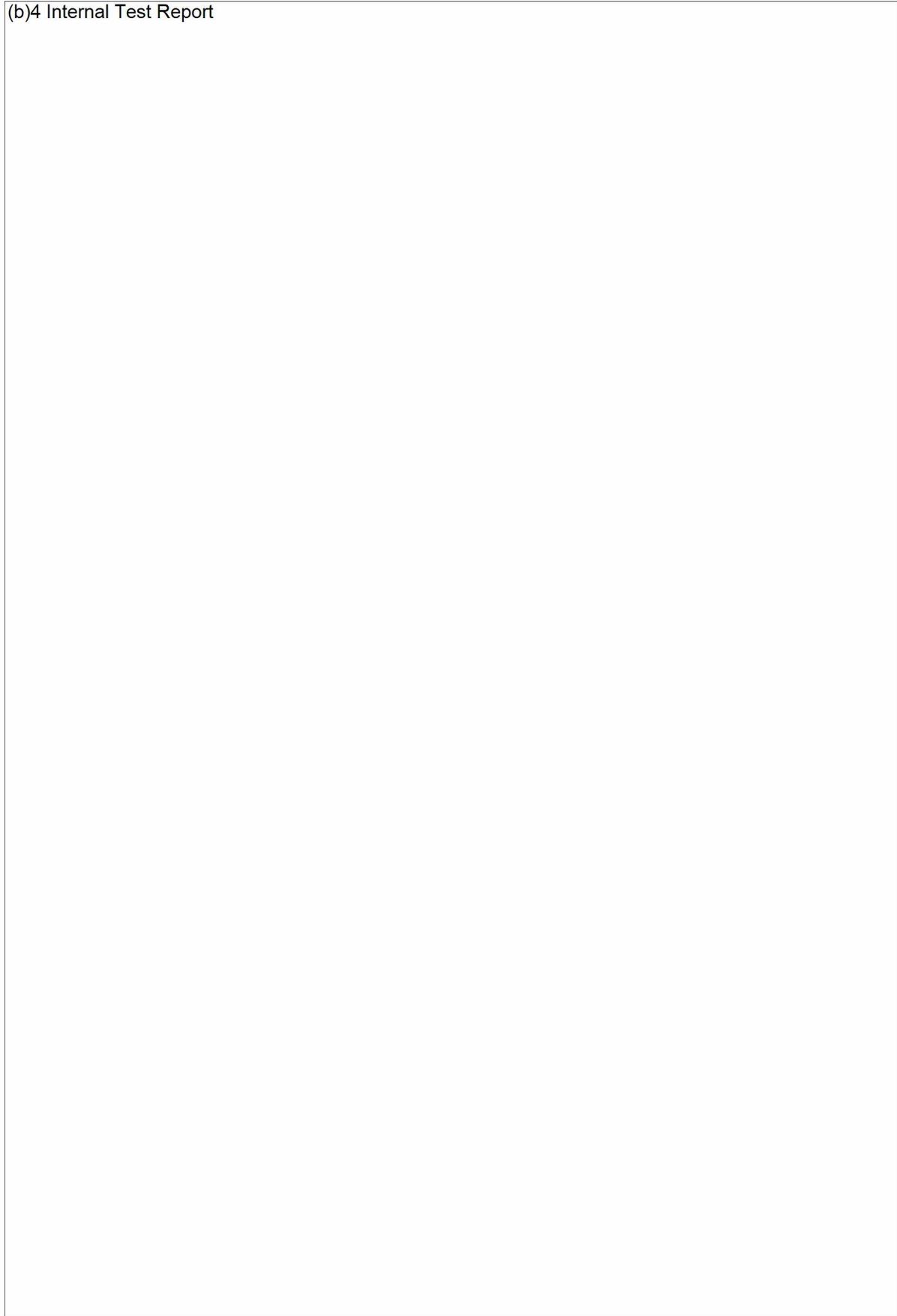
(b)4 Internal Test Report



**CONFIDENTIAL AND PROPRIETARY INFORMATION
EXEMPT FROM DISCLOSURE UNDER FOI**

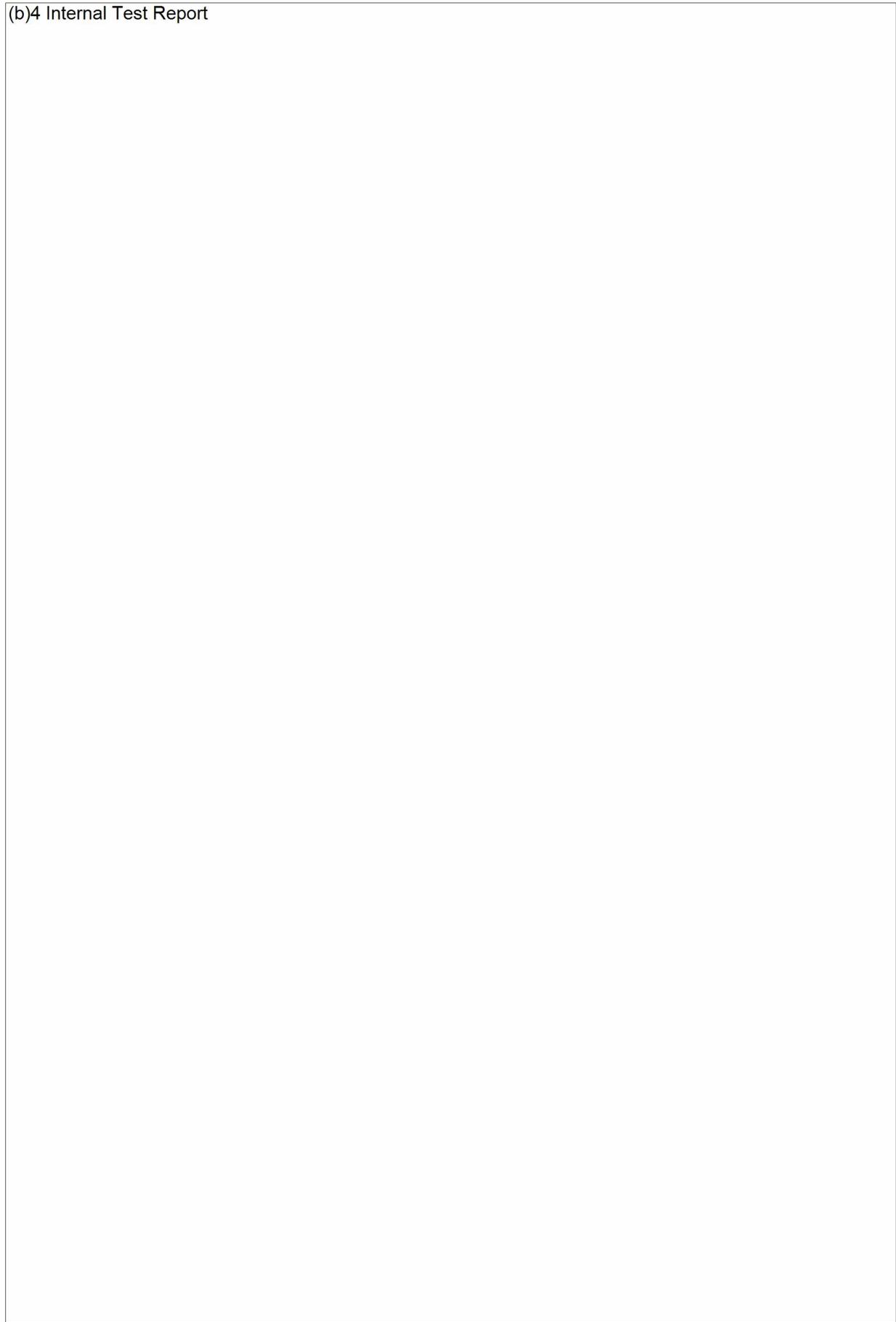
266⁰²⁰²

(b)4 Internal Test Report



(b)4 Internal Test Report

(b)4 Internal Test Report



**CONFIDENTIAL AND PROPRIETARY INFORMATION
EXEMPT FROM DISCLOSURE UNDER FOI**

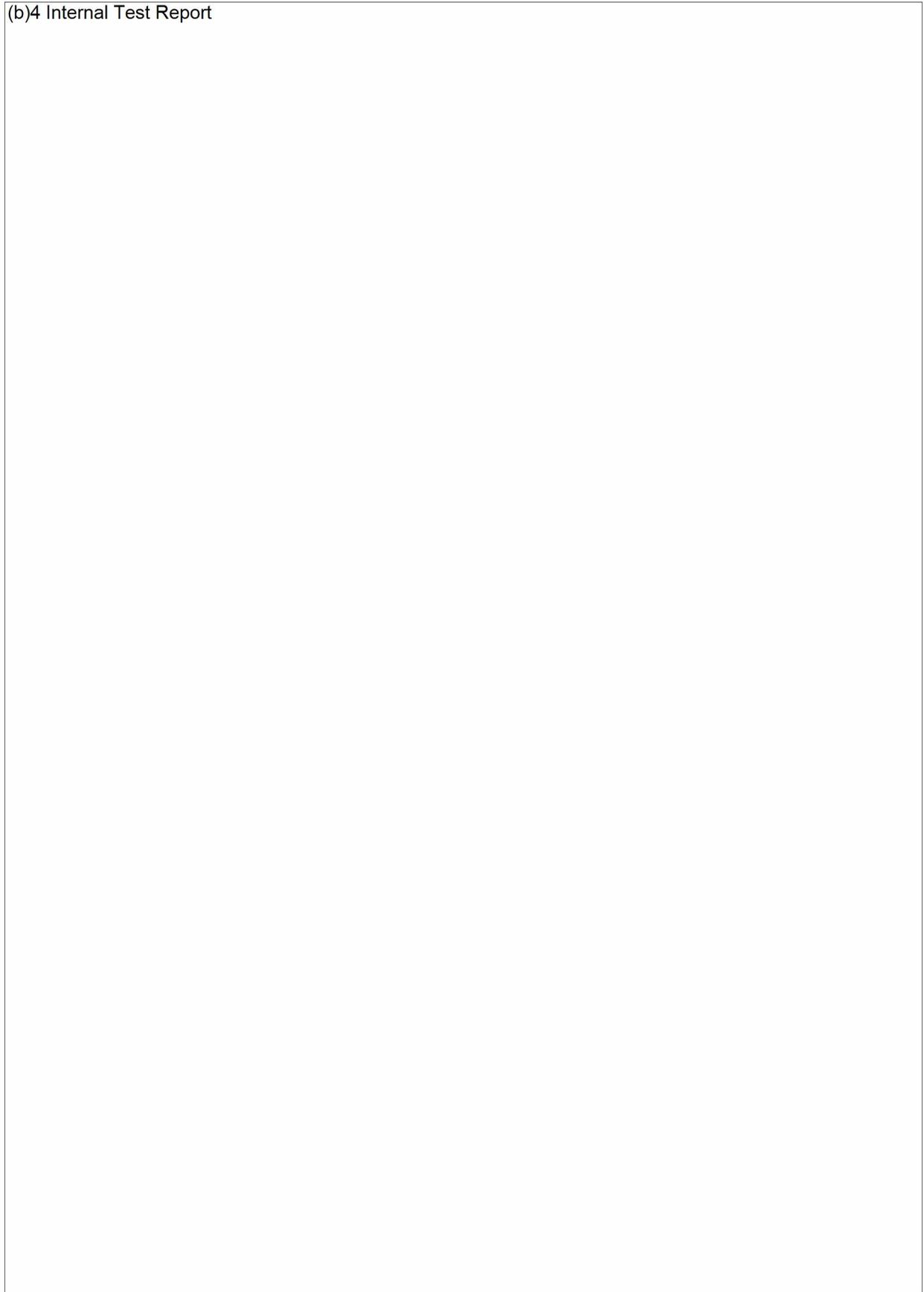
269

0205

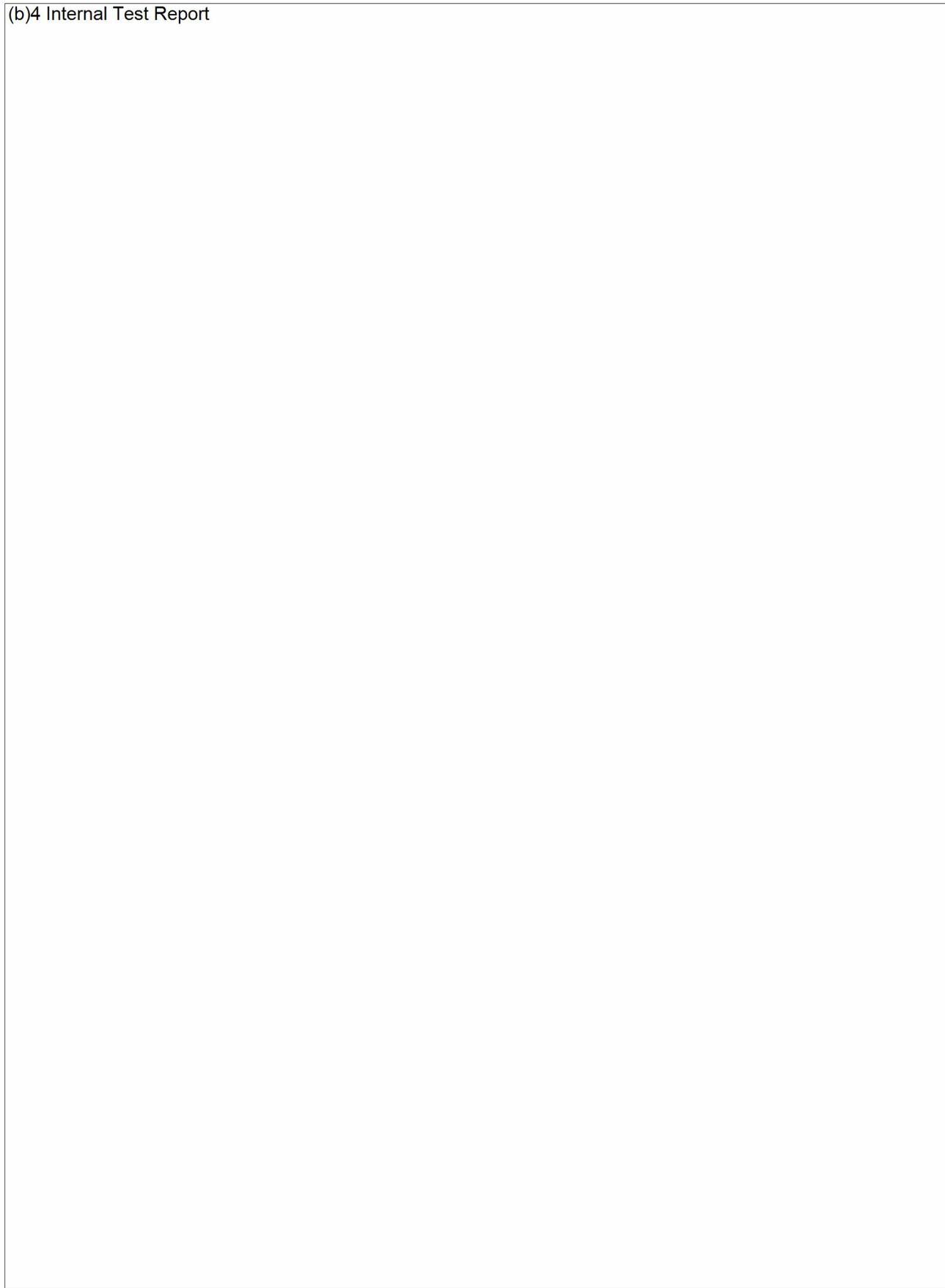
(b)4 Internal Test Report



(b)4 Internal Test Report



(b)4 Internal Test Report



(b)4 Internal Test Report

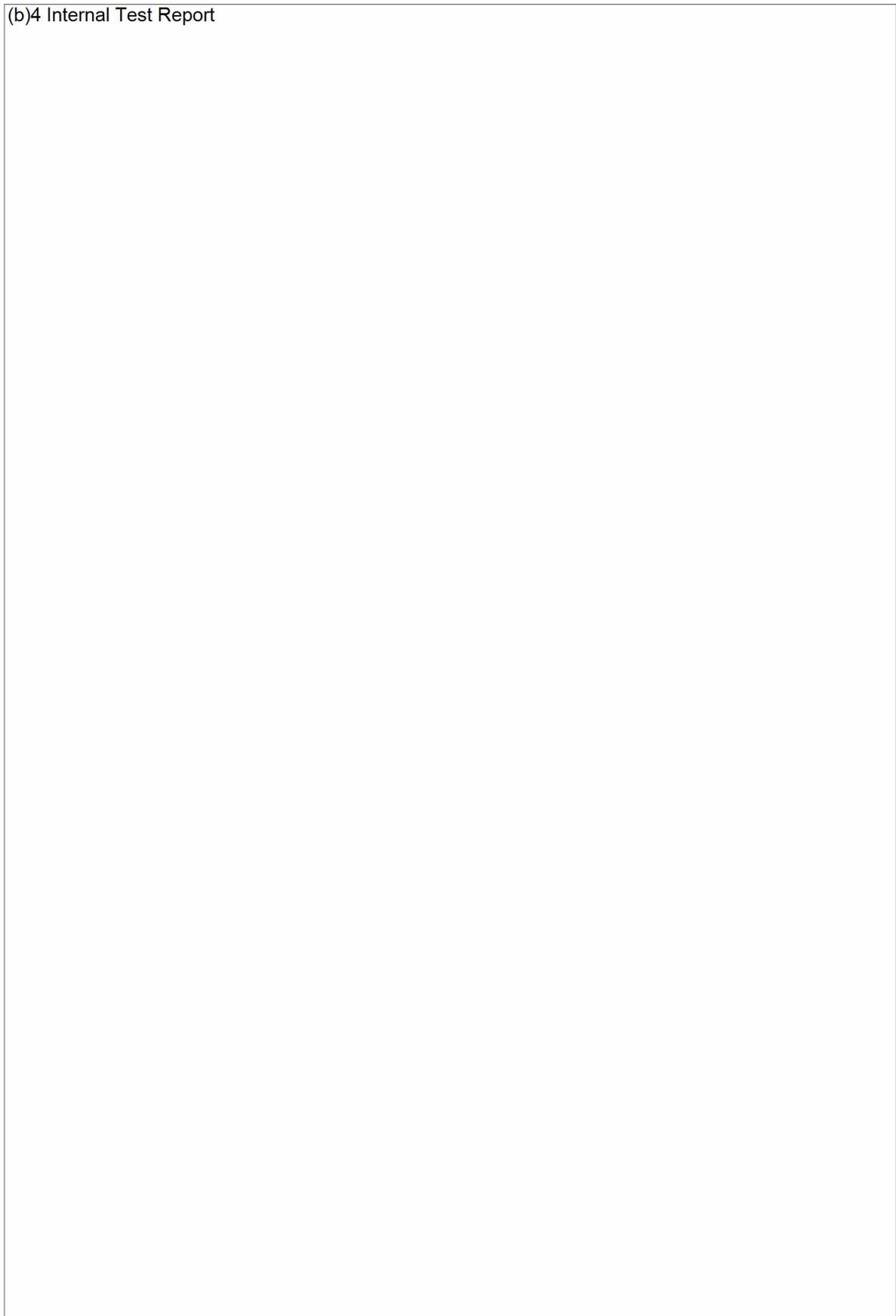
(b)4 Internal Test Report



(b)4 Internal Test Report



(b)4 Internal Test Report



(b)4 Internal Test Report



"This document discloses subject matter in which Centerpulse Orthopedics Ltd. has priority rights, neither receipt nor possession thereof confers any right to reproduce or disclose the document, an part thereof, any information contained therein, or any physical article or device, or to practice any method or proces except by written permission from, or written agreement with Centerpulse Orthopedics."

CONFIDENTIAL

Ball Head Adapter

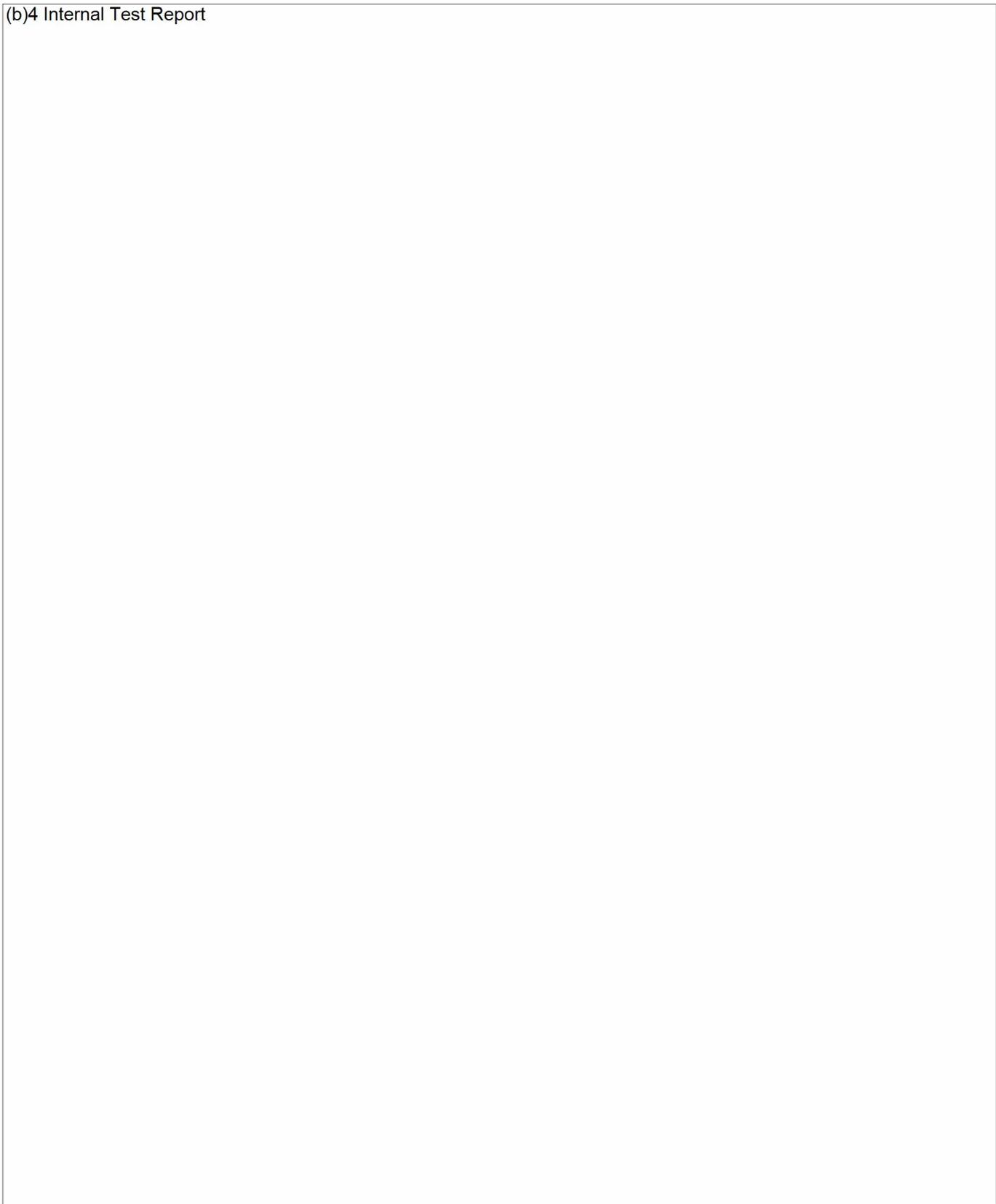
Experimental investigation of the connection strength of the ball head adapter

(b)4 Internal Test Report

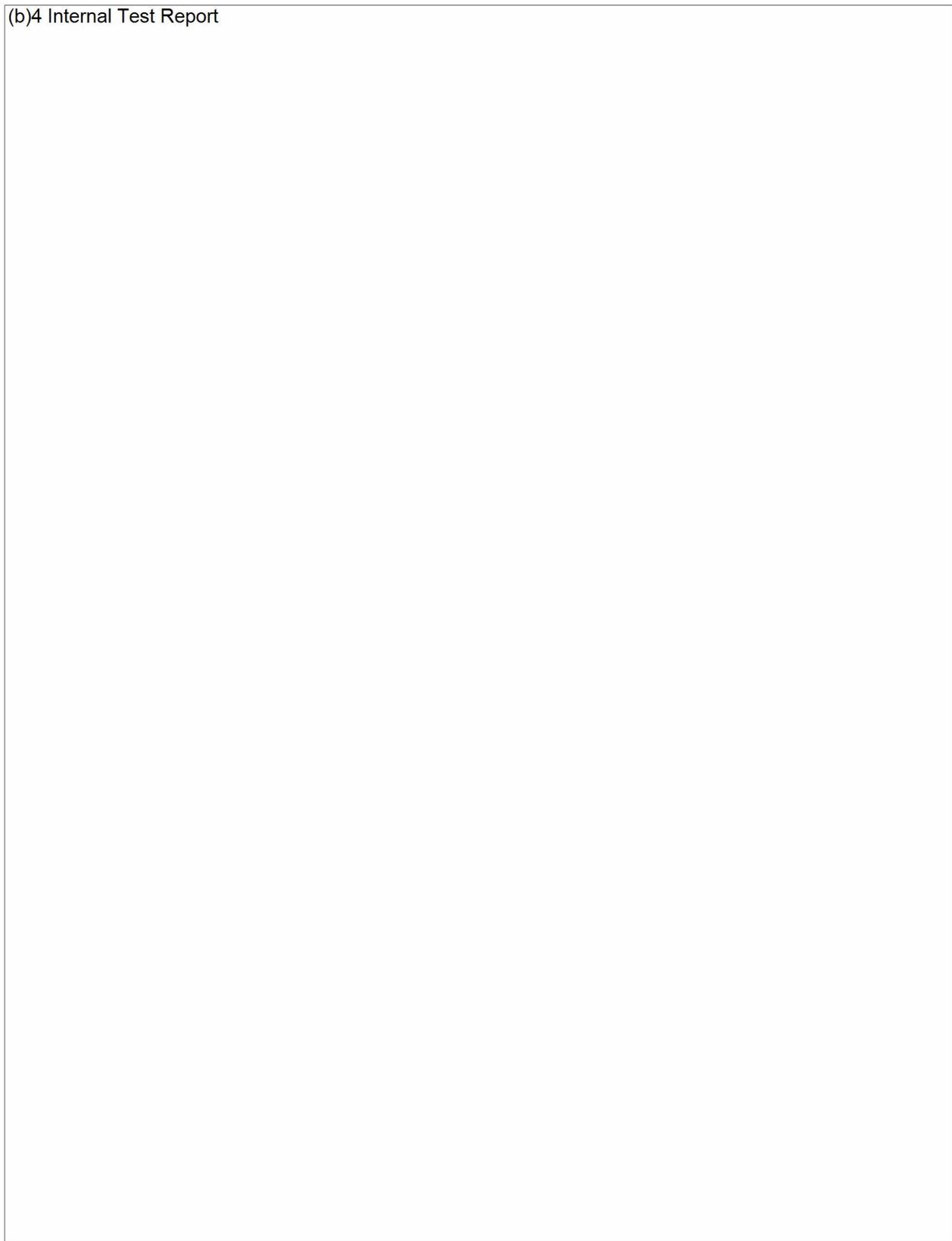
(b)4 Internal Test Report



(b)4 Internal Test Report



(b)4 Internal Test Report



(b)4 Internal Test Report



(b)4 Internal Test Report



**TECHNICAL
MEMORANDUM**



Research
Laboratories

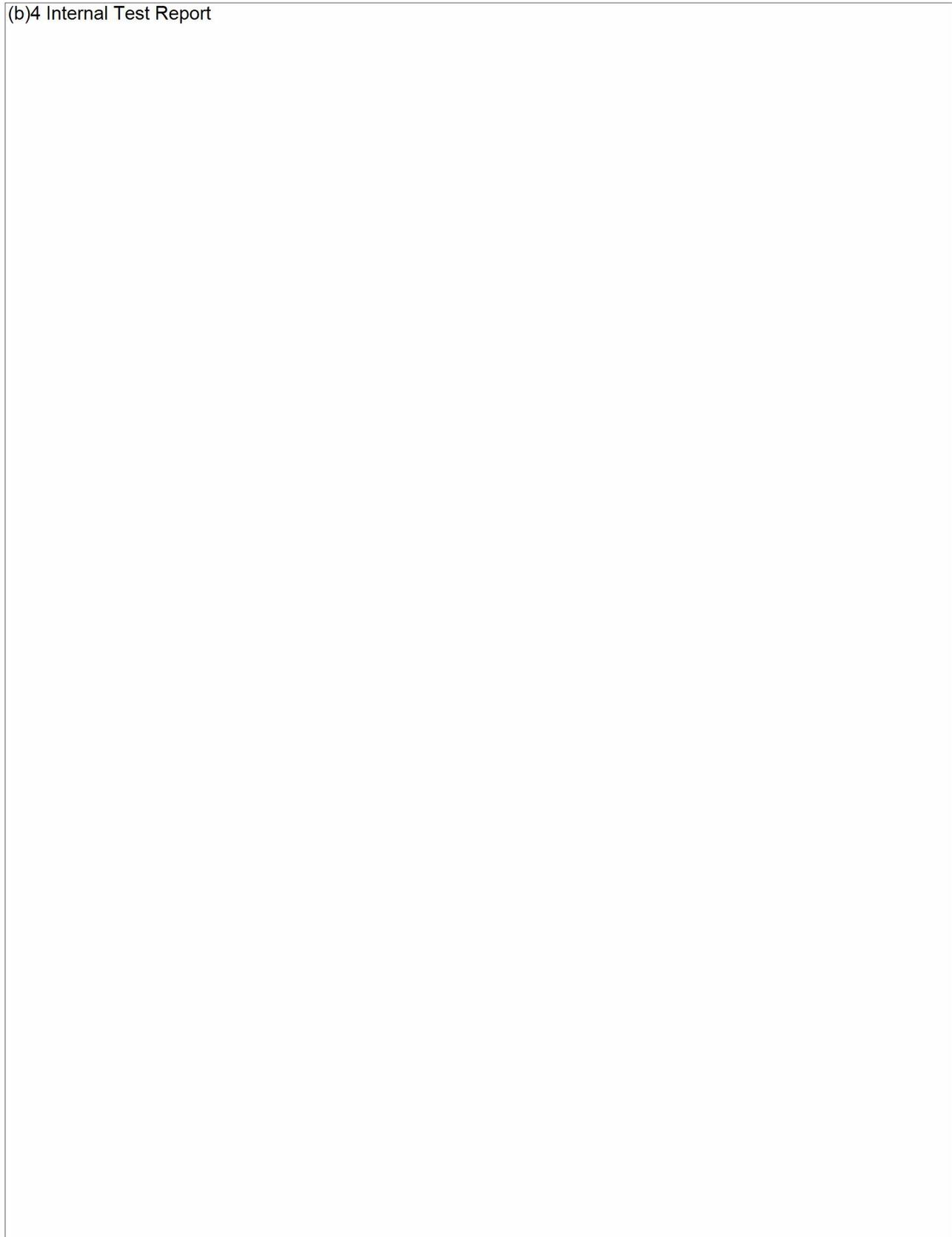
SUBJECT The Compatibility of Metasul[®] DATE March 14, 2005
LDH Femoral Heads with
Zimmer-Warsaw 12/14 Taper Stems

