



# REFLECTION I & FSO

POROUS-COATED  
ACETABULAR COMPONENT

# REFLECTION

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## I & FSO

POROUS-COATED  
ACETABULAR COMPONENT

*Technique described by*

John M. Cuckler, M.D.

**Nota Bene:** This technique description herein is made available to the healthcare professional to illustrate the author's suggested treatment for the uncomplicated procedure. In the final analysis, the preferred treatment is that which addresses the needs of the patient.

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The Reflection Acetabular System has incorporated several design features to address the problem of small particle polyethylene debris generation.

To maximize stability of the liner in the shell, the MicroStable® liner locking mechanism combines the axial and rotational lock in one noninvasive mechanism. To further reduce polyethylene debris, the inner shell surface is polished to a mirror smooth finish. This patented, highly polished inner surface, combined with the MicroStable liner locking mechanism minimize polyethylene debris. Reflection liners are now sterilized by a non-degrading method to eliminate damage associated with gamma sterilization.

Another enhancing design feature is liner/shell congruency. By maximizing the congruity between cup and liner, a better distribution of forces lowers the amount of contact stresses in the polyethylene liner which results in lower wear rates. To assure a good fit between liner and shell, a post-sintering machining process ensures precise tolerances.

The Reflection Acetabular System is available in several shell configurations. This technique describes the Reflection I and FSO (For Screws Only) shells. Reflection I has a threaded apex hole for cup insertion and visualization of the acetabulum. Reflection I is available in outside diameters, 42-70 mm in 2 mm increments. Reflection I does not offer any type of adjunctive fixation options. A threaded hole cover can be threaded into the apex hole of the Reflection I shell for shell closure. Reflection FSO is available in three hole patterns. Sizes 42 and 44 mm have a three hole pattern. A five hole pattern is available on sizes 46-68 mm, and a nine hole pattern is available on sizes 50-76 mm.

The Reflection MicroStable liner locking mechanism, highly polished inner surface, and improved cup and liner congruity, provide a better way to reduce polyethylene debris.

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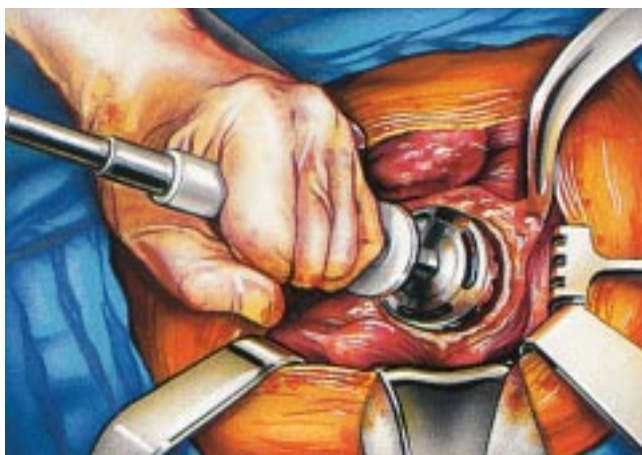
## P R E O P E R A T I V E   P L A N N I N G

Preoperative templating is essential to the precise reconstruction of the hip joint. Suggested preoperative X-rays include an A-P of the pelvis and hips, a 14" x 17" A-P view of the affected hip and femur, and a lateral view of the affected hip.

The acetabular component may be templated using the contralateral normal hip, if available, or templated directly on the affected hip. The acetabular component should congruently fit the subchondral bone and the medial aspect of the acetabulum as indicated by the teardrop. Mark the center of rotation of the acetabular component through the template for subsequent reference.

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## A C E T A B U L A R   E X P O S U R E   A N D   R E A M I N G



*Figure 1*

Complete exposure of the acetabulum is necessary to ensure a satisfactory surgical result. Resect the acetabular labrum circumferentially in order to define the landmarks of the bony acetabulum. Clean soft tissue or osteophytes from the acetabular fovea in order to define the limits of the medial wall. Surrounding soft tissues must be protected by retraction during the reaming process to avoid injury to critical structures.

Restoration of normal anatomy is an important principle of reconstructive hip surgery. The acetabulum must be medialized to restore the normal center of the hip rotation as determined by preoperative templating.

Ream the acetabulum concentrically in order to ensure an excellent fit between the acetabulum and the acetabular component (*Figure 1*). Do not reverse the reamer direction during the reaming process.

Acetabular  
Reamer Dome



Acetabular Reamer Handle

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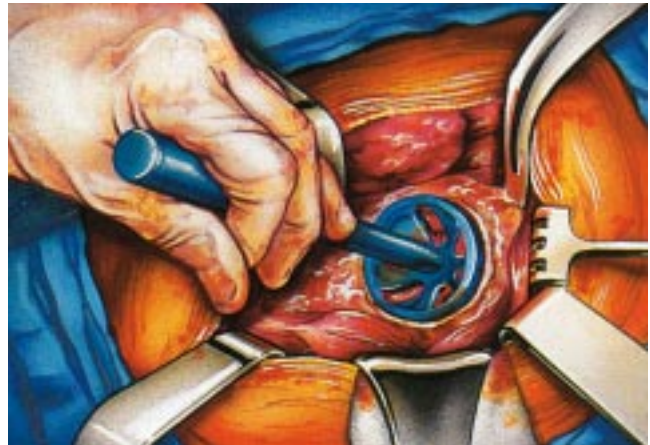
To avoid excessive medial reaming of the acetabulum, ream only until the last row of reamer fenestrations is just contained within the acetabulum as over-medialization could occur. Only Reflection (or hemispherical) reamers should be used for Reflection acetabular components.

Direct the reamer along the same axis as that desired for the final position of the acetabular prosthesis. This is generally in a position of approximately 45° of abduction and 20° to 30° of forward flexion.

Preserve subchondral bone to provide good support for the prosthesis. Clean the acetabulum of all remaining cartilage and soft tissue down to bleeding subchondral bone.

The posterior and anterior walls (columns) of the acetabulum must be considered while reaming, since they are the limiting factor in determining the largest size prosthesis that can be accommodated. Frequently palpate these structures during the reaming process to determine the maximum reamer size that should be used.

To assess the fit and stability of the prepared acetabulum, use the trial shell. Visualize through the slots in the trial to determine the trial/bone contact. Note the relationship of the trial to the surrounding bony landmarks; this will aid in determining the position for inserting the acetabular shell (*Figure 2*).



