

# REFLECTION<sup>®</sup>

CEMENTED ALL POLYETHYLENE  
ACETABULAR COMPONENT



## SURGICAL TECHNIQUE

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# REFLECTION

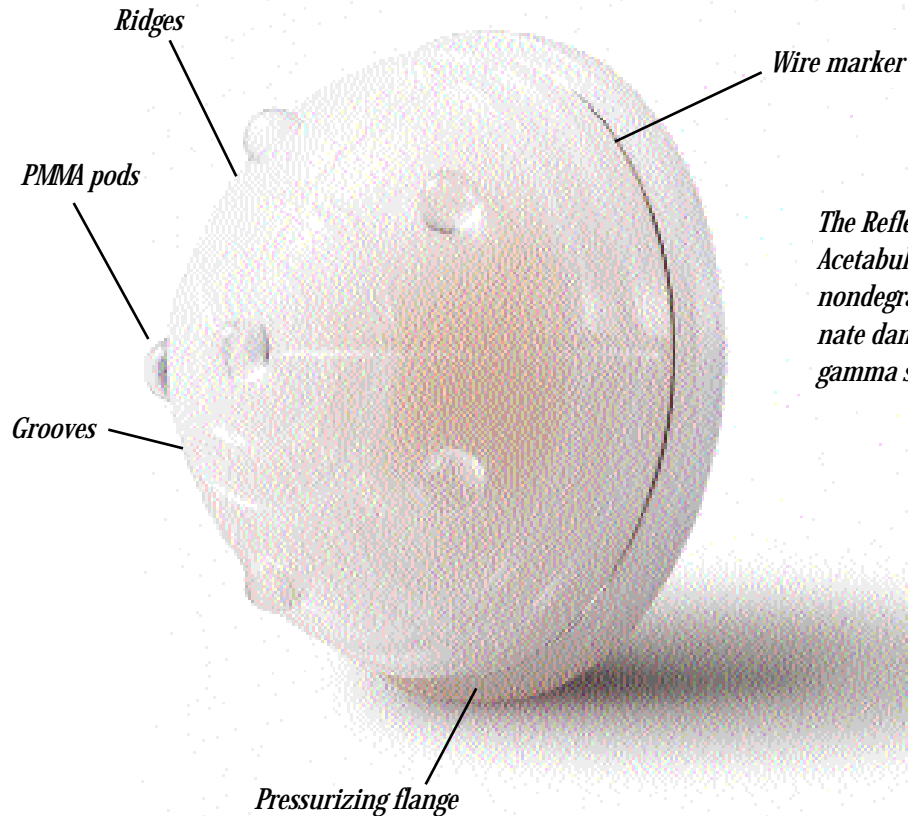
CEMENTED ALL POLYETHYLENE  
ACETABULAR COMPONENT

*designed in conjunction with*

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**Nota Bene:** This technique description herein is made available to the healthcare professional to illustrate the authors' 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 All Polyethylene Acetabular cup is sterilized by a nondegrading method to eliminate damage associated with gamma sterilization.*

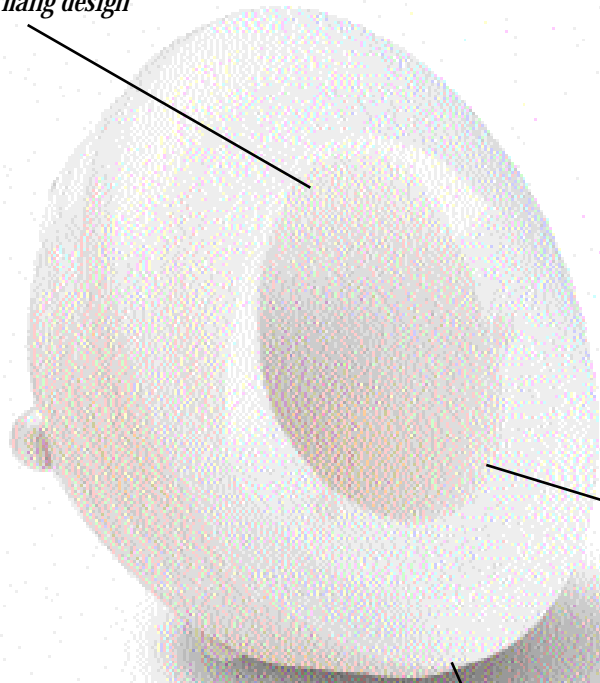
The Reflection Cemented Acetabular Component uses design features provided to maximize stability and durability in cemented acetabular cups.

