S M I T H & N E P H E W

SPECTRON EF HIP SYSTEM

SURGICAL TECHNIQUE 12/14 TAPER

SPECTRON® EF

HIP SYSTEM

Surgical technique completed
in conjunction with

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Nota Bene: The technique description herein is made available to the healthcare professional to illustrate the authors' suggested treatment for the uncomplicated procedure. In the final analysis, the preferred treatment is that which addresses the needs of the patient.

Stem Specifications

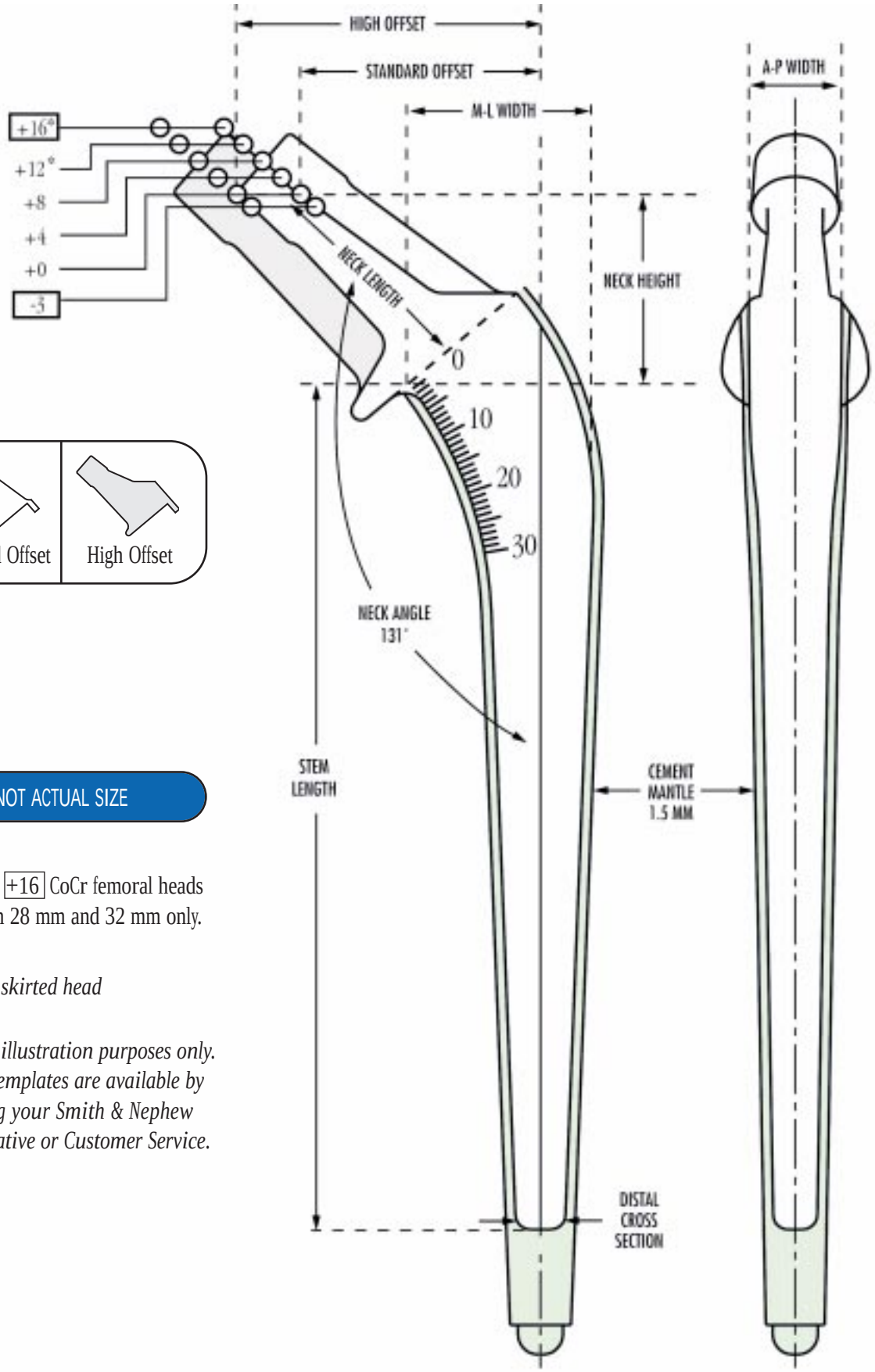
SPECIFICATIONS					
Size	Neck Angle	Distal Cross Section	Stem Length	A-P Width	M-L Width
1, 1H	131°	6 mm	115 mm	12.9 mm	25.4 mm
2, 2H	131°	7 mm	125 mm	13.7 mm	27.2 mm
3, 3H	131°	8 mm	135 mm	14.5 mm	28.9 mm
4, 4H	131°	10 mm	135 mm	15.3 mm	30.7 mm
5, 5H	131°	12 mm	135 mm	16.1 mm	32.5 mm

NECK HEIGHT MM						
	When Femoral Head Component Selected Is:					
Size	–3	+0	+4	+8	+12	+16
1	24	26	28	31	34	36
1H	24	26	28	31	34	36
2	26	28	30	33	36	38
2H	26	28	30	33	36	38
3	28	30	32	35	37	40
3H	28	30	32	35	37	40
4	30	32	34	37	39	42
4H	30	32	34	37	39	42
5	32	34	36	39	41	44
5H	32	34	36	39	41	44

NECK OFFSET MM						
	When Femoral Head Component Selected Is:					
Size	–3	+0	+4	+8	+12	+16
1	32	35	38	41	44	47
1H	38	41	44	47	50	53
2	34	36	39	42	45	48
2H	42	44	47	50	53	56
3	35	38	41	44	47	50
3H	45	48	51	54	57	60
4	37	39	42	45	48	51
4H	47	49	52	55	58	61
5	38	41	44	47	50	53
5H	48	51	54	57	60	63

NECK LENGTH MM						
	When Femoral Head Component Selected Is:					
Size	–3	+0	+4	+8	+12	+16
1	27	30	34	38	42	46
1H	31	34	38	42	46	50
2	29	32	36	40	44	48
2H	34	37	41	45	49	53
3	31	34	38	42	46	50
3H	37	40	44	48	52	56
4	33	36	40	44	48	52
4H	39	42	46	50	54	58
5	35	38	42	46	50	54
5H	41	44	48	52	56	60

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



NOT ACTUAL SIZE

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

** Denotes skirted head*

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

1. Femoral Osteotomy

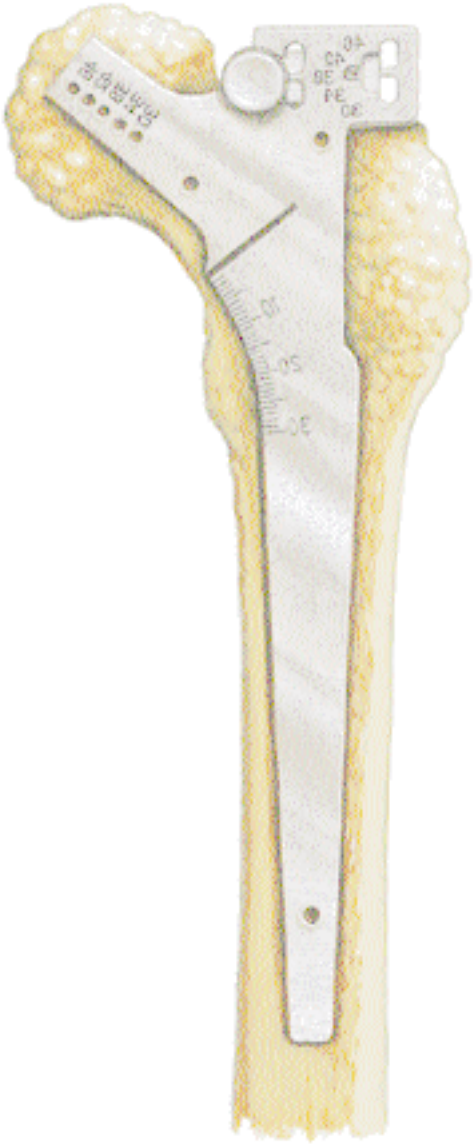
Use the osteotomy guide to determine the level of resection, using one of the following techniques:

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

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

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

In the O.R., place the greater trochanter block on the osteotomy guide at this numerical position. If the number does not match perfectly, use the lower number. Place the guide on the femur by resting the block on the top of the greater trochanter. Osteotomize the neck.



