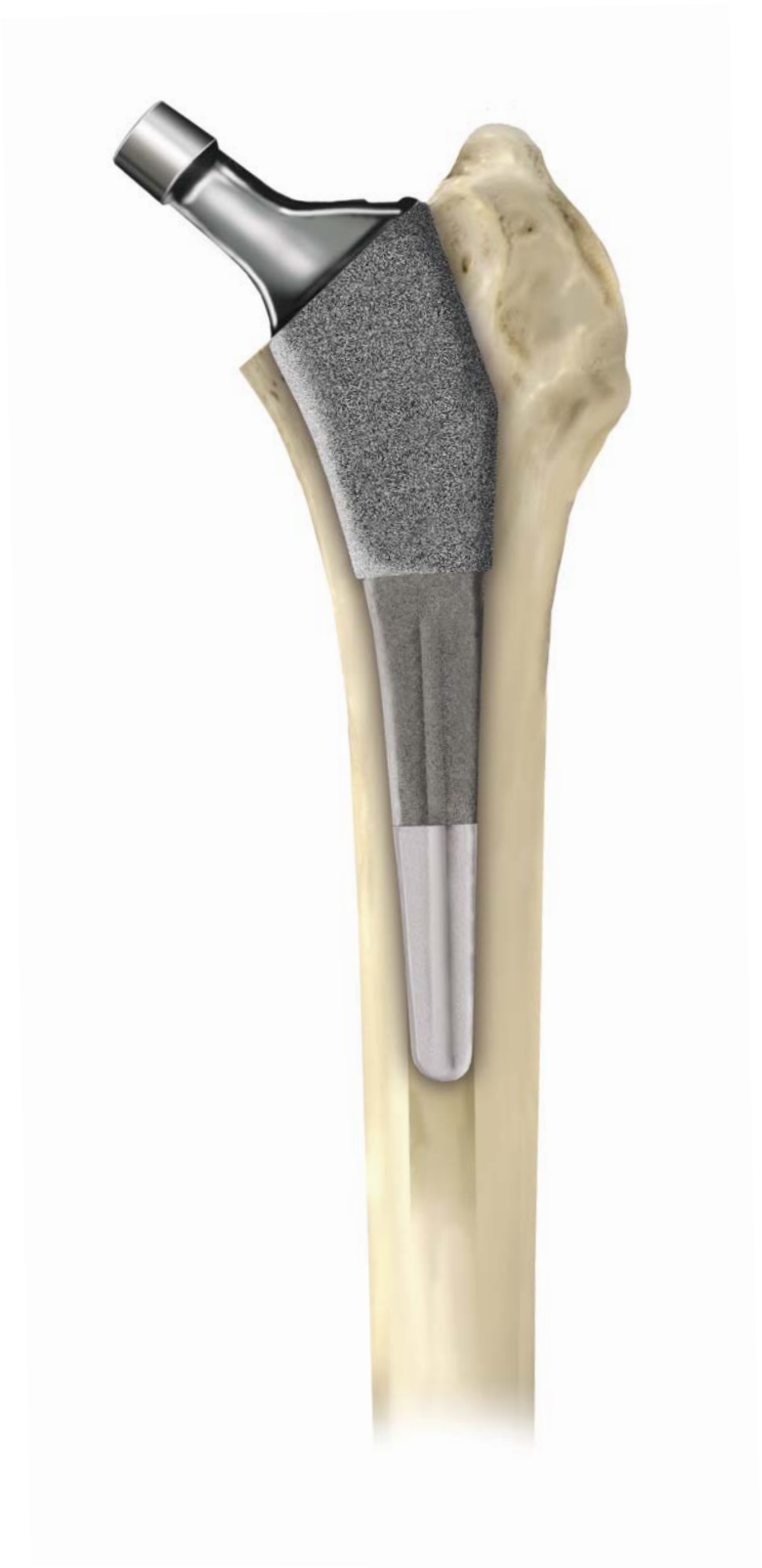
Surgical Technique

smith&nephew

ANTHOLOGY®

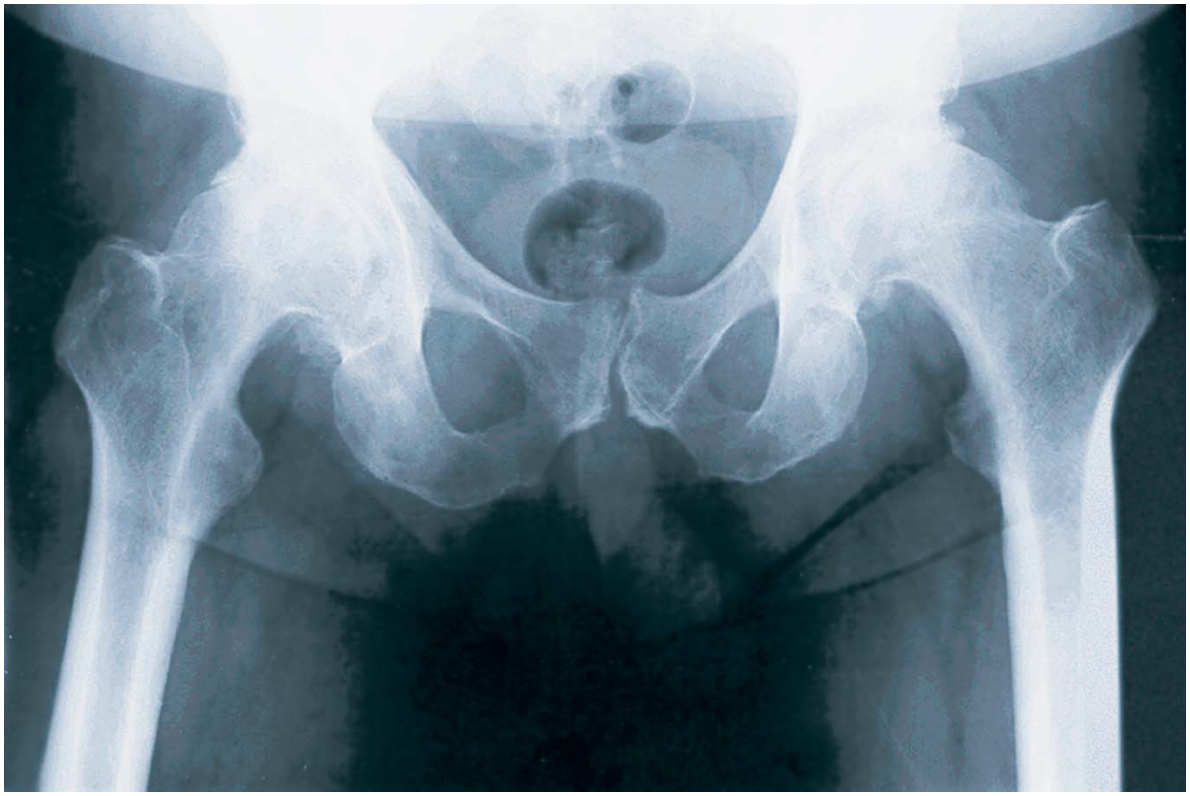
Primary Hip System



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

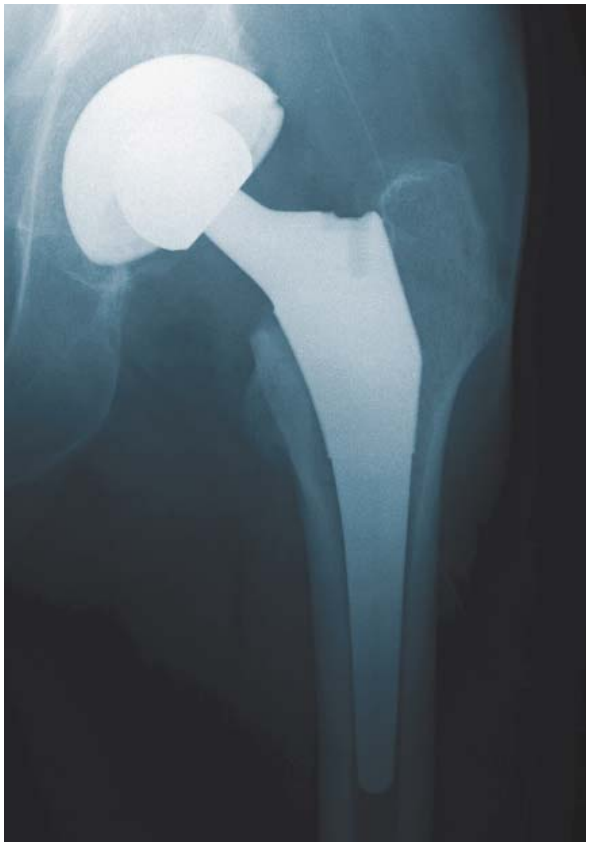
Nota Bene: The technique description herein is made available to the healthcare professional to illustrate the authors' suggested treatment for the uncomplicated procedure. In the final analysis, the preferred treatment is that which addresses the needs of the patient.