The outer surface of the cup is designed to improve the bond strength of the PE-cement-bone interface. The cup exterior is **ridged** in the radial direction and **grooved** in the polar direction. This design incorporates cement-thickness **equalizing pods** and a **continuous flange** that provides a uniform thickness of cement around the cup to even the load transfer to the cement and bone. With the extended flange, eccentric cup placement is prevented. The flange also

increases **cement intrusion** pressure and penetration into cancellous bone during cup insertion. The polar grooves increase torque resistance by creating an interlock between the cement and cup. The grooves, ridges, and cement equalizing pods have been designed to reduce the risk of cup loosening. A wire marker along the cup equator is a reference for radiographic cup orientation and wear measurement.

The Reflection Cemented Acetabular Component is available in 3 mm outer diameter increments with inner diameters of 22, 28, or 32 mm.

*20° overhang design*



*Inner diameter sizes:  
22 mm, 28 mm, 32 mm*

*Outer diameter sizes:  
40 mm to 61 mm in 3 mm increments*

The articulating surface of the polyethylene cup has distinctive design features for stability of the hip joint. Because the natural abduction angle of the acetabulum is about 60°, the positioned cup is usually precipitous which can cause superoposterior dislocation of the femoral head component. In order to prevent dislocation, the cup has to be positioned at a more horizontal angle and the cup will be exposed outside of the bony

acetabulum, particularly superoposteriorly. To avoid these problems, the articulating surface of the polyethylene cup is angled 20° toward the horizontal plane. This provides more coverage on the superoposterior aspect while keeping the center of hip rotation the same as the geometric center of the outer shell. The resulting abduction face angle of the polyethylene cup is a stable 40° (See Figure 1 on page 4).

