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.
## Stem Specifications

<table>
<thead>
<tr>
<th>Size</th>
<th>Neck Angle</th>
<th>Distal Cross Section Length</th>
<th>A-P Width</th>
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**NECK LENGTH MM**

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For use with Smith & Nephew 12/14 femoral heads only.
Surgical Templates are available by contacting your Smith & Nephew Representative or Customer Service.

Spectron EF 3 and +16 CoCr femoral heads available in 28 mm and 32 mm only.

* Denotes skirted head

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 the level of resection, using one of the following techniques:

   A. Place the template over the X-ray of the hip. Determine the stem size. Determine length of femoral head to be used. A graduation scale can be found on the medial aspect of the stem on the template. Make note of how many graduations above the lesser trochanter where the osteotomy will take place, as determined by the collar of the stem.

   In the O.R., place the osteotomy guide on the femur by referencing the lesser trochanter at the same graduation mark as noted during templating. Osteotomize the neck.

   B. Place the template over the X-ray of the hip. Determine the stem size. Determine length of femoral head to be used. Determine the base neck length on the standard offset stem as indicated on the template. Add to this number the length of the femoral head.

   In the O.R., place the greater trochanter block on the osteotomy guide at this numerical position. If the number does not match perfectly, use the lower number. Place the guide on the femur by resting the block on the top of the greater trochanter. Osteotomize the 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. Stay posterior and lateral in order to obtain a neutral stem position (Figure 1). Sound the femoral canal using the blunt medullary 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 Spectron EF broach is designed to provide a minimum 1.5 mm cement mantle per side. Additional cement mantle thickness is achieved by pressurizing the cement into the cancellous bone. The broach is 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 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 and reduce the hip to assess stability. Soft tissue tension can be improved by using the high offset trial neck instead of the standard offset trial neck without increasing leg length.

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

<table>
<thead>
<tr>
<th>Femoral Head And Neck Length Options</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial Color</strong></td>
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<tr>
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</tr>
<tr>
<td>Yellow</td>
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<tr>
<td>Red</td>
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<tr>
<td>White</td>
</tr>
<tr>
<td>Blue</td>
</tr>
<tr>
<td>Black</td>
</tr>
</tbody>
</table>

*Denotes skirted heads.
7. Placing The Buck Cement Restrictor

The proximal flange of the cement restrictor should always be larger than the distal canal diameter. Use the canal sizer to determine the distal canal diameter. Accurate cement restrictor depth placement is then determined by placing the Spectron EF stem (with attached distal centralizer) next to the inserter tool and adding 20 mm to the length (see chart below).

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.

Thread the cement restrictor onto the inserter using a clockwise motion. Insert the device to the level of the medullary canal that has been predetermined. Once this level is reached, disengage the restrictor from the inserter using a counterclockwise twisting motion. 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. The surgeon may adjust the restrictor as many times as required.

<table>
<thead>
<tr>
<th>Stem Size</th>
<th>BUCK Cement Restrictor Insertion Depth (mm)</th>
</tr>
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<tbody>
<tr>
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<td>4</td>
<td>160</td>
</tr>
<tr>
<td>5</td>
<td>160</td>
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</tbody>
</table>
8. **Preparation of the Femoral Canal**

Attach the broach handle to the broach and remove the broach. 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.

9. **Drying the Femoral Canal**

Insert the femoral canal suction absorber into the femoral canal to dry the canal while mixing the cement.
10. **Loading Cement**

Load cement powder and monomer into the MixOR™ funnel. If you load powder first, use the funnel for both. If you prefer monomer first, load monomer without funnel, then attach and load powder.

11. **Mixing**

Mix the cement according to manufacturer’s instructions using brisk plunging movements. Turn handle at top and bottom of cartridge to achieve optimal homogenous mixture. Refer to MixOR instruction card for complete mixing technique.

12. **Injecting Cement**

After removing the femoral canal suction absorber use pulsatile lavage. Insert the nozzle of the cement gun to the top of the Buck Cement Restrictor and 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.
13. **Pressurizing Cement**

Break off the long nozzle and place the femoral pressurizer over the short nozzle. Apply the disposable femoral pressurizer into the mouth of the canal. This will occlude the canal and compress the cement. Maintain firm pressure until the cement is in a doughy state and can withstand displacement and will allow for proper cement interdigitation into trabecular bone. Withdraw the femoral pressurizer and remove any extruded cement around the periphery of the canal.
14. **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 superiority 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.

