Nota Bene: The 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.

SURGICAL TECHNIQUE
COMPLETED IN CONJUNCTION WITH

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Preoperative Planning

Both an anteroposterior radiograph of the pelvis with the hips in neutral rotation and a lateral hip radiograph optimize preoperative templating. The proximal one-third of the femur should be visible on these radiographs.

Reference points should be placed at the center of the femoral head and the junction of the femoral neck and proximal border of the lesser trochanter on the anteroposterior radiograph. This should be done on both the operative and nonoperative sides. The distance between the center of the femoral head and the point at the top of the lesser trochanter should be measured with the ruler on the X-ray template.

This should be done on both the operative and nonoperative sides as shown in Figure 1. If there is a significant discrepancy, a straight line can be drawn across the inferior margins of the obturator foramina to determine where the line intersects both femora. The surgeon can then determine whether lengthening of the operative side is needed.

NOTE: Evidence of a leg length discrepancy should be corroborated by a preoperative physical examination.

The appropriate size stem should be chosen based upon the size of the femoral canal and the desired cement mantle. The cement mantle outlined on the X-ray template should reach the endosteal surface over the mid-portion of the stem as shown in Figure 2. A through-the-groin lateral X-ray can be used to more accurately determine proper stem sizing.

Figure 1. Anteroposterior radiograph demonstrating one method of determining leg length inequality.

Figure 2. Anteroposterior radiograph demonstrating proper templating of a femur.
On the anteroposterior film, the center of rotation of the prosthetic femoral head should overlay the center of rotation of the patient’s femoral head. In cases of significant distortion on the operative side, the non-operative side may be used. With the stem centered in the canal and the prosthetic center of rotation aligned with the patient’s center of rotation, the neck cut can be marked through the slot in the template. The distance between this mark for the neck cut and the mark on the lesser trochanter should be recorded. This number will aid in making the femoral neck resection at the appropriate level.

With the X-ray template in proper alignment, the femoral head neck length and stem offset should be recorded. Using this methodology helps to optimize both the leg length and offset of the proximal femur.

A properly implanted Synergy cemented stem that provides both normal leg length and offset is shown in Figure 3.

Figure 3. Anteroposterior radiograph of a properly implanted Synergy cemented stem.
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For use with Smith & Nephew 12/14 taper femoral heads only.
-3  and +16 femoral heads available in 28 mm and 32 mm only.

*Denotes skirted heads.

NOTE: For illustration purposes only. Surgical templates are available by contacting your Smith & Nephew Representative or Customer Service.
1. **Femoral Osteotomy**

The point of the femoral neck resection should be marked with electrocautery corresponding to both the preoperative templating and the intraoperative measurement. Prior to the resection of the femoral head, assemble the broach, trial neck and trial femoral head corresponding to the implant that was templated. Place this trial stem on the femur to verify that the center of the prosthetic head aligns with the center of the femoral head. This will confirm that the level of the femoral neck resection is appropriate and will reestablish the desired leg length and offset of the proximal femur. Osteotomize the femoral neck (Figures 1A and 1B.)

2. **Prepare Acetabulum**

If acetabular reconstruction is required, prepare the acetabulum using the surgical technique for the intended acetabular component.
3. Femoral Canal Preparation

Remove remnants of the femoral neck and open the medullary canal using the box osteotome (Figure 2). Use the canal finder and modular T-handle for initial femoral reaming (Figure 3).

NOTE: It is important to stay lateral with both the box osteotome and canal finder. Care should be taken to ensure that the initial reaming tract into the femur is in neutral alignment with the femoral axis.
4. Opening Of The Femoral Canal

Continue to enlarge the femoral canal sequentially using the femoral reamers. Each reamer is marked with two or three lines. Stop reaming when the mark on the reamer associated with the templated stem size is even with the medial femoral neck resection or endosteal bone resistance is encountered (Figure 4). If reaming becomes difficult before reaching the templated stem size, consider using a stem size smaller than the templated stem size.

NOTE: It is important to stay lateral with the femoral reamers to ensure that the canal is being opened in neutral alignment with the femoral axis.
5. **Broach Assembly/Disassembly**

Assemble the broach to the broach handle by placing the broach post in the clamp. Use thumb to lock the clamp onto the broach. A modular anteversion handle can be assembled to the broach handle to provide version control (Figure 5A).

Disassemble the broach from the broach handle by placing two fingers (index and middle) in the rectangular slot. Apply pressure to the release bar by squeezing the two fingers toward the thumb resting on the medial side of the broach handle frame (Figure 5B).
6. Femoral Broaching

Start the broaching procedure along the axis of the femur with a broach at least two sizes smaller than the last reamer used. Sequential broaching should then be carried out to the templated stem size. Stop broaching when the top of the last broach is slightly below the level of the resected femoral neck to facilitate calcar reaming (Figure 6).

