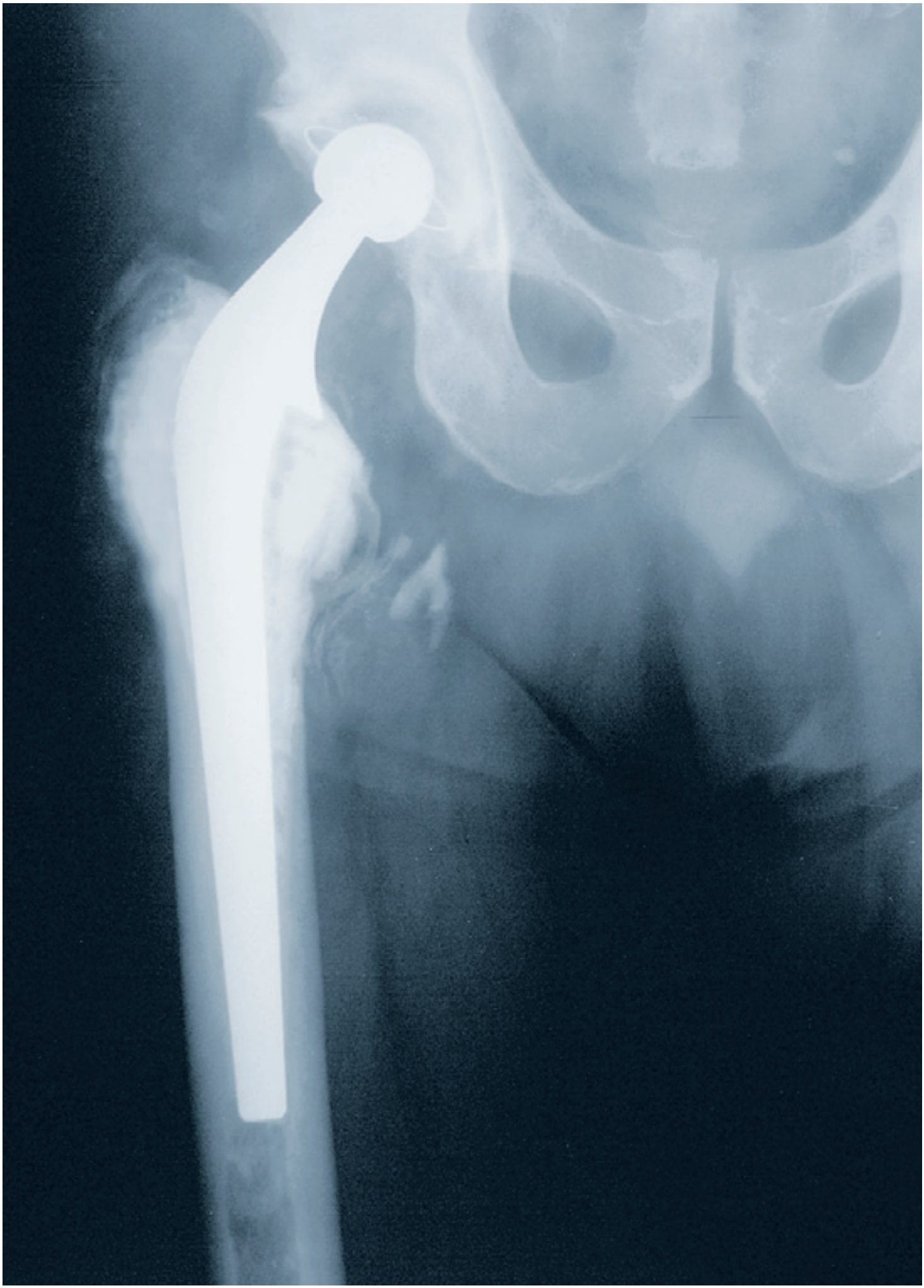
Surgical Technique

smith&nephew

SPECTRON® REVISION Hip System



SPECTRON REVISION Hip System

Surgical technique completed
in conjunction with:

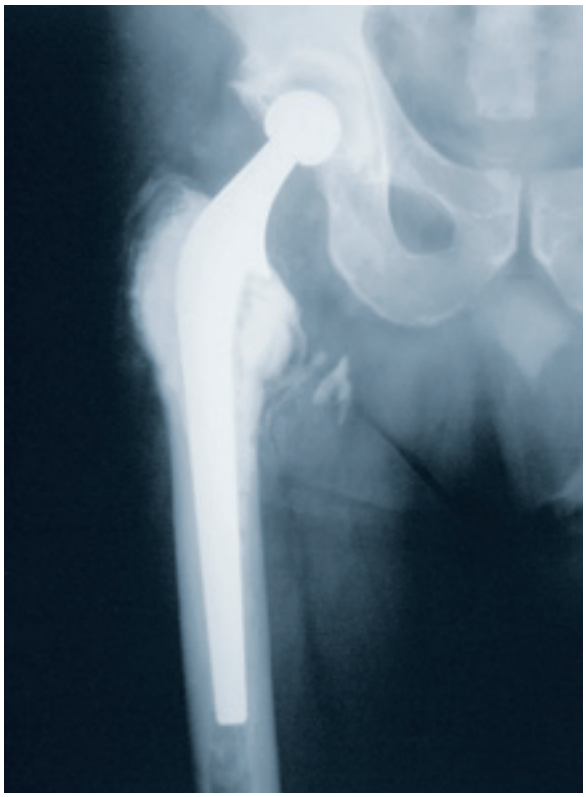
J. Rod Davey, M.D., F.R.C.S.
Acting Head of Orthopaedic Surgery,
The Toronto Hospital
Assistant Professor of the Department of Surgery,
University of Toronto
Toronto, Ontario, Canada

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.

Introduction



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.

Stem Size	Neck Angle	Stem Length	Distal Cross Section	A-P Width	M-L Width
LS – Small	131°	165, 195, 225 mm	8, 7, 6 mm	11 mm	21 mm
LS – Medium	131°	165, 195, 225 mm	9, 8, 6 mm	14 mm	25 mm
LS – Large	131°	165, 195, 225 mm	12, 10, 9 mm	16 mm	28 mm
NR – Small	131°	135, 165, 195, 225 mm	9, 8, 7, 6 mm	11 mm	21 mm
NR – Medium	131°	135, 165, 195, 225 mm	11, 9, 8, 6 mm	14 mm	25 mm
NR – Large	131°	135, 165, 195, 225 mm	13, 12, 10, 9 mm	16 mm	28 mm

Neck Length mm When Femoral Head Component Selected Is:						
Size	–3	+0	+4	+8	+12	+16
LS – Small	37	40	44	48	52	56
LS – Medium	39	42	46	50	54	58
LS – Large	39	42	46	50	54	58
NR – Small	45	48	52	56	60	64
NR – Medium	50	53	57	61	65	69
NR – Large	50	53	57	61	65	69

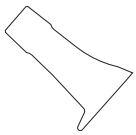
Neck Offset mm When Femoral Head Component Selected Is:						
Size	–3	+0	+4	+8	+12	+16
LS – Small	38	40	43	46	49	52
LS – Medium	43	45	48	51	54	57
LS – Large	43	45	48	51	54	57
NR – Small	38	40	43	46	49	52
NR – Medium	43	45	48	51	54	57
NR – Large	43	45	48	51	54	57

Neck Height mm When Femoral Head Component Selected Is:						
Size	–3	+0	+4	+8	+12	+16
LS – Small	28	30	33	35	38	40
LS – Medium	28	30	33	35	38	40
LS – Large	28	30	33	35	38	40
NR – Small	38	40	43	45	48	50
NR – Medium	43	45	48	50	53	55
NR – Large	43	45	48	50	53	55

