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

zimmer

September 26, 2007

Attention: Zimmer Distributor/Product Recall Contact

PRODUCT RECALL NOTIFICATION
IMMEDIATE RESPONSE REQUIRED

Zimmer GmbH is initiating a product recall of the ***DUROM Femoral Component 54 Code T and the DUROM Femoral Component 46 Code L,*** *involving* ***Catalog Numbers 01.00211.154 and 01.00211.146, Lot 2376766.***

This action is being conducted because some products of the above mentioned lot have been mixed up during packaging. The packaging for the 54 mm implant from this lot may contain a 46 mm implant and vice versa.

Affected product is shown shipped to the accounts on the attached Excel spreadsheet. Please check your inventory **immediately** for this product.

If you have this product, return it to the Zimmer Product Service Department, along with the completed questionnaire. **Do not return product recall product with other returns.** Upon return of the product, you will receive credit to your ZDI account.

If you no longer have this product, complete the attached questionnaire and fax to me at (574) 372-4265.

Please notify all of your sales associates with affected accounts of this product recall.

In order for us to advise the Food and Drug Administration about the effectiveness of this action, the questionnaire must be completed.

If you have any questions, please call us at 800-846-4637.

A. M. Recktenwall

Ann Recktenwall
Associate Manager, Field Actions
01.00211.154d.doc

Territory Number: _____ **Account Number:** _____

Account Name: _____

Account Address: _____

DISTRIBUTOR/PRODUCT RECALL CONTACT QUESTIONNAIRE
IMMEDIATE RESPONSE REQUIRED

PLEASE COMPLETE THE FOLLOWING AND RETURN TO ZIMMER:

Catalog Number	Lot Number	Quantity Returned
_____	_____	_____
_____	_____	_____

Return Product To:
Zimmer Product Service Department
1777 West Center Street
Warsaw, IN 46580

DO NOT RETURN PRODUCT RECALL PRODUCT WITH OTHER RETURNS.

_____ **No affected product to be returned. Explain:** _____

_____

NAME OF PERSON COMPLETING THIS FORM:

Printed Name:_____ Signature:_____

Title _____ Telephone: ( ) _____-_____ Date:____/____/____

NOTE: **This form and affected product must be returned to Zimmer before this action can be considered closed for your account.**

Williams, Sandra L

From: Dale Miller [dale.miller@zimmer.com]
Sent: Friday, September 28, 2007 8:00 AM
To: Williams, Sandra L
Subject: Initial notification - Zimmer GmbH product removal

Dear Ms. Williams

Following the voicemail I left this morning, Zimmer Warsaw, as importer, initiated correction/removal activities 9/19/07 on behalf of Zimmer GmbH (Winterthur, Switzerland) for [redacted] ***units*** of the Durom Resurfacing Femoral Component (K070292). The incorrect b(4) product may be contained in the packaging. A package labeled for a 54mm device may contain a 46mm device and vice versa. At the time of initiation of removal activities, the [redacted] units in the U.S. were showing as unconsumed and present in consignment inventories. Zimmer has received one report from the UK for this condition and at the time of discovery another correctly labeled unit was available to successfully complete the procedure

Our formal notification meeting the reporting requirements of 21 CFR Part 806 will be at the District Office with the specified 10 working days. Should you have questions, please do not hesitate to call me or email me.

S. Dale Miller

Dale Miller
Associate Director
Post Market Surveillance
& Regulatory Compliance
Zimmer, Inc.
(574) 372-4962
(574) 372-4605 (fax)
(574) 453-6325 (cell)

4556

Zimmer, Inc.

P.O. Box 708
Warsaw, IN 46581-0708
574.267.6131
www.zimmer.com

October 2, 2007

Sandra Williams
Compliance Officer
Food and Drug Administration
Detroit District
300 River Place, Suite 5900
Detroit, MI 48207-3179

Dear Ms. Williams:

Subject: **Recall of Zimmer Durom Femoral Component 54 CODE T and Zimmer Durom Femoral Component 46 CODE L**

This letter is to advise you of a recall which was initiated by Zimmer on September 19, 2007 for the subject device.

1) **Report Number:**

1822565-9/28/07-004-R

2) **Manufacturer/Representative Conducting Correction or Removal:**

Initial Importer:

S. Dale Miller
Associate Director, Corporate Post Market Surveillance and Regulatory Compliance
(574) 372-4262
Zimmer, Inc.
P.O. Box 708
Warsaw, IN 46581-0708

Name, Address and Telephone Number of Manufacturer: 3005233524

Patrick Tarnutzer
Engineer Product Surveillance
Tel. 41 (0) 52 262 53 88
Zimmer GmbH
Sulzer Allee 8
P.O. Box CH-8404
Winterthur, Switzerland

3) **Name of device:**

Durom Femoral Component 54 CODE T
Durom Femoral Component 46 CODE L

Intended use of device:

The Durom Femoral Hip Resurfacing Component has been designed for cemented use in patients who are likely to outlive a "conventional" hip prosthesis. Emphasis has been placed on preservation of bone stock and durable fixation of the components to the skeleton.

4) **Marketing status of device:**

Premarket Notification No.	K070292
Premarket Approval No.	No
Preamendment device	No
Device Listing No.	E621887
Product Code	KXA

5) **Catalog and Lot Number:**

01.00211.154, lot 2376766
01.00211.146, lot 2376766

6) **Description of event:**

The packaging contains the incorrect device. In packages labeled for the 54mm, there is a 46mm and vice versa.

Corrective action:

An investigation was initiated immediately when Zimmer GmbH was made aware of this mislabeling through receipt of a product complaint 9/17/07. Zimmer GmbH performed a root cause investigation of the areas where the error could have occurred. It was determined that inadequate work instructions and line clearance activities were the primary root causes. A risk analysis from this investigation was developed leading to a corrective and preventive action plan.

Immediate actions implemented included:

- Improvements in line clearance methodologies
- Improved separation of day and night shift work flows
- Revised work instructions reflecting these improvements for the affected work areas and training of operators to these work instructions
- Assignment of a dedicated training supervisor in affected areas

The balance of the action plan is in early implementation stages, and the Manager of Quality Systems is currently overseeing its effectiveness. With the measures taken and those anticipated, we believe we have addressed the root cause of the issue and will continue to monitor effectiveness.

Removal action:
Once all units are removed from the U.S. market, these will be returned to the manufacturer, Zimmer GmbH. The manufacturer will determine if product can be repackaged. Zimmer Warsaw will provide a follow up letter informing FDA of the results of this action.

7) **Injuries that have occurred with use of the device:**

No injuries have occurred with the use of the device. In the "discovery" surgery, another correctly labeled unit was available to complete the procedure.

8) **Total number of devices manufactured and distributed:**

Device	Total No. Manufactured	Distributed in U.S.	U.S. Accounts Affected
01.00211.154 Durom Fem. 54mm	[redacted]	[redacted]	[redacted]
01.00211.146 Durom Fem 46mm	[redacted]	[redacted]	[redacted]

b(4)

The [redacted] U.S. Accounts affected are detailed below. See #10. b(4)

9) **Date of Manufacture:**

July 2007 for both products

Expiration date or expected life:

01.00211.154	2012-02
01.00211.146	2012-02

10) **Name and address of domestic initial consignee of the device.**

Zimmer Great Lakes
41271 Concept Drive
Plymouth, Michigan 48170

Zimmer Tri-State
Attn: Accounts Payable
1001 Briggs Road/Ste 275
Mt Laurel, New Jersey 08054

Zimmer Carolinas
8655 Crown Crescent Court
Charlotte, North Carolina 28227

Zimmer Cook Associates, Inc
2200 Jerrold Ave Suite J
San Francisco, California 94124

11) **A copy of all communications regarding the recall (enclosed).**

The distributor in the affected U.S. territories was sent information regarding the recall action in their territory via electronic mail.

12) **A copy of the labeling (enclosed).**

Please see enclosures.

We believe these actions are adequate and will prevent a repetition of this problem. Upon completion of this recall, a closure letter will be sent.

Sincerely,

S. Dale Miller 10/2/07

S. Dale Miller
Associate Director, Corporate Post Market Surveillance and Regulatory Compliance

FDA Notification Letter.doc
Enclosures

Williams, Sandra L

From: Dale (Sidney) D Miller [dale.miller@zimmer.com]
Sent: Wednesday, October 31, 2007 6:23 PM
To: Williams, Sandra L
Cc: connie.morgan@zimmer.com
Subject: Re: Zimmer Durom hip resurfacing recall
Attachments: Card for "Dale (Sidney) D Miller" <dale.miller@zimmer.com>

Hi Sandra,

At the time the issue came to light, we did an initial assessment that shows an extremely high probability of discovery when the package is opened (in surgery). The 8mm differences in the diameters (inner and outer) of the devices means that they will not fit onto the bony site a surgeon would have already prepared for the implant he was expecting. That leaves the residual risk for surgeries where a spare implant of the same size is unavailable (a second is often present and this was true in the case of the discovery surgery). We have taken this analysis and put it into a health hazard evaluation document that we are routing for review. **I plan to send that as an attachment tomorrow.**

Regarding the [redacted] units that were recalled from the U.S., we have completed our recall activities. [redacted] of the [redacted] units b(4) were returned to Warsaw unused and we have sent them back to the manufacturing site (Zimmer GmbH in Switzerland). For the [redacted] unit, it was shipped [redacted] by our [redacted] distributor to the residence of one of their sales reps who was b(4) going to stock this at a local hospital for consignment. The package that was delivered to his residence was reported as stolen and we were not able to recover it (in 8 years of recalls at Zimmer, that is a new one for me). The information in this paragraph will be contained in the formal closure letter that Connie Morgan will send in the near future for the recall.

Please let me know if there are other questions I can answer.

Kind regards,

S. Dale Miller
Associate Director, Post Market Surveillance and Regulatory Compliance

Zimmer, Inc.
Phone 574-372-4962
Cell 574-453-6325
Fax 574-372-4265

----- Original Message -----

From: "Williams, Sandra L" <sandral.williams@fda.hhs.gov>

Date: Tuesday, October 30, 2007 5:47 pm

Subject: Zimmer Durom hip resurfacing recall

> > Hi Connie and Dale,
> >
> We have a couple of questions for you regarding the Zimmer Durom hip
> resurfacing recall.
>
> > Did Zimmer complete any kind of health hazard analysis?

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> How likely is it that a surgeon would notice that the 46mm femoral
> component is mislabeled as 54mm?
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> > If the surgeon does not notice this mislabeling and uses the device,
> > what is the likelihood of injury, and what type of injuries/long
> term> effects would you expect.
> >
> > Thanks!
> >
> Sandra
>
>

Z-275-8

Williams, Sandra L

From: Dale Miller [dale.miller@zimmer.com]
Sent: Thursday, November 01, 2007 5:29 PM
To: Williams, Sandra L
Cc: Morgan, Connie J; Bender, Karen J
Subject: RE: Zimmer Durom hip resurfacing recall
Attachments: HHA Zimmer Durom Femoral recall.pdf

Hi Sandra,

Please find attached our analysis of health hazard and discoverability for the Durom Hip Resurfacing Recall.

Kind regards,

S. Dale Miller
Associate Director, Post Market Surveillance and Regulatory Compliance

Zimmer, Inc.
Phone 574-372-4962
Cell 574-453-6325
Fax 574-372-4265

From: Williams, Sandra L [mailto:sandral.williams@fda.hhs.gov]
Sent: Wednesday, October 31, 2007 6:24 PM
To: Dale (Sidney) D Miller
Subject: RE: Zimmer Durom hip resurfacing recall

Thanks much, Dale.

From: Dale (Sidney) D Miller [mailto:dale.miller@zimmer.com]
Sent: Wednesday, October 31, 2007 6:23 PM
To: Williams, Sandra L
Cc: connie.morgan@zimmer.com
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Regarding the b(4) units that were recalled from the U.S., we have completed our recall activities. b(4) of the b(4) units were returned to Warsaw unused and we have sent them back to the manufacturing site (Zimmer GmbH in Switzerland). For the b(4) unit, it was shipped (b)(4) by our [redacted] distributor to the residence of one of their sales reps who was

going to stock this at a local hospital for consignment. The package that was delivered to his residence was reported as stolen and we were not able to recover it (in 8 years of recalls at Zimmer, that is a new one for me). The information in this paragraph will be contained in the formal closure letter that Connie Morgan will send in the near future for the recall.

Please let me know if there are other questions I can answer.

Kind regards,

S. Dale Miller
Associate Director, Post Market Surveillance and Regulatory Compliance

Zimmer, Inc.
Phone 574-372-4962
Cell 574-453-6325
Fax 574-372-4265

----- Original Message -----
From: "Williams, Sandra L" <sandral.williams@fda.hhs.gov>
Date: Tuesday, October 30, 2007 5:47 pm
Subject: Zimmer Durom hip resurfacing recall
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> > what is the likelihood of injury, and what type of injuries/long
> term> effects would you expect.
> >
> > Thanks!
> >
> Sandra
>
>

Health Hazard Analysis

The Zimmer *Durom*® Femoral Component

Product: The Zimmer *Durom*® Femoral Component (Fig.1) is a cemented device used in femoral head resurfacing. The design allows maximum femoral bone stock preservation in hemiarthroplasty applications as well as in combination with a metal acetabular bearing surface utilizing *Metasul*® technology.

Problem: Some packages from lot 2376766 may contain the incorrect sized implant. A package from Durom femoral component 54 code T (REF; 01.00211.154) was found in surgery to contain a Durom femoral component 46 code L (REF; 01.00211.146). Some units from the 46mm may contain 54mm femoral component and vice versa.

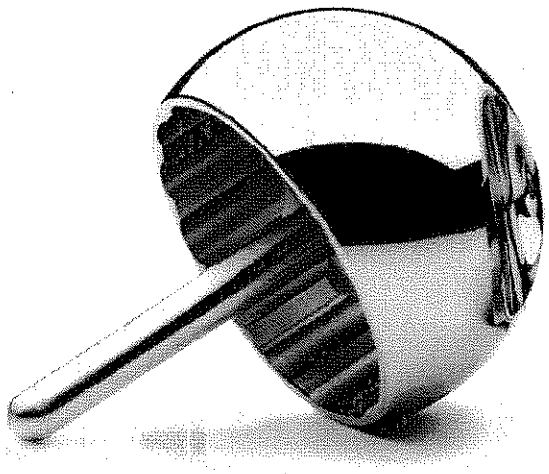

Figure 1: Sample Photo – *Durom*® Femoral Component

Corrective Action: Based on the investigation, the total affected population is [redacted] units. To capture these [redacted] units a total of [redacted] units were recalled and/or quarantined. The b(4) manufacturer, Zimmer GmbH, is in the process of identifying and implementing multiple changes to their packaging process in order to prevent similar types of mix-ups in the future.

Discoverability: There is a very high degree of probability that a misidentified femoral component can be discovered by the end user when opened in surgery. The size difference for the two components is 8mm for both the outer diameter and the inner diameter of the sphere. The misidentified product would be removed from the package by the end user after the femoral bone cuts have already been made.

- For the implantation of a 54mm device, the femoral bone would be cut down to approximately 45mm diameter. A 46mm implant coming out of the 54mm

packaging would be discovered as it has an inner dimension of 39.4mm and would not fit on a bony stump prepared for a 54mm implant.

- For the implantation of a 46mm device, the femoral bone would be cut down to approximately 37mm in diameter. A 54mm implant coming out of the 46mm packaging would be discovered as it has an inner dimension of 47.4mm and would be grossly loose if placed on bony stump prepared for a 46mm implant. In addition, the length of the central post for a 54mm implant is 11mm longer than the 46mm implant and would prevent it from fully seating into a the hole drilled for the 46mm implant.

For hip resurfacing surgeries (ex-U.S. approved only) the implants are marked with an alphabetic code that is designed to ensure compatible devices are implanted (Fig.2).

Durom Femoral Component			**Durom Acetabulum Component**			
Size = OD (mm)	**Letter Code**	**REF**	**Size**	**ID (mm)**	**Letter Code**	**REF**
38	D	01.00211.138	44	38	D	01.00214.044
40	F	01.00211.140	46	40	F	01.00214.046
42	H	01.00211.142	48	42	H	01.00214.048
44	J	01.00211.144	50	44	J	01.00214.050
46	**L**	**01.00211.146**	52	46	L	01.00214.052
48	N	01.00211.148	54	48	N	01.00214.054
50	P	01.00211.150	56	50	P	01.00214.056
52	R	01.00211.152	58	52	R	01.00214.058
54	**T**	**01.00211.154**	60	54	T	01.00214.060
56	V	01.00211.156	62	56	V	01.00214.062
58	X	01.00211.158	64	58	X	01.00214.064
60	Z	01.00211.160	66	60	Z	01.00214.066

Figure 2: Implant Letter coding chart

Risk Diagram: The following risk diagram shows the junctures where a mislabeled device would be detected and the potential consequences to the patient. The discussion only pertains to a surgery wherein the recalled lot is present in surgery.

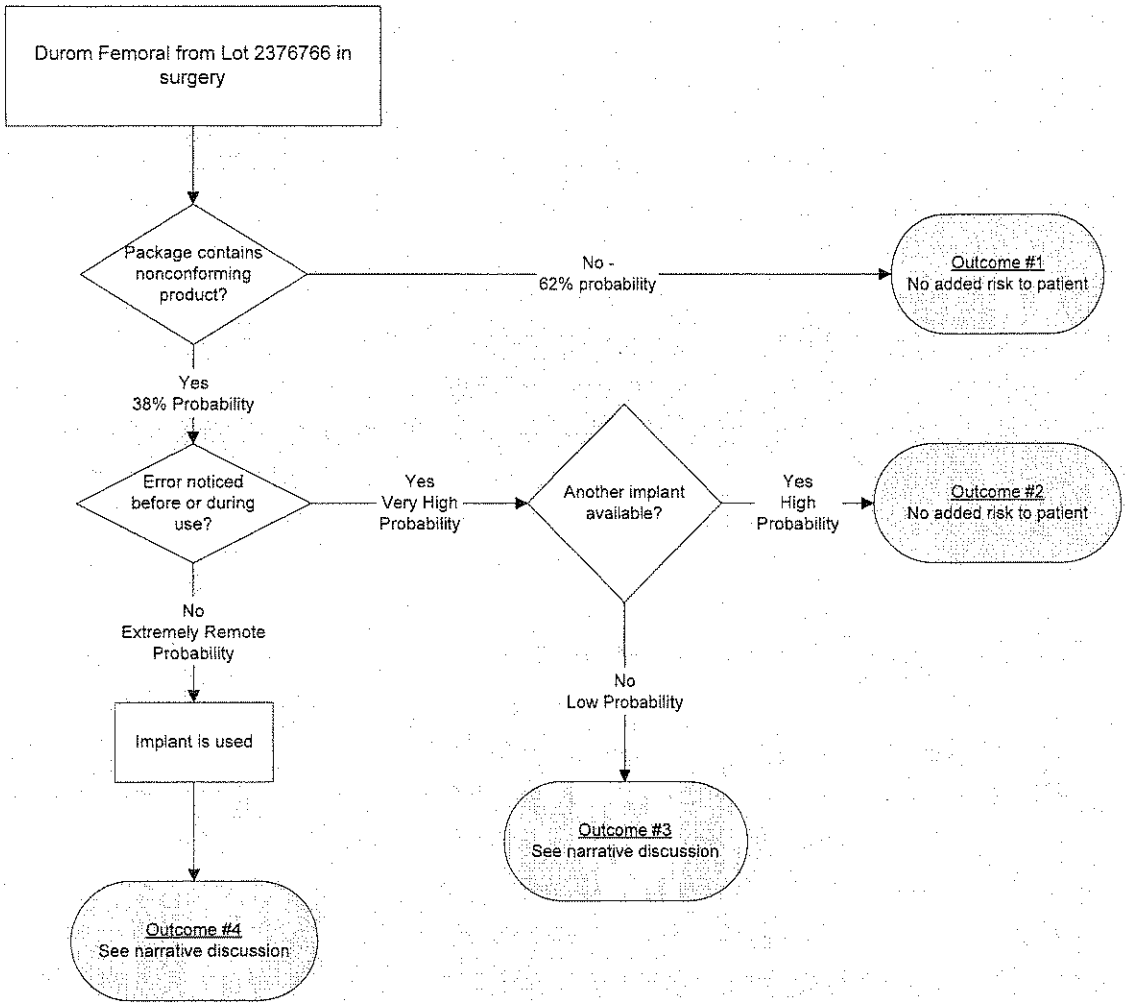

Figure 3: Risk/Discovery diagram

Outcome 1: There is no added risk to the patient if the correct device is contained in the package. [redacted] percent ([redacted] of [redacted]) of the packages contain the correct device, based on the investigation. (b)(4)

Outcome 2: When a misidentified device is discovered in surgery and another correctly packaged implant of the same item number is available, there is no added risk to the patient. A slight delay in surgery time may occur while the other implant is brought to the surgery and opened.

Outcome 3: If no replacement device is available, the surgeon would be forced to change the size of the implant or select another treatment option. In addition to the discussion below, the surgeon might also decide the abandon the use of the Durom devices entirely and switch to another hip system.

3.1 Mislabeled 54mm in Hemi-resurfacing procedure – If the surgeon were planning to do a femoral resurfacing while leaving the natural acetabulum intact, his options would be:
   a. To upsize or downsize 2mm the femoral head. To downsize he would have to remove more femoral bone. To upsize he would have to apply a thicker cement mantle to fit the bone cut for a 54mm. In either case, the fit in the natural acetabulum would not be ideal.
   b. To change to a hemiarthoplasty device requiring the removal of more bone

3.2 Mislabeled 54mm in Metal-on-Metal Resurfacing procedure (ex-U.S. approved only) – If the surgeon were doing a Durom resurfacing hip procedure his options would be:
   a. To upsize the femoral component, filling the gap with a thicker cement mantle and increase the acetabular component to 56mm. This would require additional one removal
   b. To abandon the resurfacing approach and switch to a total hip replacement utilizing a Metasul Large Diameter Head (LDH).

3.3 Mislabeled 46mm in Hemi-resurfacing procedure – If the surgeon were planning to do a femoral resurfacing while leaving the natural acetabulum intact, his options would be:
   a. To upsize or downsize 2mm the femoral head. To downsize he would have to remove more femoral bone. To upsize he would have to apply a thicker cement mantle to fit the bone cut for a 46mm. In either case, the fit in the natural acetabulum would not be ideal.
   b. To change to a hemiarthoplasty device requiring the removal of more bone

3.4 Mislabeled 46mm in Metal-on-Metal Resurfacing procedure (ex-U.S. approved only) – If the surgeon were doing a Durom resurfacing hip procedure his options would be:
   a. To upsize the femoral component, filling the gap with a thicker cement mantle and increase the acetabular component to 48mm. This would require additional bone removal
   b. To abandon the resurfacing approach and switch to a total hip replacement utilizing a Metasul Large Diameter Head (LDH).

Outcome 4: It is an extremely remote probability that an end user would not notice the 8mm difference in the implants. A large mismatch between the femoral head and the acetabular surface (natural or implant) would occur leading to instability, patient pain, compromised leg length, and certain revision surgery. Again, this is considered remote in probability.

Health Hazard Summary:

In summary, the absence of a correctly identified identical device in the surgery (Outcome #3) poses some risk to the patient as the surgeon would be forced to alter his course of treatment. This might involve more bone removal, suboptimal fit of implants, and/or a thicker cement mantle. The patient could also potentially be subjected to longer surgery time and increased anesthesia. The patient is likely to fully recover and only a small probability exists that the effects on the patient would be long term or lead to an additional, revision surgery.

Analysis prepared and compiled by:

S. Dale Miller

S. Dale Miller, CQE
Associate Director, Post Market Surveillance and Regulatory Compliance

Williams, Sandra L

From: Williams, Sandra L
Sent: Saturday, November 03, 2007 3:43 PM
To: Skrzypchak, Amy
Cc: Williams, Sandra L
Subject: FW: Zimmer Durom hip resurfacing recall
Attachments: HHA Zimmer Durom Femoral recall.pdf

From: Dale Miller [mailto:dale.miller@zimmer.com]
Sent: Thursday, November 01, 2007 5:29 PM
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Kind regards,

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Regarding the [redacted] units that were recalled from the U.S., we have completed our recall activities. [redacted] of the [redacted] units (b4) were returned to Warsaw unused and we have sent them back to the manufacturing site (Zimmer GmbH in Switzerland). For the [redacted] unit, it was shipped [redacted] by our [redacted] distributor to the residence of one of their sales reps who was (b4) going to stock this at a local hospital for consignment. The package that was delivered to his residence was reported as stolen and we were not able to recover it (in 8 years of recalls at Zimmer, that is a new one for me). The information in this paragraph will be contained in the formal closure letter that Connie Morgan will send in the near future for the recall.

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> Sandra
>
>

45326

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Detroit District
300 River Place
Suite 5900
Detroit, MI 48207
Telephone: 313-393-8100
FAX: 313-393-8139

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

December 13, 2007

Connie J. Morgan
Manager, Regulatory Compliance
Zimmer Inc.
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: Z-275/276-08

Dear Ms. Morgan:

We agree with your firm's decision to recall the following products because they were mislabeled as to size:

Z-275-08: Zimmer Durom Hip Resurfacing Systems, Femoral Component 54 Code T; Catalog No. 01.00211.154, lot 2376766.

Z-276-08: Zimmer Durom Hip Resurfacing Systems, Femoral Component 46 Code L; Catalog No. 01.00211.146, lLot 2376766.

We have reviewed your action and conclude that it meets the formal definition of a "Recall". This is significant, as your action is an alternative to a Food and Drug Administration legal action to remove your defective product from the market. These recalls have been reported in the FDA Weekly Enforcement Report.

It is suggested that you follow the FDA's "Enforcement Policy-Recalls (including Product Corrections) - Guidelines on Policy, Procedures and Industry Responsibilities" issued June 16, 1978 in conducting your recall. Feel free to call us if you need another copy of this document.

These recalls have been classified by the FDA as Class II recalls, since FDA considers these devices to be adulterated and/or misbranded. This device defect presents a moderate risk of adverse health consequences. Our evaluation indicates that your submitted recall plan is adequate.

In addition to your recall efforts, it is equally important to assure that all returned merchandise is promptly inventoried, handled, and stored in such a manner as to assure its separation from acceptable materials so it will not inadvertently be used or shipped.

We request that you submit to our Detroit District office a recall status report at monthly intervals until your recalls have been completed. We request that you advise us in your first monthly status report of the steps you have taken to insure that any returned recalled

merchandise is properly inventoried and maintained to prevent unintended use or shipment, and of your intended method for disposition of the returned goods. Recall status reports should contain the following information:

(1) Number of accounts notified of the recall, and date and method of notification.

(2) Number of accounts responding to the recall communication and number of recalled units on hand at these accounts.

(3) Number of accounts that did not respond and the name, address, phone number and contact at any non-cooperative accounts.

(4) Summary of recall effectiveness efforts, including number and type of effectiveness checks conducted.

(5) Number of units of product returned and amount under your firm's control at the initiation of the recall.

(6) Estimated time frame for completion of the recall.

(7) Any corrective action you have taken to prevent occurrence of similar problems in the future.

(8) Final disposition of held stocks and returned recalled devices.

These status reports and your response to this letter should be addressed to: Food and Drug Administration, 300 River Place, Suite 5900, Detroit, Michigan 48207, Attention: Sandra Williams, Compliance Officer.

Our judgment regarding the effectiveness of your recalls will largely be based upon your implementation of the recall guidelines. Please be advised that failure to conduct an effective

recall could result in seizure of the violative product in commerce or other legal sanctions under the Food, Drug and Cosmetic Act.

Your cooperation in this matter is important for the protection of the general public.

Sincerely yours,

Joann M. Givens
District Director
Detroit District

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Detroit District
300 River Place
Suite 5900
Detroit, MI 48207
Telephone: 313-393-8100
FAX: 313-393-8139

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

June 5, 2008

S. Dale Miller
Associate Director, Post Market
Surveillance & Regulatory Compliance
Zimmer Inc.
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: Z-275/276-08

Dear Mr. Miller:

The Food and Drug Administration has completed its audit of your firm's recall of the following products because they were mislabeled as to size:

Z-275-08: Zimmer Durom Hip Resurfacing Systems, Femoral Component 54 Code T; Catalog No. 01.00211.154, lot 2376766.

Z-276-08: Zimmer Durom Hip Resurfacing Systems, Femoral Component 46 Code L; Catalog No. 01.00211.146, lot 2376766.

We conclude that these recalls have been completed. Therefore, FDA considers these recalls to be terminated.

This letter does not relieve you or your firm from the responsibility of taking all necessary steps to assure compliance with the Food, Drug and Cosmetic Act in the future.

Sincerely yours,

Joann M. Givens
District Director
Detroit District

Zimmer, Inc.

P.O. Box 708
Warsaw, IN 46581-0708
574.267.6131
www.zimmer.com

July 22, 2008

Durom® Acetabular Component
Patient Communication Guidance for Surgeons

Overview

Due to the temporary marketing and distribution suspension of the *Durom* Acetabular Cup ("*Durom* Cup") and related communications and potential news coverage, hip replacement patients are likely to seek further information about their implant -- and those implanted with the *Durom* Cup may have special questions and needs.

Zimmer offers the following information to assist surgeons and their staffs in their effort to help patients interpret their individual situation appropriately and to help patients make informed and appropriate decisions about their care and not compromise their future care. We hope this information will:

- Help manage patient needs efficiently and effectively;
- Identify patients who may need additional help based on self-reported symptoms; and
- Address the needs of patients implanted with a *Durom* Cup who have had revision surgery or who may require it.

First and foremost, when receiving an inquiry or question, surgeons should immediately establish whether the patient was implanted with the *Durom* Cup as part of his/her THA.

Communication with Non-*Durom* Cup THA Patients

Goal: Prevent unnecessary confusion, anxiety or undue concern about the implant they received

- The implant used in your hip replacement surgery is different from the one in the news reports or that you heard/read about.

As necessary/appropriate:

- The *Durom* Cup was not "recalled" and Zimmer believes that the device performs well when placed correctly.
- It is important to keep in mind that hip replacement surgery has a high level of success.
    - The devices are designed to deliver certain benefits to patients. Those potential benefits have to be balanced with the technical challenges and skills required to use them safely and effectively as well as with the risks that the clinical outcome will not meet a patient's expectations. The vast majority of the time, potential device benefits and surgical skill requirements and the risks of an adverse outcome are in very good balance and deliver the desired results to patients.

Communication with *Durom* Cup Patients

Goal: Define individual risk in context; prevent unnecessary anxiety; educate about symptoms of potential loosening; guide to seek further help as needed

- The *Durom* Cup has been available for several years outside the U.S. with excellent clinical results. The manufacturer has confirmed that there is no evidence of a defect in the design or manufacture of these devices.
- Some surgeons in the U.S. have reported a higher than expected rate of cup loosening with the *Durom* Cup.
- Challenges with this device can occur when bone does not grow onto the cup in a normal fashion, which could create a situation where the cup becomes painful because it is loose.
- In the case of this particular implant, the manufacturer has observed that in some cases the bone has not grown onto the cup in the intended fashion.
- After thoroughly investigating the matter, Zimmer is developing a new training program focused on surgical technique and cup placement, which Zimmer believes will assist surgeons to achieve the desired clinical results with this product. Zimmer has recommended that all surgeons discontinue use of the product until they have been trained under the new program.
- The manufacturer believes the likelihood of currently implanted patients requiring revision is low.
- The product is not being recalled and there is no need for special medical tests to determine if the implant is loose. Routine follow-up evaluations should be scheduled by your surgeon. At that time, your surgeon should evaluate your clinical progress towards recovery, and examine your X-rays for indications of good bone growth on the acetabular cup.
- The main symptom of a potential problem with these implants is pain that radiates in the hip or groin area, but keep in mind hip replacement surgery is a very invasive procedure and a certain amount of pain shortly after surgery is expected.
- So, if you have hip pain it does not necessarily mean you have a loose implant. If you are experiencing pain more than three months after surgery, then you should make an appointment with your surgeon.

Additional Info for *Durom* Cup Patients

Zimmer has expanded its toll-free information line to address the basic information needs of patients. Zimmer will always refer patients' medical questions directly to their physician. However, should you have a patient who wishes to speak with Zimmer, please refer them to: 1-866-946-5633.

Zimmer is offering direct support to patients who require or who have undergone revision surgery of *Durom* components. If you have such patients in your practice, please refer them to David Royster at Zimmer at (574) 372-4712 or david.royster@zimmer.com to discuss compensation for costs associated with their revision surgery.

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Zimmer, Inc.

P.O. Box 708
Warsaw, IN 46581-0708
574.267.6131
www.zimmer.com

URGENT DEVICE CORRECTION

July 22, 2008

Dear Surgeon:

Since we last wrote to you in May 2008 regarding the *Durom*® Acetabular Component ("*Durom* Cup"), Zimmer has completed an extensive investigation of clinical experience with this product and its conformance to specifications. We are able at this time to share with you key conclusions and actions with respect to the *Durom* Cup in the United States.

- **The results of our in-depth investigation have led us to conclude that additional surgical technique instructions and training are necessary in the United States, and we strongly recommend that U.S. surgeons stop implanting the *Durom* Cup until receiving such training.**
- **Zimmer will suspend marketing and distribution of the *Durom* Cup in the U.S., while we update product labeling to provide more detailed surgical technique instructions and implement a surgical training program for U.S. surgeons.**
- **The *Durom* Cup will continue to be marketed and distributed without interruption outside the U.S.**

Our investigation included clinical and radiographic data review from users of the *Durom* Acetabular system, including those who have been pleased with their results, as well as users who are experiencing a higher than desired rate of revision. A total of twelve clinical sites that were among those with the highest patient volume for *Durom* Cup implants in both the U.S. and Europe were visited so that the largest number of patient cases could be reviewed in the shortest amount of time. More than 3,100 cases were examined overall.

