Surgical technique
completed in conjunction with

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Nota Bene: The technique description herein
is made available to the healthcare professional
to illustrate the author’s suggested treatment
for the uncomplicated procedure. In the final
analysis, the preferred treatment is that which
addresses the needs of the patient.
**COBRA 12/14 TAPER STEM SPECIFICATIONS**

*For use with Smith & Nephew 12/14 Femoral Heads Only.*

<table>
<thead>
<tr>
<th>Cat. No.</th>
<th>Size</th>
<th>Neck Angle</th>
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**NECK HEIGHT (MM)**

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

   Use the osteotomy guide to determine level of resection. Osteotomize femoral neck.

2. **Prepare Acetabulum**

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

Open the medullary canal at the transected neck using the box chisel (Figure 1). Sound the femoral canal using the T-handle reamer (Figure 2).
4. **Femoral Broaching**

Start the broaching procedure along the mid-axis of the femur with the Size 1 broach and progressively broach to the appropriate femoral stem size. Seat the broach slightly below the level of the femoral neck resection to facilitate calcar reaming.

The Cobra broach is designed to provide a minimum 1.5-mm cement mantle per side. Additional cement mantle thickness is achieved by pressuring the cement into the cancellous bone. The broach is also slightly longer than the corresponding implant to accommodate the distal centralizer.
5. **Calcar Preparation**

With the final broach fully seated, remove the broach handle and ream the calcar with the appropriate calcar reamer; the smaller calcar reamer is used with broach Sizes 1–3, and the larger calcar reamer is used with broach Sizes 4 and 5. Plane the calcar until it is level with the broach.

6. **Trialing**

Remove the calcar reamer and place the matching trial neck onto the broach post. Select the trial femoral head of desired diameter and estimated neck length and reduce the hip to assess stability. Adjust the neck length of the trial femoral head until stability is achieved.

If trialing for the universal Bipolar or Unipolar, trial according to the appropriate technique for the selected device.
7. Preparing the Femoral Canal

Attach the broach handle to the broach and remove the broach. Use a curette to remove any grossly loose cancellous bone. Irrigate the canal with saline solution and pulsatile lavage to remove all debris. Continue preparing the femur with the femoral canal brush to remove any remaining weak cancellous bone, blood clots, and marrow fats. Repeat lavaging as necessary to remove all remaining debris.
8. Placing the BUCK™ Cement Restrictor

The proximal flange of the cement restrictor should always be larger than the distal canal diameter. Accurate cement restrictor depth placement is then determined by placing the Cobra stem (with distal centralizer) next to the inserter tool and adding 20 mm to the length.

If desired, remove the vent-occluding membrane by inserting the vent opening tool into the threaded end of the restrictor and pushing the pin through the vent hole. Remove and discard the plastic debris.

Screw the cement restrictor onto the inserter with a clockwise motion. Insert the device to the level of the medullary canal you have predetermined. Once this level is reached, disengage the restrictor from the inserter with a counterclockwise twisting maneuver. Remove the inserter from the medullary canal. Should it be necessary to remove the restrictor prior to cement insertion, it can be reattached to the inserter rod and pulled out of the canal. The surgeon may adjust the restrictor as many times as required.
9. 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.
10. **Injecting 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. Continue injecting cement until the canal is completely full and the distal tip of the nozzle is clear of the canal.
11. **Pressurizing Cement**

Break off the long nozzle and place the femoral pressurizer over the short nozzle. Apply the disposable femoral cement compressor into the mouth of the canal. 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 compressor from the canal and remove any extruded cement around the periphery of the compressor.
12. **Selecting Stem & Distal Centralizer**

Use the implant which corresponds to the last broach seated in the femur. An optional distal centralizer may be placed on the stem to provide neutral alignment and predictable cement mantle. Each implant has a corresponding distal centralizer which is intended to provide a uniform 1.5-mm distal cement mantle. Note, however, all of the stems will accommodate any of the available distal centralizers to address variations in distal femoral geometries. Using clean gloves, place the round plug of the selected centralizer into the hole at the distal end of the stem and push the centralizer superiorly until snug.

<table>
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<tr>
<th>Stem Size</th>
<th>Minimum Centralizer Size</th>
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<tr>
<td>Size 5</td>
<td>13 mm</td>
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</table>

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.
13. **Stem Insertion**

Insert selected femoral stem into canal. Fit femoral stem driver into stem driving platform and push into place (Figure 1).

