Surgical Technique

smith&nephew

ANTHOLOGY®

Primary Hip System

Table of contents

Indications

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; 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.

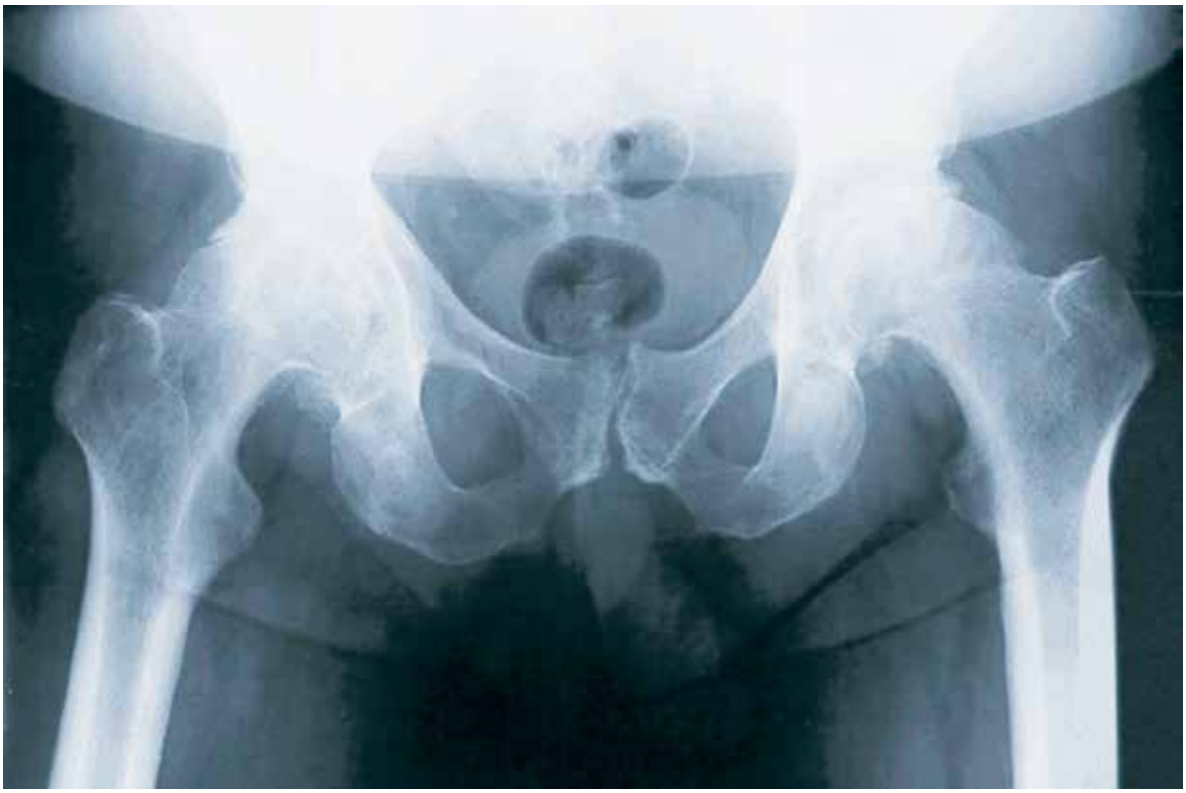
Contraindications

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, osteolysis, or other conditions which may lead to increased bone resorption.
2. Mental or neurological conditions which may 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 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. In the U.S., refer to the separate package insert provided with the ceramic acetabular liners.
6. In revision surgery, inadequate proximal implant support is contraindicated. There is an increased risk of implant failure in revision cases where proximal support is not achieved, poor bone quality exists, and smaller sized implants are utilized. The lower the implant fixation point in the femur (distance from the head center) the greater the risk of implant fracture and/or re-revision.
7. Morbid obesity.

Preoperative planning

The goal of preoperative planning is to determine the correct stem size, level of the femoral neck cut, and proper head and stem offset combination. Preoperative templating requires at least an anteroposterior (AP) radiograph of the pelvis and a lateral radiograph of the affected hip. If the opposite hip is unaffected by disease, it can often provide accurate sizing information for the femoral stem.

To determine if a patient has a leg length discrepancy, the AP radiograph should be used. Draw a line tangential to both of the ischia or both of the obturator foramens. This line should extend out until it contacts the medial cortex of bone on both femurs. If the patient's legs are of equal length, the line that has been drawn will contact both femurs at the same level. If the patient's legs are of unequal length, the lines will contact the femurs at different levels along the femur. Select a reference point along the femur, such as the bottom of the lesser trochanter. The distance between the line that has been drawn and the reference point on both femurs is measured. The difference in these measurements indicates the patient's leg length discrepancy.



Anteroposterior radiograph demonstrating leg length inequality

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.

Preoperative planning

WARNING: Hip Flexion Contracture — Don't be fooled by a hip flexion contracture which makes the leg appear short on X-Ray.

Note: Using this method of templating for leg length discrepancy assumes the patient has a normal, symmetrical pelvis and has neutral limb positioning.

When determining which size ANTHOLOGY® stem to use, the AP and the lateral radiographs should be templated. (Make sure you are looking at a true AP X-Ray. If needed, template off contralateral "normal" hip.) Using the anteroposterior radiograph, place the femoral templates over the proximal femur of both the affected and unaffected hips. The junction of the lateral femoral neck and greater trochanter serves as a good reference point for placement of the X-Ray templates. Place a mark at this junction and in the center of the femoral head. Align the lateral shoulder of the prosthesis with the mark at the junction. Find the appropriate stem that fits and fills the proximal femur and whose neck length matches the center of the femoral head.

For the ANTHOLOGY stem system, it is important to template for proximal fixation, not distal fixation. Make sure distal stem is not larger than the medullary canal width.

