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 authors’ suggested treatment for the uncomplicated procedure. In the final analysis, the preferred treatment is that which addresses the needs of the patient.
The SPECTRON cemented revision system has a proven track record of over 15 years. The revision femoral stems contain the same features that have made the primary SPECTRON stems clinically successful.

**Circulotrapezoidal Neck** — provides increased range of motion compared to a circular neck of the same strength.

**Anterior/Posterior Grooves** — increases rotational stability without increasing cement stresses.

**Trapezoidal Stem Cross Section** — ideal stem geometry to minimize tensile stresses and aid in compressing the cement under load.

**Longitudinal Stem Taper** — allows the stresses to be distributed throughout the length of the implant and enhances compressive loading of the cement.

**Forged Cobalt Chrome Material** — material of choice for cemented stems to reduce stem fractures and minimize generation of third particle debris.

The system is comprised of 21 implants in various stem lengths and head/neck offsets.

**Long Straight Implant** — designed for revision of femoral distal defects such as holes, windows, or fractures around the end of the previously implanted stem.

**Neck Replacement Implant** — In addition to the indications for the Long Straight implant, the Neck Replacement implant can be used in both primary and revision arthroplasty where bone stock is deficient to the neck area due to femoral neck fracture or failure of a primary stem leading to resorption or destruction of the calcar area.

The instrumentation is designed for a broach-only technique with a minimum number of procedural steps. This makes for a simple, straightforward surgical technique that is highly reproducible.
## Stem Specifications

*For use with Smith & Nephew 12/14 femoral heads only.*

<table>
<thead>
<tr>
<th>Stem Size</th>
<th>Neck Angle</th>
<th>Stem Length</th>
<th>Distal Cross Section</th>
<th>A-P Width</th>
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<td>165, 195, 225 mm</td>
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<td>NR – Large</td>
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### Neck Length mm

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### Neck Height mm

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Not Actual Size

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

* Denotes skirted head

Long Straight

Neck Replacement

NOTE: For illustration purposes only. Surgical Templates are available by contacting your Smith & Nephew Representative or Customer Service.
It is of high importance to preoperatively plan the procedure at hand. Templating is a vital part of this planning stage and should be done before the start of surgery.

Place the template over the X-ray of the hip to be operated on. Determine the stem size and length of implant that will best fit the canal. Determine whether a Long Straight or Neck Replacement stem is suitable by observing the level of the medial calcar. Match the indicated length of the femoral head on the template to the center of femoral head rotation. The SPECTRON REVISION system offers a wide range of head/neck lengths for a precise duplication of the patient’s hip center. Make a notation of which length of the femoral head is to be used. Count the graduation marks from the indicated osteotomy level to the top of the lesser trochanter on the medial graduation scale of the Long Straight or Neck Replacement stem template. Make a notation of the measurement.
The following is a guide to Smith & Nephew's RENOVATION Implant Removal instrumentation and suggested techniques employed in prosthesis removal.
Radial Osteotome Blades
Four Radial Osteotome Blades (7136-9310, 7136-9312, 7136-9314, and 7136-9316) and Short and Long Quick-Coupling Osteotome Handles (7136-7548 and 7136-7549) can be used to disrupt biological fixation in the lateral portion of a proximally porous-coated femoral component. The blades are rigid and curved to match the lateral contour of the implant. One edge is beveled to ensure cutting against the implant. The beveled side should be placed away from the implant, toward the bone. The Small Slap Hammer (7136-7541) is easily attached to the osteotome handle for insertion and extraction.

Thin Osteotome Blades
A variety of sizes in the Thin Osteotome Blades and Short and Long Quick-Coupling Handles (7136-7548 and 7136-7549) can be used to disrupt biological fixation in the anterior and posterior portion of a proximally porous-coated femoral component. The blades are flexible enough to follow the contour of a femoral or acetabular component, and one edge is beveled to ensure cutting against the implant. The beveled side should be placed away from the implant, toward the bone. After disrupting areas of ingrowth with the osteotomes, attempt to extract the stem using moderate force. If the stem cannot be extracted without risk of fracturing the femur, an extended trochanteric osteotomy may be required. An extended trochanteric osteotomy is often required for extensively porous-coated stems.
"V" Splitter and Chisel
The "V" Splitter (7136-7561) and Chisel (7136-9308) are used to fragment and remove any cement proximal and lateral to the prosthesis. Before attempting to extract a cemented femoral prosthesis, cement should be removed from the lateral aspect of the femoral stem or fracture of the greater trochanter may occur. The "V" Splitter and Chisel can also be used to fragment cement in the proximal region after the prosthesis is removed.