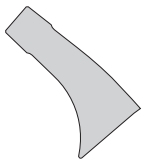
Not Actual Size

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

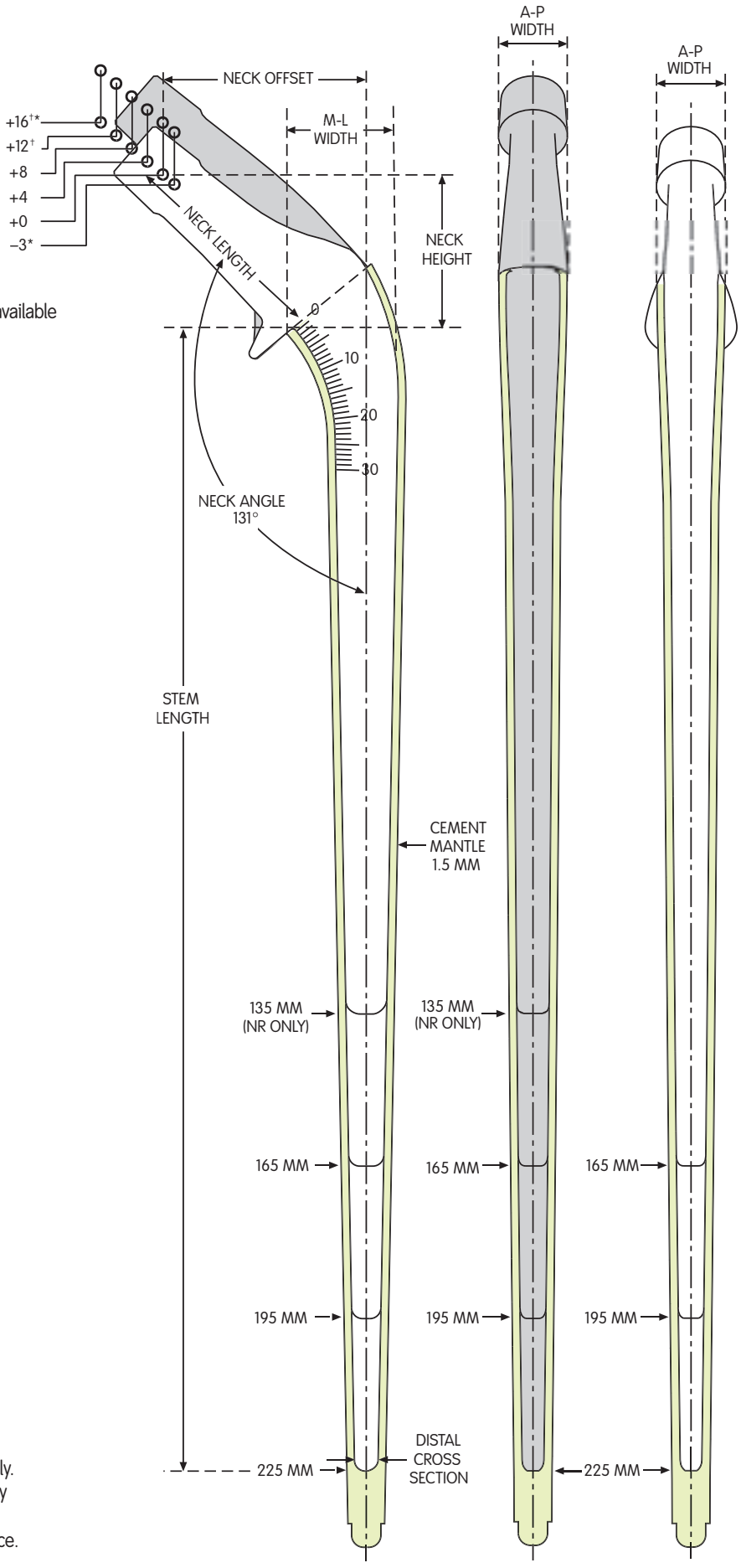
† Denotes skirted head



Long Straight

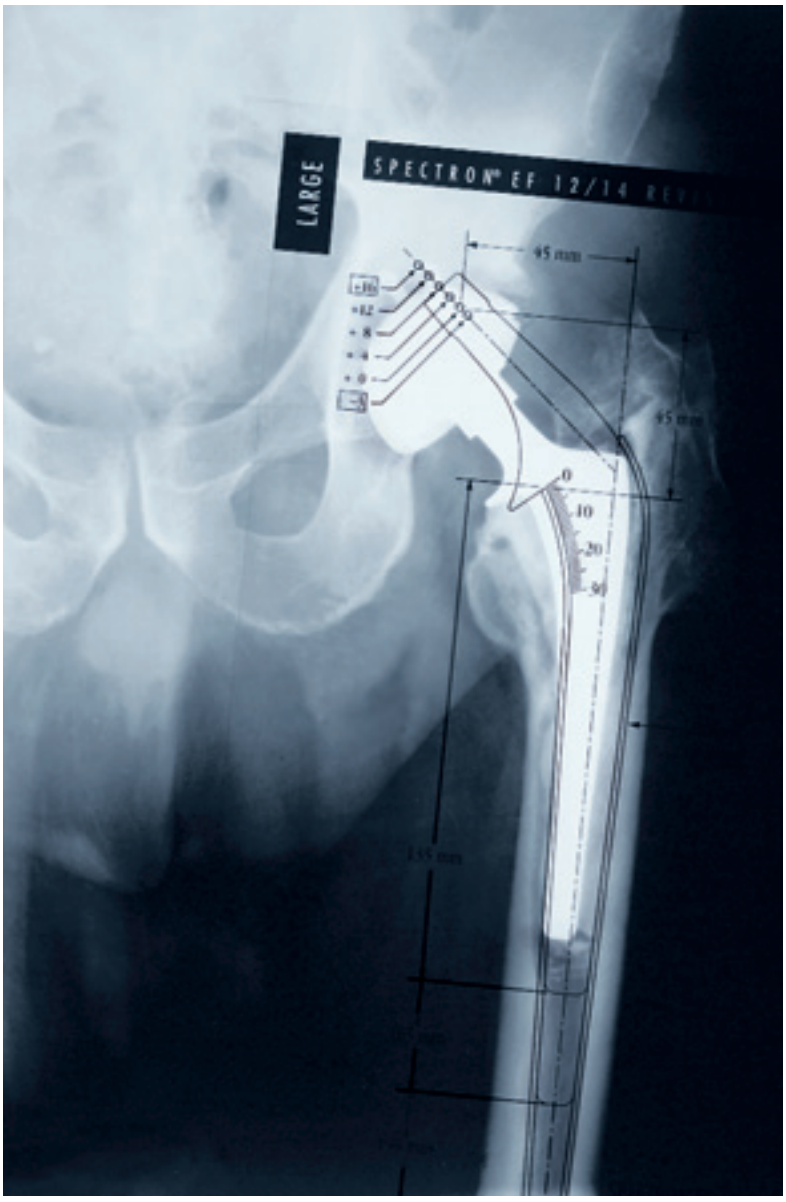


Neck Replacement



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

Templating

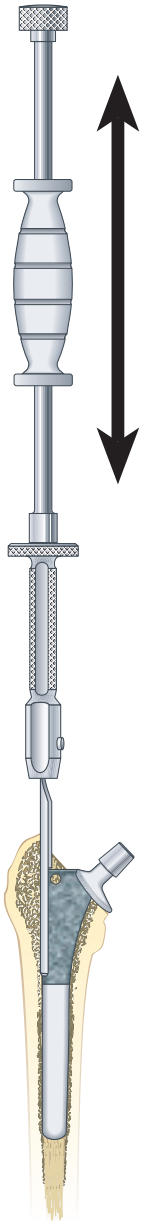


It is of high importance to preoperatively plan the procedure at hand. Templating is a vital part of this planning stage and should be done before the start of surgery.

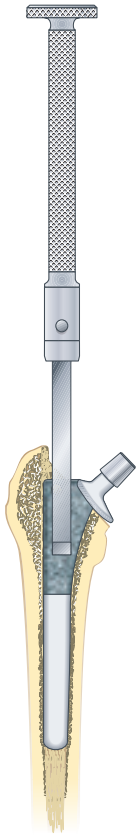
Place the template over the X-ray of the hip to be operated on. Determine the stem size and length of implant that will best fit the canal. Determine whether a Long Straight or Neck Replacement stem is suitable by observing the level of the medial calcar. Match the indicated length of the femoral head 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.

RENOVATION® Implant Removal System

The following is a guide to Smith & Nephew's RENOVATION Implant Removal instrumentation and suggested techniques employed in prosthesis removal.



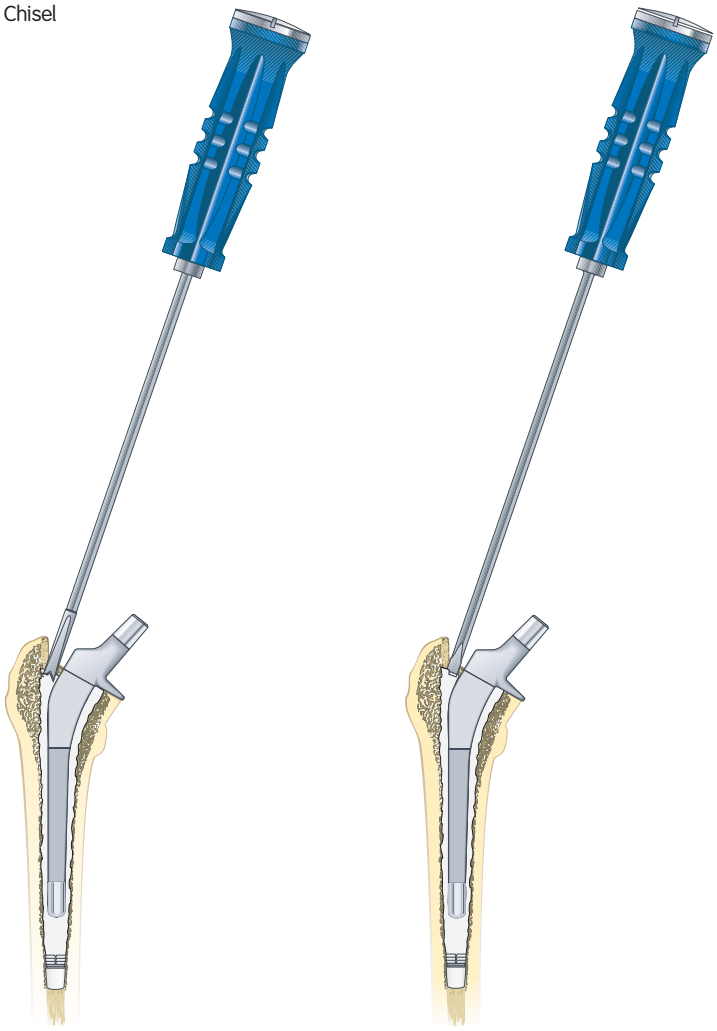
Radial Osteotome Blades
Four Radial Osteotome Blades (7136-9310, 7136-9312, 7136-9314, and 7136-9316) and Short and Long Quick-Coupling Osteotome Handles (7136-7548 and 7136-7549) can be used to disrupt biological fixation in the **lateral** portion of a proximally porous-coated femoral component. The 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.