(b)4 Internal Test Report

(b)4 Internal Test Report



(b)4 Internal Test Report



(b)4 Internal Test Report



(b)4 Internal Test Report



DUROM ACETABULAR COMPONENT – STIFFNESS EVALUATION

(b)4 Internal Test Report

(b)4 Internal Test Report

(b)4 Internal Test Report

**CONFIDENTIAL AND PROPRIETARY INFORMATION
EXEMPT FROM DISCLOSURE UNDER FOI**

299 0235

(b)4 Internal Test Report

(b)4 Internal Test Report



(b)4 Internal Test Report



**CONFIDENTIAL AND PROPRIETARY INFORMATION
EXEMPT FROM DISCLOSURE UNDER FOI**

302⁰²³⁸

**IN-VITRO FRICTION AND WEAR CHARACTERISTICS OF LARGE
DIAMETER METAL-ON-METAL ARTICULATIONS**

(b)4 Internal Test Report



(b)4 Internal Test Report

(b)4 Internal Test Report

(b)4 Internal Test Report

(b)4 Internal Test Report

**CONFIDENTIAL AND PROPRIETARY INFORMATION
EXEMPT FROM DISCLOSURE UNDER FOI**

307⁰²⁴³

(b)4 Internal Test Report

**CONFIDENTIAL AND PROPRIETARY INFORMATION
EXEMPT FROM DISCLOSURE UNDER FOI**

308 0244

(b)4 Internal Test Report



**CONFIDENTIAL AND PROPRIETARY INFORMATION
EXEMPT FROM DISCLOSURE UNDER FOI**

309 0245

(b)4 Internal Test Report

**CONFIDENTIAL AND PROPRIETARY INFORMATION
EXEMPT FROM DISCLOSURE UNDER FOI**

310⁰²⁴⁶

(b)4 Internal Test Report

(b)4 Internal Test Report

(b)4 Internal Test Report



(b)4 Internal Test Report

**CONFIDENTIAL AND PROPRIETARY INFORMATION
EXEMPT FROM DISCLOSURE UNDER FOI**

314⁰²⁵⁰

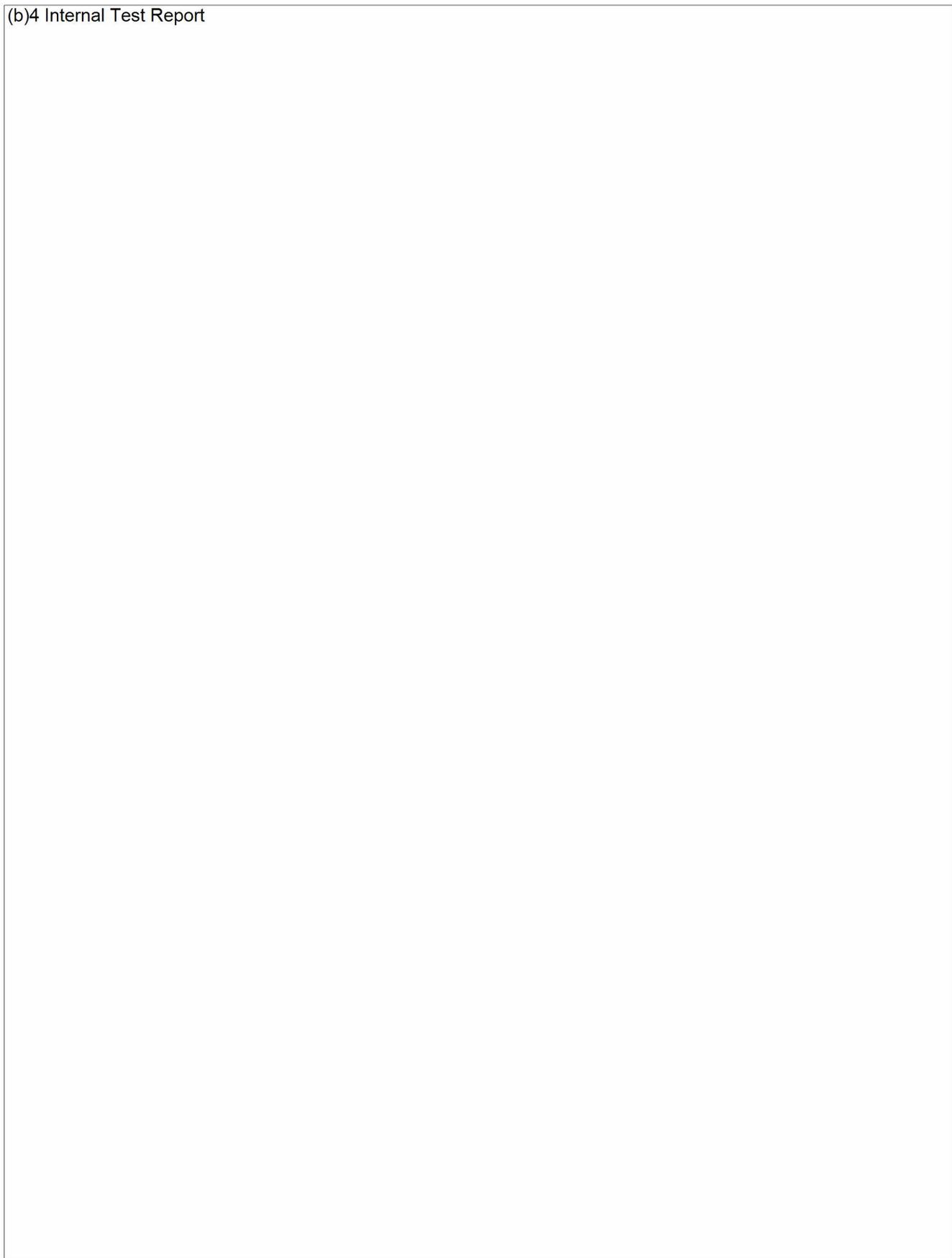
(b)4 Internal Test Report

(b)4 Internal Test Report

**CONFIDENTIAL AND PROPRIETARY INFORMATION
EXEMPT FROM DISCLOSURE UNDER FOI**

0252
316

(b)4 Internal Test Report



(b)4 Internal Test Report

**CONFIDENTIAL AND PROPRIETARY INFORMATION
EXEMPT FROM DISCLOSURE UNDER FOI**

0254
318

**PREMARKET NOTIFICATION
CLASS III CERTIFICATION AND SUMMARY
(As Required by 21 CFR 807.94)**

(To be submitted when claiming equivalence to a Class III device)

I certify that, in my capacity as Specialist, Regulatory Affairs of Zimmer GmbH, that I have conducted a reasonable search of all information known or otherwise available about the types and causes of safety and/or effectiveness problems that have been reported for components used in metal-on-metal total hip arthroplasty. I further certify that I am aware of the types of problems to which metal-on-metal hip prostheses are susceptible and that, to the best of my knowledge, the following summary of the types and causes of safety and/or effectiveness problems about metal-on-metal hip prostheses is complete and accurate.

(Attach the summary of problem data, bibliography or other citations upon which the summary is based.)


Signature of Certifier

Bernd Henningsen
Typed Name

10.12.05
Date

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

*For a new submission, leave the 510(k) number blank.

Must be signed by a responsible person of the firm required to submit the premarket notification [e.g., not a consultant for the 510(k) submitter].

SECTION VII**PUBLISHED/UNPUBLISHED CLINICAL RESULTS****A. Unpublished Clinical Studies****Device Descriptions**

The metal/metal (experimental) and metal/polyethylene (control) devices in this clinical summary report are all semi-constrained total hip prostheses from three orthopaedic device manufacturers.

The metal/metal acetabular components are two-piece modular components consisting of 28 mm, 32mm and 36mm inner diameter cobalt chromium molybdenum (Co-Cr-Mo) alloy bearing inserts fitted to the outer shells by means of a taper fit mechanism. The outer rims of the bearing inserts are either neutral or have extended lips to provide for additional coverage of the modular femoral heads. The metal outer shells are manufactured from either commercially pure (CP) titanium or titanium alloy (Ti-6Al-4V). The outer surfaces of the acetabular components have either sintered or plasma sprayed porous coatings to provide for biological ingrowth as a means for primary fixation. The porous coatings are manufactured from either CP titanium or titanium alloy. Some acetabular components have screw holes located on the outer shells to allow for adjunctive fixation with bone screws.

The metal/polyethylene acetabular components are two-piece modular components consisting of 28mm inner diameter ultrahigh molecular weight polyethylene (UHMWPe) bearing insert liners fitted to the outer shells by means of snap-fit locking mechanisms. The metal outer shells were manufactured from either commercially pure (CP) titanium or titanium alloy (Ti-6Al-4V). The outer surfaces of the acetabular components all have either sintered or plasma sprayed porous coatings to provide for biological ingrowth as a means for primary fixation. The porous coatings are manufactured from either CP titanium or titanium alloy. The acetabular components have screw holes located on the outer shells to allow for adjunctive fixation with bone screws.

The femoral prostheses components for both the investigational and control device configurations are manufactured from either titanium or cobalt chrome alloys. The femoral components have proximal tapers to receive the modular ball heads having diameters that match the inner diameters of the acetabular prostheses. Both cemented and uncemented femoral prostheses were implanted in these studies.

Survival Curves for Metal-on-Metal Implants from Three Manufacturers

Introduction

In the September 4, 1987 Federal Register, FDA issued a final rule classifying hip joint metal/metal semiconstrained prosthesis with a cemented acetabular component (888.3320) and the hip joint metal/metal semiconstrained prosthesis with an uncemented acetabular component (888.330) into Class III. On September 25, 2000, the Orthopedic Surgical Manufacturers Association (OSMA) submitted a petition under section 513 (b) (2)(A) of the Act requesting a change in the regulatory classification for these devices from Class III to Class II. The reclassification petition was reviewed at an Orthopaedic and Rehabilitation Devices Panel meeting on August 8, 2001. At that meeting, the panel voted to recommend against reclassification and cited the reasons for their recommendation. The FDA concurred with the panel, and in the Federal Register published on September 6, 2002, denied the request for reclassification and specified the reasons for this decision.

Subsequent to the decision by FDA to deny the OSMA petition, OSMA held meetings with the agency to discuss where the original petition was deficient and how these deficiencies might be addressed in a second reclassification petition. One of the deficiencies to be addressed was the lack of longer-term, i.e., 4-7 years follow-up information on the performance of the metal-on-metal hips from the studies presented in the original petition. At a meeting held at the agency on January 23, 2002 and during teleconferences held on April 25 and September 4, 2002, FDA advised the OSMA members to present a device survivorship analysis of the metal-on-metal hip devices from the clinical studies described in the original petition as a means for providing this information. The OSMA member companies agreed to this recommendation.

The following provides a comprehensive report of the device survivorship from four clinical investigations of metal-on-metal total hip prostheses sponsored by three OSMA member companies. Two of the studies, of considerably longer duration, sponsored by Zimmer (formerly Centerpulse), were not part of the original reclassification petition and are now included. (These data were added to address the concerns by FDA and the panel about the lack of longer-term data.) The other two studies, from Biomet and DePuy, were part of the original petition. All of the metal-on-metal hip devices from these studies were subsequently cleared for commercial distribution by FDA.

Materials and Methods

Data from subjects enrolled in four FDA approved Investigational Device Exemption (IDE) clinical investigations approved between May 1995 and December 1999 were used to determine the device survivorship of metal-on-metal total hip replacement prostheses. A total of 44 clinical investigators participated in the IDE studies. Information regarding the status of the metal-on-metal hip prostheses was

developed by two means: 1) the sponsors of the IDE studies supplied OSMA with the most recent data compiled from the clinical evaluations of the study subjects, and 2) subjects who were unwilling or unable to return for follow-up evaluations were contacted by the participating IDE clinical investigators and asked to complete a questionnaire to determine the status of their hip replacement. Information from the investigational device treatment groups only, i.e., those with metal-on-metal hips, and not the control device treatment groups, were used for this report.

Pooling of the data was justified based on the similarities in the materials used to manufacture these devices and on the design specifications of metal-on-metal articulations. A total of 1335 hips were enrolled in four IDE clinical investigations. Of these, there were 678 metal-on-metal hips implanted in 632 subjects (46 bilateral cases) that were made available to OSMA for analysis. The date from the most recent evaluation/questionnaire was used to determine the time point for survivorship of the hip replacement and subjects were considered as having their hip replacement prostheses in place up to the point at which they were censored. For this analysis, failure is defined as the removal of one or more of the device components for any reason. Device survivorship results were calculated and presented according to the Kaplan Meier method¹. Discrete intervals are not used in this method; survival and confidence intervals are recalculated each time a failure is observed. A survival estimate is calculated up to the time when there are 20 evaluable hips remaining that have not yet failed or been lost to follow-up, in accordance with the recommendation of Dorey and Amstutz².

Results

Excellent survival results are associated with metal-on-metal total hips. The survival curves reported here characterize survival in 678 metal-on-metal total hips implanted between September 1995 and August 2000. Company A contributed 97 cases, Company B 273, and Company C 308. Mean age at surgery was 57 years (± 13 , range 18 to 90). All were implanted in four randomized IDE studies. Mean weight was 189 lbs (± 43 , range 95 to 396); mean height was 68 inches (± 4 , range 52 to 82). Gender distribution was 276 female (41%), 402 male (59%). A primary diagnosis of osteoarthritis was recorded in 506 hips (75%). Mean follow-up was 4.1 years (± 2 , range 0 to 8). There were 26 deaths reported, none attributed to the implant.

There were ten failures where failure was defined as the surgical removal of one or more components for any reason. The average time to failure was 2.8 years (± 2.06 , range 0 to 6.2). One of the failures included was actually the result of an intra-operative error. This hip was revised immediately postoperative, just after the patient had been brought to the recovery room. It was found that an incorrect head had been installed. The reason for failure in the remaining nine implants was trauma in 3, impingement in 1, dislocation in 3, and 2 were revised for aseptic Acetabular loosening.

The failures that were definitely attributed to trauma by the investigator included (1) a fall, (2) a hip that loosened when the patient used the operative hip to move a washing machine and (3) trauma that resulted in chronic dislocation. The revision due to impingement probably reflects an error in implant positioning. The three failures associated with dislocation most likely reflect technical issues associated with soft tissue

balancing or implant positioning. Finally, there were two implants revised for acetabular loosening. In one of these two instances, the investigator suspected the cause to be a fall suffered some months previously, while roller-blading, and felt that the failure might have been avoided if screws had been used. The remaining patient revised for acetabular loosening had extensive joint disease. This patient received a second THA on the contralateral hip, and a total shoulder arthroplasty, prior to loosening of the study acetabulum.

This multi-center, multi-manufacturer group of metal-on-metal THA patients had 10 failures in 678 hips (1.5%). Excluding the intra-operative error where an incorrect head was installed, the failure rate was 1.3%. All of the failures reported fall into expected failure categories, and there was no instance where a failure was attributed by the investigator to the metal-on-metal articulation: it may be noteworthy that there was not a single deep infection reported. Accordingly, these results provide evidence that MOM articulation failure modes are equivalent in type and proportion to failures observed in metal-on-poly, ceramic-on-poly, and ceramic-on-ceramic articulation THA.

Figure 1 shows the survival curve for all metal-on-metal implants, pooled across studies. Here, the Kaplan-Meier survival estimate is 98.1% at 5 years postoperative and 97.0% at 7.3 years. Figure 2 shows the survival curve when data collected by a survey is included. The survey data came from Company A, and was conducted by mail. It did not include a physical examination of the patient. Where survey data are included, the Kaplan-Meier survival estimate is 98.2% at 5 years postoperative and 97.4% at 7.6 years. After 7.6 years, there were 19 hips with follow-up information ranging from 7.7 to a maximum of 8.5 years, with no reports of failure in any of these hips. Figure 3 shows survival for metal-on-metal hips broken down by manufacturer. The Kaplan-Meier survival estimate for Company A is 100% at 5.0 years postoperative. For Company B, the survival estimate is 99.4% at 5.0 and 7.0 years postoperative; and for Company C, the survival estimate is 96.6% at 5.0 and 7.1 years postoperative.

These results provide evidence that metal-on-metal articulation provides durable and equivalent survival results, regardless of manufacturer.

Discussion

The National Institute for Clinical Excellence (NICE, UK) "...considers it reasonable to recommend consideration of prostheses with a minimum of 3 years revision rate experience [from multi-center randomized trials] if their performance is consistent with the benchmark of a 10% revision rate at 10 years."³ This standard has been exceeded in the results presented here with respect to length of follow-up by a factor of 2.5. A 7.6-year survival estimate of 97.4% is entirely consistent with a ten-year revision rate that is substantially less than 10%. Moreover, the survival estimates achieved individually by different manufacturers, with different metal-on-metal implants, are consistent with a ten-year revision rate of less than 10% in each instance.

Accordingly, concerns regarding the survival rate of present generation metal-on-metal stemmed hip prostheses have been addressed adequately by these results. A decision to down-classify metal-on-metal hips from Class III to Class II is warranted.

Figure 1

Kaplan-Meier Survival Estimates (95% C.I.)
Data Pooled Across Manufacturers

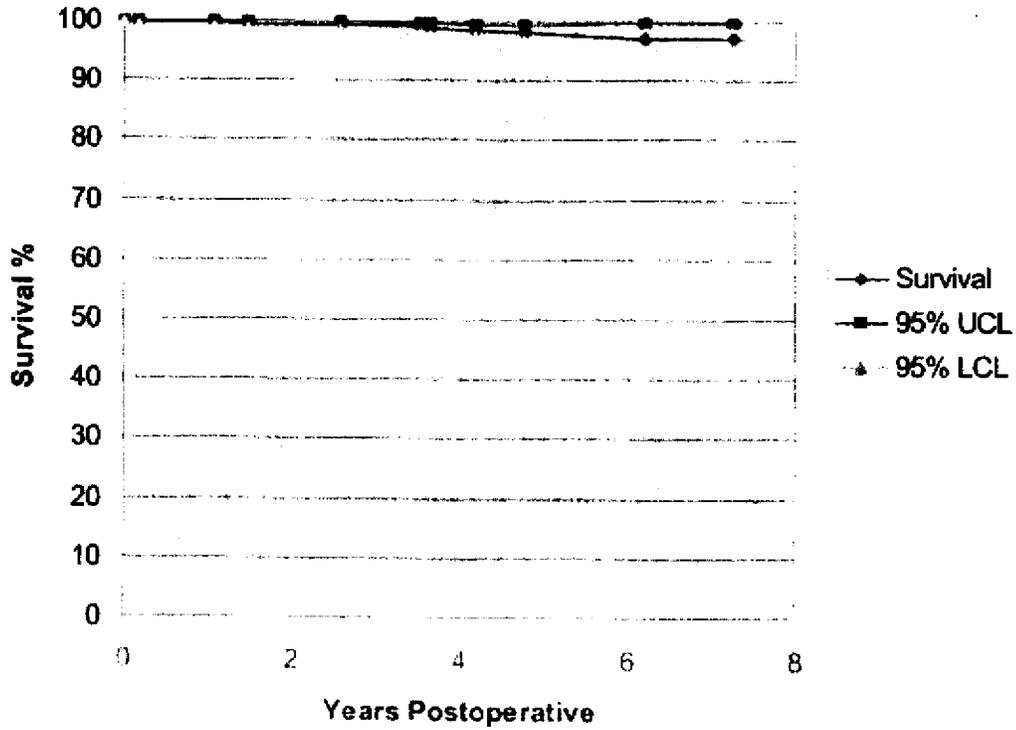


Figure 2

Kaplan-Meier Survival Estimates (95% C.I.)
Data Pooled Across Manufacturers
Non-Clinical Survey Data Included

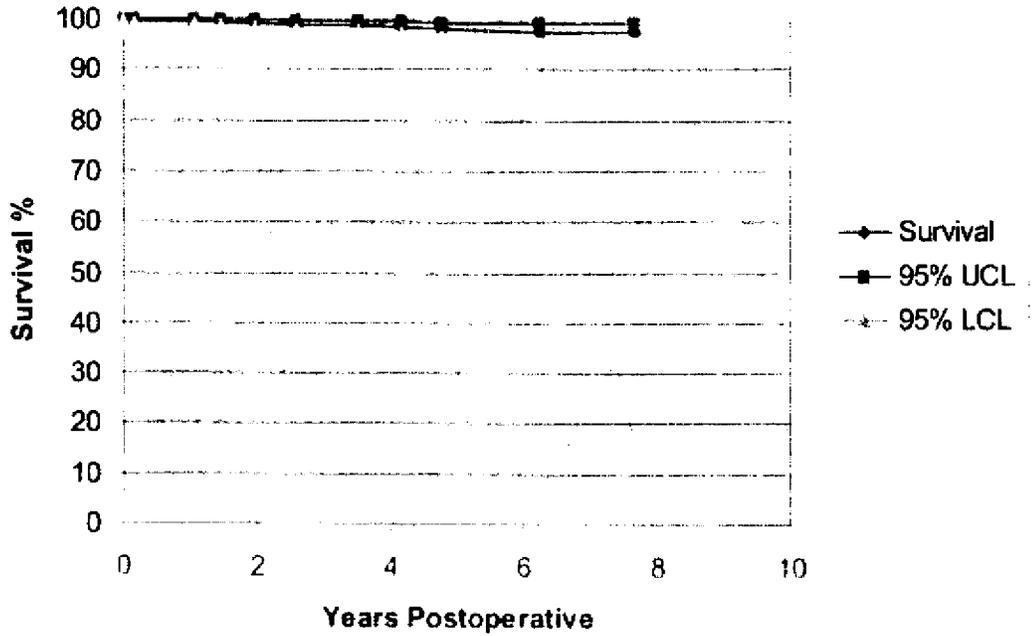
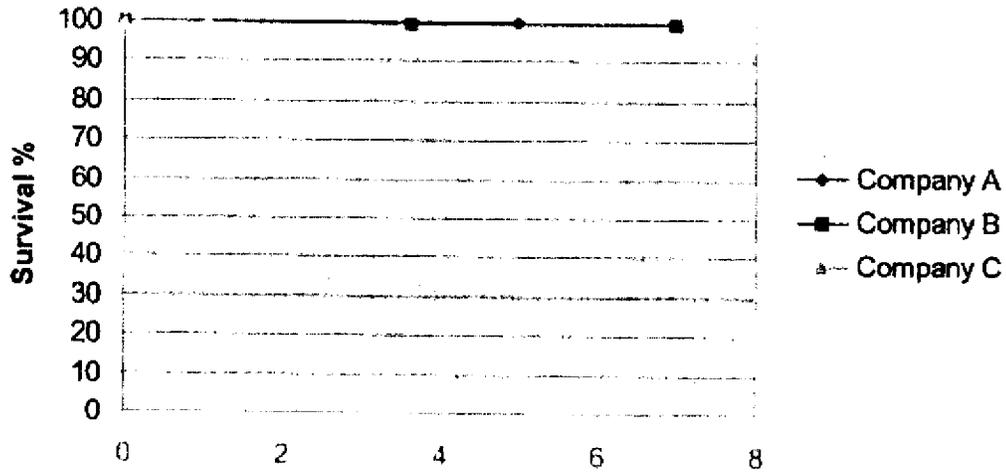


Figure 3

Kaplan-Meier Survival Estimates
Survey Data not Included



Years Postoperative
Differences Between Manufacturers
Not Statistically Significant
(Log-Rank Test, p=0.106)

¹Kaplan EL, Meier, P: Nonparametric estimation from incomplete observations. J AM Stat Assoc 53:457, 1958.

²Dorey, F, Amstutz, HC: Survivorship Analysis in the evaluation of joint replacement. The Journal of Arthroplasty Vol. 1 No. 1 pp 63-69, March 1986.

³Guidance on The Selection of Prostheses for Primary Total Hip Replacement. National Institute for Clinical Excellence (UK), April 2000.
www.nice.org.uk/pdf/Guidance_on_the_selection_of_hip_prostheses.pdf

B. Published Clinical Studies

The following is a summation of several significant articles found in published literature using a search of various medical databases.

Albrecht-Olsen P, Owen-Falkenberg T, Burgaard P, Andersen PB. Nine-year follow-up of the cementless ring hip. *Acta Orthop Scand* 1989 Feb;60(1):77-80.

Reviewed 238 Ring prostheses implanted during the period 1968-1979. Of those cases, 127 with a median follow-up of 9 years were available for evaluation with 90% of those patients demonstrating excellent/good results upon self assessment. Using the Chamley scale, 87% had a pain score of 4 or greater (score of 6 = no pain), 76% had a motion score of 4 or greater, and 57% had a walking score of 4 or greater. The author cites an infection rate of 2.5% (6 deep infections, 16 superficial infections). Four dislocations were also encountered. At the time of this evaluation, 17% (n=40) of the patients had been revised, mainly due to pain. Overall results predicted an 81% survival rate at 12 years, comparable to outcomes seen with metal-on-polyethylene articulation

Almby B, Hierton T. Total hip replacement: a ten-year follow-up of an early series. *Acta Orthop Scand* 1982 Jun;53(3):397-406.

Reported on 93 patients receiving the Muller device, 57% of which had been followed for more than 10 years. Using the Chamley scale (6 possible points in each category), 90% had pain rating of 4 or better or a range of motion greater than 100°. Nine deep infections were reported. Thirty patients died (26 unrelated to device, 1 embolus, 1 ileus, 1 renal failure, 1 septic). Twenty-nine patients were revised (19 aseptically loose, 7 septic loose, 4 stem fractures, 1 fracture). Twenty-three acetabular and 16 femoral components showed signs of loosening. Femoral loosening was secondary to calcar resorption and cement settling in most cases. Survivorship in this series was calculated to be approximately 80% at 5 years and 57% at 10 years.

Andrew TA, Berridge D, Thomas A, Duke RN. Long-term review of ring total hip Arthroplasty. *Clin Orthop* 1985 Dec;(201):111-22.

Presented his results of 116 Ring patients followed for 8 years. Using the Harris scoring system (100 points possible), 33% of the patients had 80 points or greater with another 13% exhibiting total scores of 70-80. Using the Ring evaluation, 49% of the patients rated excellent or good. Two deep infections and 4 dislocations were encountered. Other complications included grade IV heterotopic ossification (5), fracture (4), embolic event (7), and sciatic palsy (1).

August AC, Aldam CH, Pynsent PB. The McKee-Farrar hip arthroplasty. A long-term study. *J Bone Joint Surg Br* 1986 Aug;68(4):520-7.

Results of 175 patients with the McKee-Farrar device at an average 13.9 years of follow-up are presented by August⁴. Using the Harris evaluation, the average total score was 76.4,

with 48.9% having excellent/good outcomes. On self assessment, 90% of the patients rated themselves as having a satisfactory outcome. Sixty-four patients were revised, mainly for loosening, stem fracture and bone fracture. Over 50% of the stems and cups showed signs of loosening radiographically. Additionally, the cup showed signs of protrusion in 62.5% of rheumatoid patients. Heterotopic ossification (grade IV) was reported in 2.7% of the cases. August calculated survival at 84.3% at 14 years and 27.5% at 20 years.

Djerf K, Wahlstrom O. Total hip replacement comparison between the McKee-Farrar and Charnley prostheses in a 5-year follow-up study. Arch Orthop Trauma Surg 1986;105(3):158-62.

Presents results on 107 McKee-Farrar and 70 Charnley devices with 5 years followup. Analysis revealed 94% of patients to have no pain and 78% to have improved flexion. Unrelated death occurred in 12% of the patients. Six infections (3.4%) and 4 dislocations (2.3%) were reported. Other complications included trochanteric problems (2.8%), nerve injury (1.7%), deep venous thrombosis (1.7%), pulmonary embolus (0.6%), fracture (0.6%), and ossification (0.6%). Loosening was evident in 32% of the cases. Analyses showed no significant difference in the outcomes of either implant.

Jacobsson SA, Djerf K, Wahlstrom O. Twenty-year results of McKee-Farrar versus Charnley prosthesis. Clin Orthop Relat Res 1996 Aug;(329 Suppl):S60-8.

A comparison was performed by Jacobsson on a series of McKee-Farrar metal-on-metal patients and a series of Charnley metal-on-polyethylene patients. No major differences were observed between the two groups with regard to radiographs, Harris Hip Scores or walking ability. At 12 years, average Harris hip scores for the McKee-Farrar and Charnley were 82 and 83, respectively. At 20 years, average Harris hip scores were 75 and 77. Sixteen McKee-Farrar and eight Charnley devices were removed. No debris was noted in the McKee-Farrar retrievals. The infection rate is 2.8% for McKee-Farrar and 4.3% for the Charnley. The dislocation rate is 2.8% for the McKee-Farrar and 1.4% for the Charnley. Loosening of the McKee-Farrar was noted in 5 cups and 6 stems; 4 cups and 4 stems were loose in patients receiving the Charnley device. Extensive scalloping was observed in 5/11 Charnley devices. Nerve damage (1.9%) and femoral fracture (0.9%) were also reported with the McKee-Farrar device. Trochanteric pain (7.1%), deep venous thrombosis (4.3%), nerve damage (1.5%), pulmonary embolus (1.4%) and ectopic bone (1.4%) were experienced in the Charnley patients. This study determined that there was no statistically significant difference in survivorship at more than 11 years: 82% for the McKee-Farrar patients compared to 89% for the Charnley patients.

Jantsch S, Schwagerl W, Zenz P, Semlitsch M, Fertschak W. Long-term results after implantation of the McKee-Farrar total hip prostheses. Arch Orthop Trauma Surg 1991;110(5):230-7.

Analyzed followup at 14 years in a series of 248 patients with 330 McKee-Farrar devices. Only 56% of the patients were followed clinically to this period (24% died, 17% untraceable, 3% refused participation). Using the Mayo rating system, 48% of the patients

were found to have excellent/good ratings (62% if revisions are excluded). Based on radiographs available, 34% of the cups and 26% of the stems were unstable. There were 36 retrievals (22 cup and stem, 7 cup, 7 stem).

McKee GK, Chen SC. The statistics of the McKee-Farrar method of total hip replacement. Clin Orthop Relat Res 1973 Sep;95:26-33.

Reports on four series of patients treated with the various iterations of the McKee-Farrar device from 1956-1971. As shown in the attached tables, postoperative outcome improved through each design iteration, with approximately 89% achieving excellent or good outcomes in the 1965-69 series (4-7 year followup) and 97% achieving excellent or good outcomes in the 1971 series (2 year or less followup). Retrievals have occurred in 4% of the 1965-69 series and 0% of the 1971 series. Fifteen (15) deaths were reported in the 1965-69 series; two were reported in the 1971 series. The reported rate of infection was 4% in the 1965 series and 0% in the 1971 series. Two dislocations (2%) were also reported in each of these series. Other complications include pulmonary embolus, deep venous thrombosis, shaft perforation, hematoma and heterotopic ossification.

Ring PA. Five to fourteen year interim results of uncemented total hip arthroplasty. Clin Orthop Relat Res 1978 Nov-Dec;(137):87-95.

Presents results on 106 metal-metal Ring prostheses with 7-17 years followup. Postoperatively, 83% were assessed as excellent/good clinically. Outcomes of the various design iterations is again presented in this article. Thirteen retrievals have occurred (7 femoral failures, 2 pelvic failures, 3 combination failures, 1 ankylosis). Survivorship of patients implanted from 1968-73 was 81% at 18 years; survivorship was 95% at 16 years for those implanted from 1972-79.

Schmalzried TP, Szuszczewicz ES, Akizuki KH, Petersen TD, Amstutz HC. Factors correlating with long term survival of McKee-Farrar total hip prostheses. Clin Orthop Relat Res 1996 Aug;(329 Suppl):S48-59.

Thirteen McKee-Farrar patients (15 devices) with an average follow-up of 23.7 years are presented. The average Harris hip score of these patients was 86 with 11 patients having an excellent/good rating. These patients outscored a matched metal-on-poly control population on the SF36 Health Status questionnaire. Activity levels were also reported to exceed the averages for this age population. The only complication reported is that of lysis in three femurs and one acetabulum.