Modular Stem Extractor
When the proximal cement has been adequately removed or biological fixation has been disrupted, the Modular Stem Extractor (7136-7555) can be used in conjunction with the Large Slap Hammer (7136-7553) to extract the prosthesis. The Modular Stem Extractor is designed so that the line of action is parallel to the longitudinal axis of the prosthesis. If the extractor does not readily remove the stem, further interface disruption must be accomplished or fracture of the surrounding femur may occur. The two locking screws on the Modular Adapter should be positioned behind the taper and tightened with the T-Handle Wrench (7136-7556).
Hook Stem Extractor
If a proximal extraction hole is exposed, the Hook Stem Extractor (7136-7557) can be used with the Large Slap Hammer (7136-7553) to remove the prosthesis. The Hook Stem Extractor is designed to fit most prostheses with a proximal extraction hole. If the extractor does not readily remove the stem, further interface disruption must be accomplished or fracture of the surrounding femur may occur.

Fixed Head Stem Extractor
With a one-piece femoral prosthesis, the Fixed Head Stem Extractor (7136-7559) can be used with the Large Slap Hammer (7136-7553) to remove the prosthesis. The Fixed Head Stem Extractor is designed to fit over the femoral head of the prosthesis and engage the neck. If the extractor does not readily remove the stem, further cement removal must be accomplished or fracture of the surrounding femur may occur.
Flag Splitter
Once the cemented femoral component has been removed, the Flag Splitter (7136-7560) may be used to make longitudinal fractures in the proximal cement mantle. This instrument offers a slightly longer tip to guide the cutting edge along the cement mantle.

Straight and Angled Gouges
The Straight Gouge (7136-7564) and Angled Gouge (7136-7563) can be utilized to remove cement in the middle and distal third regions of the cement mantle. Preferably, these gouges are used after splitting an intact cement mantle with the Flag Splitter. Care should be taken to avoid penetrating the cortical surface of the bone.
**Rongeurs with Teeth**
The Rongeurs with Teeth (7136-9200 and 7136-9300) may be used to grasp loose cement particles in the femoral canal. The two lengths, 200 mm and 300 mm, are designed to grasp loose cement in the proximal and distal portion of the femoral canal.

**“X” Osteotome**
The “X” Osteotome (7136-9207) is very effective in removal of cement distal to the tip of the implant. It is used to progressively fragment the hard cement in this region as it is impacted and rotated repetitively.
Reverse Curettes
The Reverse Curettes (7136-9517 and 7136-9519) come in two widths, 7 mm and 9 mm. They are primarily used to scrape along the inside of the canal to remove any remnants of the cement mantle or residual membrane after cement removal.

Cement Drills and Conical Taps
If the distal cement mantle is intact and loose, the Cement Drills (7134-9045, 7136-9006, and 7136-9008) and sharp-threaded Conical Taps (7136-9007 and 7136-9009) can be used to extract the distal cement mantle as a large fragment. The risk of cortical perforation should be assessed through A/P and lateral radiographs prior to introducing the Cement Drill. Care should be taken not to introduce the drill into an eccentrically placed channel. The Cement Drills are offered in three diameters, 4.5 mm, 6 mm, and 8 mm, and are used to create a pilot hole into the cement restrictor through which the Conical Taps are passed. The Conical Taps also come in two diameters, 7 mm and 9 mm, and are used in conjunction with the Slotted Mallet (7136-7552). After the appropriate size tap is chosen, several sharp turns embed it into the cement restrictor. The Slotted Mallet is then impacted against the collar to extract the distal cement.
Carbide Punch

In the case of a fractured femoral stem, the proximal portion is usually loose and easily removed. In contrast, the distal portion remains fixed in the remaining cement mantle. The Carbide Punch (7136-7566) is an effective tool for removing the distal portion of the fractured stem. A longitudinal slot is created just distal to the top of the broken prosthesis to allow access to the broken fragment directly. The Carbide Punch is then used to make divots in the surface of the prosthesis and drive the prosthesis proximally.
Prepare The Acetabulum
If acetabular reconstruction is required, prepare the acetabulum using the technique for the intended acetabular component.