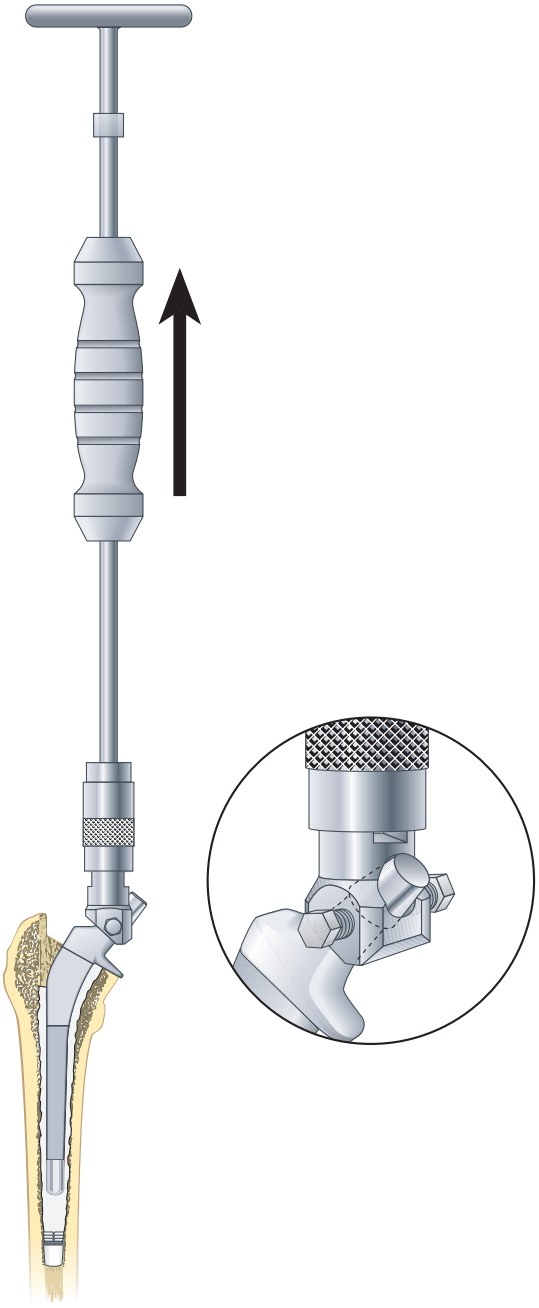


Thin Osteotome Blades
A variety of sizes in the Thin Osteotome Blades and Short and Long Quick-Coupling Handles (7136-7548 and 7136-7549) can be used to disrupt biological fixation in the **anterior** and **posterior** portion of a proximally porous-coated femoral component. The blades are flexible enough 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

Chisel



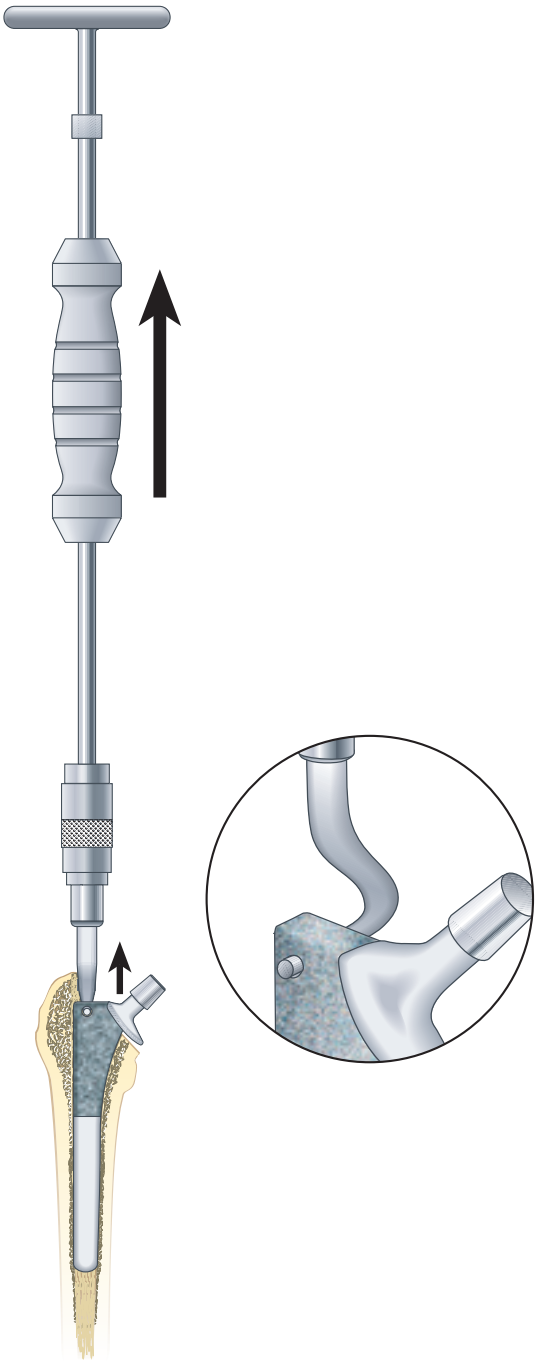


"V" Splitter and Chisel

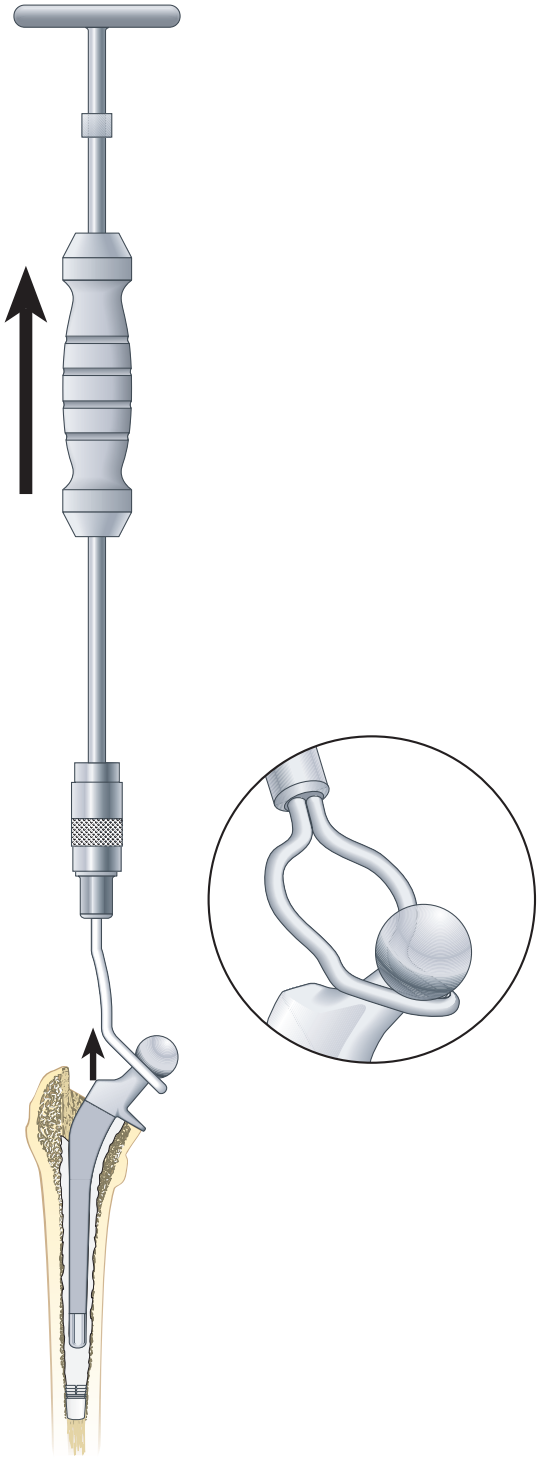
The "V" Splitter (7136-7561) and Chisel (7136-9308) are used to fragment and remove any cement proximal and lateral to the prosthesis. Before attempting to extract a cemented femoral prosthesis, cement should be removed from the lateral aspect of the femoral stem or fracture of the greater trochanter 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).



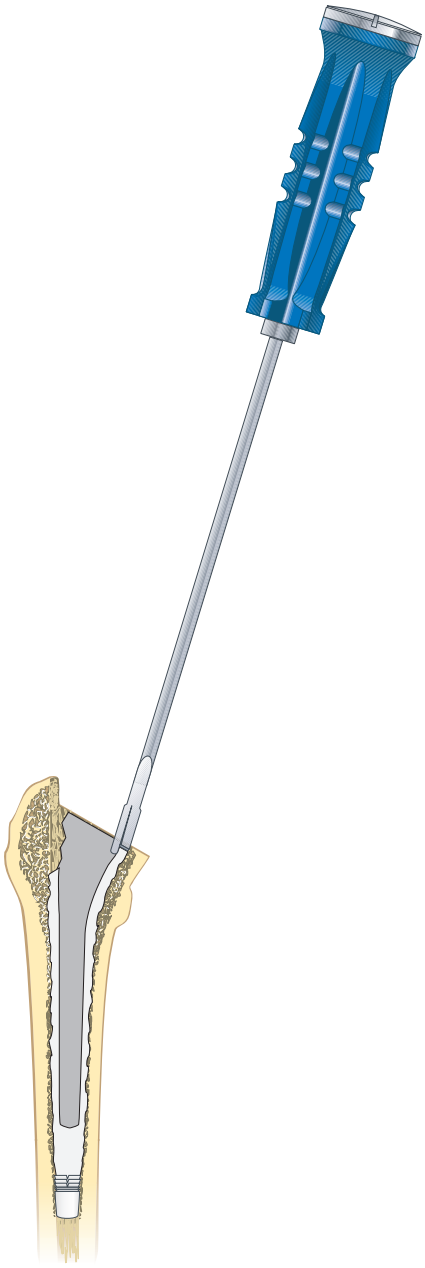
Hook Stem Extractor
If a proximal extraction hole is exposed, the Hook Stem Extractor (7136-7557) can be used with the Large Slap Hammer (7136-7553) to remove the prosthesis. The Hook Stem Extractor is designed to fit most prostheses with a proximal extraction hole. If the extractor does not readily remove the stem, further interface disruption must be accomplished or fracture of the surrounding femur may occur.