We have identified that the more successful users consistently execute crucial technique steps for *Durom* Cups in a specific manner. The steps include but are not limited to line-to-line reaming, use of trials in every case, proper cup position for this device, appropriate impaction techniques, and no repositioning. In addition to the clinical component of our investigation, Zimmer has thoroughly investigated the design and manufacturing processes associated with the *Durom* Cup. No evidence of a defect in the materials, manufacture, or design of the implant has been found.

The overall rate of revision surgery is approximately 0.6% of all the *Durom* Cups sold to date in the U.S. However, due to difficulties in gathering data and our review of the above mentioned sites, we believe this may underestimate the actual revision rate. Of the U.S. sites investigated (where every patient -- more than 1,300 -- was reviewed) that

employed the above described techniques, the combined revision rate is 1.5%. Conversely, the revision rate for other sites is 5.7%.

Zimmer has reviewed the results of its investigation with the U.S. Food and Drug Administration and will continue to update the Agency as we move forward. Revised product labeling to include more detailed surgical technique instructions will be the subject of a further communication to surgeons over the next several weeks. Zimmer also is developing a comprehensive surgical skills training curriculum, working with experts in the U.S. and in Europe, where the product has been available since 2003 with significant training support for hip resurfacing and large diameter head applications, and where clinical outcomes have been consistently positive. Following initiation of the new U.S. training program, the *Durom* Cup will be made available to surgeons as they complete training. We will update you shortly about the status of the new curriculum and how you will be able to access it in the future.

These actions will be the subject of a public announcement by Zimmer the evening of July 22nd (please see hard copy attached of an excerpt from a Zimmer press release and related information on the *Durom* Cup investigation). We recognize that communication around this issue will stir patient interest, and we are eager to assist and support your efforts to address the range of patient needs that may emerge over the next several weeks. We are implementing several related measures, including:

- Development of patient management guidelines, to assist surgeons in the ongoing evaluation of patients currently implanted with the *Durom* Cup. These are currently being finalized and will be distributed shortly.
- Provision of a brief guide to suggested patient conversation (attached), to assist you and your staff in effectively and efficiently addressing patient questions and concerns.
    - Please note that Zimmer will suggest that patients who were implanted with the *Durom* Cup or who believe they may have been implanted with the *Durom* Cup and are experiencing pain more than three months after surgery consult with their physician.
    - We also have expanded our existing *Durom* Cup toll-free information service to address the basic information needs of patients who wish to call the Company. We will continue to refer patients with medical concerns to their physicians.
- Direct support to patients who require or who have undergone revision surgery of *Durom* components. If you have such patients in your practice, please have them contact David Royster at Zimmer at (574) 372-4712 or david.royster@zimmer.com to discuss compensation for costs associated with their revision surgery.
- Outreach to relevant professional societies to ensure that their memberships have accurate information about the *Durom* Cup field action.

All monoblock metal-on-metal acetabular cups are recognized as technically challenging devices to implant. Reducing the risk of hip dislocation while conserving acetabular bone is a key benefit of these devices that must be weighed against the technique demands.

Certain aspects of implanting technique are crucial to the clinical success of the device. Please note that utilization of the *Durom* Cup in a hip resurfacing application has not received FDA clearance for use in the U.S.

We continue to believe based on the results of our comprehensive investigation that the *Durom* Cup is a safe and effective device when used as intended. However, Zimmer does recognize this is a challenging procedure and thus is strongly recommending surgeons seek further training before attempting further *Durom* Cup implantations.

If you have relevant clinical information, questions, or comments regarding this matter, please contact us via our *Durom* toll-free information line (1-866-946-5633). Alternatively, you also may contact us at durom@zimmer.com.

Sincerely,

Cheryl Blanchard

Cheryl R. Blanchard, Ph.D.
Sr. Vice President, Research and Development
Chief Scientific Officer
Zimmer, Inc.

Zimmer, Inc.

P.O. Box 708
Warsaw, IN 46581-0708
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July 22, 2008

Background on *Durom*® Cup Status

Zimmer Temporarily Suspends Marketing and Distribution of *Durom*® Acetabular Component in the United States to Update Labeling and Implement Surgical Technique Training

Zimmer Holdings, Inc (NYSE and SWX: ZMH) is temporarily suspending marketing and distribution of the *Durom*® Acetabular Component (*Durom* Cup) in the United States, while the Company updates labeling to provide more detailed surgical technique instructions to surgeons and implements its surgical training program in the U.S. The *Durom* Cup will continue to be marketed without interruption outside the U.S.

Zimmer is taking this voluntary action to address its concerns regarding reports of cup loosenings and revisions of the acetabular component used in total hip replacement procedures, in some patients who have been implanted with the *Durom* Cup in the U.S.

While many U.S. surgeons have had success implanting the *Durom* Cup, a subset have experienced elevated revision rates since the product was launched in the U.S. in 2006. These results contrast with product experience in Europe, where post-marketing data continue to show excellent clinical outcomes since the product launched in 2003. Following a comprehensive review of clinical experience and product conformance to specifications in the U.S. and Europe, Zimmer has found no evidence of a defect in the materials, manufacture, or design of the implant. The Company has identified that surgeons who regularly achieve the desired outcome with the *Durom* Cup consistently execute crucial technique steps and place the cup in a specific manner. Following its review, Zimmer has determined that revised surgical technique instructions and a surgical training program are required to more consistently achieve desired clinical results in the U.S. The Company has shared its review and conclusions with the U.S. Food and Drug Administration (FDA) and will continue to update the Agency.

While the Company believes the likelihood of currently implanted patients requiring revision is low, Zimmer has sent a letter to U.S. surgeons advising them to stop implanting the *Durom* Cup, until the updated labeling is issued providing more detailed surgical technique instructions and they receive training.

"The Company is taking the necessary steps to address the apparent surgical training need, so that patients in the U.S. can consistently experience the results for which the *Durom* Cup was developed, and which have characterized the majority of clinical experiences with this product to date," said David C. Dvorak, Zimmer Holdings President and Chief Executive Officer. "In parallel, we will work closely with U.S. surgeons to help them appropriately monitor and manage patients currently implanted with the *Durom* Cup."

Surgeon and patient support
Zimmer will provide clinical management guidelines to assist surgeons in the ongoing evaluation of patients currently implanted with the *Durom* Cup. The Company suggests that patients who were implanted with a *Durom* Cup or believe they may have been implanted with a *Durom* Cup, and are experiencing pain more than three months after surgery, consult with their physician. Patients seeking more information may contact Zimmer toll-free, 24 hours a day, seven days a week, at 1-866-946-5633.

Within the next several weeks, Zimmer will issue a further communication to U.S. surgeons providing them with updated labeling, which will include the more detailed surgical technique instructions. The Company is also developing a comprehensive surgical skills training curriculum, working with experts in Europe and the U.S. Following initiation of the new training program, the *Durom* Cup will be made available to surgeons as they complete training.

Background on Durom
Total hip arthroplasty (THA), or total hip replacement, is a common medical procedure performed on more than 442,000 patients in the U.S. each year, according to the Millennium Research Group report issued March 2008. It is designed to help relieve pain and improve joint function in people with severe hip degeneration due to arthritis or trauma. Traditional devices to replace degenerative hips utilize implantable metal or ceramic heads fitting into a modular metal-backed polyethylene bearing. One historical issue in THA has been wear of the bearing. As THA becomes more common among younger patients who want to maintain a physically active lifestyle, alternative bearing surfaces such as cross-linked polyethylene, ceramic-on-ceramic and metal-on-metal have been developed to address the issue of wear. Another issue with THA has been range of motion and instability that can lead to hip dislocation. Larger heads are inherently more stable than smaller heads and provide opportunity for greater range of motion of the joint. Because larger heads can generally cause more wear, the development of alternative bearing surfaces to improve wear has been important. Through development of products like the *Durom* Cup, improving range of motion and lowering risk of dislocation becomes more achievable.

The *Durom* Acetabular Component is a monoblock (constructed of a single piece of material) cup made of a cobalt chromium (CoCr) alloy and is designed for use in combination with Zimmer's *Metasul*® Metal-on-Metal Tribological Solution LDH™ (Large Diameter Heads) for THA. The design and material of the *Durom* Cup are key elements to its stability, wear resistance, and bone sparing characteristics. The *Durom* Cup has a pure titanium plasma-sprayed coating for fixation. In compliance with FDA requirements for abrasion testing of plasma-sprayed coatings, the coating on the *Durom* Cup sold in the U.S. has a slightly different structure and is slightly thicker (100 µm, or 0.1 mm) compared to that sold outside the U.S.

Data from clinical trials sponsored by Zimmer and conducted outside the U.S. have demonstrated no revisions with the *Durom* Cup in 386 cases, after two to seven years of

follow-up[i]. In addition, the Swedish Registry, an independent total joint registry, reports a 99.5 percent survivorship with the *Durom* Cup (222 patients with three-year follow-up).[ii]

The *Durom* Cup was launched in Europe in 2003 for hip resurfacing, a procedure that has been common practice in Europe for more than 15 years to provide patients with an earlier intervention alternative to total hip replacement. Hip resurfacing requires less bone removal than conventional THA, but necessitates a different surgical technique. The *Durom* System also was made available in Canada and Australia in 2003, India and Korea in 2005, and Argentina in 2006, with similar surgical technique training.

In the U.S., the *Durom* Cup was cleared for marketing in THA by the FDA in mid-2006. It has not received FDA approval for use in the U.S. as a hip resurfacing device. Like all metal-on-metal monoblock acetabular components, the technology and design parameters of the *Durom* Cup demand a surgical technique with a higher degree of precision and specificity compared to more common and familiar hip arthroplasty surgical techniques practiced in the U.S. Therefore, the *Durom* Cup requires training in implantation technique and cup placement for many surgeons who begin using the product and who otherwise may be expert in THA.

Durom Cup Investigation

In addition to a comprehensive review of clinical experience, which included analysis of standard post-marketing surveillance data from established international joint registries and direct evaluation of high volume clinical sites in the U.S. and Europe, Zimmer conducted a thorough investigation of the *Durom* Cup, including systematic evaluation of the manufacturing processes, design specifications, and production documentation.

Manufacturing processes were closely examined and the product was retested to ensure conformance to specifications such as cleanliness and dimensional requirements. In addition, the plasma-sprayed titanium coating was verified to meet requirements and compared to other plasma-sprayed coatings, and documentation from production lots was reviewed for any anomalies, with specific attention paid to lots involving known revisions. This investigation found no evidence of a defect in the materials, manufacture, or design of the implant.

The clinical investigation involved reviews of clinical sites in the U.S. and Europe, interviews with users of other metal-on-metal monoblock products to gain additional insight on the category of products, and a comprehensive literature review. The *Durom* Cup users sites were visited to review X-rays, analyze patient-reported data, and examine trends regarding cup placement. Interviews with surgeons were conducted to discuss the full range of clinical issues and experience that may affect outcome. These data were collected for the U.S. and Europe *Durom* Cup sites visited.

A total of twelve clinical sites that were among those with the highest patient volume for *Durom* Cup implants in both the U.S. and Europe were visited so that the largest number of patient cases could be reviewed in the shortest amount of time. Eight clinical sites

were reviewed in the U.S. and four in Europe. In the U.S., Zimmer reviewed data on more than 1,300 patients – approximately 10% of all U.S. procedures involving the *Durom* Cup to date. Similar information was gathered from the four European sites (one each in Belgium, France, Germany and UK) to better understand any differences in the clinical experience. More than 3,100 cases were examined overall.

Of the sites investigated in the U.S. that employed appropriate and necessary surgical techniques, Zimmer found that the combined revision rate was 1.5%. Conversely, the revision rate for the other sites was 5.7%.

"We continue to believe based on the results of our comprehensive investigation that the *Durom* Cup is a safe and effective device when used as intended," said Cheryl Blanchard, PhD., Senior Vice President, Research and Development, and Chief Scientific Officer. "With appropriate training support to surgeons, we are confident of achieving patient outcomes in the U.S. that are as consistent as what we have seen historically in Europe."

About Zimmer

Founded in 1927 and headquartered in Warsaw, Indiana, Zimmer is a worldwide leader in designing, developing, manufacturing and marketing orthopaedic reconstructive, spinal and trauma devices, dental implants, and related orthopaedic surgical products. Zimmer has operations in more than 25 countries around the world and sells products in more than 100 countries. Zimmer's 2007 sales were approximately $3.9 billion. The Company is supported by the efforts of more than 8,000 employees worldwide.

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Contacts

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[i] Zimmer, Inc. Data on File
[ii] Swedish Hip Arthroplasty Register Annual Report 2006; page 57

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Zimmer

Warsaw, IN

Williams, Sandra L

From: Michael Carter [michael.carter@zimmer.com]
Sent: Wednesday, July 23, 2008 6:32 AM
To: Williams, Sandra L
Subject: Final Press Release
Attachments: 2Q08 earnings release.pdf

Sandra,

Per your request.

The Durom Cup announcement was integrated into the 2nd Quarter earnings press release (page 5 is what I sent you).

Michael Carter
Vice President
Global Quality and Regulatory Affairs
(o) 574-371-8623
(c) 574-377-2000

Contacts:

Media		Investors	
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Zimmer Holdings, Inc. Reports Second Quarter 2008 Financial Results

- **Net Sales of $1.08 billion represents an increase of 11% reported (5% constant currency)**
- **Worldwide Reconstructive Sales increased 14% reported (8% constant currency)**
- **Worldwide Knee Sales increased 15% reported (10% constant currency)**
- **Diluted EPS were $0.99 reported and $1.03 adjusted, an increase of 5% adjusted over the prior year period**
- **Zimmer voluntarily suspends U.S. marketing and distribution of *Durom*® Acetabular Component while it updates labeling and implements surgical technique training**
- **Full-year Sales and EPS guidance revised**

(WARSAW, IN) July 22, 2008—Zimmer Holdings, Inc. (NYSE and SWX: ZMH) today reported financial results for the quarter ended June 30, 2008. The Company reported second quarter net sales of $1.08 billion, an increase of 11% reported and 5% constant currency over the second quarter of 2007. Diluted earnings per share for the quarter were $0.99 reported and $1.03 adjusted, an increase of 5% adjusted over the prior year period.

"During the quarter, our worldwide knee sales grew by 10% constant currency as we continue to expand our industry-leading knee business by offering surgeons a

comprehensive portfolio of proven designs and innovative new treatment options," said David Dvorak, Zimmer President and CEO. "We are making substantial progress on our operating and infrastructure initiatives, in a manner designed to position Zimmer for sustainable growth in an expanding health care market. We have also been executing plans under our enhanced compliance model, including holding numerous productive meetings with surgeons to discuss how we will continue to collaborate to improve patient care."

The Company resumed Zimmer Institute training activities, which will support the ongoing launches of several key products, including the *Zimmer*® *NexGen*® LPS-Flex Mobile Knee, the *Gender Solutions*™ *Natural-Knee*® Flex and the *Gender Solutions*™ Patello-Femoral Joint System in knees. Hip products include the *VerSys*® M/L Taper Hip with *Kinectiv*™ Technology and the *Fitmore*™ Hip stem. Absent any unforeseen events, the Company anticipates FDA clearance to market the *EPOCH*® *Gender Solutions* Hip during the second half of the year.

During the quarter, the Company utilized $276 million of cash and $220 million in borrowings to acquire 6.9 million shares. The Company completed its $1 billion stock repurchase program, which was scheduled to expire on December 31, 2008, and initiated the $1.25 billion repurchase program announced earlier in the year. Since its first repurchase program in 2006, Zimmer has used nearly $2 billion in internally generated funds to acquire more than 10% of its shares that were outstanding as of the end of 2005.

Sales Tables

The following tables provide sales results by geographic segment and product category, as well as the percentage change compared to the prior year quarter and six months on both a reported and constant currency basis.

NET SALES - THREE MONTHS ENDED JUNE 30, 2008
(in millions, unaudited)

	Net Sales	Reported % Growth	Constant Currency % Growth
Geographic Segments			
Americas	$ 595	5 %	4 %
Europe	326	22	8
Asia Pacific	159	18	6
Total	1,080	11	5
Product Categories			
Reconstructive			
Americas	480	7	6
Europe	294	23	9
Asia Pacific	130	21	10
Total	904	14	8
Knees			
Americas	280	9	9
Europe	125	24	10
Asia Pacific	62	25	14
Total	467	15	10
Hips			
Americas	149	4	3
Europe	138	21	7
Asia Pacific	56	15	3
Total	343	12	4
Extremities	31	18	14
Dental	63	12	6
Trauma	55	9	3
Spine	55	11	9
OSP and other	66	(14)	(18)

NET SALES - SIX MONTHS ENDED JUNE 30, 2008
(in millions, unaudited)

	Net Sales	Reported % Growth	Constant Currency % Growth
Geographic Segments			
Americas	$ 1,202	6 %	5 %
Europe	631	20	7
Asia Pacific	306	18	7
Total	2,139	11	6
Product Categories			
Reconstructive			
Americas	962	7	6
Europe	569	21	7
Asia Pacific	245	20	9
Total	1,776	13	7
Knees			
Americas	560	8	8
Europe	245	21	8
Asia Pacific	116	25	13
Total	921	13	8
Hips			
Americas	298	4	3
Europe	266	18	5
Asia Pacific	109	17	4
Total	673	11	4
Extremities	63	25	21
Dental	119	13	8
Trauma	110	10	4
Spine	109	14	11
OSP and other	144	(4)	(9)

Net earnings for the second quarter were $227 million on a reported basis and $237 million on an adjusted basis, an increase of 1% adjusted over the prior year period. Operating cash flow for the second quarter was $281 million. Net earnings for the first six months of 2008 were $466 million on a reported basis and were $481 million on an adjusted basis, an increase of 2% adjusted over the prior year period.

***Durom* Acetabular Component**

Zimmer is temporarily suspending marketing and distribution of the *Durom*® Acetabular Component (*Durom* Cup) in the U.S. on a voluntary basis, while the Company updates labeling to provide more detailed surgical technique instructions to surgeons and implements its surgical training program in the U.S. The *Durom* Cup will continue to be marketed without interruption outside the U.S.

While many surgeons have had success implanting the *Durom* Cup since it was launched in the U.S. in 2006, a subset have reported cup loosenings and revisions of the acetabular component used in total hip replacement procedures. These results contrast with product experience in Europe, where post-marketing data continue to show excellent clinical outcomes since the product launched in 2003. Following a comprehensive review of clinical experience and product conformance to specifications in the U.S. and Europe, Zimmer has found no evidence of a defect in the materials, manufacture, or design of the implant. The Company has identified that surgeons who regularly achieve the desired outcome with the *Durom* Cup consistently execute crucial technique steps and place the cup in a specific manner. Following its review, Zimmer has determined that revised surgical technique instructions and a surgical training program are required to more consistently achieve desired clinical results in the U.S. The Company has shared its review and conclusions with the U.S. Food and Drug Administration and will continue to update the Agency.

While the Company believes the likelihood of currently implanted patients requiring revision is low, Zimmer has sent a letter to U.S surgeons advising them to stop implanting the *Durom* Cup, until the updated labeling is issued providing more detailed

surgical technique instructions and they receive training. Additional information is being made available at www.zimmer.com.

Guidance

The Company is revising its guidance and expects full-year 2008 sales growth to be in a range of 8.5% to 9.0% over the prior year, which reflects constant currency growth of 4.5% to 5.0%. This compares with prior guidance of 10% to 11% reported and 6% to 7% constant currency growth over prior year. The adjustment to sales guidance includes a projected loss of $20 to $30 million in hip product sales pertaining to the *Durom* Cup in the U.S., weakness in U.S. Dental revenues and slower than anticipated uptake on certain new products. Adjusted diluted earnings per share for the full year are expected to be in a range of $4.05 to $4.10, as compared to prior guidance of $4.20 to $4.25. Revised earnings guidance gives effect to the reduction in sales from prior guidance as well as an increase in operating expenses associated with the global implementation of the Company's enhanced compliance program. Further details regarding the revised guidance will be discussed during tomorrow's investor conference call.

Conference Call

The Company will conduct its second quarter 2008 investor conference call tomorrow, July 23, 2008, at 8:00 a.m. Eastern Time. The live audio webcast can be accessed via Zimmer's Investor Relations website at http://investor.zimmer.com. It will be archived for replay following the conference.

Individuals who wish to dial into the conference call may do so at (888) 881-6248. International callers should dial (706) 634-6422. A digital recording will be available two hours after the completion of the conference call from July 23, 2008 to August 6, 2008. To access the recording, US/Canada callers should dial (800) 642-1687, or for International callers, dial (706) 645-9291, and enter the Conference ID, 54192735. A copy of this press release and other financial and statistical information about the periods to be presented in the conference call will be accessible through the Zimmer website at http://investor.zimmer.com.

About the Company

Founded in 1927 and headquartered in Warsaw, Indiana, Zimmer is a worldwide leader in designing, developing, manufacturing and marketing orthopaedic reconstructive, spinal and trauma devices, dental implants, and related orthopaedic surgical products. Zimmer has operations in more than 25 countries around the world and sells products in more than 100 countries. Zimmer's 2007 sales were approximately $3.9 billion. The Company is supported by the efforts of more than 8,000 employees worldwide.

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For more information about Zimmer, visit www.zimmer.com

Note on Non-GAAP Financial Measures

As used in this press release, the term **"adjusted"** refers to operating performance measures that exclude inventory step-up and acquisition, integration and other expenses. The term "**constant currency**" refers to any financial measure that excludes the effect of changes in foreign currency exchange rates. Reconciliations of these non-GAAP measures to the most directly comparable GAAP measure are included in this press release.

Zimmer Safe Harbor Statement

This press release contains forward-looking statements within the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 based on current expectations, estimates, forecasts and projections about the orthopaedics industry, management's beliefs and assumptions made by management. Forward-looking statements may be identified by the use of forward-looking terms such as "may," "will," "expects," "believes," "anticipates," "plans," "estimates," "projects," "assumes," "guides," "targets," "forecasts," and "seeks" or the negative of such terms or other variations on such terms or comparable terminology. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that could cause actual outcomes and results to differ materially. These risks and uncertainties include, but are not limited to, our compliance with the Deferred Prosecution Agreement through March 2009 and the Corporate Integrity Agreement through 2012, the impact of our enhanced healthcare compliance global initiatives and business practices on our relationships with customers and consultants, our market share and our overall financial performance, the success of our quality initiatives, the outcome of the informal investigation by the U.S. Securities and Exchange Commission into Foreign Corrupt

Practices Act matters announced in October 2007, price and product competition, rapid technological development, demographic changes, dependence on new product development, the mix of our products and services, supply and prices of raw materials and products, customer demand for our products and services, control of costs and expenses, our ability to obtain and maintain adequate intellectual property protection, our ability to successfully integrate acquired businesses, our ability to form and implement alliances, international growth, our compliance with governmental laws and regulations affecting our U.S. and international businesses including regulations of the U.S. Food and Drug Administration and foreign government regulators and tax obligations and risks, the impact of suspending U.S. distribution of one of our key hip replacement products, product liability and intellectual property litigation losses, reimbursement levels from third-party payors, cost-containment efforts of healthcare purchasing organizations, our ability to retain the independent agents and distributors who market our products, general industry and market conditions and growth rates and general domestic and international economic conditions including interest rate and currency exchange rate fluctuations. For a further list and description of such risks and uncertainties, see our periodic reports filed with the U.S. Securities and Exchange Commission. We disclaim any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be set forth in our periodic reports. Readers of this document are cautioned not to place undue reliance on these forward-looking statements, since, while we believe the assumptions on which the forward-looking statements are based are reasonable, there can be no assurance that these forward-looking statements will prove to be accurate. This cautionary statement is applicable to all forward-looking statements contained in this document.

ZIMMER HOLDINGS, INC.
CONSOLIDATED STATEMENTS OF EARNINGS
FOR THE THREE MONTHS ENDED JUNE 30, 2008 and 2007
(in millions, except per share amounts, unaudited)

	2008	2007	% Inc/(Dec)
Net Sales	$ 1,079.5	$ 970.6	11 %
Cost of products sold	262.3	216.4	21
Gross Profit	817.2	754.2	8
Research and development	50.1	53.5	(6)
Selling, general and administrative	446.2	374.3	19
Acquisition, integration and other expense	12.5	3.9	220
Operating expenses	508.8	431.7	18
Operating Profit	308.4	322.5	(4)
Interest and other	6.8	1.3	433
Earnings before income taxes and minority interest	315.2	323.8	(3)
Provision for income taxes	87.8	92.2	(5)
Minority interest	(0.3)	(0.1)	33
Net Earnings	$ 227.1	$ 231.5	(2)
Earnings Per Common Share			
Basic	$ 0.99	$ 0.98	1
Diluted	$ 0.99	$ 0.97	2
Weighted Average Common Shares Outstanding			
Basic	228.4	236.9	
Diluted	229.5	239.2	

ZIMMER HOLDINGS, INC.
CONSOLIDATED STATEMENTS OF EARNINGS
FOR THE SIX MONTHS ENDED JUNE 30, 2008 and 2007
(in millions, except per share amounts, unaudited)

	2008	2007	% Inc/(Dec)
Net Sales	$ 2,138.7	$ 1,920.8	11 %
Cost of products sold	517.0	422.8	22
Gross Profit	1,621.7	1,498.0	8
Research and development	100.1	105.8	(5)
Selling, general and administrative	861.8	735.9	17
Acquisition, integration and other expense	19.8	6.6	202
Operating expenses	981.7	848.3	16
Operating Profit	640.0	649.7	(2)
Interest and other	7.8	1.1	642
Earnings before income taxes and minority interest	647.8	650.8	0
Provision for income taxes	180.9	185.5	(2)
Minority interest	(0.5)	(0.4)	25
Net Earnings	$ 466.4	$ 464.9	0
Earnings Per Common Share			
Basic	$ 2.02	$ 1.96	3
Diluted	$ 2.01	$ 1.94	3
Weighted Average Common Shares Outstanding			
Basic	230.5	236.9	
Diluted	231.7	239.2	

ZIMMER HOLDINGS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in millions)

	June 30, 2008 (unaudited)	December 31, 2007
Assets		
Current Assets:		
Cash and equivalents	$ 388.1	$ 463.9
Restricted cash	2.8	2.5
Receivables, net	782.5	674.3
Inventories, net	800.7	727.8
Other current assets	234.0	214.2
Total current assets	2,208.1	2,082.7
Property, plant and equipment, net	1,113.7	971.9
Goodwill	2,721.3	2,621.4
Intangible assets, net	721.9	743.8
Other assets	177.4	213.9
Total Assets	$ 6,942.4	$ 6,633.7
Liabilities and Shareholders' Equity		
Current liabilities	$ 807.9	$ 748.6
Other long-term liabilities	296.9	328.4
Long-term debt	329.3	104.3
Minority interest	3.3	2.8
Shareholders' equity	5,505.0	5,449.6
Total Liabilities and Shareholders' Equity	$ 6,942.4	$ 6,633.7

ZIMMER HOLDINGS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE SIX MONTHS ENDED JUNE 30, 2008 and 2007
(in millions, unaudited)

	2008	2007
Cash flows provided by (used in) operating activities		
Net earnings	$ 466.4	$ 464.9
Depreciation and amortization	129.2	109.4
Non-cash gain on sale of assets	(8.7)	-
Share-based compensation	39.4	41.1
Income tax benefits from stock option exercises	10.0	37.9
Excess income tax benefits from stock option exercises	(6.0)	(25.6)
Changes in operating assets and liabilities		
Income taxes	(35.7)	4.1
Receivables	(81.9)	(54.2)
Inventories	(53.8)	(36.8)
Accounts payable and accrued expenses	87.6	2.4
Other assets and liabilities	(23.2)	(47.5)
Net cash provided by operating activities	523.3	495.7
Cash flows provided by (used in) investing activities		
Additions to instruments	(119.5)	(72.9)
Additions to other property, plant and equipment	(121.5)	(70.3)
Proceeds from sale of assets	12.0	-
Acquisitions, net of acquired cash	(7.5)	(112.1)
Net cash used in investing activities	(236.5)	(255.3)
Cash flows provided by (used in) financing activities		
Net borrowings under credit facilities	220.0	-
Proceeds from employee stock compensation plans	45.2	132.1
Excess income tax benefits from stock option exercises	6.0	25.6
Repurchase of common stock	(640.2)	(305.2)
Net cash used in financing activities	(369.0)	(147.5)
Effect of exchange rates on cash and equivalents	6.4	0.1
Increase (decrease) in cash and equivalents	(75.8)	93.0
Cash and equivalents, beginning of period	463.9	265.7
Cash and equivalents, end of period	$ 388.1	$ 358.7

ZIMMER HOLDINGS, INC.
NET SALES BY GEOGRAPHIC SEGMENT
FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2008 and 2007
(in millions, unaudited)

	Three Months Ended June 30,			Six Months Ended June 30,		
	2008	2007	% Inc/(Dec)	2008	2007	% Inc/(Dec)
Americas	$ 594.5	$ 568.1	5 %	$ 1,201.6	$ 1,135.9	6 %
Europe	325.8	267.2	22	631.3	526.0	20
Asia Pacific	159.2	135.3	18	305.8	258.9	18
Total	$ 1,079.5	$ 970.6	11	$ 2,138.7	$ 1,920.8	11

ZIMMER HOLDINGS, INC.
NET SALES BY PRODUCT CATEGORY
FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2008 and 2007
(in millions, unaudited)

	Three Months Ended June 30,			Six Months Ended June 30,		
	2008	2007	% Inc/(Dec)	2008	2007	% Inc/(Dec)
Reconstructive	$ 904.1	$ 794.7	14 %	$ 1,775.6	$ 1,574.2	13 %
Trauma	54.7	50.3	9	110.2	100.4	10
Spine	54.5	49.0	11	108.8	95.7	14
OSP and other	66.2	76.6	(14)	144.1	150.5	(4)
Total	$ 1,079.5	$ 970.6	11	$ 2,138.7	$ 1,920.8	11

ZIMMER HOLDINGS, INC.
RECONCILIATION OF REPORTED % GROWTH TO CONSTANT CURRENCY % GROWTH
(unaudited)

	For the Three Months Ended June 30, 2008		
	Reported % Growth	Foreign Exchange Impact	Constant Currency % Growth
Geographic Segments			
Americas	5 %	1 %	4 %
Europe	22	14	8
Asia Pacific	18	12	6
Total	11	6	5
Product Categories			
Reconstructive			
Americas	7	1	6
Europe	23	14	9
Asia Pacific	21	11	10
Total	14	6	8
Knees			
Americas	9	0	9
Europe	24	14	10
Asia Pacific	25	11	14
Total	15	5	10
Hips			
Americas	4	1	3
Europe	21	14	7
Asia Pacific	15	12	3
Total	12	8	4
Extremities	18	4	14
Dental	12	6	6
Trauma	9	6	3
Spine	11	2	9
OSP and other	(14)	4	(18)

ZIMMER HOLDINGS, INC.
RECONCILIATION OF REPORTED % GROWTH TO CONSTANT CURRENCY % GROWTH
(unaudited)

	For the Six Months Ended June 30, 2008		
	Reported % Growth	Foreign Exchange Impact	Constant Currency % Growth
Geographic Segments			
Americas	6 %	1 %	5 %
Europe	20	13	7
Asia Pacific	18	11	7
Total	11	5	6
Product Categories			
Reconstructive			
Americas	7	1	6
Europe	21	14	7
Asia Pacific	20	11	9
Total	13	6	7
Knees			
Americas	8	0	8
Europe	21	13	8
Asia Pacific	25	12	13
Total	13	5	8
Hips			
Americas	4	1	3
Europe	18	13	5
Asia Pacific	17	13	4
Total	11	7	4
Extremities	25	4	21
Dental	13	5	8
Trauma	10	6	4
Spine	14	3	11
OSP and other	(4)	5	(9)

ZIMMER HOLDINGS, INC.
Reconciliation of Net Earnings and Adjusted Net Earnings
For the Three Months Ended June 30, 2008 and 2007
(in millions, unaudited)

	Three Months Ended June 30,	
	2008	2007
Net Earnings	$ 227.1	$ 231.5
Inventory step-up	1.5	0.3
Acquisition, integration and other	12.5	3.9
Taxes on acquisition, integration and other and inventory step-up	(4.2)	(1.0)
Adjusted Net Earnings	$ 236.9	$ 234.7

ZIMMER HOLDINGS, INC.
Reconciliation of Net Earnings and Adjusted Net Earnings
For the Six Months Ended June 30, 2008 and 2007
(in millions, unaudited)

	Six Months Ended June 30,	
	2008	2007
Net Earnings	$ 466.4	$ 464.9
Inventory step-up	1.8	0.3
Acquisition, integration and other	19.8	6.6
Taxes on acquisition, integration and other and inventory step-up	(6.8)	(1.7)
Adjusted Net Earnings	$ 481.2	$ 470.1

ZIMMER HOLDINGS, INC.
Reconciliation of Diluted EPS and Adjusted Diluted EPS
For the Three Months Ended June 30, 2008 and 2007
(unaudited)

	Three Months Ended June 30,	
	2008	2007
Diluted EPS	$ 0.99	$ 0.97
Inventory step-up	0.01	-
Acquisition, integration and other	0.05	0.02
Taxes on acquisition, integration and other and inventory step-up	(0.02)	(0.01)
Adjusted Diluted EPS	$ 1.03	$ 0.98

ZIMMER HOLDINGS, INC.
Reconciliation of Diluted EPS and Adjusted Diluted EPS
For the Six Months Ended June 30, 2008 and 2007
(unaudited)

	Six Months Ended June 30,	
	2008	2007
Diluted EPS	$ 2.01	$ 1.94
Inventory step-up	0.01	-
Acquisition, integration and other	0.09	0.03
Taxes on acquisition, integration and other and inventory step-up	(0.03)	-
Adjusted Diluted EPS	$ 2.08	$ 1.97

ZIMMER HOLDINGS, INC.
Reconciliation of 2008 Projected Diluted EPS and Projected Adjusted Diluted EPS
(unaudited)

Projected Twelve Months Ended December 31, 2008:	Low	High
Diluted EPS	$ 3.97	$ 4.02
Inventory step-up	0.01	0.01
Acquisition, integration and other, net of tax	0.07	0.07
Adjusted Diluted EPS	$ 4.05	$ 4.10

zimmer

July 31, 2008

Ms. Sandra Williams
Compliance Officer
Food and Drug Administration
Detroit District
300 River Place, Suite 5900
Detroit, MI 48207-3179

Subject: **Zimmer Inc. Corrections and Removal Report:**
Zimmer Correction #9613350-07/15/2008-001-C

Dear Sandra:

Following our 7/15/08 telephone call from Zimmer VP, Global Quality and Regulatory Affairs, Michael Carter, this letter is to report a correction that Zimmer Inc. has initiated for the *Durom*® Acetabular Components listed in Attachment 1 of the enclosed Correction and Removal Report. Our initial notification to Durom system users in the form of a "Dear Surgeon" letter was mailed 7/22/2008.