Calcar Resection Level
In the O.R., place the osteotomy guide on the femur by referencing the top of the lesser trochanter at the same graduation mark as noted during templating. Make a reference mark on the calcar to facilitate calcar planing later in the procedure.

Pre-Existing Defects
When there is a pre-existing defect in the shaft, the area of the defect should be exposed. The revision stem to be implanted should pass beyond the defective area, otherwise the defect may undergo fatigue fracture. Usually, the length of the stem extending beyond the defect should be greater than two times the diameter of the femoral shaft at the area of the defect. In most cases, 4-6 cm beyond the distal most part of the defect is adequate. There is no need to use an extremely long stem. An extremely long stem may make proper cement fixation difficult.

Whenever major contained bone defects are apparent, consider using the RIG (Radial Impaction Grafting) technique.
Femoral Canal Preparation

Assemble the broach to the broach handle by placing the broach post in the clamp. Use the thumb to lock the clamp onto the broach. A modular anteversion handle can be assembled to the broach handle to provide version control (Figure 1).

Start the broaching procedure along the mid-axis of the femur with the size Small broach. Continue progressively broaching to the predetermined stem size and length. It is important to stay lateral and posterior with the femoral broaches to ensure proper alignment with the femoral axis. Seat the broach slightly below the mark on the calcar to facilitate calcar reaming (Figure 2).

Disassemble the broach from the broach handle by placing two or three fingers into the rectangular slot. Apply pressure to the release bar by squeezing the fingers toward the thumb resting on the medial side of the broach handle (Figure 3).

The SPECTRON REVISION broach is designed to provide a minimum 1.5 mm cement mantle per side. Additional cement mantle thickness can be achieved by pressurizing the cement into the remaining cancellous bone. The broach is slightly longer than the corresponding implant to accommodate the BUCK cement restrictor.
**Calcar Preparation**
With the final broach fully seated, remove the broach handle and ream the calcar. Plane the calcar until it is level with the broach.

**Trialing**
Remove the calcar reamer and place the matching Long Straight or Neck Replacement trial neck onto the broach post. Select the trial femoral head of desired diameter and neck length. Reduce the hip to assess stability and range of motion.

If trialing for the universal Bipolar or Unipolar, trial according to the appropriate technique for the selected device.
Placing The BUCK Cement Restrictor

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

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 Long Straight or Neck Replacement stem next to the inserter tool and adding 20 mm to the length (See table).

Remove the vent-occluding membrane by inserting the vent opening tool into the distal 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 re-attached to the inserter rod and pulled out of the canal. The surgeon may adjust the restrictor as many times as required.

**BUCK™ Cement Restrictor**

<table>
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<tr>
<th>Stem Size</th>
<th>Insertion Depth (mm)</th>
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<td>LS/NR – 195 mm</td>
<td>215</td>
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<tr>
<td>LS/NR – 225 mm</td>
<td>245</td>
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Preparing The Femoral Canal
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.

Drying The Femoral Canal
Insert the femoral absorber into the femoral canal to dry the canal while mixing the cement.
**Loading Cement**
The amount of cement used in a revision case is usually 80 grams. However, 120 grams may be needed depending on the width and the length of the femoral canal. The VORTEX™ Vacuum Mixer allows for mixing of 120 grams of VERSABOND™ bone cement in one mixer.

**Mixing**
Mix the cement according to the manufacturer’s instructions. Refer to VORTEX Vacuum Mixer instruction sheet for complete mixing technique.
Injecting Cement
After removing the femoral canal suction absorber, use suction to remove any remaining blood from the canal. 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.

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.
Distal Centralizer Selection
Use the implant, which corresponds to the last broach seated in the femur. An optional distal centralizer may be placed on the stem to assist in providing neutral alignment and predictable cement mantle. Each implant has a corresponding centralizer, which is intended to provide a uniform 1.5 mm distal cement mantle (See table). Using clean gloves, place the distal centralizer over the distal tip and carefully push superiorly until snug. The centralizer will be positioned approximately 125 mm distal to the collar on all stem sizes and lengths.

<table>
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<th>Centralizer Size (mm)</th>
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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 neck taper until the cement is cured.
**Final Trial Reduction**
Once the implant is fully seated and the cement has cured, a final trial reduction may be performed using trial femoral heads.