Anteroposterior radiograph of a properly implanted porous-coated ANTHOLOGY stem

Surgical technique completed in conjunction with:

David Harwood, MD
Robert W. Johnson Hospital
New Brunswick, NJ

Stefan Kreuzer, MD
Herman Memorial Bone & Joint
Houston, TX

John Masonis, MD
OrthoCarolina, Charlotte, NC

Michael Ries, MD
UCSF, San Francisco, CA

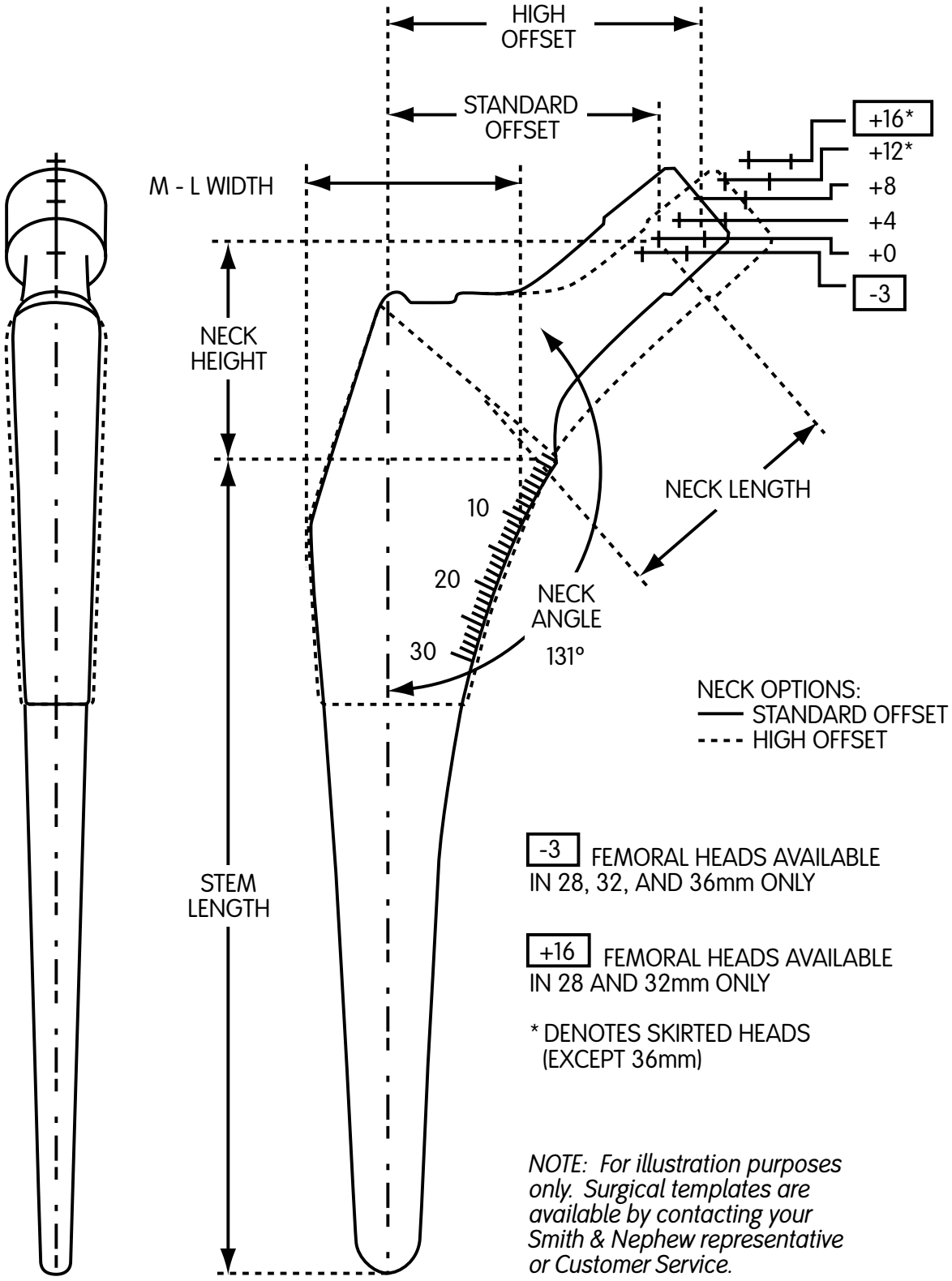
Specifications

Specifications			
Size	Neck Angle	Stem Length	M-L Width
1	131°	100mm	22mm
2	131°	102mm	23mm
3	131°	104mm	25mm
4	131°	106mm	26mm
5	131°	108mm	27mm
6	131°	110mm	29mm
7	131°	112mm	30mm
8	131°	114mm	32mm
9	131°	116mm	33mm
10	131°	118mm	34mm
11	131°	120mm	36mm
12	131°	122mm	37mm

Neck Height MM						
When Femoral Head Component Selected is:						
Size	-3	+0	+4	+8	+12	+16
1	24	26	29	31	34	37
2	25	27	29	32	35	37
3	26	27	30	33	35	38
4	26	28	31	33	36	38
5	27	29	31	34	37	39
6	27	29	32	35	37	40
7	28	30	33	35	38	40
8	29	31	33	36	38	41
9	29	31	34	36	39	42
10	30	32	35	37	40	42
11	31	33	35	38	40	43
12	31	33	36	39	41	44

Neck Offset MM												
	Standard Offset						High Offset					
Size	-3	+0	+4	+8	+12	+16	-3	+0	+4	+8	+12	+16
1	29	32	35	38	41	44	35	38	41	44	47	50
2	30	33	36	39	42	45	36	39	42	45	48	51
3	31	33	37	40	43	46	37	39	43	46	49	52
4	32	34	38	41	44	47	38	40	44	47	50	53
5	33	35	39	42	45	48	39	41	45	48	51	54
6	34	36	40	43	46	49	40	42	46	49	52	55
7	36	38	41	44	47	50	44	46	49	52	55	58
8	37	39	42	45	48	51	45	47	50	53	56	59
9	38	41	44	47	50	53	46	49	52	55	58	61
10	40	42	45	48	51	54	48	50	53	56	59	62
11	41	43	46	49	52	55	49	51	54	57	60	63
12	42	44	47	50	53	56	50	52	55	58	61	64

Neck Length MM												
	Standard Offset						High Offset					
Size	-3	+0	+4	+8	+12	+16	-3	+0	+4	+8	+12	+16
1	25	28	32	36	40	44	29	32	36	40	44	48
2	26	29	33	37	41	45	30	33	37	41	45	49
3	27	30	34	38	42	46	31	34	38	42	46	50
4	27	30	34	38	42	46	31	34	38	42	46	50
5	28	31	35	39	43	47	32	35	39	43	47	51
6	29	32	36	40	44	48	33	36	40	44	48	52
7	30	33	37	41	45	49	35	38	42	46	50	54
8	31	34	38	42	46	50	36	39	43	47	51	55
9	31	34	38	42	46	50	37	40	44	48	52	56
10	32	35	39	43	47	51	38	41	45	49	53	57
11	33	36	40	44	48	52	38	41	45	49	53	57
12	34	37	41	45	49	53	39	42	46	50	54	58



-3 FEMORAL HEADS AVAILABLE IN 28, 32, AND 36mm ONLY

+16 FEMORAL HEADS AVAILABLE IN 28 AND 32mm ONLY

* DENOTES SKIRTED HEADS (EXCEPT 36mm)

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

NOT ACTUAL SIZE

Femoral Osteotomy

Femoral Canal Preparation

Femoral Canal Preparation Contd.