The *Durom* Acetabular Implants are devices intended to replace the natural hip acetabulum of a patient during total hip arthroplasty. In order to improve expected clinical outcomes, Zimmer has determined that the written surgical technique and possibly other labeling require updating to help ensure that surgeons implant these devices utilizing certain specific techniques . Coupled with this, Zimmer will be developing and implementing a surgeon training program for U.S. users of the *Durom* Acetabular Cup system

Zimmer has received some reports of persistent post-operative pain, dislocation, and loosening of the acetabular implant leading to revision surgery. Zimmer has filed an MDR for each reported case. We have thoroughly investigated design, manufacture, labeling, clinical outcomes data, and surgical technique associated with the *Durom* Acetabular Component. No evidence of a defect in the materials, manufacture, or design of the implant has been found.

All monoblock metal-on-metal acetabular cups are recognized as technically challenging devices to implant. Reducing the risk of hip dislocation while conserving acetabular bone is a key benefit of these devices that must be weighed against the technique demands. Certain aspects of implanting technique are crucial to the clinical success of the device.

Our investigation included clinical and radiographic data review from users of the *Durom* Acetabular system who have been pleased with their results, as well as that from users who are

experiencing a higher than desired rate of revision. Zimmer has determined that additional training and a modified surgical technique document for *Durom* Acetabular Cups will be required.

Should you have any questions or concerns after reviewing the attached Correction and Removal report, please do not hesitate to contact me either by phone or e-mail.

Sincerely,

S. Dale Miller

S. Dale Miller
Associate Director, Global Regulations
Zimmer, Inc
Dale.miller@zimmer.com

Enclosures:

1) Copy of communications
    a. "Dear Surgeon" letter ("Urgent – Medical Device Correction") and attachment
    b. Documents posted on www.zimmer.com
2) Copies of labeling for affected products
    a. IFU (package insert)
    b. Original surgical technique document and other collateral labeling
3) CD Containing:
    a. Listing of all lots produced with manufacture and expiration dates
    b. U.S. distribution records
    c. Listing of recipients - U.S. surgeon letter

cc:

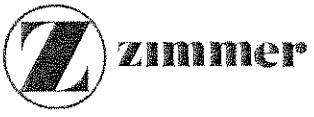
Daniel Buehler, VP Quality and Regulatory
Zimmer GmbH
Winterthur, Switzerland

Karen Bender
Sr. Director, Global Quality Systems
Zimmer Inc.

Michael Carter
VP, Global QA and RA
Zimmer Inc.

Correction and Removal Report 9613350-07/15/2008-001-C

U.S. Food and Drug Administration
Detroit District
300 River Place, Suite 5900
Detroit, MI 48207-3179



Zimmer Inc. (dba Zimmer GmbH)

Correction and Removal Report 9613350-07/15/2008-001C

1. Cover Letter, C&R Report, MDR Table
2. Communications
    a. "Dear Surgeon" Letter
    b. Communications posted on www.zimmer.com
3. Labeling
    a. Representative Product label
    b. Package insert (Instructions for Use)
    c. Surgical Technique and other publications
4. CD Containing Excel Files

Attachment I
Zimmer Inc. Removal #9613350-07/15/2008-001-C

1) **Report Number:**

9613350-07/15/2008-001-C

2) **Manufacturer/Representative Conducting Correction or Removal:**

Firm Reporting Correction:

Zimmer Inc.
P.O. Box 708
1800 W. Center St.
Warsaw, IN 46580
USA
S. Dale Miller
Associate Director, Global Regulations
Zimmer, Inc
Direct Line: (574) 372-4962
dale.miller@zimmer.com

Manufacturer:

Zimmer GmbH
Sulzer Allee 8
P.O. Box CH-8404
Winterthur, Switzerland
Paul Rowden
Associate Director, Quality Systems
Direct Line: +41 (0)52 262 1970
paul.rowden@zimmer.com

3) **Name of device:**

Durom® Acetabulum Component

Intended use of device:

- Noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis
- 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.

4) **Marketing status of device:**

Classification	510(k) number	510(k) clearance date	Device listing number	Product Code
Class II 510(k)	K053536	3/16/06	D019808	KWA

5) **Catalog Number:**

Product No.	Size (mm)	ID mm	Size Code
01.00214.144	44	38	D
01.00214.146	46	40	F
01.00214.148	48	42	H
01.00214.150	50	44	J
01.00214.152	52	46	L
01.00214.154	54	48	N
01.00214.156	56	50	P
01.00214.158	58	52	R
01.00214.160	60	54	T
01.00214.162	62	56	V
01.00214.164	64	58	X
01.00214.166	66	60	Z

Lot Numbers – See enclosed CD containing data file

6) **Description of event:**

The *Durom* Acetabular Components (Figure 1) were released for sale in the U.S. in Q2 of 2006. Based on reported or alleged revision events, the overall rate of revision surgery is approximately 0.6% of the approximately 12,500 *Durom* Acetabular Cups sold to date in the United States. However, due to difficulties in gathering data, Zimmer believes this may be an underestimation of the actual revision rate. Of the sites investigated that employed certain implantation techniques, the combined revision rate is 1.5%. Conversely, the revision rate for sites that did not adhere to these techniques is 5.7% with one site exhibiting 3-zone progressive radiolucencies in 25% of their cases.

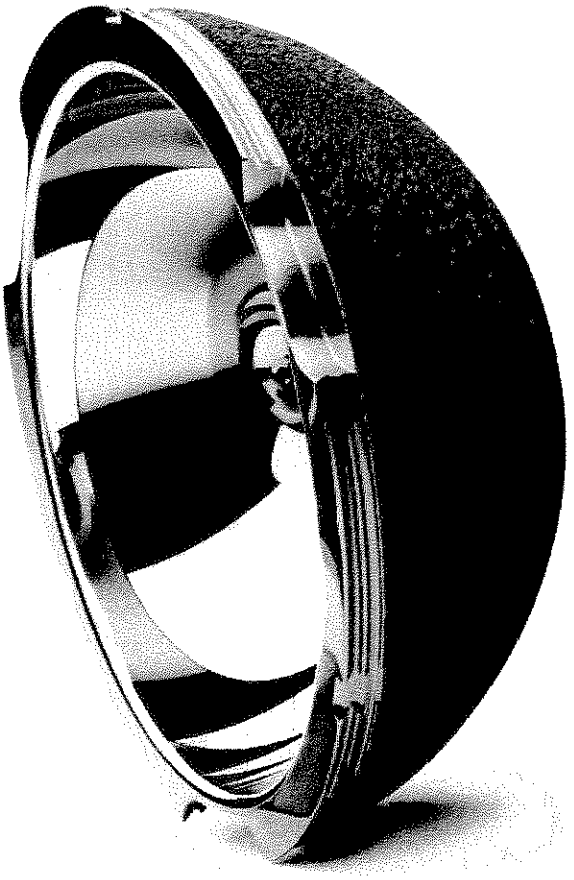


Figure 1: Representative Picture of the Durom Acetabulum Component

For the design of the *Durom* system, the implant is intended to achieve initial fixation and stability by the engagement into the host bone of circumferential fins that protrude 0.5mm (Figure 2). If a surgeon has reamed the bone for a press-fit or has not used sufficient impaction force, the fins may not be adequately engaged in host bone and/or the plasma spray surface coating may not be in apposition to bone.

Further, repositioning of an acetabular implant after impaction is a common practice employed by surgeons who implant various acetabular systems. For acetabular systems that achieve their initial fixation and stability into the host bone by the use of screws, this repositioning of the implant is of no clinical consequence. However, if a surgeon repositions the *Durom* implant after impaction, the initial fin engagement and stability may be compromised, thereby increasing the risk of fin disengagement and early revision.

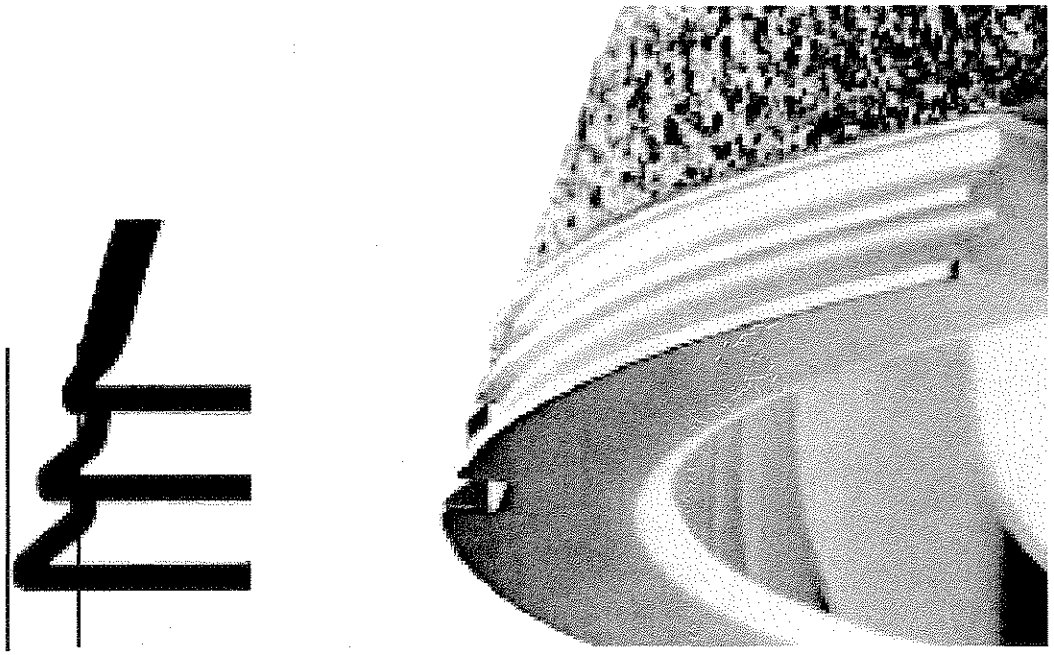


Figure 2: Flared Circumferential Fins on the Durom Acetabular Component

Correction and Removal Action:

On July 22, 2008 Zimmer sent a "Dear Surgeon" letter to all known current and former U.S. users of the *Durom* Acetabular Cup. A copy of this letter is attached to this report. In the letter, surgeons were informed that they should stop implanting these devices until receiving training. Concurrent with this, Zimmer has suspended all marketing and distribution of the subject devices.

Zimmer is in the process of developing surgeon training that incorporates the information learned during the investigation. The surgical technique document is being updated to reflect the results of the investigation. Other labeling is also being evaluated to determine if changes are necessary. Once these steps are completed, the following will occur:

1. Zimmer will conduct a removal action for all extant copies of the current surgical technique document.

2. Copies of the updated surgical technique document, and possibly other modified labeling, will be mailed to all current and former users of the *Durom* Acetabular Cup with a second "Dear Surgeon" letter. In this letter, Zimmer will make inform users of the availability of training courses for Durom.
3. Zimmer will schedule and conduct training for surgeons who wish to resume implanting the *Durom* Acetabular Cup. Only upon successful completion of training, the devices will be made available to these surgeons on an account level basis.

7) **Injuries that have occurred with use of the device:**

(i) Number of deaths: **None**
(ii) Number of injuries: **51 (Fifty-one)**
(iii) Number of Malfunctions: **None**
(iv) Additional MDR comments:
- **Zimmer also continues to pursue case details for other incomplete reports of revision surgeries and will file MDR's for these.**
- **Any MDR's filed 7/16/08 or later will contain reference to this Correction and Removal Report 9613350-07/15/2008-001C in Box H9**
- **Attachment II lists the fifty-one MDR's that have been filed for the subject Durom Acetabular Cups since 510(k) clearance up through 7/15/08**

8) **Total number of devices manufactured and distributed:**

Number of Units Manufactured	Number of Units Distributed	Devices Subject to Correction	U.S. Consignees Affected	Ex-U.S. Consignees Affected
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

b(4)

Note: Based on sales, Zimmer estimates the total number of implanted devices to be approximately [redacted] (b)(4)

9) **Date of Manufacture:**

See file in enclosed CD

10) **Names and addresses of all domestic and foreign initial consignees of the devices and dates and number of devices distributed to each consignee**

See file in enclosed CD

11) **A copy of all communications regarding the recall (enclosed).**

Note: The "Dear Surgeon" letter was sent to 946 U.S. surgeons know to have implanted Durom cups or to possibly have implanted these devices.

12) **A copy of the labeling (enclosed).**

Attachment II
Table of MDR's Filed – From Clearance of K053536 Through 7/15/08

MDR Number	Cup Item Number	Country of Occurrence	Event Description (Date of implant/explant, if known, outcome, and reason)
Not assigned (2007)	01.00214.152	US	Approx. 3 months / revision surgery, Loosening, Lack of Ingrowth
Not assigned (2007)	01.00214.156	US	Approx. 8 months / revision surgery, Pain, Loosening, Lack of Ingrowth
9613350-2008-004	01.00214.152	US	Approx. 11 months / revision surgery, loosening
9613350-2008-006	01.00214.150	US	Approx. 5 months / revision surgery, loosening
9613350-2008-007	01.00214.152	US	Approx. 10 months / revision surgery, loosening
9613350-2008-008	01.00214.154	US	Approx. 8 months / revision surgery, loosening
9613350-2008-009	01.00214.150	US	06/13/2006 – Unknown / revision surgery, Osteolysis or Lesions
9613350-2008-010	01.00214.156	US	Approx. 5 months / revision surgery, loosening
9613350-2008-011	01.00214.156	US	Unknown / cup was too small
9613350-2008-025	01.00214.058	US	Unknown / revision surgery, infection
9613350-2008-035	01.00214.154	US	Approx. 14 months / revision surgery, pain
9613350-2008-038	01.00214.156	US	Approx. 16 months / revision surgery, pain
9613350-2008-039	01.00214.154	US	Approx. 27 months / revision surgery, infection
9613350-2008-040	01.00214.160	US	Approx. 20 days / revision surgery, loosening
9613350-2008-041	01.00214.158	US	Approx. 10 days / revision surgery, loosening
9613350-2008-042	01.00214.156	US	Approx. 1 month / revision surgery, loosening
9613350-2008-043	01.00214.158	US	Approx. 12 months / revision surgery, infection
9613350-2008-045	01.00214.148	US	08/15/2006 – Unknown revision surgery, loosening, pain
9613350-2008-046	01.00214.148	US	Approx. 7 months / revision surgery, loosening
9613350-2008-047	01.00214.150	US	06/20/2006 – Unknown / revision surgery, loosening, pain

MDR Number	Cup Item Number	Country of Occurrence	Event Description (Date of implant/explant, if known, outcome, and reason)
9613350-2008-048	01.00214.148	US	Approx. 20 months / revision surgery, loosening, pain, no in growth
9613350-2008-049	01.00214.162	US	Approx. 12 months / revision surgery, loosening
9613350-2008-050	01.00214.154	US	03/26/2007 – Unknown / revision surgery, loosening, pain
9613350-2008-051	01.00214.148	US	05/28/2007 – Unknown / revision surgery, loosening, pain
9613350-2008-052	01.00214.150	US	Approx. 11 months / revision surgery, loosening, pain
9613350-2008-053	01.00214.150	US	Approx. 4 months / revision surgery, loosening
9613350-2008-054	01.00214.150	US	Approx. 18 days / revision surgery, loosening
9613350-2008-055	01.00214.1xx	US	UNK / revision surgery, loosening
9613350-2008-058	01.00214.1xx	US	Unknown / cup fixation
9613350-2008-059	01.00214.152	US	08/14/2006 – Unknown / revision surgery, loosening, pain
9613350-2008-061	01.00214.150	US	Unknown – 04/04/2007 / revision surgery, no in-growth
9613350-2008-062	01.00214.150	US	08/20/2007 – 07/30/2007 / revision surgery, loosening
9613350-2008-063	01.00214.156	US	Unknown – 04/30/2008 / revision surgery, no in-growth, loosening
9613350-2008-064	01.00214.158	US	07/24/2007 – 04/26/2008 / revision surgery, no in-growth, pain
9613350-2008-065	01.00214.152	US	01/20/2008 – Unknown / revision surgery, no in-growth, pain
9613350-2008-066	01.00214.166	US	05/01/2007 – Unknown / revision surgery, pain
9613350-2008-067	01.00214.150	US	03/20/2007 – Unknown / revision surgery, loosening, pain
9613350-2008-068	01.00214.160	US	05/08/2007 – Unknown / / revision surgery, no in-growth
9613350-2008-069	01.00214.158	US	02/27/2007 - 05/14/2008 / revision surgery, pain
9613350-2008-070	01.00214.154	US	04/26/2007 – 05/21/2008 / revision surgery, no in-growth
9613350-2008-071	01.00214.152	US	05/06/2007 – 05/20/2008 / revision surgery, loosening, no in-growth

MDR Number	Cup Item Number	Country of Occurrence	Event Description (Date of implant/explant, if known, outcome, and reason)
9613350-2008- 073	01.00214.158	US	06/28/2007 – 01/17/2008 / revision surgery, loosening, pain
9613350-2008- 074	01.00214.154	US	12/21/2006 – 12/20/2007 / revision surgery, loosening, pain
9613350-2008- 075	01.00214.150	US	08/06/2007 – 05/19/2008 / revision surgery, loosening, no in-growth
9613350-2008- 076	01.00214.150	US	05/29/2007 – 06/03/2008 / revision surgery, no in-growth
9613350-2008- 077	01.00214.152	US	09/25/2007 – 06/10/2008 / revision surgery, loosening, pain, no in- growth
9613350-2008- 080	01.00214.1xx	US	07/12/2006 – UNKNOWN / revision surgery, pain
9613350-2008- 081	01.00214.1xx	US	17/10/2007 – UNKNOWN / revision surgery, pain
9613350-2008- 082	01.00214.1xx	US	05/03/2007 – 06/23/2008 / revision surgery, pain
9613350-2008- 083	01.00214.1xx	US	05/31/2006 – 06/20/2008 / revision surgery, pain
9613350-2008- 084	01.00214.156	US	10/17/2007 – 06/18/2008 / revision surgery, pain, no in- growth

Durom Correction Communications

Mailed to U.S. Surgeon Users

Durom Correction Communications

Posted on www.zimmer.com

Zimmer, Inc.

P.O. Box 708
Warsaw, IN 46581-0708
574.267.6131
www.zimmer.com

URGENT DEVICE CORRECTION

July 22, 2008

Dear Surgeon:

Since we last wrote to you in May 2008 regarding the *Durom*® Acetabular Component ("*Durom* Cup"), Zimmer has completed an extensive investigation of clinical experience with this product and its conformance to specifications. We are able at this time to share with you key conclusions and actions with respect to the *Durom* Cup in the United States.

- **The results of our in-depth investigation have led us to conclude that additional surgical technique instructions and training are necessary in the United States, and we strongly recommend that U.S. surgeons stop implanting the *Durom* Cup until receiving such training.**
- **Zimmer will suspend marketing and distribution of the *Durom* Cup in the U.S., while we update product labeling to provide more detailed surgical technique instructions and implement a surgical training program for U.S. surgeons.**
- **The *Durom* Cup will continue to be marketed and distributed without interruption outside the U.S.**

Our investigation included clinical and radiographic data review from users of the *Durom* Acetabular system, including those who have been pleased with their results, as well as users who are experiencing a higher than desired rate of revision. A total of twelve clinical sites that were among those with the highest patient volume for *Durom* Cup implants in both the U.S. and Europe were visited so that the largest number of patient cases could be reviewed in the shortest amount of time. More than 3,100 cases were examined overall.

We have identified that the more successful users consistently execute crucial technique steps for *Durom* Cups in a specific manner. The steps include but are not limited to line-to-line reaming, use of trials in every case, proper cup position for this device, appropriate impaction techniques, and no repositioning. In addition to the clinical component of our investigation, Zimmer has thoroughly investigated the design and manufacturing processes associated with the *Durom* Cup. No evidence of a defect in the materials, manufacture, or design of the implant has been found.

The overall rate of revision surgery is approximately 0.6% of all the *Durom* Cups sold to date in the U.S. However, due to difficulties in gathering data and our review of the above mentioned sites, we believe this may underestimate the actual revision rate. Of the U.S. sites investigated (where every patient -- more than 1,300 -- was reviewed) that

employed the above described techniques, the combined revision rate is 1.5%. Conversely, the revision rate for other sites is 5.7%.

Zimmer has reviewed the results of its investigation with the U.S. Food and Drug Administration and will continue to update the Agency as we move forward. Revised product labeling to include more detailed surgical technique instructions will be the subject of a further communication to surgeons over the next several weeks. Zimmer also is developing a comprehensive surgical skills training curriculum, working with experts in the U.S. and in Europe, where the product has been available since 2003 with significant training support for hip resurfacing and large diameter head applications, and where clinical outcomes have been consistently positive. Following initiation of the new U.S. training program, the *Durom* Cup will be made available to surgeons as they complete training. We will update you shortly about the status of the new curriculum and how you will be able to access it in the future.

These actions will be the subject of a public announcement by Zimmer the evening of July 22nd (please see hard copy attached of an excerpt from a Zimmer press release and related information on the *Durom* Cup investigation). We recognize that communication around this issue will stir patient interest, and we are eager to assist and support your efforts to address the range of patient needs that may emerge over the next several weeks. We are implementing several related measures, including:

- Development of patient management guidelines, to assist surgeons in the ongoing evaluation of patients currently implanted with the *Durom* Cup. These are currently being finalized and will be distributed shortly.
- Provision of a brief guide to suggested patient conversation (attached), to assist you and your staff in effectively and efficiently addressing patient questions and concerns.
    - Please note that Zimmer will suggest that patients who were implanted with the *Durom* Cup or who believe they may have been implanted with the *Durom* Cup and are experiencing pain more than three months after surgery consult with their physician.
    - We also have expanded our existing *Durom* Cup toll-free information service to address the basic information needs of patients who wish to call the Company. We will continue to refer patients with medical concerns to their physicians.
- Direct support to patients who require or who have undergone revision surgery of *Durom* components. If you have such patients in your practice, please have them contact David Royster at Zimmer at (574) 372-4712 or david.royster@zimmer.com to discuss compensation for costs associated with their revision surgery.
- Outreach to relevant professional societies to ensure that their memberships have accurate information about the *Durom* Cup field action.

All monoblock metal-on-metal acetabular cups are recognized as technically challenging devices to implant. Reducing the risk of hip dislocation while conserving acetabular bone is a key benefit of these devices that must be weighed against the technique demands.

Certain aspects of implanting technique are crucial to the clinical success of the device. Please note that utilization of the *Durom* Cup in a hip resurfacing application has not received FDA clearance for use in the U.S.

We continue to believe based on the results of our comprehensive investigation that the *Durom* Cup is a safe and effective device when used as intended. However, Zimmer does recognize this is a challenging procedure and thus is strongly recommending surgeons seek further training before attempting further *Durom* Cup implantations.

If you have relevant clinical information, questions, or comments regarding this matter, please contact us via our *Durom* toll-free information line (1-866-946-5633). Alternatively, you also may contact us at durom@zimmer.com.

Sincerely,

Cheryl Blanchard

Cheryl R. Blanchard, Ph.D.
Sr. Vice President, Research and Development
Chief Scientific Officer
Zimmer, Inc.

Zimmer, Inc.

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Warsaw, IN 46581-0708
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Durom Acetabular Component

Zimmer is temporarily suspending marketing and distribution of the *Durom*® Acetabular Component (*Durom* Cup) in the U.S. on a voluntary basis, while the Company updates labeling to provide more detailed surgical technique instructions to surgeons and implements its surgical training program in the U.S. The *Durom* Cup will continue to be marketed without interruption outside the U.S.

While many surgeons have had success implanting the *Durom* Cup since it was launched in the U.S. in 2006, a subset have reported cup loosenings and revisions of the acetabular component used in total hip replacement procedures. These results contrast with product experience in Europe, where post-marketing data continue to show excellent clinical outcomes since the product launched in 2003. Following a comprehensive review of clinical experience and product conformance to specifications in the U.S. and Europe, Zimmer has found no evidence of a defect in the materials, manufacture, or design of the implant. The Company has identified that surgeons who regularly achieve the desired outcome with the *Durom* Cup consistently execute crucial technique steps and place the cup in a specific manner. Following its review, Zimmer has determined that revised surgical technique instructions and a surgical training program are required to more consistently achieve desired clinical results in the U.S. The Company has shared its review and conclusions with the U.S. Food and Drug Administration and will continue to update the Agency.

While the Company believes the likelihood of currently implanted patients requiring revision is low, Zimmer has sent a letter to U.S surgeons advising them to stop implanting the *Durom* Cup, until the updated labeling is issued providing more detailed surgical technique instructions and they receive training. The surgeon letter and related information is available at www.zimmer.com.

Durom Package Label

Representative Sample – Size 46/40

Similar scheme for each component in the series

Product No.	Size (mm)	ID mm	Size Code
01.00214.144	44	38	D
01.00214.146	46	40	F
01.00214.148	48	42	H
01.00214.150	50	44	J
01.00214.152	52	46	L
01.00214.154	54	48	N
01.00214.156	56	50	P
01.00214.158	58	52	R
01.00214.160	60	54	T
01.00214.162	62	56	V
01.00214.164	64	58	X
01.00214.166	66	60	Z

zimmer

Rx only

CE 0086

Acetabular cups

D011 500 213 - en/da/nl/fr/de/el/it/pt/es/sv – Ed. 08/07

Zimmer GmbH
Sulzer-Allee 8
CH-8404 Winterthur, Switzerland
www.zimmer.com

Representative in the USA:
Zimmer, Inc.
1800 West Center Street
Warsaw, Indiana, 46580, USA

ENGLISH

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

Acetabular cups

Important information for the operating surgeon

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 available product-specific information (e.g., product literature, written surgical technique). Zimmer is not liable for complications arising from the use of the device outside of its indicated uses, surgical technique or judgment, product selection, and similar matters outside the control of Zimmer.

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 all Zimmer orthopaedic companies, which include 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 must 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.

DESCRIPTION

An acetabular cup component is used in conjunction with a femoral head component for replacement of the acetabulum in total hip arthroplasty.
Acetabular cup components are available in different designs, materials and sizes.

This physicians insert is valid for the following acetabular cup components:

INTENDED ONLY FOR USE WITH BONE CEMENT:

- **Low profile Acetabular Cup (*Sulene*® PE [UHMWPE - ISO 5834-1/-2])**
  Cemented, all-polyethylene components for use with reinforcement rings and cages.
- **Full profile Acetabular Cup (*Sulene* PE [UHMWPE - ISO 5834-1/-2])**
  Cemented, all-polyethylene components for use with reinforcement rings and cages.

INTENDED ONLY FOR USE WITHOUT BONE CEMENT:

- **Acetabular Roof Reinforcement Rings and Cages; *Burch-Schneider*™ Reinforcement Cage, *Original M.E. Müller*™ Ring, Roof Reinforcement Ring (*Protasul*® Ti [ISO 5832-2 Grade 1])**
  Metallic, plate-like, flanged/hooked acetabular components with multiple screwholes for acetabular deficiencies/reconstruction.
- ***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*® *Alloclassic*® 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 *Metasul*® Acetabular Component with Ti-VPS coating and circumferential fins for additional primary fixation.

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 femoral heads provided for this purpose. The operating surgeon must always make sure that the chosen cup and femoral head match each other in accordance with this requirement.

INDICATIONS

- Noninflammatory degenerative joint disease (NIDJD), e.g. avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g. rheumatoid arthritis.
- 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 handicapped 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.

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.
- 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.

WARNINGS
- Implants are for single use only. Do not reuse.
- Do not use any component if damage is found or caused during setup or insertion.
- Implants and implant parts must only be combined with components belonging to the same system. No liability is accepted for products of third parties that are used by the purchaser or user.
- Use only instruments and provisionals specifically designed for use with these devices to help ensure accurate surgical implantation and evaluation of joint function.
- Complications or failure of any total hip prosthesis are more likely to occur in heavy patients.
- The load-bearing capacity of the implant can be compromised by notching, scratching, or striking the prosthesis, repeated assembly/disassembly of the modular components, or failing to provide metaphyseal support to the implant.
- Do not mate titanium alloy components with stainless steel. (Only applicable for the USA.)
- Improper selection, placement, positioning, and fixation of the implant components may result in unusual stress conditions reducing the service life of the prosthetic implants.
- Do not use this product for other than labeled indications (off-label use).
- 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.

PRECAUTIONS
- Continued surveillance for new or recurrent sources of infection should be continued as long as the device is in place.
- Do not assemble the mating components without ensuring that the surfaces are free of blood or debris. Failure to ensure that mating surfaces are clean and dry could result in inadequate seating of one component upon the other and subsequent disassembly of the mated components or fracture of the implant.
- Repeated assembly and disassembly of modular components could compromise the critical locking action of the Morse-type tapers. Use the provisional components during trial reductions. Change the components only when clinically necessary.
- Implants must not be machined or altered in any way, unless this is expressly envisaged in the design and in the surgical technique.

ADVERSE EFFECTS
The following adverse effects have been reported:

Peripheral neuropathies
Deep wound infections
Perforation of the acetabulum or femur
Wear
Heterotopic bone formation
Metal sensitivity
Inflammatory reactions and osteolysis
Dislocation and subluxation
Vascular complications
Trochanteric problems
Subclinical nerve damage
Corrosion of metal implants
Early or late loosening of components
Pelvic, femoral, or acetabular fractures
Disassembly of modular components
Fatigue fracture

STERILIZATION

- Gamma irradiation is indicated by the "Sterile-R" symbol and sterilization with Ethylene Oxide Gas (*Durasul*® Implants) with the "Sterile-EO" symbol on the labeling. These devices remain sterile as long as the package integrity has not been violated.
- Inspect each package prior to use and do not use the component if any seal or cavity is damaged, breached, or if the expiration date has been exceeded.
- Once opened, the component must be used, discarded, or resterilized.
- If the packaging is damaged or the sterility expiration date has been reached, the implants must be returned to the manufacturer. (Not applicable for the USA.)

RESTERILIZATION INFORMATION

- The recommendations set forth under this point are provided for informational purposes only. No liability is accepted regarding sterility for devices that are cleaned and sterilized or resterilized by the purchaser or user.
- Do not resterilize:
  - Single use only components that have been contaminated with body fluids or debris or previously implanted.
  - Factory assembled Polyethylene (PE) Implants like:
    - PE-*Metasul* Implants.
    - PE-Implants with radiographic wire.
    - PE-Implants with pole plate (e.g., *Alloclassic* and CSF Implants).
- These reprocessing/sterilization instructions should be used for sterile items that were opened but unused. These reprocessing instructions have been validated in accordance with ANSI/AAMI/ISO standards and are consistent with AORN recommended practices.
- Zimmer recommends that all implants should be cleaned and resterilized by the manufacturer, provided resterilization is permitted and is possible. In this case, an essential pre-requisite is that the innermost original sterile packaging should still be intact and unopened. Implants that have been completely unpacked cannot be returned to Zimmer for resterilization. (Not applicable for the USA.)
- The country-specific resterilization guidelines as well as the mentioned exclusions are to be followed under all circumstances.
- Do not use the original plastic cavities or lids for sterilization/resterilization. After cleaning as appropriate (rinse only with USP purified water) the components must be placed in suitable sterilization packing. Single devices may use a standard *Tyvek*® pouch or other sterilization wrap. Ensure that the pouch is large enough to contain the device without stressing the seals or tearing the pouch.
- Do not use cleaning agents or detergents of any type on single use implant components. Only USP purified water may be used.
- Materials like Ti-VPS (Titanium-vacuum-plasma spray), *CSTi*™ (cancellous structured titanium) coated components and *Sulmesh*® Surface Structure* must not be cleaned with any detergents.
- Implants shall not come into contact with substances containing chlorine, phosphorus or fluorine or with detergents containing fats.
- Modular components must be processed in the unassembled state to ensure sterilization to the intended sterility assurance level. Also, the components may be made from alloys differing in expansion and contraction characteristics which could cause internal stresses during heating and cooling.
- Zimmer products sterilized/resterilized by the user, should be indicated in the corresponding patient documentation (i.e., in the Operation Report/Surgeon's Notes), and relevant documents (all labeling, instructions for use) kept on file.
- All polymers must be used immediately after resterilization by EO or Gas plasma unless otherwise noted.
- Implants made of synthetic materials and components with synthetic parts may not be re-sterilized or industrially processed for reuse by steam, as this can cause deterioration of the material.