**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 mallet.
SPECTRON® 12/14 REVISION Femoral Stem & Head Components

### Neck Replacement Implants 12/14 Taper
Forged Cobalt Chromium - ASTM F799

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### Long Straight Implants 12/14 Taper
Cobalt Chromium - ASTM F799

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</table>

### CoCr 12/14 Taper Femoral Heads

**Cobalt Chromium – ASTM F 799**

<table>
<thead>
<tr>
<th>Neck Length</th>
<th>22 mm</th>
<th>26 mm</th>
<th>28 mm</th>
<th>32 mm</th>
</tr>
</thead>
<tbody>
<tr>
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<td>7130-2204</td>
<td>7130-2604</td>
<td>7130-2804</td>
<td>7130-3204</td>
</tr>
<tr>
<td>+8</td>
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<td>7130-2808</td>
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<td>7130-2612</td>
<td>7130-2812</td>
<td>7130-3212</td>
</tr>
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<td>7130-2816</td>
<td>7130-3216</td>
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### Trial 12/14 Taper Femoral Heads

<table>
<thead>
<tr>
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<th>28 mm</th>
<th>32 mm</th>
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<tbody>
<tr>
<td>–3</td>
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<td>—</td>
<td>7135-2803</td>
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<tr>
<td>+12</td>
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<td>7135-2212</td>
<td>7135-2612</td>
<td>7135-2812</td>
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<td>+16</td>
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<td>—</td>
<td>7135-2816</td>
<td>7135-3216</td>
</tr>
</tbody>
</table>
NOTE: The SPECTRON EF Primary Instrument Tray needs to be brought into the O.R. to access the following instruments: Broach Handle (7136-4007); 12/14 Trial Heads; Stem Driver (11-9817); and the Femoral Head Impactor (7136-4009).

SPECTRON 12/14 REVISION Instrument Tray Set
Cat. No. 7136-9115
Set includes: 7136-9401; 7136-9402; and 7136-9114.

Small Exterior Carrying Case
Cat. No. 7136-9401

Lid for Exterior Carrying Case
Cat. No. 7136-9402

Interior Tray
Cat. No. 7136-9114
### Long Straight Neck Replacement Broaches/Trials

<table>
<thead>
<tr>
<th>Size</th>
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<th>Cat. No.</th>
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<tr>
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<tr>
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<td>Large*</td>
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<tr>
<td>Small</td>
<td>165 mm</td>
<td>7136-5129</td>
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<tr>
<td>Medium</td>
<td>165 mm</td>
<td>7136-5132</td>
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<tr>
<td>Large</td>
<td>165 mm</td>
<td>7136-5135</td>
</tr>
<tr>
<td>Small</td>
<td>195 mm</td>
<td>7136-5130</td>
</tr>
<tr>
<td>Medium</td>
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<td>7136-5133</td>
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<tr>
<td>Large</td>
<td>195 mm</td>
<td>7136-5136</td>
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<tr>
<td>Small</td>
<td>225 mm</td>
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<tr>
<td>Large</td>
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</table>

*Only available with neck replacement implants.

### SPECTRON REVISION Centralizer

<table>
<thead>
<tr>
<th>Size</th>
<th>O.D.</th>
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<tr>
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<tr>
<td>Large</td>
<td>16 mm</td>
<td>7131-3316</td>
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### Long Straight Trial Necks 12/14 Taper

<table>
<thead>
<tr>
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<tbody>
<tr>
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<tr>
<td>Medium/Large</td>
<td>7136-5099</td>
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### Neck Replacement Trial Necks 12/14 Taper

<table>
<thead>
<tr>
<th>Size</th>
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<tbody>
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<td>7136-5096</td>
</tr>
<tr>
<td>Medium/Large</td>
<td>7136-5097</td>
</tr>
</tbody>
</table>

### Osteotomy Guide

Cat. No. 7136-4000
### RENOVATION™ Implant Removal Kit

*Includes the Acetabular and Femoral Implant Removal Trays and Instruments. Disposable Osteotome Blades are not included.*