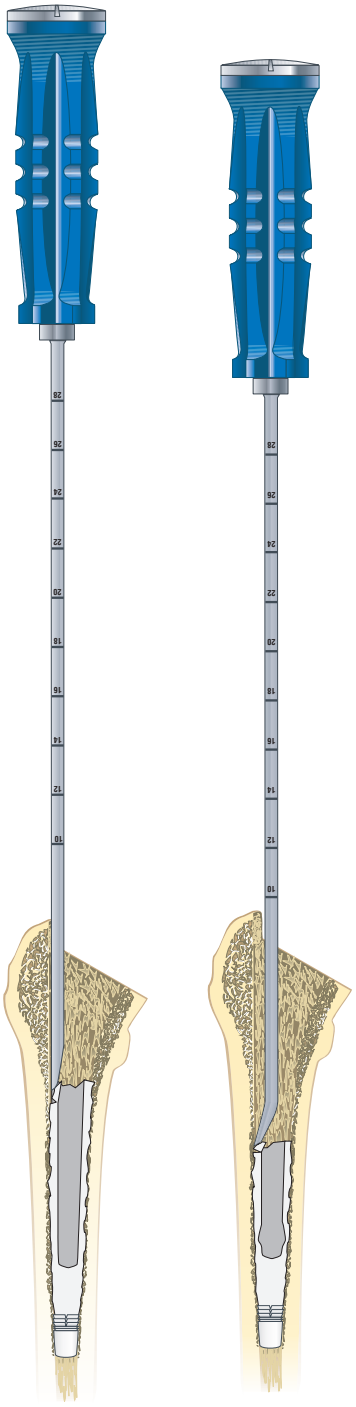


Fixed Head Stem Extractor
With a one-piece femoral prosthesis, the Fixed Head Stem Extractor (7136-7559) can be used with the Large Slap Hammer (7136-7553) to remove the prosthesis. The Fixed Head Stem Extractor is designed to fit over the femoral head of the prosthesis and engage the neck. If the extractor does not readily remove the stem, further cement removal must be accomplished or fracture of the surrounding femur may occur.

Flag Splitter

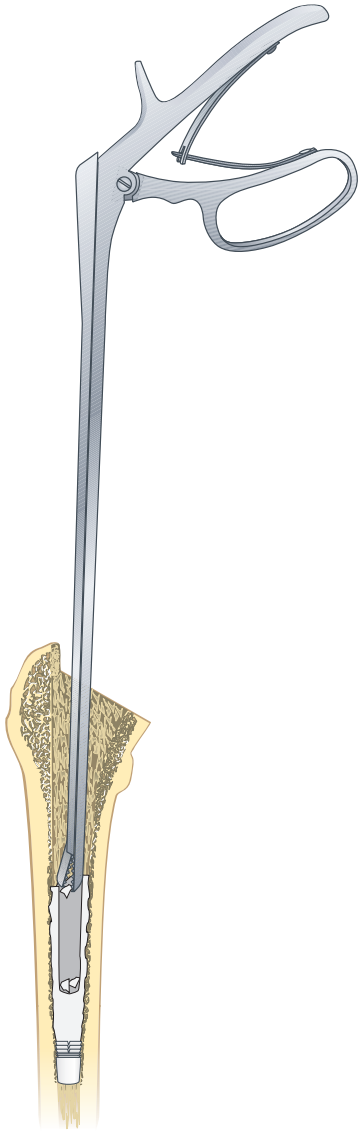
Straight Gouge





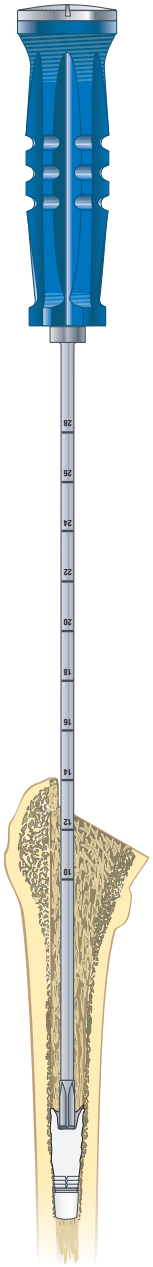
Flag Splitter
Once the cemented femoral component has been removed, the Flag Splitter (7136-7560) may be used to make longitudinal fractures in the proximal cement mantle. This instrument offers a slightly longer tip to guide the cutting edge along the cement mantle.

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.

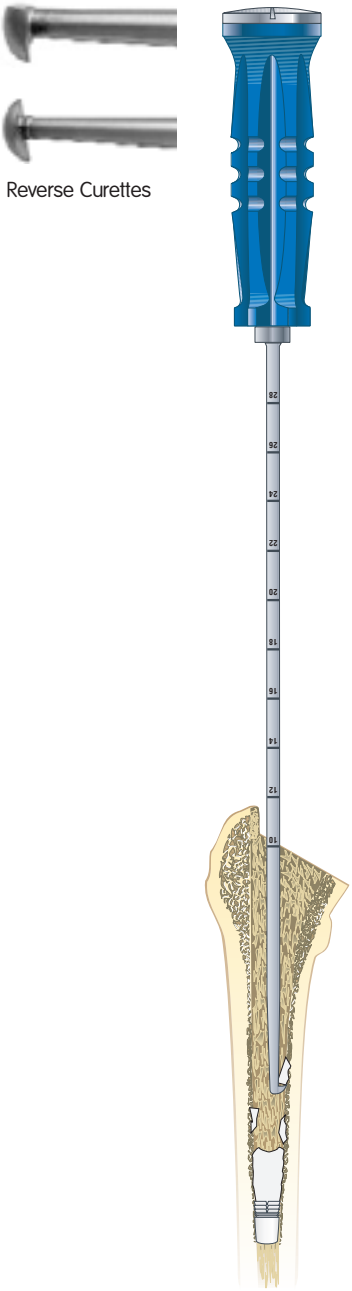


Rongeurs with Teeth
The Rongeurs with Teeth (7136-9200 and 7136-9300) may be used to grasp loose cement particles in the femoral canal. The two lengths, 200 mm and 300 mm, are designed to grasp loose cement in the proximal and distal portion of the femoral canal.

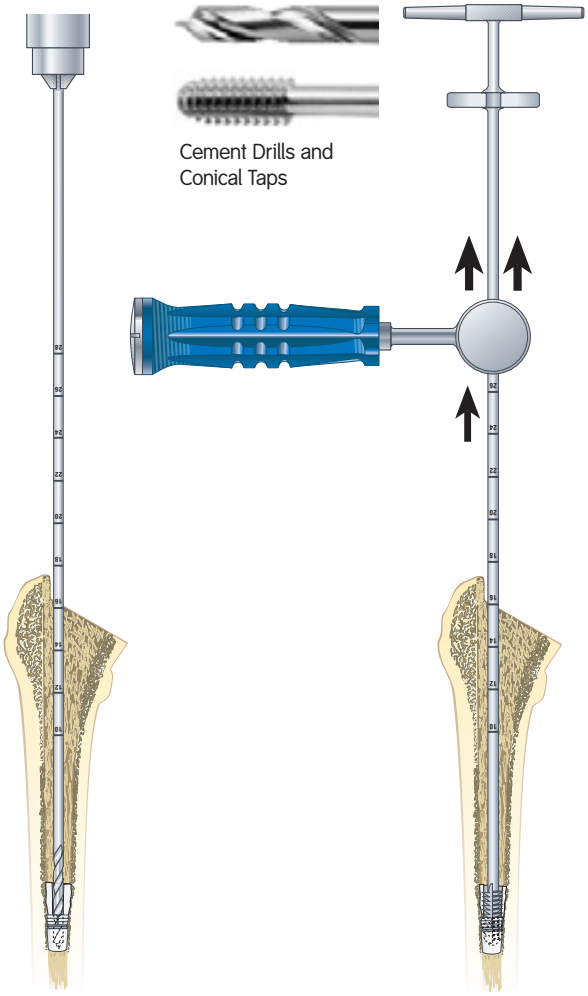
"X" Osteotome



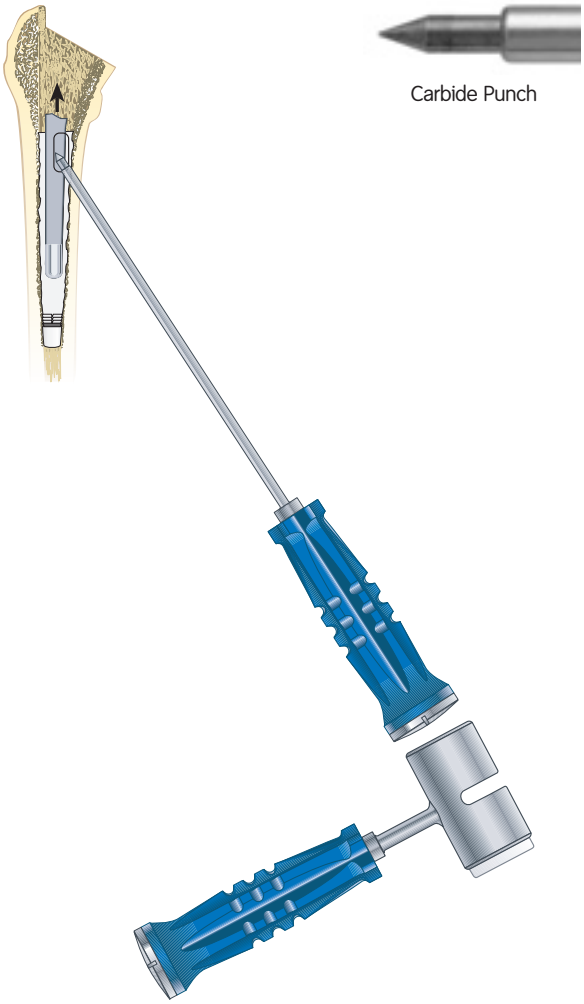
“X” Osteotome
The “X” Osteotome (7136-9207) is very effective in removal of cement distal to the tip of the implant. It is used to progressively fragment the hard cement in this region as it is impacted and rotated repetitively.



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.