Starter Broach Assembly/Disassembly

Broach Assembly/Disassembly

Femoral Broaching

Calcar Preparation

Trial Reduction

Stem Insertion for Rigid Insertion

Stem Insertion for Non-Rigid Insertion

Final Trial Reduction

Femoral Head Assembly

Femoral Osteotomy

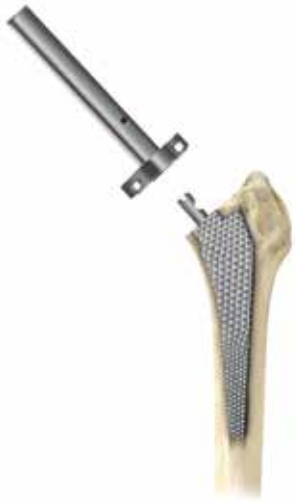
Femoral Canal Preparation

Starter Broach Assembly/Disassembly

Broach Assembly/Disassembly

Femoral Broaching

Calcar Preparation



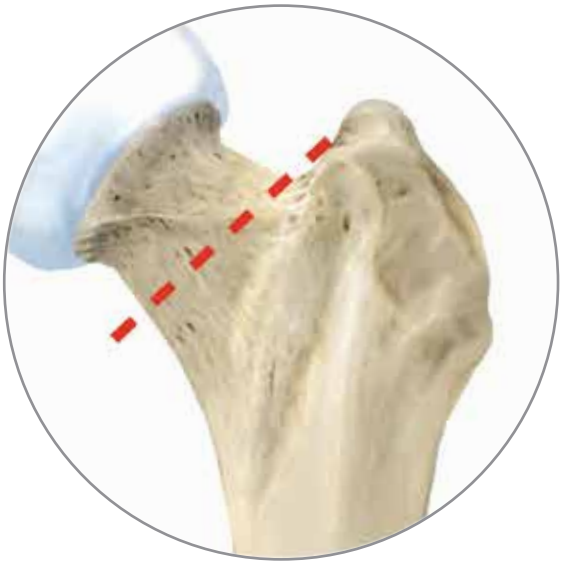
Trial Reduction

Stem Insertion for Non-Rigid Insertion

Final Trial Reduction

Femoral Head Assembly

Before surgery, review instrument sets to ensure all instruments are present and working properly.

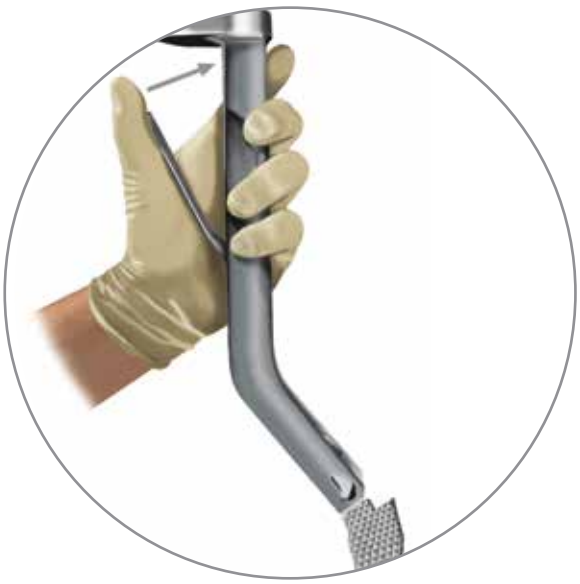


Femoral Osteotomy
Choose the appropriate osteotomy guide based on preoperative templating. The silver guide is for standard offset implants and the gold guide is for high offset implants. Thread the anteversion handle into the osteotomy guide. If templating based on the femoral head location, assemble the sliding head guide to the osteotomy guide. Based on preoperative templating, line the sliding head guide up with the appropriate stem size lasermarked on the osteotomy guide. Place the assembled guide against the femur aligning the femoral head with the sliding head guide. The femoral neck resection can then be marked using electrocautery. If templating based on using the tip of the greater trochanter, the sliding head guide is not needed. Use a spinal needle to find trochanter tip. Place the appropriate osteotomy guide (standard or high offset) against the femur and locate it using the distance from the tip of the greater trochanter to the top of the prosthesis. The 0mm measurement on the osteotomy guide is the top of the prosthesis. The femoral neck resection can then be marked using electrocautery.

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

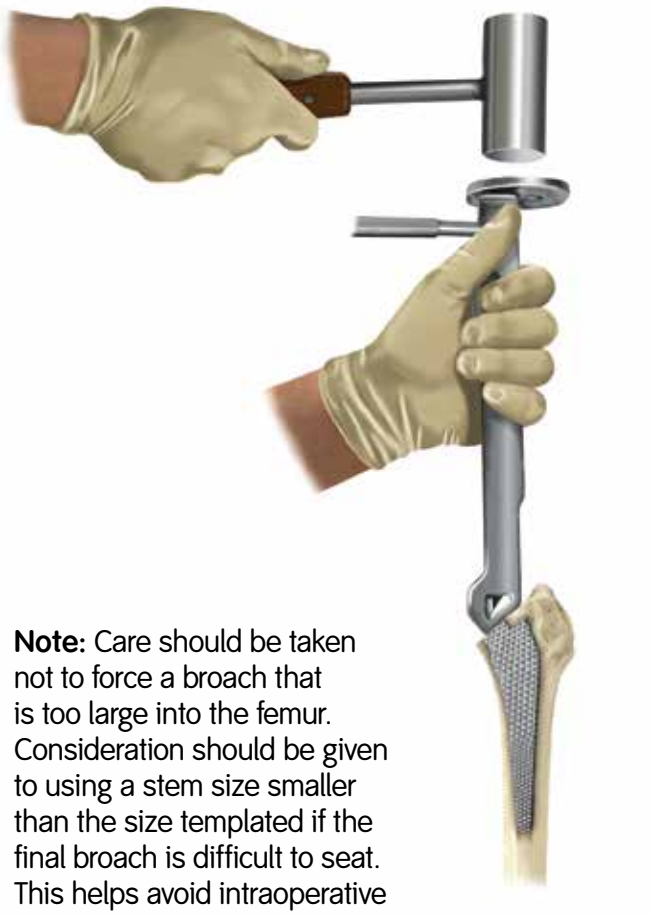
Femoral Canal Preparation
Use the box osteotome and canal finder for initial entry into femoral canal.

Note: It is important to stay lateral with the box osteotome and the canal finder. Care should be taken to ensure that the initial reaming tract into the femur is in neutral alignment with the femoral axis.



Note: For Anterior approach, use offset handle.

Broach Assembly/Disassembly
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. Disassemble the broach from the broach handle by lifting the lever to release the handle from the broach post.