Zaoussis AL, Patikas AF. Experience with total hip Arthroplasty in Greece, the first 20 years. A particular reference to long-term results with the McKee-Farrar technique. Clin Orthop Relat Res 1989 Sep;(246):39-47.

Presents results on 38 McKee Farrar patients followed for 12-20 years, with 26 having greater than 15 years followup. At the time of this evaluation, 45% were found to have

very good outcomes. Fifty-three percent (53%) of the patients were pain free and 79% had 60-90° range of motion. Three infected components and four loose components were retrieved. There have been five dislocations (all in one patient). Nine components show looseness. Other complications include five peroneal nerve palsies, one cortical perforation and one ossification.

Lombardi AV Jr, Mallory TH, Ranaway CS, Williams J, Wixson R, Hartman JF, Capps SG, Kefauver CA. Short-term results of the M² a-taper metal-on-metal articulation. *J Arthroplasty* 2001 Dec;16(8 Suppl 1):122-8.

A polyethylene-free metal-on-metal acetabular system was designed in an effort to improve total hip arthroplasty (THA) longevity. Minimum 2- year follow-up results involving 72 polyethylene (PE) liner THAs and 78 metal liner THAs from a multicenter, randomized, controlled, investigational device exemption study was reported. Mean Harris hip scores of 95.54 (PE liner group) and 95.23 (metal liner group) were reported at mean follow-up intervals of 3.29 and 3.23 years. Radiographic evaluation revealed no evidence of early failure. No acetabular components were revised or were pending revision. No statistically significant differences in the data were calculated between liner types except for the immediate postoperative (P=.0415) and minimum 2-year follow-up (P=.0341) angles of inclination. The M² a-taper metal-on-metal articulation may represent a viable alternative for THA in younger, higher demand patients.

Dorr LD, Wan Z, Longjohn DB, Dubois B, Murken R. Total hip arthroplasty with use of the Metasul metal-on-metal articulation. *J Bone Joint Surg Am* 2000 Jun;82(6):789-98.

Between 1991 and 1994, seventy patients had a total hip replacement with the Metasul metal-on-metal articulation and a cemented Weber cup. Fifty six patients had complete clinical and radiographic data four to 6.8 years after the operation. There was one mechanical failure (2 percent). Thirty six of 47 patients who completed the patient self assessment form rated their result as excellent; seven, as very good; two, as good; one, as fair; and one, as poor. Wear could not be measured on radiographs because of the metal-on-metal articulation. No hip had radiographic evidence of acetabular osteolysis and two hips had calcar resorption, but there was no other evidence of focal osteolysis. From their four to seven year experience with the device the authors feel that the clinical results are similar to those of total hip replacements with a metal-on-polyethylene articulation. They believe the device may have a role in reducing the wear that occurs with total hip replacement and that the device appears particularly indicated for younger patients.

MacDonald SJ, McCalden RW, Chess DG, Bourne RB, Rorabeck CH, Cleland D, Leung F. Metal-on-metal versus polyethylene in hip arthroplasty: a randomized clinical trial. *Clin Orthop Relat Res* 2003 Jan;(406):282-96.

A prospective, randomized blinded clinical trial was done to evaluate polyethylene versus metal bearing surfaces in total hip replacement. Forty one patients were randomized to receive either a metal (23 patients) or a polyethylene (18 patients) insert. The femoral and acetabular components were identical with the acetabular insert the only variable.

Patients were assessed preoperatively and postoperatively using radiographs, multiple outcome measures (Western Ontario MacMaster University Score, Harris hip score, Short Form-12), erythrocyte metal ion analysis (cobalt, chromium, titanium). Patients were followed up for a minimum of two years (mean 3.2 years; range, 2.2-3.9 years). There were no differences in radiographic outcomes or outcome measurement tools between patients. Patients receiving a metal-on-metal articulation had significantly elevated erythrocyte and urine metal ions compared to patients receiving a polyethylene insert. Patients who had metal-on-metal inserts had on average a 7.9 fold increase in erythrocyte cobalt, a 2.3 fold increase in erythrocyte chromium, a 1.7 fold increase in erythrocyte titanium, a 35.1 fold increase in urine cobalt, a 17.4 fold increase in urine chromium, and a 2.6 fold increase in urine titanium at 2 years follow-up. Patients receiving a polyethylene insert had no change in erythrocyte titanium, urine cobalt or urine chromium and a 1.5 fold increase in erythrocyte cobalt, a 2.2 fold increase in erythrocyte chromium, and a 4.2 fold increase in urine titanium. Forty-one percent of patients receiving metal-on-metal articulations had increasing metal ion levels at the latest follow-up. The clinical significance of this remains unknown. Only through thorough long-term clinical analysis will appropriate conclusions be valid. Metal-on-metal total hip replacements perform well clinically; however, only with time will the risk to benefit ratio become clear.

Lhotka C, Szekeres T, Steffan I, Zhuber K, Zweymuller K. Four-year study of cobalt and chromium blood levels in patients managed with two different metal-on-metal total hip replacements. *J Orthop Res* 2003 Mar;21(2):189-95.

In 259 patients with total hip replacement, blood cobalt and chromium concentrations were measured with atomic absorption spectrophotometry over a period of four years after arthroplasty. Of the patients enrolled in the study, 131 had been managed with a METASUL cobalt-chromium alloy metal-on-metal bearing combination, while 128 had been given a SIKO-MET-SM21 cobalt-chromium alloy metal-on-metal combination. The control group consisted of 31 age- and gender-matched subjects. Compared with the controls, all of the patients had higher cobalt and chromium levels. Cobalt concentrations were up to 50 times higher, while chromium concentrations were up to 100 times higher. Both systems showed evidence, in the whole-blood samples, of wear debris production by the implants. Therefore, patients managed with metal-on-metal bearing combinations should be carefully monitored in order to ensure that any local or systemic complications are detected early on. According to the authors, the cause and effect relationship between metal wear debris and local or systemic disease has not been conclusively proved, although complications from metal wear products are a subject of concern. Any metal-on-metal bearing combination used in joint replacements must, therefore, be designed and manufactured in such a way as to produce minimal debris.

Lombardi AV Jr, Mallory TH, Cuckler JM, Williams J, Berend KR, Smith TM. Mid-term results of a polyethylene-free metal-on-metal articulation. *J Arthroplasty* 2004 Oct;19(7 Suppl 2):42-7.

One hundred ninety-three patients (195 hips) were enrolled into this prospective, randomized, controlled multi-center investigational device exemption study. Ninety eight patients (99 hips) with 46 polyethylene liners and 53 metal liners had minimum 5-year followup (mean 5.7 years). Average followup, Harris hip score improvement, and radiographic analysis were not statistically different between groups. No stress shielding or osteolysis was observed in either group. Three polyethylene liners and no metal liners had acetabular radiolucencies >1 mm in 1 or more zones. There were no device related complications, no acetabular revisions performed, and none pending in either group. Based on these mid-term results, the authors conclude that a metal-on-metal articulation represents a viable alternative in young, high-demand, active patients. The device used was a M² a Taper Metal-on-Metal Articulation (Biomet Orthopaedics, Warsaw, IN).

Jacobs M, Gorab R, Mattingly D, Trick L, Southworth C. Three- to six-year results with the Ultima metal-on-metal hip articulation for primary total hip arthroplasty. *J Arthroplasty* 2004 Oct;19(7 Suppl 2):48-53.

One hundred seventy-one primary total hip arthroplasties were evaluated in a prospective, randomized study. Ninety-five involved a metal-backed cup with an all-metal liner and 76 involved a metal backed polyethylene cup that was used as the control. All were implanted with an S-ROM cementless femoral component with a 28-mm head. The mean followup period was 3.7 years (range 3.0-5.7). The average postoperative Harris hip score was 95.4 (range 65-100) for the metal-on-metal group and 96.1 (range 65-100) for the metal- on- polyethylene group. Radiographic results were not statistically different between the two groups. Early results show metal-on-metal articulation has been successful to date and justify continued clinical use.

Long WT, Dorr LD, Gendelman V. An American experience with metal-on-metal total hip arthroplasties—a seven year follow-up study. *J Arthroplasty* 2004 Dec;19(8 Suppl 3):29-34.

This study reviews the clinical performance of 161 hip arthroplasties (154 patients) with the Metasul metal-on-metal articulation and an uncemented modular acetabular component. Between 1995 and 2002 clinical evaluation and radiographic follow-up of patients included Harris hip scores, patient self-assessment, and radiographs. Twelve operative site complications (7.5%) included 6 revision operations (3.7%) and 3 other complications (1.9 %) not needing reoperation. Six revision operations (3.7%) included 1 femoral revision for aseptic loosening (0.06%) and 5 acetabular revisions (3.1%). One cup revision was for recurrent dislocation, 1 for disassociation of the acetabular insert from the cup, 1 for infection, and 2 for unexplained pain. Histologic evidence did not support the diagnosis of metal hypersensitivity in either case of unexplained pain, and 1 had relief following spine surgery. A focal radiolucency, identified as calcar resorption, was observed in 9 patients. Metal ion levels were not tested in patients as part of these studies. The authors note that after 40 years of use, there is no evidence that metal-on metal articulations have been a cause of cancer. The strength of this study is that it confirms that the high incidence of early aseptic loosening has been improved with this modern metal-on-metal articular system.

Delaunay CP. Metal-on-metal bearings in cementless primary total hip arthroplasty. *J Arthroplasty* 2004 Dec;19(8 Suppl 3):35-40.

One hundred cementless titanium primary total hip arthroplasties with 28 mm Metasul bearings were prospectively studied (osteoarthritis in 76% of hips, mean age 59.6 years). Ninety-eight were reviewed after a 6-year average follow-up (range, 17-126 months) with clinical results graded excellent and good in 97%. One femoral component was revised for aseptic loosening at 7.8 years. Postoperative cobalt level was higher than the upper "normal" value (5µg/L in whole blood) for 16 cases. No significant relationship could be established between cobalt concentration increase and any demographic or surgical data, including activity level, except anteversion of the cup >25°. In this early experience, impingement due to a head sleeve has been the main cause of dislocation and failure, and systemic cobalt survey appeared to be a good indicator of metal-on-metal bearing mechanical behavior. According to the author, the absence of detectable wear and, above all, the lack of relationships among increased cobalt level, age and high patient activity are encouraging findings for continued use of metal-on-metal bearings in young and/or active patients.

Migaud H, Jobin A, Chantelot C, Giraud F, Laffargue P, Duquennoy A. Cementless metal-on-metal hip arthroplasty in patients less than 50 years of age: comparison with a matched control group using ceramic-on-polyethylene after a minimum 5-year follow-up. *J Arthroplasty* 2004 Dec;19(8 Suppl 3):23-8.

Thirty nine cementless hip arthroplasties using metal-on-metal articulation (Metasul) were consecutively implanted in 30 patients less than 50 years of age and compared to a matched control group (by age, diagnosis, Devane activity, and Harris hip scores) of cementless arthroplasties using ceramic-on polyethylene articulation. The Harris hip score at follow-up (minimum 5 years) for the metal-on-metal was 94.9 (range 74-100). After the same follow-up, the results with the ceramic-on-polyethylene were significantly worse; 9 osteolyses and 7 surgical revisions related to wear (none in the metal-on-metal). Five year survival rates were 97% ±2% for the ceramic-on-polyethylene and 100 % for the metal-on-metal. The metal-on-metal may be recommended to prevent wear problems in younger and more active patients; however, a longer follow-up is required to confirm this encouraging data.

Dorr LD, Long WT, Sirianni L, Campana M, Wan Z. The argument for the use of Metasul as an articulation surface in total hip replacement. *Clin Orthop Relat Res* 2004 Dec;(429):80-5.

Metasul metal-on-metal articulations have been used for 15 years in approximately 300,000 total hip replacements. The authors have used Metasul articulations in three clinical studies and have shown clinical success as measured by Harris Hip Scores and patient self-assessment. The authors have noted the usual mechanical complications. The only complications have been mechanical, including two-cup loosening and 24 dislocations in a total of 582 patients (619 hips; 3.8%) who had Metasul articulations and

were included in these studies. In the randomized study, the group who had Metasul articulations had no clinical results or complications different from the control ceramic-on-polyethylene group. Authors of retrieval results in the literature report low annual linear wear rates and no consequences of elevated Co ion levels. Currently, the scientific evidence of the results using the Metasul articulation would recommend its continued use in any patient who does not have compromised renal function.

The review of the published literature suggests that good long-term results comparable to current metal-on-polyethylene prostheses can be achieved with well-designed metal-on-metal devices. As outlined, the complications encountered with metal-on-metal devices are common to current total hip arthroplasty. This review further highlights the importance of preventive therapies and proper surgical technique in good clinical outcomes.

Published reports by Dorr, et al. (1996), (2000), (2004), Hilton, et al. (1996), Wagner and Wagner (1996) and Weber (1996) of the clinical experience with the Metasul® (Sulzer Orthopedics, Austin, TX) metal/metal semi-constrained hip designs lend further support to the conclusions drawn from the results reported here. Copies of these reference articles are provided in Appendix 3.

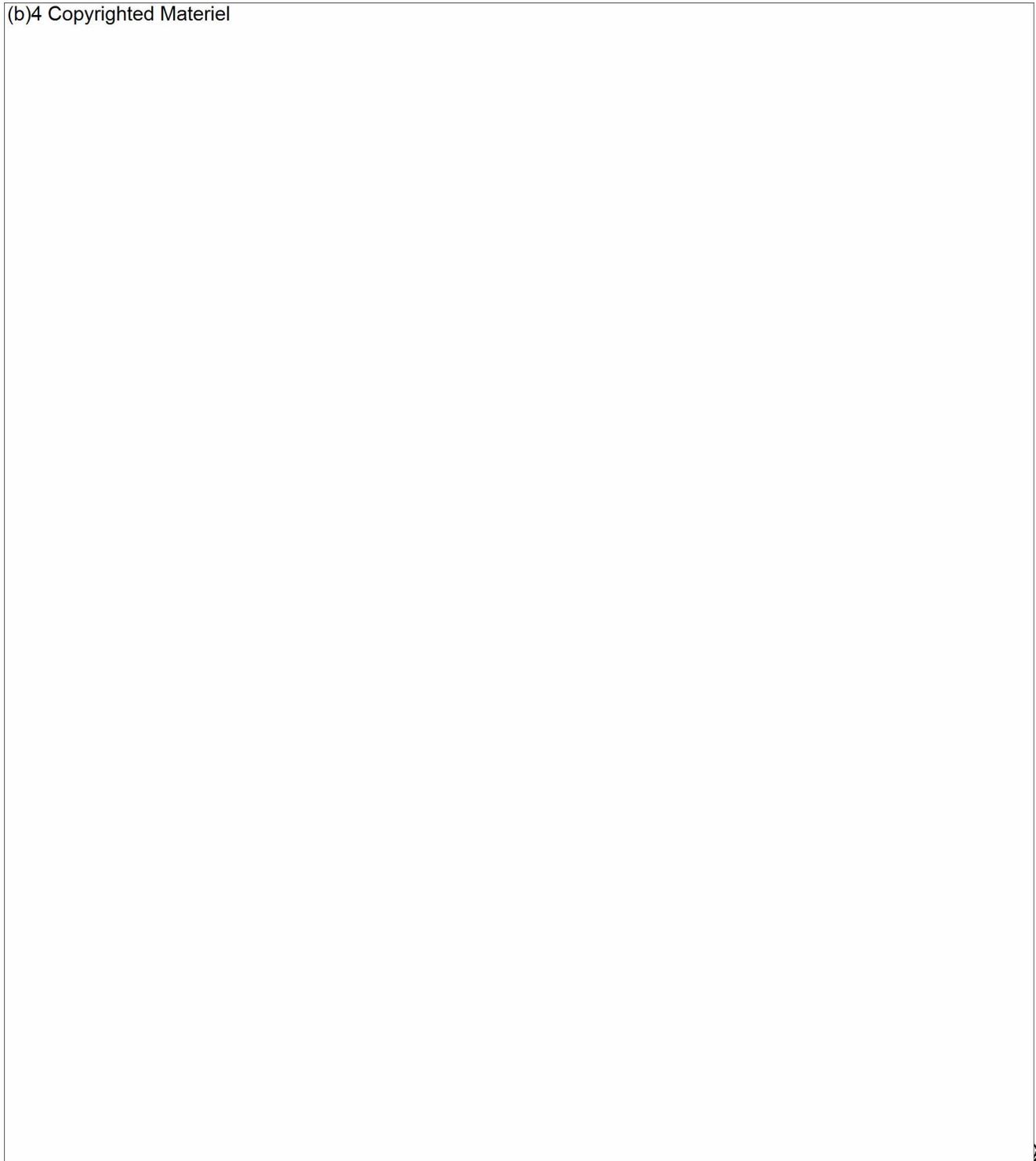
C. Published Biological Studies

Short and Long-Term Biological Effects Of Metal-On-Metal Total Hip Replacement

From Human Retrieval Studies and In Vitro Studies

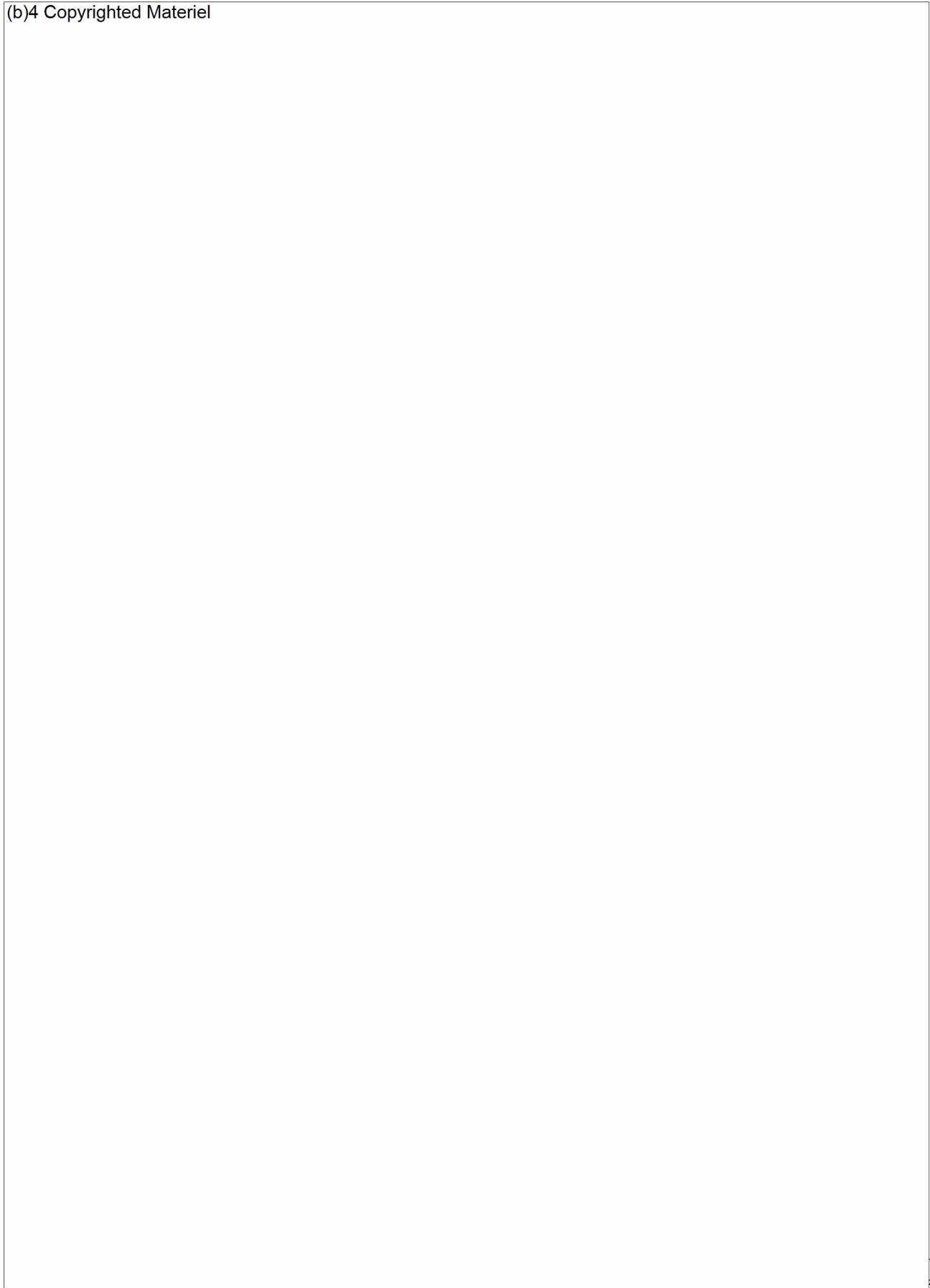
Information from studies of long-term hip replacements at revision or autopsy

(b)4 Copyrighted Material



26

(b)4 Copyrighted Material



37

(b)4 Copyrighted Material

(b)4 Copyrighted Material



(b)4 Copyrighted Material

(b)4 Copyrighted Material

(b)4 Copyrighted Material

(b)4 Copyrighted Material

(b)4 Copyrighted Materiel

344 0280

(b)4 Copyrighted Material

545

(b)4 Copyrighted Material

546 0282

(b)4 Copyrighted Material

(b)4 Copyrighted Material

(b)4 Copyrighted Material

349₀₂₈₅

(b)4 Copyrighted Material

550 0286

(b)4 Copyrighted Material

351 0287

(b)4 Copyrighted Material

52

(b)4 Copyrighted Material

53

(b)4 Copyrighted Material



54
0290

(b)4 Copyrighted Material

SECTION VIII.**MEDICAL DEVICE REPORTS AND ADVERSE EVENTS FROM THE LITERATURE****METAL/METAL SEMI-CONSTRAINED TOTAL HIP PROSTHESES**

Inclusive dates: January 1, 1992 to March 31, 2005.

A reasonable effort was made to find all adverse reports made for these devices under the Medical Device Reporting (MDR) regulations. A search of the publicly available information yielded fifty nine reports filed for metal/metal semi-constrained total hip prostheses. However, it is possible that a small number of additional reports could have been made using improper product codes, erroneous device descriptions, etc. In addition, the FDA may have access to additional reports made after March 31, 2005.

A review of the published literature was performed to provide a summary of the device related adverse events reported for metal/metal hip prostheses.

A. MDR Reports

A summary of the fifty four MDR reports obtained for a metal/metal hip prosthesis is provided below. There were no vigilance reports obtained from searches conducted of the databases available for the member states comprising the European Economic Community (EEC).

Manufacturer: Sulzer Orthopaedics, Inc.
9900 Spectrum
Austin, TX 78717

Device Description: Acetabular Insert 28x55 Metasul APR
MDR Report Key: 29355620-2000-00012
Product Code: KWA
Report Date: 4/24/2000
Catalog No.: 4340-28-055
Device Lot No.: 1251199
Event Description: Allegedly the anti-rotation pin became dislodged from the polyethylene acetabular insert.
Patient Outcome: Hospitalization.

Device Description: Acetabular Insert 28x49 Metasul APR
MDR Report Key: 2935620-2000-00062
Product Code: KWA
Report Date: 11/6/2000
Catalog No.: 4340-28-049

Device Lot No.: 1303668
Event Description: Pin in Metasul insert came out after 1.5 years
Patient Outcome: Hospitalization

Device Description: Acetabular Insert 28x49 Metasul APR
MDR Report Key: 2935620-2000-0075
Product Code: KWA
Report Date: 12/8/2000
Catalog No.: 4340-28-049
Device Lot No.: 1297149
Event Description: Patient underwent Total Hip Arthroplasty (THA) on 2/4/98.
Revised three times due to dislocations. Underwent last
THA on 11/7/00—insert and ball head replaced.
Patient Outcome: Unknown

Device Description: Acetabular Insert 28x49 Metasul APR
MDR Report Key: 2935620-2001-0003
Product Code: KWA
Report Date: 1/23/2001
Catalog No.: 4340-28-049
Device Lot No.: 1230114
Event Description: It was reported on 11/13/00 that there was a sudden clunk in
hip and patient could not walk. X-ray in ER showed
disassociation of Metasul insert from APR II shell. Patient
experienced 2 heavy falls, one on her back in March 2000
and one fall forward.
Patient outcome: Unknown

Device Description: Acetabular Insert 28x49 Metasul APR
MDR Report Key: 2935620-2001-01058
Product Code: KWA
Report Date: 5/10/2001
Catalog No.: 4340-28-049
Device Lot No.: 1427124
Event Description: When Dr. impacted insert into shell it did not seat. When
insert pulled out for inspection the locking pin missing.
Resulted in 30 minute delay in surgery.
Patient Outcome: Unknown

Device Description: Acetabular Insert 28x49 Metasul APR
MDR Report Key: 2935620-2001-01162
Product Code: KWA
Report Date: 6/18/2001
Catalog No.: 4340-28-049
Device Lot No.: 1299668

Event Description: Metasul insert dislocation after 4 years, significant metallosis
and severe pain
Patient Outcome: Revision surgery

Device Description: Acetabular Insert 28x49 Metasul APR
MDR Report Key: 2935620-2001-01193
Product Code: KWA
Report Date: 5/23/2001
Catalog No.: 4340-28-049
Device Lot No.: 1303666
Event Description: Revision surgery
Patient Outcome: Unknown

Device Description: Acetabular Insert 28x49 Metasul APR
MDR Report Key: 2935620-2001-01806
Product Code: KWA
Report Date: 12/12/2001
Catalog No.: 4340-28-049
Device Lot No.: 1302992
Event Description: Anti-rotation pin dislocated from insert
Patient Outcome: Unknown

Device Description: Acetabular Insert 28x49 Metasul APR
MDR Report Key: 2935620-2002-00048
Product Code: KWA
Report Date: 2/11/2002
Catalog No.: 4340-28-049
Device Lot No.: 1181945
Event Description: Plaintiff alleged the Metasul insert loosened from APR II
shell
Patient Outcome: Unknown

Device Description: Acetabular Insert 28x49 Metasul APR
MDR Report Key: 2935620-2002-00141
Product Code: KWA
Report Date: 4/15/2002
Catalog No.: 4340-28-049
Device Lot No.: 1322215
Event Description: Disassociation of insert 2 yrs 9 mo after initial surgery
Patient Outcome: Unknown

Device Description: Acetabular Insert 28x49 Metasul APR
MDR Report Key: 2935620-2003-00135
Product Code: KWA
Report Date: 6/10/2003
Catalog No.: 4340-28-049

Device Lot No.: 1230114
Event Description: Patient felt pain due to dislocation.
Patient Outcome: Revision surgery 6/5/03

Device Description: Acetabular Insert 28x49 Metasul APR
MDR Report Key: 2935620-2003-00142
Product Code: KWA
Report Date: 6/25/2003
Catalog No.: 4340-28-049
Device Lot No.: 1322216
Event Description: Dislocation
Patient Outcome: Revision surgery

Device Description: Acetabular Insert 28x49 Metasul APR
MDR Report Key: 2935620-2003-00279
Product Code: KWA
Report Date: 11/26/2003
Catalog No.: 4340-28-049
Device Lot No.: 1230114
Event Description: Dislocation of Metasul insert
Patient Outcome: Revision surgery

Device Description: Acetabular Insert 28x49 Metasul APR
MDR Report Key: 2935620-2004-00005
Product Code: KWA
Report Date: 1/13/2004
Catalog No.: 4340-28-049
Device Lot No.: 1299671
Event Description: Dislocation of Metasul insert
Patient Outcome: Unknown

Device Description: Acetabular Insert 28x51 Metasul APR
MDR Report Key: 2935620-2001-01841
Product Code: KWA
Report Date: 12/5/2001
Catalog No.: 4340-29-051
Device Lot No.: 1245308
Event Description: Dr reported patient with pain. Disassociation of liner from shell
Patient Outcome: Unknown

Device Description: Acetabular Insert 28x51 Metasul APR
MDR Report Key: 2935620-2002-00069
Product Code: KWA
Report Date: 2/20/2002
Catalog No.: 4340-29-051

Device Lot No.: 1181946
Event Description: Advised on an APR Metasul acetabular liner disassociation.
Patient Outcome: Revision surgery 2/26/02

Device Description: Acetabular Insert 28x51 Metasul APR
MDR Report Key: 2935620-2002-00106
Product Code: KWA
Report Date: 3/15/2002
Catalog No.: 4340-29-051
Device Lot No.: 1245308
Event Description: Implant breakage. Patient reported pain.
Patient Outcome: Revision surgery

Device Description: Acetabular Insert 28x51 Metasul APR
MDR Report Key: 2935620-2003-00143
Product Code: KWA
Report Date: 6/19/2003
Catalog No.: 4340-29-051
Device Lot No.: 1303680
Event Description: Dislocation of APR Metasul insert.
Patient Outcome: Unknown

Device Description: Acetabular Insert 28x53 Metasul APR
MDR Report Key: 2935620-1999-00011
Product Code: KWA
Report Date: 3/5/1999
Catalog No.: 4340-29-053
Device Lot No.: 1272471
Event Description: Anteverted cup and posterior impingement
Patient Outcome: Unknown

Device Description: Acetabular Insert 28x53 Metasul APR
MDR Report Key: 2935620-2000-00030
Product Code: KWA
Report Date: 7/21/2000
Catalog No.: 4340-29-053
Device Lot No.: 1187760
Event Description: Impingement between femoral stem and acetabular insert.
Patient Outcome: Revision surgery

Device Description: Acetabular Insert 28x53 Metasul APR
MDR Report Key: 2935620-2001-1531
Product Code: KWA
Report Date: 8/23/2001
Catalog No.: 4340-29-053
Device Lot No.: 1348667-B

Event Description: APR insert disengaged 9 mo post surgery
Patient Outcome: Unknown

Device Description: Acetabular Insert 28x53 Metasul APR
MDR Report Key: 2935620-2001-01765
Product Code: KWA
Report Date: 11/6/2001
Catalog No.: 4340-29-053
Device Lot No.: 1245313
Event Description: Disassociation of liner from cup
Patient outcome: Unknown

Device Description: Acetabular Insert 28x53 Metasul APR
MDR Report Key: 2935620-2003-00202
Product Code: KWA
Report Date: 7/9/2003
Catalog No.: 4340-29-053
Device Lot No.: 1348666
Event Description: Metasul insert dislocation
Patient Outcome: Unknown

Device Description: Acetabular Insert 28x55 Metasul APR
MDR Report Key: 2935620-2000-00012
Product Code: KWA
Report Date: 4/24/2000
Catalog No.: 4340-29-055
Device Lot No.: 1251199
Event Description: Anti-rotation pin dislodged from Polyethylene acetabular liner
Patient Outcome: Unknown

Device Description: Acetabular Insert 28x55 Metasul APR
MDR Report Key: 2935620-2001-01192
Product Code: KWA
Report Date: 5/23/2001
Catalog No.: 4340-29-055
Device Lot No.: Unknown
Event Description: Disassociation of left Metasul acetabular liner
Patient Outcome: Revision Surgery

Device Description: Acetabular Insert 28x55 Metasul APR
MDR Report Key: 2935620-2003-00282
Product Code: KWA
Report Date: 12/17/2003
Catalog No.: 4340-29-055
Device Lot No.: 1223168

Event Description: Polyethylene spinning, locking mechanism
Patient Outcome: Revision surgery

Device Description: Acetabular Insert 28x57 Metasul APR
MDR Report Key: 2935620-2002-00105
Product Code: KWA
Report Date: 3/15/2002
Catalog No.: 4340-29-057
Device Lot No.: 1181949
Event Description: Disassociation of an APR Metasul insert
Patient Outcome: Revision surgery

Device Description: Acetabular Insert 28x59 Metasul APR
MDR Report Key: 2935620-2002-00026
Product Code: KWA
Report Date: 1/28/2002
Catalog No.: 4340-29-059
Device Lot No.: 1230120
Event Description: Disassociation of APR acetabular insert.
Patient Outcome: Patient fell in September 2001

Device Description: 28x55 Std Metasul Insert I-O
MDR Report Key: 2935620-2001-01060
Product Code: KWA
Report Date: 5/14/2001
Catalog No.: 4372-28-055
Device Lot No.: 1417750
Event Description: Patient complained of hearing and feeling a "pop"
Patient Outcome: Hip dislocated, revision surgery

Device Description: 28x55 Std Metasul Insert I-O
MDR Report Key: 2935620-2003-00246
Product Code: KWA
Report Date: 6/16/2000
Catalog No.: 4372-28-055
Device Lot No.: 1426338-A
Event Description: Delay in surgery
Patient Outcome: Unknown

Device Description: 28x57 Std Metasul Insert I-O
MDR Report Key: 2935620-2000-00045
Product Code: KWA
Report Date: 6/16/2000
Catalog No.: 4372-28-057
Device Lot No.: 1330653

Event Description: Patient weight-bearing just one week then developed debilitating pain. Deep infection reported
Patient Outcome: Device explanted at surgery on 6/1/00.