REFLECTION  
ALL POLY  
CUP DESIGN

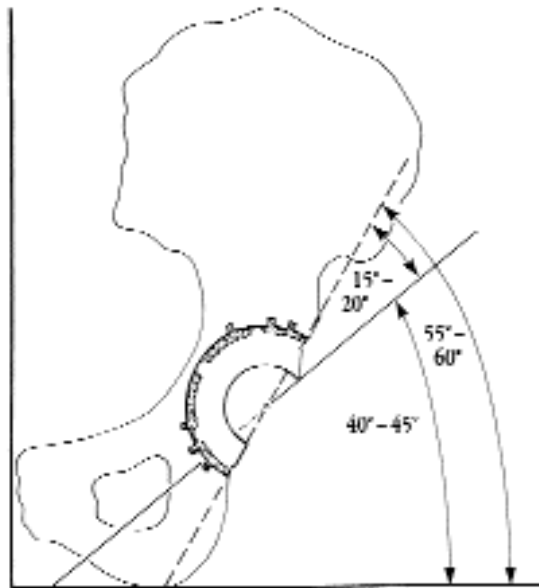


Figure 1

ALL POLY  
COMPETITIVE  
CUP DESIGN

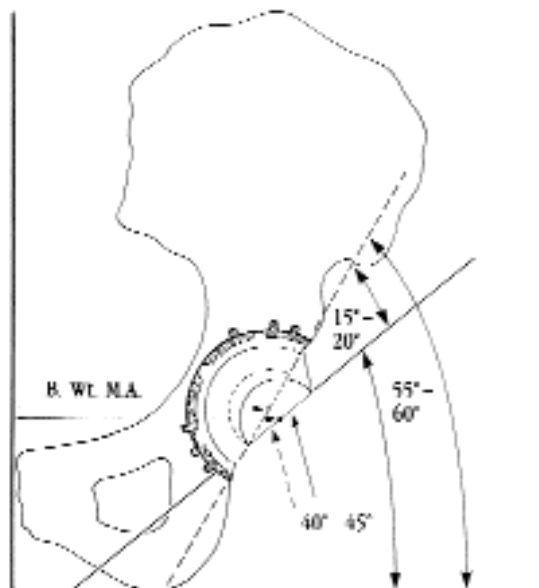
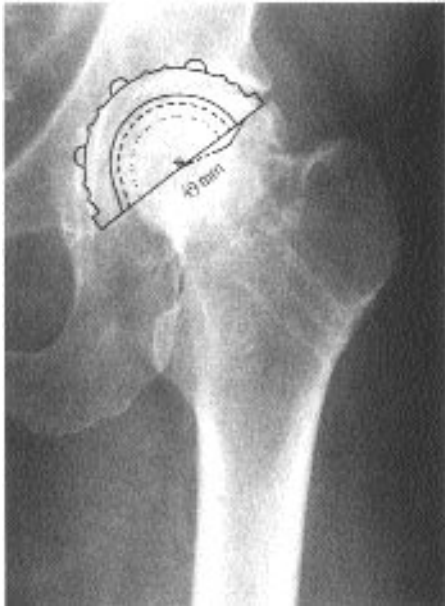


Figure 2

The Reflection cup does not lateralize the center of the natural acetabulum, an important design feature for reconstruction of hip geometry (*Figure 1*). Some competitive designs can lateralize the natural center of the joint (*see Figure 2*). When the center of hip rotation is lateralized, the body weight moment arm is increased and the abductor moment arm is relatively decreased. Thus, joint force is increased and the resultant joint force direction is lateralized. This acts on the

overhang portion of the cup which will tend to rock the implant and cause plastic deformation and may lead to eventual early loosening of the implant (*Figure 2*).

In addition, the laterally protruded large overhang that other systems employ makes reduction of the femoral head extremely difficult during the reduction maneuver. The Reflection All Polyethylene cup design minimizes these problems.



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 and cement pods 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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ACETABULAR EXPOSURE AND REAMING

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 the soft tissue of osteophytes from the acetabular fovea in order to define the limits of the medial wall. Retract surrounding soft tissues to protect them during the reaming process. This will help avoid injury to critical structures.

To expose the acetabular rim, first place a double angled, sharp Hohman retractor in the 3 o'clock position (for the right hip) over the anterior acetabular rim, taking care to maintain the top of the retractor against the anterior aspect of the pelvis.

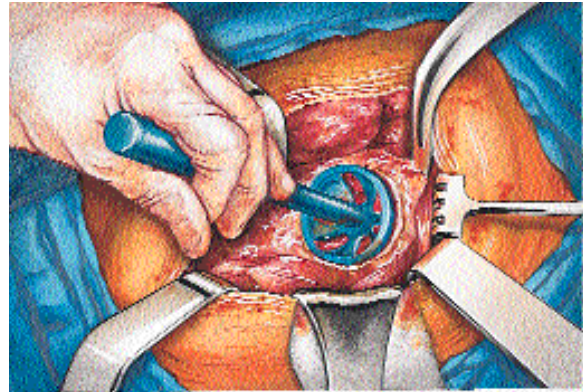
Place an inferior retractor in approximately the 7 o'clock position adjacent to the ischium. If desired, place a sharp, straight Hohman retractor in the 12 o'clock position beneath the abductors, approximately 2.5 cm above the superior rim of the acetabulum, and impact into the bone to enhance retraction of the abductors.

Restoration of natural anatomy is the general goal of acetabular preparation. The acetabulum is medialized to restore the normal center of hip rotation. Additionally, remaining cartilage and weak osteophytes are removed to prepare bone surface for cement interdigitation.

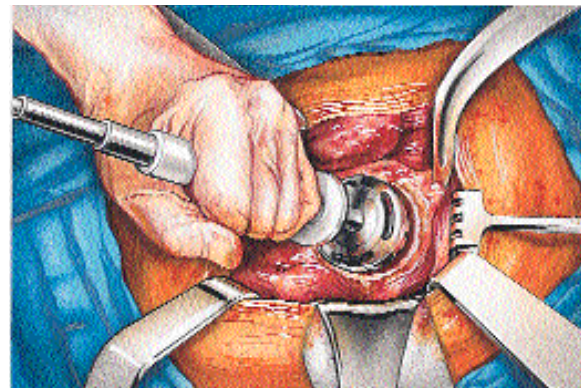
After performing the femoral osteotomy, an initial sizing of the acetabulum can be performed by using the trial shells and trial handle (*Figure 3*).