#### Acetabular Implant Removal Tray

**Tray Accepts the Following:**

- 7136-7573 Acetabular Implant Removal Tray Insert
- 7136-7547 Osteotome System Tray Insert
- 7136-7541 Small Slap Hammer
- 7136-7542 Acetabular Component Gripper
- 7136-7543 Acetabular Component Forceps
- 7136-7544 Curved Acetabular Chisel
- 7136-7545 Round Acetabular Cement Splitter
- 7136-7548 Quick-Coupling Osteotome Handle, Short
- 7136-7549 Quick-Coupling Osteotome Handle, Long
- 7136-7550 Acetabular Gouge, Size 46
- 7136-7551 Acetabular Gouge, Size 50
- 7136-7552 Acetabular Gouge, Size 54
- 7136-7553 Acetabular Gouge, Size 58
- 7136-7554 Acetabular Gouge, Size 62
- 7136-7556 Small Acetabular Gouge

#### Disposable Osteotome Blades (Sterile)

- 7136-9310 Radial Osteotome Blade, Size 10
- 7136-9312 Radial Osteotome Blade, Size 12
- 7136-9314 Radial Osteotome Blade, Size 14
- 7136-9316 Radial Osteotome Blade, Size 16
- 7136-9208 Thin Osteotome Blade, 8 mm x 3”
- 7136-9210 Thin Osteotome Blade, 10 mm x 3”
- 7136-9212 Thin Osteotome Blade, 12 mm x 3”
- 7136-9220 Thin Osteotome Blade, 20 mm x 3”
- 7136-9410 Thin Osteotome Blade, 10 mm x 5”
- 7136-9408 Thin Osteotome Blade, 8 mm x 5”

#### Femoral Implant Removal Tray

**Tray Accepts the Following:**

- 7136-7571 Femoral Implant Removal Tray Insert #1
- 7136-7572 Femoral Implant Removal Tray Insert #2
- 7136-7552 Slotted Mallet
- 7136-7553 Large Slap Hammer
- 7136-7554 Modular Stem Extractor
- 7136-7556 T-Handle Wrench
- 7136-7557 Hook Stem Extractor
- 7136-7559 Fixed Head Stem Extractor
- 7136-9007 Conical Tap, 7 mm
- 7136-9009 Conical Tap, 9 mm
- 7136-9045 Cement Drill, 4.5 mm
- 7136-9006 Cement Drill, 6 mm
- 7136-9008 Cement Drill, 8 mm
- 7136-7560 Flag Splitter
- 7136-7561 "V" Splitter
- 7136-9308 Chisel, 8 mm x 17”
- 7136-7563 Angled Gouge
- 7136-7564 Straight Gouge
- 7136-7566 Carbide Punch
- 7136-9517 Reverse Curette, 7 mm x 17”
- 7136-9519 Reverse Curette, 9 mm x 17”
- 7136-9207 “X” Osteotome, 7 mm x 17”
- 7136-9200 Rongeur 200 mm with Teeth
- 7136-9300 Rongeur 300 mm with Teeth
- 7136-9310 Radial Osteotome Blade, Size 10
- 7136-9312 Radial Osteotome Blade, Size 12
- 7136-9314 Radial Osteotome Blade, Size 14
- 7136-9316 Radial Osteotome Blade, Size 16
- 7136-9208 Thin Osteotome Blade, 8 mm x 3”
- 7136-9210 Thin Osteotome Blade, 10 mm x 3”
- 7136-9212 Thin Osteotome Blade, 12 mm x 3”
- 7136-9220 Thin Osteotome Blade, 20 mm x 3”
- 7136-9410 Thin Osteotome Blade, 10 mm x 5”
- 7136-9408 Thin Osteotome Blade, 8 mm x 5”

---

**28**
Cement & Accessories

VERSABOND®
Cat. No. 7127-1140

PREP-IM® Total Hip Preparation Kit
Cat. No. 12-1010 Includes the following:
- 2 BUCK Cement Restrictors
- 1 Femoral Canal Brush
- 1 BUCK Disposable Inserter
- 1 Femoral Canal Suction Absorber
- 2 Concise Cement Sculps
- 1 Medium Femoral Pressurizer

BUCK® Cement Restrictor
Cat. No. Size
91-4535 13 mm
12-9418 18.5 mm
12-9419 25 mm
7127-9420 30 mm
7127-9421 35 mm

Vent Opening Tool
Cat. No. 11-0028

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

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

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

<table>
<thead>
<tr>
<th>Cat. No.</th>
<th>Description</th>
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<tr>
<td>11-0003</td>
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<tr>
<td>11-0033</td>
<td>12.5 mm</td>
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</table>