Device Description: 28x61 Std Metasul Insert I-O
MDR Report Key: 2935620-1999-00048
Product Code: KWA
Report Date: 12/2/1999
Catalog No.: 4372-28-061
Device Lot No.: 1324824
Event Description: Liner would not seat in shell.
Patient Outcome: Unknown

Device Description: Co-Cr Head 12/14 Neck Neutral 28mm Metasul
MDR Report Key: 2935620-2002-00178
Product Code: KWA
Report Date: 6/4/2002
Catalog No.: 7340-28-000
Device Lot No.: 1426357
Event Description: Hip dislocated. Patient originally had recall Inter-Op shell
Patient Outcome: This was the second revision for this patient

Device Description: Co-Cr Head 12/14 Neck Neutral 28mm Metasul
MDR Report Key: 2935620-2003-00062
Product Code: KWA
Report Date: 3/4/2003
Catalog No.: 7340-28-000
Device Lot No.: 1171205
Event Description: Patient revised on 4/23/01
Patient Outcome: Unknown

Device Description: Co-Cr Head 12/14 +4mm Neck 28mm Metasul
MDR Report Key: 2935620-2001-01186
Product Code: KWA
Report Date: 6/8/2001
Catalog No.: 7340-28-400
Device Lot No.: 1327368-F
Event Description: Revision of femoral head on 12/11/99
Patient Outcome: Unknown

Device Description: Co-Cr Head 12/14 +4mm Neck 28mm Metasul
MDR Report Key: 2935620-2002-00393
Product Code: KWA
Catalog No.: 7340-28-400
Device Lot No.: 1409774
Event Description: Second revision required because of hip instability

Patient Outcome: Patient operated on 10-01-01

Device Description: Acetabular Insert 28x53 mm Metasul APR
Report Date: 12/15/04
MDR Report Key: 2935620-2004-00113
Product Code: KWA
Catalog No.: 4340-28-053
Device Lot No.: 1245313
Event Description: Acetabular insert dissociation. The shell was well fixed. At the time of surgery the insert was out of the shell. The metal pin was broken and the poly plug and lip liner had sheared off.

Device Description: Acetabular Insert 28x49 mm Metasul APR
Report Date: 12/15/04
MDR Report Key: 2935620-2004-00114
Product Code: KWA
Catalog No.: 4340-28-049
Device Lot No.: 1245303
Event Description: On January 23, 2004, the patient experienced a sudden onset of pain and instability in the right hip. The primary surgery had been performed on October 23, 1996. No significant causative event occurred prior to the onset of pain/instability. X-Ray examination confirmed disassociation of APR Metasul liner. Patient was admitted to hospital and APR Metasul liner revised to a polyethylene liner on January 28, 2004.

Manufacturer: Biomet
Airport Industrial Park
Warsaw, IN 46580

Device Description: M2A Modular Head Prosthesis
MDR Report No.: 1825034-2002-00129
Product Code: KWA
Report Date: 11/8/2002
Catalog No.: 11-173660
Device Lot No.: 698740
Event Description: Report from hospital indicated five of eleven cases of hip replacement procedures resulted in post-operative infections. No information that infections are related to devices used.

Patient outcome: Unknown

Device Description: M2A Modular Head
MDR Report No. 1825034-2003-0001

Product Code: KWA
Report Date: 1/7/2003
Catalog No. : 11-173661
Device Lot. No.: 321210
Event Description: Patient experienced pain, osteophytes removed.
Modular head component exchanged.
Patient outcome: Revision surgery

Device Description: M2A M/H Radial Solid Shell
MDR Report No. 1825034-2003-0034
Product Code: KWA
Report Date: 1/6/2003
Catalog No.: 15-104090
Device Lot No.: 986560
Event Description: Hip dislocated, acetabular components and
Modular head replaced.
Patient outcome: Revision surgery

Device Description: M2A M/H Radial Solid Shell
MDR Report No.: 1825034-2003-00035
Product Code: KWA
Report Date: 1/6/2003
Catalog No.: 15-105004
Device Lot No.: 916180
Event Description: Hip dislocated, acetabular components and
Modular head replaced.
Patient Outcome: Revision surgery

Device Description: M2A M/H Radial Solid Shell
MDR Report No.: 1825034-2003-00036
Product Code: KWA
Report Date: 1/6/2003
Catalog No.: 11-173670
Device Lot No.: 816160
Event Description: Hip dislocated, acetabular components and
Modular head replaced.
Patient Outcome: Revision surgery

Device Description: M2A Modular Head
MDR Report No.: 1825034-2003-0001

Device Description: M2A Ringloc LP Custom Liner
MDR Report No.: 1825034-2004-00041
Product Code: KWA

Report Date: 3/22/2004
Catalog No.: CP 160602
Device Lot No.: 394100
Event Description: Multiple dislocations, resulted in disassociation of liner
component---acetabular liner replaced.
Patient Outcome: Revision surgery

Device Description: M2A Taper Liner
MDR Report No.: 1825034-2004-00106
Product Code: KWY
Report Date: 12/21/2004
Catalog No.: 15-105004
Device Lot. No.: 916140
Event Description: Patient underwent left revision total hip arthroplasty in 2001.
Due to dislocation, closed reduction performed in 2004.
Following multiple dislocations, left revision arthroplasty
Performed in 2004. Metallosis of adjacent tissue was noted and
Acetabular components were replaced.
Patient Outcome: Unknown

Device Description: M2A Modular Head
MDR Report No.: 1825034-2004-0017
Product Code: KWA
Report Date: 12/21/2004
Catalog No.: 11-163670
Device Lot No.: 889090
Event Description: Patient underwent left revision hip replacement in 2001. Due to
Dislocation closed reduction performed in January 2004.
Following multiple dislocations, left revision hip arthroplasty
performed 2 weeks later. Metallosis of the adjacent tissue was
noted and acetabular components were replaced.
Patient outcome: Unknown

Device Description: M2A T-Universal 2 hole Shell
MDR Report No.: 1825034-2004-00073
Product Code: KWA
Report Date: 8/20/2004
Catalog No.: 15-103654
Device Lot No.: 513150
Event Description: Patient underwent total hip arthroplasty in 2000. Due to
loosening, revision performed in 2004 to replace acetabular
components.
Patient outcome: Unknown

Device Description: M2A Taper Liner 37/28mm
MDR Report No.: 1825034-2004-00074

Product Code: KWA
Report Date: 8/20/2004
Catalog No.: 15-105000
Device Lot No.: 011380
Event Description: Patient underwent total hip arthroplasty in 2000. Due to loosening revision performed in 2004 to replace acetabular components.
Patient outcome: Unknown

Device Description: M2A Modular Head Prosthesis
MDR Report No.: 1825034-2004-00075
Product Code: KWA
Report Date: 8/20/2004
Catalog No.: 11-163662
Device Lot No.: 11-163662
Event Description: Patient underwent total hip arthroplasty in 2000. Due to loosening revision performed in 2004 to replace acetabular components.
Patient outcome: Unknown

Device Description: M2A Taper Liner 37x28mm
MDR Report No.: 1825034-2004-00071
Product Code: KWA
Report Date: 8/17/2004
Catalog No.: 15-105000
Device Lot No.: 674440
Event Description: Patient underwent total hip arthroplasty in 2000. Operative report indicates that loose acetabular components were replaced during revision surgery in 2003.
Patient outcome: Unknown

Device Description: M2A Modular Head Prosthesis
MDR Report No.: 1825034-2004-00072
Product Code: KWA
Report Date: 8/17/2004
Catalog No.: 11-163663
Device Lot No.: 724130
Event Description: Patient underwent right total hip arthroplasty in 2000. Operative Report indicates loose acetabular components were replaced during revision surgery in 2003.
Patient outcome: Unknown

Device Description: M2A T-Universal 2-Hole Shell
MDR Report No.: 1825034-2004-00070
Product Code: KWA
Report Date: 8/17/2004

Catalog No.: 15-103656
Device Lot No.: 710160
Event Description: Patient underwent right total hip replacement in 2000. Operative report indicates that loose acetabular components were replaced during revision surgery in 2003.
Patient outcome: Unknown

Device Description: M2A Modular Head
MDR Report No.: 1825034-2005-00010
Product Code: KWA
Report Date: 1/4/05
Catalog No.: 11-173663
Device Lot No.: 819060
Event Description: It was reported that patient underwent total hip arthroplasty on November 6, 2000. Due to multiple dislocations revision was performed November 18, 2004. Acetabular components were replaced.
Patient outcome: Unknown

Device Description: M2A 38 mm Cup
MDR Report No.: 1825034-2005-0009
Product Code: KWA
Report Date: 1/4/05
Catalog No.: RD118852
Device Lot No.: 634220
Event Description: It was reported that patient underwent total hip arthroplasty on November 6, 2002. Due to multiple dislocations, revision was performed November 18, 2004. Acetabular components were replaced.
Patient outcome: Unknown

Device Description: Alternate Bearing Surface Liner 10 Degree
MDR Report No.: 1825034-2005-00019
Product Code: KWA
Report Date: 2/21/05
Catalog No.: RD157015
Device Lot No.: 619210
Event Description: Patient underwent right total hip arthroplasty on May 27, 1998. Onset of right hip pain noted in July, 2004 and patient underwent revision surgery on February 3, 2005. Surgeon noted osteolysis involving proximal femur and acetabulum.
Patient outcome: Unknown

Device Description: Alternate Bearing Modular Head Taper 1
MDR Report No.: 1825034-2005-00020
Product Code: KWA

Report Date: 2/21/05
Catalog No.: RD157606
Device Lot No.: 300670
Event Description: Patient underwent right hip arthroplasty on May 27, 1998. Onset of right hip pain noted in July, 2004 and patient underwent revision surgery on February 3, 2005. Surgeon noted osteolysis involving proximal femur and acetabulum.
Patient outcome: Unknown

Manufacturer: DePuy Orthopaedics, Inc.
P.O. Box 988
Orthopaedic Drive
Warsaw, IN 46581-0988

Device Description: Ultamet MOM Insert 54 OD x 36 ID
MDR Report Key: 0202391C-1
Product Code: KWA
Report Date: 12/13/2002
Catalog No.: 121887354
Device Lot No.: YMD 59
Event Description: Package split—inner plastic portion—no revision surgery
Patient outcome: unknown

Device Description: Ultamet MOM Insert 52 ID x 36 ID
MDR Report Key: 0300405C-2
Product Code: KWA
Report Date: 3/3/2003
Catalog No.: 121887352
Device Lot No.: 1070181
Event Description: Metal insert locked into shell off axis and could not be removed from acetabular shell. Delay in surgery
Patient outcome: unknown

Device Description: Ultamet MOM Insert 62 OD x 36 ID
MDR Report Key: WPC 354-2003
Product Code: KWA
Report Date: 12/22/2003
Catalog No.: 121887362
Device Lot No.: YHT 84
Event Description: Metal insert did not seat properly, surgery extended 30 minutes.
Patient outcome: Unknown

B. Summary of Published Adverse Events from the Literature

A survey of the published literature resulted in the following adverse events reported for these devices.

1. Wagner, Michael and Heinz Wagner. "Preliminary Results of Uncemented Metal on Metal Stemmed and Resurfacing Hip Replacement Arthroplasty."; Clin. Orthop., No. 329S (1996): S78-S88.

This article reports on a series of 70 patients in Europe with metal/metal semi-constrained total hips implanted during 1990-1992. There was one early dislocation with the patient refusing further treatment; one late infection requiring removal of the prosthetic implant components. Periarticular calcification in two patients requiring reoperations was also reported.

2. Dorr, L. D., K. R. Hilton, Z. Wan, G.D. Markovich, and R. Bloebaum, Ph.D. "Modern Metal on Metal Articulation for Total Hip Replacements."; Clin. Orthop., No. 333 (1996): 108-117.

This article reports on a series of 54 patients treated in the U.S. with metal on metal semi-constrained total hips from 1991-1994. There was one infection and two dislocations; one of these dislocations required revision of the prosthesis three years postoperatively.

3. Weber, B.G. "Experience With the Metasul Total Hip Bearing System."; Clin. Orthop., No. 329S (1996): S69-S77.

This article reports on a series of 110 patients treated in Europe with metal on metal semi-constrained total hips from 1988-1992. There were five early failures attributed to loosening reported. There were two additional complications of trochanteric bursitis (one case) and painful ectopic ossification (one case), neither case required reoperation.

4. Hilton, K.R., L.D. Dorr, Z. Wan and E.J. McPherson. "Contemporary Total Hip Replacement With Metal on Metal Articulation."; Clin. Orthop. No. 329S (1996): S99-S105.

This article updates a previous report by Dorr, et al. (See ref. 2) There was one additional dislocation reported for this series.

5. Doorn, P.F., J.M. Mirra, P.A. Campell, and H.C. Amstutz. "Tissue Reaction to Metal on Metal Total Hip Prostheses."; Clin. Orthop. No. 329S (1996): S187-S205.

Nine metal/metal hip implants retrieved from nine patients underwent histological evaluation to study the tissue reaction around the prostheses. Four McKee-Farrar, one APR and one Apollo metal/metal total hip prostheses and three McMinn

metal/metal total surface replacement hip prostheses were evaluated. The duration of implantation ranged between seven months and 25 years. Implants were retrieved due to aseptic loosening (4), pain (2), dislocation (1), femoral fracture (1) and death (1). While many of the common tissue responses to metal/polyethylene articulations were also noted for the metal/metal devices, however, overall these reactions appeared less intense.

6. Iida, H., E. Kaneda, H. Takada, K. Uchida, K. Kawanabe, and T. Nakamura. "Metallosis Due to Impingement Between the Socket and the Femoral Neck in a Metal-on-Metal Bearing Total Hip Prosthesis: A Case Report."; *J Bone Joint Surg.* Vol. 81(A) (1999): 400-3.

This article reports on a single patient who suffered a failure of her metal-on-metal hip prosthesis 12 months following her surgery. The patient had no prior history of dislocation or other major complication. The prosthesis was shown to be loose on x-rays at 12 months and osteolysis was suspected in the calcar and trochanter regions of the femur. Examination of the retrieved titanium alloy femoral prosthesis and the cobalt-chrome alloy acetabular prostheses revealed markings consistent with impingement between the socket and the femoral neck during maximum hip flexion. Histological examination of the pseudocapsular tissue revealed particles of titanium, but cobalt and chromium were not detected. The authors concluded that the source of the metal debris was from the femoral prosthesis. The authors further concluded that this type of complication can occur anytime, without symptoms or associated complications and questioned the use of titanium in the manufacture of this implant.

7. Campbell, P., H. McKellop, R. Alim, J. Mirra, S. Nutt, L. Dorr, and H.C. Amstutz. "Metal-On-Metal Hip Replacements: Wear Performance and Cellular Response to Wear Particles." In Cobalt-Based Alloys for Biomedical Applications. ASTM STP 1365., editors J.A. Disegi, R.L. Kennedy and R. Pilliar, (1999) 193-209. West Conshohocken, PA: ASTM publishers.

This article reports on 20 second generation metal-on-metal hip prostheses retrieved from patients after use ranging from nine months to 6.5 years. The specific aims of this study of retrieved devices were to examine the amount of wear, study the histological appearance of the periprosthetic tissues and characterize the wear particles generated *in vivo*. There were 10 total hip and 10 surface replacement hip prostheses configurations available for evaluation. Implants were made available due to a variety of reasons including loosening, debonding, component breakage, infection and death.

Eighteen of the 20 retrieved prostheses had at least one component measured for wear. For those components in which wear could be measured, the amount of wear ranged from 3-32 microns. Two of the total hip prostheses exhibited clusters of micropits in the main bearing area, but these did not appear to be associated with high wear.

Histological evaluation revealed metallosis occurred in five cases. Impingement of the titanium alloy femoral components with the acetabular shell, debonding of the porous coating and breakage of the femoral component were cited as the likely causes in four of these cases. For the fifth case, discoloration was likely due to cobalt-chrome particles released during the wear-in phase of the components. The histology for another case revised due to distal femoral osteolysis, was inconsistent with wear-induced osteolysis. Extensive necrosis was noted for two other cases, but no clear association between necrosis and metal wear particles could be made. Except for the five metallosis cases, there were fewer macrophages and wear particles than is typically seen in tissues around metal-polyethylene hip prostheses. Two consistent forms of cobalt-chrome particles were noted. One was a dense elongated form that commonly had a defined edge. The second, and the most common, form had less defined edges with a non-homogeneous, amorphous texture. Particle size was comparable between the total hip and surface replacement hip prostheses.

Conclusions are summarized as follows: 1) wear of the metal-on-metal articulations was substantially lower than for metal-polyethylene articulations, 2) third body damage was noted in varying degrees on all components, 3) histology and particle morphology were consistent with the low wear of these bearings, 4) cellular reaction to the metal particles could be described as mild, and 5) further histopathological studies and measurements of *in vivo* wear of metal-on-metal total hip replacements are recommended.

8. Albrecht-Olsen, P, Owen-Falkenberg, T, Burgaard, P, Andersen, PB. Nine-Year Follow-up of the Cementless Ring Hip. *Acta Orthop Scand*, 60:1:77-80, 1989.

Albrecht-Olsen et al. reviewed 238 Ring prostheses implanted during the period 1968-1979. Of those cases, 127 with a median follow-up of 9 years were available for evaluation with 90% of those patients demonstrating excellent/good results upon self assessment. Using the Charnley scale, 87% had a pain score of 4 or greater (score of 6 = no pain), 76% had a motion score of 4 or greater, and 57% had a walking score of 4 or greater. The author cites an infection rate of 2.5% (6 deep infections, 16 superficial infections). Four dislocations were also encountered. At the time of this evaluation, 17% (n=40) of the patients had been revised, mainly due to pain. Overall results predicted an 81% survival rate at 12 years, comparable to outcomes seen with metal-on-polyethylene articulation

9. Almby, B, Hierton, T. Total Hip Replacement: A Ten-Year Follow-up of an Early Series. *Acta Orthop. Scand.*, 53:397-406, 1982.

Almby reported on 93 patients receiving the Muller device, 57% of which had been followed for more than 10 years. Using the Charnley scale (6 possible points in each category), 90% had pain rating of 4 or better or a range of motion greater than 100°. Nine deep infections were reported. Thirty patients died (26 unrelated to device, 1 embolus, 1 ileus, 1 renal failure, 1 septic). Twenty-nine patients were revised (19 aseptically loose, 7 septically loose, 4 stem fractures, 1 fracture).

Twenty-three acetabular and 16 femoral components showed signs of loosening. Femoral loosening was secondary to calcar resorption and cement settling in most cases. Survivorship in this series was calculated to be approximately 80% at 5 years and 57% at 10 years.

10. Andrew, T.A., Berridge, D, Thomas, A, Duke, RNF. Long-term Review of Ring Total Hip Arthroplasty. *Clinical Orthopedics and Related Research*, 201:111-122, 1980.

Andrew presented his results of 116 Ring patients followed for 8 years. Using the Harris scoring system (100 points possible), 33% of the patients had 80 points or greater with another 13% exhibiting total scores of 70-80. Using the Ring evaluation, 49% of the patients rated excellent or good. Two deep infections and 4 dislocations were encountered. Other complications included grade IV heterotopic ossification (5), fracture (4), embolic event (7), and sciatic palsy (1).

11. Djerf, K, Wahlstrom, O. Total Hip Replacement Comparison Between the McKee-Farrar and Charnley Prostheses in a 5-Year Follow-up Study. *Acta Orthop. Scand.*, 105:158-162, 1986.

Djerf presents results on 107 McKee-Farrar and 70 Charnley devices with 5 years followup. Analysis revealed 94% of patients to have no pain and 78% to have improved flexion. Unrelated death occurred in 12% of the patients. Six infections (3.4%) and 4 dislocations (2.3%) were reported. Other complications included trochanteric problems (2.8%), nerve injury (1.7%), deep venous thrombosis (1.7%), pulmonary embolus (0.6%), fracture (0.6%), and ossification (0.6%). Loosening was evident in 32% of the cases. Analyses showed no significant difference in the outcomes of either implant.

12. August, AC, Aldam, CH, Pynsent, PB. The McKee-Farrar Hip Arthroplasty: A Long Term Study. *Journal of Bone and Joint Surgery*, 68B:4:520-527, Aug. 1986.

Results of 175 patients with the McKee-Farrar device at an average 13.9 years of follow-up are presented by August. Using the Harris evaluation, the average total score was 76.4, with 48.9% having excellent/good outcomes. On self assessment, 90% of the patients rated themselves as having a satisfactory outcome. Sixty-four patients were revised, mainly for loosening, stem fracture and bone fracture. Over 50% of the stems and cups showed signs of looseness radiographically. Additionally, the cup showed signs of protrusion in 62.5% of rheumatoid patients. Heterotopic ossification (grade IV) was reported in 2.7% of the cases. August calculated survival at 84.3% at 14 years and 27.5% at 20 years.

13. Jantsch, S, Schwagerl, W, Zenz, P, Semlitsch, M, Fertschak, W. Long-term Results After Implantation of McKee-Farrar Total Hip Prostheses. *Acta Orthop. Scand.*, 110:230-237, 1991.

Jantsch analyzed followup at 14 years in a series of 248 patients with 330 McKee-Farrar devices. Only 56% of the patients were followed clinically to this period (24% died, 17% untraceable, 3% refused participation). Using the Mayo rating system, 48% of the patients were found to have excellent/good ratings (62% if revisions are excluded). Based on radiographs available, 34% of the cups and 26% of the stems were unstable. There were 36 retrievals (22 cup and stem, 7 cup, 7 stem).

14. McKee, GK, Chen, SC. The Statistics of the McKee-Farrar Method of Total Hip Replacement. *Clinical Orthopedics and Related Research*, 95:26-33, Sept. 1973.

McKee reports on four series of patients treated with the various iterations of the McKee-Farrar device from 1956-1971. Postoperative outcome improved through each design iteration, with approximately 89% achieving excellent or good outcomes in the 1965-69 series (4-7 year followup) and 97% achieving excellent or good outcomes in the 1971 series (2 year or less followup). Retrievals have occurred in 4% of the 1965-69 series and 0% of the 1971 series. Fifteen (15) deaths were reported in the 1965-69 series; two were reported in the 1971 series. The reported rate of infection was 4% in the 1965 series and 0% in the 1971 series. Two dislocations (2%) were also reported in each of these series. Other complications include pulmonary embolus, deep venous thrombosis, shaft perforation, hematoma and heterotopic ossification.

15. Ring, P. Press-Fit Prostheses: Clinical Experience. *Osteoarthritis in the Young Adult Hip: Options for Surgical Management*. Pp. 220-232, edited by D Reynolds and M Freeman, Churchill Livingstone Publishing, 1989.

Ring presents results on 106 metal-metal Ring prostheses with 7-17 years followup. Postoperatively, 83% were assessed as excellent/good clinically. Outcomes of the various design iterations is again presented in this article. Thirteen retrievals have occurred (7 femoral failures, 2 pelvic failures, 3 combination failures, 1 ankylosis). Survivorship of patients implanted from 1968-73 was 81% at 18 years; survivorship was 95% at 16 years for those implanted from 1972-79.

16. Schmalzried, TP, Szuszczewicz, ES, Akizuki, KH, Petersen, TD, Amstutz, HC. Factors Correlating with Long Term Survival of McKee-Farrar Total Hip Prostheses. *Clinical Orthopedics and Related Research*, 329S:48-59, Aug. 1996.

Thirteen McKee-Farrar patients (15 devices) with an average follow-up of 23.7 years are presented by Schmalzried. The average Harris hip score of these patients was 86 with 11 patients having an excellent/good rating. These patients outscored a matched metal-on-poly control population on the SF-36 Health Status questionnaire. Activity levels were also reported to exceed the averages for this age population. The only complication reported is that of lysis in three femurs and one acetabulum.

17. Zaoussis, AL, Patikas, AF. Experience with Total Hip Arthroplasty in Greece, the First 20 Years: A Particular Reference to Long-Term Results with the McKee-Farrar Technique. *Clinical Orthopedics and Related Research*, 246:39-47, Sept. 1989.

Zaoussis presents results on 38 McKee Farrar patients followed for 12-20 years, with 26 having greater than 15 years followup. At the time of this evaluation, 45% were found to have very good outcomes. Fifty-three percent (53%) of the patients were pain free and 79% had 60-90° range of motion. Three infected components and four loose components were retrieved. There have been five dislocations (all in one patient). Nine components show looseness. Other complications include five peroneal nerve palsies, one cortical perforation and one ossification.

18. Archibald, MJ, Jacobs, JJ and Black, J. Alternative Bearing Surfaces in Total Joint Arthroplasty. *Clinical Orthopaedics and Related Research*, 379:12-21, Oct. 2000

This review article describes the local effects of metal and ceramic particles, which appear similar to that seen with ultrahigh molecular weight polyethylene. Volumetric wear of metal particles is generally reduced but this effect may be mitigated by the finer particles generated by metal-on-metal wear. The systemic effects of these particles are largely unknown. All particle types can elicit a cell response that varies with cell type and the specific response measured. According to the authors, additional investigation is needed to identify the potential beneficial or harmful effects of alternative bearing surfaces.

19. Brodner, W et al. Serumcobalt- und Serumchromspiegel bei zwei chronisch niereninsuffizienten Patientinnen mit Hüfttotalendoprothese und Metall-Metall-Gleitpaarung. *Z Orthop Ihre Grenzgeb* 138:425-429, 2000

The influence of chronic renal failure on serum cobalt and serum chromium in two patients with metal-on-metal bearing (Metasul) and cementless total hip arthroplasty (Alloclassic) were investigated. Maximum values were found to be more than 100-fold elevated when compared to the reported median serum cobalt concentrations in patients with the same prosthesis type and no known renal disease. The authors concluded that chronic renal failure seems to be responsible for the marked elevation of serum cobalt and serum chromium. In their opinion, metal-on-metal bearings in THA should not be inserted in patients with chronic renal failure.

20. Hallab, N et al. Metal Sensitivity in Patients with Orthopaedic Implants. *JBJS* 83-A(3):428-436, 2001

Specific types of implants with a greater propensity to release metal *in vivo* may be more prone to induce metal sensitivity. Failures of total hip prostheses with metal-on-metal bearing surfaces have been associated with a greater prevalence of metal sensitivity than have those of similar designs with metal-on-ultra-high molecular weight polyethylene bearing surfaces. In contrast, other studies have indicated that, after total joint replacement with metallic components, some patients show an induction

of metal tolerance--that is, a previously detected metal sensitivity abates after implantation of a metal containing prosthesis. Until the roles of delayed hypersensitivity and humoral immune responses to metallic orthopaedic implants are more clearly defined, the risk to patients may be considered minimal.

21. Tharani, BS et al. The Risk of Cancer Following Total Hip or Knee Arthroplasty. *JBJS* 83-A(5):774-780, 2001

There has been concern that metal-on-metal total joint replacements may be associated with an increased risk of cancer because of an increased exposure to metal particles or ions. The risk of cancer after metal-on-metal total hip replacement has been assessed specifically in only one epidemiological study. In that study, the relative risk of cancer was reported to be 0.95 (95 % confidence interval, 0.79 to 1.13), suggesting that there is no apparent increased risk of cancer after metal-on-metal total hip arthroplasty. In addition, the risk of sarcoma after metal-on-metal total hip replacement was found to be 0.00 (95 % confidence interval, 0.00 to 6.59). However, those same authors found the relative risk of hematopoietic cancer to be 1.59 (95 % confidence interval, 0.82 to 2.77) following metal-on-metal total hip replacement and 3.77 (95 % confidence interval, 0.96 to 17.6) for leukemia when metal-on-metal implants were compared with metal on polyethylene implants. From an epidemiological perspective, these data are limited because of the small number of patients (579) who underwent metal-on-metal total hip replacement. Because this number is small and the numbers of both observed and expected cases are also small, the strength of the probability analysis is quite limited. In their summary, the authors noted that the available data do not support a causal link between total hip or knee arthroplasty and the development of cancer. Although it is biologically possible for the materials used in total joint replacement to induce malignant generation, this relationship has not been demonstrated.

22. Lombardi, AV. Short-Term Results of the M² a-Taper Metal-on-Metal Articulation. *J. Arthroplasty* 16(8) Suppl. 1:122-128, 2001

A polyethylene-free metal-on-metal acetabular system was designed in an effort to improve total hip arthroplasty (THA) longevity. Minimum 2- year follow-up results involving 72 polyethylene (PE) liner THAs and 78 metal liner THAs from a multicenter, randomized, controlled, investigational device exemption study was reported. Mean Harris hip scores of 95.54 (PE liner group) and 95.23 (metal liner group) were reported at mean follow-up intervals of 3.29 and 3.23 years. Radiographic evaluation revealed no evidence of early failure. No acetabular components were revised or were pending revision. No statistically significant differences in the data were calculated between liner types except for the immediate postoperative (P=.0415) and minimum 2-year follow-up (P=.0341) angles of inclination. The M² a-taper metal-on-metal articulation may represent a viable alternative for THA in younger, higher demand patients.

23. Harding, I. et al. Serum Levels of Cobalt and Chromium in a Complex Modular Total Hip Arthroplasty System. *J. Arthroplasty* 17(7):893-95, 2002

This study measured the serum cobalt and chromium levels in patients with an Oxford Universal Hip (Corin, Cirencester, UK), which has a modular sliding mechanism; patients with a similarly manufactured hip with no sliding mechanism; and a control group. Loosening was excluded clinically and radiographically. Arthroplasty patients had statistically higher levels of serum cobalt and chromium than controls, but there was no significant difference in levels between the implanted groups. Although it is not known what the long-term effects of chronic low-grade exposure to these ions are, the levels are many orders below the toxic range.

24. Brodner, W, et al: Serum Cobalt Levels After Metal-on-Metal Total Hip Arthroplasty. *JBJS (Am)*, 85:2168-2173, 2003

A total hip arthroplasty was performed without cement in 100 consecutive patients who have either unilateral osteoarthritis or unilateral osteonecrosis. Fifty patients were randomized to be treated with Metasul metal-on-metal articulation, and fifty patients with a ceramic-on-polyethylene bearing. Blood samples were taken before the operation and at multiple time points for five years after the operation. Serum cobalt concentrations were measured with atomic absorption spectrometry. In the metal-on-metal group, the median serum cobalt concentration was 1 µg/L at one year after surgery and 0.7 µg/L at five years. The median of the serum cobalt concentrations measured from 3 to 12 months did not differ from the median of subsequent measurements. The median serum cobalt level in the control group of patients treated with ceramic-on-polyethylene articulation was below the detection limit at all time points. The authors did not determine what serum cobalt levels reflect or whether they corresponded to wear of the articulating metal surfaces. They believed that there was little doubt that renal function influences serum metal concentrations. However, they did not believe that routine determination of serum metal levels or routine monitoring of renal function is needed for patients with metal-on-metal articulation. They do recommend careful follow-up with monitoring of serum cobalt concentrations as well as renal function when renal disease develops in a patient with a metal-on-metal articulation. Until more information is available, the authors are concerned about patients with high levels of serum cobalt, and believe it prudent to observe such patients. They recommend informing patients that, so far, elevated serum cobalt concentrations after total hip replacement with a metal-on-metal articulation have not been linked to adverse health reactions but the effects of long-term elevation of serum cobalt levels are not yet known.