Once collar is fully seated on calcar, trim away excess cement with Concise™ cement sculps. Maintain steady pressure on stem driver until cement is cured.
14. **Final Trial Reduction**

A final trial reduction may be performed at this time using trial femoral heads.

15. **Femoral Head Assembly**

Clean and dry the neck taper with a clean sterile cloth, place prosthetic femoral head on neck taper, and firmly impact several times with head impactor and mallet.
COBRA 12/14 TAPER FEMORAL STEM & HEAD COMPONENTS

Cobra 12/14 Taper Primary Collared Stems
Cobalt Chromium – ASTM F 799

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Zirconia 12/14 Taper Femoral Heads

Neck Length 22 mm 26 mm 28 mm
+0 7132-0026 7132-0028
+4 7132-0422 7132-0428
+8 7132-0822 7132-0828

CoCr 12/14 Taper Femoral Heads
Cobalt Chromium – ASTM F 799

Neck Length 22 mm 26 mm 28 mm 32 mm
-3 — — 7130-2803 7130-3203
+0 7130-2200 7130-2600 7130-2800 7130-3200
+4 7130-2204 7130-2604 7130-2804 7130-3204
+8 7130-2208 7130-2608 7130-2808 7130-3208
+12 7130-2212 7130-2612 7130-2812 7130-3212
+16 — — 7130-2816 7130-3216

Distal Centralizers

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Distal Centralizers

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COBRA 12/14 TAPER INSTRUMENTATION

12/14 Taper Sterilization Tray
Cat. No. 7136-9113

Trial 12/14 Taper Femoral Heads

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Osteotomy Guide
Cat. No. 7136-5036
Sizes 1–5

Box Osteotome
Cat. No. 7136-4002
Small

Blunt Medullary Reamer
Cat. No. 11-9657

Broach Handle
Cat. No. 7136-4007

Anteversion Handle
Cat. No. 7136-4012
Broaches/Trials
Cat. No.  Size
7136-5001  Size 1
7136-5002  Size 2
7136-5003  Size 3
7136-5004  Size 4
7136-5005  Size 5

Calcar Reamers
Cat. No.  Size
7136-5023  Size 1–3
7136-5025  Size 4–5

Trial Necks
Cat. No.  Size
7136-5081  Size 1
7136-5082  Size 2
7136-5083  Size 3
7136-5084  Size 4
7136-5085  Size 5

Femoral Component Driver
Cat. No. 11-9817

Femoral Head Impactor
Cat. No. 7136-4009
AdditionaL Cobra 12/14 Taper Instrumentation

Box Chisel
Cat. No. 7136-4003
Size Large

Slotted Hammer
Cat. No. MT-1901

Femoral Head Removal Tool
Cat. No. 11-9683
Includes:
- Pry Tool—Thin
- Platform—Left
- Pry Tool—Thick
- Platform—Right

Femoral Component Extractor
Cat. No. 11-9871

Side-Angled Curette
Cat. No. 11-9672
Size Right
11-9673
Size Left

Dead-Blow Mallet
Cat. No. 7136-2106
### C E M E N T & A C C E S S O R I E S

**PREP-IM® Kit**
Gat. No. 12-1000

Kit contains the following:

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<td>Buck Cement Restrictor, 25 mm</td>
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<td>Femoral Canal Brush, 19 mm</td>
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<tr>
<td>11-1000</td>
<td>Concise™ Cement Sculps Kit</td>
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<tr>
<td>11-0037</td>
<td>Femoral Canal Suction Absorber, 19 mm</td>
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**Buck Femoral Cement Restrictor Inserter**
Gat. No. 11-2428

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

**Buck Cement Restrictor**

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**Femoral Pressurizers**

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**Femoral Canal Brush**

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

Femoral Canal Suction Absorber
Cat. No. Size
11-0037 19 mm
11-0038 25 mm

Femoral Cement Compressor
Cat. No. 11-1434

Disposable Femoral Cement Compressor Cap
Cat. No. 11-1435

Palacos® R Radiopaque Bone Cement
Cat. No. 12-0001
Description
Single Unit (40 g Copolymer Powder; 20 ml Monomer Liquid); Sterile Monomer is Filtration-Sterilized; Powder is ETO-Sterilized.