*Figure 2*



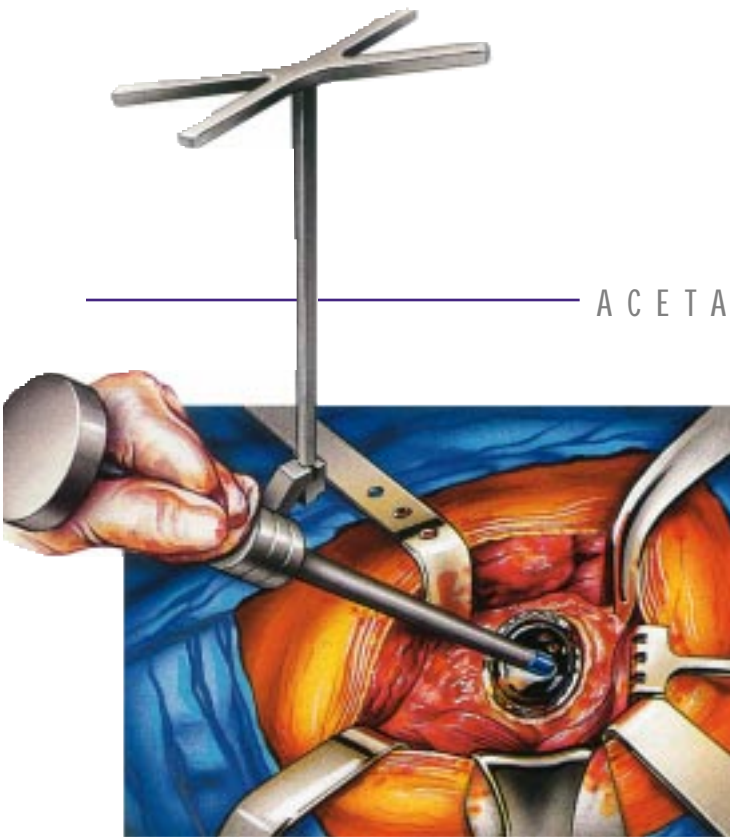
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Make sure the acetabular shell will be contained as completely as possible without exposing the porous coating. If the position is not correct, further ream the acetabulum as necessary. An intraoperative X-ray may help evaluate the position and remaining bone stock of the acetabulum.

For press-fit of a porous-coated prosthesis, it is best to under-ream the acetabulum by 1 to 2 mm. The quality of bone stock should determine whether under-reaming is appropriate. Subchondral bone should be preserved whenever possible.

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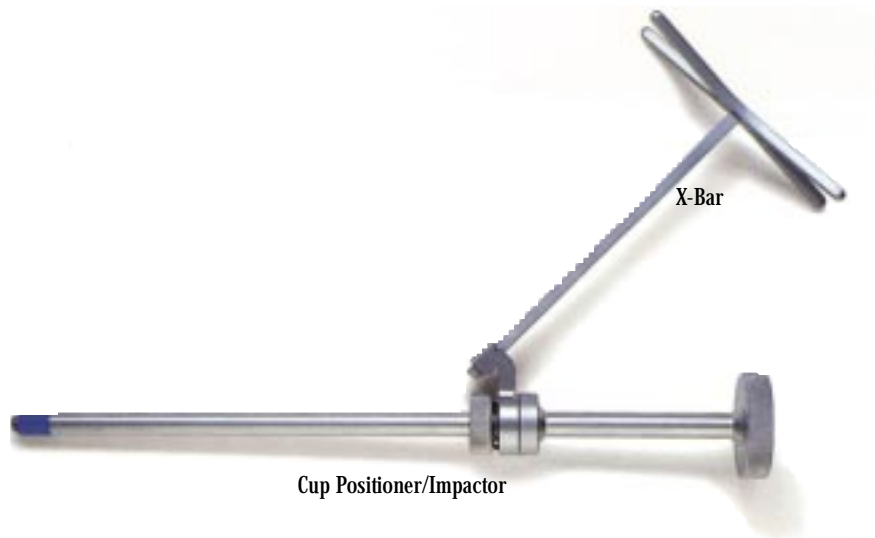
## ACETABULAR SHELL INSERTION



*Figure 3*

Select the appropriate acetabular implant. Attach the selected prosthesis to the cup positioner/impactor and insert it into the acetabulum.

The positioner references 45° of abduction and 20° of forward flexion. Position the X-bar so that the vertical bar is perpendicular to the long axis of the body and the appropriate crossbar aligns with the long axis of the body (*Figure 3*). Firmly impact the inserter with a mallet. Assess the stability and contact of the prosthesis by pushing on the rim of the device with a femoral head pusher or a similar instrument. No motion should be apparent during the evaluation, indicating excellent press-fit of the prosthesis.



If adjunctive fixation is required, the FSO shell is available in a five and nine hole pattern. The 42 and 44 mm FSO shells have three screw holes. Adjunctive fixation is not available for Reflection I.

Generally, cancellous screws will provide satisfactory adjunctive fixation. Four drill bits of progressively increasing length are available.

CANCELLOUS SCREW OPTIONS		
Screw Length	Drill Length	Drill Cat. No.
15 mm	15 mm	7136-2115
20 mm, 25 mm	25 mm	7136-2125
30 mm, 35 mm	35 mm	7136-2135
40 mm, 50 mm	50 mm	7136-2150

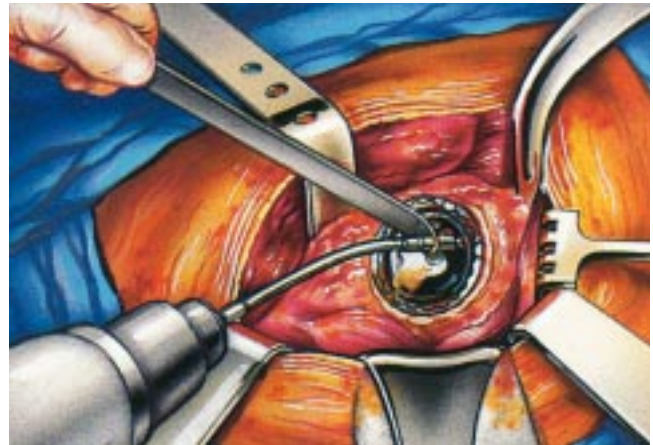


Figure 4

When positioning screw fixation holes, keep in mind that the best quality bone for fixation screw holes is in the superior, medial (weight bearing) region of the acetabulum. The ischium and pubis will provide less satisfactory engagement of screw threads. Take care, when positioning and drilling holes, to avoid penetration of the inner cortex of the pelvis, penetration of the sciatic notch, or damage to vital neurovascular structures. **Do not place a screw in the center hole of the acetabular prosthesis.**

Placement of drills and screws in the anterior or medial portions of the prosthesis is associated with a high risk of potentially fatal vascular injury.