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

Mike Ries, MD
UCSF, San Francisco, CA

ANTHOLOGY® Primary Hip System

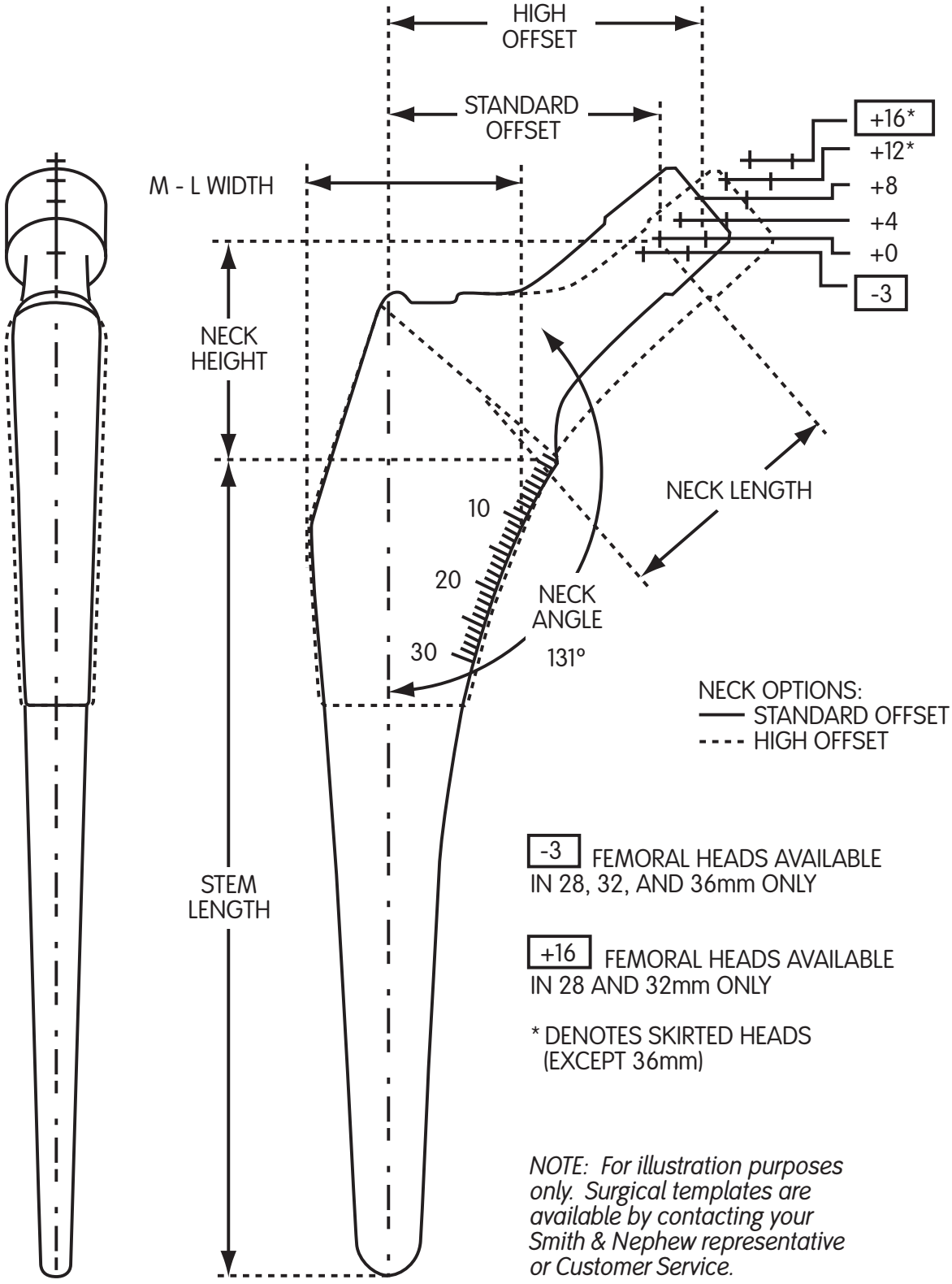
Specifications

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

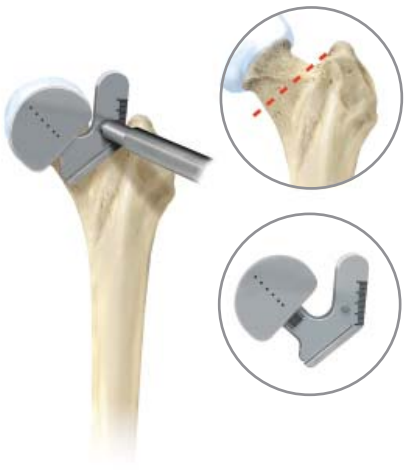
Neck Length MM												
	Standard Offset						High Offset					
Size	-3	+0	+4	+8	+12	+16	-3	+0	+4	+8	+12	+16
1	25	28	32	36	40	44	29	32	36	40	44	48
2	26	29	33	37	41	45	30	33	37	41	45	49
3	27	30	34	38	42	46	31	34	38	42	46	50
4	27	30	34	38	42	46	31	34	38	42	46	50
5	28	31	35	39	43	47	32	35	39	43	47	51
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