25. Reinisch, G, et al: Retrieval Study of Uncemented Metal-Metal Prosthesis Revised for Early Loosening. *Biomaterials*, 24:1081-1091, 2003

A tribologic assessment was performed on 22 metal-metal hip prostheses from a single manufacturer, following removal for early aseptic loosening after a mean service life of 32 months (range 12-59 months). The mean linear wear rate was 7.6 µm/year (range, 2.9–12.8 µm/year). This was below the rates previously observed in other metal-metal combinations. A novel contour analysis technique using a coordinate measuring machine showed the mean volumetric wear rate to be 2.02 mm³/year (range, 0.55–3.74 mm³/year), which corresponds to a mean gravimetric wear rate of 16.9 mg/year (range, 4.6–

31.4 mg/year). The mean clearance of 39.8 μm (range 30-50 μm) was within the optimal range for hard-hard bearing combinations. Evidence of abrasive, adhesive, and third-body wear was found on all bearing surfaces. The tribologic assessment did not indicate manufacturing defects as a cause for early loosening. Equally third-body wear was too low to be considered a causative factor for early loosening.

26. Brown, SR et al: Long-term Survival of McKee-Farrar Total Hip Prostheses. *Clin Orth Rel Res* 402:157-163, 2002

The long-term results of 153 consecutive McKee-Farrar total hip arthroplasties done in 129 patients by one surgeon between 1969 and 1973 were evaluated. The average age of the patients at implantation surgery was 61 years (range 28-85 years) and these patients were observed as many as 28 years. Primary diagnosis included osteoarthritis (49% of implants), rheumatoid arthritis (38%), and other conditions (13%). During the 28 years of followup, five implants were revised for infection and 14 implants were revised for aseptic loosening. Survivor analysis of the McKee-Farrar prostheses had a 20-year probability of implant survivorship of 84%, and a 28-year survivorship of 74%. Excellent long-term results were seen. Given the inherent problems associated with implant wear debris, especially polyethylene wear particles, second generation metal-on-metal bearing implants may offer a viable alternative to current designs. Their excellent long-term survival may infer particular suitability for use in younger patients.

27. Signorello LB et al: Nationwide Study of Cancer Risk Among Hip Replacement Patients in Sweden. *J Natl Cancer Inst* 93:1405-10, 2001

The authors conducted a nationwide cohort study in Sweden to examine cancer incidence among 116,727 patients who underwent hip replacement surgery during the period from 1965 through 1994. Through record linkage to the Swedish Cancer Register, they identified all incident cancers through 1995 in this population (693,954 person-years of observation). For each cancer type, the observed number of cases was divided by that expected in the general Swedish population to produce standardized incidence ratios (SIRs). Relative to the general population, the cohort had no overall cancer excess (SIR=1.10; 95% confidence interval [CI] = 0.99 to 1.03). However, they observed elevated SIRs for prostate cancer (SIR=1.16; 95% CI = 1.11 to 1.22) and melanoma (SIR=1.15; 95% CI = 1.10 to 1.20) and a reduction in stomach cancer risk (SIR=0.83; 95% CI = 0.75 to 0.92). Longer-term followup (>15 years) revealed an excess of multiple myeloma (SIR=1.86; 95% CI = 1.01 to 3.11) and a statistically nonsignificant increase in bladder cancer (SIR=1.42; 95% CI = 0.98 to 1.99). There was no material increase in risk for bone or connective tissue cancer for either men or women in any followup period. The conclusion was that in this, the largest study to date, hip implant patients had similar rates of most types of cancer in those in the general population. There was no mention of whether the devices studied were metal or metal on polyethylene or polyethylene on metal.

28. Campbell PA et al: Positive Cytokine Production in Failed Metal-on-Metal Total Hip Replacements. *Acta Orthop Scand* 73(5):506-512, 2002

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

29. Dorr, LD et al: Total Hip Arthroplasty with Use of the Metasul Metal-on-Metal Articulation. JBJS 82-A(6):789-798, 2000

Between 1991 and 1994, seventy patients had a total hip replacement with the Metasul metal-on-metal articulation and a cemented Weber cup. Fifty six patients had complete clinical and radiographic data four to 6.8 years after the operation. There was one mechanical failure (2 percent). Thirty six of 47 patients who completed the patient self assessment form rated their result as excellent; seven, as very good; two, as good; one, as fair; and one, as poor. Wear could not be measured on radiographs because of the metal-on-metal articulation. No hip had radiographic evidence of acetabular osteolysis and two hips had calcar resorption, but there was no other evidence of focal osteolysis. From their four to seven year experience with the device the authors feel that the clinical results are similar to those of total hip replacements with a metal-on-polyethylene articulation. They believe the device may have a role in reducing the wear that occurs with total hip replacement and that the device appears particularly indicated for younger patients.

30. Savarino, L, et al: Ion Release in Patients with Metal-on-Metal Hip Bearings in Total Joint Replacement: A Comparison with Metal-on-Polyethylene Bearings. J Biomed Mater Res. 63(5):467-74, 2002

This study compared ion release in the serum of two groups of patients who had the same type of stable cementless prosthesis, but different bearing: 26 with metal-on-metal (Group A), and 15 with metal-on-PE bearing (Group B). The follow-up was 14-38 months for group A and 18-34 months for group B. The serum concentration of chromium (Cr), cobalt (Co) and molybdenum (Mo) was measured. Twenty two patients before surgery were used for comparison group (Group C). The reference values were obtained from a population of twenty two healthy subjects (Group D). Their findings indicate that metal-on-metal bearings produce a significantly higher systemic release of cobalt and chromium (ng/ml) when compared with levels found in metal-on-PE, pre-surgery, and reference groups. Such a high release should induce to improve the bearing materials or, at least, to study the biologic fate of metal ions and consequently their long-term effects. In such a way a risk-to-benefit ratio for the patient could be established.

31. Adami, G, et al: Cobalt Blood Levels after Total Hip Replacement: A New Follow-up Study in Trieste (Italy). *Annali di Chimica* 93:1-9, 2003

According to the authors there is little information in the literature regarding cobalt and chromium release following metal-on-metal total hip replacement. This is due to the fact that blood levels can change depending on physical and working activity, individual feeding and metabolism. The results obtained confirm the presence of an increase of cobalt in the blood of patients after THR, while the chromium levels are almost alike; average values in patients operated are $4.1 \pm 1.5 \mu\text{g/L}$ for cobalt ($0.3 \pm 0.1 \mu\text{g/L}$ in the control group) and $4.5 \pm 2.9 \mu\text{g/L}$ for chromium ($4.7 \pm 2.4 \mu\text{g/L}$ in the control group). In spite of the cobalt values that stand below the concentration generally considered dangerous, the difference between the two examined groups points out that a risk exists for the health of these patients. These results must be confirmed by further studies, providing better information and more reliable and biocompatible materials.

32. MacDonald, S.J. et al: Metal-on-Metal Versus Polyethylene in Hip Arthroplasty: A Randomized Clinical Trial. *Clin Orth & Rel Res* 406:282-296, 2003

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

33. Reinisch, G., et al: Retrieval Study of Uncemented Metal-Metal Hip Prostheses Revised for Early Loosening. *Biomaterials* 24:1081-1091, 2003

A tribologic assessment was performed on 22 metal-metal hip prostheses from a single manufacturer, following removal for early aseptic loosening after a mean service life of 32 months (range, 12-59 months). The mean linear wear rate was 7.6 μ m/year (range, 2.9-12.8 μ m/year). This was below the rates previously observed in other modern metal-metal articulations. A novel contour analysis using a coordinate measuring machine showed the mean volumetric wear rate to be 2.02 mm³/year (range, 0.55-3.74 mm³/year), which corresponds to a mean gravimetric wear rate of 16.9 mg/year (range, 4.6-31.4 mg/year). The mean clearance of 39.8 μ m (range, 30-50 μ m) was within the optimal range for hard-hard bearing combinations. Evidence of abrasive, adhesive, and third-body wear was found on all bearing surfaces. The tribologic assessment did not indicate manufacturing defects as a cause of early loosening. Equally, third-body wear was too low to be considered a causative factor for early loosening. The implants investigated were uncemented total hip prostheses with a metal-metal bearing combination, from a single manufacturer (Plus Endoprothetik AG, Rotkreuz, Switzerland).

34. Lhotka, C, et al: Four-year Study of Cobalt and Chromium Blood Levels in Patients Managed with Two Different Metal-on-Metal Total Hip Replacements. *J Orth Res* 21:189-195, 2003

In 259 patients with total hip replacement, blood cobalt and chromium concentrations were measured with atomic absorption spectrophotometry over a period of four years after arthroplasty. Of the patients enrolled in the study, 131 had been managed with a METASUL cobalt-chromium alloy metal-on-metal bearing combination, while 128 had been given a SIKO-MET-SM21 cobalt-chromium alloy metal-on-metal combination. The control group consisted of 31 age- and gender-matched subjects. Compared with the controls, all of the patients had higher cobalt and chromium levels. Cobalt concentrations were up to 50 times higher, while chromium concentrations were up to 100 times higher. Both systems showed evidence, in the whole-blood samples, of wear debris production by the implants. Therefore, patients managed with metal-on-metal bearing combinations should be carefully monitored in order to ensure that any local or systemic complications are detected early on. According to the authors, the cause and effect relationship between metal wear debris and local or systemic disease has not been conclusively proved, although complications from metal wear products are a subject of concern. Any metal-on-metal bearing combination used in joint replacements must, therefore, be designed and manufactured in such a way as to produce minimal debris.

35. Clarke, MT, et al: Levels of Metal Ions after Small- and Large-Diameter Metal-on-Metal Hip Arthroplasty. *JBJS (Br)* 85-B:913-917, 2003

Metal-on-metal bearings for hip arthroplasty are increasing in popularity but concern remains regarding the potential toxicological effects which these bearings release. The serum levels of cobalt and chromium in 22 patients who had undergone MOM resurfacing arthroplasty were compared with a matched group of 22 patients who had undergone 28 mm MOM total hip arthroplasty (THA). At a median of 16 months (7 to 56) after resurfacing arthroplasty, the authors found the median serum levels of cobalt and chromium to be 38nmol/l (14 to 44) and 53 nmol/l (23 to 165) respectively. These were

significantly greater than the levels after 28 mm MOM THA which were 22 nmol/l (15 to 87, $p=0.021$) and 19 nmol/l (2 to 58, $p<0.001$) respectively. Since the upper limit for normal patients with implants is typically 5 nmol/l, both groups had significantly raised levels of metal ions. MOM bearings of large diameter, however, result in a greater systemic exposure of cobalt and chromium ions than bearings of small diameter. This may be of relevance for potential long-term side effects. It is not known to what extent this difference is due to corrosion of the surfaces of the component or of the wear particles produced.

36. Clarke MT, et al: Dislocation after Total Hip Replacement in Relation to Metal-on-Metal Bearing Surfaces. JBJS (Br) 85-B650-4, 2003

Metal-on metal (MOM) is a commonly used bearing noted for its "suction fit" when lubricated. A clinical study was conducted to compare the rate of dislocation of MOM bearings with those of ceramic-on-polyethylene (COP) bearings and found that one MOM bearing dislocated in a series of 109 hips (0.9%) compared with nine of 145 hips (6.2%) in the COP group ($p=0.02$). An in vitro investigation was performed comparing the peak forces generated during forced separation of the two bearings of the same dimensions at velocities from 1 to 50 cm/s. This revealed that the MOM bearing generated significant resistance to separation at all velocities (maximum mean 24N), whereas the COP did not (maximum mean 1.9N, $p<0.001$). The authors conclude that MOM bearings are more stable to dislocation than COP bearings as a result of the interfacial forces provided by a thin, lubricating fluid.

37. Savarino, L, et al: Ion Release in Stable Hip Arthroplasties using Metal-on-Metal Articulating Surfaces; A Comparison Between Short- and Medium-Term Results. J Biomed Mater Res 66A(3):450-456, 2003

The use of metallic heads articulating with metallic cups could solve the problem of polyethylene (PE) wear in total hip replacement (THR) with metal-on-PE bearings. A conspicuous release of metal ions from new models on metal-on-metal bearings has been found in the short-term, but it is yet unclear whether the medium-term corrosion rate is high, or, on the contrary, it becomes negligible, because of the continuous surface finishing. The purpose of the study was to compare the serum ion values (nanograms per milliliter) in 15 patients with metal-on-metal stable prosthesis (Group A), in the short-term (subgroup A₁; mean follow-up; 24 months) and medium term (subgroup A₂; mean follow-up: 52 months), in order to determine whether the ion release decreased with time of implant. Chromium (Cr), cobalt (Co), molybdenum (Mo) and Aluminum (Al) were analyzed. Twenty-two presurgical patients were used for comparison (Group B). The reference range was obtained from a population of 27 healthy subjects (Group C). Co and Cr levels in the medium term (subgroup A₂) were not decreased in comparison with the short-term values (subgroup A₁) and were significantly higher ($p<0.001$) than presurgical and reference values. Otherwise, Mo and Al concentrations were not significantly increased in comparison with reference values. In conclusion, despite the apparent advantage of metal-on-metal coupling especially in younger patient populations, there is a major concern about the extent and duration of the relevant "internal" exposure

to Cr and Co ions. This exposure should be carefully monitored, in order to clarify the biologic effects of ion dissemination and, consequently, to identify risks concerning long-term toxicity of metals.

38. Campbell, P. et al: Autopsy Analysis Thirty Years After Metal-on-Metal Total Hip Replacement. JBJS 85-A(11):2218-2222, 2003

This report describes an autopsy retrieval to assess the distribution of wear products in the tissues immediately surrounding as well as at a distance from a McKee Farrar metal-on-metal bearing total hip replacement after nearly 30 years in situ. The patient had been highly satisfied with the results of arthroplasty because her hip was free of pain and did not limit her function. Radiographs demonstrated good positioning and fixation of the implant with no evidence of loosening or osteolysis. Blood and urine samples were obtained for measuring cobalt and chromium ions. Following the patient's death in 1999, the left hip joint with surrounding acetabular and femoral bone, pseudocapsular tissue and the prosthesis were removed en bloc. Tissue samples were obtained from the liver, spleen, left kidney, left inguinal and abdominal lymph nodes, and muscle of the left thigh. Whole blood was aspirated from the bladder for analysis of ion content. Tissue analysis of the membrane present within the femoral canal revealed fibrous tissue containing histiocytes and giant cells with spaces consistent with dissolved bone cement. Capsular tissues were fibrous, with areas of adipose or necrotic tissue. A distinct inflammatory zone on the edge facing the implant contained macrophages, giant cells, blood vessels and wear particles of cobalt-chromium and polymethylmethacrylate. Lymphocytes and plasma cells were rare and polymorphonuclear leukocytes were absent. No histological abnormalities were noted in any organ samples. It was not possible to obtain serum levels of cobalt or chromium ions. The liver samples contained measurable levels of cobalt and chromium that were higher than those found in control samples. According to the authors it was difficult to assess the possible clinical implications of ion levels of cobalt and chromium in the urine, blood, and liver without validated threshold levels of toxicity, carcinogenicity, and other possible systemic effects. Studies that have examined the rates of cancer in patients who had total hip replacements, including those who had metal-on-metal prostheses, have demonstrated conflicting results, but there is a consensus that longer and broader studies need to be carried out.

39. Brodner W. et al: Serum Cobalt Levels After Metal-on-Metal Total Hip Arthroplasty JBJS 85-A(11):2168-2173, 2003

Systemic cobalt dissemination from the Metasul Co-28Cr-6Mo-0.2C metal-on-metal total hip prosthesis has been demonstrated in the first year after implantation. This study was designed to monitor the serum cobalt concentrations in patients during the first five years after total hip arthroplasty. Fifty patients were randomized to be treated with a metal-on-metal articulation and fifty with a ceramic-on polyethylene bearing. The femoral stem was made from Ti-6Al-7Nb alloy, and the threaded acetabular cup from commercially pure titanium. Blood samples were taken before the operation and at multiple time points for five years thereafter. Serum cobalt concentrations were measured with atomic absorption spectrometry. In the metal-on-metal group, the median serum cobalt

concentration was 1 µg/L at one year after surgery and 0.7 µg/L at five years. The median of the serum cobalt concentrations measured from three to twelve months did not differ from the median of subsequent measurements, with the numbers available. The median serum cobalt level in the control group of patients treated with the ceramic-PE articulation was below the detection level at all time points. In their conclusion the authors noted that systemic cobalt release was demonstrated throughout the five year study period and that median serum cobalt concentrations were found to be slightly above the detection limit and remained in a constant range. The serum cobalt concentrations did not reflect a so-called run-in wear period of the metal-on-metal articulations. The authors did not believe that routine determination of serum metal levels or routine monitoring of renal function is necessary for patients with metal-on-metal articulations. They do regard end-stage chronic renal diseases a contraindication. The authors also believe that allergy to cobalt or chromium or advanced age are reasons to avoid metal-on-metal hip replacements. They recommend informing patients that, so far, elevated serum cobalt concentrations after total hip replacement with a metal-on-metal articulation have not been linked to adverse health reactions but the effects of long-term elevation of serum cobalt levels are not yet known.

40. Lombardi, AV et al: Mid-Term Results of a Polyethylene-Free Metal-on-Metal Articulation. *J. Arthroplasty* 19(7) Supp 2:42-47, 2004

One hundred ninety-three patients (195 hips) were enrolled into this prospective, randomized, controlled multi-center investigational device exemption study. Ninety eight patients (99 hips) with 46 polyethylene liners and 53 metal liners had minimum 5-year followup (mean 5.7 years). Average followup, Harris hip score improvement, and radiographic analysis were not statistically different between groups. No stress shielding or osteolysis was observed in either group. Three polyethylene liners and no metal liners had acetabular radiolucencies >1 mm in 1 or more zones. There were no device related complications, no acetabular revisions performed, and none pending in either group. Based on these mid-term results, the authors conclude that a metal-on-metal articulation represents a viable alternative in young, high-demand, active patients. The device used was a M²a Taper Metal-on-Metal Articulation (Biomet Orthopaedics, Warsaw, IN).

41. Jacobs, M. et al: Three-to Six Year Results with the Ultima Metal-on-Metal Hip Articulation for Primary Total Hip Arthroplasty. *J. Arthroplasty* 19(7) Supp 2:48-52, 2004

One hundred seventy- one primary total hip arthroplasties were evaluated in a prospective, randomized study. Ninety-five involved a metal-backed cup with an all-metal liner and 76 involved a metal backed polyethylene cup that was used as the control. All were implanted with an S-ROM cementless femoral component with a 28-mm head. The mean followup period was 3.7 years (range 3.0-5.7). The average postoperative Harris hip score was 95.4 (range 65-100) for the metal-on-metal group and 96.1 (range 65-100) for the metal- on- polyethylene group. Radiographic results were not statistically different between the two groups. Early results show metal-on-metal articulation has been successful to date and justify continued clinical use.

42. Naudie, D et al: Metal-on-Metal Versus Metal-on-Polyethylene Bearings in Total Hip Arthroplasty. *J. Arthroplasty* 19(7) Supp 2:35-41, 2004

This is a report of a case- control study performed to investigate the hypothesis that metal-on-metal (MOM) bearings reduce the risk of aseptic component loosening when compared with metal-on-polyethylene (M-PE) bearings. Cases were identified from a computerized joint database as patients who had received a primary total hip arthroplasty using an MOM or M-PE bearing and had documented revision or radiographic loosening of the stem or cup. Multiple controls were matched to each case for gender, age, diagnosis, hospital, operation date, followup, stem type and cup design. Odds ratios were determined to identify the risk of component loosening for either bearing surface. In all, 505 cases and 1,605 controls were identified. MOM bearings demonstrated a lower risk of aseptic stem and/or cup loosening than M-PE bearings; however, this was not statistically significant.

43. Ladon, D et al: Changes in Metal Levels and Chromosome Aberrations in the Peripheral Blood of Patients after Metal-on-Metal Hip Arthroplasty. *J. Arthroplasty* 19(8) Supp 3:78-87, 2004

A prospective study was performed to investigate changes in metal levels and chromosome aberrations in patients within 2 years of receiving metal-on-metal hip arthroplasties. There was a statistically significant increase of cobalt and chromium concentrations, with a small increase in molybdenum, in whole blood at 6, 12, and 24 months after surgery. There was also a statistically significant increase in both chromosome translocations and aneuploidy in peripheral blood lymphocytes at 6, 12, and 24 months after surgery. The changes were generally progressive with time, but the change in aneuploidy was much greater than in chromosome translocations. No statistically significant correlations were found in secondary analyses between chromosome translocation indices and cobalt or chromium concentration in whole blood. Although the clinical consequences of these changes, if any, are unknown, future epidemiological studies could usefully include direct comparisons of patients with implants of different composition. A total of 95 patients with Metasul metal-on-metal total hip arthroplasty were recruited to provide data for this study.

44. Huk, OL et al: Induction of Apoptosis and Necrosis by Metal Ions *In Vitro*. *J. Arthroplasty* 19 (8) Supp 3:84-87, 2004

There has been a renewed interest in the use of metal-on-metal (MOM) implants for total hip arthroplasty. It is well known, however, that the MOM articulation generates both metal particles and ions. The physiologic effects of these ions is poorly understood and their potential toxicity remains a cause for concern. In the present study, murine J774 macrophages were incubated with Co^{2+} and Cr^{3+} ions and the mode of cell death (apoptosis/necrosis) was evaluated *in vitro* by transmission electron microscopy and cell death ELISA. Overall, results demonstrated that the mode of cell death was dependent on the ion concentration and incubation time. Indeed, at short incubation times (24 h),

the noninflammatory process of apoptosis was predominant. At longer incubation times (48h), however, necrosis was predominant at higher ion concentrations. According to the authors, the effect of metal particles and ions on remote organs beyond the hip joint is poorly understood, however, and deserves close scrutiny by the orthopaedic community.

45. Hallab, NJ et al: Immune Responses Correlate with Serum-Metal in Metal-on-Metal Hip Arthroplasty. *J Arthroplasty* 19(8) Supp 3:88-93, 2004

Cell-mediated hypersensitivity associated with metal components may be related to levels of implant debris. The authors tested this hypothesis by comparing lymphocyte reactivity to soluble Co, Cr, Ni and Ti of patients with metal-on-polyethylene and metal-on-metal arthroplasties with healthy controls, and patients with osteoarthritis. The metal-on-metal group (n=9) demonstrate significantly elevated Co and Cr concentrations (13- and 58 fold, $P < 0.5$, respectively) and significantly elevated lymphocyte reactivity to Co (SI > 5, $P < .004$) and Ni (SI > 2.5, $P < .01$) when compared to controls (n=12) and subjects with metal-on-poly implants (n=7). These elevated *in vivo* metal levels demonstrated positive linear correlation with lymphocyte reactivity supporting our hypothesis that lymphocyte metal induced reactivity increases with increased metal exposure. These results represent the first direct link between *in vivo* metal exposure and lymphocyte reactivity. Whether this lymphocyte reactivity to metal debris is etiologically linked to poor implant performance remains uncertain.

46. Long, WT et al: An American Experience with Metal-on-Metal Total Hip Arthroplasties—A Seven Year Follow-up Study, *J Arthroplasty* 19(8) Supp 3:29-34, 2004

This study reviews the clinical performance of 161 hip arthroplasties (154 patients) with the Metasul metal-on-metal articulation and an uncemented modular acetabular component. Between 1995 and 2002 clinical evaluation and radiographic follow-up of patients included Harris hip scores, patient self-assessment, and radiographs. Twelve operative site complications (7.5%) included 6 revision operations (3.7%) and 3 other complications (1.9%) not needing reoperation. Six revision operations (3.7%) included 1 femoral revision for aseptic loosening (0.06%) and 5 acetabular revisions (3.1%). One cup revision was for recurrent dislocation, 1 for disassociation of the acetabular insert from the cup, 1 for infection, and 2 for unexplained pain. Histologic evidence did not support the diagnosis of metal hypersensitivity in either case of unexplained pain, and 1 had relief following spine surgery. A focal radiolucency, identified as calcar resorption, was observed in 9 patients. Metal ion levels were not tested in patients as part of these studies. The authors note that after 40 years of use, there is no evidence that metal-on-metal articulations have been a cause of cancer. The strength of this study is that it confirms that the high incidence of early aseptic loosening has been improved with this modern metal-on-metal articular system.

47. Delaunay, CP: Metal-on-Metal Bearings in Cementless Primary Total Hip Arthroplasty. *J Arthroplasty* 19(8) Supp 3:35-40, 2004

One hundred cementless titanium primary total hip arthroplasties with 28 mm Metasul bearings were prospectively studied (osteoarthritis in 76% of hips, mean age 59.6 years). Ninety-eight were reviewed after a 6-year average follow-up (range, 17-126 months) with clinical results graded excellent and good in 97%. One femoral component was revised for aseptic loosening at 7.8 years. Postoperative cobalt level was higher than the upper "normal" value (5µg/L in whole blood) for 16 cases. No significant relationship could be established between cobalt concentration increase and any demographic or surgical data, including activity level, except anteversion of the cup >25°. In this early experience, impingement due to a head sleeve has been the main cause of dislocation and failure, and systemic cobalt survey appeared to be a good indicator of metal-on-metal bearing mechanical behavior. According to the author, the absence of detectable wear and, above all, the lack of relationships among increased cobalt level, age and high patient activity are encouraging findings for continued use of metal-on-metal bearings in young and/or active patients.

48. MacDonald, SJ: Can a Safe Level of Metal Ions in Patients with Metal-on-Metal Total Hip Arthroplasties Be Determined? *J Arthroplasty* 19(8) Supp 3:71-77,2004

The single most significant obstacle preventing a broader application of metal-on-metal hip arthroplasties continues to be the concerns regarding elevated metal ion levels in the blood and urine of patients with this bearing. A safe level for metal ions has yet to be defined for patients with metal-on-metal hip arthroplasties. A review of occupational exposure data gives some insight; however, longitudinal studies of large numbers of patients with metal-on-metal implants will ultimately be required to answer specific clinical concerns. The author notes that there can be no doubt that patients with metal-on-metal implants will be exposed to elevated levels of metal ions locally, in their blood and in their urine. The outstanding question remains the clinical impact of these elevated ion levels. According to the author, there is no conclusive evidence for a detrimental clinical effect. Furthermore, to date, from current publications there is no evidence that prolonged exposure to elevated metal ions produced from a metal-on-metal arthroplasty results in a statistically significant increase in risk of cancer development in these patients.

49. Brodner, W et al: Does the Placenta Inhibit the Passage of Chromium and Cobalt After Metal-on-Metal Total Hip Arthroplasty? *J Arthroplasty* 19(8) Supp 3:102-106, 2004

Umbilical cord serum and corresponding maternal serum of 3 women with uncemented Metasul total hip arthroplasties were analyzed for cobalt and chromium. The women were an average 3.8 (range 2-5) years after hip surgery. At the time of delivery, the maternal chromium concentrations were 1.6 µg/l, 0.5 µg/l, and 0.9 µg/l, respectively, and the maternal cobalt concentration was 1 µg/l in the first woman and below the detection limit in the other 2. Cobalt and chromium concentrations of the 3 umbilical cord sera were below the detection limit. This indicates that ---with regard to the detection limit in our laboratory---we were unable to observe a passage of cobalt and chromium ions from metal-on-metal articulations across the placenta at the time of delivery.

50. Migaud, H et al: Cementless Metal-on-Metal Hip Arthroplasty in Patients Less than 50 Years of Age. *J Arthroplasty* 19(8) Supp 3:23-28, 2004

Thirty nine cementless hip arthroplasties using metal-on-metal articulation (Metasul) were consecutively implanted in 30 patients less than 50 years of age and compared to a matched control group (by age, diagnosis, Devane activity, and Harris hip scores) of cementless arthroplasties using ceramic-on-polyethylene articulation. The Harris hip score at follow-up (minimum 5 years) for the metal-on-metal was 94.9 (range 74-100). After the same follow-up, the results with the ceramic-on-polyethylene were significantly worse; 9 osteolyses and 7 surgical revisions related to wear (none in the metal-on-metal). Five year survival rates were 97% \pm 2% for the ceramic-on-polyethylene and 100 % for the metal-on-metal. The metal-on-metal may be recommended to prevent wear problems in younger and more active patients; however, a longer follow-up is required to confirm this encouraging data.

51. Campbell, P et al: Biologic and Tribologic Considerations of Alternative Bearing Surfaces. *Clin Orthop* 418:98-111, 2004

Patients who are young or active or both who require total joint replacement pose a unique challenge; their high activity demands wear-resistant bearings that will perform for decades, without suffering from the adverse effects of accumulated wear products. The authors discuss the tribologic and biologic properties of newly introduced bearing materials for hip prostheses. The new polyethylenes (PE) are intended to address the aseptic loosening problem by reducing the volume of submicron PE particles to a level well below that historically associated with osteolysis. However, choosing among the several variations of the cross-linked thermally stabilized PEs is confounded by conflicting opinions regarding the optimum balance between long-term wear resistance and mechanical strength, and regarding potential effects of differences in morphologic features of the submicron-sized wear particles on their relative osteolytic potential. Metal-on-metal bearings have clinically proven wear resistance and the advantage of self-polishing, but the long-term biologic effects of metallic ions remain unknown. Ceramic-on-ceramic bearing have the advantage of high biocompatibility and usually very low wear, but fracture remains a rare but catastrophic complication. The choice of an appropriate bearing couple should be made after a thorough consideration of the relative risks and potential benefits of each of these materials.

52. MacDonald, SJ: Metal on Metal Total Hip Arthroplasty. *Clin Orth* 429:86-93, 2004

According to the author, metal on metal bearings are having a resurgence in clinical applications for total hip and knee resurfacing technologies. The most noteworthy advantage is the improved wear characteristics seen in vitro on wear simulators and in vivo with retrieved implants. All bearings have disadvantages, and a metal-on-metal bearing is no exception. Concerns exist regarding the generation of metal ions seen in the blood and urine of patients. These elevated metal ions have theoretical, although not

proven, risks related to carcinogenic and biologic concerns. Additionally, concerns exist regarding hypersensitivity, increased incidence of instability and increased costs. Specific patient selection issues arise with metal-on-metal implants. The current generation of implants has only early and mid-term results available, with no long-term series yet published. Therefore, although a metal bearing may be considered a viable alternative to either polyethylene or ceramic implants, outstanding and unresolved issues continue to exist with this bearing, as they do with the alternatives.