2. Prepare Acetabulum

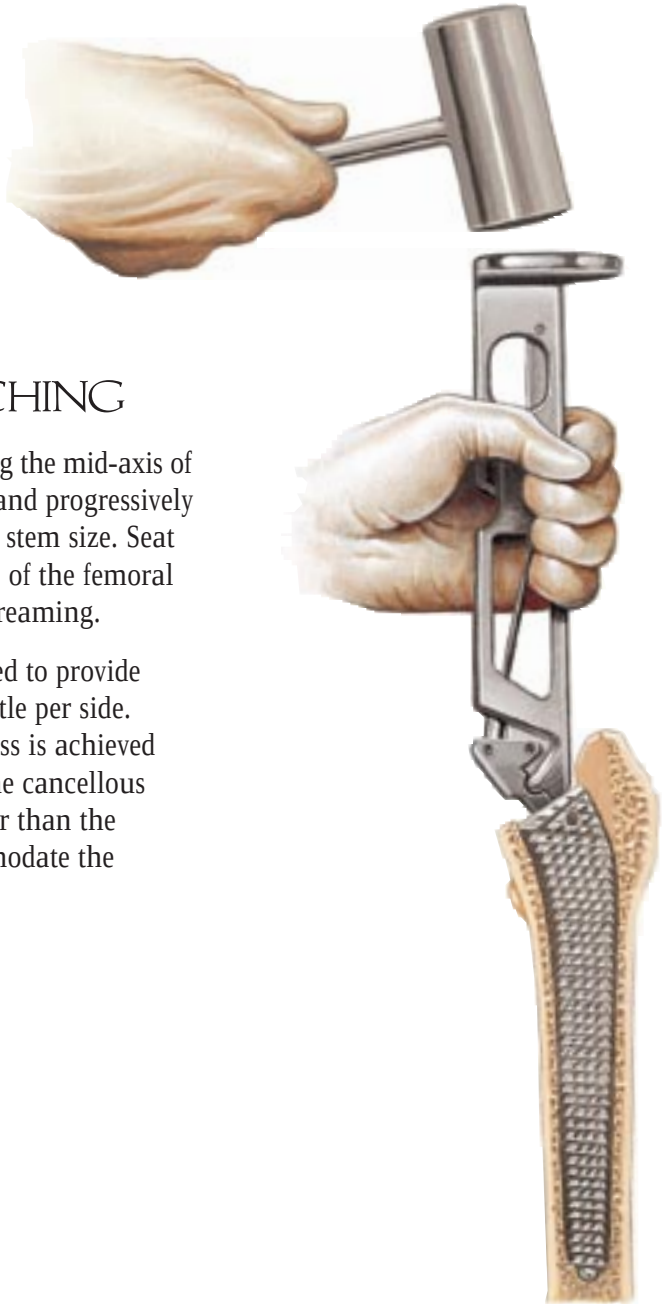
If acetabular reconstruction is required, prepare acetabulum using the technique for the intended acetabular component.

3. Femoral Canal Preparation

Open the medullary canal at the transected neck using the box chisel. Stay posterior and lateral in order to obtain a neutral stem position *(Figure 1)*. Sound the femoral canal using the blunt medullary reamer *(Figure 2)*.

Figure 1

Figure 2



4. Femoral Broaching

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

The Spectron EF broach is designed to provide a minimum 1.5 mm cement mantle per side. Additional cement mantle thickness is achieved by pressurizing the cement into the cancellous bone. The broach is slightly longer than the corresponding implant to accommodate the distal centralizer.

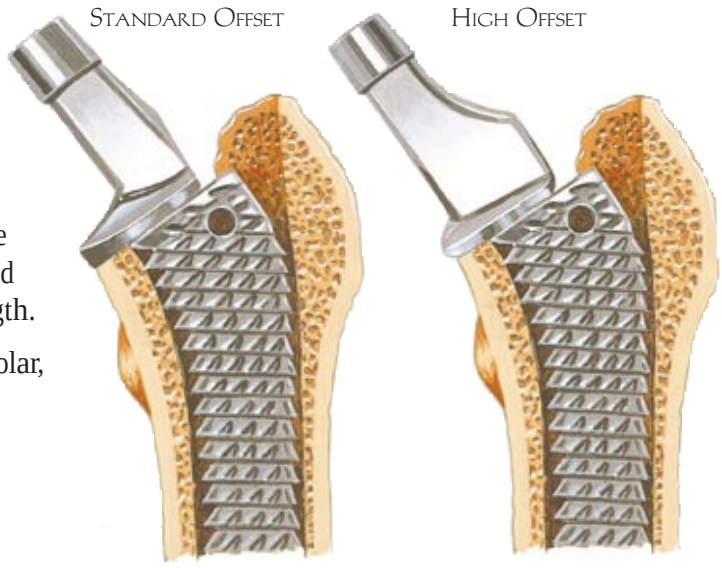
5. Calcar Preparation

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

6. Trialing

Remove the calcar reamer and place the matching standard or high offset trial neck (as determined by templating) onto the broach post. Select the trial femoral head of desired diameter and neck length and reduce the hip to assess stability. Soft tissue tension can be improved by using the high offset trial neck instead of the standard offset trial neck without increasing leg length.

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



Femoral Head And Neck Length Options				
Trial Color	22 mm	26 mm	28 mm	32 mm
Green	—	—	–3	–3
Yellow	+0	+0	+0	+0
Red	+4	+4	+4	+4
White	+8	+8	+8	+8
Blue	+12*	+12*	+12*	+12*
Black	—	—	+16*	+16*

**Denotes skirted heads.*

7. Placing The Buck Cement Restrictor

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

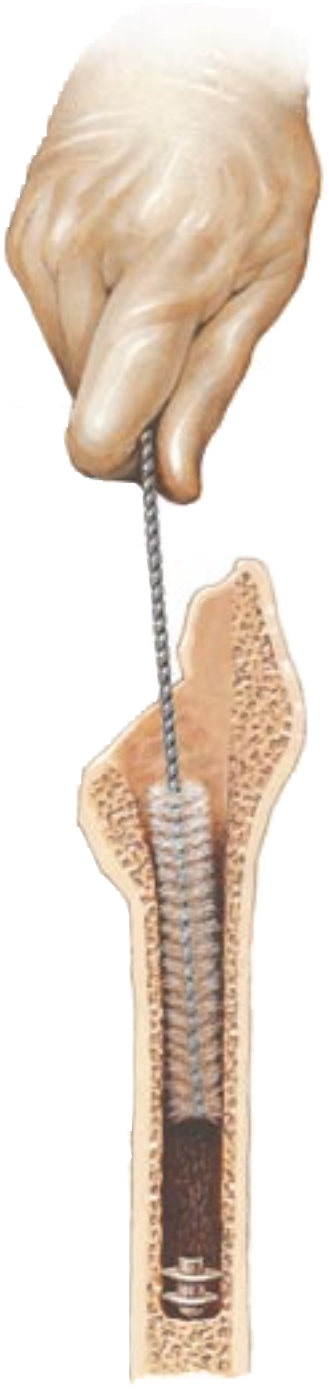
Remove the vent-occluding membrane by inserting the vent opening tool into the threaded end of the restrictor and pushing the pin through the vent hole. Remove and discard the plastic debris.