**To predrill each screw hole, first seat the screw drill guide fully through the correct hole in the acetabular shell (Figure 4).**

Drill each screw hole, taking care to not drill directly medially or directly anteriorly. When screws are to be placed in the direction of the sciatic notch, palpate the notch so that injury to the sciatic nerve can be avoided.

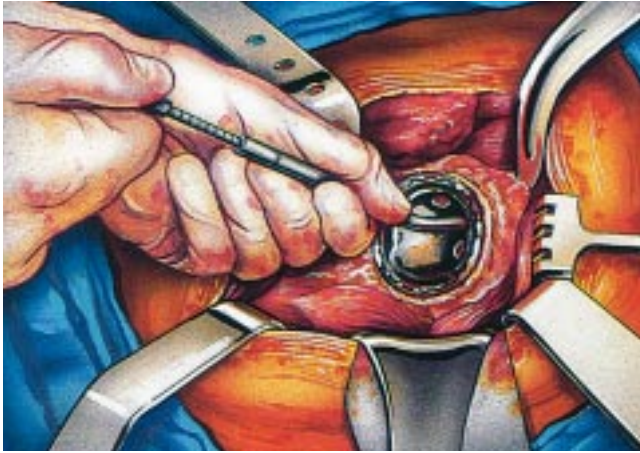


Screw Drill



Screw Drill Guide

ADJUNCTIVE FIXATION AVAILABLE FOR REFLECTION FSO ONLY.



*Figure 5*

Before inserting the screws, use the depth gauge to verify the appropriate screw length(s) (*Figure 5*). This will help avoid penetration of the screws through the inner table of the pelvis.

Use the screw holding forceps or the universal screwdriver to hold the screw. Flex the tip of the universal screwdriver in an upward position to hold the screw. Introduce the screw into the hole and screw it into place (*Figure 6*). Make sure the screw is fully seated within the screw hole so that it will not impinge on the acetabular shell liner.

Reassess stability of the prosthesis by pushing on it and noting any motion. No motion should be observed. If instability is noted, consider inserting the next larger prosthesis or using cement fixation.

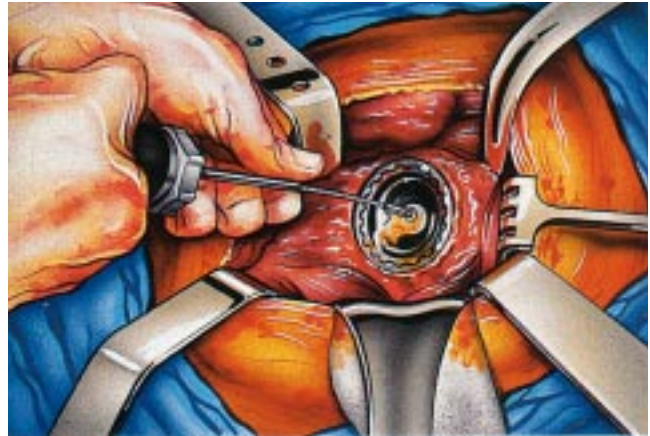
*Figure 6*



ADJUNCTIVE FIXATION AVAILABLE FOR REFLECTION FSO ONLY.

**Threaded Hole Cover**

A threaded hole cover can be used with the Reflection I shell to close the center apex hole. Before inserting the threaded hole cover, use pulsatile lavage and suction to clean the apex hole. Insert the threaded hole cover into the center hole using the Reflection screwdriver (*Figure 7*). Tighten the threaded hole cover until it stops. If the threaded hole cover is not flush with the inner diameter of the shell, the screwdriver should be reinserted and the hole cover should be tightened further.



*Figure 7*

## ACETABULAR LINER INSERTION

With the acetabular shell firmly positioned, place the appropriate trial liner into the acetabular shell and perform a trial reduction. Insertion of the trial liner may help assess possible tissue impingement at the locking mechanism. (Alternatively, the permanent acetabular liner may be inserted at this time.)

POLYETHYLENE THICKNESS									
ACETABULAR CUP SIZE									
Femoral Head Size	42	44	46-48	50-52	54-56	58-60	62-64	66-68	70-76
22 mm	6	7	8	10	12	13	15	17	19
26 mm	NA	5	6	8	10	11	13	15	17
28 mm	NA	NA	5	7	9	10	12	14	16
32 mm	NA	NA	NA	5	7	8	10	12	14

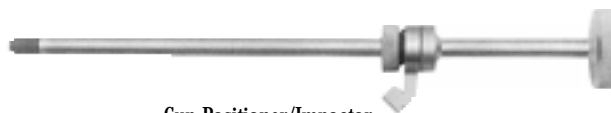
Socket liners are available with internal diameters of 22 mm, 26 mm, 28 mm, and 32 mm, with or without 20° rim extensions. The surgeon should select a femoral head size to maximize polyethylene thickness, i.e., small femoral heads should be used for small acetabular prostheses. Position the extension to optimize the stability of the reconstruction (generally in the superior/ posterior position).

Before inserting the acetabular shell liner, the rim and interior of the acetabular shell should be carefully cleaned of any remaining soft tissue or bone debris. Then insert the liner, keeping the extension (if used) in the same position determined during the trial reduction. **During liner insertion, make sure soft tissue does not interfere with the shell/liner interface.** For liner impaction, place the appropriate liner impactor head on the end of the cup positioner/impactor. Prior to impacting the liner, ensure the splines on the liner are aligned with the splines of the shell.



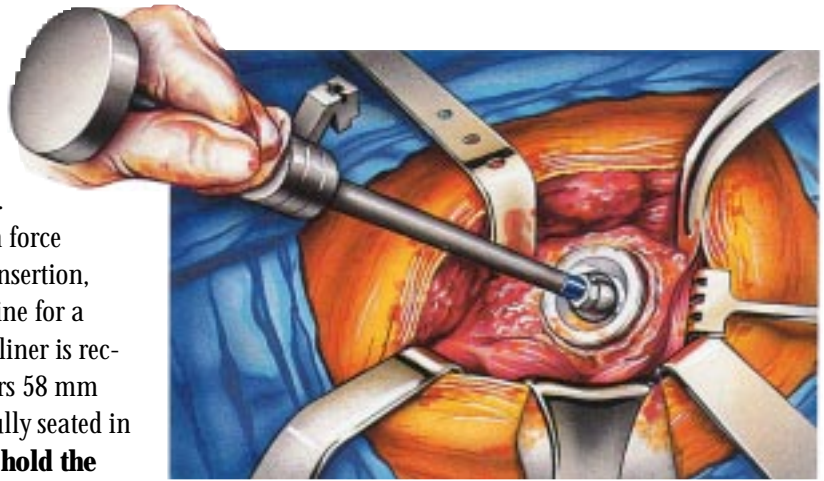
Trial Liner

Liner Impactor Head



Cup Positioner/Impactor

The Reflection MicroStable liner requires an impaction force between 120 and 200 pounds at room temperature. The required impaction force increases with the diameter of the shell. Chilling the liner reduces the impaction force required to seat the liner. To ease liner insertion, chill the liner in refrigerated or iced saline for a minimum of five minutes. Chilling the liner is recommended for all liners, especially liners 58 mm and larger. Impact the liner until it is fully seated in the shell (*Figure 8*). **It is important to hold the impactor perpendicular to the face of the cup while impacting the liner.** Inspect to make sure the liner is properly seated.