53. Davies, AP et al: An Unusual Lymphocytic Perivascular Infiltration in Tissues Around Contemporary Metal-on-Metal Joint Replacements. *JBJS 87-A (1):18-27, 2005*

Tissue samples obtained from hips with metal-on-metal implants displayed a pattern of well-demarcated tissue layers. A prominent feature, seen in seventeen of twenty five tissue samples, was a pattern of perivascular infiltration of lymphocytes. In ten of the tissue samples obtained from hips with metal-on-metal prostheses, there was also an accumulation of plasma cells in association with macrophages that contained metallic wear debris particles. The surfaces of tissues obtained from hips with metal-on-metal prostheses were more ulcerated than those obtained from hips with other types of implants, particularly in the region immediately superficial to areas of perivascular lymphocytic infiltration. The lymphocytic infiltration was more pronounced in samples obtained at the time of revision because of aseptic failure than in samples retrieved at the time of autopsy or during arthrotomy for reasons other than aseptic failure. Total joint replacement and surface replacement designs of metal-on-metal prostheses were associated with similar results. Tissue samples obtained from hips with metal-on-polyethylene implants showed far less surface ulceration, much less distinction between tissue layers, no pattern of lymphocytic infiltration, and no plasma cells. The inflammation was predominantly histiocytic. Tissues retrieved from hips undergoing primary joint replacement showed dense scar tissue and minimal inflammation. The pattern and type of inflammation seen in periprosthetic tissues obtained from hips with metal-on-metal and metal-on-polyethylene implants are very different. At the present time, the authors do not know the prevalence or clinical implications of these histologic findings, but suggest that they may represent a novel mode of failure for some metal-on-metal joint replacements.

54. Dorr, LD et al: The Argument for the Use of Metasul as an Articulation Surface in Total Hip Replacement. *Clin Orth Rel Res 429:80-85, 2004*

Metasul metal-on-metal articulations have been used for 15 years in approximately 300,000 total hip replacements. The authors have used Metasul articulations in three clinical studies and have shown clinical success as measured by Harris Hip Scores and patient self-assessment. The authors have noted the usual mechanical complications. The only complications have been mechanical, including two cup loosening and 24 dislocations in a total of 582 patients (619 hips; 3.8%) who had Metasul articulations and were included in these studies. In the randomized study, the group who had Metasul articulations had no clinical results or complications different from the control ceramic-

on-polyethylene group. Authors of retrieval results in the literature report low annual linear wear rates and no consequences of elevated Co ion levels. Currently, the scientific evidence of the results using the Metasul articulation would recommend its continued use in any patient who does not have compromised renal function.

55. Dumbleton, JH and Manley, MT: Metal on Metal Total Hip Replacement-What Does the Literature Say? *J. Arthroplasty* 20(2):174-187, 2005

Second generation metal-on-metal (M/M) total hip replacements were introduced into clinical use in the late 1980s and demonstrate equivalent survivorship to conventional metal-on-polyethylene prostheses. Wear rates are comparable to those of first generation designs that survived for a long time in the body. Biological effects from metal ions remain a concern. Patients with both first and second generation M/M hips have higher levels of cobalt and chromium in their blood and urine than either patients with metal-on-polyethylene devices or unoperated patients. Concerns include the potential for acquired hypersensitivity, mutagenicity, and carcinogenicity. However, reports of proven adverse effects are scant. Prospective, randomized trials with follow-up in excess of 15 years will be needed to differentiate between the performance and effects of M/M and other bearing combinations. According to the authors, the literature does not address the long-term risks with M/M bearings. It appears reasonable to assume that the biological risk is higher than for metal-on-polyethylene, ceramic-on-polyethylene, or ceramic-on-ceramic bearings because of a demonstrated higher level of metal ion release. It also appears reasonable to assume that the risk increases with time of implantation.

56. Park, Y-S et al: Early Osteolysis Following Second Generation Metal-on-Metal Hip Replacement. *JBJS* 87-A (7):1515-21, 2005

The authors analyzed 165 patients (169 hips) who had undergone primary cementless total hip replacement with a contemporary (Ultima-DePuy) metal on metal bearing cup design between 2000 and 2002. After a minimum duration of follow-up of 23 months, nine patients (10 hips) had an osteolytic lesion localized to the greater trochanter. Skin patch tests for hypersensitivity to metals were performed on the nine patients and on nine randomly selected patients with total hip replacements who did not have osteolytic changes and who were matched to the study cohort for age and gender. Microbiological cultures, histopathologic examinations, and immunohistochemical analysis were performed on samples of periprosthetic tissue that were collected during revision arthroplasty on two hips with early osteolysis. The patients with early osteolysis had a significantly higher rate of hypersensitivity reaction to cobalt compared with controls ($p=0.031$). The retrieved periprosthetic tissues showed no evidence of metallic staining, but histologic analysis revealed a perivascular accumulation of CD3-positive T-cells and CD68-positive macrophages and an absence of both particle-laden macrophages and polymorphonuclear cells. Immunohistochemical analysis demonstrated that bone-resorbing cytokines such as IL-1 β and TNF- α were produced mainly by infiltrating lymphocytes and activated macrophages. According to the authors, these findings raise the possibility that early osteolysis in patients with this second generation metal-on-metal hip replacement is associated with abnormalities consistent with delayed-type

hypersensitivity to metal. A prospective study in which a large group of patients is evaluated with multiple diagnostic methods is needed in order to establish whether there is a causal relationship between metal hypersensitivity and osteolysis.

57. Clarke, MT et al: Long-Term Clinical, Radiological and Histopathological Follow-Up of a Well-Fixed McKee-Farrar Metal-on-Metal Total Hip Arthroplasty. *J. Arthroplasty* 20(4):542-6, 2005

The authors present a unique postmortem case of a well-fixed metal-on-metal, McKee-Farrar total hip arthroplasty implanted 30 years previously that was clinically asymptomatic in life. The total hip arthroplasty was found to be well fixed without evidence of loosening, wear particle formation or adverse tissue reactions. Although a full tribological bearing analysis of this retrieval was hindered by the lack of pre-implantation measurements, the data available would support a low estimated linear wear rate of less than 2 μ m per year. This wear rate is in agreement with data from in vitro simulation where large diameter MOM bearings have achieved similar wear rates under a variety of simulator conditions. For contemporary MOM bearings, a deviation from roundness of less than 10 μ m, surface roughness less than 0.05 μ m and diametric clearance between 50 and 250 μ m are considered desirable. This case highlights the observation that when the tribological conditions are met, MOM bearings are tolerated by the host and can function for long periods with little wear.

CDs Received

WITS Entry

1 CD with entire submission

1CDDT

CDS with entire submission

XCDDT

1 CD with each copy of submission

1CDPC

CDS with each copy of submission

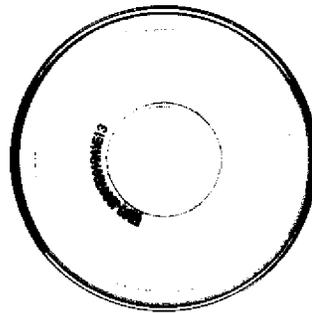
XCDPC

Check here if CDs were bound into volume(s) XCDDTB - XCDPCB

Letter Stated CD(s) - NO CDs found in Packaging LSCD - NO CDs

True Electronic Submission (E-Sub) - w/proper cover letter stating so ESUB 1/X - 1 or X CDs

**510(k) Notification-Traditional
Durom Acetabular Component and
Metasul LDH Large Diameter Heads
December 16, 2005**



LiveLink/Regulatory Affairs/Submission Master/Zimmer OmBNK-XXXXXXXX 2005-12-16 001.01 Initial Submission/4:00 p.m.



ZIMMER
P.O. Box 708
Warsaw, IN 46581-0708

Thanks!

- Peter Allen Ram 330 W

Due Out
Day 90
3/17/06

Zimmer GmbH
C/O Laura D. Williams, RAC
Manager, Corporate Regulatory Affairs
Zimmer, Inc.
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K053536

Trade/Device Name: *Durom*[®] Acetabular Component and *Metasul*[®] LDH[™] Large Diameter Heads

Regulation Number: 21 CFR 888.3330

Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis

Regulatory Class: III

Product Codes: KWA

Dated: December 16, 2006⁵

Received: December 19, 2005

Dear Ms. Williams:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

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

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ- 410 Division
D.O.
f/t:PAllen: :00-00-05

6

From: Reviewer(s) - Name(s) Peter Allen

Subject: 510(k) Number K053536

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

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

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

- Truthful and Accurate Statement Requested Enclosed
- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices (p. 255)
- The indication for use form

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

Animal Tissue Source YES NO Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):
 No Confidentiality Confidentiality for 90 days Continued Confidentiality exceeding 90 days

Predicate Product Code with class: KWA, 888.3330, III Additional Product Code(s) with panel (optional):

Review: [Signature] GTDB 3/15/06
(Branch Chief) (Branch Code) (Date)

Final Review: [Signature] 3/16/06
(Division Director) (Date)

510(k) MEMORANDUM

TO: K053536
FROM: Peter G. Allen, Biomedical Engineer
ODE/DGRND/Orthopedic Joint Devices Branch
DATE: March 13, 2006
SUBJ: **Durom[®] Acetabular Component and Metasul[®] LDH[™] Large Diameter Heads**
Product Code: KWA, 21 CFR 888.3330 – hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis; Class III
Firm: Zimmer GmbH (submission sponsor)
Contact: Laura D. Williams, RAC, Manager Corporate Regulatory Affairs, Zimmer Inc. (submission correspondent for Zimmer GmbH)
Phone: (574) 372-4523 Email: laura.williams@zimmer.com Fax: (574) 372-4605

Recommendation: Based on the similarities in intended use, materials, design, and method of fixation, I recommend that the subject device be found substantially equivalent (SE) to other legally marketed predicate devices.

Review:

1. Administrative Requirements:

Notification contains a 510(k) Summary, Truthful and Accuracy Statement, and Indications for Use page.

In accordance with 21 CFR 807.94 and 807.87(j), a Class III Certification and Summary was included in Exhibit L. In order to fulfill the requirements of this part, Zimmer conducted a review of international complaints received for the *Durom* Acetabular Cup and the *Metasul LDH Large Diameter Heads*, which have been sold internationally since September 2003. An estimated (b)(4)

(b)(4)

included excerpted information from the Metal-on-Metal Hip Reclassification petition submitted to FDA by the Orthopedic Surgical Manufacturers Association (OSMA) in September 2005. This includes a summary of published and unpublished clinical results, and medical device reports and adverse events from the literature.

EXPLANATIONS TO "YES" RESPONSES TO QUESTIONS 4, 6, 8, and 11 AND EVERY "NO" RESPONSE ON THE "SE" DECISION MAKING CHECKLIST AS NEEDED:

Questions 4, 6, and 8 are not applicable. See SE Decision Making Checklist.

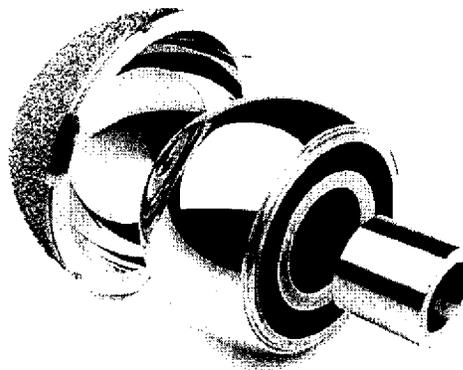
7. *Are the descriptive characteristics precise enough?* No. Testing with an analytical analysis of the effect of the new sizes must be performed to demonstrate equivalence to predicate devices.
10. *Are performance data available?* Yes. Testing was provided.
11. *Data Demonstrate Equivalence?* Yes. Testing demonstrates that the subject femoral heads and acetabular components should perform as intended and are comparable to marketed predicate devices.

2. **Device Description:**

The *Metasul*® *LDH*™ Large Diameter Head System consists of a *Metasul* large diameter femoral head, a metal *Durom*® acetabular component and a neck adaptor (Figure 1).

The *Metasul LDH* System is designed to reduce the potential for postoperative impingement and dislocation. The large femoral head coupled with the reduced hemisphere of the *Durom* cup naturally increases range of motion (ROM). By maximizing ROM and increasing the distance that must be overcome prior to dislocation, large diameter femoral head systems have been shown to increase the stability and decrease impingement of the replaced hip joint. Like the predicates, the metal *Durom* acetabular component articulates with the *Metasul* femoral head, resulting in a metal-on-metal articulation. It has also been reported that metal-on metal articulation with large diameter heads *may* produce decreased wear rates.

Figure 1. *Metasul LDH* and *Durom* Acetabular Cup System



Component Design

The components of the *Metasul LDH* System have been designed for ‘optimum wear performance’.

○ **Material**

Chemical composition and material processing have a significant impact on the wear performance of metal-on-metal bearings. The articulating surfaces of the *LDH* femoral heads and the *Durom* acetabular cup are wrought, high carbon alloys – CoCrMo alloy conforming to ISO 5832-12 (trade name of *Protasul*®-21 WF). The head/neck adaptors are manufactured from a wrought, low carbon CoCrMo alloy (trade name *Protasul*-20) also conforming to ISO 5832-12.

The chemical composition of the commercially pure titanium powder to be vacuum plasma sprayed on the *Durom* Acetabular component conforms to ISO 5832-2, and ASTM F67 grade 4. The vacuum plasma sprayed coating was also verified by EDX to be cp Ti. This is a *new* coating for Zimmer products (trade name *Porolock*™ Titanium Vacuum Plasma Sprayed [Ti VPS] coating).

○ **Sphericity & Surface Finish**

Sphericity and surface roughness are also parameters which influence the wear behavior of metal-on-metal bearings. A high degree of sphericity in metal-on-metal articulation results in

uniform clearance between the head and cup, while low surface roughness minimizes frictional torque and improves lubrication, resulting in lower wear. The *LDH* femoral head is precision manufactured to tightly-controlled sphericity ($<10 \mu\text{m}$) and surface finish ($R_a \leq 0.006 \mu\text{m}$) specifications to minimize wear.

o **Diametral Clearance**

The clearance between the head and the cup – also a key parameter in metal-on-metal articulation – has been chosen based on wear simulator testing. It has been shown that decreasing diametral clearance results in reduced contact stresses and wear; however, the clearance must be adequate to allow lubrication and avoid clamping – a condition in which equatorial loading of the head occurs as a result of deformation of the acetabular component. The diametral clearance between the *LDH* femoral heads and the *Durom* cup is size-dependent – the larger diameter bearing surfaces have larger clearances – and ranges from 120 to 250 microns. The following table depicts the range of diametral clearances for each diameter of head/acetabulum. Ranges are based on the minimum and maximum tolerances specified for the diameters of the femoral head and acetabular articulating surfaces. I discussed this method of diametral clearance calculation with Beth Frank a reviewer in OJDB, who is currently working on the metal-metal reclassification petition, and she confirmed that this way of determining these values is consistent with what she has seen in other metal-metal submissions, as well as the petition.

Table 1: Diametral clearance ranges for *Metasul Durom* Cup and *Metasul LDH* head pairing

Diameter (mm)	Diametral Clearance Range (min. – nominal – max.) (μm)
38 – 56	(b)(4)
58	
60	

These values fall within the range of diametral clearances identified for the predicate devices (K042037-Biomet, K021349-WMT), which range from 90 - 300 μm for similarly sized components.

Metasul LDH Large Diameter Head and Head/Neck Adaptor

The *Metasul LDH* large diameter head is modular (two-piece) in design, and consists of a large diameter femoral head and a head/neck adaptor. The head is manufactured from CoCrMo alloy (*Protasul*® 21 WF), and has an internal 18/20 taper which mates with the head/neck adaptor.

The head/neck adaptor is also manufactured from CoCrMo alloy (*Protasul-20*), and is available in four sizes to allow neck length variation from -4, 0, +4, and +8mm. The inner taper of the head/neck adaptor is a standard 12/14 taper, and mates with any *Zimmer* femoral stem which incorporates a 12/14 taper (see Exhibit C).

The *Metasul LDH* head is an extended hemisphere which, in combination with the *Metasul Durom* acetabular component, allows a higher range of motion than smaller femoral heads. The large diameter head is available in 12 sizes with outer diameters (O.D.) ranging from 38 to 60mm. Head sizes 38mm to 48mm have a solid construction, while sizes 50mm to 60mm are partially hollowed out to reduce implant weight. These head sizes are similar to the predicate Biomet and WMT devices (maximum of 60mm and 54mm, respectively).

11

Durom Acetabular Component

Like the natural acetabulum, the *Metasul Durom* acetabular component is a reduced hemisphere (165°), which promotes maximum range of motion and preservation of natural acetabular bone stock. Due to the large size of femoral heads and reduced hemisphere design of the acetabular cup the *Metasul LDH* with *Durom* Acetabular components, depending on size, have a range of motion (ROM) of between 144° and 168°. This maximum value is slightly greater than that of the identified large head metal-metal predicates from Biomet and WMT (163° and 167°, respectively).

The *Durom* Acetabular component is monoblock in design – fabricated from a single piece of metal – and is available in 12 sizes, ranging from 44 to 66mm O.D. in 2mm increments. The wall thickness of the acetabular component is 4mm for all sizes. This measurement includes the plasma sprayed coating; the substrate itself is (b)(4) thick. This thickness is intended to allow for minimal bone removal, yet to maintain adequate implant strength. It is noted that sizing nomenclature does not exactly match the diameters of the acetabular components, e.g., the O.D. of the ‘66mm’ cup is actually 67.4mm without the coating, 68.1mm with the coating.

The acetabular component is a high-carbon CoCrMo alloy (*Protasul 21 WF*) monoblock cup with a plasma sprayed commercially pure titanium coating (*Porolock™ Ti VPS*) on the outer surface. The articular surface is highly-polished for minimum wear, with a maximum surface roughness of .006 microns.

The *Durom* acetabular component was designed to be implanted without cement. Primary fixation of the acetabular component is achieved via a 2mm press-fit, circumferential fins and high surface roughness. The surface roughness (R_a) of the Ti VPS coating is (b)(4), and the fins have an oversize of 0.5mm. The average coating thickness is (b)(4), average coating porosity is (b)(4) and average pore size is (b)(4). It is noted that the Zimmer specification for coating thickness is (b)(4) FDA’s requirement of 500 – 1500 μm for a porous coating (see 21 CFR 888.3358). Their specification for percentage porosity is (b)(4) which is below FDA’s minimum value of 30%. In addition, their average pore size (b)(4) FDA’s average pore size requirement of 100 – 1000 μm . (b)(4) which is also required for a ‘porous coating’ determination. Therefore, this coating does not qualify, according to FDA requirements, as a truly ‘porous coating’. According to the sponsor, “long-term secondary fixation is achieved by bone ingrowth into the *Porolock* Ti VPS porous coating on the outer surface of the cup”. It is noted that the original package insert did not include this claim of bone ingrowth but *did* include reference to biological fixation. Since this coating is not actually a porous coating as defined by 21 CFR 888.3358 (metal/poly/metal porous coated hips for uncemented use), and they have not demonstrated equivalence to a coating that was cleared under this regulation (i.e., animal data or clinical data), they will not get to make a claim of biological fixation, either. The rationale for this decision was discussed and confirmed by John Goode, acting branch chief of OJDB.

Compatible Femoral Stems

The *Metasul LDH* femoral heads and neck adaptors are designed for use with any Zimmer 12/14 taper femoral stem. A list of compatible femoral stems, with their 510k numbers, is included in Exhibit C.

3. **Intended Use:**

The indications for use for the *Durom* Acetabular Component and *Metasul LDH* Large Diameter

Heads are:

- Patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis.
- Those patients with failed previous surgery where pain, deformity or dysfunction persists.
- Revision of a previously failed hip arthroplasty.

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

4. **Sterilization:**

Device is provided Sterile

Method: 25 - 40 kGy (2.5 – 4.0 Mrad) of gamma radiation from a Co 60 source

Sterility validation method: ANSI/AAMI/ISO 11137-1994 “Sterilization of health care products – Requirements for validation and routine control - Radiation Sterilization”, also EN 552.

Sterility assurance level: 10^{-6}

Pyrogenicity: no claims made, per USP XXVII, requirements for specified endotoxin levels do not apply to orthopedic implants.

Description of packaging: Acetabular components are vacuum packaged in double peelable pouches of polyamide/polyethylene, followed by a third non-peelable polyamide/polyethylene pouch. The unit is then placed into a corrugated paperboard ‘drawer’ and ‘sleeve’. The heads are double packaged in a rigid, transparent injection molded styrene inner tray then an outer thermoformed tray of PETG. The lids of both trays are spun bonded Tyvek 1073 PE. The unit is then placed into a corrugated paperboard ‘drawer’ and ‘sleeve’.

Recommended re-sterilization method: various components may be re-sterilized by steam, ethylene oxide, and/or STERRAD gas plasma methods (specific guidelines, e.g. concentration, time, temperature, etc., are given in the package insert).

Sterility validation method: An SAL of 10^{-6} was verified for each method. AAMI TIR 12 was used as the reference document for all three methods.

5. **Labeling:**

Labeling in the form of draft package labels, and a package insert were provided. Individual package inserts were provided for femoral stems, acetabular cups, and modular femoral heads. Package labels were provided for femoral heads, acetabular components, and neck adaptors. They contain all necessary information and are acceptable. The package label for the *Durom* Acetabular component specifically refers to the device as the *Metasul Durom* Acetabular Component and further denotes it as a component of the *Metasul* system. This is good, as the package insert for modular femoral heads specifically says that for metal/metal use the *Metasul* femoral heads must only be used with a *Metasul* cup.

It is noted that the original package insert included reference to biological fixation. Since this coating is not actually a porous coating as defined by 21 CFR 888.3358 (metal/poly porous coated hips for uncemented use), and they have not demonstrated equivalence to a coating that was cleared under this regulation, they do not get to make a claim of biological fixation. The sponsor was advised of this in an email of 3/2/06. In the sponsor’s reply email of 3/12/06 the sponsor provided a revised package insert that removed the reference to biological fixation.

6. **Testing:**

The sponsor has conducted characterization testing of their *Porolock*TM Ti VPS coating including a morphological characterization as well as physical testing. They have also performed testing to evaluate the connection strength of the ball head adapter, compatibility of the LDH femoral heads with Zimmer 12/14 taper stems, stiffness (FEA) of the Durom Acetabular component, and in-vitro friction and wear characterization of the metal/metal articulation, and FEA of larger cups (58/64, 60/66).

Testing of Metallic Plasma Sprayed Coating

Mechanical Properties of Ti-VPS Coating on the Durom Cup were investigated in accordance with FDA's *Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements*, dated February 2, 2000. The following results meet FDA minimum specifications:

- o The static tensile strength is (b)(4)
- o The static shear strength is (b)(4)
- o The estimated fatigue shear strength is (b)(4)
- o A cumulative mass loss of (b)(4) was observed

A complete test report is included in Exhibit K.

Morphological Properties of Ti-VPS Coating on the Durom Cup were also evaluated in accordance with FDA's *Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements*, dated February 2, 2000. The results, which were revised in an email from the sponsor on 3/12/06, are as follows:

- o Average surface roughness Rz of the coating is (b)(4)
 - o The average coating thickness is (b)(4)
 - o The average coating porosity is (b)(4)
 - o The average pore size is (b)(4)
 - o SEM pictures were taken and confirm the uniform and rough appearance of the surface
 - o The chemical composition of the coating powders is corresponds to ISO 5832-2 and ASTM F67 grade 4 commercially pure titanium (cp-Ti).
 - o The chemical composition of the coating was verified by EDX analysis to be pure Titanium
- A complete test report is included in Exhibit K (and updated in the email of 3/12/06).

The sponsors proposed plasma sprayed coating fails to meet *all* FDA requirements outlined in 21 CFR 888.3358 for a porous coating that is intended for biological fixation, as highlighted above, and the coating has not been demonstrated to be equivalent to a predicate device in terms of morphological properties, or in its ability to allow for biological ingrowth (i.e., animal or clinical studies). Since the sponsor has not demonstrated either of these, they have revised, at FDA's request, appropriate parts of their submission to remove reference to the terms 'porous' coating and 'biological fixation' (i.e., labeling, 510k Summary, etc.).

In response to our request for additional information the sponsor identified predicate Zimmer devices that have titanium alloy powder 'porous' plasma sprayed coatings that were found SE under the LPH product code (888.3358). A comparison follows:

A comparison of the key parameters:

Parameter	FDA Specs*	Proposed Durom Cup	M/L Taper Hip Prosthesis (K032726)	ZMR Porous Revision (K994286)
Static Shear, MPa	>20	(b)(4)		
Shear Fatigue, MPa	None			
Static Tensile, MPa	>22			
Abrasion Resistance (Taber Abrader - mg cumulative mass loss)	<65			
R _a , microns	None			
Thickness, microns	500 – 1500 (888.3358)			
Porosity, percent	30 – 70 (888.3358)			
Pore Size, microns	100 – 1000 (888.3358)			

* Except where noted these values are from FDA's *Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements*

(b)(4)

As noted in the Device Description section above, Zimmer's *specifications* for the subject coating do not meet with FDA requirements for these morphological properties. As it currently stands, the sponsor will not be able to get the clearance under a porous coating/biological fixation regulation. They may receive clearance for uncemented use only, i.e. 21 CFR 888.3330.

Compatibility of Metasul LDH Femoral Heads with Zimmer-Warsaw 12/14 Taper Stems

(b)(4) Metasul LDH large diameter femoral heads were mated with corresponding head/neck adapters to Zimmer-Warsaw 12/14 taper titanium alloy femoral hip stems to evaluate anatomic fatigue performance, post fatigue interface distraction strength, and fretting fatigue characteristics. Tests were conducted at Zimmer Warsaw. The XL +8mm head/neck adapters were used in testing as they represent the largest available offset, and they have the smallest surface contact with the femoral head. All samples completed (b)(4) fatigue cycles with no fractures at (b)(4) peak loading (b)(4). The average distraction force of the head and head/neck adaptor from the stem was (b)(4). Sponsor claims this compares favorably to other distraction force testing of Zimmer femoral heads on titanium alloy tapers (b)(4). No fretting debris was observed. This test demonstrates that the Metasul LDH femoral heads and head/neck adaptors are compatible with Zimmer-Warsaw 12/14 taper femoral stems.

For comparison the Z – Series Modular Total Hip System and OMEGA II Modular Hip Stems from OTI (K032729, K984227) had disengagement loads of 606 to 1517 lbs. Tests were also conducted after fatigue testing of these components.

A complete test report is included in Exhibit K.

Experimental Investigation of the Connection Strength of the Ball Head Adapter

This testing was conducted to investigate the strength of the connection between the femoral head, the head/neck adaptor, and Centerpulse stem tapers. The pull-off and torque-off values were compared to those for the head/stem connection of the legally marketed predicate (K033634), and were found to be acceptable. Tests were conducted (b)(4) components at Centerpulse Orthopedics in Winterthur Switzerland (January, 2004) using a slightly different pull-off method than in the above test. Results demonstrated average pull-off strength (b)(4) lbf for the ball head and head/neck adapter from the stem taper (b)(4) and a force (b)(4) for the head from the head/neck adapter (b)(4). Results were better than for comparable testing using (b)(4) head on a titanium alloy stem (K033634), which averaged (b)(4). Additional testing to remove the remaining 5 head/neck adapters from their stem tapers averaged (b)(4).

Torque off moments between the head/neck adapters and the Centerpulse stem tapers revealed an average moment of (b)(4). This was comparable to the 28mm heads (b)(4) (b)(4) moment. This is as expected (i.e., a larger head would require less torque to loosen due to the larger moment arm).

A complete test report is included in Exhibit K.

In-vitro Friction and Wear Characteristics of Large Diameter Metal-on-Metal Articulations

In-vitro testing was conducted to demonstrate that the technological characteristics of the *Metasul LDH* system do not affect safety and effectiveness as compared to the predicate devices. The clearance effect on wear of 38 – 56mm metal-on-metal articulations was evaluated using two existing designs, (b)(4) and a *Durom* prototype (54 & 56mm). The *Durom* prototype cup had a CoCr wall thickness (b)(4). The CoCr wall thickness of (b)(4) cups, (b)(4), respectively, was thinner than the *Durom* prototype. Hence, a worst case scenario regarding the potential cup deformation interfering with clearance was included in this study. The CoCr wall thickness of the *Durom* cup was increased by 1 mm over these designs to reduce the potential for cup deformation. Also, the femoral heads tested with all three of these acetabular devices had a sphericity of 40 µm, whereas the *Metasul LDH* heads have a sphericity of less than 10 µm. An improvement in the sphericity will improve wear performance; therefore, the tested prototype represents a worst case component. With these changes, the new clearance range could be reduced to 120 – 220 µm.

In the wear study, diametral clearances from (b)(4) were tested on an AMTI (b)(4) hip simulator for 5 million cycles for 38mm, 50mm, 54mm and 56mm components. The wear results are shown in Figure 2 on page 22 of the submission. For all clearances and diameters evaluated, a running-in wear was observed. After the running-in wear, no measurable wear was observed. There was good correlation (b)(4) between the clearance and the amount of running-in wear. In addition, there was good correlation (b)(4) between the clearance and the number of cycles required to reach the steady-state wear, i.e., lower clearances required less cycles to reach steady-state wear. In contrast, neither the diameter nor the cup thickness appeared to have an influence on wear. These wear results suggested that clearance had the dominant effect on wear, i.e., a lower clearance resulted in lower wear. Figure 3 on page 23 of the submission shows the wear simulator results compared to the data from existing *Metasul* 28mm and 32mm retrievals (K033634). The comparison suggested that a diametral clearance of less than 260 µm was desirable for consideration in the final design of the *Durom* cups.

Frictional torque measurements were carried out by (b)(4) to verify the friction characteristics in the final design of *Durom* cups. *Durom* components with head diameters of 38 to 54mm and clearances ranging from (b)(4) were examined. The frictional torque results were compared to data collected from the *Metasul* Alpha 32mm system and the comparison suggests that no significantly higher frictional torque is associated with the *Durom* Cups. In general, a decrease in the frictional torque with increasing clearance was seen. When clearance was held constant frictional torque values exhibited a slightly increasing trend with the head diameters, however, these values were still quite similar to the data for the *Metasul* Alpha 32mm couples. For example, with a constant clearance of 120 µm (i.e., lowest clearance therefore worst case), the *Durom* 38 – 46mm cups exhibited significantly less frictional torque, the 50mm cups slightly less (but not significantly), and the 54 mm cups slightly higher (although not significantly).

Clinical Retrievals of (b)(4)

(b)(4)

retrievals. It was found that a lower clearance resulted in less linear wear in the first year in-vivo, presumably still in running-in wear phase while under sub-optimal clinical conditions (see Figure 4 on page 24 of the submission). These results supported the findings from the AMTI hip simulator testing.

Durom Acetabular Component – Stiffness Evaluation

Additionally, two diameters, 58/64mm and 60/66mm (I.D./O.D.)*, not included in the previous testing were included in the final design of the *Durom* cup. The newly added sizes would be subject to additional deformation resulting in decreased clearance, since hemispherical cups with a constant wall thickness of 4 mm tended to be more flexible at larger diameters. Due to the diameter increase in these two sizes, an additional finite element analysis (FEA) was performed to estimate the amounts of clearance increase required. The (b)(4) results showed noticeable increases in the *Durom* cup deformation with the larger diameters when under the same contact load. The deformation increased by (b)(4) in size 58/64 and (b)(4) the largest size 60/66 compared to the reference size 54/60. Therefore, the sponsor included additional amounts of clearance in the two larger sizes to accommodate for the increased deformation. The diametral clearances for these two cups included the same (b)(4) safety factor as that applied to all other cup diameters.

* Although the stated I.D./O.D. appears to show a difference of 6mm, and hence a wall thickness of 6mm, which differs from the stated thickness of 4mm, this is not actually the case. These numbers (I.D./O.D) are approximations provided for sizing nomenclature only. The total wall thickness is 4.0mm, with the substrate (b)(4) and the plasma sprayed coating (b)(4) thick.

7. **Sponsor's information in support of SE:**

K042037, M²A Magnum System, Biomet Inc.
K021349, Metal TRANSCEND System, Wright Medical Technology
K033634, *Epsilon Metasul* System, Centerpulse Orthopaedics (now owned by Zimmer)
K032726, Zimmer M/L Taper Hip Prosthesis, Zimmer Inc.
K994286, ZMR Hip System Porous Revision, Zimmer Inc.