Note: Care should be taken not to force a broach that is too large into the femur. Consideration should be given to using a stem size smaller than the size templated. This helps avoid intraoperative fractures of the femur.

The Synergy broach is designed to provide a minimum 1 mm cement mantle per side and a 2-3 mm cement mantle in the medial curve of the stem. Additional cement mantle thickness is achieved by pressurizing the cement into cancellous bone.
7. **Calcar Preparation**

With the final broach fully seated, remove the broach handle. Place the calcar reamer over the post of the broach and machine the femoral neck for optimal implant collar/femoral neck contact (Figure 7).

8. **Trial Reduction**

Place the standard or high offset trial neck (as determined by templating) onto the broach post. Select the trial femoral head of desired diameter and neck length (Figure 8A and Table 1). Measure the distance between the mark at the lesser trochanter and the center of the trial femoral head. This number should correspond to the preoperative and intraoperative measurements. Adjustments in neck length and/or offset can be made at this time.

If trialing for a Unipolar or Bipolar, trial according to the appropriate technique for the selected device.

---

**FEMORAL HEAD AND NECK LENGTH OPTIONS**

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*Denotes skirted heads.

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Table 1. Femoral head and neck length options.
8. **Trial Reduction** (cont.)

Reduce the hip and evaluate in the following ways:

1. **Soft tissue tension** – some shuck is normal when applying a longitudinal distraction force to the hip. Shuck should not be excessive, and the hip should not dislocate (Figure 8B).

2. **Anterior stability** – place the leg in full adduction, full extension and hyperextension, while exerting an external rotation force. If the hip cannot be fully extended, it may be too tight. If it dislocates easily, it is too loose and impingement must be addressed or component malposition exists (Figure 8C).

3. **Posterior stability** – place the leg in neutral adduction and 90° flexion. Gradually rotate internally. If it dislocates with minimal internal rotation, it is too loose and impingement must be addressed or component malposition exists (Figure 8D).

4. **Sleep position** – place the leg in the “sleep position” with the operated leg semiflexed, adducted and internally rotated over the other leg. Apply axial force to try to dislocate. This position represents a dangerously unstable position that may be adopted by a patient sleeping on their nonoperated side (Figure 8E).
9. Placing The Buck™ Cement Restrictor

Dislocate the hip and remove all trial components. The proximal flange of the cement restrictor should always be larger than the distal canal diameter. Screw the cement restrictor onto the inserter using a clockwise motion. Insert the device to the level of the medullary canal that has been predetermined (usually 1.5-2 cm below the end of the stem). A recommended cement restrictor depth is provided in Table 2. Once this level is reached, disengage the restrictor from the inserter using a counterclockwise twisting motion (Figure 9). Remove the inserter from the medullary canal. If it is necessary to remove the restrictor prior to cement insertion, it can be reattached to the inserter rod and pulled out of the canal.

10. Selecting The Stem & Distal Centralizer

Select the implant that corresponds to the last reamer and broach used. An optional distal centralizer may be placed on the stem to assist in obtaining neutral alignment of the stem and a predictable cement mantle. Each implant has a recommended distal centralizer (Table 3).

NOTE: All of the femoral stems will accept any of the available distal centralizers to address variations in distal femoral geometries.

Using clean gloves, place the post of the selected centralizer into the hole at the distal end of the stem and push the post of the centralizer superiorly until snug.

NOTE: If a distal centralizer is not used, place the distal hole plug, which is packaged with the implant, into the centralizer hole prior to inserting the stem.
11. Preparing The Femoral Canal

Use a curette to remove any grossly loose cancellous bone. Irrigate the canal and pulsatile lavage to remove all debris. Continue preparing the femur with a femoral canal brush to remove any weak, cancellous bone, blood clots and marrow fats (Figure 11). Repeat lavaging as necessary to remove all remaining debris.

12. Drying The Femoral Canal

Connect O.R. suction to the femoral suction absorber handle. Insert the femoral absorber into the femoral canal to dry the canal while mixing the cement (Figure 12).
13. Injecting The Cement

After removing the femoral canal suction absorber, immediately insert the nozzle of the cement gun deep into the femoral canal. Beginning at the distal end of the femoral canal, inject cement into the canal in retrograde fashion (Figure 13). Continue injecting cement until the canal is completely full and the distal tip of the nozzle is clear of the canal.

14. Pressurizing The Cement

Break off the long nozzle and place the femoral pressurizer over the short nozzle. Insert the femoral cement compressor into the mouth of the canal (Figure 14). This will occlude the canal and compress the cement. Maintain firm pressure for 30-60 seconds, depending on cement viscosity to allow good cement interdigitation into trabecular bone. Withdraw the cement compressor from the canal and remove any extruded cement around the periphery of the compressor.
15. **Implant Insertion**

Insert the selected femoral stem into the canal while verifying proper alignment. Fit the non-threaded, femoral stem driver into the stem driving platform and push the implant into place. Once the collar of the implant is fully seated on the calcar bone, excess cement is removed and the component is held firmly until the cement has fully cured (Figure 15).