HIGH OFFSET
STANDARD OFFSET
M - L WIDTH
+16*
+12*
+8
+4
+0
-3
NECK HEIGHT
NECK LENGTH
10
20
30
NECK ANGLE
131°
NECK OPTIONS:
STANDARD OFFSET
HIGH OFFSET
STEM LENGTH
-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

ANTHOLOGY◇ Primary Hip System

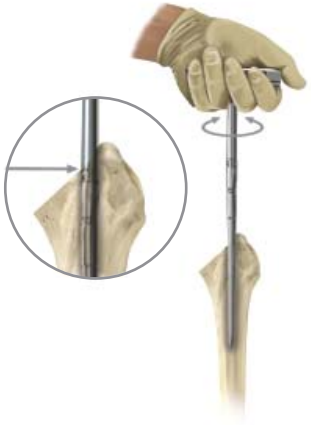
Short Technique Posterior Approach

Femoral Osteotomy



Femoral Canal Preparation

Femoral Canal Preparation Contd.

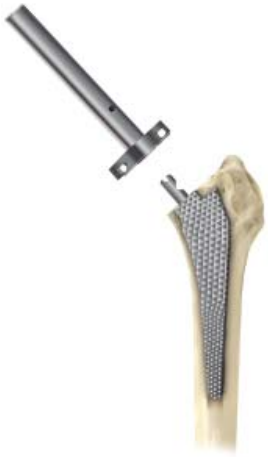


Starter Broach Assembly/Disassembly

Broach Assembly/Disassembly

Femoral Broaching

Calcar Preparation



Trial Reduction

Stem Insertion for Rigid Insertion

Stem Insertion for Non-Rigid Insertion

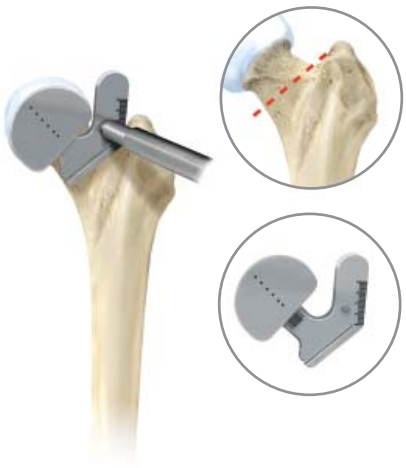
Final Trial Reduction

Femoral Head Assembly

ANTHOLOGY◇ Primary Hip System

Short Technique Anterior Approach

Femoral Osteotomy