<table>
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<tr>
<th>Stem Size</th>
<th>Minimum Centralizer Size</th>
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<td>Sizes 4, 4H</td>
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<tr>
<td>Sizes 5, 5H</td>
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</table>
15. **Stem Insertion**

Insert the selected femoral stem into the canal. Fit the femoral stem driver into the stem driving platform and push into place. Advance the stem approximately 1 cm per second to avoid air inclusions in the stem/cement interface.

Trim away excess cement with Concise™ cement sculps. Remove the stem driver and maintain steady pressure with the thumb on the stem taper until cement is cured.

16. **Final Trial Reduction**

A final trial reduction may be performed at this time using trial femoral heads.
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 several times with a head impactor and a mallet.
### Spectron EF 12/14 Femoral Stem & Head Components

#### Primary Collared Stems
- **Cobalt Chromium – ASTM F 799**

<table>
<thead>
<tr>
<th>Size</th>
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<th>Implant Broach/Trial Neck</th>
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#### Primary High Offset Stems
- **Cobalt Chromium – ASTM F 799**

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#### Zirconia 12/14 Taper Femoral Heads
- **Neck Length**
  - 22 mm: 7132-0026, 7132-0028
  - 26 mm: 7132-0426, 7132-0428
  - 28 mm: 7132-0826, 7132-0828

#### Spectron Invis™ Distal Centralizers
- **Cat. No.**
- **Size**
- **O.D.**
  - 7131-3101: 1, 8 mm
  - 7131-3102: 2, 9 mm
  - 7131-3103: 3, 10 mm
  - 7131-3104: 4, 12 mm
  - 7131-3105: 5, 13 mm

#### CoCr 12/14 Taper Femoral Heads
- **Neck Length**
  - 22 mm: 7130-2200, 7130-2204, 7130-2208, 7130-2212, 7130-2216
  - 26 mm: 7130-2600, 7130-2604, 7130-2608, 7130-2612, 7130-2616

#### Invis™ Distal Centralizers
- **Cat. No.**
- **O.D.**
- **Cat. No.**
- **O.D.**
  - 7131-3208: 8 mm, 7131-3215: 15 mm
  - 7131-3209: 9 mm, 7131-3216: 16 mm
  - 7131-3210: 10 mm, 7131-3217: 17 mm
  - 7131-3211: 11 mm, 7131-3218: 18 mm
  - 7131-3212: 12 mm, 7131-3219: 19 mm
  - 7131-3213: 13 mm, 7131-3220: 20 mm
  - 7131-3214: 14 mm, 7131-3221: 21 mm
CATALOG INFORMATION

S P E C T R O N  E F  1 2 / 1 4  I N S T R U M E N T A T I O N

12/14 Dual Offset Sterilization Tray
Cat. No. 7136-9112

12/14 Standard Offset Sterilization Tray
(Not Shown)
Cat. No. 7136-9113

Osteotomy Guide
Cat. No. 7136-5036
Size: 1-5

Broach Handle
Cat. No. 7136-4007

Box Chisel
Cat. No. 7136-4002
Size: Small

Anteversion Handle
Cat. No. 7136-4012

Blunt Medullary Reamer
Cat. No. 11-9657

Broaches/Trials
Cat. No. 7136-5001
Size: 1
7136-5002
Size: 2
7136-5003
Size: 3
7136-5004
Size: 4
7136-5005
Size: 5
SPECTRON EF 12/14 INSTRUMENTATION

**Femoral Impactor**
Cat. No. 7136-4009

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

**Femoral Component Driver**
Cat. No. 11-9817

**12/14 Taper Trial Necks**

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**Femoral Component Driver**
Cat. No. 11-9817

**12/14 Taper Trial Necks**

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**Trial 12/14 Taper Femoral Heads**

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<td>7135-2816</td>
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</tr>
</tbody>
</table>

*Space allowed for 26 mm and 28 mm heads in instrument tray.*
ADDITONAL SPECTRON EF 12/14 INSTRUMENTS

**Box Chisel**
- **Cat. No.** 7136-4003
- **Size** Large

**Femoral Component Extractor**
- **Cat. No.** 11-9871

**Slotted Hammer**
- **Cat. No.** MT-1901

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

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

**Dead Blow Mallet**
- **Cat. No.** 7136-2106

**Canal Sizer**
- **Cat. No.** 7136-7301
**CEMENT & ACCESSORIES**

**Buck Cement Restrictor**
Cat. No. 12-9418
Size 18.5 mm
Cat. No. 12-9419
Size 25 mm
Cat. No. 11-0003
Description Femoral Canal Brush, 19 mm
Cat. No. 11-1000
Description Concise Cement Sculps Kit
Cat. No. 11-0037
Description Femoral Canal Suction Absorber, 19 mm