16. **Final Trial Reduction**

A final trial reduction may be performed at this time using trial femoral heads (Figure 16).
17. **Femoral Head Assembly**

Clean and dry the neck taper with a clean, sterile cloth. Place the prosthetic femoral head on the neck taper and firmly impact with the femoral head impactor and a mallet several times (Figure 17).
### Synergy Femoral Stems & Head Components

#### Cemented Synergy Stems
*Forged CoCr*

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#### Conquest Fx™ Stems
*CoCr*

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### Zirconia 12/14 Taper Femoral Heads

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<th>28 mm</th>
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### CoCr 12/14 Femoral Heads

<table>
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<th>Neck Length</th>
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<tr>
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### Invis™ Distal Centralizers

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<th>O.D.</th>
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SYNERGY™

CATALOG INFORMATION
Femoral Instrumentation Tray No. 1
Cat. No. 7136-6201

Osteotomy Guide
Cat. No. 7136-4000

Box Osteotome
Cat. No. Size
7136-4002 Small
7136-4003 Large

Canal Finder
Cat. No. 7136-4001

T-Handle
Cat. No. 7136-4006

Tapered Reamer
Cat. No. Size
7136-6209  8-9-10
7136-6211  11-12
7136-6213  13-14
7136-6215  15-16
7136-6217  17-18

Broach Handle
(Two Per Set)
Cat. No. 7136-4007

Anteversion Handle
Cat. No. 7136-4012
Femoral Instrumentation Tray No. 2
Cat. No. 7136-6203

Tapered Broach
Cat. No. Size
7136-6308 8
7136-6309 9
7136-6310 10
7136-6311 11
7136-6312 12
7136-6313 13
7136-6314 14
7136-6315 15
7136-6316 16
7136-6317 17
7136-6318 18

Calcar Reamer
Cat. No. Size
7136-4004 Small
7136-4005 Large

Femoral Head Impactor
Cat. No. 7136-4009

Stem Inserter Frame
Cat. No. 7136-4008

Slap Hammer Weight
Cat. No. 7136-4010

Trial 12/14 Taper Femoral Heads

<table>
<thead>
<tr>
<th>Neck Length</th>
<th>Color Code</th>
<th>22 mm</th>
<th>26 mm</th>
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Cemented Stem Inserter
Cat. No. 7136-4014

Slap Hammer Weight
Cat. No. 7136-4010

Neck Color
- Green
- Yellow
- Red
- White
- Blue
- Black

Trial Neck
Cat. No. Size
7136-6408 8-13
7136-6414 14-18
7136-6508 8-13
7136-6514 14-18

Neck Color
- Green
- Yellow
- Red
- White
- Blue
- Black

Trial 12/14 Taper Femoral Heads

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| Cat. No.             | Size |
| 7136-6714            | 14   |
| 7136-6715            | 15   |
| 7136-6716            | 16   |
| 7136-6717            | 17   |
| 7136-6718            | 18   |
### CEMENT & ACCESSORIES

**PREP-IM® Kit**  
Cat. No. 12-1000  
Kit contains the following:

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<th>Description</th>
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<td>Buck Cement Restrictor, 18.5 mm</td>
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<tr>
<td>12-9419</td>
<td>Buck Cement Restrictor, 25 mm</td>
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<tr>
<td>11-0003</td>
<td>Femoral Canal Brush, 19 mm</td>
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<tr>
<td>11-1000</td>
<td>Concise Cement Sculps Kit</td>
</tr>
<tr>
<td>11-0037</td>
<td>Femoral Canal Suction Absorber, 19 mm</td>
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<tr>
<td></td>
<td>Disposable Cement Restrictor Tool (Available in kit only)</td>
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**Buck Femoral Cement Restrictor Inserter**  
Cat. No. 11-2428

**Concise™ Cement Sculps Kit**  
(one of each)  
Cat. No. 11-1000

**Vent Opening Tool**  
Cat. No. 11-0028

**Femoral Canal Suction Absorber**  
Cat. No. 11-0037  
Cat. No. 11-0038  

<table>
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**Buck Cement Restrictor**  
Cat. No. 12-9418  
Cat. No. 12-9419  
Cat. No. 7127-9420  
Cat. No. 7127-9421

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**Femoral Cement Compressor**  
Cat. No. 11-1434

**Femoral Pressurizers**  
Cat. No. 7127-0026  
Cat. No. 7127-0027  
Cat. No. 7127-0028

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<td>Large</td>
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**Disposable Femoral Cement Compressor Cap**  
Cat. No. 11-1435
MixOR™ Vacuum Mixing System with Syringe
Cat. No. 7127-0020

MixOR™ Pump and Hose Kit
Cat. No. 7127-0040

MixOR Hose Only
(not shown)
Cat. No. 7127-0041

MixOR Pump Only
(not shown)
Cat. No. 7127-0042

InjectOR™ Gun
Cat. No. 7127-2000

Connector, Schraeder
Cat. No. 7127-0050

Connector, Drager
Cat. No. 7127-0051

Connector, D.I.S.S.
Cat. No. 7127-0052

Palacos® Bone Cement
(available in U.S. and Canada only)
Cat. No. 12-0001

Osteopal® Bone Cement
(available in U.S. and Canada only)
Cat. No. 7127-1200
The Total Hip System is manufactured from materials as outlined below. The component material is provided on the outside carton label.