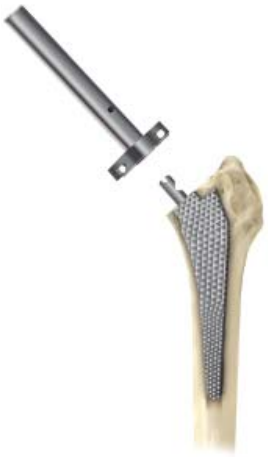
Femoral Canal Preparation

Starter Broach Assembly/Disassembly

Broach Assembly/Disassembly

Femoral Broaching

Calcar Preparation



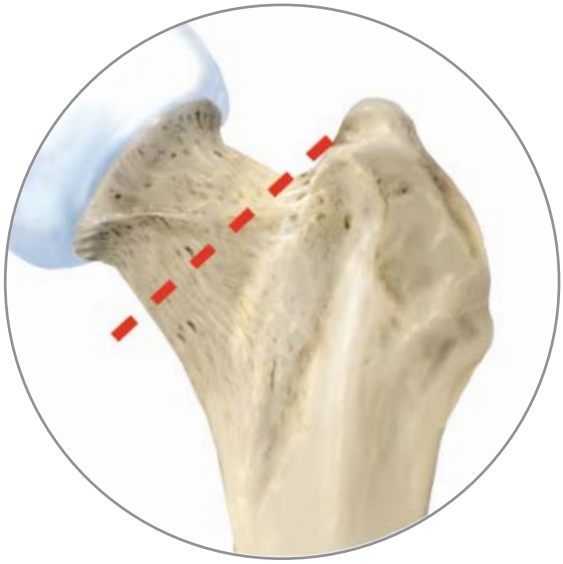
Trial Reduction

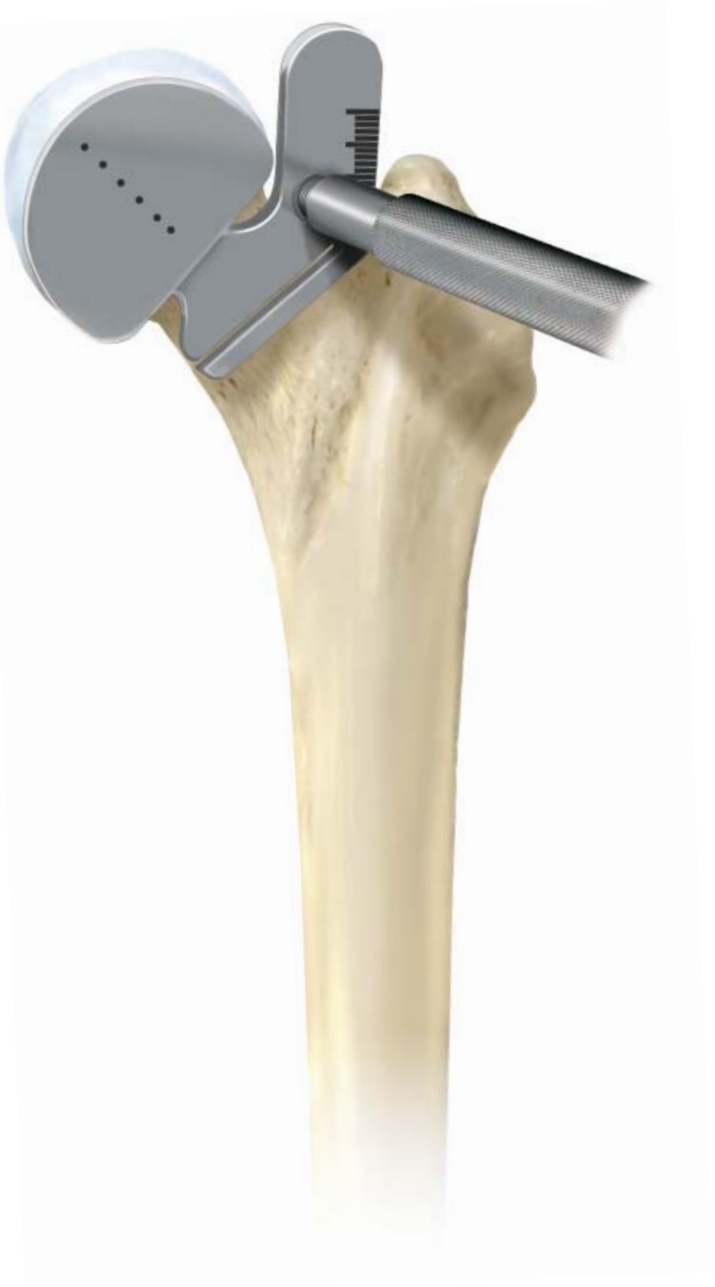
Stem Insertion for Non-Rigid Insertion

Final Trial Reduction

Femoral Head Assembly

Surgical Technique



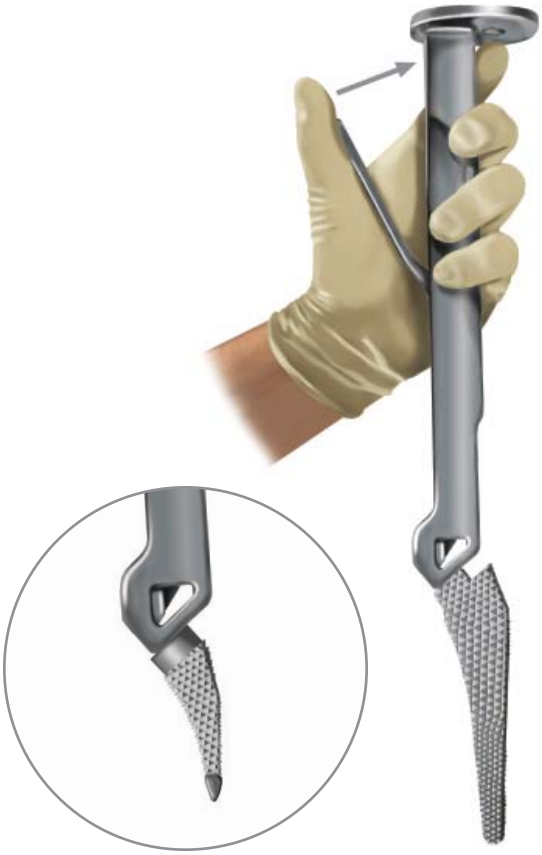


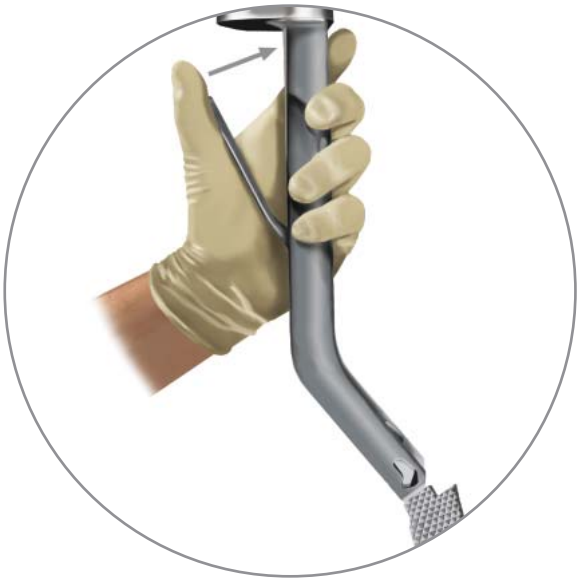
Femoral Osteotomy
Choose the appropriate osteotomy guide based on preoperative templating. The silver guide is for standard offset implants and the gold guide is for high offset implants. Thread the anteversion handle into the osteotomy guide. If templating based on the femoral head location, assemble 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.