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

Recommended sterilization/ resterilization specifications
Solid metal implants

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	

UHMWPE 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

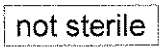
STERRAD Gas Plasma Sterilization

Gas Concentration	Temperature	Exposure Time
6 mg/L (59% Hydrogen Peroxide)	45°C (113°F)	65 minutes

STORAGE AND HANDLING
- 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. (Not applicable for the USA.)

PATIENT COUNSELING INFORMATION
Complications and/or failure of prosthetic implants are more likely to occur in patients with unrealistic functional expectations, heavy patients, physically active patients and/or with patients who fail to follow through with the required rehabilitation program. Physical activity can result in loosening, wear and/or fracture of the implant. The prospective implant patient must be counseled about the capabilities of the implant and the impact it will have on his or her lifestyle. 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 replaced. The implant may not last the rest of the patient's life, or any particular length of time. Because prosthetic implants are not as strong, reliable, or durable as natural, healthy tissues/bones, all such devices may need to be replaced at some point.

* where available



Symbol for «Contents packed without sterilization»

Metasul® LDH™ Large Diameter Head

Surgical Technique

Enhancing Stability and Increasing Range of Motion

zimmer
Confidence in your hands

Metasul LDH Large Diameter Head Surgical Technique

Table of Contents

Overview

The combination of a large range of motion and excellent articular stability, along with proven clinical results, make the *Metasul LDH* large diameter head system an ideal solution for THA patients.

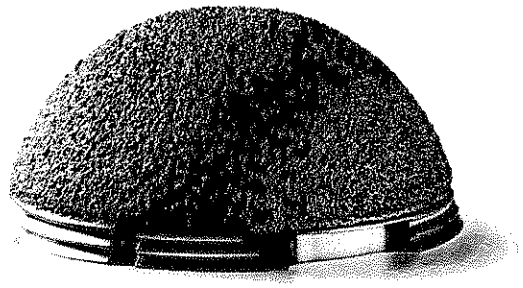
The *Metasul* articulation provides excellent resistance to wear[1]. It has been implanted in more than 300,000 patients since 1988. No other metal-on-metal combination has achieved comparable long-term clinical results.

This experience forms the basis of the latest generation of metal-on-metal articulations, the *Metasul LDH* large-diameter head system.

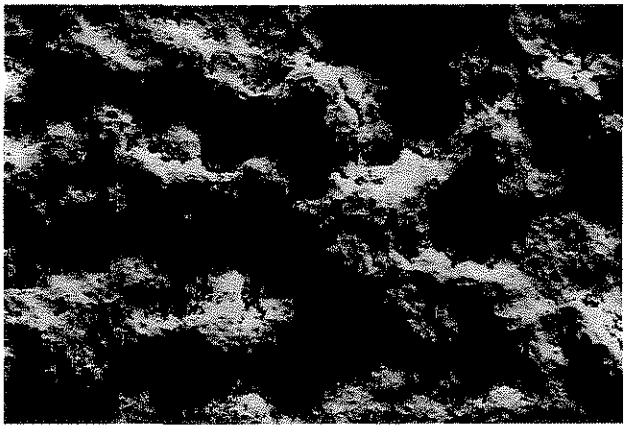
The *Durom*® Acetabular Component, which mates with the *Metasul LDH* large diameter head, was designed to preserve bone stock and optimize range of motion. The wall thickness of the acetabular component is reduced to a strict minimum, and the cup sustains an angle of 165 degrees, comparable to that of the natural acetabulum.

Range of motion varies from 144° to 168° based upon the determined size of the acetabular component and the mating large diameter head. Range of motion is essential in total hip replacements in order to obtain unrestricted walking and optimized functioning of the hip, while reducing the potential 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.

The *Porolock*™ Ti VPS surface coating of the *Durom* acetabular component is pure titanium deposited using vacuum plasma spray technology. This process, carefully controlled, allows a very high adhesive strength between the cobalt chrome substrate and the *Porolock* Ti VPS coating, minimizing the potential risk of titanium particle generation. The circumferential fins, high surface roughness, and initial 2mm pressfit allow initial implant stability while the *Porolock* plasma sprayed material promotes reliable scratch fit.



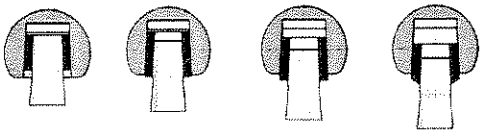
Durom acetabular component



CP-Ti (*Durom* component) Plasma Sprayed on Ti-6Al-4VT, Magnified 50x

CP-Ti (*Durom* component) Plasma Sprayed on Ti-6Al-4VT, Magnified 500x

In order to optimize restoration of joint kinematics, the *Metasul LDH* large diameter head system has been developed with 4 neck lengths (S, M, L and XL).



Adaptation of the neck length

Range of sizes

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

The range of heads covers 12 sizes from 38 to 60 mm. From size 38 to size 48, the heads are solid, 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

Range of Implants

A *Durom* acetabular component is combined with a *Metasul LDH* large diameter head 6mm 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 *Durom* acetabular component has been designed to be implanted without cement. The *Metasul LDH* large diameter heads may be used with a wide range of Zimmer hip stems.
- The actual equatorial diameter of an acetabular component is greater than its nominal diameter by 2mm. **For example a 54N acetabular component has an actual outer diameter of 56mm.** If the last reamer used is 54mm, the 54mm trial implant will be used (the trial implant is line to line with the reamer), and the stated size of the acetabular implant is 54/N. As a result, there is a press-fit of 2mm.

***Durom* acetabular component combined with *Metasul* head**

***Durom* acetabular component**			***Metasul LDH* large diameter head**		
Size mm	Inner Diameter mm	Code	Size mm	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

Preoperative Planning

Templates of the *Durom* acetabular component are available for preoperative planning. They are available in 120% magnification for conventional radiographs and 100% magnification for digital x-rays (Fig. 1a & 1b).

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 observe several key criteria, when planning the procedure:

- the physiological center of rotation (from the opposite side)
- the ideal position and depth of the acetabular component as well as its inclination, which should be between 40 and 45° depending upon specific patient anatomy
- the approximate size of the implant

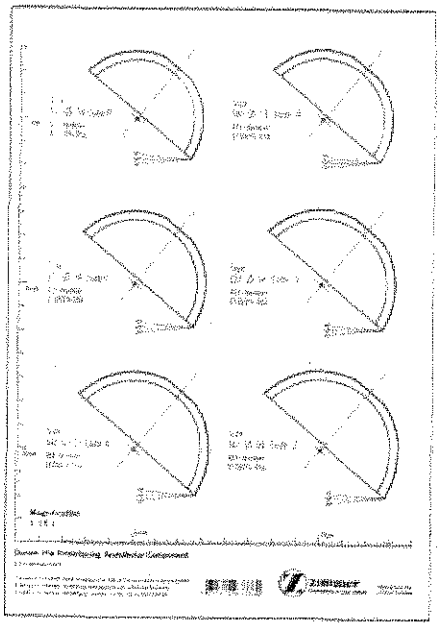


Fig. 1a
Durom acetabular component template

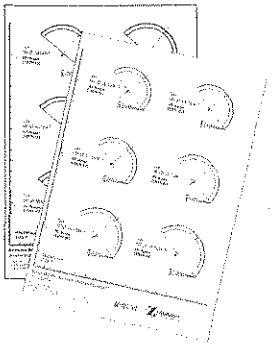


Fig. 1b
Planning templates
Durom Acetabular component

Surgical Technique

Surgeon preference will dictate the choice of surgical approach used to implant the *Durom* Acetabular Component.

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.

Reaming
Sequential reaming is carried out with the hemispherical acetabular reamers (Fig. 2). The *Durom* acetabular component has a truncated hemisphere of 165°. It is, therefore, not necessary to over deepen the acetabulum. In hard bone, it is advisable to use reamers in 1mm increments when approaching the definitive acetabular size. Assuming that a near hemispherical cavity has been created and adequate cancellous bone has been exposed, reaming is stopped. In case of sclerotic acetabular bone, a 1mm press-fit should allow the acetabular component to seat properly with sufficient primary stability.

Note: During the acetabular preparation, one must be particularly careful in order to prevent excessive reaming of the bone and to maintain a hemispherical cavity (Fig. 3).

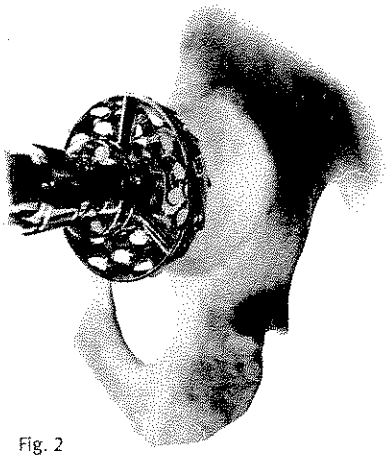


Fig. 2

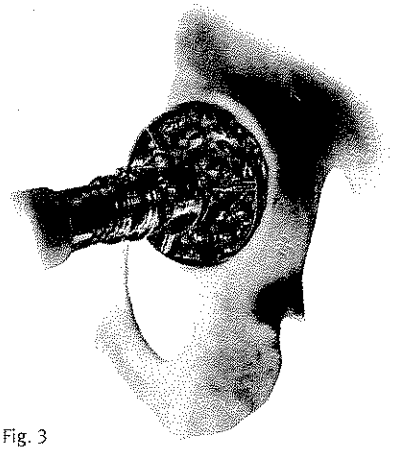


Fig. 3

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 (Fig. 4). 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. The trials are used to evaluate the quality of acetabular preparation. The nominal size of the *Durom* acetabular component is the same as the acetabular trial: e.g. a 54mm acetabular trial component will be used with implant size 54/N. The outer diameter of the implanted acetabular component is larger than the acetabular trial allowing for a 2mm press fit.

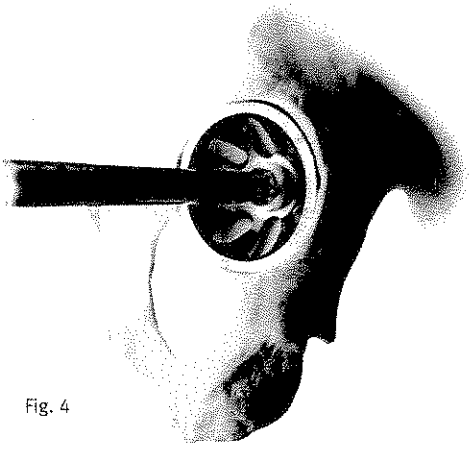


Fig. 4

Impaction of the acetabular component

The definitive acetabular component is attached to 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 45° of inclination or abduction (Fig. 5).

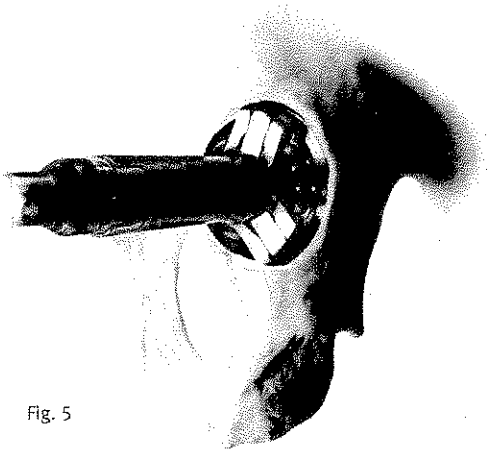


Fig. 5

Final impaction of the acetabular component
When the acetabular component is fully seated, (Fig. 6) the cup inserter is removed by unscrewing the impactor head and loosening the threaded rod (Fig. 7a & 7b). If necessary, the appropriately sized cup impactor can be used to complete the insertion of the acetabular component.

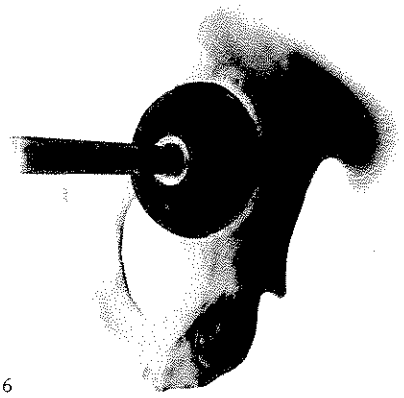


Fig. 6

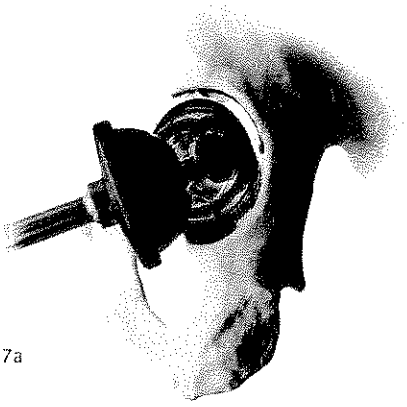


Fig. 7a

Fig. 7b

Assembly of the Metasul LDH large diameter head and adapter

Use of the trial head and adapter
Assemble the appropriately sized trial head adapter on the femoral stem, ensuring it is sitting flush on the taper.

The femoral head trial corresponding to the inner diameter of the *Durom* acetabular component is then attached to the adapter (Fig. 8).

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

Fig. 8

Assembly of the Head Adapter

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

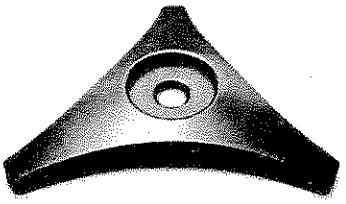


Fig. 9

The metal base plate (Fig. 9) and its plastic assembly inlay are positioned on a stable support. Make sure the inlay sits firmly within the base plate (Fig. 10).

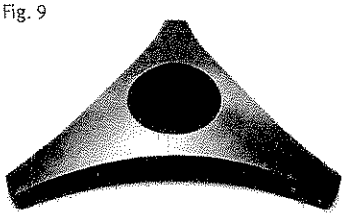


Fig. 10

Position the femoral head on the inlay (Fig. 11) as shown in the illustration.

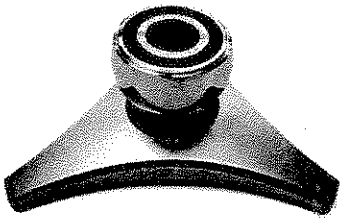


Fig. 11

Place the appropriately sized head adapter into the female taper of the femoral head (Fig. 12).

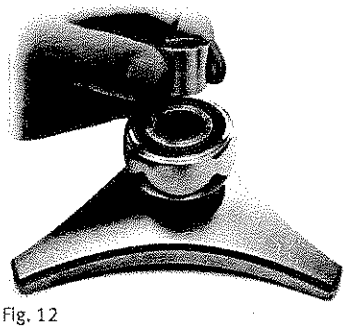


Fig. 12

Note: properly check the position of the appropriate head adaptor before final impaction into *Metasul LDH* large diameter head (Fig. 13).

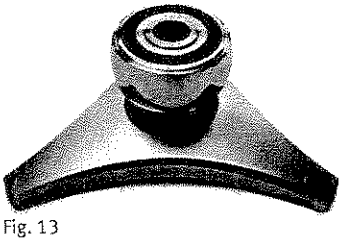


Fig. 13

With the impactor handle and its 12/14 assembly attachment, (Fig. 14) the head adapter is impacted into the femoral head by means of a firm and strong strike with a heavy mallet, preferably heavier than 500g (Fig. 15).

Clean and dry the stem taper, removing any residue.

Place the selected femoral head on the stem taper and secure it by twisting firmly. With the plastic impactor attachment, (Fig. 16) strike the *Metasul LDH* large diameter head to ensure full seating of the stem taper.

Fig. 14

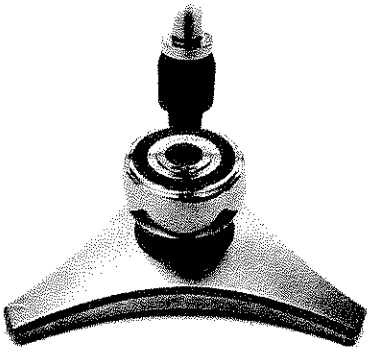


Fig. 15

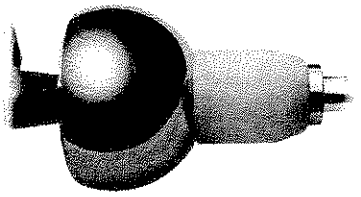


Fig. 16

In Situ Extraction of the Head

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

Mount the head disassembly attachment on the impactor handle (Fig. 17) and position the instrument on the lower edge of the femoral head (Fig. 18).

Fig. 17

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

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

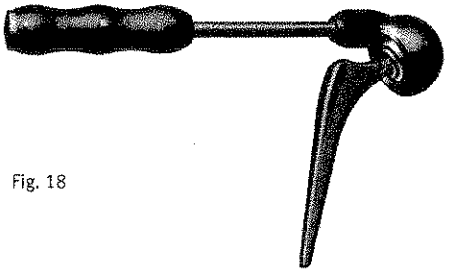


Fig. 18

In the case where the head comes off of the stem taper without the head adapter, the adapter 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 off of the taper (Fig. 19). The taper should not be damaged by this procedure (Fig. 20).

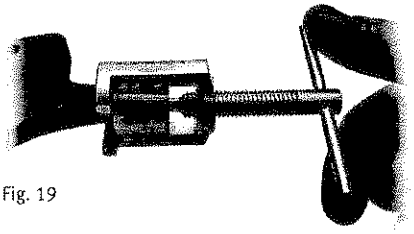


Fig. 19

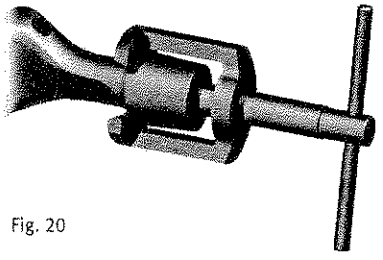


Fig. 20

Disassembly of the head adapter and the large diameter head

In cases where the head adapter cannot be extracted and remains attached to the head, use the adapter extractor for a 12/14 taper (Fig. 21) and proceed as follows:

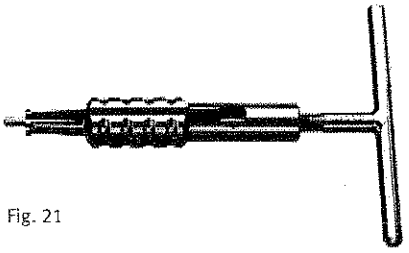


Fig. 21

Slide the sleeve into the head adapter (Fig. 22) until you feel or hear that its end is completely docked.

Push the handle through the sleeve and turn clockwise (Fig. 23).

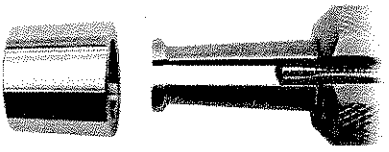


Fig. 22

After several turns, the handle reaches the bottom of the female taper of the large diameter head (Fig. 24). You will notice an increase in resistance at that time. Continue to turn and the handle will then separate the adapter from the head.

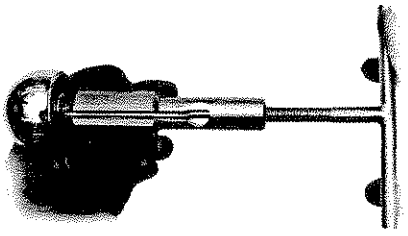


Fig. 23

Carefully remove the head adapter to prevent the head from falling (Fig. 25).

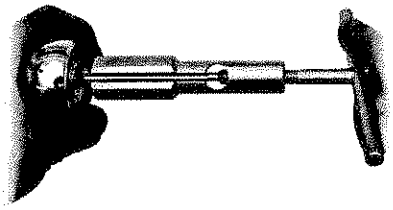


Fig. 24

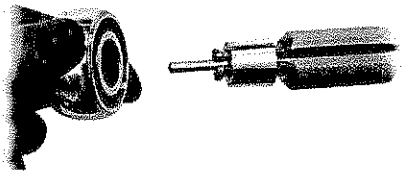
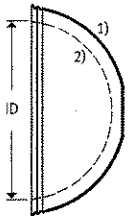


Fig. 25

Implants

Durom **Acetabular Component**



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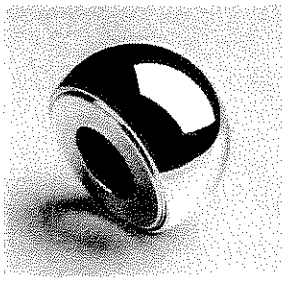
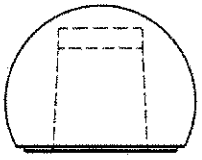
48	42	H	01.00214.148
50	44	J	01.00214.150
52	46	L	01.00214.152
54	48	N	01.00214.154
56	50	P	01.00214.156
58	52	R	01.00214.158
60	54	T	01.00214.160
62	56	V	01.00214.162
64	58	X	01.00214.164
66	60	Z	01.00214.166

Metasul LDH **Head**





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44	J	01.00181.440
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48	N	01.00181.480
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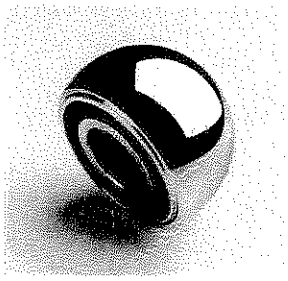
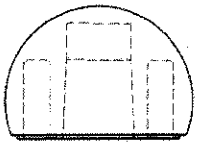
Metasul LDH **Head**





Size	Code	Product No.
–		
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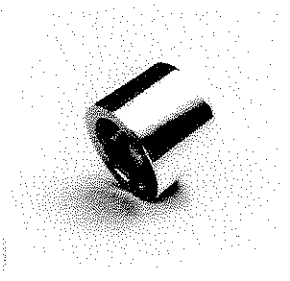
58	X	01.00181.580
60	Z	01.00181.600

Head Adapter



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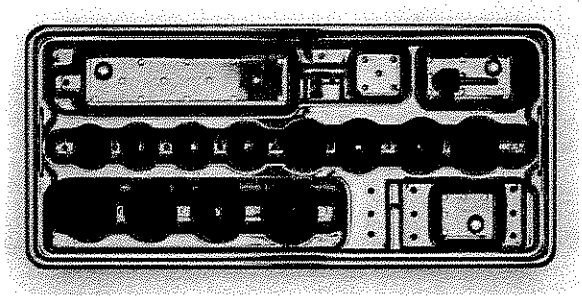
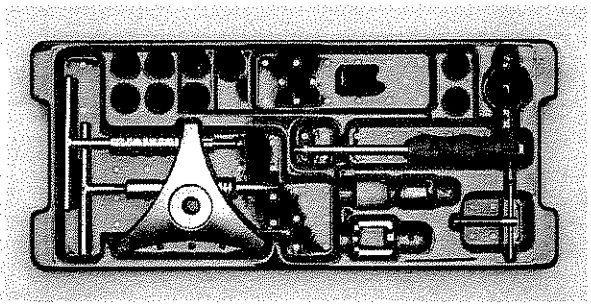
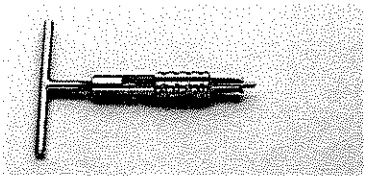
M	12/14	01.00185.146
L	12/14	01.00185.147
XL	12/14	01.00185.148

Instruments

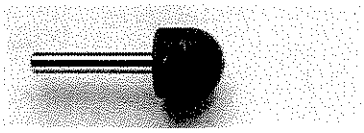




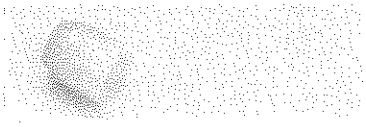
Description	Product No.
Base tray (empty)	01.00189.210
Insert for tray (empty)	01.00189.211
Standard container cover, gray	01.00029.031



Description	Taper	Product No.
Extractor	12/14	01.00189.151



Description	Product No.
Insert remover pusher	75.10.01



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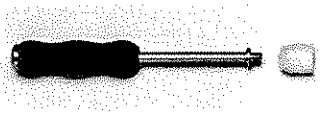
Ball-head impactor attachment	78.00.38

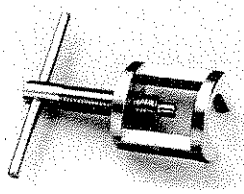


Description	Product No.
Handle reduction and impaction	75.11.00-02

Description	Product No.
Assembly base plate	01.00189.100

Description	Product No.
Assembly attachment	01.00189.102

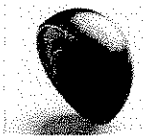
Description	Product No.
Assembly inlay	01.00189.104



Description	Product No.
Adapter extractor	01.00189.150

Description	Product No.
Head disassembly attachment metal	01.00189.103

Description	Product No.
Head disassembly attachment plastic	01.00189.110



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Ø48mm	01.00189.480
Ø50mm	01.00189.500
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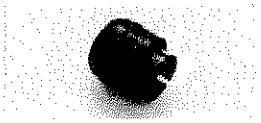
Ø58mm	01.00189.580
Ø60mm	01.00189.600



Size	Taper	Product No.
S	12/14	01.00189.145
M	12/14	01.00189.146
L	12/14	01.00189.147
XL	12/14	01.00189.148

1. Tipper JL, Firkins PJ, Ingham E, Fisher J, Stone MH, Farrar R, Quantitative analysis of the wear and wear debris from low and high carbon content coboit chrome alloys used in metal on metal total hip replacements. *Journal of Materials Science: Materials in Medicine* 10 (1999) 353-362

97-1081-002-00 7.5ML Printed in USA

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Durom Acetabular Component Insertion Tips & Pearls

Robert Middleton, MD, Martin Lavigne, MD

The *Durom*® Acetabular Cup is an anatomic, forged high-carbon CoCr monoblock acetabular shell that is used in conjunction with *Metasul*® Metal-on-Metal Tribological Solution *LDH*™ Large Diameter Heads for THA metal-on-metal articulations. The system is comprised of 12 shells that range from 44 to 66mm (nominal sizes) and match up individually with large diameter femoral heads sized 38 to 60mm. Thus, there is a 6mm nominal difference between the shell outer diameter and the diameter of the femoral head. However, when implanting the *Durom* Cup, it is important to remember that the true head/shell difference is actually 8mm. This is because of a 2mm pressfit built into each *Durom* Acetabular Cup. **Thus, a shell nominally labeled size 56 has an actual diameter of 58mm.**

The *Durom* Acetabular Cup has been used in international markets since 2001. This system utilizes the same *Metasul* Metal-on-Metal Technology that has been in clinical use since 1988, with over 275,000 implantations worldwide.[1] The *Durom* Acetabular Cup is designed to optimize the metal-on-metal articulation within the acetabulum through both its material differences and shell geometry. As a result, the cup design is different in shape and tactical feel than a modular hemispherical cup. Some of these key differences are:

Material: All *Durom* Cups have a cobalt chromium substrate and utilize a pure titanium plasma spray coating for enhanced surface roughness and scratch fit. CoCr was chosen for the substrate of this cup because of its optimal properties for metal-on-metal articulation. It is important to note that the CoCr material is a stiffer material than titanium, and more force may be required to fully seat the shell during final cup impaction.

Geometry: The *Durom* Acetabular Cup is designed with a shape closer to the true acetabulum and has a truncated hemisphere of 165° (Fig. 1).[2] This design allows more bone to be conserved during acetabular preparation. It also allows excellent range of motion and an increase in hip stability, potentially lowering the risk of dislocation. Because of the low profile geometry, the *Durom* Shell will seat differently than a hemispherical shell. Additionally, there are circumferential fins that protrude 0.5mm from the rim of the shell (Fig. 1). These fins improve the stability of the cup by enhancing rotational stability and providing 1mm of additional purchase at the periphery of the shell.

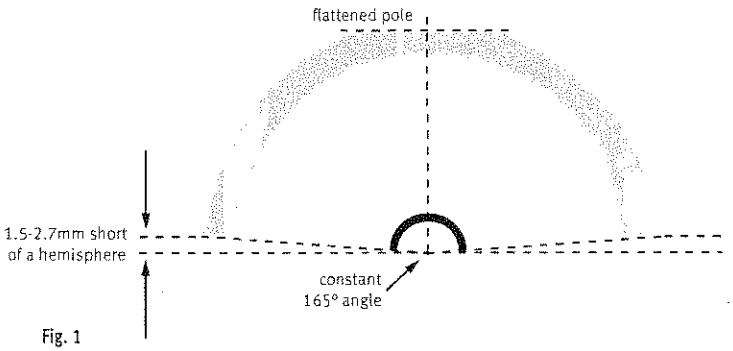
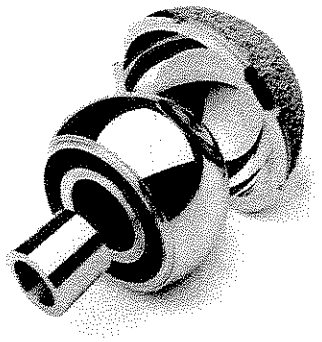


Fig. 1

It is essential that these fins engage in the cortical bone around the periphery of the acetabular rim, specifically in the anterior and posterior walls, in order to maximize initial cup stability.



The following tips and pearls have been developed to help surgeons through the learning curve of implanting the *Durom* Acetabular Cup.

Obtain Adequate Exposure

At times, it may be difficult to insert the shell past soft tissues during initial seating. A larger exposure may be needed to ensure that all labrum and soft tissue is removed from the acetabular rim.

Do Not Over Medialize The Reamer

The *Durom* Acetabular Cup has a 165° low profile design and is flat in the polar region (Fig. 1). Because of these features, it is important that the surgeon not ream the acetabulum too deep. The shell's initial stability is achieved by its 2mm press fit and at the rim via the circumferential fins (Fig. 2). Obtaining an adequate subchondral bone bleeding surface area without aggressive medialization will also maximize bone conservation. The surgeon should ream to the templated shell size, and then use the trial shell to assess the depth of the ream. The acetabular trials have the same diametrical measurement as the acetabular reamers, therefore if the last reamer size is 54mm, then a 54mm trial cup should be used to assess the acetabular preparation (Fig. 3). A 56mm provisional can be used to check the press fit for a 54mm sized cup since *Durom* Cups have a 2mm built-in press fit.

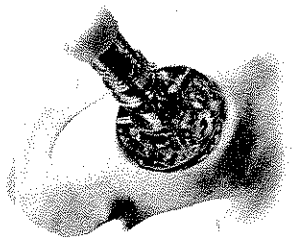


Fig. 2

Fig. 3

Adjust Reaming According To Bone Quality

Remember that the *Durom* Acetabular Shells are made of cobalt chrome, and thus are less flexible than modular titanium cups. After reaming to 54mm, the 54mm trial shell (true 54mm diameter) should sit easily in the acetabulum without having to use a mallet. If complete seating of the trial shell is not possible by hand, reaming with the 54mm reamer should be performed again to ensure the mouth of the acetabulum is adequately opened. Reaming up an additional 1mm (55mm) can facilitate cup insertion in sclerotic acetabulae. Peripheral osteophytes should be removed since they may interfere with cup impaction and do not offer optimal bone quality for peripheral fin engagement. **Note: The amount of press fit used should be determined at time of surgery and be based upon bone quality.**

Do Not Oversize Implant

The surgeon will achieve an initial 2mm press fit of the cup, and an additional 1mm by engaging the circumferential fins for a total of 3mm at the periphery of the cup. The surgeon should seek to use the smallest acetabular component possible in order to preserve the subchondral and sclerotic host bone. Because of the 8mm difference between the true shell diameter and femoral head diameter, the use of large heads is still possible within relatively small shell diameters.

Remember The 2mm Press-Fit

When implanting the *Durom* Acetabular Cup, the surgeon will obtain 2mm of initial pressfit. The surgical technique for implanting a size 54mm shell is:

1. Ream to a size 54
2. Insert a 54mm shell trial
3. Implant a size labeled 54mm, understanding that the true diameter of the *Durom* Shell is 56mm.

This is different than the preparation for a *Trilogy*® Acetabular System Cup, for which the surgeon typically will under ream by 2mm. The 2mm initial press-fit is already built into the nominal size of the *Durom* Acetabular Cup.

Engage The Circumferential Fins

It is important to ensure that these fins are engaged for optimal initial implant stability. When the trial implant is fully seated, it should leave at least 2mm of peripheral bone protruding to allow optimal peripheral fine engagement. Contact of these fins with the anterior and posterior wall of the acetabulum is critical. If the acetabulum is shallow, dysplastic, or if the surgeon closes the cup so that the fins are not entirely engaged superiorly, the implant may still be adequately secure providing that these fins have engaged both the anterior and posterior acetabular walls.

0.5mm circumferential fins

Use A Large Mallet

Because of the stiffer CoCr material and geometry of the shell, it may be more difficult to fully seat the implant. The use of a large mallet is recommended for initial impaction. It is important, however, not to over-impact the cup. Once the circumferential fins have engaged the periphery of the acetabulum, further impaction may cause the fins to breach the outer peripheral sclerotic bone and engage softer cortical bone. This might compromise initial component stability.

Fig. 4

Fig. 5

There are two steps to impacting the *Durom* Cup. The first inserter connects to the cup's rim with three locking tabs. This cup inserter does not overhang the rim of the implant so that it will not engage soft tissue or bone during insertion (Fig. 4). This inserter is used for initial placement and impaction of the cup. A second, plastic rim impactor may be used if the cup is not fully seated into its final position (Fig. 5). The key to final implant placement is to engage as much of the equatorial fins as possible.