Using the existing anatomy as the reamer guide, ream the acetabulum concentrically, starting with a reamer two sizes smaller than the estimated final size. Proceed with reaming to expand the acetabulum until bleeding subchondral bone is reached (*Figure 4*).

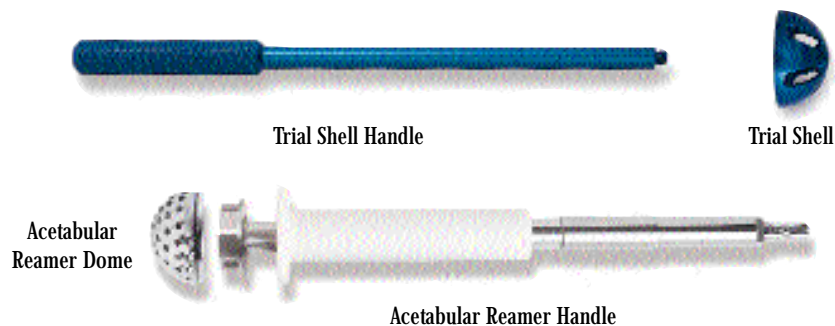
**The outer diameter of the last reamer used should be equal to the size of the cup to be implanted.** A final confirmation of acetabular size can be made after reaming by using the trial shell and trial handle.



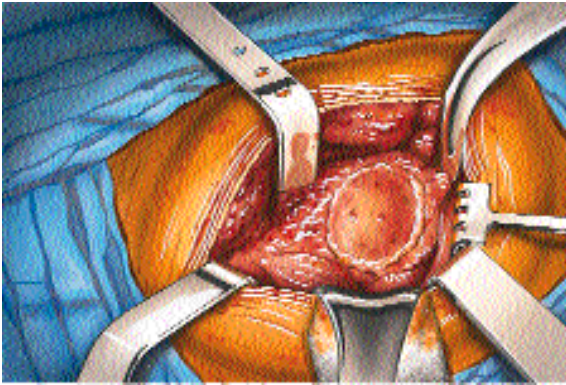
*Figure 3*



*Figure 4*



## ACETABULAR PREPARATION



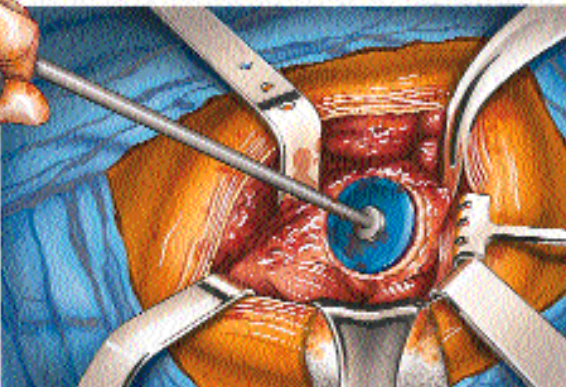
*Figure 5*

Multiple small anchoring holes in the pubic, ischial, and iliac portions of the acetabulum will provide greater fixation and torsional resistance for the cement mantle. Use an angled, depth-controlled drill, taking care not to penetrate into the pelvis (*Figure 5*).

Irrigate the acetabulum with antibiotic solution. Remove bone and blood debris with an acetabular brush connected to a power drill.

To achieve good cement intrusion into cancellous bone and anchor holes, the acetabulum must be clean and dry. Pack gauze into the socket until cement is ready to be introduced.

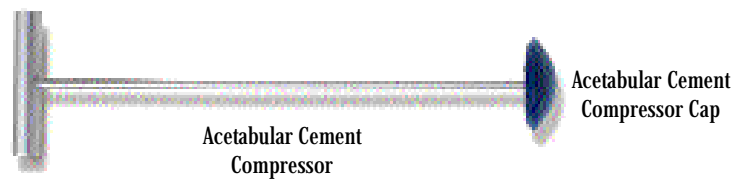
## CEMENT COMPRESSION



*Figure 6*

Remove gauze and introduce cement as a bolus. Using a cement compressor larger than than the acetabular mouth, apply sustained, firm pressure for 15 seconds (*Figure 6*).