**Femoral Pressurizers**
Cat. No. Size
7127-0026 Small
7127-0027 Medium
7127-0028 Large

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

**Buck Femoral Cement Restrictor Inserter**
Cat. No. 11-2428

**PREP-IM® Kit**
Cat No. 12-1000
Kit contains the following:
Cat. No. Description
12-9418 Buck Cement Restrictor, 18.5 mm
12-9419 Buck Cement Restrictor, 25 mm
11-0003 Femoral Canal Brush, 19 mm
11-1000 Concise Cement Sculps Kit
11-0037 Femoral Canal Suction Absorber, 19 mm
— Disposable Cement Restrictor Tool
(Available in kit only)

**Femoral Canal Brush**
Cat. No. O.D.
11-0003 19 mm
11-0033 12.5 mm

**MixOR™ Vacuum Mixing System with Syringe**
Cat. No. 7127-0020

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

**Femoral Cement Compressor**
Cat. No. 11-1434
**CEMENT & ACCESSORIES**

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

- **Connector, Schraeder**
  Cat. No. 7127-0050

- **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

- **Connector, Drager**
  Cat. No. 7127-0051

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

- **InjectOR Gun**
  Cat. No. 7127-2000

- **Palacos®**
  (available in US and Canada only)
  Cat. No. 12-0001

- **Osteopal®**
  (available in US and Canada only)
  Cat. No. 7127-1200
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 1/2 taper sizes. Never place more than one taper sleeve on a femoral component.

Femoral Heads

Cobalt chromium (22, 26, 28, and 32 mm) and ceramic heads (22, 26, 28, and 32 mm) are available in multiple neck lengths for proper anatomical and musculoskeletal fit. Heads are highly polished for reduced friction and wear. The following zirconia ceramic heads are available for use only with small (0.404) and large (0.564) taper femoral components.

Zirconia Ceramic

<table>
<thead>
<tr>
<th>Head</th>
<th>Diameter</th>
<th>Neck Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>42-7815</td>
<td>32 mm</td>
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<tr>
<td>42-7816</td>
<td>32 mm</td>
<td>Long 4 mm</td>
</tr>
<tr>
<td>42-7817</td>
<td>32 mm</td>
<td>X-Long 8 mm</td>
</tr>
<tr>
<td>42-7818</td>
<td>28 mm</td>
<td>Standard 0 mm</td>
</tr>
<tr>
<td>42-7819</td>
<td>28 mm</td>
<td>Long 4 mm</td>
</tr>
<tr>
<td>42-7820</td>
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</tr>
</tbody>
</table>

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

In addition to the components listed above, the following components are available for use only with small (0.404) taper femoral components.

Zirconia Ceramic

<table>
<thead>
<tr>
<th>Head</th>
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<tr>
<td>7132-0006</td>
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</table>

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

Femoral Heads

Ceramic heads are available only for use with 12/14 taper femoral components.

Zirconia Ceramic

<table>
<thead>
<tr>
<th>Head</th>
<th>Diameter</th>
<th>Neck Length</th>
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<tr>
<td>7132-0029</td>
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<td>28 mm</td>
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<td>7132-0031</td>
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<td>7132-0032</td>
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<td>7132-0033</td>
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<td>7132-0034</td>
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<td>X-Long 8 mm</td>
</tr>
<tr>
<td>7132-0035</td>
<td>22 mm</td>
<td>Standard 0 mm</td>
</tr>
</tbody>
</table>

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 component.

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

INDICATIONS, CONTRAINDICATIONS, AND ADVERSE EFFECTS

Ht components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in reha-

bilitating hips damaged as a result of trauma or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

Ht components are also indicated for inflammatory degenerative joint disease including Rheumatoid arthritis, ankylosing spondylitis, and a variety of diseases and ailments, and congenital dysplasia; old, remote osteomyelitis with an extended drainage-free period, in which case, the patient should be warned that normal danger of infection post-

operatively; treatments of nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with heads involvement that are unmanageable using other techniques; endoprostheses, femoral osteotomy, or Girdlestone resection; fracture-dislocation of the hip; and correction of deformity.