Remove All Soft Tissue/Capsule From The Bearing Surface

During reduction of the large diameter head into the *Durom* Acetabular Cup, it is important to clear the articulation surface of all debris. Soft tissue/capsule may be difficult to identify because of the large diameter head potentially blocking visualization of the inner diameter of the shell. There are two methods to remove this material. The first method is to have the surgeon hold the capsule and soft tissues back with both hands while visualizing the hip reduction performed by his/her assistant. The second method is to fill the cup with saline solution, and as the hip is reduced the saline will displace any soft tissue from the articulation interface.

References

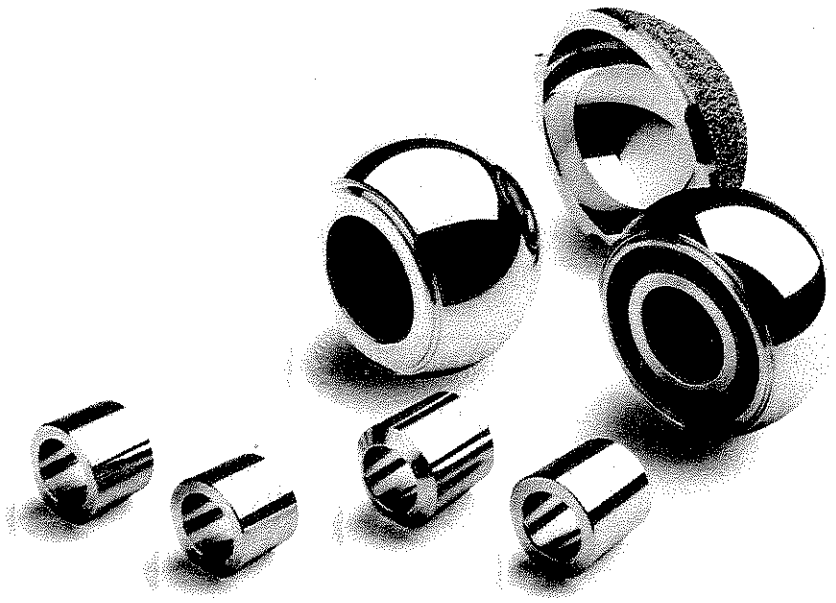
1. Claude B. Rieker, PhD, Rolf Scho¨n, and Petra Kottig. Development and Validation of a Second-Generation Metal-on-Metal Bearing, *J Arthroplasty*. Vol. 19. No. 8. Suppl 3. 2004.
2. Thompson MS, Dawson T, Kulper JH, Northmore-Ball MD, Tanner KE, *J Biomech* 2000 Dec; 33(12):1645-53

97-1081-016-00 5MZ Printed in U.S.A.

Metasul LDH Technology: Enhancing Stability and Increasing ROM

The *Metasul*® Metal-on-Metal *LDH*® Technology is the result of in-depth research, development and clinical evaluation that began in 1988. Four decades of metal-on-metal experience have led to the development of the *Metasul* bearing, which has been shown to reduce wear 200 times over conventional polyethylene.[1] Now combined with large diameter heads that increase range of motion and enhance stability, the *Durom*® Shell with *Metasul LDH* Large Diameter Head is a solution that offers the following benefits:

- Excellent initial fixation
- Reduced wear
- Joint restoration that replicates the natural anatomy
- Optimized range of motion
- Reduced opportunity for post-operative dislocation



Durom Acetabular Shell with Metasul LDH System

The *Durom* Shell with *Metasul LDH* system is comprised of a forged high-carbon CoCr *Metasul* Large Diameter head that mates with a forged high-carbon CoCr *Durom* shell. The system utilizes the same *Metasul* metal-on-metal technology that has been in clinical use for 18 years, with over 250,000 implantations worldwide.[2] The system is comprised of twelve head/shell sizes with a 6mm nominal difference between the size of the head and shell. Keep in mind that there is a 2mm press fit built into the *Durom* shell. Thus a shell labeled 56mm is actually 58mm in diameter. A letter code confirms the appropriate combination of head and shell. For example, the 56/P *Durom* acetabular shell must be used with a 50/P *Metasul* LDH large diameter head. The following chart shows the *Metasul LDH* heads and corresponding *Durom* shells:

Metasul LDH Large Diameter Head

Labeled Size	Head Diameter	Letter Code
38	38mm	D
40	40mm	F
42	42mm	H
44	44mm	I
46	46mm	L
48	48mm	N
50	50mm	P
52	52mm	R
54	54mm	T
56	56mm	V
58	58mm	X
60	60mm	Z

Durom Acetabular Shell

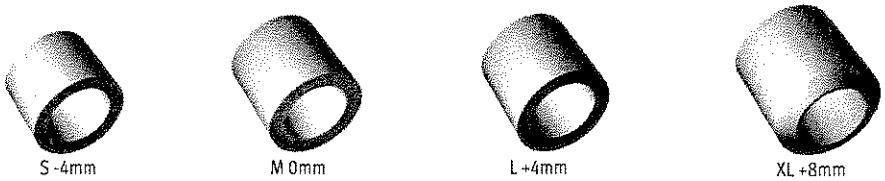
Labeled Size	Inner Diameter	Outer Diameter	Letter Code
44	38mm	46mm	D
46	40mm	48mm	F
48	42mm	50mm	H
50	44mm	52mm	I
52	46mm	54mm	L
54	48mm	56mm	N
56	50mm	58mm	P
58	52mm	60mm	R
60	54mm	62mm	T
62	56mm	64mm	V
64	58mm	66mm	X
66	60mm	68mm	Z

Metasul Large Diameter Heads

The forged high-carbon CoCr (*Protasul*® 21WF) large diameter heads range from 38mm to 60mm in 2mm increments, allowing for maximum ROM and stability. Sizes 38-48 are solid while sizes 50-60 are hollowed-out in order to reduce the overall weight of the implant.

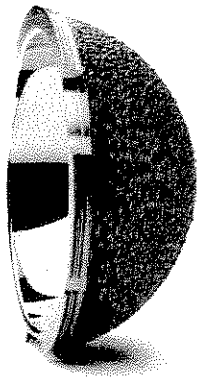
Head Size (mm)	38	40	42	44	46	48	50	52	54	56	58	60
Approximate Weight (grams)	146	174	206	240	276	316	254	277	299	326	351	382

Sleeve adapters are used to provide four neck lengths for the *Metasul* large diameter heads (S,M,L & XL). These correspond to neck lengths of -4, +0, +4, and +8mm. The *Metasul* LDH large diameter heads may be used with all collarless 12/14 taper Zimmer femoral hip stems.



S -4mm M 0mm L +4mm XL +8mm

Durom Acetabular Shell



The *Durom* acetabular shell is an anatomic, forged high-carbon CoCr monoblock acetabular shell that is 4mm thick. The shell has been used in international markets since 2001. The *Durom* acetabular shell is designed to optimize the metal-on-metal articulation within the acetabulum through both its material differences and shell geometry.

Durom Shells have a CoCr articulating surface (*Protasul* Surface Structure 21WF) and a pure titanium plasma spray coating (*Porolock*® Titanium Ti-VPS) for enhanced surface roughness and scratch fit. (Fig. 1)

The *Durom* acetabular shell is designed with a shape closer to the true acetabulum and has a truncated hemisphere of 165°. (Fig. 2) This design allows more bone to be conserved during acetabular preparation. It also allows for excellent range of motion and a resultant increase in hip stability, potentially lowering the risk of impingement and dislocation. Because of the low profile geometry, the *Durom* shell will seat differently than a hemispherical shell.** An additional feature of the *Durom* shell is the circumferential fins that protrude 0.5mm from the rim of the shell. (Fig. 3) These fins improve initial stability by providing 1mm of additional purchase at the periphery of the shell. It is essential that these fins engage in the cortical bone around the periphery of the acetabular rim, specifically in the anterior and posterior walls, in order to maximize initial cup stability.

**Note that it is important to consider the low profile geometry when reaming. Do not ream too deep when preparing the acetabulum. See the *Metasul LDH* Surgical Technique and the *Durom* Shell Tips and Pearls white paper for more detailed shell insertion instructions.

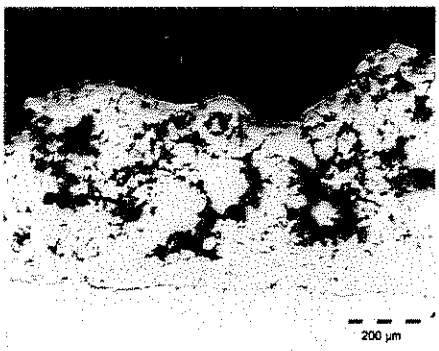


Fig. 1 *Porolock* Titantium Ti-VPS

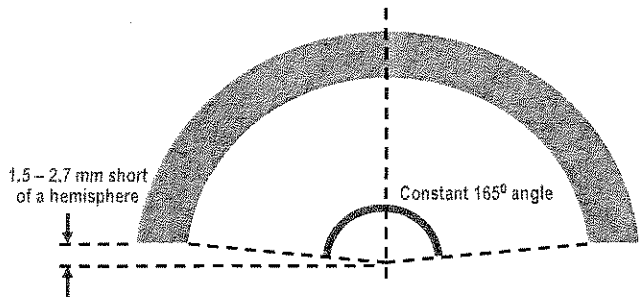


Fig. 2 *Durom* Low Profile Shell

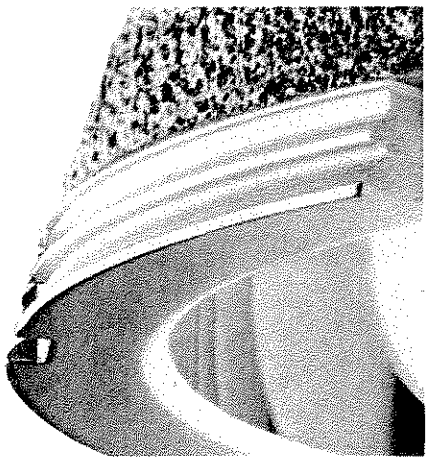
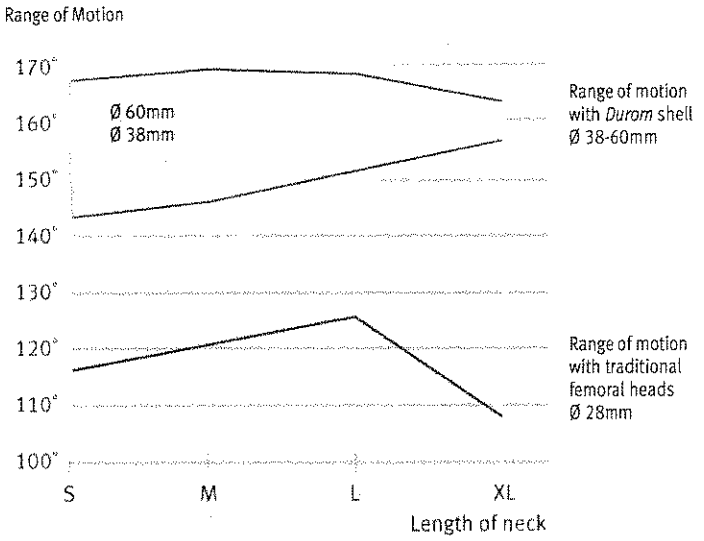


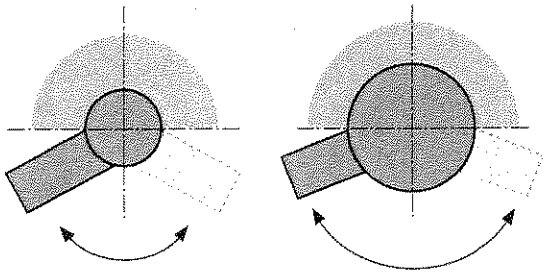
Fig. 3 The circumferential fins will protrude 0.5mm from the rim of the shell.

Increased Stability and ROM

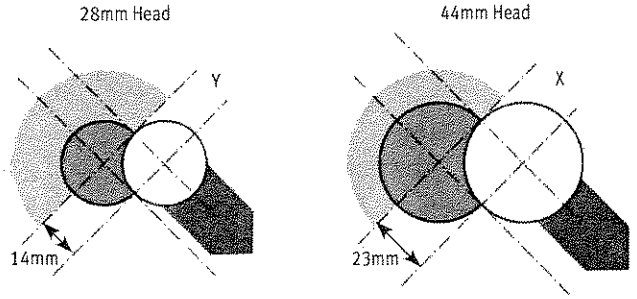
Metasul LDH large diameter heads along with the *Durom* low profile shell provide optimal range of motion and stability. "Increased femoral head size can increase stability by increasing the prosthetic impingement-free range of hip motion and by increasing the inferior head displacement required before hip dislocation."[3]

In a properly oriented shell (~ 45° abduction angle), a direct correlation exists between the size of the femoral head and the distance required for displacement for dislocation. The head-to-neck diameter ratio of *Metasul LDH* provides maximum ROM therefore reducing the risk of prosthetic impingement.



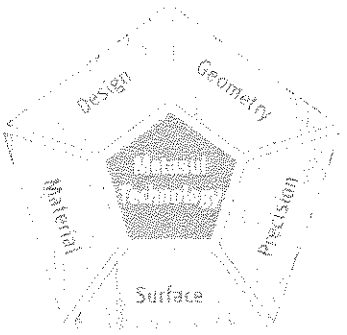


Large diameter femoral heads are the most direct way to increase head-to-neck diameter ratio



Large diameter femoral heads increase the distance the head must displace before dislocation (X > Y)

Metasul Metal-on-Metal Technology



Sulzer (now Zimmer) has established extensive experience in metal-on-metal articulation during the past four decades. Wear performance is directly controlled by careful engineering and modern manufacturing. Advances in manufacturing technology, thorough research, and clinical experience have led to the identification of five key factors for success in a modern metal-on-metal bearing. Successful metal-on-metal bearings must incorporate:

- Optimal chemical composition of the material
- Improved processing of the material
- Precise manufacturing of components
- Optimal clearance and low surface roughness
- Optimal prosthesis design

The *Metasul* Technology Design Rationale brochure explains and illustrates how the *Metasul LDH* forged high-carbon head coupled with the *Durom* forged high-carbon shell employ these key success factors to minimize wear. *Metasul* metal-on-metal bearings have demonstrated, both experimentally and clinically, up to 200 times less volumetric wear than conventional bearings. Clinical results and extended analysis from retrievals up to 12 years postoperatively confirm the excellent performance of *Metasul* articulations.[1]

Metasul LDH Collaterals

97-1081-001-00 *Metasul LDH* Brochure
97-1081-002-00 *Metasul LDH* Surgical Technique
97-1081-004-00 *Metasul* Alloy Comparison Pocket Guide
97-1081-007-00 *Metasul* Technology Design Rationale
97-1081-016-00 *Durom* Shell Implantation Tips and Pearls
97-1081-022-00 *Metasul LDH* Overview Materials CD
97-1081-050-00 *Metasul LDH* Templates

Metasul Technology Clinical References

Dorr, LD et al: The Argument for the Use of Metasul as an Articulation Surface in Total Hip Replacement. *CORR*, 2004. 429:80-85

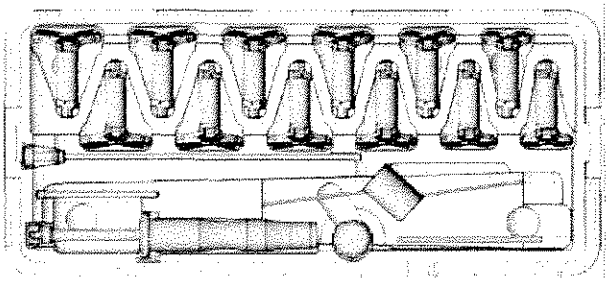
Long, WT, Dorr LD, and Gendelman, V. An American Experience with Metal-on-Metal Total Hip Arthroplasties. *J Arthroplasty* 2004. Vol.19 No.8: 29-34

Instrumentation

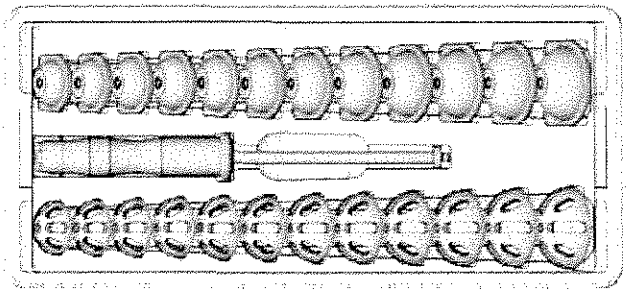
There are two different versions of acetabular instruments used with the *Durom* acetabular component. The first available instrument sets will come with a straight handle. This handle attaches to the various sizes of cup inserters and are used for initial insertion of the *Durom* shell (see Main tray). A second tray houses an additional handle that attaches to a second set of black spherical impactors and the shell trials (see Top tray). By ordering instrument kit DAC00219100 you will receive both trays.

DAC00219100

Prod. No.	Description
DAC00219100	***DUROM* ACETABULAR INST SET (STRAIGHT)**
0100219100	BASE TRAY ACETABULUM STRAIGHT
0100029031	INSTRUMENT CASE COVER
0100219815	*DUROM* CUP COUPLING
0100219816	*DUROM* CUP THREADED HANDLE ROD
0100219817	*DUROM* CUP IMPACTOR HEAD HANDLE
0100219382	*DUROM* CUP INSERTER 44 / D (STRAIGHT)
0100219402	*DUROM* CUP INSERTER 46 / F (STRAIGHT)
0100219422	*DUROM* CUP INSERTER 48 / H (STRAIGHT)
0100219442	*DUROM* CUP INSERTER 50 / J (STRAIGHT)
0100219462	*DUROM* CUP INSERTER 52 / L (STRAIGHT)
0100219482	*DUROM* CUP INSERTER 54 / N (STRAIGHT)
0100219502	*DUROM* CUP INSERTER 56 / P (STRAIGHT)
0100219522	*DUROM* CUP INSERTER 58 / R (STRAIGHT)
0100219542	*DUROM* CUP INSERTER 60 / T (STRAIGHT)
0100219562	*DUROM* CUP INSERTER 62 / V (STRAIGHT)
0100219582	*DUROM* CUP INSERTER 64 / X (STRAIGHT)
0100219602	*DUROM* CUP INSERTER 66 / Z (STRAIGHT)
0100219820	*DUROM* CUP TIGHTENING BAR
758519	*DUROM* CUP ALIGNMENT GUIDE
758500	THREADED ROD FOR ALIGNMENT GUIDE
0100219110	TOP TRAY ACETABULUM STRAIGHT
0100219384	*DUROM* CUP IMPACTOR 44 / D
0100219404	*DUROM* CUP IMPACTOR 46 / F
0100219424	*DUROM* CUP IMPACTOR 48 / H
0100219444	*DUROM* CUP IMPACTOR 50 / J
0100219464	*DUROM* CUP IMPACTOR 52 / L
0100219484	*DUROM* CUP IMPACTOR 54 / N
0100219504	*DUROM* CUP IMPACTOR 56 / P
0100219524	*DUROM* CUP IMPACTOR 58 / R
0100219544	*DUROM* CUP IMPACTOR 60 / T
0100219564	*DUROM* CUP IMPACTOR 62 / V
0100219584	*DUROM* CUP IMPACTOR 64 / X
0100219604	*DUROM* CUP IMPACTOR 66 / Z
0100219421	*DUROM* TRIAL CUP 48 / H
0100219441	*DUROM* TRIAL CUP 50 / J
0100219461	*DUROM* TRIAL CUP 52 / L
0100219481	*DUROM* TRIAL CUP 54 / N
0100219501	*DUROM* TRIAL CUP 56 / P
0100219521	*DUROM* TRIAL CUP 58 / R
0100219541	*DUROM* TRIAL CUP 60 / T
0100219561	*DUROM* TRIAL CUP 62 / V
0100219581	*DUROM* TRIAL CUP 64 / X
0100219601	*DUROM* TRIAL CUP 66 / Z
0100219808	HANDLE FOR TRIAL/CUP IMPACTION



Main tray with instruments

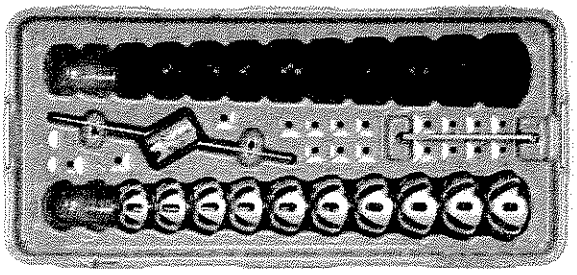


Top Tray insert with instruments

Shortly after the initial launch of the *Durom* shell with the *Metasul LDH* system in the US, we will make available a new set of curved instruments for the *Durom* shell. These instruments are designed for use with smaller incisions. This new instrument set contains new curved handles and modified cup inserters. Once these sets are available, we will only be releasing the curved instrument set to the U.S. field. We expect that these new instruments will be available to order in the 3rd quarter, 2006. There will be two new kit numbers that you need to order for the curved set of instruments. The first is kit DAC00219105 and will contain the black spherical impactors, alignment guide, and shell trials (see Trial tray). The second kit is DAC00219110 and will contain the new modified cup inserters and curved handles (see Main and Curved handle trays). BOTH kits are necessary for surgery.

DAC00219105

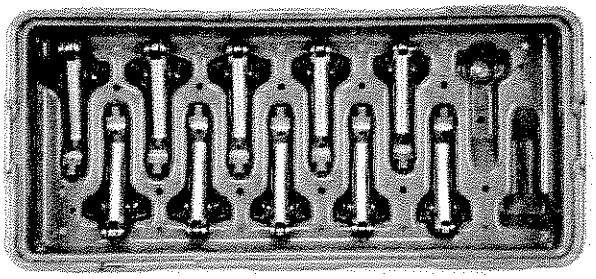
Prod. No.	Description
DAC00219105	***DUROM* CURVED ACETABULAR INSTRUMENT SET TRAY 1**
0100219103	*DUROM* BASE TRAY CURVED
0100029031	INSTRUMENT CASE COVER
0100219384	*DUROM* CUP IMPACTOR 44 / D
0100219404	*DUROM* CUP IMPACTOR 46 / F
0100219424	*DUROM* CUP IMPACTOR 48 / H
0100219444	*DUROM* CUP IMPACTOR 50 / J
0100219464	*DUROM* CUP IMPACTOR 52 / L
0100219484	*DUROM* CUP IMPACTOR 54 / N
0100219504	*DUROM* CUP IMPACTOR 56 / P
0100219524	*DUROM* CUP IMPACTOR 58 / R
0100219544	*DUROM* CUP IMPACTOR 60 / T
0100219564	*DUROM* CUP IMPACTOR 62 / V
0100219584	*DUROM* CUP IMPACTOR 64 / X
0100219604	*DUROM* CUP IMPACTOR 66 / Z
0100219381	*DUROM* TRIAL CUP 44 / D
0100219401	*DUROM* TRIAL CUP 46 / F
0100219421	*DUROM* TRIAL CUP 48 / H
0100219441	*DUROM* TRIAL CUP 50 / J
0100219461	*DUROM* TRIAL CUP 52 / L
0100219481	*DUROM* TRIAL CUP 54 / N
0100219501	*DUROM* TRIAL CUP 56 / P
0100219521	*DUROM* TRIAL CUP 58 / R
0100219541	*DUROM* TRIAL CUP 60 / T
0100219561	*DUROM* TRIAL CUP 62 / V
0100219581	*DUROM* TRIAL CUP 64 / X
0100219601	*DUROM* TRIAL CUP 66 / Z
758500	THREADED ROD FOR ALIGNMENT GUIDE
758519	*DUROM* CUP ALIGNMENT GUIDE



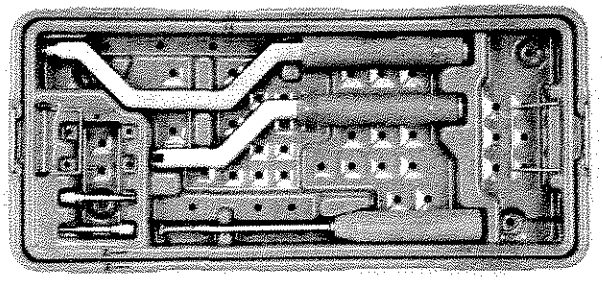
Trial tray with instruments

DAC00219110

Prod. No.	Description
DAC00219110	**DUROM CURVED ACETABULAR INSTRUMENT SET TRAY 2**
0100219101	*DUROM* CURVED BASE TRAY 2
0100029031	INSTRUMENT CASE COVER
0100219644	*DUROM* CUP INSERTER 44/D (CURVED)
0100219646	*DUROM* CUP INSERTER 46/F (CURVED)
0100219648	*DUROM* CUP INSERTER 48/H (CURVED)
0100219650	*DUROM* CUP INSERTER 50/J (CURVED)
0100219652	*DUROM* CUP INSERTER 52/L (CURVED)
0100219654	*DUROM* CUP INSERTER 54/N (CURVED)
0100219656	*DUROM* CUP INSERTER 56/P (CURVED)
0100219658	*DUROM* CUP INSERTER 58/R (CURVED)
0100219660	*DUROM* CUP INSERTER 60/T (CURVED)
0100219662	*DUROM* CUP INSERTER 62/V (CURVED)
0100219664	*DUROM* CUP INSERTER 64/X (CURVED)
0100219666	*DUROM* CUP INSERTER 66/Z (CURVED)
0100219102	*DUROM* CURVED TOP TRAY
0100219835	HANDLE FOR TRIAL CUP / BLACK IMPACTORS
0100529101	HEX BALL SCREWDRIVER
0100219834	*DUROM* CURVED IMPACTOR SCREW
0100219833	*DUROM* CURVED IMPACTOR HANDLE



Main tray with instruments

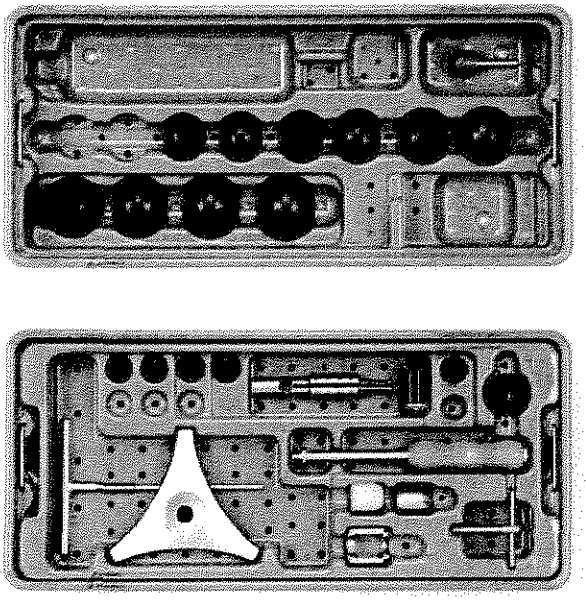


Curved handle tray with instruments

Finally, there is an additional kit number that you will need to order for the *Metasul LDH* large diameter head instrumentation. These instruments are in the kit LDH00189211 and are specific to the large diameter heads and head/neck adapters. **You will need to order this kit whenever you order a set of the straight handle instruments or curved handle instruments.**

LDH000189211

Prod. No.	Description
LDH00189211	***METASUL LDH* LARGE DIAMETER HEAD INST SET**
0100189210	BASE TRAY LARGE DIAMETER HEAD
0100189211	LARGE DIAMETER HEAD TRAY INSERT
0100029031	INSTRUMENT CASE COVER
0100189145	TRIAL ADAPTER 12/14 -4MM S
0100189146	TRIAL ADAPTER 12/14 +0MM M
0100189147	TRIAL ADAPTER 12/14 +4MM L
0100189148	TRIAL ADAPTER 12/14 +8MM XL
751001	INSERT REMOVER PUSHER
780038	PLASTIC TOP
75110002	*LDH* HEAD IMPACTOR HANDLE
0100189100	ASSEMBLY BASE PLATE
0100189102	ASSEMBLY ATTACHMENT 12/14
0100189104	BASE PLATE INLAY
0100189150	ADAPTER EXTRACTOR
0100189151	ADAPTER EXTRACTOR 12/14
0100189103	HEAD DISASSEMBLY ATTACHMENT METAL
0100189110	HEAD DISASSEMBLY ATTACHMENT PLASTIC
0100189420	*METASUL LDH* TRIAL HEAD 42MM
0100189440	*METASUL LDH* TRIAL HEAD 44MM
0100189460	*METASUL LDH* TRIAL HEAD 46MM
0100189480	*METASUL LDH* TRIAL HEAD 48MM
0100189500	*METASUL LDH* TRIAL HEAD 50MM
0100189520	*METASUL LDH* TRIAL HEAD 52MM
0100189540	*METASUL LDH* TRIAL HEAD 54MM
0100189560	*METASUL LDH* TRIAL HEAD 56MM
0100189580	*METASUL LDH* TRIAL HEAD 58MM
0100189600	*METASUL LDH* TRIAL HEAD 60MM



Large Diameter Head Instrument Set

LDH00189220

Prod. No.	Description
LDH00189220	***METASUL* LDH MICRO KIT**
0100189380	*DUROM* TRIAL HEAD 38MM
0100189400	*DUROM* TRIAL HEAD 40MM
0100219381	*DUROM* TRIAL CUP 44 / D
0100219401	*DUROM* TRIAL CUP 46 / F

If you have any questions about the *Metasul LDH* large diameter head and *Durom* Acetabular cup system please contact either Ryan Van Puffelen or Brian Parker.

Ryan Van Puffelen
Associate Product Manager
Office: 574-372-4163

Brian Parker
Product Manager
Office: 574-372-4057

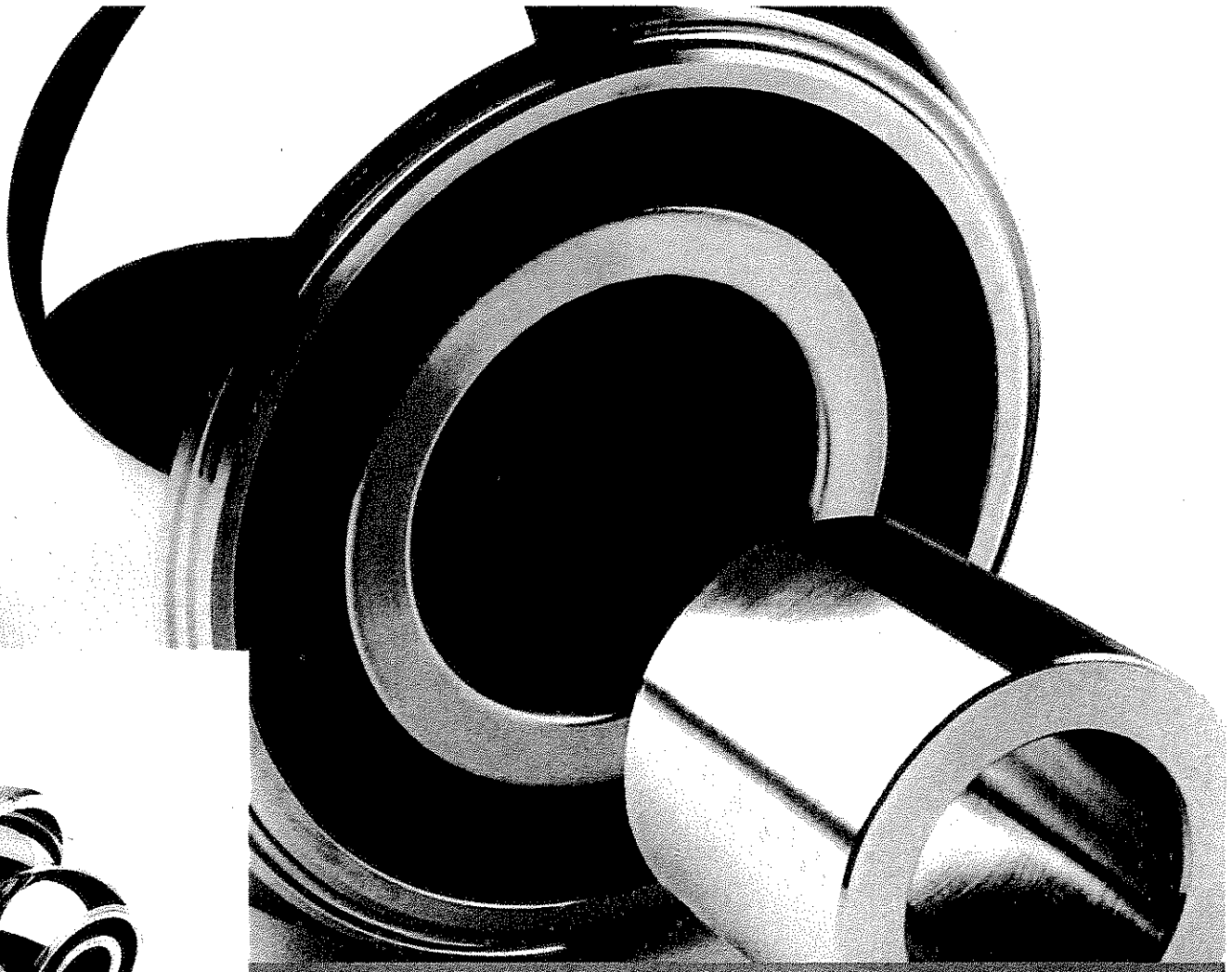
References

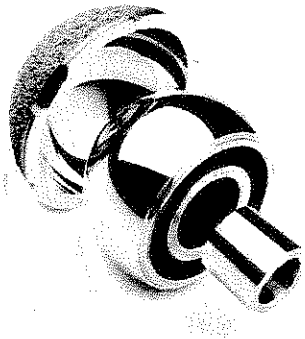
1. Rieker C, et al, In vivo tribological performance of 231 metal-on-metal hip articulations. *Hip International* Vol. 12, No. 2, 2002, 73-76.