Remove extruded cement from the periphery of the compressor and twist compressor end out of cement. Any blood oozing onto the surface of the cement should be dried with a sponge before inserting the acetabular component.



## ACETABULAR CUP INSERTION

Select an acetabular component equal in size to the last reamer used.

Position the cup onto the Positioner/ Placement Head. Orient the Positioner/ Placement Head to indicate left or right THA. Engage the two pins on the placement head into the corresponding holes of the cup to firmly hold it in place (*Figure 7*).

Vertical orientation of the X-bar and alignment of the appropriate cross bar with the body axis provides 45° of abduction and 20° of anteversion.

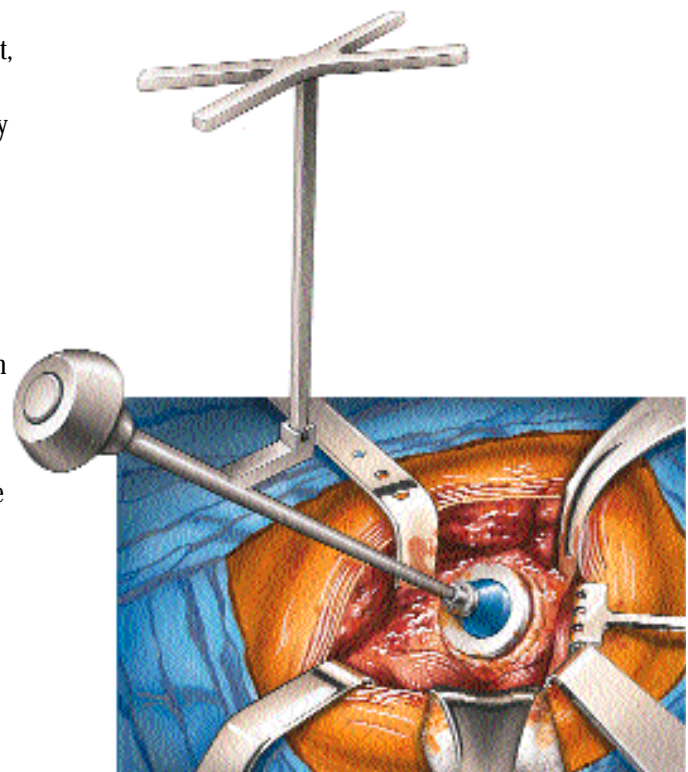
Insert the cup into the cement and fully seat, positioning the overhang in the postero-superior position to provide greatest stability (*Figure 8*). **The PMMA spacer pods provide a uniform 2.5 mm cement mantle.** Trim away excess cement from the periphery of the cup once it has become doughy.

Disengage the cup by pushing the button on the cup positioner.

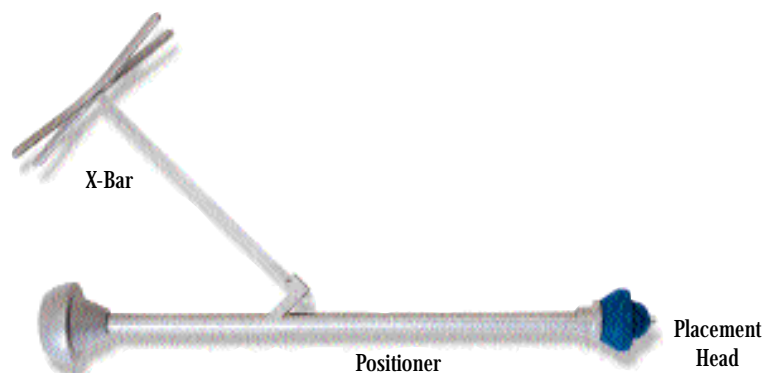
Cover the acetabular area with a sponge while preparing the femur and inserting the femoral prosthesis.