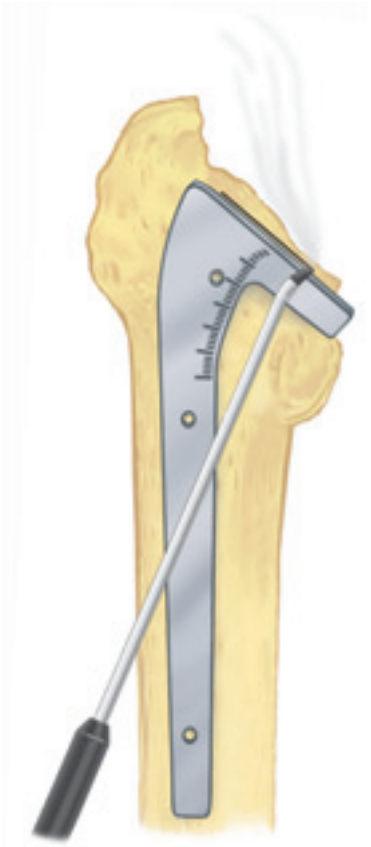
Cement Drills and Conical Taps
If the distal cement mantle is intact and loose, the Cement Drills (7134-9045, 7136-9006, and 7136-9008) and sharp-threaded Conical Taps (7136-9007 and 7136-9009) can be used to extract the distal cement mantle as a large fragment. The risk of cortical perforation should 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.

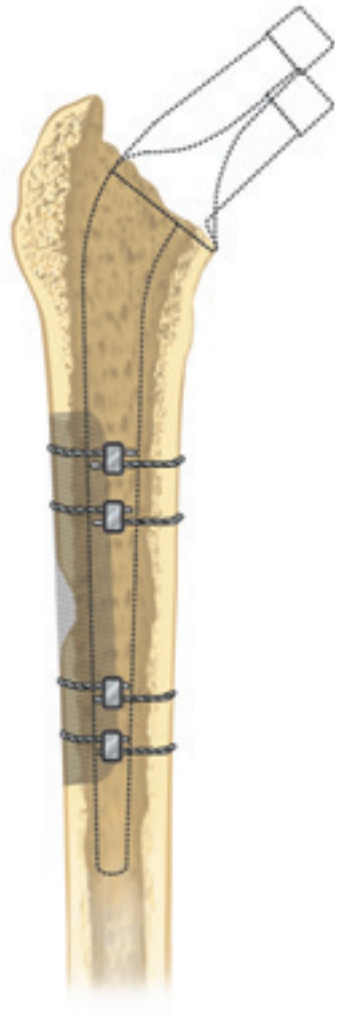


Carbide Punch

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.

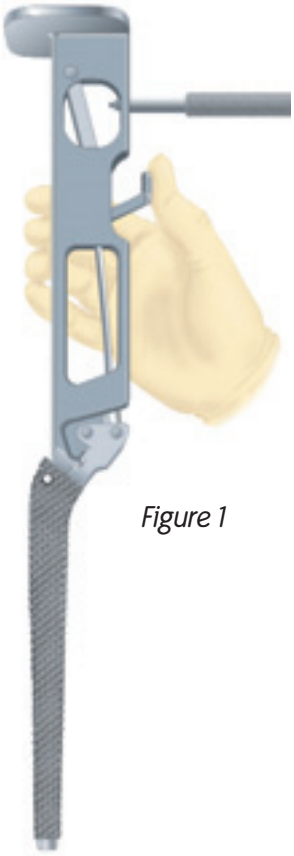


Figure 1

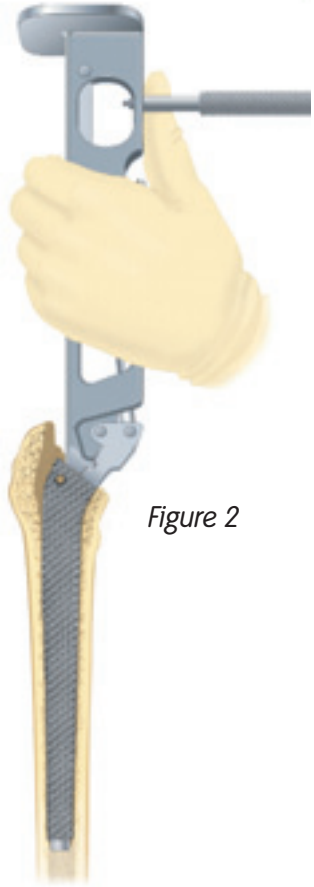


Figure 2

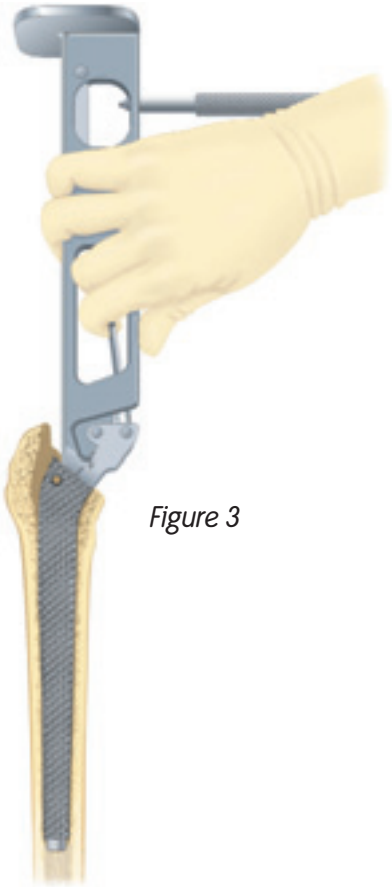


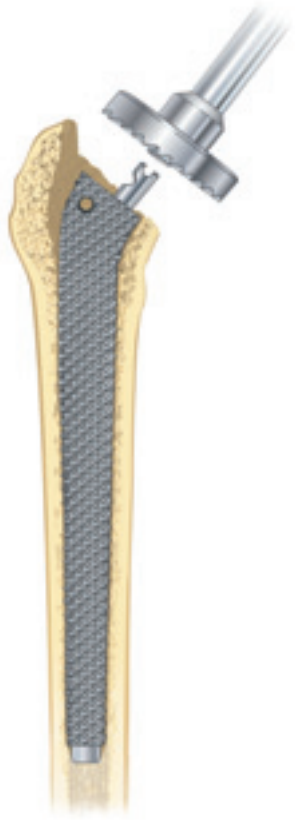
Figure 3

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)*.

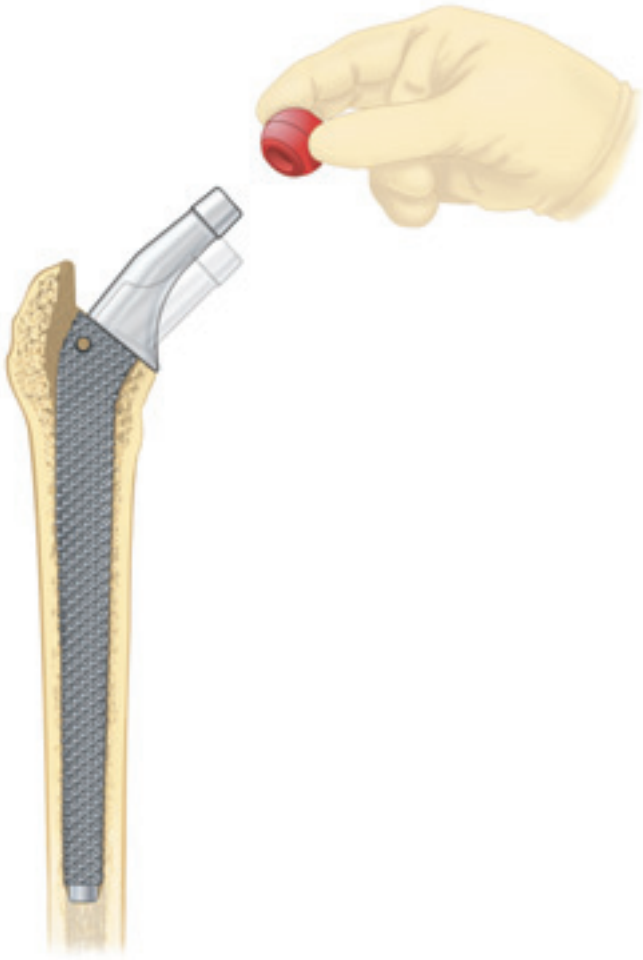
Start the broaching procedure along the mid-axis of the femur with the size Small broach. Continue progressively broaching to the predetermined stem size and length. It is important to stay lateral and posterior with the femoral broaches to ensure proper alignment with the femoral axis. Seat the broach 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.

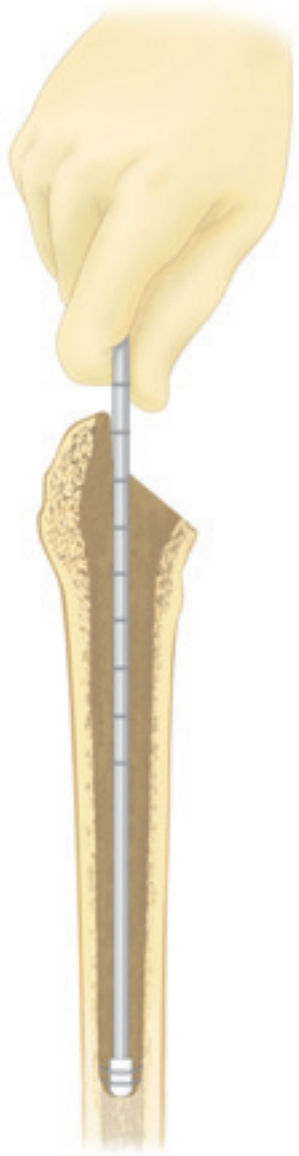


Calcar Preparation
With the final broach fully seated, remove the broach handle and ream the calcar. Plane the calcar until it is level with the broach.