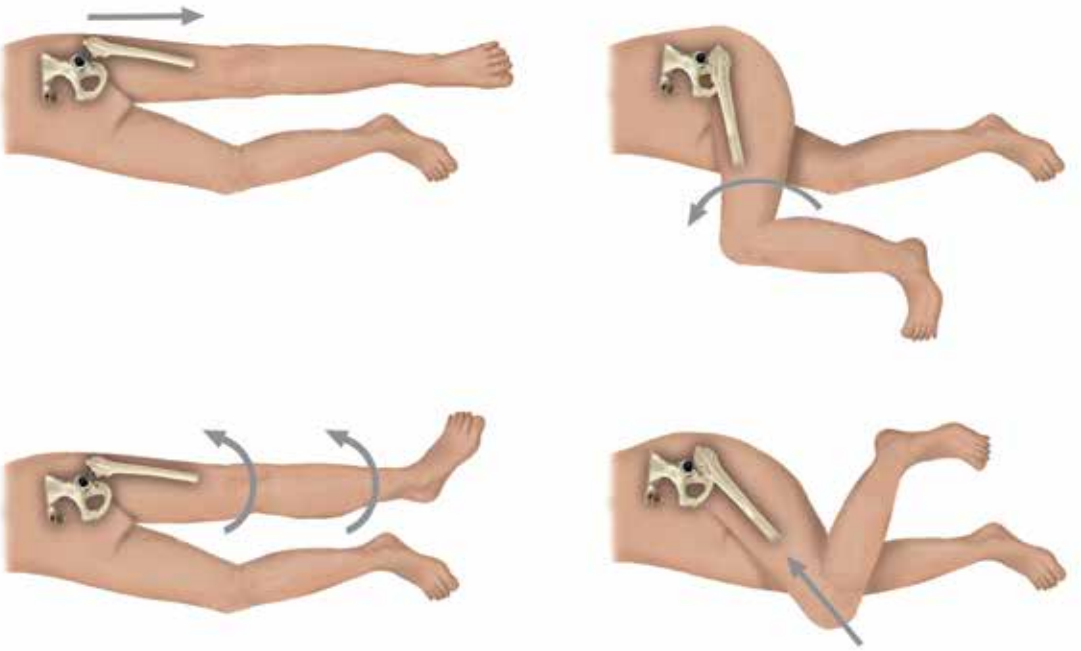
Femoral Broaching
Start the broaching procedure along the axis of the femur with the starter broach. Sequential broaching should then be carried out to the templated stem size using valgus force on the stem handle. Taking care to preserve the greater trochanter, the starter broach can be used to rasp laterally beneath the greater trochanter. Be sure to check the stability of the broach rotationally, medially and laterally. When broaching keep version constant. Stop broaching only when stability is achieved. It is important to maintain broach rotation due to the rectangular geometry of the implant.

Note: Care should be taken not to force a broach that is too large into the femur. Consideration should be given to using a stem size smaller than the size templated if the final broach is difficult to seat. This helps avoid intraoperative fractures of the femur.

Calcar Preparation
With the final broach fully seated, remove the broach handle. Place the calcar reamer over the post of the broach and machine the femoral neck, ensuring alignment to avoid femur fracture.

Trial Reduction
Place the standard or high offset trial neck (as determined by templating) onto the broach post using the forceps. Select the trial femoral head of desired diameter and +0 neck length and place onto the trial neck. Reduce the hip and re-measure leg length. Compare to previous measurements recorded from preoperative templating or leg length before dislocation. Adjustments in neck length and/or offset can be made at this time. If trialing for a unipolar or bipolar, trial according to the appropriate technique for the selected device.

Trial Reduction



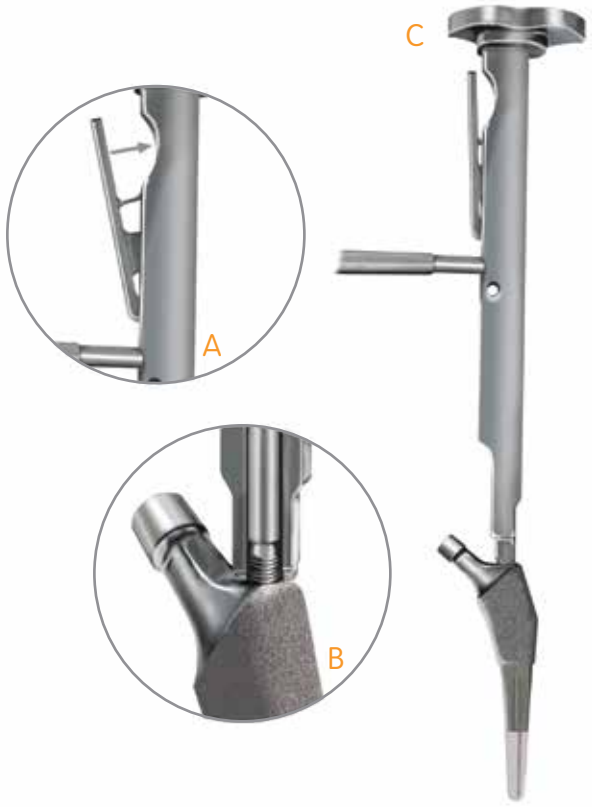
Reduce the hip and evaluate in the following ways:

Soft tissue tension
Some shuck is normal when applying a longitudinal distraction force to the hip. Shuck should not be excessive, and the hip should not dislocate in straight traction.

Anterior stability
Place the leg in full adduction and hyperextension, while exerting an external rotation force. If the hip cannot be fully extended, it may be too tight. If it dislocates easily, it is too loose and impingement must be addressed or component malposition exists.

Posterior stability
Place the leg in adduction and 90° flexion. Gradually rotate internally. The hip should be stable with 45° of internal rotation. If it dislocates with minimal internal rotation, it is too loose and impingement must be addressed or component malposition exists.