*Figure 7*



*Figure 8*



**Polyethylene Cup**



Cat. No.	O.D.	I.D.
7135-2240	40 mm	22 mm
7135-2243	43 mm	22 mm
7135-2246	46 mm	22 mm
7135-2249	49 mm	22 mm
7135-2252	52 mm	22 mm
7135-2255	55 mm	22 mm
7135-2258	58 mm	22 mm
7135-2261	61 mm	22 mm
7135-2846	46 mm	28 mm
7135-2849	49 mm	28 mm
7135-2852	52 mm	28 mm
7135-2855	55 mm	28 mm
7135-2858	58 mm	28 mm
7135-2861	61 mm	28 mm
7135-3249	49 mm	32 mm
7135-3252	52 mm	32 mm
7135-3255	55 mm	32 mm
7135-3258	58 mm	32 mm
7135-3261	61 mm	32 mm



**Trial Shell**

Cat. No.	Size	Cat. No.	Size
73-0040	40 mm	73-0051	51 mm
73-0041	41 mm	73-0052	52 mm
73-0042	42 mm	73-0053	53 mm
73-0043	43 mm	73-0054	54 mm
73-0044	44 mm	73-0055	55 mm
73-0045	45 mm	73-0056	56 mm
73-0046	46 mm	73-0057	57 mm
73-0047	47 mm	73-0058	58 mm
73-0048	48 mm	73-0059	59 mm
73-0049	49 mm	73-0060	60 mm
73-0050	50 mm	73-0061	61 mm

ACETABULAR COMPONENT INSTRUMENTATION

**Trial Shell Handle**

Cat. No. 73-2119



**Acetabular Reamer Handle**

Cat. No. 11-4265



**Acetabular Reamer Dome**

Cat. No.	Size	Cat. No.	Size
41-7138	38 mm	41-7150	50 mm
41-7139	39 mm	41-7151	51 mm
41-7140	40 mm	41-7152	52 mm
41-7141	41 mm	41-7153	53 mm
41-7142	42 mm	41-7154	54 mm
41-7143	43 mm	41-7155	55 mm
41-7144	44 mm	41-7156	56 mm
41-7145	45 mm	41-7157	57 mm
41-7146	46 mm	41-7158	58 mm
41-7147	47 mm	41-7159	59 mm
41-7148	48 mm	41-7160	60 mm
41-7149	49 mm	41-7161	61 mm



**Positioner**

Cat. No. MF-2200



**X-Bar**

Cat. No. MF-2201



**Placement Head**

Cat. No.	Size
MF-2222	22 mm
MF-2228	28 mm
MF-2232	32 mm



CEMENT ACCESSORIES



**Acetabular Brush**  
6 per box  
Cat. No. 11-0032



**Concise Cement Sculps Kit**  
Cat. No. 11-1000



**Disposable Acetabular Cement Compressor Cap with Shield**  
5 per box

Cat. No.	Size
11-1431	Small, 54 mm dia.
11-1432	Medium, 62 mm dia.
11-1433	Large, 70 mm dia.



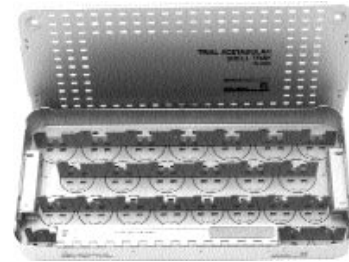
**Acetabular Cement Compressor**  
Cat. No. 11-1430

ACETABULAR TRAYS

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**Trial Acetabular Shell Tray**

Cat. No. 73-1003



**Reamer Dome Tray**

38 mm - 70 mm

Cat. No. 73-1004





# 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. The component material is provided on the outside carton label.

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	UHMWPE	ASTM F 648
Acetabular liners	Alumina Ceramic	ASTM F 603 and ISO 6474
Femoral centralizers	PMMA PMMA, Barium Sulfate	Not applicable
Acetabular spacer pods	PMMA	Not applicable
X-ray marking wire	Co-Cr-Mo Stainless Steel	ASTM F 90 and ISO 5832/5 ASTM F 138 and ISO 5832/1
Acetabular reconstruction ring	CP Titanium	ASTM F 67 and ISO 5832/2
Acetabular reinforcement ring		
Femoral Heads	Co-Cr-Mo Zirconia Ceramic Alumina Ceramic	ASTM F 799 and ISO 5832/12 ISO 13356 ASTM F 603 and ISO 6474

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 applied either on a grit blasted or porous surface. NOTE: HA coated porous implants are not available in the USA.