MixOR® Vacuum Mixing System with Cartridge and Nozzle
Cat. No. 7127-0020
decrease pain, increase function, and increase mobility. The goals of total hip replacement are to decrease pain, increase function, and increase mobility.

### Femoral Components

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<thead>
<tr>
<th>Component</th>
<th>Material</th>
<th>Material Standards</th>
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<td>Ti-6Al-4V or Co-Cr-Mo</td>
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### Acetabular Reconstruction Ring

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<th>Material Standards</th>
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<td>ASTM F 648</td>
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<td>Acetabular Space</td>
<td>Co-Cr-Mo</td>
<td>ASTM F 799 and ISO 5832-35</td>
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<td>Co-Cr-Mo</td>
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### Femoral Heads

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<th>Component</th>
<th>Material</th>
<th>Material Standards</th>
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<td>Femoral Heads</td>
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### Acetabular Components

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<tr>
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<th>Material</th>
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### Contraindications

- Conditions that would eliminate or tend to eliminate adequate blood supply to the prosthesis and/or bone support, e.g., hypertension, peripheral vascular disease, severe arteriosclerosis, peripheral nerve deficit, or muscle deficiency.
- 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., joint, muscle, joint defects, multiple joint disabilities, etc.
- Skulldy.
- The zirconia ceramic head is contraindicated for use with any other product than an UHMW polyethylene cup or a metal backed UHMW polyethylene cup.

### Possible Adverse Effects

1. Wear of the polyethylene articulating surfaces of acetabular components has been reported following total hip replacement. Higher rates of wear may be indicated in 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.
2. With all joint replacements, asymptomatic, localized, progressive bone resorption (osteoossity) may occur around the prosthetic components as a consequence of foreign-body reaction to particulate wear debris. Particles are generated by interconnection between components, as well as between the components and bone, primarily through wear mechanisms of abrasion, erosion, and fatigue. Secondarily, particles may also be generated by third-body particles lodged in the polyethylene articular surface. Osteolysis can lead to future complications necessitating the removal or replacement of prosthetic components.
3. Loosening, bending, cracking, or fracture of implant components may result from failure to observe the Warnings and Precautions below. Fracture of the implant can occur as a result of trauma, strenuous activity, improper alignment, or duration of service.
4. Dislocations, subluxation, decreased range of motion, or lengthening or shortening of the femur caused by improper neck selection, positioning, loosening of acetabular or femoral components, extra-osseous penetration of the femoral prosthesis through the shaft of the femur, fracture of the acetabulum, intraarticular protrusion of acetabular component, femoral impingement, periarticular calcification, and trochanteric fragmenting.
5. 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 b想着choring, and/or severe osteoporosis.
6. Infection, both acute post-operative wound infection and late deep wound sepsis.
7. Neuropathies; femoral, sciatic, peroneal nerve, and lateral femoral cutaneous neuropathies have been reported. Temporary or permanent nerve damage resulting in pain or numbness of the affected limb.
8. Wound hematoma, thromboembolic disease including venous thrombosis, pulmonary embolus, or myocardial infarction.
9. Myositis ossificans, especially in males with hypertrophic arthritis, limited pre-operative range of motion and/or previous myositis. Also, periacetabular calcification with or without impingement to joint mobility can cause decreased range of motion.
10. Trochanteric nonunion usually associated with early weight bearing and/or improper fixation of the trochanter, when a transtrochanteric surgical approach is used.
11. Although rare, metal sensitivity reactions and/or allergic reactions 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.
16. Failure of the porous coating/substrate interface or hydroxyapatite coating/porous coating bonding may result in bead separation, bead dimpling, or bead delamination.

17. Stem migration or subsidence has occurred in conjunction with compaction grafting procedures usually resulting from insufficient graft material or improper postoperative techniques. Varus stem align- ment 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 muscle, and that the implant may 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 use components from different manufacturers. Additional Warnings and Precautions may be included in component literature.

Proper Care

1. Use extreme care in handling and storage of implant components. Cutting, reaming, or any internal stresses that are not obvious to the eye and may lead to frac- ture of the component. Implants and instruments should be pro- tection 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 infre- quent, should be considered, tested for (if appropriate), and ruled out preoperatively.