*Figure 8*

If removal of the liner is necessary, place the end of the acetabular liner removal tool into the slot in the rim of the acetabular shell until it engages the liner and the liner disengages from the shell. If the liner has not been damaged, it may be reinserted one time only.



Liner Removal Tool

# ACETABULAR COMPONENTS



## Reflection I and FSO Shells

Reflection I Shell Cat. No.	FSO3 & 5 Shell Cat. No.	FSO9 Shell Cat. No.	O.D. (mm)	Liner Size	Liner I.D. (mm)
74-3042	7133-0042	—	42	B	22
74-3044	7133-0044	—	44	C	22, 26
74-3046	7133-0046	—	46	D	22, 26, 28
74-3048	7133-0048	—	48	D	22, 26, 28
74-3050	7133-0050	7133-1050	50	E	22, 26, 28, 32
74-3052	7133-0052	7133-1052	52	E	22, 26, 28, 32
74-3054	7133-0054	7133-1054	54	F	22, 26, 28, 32
74-3056	7133-0056	7133-1056	56	F	22, 26, 28, 32
74-3058	7133-0058	7133-1058	58	G	22, 26, 28, 32
74-3060	7133-0060	7133-1060	60	G	22, 26, 28, 32
74-3062	7133-0062	7133-1062	62	H	22, 26, 28, 32
74-3064	7133-0064	7133-1064	64	H	22, 26, 28, 32
74-3066	7133-0066	7133-1066	66	J	22, 26, 28, 32
74-3068	7133-0068	7133-1068	68	J	22, 26, 28, 32
74-3070	—	7133-1070	70	K	22, 26, 28, 32
—	—	7133-1072	72	K	22, 26, 28, 32
—	—	7133-1074	74	K	22, 26, 28, 32
—	—	7133-1076	76	K	22, 26, 28, 32

### Reflection Acetabular Liners

0° Liner Cat. No.	20° Liner Cat. No.	I.D. (mm)	O.D. (mm)	Liner Size
7174-2042	7174-2242	22	42	B
7174-2044	7174-2244	22	44	C
7174-2046	7174-2246	22	46-48	D
7174-2050	7174-2250	22	50-52	E
7174-2054	7174-2254	22	54-56	F
7174-2058	7174-2258	22	58-60	G
7174-2062	7174-2262	22	62-64	H
7174-2066	7174-2266	22	66-68	J
7174-2070	7174-2270	22	70-76	K
7174-0644	7174-2644	26	44	C
7174-0646	7174-2646	26	46-48	D
7174-0650	7174-2650	26	50-52	E
7174-0654	7174-2654	26	54-56	F
7174-0658	7174-2658	26	58-60	G
7174-0662	7174-2662	26	62-64	H
7174-0666	7174-2666	26	66-68	J
7174-0670	7174-2670	26	70-76	K
7174-0846	7174-2846	28	46-48	D
7174-0850	7174-2850	28	50-52	E
7174-0854	7174-2854	28	54-56	F
7174-0858	7174-2858	28	58-60	G
7174-0862	7174-2862	28	62-64	H
7174-0866	7174-2866	28	66-68	J
7174-0870	7174-2870	28	70-76	K
7174-0250	7174-3250	32	50-52	E
7174-0254	7174-3254	32	54-56	F
7174-0258	7174-3258	32	58-60	G
7174-0262	7174-3262	32	62-64	H
7174-0266	7174-3266	32	64-68	J
7174-0270	7174-3270	32	70-76	K



### Reflection Lateralized Liners

0° Liner Cat. No.	20° Liner Cat. No.	I.D. (mm)	O.D. (mm)	Liner Size
7133-0446	7133-2446	28	46-48	D
7133-0450	7133-2450	28	50-52	E
7133-0454	7133-2454	28	54-56	F
7133-0458	7133-2458	28	58-60	G
7133-0462	7133-2462	28	62-64	H
7133-0466	7133-2466	28	66-68	J
7133-0470	7133-2470	28	70	K



### Universal Acetabular Cancellous Screws

6.5 mm

Cat. No.	Length
7133-6515	15 mm
7133-6520	20 mm
7133-6525	25 mm
7133-6530	30 mm
7133-6535	35 mm
7133-6540	40 mm
7133-6550	50 mm



### Reflection Threaded Hole Cover

Cat. No. 7133-6500





**Reflection Trial Acetabular Shells**

Cat. No.	O.D.	Cat. No.	O.D.
73-0040	40 mm	73-0059	59 mm
73-0041	41 mm	73-0060	60 mm
73-0042	42 mm	73-0061	61 mm
73-0043	43 mm	73-0062	62 mm
73-0044	44 mm	73-0063	63 mm
73-0045	45 mm	73-0064	64 mm
73-0046	46 mm	73-0065	65 mm
73-0047	47 mm	73-0066	66 mm
73-0048	48 mm	73-0067	67 mm
73-0049	49 mm	73-0068	68 mm
73-0050	50 mm	73-0069	69 mm
73-0051	51 mm	73-0070	70 mm
73-0052	52 mm	73-0071	71 mm
73-0053	53 mm	73-0072	72 mm
73-0054	54 mm	73-0073	73 mm
73-0055	55 mm	73-0074	74 mm
73-0056	56 mm	73-0075	75 mm
73-0057	57 mm	73-0076	76 mm
73-0058	58 mm		