Some of the alloys needed to produce orthopedic implants contain some metallic components that may be carcinogenic in tissue cultures or intact organisms 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 designed for single use only.

#### Femoral Components

Femoral components are available in a variety of sizes. Porous coated components are coated for biological ingrowth. 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.

Femoral components are available with a small, large (14/16), or 12/14 global taper.

Small taper femoral components mate and lock directly with a 22 mm metal or ceramic 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), bipolar 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), bipolar or unipolar components.

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

Small, large, and 12/14 taper femoral component tapers are machined to mate and lock with ceramic heads, thus preventing rotation of the ceramic head on the stem, which would cause wear of the stem taper.

#### 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 (22, 26, 28, and 32 mm) and ceramic (22, 26, 28, and 32 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 and large taper femoral components.

Zirconia Ceramic	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

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

In addition to the components listed above, the following components are available for use only with small taper femoral components

Zirconia Ceramic	Head Diameter	Neck Length
7132-0002	22 mm	Long +4 mm
7132-0006	22 mm	X-Long +8 mm

Note: 22 mm Zirconia Ceramic Heads used with small taper femoral components are not available in the USA.

The following zirconia ceramic heads are available for use only with 12/14 taper femoral components:

Zirconia Ceramic	Head Diameter	Neck Length
7132-0028	28 mm	0 mm
7132-0428	28 mm	+4 mm
7132-0828	28 mm	+8 mm
7132-0026	26 mm	0 mm
7132-0426	26 mm	+4 mm
7132-0826	26 mm	+8 mm
7132-0422	22 mm	+4 mm
7132-0822	22 mm	+8 mm

The following alumina ceramic heads are available for use only with 12/14 taper femoral components:

Alumina Ceramic	Head Diameter	Neck Length
7133-2800	28 mm	0 mm
7133-2804	28 mm	+4 mm
7133-2808*	28 mm	+8 mm
7133-3200	32 mm	0 mm
7133-3204	32 mm	+4 mm
7133-3208	32 mm	+8 mm

\* The alumina 28 mm +8 head size is not for use with a Co-Cr-Mo taper in the U.S.A.

#### Acetabular Components

Acetabular components can be one-piece, all-polyethylene or two-piece components consisting of a titanium shell and a polyethylene liner or a titanium shell and an alumina ceramic liner. Please see Warnings and Precautions for specific information on screws, pegs and hole covers use. Acetabular reinforcement and reconstruction rings are used with an all polyethylene acetabular component. Note: The metal shell and ceramic liner in the Ceramic/Ceramic Acetabular System are not available in the U.S.A.

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

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.

Hip components are also indicated for inflammatory degenerative joint disease including 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 head involvement that are unmanageable using other techniques; endoprosthesis, femoral osteotomy, or Girdlestone resection; fracture-dislocation of the hip; and correction of deformity.

Acetabular reinforcement and reconstruction rings 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 indi-

cations 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

- 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 other product than a UHMW polyethylene cup or a metal backed UHMW polyethylene cup.
- The alumina ceramic liner is contraindicated for use with any product other than the metal shell with the correlating inner taper geometry and the appropriate sized alumina ceramic head. The alumina ceramic liner should only be used with the alumina ceramic head.

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 and ceramic articulating surfaces of acetabular components may occur. 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 surfaces. Osteolysis can lead to future complications necessitating the removal or replacement of prosthetic components.
- 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 services.
- 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.
- Wound hematoma, thromboembolic disease including venous thrombosis, pulmonary embolus, or myocardial infarction.
- 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.
- 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 mediatization, or muscle deficiency.
16. Failure of the porous coating/ substrate interface or hydroxylapatite coating/ porous coating bonding may result in bead separation delamination.
17. Stem migration or subsidence has occurred in conjunction with compaction grafting procedures usually resulting from insufficient graft material or improper cement techniques. Varus stem alignment may also be responsible.