BUCK Femoral Cement Restrictor Inserter
Cat. No. 11-2428

VORTEX™ Vacuum Mixer
Cat. No. 7127-0070

VORTEX Nozzles

<table>
<thead>
<tr>
<th>Cat. No.</th>
<th>Description</th>
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<tbody>
<tr>
<td>7127-0080</td>
<td>Standard Breakaway</td>
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<tr>
<td>7127-0081</td>
<td>Long Tapered</td>
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<tr>
<td>7127-0084</td>
<td>Revision</td>
</tr>
<tr>
<td>7127-0085</td>
<td>Umbrella</td>
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<tr>
<td>7127-0071</td>
<td>Re-use Kit (not shown)</td>
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<tr>
<td>7127-0072</td>
<td>Adaptor</td>
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</table>

Connector, Schraeder
Cat. No. 7127-0050

Connector, Drager
Cat. No. 7127-0051

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

POWERPULSE™ Handpiece with Zimmer Coupling
Cat. No. 7127-7000

POWERPULSE Powerhose with Zimmer Coupling
Cat. No. 7127-7001
POWERPULSE Hip with Suction
Cat. No. 7127-7004

POWERPULSE Hip without Suction
Cat. No. 7127-7005

MIXOR® Vacuum Mixing System with Syringe
Cat. No. 7127-0020

Femoral Cement Compressor
Cat. No. 11-1434

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

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

<table>
<thead>
<tr>
<th>Alumina Ceramic</th>
<th>Zirconia Ceramic</th>
<th>Head Diameter</th>
<th>Neck Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zirconia 2500</td>
<td>Aluminum 2500</td>
<td>28 mm</td>
<td>+4 mm</td>
</tr>
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<td>Zirconia 2501</td>
<td>Aluminum 2501</td>
<td>28 mm</td>
<td>+4 mm</td>
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<td>Zirconia 2502</td>
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<td>+4 mm</td>
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<td>Zirconia 2503</td>
<td>Aluminum 2503</td>
<td>28 mm</td>
<td>+4 mm</td>
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<tr>
<td>Zirconia 2504</td>
<td>Aluminum 2504</td>
<td>28 mm</td>
<td>+4 mm</td>
</tr>
<tr>
<td>Zirconia 2505</td>
<td>Aluminum 2505</td>
<td>28 mm</td>
<td>+4 mm</td>
</tr>
<tr>
<td>Zirconia 2506</td>
<td>Aluminum 2506</td>
<td>28 mm</td>
<td>+4 mm</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Alumina Ceramic</th>
<th>Zirconia Ceramic</th>
<th>Head Diameter</th>
<th>Neck Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alumina 2500</td>
<td>Zirconia 2500</td>
<td>28 mm</td>
<td>+4 mm</td>
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<tr>
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<tr>
<td>Alumina 2505</td>
<td>Zirconia 2505</td>
<td>28 mm</td>
<td>+4 mm</td>
</tr>
<tr>
<td>Alumina 2506</td>
<td>Zirconia 2506</td>
<td>28 mm</td>
<td>+4 mm</td>
</tr>
</tbody>
</table>

Zirconia Ceramic Heads

### Acetabular Components

Acetabular components can be made of all polyethylene, or two-piece components consisting of a titanium shell and a polyethylene liner or an alumina ceramic liner. Please see Warnings and Precautions for specific information on screws, pegs and head covers. Acetabular reinforcement and reorientation rings are used with all polyethylene acetabular component.

### INDICATIONS, CONTRAINDICATIONS, AND ADVERSE EFFECTS

Hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma or noninflammatory degenerative joint disease (NJD). Bi or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and dislocations of the hip.

Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis, arthritis secondary to a variety of diseases and anesthetics, and congenital displasia, old, remote osteomyelitis with an extended drainage-free period, in which case, the patient should be warned of an abnormal danger of infection postoperatively, treatments of nonfusal, femoral neck fracture and traumatic fractures of the proximal femur with head involvement that are unmanageable using other techniques, endoprostheses, femoral osteotomy, or Girdlestone resection; fracture-dislocation of the hip, and correction of deformities.