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.



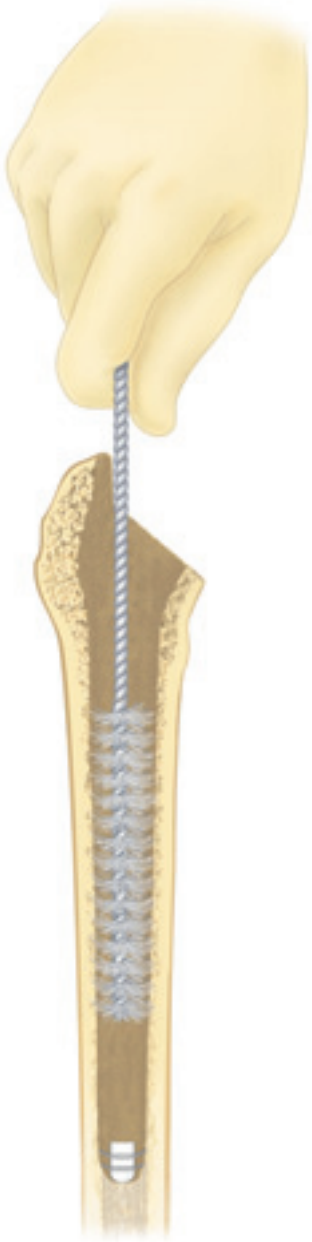
BUCK® Cement Restrictor	
Stem Size	Insertion Depth (mm)
NR – 135 mm	155
LS/NR – 165 mm	185
LS/NR – 195 mm	215
LS/NR – 225 mm	245

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.

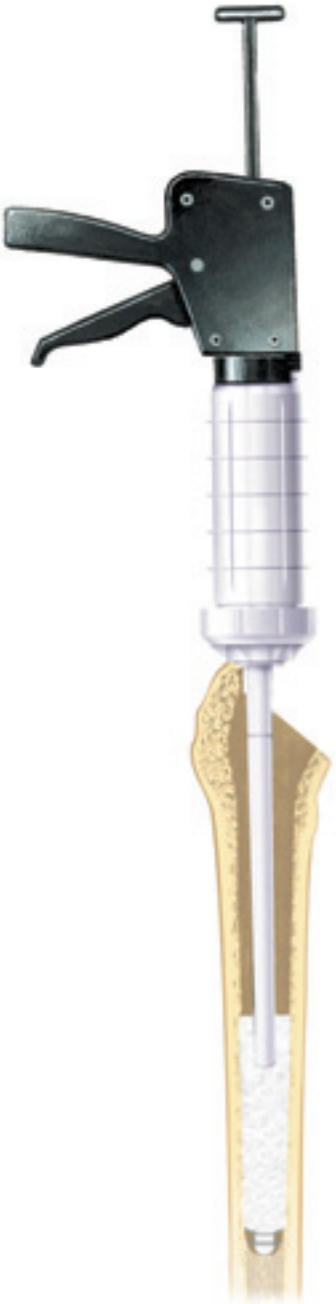


Preparing The Femoral Canal
Irrigate the canal with saline solution and pulsatile lavage to remove all debris. Continue preparing the femur with the femoral canal brush to remove any remaining weak cancellous bone, blood clots, and marrow fats. Repeat lavaging as necessary to remove all remaining debris.

Drying The Femoral Canal
Insert the femoral absorber into the femoral canal to dry the canal while mixing the cement.

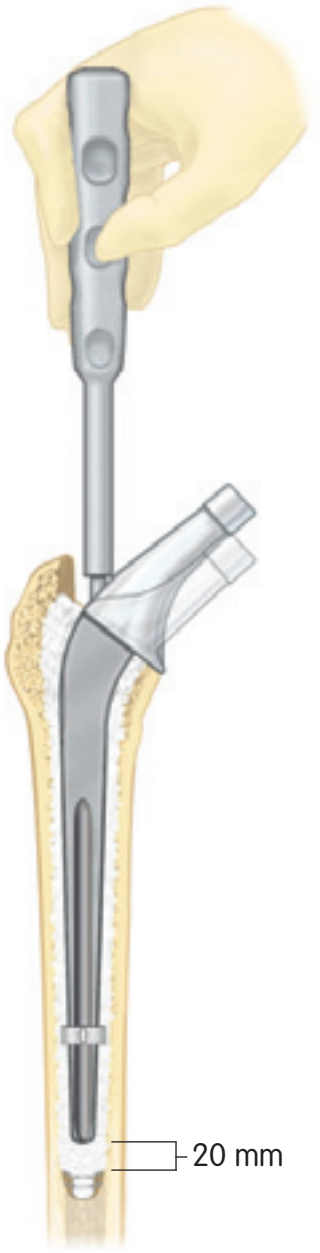
Loading Cement
The amount of cement used in a revision case is usually 80 grams. However, 120 grams may be needed depending on the width and the length of the femoral canal. The VORTEX® Vacuum Mixer allows for mixing of 120 grams of VERSABOND® bone cement in one mixer.

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.

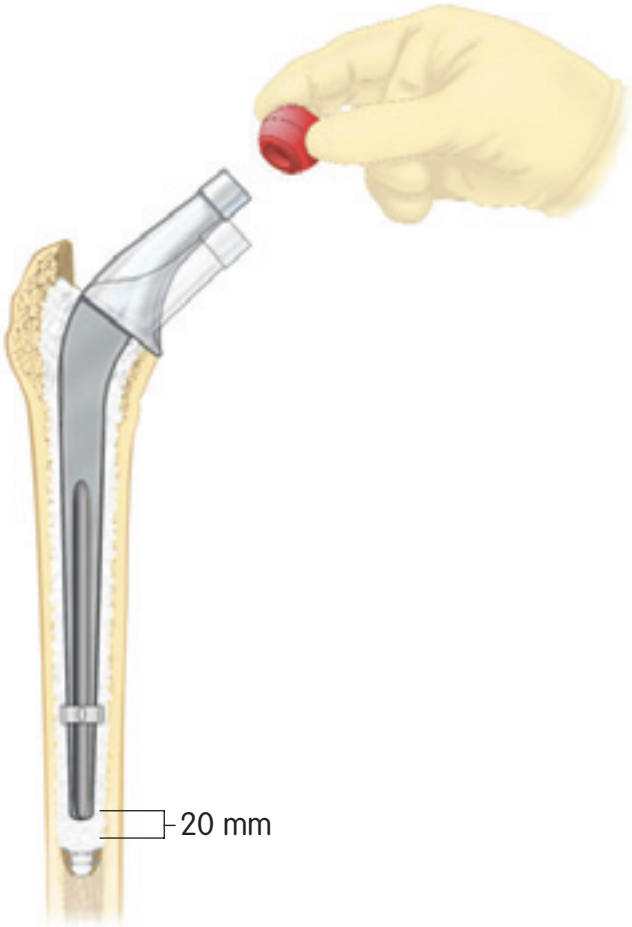


Stem Size	Centralizer Size (mm)	O.D. (mm)
Small	Small	12
Medium	Medium	14
Large	Large	16

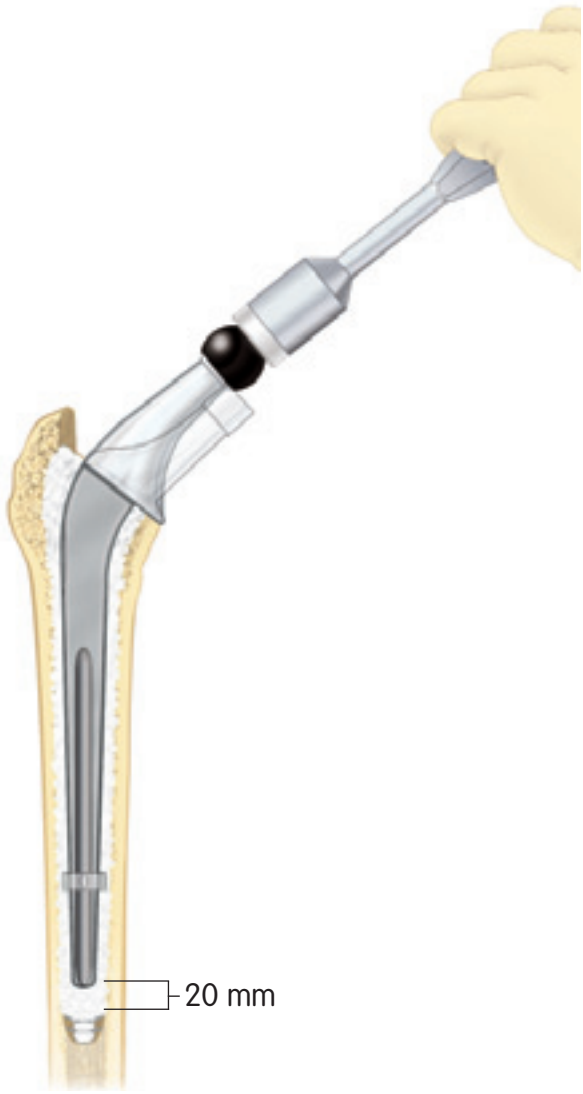
Distal Centralizer Selection
Use the implant, which corresponds to the last broach seated in the femur. An optional distal centralizer may be placed on the stem to assist in providing neutral alignment and predictable cement mantle. Each implant has a corresponding centralizer, which is intended to provide 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.