Thread the cement restrictor onto the inserter using a clockwise motion. Insert the device to the level of the medullary canal that has been predetermined. Once this level is reached, disengage the restrictor from the inserter using a counterclockwise twisting motion. Remove the inserter from the medullary canal. If it is necessary to remove the restrictor prior to cement insertion, it can be reattached to the inserter rod and pulled out of the canal. The surgeon may adjust the restrictor as many times as required.

Stem Size	BUCK Cement Restrictor Insertion Depth (mm)
1	140
2	150
3	160
4	160
5	160

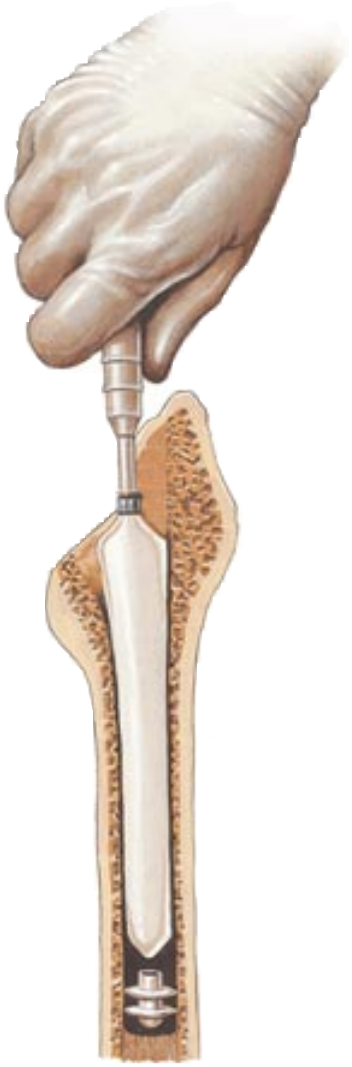
8. Preparing The Femoral Canal

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



9. Drying The Femoral Canal

Insert the femoral canal suction absorber into the femoral canal to dry the canal while mixing the cement.

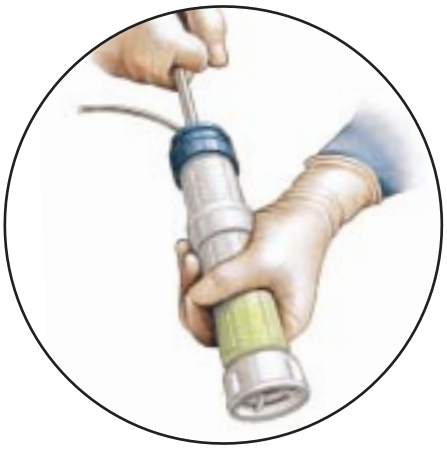


10. Loading Cement

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

11. Mixing

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

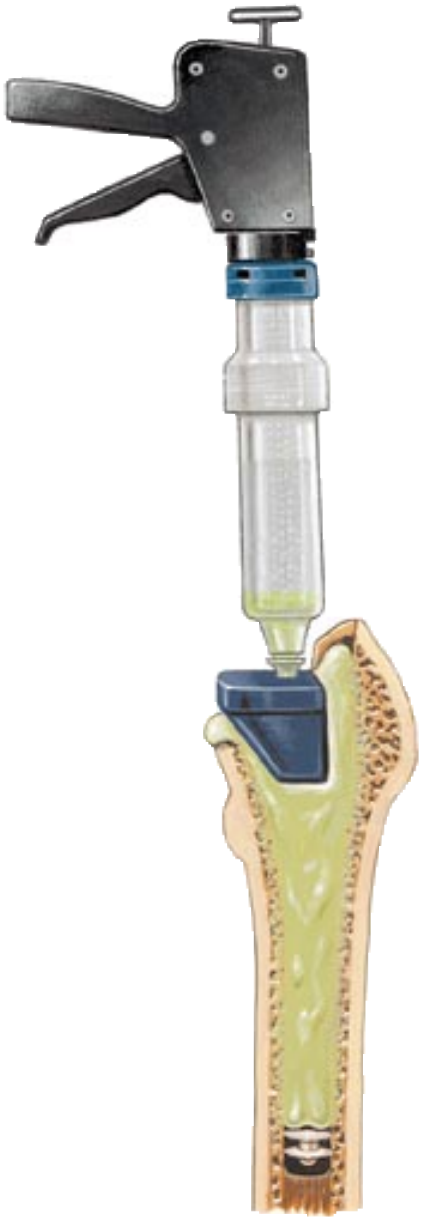


12. Injecting Cement

After removing the femoral canal suction absorber use pulsatile lavage. Insert the nozzle of the cement gun to the top of the Buck Cement Restrictor and inject cement into the canal in retrograde fashion. Continue injecting cement until the canal is completely full and the distal tip of the nozzle is clear of the canal.

13. Pressurizing Cement

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



14. Selecting Stem & Distal Centralizer

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

NOTE: If a distal centralizer is not used, place the distal hole plug which is packaged with the implant into the centralizer hole prior to inserting the stem.

Stem Size	Minimum Centralizer Size
Sizes 1, 1H	8 mm
Sizes 2, 2H	9 mm
Sizes 3, 3H	10 mm
Sizes 4, 4H	12 mm
Sizes 5, 5H	13 mm

