REFLECTION
CEMENTED ALL POLYETHYLENE
ACETABULAR COMPONENT

SURGICAL TECHNIQUE
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.
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.
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).
The Reflection cup does not laterize the center of the natural acetabulum, an important design feature for reconstruction of hip geometry (Figure 1). Some competitive designs can laterize the natural center of the joint (see Figure 2). When the center of hip rotation is lateraled, 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.

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.
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.

Remove gauze and introduce cement as a bolus. Using a cement compressor larger 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.
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 posterosuperior 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.
### Polyethylene Cup

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Trial Shell Handle
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Acetabular Reamer Handle
Cat. No. 11-4265

Acetabular Reamer Dome
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41-7139  39 mm
41-7140  40 mm
41-7141  41 mm
41-7142  42 mm
41-7143  43 mm
41-7144  44 mm
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41-7146  46 mm
41-7147  47 mm
41-7148  48 mm
41-7149  49 mm

Positioner
Cat. No. MT-2200

X-Bar
Cat. No. MT-2201

Placement Head
Cat. No.  Size
MT-2222  22 mm
MT-2228  28 mm
MT-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

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 mobility 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**
- **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**
  - Plain or porous
t- **Proximal pads**
  - Distal sleeves
  - Fixation screws and pegs
  - Hole covers
- **Acetabular components**
  - UHMWPE
  - Alumina Ceramic
  - Stainless Steel
- **Acetabular liners**
  - Femoral centralizers
  - Acetabular reinforcement ring
- **Hip Heads**
  - Ceramic
  - Stainless Steel
  - Ti-6Al-4V 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

**Porous titanium components and porous Co-Cr-Mo components are coated with commercially pure (C.P.) titanium (ASTM F 67 and ISO 5832/2) and Co-Cr-Mo beads (ASTM F 75), respectively. Hydroxyapatite 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 inhibit 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, hydroxyapatite (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 Heads**
Femoral components are available in a small, large, (14/16), or 12/14 global taper.

**Small taper femoral components**
- 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**
- 22 mm metal or ceramic head.
- The large 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.

**Components with a 12/14 taper**
- 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.

**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 musculoskeletal fit. Heads are highly polished for reduced friction and wear. The following zirconia ceramic heads are available for use with only small and large taper femoral components.

**Zirconia Ceramic Heads**
- 22 mm Ceramic Head (standard neck length +6 mm)
- 28 mm Ceramic Head (standard neck length +8 mm)
- 32 mm Ceramic Head (standard neck length +10 mm)

**Fractures**
Fractures, 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 embolism, or myocardial infarction.
Myositis ossificans, especially in males with hypertrophic arthritis, limited pre-operative range of motion and/or previous muscle trauma. Also, periarticular calcification with or without impairment to joint mobility can cause decreased range of motion.
Tension or attenuation of the peroneal nerve usually occurs 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 surgery.

12. Damage to blood vessels.

13. Traumatic arthrosis of the knee from intraoperative positioning of the extremity.


15. Aggravated problems of the affected limb or contralateral extremity caused by leg length discrepancy, excess femoral medalization, or muscle deficiency.

16. Failure of the porous coating/substrate interface or hydroxylapatite/porous coating bonding may result in bead separation or delaminations.

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.

**Proper Use**

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 these. In some cases, they may induce internal stresses that are not obvious to the eye and may lead to fracture of the component. Instruments and implants should be protected from contamination such as dirt or debris 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 situ should be thoroughly assessed.

4. Surgical technique information is available upon request. The surgeon should be familiar with the procedure and the technique.

5. Before surgery, the correct selection of the implant is extremely important. The correct selection of the neck length and cup, and stem positioning is critical to implant performance.

6. Do not cold water quench ceramic components and never sterilize with drying air. Cold water quenching or drying may induce residual stresses. Instruments which have experienced extensive use or excessive force or pressure are not acceptable to use. Instruments should be examined for wear, or damage, prior to surgery.

7. Do not cold water quench ceramic components and never sterilize ceramic head or head while fixed on the stem end. (See sterilization section, below.)

8. 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.

9. Select only Smith & Nephew femoral components that indicate their use with ceramic heads. This is important because the taper on both ceramic head and acetabular shell cannot be accurately measured. Instruments should be examined for wear, or damage, prior to surgery.

10. Do not use cold water quench ceramic components and never sterilize ceramic head or head while fixed on the stem end. (See sterilization section, below.)

11. Prior to seating modular components, surgical debris including tissue, 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 tool to assist in locking the liner. During liner insertion, make sure soft tissue does not interfere with the shellliner interface. Chilling the liner reduces the impaction force required to seat the acetabular components. Instruments 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 to prevent stress concentration which may lead to failure of the procedure. During curing of the cement, care should be taken to prevent rotation of the implant components.

14. If components are to be left in place at revision surgery, they should be thoroughly cleaned for signs of looseness, etc. and replaced. The ceramic head 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 failure of these components.

16. With the congenitally dislocated hip, special care should be taken to prevent sciotic 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 difficult to follow. A false acetabulum should not ordinarily be utilized as a cup placement site for anatomical and biomechanical reasons.

17. With tuberous or osteoarthritic, especially for those patients on steroids, bone loss is extreme and, for these patients, 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 execute. 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 immobilization as well as excessive blood loss can result. In summary, increased operative time, blood loss, increased incidence of pulmonary emboli and deep vein thrombosis, and postoperative 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 disassociation or painfull or restricted motion. Range of motion should be thoroughly checked for early 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 loosening and early 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 gradually of activities.

5. Periodic X-rays are recommended for close comparison with immediate postoperative conditions to detect long-term evidence of changes in position, loose components, and any signs of loosening, impingement which could lead to early failure, premature wear, or damage of components or bone loss. With evidence of these conditions, patients should be closely observed, the possibilities of further deterioration evaluated, and if necessary, revised.

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 supplied 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. Properly packaged 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**

Non-oxide ceramic-on-metal HA components may be initially sterilized or resterilized, if necessary, by steam autoclaving in appropriate protective wrapping, after removal of 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:

- **Prewash:** 4 hours (maximum 24.0 psig [2.8 bars] & Minimum 10.0 kg) [339 mmHg] 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 kg [339 milbars] 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 a minimum of 15 minutes of vacuum drying at 10 kg [339 milbars] 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 unsold 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:

- **First Stage:** 85°C / 20 psig [1450 mmHg] for 15 minutes.
- **Second Stage:** 131°F / 15 psig [1050 mmHg] for 45 minutes.