Acetabular 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 listed previously.

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

Contraindications

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

b. insufficient quantity or quality of bone support, e.g., osteoporosis, or metabolic disorders which may impair bone formation, and osteomalacia; and

c. infections or other conditions which lead to increased bone resorption.

2. Mental or neurological conditions which tend to impair the patient's ability or willingness to restrict activities.

3. Physical conditions or activities which tend to place extreme loads on implants, e.g., Charcot joints, muscle deficiencies, multiple joint disabilities, etc. as between the components and bone, primarily through wear mechanisms of abrasion, adhesion, and fatigue. Secondary, 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. Lossening, 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, stress, activity, improper alignment, or duration of service.

4. Dislocations, subluxation, decreased range of motion, or lengthen-

ing or shortening of the femur caused by improper neck selection, positioning, loosening of acetabular or femoral components, exces-

sive bone loss, penetration of the femoral prosthesis through the shaft of the femur, fracture of the acetabulum, intraarticular protrusion of acetabular component, femoral impingement, periarthritic calcifi-

cation, and excessive reaming.

5. Fracture of the pelvis or femur: postoperative pelvic fractures are usually stress fractures. Femoral fractures are often caused by dislocation of the femoral head or during hip repositioning, etc.

Intraoperative fractures are usually associated with old congenital deformity, improper stem selection, improper broaching, 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 perma-

nent nerve damage resulting in pain or numbness of the affected limb.

8. Wound hematoma, thromboembolic disease including venous thrombosis, pulmonary embolus, or myocardial infarction.

9. Myositis ossificans, especially in males with hypertrophic arthritis, limited pre-operative range of motion and/or previous myositis. Also, periarticular calcification with or without impairment to joint mobility can cause decreased range of motion.

10. Trochanteric nonunion usually associated with early weight bearing and/or improper fixation of the trochanter, when a transtrochanteric surgical approach is used.

11. Although rare, metal sensitivity reactions and/or allergic reactions to foreign materials have been reported in patients following joint replacement.

12. Damage to blood vessels.

13. Traumatic arthritis 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 medialization, or muscle deficiency.
16. Failure of the porous coating/substrate interface or hydroxylapatite coating may result in loosening, bending and/or fracture of components. Increased neck length and varus or improper positioning of components. Postoperative instability, changes in position, loosening, bending and/or cracking of components, and patient care, are extremely important. Gradual weight bearing is begun after surgery in the initial stages. 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 unsanitary activity, particularly use of tooilet facilities and other activities requiring excessive motion of the hip.

3. Use extreme care in patient handling. Support should be provided to the operative leg when moving the patient. While placing the patient on bedpans, changing dressings, and clothing, and similar activities, precautions should be taken to avoid placing excessive load on the operative part of the body.

4. Postoperative therapy should be structured to regain muscle strength around the hip and a gradual increase in activities.

5. Periodic x-rays are recommended for close comparison with immediate postoperative conditions to detect long-term evidence of changes in position, loosening, bending and/or cracking of components or bone loss. With evidence of these conditions, patients should be closely observed, the possibilities of further deterioration evaluated, and the benefits of early revision considered.

6. Prophylactic antibiotics should be recommended to the patient similar to those suggested by the American Heart Association for conditions or situations that may result in bacteremia.

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

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

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

- **Prevacuum Cycle:** 4 pulses (maximum = 26.0 psig [2.8 bars] & minimum = 10.0 ± 1 mg [339 millibars]) with a minimum dwell time of 4 minutes at 270°F to 275°F (132°C to 135°C), followed by a 1 minute purge and an additional 15 minutes of vacuum drying at 10 kGy (339 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 kGy (339 millibars) minimum.

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

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

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

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

- **Sterilant**
  - **Temp.**
  - **Humidity**
  - **Maximum Pressure**
  - **Concentration**
  - **Exposure Time**

<table>
<thead>
<tr>
<th>Sterilant</th>
<th>Temp.</th>
<th>Humidity</th>
<th>Maximum Pressure</th>
<th>Concentration</th>
<th>Exposure Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>0% CO2</td>
<td>130°F</td>
<td>40-60%</td>
<td>15 psig (101.3 kPa)</td>
<td>550 mg/L</td>
<td>6 hours</td>
</tr>
<tr>
<td>10% CO2</td>
<td>130°F</td>
<td>40-60%</td>
<td>15 psig (101.3 kPa)</td>
<td>550 mg/L</td>
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<td>15 psig (101.3 kPa)</td>
<td>550 mg/L</td>
<td>6 hours</td>
</tr>
</tbody>
</table>

Suggested initial starting point for aeronation validation is 12 hours at 122°F (50°C) with power aerator. 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.