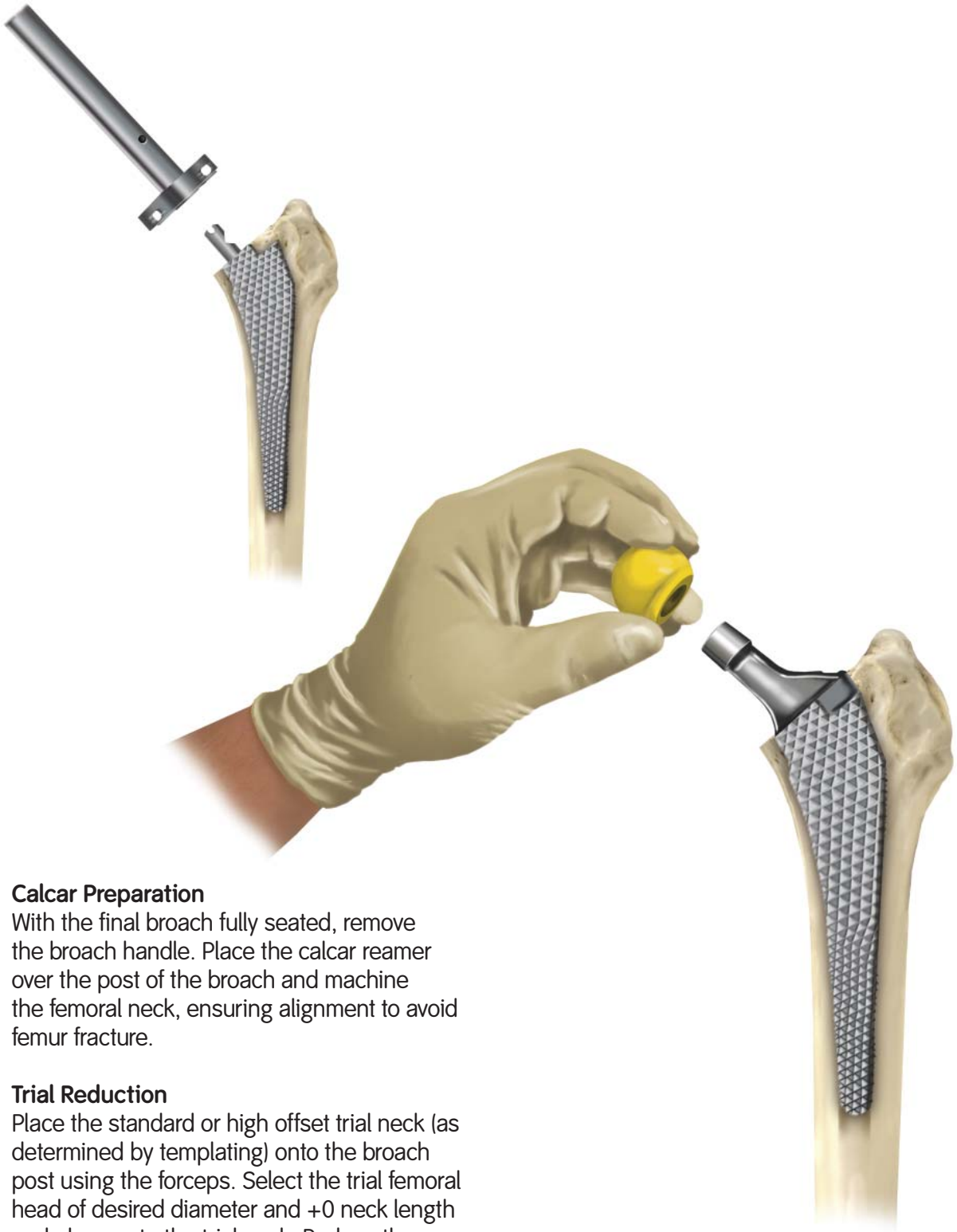


Note: For Anterior approach, use offset handle.

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.