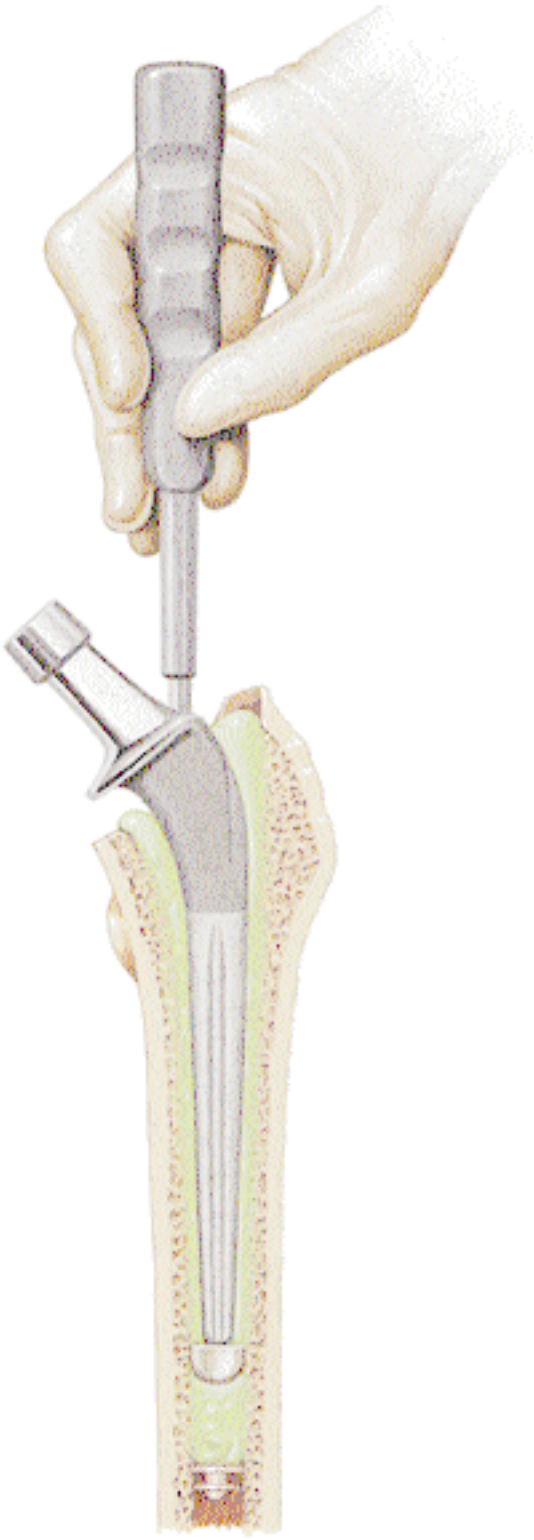
15. Stem Insertion

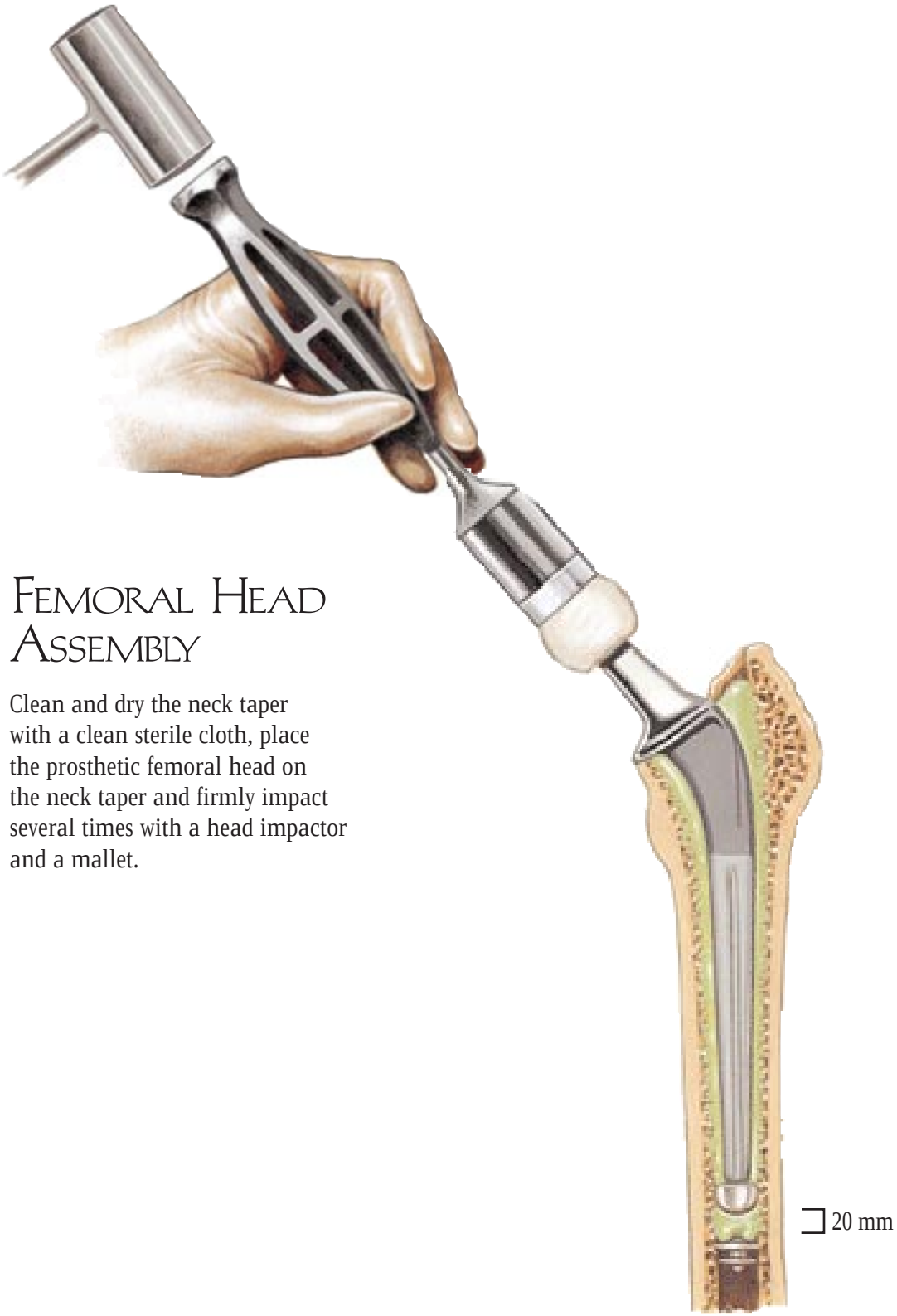
Insert the selected femoral stem into the canal. Fit the femoral stem driver into the stem driving platform and push into place. Advance the stem approximately 1 cm per second to avoid air inclusions in the stem/cement interface.

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

16. Final Trial Reduction

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





17. Femoral Head Assembly

Clean and dry the neck taper with a clean sterile cloth, place the prosthetic femoral head on the neck taper and firmly impact several times with a head impactor and a mallet.

Spectron EF 12/14 Primary Collared Stems

Cobalt Chromium – ASTM F 799

Size	Stem Length	Implant Cat. No.	Broach/Trial Cat. No.	Trial Neck Cat. No.
1	115 mm	7131-2101	7136-5001	7136-5081
2	125 mm	7131-2102	7136-5002	7136-5082
3	135 mm	7131-2103	7136-5003	7136-5083
4	135 mm	7131-2104	7136-5004	7136-5084
5	135 mm	7131-2105	7136-5005	7136-5085

Zirconia 12/14 Taper Femoral Heads

Neck Length	22 mm	26 mm	28 mm
+0	—	7132-0026	7132-0028
+4	7132-0422	7132-0426	7132-0428
+8	7132-0822	7132-0826	7132-0828

Spectron EF 12/14 Primary High Offset Stems

Cobalt Chromium – ASTM F 799

Size	Stem Length	Implant Cat. No.	Broach/Trial Cat. No.	Trial Neck Cat. No.
1H	115 mm	7131-2111	7136-5001	7136-5091
2H	125 mm	7131-2112	7136-5002	7136-5092
3H	135 mm	7131-2113	7136-5003	7136-5093
4H	135 mm	7131-2114	7136-5004	7136-5094
5H	135 mm	7131-2115	7136-5005	7136-5095

CoCr 12/14 Taper Femoral Heads

Cobalt Chromium – ASTM F 799

Neck Length	22 mm	26 mm
-3	—	—
+0	7130-2200	7130-2600
+4	7130-2204	7130-2604
+8	7130-2208	7130-2608
+12	7130-2212	7130-2612
+16	—	—

Neck Length	28 mm	32 mm
-3	7130-2803	7130-3203
+0	7130-2800	7130-3200
+4	7130-2804	7130-3204
+8	7130-2808	7130-3208
+12	7130-2812	7130-3212
+16	7130-2816	7130-3216

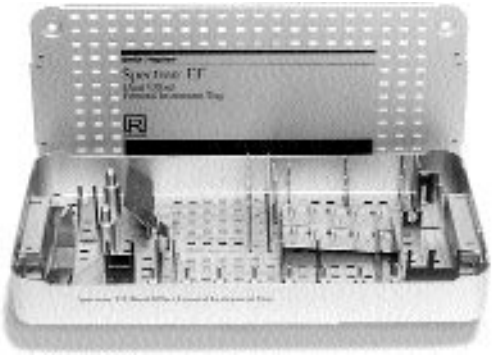
Spectron Invis™ Distal Centralizers

Cat. No.	Size	O.D.
7131-3101	1	8 mm
7131-3102	2	9 mm
7131-3103	3	10 mm
7131-3104	4	12 mm
7131-3105	5	13 mm

Invis™ Distal Centralizers

Cat. No.	O.D.	Cat. No.	O.D.
7131-3208	8 mm	7131-3215	15 mm
7131-3209	9 mm	7131-3216	16 mm
7131-3210	10 mm	7131-3217	17 mm
7131-3211	11 mm	7131-3218	18 mm
7131-3212	12 mm	7131-3219	19 mm
7131-3213	13 mm	7131-3220	20 mm
7131-3214	14 mm	7131-3221	21 mm