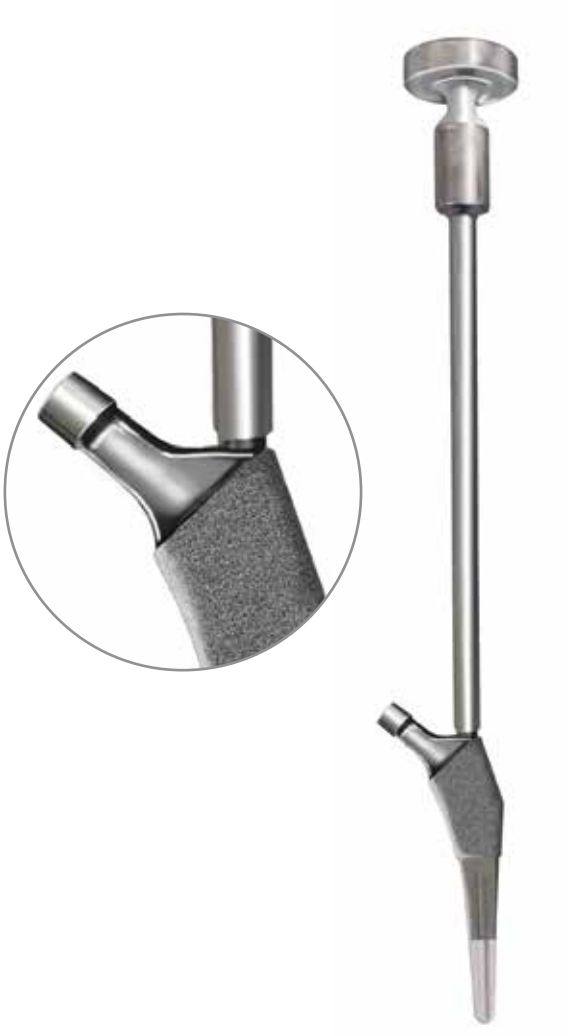
Sleep position
Place the leg in the "sleep position" with the operated leg semiflexed, adducted and internally rotated over the other leg. Apply axial force to try to dislocate. This position represents a dangerously unstable position that may be adopted by a patient sleeping on their non-operated side.

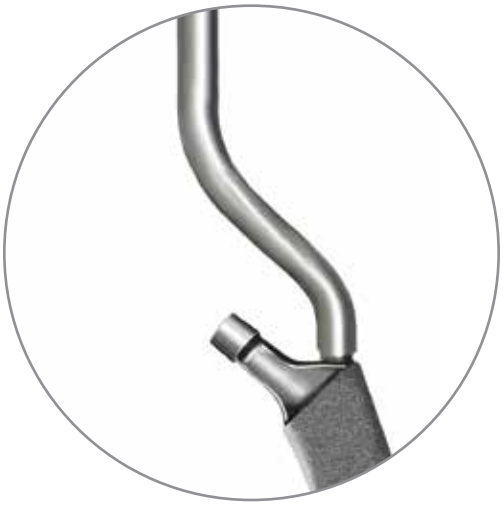


Stem Insertion
For a rigid insertion stand the stem inserter upright so that the threaded tip is pointed up. Ensure that the lever handle is open (A) on the stem inserter and screw the implant onto the threaded tip as far as possible. Flip the assembly over so that the stem tip is now pointing down. Engage the frame tines into the slots adjacent to the threaded hole on the stem (B). Screw the pommel until assembly is secure but not overtight (C). The lever should then be closed to ensure that the stem inserter thread does not disengage with the implant. Apply hand pressure and rotate the stem into the correct position. Use gentle mallet blows with valgus force on the inserter to seat the stem to the position of the neck resection. Check stem stability. If the implant has stopped moving with gentle mallet blows and is not completely seated, remove the stem and repeat the same size broaching steps.

CAUTION: Do not use excessive force to seat the stem.

Note: Make sure the stem inserter is not impinging on the trochanter. This may cause inadequate stem seating or trochanteric fracture or varus positioning.





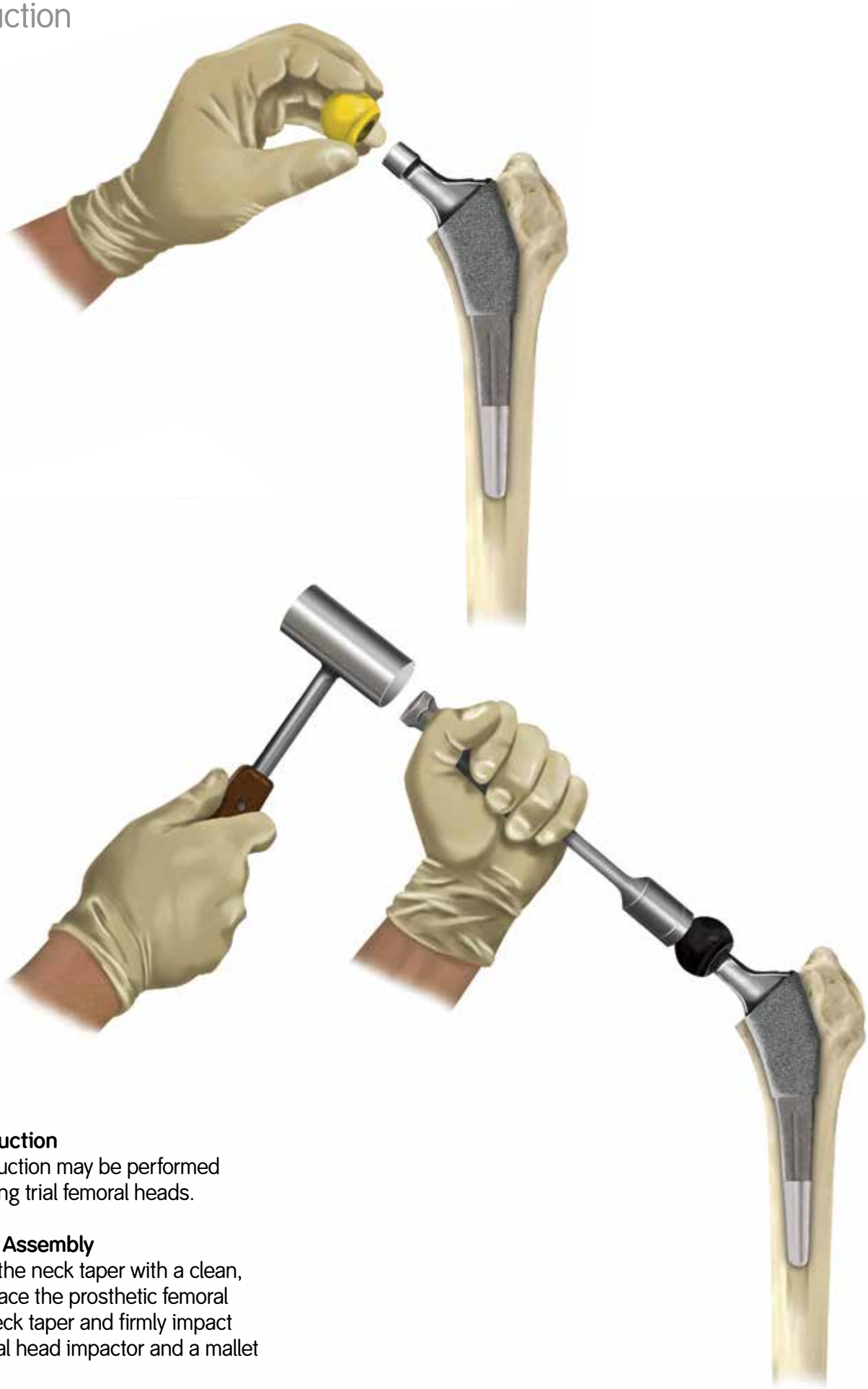
Note: For Anterior approach, use offset handle.