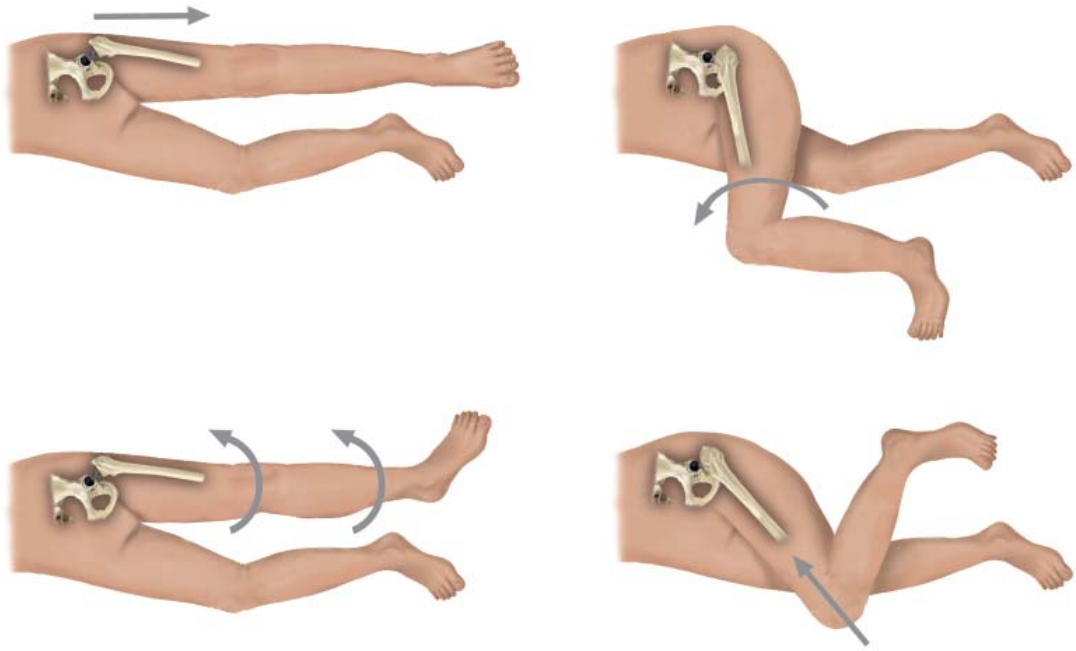
Note: Care should be taken not to force a broach that is too large into the femur. Consideration should be given to using a stem size smaller than the size templated if the final broach is difficult to seat. This helps avoid intraoperative fractures of the femur.



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



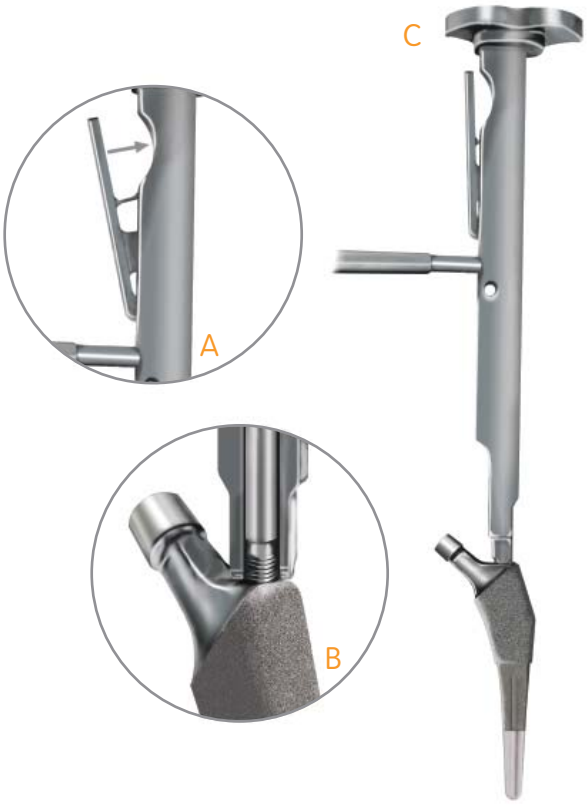
Reduce the hip and evaluate in the following ways:

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.