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

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

Size	Length	Cat. No.
Small	165 mm	7131-2231
Medium	165 mm	7131-2232
Large	165 mm	7131-2233
Small	195 mm	7131-2234
Medium	195 mm	7131-2235
Large	195 mm	7131-2236
Small	225 mm	7131-2237
Medium	225 mm	7131-2238
Large	225 mm	7131-2239

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

Size	Length	Cat. No.
Small	135 mm	7131-2240
Medium	135 mm	7131-2241
Large	135 mm	7131-2242
Small	165 mm	7131-2243
Medium	165 mm	7131-2244
Large	165 mm	7131-2245
Small	195 mm	7131-2246
Medium	195 mm	7131-2247
Large	195 mm	7131-2248
Small	225 mm	7131-2249
Medium	225 mm	7131-2250
Large	225 mm	7131-2251

OXINIUM® 12/14 Taper Femoral Heads

Neck Length	28 mm	32 mm	36 mm
–3	7134-2803	7134-3203	7134-3603
+0	7134-2800	7134-3200	7134-3600
+4	7134-2804	7134-3204	7134-3604
+8	7134-2808	7134-3208	7134-3608
+12	7134-2812	7134-3212	7134-3612
+16	7134-2816	7134-3216	—

CoCr 12/14 Taper Femoral Heads

Cobalt Chromium – ASTM F 799

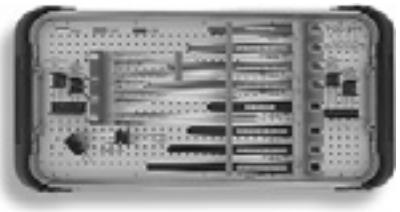
Neck Length	22 mm	26 mm	28 mm	32 mm
–3	—	—	7130-2803	7130-3203
+0	7130-2200	7130-2600	7130-2800	7130-3200
+4	7130-2204	7130-2604	7130-2804	7130-3204
+8	7130-2208	7130-2608	7130-2808	7130-3208
+12	7130-2212	7130-2612	7130-2812	7130-3212
+16	—	—	7130-2816	7130-3216

Trial 12/14 Taper Femoral Heads

Neck Length	Color Code	22 mm	26 mm	28 mm	32 mm
–3	Green	—	—	7135-2803	7135-3203
+0	Yellow	7135-2200	7135-2600	7135-2800	7135-3200
+4	Red	7135-2204	7135-2604	7135-2804	7135-3204
+8	White	7135-2208	7135-2608	7135-2808	7135-3208
+12	Blue	7135-2212	7135-2612	7135-2812	7135-3212
+16	Black	—	—	7135-2816	7135-3216

SPECTRON 12/14 REVISION Instrumentation

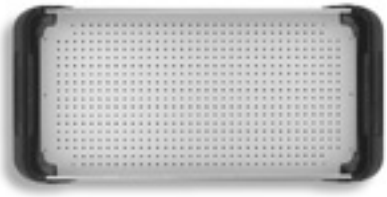
NOTE: *The SPECTRON EF Primary Instrument Tray needs to be brought into the O.R. to access the following instruments: Broach Handle (7136-4007); 12/14 Trial Heads; Stem Driver (11-9817); and the Femoral Head Impactor (7136-4009).*



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

Size	Length	Cat. No.
Small*	135 mm	7136-5126
Medium*	135 mm	7136-5127
Large*	135 mm	7136-5128
Small	165 mm	7136-5129
Medium	165 mm	7136-5132
Large	165 mm	7136-5135
Small	195 mm	7136-5130
Medium	195 mm	7136-5133
Large	195 mm	7136-5136
Small	225 mm	7136-5131
Medium	225 mm	7136-5134
Large	225 mm	7136-5137

**Only available with neck replacement implants.*

SPECTRON REVISION Centralizer

Size	O.D.	Cat. No.
Small	12 mm	7131-3312
Medium	14 mm	7131-3314
Large	16 mm	7131-3316

Long Straight Trial Necks 12/14 Taper

Size	Cat. No.
Small	7136-5098
Medium/Large	7136-5099

Neck Replacement Trial Necks 12/14 Taper

Size	Cat. No.
Small	7136-5096
Medium/Large	7136-5097

Osteotomy Guide

Cat. No. 7136-4000

REVISION Implant Removal System Instrumentation

7136-7500	**RENOVATION® Implant Removal Kit** *Includes the Acetabular and Femoral Implant Removal Trays and Instruments. Disposable Osteotome Blades are not included.*

7136-7540	**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"

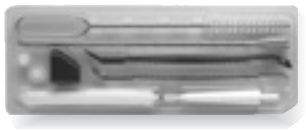
7136-7551	**Femoral Implant Removal Tray** **Tray Accepts the Following:**
7136-7571	Femoral Implant Removal Tray Insert #1
7136-7572	Femoral Implant Removal Tray Insert #2
7136-7552	Slotted Mallet
7136-7553	Large Slap Hammer
7136-7555	Modular Stem Extractor
7136-7556	T-Handle Wrench
7136-7557	Hook Stem 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

Cat. No.	O.D.
11-0003	19 mm
11-0033	12.5 mm

BUCK Femoral Cement Restrictor Inserter

Cat. No. 11-2428

VORTEX° Vacuum Mixer

Cat. No. 7127-0070

VORTEX Nozzles

Cat. No.	Description
7127-0080	Standard Breakaway
7127-0081	Long Tapered
7127-0084	Revision
7127-0085	Umbrella
7127-0071	Re-use Kit (not shown)
7127-0072	Adaptor

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

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, OXINIUM® oxidized zirconium or stainless steel. Acetabular liners are ultra-high molecular weight polyethylene or alumina ceramic. All poly acetabular components are ultra-high molecular weight polyethylene. Acetabular shells are titanium 6Al-4V alloy. The component material is provided on the outside carton 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 organism 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 phenomenon, 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, hydroxylapatite (HA) coated, or HA porous coated. All implantable devices are designed for single use only.

Femoral Components

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

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), bipolars or unipolar components.

Femoral components with a 12/14 taper mate and lock with either metal heads, oxidized zirconium heads, ceramic heads,bipolar 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. Heads are highly polished for reduced friction and wear. The following zirconia ceramic heads are available for use only with Small and Large taper femoral components:

Zirconia Ceramic	Head Diameter	Neck Length	
42-7815	32 mm	Standard	0 mm
42-7816	32 mm	Long	+4mm
42-7817	32 mm	X-Long	+8mm
42-7818	28 mm	Standard	0 mm
42-7819	28 mm	Long	+4mm
42-7820	28 mm	X-Long	+8mm

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

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

Zirconia Ceramic	Head Diameter	Neck Length	
7132-0002	22 mm	Long	+4 mm
7132-0006	22 mm	X-Long	+8mm

Note: 22 mm Zirconia Ceramic Heads used with Small taper femoral components are not available in the USA.

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

Zirconia Ceramic	Head Diameter	Neck Length	
7132-0028	28 mm	Standard	0 mm
7132-0428	28 mm	Long	+4 mm
7132-0828	28 mm	X-Long	+8 mm
7132-0026	26 mm	Standard	0 mm
7132-0426	26 mm	Long	+4 mm
7132-0826	26 mm	X-Long	+8 mm
7132-0422	22 mm	Long	+4 mm
7132-0822	22 mm	X-Long	+8 mm

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

Alumina Ceramic	Head Diameter	Neck Length	
7133-2800	28 mm	Standard	0 mm
7133-2804	28 mm	Long	+4 mm
7133-2808	28 mm	X-Long	+8 mm
7133-3200	32 mm	Standard	0 mm
7133-3204	32 mm	Long	+4 mm
7133-3208	32 mm	X-Long	+8 mm
7133-3600	36 mm	Standard	0 mm
7133-3604	36 mm	Long	+4 mm
7133-3608	36 mm	X-Long	+8 mm

Acetabular Components

Acetabular components can be one piece 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 use. Acetabular reinforcement and reconstruction rings are used with an all polyethylene acetabular component.

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

Note: 10 Mrad cross-linked polyethylene (UHMWPE) Reflection® acetabular liners may be used with metal (CoCr), oxidized zirconium, alumina ceramic or zirconia ceramic femoral heads.

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

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 (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.

Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis, arthritis secondary to a variety of diseases and anomalies, and congenital dysplasia; old, remote osteomyelitis with an extended drainage-free period, in which case, the patient should be warned of an above normal danger of infection postoperatively; treatments of nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; endoprosthesis, 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.
4. Skeletal immaturity.
5. The zirconia ceramic head is contraindicated for use with any other product than an UHMW polyethylene cup or a metal backed UHMW polyethylene cup.
6. The alumina ceramic liner is contraindicated for use with any product other than the metal shell with the correlating 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: osteoporosis, metabolic disorders which may impair bone formation, and osteomalacia.

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 during or as a result of the surgical procedure and cause abrasion of the articulating surfaces. Higher rates of wear may shorten the useful life of the prosthesis and lead to early revision surgery to replace the worn prosthetic components.
2. With all joint replacements, asymptomatic, localized, progressive bone resorption (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 adhesion, abrasion, and fatigue. Secondarily, particles may also be generated by third-body particles lodged in the polyethylene or ceramic articular surfaces. Osteolysis can lead to future complications necessitating the removal or replacement of prosthetic components.
3. Loosening, bending, cracking, or fracture of implant components may result from failure to observe the Warnings and Precautions below. Fracture of the implant can occur as a result of trauma, strenuous activity, improper alignment, or duration of service.
4. Dislocations, subluxation, decreased range of motion, or lengthening or shortening of the femur caused by improper neck selection, positioning, 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 misdirected reaming, 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 permanent nerve damage resulting in pain or numbness of the affected limb.
8. Wound hematoma, thromboembolic disease including venous thrombosis, pulmonary embolus, or myocardial infarction.
9. Myositis ossificans, especially in males with hypertrophic arthritis, limited pre-operative range of motion and/or previous myositis. Also, periarticular calcification with or without impediment 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 arthrosis of the knee from intraoperative positioning of the extremity.
14. Delayed wound healing.
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/ porous coating bonding may result in bead separation delamination.
17. Stem migration or subsidence has occurred in conjunction with compaction grafting procedures usually resulting from insufficient graft material or improper cement techniques. Varus stem alignment may also be responsible.