**Reflection Trial Acetabular Liners**

0° Cat. No.	20° Cat. No.	I.D.	O.D. (mm)	Liner Size
7136-2042	73-2242	22 mm	42	B
7136-2044	73-2244	22 mm	44	C
7136-2046	73-2246	22 mm	46-48	D
7136-2050	73-2250	22 mm	50-52	E
7136-2054	73-2254	22 mm	54-56	F
7136-2058	73-2258	22 mm	58-60	G
7136-2062	73-2262	22 mm	62-64	H
7136-2066	73-2266	22 mm	66-68	J
7136-2070	73-2270	22 mm	70-76	K
7136-0644	73-2644	26 mm	44	C
7136-0646	73-2646	26 mm	46-48	D
7136-0650	73-2650	26 mm	50-52	E
7136-0654	73-2654	26 mm	54-56	F
7136-0658	73-2658	26 mm	58-60	G
7136-0662	73-2662	26 mm	62-64	H
7136-0666	73-2666	26 mm	66-68	J
7136-0670	73-2670	26 mm	70-76	K
7136-0846	73-2846	28 mm	46-48	D
7136-0850	73-2850	28 mm	50-52	E
7136-0854	73-2854	28 mm	54-56	F
7136-0858	73-2858	28 mm	58-60	G
7136-0862	73-2862	28 mm	62-64	H
7136-0866	73-2866	28 mm	66-68	J
7136-0870	73-2870	28 mm	70-76	K
7136-0250	73-3250	32 mm	50-52	E
7136-0254	73-3254	32 mm	54-56	F
7136-0258	73-3258	32 mm	58-60	G
7136-0262	73-3262	32 mm	62-64	H
7136-0266	73-3266	32 mm	64-68	J
7136-0270	73-3270	32 mm	70-76	K



**Reflection Trial Lateralized Liners**

0° Liner Cat. No.	20° Liner Cat. No.	I.D. (mm)	O.D. (mm)	Liner Size
7136-0446	7136-2446	28	46-48	D
7136-0450	7136-2450	28	50-52	E
7136-0454	7136-2454	28	54-56	F
7136-0458	7136-2458	28	58-60	G
7136-0462	7136-2462	28	62-64	H
7136-0466	7136-2466	28	66-68	J
7136-0470	7136-2470	28	70	K

**Acetabular Reamer Handle**

38 mm–70 mm

Cat. No. 11-4265



**Acetabular Reamer Domes**

Cat. No.	Size	Cat. No.	Size
41-7138	38 mm	41-7158	58 mm
41-7139	39 mm	41-7159	59 mm
41-7140	40 mm	41-7160	60 mm
41-7141	41 mm	41-7161	61 mm
41-7142	42 mm	41-7162	62 mm
41-7143	43 mm	41-7163	63 mm
41-7144	44 mm	41-7164	64 mm
41-7145	45 mm	41-7165	65 mm
41-7146	46 mm	41-7166	66 mm
41-7147	47 mm	41-7167	67 mm
41-7148	48 mm	41-7168	68 mm
41-7149	49 mm	41-7169	69 mm
41-7150	50 mm	41-7170	70 mm
41-7151	51 mm	7173-0971	71 mm
41-7152	52 mm	7173-0972	72 mm
41-7153	53 mm	7173-0973	73 mm
41-7154	54 mm	7173-0974	74 mm
41-7155	55 mm	7173-0975	75 mm
41-7156	56 mm	7173-0976	76 mm
41-7157	57 mm		



**Trial Shell Handle**

Cat. No. 73-2119



**Acetabular Cup Positioner/Impactor**

Cat. No. 73-2120



**Acetabular Cup Positioner/Impactor Tip Replacement**

Cat. No. 73-2108



**X-Bar**

Cat. No. MF-2201



**T-Handle Hex Wrench**

Cat. No. 21-0009



**Acetabular Screw Drill Guide**

Cat. No. 7136-2101



# ACETABULAR COMPONENT INSTRUMENTATION



## Acetabular Screw Drill

Cat. No.	Length
7136-2115	15 mm
7136-2125	25 mm
7136-2135	35 mm
7136-2150	50 mm



## Angled Depth Gauge

Cat. No. 73-2109



## Reflection Curved Screw Forceps

Cat. No.	Bend
73-2136	35°
73-2137	75°



## Acetabular Cup Screwdriver Ratchet Handle

Cat. No. 73-2112



## Acetabular Cup Universal Screwdriver Shaft

Cat. No. 73-2113



## Flexible Shaft

Cat. No. 7136-2010



## Acetabular Cup Liner Impactor Heads (Primary Tray Holds Two Impactor Heads)

Cat. No.	Size
73-2122	22 mm
73-2126	26 mm
73-2128	28 mm
73-2132	32 mm



## Acetabular Liner Extractor

Cat. No. 73-2107

## OPTIONAL ACETABULAR COMPONENT INSTRUMENTATION —

### **Reamer Handle with Positive Lock**

Cat.No. 7136-2105



### **Depth Gauge**

Cat. No. 7136-2012



### **Acetabular Cup Flexible Screwdriver Shaft with Captive Twist**

Cat. No. 73-2114



### **Straight Shaft**

Cat. No. 7136-2011



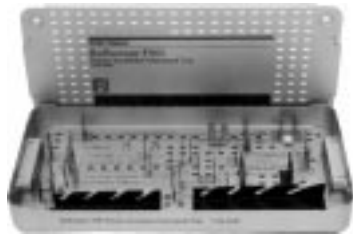
### **Reflection Mallet**

Cat. No. 7136-2106

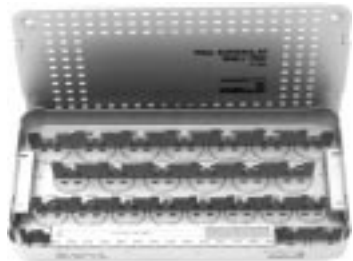


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## ACETABULAR TRAYS



**Primary Instrument Tray**  
Cat. No. 7136-2100



**Trial Acetabular Shell Tray**  
Cat. No. 73-1003



**Reamer Dome Tray**  
38 mm - 70 mm  
Cat. No. 73-1004



**Reflection Screw Caddy**  
Cat. No. 7136-2108

# IMPORTANT MEDICAL INFORMATION

## Warnings and Precautions TOTAL HIP SYSTEM

### IMPORTANT NOTE

Total hip replacement arthroplasty has become a successful procedure for relieving pain and restoring motion in patients who are disabled from hip arthropathy. The goals of total hip replacement are to decrease pain, increase function, and increase mobility.