**Femoral Heads**
- **Zirconia**: ASTM F 799 and ISO 5832/12
- **Ceramic**: ASTM F 13356

**Femoral Components**
- **Acetabular shells**
- **Proximal pads**
- **Taper sleeves**
- **Distal sleeves**
- **Fixation screws and pegs**

**Acetabular components**
- **Acetabular liners**: UHMWPE ASTM F 648
- **Femoral centralizers**
- **Femoral stems with pads**: PMMA Not applicable
- **X-ray marking wire**: Co-Cr-Mo ASTM F 90 and ISO 5832/25

**Acetabular Reconstruction Ring**
- **Acetabular Reinforcement Ring**: CP Titanium ASTM F 667 and ISO 5832/2

**Porous titanium components and porous Co-Cr-Mo components are coated with commercially pure (CP) 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.

**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 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 phenomena, 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, 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 in a concentric manner.

Femoral components are available with a small, large (14/16), or 12/14 global taper (gage diameters 0.404, 0.564, and 0.500 inches, respectively).

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 (22, 28, or 35 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 (26 or 28 mm), bipolar or unipolar components.

Small, large, and 12/14 taper femoral component taper sleeves are 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 taper.

**Acetabular Components**

Acetabular components can be one piece all polyethylene or two-piece components 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 reinforcement and reconstruction rings are used with all polyethylene acetabular components.

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 femoral head.

**INDICATIONS, CONTRAINDICATIONS, AND ADVERSE EFFECTS**

Hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rela-
tively bYPASSING hips damaged as a result of trauma or noninflammatory degenerative joint disease (NIJD) 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 osteoarthritis with an unknown etiology period, in which the patient should be warned of an above normal danger of infection post-operatively: treatments of nonunions, femoral neck fracture and trochanteric fractures of the proximal femur with heads involvement that are unmanageable using other techniques; endoprostheses, femoral osteotomy, Girdlestone resection; fracture-dislocation of the hip, and correction of deformities.

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 indications previously listed.

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.:
   a. blood supply limitations;
16. Failure of the porous coating/substrate interface or hydroxyapatite coating/porous coating bonding may result in bead separation details.

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 activity, and that the implant can break or become damaged as a result of strenuous activity or trauma, and that it has a limited expected service life and may need to be replaced in the future. Do not use 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, beveling, or scoring 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 or 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, 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 the component insertion instruments.

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 wear in comparison to metal, care should be taken to prevent movements of the ceramic head. The component should be firmly seated with the component insertion instrument which may lead to failure of the procedure. During curing of the cement, care should be taken to prevent movement of the implant components.

10. 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 scapula 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 component liner into the shell can lead to disassociation of the liner from the shell.

11. Avoid repeated assembly and disassembly of the modular components which could compromise the critical locking action of the locking mechanism.

12. 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.

13. 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.

14. 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.

15. Do not resterilize ceramic femoral heads.

16. With the congenitally dislocated hip, special care should be taken to prevent sciatic nerve palsy. Also, note that the femoral canal is rudimentary and shallow. A false acetabulum should not ordinarily be used.

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 shell or fracture of the medullary canal.

18. Revision procedures for previous arthroplasty, Girdlestone, etc., are not recommended. They are associated with an increased risk of complications. Common errors include misplacement of the incision, inadequate exposure or mobilization of the femur, inadequate removal of ectopic bone, or improperreaming. 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 cements, bone chips, and ectopic bone, etc. Ectopic bone and bone spurs may lead to adverse local reactions or restricted motion. Range of motion should be thoroughly checked for 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 excess 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 leg.

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, wear, 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 and package label, 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 = 0.4 psig [0.03 bar]) 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 (393 millibars) minimum.
- Gravity Cycle: 270°F to 275°F (132°C to 135°C) with a minimum dwell time at temperature of 15 minutes, followed by a 1 minute purge and at least 15 minutes of vacuum drying at 10 inHg (393 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 implants are inadvertently contaminated, return the unsoldered prosthesis to Smith & Nephew for resterilization. Do NOT RESTERILIZE porous coated implants. The porous coating requires special cleaining 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 Concentration Exposure Time