WARNINGS AND PRECAUTIONS

The patient should be warned of surgical risks, and made aware of possible adverse effects. The patient should be warned that the device does not replace normal 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. Implants and instruments 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. Allergies and other reactions to device materials, although infrequent, should be considered, tested for (if appropriate), and ruled out preoperatively.
3. Fixation and expected longevity of components expected to be left in place at revision surgery should be thoroughly assessed.
4. Surgical technique information is available upon request. The surgeon should be familiar with the technique. 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 heads while fixed on the stem taper. (See sterilization section, below.)
7. Select components such that the Zirconia ceramic, oxidized zirconium, and alumina heads always articulates with a UHMW polyethylene cup or a metal backed UHMW polyethylene cup. Zirconia ceramic, oxidized zirconium, and alumina heads should never articulate against metal because severe wear of the metal will occur.
8. 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.
9. The zirconia ceramic head is composed of a new ceramic material with limited clinical history. Although mechanical testing demonstrates that when used with a polyethylene acetabular component the yttria stabilized zirconia ball produces a relatively low amount of particulates, 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.
10. Alumina ceramic should never articulate against metal because severe wear could occur.

Intraoperative

1. The general principles of patient selection and sound surgical judgment apply. The correct selection of the implant is extremely important. The appropriate type 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-section component which will allow adequate bone support to be maintained is preferred. Failure to use the optimum-sized component may result in loosening, bending, cracking, or fracture of the component and/or bone.
2. Correct selection of the neck length and cup, and stem positioning, are important. Muscle looseness and/or malpositioning of components may result in loosening, subluxation, dislocation, and/or fracture of components. Increased neck length and varus positioning will increase stresses which must be borne by the stem. The component should be firmly seated with the component insertion instruments.
3. Care should be taken not to scratch, bend (with the exception of the Reconstruction Rings) or cut implant components during surgery for the reasons stated in Number One of the "Pre-Operative" section of "Warnings and Precautions."
4. **A +12 mm or +16 mm femoral head should not be used with any Small taper stems.**
5. **Distal sleeves should not be used to bridge cortical defects that lie within 25 mm of the tip of the base stem.**
6. MATRIX® Small taper stem sizes 8S - 10L must have a minimum neck length of +8 mm when used with a bipolar component; and Small taper stem sizes 12S - 16L must have a minimum neck length of +4 mm when used with a bipolar component.
7. Modular heads and femoral components should be from the same manufacturer to prevent mismatch of tapers.
8. Stainless steel heads and stainless steel stems should only be used together. Neither should be used with other metal components.
9. Use only Reflection Liners with Reflection Shells.
10. Clean and dry stem taper prior to impacting the femoral head or taper sleeve. The modular femoral head component must be firmly seated on the femoral component to prevent disassociation.
11. Take care, when positioning and drilling screw and peg holes, to avoid penetration of the inner cortex of the pelvis, penetration of the sciatic notch, or damage to vital neurovascular structures. Perforation of the pelvis with screws that are too long can rupture blood vessels causing the patient to hemorrhage. Do not place a screw in the center hole of the acetabular prosthesis. Placement of drills and screws in the anterior or medial portions of the prosthesis is associated with a high risk of potentially fatal vascular injury. Bone screws must be completely seated in the holes of the shell to allow proper locking for the acetabular component liner. If the tapered pegs need to be removed from the shell after impaction of the pegs, do not reuse the pegs or the peg shell holes. Use new pegs and different shell holes, or a new shell if necessary.
12. USE ONLY REFLECTION TITANIUM SPHERICAL HEAD BONE SCREWS, UNIVERSAL CANCELLOUS BONE SCREWS, TAPERED PEGS, AND HOLE COVERS with the Reflection Acetabular Component and USE ONLY OPTI-FIX® TITANIUM BONE SCREWS AND UNIVERSAL CANCELLOUS BONE SCREWS with the Opti-Fix Acetabular Component. Reflection Spherical Head Screws are only for use with SP3, FSO and InterFit Shells. The Reflection SP3, V, InterFit® and the Reflection For Screws Only (FSO) shells accept Universal Cancellous, Reflection screws, and tapered screw-hole covers, not pegs. Reflection Peripheral Hole Screws should only be used with Reflection Peripheral Hole Shells. Locking Head Pegs and Reflection Screw Hole Covers are only for use with SP3 Shells. Tapered pegs can only be used with Reflection V Shells. The threaded center hole in Reflection Shells only accepts the threaded hole cover, not screws or pegs. The InterFit threaded hole cover is only for use with Reflection InterFit, SP3, Spiked and No Hole Shells. The Reflection threaded hole cover can be used with all Reflection shells. Refer to product literature for proper adjunctive fixation and hole cover usage.
13. Prior to seating modular components, surgical debris including tissue must be cleaned from the surfaces. Debris, including bone cement, may inhibit the component locking mechanism. If the shell is to be cemented in place, remove extraneous cement with a plastic sculps tool to ensure proper locking of the liner. During liner insertion, make sure soft tissue does not interfere with the shell/liner interface. Chilling the liner reduces the impaction force required to seat the liner. Modular components must be assembled securely to prevent disassociation. Debris inhibits the proper fit and locking of modular components which may lead to early failure of the procedure. Failure to properly seat the acetabular liner into the shell can lead to disassociation of the liner from the shell.
14. Avoid repeated assembly and disassembly of the modular components which could compromise the critical locking action of the locking mechanism.
15. Care is to be taken to assure complete support of all parts of the device embedded in bone cement to prevent stress concentration which may lead to failure of the procedure. During curing of the cement, care should be taken to prevent movement of the implant components.
16. If the head is removed from a femoral component that will be left in place at revision surgery, it is recommended that a metal head be used. A ceramic head may fracture from irregularities on the femoral component taper.
17. If components are to be left in place at revision surgery, they should first be thoroughly checked for signs of looseness, etc. and replaced if necessary. The head/neck component should be changed only when clinically necessary.
18. Once removed from the patient, implants previously implanted should never be reused, since internal stresses which are not visible may lead to early bending or fracture of these components.
19. With the congenitally dislocated hip, special care should be taken to prevent sciatic nerve palsy. Also, note that the femoral canal is often very small and straight and may require an extra-small straight femoral prosthesis; however, a regular-sized prosthesis should be used when possible. Note that the true acetabulum is rudimentary and shallow. A false acetabulum should not ordinarily be utilized as a cup placement site for anatomical and biomechanical reasons.
20. With rheumatoid arthritis, especially for those patients on steroids, bone may be extremely osteoporotic. Care should be taken to prevent excessive penetration of the acetabular floor or fracture of the medial acetabular wall, femur, or greater trochanter.
21. Revision procedures for previous arthroplasty, Girdlestone, etc., are technically demanding and difficult to exercise. Common errors include misplacement of the incision, inadequate exposure or mobilization of the femur, inadequate removal of ectopic bone, or improper positioning of components. Postoperative instability as well as excessive blood loss can result. In summary, increased operative time, blood loss, increased incidence of pulmonary embolus and wound hematoma can be expected with revision procedures.
22. Prior to closure, the surgical site should be thoroughly cleaned of cement, bone chips, ectopic bone, etc. Ectopic bone and/or bone spurs may lead to dislocation or painful or restricted motion. Range of motion should be thoroughly checked for early contact or instability.
23. Proper positioning of the components is important to minimize impingement which could lead to early failure, premature wear, and/or dislocation.
24. In order to minimize the risks of dislocation and loosening of the shell-acetabular bone or shell-bone cement interface that may occur when using a metallic shell intended for biological fixation or cemented use only, surgeons should consider providing immediate resistance to tensile forces between the metallic shell and the acetabular bone or bone cement interface through the use of orthopedic bone fixation devices such as bone screws, spikes, screw threads, pegs, fins, or other bone fixation devices.
25. Physicians should consider component malposition, component placement, and the effect on range of motion when using modular heads (with sleeves or skirts) and extended liners.

Postoperative

1. Postoperative directions and warnings to patients by physicians, and patient care, are extremely important. Gradual weight bearing is begun after surgery in ordinary total hip arthroplasty. However, with trochanter osteotomy or certain complex cases, weight-bearing status should be individualized with the non or partial weight-bearing period extended.
2. Patients should be warned against unassisted activity, particularly use of toilet facilities and other activities requiring 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 of activities.
5. Periodic x-rays are recommended for close comparison with immediate postoperative conditions to detect long-term evidence of changes in position, loosening, 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. If the sterile barrier has been broken, return the component to Smith & Nephew, Inc.

STERILIZATION/RESTERILIZATION

Most implants are supplied sterile 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 kiloGrays of gamma radiation. 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 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, 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 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 2010. The recommended prevacuum sterilization cycle is: Evacuation to 100mBar for 2-3 minutes, Negative Pressure pulsing (5): 800mBar-100mBar, Positive Pressure pulsing (5): 2.2Bar – 1.1 Bar, Sterilization exposure: 3 minutes at 134°-137°C, Drying vacuum 40mBar for 5-10 minutes. **Note:** mBar absolute.

• Gravity Cycle: 270°F to 275°F (132°C to 135°C) with a minimum dwell time at temperature of 10 minutes, followed by a 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 sterilization on implants.

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 RESTERILIZE porous coated or HA 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
100% EtO	131°F (55°C)	40-80% (70% Target)	10 PSIA (689 millibar)	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
1450 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

81004721 Rev. 0 10/02 CE0123

Smith & Nephew, Inc.
1450 Brooks Road
Memphis, TN 38116
USA

Phone: (901) 396-2121
Information: 1-800-821-5700
Orders and Inquiries: 1-800-238-7538

www.smith-nephew.com

Printed in USA
45600102 7138-0631 09/03