3. Fixation and expected longevity of components expected to be left in place should always be thoroughly assessed. Instruments which have experienced extensive use or excessive force are susceptible to fracture. Instruments should be examined preoperatively and wear patterns noted.

4. Do not cold water quench ceramic components and never sterilize ceramic heads while fixed on the stem taper. (See sterilization sec- tion, below.)

5. Select components that the Zirconia ceramic head always articulated with a UHMW polyethylene cup or an acetabular UHMW polyethylene cup. Zirconia ceramic should never articulate against metal because severe wear of the metal will occur.

6. Select only Smith & Nephew femoral components that indicate their use with ceramic heads. This is important because the taper of ceramic should be firmly seated on the femoral component to prevent disassociation.

7. The Zirconia ceramic head is composed of a new ceramic material with limited clinical history. Although mechanical testing demon- strates that when used with a polyethylene acetabular component, the ultra-stabilized zirconia ball produces a relatively low amount of particulates, the total amount of particulate remains undeter- mined. Because of the limited clinical and preclinical experience, the biological effect of these particulates can not be predicted.

Intraoperative

1. General principles of patient selection and sound surgical judg- ment apply. The correct selection of the implant is extremely important. The appropriate type and size should be selected for patients of normal body build and biological factors such as patient age and activity levels, weight, bone and mus- cle conditions, any prior surgery and anticipated future surgeries, etc. Greater detail selection of the 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 bone.

2. Correct selection of the neck length and cup, and stem position- ing, 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 compo- nent insertion instruments.

Care should be taken not to scratch, bend (with the exception of the Reconstructing Rings) or cut metal components during surgery for the reasons stated in Number One of the “Preoperative” section of “Warnings and Precautions.”

A 4.1 mm or 16 mm femoral head should not be used with any small taper stems.

Distal sleeves should not be used to bridge cortical defects that lie within 25 mm of the tip of the base stem.

Matrix small taper stem sizes 8S - 10L must have a minimum neck length of 44 mm when used with a bipolar component.

Modular heads and femoral components should be from the same manufacturer to prevent mismatch of tapers.

Clean and dry stem taper prior to impacting the femoral head or taper sleeve. The modular head component must be firm- ly seated on the femoral component to prevent disassociation.

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-bear- ing status should be individualized with the non or partial weight-bearing period extended.

2. Patients should be warned against resisted 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 bedrails, change of position, 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 imme- diate postoperative conditions to detect long-term evidence of changes in position, loosening, bending and/or cracking of compo- nents or bone loss. With evidence of these conditions, patients should be closely observed through the periods of further dereliction evaluated, and the benefits of early revision considered.

6. Prophylactic antibiotics should be administered to the patient simi- lar to those suggested by the American Heart Association for con- ditions or situations that may result in bacteremia.

PACKAGING AND LABELING

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

Metal Components

Most 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 from all metal surfaces, with contact from metal or other hard objects which could damage the product. The following process parameters are recommended for these devices:

- **Vacuum Cycle:** 4 pulses (Maximum = 26.0 psig (2.8 bars) & Minimum = 0.10 inHg (339 millibars)) with a minimum dwell time of 4 minutes. Force is applied and removed from the modular compo- nents which could compromise the critical locking action of the locking mechanism.

- **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 (339 mil-libars) minimum.

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

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

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

Plastic Components

Plastic metal components may be resterilized by ethylene oxide gas. The fol- lowing parameters are recommended as starting points for cycle vali- dation by the health care facility:

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Suggested initial starting point for aeration validation is 12 hours at 122°F (50°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.

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.
DESCRIPTION
Palacos R Cement 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%  0.20–0.4 g
  Zirconium dioxide  5.94 g
Liquid (Monomer)—20 ml
Methylmethacrylate (stabilized with hydroquinone)  18.424 g
N,N-dimethyl-p-toluidine  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 its 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 USE 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 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 require 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.

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 transient 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.

Possible adverse reactions: Thrombophlebitis, pulmonary embolism, hemorrhage associated with 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, myoccardial infarction, cerebrovascular accident.

IMPORTANT SURGEON INFORMATION

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.

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*FOR MORE COMPLETE AND DETAILED DESCRIPTION, REFER TO PACKAGE INSERT Supplied with the Product.