<table>
<thead>
<tr>
<th>Gas</th>
<th>°C</th>
<th>%</th>
<th>Pressure</th>
<th>mL</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>10% EO</td>
<td>131°F</td>
<td>38°C</td>
<td>28 PSIA</td>
<td>60-650 mL</td>
<td>120 minutes</td>
</tr>
<tr>
<td>80-90% H2O</td>
<td>131°F</td>
<td>38°C</td>
<td>28-35 PSIA</td>
<td>60-650 mL</td>
<td>6 hours</td>
</tr>
<tr>
<td>100% EO</td>
<td>131°F</td>
<td>38°C</td>
<td>28 PSIA</td>
<td>60-650 mL</td>
<td>6 hours</td>
</tr>
<tr>
<td>10% EO</td>
<td>131°F</td>
<td>38°C</td>
<td>28 PSIA</td>
<td>60-650 mL</td>
<td>30 minutes</td>
</tr>
</tbody>
</table>

Suggested initial starting point for aeration validation is 12 hours at 122°F (50°C) with post sterilization. Consult aseptor 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 customers 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.
DESCRIPTION
Palacos R provides two separate, premeasured sterilized components which, when mixed, form a radiopaque, rapidly setting bone cement.

Powder Component—40 g
Methylmethacrylate—
  methyl acrylate copolymer containing chlorophyll 33.86–33.42 g
  Benzoyl peroxide, hydrous 75% 0.20–0.64 g
  Zirconium dioxide 5.94 g

Liquid (Monomer)—20 ml
Methylmethacrylate (stabilized with hydroquinone) 18.424 g
N,N-dimethyl-p-toluclidine 0.376 g
Chlorophyll 0.4 mg

Green pigment (chlorophyll) is added to both the powder (copolymer) and liquid (monomer) to produce a greenish tint in the final cement. This renders it possible to distinguish between bone and cement within the surgical field. As polymerization proceeds, a sticky dough-like mass is formed which can be molded for about 3 minutes (at 23°C [73°F]) after about 30 seconds. (See graphs and tables for temperature variations in package insert.)

INDICATIONS
Palacos R Bone Cement is indicated for use as bone cement in arthroplastic procedures of the hip, knee, and other joints to fix plastic and metal prosthetic parts to living bone when reconstruction is necessary because of osteoarthritis, rheumatoid arthritis, traumatic arthritis, avascular necrosis, nonunion of fractures of the neck of the femur, sickle cell anemia, osteoporosis, secondary severe joint destruction following trauma or other conditions (also for fixation of unstable fractures in metastatic malignancies), and revision of previous arthroplasty procedures.

CONTRAINDICATIONS
Palacos R bone cement is contraindicated in patients allergic to any of its components. The use of Palacos R is contraindicated in patients with infectious arthritis, and in active infection of the joint or joints to be replaced or if there is a history of such infection. The device is also contraindicated where loss of musculature or neuromuscular compromise in the affected limb would render the procedure unjustifiable.

WARNINGS
THE LIQUID MONOMER IS HIGHLY VOLATILE AND FLAMMABLE. APPROPRIATE PRECAUTION SHOULD BE TAKEN, PARTICULARLY WITH ITS USES IN THE OPERATING ROOM. THE MONOMER IS ALSO A POTENT LIPID SOLVENT AND SHOULD NOT BE ALLOWED TO COME IN DIRECT CONTACT WITH THE BODY OR RUBBER GLOVES BEFORE IT IS MIXED WITH THE POWDER.

CARE SHOULD BE EXERCISED DURING THE MIXING OF THE TWO COMPONENTS TO PREVENT EXCESSIVE EXPOSURE TO THE CONCENTRATED VAPORS OF THE MONOMER. THESE MAY IRRITATE THE RESPIRATORY TRACT AND EYES, AND MAY POSSIBLY BE HARMFUL TO THE LIVER. SKIN REACTIONS APPARENTLY RESULTING FROM CONTACT WITH THE MONOMER HAVE BEEN REPORTED.

It has been recommended by manufacturers of soft contact lenses that such lenses should be removed “in the presence of noxious and irritating vapors.” Since soft contact lenses are quite permeable, they should not be worn in an operating room where methyl methacrylate is being mixed.

Although the results of animal teratology studies were negative, the implantation of Palacos R bone cement in pregnant women or by women of childbearing age is contraindicated in patients allergic to any of its components, infectious arthritis, or by women of childbearing age. Although the results of animal teratology studies were negative, the implantation of bone cement is contraindicated in patients allergic to any of its components, infectious arthritis, or by women of childbearing age.

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Although the results of animal teratology studies were negative, the implantation of Palacos R bone cement in pregnant women or by women of childbearing age requires that the potential benefits be weighed against the possible hazards to the mother or fetus.

NOTE:
1. The copolymer powder does not withstand heat sterilization treatment. If a packet is accidentally opened, it must not be used.
2. Ascertain that sufficient material be removed from stock and stored at about 23°C (73°F) for 24 hours before use.