#### 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. Do not mix components from different manufacturers. 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 taper. (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 taper 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.
10. Alumina ceramic should never articulate against metal because severe wear could occur.

#### 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 impactation 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) shells accept Universal Cancellous, Reflection screws, and tapered screw-hole covers, not pegs. 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. The InterFit threaded hole cover is only for use with Reflection Interfit. The Reflection threaded hole cover can be used with both Reflection and InterFit shells. 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 sculpt tool to ensure proper locking of the liner. During liner insertion, make sure soft tissue 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 of modular components which may lead to early failure of the procedure. Failure to properly seat the acetabular liner into the shell can lead to disassociation of the liner from the shell.
12. Avoid repeated assembly and disassembly of the modular components which could compromise the critical locking action of the locking mechanism.
13. Care is to be taken to assure complete support of all parts of the device embedded in bone cement to prevent stress concentration which may lead to failure of the procedure. During curing of the cement, care should be taken to prevent movement of the implant components.
14. If components are to be left in place at revision surgery, they should first be thoroughly checked for signs of looseness, etc. and replaced if necessary. The head/neck component should be changed only 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 early 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 straight femoral prosthesis; however, a regular-sized prosthesis should be used when possible. Note that the 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 those patients on steroids, bone may be extremely osteoporotic. Care should be taken to prevent excessive penetration of the acetabular floor or fracture of the 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 misplacement of the incision, inadequate exposure or 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 for early contact or instability.
20. When using a ceramic liner and metal shell, proper shell and liner alignment and positioning are critical to implant performance. If the ceramic liner and shell are not fully seated or are aligned incorrectly and final impaction, it will be necessary to revise the

shell and liner with new components. An improper impaction will damage the shell and liner taper which can increase the chance of subsequent liner fracture or other component failure. Refer to the surgical technique for specific information on shell assembly and the implantation method.

21. Proper positioning of the components is important to minimize impingement which could lead to early failure, premature wear, and/or dislocation.

#### 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 bedpans, changing dressings, and clothing, and similar 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 conditions 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.

#### PACKAGING AND LABELING

Components should only be accepted if received by the hospital or surgeon with the factory packaging and labeling intact.

#### STERILIZATION/RESTERILIZATION

Most implants are supplied sterile and have been packaged in protective trays. The method of sterilization is noted on the package label. All radiation sterilized components have been exposed to a minimum of 25 kilo-Grays of gamma radiation. If not specifically labeled sterile, the implants and instruments are supplied non-sterile and must be sterilized prior to use. Inspect packages for punctures or other damage prior to surgery.

#### Metal Components

Nonporous or non-HA metal components may be initially sterilized or resterilized, if necessary, by steam autoclaving in appropriate protective wrapping, after removal of all original packaging and labeling. Protect the devices, particularly mating surfaces, from contact with metal or other hard objects which could damage the product. The following process parameters are recommended for these devices:

- Prevacuum Cycle: 4 pulses (Maximum = 26.0 psig [2.8 bars] & Minimum = 10.0 inHg [339 millibars]) with a minimum dwell time of 4 minutes at 270°F to 275°F (132°C to 135°C), followed by a 1 minute purge and at least 15 minutes of vacuum drying at 10 inHg (339 millibars) minimum.
- Gravity Cycle: 270°F to 275°F (132°C to 135°C) with a minimum dwell time at temperature of 10 minutes, followed by a 1 minute purge and at least 15 minutes of vacuum drying at 10 inHg (339 millibars) minimum.

**Smith & Nephew does not recommend the use of low temperature gravity cycles or flash sterilization on implants.**

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

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

#### Plastic Components

Plastic components may be resterilized by ethylene oxide gas. The following parameters are recommended as starting points for cycle validation by the health care facility:

Sterilant	Temp.	Humidity	Maximum Pressure	Concentration	Exposure Time
100% EtO	131°F (55°C)	40-80% (70% Target)	10 PSIA (689 millibar)	725 mg/l	60-180 minutes

Suggested initial starting point for aeration validation is 12 hours at 120°F (49°C) 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.

Authorized EC Representative: Smith & Nephew Orthopaedics GmbH, Tuttlingen, Germany.

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

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