2. Rieker C, et al., Development and validation of a second-generation metal-on-metal bearing. Laboratory study and analysis of retreievals. *J Arthroplasty* 19 (8, Supplement 3) 2005, 5-11.

3. Crowninshield RD, Maloney WJ, et al., Biomechanics of large femoral heads. *CORR*, 2004 429:102-7

Metasul® LDH™ Large Diameter Head



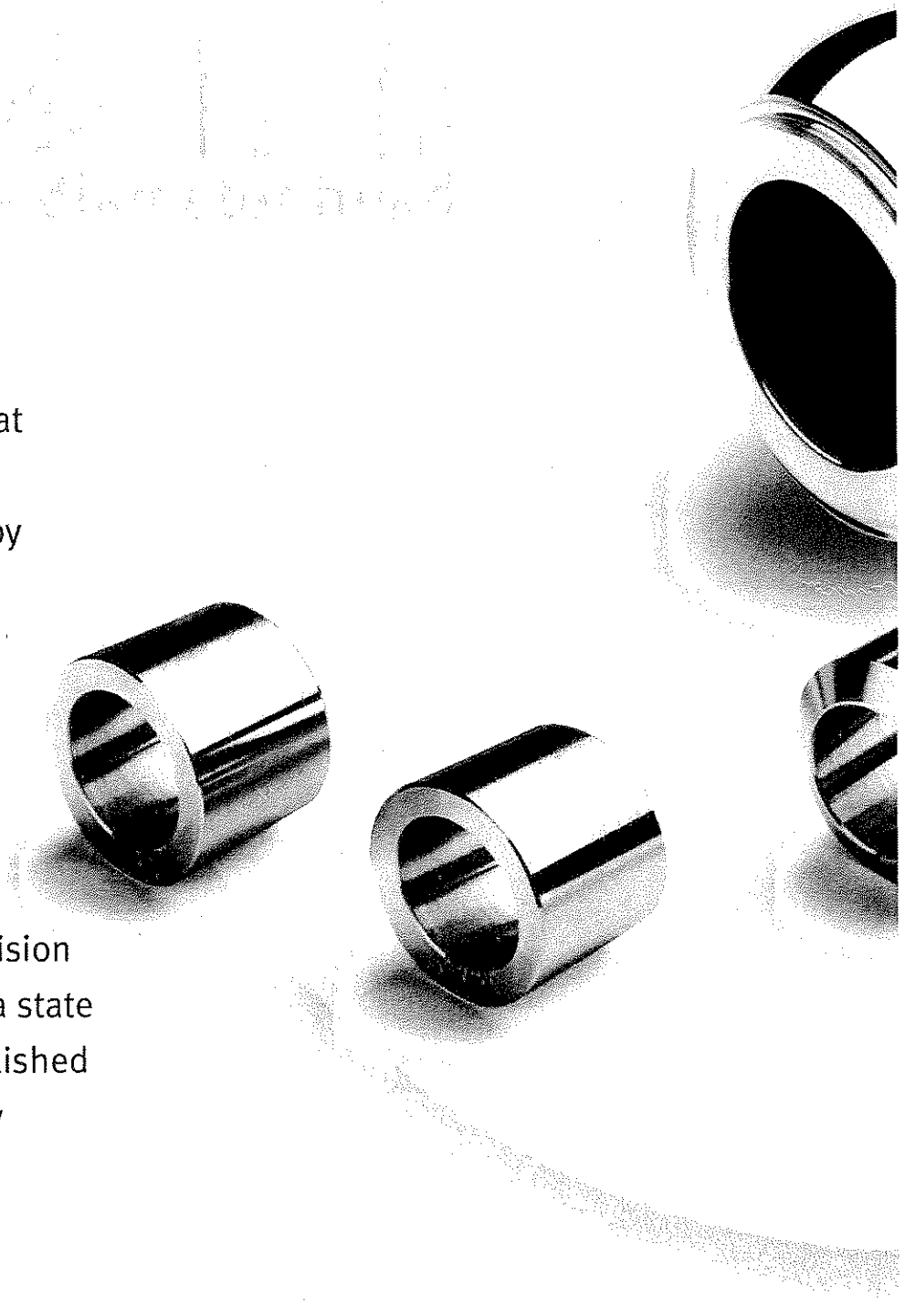


Enhancing stability and increasing range of motion

zimmer
Confidence in your hands

The *Metasul* large diameter head technology is the result of in-depth research, development and clinical experience that began in 1988.

Metasul Metal-on Technolo



The use of large diameter heads increases the displacement distance that must be traversed before dislocation occurs, thereby increasing joint stability and, at the same time, increasing the range of motion.

The combination of advanced materials technology and high precision manufacturing results in a state of the art, clinically established solution for a wide variety of patient indications.

Metasul LDH large diameter head

A proven solution with low wear and improved joint stability

-Metal -
gy

Metasul technology is a proven solution that addresses the issue of polyethylene wear.[1]

Patient function is improved by:

- joint restoration that is closer to its natural anatomy
- maximized range of motion
- reduced potential for post operative dislocation

The *Metasul LDH* components can be combined with a wide range of Zimmer hip stems.

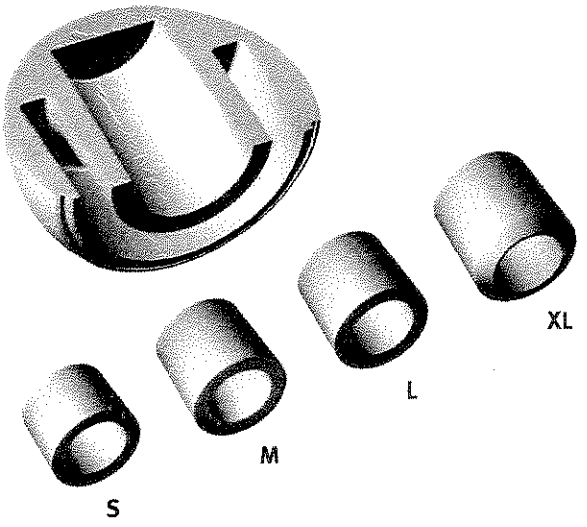
Its combined features help to restore the patient's true anatomy while offering exceptional range of motion, increased stability, and decreased wear.

A *Metasul LDH* large diameter head, used in conjunction with the *Durom*® Acetabular Component is designed to be a solution for active patients*.

* Please refer to the package insert for important patient counseling information.

Metasul LDH Technology: Differences that count

The *Metasul* bearing has been the target of continuous research and development, with clinical results since 1988. This technology is not only the basis for the modular large diameter heads – *Metasul LDH* components– but is also an industrial benchmark for combinations with low metal-on-metal wear. The size range includes 12 diameters from 38 to 60mm with neck length adaptors from –4 to +8mm.



Range of sizes

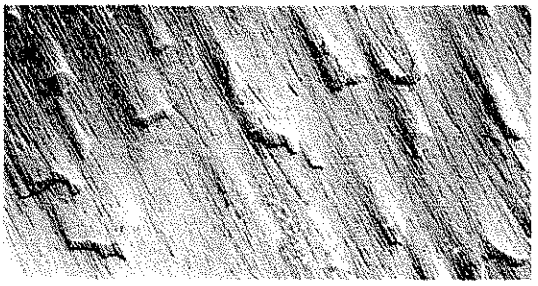
Taper	Length of neck (mm)			
	S	M	L	XL
12/14	–4	0	+4	+8

Lubrication and wear

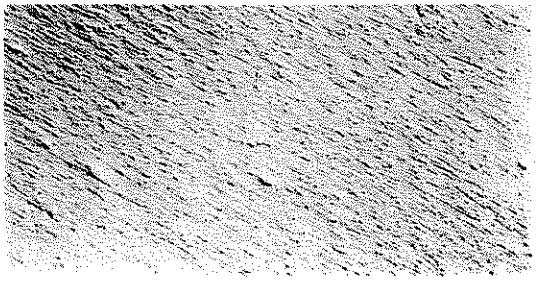
The most effective way to minimize wear on a metal-on-metal joint is to improve its lubrication[2,3]. A suitable lubricant film thickness allows for stable and dynamic joint lubrication, thereby minimizing the amount of wear. Lubrication is dependent on minimum surface roughness, joint clearance and articulation diameter.

A high-carbon and wear-resistant CoCr alloy

The *Metasul LDH* pair (head and shell) is manufactured from *Protasul*® 21 WF, a forged chromium-cobalt-molybdenum alloy with high carbon content (0.20 –0.25% C). Chromium-cobalt alloys with high carbon content provide increased hardness due to the presence of carbides. The carbides are at least 8 times smaller than those present in cast chromium-cobalt combinations. Surface roughness is greatly reduced, which leads to a reduction in the rate of wear in comparison to cast chromium-cobalt alloys[4,5,6].



Cast CoCrMo alloy



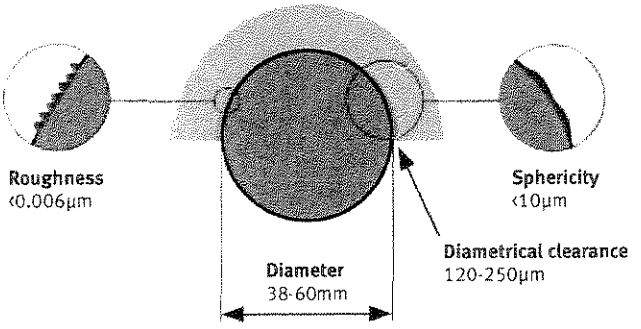
Metasul Wrought Forged CoCrMo alloy

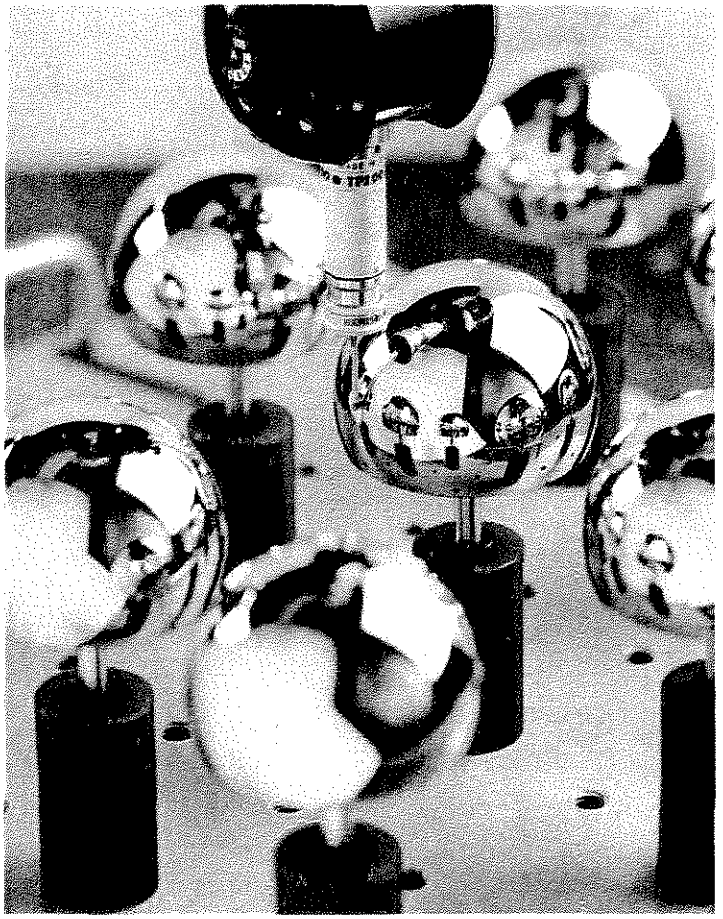
Clearance and its limits

Clearance is one of the factors that influences wear. The diametrical clearance is the difference in articulation diameter between acetabular cup and the femoral head. The differences in diameter between the two friction surfaces have been optimized to ensure ideal tribological behavior with manufacturing tolerances of several microns.

Manufacturing precision is essential for providing increased congruence in order to avoid clamping or polar contact. The high level of sphericity (deviation with regard to a theoretically perfect sphere) leads to a constant clearance for the entire surface, thereby increasing contact surface and lowering surface stress.

Parameters determining resistance to wear





Rigorous quality control

Each *Metasul LDH* component is subjected to a dimensional and visual check that provides optimal function.

Stability and Range of Motion

Large diameter heads increase stability

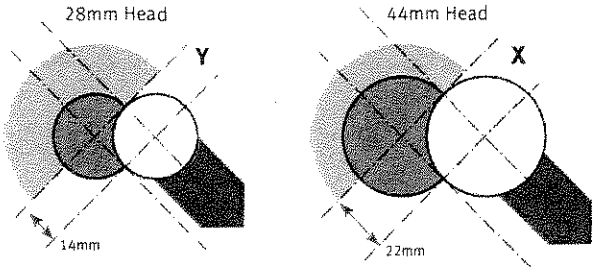
Currently, dislocation is a recurring problem in total hip arthroplasties. Further in-hospital treatment is required, which increases costs and has a negative effect on patients. Surgery is often necessary for recurring dislocations.

Recent clinical studies show that large diameter heads reduce the rate of dislocation[7,8]. Large diameter heads increase the displacement and height distance that must be covered before dislocation occurs, e.g., a displacement of 14mm is necessary to dislocate a 28mm head outside of the cup, versus 22mm for a 44mm femoral head. Prosthetic impingement is reduced by the increased range of motion of these large diameter heads.

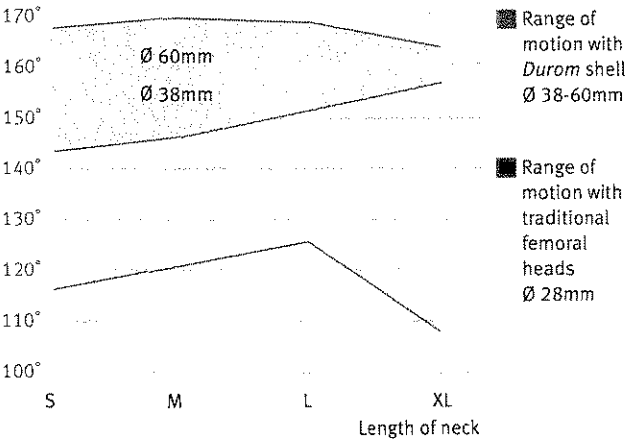
The combination of a *Metasul LDH* large diameter head and a *Durom* acetabular component makes it possible to increase the maximum range of motion without sacrificing prosthesis stability. The theoretical range of motion for a *Metasul LDH* head and *Durom* shell ranges from 144° to 168°.

Dislocation Distance (X>Y)

Large diameter heads increase the distance the head must displace before dislocation (X>Y)



Range of Motion



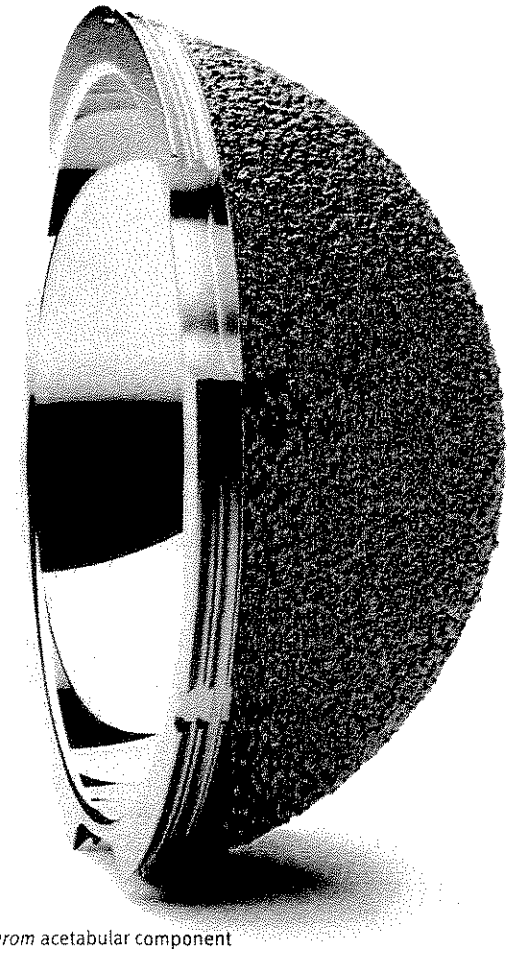
Range of motion measured with a Durom *acetabular component*

Flexion/Extension

Head diameter	Adapter S (-4mm)	M (0mm)	L (+4mm)	XL (+8mm)
Ø 38	144	147	151	154
Ø 40	146	149	152	155
Ø 42	151	150	154	157
Ø 44	157	152	155	158
Ø 46	160	153	155	158
Ø 48	162	154	156	159
Ø 50	163	159	157	160
Ø 52	164	163	158	160
Ø 54	164	165	159	161
Ø 56	165	167	161	162
Ø 58	166	167	164	162
Ø 60	166	168	167	163

Minimum thickness, maximum stability
Like the anatomical acetabulum, the *Durom* acetabular cup is smaller than a hemisphere, offering increased range of motion and greater preservation of host bone stock.

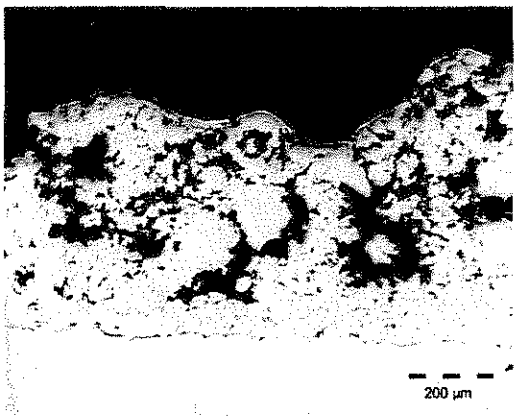
Implant wall thickness is 4mm for all sizes, which allows a much greater quantity of bone to be preserved while still ensuring optimal resistance to implant clamping or deformation.



Durom acetabular component

Porolock™ Ti VPS, a pure titanium coating, is applied to the exterior surface with the aid of sophisticated vacuum plasma spray technology.

Porolock Ti VPS is a plasma spray coating with a high surface roughness that allows a good initial scratch fit against host bone. The equatorial fins, increased surface roughness of the *Porolock* Ti VPS surface and initial 2mm press-fit allow excellent initial implant stability.



Porolock Ti Vacuum Plasma Spray

1 Delaunay CP, 'Metal-on-metal bearings in cementless primary total hip arthroplasty'. *J Arthroplasty*. Dec. 2004; 19(8 Suppl 3):35-40.
2 Chan FW, Bobyn JD, Medley JB, Krygier JJ, Tanzer M; 'Wear and lubrication of metal-on-metal hip implants'. *Clin Orthop* Relat Res. Dec. 1999 (369):10-24
3 Jin ZM; 'Analysis of mixed lubrication mechanism in metal-on-metal hip joint replacements'. Proc Inst Mech Eng [H]. 2002;216(1):85-9
4 Wang A, et al: Surface characterization of metal-on-metal hip implants tested in a hip simulator. Wear 225-229, 1999, 708-715.
5 Fisher J, et al: Wear and debris generation in artificial hip joints, in: Reliability and Long-term Results of Ceramics in Orthopaedics. Sedel L, Willmann G (eds), Stuttgart-New York, Thieme, 1999, 78-81
6 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 10, 1999, 353-362.
7 Amstutz HC, Le Duff MJ, Beaule PE.; 'Prevention and treatment of dislocation after total hip replacement using large diameter balls'. *Clin Orthop* Relat Res. Dec. 2004, (429):108-16.
8 Cuckler JM, Moore KD, Lombardi AV Jr., McPherson E, Emerson R; 'Large versus small femoral heads in metal-on-metal total hip arthroplasty', *J Arthroplasty*. Dec. 2004, 19(8 Suppl 3):41-4.

Please refer to package insert for complete product information, including contraindications, warnings, precautions, and adverse effects.

Contact your Zimmer representative or visit us at www.zimmer.com

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Confidence in your hands®

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49079
2-2415/2426-8

October 2, 2008

Ms. Sandra Williams
Compliance Officer
Food and Drug Administration
Detroit District
300 River Place, Suite 5900
Detroit, MI 48207-3179

Subject: **Zimmer, Inc. Corrections and Removal Report Addenda:**
Addenda to Zimmer Correction #9613350-07/15/2008-001-C

Dear Sandra:

For the correction that Zimmer, Inc. initiated for the *Durom*® Acetabular Component ("*Durom* Cup") in July 2008 we are providing additional information in keeping with the requirements of 21 CFR Part 806.

Attached are copies of the following additional communications that have been sent to *Durom* Cup users as part of this correction:

- A "Dear Surgeon" letter mailed August 4, 2008 providing Patient Management Guidelines.
- The "Urgent Device Correction Update" letter sent to *Durom* Cup surgeons on August 16, 2008. With this letter, the users received the updated Surgical Technique and Instructions for Use documents and were instructed to discard previous versions of surgical technique documents. The letter also contained information regarding available training programs, including logon information unique to each surgeon receiving the letter that would allow him/her to access the online training program.
- The revised Surgical Technique Document (97-1081-002-00, Rev. 1) included with the August 16th letter.
- The revised Instructions for Use document (D011 500 213, Ed. 07/08) included with the August 16th letter.
- The revised Instructions for Use document (D011 500 111, Ed. 07/08) included with the August 16th letter.
- A "Dear Surgeon" letter mailed September 25, 2008 providing additional information regarding training programs.

These communications went to the same population of surgeons identified with our original Correction and Removal report. As our August 16, 2008 letter states, *Durom* Cup surgeons who have completed the online training now have the devices made available to them for use.

Should you have any questions or concerns after reviewing the attached Addenda information for this Correction and Removal report, please do not hesitate to contact me either by phone or e-mail.

Sincerely,

S. Dale Miller

S. Dale Miller
Associate Director, Global Regulations
Zimmer, Inc
Dale.miller@zimmer.com

Enclosures:

cc:

Daniel Buehler, VP Quality and Regulatory
Zimmer GmbH
Winterthur, Switzerland

Michael Carter
VP, Global QA and RA
Zimmer Inc.

August 4, 2008

Dear Surgeon:

We last wrote to you on July 22, 2008 to announce the temporary suspension of marketing and distribution of the *Durom*® Acetabular Component (*Durom* Cup) in the United States, while Zimmer provides more detailed surgical technique instructions and implements a surgical training program for U.S. surgeons. As promised in that communication, we are providing Patient Management Guidelines to assist you in the ongoing evaluation of patients currently implanted with the *Durom* Cup.

This document draws directly on input and feedback Zimmer has received from surgeons who have managed patients experiencing cup loosenings following total hip arthroplasty using the *Durom* Cup. The Guidelines are intended to provide practical insight into appropriate evaluation and management of your *Durom* Cup patients.

General Observations

Symptomatic patients sometimes indicate that they have experienced minimal pain relief since their operation. Some symptomatic patients have also described a sensation that their leg wants to give out on them or that it feels like something is loose. These clinical symptoms have appeared from 3 – 22 months post-operative.

The following points have been noted by some surgeons about some patients who are implanted with this product and who have been identified as candidates for revision:

- Some patients with apparent good x-rays can be painful.
- Some patients with apparent progressive radiolucencies can be asymptomatic.

Surgeons also emphasize that when evaluating patients, it is important to consider other causes of pain besides the acetabular component. Infection, heterotopic ossification, impingement, stem mal-positioning and spinal issues should be ruled out as potential causes of pain. It is also noted by surgeons that exposing the anterior portion of the acetabular component through under anteversion of the cup or reducing the anterior wall of the pelvis through over-reaming may result in rubbing of the iliopsoas on the equatorial fins that can also result in pain.

Clinical Symptoms

The most common clinical symptoms are pain and stiffness. Surgeons have noted the following feedback from their patients with symptoms more than three months post-operative:

- Pain and stiffness on startup or when rising from a chair. Onset of pain can be rapid.
- As they move from a bent to an upright position, they have a sharp pain in the groin.
- The pain is typically located anterior/medial in the groin and sometimes buttock.
- Pain at rest is significantly less than at weight bearing.
- These patients may have difficulty climbing stairs; they limp; or they have little endurance.

Patient Examination

When examining their patients, these surgeons have noted the following:

- With the patient lying supine, pain or weakness occurs when raising the straight leg against resistance (positive Stinchfield sign).
- Patients may have pain with passive hip flexion and internal rotation or extreme external rotation.
- Patients may be weaker in hip flexion than hip abduction.

Radiographic Examination
As noted above, patients with progressive radiolucencies can be asymptomatic. Surgeons have identified the following key steps and observations in their radiographic examination of these patients.

Potential Indications of Loosening

- Gaps at the dome in the post-operative x-ray do not necessarily mean the cup is not seated. However, patients should be monitored for changes in these gaps.
- X-rays should be reviewed for progressive radiolucencies, especially patients that are more than 1 year post-operative. While it may seem self-evident, it is important to compare the immediate post-op x-ray to the most recent x-ray and examine them for the presence of a new thin radiolucent line in zones 1, 2, and/or 3.
- Look for cup migration on cases more than 1 year post-operative. Position changes identified to date include angle of inclination, position of the medial shell relative to the teardrop, and/or migration of the cup within the bony acetabulum, either medially or superiorly into the pelvis.

Potential Indications of Secure Fixation

- No evidence of cup migration and absence of radiolucent lines.
- Look for localized bone resorption around the lateral or medial fins. This can indicate that the cup has achieved stable fixation.
- Some x-rays show "spot welds" or patterns of trabecular remodeling, particularly in zone 1 on the Anterior/Posterior x-ray, which can indicate stable fixation of the shell.

Revision
As stated in previous information, Zimmer believes the likelihood of currently implanted patients requiring revision is low. However, when revision surgery has been deemed necessary, surgeons who have explanted the device have noted that a loose cup is easily dislodged by striking the rim with a bone tamp and mallet. If the cup is found to be stable and secure (i.e., not easily dislodged or has a ringing sound like a well-fixed cup), other potential causes of pain, such as the iliopsoas rubbing on the equatorial fins or impingement, should be investigated.

The information contained herein is intended to provide information to the surgeon community regarding the experience and observations of surgeons as they have reviewed and monitored their patients implanted with the *Durom* Cup. We sincerely hope you find this information helpful.

If you have relevant clinical information, questions, or comments regarding this matter, please contact us via our *Durom* Cup surgeon number (1-866-946-5633). Alternatively, you also may contact us at durom@zimmer.com.

Sincerely,

Cheryl Blanchard

Cheryl R. Blanchard, Ph.D.
Sr. Vice President, Research and Development
Chief Scientific Officer
Zimmer, Inc.

Zimmer, Inc.

P.O. Box 708
Warsaw, IN 46851-0708
574.267.6131
www.zimmer.com

URGENT DEVICE CORRECTION - UPDATE

August 16, 2008

Dear Surgeon:

In our July 22, 2008 letter to you regarding the temporary suspension of marketing and distribution of the *Durom*® Acetabular Component (*Durom* Cup) in the United States, Zimmer announced it would take the necessary steps to address the surgical training needs the Company identified through its extensive clinical investigation. We are now pleased to provide you with updated product labeling on the *Durom* Cup, more detailed surgical technique instructions and specific information regarding a comprehensive surgical training program, which Zimmer has developed in collaboration with several experts.

Enclosed with this letter are updated surgical technique instructions (*Metasul*® *LDH*® Large Diameter Head with *Durom* Acetabular Component).

> **The updated surgical technique instructions are the subject of our Urgent Device Correction of July 22, 2008. Please discard all previous versions of surgical technique instructions for the *Durom* Cup in the U.S., including Surgical Technique # 97-1081-002-00 and "Tips and Pearls" # 97-1081-016-00 and # 97-1081-023-00 (DVD).**

Also included with this letter are updated Instructions For Use (IFUs), commonly called package inserts or product labeling, for the *Durom* Cup and the *Metasul* Metal-on-Metal Tribological Solution *LDH* for Total Hip Arthroplasty. Both the enclosed surgical technique instructions and IFUs contain updated information based on the findings of our clinical investigation. If you have any questions about these updated materials, please contact us via the *Durom* Cup toll-free information line (1-866-946-5633) or at durom@zimmer.com.

Surgical skills training program

In addition to this updated documentation, we are launching a comprehensive surgical skills training curriculum, key elements of which are available to surgeons as of August 19, 2008. In collaboration with experts from the U.S. and Europe, we have produced training curricula to provide training through several different learning modalities. These modalities include an online surgical training module, Web cast training sessions with experts, surgical skills courses through The Zimmer Institute and surgeon-to-surgeon training.

As we have communicated, the *Durom* Cup will be made available upon completion of training. While each modality offers a unique learning opportunity, the minimum required training for resumption of product usage is completion of the online training course. We have developed a comprehensive, user-friendly, online program that addresses the most critical technique issues in a concise and clear manner that also provides ease of access and verification of comprehension through online assessment. However, we encourage surgeons to consider the additional training opportunities based on their comfort level with the product.

Following are the details of the available training programs.

- **Online Training:** This course will be offered starting Tuesday, August 19, 2008. It will review the critical aspects of the *Durom* Cup design, preoperative planning considerations and comprehensive information regarding the critical technique steps to implant the device. The program includes videos, information from the experts and questions to evaluate comprehension. **This is the minimum required training to resume product use.**

  The Online Training module can be accessed at the following secure Web site. Please type the link into your Internet browser and login with your username and password information outlined below. Once you have logged in, instructions on how to use the training program will be given.

  Link: http://zols.zimmer.com/durom

  Your Username: Your Password:

  Attached are more detailed instructions for accessing the training. If you have any questions or problems, contact the Zimmer Helpdesk (available 24 hours, seven days a week) at 1-800-999-0506. To help ensure the security of the system, upon completion of the online training course your user name and password will be reset. For future access or questions, please contact the Zimmer Helpdesk.

- **Web casts:** These courses will review information similar to the online course, followed by a *live* question and answer session with an expert. The Web casts have been designed specifically as a follow-up to the online training. Further information on Web cast availability will be provided soon.

- **The Zimmer Institute Surgical Skills Courses:** These courses offer a didactic learning session and hands-on experience with cadavers to practice implantation of the *Durom* Cup in a controlled environment. These courses also serve as a follow-up to the online training. The Zimmer Institute courses will be offered according to the following schedule (additional dates and locations will be offered):

- September 25 – Baltimore, MD
- October 9 – Warsaw, IN
- October 16 – Denver, CO
- October 23 – Phoenix, AZ (location to be confirmed)

- **Surgeon-to-Surgeon Training:** These courses will offer one-on-one learning from an expert in the operating room and will include a pre-operative planning discussion, personal education on the crucial technique steps of product implantation and consultation with the expert.

To access the Web casts, surgical skills, and surgeon-to-surgeon courses, please contact your Zimmer sales representative for further information.

We are pleased to offer these new materials and training programs and hope that you find them useful in the continuing management of your patients. We want to sincerely thank you for your ongoing support and patience during their development.

If you have relevant clinical information, questions or comments regarding this matter, please contact us via our *Durom* Cup toll-free information line (1-866-946-5633) or via email at durom@zimmer.com.

Sincerely,

Cheryl Blanchard

Cheryl R. Blanchard, Ph.D.
Sr. Vice President, Research and Development
Chief Scientific Officer
Zimmer, Inc.

zimmer

Rx only

CE 0086

Acetabular cups

D011 500 213 - en/da/nl/fr/de/el/it/pt/es/sv – Ed. 07/08

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ENGLISH

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

Acetabular cups

Important information for the operating surgeon

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 available product-specific information (e.g., product literature, written surgical technique). Zimmer is not liable for complications arising from the use of the device outside of its indicated uses, surgical technique or judgment, product selection, and similar matters outside the control of Zimmer.

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 all Zimmer orthopaedic companies, which include 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 must 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.

DESCRIPTION

An acetabular cup component is used in conjunction with a femoral head component for replacement of the acetabulum in total hip arthroplasty.
Acetabular cup components are available in different designs, materials and sizes.

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

INTENDED ONLY FOR USE WITH BONE CEMENT:

- **Low profile Acetabular Cup (*Sulene*® PE / Durasul® PE [UHMWPE - ISO 5834-1/-2])**
  Cemented, all-polyethylene components for use with reinforcement rings and cages.
- **Full profile Acetabular Cup (*Sulene* PE [UHMWPE - ISO 5834-1/-2])**
  Cemented, all-polyethylene components for use with reinforcement rings and cages.

INTENDED ONLY FOR USE WITHOUT BONE CEMENT:

- **Acetabular Roof Reinforcement Rings and Cages; *Burch-Schneider*™ Reinforcement Cage, *Original M.E. Müller*® Ring, Roof Reinforcement Ring (*Protasul*® Ti [ISO 5832-2 Grade 1])**
  Metallic, plate-like, flanged/hooked acetabular components with multiple screwholes for acetabular deficiencies/reconstruction.
- ***Alloclassic*® *Zweymüller*® Acetabular Cup System (*Protasul* Ti [ISO 5832-2 Grade 1/-4A] / *Protasul* 100 [ISO 5832-11])**
  Threaded acetabular shell system.
- ***CLS*® *Spotorno*® Acetabular Cup System (*Protasul*-100 [ISO 5832-11])**
  Flattened, hemispherical shell with sharp, toothed expansion lobes for fixation.
- ***Allofit*® *Alloclassic*® Acetabular Cup System (*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 *Metasul*® Acetabular Component with Ti-VPS coating and circumferential fins for additional primary fixation.

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

INDICATIONS

- Noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis.
- 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 handicapped 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.

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.
- 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.