Acetabular reinforcement and reorientation 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.:
   - Blood supply limitations.
   - Insufficient quantity or quality of bone support, e.g., osteoporosis, or metabolic disorders which may impair bone formation, and osteomyelitis.
   - Infections or other conditions which lead to increased bone resorption.
   - Mental or neurological conditions which tend to impair the patient's ability or willingness to restrict activities.
   - Physical conditions or activities which tend to place extreme loads on implants, e.g., Charcot joints, muscle deficiencies, multiple joint disabilities, etc.
   - Skeletal immaturity.
   - The zirconia ceramic head is contraindicated for use with any other product than an UHMW polyethylene cup or a metal backed UHMW polyethylene cup.
   - The alumina ceramic liner is contraindicated for use with any product other than the metal stem with the correlating inner taper geometry and the appropriate sized alumina ceramic head.

Contraindications may be relative or absolute and must be carefully weighed against the patient's entire evaluation and the prognosis for possible alternative procedures such as non-operative treatment, arthrodesis, femoral osteotomy, pelvic osteotomy, resection arthroplasty, hemiarthroplasty and others.

Conditions presenting increased risk of failure include: osteoporosis, metabolic disorders which may impair bone formation, and osteomyelitis.

### Possible Adverse Effects

1. Wear of the polyethylene and ceramic articulating surfaces of acetabular components may occur. Higher rates of wear may be initiated by the presence of particles of cement, metal, or other debris which can develop or result as a result of the surgical procedure and cause abrasion of the articular surfaces. Higher rates of wear may shorten the useful life of the prosthesis and lead to early revision surgery to replace the worn portions of the implant.

2. With all joint replacements, asymptomatic, localized, progressive bone resorption isostatic) may occur around the prosthetic components as a consequence of foreign-body reaction to particulate wear debris. Particles are generated by interaction between components, as well as between the components and bone, primarily through wear mechanisms of adhesion, abrasion, and fatigue. Secondly, particles may also be generated by third-body particles lodged in the polyethylene or ceramic articulating surfaces. Osteolysis can lead to future complications necessitating the removal or replacement of prosthetic components.

3. Loosening, bending, cracking, or fracturing of implants may result from failure to observe the Warnings and Precautions below: Fracture of the implant can occur as a result of a trauma, strenuous activity, improper alignment, or duration of service.

4. Dislocations, subluxation, decreased range of motion, or shortening of the femur caused by improper neck selection, positioning, looseness of acetabular or femoral components, extraneous bone, penetration of the femoral prosthesis through the shaft of the femur, fracture of the acetabulum, intrapelvic protrusion of acetabular component, femoral impingement, periarticular calcification, and/or excessive reaming.

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 inadequate reaming, etc. Intraoperative fractures are usually associated with cortical defect, improper stem selection, imporper broaching, and/or severe osteoporosis.

6. Infection, both acute post-operative wound infection and late deep wound infection.

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 thrombi, pulmonary emboli, or myocardial infarction.

9. Myositis ossificans, especially in males with hypertrophic arthritis, limit-
ed pre-operative range of motion and/or pre-existing myalgias. Also, periar-
ticular 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. Arthritis, 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 arthroisis of the knee from intraoperative positioning of the extremity.


15. Aggregated 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 hydroxyapatite coating/porous coating bonding may result in bone separation deterioration.

17. Stem migration or subsidence has occurred in conjunction with compaction grafting procedures usually resulting from insufficient graft mate-
rnal or improper cement techniques. Varus stem alignment may also be responsible.

**WARNINGS AND PRECAUTIONS**

The patient should be warned of surgical risks, and made aware of possible adverse effects. The patient should be warned that the device does not replace normal healthy bone, that the implant can break or become damaged as a result of strenuous activity or trauma, and that it has a finite expected service life and may need to be replaced in the future. Do not mix components from different manufacturers. Additional Warnings and Precautions may be included in component literature.

**Preoperative**

1. Use extreme care in handling and storage of implant components.
Cutting, bending, or scratching the surface of components can significantly decrease wettability, fatigue resistance, and 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. The integrity of components should be protected from corrosive environmental such as salt air during storage. Do not allow the porous sur-
faces to come in contact with cloth or other fiber-releasing materials.

2. Do not store or transport the device materials, although infections, should be tested, if (appropriately), and rolled up properly.

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. To refer medical or manufacturer literature for specific product information.

5. Intraoperative fracture or breaking of instruments can occur. Instruments which have experienced extensive use or excessive force are susceptible to fracture. Instruments should be examined for wear, or damage, prior to surgery.