8. **Review of other 510(k)s for SE:**

K032729, Z – Series Modular Total Hip System, OTI
K984227, OMEGA II Modular Hip Stems, OTI

9. **Summary:**

Based on the similarities in intended use, materials, design, sizes, method of fixation, and test results; I recommend that the subject device be found substantially equivalent (SE) to other appropriate legally marketed predicate devices.

10. **Contact History/Requests for More Information:**

3/12/06 – The sponsor sent in a revised package insert and 510k Summary as previously requested. The revised documents remove mention of the terms ‘porous’ coating and ‘biological fixation’. In addition, the sponsor provided a revised test report for the *Morphological Properties of Ti-VPS Coating on Durom Cup*, which was originally included in Exhibit K. The revised report addresses the questions raised by this reviewer in my email of 3/8/06, regarding stated morphological properties. The sponsor agreed that an error had been made in reporting the percentage porosity in the text of the report as well as elsewhere in the 510k submission. But the original value in the raw data table was correct. In addition, they noted that errors were made in calculating standard deviations provided in the report. As a result, they submitted an updated version of the report with appropriate corrections. This information adequately addresses the deficiencies identified by this reviewer. No additional information is necessary. I recommend SE.

3/10/06 – The sponsor sent via email an article that they suggested demonstrated an animal study results comparing the histomorphometric evaluation of bone ingrowth in a very similar plasma sprayed ‘porous’ coating to other legally marketed porous coatings. The sponsor felt this information might demonstrate the ability of the subject coating to support ‘biological fixation’. However, after in-depth review of the article and the references cited in the article, this reviewer came to the realization that what the authors were talking about was not ingrowth but surface *ongrowth*. And when they referred to porosity of an implant, what they were referring to, and evaluating, was surface porosity (i.e., surface roughness), not internal interconnecting bulk porosity. This latter type of porosity is what we need to see evaluated for purposes of making a porous coating / biological fixation determination. Therefore, I phoned the sponsor and informed them that this information was not sufficient to make that determination, and that in order to grant an SE for this submission (for uncemented use) they would need to make the previously requested changes to the package insert and 510k Summary.

3/8/06 - I had a question regarding the average percent porosity for this coating that was cited in this submission and in the sponsor’s email of 3/7 (see below). In particular the average coating porosity (%) cited in the submission was stated to be (b)(4). However, the raw test results listed on page 189 do not confirm this value as the overall average value for (b)(4) samples evaluated is shown to be (b)(4) (see last row at bottom of table on p. 189). I just wanted to point that out and see if I was missing something, or if this (b)(4) was just an error on the sponsor’s part.

3/7/06 – The sponsor sent an email with updated sections to the 510k that included the two new porous coated predicates (i.e., 510k Summary, Substantial Equivalence section, predicate comparison table). Both predicates were cleared under procode LPH, and 21 CFR 888.3358. (b)(4)

(b)(4)

(b)(4)

The subject coating meets none of the requirements, but the sponsor claims the coating characteristics are ‘similar’ to the predicates. I did not place the submission on hold while I evaluated this additional information. See their response below.

The Ti porous coating on the proposed device is comparable to the Ti alloy porous coating on the following legally marketed devices:

1. Zimmer M/L Taper Hip Prosthesis, K032726, cleared October 22, 2003.
2. Zimmer ZMR® Hip System Porous Revision, K994286, cleared March 10, 2000.

Below please find a comparison of the key parameters:

Parameter	Proposed Durom Cup	M/L Taper Hip Prosthesis (K032726)	ZMR Porous Revision (K994286)
Static Shear, MPa	(b)(4)		
Shear Fatigue, MPa	(b)(4)		
Static Tensile, MPa	(b)(4)		
Abrasion Resistance (Taber Abrader - mg cumulative mass loss)	(b)(4)		
R _a , microns	(b)(4)		
Thickness, microns	(b)(4)		
Porosity, percent	(b)(4)		
Pore Size, microns	(b)(4)		

The above comparison demonstrates that there is no significant statistical difference between the static shear, static tensile, abrasion resistance, thickness, porosity, and pore size of the proposed coating and a legally marketed predicate. The proposed coating demonstrates a higher estimated shear fatigue strength and higher surface roughness, neither of which would adversely affect safety or efficacy of the device.

For your review and as agreed, I have attached:

- A revised CDRH submission cover sheet, listing the above devices as predicates.
- A revised Substantial Equivalence Comparison Table (with changes highlighted).
- A revised Summary of Safety and Effectiveness, listing the above devices as predicates.

- It is noted that this % porosity is in actuality (b)(4) not (b)(4) And, all three morphological properties of the subject coating fall below the FDA requirements outlined in 888.3358. Those properties that fail to meet the FDA requirements are presented in **boldface**. - PGA

3/6/06 – I spoke with Ms. Williams regarding the deficiencies emailed on 3/2. She stated that the coating was very similar to other coatings they've previously had cleared for use on similar hip components. She asked that if they could provide these devices (510ks) as predicates and include a comparison of the coating characteristics to satisfy our request. I said they could, but in addition to the information requested in the FDA draft guidance "*Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements*" (tensile strength, static shear, shear fatigue, and abrasion resistance), they also needed to demonstrate that their coating meets the requirements identified in 21 CFR 888.3358 with respect to % porosity, coating thickness, and pore size, or, failing to meet these criteria they would have to demonstrate that they are equivalent to a predicate device that has been cleared under this regulation number if they want to claim a porous coating for biological fixation. This could be done by providing animal or clinical data, or if the predicate device and subject device have similar coating characteristics, through a comparison of these above mentioned

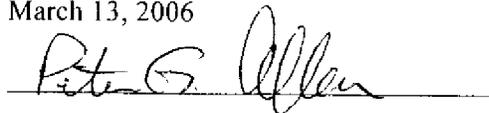
morphological properties.

3/2/06 -- I emailed Ms. Laura Williams of Zimmer to request the following additional information.

- o In the last paragraph of the Device Description section of the 510(k) Summary you describe your acetabular cup as having a porous coating of titanium plasma spray. However, your coating does not meet with FDA's definition of a porous coating for an orthopedic device (e.g. see 21 CFR 888.3358) and you have not demonstrated that this coating is equivalent to another porous coating previously cleared for use (i.e., via animal studies, or clinical data). Therefore, please remove the word 'porous' from the description.
- o In the package insert for the Acetabular Cups, under section 1.2 Product Description and Implant Materials, the description for the Durom Acetabular component states that the component has a Ti-VPS coating for biological fixation. To claim 'biological fixation' we require that you demonstrate you're your coating meets our definition of a porous coating, which, as noted in the bullet above, you have not done. Therefore, please revise your package insert by removing the term 'biological fixation' from the description.

If you cannot provide these items by Wednesday, March 8th, I will place this submission on phone hold until receipt of the requested information.

Peter G. Allen, MS; Biomedical Engineer
ODE/DGRND/OJDB
March 13, 2006



Allen, Peter

From: Allen, Peter
Sent: Friday, March 03, 2006 4:38 PM
To: 'laura.williams@zimmer.com'
Cc: Allen, Peter
Subject: K053536 - Metasul LDH and Durom Acetabular

Laura,

I am a reviewer in the Orthopedics Branch at FDA and I am the lead reviewer on the above referenced 510k. I have essentially completed my review and have identified 2 relatively minor deficiencies that I believe can be cleared up quite quickly. If you could provide me responses via email I can process this submission out with an SE determination. Here are my deficiencies:

- In the last paragraph of the Device Description section of the 510(k) Summary you describe your acetabular cup as having a porous coating of titanium plasma spray. However, your coating does not meet with FDA's definition of a porous coating for an orthopedic device (e.g. see 21 CFR 888.3358) and you have not demonstrated that this coating is equivalent to another porous coating previously cleared for use (i.e., via animal studies, or clinical data). Therefore, please remove the word 'porous' from the description.
- In the package insert for the Acetabular Cups, under section 1.2 Product Description and Implant Materials, the description for the Durom Acetabular component states that the component has a Ti-VPS coating for biological fixation. To claim 'biological fixation' we require that you demonstrate you're your coating meets our definition of a porous coating, which, as noted in the bullet above, you have not done. Therefore, please revise your package insert by removing the term 'biological fixation' from the description.

If you cannot provide these items by Wednesday, March 8th, I will place this submission on phone hold until receipt of the requested information. These revised items may be submitted as email attachments and sent directly to me. Once I have these I can process your submission out with a substantially equivalent determination. Please call or email me if any questions.

Sincerely,

Pete

Peter G. Allen, MS
 Biomedical Engineer
 Orthopedic Devices Branch (ORDB)
 FDA/CDRH/ODE/DGRND
 Ph: (301) 594-2036 x157
 Fax: (301) 827-4349
 Email: peter.allen@fda.hhs.gov



Protecting and Promoting Public Health

21

3/13/2006

Allen, Peter

From: Allen, Peter
Sent: Wednesday, March 08, 2006 3:39 PM
To: 'laura.williams@zimmer.com'
Subject: RE: K053536 -- Metasul LDH and Durom Acetabular Cup 510(k)

Laura,

I had a question regarding the average percent porosity for this coating that was cited in this submission and in your email of 3/7. In particular the average coating porosity (%) cited in the submission was stated to be (b)(4) (b)(4) p. 20, 178, and 183). However, the raw test results listed on page 189 do not confirm this value as the overall average value for the 15 samples evaluated is shown to (b)(4) (see last row at bottom of table on p. 189). I just wanted to point that out and see if I was missing something, or if this (b)(4) was just an error on your part. Thanks.

Pete

Peter G. Allen, MS
 Biomedical Engineer
 Orthopedic Devices Branch (ORDB)
 FDA/CDRH/ODE/DGRND
 Ph: (301) 594-2036 x157
 Fax: (301) 827-4349
 Email: peter.allen@fda.hhs.gov



Protecting and Promoting Public Health

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone.

From: Laura D Williams [mailto:laura.williams@zimmer.com]
Sent: Tuesday, March 07, 2006 4:33 PM
To: Allen, Peter
Subject: K053536 -- Metasul LDH and Durom Acetabular Cup 510(k)

22

3/13/2006

Allen, Peter

Fri 3/10/06

Hi Peter,

The paper we discussed earlier today is attached.

Regards,



Laura D. Williams, RAC
Manager, Corporate Regulatory Affairs
Zimmer, Inc.
574-372-4523 (office)
574-527-9180 (cell)
574-372-4605 (fax)

CONFIDENTIAL NOTICE: The materials in this electronic mail transmission (including all attachments) are private and confidential and are the property of the Zimmer, Inc. The information contained in the material is privileged and is intended only for the use of the named address(es) above. If you are not the intended addressee, be advised that any unauthorized disclosure, copying, distribution or the taking of any action in reliance on the contents of this material is strictly prohibited. If you have received this electronic mail transmission in error, please immediately notify the sender by telephone at 574-372-4523 or send an electronic message to laura.williams@zimmer.com and thereafter, destroy it immediately.

23

3/13/2006

**Comparative histomorphometric evaluation of bone ingrowth of
titanium implants with different surface structures
- a study with goettinger minipigs -**

A. Wilke¹, P. Knöll², H. Frank², M. Wilke², A. Thon¹, M. Kratz², S. Endres¹, M. Windler³

¹ Orthopädische Universitätsklinik Marburg (Baldingerstraße, 35043 Marburg, Germany)

² Labor für experimentelle Orthopädie und Biomechanik der Philipps-Universität Marburg

³ Centerpulse Orthopedics (Winterthur, Switzerland)

(b)4 Copyrighted Material

(b)4 Copyrighted Material

(b)4 Copyrighted Materiel

(b)4 Copyrighted Materiel

(b)4 Copyrighted Materiel

Allen, Peter

From: Laura D Williams [laura.williams@zimmer.com]
Sent: Friday, March 10, 2006 5:04 PM
To: Allen, Peter
Subject: K053536

Hi Peter,

Thanks again for your help with this submission. I wanted to let you know that I need to be out of the office on Monday. I will have limited access to voice and e-mail, but if you agree, I would prefer to finalize and resolve the outstanding issues with this submission on Tuesday, March 14th. Please let me know if you have concerns – otherwise, I'll plan to contact you on Tuesday.

Regards,



Laura D. Williams, RAC
Manager, Corporate Regulatory Affairs
Zimmer, Inc.
574-372-4523 (office)
574-527-9180 (cell)
574-372-4605 (fax)

CONFIDENTIAL NOTICE: The materials in this electronic mail transmission (including all attachments) are private and confidential and are the property of the Zimmer, Inc. The information contained in the material is privileged and is intended only for the use of the named address(es) above. If you are not the intended addressee, be advised that any unauthorized disclosure, copying, distribution or the taking of any action in reliance on the contents of this material is strictly prohibited. If you have received this electronic mail transmission in error, please immediately notify the sender by telephone at 574-372-4523 or send an electronic message to laura.williams@zimmer.com and thereafter, destroy it immediately.

3/13/2006

29

Allen, Peter

Sun 3/12/06

Peter:

In response to your e-mail request of March 3, 2006, attached please find:

- A revised Package Insert, with the term "biological fixation" removed from Section 1.2, and
- A revised Summary of Safety and Effectiveness, with the term "porous" removed from the Device Description.

In response to your e-mail correspondence of March 8, 2006, attached please find a revised version of Zimmer Research Report ZRR_WI_0040_05. A memorandum summarizing the changes precedes the revised document.

Please contact me should you have any questions or require any additional information.

Regards,



Laura D. Williams, RAC
Manager, Corporate Regulatory Affairs
Zimmer, Inc.
574-372-4523 (office)
574-527-9180 (cell)
574-372-4605 (fax)

CONFIDENTIAL NOTICE: The materials in this electronic mail transmission (including all attachments) are private and confidential and are the property of the Zimmer, Inc. The information contained in the material is privileged and is intended only for the use of the named address(es) above. If you are not the intended addressee, be advised that any unauthorized disclosure, copying, distribution or the taking of any action in reliance on the contents of this material is strictly prohibited. If you have received this electronic mail transmission in error, please immediately notify the sender by telephone at 574-372-4523 or send an electronic message to laura.williams@zimmer.com and thereafter, destroy it immediately.

3/13/2006

30

Traditional 510(k) Premarket Notification

Table of Contents

Revised Package Insert	6
Revised Summary of Safety and Effectiveness	13
Zimmer Research Report - Revision Summary	15
Revised Zimmer Research Report	16

Acetabular cups



Important information for the operating surgeon

CE 0123 (The CE mark is valid only if it is also printed on the product label)

Zimmer GmbH
P.O. Box
CH-8404 Winterthur, Switzerland
Telephone +41/ (0)52 262 60 70
Fax +41/ (0)52 262 01 39
www.zimmer.com

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

Manufacturer: Zimmer GmbH Sulzer-Allee 8 CH-8404 Winterthur, Switzerland	Representative in the USA: Zimmer Austin, Inc. 9900 Spectrum Drive Austin, Texas 78717, USA	Art. No. D011 500 213 - e/d/f/i/sp/sw - Ed. 08/05
---	--	---

1. Instructions for use

Before using a product placed on the market by Zimmer, the operating surgeon should study carefully the following recommendations, warnings and instructions, as well as the product-specific information (technical product description, description of the surgical technique, catalogue sheet, etc.). Additional product information can be found in the description of the surgical technique, in the technical description of the product or on the appropriate catalogue sheet. Zimmer also recommends attending the appropriate user-training courses. The aforementioned documents and details of the training courses may be obtained from the appropriate representatives in the various countries.

The manufacturer, the importer and the suppliers of Zimmer products are not liable for complications or other effects that might occur for reasons such as incorrect indications or surgical technique, unsuitable choice of material or handling thereof, unsuitable use or handling of the instruments, asepsis and so on.

Patient Counseling Information

Complications and/or failure of total hip prostheses are more likely to occur in patients with unrealistic functional expectations, heavy patients, physically active patients, and/or patients that fail to follow through with the required rehabilitation program. Patients should be cautioned that these devices do not have the strength, elasticity, and/or durability characteristics of healthy bone. The patient must be instructed about all postoperative restrictions, particularly those related to occupational and sports activities, and about the possibility that the implant or its components may wear out, fail, or need to be removed and/or replaced.

1.1 General instructions

- Zimmer products may be implanted only by operating surgeons who are familiar with the general problems of joint replacement and who are able to master the product-specific surgical techniques. The surgical techniques for Zimmer implants may be learned by attending courses held at hospitals that have experience with these implants.
- Implantation is to take place in accordance with the instructions for the recommended surgical procedure.
- Zimmer has not tested the safety or effectiveness of these devices for use in combination with non-Zimmer products or components. If surgeons elect to assemble and implant a construct that includes components not manufactured or distributed by Zimmer, they do so in reliance on their own clinical judgment and should so inform their patients.
- Due to the acquisition of pre-existing product lines, Zimmer has initiated a testing program to evaluate the **compatibility of these devices** with implants and components made or distributed by other Zimmer companies, including those of Zimmer GmbH (previously Centerpulse Orthopedics Ltd.), Zimmer, Inc., Zimmer Trabecular Metal Technology, Inc. (previously Implex Corp.), Zimmer U.K. Ltd., and Zimmer Austin, Inc. (previously Centerpulse Orthopedics, Inc.). Only authorized combinations should be used. To determine whether these devices have been authorized for use in a proposed combination, please contact your Zimmer sales representative or visit the Zimmer website: www.productcompatibility.zimmer.com. A printout of the website information can also be obtained by calling Zimmer, Inc. Customer Service, 1-800-348-2759 (U.S.) or the local international access code +1-574-372-4999 (outside the U.S.). Former Centerpulse and Implex products that are now packaged in Zimmer boxes, and for which

compatibility could be an issue, have been labeled «former Centerpulse» and «former Implex» to provide clarification for the user.

- Product marking, especially size and taper specific information, should be checked to ensure correspondence with the product labeling. The taper size is indicated on the product label and – if possible – on the implant itself. **It is critical that the user ensures taper compatibility.**
- Implants and the corresponding instrumentation should be carefully checked before they are used or implanted. Implants or implant parts that are contaminated, not sterile, damaged or scratched or that have been improperly handled or processed without authorization may not be implanted or used under any circumstances. The use of damaged implants or instruments that have been processed without authorization in any way may lead to premature failure.
- Implants must not be machined or altered in any way, unless this is expressly shown in the design and in the surgical technique.
- Before attaching mating components such as the acetabular insert/shell or femoral head/stem taper, each surface must be cleaned and dried.
- Reliable seating of the femoral head on the acetabular cup is only possible when both mating surfaces are completely intact. If the femoral head or the acetabular cup is damaged in any way, the head and the cup must not be used and should be replaced. **It is absolutely essential that the size of the head fit with the size of the cup.**
- *Cup components should be implanted according to the surgical technique. Generally, this implantation is with an inclination of between 40 and 45° and an anteversion of between 10 and 20°. Outside these limits, the range of motion is diminished and this may lead to subluxation and/or dislocation of the head out of the cup.*
- Implants are intended for single use only.
- Functioning of implants is of limited duration (see also Points 1.3 and 2.4).
- If a Zimmer product is passed on to a third party, the party who passes it on must ensure that the relevant batch-tracking is possible at any time (traceability).

Important information for the users of Zimmer hip systems with METASUL metal pairings:

Hard Metasul metal-metal pairings consist of two articulating joint surfaces featuring a precisely defined geometry and a precisely defined material.

Cup systems intended for Metasul pairings may only be paired with the corresponding Metasul ball heads provided for this purpose. The operating surgeon must always make sure that the chosen cup and ball head match each other in accordance with this requirement.

1.2 Product description and implant materials

An acetabular cup component is used in conjunction with a femoral head component for replacement of resurfacing of the acetabulum during total hip arthroplasty.

Acetabular cup components are available in different designs, materials and sizes.

Acetabular cup components for Total Hip Arthroplasty

This Physicians Insert is valid for the following acetabular cup components:

INTENDED ONLY FOR USE WITH BONE CEMENT:

Low Profile Acetabular Cup (UHMW Polyethylene Sulene-PE [ISO 5834-1/-2])

Cemented, all-polyethylene components for use with reinforcement rings and cages.

Full Profile Acetabular Cup (UHMW Polyethylene Sulene-PE [ISO 5834-1/-2])

Cemented, all-polyethylene components for use with reinforcement rings and cages.

Acetabular Roof Reinforcement Rings and Cages; Burch-Schneider Cage, Müller Ring, Ganz Ring (Protasul-Ti [ISO 5832-2 Grade 1])

Metallic, plate-like, flanged/hooked acetabular components with multiple screwholes for acetabular deficiencies/reconstruction.

INTENDED ONLY FOR USE WITHOUT BONE CEMENT:

Alloclassic Zweymüller Acetabular Cup (Protasul-Ti [ISO 5832-2 Grade 1/-4A] / Protasul-100 [ISO 5832-11])

Threaded acetabular shell system.

CLS Spotorno Acetabular Cup (Protasul-100 [ISO 5832-11])

Flattened, hemispherical shell with sharp, toothed expansion lobes for fixation.

Allofit Acetabular Cup (Protasul-Ti [ISO 5832-2 Grade 1/-4A])

Flattened, hemispherical shell with toothlike circumferential macrotexture for fixation.

Durom Acetabular Component (Protasul-21WF [ISO 5832-12], Porolock™ (Ti-VPS) [ISO 5832-2])

Uncemented, monobloc acetabular component with Ti-VPS coating and circumferential fins for additional primary fixation

Information about the chemical composition and the mechanical properties of the materials used can be found in the appropriate sheets of the materials catalogue or in the appropriate product information documents.

1.3 General information on indications, contraindications and risk factors

- An implantation may only be considered if all other therapeutic possibilities have been carefully weighed and found unsuitable or inappropriate.
- Every implant is subject to unavoidable wear and aging. In the course of time, an implant initially implanted in a stable manner can loosen or its functionality can become impaired. Wear, aging and loosening of an implant can lead to the need for re-operation.
- An infection in the region of an implant will have negative consequences for the patient in most cases, because it will usually necessitate removal of the implant.
- Indications and contraindications for the use of artificial hip joints may be relative or absolute, and must be carefully weighed, taking the overall condition of the patient into account including other alternative procedures, e.g. non-surgical treatment, arthrodesis.
- The selection of patients depends to a great extent on age, his/her general state of health, the condition of the existing bone, previous operations and anticipated further surgery. Normally speaking, an implantation is only indicated for patients whose skeleton is fully developed.

A. Indications

- Patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis.
- Those patients with failed previous surgery where pain, deformity, or dysfunction persists.
- Revision of previously failed hip arthroplasty.
- Total hip replacements may be considered for younger patients if any unequivocal indication outweighs the risks associated with the age of the patient and modified demands regarding activity and hip joint loading are assured. This includes severely crippled patients with multiple joint involvement, for whom an immediate need of hip mobility leads to an expectation of significant improvement in the quality of their lives.

B. Contraindications

- Patient's physical conditions that would eliminate or tend to eliminate adequate implant support or prevent the use of an appropriately sized implant, e.g., previous surgery, insufficient quality or quantity of bone resulting from conditions such as cancer or congenital dislocation, metabolic bone disease of the upper femur or pelvis, femoral osteotomy revision, girdlestone revision, osteoporosis, osteomyelitis, neuromuscular compromise or vascular deficiency in the affected limb in sufficient degree to render the procedure unjustifiable (e.g., absence of musculoligamentous supporting structures, joint neuropathy) or other conditions that may lead to inadequate skeletal fixation.
- Active infection of the hip, old or remote infection. This may be an absolute or relative contraindication. Every effort should be undertaken to rule out preoperative infection in a patient with suspicious symptoms, such as a history of, or when there are signs of, local inflammation, abscesses, fever, increased blood sedimentation rate, evidence of rapid joint destruction or bone resorption.
- Allergy to the implanted material, above all to metal (e.g. cobalt, chromium, nickel etc.).
- Kidney insufficiency: In spite of the fact that there is no currently known causal relationship with increased serum cobalt and serum chromium levels, it is not possible to exclude completely any impairments of health due to low long-term additional loading. In the presence of chronic kidney insufficiency, however, a Metasul metal / metal pair should not be used or should only be used subject to close monitoring of progress (serum cobalt, serum chromium, serum creatine, BUN, echocardiography) in order to avoid increased serum cobalt and serum chromium levels and after carefully weighing the therapeutic benefits against the risks.
- Local bone tumours and/or cysts.
- Pregnancy.

C. Risk factors

Risk factors can influence the success of the operation.

- Charcot's joints.
- Muscle deficiencies.
- Multiple joint disabilities.
- Refusal to modify postoperative physical activities.
- Heavy patients, obesity (especially over 220 pounds (100 kg)).
- Small-boned patients.
- Heavy labor.
- Active sports.
- History of falls.
- General neurological abnormalities or neurological conditions including mental conditions (e.g., mental illness, senility, drug use, alcoholism) that tend to pre-empt the patient's ability or willingness to follow the surgeon's postoperative instructions.
- Marked osteoporosis, osteomalacia.
- Systemic and metabolic disorders leading to progressive deterioration of bone, (e.g., cortisone therapies, immunosuppressive therapies).
- Patient's resistance generally weakened (HIV, tumor, infection).
- Suspected allergic reactions to implant materials.
- Other joint disability (i.e., knees or ankles).
- Severe deformity leading to impaired anchorage or improper positioning of implants.

2. Warnings

2.1 Preoperative

- The preoperative planning and surgical technique for an implantation represent principles that are basic to sound surgical management in total hip replacement. Thorough familiarity with the surgical technique is essential. The use of certain surgical instruments is suggested in the performance of every surgery.
- Patients receiving hip joint replacements should be advised that the longevity of the implant may depend on their weight and level of activity.
- The doctor must explain the risks of inserting an implant to the patient, including the possible impact of the factors mentioned under Point 1.3 on the success of the operation and the possible negative effects mentioned under Point 2.4. The patient should also be informed as to what steps he/she can take in order to reduce the possible effects of these factors.
- When an implantation is being considered, particularly for the young and the active patient, the surgeon should discuss all aspects of the surgery and the implant with the patient before surgery. The discussion should include the limitations of joint reconstruction, limitations particular to the patient, the possible consequences resulting from these limitations and, therefore, the necessity of following the doctor's preoperative instructions.
- Allergies and other reactions to implant materials, although rare, should be considered and ruled out preoperatively.
- X-ray templates should be used for evaluating the implant size, position and alignment of the joint. A full inventory of implant sizes should be at disposal for the operation.
- Re-use of an implant that was already implanted in the patient's body is strictly forbidden. Re-using an implant that has come into contact with the body fluids or tissues of a third party is also forbidden.
- The use of polymethylmethacrylate (PMMA) bone cement can be useful in securing, supporting and stabilizing those devices intended for cemented fixation in bone, but it neither replaces the support function of sound bone nor eliminates the need for additional support during healing. In using cement for implant fixation, care should be used to ensure complete cement support on all parts of the device embedded in the bone cement to help prevent possible stress concentrations that may lead to failure.
- The safety and effectiveness of the use of this device in bilateral applications have not been established.

Failure to carry out proper preoperative planning can lead to errors (e.g. with regard to incorrect positioning and the choice and size of the implant).

2.2 Intraoperative

- The correct selection of the implant is extremely important. Selection of the implant refers to the appropriate type and size for each patient with consideration of the anatomical and biomechanical factors involved. Such factors include patient age, activity level, weight, bone and muscle conditions.
- Prior to closure, the surgical site should be thoroughly cleansed of bone chips, ectopic bone, bone cement, etc. Foreign particles at the articular interface may cause excessive wear and/or friction. Ectopic bone and/or bone spurs may lead to

dislocation or painful and restricted motion. Range of motion should be thoroughly checked for early contact or instability.

- The largest cross-section component that allows for adequate bone support to be maintained is recommended. Failure to use the optimum size may result in loosening, bending, cracking, or fracture of the component, bone, or cement (if cement used).
- Stem and cup positioning and neck length are of critical importance. Subluxation, dislocation, and/or fracture of components may result due to muscle looseness and/or malpositioning of components.
- The rules of asepsis are to be observed during the implantation.

2.3 Postoperative

- Immediate postoperative care must be carefully planned in order to retain mobility and to prevent dislocation and thromboembolism. The patient must be instructed as to the limits of the implant as well as its lower loadability, the range of motion and the permissible level of activity. Early weight-bearing must be carefully controlled. A prosthesis-bearer's card should also be completed for the patient.
- Postoperative treatment, care of the patient and his/her activity must be planned in such a way as to avoid excess loading of the operated limb. Depending on the type of operation chosen, the age of the patient and his/her bone quality, it may be necessary to spare the joint for a long period by limiting weight-bearing.
- Regular X-ray checks are recommended in order to detect any changes in the position of the implant, cracking of component or cement, and signs of loosening or breakage of components.
- The patient should be urged to inform his doctor immediately of any unusual changes to the operated limb.
- The patient must be told that implants can affect the results of computer tomography (CT) or magnetic resonance imaging (MRI) scans.

2.4 Side effects

The general risks involved in endoprosthetics are allergic reactions to the implant material used, loosening, wear, corrosion, incorrect positioning, dislocation, aging, deterioration and fracture of the implant or implant parts and revision or reoperation.

Possible consequences of a total hip replacement:

- Implants, implant parts and instruments can fracture, become loose or undergo excessive wear, or their functioning may be impaired if they are subjected to excessive loading, are damaged or have been implanted incorrectly or handled improperly.
- Changing position of the implant (bending, fracture and/or disassembly of components or cement) with or without loosening or clinical symptoms.
- Perforation, fissure of the acetabulum, femur or trochanter, and/or trochanter avulsion.
- Fractures of the femur resulting from stress, bone defects resulting from earlier surgical procedures, deformity and/or osteoporosis.
- Early or late infections.
- Dislocation, subluxation, insufficient range of movement, undesirable shortening or lengthening of the limb involved due to less than optimal positioning of the implant.
- Wound haematoma and slow wound healing.
- Restricted freedom of movement.
- Circulatory disorders, including injury of blood vessels (iliac artery, obturator artery and femoral arteries), venous thrombosis, pulmonary embolism and myocardial infarction.
- Temporary or permanent nerve diseases involving the femoral, sciatic, peroneal or obturator nerves.
- Lung diseases, including pneumonia and atelectasis.
- Aggravation of conditions involving other joints or the back due to intraoperative trauma, differences in leg lengths, femoral medialisation or weakening of the muscles.
- Excessive wear of the acetabular component from damage to mating wear surfaces or debris particles.
- Tissue reactions and allergies to the products of corrosion or wear and cement particles.
- Urological complications, in particular urinary retention and infections.
- Aseptic loosening.
- Other complications associated with surgery in general, with medication, with other instruments used, with blood, anesthesia and so on.
- Ectopic ossification.
- Pain.

2.5 Sterilization

Metallic acetabular shell components, Metasul acetabular inserts and polyethylene (Sulene) acetabular inserts are sterilised by a minimum of 25 KGy (2.5 Mrad) of gamma irradiation.

Durasul acetabular inserts are sterilized using ethylene oxide gas.

2.6 Re-sterilization

Implants and instruments may not come into contact with substances containing chlorine, phosphorus or fluorine or with detergents containing fats.

These sterilization instructions are consistent with AORN and ANSI/AAMI/ISO guidelines. They should be used for items supplied non-sterile, for reprocessing reusable devices, or for sterile items that were opened but unused.