WARNINGS

- Implants are for single use only. Do not reuse.
- Do not use any component if damage is found or caused during setup or insertion.
- Implants and implant parts must only be combined with components belonging to the same system. No liability is accepted for products of third parties that are used by the purchaser or user.
- Use only instruments and provisionals specifically designed for use with these devices to help ensure accurate surgical implantation and evaluation of joint function.
- Complications or failure of any total hip prosthesis are more likely to occur in heavy patients.
- The load-bearing capacity of the implant can be compromised by notching, scratching, or striking the prosthesis, repeated assembly/disassembly of the modular components, or failing to provide metaphyseal support to the implant.
- Do not mate titanium alloy components with stainless steel. (Only applicable for the USA.)
- Improper selection, placement, positioning, and fixation of the implant components may result in unusual stress conditions reducing the service life of the prosthetic implants.
- Do not use this product for other than labeled indications (off-label use).
- Cup components should be implanted according to the surgical technique. Generally, this implantation is with an inclination of between 40° and 50° 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.
- The *Durom* Acetabular Component should not be repositioned after engagement of the circumferential fins. Repositioning may lead to early loosening of the acetabular component.
- Reaming for the *Durom* acetabular component must be verified with the corresponding provisional shell and performed according to the surgical technique. Failure to ream properly may lead to component loosening and persistent groin pain.
- The potential long-term toxicity of metal wear debris and metal ion production is not known.

PRECAUTIONS

- Continued surveillance for new or recurrent sources of infection should be continued as long as the device is in place.
- Do not assemble the mating components without ensuring that the surfaces are free of blood or debris. Failure to ensure that mating surfaces are clean and dry could result in inadequate seating of one component upon the other and subsequent disassembly of the mated components or fracture of the implant.
- Countersink screw heads/hole plugs below the interior shell surface to prevent contact between the liner and the screw head/hole plug.
- Repeated assembly and disassembly of modular components could compromise the critical locking action of the Morse-type tapers. Use the provisional components during trial reductions. Change the components only when clinically necessary.
- Implants must not be machined or altered in any way, unless this is expressly envisaged in the design and in the surgical technique.
- Implants should only be rinsed with sterile solution such as USP purified water or ringer solution.

ADVERSE EFFECTS

The following adverse effects have been reported:

Peripheral neuropathies
Deep wound infections
Perforation of the acetabulum or femur
Wear
Heterotopic bone formation
Metal sensitivity
Inflammatory reactions and osteolysis
Dislocation and subluxation
Vascular complications
Trochanteric problems
Subclinical nerve damage
Corrosion of metal implants
Early or late loosening of components
Pelvic, femoral, or acetabular fractures
Disassembly of modular components
Fatigue fracture

STERILIZATION

- Gamma irradiation is indicated by the "Sterile-R" symbol and sterilization with Ethylene Oxide Gas (*Durasul*® PE Implants) with the "Sterile-EO" symbol on the labeling. These devices remain sterile as long as the package integrity has not been violated.
- Inspect each package prior to use and do not use the component if any seal or cavity is damaged, breached, or if the expiration date has been exceeded.
- Once opened, the component must be used, discarded, or resterilized.
- If the packaging is damaged or the sterility expiration date has been reached, the implants must be returned to the manufacturer. (Not applicable for the USA.)

RESTERILIZATION INFORMATION

- The recommendations set forth under this point are provided for informational purposes only. No liability is accepted regarding sterility for devices that are cleaned and sterilized or resterilized by the purchaser or user.
- Do not resterilize:
  - Single use only components that have been contaminated with body fluids or debris or previously implanted.
  - Hydroxyapatite/calcium phosphate coated components
  - Factory assembled Polyethylene (PE) Implants like:
    - PE-*Metasul* Implants.
    - PE-Implants with radiographic wire.
    - PE-Implants with pole plate (e.g., *Alloclassic Zweymüller* CSF Liners).
- These reprocessing/sterilization instructions should be used for sterile items that were opened but unused. These reprocessing instructions have been validated in accordance with ANSI/AAMI/ISO standards and are consistent with AORN recommended practices.
- Zimmer recommends that all implants should be cleaned and resterilized by the manufacturer, provided resterilization is permitted and is possible. In this case, an essential pre-requisite is that the innermost original sterile packaging should still be intact and unopened. Implants that have been completely unpacked cannot be returned to Zimmer for resterilization. (Not applicable for the USA.)
- The country-specific resterilization guidelines as well as the mentioned exclusions are to be followed under all circumstances.
- Do not use the original plastic cavities or lids for sterilization/resterilization. After cleaning as appropriate (rinse only with USP purified water), the components must be placed in suitable sterilization packing. Single devices may use a standard *Tyvek*® pouch or other sterilization wrap. Ensure that the pouch is large enough to contain the device without stressing the seals or tearing the pouch.
- Do not use cleaning agents or detergents of any type on single use implant components. Only USP purified water may be used.
- Materials like Ti-VPS (Titanium-vacuum-plasma spray), *CSTi*™ (cancellous structured titanium) coated components and *Sulmesh*® Surface Structure* must not be cleaned with any detergents.
- Implants shall not come into contact with substances containing chlorine, phosphorus or fluorine or with detergents containing fats.

- Modular components must be processed in the unassembled state to ensure sterilization to the intended sterility assurance level. Also, the components may be made from alloys differing in expansion and contraction characteristics which could cause internal stresses during heating and cooling.
- Zimmer products sterilized/resterilized by the user should be indicated in the corresponding patient documentation (i.e., in the Operation Report/Surgeon's Notes), and relevant documents (all labeling, instructions for use) kept on file.
- All polymers must be used immediately after resterilization by EO or Gas plasma unless otherwise noted.
- Implants made of synthetic materials and components with synthetic parts may not be re-sterilized or industrially processed for reuse by steam, as this can cause deterioration of the material.
- Products past their «Use By» dates may not be repacked and resterilized by third-party firms, since traceability would no longer be guaranteed.

Recommended sterilization/ resterilization specifications

Solid metal implants

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	

UHMWPE 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

STERRAD Gas Plasma Sterilization

Gas Concentration	Temperature	Exposure Time
6 mg/L (59% Hydrogen Peroxide)	45°C (113°F)	65 minutes

STORAGE AND HANDLING

- 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. (Not applicable for the USA.)

PATIENT COUNSELING INFORMATION

Complications and/or failure of prosthetic implants are more likely to occur in patients with unrealistic functional expectations, heavy patients, physically active patients and/or with patients who fail to follow through with the required rehabilitation program. Physical activity can result in loosening, wear and/or fracture of the implant. The prospective implant patient must be counseled about the capabilities of the implant and the impact it will have on his or her lifestyle. 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 replaced. The implant may not last the rest of the patient's life, or any particular

length of time. Because prosthetic implants are not as strong, reliable, or durable as natural, healthy tissues/bones, all such devices may need to be replaced at some point.

* where available

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zimmer

Rx only

CE 0086

Modular Femoral Heads

D011 500 111 - en/da/nl/fr/de/el/it/pt/es/sv - 07/08

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ENGLISH

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

Modular Femoral Heads

Important information for the Operating Surgeon

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 available product-specific information (e.g., product literature, written surgical technique). Zimmer is not liable for complications arising from the use of the device outside of its indicated uses, surgical technique or judgment, product selection, and similar matters outside the control of Zimmer.

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 all Zimmer orthopaedic companies, which include 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 must 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.

DESCRIPTION

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 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 Physicians Insert is valid for the following modular femoral heads:

- **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* Metal-on-Metal Articulation or conventional polyethylene (PE).
  As a metal-metal combination, the *Metasul* Femoral Head must only be used in combination with a *Metasul* Cup or *Metasul* Inlay. *Metasul* Femoral Heads are also marked with a groove in the area of the taper which is evident on x-rays.
- ***Metasul LDH*® Large Diameter Heads (*Protasul*-21WF [ISO 5832-12])**
  May only be used with *Durom*® Acetabular Component.
- ***Protasul* S30 Femoral Heads (ISO 5832-9)**
  May only be used in combination with conventional polyethylene (PE).

INDICATIONS

- Noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis.
- 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 handicapped 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.

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.
- Allergy to the implanted material, above all to metal (e.g., cobalt, chromium, nickel, etc.).
- Local bone tumours and/or cysts.
- Pregnancy.

WARNINGS

- Implants are for single use only. Do not reuse.
- Do not use any component if damage is found or caused during setup or insertion.
- Implants and implant parts must only be combined with components belonging to the same system. No liability is accepted for products of third parties that are used by the purchaser or user.
- Use only instruments and provisionals specifically designed for use with these devices to help ensure accurate surgical implantation, and evaluation of joint function.
- 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.
- The load-bearing capacity of the implant can be compromised by notching, scratching, or striking the prosthesis, repeated assembly/disassembly of the modular components, or failing to provide metaphyseal support to the implant.
- 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.
- Do not use Zimmer femoral heads with Zimmer femoral stems using a different taper.
- Do not mate titanium alloy components with stainless steel. (Only applicable for the USA.)

- Improper selection, placement, positioning, and fixation of the implant components may result in unusual stress conditions reducing the service life of the prosthetic implants.
- Do not use this product for other than labeled indications (off-label use).
- 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 visibly damaged, the stem must be replaced. It is absolutely essential that the taper of the femoral stem fit perfectly with the taper of the head.
- The potential long-term toxicity of metal wear debris and metal ion production is not known.

PRECAUTIONS

- Continued surveillance for new or recurrent sources of infection should be continued as long as the device is in place.
- Do not assemble the mating components without ensuring that the surfaces are free of blood or debris. Failure to ensure that mating surfaces are clean and dry could result in inadequate seating of one component upon the other and subsequent disassembly of the mated components or fracture of the implant.
- Place the femoral head on the stem taper with a rotary motion until it locks. For fixation of the femoral head, strike the plastic impactor with a mallet in an axial direction as necessary.
- Repeated assembly and disassembly of modular components could compromise the critical locking action of the Morse-type tapers. Use the provisional components during trial reductions. Change the components only when clinically necessary.
- Handle heads of femoral hip prostheses with care. Remove the protective covers only prior to implantation.
- Implants must not be machined or altered in any way, unless this is expressly envisaged in the design and in the surgical technique.
- Implants should only be rinsed with sterile solution such as USP purified water or ringer solution.

ADVERSE EFFECTS

The following adverse effects have been reported:

Peripheral neuropathies	Vascular complications
Deep wound infections	Trochanteric problems
Perforation of the acetabulum or femur	Subclinical nerve damage
Wear	Corrosion of metal implants
Heterotopic bone formation	Early or late loosening of components
Metal sensitivity	Pelvic, femoral, or acetabular fractures
Inflammatory reactions and osteolysis	Disassembly of modular components
Dislocation and subluxation	Fatigue fracture

STERILIZATION

- Gamma irradiation is indicated by the "Sterile-R" symbol on the labeling. These devices remain sterile as long as the package integrity has not been violated.
- Inspect each package prior to use and do not use the component if any seal or cavity is damaged or breached or if the expiration date has been exceeded.
- Once opened, the component must be used immediately, discarded, or resterilized.
- If the packaging is damaged or the sterility expiration date has been reached, the implants must be returned to the manufacturer. (Not applicable for the USA.)

RESTERILIZATION INFORMATION

- The recommendations set forth under this point are provided for informational purposes only. No liability is accepted regarding sterility for devices that are cleaned and sterilized or resterilized by the purchaser or user.
- Do not resterilize:
  Single use only components that have been contaminated with body fluids or debris or previously implanted.
- These reprocessing/sterilization instructions should be used for items supplied non-sterile and for sterile items that were opened but unused. These reprocessing instructions have been validated in accordance with ANSI/AAMI/ISO standards and are consistent with AORN recommended practices.
- Zimmer recommends that all implants should be cleaned and resterilized by the manufacturer, provided resterilization is permitted and is possible. In this case, an essential pre-requisite is that

the innermost original sterile packaging should still be intact and unopened. Implants that have been completely unpacked cannot be returned to Zimmer for resterilization. (Not applicable for the USA.)

- The country-specific resterilization guidelines, as well as the mentioned exclusions are to be followed under all circumstances.
- Do not use the original plastic cavities or lids for sterilization/resterilization. After cleaning as appropriate (rinse only with USP purified water), they must be placed in suitable sterilization packing. Single devices may use a standard *Tyvek*® pouch or other sterilization wrap. Ensure that the pouch is large enough to contain the device without stressing the seals or tearing the pouch.
- Do not use cleaning agents or detergents of any type on single use implant components. Only USP purified water may be used.
- Implants shall not come into contact with substances containing chlorine, phosphorus or fluorine or with detergents containing fats.
- Modular components must be processed in the unassembled state to ensure sterilization to the intended sterility assurance level. Also, the components may be made from alloys differing in expansion and contraction characteristics which could cause internal stresses during heating and cooling.
- Zimmer products sterilized/resterilized by the user, should be indicated in the corresponding patient documentation (i.e., in the Operation Report/Surgeon's Notes), and relevant documents (all labeling, instructions for use) kept on file.
- Products past their «Use By» dates may not be repacked and resterilized by third-party firms, since traceability would no longer be guaranteed.

Recommended Sterilization/Resterilization Specifications

Solid Metal Implants

Steam Sterilization

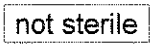
Type	Minimum Temperature	Minimum Exposure Time	Dry Time
Gravity Displacement	121°C (250°F)	30 Minutes	Varies by load configuration and sterilizer type
Gravity Displacement	132°C (270°F)	15 Minutes	
Pre-vacuum	132°C (270°F)	4 Minutes	

STORAGE AND HANDLING

- 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 (not applicable for the USA).

PATIENT COUNSELING INFORMATION

Complications and/or failure of prosthetic implants are more likely to occur in patients with unrealistic functional expectations, heavy patients, physically active patients and/or with patients who fail to follow through with the required rehabilitation program. Physical activity can result in loosening, wear and/or fracture of the implant. The prospective implant patient must be counseled about the capabilities of the implant and the impact it will have on his or her lifestyle. 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 replaced. The implant may not last the rest of the patient's life, or any particular length of time. Because prosthetic implants are not as strong, reliable, or durable as natural, healthy tissues/bones, all such devices may need to be replaced at some point.



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September 25, 2008

Dear Surgeon:

On August 16, 2008 we provided updated surgical technique instructions, product labeling, and information regarding training for the *Durom*® Acetabular Component ("*Durom* Cup"). This letter is to provide additional information regarding the options available for training on the product.

As noted in the previous communication, a variety of training modalities have been developed. Currently, the *Durom* Cup is being made available upon completion of training. While each modality offers a unique learning opportunity, the minimum required training for resumption of product usage is completion of the online training course. We continue to encourage surgeons to consider the additional training opportunities based on their comfort level with the product.

- **Online Training**: This course is currently available at your convenience. It reviews the critical aspects of the *Durom* Cup design, preoperative planning considerations and comprehensive information regarding the critical technique steps to implant the device. The program includes videos, information from the experts and questions to evaluate comprehension. The website link and your specific user name and password were provided in the August 16, 2008 communication. Please contact your sales representative if you need further assistance with accessing the online training.

- **Web casts**: These courses will review information similar to the online course, followed by a *live* question and answer session with an expert. The Web casts have been designed specifically as a follow-up to the online training. The first Web cast is scheduled for **October 9 at 9:00 EDT**. For access to the Web cast, please contact us via email at durom@zimmer.com or on our toll free information line at 1-866-946-5633.

- **The Zimmer Institute Surgical Skills Courses**: These courses offer a didactic learning session and hands-on experience with cadavers to practice implantation of the *Durom* Cup in a controlled environment. These courses also serve as a follow-up to the online training. The Zimmer Institute courses will be offered according to the following schedule:

- October 9 – Warsaw, IN
- October 16 – Denver, CO
- October 23 – Phoenix, AZ

- **Surgeon-to-Surgeon Training**: These courses will offer one-on-one learning from an expert in the operating room and will include a pre-operative planning discussion, personal education on the crucial technique steps of product implantation and consultation with the expert.

To access the surgical skills and surgeon-to-surgeon courses, please contact your Zimmer sales representative for further information. We are pleased to offer these training programs and hope that you find them useful in the continuing management of your patients.

If you have relevant clinical information, questions or comments regarding this matter, please contact us via our *Durom* Cup toll-free information line (1-866-946-5633) or via email at durom@zimmer.com.

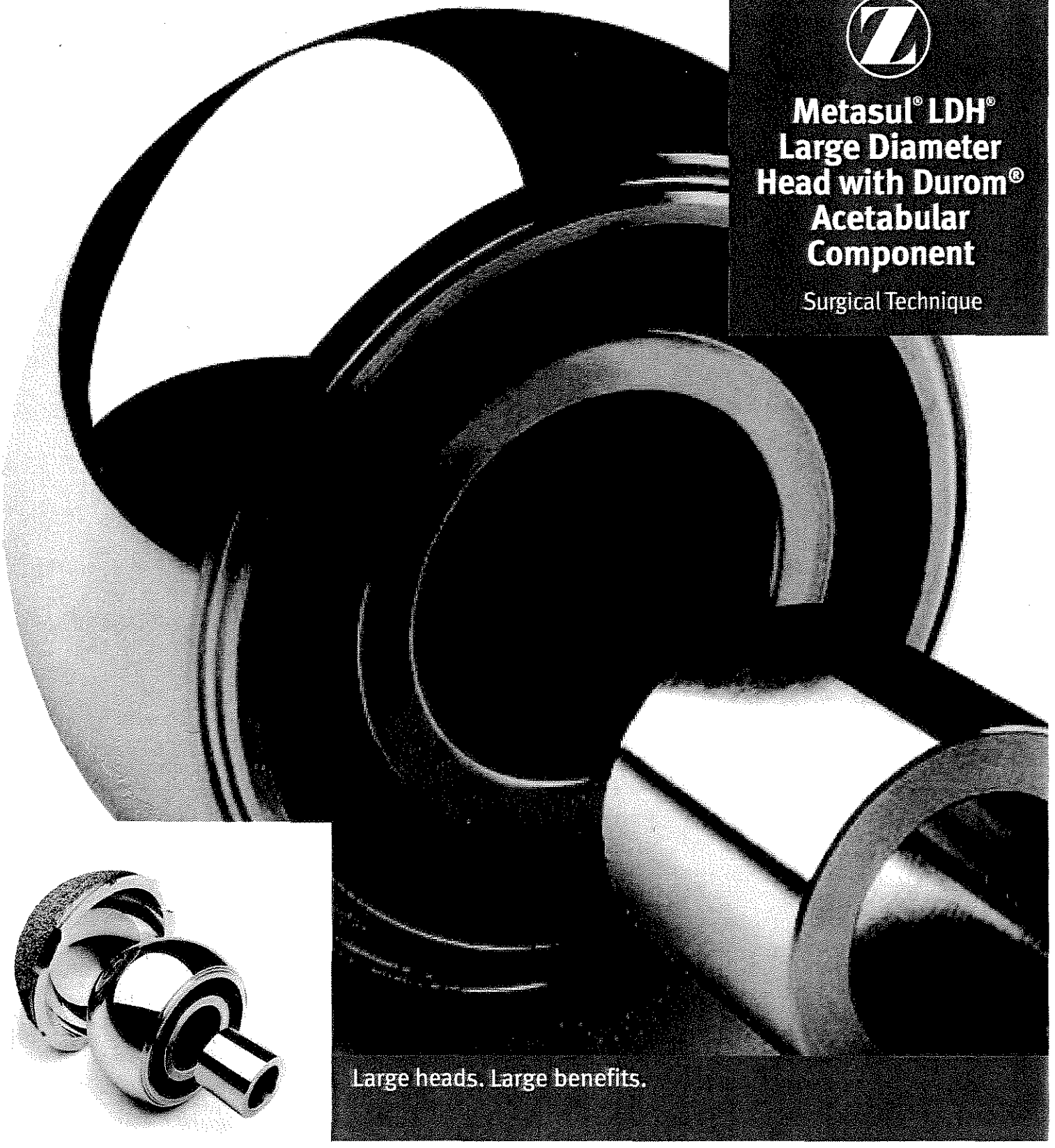
Sincerely,

Cheryl Blanchard

Cheryl R. Blanchard, Ph.D.
Sr. Vice President, Research and Development
Chief Scientific Officer
Zimmer, Inc.

Metasul® LDH® Large Diameter Head with Durom® Acetabular Component

Surgical Technique



zimmer

Confidence in your hands®

Metasul LDH Large Diameter Head with Durom Acetabular Component Surgical Technique

Table of Contents

Additional didactic, cadaveric, and surgeon to surgeon training for the *Metasul LDH* large diameter head technique is available through The Zimmer Institute. For more information, please go to www.zimmer.com.

General Description of the Implant

The combination of a very large range of motion and excellent articular stability[1], along with proven clinical results on the metal/metal articulations[2], make the *Metasul LDH* large diameter head concept an ideal solution for numerous patients.

Bearing Surface

The *Metasul LDH* large diameter head with *Durom* acetabular component system utilizes a *Metasul* bearing, which is a forged CoCr on forged CoCr metal/metal articulation. This is a proven low-wear, low-friction articulation[3], which has been implanted in over 350,000 patients since 1988[4]. No other metal/metal bearing has such a long and successful track record.

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

Preservation of Bone Stock

The *Durom* acetabular component has been designed to allow maximum preservation of bone stock. The 4mm wall thickness of the acetabular component is as low as practically possible to resist deformation (CoCr is a stiffer material than titanium material) under load while allowing a low clearance (diametrical mismatch) of the articulation. The cup subtends an angle of 165°, which is similar to the natural acetabulum. These features facilitate significant preservation of acetabular bone stock.

Durable Fixation

The *Durom* acetabular component has been designed to be press fit. It is a truncated hemisphere which derives initial fixation from a built-in 1–2mm press fit produced by under-reaming (Fig. 1). In addition, the presence of circumferential equatorial fins which lock into the acetabular rim result in an extra 1mm press fit at the rim only (Fig. 2).

The surface coating of the *Durom* acetabular component is vacuum plasma sprayed pure titanium (*Porolock*® Surface Ti-VPS). This process, carefully controlled, allows a very high adhesive strength between the cobalt chrome substrate and the *Porolock* Ti-VPS coating, minimizing the potential risk of titanium particle generation. Titanium vacuum plasma sprayed coatings have been associated with reliable bone on-growth allowing durable secondary fixation.

The circumferential fins, high surface roughness, and initial 2mm press fit allow initial implant stability while the *Porolock* plasma sprayed material promotes reliable scratch fit.

Joint Stability

Range of motion varies from 144° to 168° based upon the determined size of the acetabular component and the mating large diameter head. Range of motion is essential in total hip replacements to obtain unrestricted walking and optimized functioning of the hip, while reducing the potential risks of prosthetic impingement. The *Metasul LDH* large diameter heads are available from 38 to 60mm and must be used in combination with the *Durom* acetabular component.

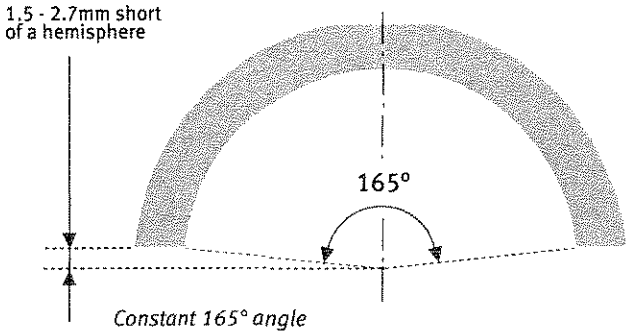


Fig. 1 The shape of the *Durom* Cup is a flattened, truncated hemisphere which subtends an angle of 165°.

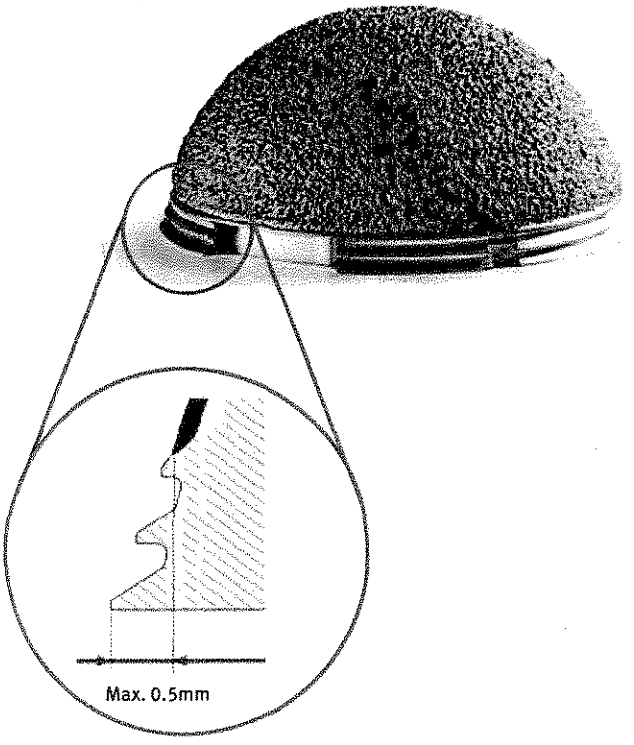


Fig. 2 Circumferential equatorial fins.

Overview of Implant Sizing

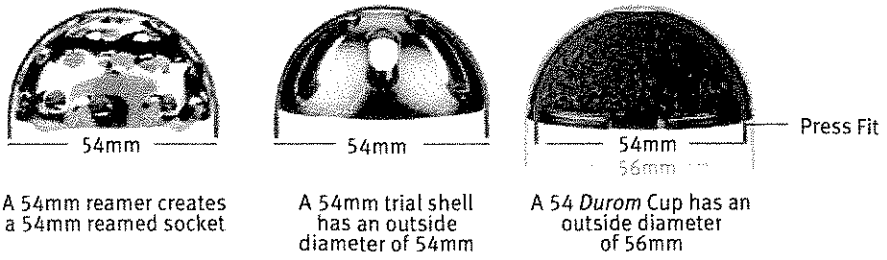
The actual diameter of the *Durom* acetabular component is 2mm greater than its labeled size. For example, a size 54 cup measures 56mm on the outer diameter at the coated area. This results in a 2mm press fit when reaming to 54mm and implanting a size 54 *Durom* Cup. Trials are line to line and do not feature any press fit (Fig. 3).

The inner diameter of a *Durom* acetabular component mates with a corresponding *Metasul LDH* large diameter head. A letter code confirms the appropriate combination. For example, a 54/N *Durom* Cup must be used with a 48/N *Metasul LDH* large diameter head.

The *Metasul LDH* large diameter heads may be used with a wide range of Zimmer hip stems.

Important information regarding Metasul Metal Pairings

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. *Metasul* femoral heads are designated with a groove in the area of the taper, which is evident on the x-rays.



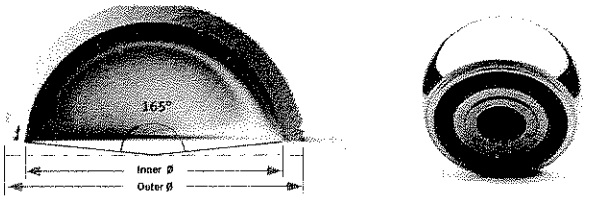
A 54mm reamer creates a 54mm reamed socket

A 54mm trial shell has an outside diameter of 54mm

A 54 *Durom* Cup has an outside diameter of 56mm

Fig. 3 Reamer, cup trial and implant outside diameters.

Durom Cup and Metasul LDH Sizing Guide

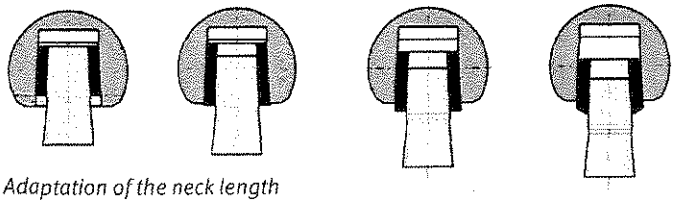


Durom Acetabular Component				Metasul LDH Large Diameter Head	
Size	Outer Ø	Inner Ø	Code	Size	Outer Ø
44	46mm	38mm	D	38	38mm
46	48mm	40mm	F	40	40mm
48	50mm	42mm	H	42	42mm
50	52mm	44mm	J	44	44mm
52	54mm	46mm	L	46	46mm
54	56mm	48mm	N	48	48mm
56	58mm	50mm	P	50	50mm
58	60mm	52mm	R	52	52mm
60	62mm	54mm	T	54	54mm
62	64mm	56mm	V	56	56mm
64	66mm	58mm	X	58	58mm
66	68mm	60mm	Z	60	60mm

Each size pair is designated with a suffix letter which is also marked on all the instrumentation and implant packaging for safety and ease of use.

In order to optimize restoration of joint kinematics, the *Metasul LDH* large diameter head system has been developed with 4 neck lengths (S, M, L and XL).

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



Adaptation of the neck length

Range of sizes

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

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

Patient Selection

The *Metasul LDH* large diameter head when used in conjunction with a *Durom* acetabular component may be used for a wide variety of indications and is most appropriate for patients with good bone quality and adequate acetabular bone stock.

Indications for Use

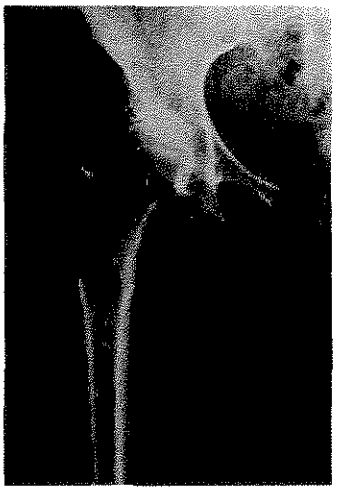
- Patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis.
- Those patients with failed previous surgery where pain, deformity, or dysfunction persists.
- Revision of previously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

Total hip replacements may be considered for younger patients if any unequivocal indication outweighs the risk 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.

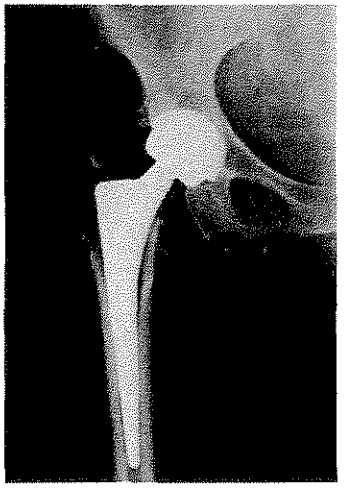
Contraindications

- 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.
- Allergy to the implanted material, above all to metal (e.g., cobalt, chromium, nickel, etc.).
- Local bone tumors and/or cysts.
- Pregnancy.
- 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.

Osteoarthropathy in a 56-year-old patient



Preoperative



One month postoperative

Preoperative Planning

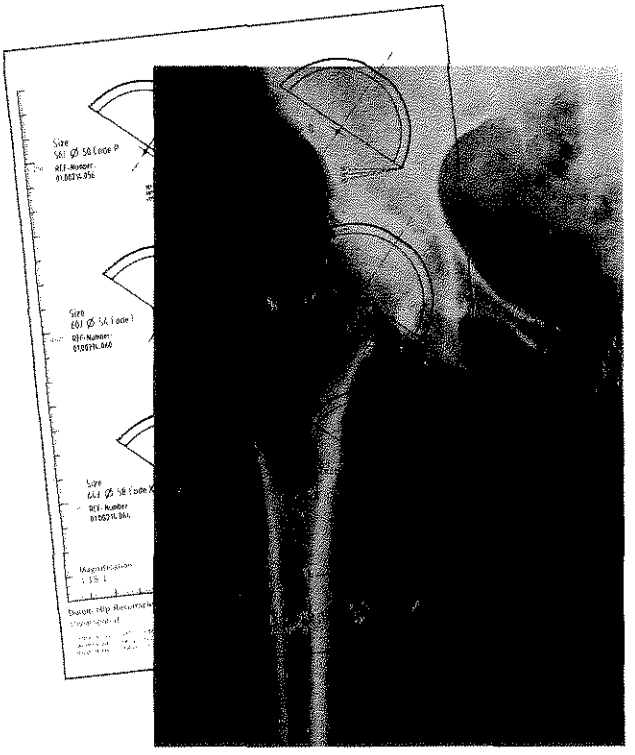
Templates of the *Durom* acetabular component are available for preoperative planning. They are available in 120% magnification for conventional radiographs.

Magnification is greater in heavier 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 angles
- the approximate size of the implant

Note: Because the risk of dislocation of the *Metasul LDH* large diameter head is much lower than lesser diameter articulations (e.g., 28 and 32mm), the acetabular component can be positioned to better fit the acetabulum to an extent from the conventional orientation to maximize bony support and fixation. Placement will generally fall within 40°– 50° abduction angle and 10°–20° anteversion angle.



Planning templates
Durom Acetabular component
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Acetabular Preparation

1. Acetabular Preparation

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

Technique Tip: It is important to excise soft tissue to **visualize the entire rim** of the acetabulum. This will help when using trial cups to assess the depth reamed. It will also reduce the likelihood of soft tissue entrapment which may prevent the cup from seating during cup insertion.

2. Reaming

Note: This technique demonstrates the use of 180° hemispherical reamers to prepare the acetabulum. If using reamers other than 180° hemispherical reamers, visual cues to assess reaming should be adjusted (Fig. 4).

Sequential reaming is carried out with hemispherical acetabular reamers. It is important to ream to a spherical socket. Hold the reamer steady and apply pressure in the same direction that the prosthesis will be implanted. **Orbital reaming should not be utilized.** Start with a reamer 2 sizes smaller than the templated implant size or if a small reamer is used to create a center of ream, care should be taken not to over medialize.

One should not over-deepen the acetabulum. The reamers subtend an angle of 180° whereas the acetabular components and trials subtend an angle of 165°. This means that the acetabular trials are nominally 2.3–3.8mm shallower than the corresponding reamer, depending on diameter (Fig. 5). Consequently, the acetabulum should only be deepened until the edge of the hemispherical reamer is almost flush with the true bony rim of the acetabulum. The socket will then be deep enough to fully insert the corresponding *Durom* acetabular component taking into account the 2mm diametrical (1mm radial) oversizing of the implant compared to the reamer.