Stem Insertion
For a non-rigid insertion insert the selected femoral stem into the canal as far as possible by hand (should sit approximately 1cm proud). Take the non-threaded stem inserter and place it into the driving platform of the stem. Apply hand pressure and rotate the stem into the correct position. Use gentle mallet blows to seat the stem to the position of the neck resection. Check stem stability. If the implant has stopped moving with gentle mallet blows and is not completely seated, remove the stem and repeat the same size broaching steps.

CAUTION: Do not use excessive force to seat the stem.

Note: Make sure the stem inserter is not impinging on the trochanter. This may cause inadequate stem seating or trochanteric fracture or varus positioning.

Trial Reduction



Final Trial Reduction
A final trial reduction may be performed at this time 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 with the femoral head impactor and a mallet several times.

ANTHOLOGY® Standard Offset Implant Set — Cat. No. 7135-6000

ANTHOLOGY Standard Offset Porous Stem

Size	Cat. No.	Size	Cat. No.	Size	Cat. No.
1	7135-6001	5	7135-6005	9	7135-6009
2	7135-6002	6	7135-6006	10	7135-6010
3	7135-6003	7	7135-6007	11	7135-6011
4	7135-6004	8	7135-6008	12	7135-6012

Sample 7137-6007

ANTHOLOGY High Offset Implant Set — Cat. No. 7135-6100

ANTHOLOGY High Offset Porous Stem

Size	Cat. No.	Size	Cat. No.	Size	Cat. No.
1	7135-6101	5	7135-6105	9	7135-6109
2	7135-6102	6	7135-6106	10	7135-6110
3	7135-6103	7	7135-6107	11	7135-6111
4	7135-6104	8	7135-6108	12	7135-6112

Sample 7137-6107

ANTHOLOGY Standard Offset Plus HA Implant Set — Cat. No. 7135-7000

ANTHOLOGY Standard Offset Porous Plus HA Stem

Size	Cat. No.	Size	Cat. No.	Size	Cat. No.
1	7135-7001	5	7135-7005	9	7135-7009
2	7135-7002	6	7135-7006	10	7135-7010
3	7135-7003	7	7135-7007	11	7135-7011
4	7135-7004	8	7135-7008	12	7135-7012

ANTHOLOGY High Offset Plus HA Implant Set — Cat. No. 7135-5700

ANTHOLOGY High Offset Porous Plus HA Stem

Size	Cat. No.	Size	Cat. No.	Size	Cat. No.
1	7135-7101	5	7135-7105	9	7135-7109
2	7135-7102	6	7135-7106	10	7135-7110
3	7135-7103	7	7135-7107	11	7135-7111
4	7135-7104	8	7135-7108	12	7135-7112

OXINIUM® Femoral Heads 12/14 Taper

Neck Length	28mm	32mm	36mm
-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	——

OXINIUM Modular Femoral Heads

40mm	44mm
7134-2340	7134-2344

Titanium Modular 12/14 Taper Sleeve

Neck Length	
-4	7134-4245
+0	7134-4247
+4	7134-4248
+8	7134-4249

*Use with 40mm and 44mm OXINIUM and CoCr Modular Femoral Heads

CoCr Femoral Heads 12/14 Taper – Cobalt Chromium – ASTM F 799

Neck Length	22mm	26mm	28mm	32mm	36mm
-3	——	——	7130-2803	7130-3203	7130-3603
+0	7130-2200	7130-2600	7130-2800	7130-3200	7130-3600
+4	7130-2204	7130-2604	7130-2804	7130-3204	7130-3604
+8	7130-2208	7130-2608	7130-2808	7130-3208	7130-3608
+12	7130-2212	7130-2612	7130-2812	7130-3212	——
+16	——	——	7130-2816	7130-3216	——

CoCr Modular Femoral Heads – Cobalt Chromium – ASTM F 799

40mm	44mm
7134-2640	7134-2644

Titanium Modular 12/14 Taper Sleeve

Neck Length	
-4	7134-4245
+0	7134-4247
+4	7134-4248
+8	7134-4249

*Use with 40mm and 44mm OXINIUM® and CoCr Modular Femoral Heads

Biolox® *forte* Ceramic Femoral Heads 12/14 Taper

Neck Length	28mm	32mm	36mm
S/+0	7133-0280	7133-0320	7133-2084
M/+4	7133-0284	7133-0324	7133-2085
L/+8	7133-0288	7133-0328	7133-2086

Biolox® *delta* Ceramic Femoral Heads 12/14 Taper

Neck Length	32mm	36mm	40mm
S/+0	7653-9160	7653-9165	7134-6004
M/+4	7653-9161	7653-9166	7134-6005
L/+8	7653-9162	7653-9167	7134-6006

ANTHOLOGY® High Offset Neck Cut Guide
Cat. No. 7136-5920

ANTHOLOGY Standard Offset Neck Cut Guide
Cat. No. 7136-5704

ANTHOLOGY Neck Cut Guide Sliding Head
Cat. No. 7136-5921

Box Osteotome
Cat. No. 7136-4002

ANTHOLOGY® Starter Broach
Cat. No. 7136-5600

ANTHOLOGY Calcar Reamer
Cat. No. 7136-5702

MI Trial Femoral Head

Neck Length	28mm	32mm	36mm
-3	7136-9708	7136-9714	7136-9720
+0	7136-9709	7136-9715	7136-9721
+4	7136-9710	7136-9716	7136-9722
+8	7136-9711	7136-9717	7136-9723
+12	7136-9712	7136-9718	7136-9724
+16	7136-9713	7136-9719	——

Femoral Head Trial (optional)

Neck length	40mm	44mm
-4	7136-6516	7136-0812
+0	7136-6517	7136-0813
+4	7136-6518	7136-0814
+8	7136-6519	7136-0815