Recommended Sterilization/Resterilization Specifications:

Solid Metal Implants, and PMMA-Coated Metal Implants and Provisionals

Steam Sterilization			
Type	Minimum Temperature	Minimum Exposure Time	Dry Time
Gravity Displacement	121°C (250°F)	30 minutes	Varies by load configuration and sterilizer type
Gravity Displacement	132°C (270°F)	15 minutes	
Pre-vacuum	132°C (270°F)	4 minutes	

All Reusable Instruments and Provisionals

Steam Sterilization			
Type	Minimum Temperature	Minimum Exposure Time	Dry Time
Pre-vacuum	132°C (270°F)	4 minutes	Varies by load configuration and sterilizer type

Follow the sterilizer manufacturer's Instructions for loading patterns and selection of sterilization parameters. Drying times vary according to load size and should be increased for larger loads.

Note: Where there is a concern about TSE/vCJD contamination, decontaminate using a prevacuum autoclave cycle at a minimum of 134 °C (273 °F) for at least 18 minutes or use a gravity autoclave cycle at a minimum of 121°C (250 °F) for at least 60 minutes. World Health Organization (WHO/CDS/CSR/APH 200.3, "WHO Infection Control Guidelines for TSE," March 1999).

UHMWPE Implants, PMMA Implants and Metal/Polymer Combination Implants

100% Ethylene Oxide (EO) Sterilization			
Gas Concentration	Temperature	Exposure Time	Relative Humidity
725 mg/L EO	55°C (131°F)	60 minutes	70%

The recommended aeration period for EO is a minimum of 12 hours at 130 °F (54°C) in a heated mechanical aerator.

UHMWPE implants, PMMA Implants

STERRAD Gas Plasma Sterilization		
Gas Concentration	Temperature	Exposure Time
6 mg/L (59% hydrogen peroxide)	45°C (113°F)	65 minutes

Do not reuse instruments or devices labeled for single use only.

Do not re-sterilize single use only components that have been contaminated with body fluids or debris or previously implanted.

Do not use the original plastic cavities or lids for re-sterilization. Single devices may use a standard Tyvek pouch. Ensure that the pouch is large enough to contain the device without stressing the seals or tearing the pouch.

Do not expose polyethylene or polymethyl methacrylate (PMMA) components to steam sterilization (including flash sterilization). The high temperatures may cause softening, warping, cracking, or dimensional and material property changes.

Rinse porous, PMMA or PMMA-coated components to remove lint or debris (using USP purified water) and enclose in a lint-free sterilization wrap but do not allow any PMMA surface to contact the wrap or tray. During sterilization the coating softens and may be damaged by contact. Cool naturally and do not force cooling by immersion in room temperature water or saline. Any fine lines in the coating that develop during sterilization will not affect bonding of the PMMA.

Modular implant components must be sterilized separately to minimize potential bioburden buildup in the dead space and expansion/contraction stresses.

Implants made of synthetic materials and components with synthetic parts may not be re-sterilized or industrially processed for re-use, as this can cause deterioration of the material.

If a Zimmer product is sterilized or re-sterilized by the user, this should be indicated in the corresponding patient documentation (i.e. in the Operation Report), and the relevant documents kept on file.

Validation of the cleaning, disinfecting and sterilizing or re-sterilizing procedures and especially the correct settings of the relevant equipment should be verified regularly.

Products past their «Use By» dates may not be repacked and re-sterilized by third-party firms, since this would mean that traceability would no longer be guaranteed.

The recommendations set forth under this point are provided for informational purposes only. No liability is accepted regarding sterility for implants or instruments that are cleaned and sterilized or re-sterilized by the purchaser or the user.

3. Storage and Handling

- Implants must be stored unopened in their original packaging.
- Before sterile implants are removed from their packaging, the protective wrapping must be examined for possible damage as this could jeopardize their sterility. If an expiration date for sterility of the product is indicated, this must be observed. If the packaging is damaged or the sterility expiration date has been reached, the implants must be returned to the manufacturer.
- Protective caps or other protective devices must not be removed until immediately before use.
- Implants are extremely sensitive to damage. Even small scratches or marks left by impacts on the surfaces will cause excessive wear and may give rise to complications. Extremely careful handling is therefore strongly recommended.
- Instruments are subject to a certain degree of wear and therefore have to be considered non-durable materials. They must be checked for correct functioning before use and, if necessary, they must be returned to the appropriate local representative for repair.
- Any additional instructions (e.g. adhesive instruction labels on the packaging) are to be followed.

3.1 Color Coding for products of joint replacement

Left	Red
Right	Green
Cemented	Yellow
Uncemented	Blue
Metasul	Magenta
Ceramic	Grey

4. Pictograms



Symbol for «Follow the Instructions for Use»



Symbol for «Not to be re-used »



Symbol for «To be used by... » (Year, Month)

not sterile

Symbol for «Contents packed without sterilization»

STERILE R

Symbol for «Sterile» and «Sterilization by radiation»

STERILE EO

Symbol for «Sterile» and «Sterilization with ethylene oxide gas»

5. Trademarks

PROTASUL®, METASUL®, DURASUL®, SULENE®, ALLOCLASSIC®, ZWEYMÜLLER®, CLS™, SPOTORNO™ and ALLOFIT™ are trademarks of the manufacturer.

Summary of Safety and Effectiveness

Submitter Zimmer GmbH
Sulzer Allee 8
Winterthur, Switzerland CH-8404

Contact Person Laura D. Williams, RAC
Manager, Corporate Regulatory Affairs
Telephone: (574) 372-4523
Fax: (574) 372-4605

Date December 16, 2005

Trade Name *Durom*® Acetabular Component
Metasul® *LDH*™ Large Diameter Heads

Common Name Total hip prosthesis

Classification Name Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis

Classification Reference 21 CFR § 888.3330

Predicate Devices

- Biomet M²A Magnum System (K042037)
- Wright Metal Transcend Articular System (K021349)
- Centerpulse/Zimmer *Epsilon*™ *Metasul*® Acetabular Insert and *Metasul* Modular Femoral Head (K033634)

Device Description

The *Metasul LDH* large diameter head system consists of large diameter femoral heads, *Durom* acetabular components and neck adapters for neck length variation.

The *Metasul LDH* femoral heads are made of CoCrMo alloy, and are available in diameters ranging from 38 to 60mm. They are modular in design, and are for use with four head/neck length adaptors (-4 to +8mm), also manufactured from CoCrMo alloy. The femoral heads and neck adapters are compatible with 12/14 taper femoral stems.

The *Durom* Acetabular component is a metal monoblock CoCrMo alloy cup with a coating of titanium plasma spray. It is available in sizes from 44 to 66mm, and is intended for press-fit fixation in the acetabulum.

Intended Use

- Patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis.
- Those patients with failed previous surgery where pain, deformity, or dysfunction persists.
- Revision of previously failed hip arthroplasty.

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

Comparison to Predicate Device

The proposed device has the same intended use, has similar performance characteristics, is manufactured from similar materials using similar processes, and is similar in design to the predicate devices.

Performance Data (Nonclinical and/or Clinical)

The results of non-clinical analysis demonstrate that the device is safe and effective and substantially equivalent to the predicate device(s).



zimmer

Zimmer GmbH
P.O. Box
CH-8404 Winterthur

Phone +41 (0)52 262 60 70
Fax +41 (0)52 262 01 39
www.zimmer.com

Memo

From Adrian Spiegel
Telephone +41 (0)52 262 71 62
E-mail adrian.spiegel@zimmer.com
To L. Williams, FDA
Date March 9, 2006
Subject **Revision of ZRR_WI_0040_05**

Based on input from the FDA, report ZRR_WI_0040_05 was revised and a new version was distributed (ZRR_WI_0040_05_2). The following changes to the original document were made:

(b)(4)



Adrian Spiegel



Zimmer ResearchReport

Page 1 of 15

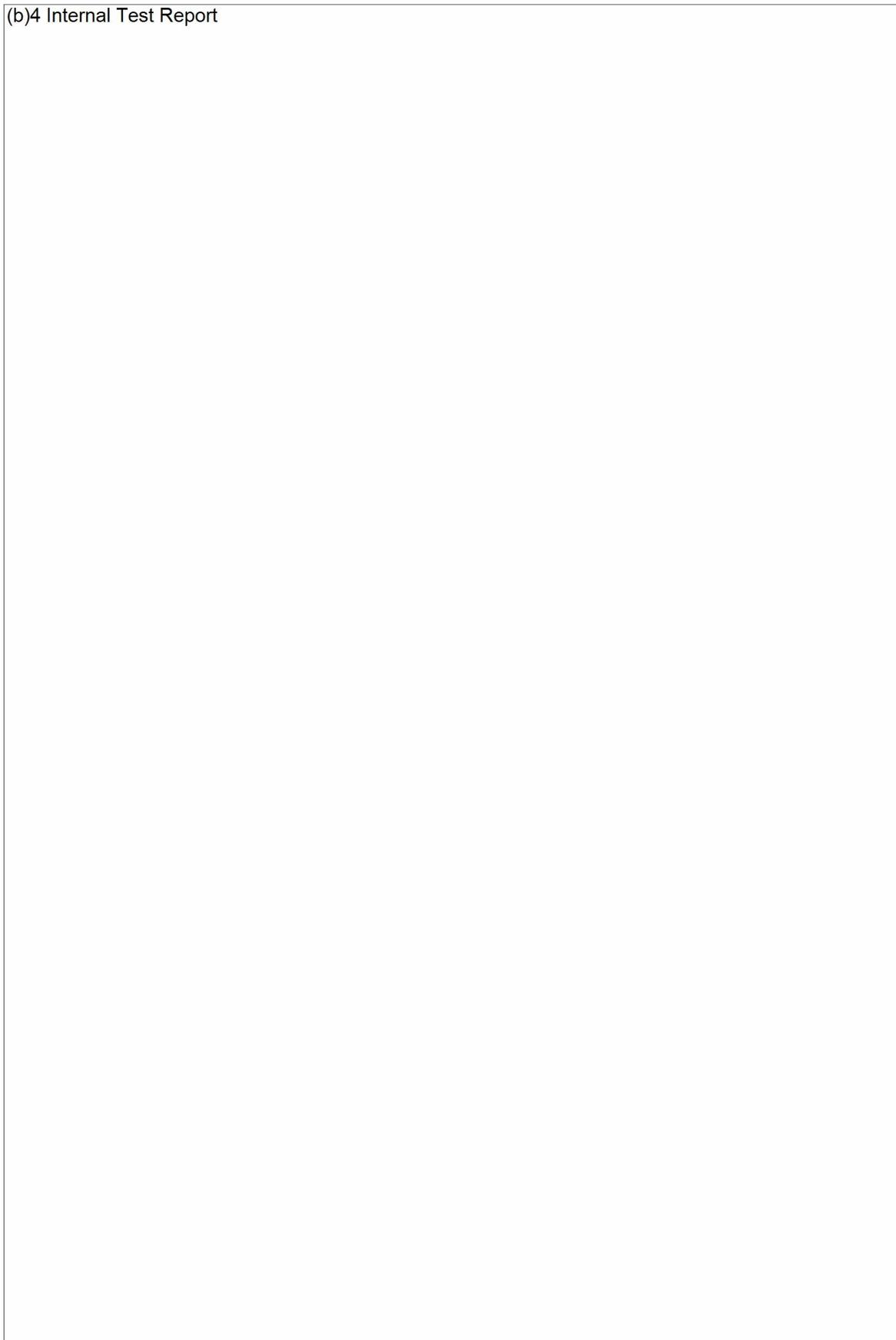
MORPHOLOGICAL PROPERTIES OF Ti-VPS COATING ON US DUROM CUP

(b)4 Internal Test Report

(b)4 Internal Test Report

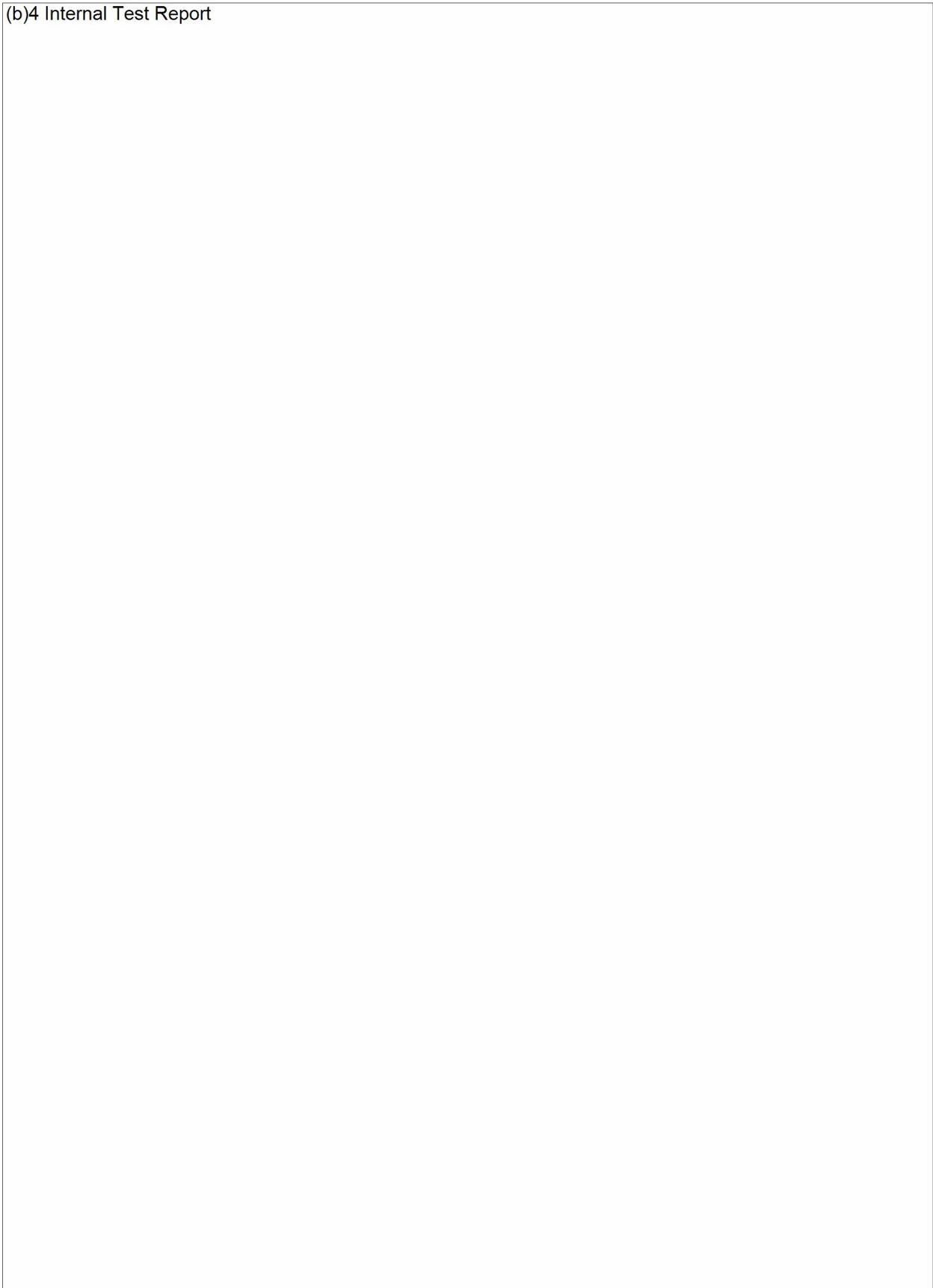
(b)4 Internal Test Report

(b)4 Internal Test Report



(b)4 Internal Test Report

(b)4 Internal Test Report



(b)4 Internal Test Report

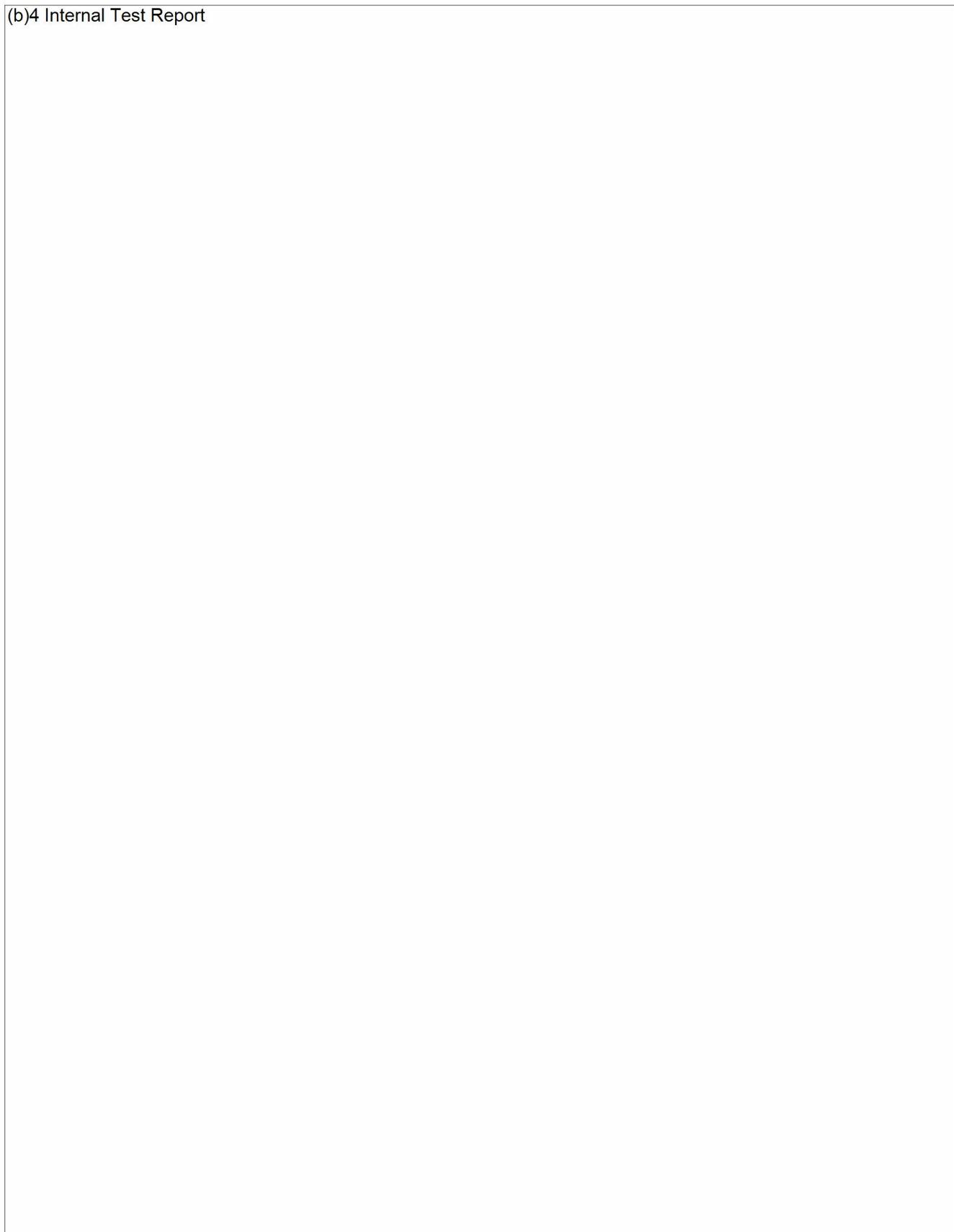


(b)4 Internal Test Report



(b)4 Internal Test Report

(b)4 Internal Test Report

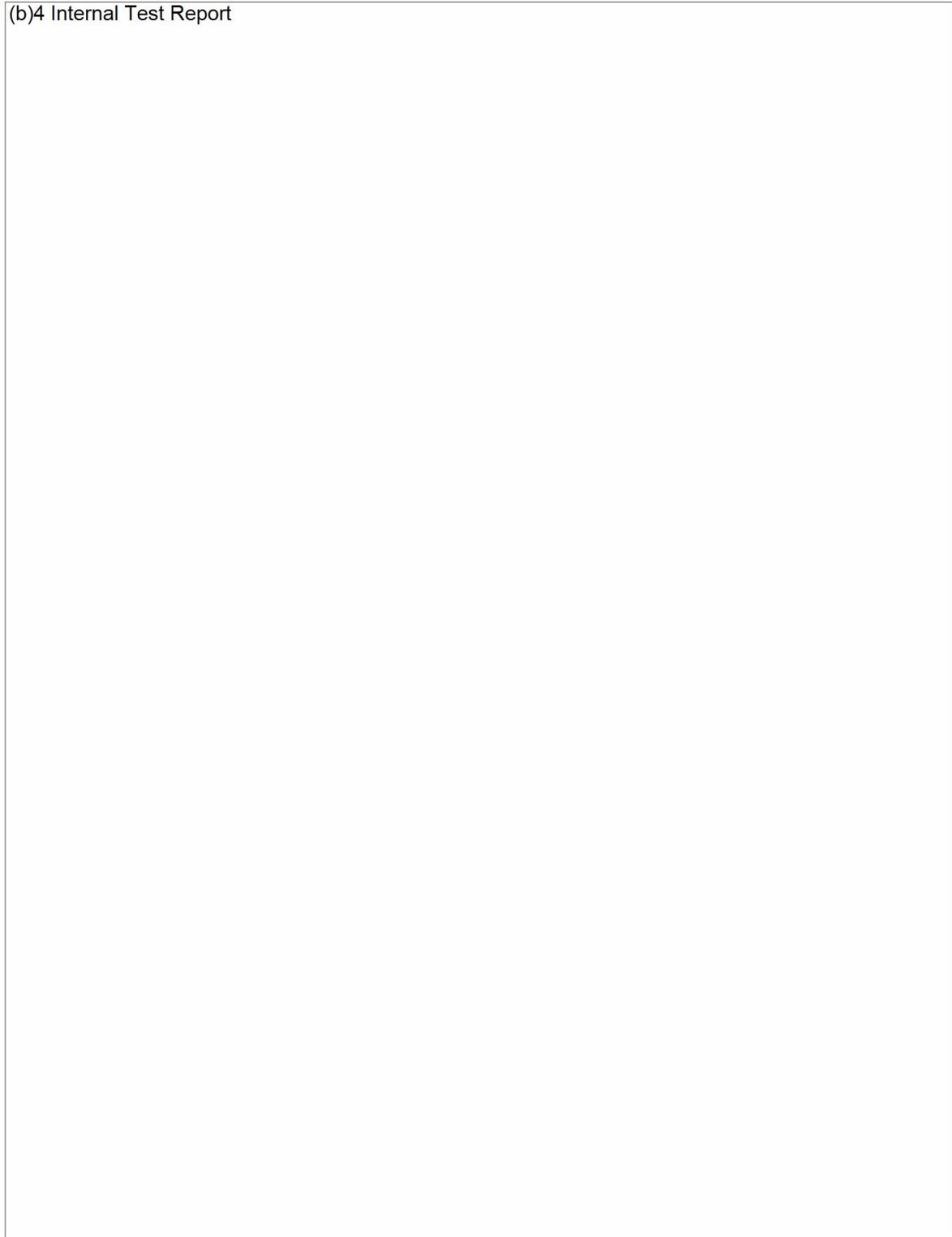


(b)4 Internal Test Report

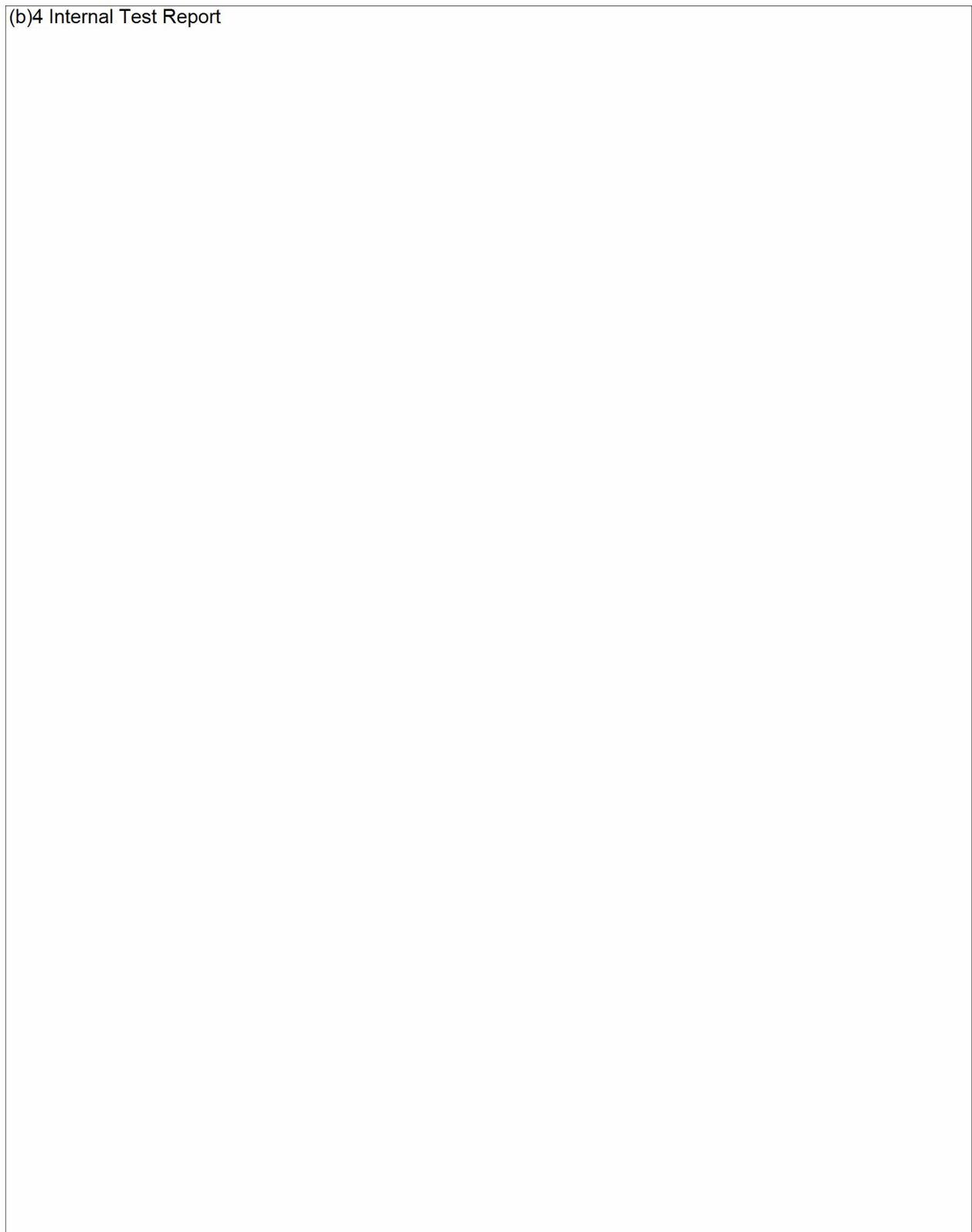
(b)4 Internal Test Report



(b)4 Internal Test Report



(b)4 Internal Test Report



(b)4 Internal Test Report

Internal Administrative Form

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

**SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS**

510(k) Number: R053536

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

- Special 510(k) - Do Sections 1 and 2
- Abbreviated 510(k) - Do Sections 1, 3 and 4
- Traditional 510(k) or no identification provided - Do Sections 1 and 4

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

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

* - May not be applicable for Special 510(k)s.

** - Required for Class III devices, only.

*** - See pages 3-12 and 3-13 in the Premarket Notification [510] Manual and the Convenience Kits Interim Regulatory Guidance.

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

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

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

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

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

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

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

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

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

Passed Screening Yes No
 Reviewer: Peter Allen
 Concurrence by Review Branch: _____

Date: _____

60

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

61

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

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

Reviewer: Peter Allen ^{K 053536}

Division/Branch: DGRAD / OJOB

Device Name: Duram Acetabular Component and Metasul LDH Large Diameter Heads

Product To Which Compared (510(K) Number If Known): K033634, K042037, K021349

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

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation. Questions 4, 6, and 8 are not applicable, for responses to Q.7 (no) and Q.11 (yes) see memo.

1. Intended Use:

See Memo

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

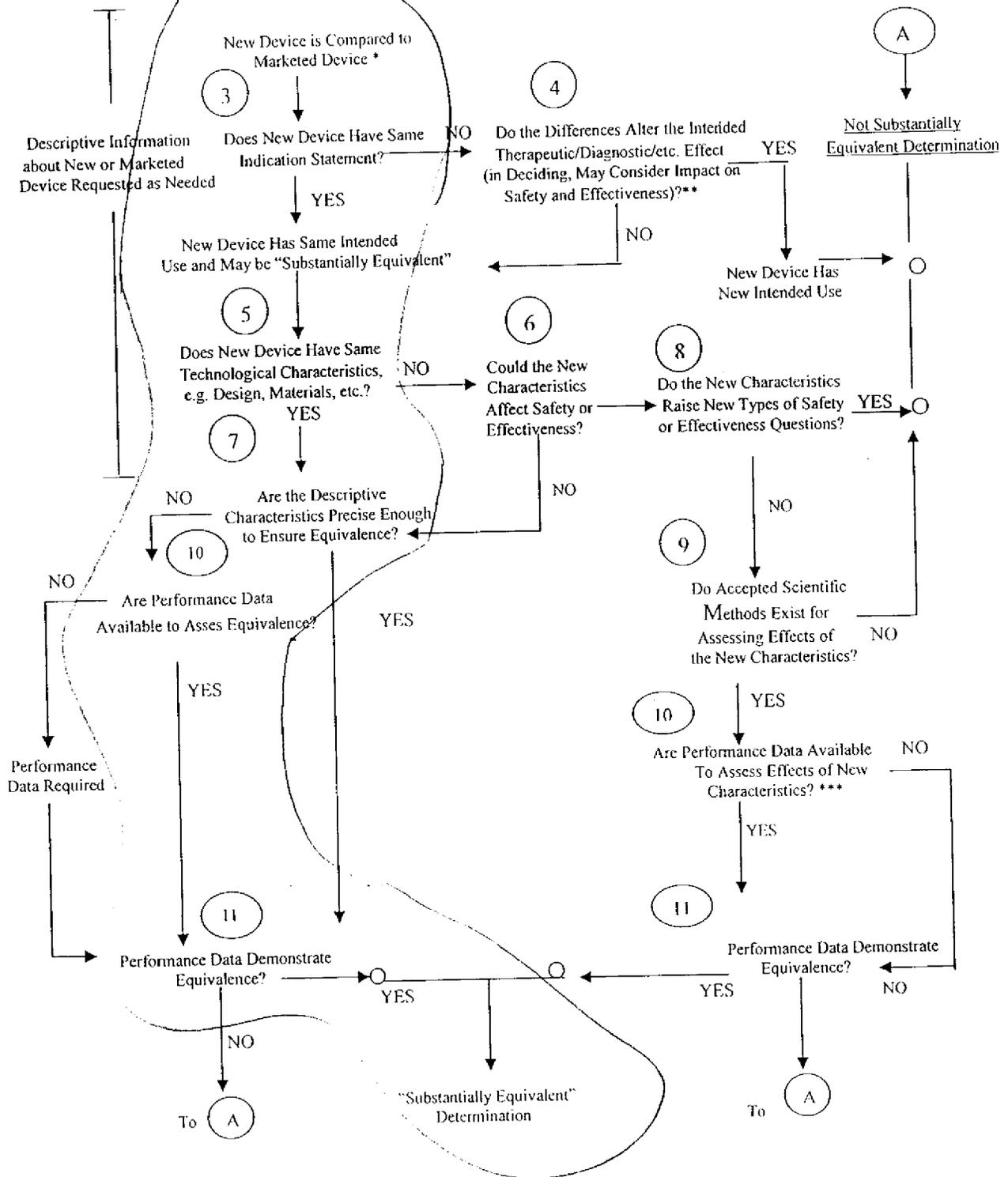
EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

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

ATTACH ADDITIONAL SUPPORTING INFORMATION

63

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



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