SPECTRON EF 12/14 INSTRUMENTATION



12/14 Dual Offset Sterilization Tray

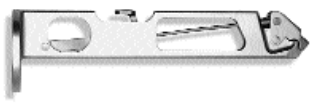
Cat. No. 7136-9112

12/14 Standard Offset Sterilization Tray

(Not Shown)
Cat. No. 7136-9113

Osteotomy Guide

Cat. No.	Size
7136-5036	Sizes 1–5



Broach Handle

Cat. No. 7136-4007

Box Chisel

Cat. No.	Size
7136-4002	Small

Anteversion Handle

Cat. No. 7136-4012

Blunt Medullary Reamer

Cat. No. 11-9657

Broaches/Trials

Cat. No.	Size
7136-5001	Size 1
7136-5002	Size 2
7136-5003	Size 3
7136-5004	Size 4
7136-5005	Size 5

Calcar Reamers

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

Femoral Component Driver

Cat. No. 11-9817

12/14 Taper Trial Necks

Size	Primary Collared Cat. No.	Size	Primary High Offset Cat. No.
1	7136-5081	1H	7136-5091
2	7136-5082	2H	7136-5092
3	7136-5083	3H	7136-5093
4	7136-5084	4H	7136-5094
5	7136-5085	5H	7136-5095

Femoral Head Impactor

Cat. No. 7136-4009

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

**Space allowed for 26 mm and 28 mm heads in instrument tray.*

ADDITIONAL SPECTRON EF 12/14 INSTRUMENTS

Box Chisel

Cat. No.	Size
7136-4003	Large

Femoral Component Extractor

Cat. No. 11-9871

Slotted Hammer

Cat. No. MT-1901

Side Angled Curette

Cat. No.	Size
11-9672	Right
11-9673	Left

Femoral Head Removal Tool

Cat. No. 11-9683

Includes:

Pry Tool—Thin Platform—Left

Pry Tool—Thick Platform—Right

Dead Blow Mallet

Cat. No. 7136-2106

Canal Sizer

Cat. No. 7136-7301

PREP-IM® Kit

Cat. No. 12-1000

Kit contains the following:

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

Femoral Pressurizers

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

Buck Femoral Cement Restrictor Inserter

Cat. No. 11-2428

Vent Opening Tool

Cat. No. 11-0028

Buck Cement Restrictor

Cat. No.	Size
12-9418	18.5 mm
12-9419	25 mm
7127-9420	30 mm
7127-9421	35 mm

Femoral Canal Brush

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

Concise Cement Sculps Kit

Cat. No. 11-1000
(one of each)

MixOR™ Vacuum Mixing System with Syringe

Cat. No. 7127-0020

Femoral Canal Suction Absorber

Cat. No.	Size
11-0037	19 mm
11-0038	25 mm

Femoral Cement Compressor

Cat. No. 11-1434

CEMENT & ACCESSORIES

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

Connector, Schraeder
Cat. No. 7127-0050

MixOR Pump and Hose Kit
Cat. No. 7127-0040

MixOR Hose Only
(not shown)
Cat. No. 7127-0041

MixOR Pump Only
(not shown)
Cat. No. 7127-0042

Connector, Drager
Cat. No. 7127-0051

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

InjectOR Gun
Cat. No. 7127-2000

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

Osteopal®
(available in US and Canada only)
Cat. No. 7127-1200

IMPORTANT MEDICAL INFORMATION

Warnings and Precautions

Total Hip System

IMPORTANT NOTE

Total hip replacement 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

The Total Hip System is manufactured from materials as outlined below. The component material is provided on the outside carton label.

Component	Material	Material Standards
Femoral Components	Ti-6Al-4V or Co-Cr-Mo	ASTM F 136 and ISO 5832/3 or ASTM F 1472 and ISO 5832/3 or ASTM F 799 and ISO 5832/12 or ASTM F 75 and ISO 5832/4
Acetabular shells Proximal pads Taper sleeves Distal sleeves Fixation screws and pegs Hole covers	Ti-6Al-4V	ASTM F 1472 and ISO 5832/3
Acetabular components Acetabular liners	UHMWPE	ASTM F 648
Femoral centralizers Acetabular spacer pods	PMMA	Not applicable
X-ray marking wire	Co-Cr-Mo	ASTM F 90 and ISO 5832/5
Acetabular Reconstruction Ring Acetabular Reinforcement Ring	CP Titanium	ASTM F 67 and ISO 5832/2
Femoral Heads	Co-Cr-Mo Zirconia Ceramic	ASTM F 799 and ISO 5832/12 ISO 13356

Porous titanium components and porous Co-Cr-Mo components are coated with commercially pure (C.P.) titanium beads (ASTM F 67 and ISO 5832/2) and Co-Cr-Mo beads (ASTM F 75), respectively. Hydroxylapatite coatings include HA (ASTM F 1185) that is applied either on a grit blasted or porous surface. NOTE: HA coated porous implants are not available in the USA.

Zirconia ceramic femoral heads are yttria stabilized zirconia ceramic.

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 in a concentric manner.

Femoral components are available with a small, large (14/16), or 12/14 global taper (gage diameters 0.404, 0.564, and 0.500 inches, respectively).

Small taper femoral components mate and lock directly with a 22 mm metal 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 (22, 28 or 32 mm), bipolar or unipolar components.

Femoral components with a 12/14 taper mate and lock with either metal heads (22, 26, 28, or 32 mm), ceramic heads (26 or 28 mm), 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, the latter 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 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 (22, 26, 28, and 32 mm) and ceramic (22, 26, 28, and 32 mm) 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 (0.404) and large (.564) taper femoral components.

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

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 (0.404) taper femoral components

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

Note: 22 mm Zirconia Ceramic Heads used with small (0.404) 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

Acetabular Components

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

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 post-operatively; treatments of nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with heads 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.

Contraindications may be relative or absolute and must be carefully weighted 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 articulating surfaces of acetabular components has been reported following total hip replacement. 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 articular surface. Osteolysis can lead to future complications necessitating the removal or replacement of prosthetic components.
3. Loosening, bending, cracking, or fracture of implant components may result from failure to observe the Warnings and Precautions below. Fracture of the implant can occur as a result of trauma, strenuous activity, improper alignment, or duration of service.
4. Dislocations, subluxation, decreased range of motion, or lengthening or shortening of the femur caused by improper neck selection, positioning, 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.
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 head always articulates with a UHMW polyethylene cup or a metal backed UHMW polyethylene cup. Zirconia ceramic 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.

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 metal components during surgery for the reasons stated in Number One of the "Preoperative" 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. 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.
9. 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 hemorrage. 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.
10. USE ONLY REFLECTION® TITANIUM 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. The Reflection Interfit and the Reflection For Screws Only (FSO) shells accept Universal Cancellous, Reflection screws, and tapered screw-hole covers, not pegs. 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. The Reflection threaded hole cover can be used with both Reflection and InterFit shells. Refer to product literature for proper adjunctive fixation and hole cover usage.
11. 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.
12. Avoid repeated assembly and disassembly of the modular components which could compromise the critical locking action of the locking mechanism.
13. 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.
14. 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.
15. 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.
16. 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.
17. 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.
18. 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.
19. 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.

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.

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 kilo Grays 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 metal components may be initially sterilized or resterilized, if necessary, by steam autoclaving in appropriate protective wrapping, after removal of all original packaging and labeling. Protect the devices, 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.
- Gravity Cycle: 270°F to 275°F (132°C to 135°C) with a minimum dwell time at temperature of 15 minutes, followed by a 1 minute purge and at least 15 minutes of vacuum drying at 10 inHg (339 millibars) minimum.

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

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

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

Plastic Components

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

Sterilant	Temp.	Humidity	Maximum Pressure	Concentration	Exposure Time
10% EtO 90% HCFC	130˚F (55˚C)	40-60%	28 PSIA (1930 millibar)	550-650 mg/L	120 minutes
10% EtO 90% HCFC	100˚F (38˚C)	40-60%	28 PSIA (1930 millibar)	550-650 mg/L	6 hours
100% EtO	131˚F (55˚C)	30-60%	10 PSIA (689 millibar)	736 mg/L	30 minutes

Suggested initial starting point for aeration validation is 12 hours at 122˚F (50˚C) with power aeration. Consult aerator manufacturer for more specific instructions.