ANTHOLOGY Standard Offset Trial Neck

Size	Standard Cat. No.	Size	Standard Cat. No.
1-6	7136-5701	7-12	7136-5707

ANTHOLOGY High Offset Trial Neck

Size	High Offset Cat. No.	Size	High Offset Cat. No.
1-6	7136-5801	7-12	7136-5807

Femoral Head Impactor
Cat. No. 7136-4009

Anteversion Handle
Cat. No. 7136-4012

Catalog

ANTHOLOGY® Core Instrument Set — Cat. No. 7136-5220

ANTHOLOGY Core Instrument Tray
Cat. No. 7136-5715

ANTHOLOGY Posterior Broach Handle Set — Cat. No. 7136-5240

ANTHOLOGY Broach Handle Tray
Cat. No. 7136-5714

ANTHOLOGY Anterior Broach Handle Set — Cat. No. 7136-5230

ANTHOLOGY Broach Handle Tray
Cat. No. 7136-5714

Blunt Medullary Reamer
Cat. No. 11-9657

Low Profile Broach Handle
Cat. No. 7136-4021

ANTHOLOGY Inserter Posterior Hard
Cat. No. 7136-5705

ANTHOLOGY Inserter Posterior Soft
Cat. No. 7136-5706

Offset Broach Handle
Cat. No. 7136-5703

Dual Offset Broach Handle Set — Cat. No. 7136-0070

Left Dual Offset Broach Handle
Cat. No. 7136-0089

Right Dual Offset Broach Handle
Cat. No. 7136-0090

ANTHOLOGY Inserter Anterior Soft
Cat. No. 7136-5721

ANTHOLOGY® Broach

Size	Cat. No.	Size	Cat. No.
1	7136-5201	7	7136-5607
2	7136-5202	8	7136-5608
3	7136-5603	9	7136-5609
4	7136-5604	10	7136-5610
5	7136-5605	11	7136-5611
6	7136-5606	12	7136-5612

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, OXINIUM® oxidized zirconium, BIOLOX® *forte* alumina ceramic, BIOLOX delta alumina/zirconia ceramic or stainless steel. Acetabular liners are ultra-high molecular weight polyethylene (UHMWPE), cobalt chromium (CoCr) alloy, BIOLOX *forte* alumina ceramic, or BIOLOX delta alumina/zirconia ceramic. All poly acetabular components are UHMWPE. Acetabular shells are titanium 6Al-4V alloy or cobalt chromium (CoCr). The component material is provided on the outside carton label. Note: BIOLOX delta ceramic liners are not available in the US.

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, modular necks, proximal sleeves, taper 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 and are intended to be used without cement. Modular femoral components are available with an oval taper to accept Smith & Nephew, Inc. CoCr modular necks and/or a Morse type taper to accept proximal sleeves. 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 taper.

Small taper femoral components mate and lock directly with a 22 mm metal or oxidized zirconium or ceramic heads. 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), oxidized zirconium (28, 32, or 36mm), bipolars or unipolar components.

Femoral components or modular necks 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.

Modular Necks
Modular necks are available in a variety of configurations. The modular neck mates and locks with the oval taper of a modular femoral component on one end and the taper of a 12/14 femoral head on the other end.

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 BIOLOX *forte* ceramic heads and BIOLOX delta ceramic heads are available for use only with 12/14 taper femoral components:

BIOLOX *forte* Ceramic Heads

			Head Diameter	Neck Length
71332800	71330280*	526969	28mm	S/+0
71332804	71330284*	526970	28mm	M/+4
71332808	71330288*	526971	28mm	L/+8
71333200	71330320**	526914	32mm	S/+0
71333204	71330324**	526915	32mm	M/+4
71333208	71330328**	526916	32mm	L/+8
71331047	71332084***	76539150	36mm	S/+0
71331048	71332085***	76539151	36mm	M/+4
71331049	71332086***	76539152	36mm	L/+8

*Used with REFLECTION BIOLOX *forte* Ceramic Acetabular Liners in the US.
**Used with REFLECTION BIOLOX *forte* Ceramic Acetabular Liners and R3 BIOLOX *forte* Ceramic Acetabular Liners in the US.
***Used with R3 BIOLOX *forte* Ceramic Acetabular Liners in the US.

BIOLOX *delta* Ceramic Heads

	Head Diameter	Neck Length
71346001	28mm	S/+0
71346002	28mm	M/+4
71346003	28mm	L/+8
76539160	32mm	S/+0
76539161	32mm	M/+4
76539162	32mm	L/+8
76539165	36mm	S/+0
76539166	36mm	M/+4
76539167	36mm	L/+8
76539153*	36mm	XL/+12
71346004	40mm	S/+0
71346005	40mm	M/+4
71346006	40mm	L/+8
71330029	44mm	S/+0
71330031	44mm	M/+4
71330032	44mm	L/+8

*Not available in the US.

The following CoCr BIRMINGHAM HIP® (BH) modular heads* should be used only with BIRMINGHAM HIP acetabular cups and R3 metal acetabular liners:

74222138	Modular Head 38mm
74222140	Modular Head 40mm
74222142	Modular Head 42mm
74222144	Modular Head 44mm
74222146	Modular Head 46mm
74222148	Modular Head 48mm
74222150	Modular Head 50mm
74222152	Modular Head 52mm
74222154	Modular Head 54mm
74222156	Modular Head 56mm
74222158	Modular Head 58mm

*BH Modular Heads are not available in the US.

Acetabular Components
Acetabular components can be one-piece all polyethylene, or two-piece, consisting of a titanium shell and either a UHMWPE liner, BIOLOX *forte* ceramic liner, BIOLOX delta ceramic liner or CoCr metal liner. For BIOLOX *forte* ceramic liners available for use with the REFLECTION® Ceramic Acetabular System in the US, refer to the separate package insert provided with these components. 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: BIOLOX delta ceramic liners are not available in the US. For R3 metal liners available for use with the BIRMINGHAM HIP Resurfacing (BHR) System in the US, refer to the separate package insert provided with these components.

Note: 10 Mrad cross-linked UHMWPE acetabular liners may be used with metal (CoCr), oxidized zirconium, BIOLOX *forte* ceramic heads or BIOLOX delta ceramic 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. Acetabular liners are designed for use only with acetabular shells from the same product family (i.e. REFLECTION liners can only be used with REFLECTION shells; R3 liners can only be used with R3 shells).

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; 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.

Total hip systems may be indicated for use with bone cement, without bone cement, or for use with or without cement.

The MDF revision hip system is intended to be used without cement ☒. In the EU, MDF is indicated for revision surgery only.

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 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.
18. Stem loosening or fracture, particularly of smaller sized stems, is most likely to occur in patients who are young, physically active, and/or heavy.
19. Temporary or permanent device related noise such as clicking or squeaking.