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

7. Modular heads and femoral components should be from the same lot. Although mechanical testing demonstrates that when used with a polyethylene acetabular component the yttria stabilized zirconia ball produces a relatively low amount of particulate, the total amount of particulate remains undetermined. Because of the limited clinical and preclinical experience, the biological effect of these particulates can not be predicted.

8. Alumina ceramic may never articulate against metal because severe wear does not occur.

Intraoperative

1. The general principles of patient selection and sound surgical judgment apply. The correct selection of the implant is extremely important. The approach, size, and size should be selected for patients with consideration of anatomical and biomechanical factors such as patient age and activity levels, weight, bone and muscle conditions, any prior surgery and anticipated future surgeries, etc. Generally, the largest cross-sectional component which will allow adequate bone support to be maintained is preferred. Failure to use the optimum-sized component may result in poor function, overload of the implant, and fracture of the component and/or bone.

2. Correct selection of the neck length and cut, and stem positioning, are important. Muscle stability and malinge of components may result in loosening, subluxation, dislocation, and/or fracture of the component and/or bone.

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1. The general principles of patient selection and sound surgical judgment apply. The correct selection of the implant is extremely important. The approach, size, and size should be selected for patients with consideration of anatomical and biomechanical factors such as patient age and activity levels, weight, bone and muscle conditions, any prior surgery and anticipated future surgeries, etc. Generally, the largest cross-sectional component which will allow adequate bone support to be maintained is preferred. Failure to use the optimum-sized component may result in poor function, overload of the implant, and fracture of the component and/or bone.

2. Correct selection of the neck length and cut, and stem positioning, are important. Muscle stability and malinge of components may result in loosening, subluxation, dislocation, and/or fracture of the component and/or bone.

3. Correct selection of the neck length and cut, and stem positioning, are important. Muscle stability and malinge of components may result in loosening, subluxation, dislocation, and/or fracture of the component and/or bone.

4. Surgical technique information is available upon request. The surgeon should be familiar with the technique. To refer medical or manufacturer literature for specific product information.

5. Intraoperative fracture or breaking of instruments can occur. Instruments which have experienced extensive use or excessive force are susceptible to fracture. Instruments should be examined for wear, or damage, prior to surgery.

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

7. Modular heads and femoral components should be from the same lot. Although mechanical testing demonstrates that when used with a polyethylene acetabular component the yttria stabilized zirconia ball produces a relatively low amount of particulate, the total amount of particulate remains undetermined. Because of the limited clinical and preclinical experience, the biological effect of these particulates can not be predicted.

8. Alumina ceramic may never articulate against metal because severe wear does not occur.

Intraoperative

1. The general principles of patient selection and sound surgical judgment apply. The correct selection of the implant is extremely important. The approach, size, and size should be selected for patients with consideration of anatomical and biomechanical factors such as patient age and activity levels, weight, bone and muscle conditions, any prior surgery and anticipated future surgeries, etc. Generally, the largest cross-sectional component which will allow adequate bone support to be maintained is preferred. Failure to use the optimum-sized component may result in poor function, overload of the implant, and fracture of the component and/or bone.

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5. Intraoperative fracture or breaking of instruments can occur. Instruments which have experienced extensive use or excessive force are susceptible to fracture. Instruments should be examined for wear, or damage, prior to surgery.

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7. Modular heads and femoral components should be from the same lot. Although mechanical testing demonstrates that when used with a polyethylene acetabular component the yttria stabilized zirconia ball produces a relatively low amount of particulate, the total amount of particulate remains undetermined. Because of the limited clinical and preclinical experience, the biological effect of these particulates can not be predicted.

8. Alumina ceramic may never articulate against metal because severe wear does not occur.
<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>EtO</td>
<td>55°C</td>
<td>70% Target</td>
<td>689 millibar</td>
<td>725 mg/l</td>
<td>60-180 minutes</td>
</tr>
</tbody>
</table>

Suggested initial starting point for aeration validation is 12 hours at 120°F (49°C) with power aeration. Consult aeration manufacturer for more specific instructions.

**Ceramic Components**

Do not resterilize ceramic femoral heads or liners.

**INFORMATION**

For further information, please contact Customer Service at (800) 238-7538 for calls within the continental USA and (901) 396-2121 for all international calls.

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

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

**H2O2 – hydrogen peroxide sterilization**


Manufacturing facilities and EC representative:

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450 Brooks Road
Memphis, TN 38116 U.S.A.
Tel.: 901-396-2121

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