PRECAUTIONS
Data from clinical trials dictate the absolute necessity of strict adherence to good surgical principles and technique. Deep wound infection is a serious postoperative complication and may required total removal of the prosthesis and embedded cement. Deep wound infection may be latent and not manifest itself even for several years postoperatively.

Blood pressure, pulse, and respiration should be carefully monitored during and immediately after implantation of the bone cement. Any significant alteration in these vital signs should be corrected with appropriate measures. Care should be taken to clean and aspirate the proximal portion of the femoral medullary canal just prior to insertion of bone cement.

SUMMARY OF IMPORTANT MEDICAL INFORMATION* PALACOS R

The powder and liquid components have been carefully compounded. The entire contents of both the packet and ampule must be utilized. DO NOT USE PARTIAL AMOUNTS OF EITHER.

MIXING INSTRUCTIONS
1. Pour the liquid into a bowl.
2. Add the powder.
3. Stir vigorously, but carefully, for about 30 seconds until a sticky mass is obtained.

ADVERSE REACTIONS
A transitory fall in blood pressure immediately after implantation of bone cement and embolization can be observed. Rare cases have been reported in which the hypotension was associated with cardiac arrest and sudden death, connected with lung embolism.

Possible adverse reactions: Thrombophlebitis, pulmonary embolism, hemorrhage and hematoma, loosening or displacement of the prosthesis, superficial wound infection, deep wound infection, trochanteric bursitis, trochanteric separation, heterotopic new bone, short-term irregularities in cardiac conduction, myocardial infarction, cerebrovascular accident.

IMPORTANT SURGEON INFORMATION
ADVERSE REACTIONS AFFECTING THE CARDIOVASCULAR SYSTEM APPEAR TO BE RELATED TO THE INTRAVASATION OF UNPOLYMERIZED LIQUID MONOMER. THE MONOMER, HOWEVER, UNDERGOES RAPID HYDROLYSIS TO METHACRYLIC ACID. BETWEEN THE CIRCULATING CONCENTRATIONS OF METHACRYLIC ACID AND BLOOD PRESSURE CHANGES, NO CORRELATIONS HAVE BEEN ESTABLISHED. THE DIRECT PRESSURE FROM THE FORCING OF BOTH THE CEMENT AND THE PROSTHESIS INTO THE MEDULLARY CAVITY RESULT IN FAT AND BONE MARROW EMBOLI WHICH WOULD SEEM TO BE A GREATER RISK FOR THE CAUSE OF HYPOTENSION. THE REPORTED RARE INSTANCES OF CARDIAC ARREST ARE UNCLEAR, BUT MAY WELL RESULT FROM DIRECT PULMONARY EMBOLISM EFFECTS OR SECONDARY TO HYPOXIA CAUSED BY PULMONARY PHENOMENA.


THE DEGREE OF HYPOTENSION OBSERVED APPEARS TO BE MORE MARKED IN PATIENTS WITH ELEVATED OR HIGH NORMAL BLOOD PRESSURE, IN HYPOVOLMIC CONDITIONS AND IN INDIVIDUALS WITH PREEXISTING CARDIOVASCULAR ABNORMALITIES. THE DURATION OF THE HYPOTENSIVE REACTION MAY BEGIN 10–165 SECONDS AFTER INSERTION OF BOTH CEMENT AND PROSTHESIS AND MAY LAST UP TO 5–10 MINUTES.

INTRODUCTION OF LIQUID CEMENT UNDER PRESSURE INTO A CLEAN MEDULLARY CANAL HAS BEEN SHOWN TO APPRECIABLY ENHANCE THE FILLING OF THE BONE CAVITIES WITH MARKED IMPROVEMENT IN THE SECURITY OF THE BONE-CEMENT INTERFACE. CARE MUST BE EXERCISED IN INTRODUCING THE CEMENT CONTINUOUSLY FROM DISTAL TO PROXIMAL TO AVOID LAMINATIONS IN THE CEMENT.

CAUTION
Federal law restricts this device to sale, distribution, and use by or on the order of a physician.

Manufactured by Heraeus Kulzer GmbH, Kulzer Division 6393 Wehrheim, Federal Republic of Germany
Under license from E. Merck, Darmstadt, F.R. of Germany
Palacos is a trademark of Heraeus Kulzer GmbH.