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 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 unless specially approved by the manufacturer of the components. For purposes of product inter-compatibility, products manufactured and labeled by entities formerly known as Plus Endoprothetik, Intraplant, Precision Implants and Plus Orthopedics (now Smith & Nephew Orthopaedics AG) may be considered as the same manufacturer, Smith & Nephew. 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. Single use devices should not be reused due to risks of breakage, failure or patient infection.
6. Do not cold water quench ceramic components and never sterilize ceramic heads while fixed on the stem taper. (See sterilization section, below.)
7. OXINIUM® oxidized zirconium femoral heads and cobalt chrome femoral heads are designed to articulate with UHMWPE bearing surfaces. BIOLOX *forte* ceramic femoral heads and BIOLOX delta ceramic femoral heads articulate with UHMWPE liners or cups, BIOLOX *forte* ceramic liners or BIOLOX delta ceramic liners. OXINIUM oxidized zirconium femoral heads, cobalt chrome femoral heads, BIOLOX *forte* ceramic femoral heads and BIOLOX delta ceramic femoral heads should never articulate against metal because severe wear of the bearing surfaces may occur. BHR resurfacing heads and Birmingham Hip CoCr modular heads articulate with Birmingham Hip acetabular cups or R3 metal liners. Note: BIOLOX delta ceramic liners and Birmingham Hip CoCr modular heads are not available in the US.
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. Alumina ceramic should never articulate against metal because severe wear could occur.
10. The SL-PLUS® Stems, SL-PLUS Lateralized Stems, SLR-PLUS® Stems and SL-PLUS MIA Stems are compatible with Smith & Nephew ball heads, including Unipolar and Bipolar, with the exception of +16 offset all sizes. Do not use the Smith & Nephew +16 heads with SL-PLUS Stems and SLR-PLUS Stems.
11. If a computer assisted surgery system is used, consult the applicable software and hardware reference manuals provided by the manufacturer to ensure proper operation of this equipment.

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. 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.-
6. Modular heads, modular necks, modular sleeves and femoral components should be from the same manufacturer unless specially approved by the manufacturer of the components to prevent mismatch.
7. Stainless steel heads and stainless steel stems should only be used together. Neither should be used with other metal components.
8. Use only REFLECTION Liners with REFLECTION Shells. Use only R3 Liners with R3 Shells.
9. Clean and dry all taper connections prior to impacting for assembly. The modular femoral head, neck and/or sleeve components must be firmly seated on the femoral component to prevent disassociation.
10. 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.
11. REFLECTION Three Hole, FSO, INTERFIT® and R3 Shells accept both REFLECTION spherical head screws and Universal cancellous bone screws. REFLECTION FSO and INTERFIT Shells accept the Modified REFLECTION screw hole covers. The REFLECTION V Shell only accepts Universal Cancellous, REFLECTION screws, tapered screw-hole covers and tapered, pegs. REFLECTION Peripheral Hole Screws should only be used with REFLECTION Peripheral Hole Shells. Locking Head Pegs and REFLECTION Locking Head Screw Hole Covers are only for use with REFLECTION Three Hole Shells. The threaded center hole in REFLECTION Shells only accepts threaded hole covers, not screws or pegs. The INTERFIT threaded hole cover is only for use with REFLECTION INTERFIT, Spiked and No Hole Shells. The REFLECTION threaded hole cover can be used with all REFLECTION and R3 shells. The R3 screw hole cover can be used with R3 and REFLECTION Three Hole shells. Refer to product literature for proper adjunctive fixation and hole cover usage.
12. 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.
13. Avoid repeated assembly and disassembly of the modular components which could compromise the critical locking action of the locking mechanism.
14. 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.
15. 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.
16. 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.
17. 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. Reuse may also increase the risk of patient infection.
18. 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.
19. 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.
20. 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.
21. 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.
22. Proper positioning of the components is important to minimize impingement which could lead to early failure, premature wear, and/or dislocation.
23. 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.
24. 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.
25. For computer assisted surgery systems, it is extremely important to correctly select input parameters (e.g. bony landmarks). Operators of this equipment should be familiar with the anatomy relevant to the procedure. Failure to provide proper input could cause problems such as violation of critical anatomical structures and malpositioned implants.
26. Do not implant HA-coated devices in bone cement.

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.
7. Normal daily activity may be resumed at the physician's direction. Patients should be directed to seek medical opinion before entering potentially adverse environments that could affect the performance of the implant, such as electromagnetic or magnetic fields, including a magnetic resonance environment.

Magnetic Resonance Imaging (MRI) Safety

Smith & Nephew hip systems have not been evaluated for safety and compatibility in the MR environment. Hip system components have not been tested for heating or migration in the MR environment.

Packaging and Labeling

Implants 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

Implant components are supplied sterile to a Sterility Assurance Level (SAL) of 10^{-6}. Implant components are supplied in protective packaging. Inspect packages for punctures or other damage prior to surgery. The method of sterilization is noted on the package label.

DO NOT REUSE OR RESTERILIZE implant components or single use disposable instruments. Contact your local Smith & Nephew, Inc. Sales Representative regarding procedures to return components. If not specifically labeled sterile, instruments are supplied non-sterile and must be cleaned and sterilized prior to surgery. Please see also the document, "Recommendations for decontamination and sterilization of Smith & Nephew orthopaedic devices", which is provided with Smith & Nephew instrument sets, for further information on cleaning instructions and validated sterilization procedures.

Recommended Steam Sterilization Cycle Parameters

- Dynamic Air Removal (Prevacuum) Steam Cycle: 132°C (270°F) for 4 minutes or 135°C (275°F) for 3 minutes and a minimum vacuum drying time of 30 minutes.
- Gravity Displacement Steam Cycle: 132°C (270°F) for 30 minutes and a minimum vacuum drying time of 30 minutes.
- Flash Steam Cycle (Reusable instruments only): 132°C (270°F) for 10 minutes in a Gravity Displacement Cycle or 4 minutes in a Dynamic Air Removal (Prevacuum) Cycle.
- United Kingdom Steam Cycle: 134° C (273°F) for 3 minutes and a minimum vacuum drying time of 30 minutes. (Note: Sterilization evacuation and pulsing should be carried out in accordance with HTM 2010).

Containment devices should be wrapped with a central supply wrap (CSR) or placed in a reusable rigid container for sterilization. Note to US Customers: FDA cleared sterilizers and wraps are to be used in your sterilization processes.

Retrieval and Analysis of Removed Implants
The most important part of surgical implant retrieval is preventing damage that would render scientific examination useless. Special care should be given to protect the implant from damage during handling and shipment. Follow internal hospital procedures for the retrieval and analysis of implants removed during surgery. When handling removed implants, use precautions to prevent spread of bloodborne pathogens.

If the implant will be returned to Smith & Nephew, Inc. for analysis, contact Customer Service using the phone numbers outlined in the Information section.

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.

Manufacturing facilities and EC representative:

Smith & Nephew Inc.
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

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

H2O2 – hydrogen peroxide sterilization

– For cemented use only

– For uncemented use only

81073299 Rev. 0 2010-05 CE

Smith & Nephew, Inc.
7135 Goodlett Farms Pkwy
Cordova, TN 38106
USA

Telephone: 1-901-396-2121
Information: 1-800-821-5700
Orders and Inquiries: 1-800-238-7538

www.smith-nephew.com

00811 V1 10/13