6. Matrix small taper stem sizes 8S–10L must have a minimum neck length of 10 mm when used with a bipolar component.
SUMMARY OF IMPORTANT MEDICAL INFORMATION* PALACOS R

DESCRIPTION
Palacos R provides two separate, premixed 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-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 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 osteoartitis, 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 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 postsurgical 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.

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 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 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 CANAL RESULTS 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 NORMAL BLOOD PRESSURE. IN HYPOVOLEMIC 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:
Smith & Nephew Richards Inc. 7666 Bath Road
1450 Brooks Road
Memphis, Tennessee 38116
(901) 396-2121
Call Toll Free: 1-800-238-7538

In Canada, Richards Surgical Limited
7666 Bath Road
Mississauga, Ontario
L4T1L2
(416) 677-9744
Under the license of E. Merck, Darmstadt Fed. Rep. of Germany

*FOR MORE COMPLETE AND DETAILED DESCRIPTION, REFER TO PACKAGE INSERT SUPPLIED WITH THE PRODUCT.
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:

- Methyleneacrylate – methyl acrylate copolymer containing chlorophyll 33.20–33.50 g
- Benzoyl peroxide, hydrous 75% 0.50–0.80 g
- Zirconium dioxide 6.00 g

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

- Methyleneacrylate (stabilized with hydroquinone) 18.42 g
- N, N-dimethyl-p-toluidine 0.38 g
- Chlorophyll 0.4 mg

The liquid monomer is sterile filtered. The powder is sterilized with ethylene oxide. The polyethylene-coated paper packets containing the powder as well as the exterior of the ampoule containing the liquid are sterilized with ethylene oxide.

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.

When the powder (copolymer) and the liquid (monomer) are mixed, the dimethyl-p-toluidine (DMpT) in the liquid activates the benzoyl peroxide catalyst in the powder. This initiates the polymerization of the monomer which then binds together granules of polymer. As polymerization proceeds, a sticky dough like mass is formed which can be molded. (See curves for temperature variations.) After mixing, the cement can be introduced into the bone cavity and compressed with the use of a pressurizer. The prosthesis should be inserted within 5-7 minutes after the start of mixing (depending on temperature). Polymerization is an exothermic reaction which causes heat production. Although the spontaneous generation of heat accelerates the reaction, the polymerization of this self-curing resin occurs even if the temperature is reduced by irrigation with a cool physiologic saline solution.

ACTION

Osteopal® Bone Cement is an acrylic cement-like substance which allows seating and fixation of prosthesis to bone. After complete polymerization, the cement is a buffer for even weight distribution and other stresses between prosthesis and bone. Insoluble zirconium dioxide provides the radiopaque quality of the formulation.

INDICATIONS

Osteopal® 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 osteoarthrosis, 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

Osteopal® Bone Cement is contraindicated in patients allergic to any of its components. The use of Osteopal® 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

Prior to using Osteopal® Bone Cement, surgeons should be thoroughly familiar with its properties, handling characteristics and application to arthroplasty. (See Description, Precautions and Dosage and Administration.) It is advisable for the surgeon to go through the entire mixing, handling, and setting process in vitro before using Osteopal® bone cement in an actual surgical procedure for the first time.

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 lipop 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 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 longterm 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 endoprosthesis 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
- Trochanteric separations
- 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 BLEEDING 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 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 EMBOLI PNEUMONIA.

Inroduction of such episodes, the medullary cavity should be cleaned thoroughly prior to the application of the cement. Further, during the application of the cement, the medullary canal pressure should be minimized by suctioning and venting the cavity. Another alternative is using a plug. The circulating blood volume should be kept well balanced.

The degree of hypotension observed appears to be more marked in patients with elevated or high normal blood pressure. In hypo-volemic conditions and in individuals with preexisting cardiovascular abnormalities, the duration of the hypotensive reaction may be 5–15 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.

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DOSEAGE 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 packet of 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 20 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 mixing time may be affected by temperature (see curve and table for working and hardening 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 with 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

A: MIXING PHASE
B: DOUGH PHASE
C: WORKING PHASE
D: HARDENING PHASE

Temperature vs. Time
Use with Vacuum Mixing

Distributed by:
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