Surgical technique completed in conjunction with:

**J. Rod Davey, M.D., F.R.C.S.**
Acting Head of Orthopaedic Surgery,
The Toronto Hospital
Assistant Professor of the Department of Surgery,
University of Toronto
Toronto, Ontario, Canada

**Paul Di Cesare, M.D., F.A.C.S.**
Hospital for Joint Diseases
Orthopaedic Institute
Director of Musculoskeletal Research Center
Co-Director of Surgical Arthritis Service
Assistant Professor of Orthopaedic Surgery,
New York University School of Medicine
New York, New York

**Henrik Malchau, M.D., Ph.D.**
Sahlgrenska University Hospital
Professor
Department of Orthopaedics
Göteborg, Sweden

**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.
### Neck Height mm
When Femoral Head Component Selected Is:

<table>
<thead>
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<th>Size</th>
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### Neck Length mm
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<td>NR – Large</td>
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### Stem Specifications

<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>
<th>M-L Width</th>
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<td>8, 7, 6 mm</td>
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<td>LS – Medium</td>
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<td>165, 195, 225 mm</td>
<td>9, 8, 6 mm</td>
<td>14 mm</td>
<td>25 mm</td>
</tr>
<tr>
<td>LS – Large</td>
<td>131°</td>
<td>165, 195, 225 mm</td>
<td>12, 10, 9 mm</td>
<td>16 mm</td>
<td>28 mm</td>
</tr>
<tr>
<td>NR – Small</td>
<td>131°</td>
<td>135, 165, 195, 225 mm</td>
<td>9, 8, 7, 6 mm</td>
<td>11 mm</td>
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</tr>
<tr>
<td>NR – Medium</td>
<td>131°</td>
<td>135, 165, 195, 225 mm</td>
<td>11, 9, 8, 6 mm</td>
<td>14 mm</td>
<td>25 mm</td>
</tr>
<tr>
<td>NR – Large</td>
<td>131°</td>
<td>135, 165, 195, 225 mm</td>
<td>13, 12, 10, 9 mm</td>
<td>16 mm</td>
<td>28 mm</td>
</tr>
</tbody>
</table>
Not Actual Size

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

¹ Denotes skirted head

NOTE: For illustration purposes only. Surgical Templates are available by contacting your Smith & Nephew Representative or Customer Service.
Templating

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.
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.
SPECTRON REVISION Technique
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

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<th>Stem Size</th>
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<tr>
<td>LS/NR – 165mm</td>
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<tr>
<td>LS/NR – 225 mm</td>
<td>245</td>
</tr>
</tbody>
</table>
Preparation of 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>
<thead>
<tr>
<th>Stem Size</th>
<th>Centralizer Size (mm)</th>
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<td>Large</td>
<td>16</td>
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</table>

**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.
### 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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### OXINIUM™ 12/14 Taper Femoral Heads

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### 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>
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<tr>
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### Trial 12/14 Taper Femoral Heads

<table>
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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

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*Only available with neck replacement implants.*

### Neck Replacement Trial Necks 12/14 Taper

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### Neck Replacement Trial Necks 12/14 Taper

<table>
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<td>Medium/Large</td>
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### SPECTRON REVISION Centralizer

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<td>Large</td>
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### Osteotomy Guide

Cat. No. 7136-4000
### 7136-7500 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
- 7136-7546 Acetabular Gouge, Size 46
- 7136-7550 Acetabular Gouge, Size 50
- 7136-7554 Acetabular Gouge, Size 54
- 7136-7558 Acetabular Gouge, Size 58
- 7136-7562 Acetabular Gouge, Size 62
- 7136-7567 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”
- 7136-9412 Thin Osteotome Blade, Rounded End, 12 mm
- 7136-9420 Thin Osteotome Blade, Rounded End, 20 mm
- 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
- 7136-7555 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
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**

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<td>11-0033</td>
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**BUCK Femoral Cement Restrictor Inserter**
Cat. No. 11-2428

**VORTEX® Vacuum Mixer**
Cat. No. 7127-0070

**VORTEX Nozzles**

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<td>7127-0081</td>
<td>Long Tapered</td>
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<tr>
<td>7127-0084</td>
<td>Revision</td>
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<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>
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**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
<table>
<thead>
<tr>
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<td><strong>POWERPULSE Hip with Suction</strong></td>
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<tr>
<td><strong>POWERPULSE Hip without Suction</strong></td>
<td>7127-7005</td>
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<td><strong>MIXOR™ Vacuum Mixing System with Syringe</strong></td>
<td>7127-0020</td>
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<tr>
<td><strong>Femoral Cement Compressor</strong></td>
<td>11-1434</td>
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<td><strong>Disposable Femoral Cement Compressor Cap</strong></td>
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<td><strong>MIXOR Pump Only</strong></td>
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<tr>
<td><strong>InjectOR Gun</strong></td>
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</table>
**Important Medical Information**

**Warnings and Precautions**

**Total Hip System**

**IMPORTANT NOTE**

Total hip replacement (THR) arthroplasty has become a successful procedure for relieving pain and restoring motion in patients who are disabled from hip arthropathy. The goals of total hip replacement are to decrease pain, increase function, and increase mobility.