Distributed by:
In Canada, Richards Surgical Limited
Smith & Nephew Richards Inc.
7666 Bath Road
1450 Brooks Road
Memphis, Tennessee 38116
(901) 896-2121
L4T1L2
Call Toll Free: 1-800-238-7538

Under license from E. Merck, Darmstadt
Fed. Rep. of Germany
*FOR MORE COMPLETE AND DETAILED DESCRIPTION, REFER TO PACKAGE INSERT SUPPLIED WITH THE PRODUCT.
Osteopal®
Radiopaque Bone Cement
Methyl Methacrylate, Methyl Acrylate Copolymer

DESCRIPTION
Osteopal® Bone Cement provides two separate, premeasured sterilized components which, when mixed, form a radiopaque rapidly setting bone cement. One component is supplied in a polyethylene-coated paper packet. It consists of 40 g power (copolymer) with the following composition:

- Methylmethacrylate – 33.20–33.50 g
- Benzoyl peroxide, hydrous 0.50–0.80 g
- Chloropropyl, hydrous 0.4 mg
- Benzoyl peroxide, hydrous 0.50–0.80 g

The other component is supplied in an amber ampoule. It consists of 20 ml liquid (monomer) with the following composition:

- Methylmethacrylate (stabilized with hydroquinone) 14.82 g
- N, N-dimethyl-p-toluidine 0.38 g
- Chloropropyl 0.4 mg
- Chloropropyl 0.4 mg

It has been recommended by manufacturers of soft contact lenses that such lenses should be removed in the presence of noxious and irritating vapors. Since soft contact lenses are quite permeable, they should not be worn in an operating room where methylmethacrylate is being mixed.

Although the results of animal teratology studies were negative, the implantation of Osteopal® Bone Cement in pregnant women or by women of childbearing age requires that the potential benefits be weighed against the possible hazards to the mother or fetus. The surgeon should decide whether the benefits expected from an arthroplasty outweigh any possible long-term adverse effects.

It has been reported in literature that N, N-dimethyl-p-toluidine (DMpT) may cause hyper-sensitivity and aseptic loosening of cemented total hip replacements. Testing (e.g., skin patch testing) may be necessary in high risk cases.

PRECAUTIONS
Data from clinical trials dictate the absolute necessity of strict adherence to good surgical principles and technique. Deep wound infection is a serious postoperative complication and may require total removal of the prostheses and embedded cement. Deep wound infection may be latent and not manifest itself even for several years postoperatively.

Blood pressure, pulse, and respiration should be carefully monitored during and immediately after implantation of the bone cement. Any significant alteration in these vital signs should be corrected with appropriate measures. Care should be taken to clean and aspirate the proximal portion of the femoral medullary canal just prior to insertion of bone cement.

The powder and liquid components have been carefully compounded. The entire contents of both packet and ampoule must be used. DO NOT USE PARTIAL AMOUNTS OF EITHER. Mix thoroughly and slowly for 20 seconds until a sticky mass is obtained.

ADVERSE REACTIONS
A transitory fall in blood pressure immediately after implantation of bone cement and endoprostheses can be observed. Rare cases have been reported in which the hypotension was associated with cardiac arrest and sudden death, connected with lung embolism.

The following additional adverse reactions have been reported with the use of methylmethacrylate-methylmethacrylate bone cements in orthopedic surgery:

- • Thrombophlebitis
- • Pulmonary embolism
- • Hemorrhage and hematoma
- • Loosening or displacement of the prosthesis
- • Others which have been observed;
- • Heterotopic new bone
- • Short-term irregularities in cardiac conduction
- • Myocardial infarction
- • Cerebrovascular accident

IMPORTANT SURGEON INFORMATION
ADVERSE REACTIONS AFFECTING THE CARDIOVASCULAR SYSTEM APPEAR TO BE RELATED TO THE INTRAVASATION OF UNPOLYMERIZED LIQUID MONOMER. THE MONOMER, HOWEVER, UNDERGOES RAPID HYDROLYSIS TO METHACRYLIC ACID. BETWEEN THE CIRCULATING CONCENTRATIONS OF METHACRYLIC ACID AND BLOOD PRESSURE CHANGES, NO CORRELATIONS HAVE BEEN ESTABLISHED. THE DIRECT PRESSURE FROM THE FORCING OF BOTH THE CEMENT AND THE PROSTHESIS INTO THE MEDULLARY CANAL RESULTS IN FAT AND BONE LAR ABNORMALITIES. THE DURATION OF THE HYPOTENSIVE REACTION MAY VARY DEPENDING ON THE HYPOTENSIVE REACTION MAY VARY DEPENDING ON THE DEGREE OF HYPOTENSION. THE REPORTED RARE INSTANCES OF CARDIAC ARREST ARE UNCLEAR, BUT MAY WELL RESULT FROM DIRECT PULMONARY EMBOLISM EFFECTS OR SECONDARY TO HYPOXIA CAUSED BY PULMONARY EMBOLI PHE-NOMENA.


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DOSE AND ADMINISTRATION

Osteopal® powder is double packaged. The inner polyethylene-coated paper packet is enclosed in a peelable film and paper packet which is sterilized with ethylene oxide and is enclosed in a non-sterile foil-lined protective overwrap. (At least one extra unit of Osteopal® should be available before starting a surgical procedure.) The ampoule containing the sterile filtered liquid monomer is packaged in a protective polyvinyl blister pack. The outside of ampoule and inside of blister pack are sterilized with ethylene oxide.