### MATERIALS

The Total Hip System is manufactured from materials as outlined below:

COMPONENT	MATERIAL	MATERIAL STANDARDS
Femoral Components	Ti-6Al-4V or Co-Cr-Mo	ASTM F 136 and ISO 5832/3 or ASTM F 1472 and ISO 5832/3 or ASTM F 799 and ISO 5832/12 or ASTM F 75 and ISO 5832/4
Acetabular shells Proximal pads Taper sleeves Distal sleeves Fixation screws and pegs Hole covers	Ti-6Al-4V	ASTM F 1472 and ISO 5832/3
Acetabular components Acetabular liners	UHMWPE	ASTM F 648
Femoral centralizers Acetabular spacer pads	PMMA	Not applicable
X-ray marking wire	Co-Cr-Mo	ASTM F 90 and ISO 5832/5
Acetabular reconstructive shell	CP Titanium	ASTM F 67 and ISO 5832/2
Acetabular roof reinforcement shell		
Femoral Heads	Co-Cr-Mo Zirconia Ceramic	ASTM F 799 and ISO 5832/12 Not applicable

Porous titanium components and porous Co-Cr-Mo components are coated with commercially pure (C.P.) titanium beads (ASTM F 67 and ISO 5832/2) and Co-Cr-Mo beads (ASTM F 75), respectively. Hydroxylapatite coatings include HA (ASTM F 1185) that is supplied either on grit blasted or porous surface. NOTE: HA coated porous implants are not available in the USA.

Zirconia ceramic femoral heads are yttria stabilized zirconia ceramic.

Some of the alloys needed to produce orthopedic implants contain some metallic components that may be carcinogenic in tissue cultures or intact organism under very unique circumstances. Questions have been raised in the scientific literature as to whether or not these alloys may be carcinogenic in implant recipients. Studies conducted to evaluate this issue have not identified conclusive evidence of such phenomenon, in spite of the millions of implants in use.

### DESCRIPTION OF SYSTEM

The Total Hip System consists of femoral components, proximal pads, taper sleeves, distal sleeves, acetabular components, fixation screws and pegs, hole covers, centralizers, and femoral heads. Components may be grit blasted, porous coated, hydroxylapatite (HA) coated, or HA porous coated. All implantable devices are for single use.

### Femoral Components

Femoral components are available in a variety of sizes. Porous coated components are coated for biological growth. Proximally and distally modular femoral components accept proximal pads and distal sleeves, respectively. Non-porous femoral components can feature PMMA centralizers that help produce a uniform thickness of cement in a concentric manner.

Femoral components are available with a small, large (14/16), or 12/14 global taper (gauge diameters 0.404, .564, and 0.500 inches, respectively).

Small taper femoral components mate and lock directly with a 22 mm metal head. The small taper also mates with a taper sleeve which, in turn, mates with either metal or ceramic heads (26, 28, or 32 mm), bipolars, or unipolar components.

Large taper femoral components mate and lock with either metal heads (26, 28, or 32 mm), ceramic heads (28 or 32 mm), bipolars, or unipolar components.

Femoral components with a 12/14 taper mate and lock with either metal heads (22, 26, 28, or 32 mm), bipolars, or unipolar components.

Small and large taper femoral component trunnions are precisely machined to mate and lock with ceramic heads, thus preventing rotation of the ceramic head on the stem, the latter would cause wear of the stem trunnion.

### Taper Sleeves

A taper sleeve is required to be impacted on the small taper femoral component prior to impacting a femoral head size 26, 28, or 32 mm. A taper sleeve is required to attach a unipolar head. Unipolar taper sleeves are available in small, large, and 12/14 tapers. Never place more than one taper sleeve on a femoral component.

### Femoral Heads

Cobalt chromium (32, 28, 26, and 22 mm) and ceramic (32 and 28 mm) heads are available in multiple neck lengths for proper anatomic and musculature fit. Heads are highly polished for reduced friction and wear. The following zirconia ceramic heads are available for use only with small (0.404) and large (.564) taper femoral components:

Zirconia Ceramic Head	Head Diameter	Neck Length
42-7815	32 mm	Standard 0 mm
42-7816	32 mm	Long 4 mm
42-7817	32 mm	X-Long 8 mm
42-7818	28 mm	Standard 0 mm
42-7819	28 mm	Long 4 mm
42-7820	28 mm	X-Long 8 mm

32 mm heads with a -3 mm neck length are not available for use with the small taper stems.

### Acetabular Components

Acetabular components can be one piece all polyethylene or two-piece component consisting of a titanium shell and a polyethylene liner. Please see Warnings and Precautions for specific information on screws, pegs and hole covers use. Acetabular roof reinforcement and reconstruction shells are used with an all polyethylene acetabular component.

Femoral components and femoral heads are designed for use with any Smith & Nephew polyethylene acetabular component or polyethylene-lined, metal-backed acetabular component having an appropriately-sized inside diameter.

### INDICATIONS, CONTRAINDICATIONS, AND ADVERSE EFFECTS

Porous hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

Nonporous hip components are also indicated for inflammatory degenerative joint disease including osteoarthritis, avascular necrosis, trauma arthritis, rheumatoid arthritis, arthritis secondary to a variety of diseases and anomalies, and congenital dysplasia; old, remote osteomyelitis with an extended drainage-free period, in which case, the patient should be warned of an above normal danger of infection postoperatively; treatments of nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with heads involvement that are unmanageable using other techniques; endoprostheses, femoral osteotomy, or Girdlestone resection; fracture-dislocation of the hip; and correction of deformity.

Acetabular roof reinforcement and reconstruction shells are intended to be used in primary and revision surgeries where the acetabulum has the deficiencies of the acetabular roof, anterior or posterior pillar, medial wall deficiency, and/or protrusion as a result of the indications listed previously.

Some of the diagnoses listed above and below may also increase the chance of complications and reduce the chance of a satisfactory result.

### Contraindications

1. Conditions that would eliminate or tend to eliminate adequate implant support or prevent the use of an appropriately-sized implant, e.g.:

- blood supply limitations;
- insufficient quantity or quality of bone support, e.g., osteoporosis, or metabolic disorders which may impair bone formation, and osteomalacia; and
- infections or other conditions which lead to increased bone resorption.

- Mental or neurological conditions which tend to impair the patient's ability or willingness to restrict activities.
- Physical conditions or activities which tend to place extreme loads on implants, e.g., Charcot joints, muscle deficiencies, multiple joint disabilities, etc.
- Skeletal immaturity.
- The zirconia ceramic head is contraindicated for use with any product other than an UHMW polyethylene cup or a metal backed UHMW polyethylene cup.

Contraindications may be relative or absolute and must be carefully weighted against the patient's entire evaluation and the prognosis for possible alternative procedures such as non-operative treatment, arthrodesis, femoral osteotomy, pelvic osteotomy, resection arthroplasty, hemiarthroplasty and others.

Conditions presenting increased risk of failure include: osteoporosis, metabolic disorders which may impair bone formation, and osteomalacia.