Ceramic Components

Do not resterilize ceramic femoral heads.

INFORMATION

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

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

SUMMARY OF IMPORTANT MEDICAL INFORMATION* PALACOS R

DESCRIPTION

Palacos R provides two separate, premeasured sterilized components which, when mixed, form a radiopaque, rapidly setting bone cement.

Powder Component—40 g

Methylmethacrylate—	
methyl acrylate copolymer containing chlorophyll	33.86–33.42 g
Benzoyl peroxide, hydrous 75%	0.20–0.64 g
Zirconium dioxide	5.94 g

Liquid (Monomer)—20 ml

Methylmethacrylate (stabilized with hydroquinone)	18.424 g
N,N-dimethyl-p-toluidine	0.376 g
Chlorophyll	0.4 mg

Green pigment (chlorophyll) is added to both the powder (copolymer) and liquid (monomer) to produce a greenish tint in the final cement. This renders its possible to distinguish between bone and cement within the surgical field. As polymerization proceeds, a sticky dough-like mass is formed which can be molded for about 3 minutes (at 23° C [73°F]) after about 30 seconds. (See graphs and tables for temperature variations in package insert.)

INDICATIONS

Palacos R Bone Cement is indicated for use as bone cement in arthroplastic procedures of the hip, knee, and other joints to fix plastic and metal prosthetic parts to living bone when reconstruction is necessary because of osteoarthritis, rheumatoid arthritis, traumatic arthritis, avascular necrosis, nonunion of fractures of the neck of the femur, sickle cell anemia, osteoporosis, secondary severe joint destruction following trauma or other conditions (also for fixation of unstable fractures in metastatic malignancies), and revision of previous arthroplasty procedures.

CONTRAINDICATIONS

Palacos R bone cement is contraindicated in patients allergic to any of its components. The use of **Palacos R** is contraindicated in patients with infectious arthritis, and in active infection of the joint or joints to be replaced or if there is a history of such infection. The device is also contraindicated where loss of musculature or neuromuscular compromise in the affected limb would render the procedure unjustifiable.

WARNINGS

THE LIQUID MONOMER IS HIGHLY VOLATILE AND FLAMMABLE. APPROPRIATE PRECAUTION SHOULD BE TAKEN, PARTICULARLY WITH ITS USES IN THE OPERATING ROOM. THE MONOMER IS ALSO A POTENT LIPID SOLVENT AND SHOULD NOT BE ALLOWED TO COME IN DIRECT CONTACT WITH THE BODY OR RUBBER GLOVES BEFORE IT IS MIXED WITH THE POWDER.

CARE SHOULD BE EXERCISED DURING THE MIXING OF THE TWO COMPONENTS TO PREVENT EXCESSIVE EXPOSURE TO THE CONCENTRATED VAPORS OF THE MONOMER. THESE MAY IRRITATE THE RESPIRATORY TRACT AND EYES, AND MAY POSSIBLY BE HARMFUL TO THE LIVER, SKIN REACTIONS APPARENTLY RESULTING FROM CONTACT WITH THE MONOMER HAVE BEEN REPORTED.

It has been recommended by manufacturers of soft contact lenses that such lenses should be removed "in the presence of noxious and irritating vapors." Since soft contact lenses are quite permeable, they should not be worn in an operating room where methyl methacrylate is being mixed.

Although the results of animal teratology studies were negative, the implantation of **Palacos R** bone cement in pregnant women or by women of childbearing age requires that the potential benefits be weighed against the possible hazards to the mother or fetus.

NOTE:

1. The copolymer powder does not withstand heat sterilization treatment. If a packet is accidentally opened, it must not be used.
2. Ascertain that sufficient material be removed from stock and stored at about 23°C (73°F) for 24 hours before use.

PRECAUTIONS

Data from clinical trials dictate the absolute necessity of strict adherence to good surgical principles and technique. Deep wound infection is a serious postoperative complication and may required total removal of the prosthesis and embedded cement. Deep wound infection may be latent and not manifest itself even for several years postoperatively.

Blood pressure, pulse, and respiration should be carefully monitored during and immediately after implantation of the bone cement. Any significant alteration in these vital signs should be corrected with appropriate measures. Care should be taken to clean and aspirate the proximal portion of the femoral medullary canal just prior to insertion of bone cement.

The powder and liquid components have been carefully compounded. The entire contents of both the packet and ampule must be utilized. DO NOT USE PARTIAL AMOUNTS OF EITHER.

MIXING INSTRUCTIONS

1. Pour the liquid into a bowl.
2. Add the powder.
3. Stir vigorously, but carefully, for about 30 seconds until a sticky mass is obtained.

ADVERSE REACTIONS

A transitory fall in blood pressure immediately after implantation of bone cement and endoprosthesis can be observed. Rare cases have been reported in which the hypotension was associated with cardiac arrest and sudden death, connected with lung embolism.

Possible adverse reactions: Thrombophlebitis, pulmonary embolism, hemorrhage and hematoma, loosening or displacement of the prosthesis, superficial wound infection, deep wound infection, trochanteric bursitis, trochanteric separation, heterotopic new bone, short-term irregularities in cardiac conduction, myocardial infarction, cerebrovascular accident.

IMPORTANT SURGEON INFORMATION

ADVERSE REACTIONS AFFECTING THE CARDIOVASCULAR SYSTEM APPEAR TO BE RELATED TO THE INTRAVASATION OF UNPOLYMERIZED LIQUID MONOMER. THE MONOMER, HOWEVER, UNDERGOES RAPID HYDROLYSIS TO METHACRYLIC ACID. BETWEEN THE CIRCULATING CONCENTRATIONS OF METHACRYLIC ACID AND BLOOD PRESSURE CHANGES, NO CORRELATIONS HAVE BEEN ESTABLISHED. THE DIRECT PRESSURE FROM THE FORCING OF BOTH THE CEMENT AND THE PROSTHESIS INTO THE MEDULLARY CANAL RESULTS IN FAT AND BONE MARROW EMBOLI WHICH WOULD SEEM TO BE A GREATER RISK FOR THE CAUSE OF HYPOTENSION. THE REPORTED RARE INSTANCES OF CARDIAC ARREST ARE UNCLEAR, BUT MAY WELL RESULT FROM DIRECT PULMONARY EMBOLISM EFFECTS OR SECONDARY TO HYPOXIA CAUSED BY PULMONARY PHENOMENA.

FOR REDUCTION OF SUCH EPISODES, THE MEDULLARY CAVITY SHOULD BE CLEANED THOROUGHLY PRIOR TO THE APPLICATION OF THE CEMENT, FURTHER, DURING THE APPLICATION OF THE CEMENT, THE MEDULLARY CANAL PRESSURE SHOULD BE MINIMIZED BY SUCTIONING AND VENTING THE CAVITY. ANOTHER ALTERNATIVE IS USING A PLUG. THE CIRCULATING BLOOD VOLUME SHOULD BE KEPT WELL BALANCED.

THE DEGREE OF HYPOTENSION OBSERVED APPEARS TO BE MORE MARKED IN PATIENTS WITH ELEVATED OR HIGH NORMAL BLOOD PRESSURE, IN HYPOVOLEMIC CONDITIONS AND IN INDIVIDUALS WITH PREEXISTING CARDIOVASCULAR ABNORMALITIES. THE DURATION OF THE HYPOTENSIVE REACTION MAY BEGIN 10–165 SECONDS AFTER INSERTION OF BOTH CEMENT AND PROSTHESIS AND MAY LAST UP TO 5–10 MINUTES.