**MATERIALS**

Femoral components are cobalt chromium alloy, titanium 6Al-4V alloy or stainless steel. Femoral heads are cobalt-chromium alloy, zirconia ceramic, alumina ceramic, COC/RUN oxidized zirconium or stainless steel. All poly acetabular components are ultra-high molecular weight polyethylene. Alumina shells are titanium 6Al-4V alloy. The component material is provided on the outside container label.

**Note:** Ceramic/ceramic implants are not available in the USA.

Some of the alloys needed to produce orthopedic implants contain some metallic components that may be carcinogenic in tissue cultures or intact organisms under very unique circumstances. Questions have been raised in the scientific literature as to whether or not these alloys may be carcinogenic in implant recipients. Studies conducted to evaluate this issue have not identified conclusive evidence of such phenomena, in spite of the millions of implants in use.

**DESCRIPTION OF SYSTEM**

The Total Hip System consists of femoral components, proximal pads, taper sleeves, distal sleeves, acetabular components, fixation screws and pegs, hole covers, centralizers, and femoral heads. Components may be grit blasted, porous coated, hydroxyapatite (HA) coated, or HA porous coated. All implantable devices are designed for single use only.

**Femoral Components**

Femoral components are available in a variety of sizes. Porous coated components are coated for biological ingrowth. Distally and medially distal femoral components accept proximal pads and distal sleeves, respectively. Non-porous femoral components can feature PWAKA centralizers that help produce a uniform thickness of cement.

Femoral components are available with a Small (10/12), Large (14/16), or 12/14 global taper.

Small taper femoral components mate and lock directly with a 22 mm metal, oxidized zirconium or ceramic head. The Small taper also mates with a taper sleeve which, in turn, mates with either metal or ceramic heads (26, 28, or 32 mm), bipolar or unipolar components.

Large taper femoral components mate and lock with either metal heads (26, 28, or 32 mm), ceramic heads (28 or 32 mm), bipolar or unipolar components.

Femoral components with a 12/14 taper mate and lock with either metal heads, oxidized zirconium/ceramic heads, ceramic heads/unipolar or unipolar components.

Small, Large, and 12/14 taper femoral component tapers are machined to mate and lock with ceramic heads, thus preventing rotation of the ceramic head on the stem, which would cause wear of the stem taper.

**Taper Sleeves**

A taper sleeve is required to be impacted on the Small taper femoral component prior to impacting a Large (14/16) taper femoral head size 26, 28, or 32 mm. A taper sleeve is required to attach a unipolar head. Unipolar taper sleeves are available in Small, Large, and 12/14 tapers. Never place more than one taper sleeve on a femoral component.

**Femoral Heads**

Cobalt chromium, stainless steel, oxidized zirconium, and ceramic heads are available in multiple neck lengths for proper anatomic and musculature fit. Cobalt chromium, stainless steel, oxidized zirconium, and ceramic heads are available for use only with Small taper femoral components.

**In addition to the components listed above, the following components are available for use only with Small taper femoral components:**

- **Zirconia Ceramic Heads:**
  - 712-0026: 28 mm Long +4 mm
  - 712-0027: 28 mm X-Long +6 mm

- **Alumina Ceramic Heads:**
  - 712-2800: 28 mm Standard +0 mm
  - 712-2802: 28 mm X-Long +8 mm

**Acetabular Components**

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

**Note:** The metal shell and ceramic liner in the Ceramic/Ceramic Acetabular System are not available in the USA.

**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) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and dislocation.

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

Acetabular reinforcement and reconstitution 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 osteomalacia.
   - 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, musculoskeletal 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 shell with the corollating inner taper geometry and the appropriate sized alumina ceramic head.**

   The alumina ceramic liner should only be used with the 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: osteoarthrosis, metabolic disorders which may impair bone formation, and osteomalacia.**

**Possible Adverse Effects**

- 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 during or as a result of the surgical procedure and cause abrasion of the articulating surfaces. Higher rates of wear may shorten the useful life of the prosthesis and lead to early revision surgery to replace the worn components.

- With all joint replacements, asymptomatic, localized, progressive bone resorption (osteolysis) 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 abrasion, adhesion, 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.