### Possible Adverse Effects

- Wear of the polyethylene articulating surfaces of acetabular components has been reported following total hip replacement. Higher rates of wear may be initiated by the presence of particles of cement, metal, or other debris which can develop during or as a result of the surgical procedure and cause abrasion of the articulating surfaces. Higher rates of wear may shorten the useful life of the prosthesis, and lead to early revision surgery to replace the worn prosthetic components.
- With all joint replacements, asymptomatic, localized, progressive bone resorption (osteolysis) may occur around the prosthetic components as a consequence of foreign-body reaction to particulate wear debris. Particles are generated by interaction between components, as well as between the components and bone, primarily through wear mechanisms of adhesion, abrasion, and fatigue. Secondly, particles may also be generated by third-body particles lodged in the polyethylene articular surface. Osteolysis can lead to future complications necessitating the removal or replacement of prosthetic components. See "Important Physician Information" section for more information.
- Loosening, bending, cracking, or fracture of implant components may result from failure to observe the Warnings and Precautions below. Fracture of the implant can occur as a result of trauma, strenuous activity, improper alignment, or duration of service.
- Dislocations, subluxation, decreased range of motion, or lengthening or shortening of the femur caused by improper neck selection, positioning, looseness of acetabular or femoral components, extraneous bone, penetration of the femoral prosthesis through the shaft of the femur, fracture of the acetabulum, intrapelvic protrusion of acetabular component, femoral impingement, periarticular calcification, and/or excessive reaming.
- Fracture of the pelvis or femur: post-operative pelvic fractures are usually stress fractures. Femoral fractures are often caused by defects in the femoral cortex due to misdirected reaming, etc. Intraoperative fractures are usually associated with old congenital deformity, improper stem selection, improper broaching, and/or severe osteoporosis.
- Infection, both acute post-operative wound infection and late deep wound sepsis.
- Neuropathies: femoral, sciatic, peroneal nerve, and lateral femoral cutaneous neuropathies have been reported. Temporary or permanent nerve damage resulting in pain or numbness of the affected limb.

8. Wound hematoma, thromboembolic disease including venous thrombosis, pulmonary embolus, or myocardial infarction.
9. Myositis ossificans, especially in males with hypertrophic arthritis, limited pre-operative range of motion and/or previous myositis. Also, periarticular calcification with or without impediment to joint mobility can cause decreased range of motion.
10. Trochanteric nonunion usually associated with early weight bearing and/or improper fixation of the trochanter, when a transtrochanteric surgical approach is used.
11. Although rare, metal sensitivity reactions and/or allergic reactions to foreign materials have been reported in patients following joint replacement.
12. Damage to blood vessels.
13. Traumatic arthrosis of the knee from intraoperative positioning of the extremity.
14. Delayed wound healing.
15. Aggravated problems of the affected limb or contralateral extremity caused by leg length discrepancy, excess femoral medialization, or muscle deficiency.
16. Failure of the porous coating/ substrate interface or hydroxylapatite coating/ porous coating bonding may result in bead separation delamination.

#### WARNINGS AND PRECAUTIONS

The patient should be warned of surgical risks, and made aware of possible adverse effects. The patient should be warned that the device does not replace normal healthy bone, that the implant can break or become damaged as a result of strenuous activity or trauma, and that it has a finite expected service life and may need to be replaced in the future. Additional Warnings and Precautions may be included in component literature.

#### Preoperative

1. Use extreme care in handling and storage of implant components. Cutting, bending, or scratching the surface of components can significantly reduce the strength, fatigue resistance, and/or wear characteristics of the implant system. These, in turn, may induce internal stresses that are not obvious to the eye and may lead to fracture of the component. Implants and instruments should be protected from corrosive environments such as salt air during storage. Do not allow the porous surfaces to come in contact with cloth or other fiber-releasing materials.
2. Allergies and other reactions to device materials, although infrequent, should be considered, tested for (if appropriate), and ruled out preoperatively.
3. Fixation and expected longevity of components expected to be left in place at revision surgery should be thoroughly assessed.
4. Surgical technique information is available upon request. The surgeon should be familiar with the technique.
5. Intraoperative fracture or breaking of instruments can occur. Instruments which have experienced extensive use or excessive force are susceptible to fracture. Instruments should be examined for wear, or damage, prior to surgery.
6. Do not cold water quench ceramic components and never sterilize ceramic heads while fixed on the stem trunnion. (See sterilization section, below.)
7. Select components such that the Zirconia ceramic head always articulates with a UHMW polyethylene cup or a metal backed UHMW polyethylene cup. Zirconia ceramic should never articulate against metal because severe wear of the metal will occur.
8. Select only Smith & Nephew femoral components that indicate their use with ceramic heads. This is important because the trunnion on the stem is machined to tightly mate and lock with the ceramic head thus preventing rotation of the ceramic head on the stem. Also, an improperly dimensioned taper could result in fracture of the ceramic head.
9. The zirconia ceramic head is composed of a new ceramic material with limited clinical history. Although mechanical testing demonstrates that when used with a polyethylene acetabular component, the yttria stabilized zirconia ball produces a relatively low amount of particulates, the total amount of particulate remains undetermined.

Because of the limited clinical and preclinical experience, the biological effect of these particulates can not be predicted.

#### Intraoperative

1. The general principles of patient selection and sound surgical judgment apply. The correct selection of the implant is extremely important. The appropriate type and size should be selected for patients with consideration of anatomical and biomechanical factors such as patient age and activity levels, weight, bone and muscle conditions, any prior surgery and anticipated future surgeries, etc. Generally, the largest cross-section component which will allow adequate bone support to be maintained is preferred. Failure to use the optimum-sized component may result in loosening, bending, cracking, or fracture of the component and/or bone.
2. Correct selection of the neck length and cup, and stem positioning, are important. Muscle looseness and/or malpositioning of components may result in loosening, subluxation, dislocation, and/or fracture of components. Increased neck length and varus positioning will increase stresses which must be borne by the stem. The component should be firmly seated with the component insertion instruments.
3. Care should be taken not to scratch, bend (with the exception of the Reconstruction Rings) or cut metal components during surgery for the reasons stated in Number One of the "Preoperative" section of "Warnings and Precautions."
4. A +12 mm or +16 mm femoral head should not be used with any small taper stems.
5. Distal sleeves should not be used to bridge cortical defects that lie within 25 mm of the tip of the base stem.
6. Matrix small taper stem sizes 8S-10L must have a minimum neck length of +8 mm when used with a bipolar component; and small taper stem sizes 12S-16L must have a minimum neck length of +4 mm when used with a bipolar component.
7. Modular heads and femoral components should be from the same manufacturer to prevent mismatch of tapers.
8. Clean and dry stem taper prior to impacting the femoral head or taper sleeve. The modular femoral head component must be firmly seated on the femoral component to prevent disassociation.
9. Take care, when positioning and drilling screw and peg holes, to avoid penetration of the inner cortex of the pelvis, penetration of the sciatic notch, or damage to vital neurovascular structures. Perforation of the pelvis with screws that are too long can rupture blood vessels causing the patient to hemorrhage. Do not place a screw in the center hole of the acetabular prosthesis.  
  