INTRODUCTION OF LIQUID CEMENT UNDER PRESSURE INTO A CLEAN MEDULLARY CANAL HAS BEEN SHOWN TO APPRECIABLY ENHANCE THE FILLING OF THE BONE CAVITIES WITH MARKED IMPROVEMENT IN THE SECURITY OF THE BONE-CEMENT INTERFACE. CARE MUST BE EXERCISED IN INTRODUCING THE CEMENT CONTINUOUSLY FROM DISTAL TO PROXIMAL TO AVOID LAMINATIONS IN THE CEMENT.

CAUTION

Federal law restricts this device to sale, distribution, and use by or on the order of a physician.

Manufactured by Heraeus Kulzer GmbH, Kulzer Division
6393 Wehrheim, Federal Republic of Germany
Under license from E. Merck, Darmstadt, F.R. of Germany
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*FOR MORE COMPLETE AND DETAILED DESCRIPTION, REFER TO PACKAGE INSERT SUPPLIED WITH THE PRODUCT.

Osteopal®
Radiopaque Bone Cement
Methyl Methacrylate, Methyl Acrylate Copolymer

DESCRIPTION

Osteopal® Bone Cement provides two separate, premeasured sterilized components which, when mixed, form a radiopaque rapidly setting bone cement. One component is supplied in a polyethylene-coated paper packet. It consists of 40 g power (copolymer) with the following composition:

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

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

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

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

Green pigment (chlorophyll) is added to both the powder (copolymer) and liquid (monomer) to produce a greenish tint in the final cement. This renders it possible to distinguish between bone and cement within the surgical field.

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

Although the spontaneous generation of heat accelerates the reaction, the polymerization of this self-curing resin occurs even if the temperature is reduced by irrigation with a cool physiologic saline solution.

ACTION

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

INDICATIONS

Osteopal® Bone Cement is indicated for use as bone cement in arthroplastic procedures of the hip, knee, and other joints to fix plastic and metal prosthetic parts to living bone when reconstruction is necessary because of osteoarthritis, rheumatoid arthritis, traumatic arthritis, avascular necrosis, nonunion of fractures of the neck of the femur, sickle cell anemia, osteoporosis, secondary severe joint destruction following trauma or other conditions (also for fixation of unstable fractures in metastatic malignancies), and revision of previous arthroplasty procedures.

CONTRAINDICATIONS

Osteopal® Bone Cement is contraindicated in patients allergic to any of its components. The use of Osteopal® is contraindicated in patients with infectious arthritis, and in active infection of the joint or joints to be replaced or if there is a history of such infection. The device is also contraindicated where loss of musculature or neuromuscular compromise in the affected limb would render the procedure unjustifiable.

WARNINGS

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

THE LIQUID MONOMER IS HIGHLY VOLATILE AND FLAMMABLE. APPROPRIATE PRECAUTION SHOULD BE TAKEN PARTICULARLY WITH ITS USE IN THE OPERATING ROOM, THE MONOMER IS ALSO A POTENT LIPID SOLVENT AND SHOULD NOT BE ALLOWED TO COME IN DIRECT CONTACT WITH THE BODY OR RUBBER GLOVES BEFORE IT IS MIXED WITH THE POWDER.

CARE SHOULD BE EXERCISED DURING THE MIXING OF THE TWO COMPONENTS TO PREVENT EXCESSIVE EXPOSURE TO THE CONCENTRATED VAPORS OF THE MONOMER, THESE MAY IRRITATE THE RESPIRATORY TRACT AND EYES, AND MAY POSSIBLY BE HARMFUL TO THE LIVER. SKIN REACTIONS APPARENTLY RESULTING FROM CONTACT WITH THE MONOMER HAVE BEEN REPORTED.

It has been recommended by manufacturers of soft contact lenses that such lenses should be removed in the presence of noxious and irritating vapors. Since soft contact lenses are quite permeable, they should not be worn in an operating room where methylmethacrylate is being mixed.

Although the results of animal teratology studies were negative, the implantation of Osteopal® Bone Cement in pregnant women or by women of childbearing age requires that the potential benefits be weighed against the possible hazards to the mother or fetus. The surgeon should decide whether the benefits expected from an arthroplasty outweigh any possible longterm adverse effects.

It has been reported in literature that N, N-dimethyl-p-toluidine (DMpt) may cause hypersensitivity and aseptic loosening of cemented total hip replacements. Testing (e.g. skin-patch testing) may be necessary in high risk cases.

PRECAUTIONS

Data from clinical trials dictate the absolute necessity of strict adherence to good surgical principles and technique. Deep wound infection is a serious postoperative complication and may require total removal of the prostheses and embedded cement. Deep wound infection may be latent and not manifest itself even for several years postoperatively.

Blood pressure, pulse, and respiration should be carefully monitored during and immediately after implantation of the bone cement. Any significant alteration in these vital signs should be corrected with appropriate measures. Care should be taken to clean and aspirate the proximal portion of the femoral medullary canal just prior to insertion of bone cement.

The powder and liquid components have been carefully compounded. The entire contents of both packet and ampoule must be used. DO NOT USE PARTIAL AMOUNTS OF EITHER. Mix thoroughly and slowly for 20 seconds until a sticky mass is obtained.

ADVERSE REACTIONS

A transitory fall in blood pressure immediately after implantation of bone cement and endoprosthesis can be observed. Rare cases have been reported in which the hypotension was associated with cardiac arrest and sudden death, connected with lung embolism.

The following additional adverse reactions have been reported with the use of methylmethacrylate-methylacrylate bone cements in orthopedic surgery;

- Thrombophlebitis
- Pulmonary embolism
- Hemorrhage and hematoma
- Loosening or displacement of the prosthesis
- Superficial wound infection
- Deep wound infection
- Trochanteric bursitis
- Trochanteric separation

Others which have been observed;

- Heterotopic new bone
- Short-term irregularities in cardiac conduction
- Myocardial infarction
- Cerebrovascular accident

IMPORTANT SURGEON INFORMATION

ADVERSE REACTIONS AFFECTING THE CARDIOVASCULAR SYSTEM APPEAR TO BE RELATED TO THE INTRAVASATION OF UNPOLYMERIZED LIQUID MONOMER. THE MONOMER, HOWEVER, UNDERGOES RAPID HYDROLYSIS TO METHACRYLIC ACID. BETWEEN THE CIRCULATING CONCENTRATIONS OF METHACRYLIC ACID AND BLOOD PRESSURE CHANGES, NO CORRELATIONS HAVE BEEN ESTABLISHED. THE DIRECT PRESSURE FROM THE FORCING OF BOTH THE CEMENT AND THE PROSTHESIS INTO THE MEDULLARY CANAL RESULTS IN FAT AND BONE MARROW EMBOLI WHICH WOULD SEEM TO BE A GREATER RISK FOR THE CAUSE OF HYPOTENSION. THE REPORTED RARE INSTANCES OF CARDIAC ARREST ARE UNCLEAR, BUT MAY WELL RESULT FROM DIRECT PULMONARY EMBOLISM EFFECTS OR SECONDARY TO HYPOXIA CAUSED BY PULMONARY EMBOLI PHENOMENA.

FOR REDUCTION OF SUCH EPISODES, THE MEDULLARY CAVITY SHOULD BE CLEANED THOROUGHLY PRIOR TO THE APPLICATION OF THE CEMENT, FURTHER, DURING THE APPLICATION OF THE CEMENT, THE MEDULLARY CANAL PRESSURE SHOULD BE MINIMIZED BY SUCTIONING AND VENTING THE CAVITY. ANOTHER ALTERNATIVE IS USING A PLUG. THE CIRCULATING BLOOD VOLUME SHOULD BE KEPT WELL BALANCED.

THE DEGREE OF HYPOTENSION OBSERVED APPEARS TO BE MORE MARKED IN PATIENTS WITH ELEVATED OR HIGH NORMAL BLOOD PRESSURE, IN HYPOVOLEMIC CONDITIONS AND IN INDIVIDUALS WITH PREEXISTING CARDIOVASCULAR ABNORMALITIES. THE DURATION OF THE HYPOTENSIVE REACTION MAY BEGIN 10–165 SECONDS AFTER INSERTION OF BOTH CEMENT AND PROSTHESIS AND MAY LAST UP TO 5–10 MINUTES.