Note: Actual reaming depth should only be assessed using the trials and not the reamers.

Technique Tip: In hard bone it is advisable to use reamers in 1mm increments when approaching the definitive acetabular size.

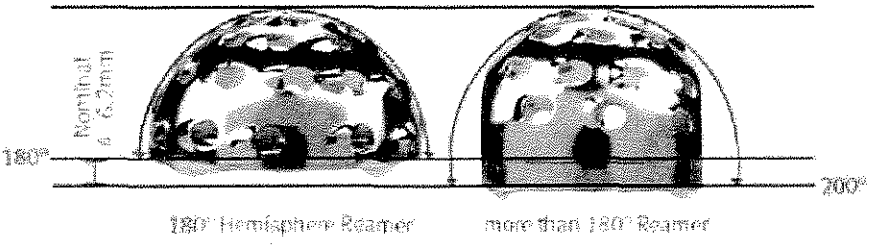


Fig. 4 180° hemispherical reamer versus a reamer that extends beyond 180°

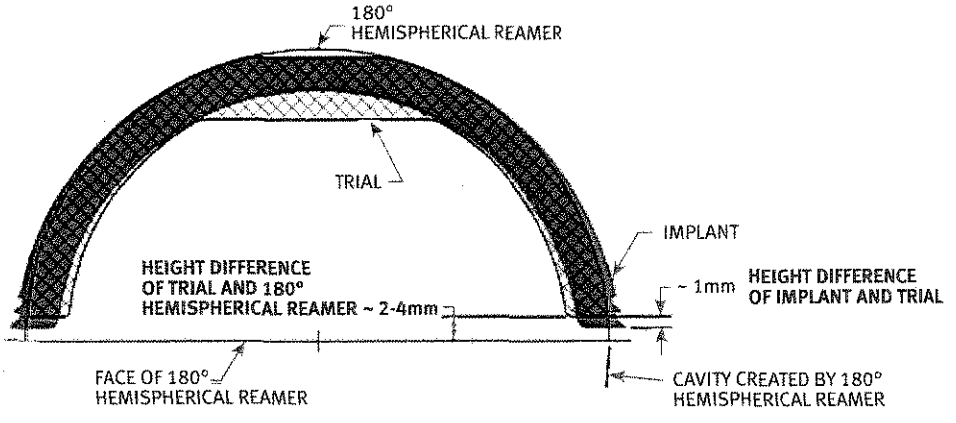


Fig. 5 Reamer to trial cup to implant depth comparison

3. The Use of the Acetabular Trial Implant

The accuracy of reaming and the optimal position of the implant are assessed using an acetabular trial the same size as the last used even numbered reamer. The acetabular trials are not used to test stability. They are "line to line" with the same-sized reamer and should seat within the prepared acetabulum. The diameter of the corresponding definitive acetabular component is 2mm greater than the trial cup, generating the press-fit.

The trial cup should be placed parallel to the anatomical bony rim of the acetabulum following the anterior and posterior walls. Anteversion and inclination angles are noted for final implantation of the acetabular component.

Note: It is important to trim any rim osteophytes to within 2–4mm of the true rim, as they can block the full insertion of the definitive implant.

Following the trimming of rim osteophytes it should be possible to reinsert the acetabular trial in the desired position with gentle tapping. If there is still resistance to fully seating and removing the acetabular trial, this indicates that the rim is too tight and that it will be difficult to insert the corresponding acetabular component.

Note: If the acetabulum is small or the bone is sclerotic, re-reaming using a 1mm larger reamer is appropriate, resulting in a nominal overall 1mm press-fit. The amount of press fit used should be determined at time of surgery and based upon bone quality.

Alternatively, "focal reaming" of the tight spots of the acetabular rim can be used: the trial cup is fully inserted and then rocked to determine the pivot points where the rim is over-tight. These are usually the areas of sclerotic bone adjacent to the anterior-inferior iliac spine and the ischium (Fig. 6). The tight spots are relieved by gently placing a small diameter reamer (e.g., 46mm) against the sclerotic bone, removing just ½ to 1mm of bone locally (Fig. 7). **Attention: Care must be taken not to remove excess bone when focal reaming.**

At the completion of acetabular preparation, reassess with the trial cup. At this time, it should be possible to fully seat the trial in the desired orientation with light taps of the mallet. There should be 1–2mm of peripheral bone protruding (anterior and posterior walls) for engagement of the equatorial fins of the implant.

Note: The acetabular implant is 1mm taller than its corresponding trial.

Technique Tip: When final press fit and cup position are determined with the trial cup, it is important to note landmarks of cup depth, abduction angle and anteversion. At this point it is helpful to leave the trial cup in final position until the *Durom* acetabular component impaction is imminent for a visual reference to cup placement.

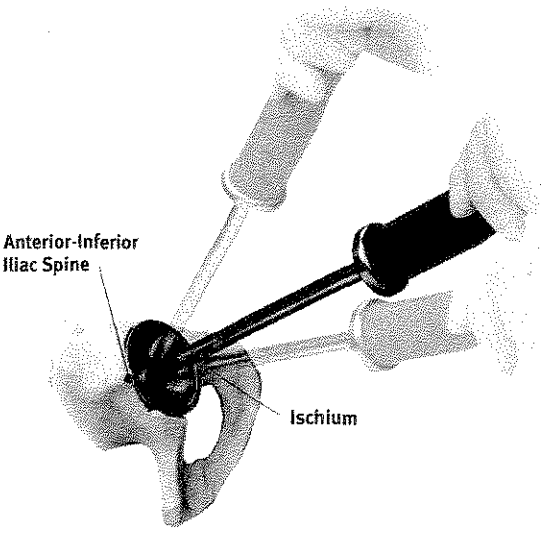


Fig. 6 Cup trial rocking on pivot points where rim is over-tight.

Fig. 7 Careful focal reaming of tight spots.

Acetabular Implantation

1. Mounting the Acetabular Component

The definitive acetabular component is placed on the disposable cup holder, which is provided with the packaging (Fig. 8). The appropriately sized cup inserter is then mounted on to the acetabular component. The threaded rod is tightened securely with the tightening bar and the inserter cap is then screwed onto the cup introducer handle (Fig. 9).

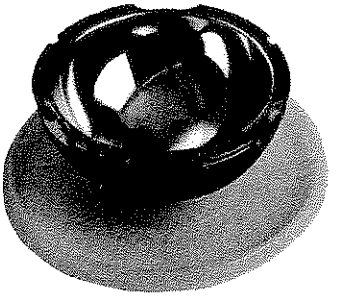


Fig. 8 *Durom* cup and disposable cup holder.

2. Insertion of the Acetabular Component

Any remaining soft tissue which may prevent the acetabular component from seating during insertion should be excised.

The acetabular component is impacted into the prepared acetabulum using a heavy mallet. As much of the circumferential equatorial fins as possible should engage in the bony rim to ensure primary stability.

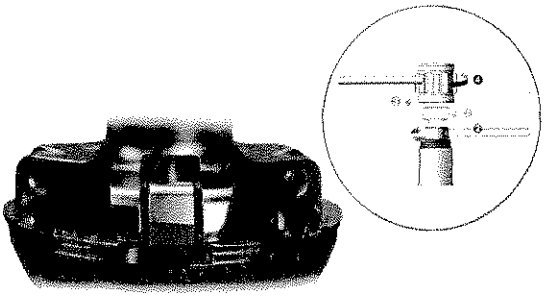


Fig. 9 Mounting the acetabular component.

Because the risk of dislocation of *Metasul LDH* large diameter head is much lower than traditional diameter articulations, the acetabular component can be positioned to better fit the acetabulum to an extent from the conventional orientation to maximize bony support and fixation. Placement will generally fall within 40°–50° abduction angle and 10°–20° anteversion angle.

It is important to note that the CoCr is a stiffer material than titanium, and more force may be required to fully seat the acetabular component during final cup impaction.

Attention: It is critical that the fins fully engage in the anterior and posterior walls, not only to maximize primary stability but also to reduce the risk of psoas tendon irritation anteriorly. On occasion, particularly in cases of developmental hip dysplasia, the rim of the implant will be exposed in the postero-superior quadrant of the acetabulum. This is acceptable (Fig. 10).

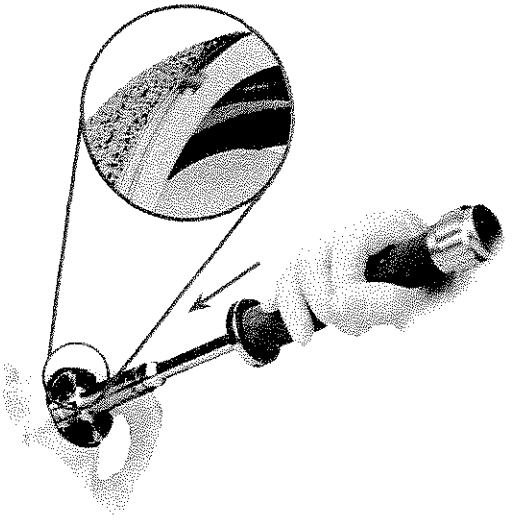


Fig. 10 Insertion of the acetabular component.

3. Final Impaction of the Acetabular Component

When the acetabular component is seated and stable, the cup inserter is removed by unscrewing the inserter cap and loosening the threaded rod with the tightening bar. The appropriately sized final cup impactor should be used to complete the insertion of the acetabular component. The key to final implant placement is to engage as much of the equatorial fins as possible and to fully seat the cup to the level previously identified using the trial (Fig. 11).

Note: Only the cup impactor should be used for final impaction of the acetabular component.

Warning: The *Durom* acetabular component should not be adjusted in the acetabulum after impaction. Moving the cup will dislodge the circumferential equatorial fins, disrupt the prepared bed of the acetabulum, and will make it difficult to re-engage the fins in the rim of the acetabulum. This can compromise fixation of the cup.

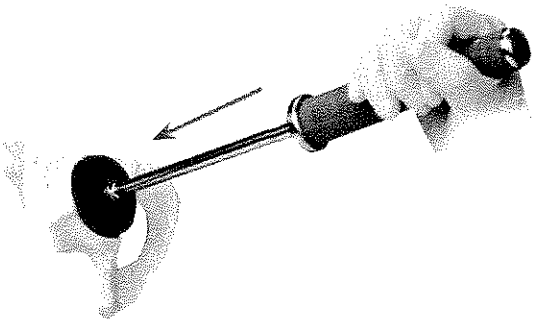


Fig. 11 Final impaction of the acetabular component.

Use of the Trial Head

Use of the Trial Head with its Head Adaptor

The femoral trial head corresponding to the inner diameter of the *Durom* acetabular component is selected and the appropriately sized trial head adapter is placed into the femoral head. The femoral head with trial adapter is mounted onto the femoral stem, ensuring that the latter is fully seated on the femoral stem taper (Fig. 12).

The hip is then reduced. The length of the neck, the ligament tension and the range of motion are checked. If the results are not acceptable, the same procedure must be repeated with different sizes of head adapters.

Following reduction, the circumference of the acetabular component is checked to make sure there is no entrapment of soft tissue.

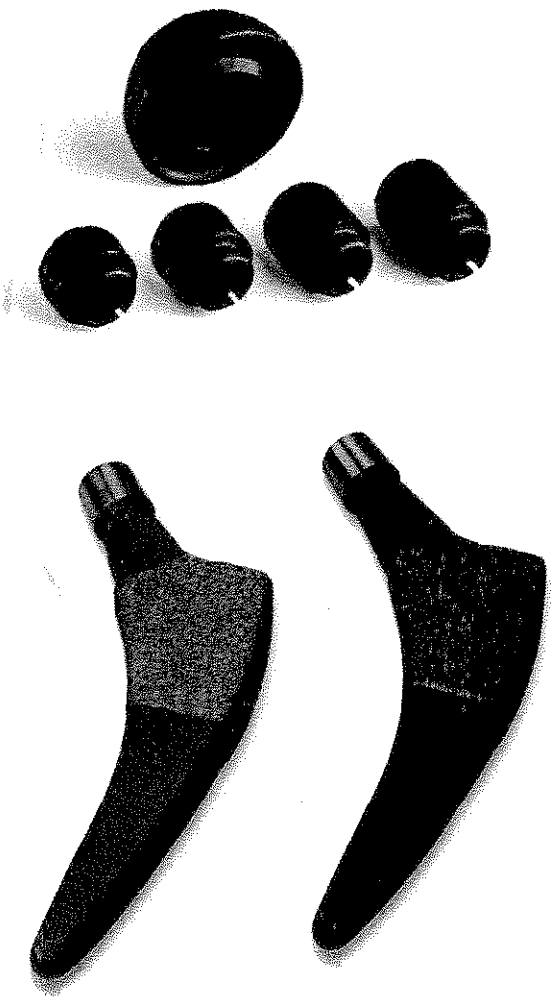


Fig. 12 ***Metasul LDH*** **trial head and trial adaptors shown with stems.**

Assembly of the Head Adaptor

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

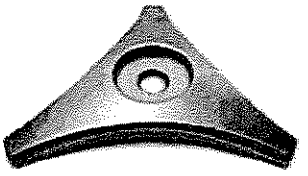


Fig. 13

The metal base plate and its plastic assembly inlay are positioned on a stable support (Fig. 13). Make sure the inlay sits firmly within the base plate (Fig. 14).

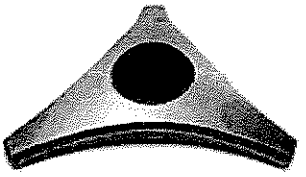


Fig. 14

Position the femoral head on the inlay as shown in the illustration (Fig. 15).

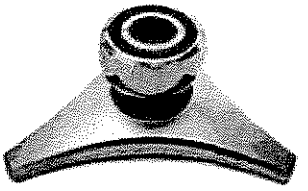


Fig. 15

Place the appropriately sized head adapter into the female taper of the femoral head (Fig. 16).

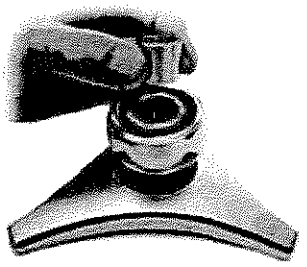


Fig. 16

Note: Properly check the position of the appropriate head adaptor before final impaction into *Metasul LDH* large diameter head (Fig. 17).

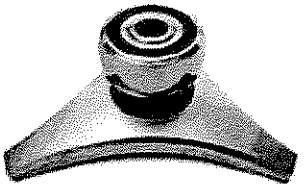


Fig. 17

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 strike with a heavy mallet (Fig. 18 & 19).

Clean and dry the stem taper, removing any residue. Place the selected femoral head on the stem taper and secure it by twisting firmly. With the plastic impactor attachment, strike the *Metasul LDH* large diameter head to ensure full seating of the stem taper (Fig. 20).

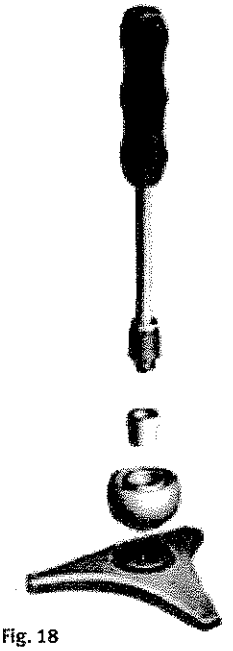


Fig. 18

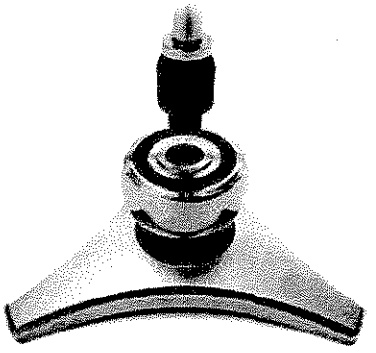


Fig. 19

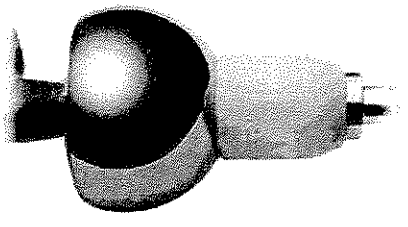


Fig. 20

Final Reduction

When using the posterior approach, the acetabular component is exposed by retraction of the posterior capsular flap. Reduce the *Metasul LDH* large diameter head with the femoral pusher while applying longitudinal traction and external rotation of the leg (Fig. 21). It is important to ensure that the femoral head does not make contact with the edge of the acetabular component, as this could result in scratching of the femoral head (Fig. 22).

Note: If a cemented stem is used, the femoral head should be cleaned with pulsed lavage and wet swabs.

Following reduction, the circumference of the acetabular component is checked to make sure there is no entrapment of soft tissue. The hip is then checked for range of movement, impingement, stability, and leg length.

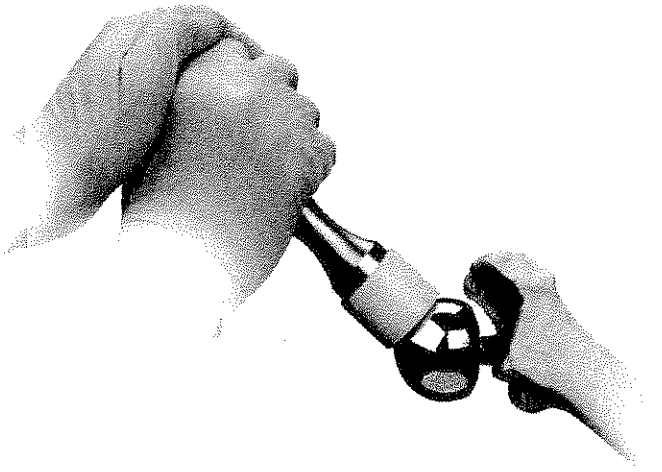


Fig. 21 *Metasul LDH* large diameter head pushed using the femoral pusher

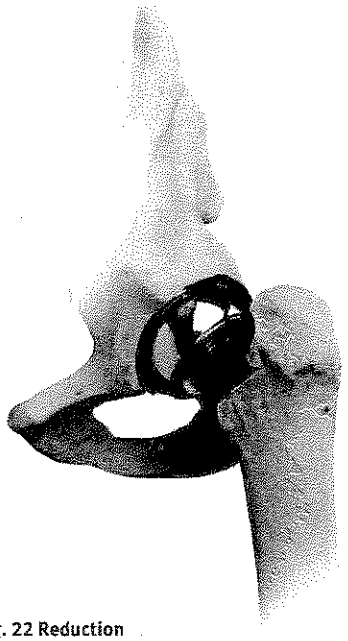


Fig. 22 Reduction

In Situ Extraction of the Head

In 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 (Fig. 23 & 24).

Fig. 23

Loosening of the head and the stem taper is done with small successive blows. The use of this device helps prevent unintended stem taper damage.

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

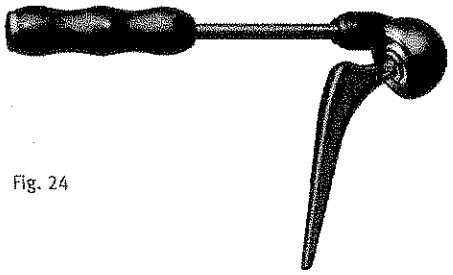


Fig. 24

In the case where the head comes off of the stem taper without the head adapter, the adapter must be removed from the stem separately. Carefully slide the adapter extractor around the neck of the stem and turn the threaded crank at the same time to pull the head adapter off of the taper. The taper should not be damaged by this procedure (Fig. 25 & 26).

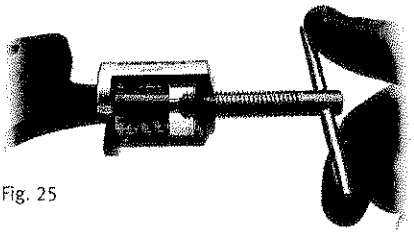


Fig. 25

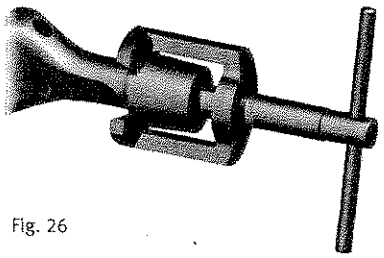


Fig. 26

Disassembly of the head adapter and the large diameter head

In cases where the head adapter cannot be extracted and remains attached to the head, use the adapter extractor for a 12/14 taper and proceed as follows (Fig. 27):

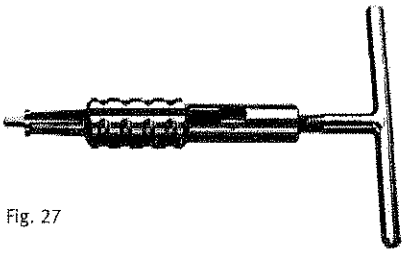


Fig. 27

Slide the sleeve into the head adapter until you feel or hear that its end is completely docked (Fig. 28).

Fig. 28

Push the handle through the sleeve and turn clockwise (Fig. 29).

After several turns, the handle reaches the bottom of the female taper of the large diameter head. You will notice an increase in resistance at that time (Fig. 30). Continue to turn and the handle will then separate the adapter from the head.

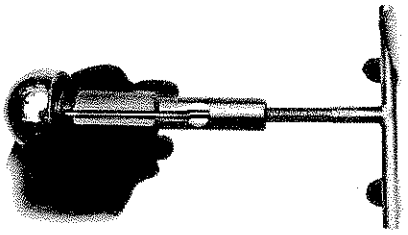


Fig. 29

Carefully remove the head adapter to prevent the head from falling (Fig. 31).

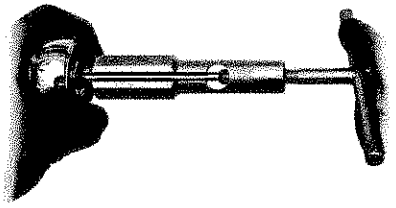


Fig. 30

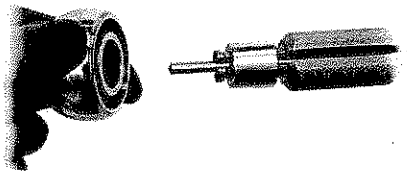
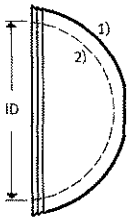


Fig. 31

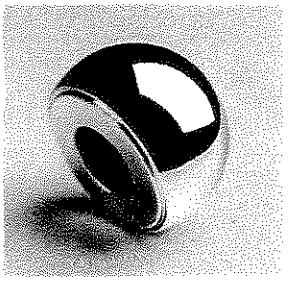
Implants

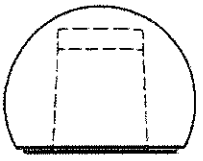
Durom **Acetabular Component**



Size	ID mm	Code	Product No.
44	38	D	01.00214.144
46	40	F	01.00214.146
48	42	H	01.00214.148
50	44	J	01.00214.150
52	46	L	01.00214.152
54	48	N	01.00214.154
56	50	P	01.00214.156
58	52	R	01.00214.158
60	54	T	01.00214.160
62	56	V	01.00214.162
64	58	X	01.00214.164
66	60	Z	01.00214.166

Metasul LDH **Head**





Size	Code	Product No.
38	D	01.00181.380
40	F	01.00181.400
42	H	01.00181.420
44	J	01.00181.440
46	L	01.00181.460
48	N	01.00181.480
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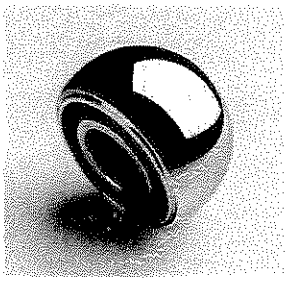
Metasul LDH **Head**



Size	Code	Product No.
–		
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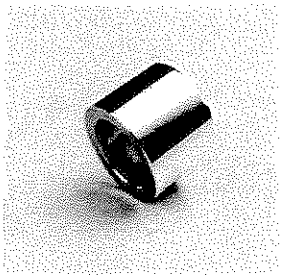
50	P	01.00181.500
52	R	01.00181.520
54	T	01.00181.540
56	V	01.00181.560
58	X	01.00181.580
60	Z	01.00181.600

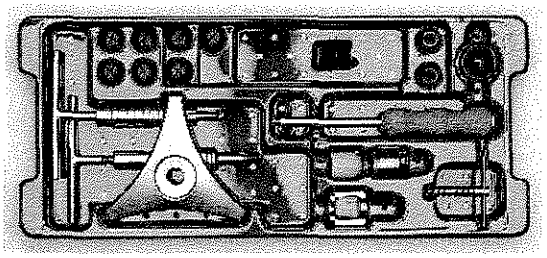
Head Adapter



Size	Taper	Product No.
S	12/14	01.00185.145
M	12/14	01.00185.146
L	12/14	01.00185.147
XL	12/14	01.00185.148

Instruments

Metasul LDH large diameter head Set



Insert for Tray Femoral Component

Insert for tray (empty)

REF
01.00189.211

Standard container cover, gray

REF
01.00029.031

Handle reduction and impaction attachment

REF
75.11.00-02

Assembly base plate

REF
01.00189.100

Assembly attachment

Taper	REF
8/10	01.00189.101
12/14	01.00189.102

Assembly inlay

REF
01.00189.104

Adapter extractor

REF
01.00189.150

Head disassembly attachment metal

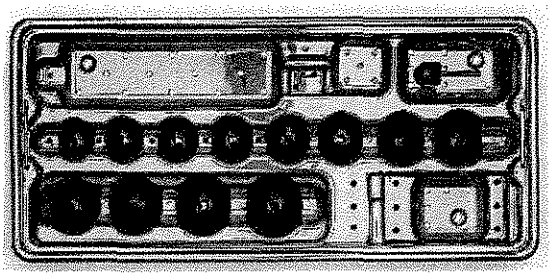
REF
01.00189.103

Head disassembly attachment plastic

REF
01.00189.110

Trial Adaptor

S	12/14	01.00189.145
M	12/14	01.00189.146
L	12/14	01.00189.147
XL	12/14	01.00189.148



Base Tray Femoral Component

Base tray (empty)

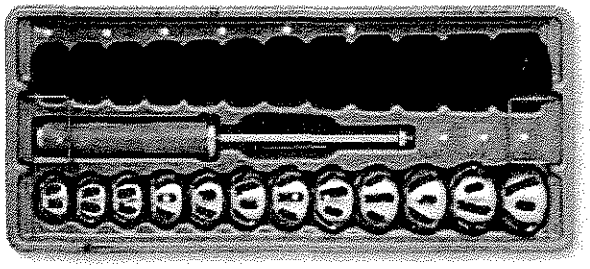
REF
01.00189.210

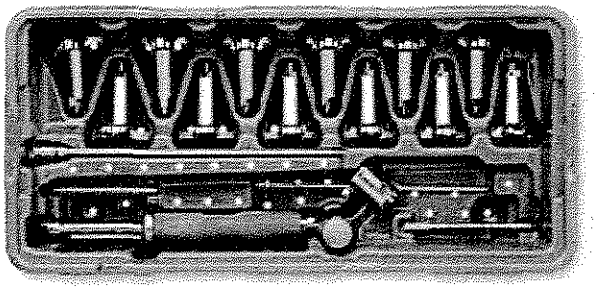
Large trial head

Size	REF
≥ 38 mm	01.00189.381
≥ 40 mm	01.00189.401
≥ 42 mm	01.00189.421
≥ 44 mm	01.00189.441
≥ 46 mm	01.00189.461
≥ 48 mm	01.00189.481
≥ 50 mm	01.00189.501
≥ 52 mm	01.00189.521
≥ 54 mm	01.00189.541
≥ 56 mm	01.00189.561
≥ 58 mm	01.00189.581
≥ 60 mm	01.00189.601

Instruments

Straight Handle Set for Durom Acetabular Component





Insert for Tray, Cup

Insert for tray cup (empty)
REF
01.00219.110

Tray cover
REF
01.00029.031

Cup impactors

Size	REF
44/D	01.00219.384
46/F	01.00219.404
48/H	01.00219.424
50/J	01.00219.444
52/L	01.00219.464
54/N	01.00219.484
56/P	01.00219.504
58/R	01.00219.524
60/T	01.00219.544
62/V	01.00219.564
64/X	01.00219.584
66/Z	01.00219.604

Trial cups

Size	REF
44/D	01.00219.381
46/F	01.00219.401
48/H	01.00219.421
50/J	01.00219.441
52/L	01.00219.461
54/N	01.00219.481
56/P	01.00219.501
58/R	01.00219.521
60/T	01.00219.541
62/V	01.00219.561
64/X	01.00219.581
66/Z	01.00219.601

Handle for trial cup/cup impactor
REF
01.00219.808

Base Tray, Acetabulum Straight

Base tray acetabulum straight (complete)
REF
ZS01.00219.100

Base tray acetabulum straight (empty)
REF
01.00219.100

Cup-coupling handle
REF
01.00219.815

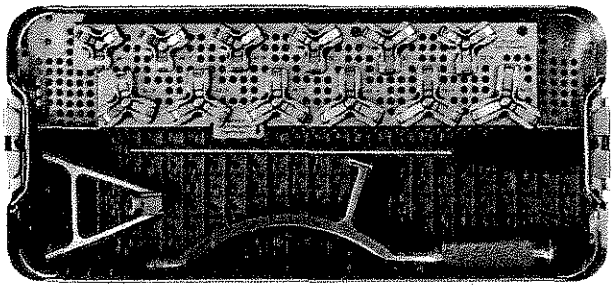
Threaded rod for cup-coupling handle
REF
01.00219.816

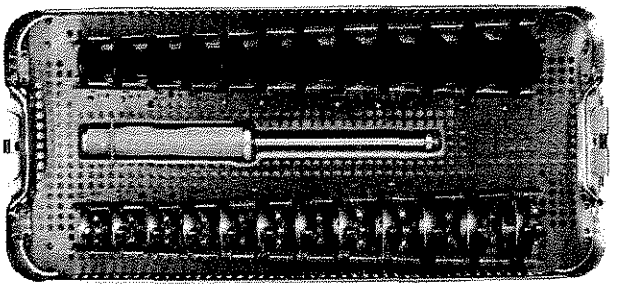
Impactor head for handle
REF
01.00219.817

Cup inserters

Size	REF
44/D	01.00219.382
46/F	01.00219.402
48/H	01.00219.422
50/J	01.00219.442
52/L	01.00219.462
54/N	01.00219.482
56/P	01.00219.502
58/R	01.00219.522
60/T	01.00219.542
62/V	01.00219.562
64/X	01.00219.582
66/Z	01.00219.602

Curved Handle Set for Durom Acetabular Component





DTI0021901

00-6300-001-00	Durom Adapter Tray
00-5900-099-0	Case Lid
01.00219.744	Durom Cup Adapter 44 / D
01.00219.746	Durom Cup Adapter 46 / F
01.00219.748	Durom Cup Adapter 48 / H
01.00219.750	Durom Cup Adapter 50 / J
01.00219.752	Durom Cup Adapter 52 / L
01.00219.754	Durom Cup Adapter 54 / N
01.00219.756	Durom Cup Adapter 56 / P
01.00219.758	Durom Cup Adapter 58 / R
01.00219.760	Durom Cup Adapter 60 / T
01.00219.762	Durom Cup Adapter 62 / V
01.00219.764	Durom Cup Adapter 64 / X
01.00219.766	Durom Cup Adapter 66 / Z

Optional Instruments Not In Set

00-7804-025-20	Trilogy® Hybrid Shell Inserter
00-7804-025-21	Hybrid Provisional Shell Adapter
9375-00-32	Ball Hex Screwdriver
00-7807-015-02	Lateral Alignment Frame

KT-0219-000-01

00-6300-002-00	Durom Trial Cups & Impactors Tray
00-5900-099-00	Case Lid
01.00219.384	Durom Cup Impactor 44 / D
01.00219.404	Durom Cup Impactor 46 / F
01.00219.424	Durom Cup Impactor 48 / H
01.00219.444	Durom Cup Impactor 50 / J
01.00219.464	Durom Cup Impactor 52 / L
01.00219.484	Durom Cup Impactor 54 / N
01.00219.504	Durom Cup Impactor 56 / P
01.00219.524	Durom Cup Impactor 58 / R
01.00219.544	Durom Cup Impactor 60 / T
01.00219.564	Durom Cup Impactor 62 / V
01.00219.584	Durom Cup Impactor 64 / X
01.00219.604	Durom Cup Impactor 66 / Z
01.00219.808	Handle for Trial Cup/Cup Impactors
01.00219.381	Durom Trial Cup 44 / D
01.00219.401	Durom Trial Cup 46 / F
01.00219.421	Durom Trial Cup 48 / H
01.00219.441	Durom Trial Cup 50 / J
01.00219.481	Durom Trial Cup 54 / N
01.00219.501	Durom Trial Cup 56 / P
01.00219.521	Durom Trial Cup 58 / R
01.00219.541	Durom Trial Cup 60 / T
01.00219.561	Durom Trial Cup 62 / V
01.00219.581	Durom Trial Cup 64 / X
01.00219.601	Durom Trial Cup 66 / Z

[1] Crowninshield RD, Maloney WJ, Wentz DH, Humphrey SM, Blanchard CR. Biomechanics of large femoral heads what they do and don't do. Clin Orthop Rel Res. 2004; 429:102-107

[2] Grübl A, Marker M, Brodner W, Giurrea A, Heinze G, Meisinger V, Zehetgruber H, Kotz R. Long-term follow-up of metal-on-metal total hip replacement. J Orthop Res. July 2007

[3] Rieker CB, Schön R, Köttig P, Development and validation of a second-generation metal-on-metal bearing. J. Arthrop. 2004; Vol 19 No. 8 & Suppl. 3; p 5-11

[4] Data on file at Zimmer

Please refer to package insert for complete product information, including contraindications, warnings, precautions, and adverse effects.

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