Placement of drills and screws in the anterior or medial portions of the prosthesis is associated with a high risk of potentially fatal vascular injury.  
  
Bone screws must be completely seated in the holes of the shell to allow proper locking for the acetabular component liner. If the tapered pegs need to be removed from the shell after impaction of the pegs, do not reuse the pegs or the peg shell holes. Use new pegs and different shell holes, **or a new shell if necessary.**
10. **USE ONLY REFLECTION® TITANIUM BONE SCREWS, UNIVERSAL CANCELLOUS BONE SCREWS, TAPERED PEGS, AND HOLE COVERS with the Reflection Acetabular Component and USE ONLY OPTI-FIX® TITANIUM BONE SCREWS AND UNIVERSAL CANCELLOUS BONE SCREWS with the Opti-Fix Acetabular Component.** The Reflection Interfit and the Reflection For Screws Only (FSO) accepts only Universal Cancellous Screws, not pegs or hole covers. Tapered pegs can only be used with Reflection V Shells. The threaded center hole in Reflection Shells only accepts the threaded hole cover, not screws or pegs. Refer to product literature for proper adjunctive fixation and hole cover usage.
11. Prior to seating modular components, surgical debris including tissue must be cleaned from the surfaces. Debris, including bone cement, may inhibit the component locking mechanism. If the shell is to be cemented in place, remove extraneous cement with a plastic sculps tool to ensure proper locking of

the liner. During liner insertion, make sure soft sue does not interfere with the shell/liner interface. Chilling the liner reduces the impaction force required to seat the liner. Modular components must be assembled securely to prevent disassociation. Debris inhibits the proper fit and locking modular components which may lead to early wear of the procedure. Failure to properly seat acetabular liner into the shell can lead to disassociation of the liner from the shell.

12. Avoid repeated assembly and disassembly of modular components which could compromise critical locking action of the locking mechanism.
13. Care is to be taken to assure complete support all parts of the device embedded in bone cement prevent stress concentration which may lead to wear of the procedure. During curing of the cement care should be taken to prevent movement of implant components.
14. If components are to be left in place at revision surgery, they should first be thoroughly checked for signs of loosening, etc. and replaced if necessary. The head/neck component should be changed when clinically necessary.
15. Once removed from the patient, implants previously implanted should never be reused, since internal stresses which are not visible may lead to bending or fracture of these components.
16. With the congenitally dislocated hip, special care should be taken to prevent sciatic nerve palsy. Also, note that the femoral canal is often very small and straight and may require an extra-small stem femoral prosthesis; however, a regular-sized prosthesis should be used when possible. Note that true acetabulum is rudimentary and shallow. A false acetabulum should not ordinarily be utilized as a cup placement site for anatomical and biomechanical reasons.
17. With rheumatoid arthritis, especially for patients on steroids, bone may be extremely osteoporotic. Care should be taken to prevent excessive penetration of the acetabular floor or fracture of medial acetabular wall, femur, or greater trochanter.
18. Revision procedures for previous arthroplasty (Girdlestone, etc.), are technically demanding and difficult to exercise. Common errors include improper placement of the incision, inadequate exposure, mobilization of the femur, inadequate removal of ectopic bone, or improper positioning of components. Postoperative instability as well as excessive blood loss can result. In summary, increased operative time, blood loss, increased incidence of pulmonary embolus and wound hematoma can be expected with revision procedures.
19. Prior to closure, the surgical site should be thoroughly cleaned of cement, bone chips, ectopic bone, etc. Ectopic bone and/or bone spurs may lead to dislocation or painful or restricted motion. Range of motion should be thoroughly checked early contact or instability.

#### Postoperative

1. Postoperative directions and warnings to patients by physicians, and patient care, are extremely important. Gradual weight bearing is begun after surgery in ordinary total hip arthroplasty. However, with trochanter osteotomy or certain complex cases, weight-bearing status should be individualized with the non or partial weight-bearing period extended.
2. Patients should be warned against unassisted activity, particularly use of toilet facilities and other activities requiring excessive motion of the hip.
3. Use extreme care in patient handling. Support should be provided to the operative leg when moving the patient. While placing the patient on the table, changing dressings, and clothing, and during activities, precautions should be taken to avoid placing excessive load on the operative part of the body.
4. Postoperative therapy should be structured to regain muscle strength around the hip and a gradual increase of activities.
5. Periodic x-rays are recommended for close comparison with immediate postoperative condition to detect long-term evidence of changes in position, loosening, bending and/or cracking of components or bone loss. With evidence of these conditions

patients should be closely observed, the possibilities of further deterioration evaluated, and the benefits of early revision considered.

6. Prophylactic antibiotics should be recommended to the patient similar to those suggested by the American Heart Association for conditions or situations that may result in bacteremia.
7. Failure of the porous coating/ substrate interface or hydroxylapatite coating/porous coating bonding may result in bead separation delamination.

#### **PACKAGING AND LABELING**

Implants should be accepted only if received by the hospital or surgeon with the factory packaging and labeling intact. If the sterile barrier has been broken, refer to the "Resterilization" section below.

#### **STERILIZATION**

All metal components have been sterilized by a minimum of 25 kiloGrays of gamma irradiation. Plastic components have been sterilized by ethylene oxide gas. All components are supplied in protective trays. Inspect packages for punctures or other damage prior to surgery.

#### **RESTERILIZATION**

##### **Metal Components**

Metal components may be resterilized, if necessary, by steam autoclaving in appropriate protective wrapping, after removal of all the original packaging and labeling. Protect the prosthesis, particularly mating surfaces, from contact with metal or other hard objects. The following process parameters are recommended for these devices: Prevacuum cycle, 4 minutes at 132° to 135°, followed by 20 minutes of drying time.

Do not resterilize femoral prostheses with ceramic heads seated on the stem.

If porous coated implants are inadvertently contaminated, return the unsoiled prosthesis to Smith & Nephew for resterilization. DO NOT RESTERILIZE porous coated implants. The porous coating requires special cleaning procedures.

##### **Plastic Components**

Plastic components may be resterilized by ethylene oxide gas, using the following procedures:

Suggested aeration time is 12 hours at 50° with power aeration. Consult aerator manufacturer for more specific instructions.

##### **Ceramic Components**

Do not resterilize ceramic femoral heads.

#### **INFORMATION**

For further information, please contact Customer Service at (800) 238-7538 for calls within the continental USA and (901) 396-2121 for all international calls.

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

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