- Loosening, bending, cracking, shifting, and separation of components may result from failure to observe the Warnings and Precautions below. Fracture of the implant can occur as a result of trauma, strenuous activity, improper alignment, or duration of service.

- Dislocations, subluxation, decreased range of motion, or shortening 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, periacetabular calcification, and/or excessive reaming.

- 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 inappropriately reaming. Intraoperative fractures are usually associated with cortical defects, improper stem selection, improper broaching, and/or severe osteoporosis.

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

- Neuropathies; femoral, sciatic, peroneal nerve, and lateral femoral cutaneous neuropathies have been reported. Temporary or permanent nerve damage resulting in pain or numbness of the affected limb.

- Wound hematoma, thromboembolic disease including venous thromboembolism, pulmonary embolus, or myocardial infarction.

- Myositis ossificans, especially in males with hyperthyroid arthritis, limited pre-operative range of motion and/or previous mycosis. Also, periar- ticular calcification with or without impingement to joint mobility can cause decreased range of motion.

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

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

- Damage to blood vessels.

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

- Delayed wound healing.

- Aggressive problems of the affected limb or contralateral extremity caused by leg length discrepancy, excess femoral medialization, or muscular imbalance.

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

- Stem migration or subsidence has occurred in conjunction with compaction grafting procedures usually resulting from insufficient graft materi- als 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 reduce the strength, fatigue resistance, and/or wear characteristics of the implant system. These, in turn, may induce internal stresses that are not obvious to the eye and may lead to fracture of the component. Important features of components should be protected from corrosive environments such as salt air during storage. Do not allow the porous surfaces to come in contact with cloth or other fiber-releasing materials.

2. Nondesicer and other device materials, although insufficient, should be tested, if it appropriate, and ruled out prophylactically.

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. Refer to 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. Select only Smith & Nephew femoral components that indicate their use with ceramic heads. This is important because the taper on the stem is machined to tightly mate and lock with the ceramic head thus preventing rotation of the ceramic head on the stem. Also, an improperly dimensioned taper could result in fracture of the ceramic head.

8. The zirconia ceramic head is composed of a new ceramic material with limited clinical and preclinical experience. The biological effect of these particular ceramic heads cannot be predicted.

9. Alumina ceramic should never articulate against metal because severe wear of the metal will occur.

10. The zirconia ceramic head should never be used to bridge cortical defects that lie within 25 mm of the tip of the base stem.

11. Take care, when positioning and drilling screw and peg holes, to avoid penetrate of the inner cortex of the pelvis, penetration of the sciatic nerve palsy. Also, note that the femoral canal is often very small and may be extremely osteoporotic. Care should be taken to prevent punctures or other damage prior to surgery.

12. 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. If the sterile barrier has been broken, return the component to Smith & Nephew, Inc.

STERILIZATION/RESTERILIZATION

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

Metal Components

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

- Pneumatic Cycle: 4 pulses (Maximum = 26.0 psig (2.8 bars) & Minimum = 10.0 inHg (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 at least 15 minutes of vacuum drying at 10 inHg (339 millibars) minimum.
- For the United Kingdom, sterilization should be carried out in accordance with HTM 2000. The recommended pneumatic sterilization cycle is: Evacuation to 100mbar for 2-3 minutes, Negative Pressure pulsing (3) 800mbar-100mbar, Positive Pressure pulsing (5) 2.2 bar-11 bar, Sterilisation exposure: 3 minutes at 143°C-157°C, Drying vacuum 40mbar for 5-10 minutes.
- Pneumatic Cycle: 270°F to 275°F (132°C to 135°C) with a minimum dwell time at temperature of 10 minutes, followed by 1 minute purge and at least 15 minutes of vacuum drying at 10 inHg (339 millibars) minimum.

Smith & Nephew does not recommend the use of low temperature gravity cycles or flash sterilizers. Do not resterilize femoral prostheses with ceramic heads seated on the stem. Do not steam autoclave femoral prostheses with proximal or distal centralizers attached. If resterilization is required for femoral prostheses with proximal or distal centralizers attached, use ethylene oxide gas. If porous coated or HA coated implants are inadvertently contaminated, return the unsoiled prosthesis to Smith & Nephew for resterilization. DO NOT USE any form of resterilization for 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
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ETO 131°F (55°C) 40-80% 10 PSIA 725 mg/l 60-180 minutes

Suggested initial starting point for aeration validation is 12 hours at 120°F (49°C) with power aeration. Consult aerator 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:
Smith & Nephew Inc., Orthopaedic Division
450 Brooks Road
Memphis, TN 38116 U.S.A.
Tel.: 901-396-2121

Smith & Nephew Orthopaedics GmbH
Alemannenstrasse 14
78532 Tuttlingen, Germany
Tel.: 07462/208-0
Fax: 07462/208-135

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