A unit is prepared by mixing the entire contents of one (1) packet of powder (40 g copolymer) with one (1) ampoule of liquid (20 ml monomer). One or two units will usually suffice, although this will depend upon the specific surgical procedure and the techniques employed. Each unit is prepared separately.

The following are required for preparation of the bone cement:

* Sterile working area
* Sterile porcelain or stainless steel bowls or a plastic bowl approved for use with monomers
* Sterile mixing spoons or spatulas
* Vacuum mixing system is optional.

The peelable film and paper package and the blister pack are opened by a circulating nurse or assistant and the sterile paper packet and ampoule are aseptically placed on a sterile table. The paper packet and the ampoule are opened under sterile conditions, since each ampoule power contains a premeasured quantity of copolymer to react with a premeasured quantity of monomer, care should be taken to mix the entire contents of one packet with the entire contents of one ampoule. Partial amounts should not be used.

MIXING INSTRUCTIONS

DO NOT CENTRIFUGE CEMENT. The zirconium dioxide may separate from the bulk cement.

Application by Hand – Pour the liquid into a bowl. Add the powder. Stir with a spatula slowly and carefully, for about 30 seconds, during which time it forms an homogenous fluid. Allow to stand for the escape of air until a dough-like mass is formed which does not adhere to rubber gloves.

IN ORDER TO ASCERTAIN THAT THE DOUGH-LIKE MASS DOES NOT STICK TO THE RUBBER GLOVES, DEPENDING ON ROOM TEMPERATURE, WAIT SEVERAL MINUTES (SEE CURVES). The working time may be affected by temperature (see curve and table for working times). The ideal working consistency of the Osteopal® cement for manual application to the bone is best determined by the surgeon’s experience in using the preparation. The entire procedure from mixing to complete insertion takes approximately eight to ten minutes. To assure adequate fixation, the prosthesis should be held securely in place without movement until the bone cement has fully hardened.

Vacuum Mixing – Add monomer first, the polymer powder, and follow the manufacturer’s instructions to vacuum mix.

Injection From a Cement Gun – Cement can be injected from the gun from approximately 2-3 minutes onwards, but has to be controlled carefully by the surgeon, or it may flow out of the bony cavity since it is still fluid at this stage. The use of a bone cement restrictor or a bond plug in the femoral canal is recommended. If the femoral canal is filled from the distal end, an air vent is not necessary. The implant should be in place approximately 5 to 7 minutes (depending on temperature) after mixing the components of the cement, which heats up at approximately 7-1/2 minutes and generally hardens by 9-1/2 minutes.

Whether applied by hand or by using a cement gun, pressure should be applied to the cement, until the prosthesis is inserted. Excess cement must be removed while it is still soft. When using a cement gun, time intervals may be longer due to reduced handling of the cement. Handling the cement warms it slightly during the early stages of polymerization and accelerates the process.

The times previously given for kneading, working and setting apply at approximately 20°C (68°F). Higher temperatures will reduce the required time and lower temperatures will prolong it. The temperature vs. time curves estimate temperature behavior of the mixed cement.

Curves will differ slightly according to environment conditions such as temperature, air flow rate, and relative humidity. It is advisable for the surgeon to go through the entire mixing, handling, and setting process in vitro before using Osteopal® Bone Cement.

The completion of polymerization occurs in the patient and is associated with the liberation of heat. The long-term effect of this heat on the tissues surrounding the bone cement are not known. To more rapidly dissipate the heat, the polymerizing cement may be irrigated with a cool physiologic saline solution.

DISPOSAL OF EXPIRED BONE CEMENT

Osteopal® has a shelf life of five years and should be disposed of after that time. The expired liquid monomer component can be mixed with the powder component in the usual manner to polymerize. The polymerized material can then be disposed of in a landfill. The liquid monomer can also be evaporated under a hood. The powder component can be disposed of in a landfill.

WARNINGS

1. The copolymer powder does not withstand heat sterilization treatment. If a packet is accidentally opened, it must not be used.
2. Ascertain that sufficient material be removed from inventory and stored at about 20°C (68°F) for 24 hours before use.

CAUTION

Federal Law (U.S.A.) restricts this device to sale, distribution, and use by or on the order of a physician.

HOW SUPPLIED

Carton consisting of:
1 packet copolymer powder containing 40g
1 ampoule liquid monomer containing 20 ml

NOTE:

Osteopal® is a medium viscosity cement.

Osteopal® bone cement is manufactured by: Heraeus Kulzer GmbH, Kulzer Division, Wehrheim/TS., Germany and is under license from: Merck KGaA, Darmstadt, Germany

Osteopal® is a trademark of Heraeus, Kulzer GmbH.

Osteopal®
Temperature vs. Time
Manual Application

Temperature vs. Time
Use with Vacuum Mixing

Distributed by:
Smith & Nephew, Inc.
Orthopaedic Division
Information:
For further information, please contact the Customer Service Department at (800) 238-7538 or (901) 396-2121.
3433121 Rev. B