INTRODUCTION OF LIQUID CEMENT UNDER PRESSURE INTO A CLEAN MEDULLARY CANAL HAS BEEN SHOWN TO APPRECIABLY ENHANCE THE FILLING OF THE BONE CAVITIES WITH MARKED IMPROVEMENT IN THE SECURITY OF THE BONE CEMENT INTERFACE. CARE MUST BE EXERCISED IN INTRODUCING THE CEMENT CONTINUOUSLY FROM DISTAL TO PROXIMAL TO AVOID LAMINATIONS IN THE CEMENT.

DOSAGE AND ADMINISTRATION

Osteopal® powder is double packaged. The inner polyethylene-coated paper packet is enclosed in a peelable film and paper packet which is sterilized with ethylene oxide and is enclosed in a non-sterile foil-lined protective overwrap. (At least one extra unit of Osteopal® should be available before starting a surgical procedure.) The ampoule containing the sterile filtered liquid monomer is packaged in a protective polyvinyl blister pack. The outside of ampoule and inside of blister pack are sterilized with ethylene oxide.

A unit is prepared by mixing the entire contents of one (1) packet of powder (40 g copolymer) with one (1) ampoule of liquid (20 ml monomer). One or two units will usually suffice, although this will depend upon the specific surgical procedure and the techniques employed. Each unit is prepared separately.

The following are required for preparation of the bone cement;

- Sterile working area
- Sterile porcelain or stainless steel bowls or a plastic bowl approved for use with monomers

* Sterile mixing spoons or spatulas

- Vacuum mixing system is optional.

The peelable film and paper package and the blister pack are opened by a circulating nurse or assistant and the sterile paper packet and ampoule are aseptically placed on a sterile table. The paper packet and the ampoule are opened under sterile conditions. since each packet of power contains a premeasured quantity of copolymer to react with a premeasured quantity of monomer, care should be taken to mix the entire contents of one packet with the entire contents of one ampoule. Partial amounts should not be used.

MIXING INSTRUCTIONS

DO NOT CENTRIFUGE CEMENT. The zirconium dioxide may separate from the bulk cement.

Application by Hand – Pour the liquid into a bowl. Add the powder. Stir with a spatula slowly and carefully, for about 20 seconds, during which time it forms an homogenous fluid. Allow to stand for the escape of air until a dough-like mass is formed which does not adhere to rubber gloves.

IN ORDER TO ASCERTAIN THAT THE DOUGH-LIKE MASS DOES NOT STICK TO THE RUBBER GLOVES, DEPENDING ON ROOM TEMPERATURE, WAIT SEVERAL MINUTES (SEE CURVES).

The working time may be affected by temperature (see curve and table for working and hardening times). The ideal working consistency of the Osteopal® cement for manual application to the bone is best determined by the surgeon's experience in using the preparation. The entire procedure from mixing to complete insertion takes approximately eight to ten minutes. To assure adequate fixation, the prosthesis should be held securely in place without movement until the bone cement has fully hardened.

Vacuum Mixing – Add monomer first, the polymer powder, and follow the manufacturer's instructions to vacuum mix.

Injection From a Cement Gun – Cement can be injected from the gun from approximately 2-3 minutes onwards, but has to be controlled carefully by the surgeon, or it may flow out of the bony cavity since it is still fluid at this stage. The use of a bone cement restrictor or a bond plug in the femoral canal is recommended. If the femoral canal is filled from the distal end, an air vent is not necessary. The implant should be in place approximately 5 to 7 minutes (depending on temperature) after mixing the components of the cement, which heats up at approximately 7-1/2 minutes and generally hardens by 9-1/2 minutes.

Whether applied by hand or by using a cement gun, pressure should be applied to the cement, until the prosthesis is inserted. Excess cement must be removed while it is still soft. When using a cement gun, time intervals may be longer due to reduced handling of the cement. Handling the cement warms it slightly during the early stages of polymerization and accelerates the process.

The times previously given for kneading, working and setting apply at approximately 20°C (68°F). Higher temperatures will reduce the required time and lower temperatures will prolong it. The temperature vs. time curves estimate temperature behavior of the mixed cement.

Curves will differ slightly according to environment conditions such as temperature, air flow rate, and relative humidity. It is advisable for the surgeon to go through the entire mixing, handling, and setting process in vitro before using Osteopal® Bone Cement.

The completion of polymerization occurs in the patient and is associated with the liberation of heat. The long-term effect of this heat on the tissues surrounding the bone cement are not known. To more rapidly dissipate the heat, the polymerizing cement may be irrigated with a cool physiologic saline solution.

DISPOSAL OF EXPIRED BONE CEMENT

Osteopal® has a shelf life of five years and should be disposed of after that time. The expired liquid monomer component can be mixed with the powder component in the usual manner to polymerize. The polymerized material can then be disposed of in a landfill. The liquid monomer can also be evaporated under a hood. The powder component can be disposed of in a landfill.

WARNINGS

1. The copolymer powder does not withstand hear sterilization treatment. If a packet is accidentally opened, it must not be used.
2. Ascertain that sufficient material be removed from inventory and stored at about 20C (68°F) for 24 hours before use.

CAUTION

Federal Law (U.S.A.) restricts this device to sale, distribution, and use by or on the order of a physician.

HOW SUPPLIED

Carton consisting of:

1 packet copolymer powder containing 40g

1 ampoule liquid monomer containing 20 ml

NOTE:

Osteopal® is a medium viscosity cement.

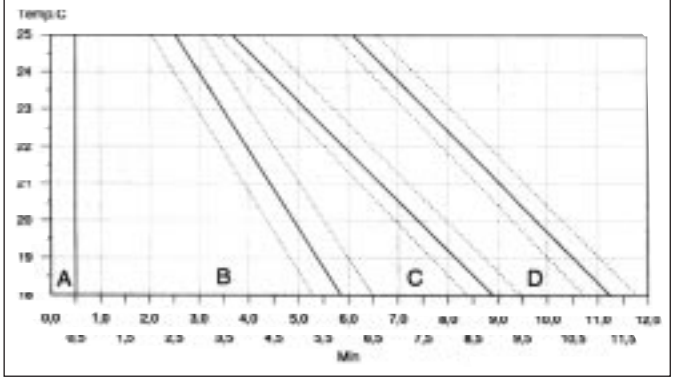
Osteopal® bone cement is manufactured by: Heraeus Kulzer GmbH, Kulzer Division, Wehrheim/TS., Germany and is under license from: Merck KGaA, Darmstadt, Germany

Osteopal® is a trademark of Heraeus, Kulzer GmbH.

Osteopal®

Temperature vs. Time

Manual Application



A: MIXING PHASE

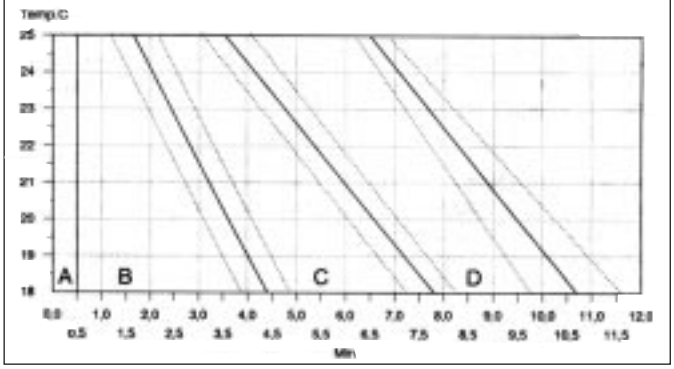
B: DOUGH PHASE

C : WORKING PHASE

D: HARDENING PHASE

Temperature vs. Time

Use with Vacuum Mixing



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