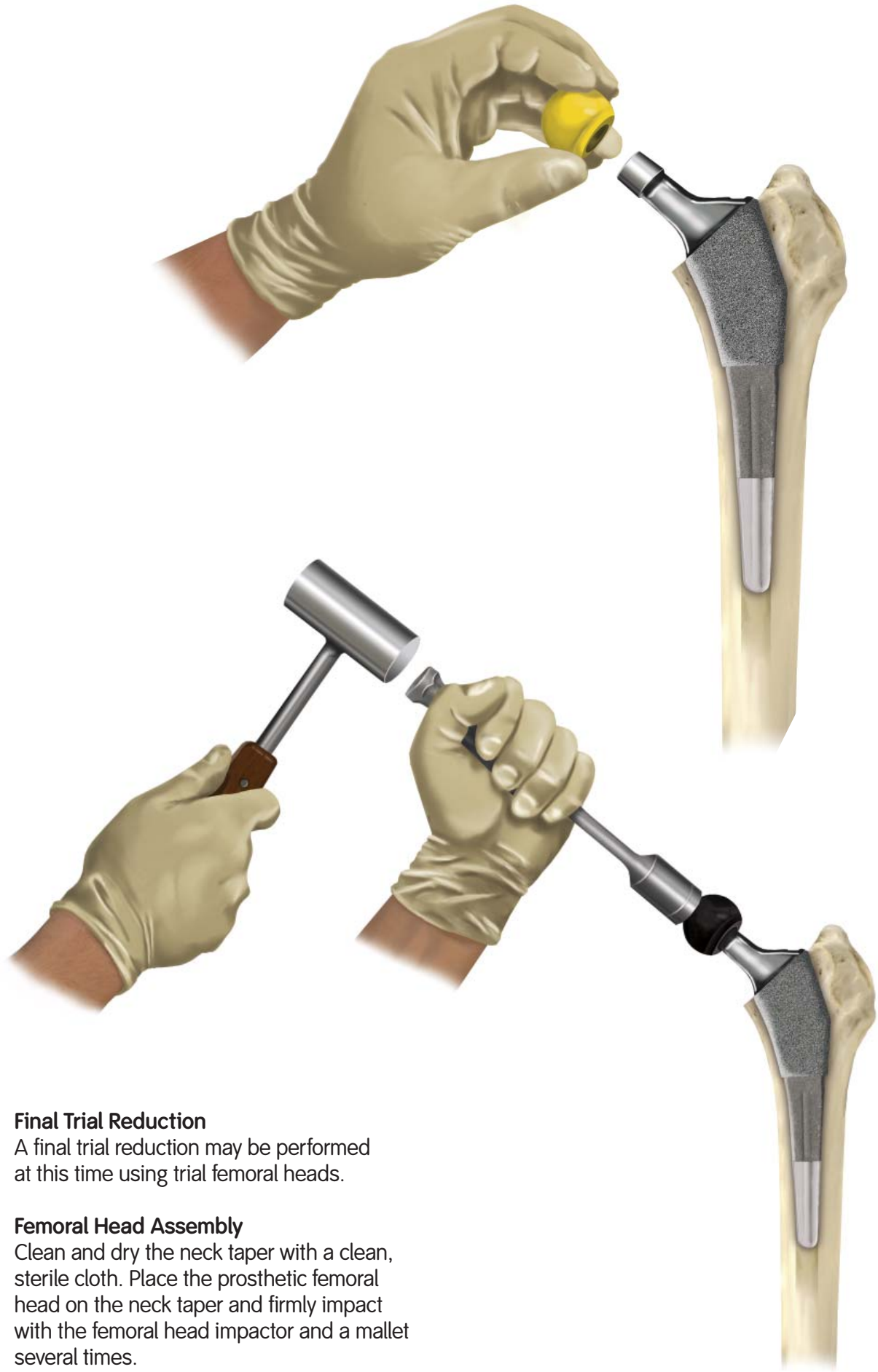
Note: Make sure the stem inserter is not impinging on the trochanter. This may cause inadequate stem seating or trochanteric fracture or varus positioning.

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 ster 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.



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.

Catalog

ANTHOLOGY Standard Offset Implant Set — Cat. No. 71356000

ANTHOLOGY Standard Offset Porous Stem

Size	Cat. No.	Size	Cat. No.	Size	Cat. No.
1	71356001	5	71356005	9	71356009
2	71356002	6	71356006	10	71356010
3	71356003	7	71356007	11	71356011
4	71356004	8	71356008	12	71356012

ANTHOLOGY High Offset Implant Set — Cat. No. 71356100

ANTHOLOGY High Offset Porous Stem

Size	Cat. No.	Size	Cat. No.	Size	Cat. No.
1	71356101	5	71356105	9	71356109
2	71356102	6	71356106	10	71356110
3	71356103	7	71356107	11	71356111
4	71356104	8	71356108	12	71356112

ANTHOLOGY High Offset Plus HA Implant Set — Cat. No. 71357000

ANTHOLOGY Standard Offset Porous Plus HA Stem

Size	Cat. No.	Size	Cat. No.	Size	Cat. No.
1	71357001	5	71357005	9	71357009
2	71357002	6	71357006	10	71357010
3	71357003	7	71357007	11	71357011
4	71357004	8	71357008	12	71357012

ANTHOLOGY High Offset Plus HA Implant Set — Cat. No. 71355700

ANTHOLOGY High Offset Porous Plus HA Stem

Size	Cat. No.	Size	Cat. No.	Size	Cat. No.
1	71357101	5	71357105	9	71357109
2	71357102	6	71357106	10	71357110
3	71357103	7	71357107	11	71357111
4	71357104	8	71357108	12	71357012

OXINIUM® Femoral Heads 12/14 Taper

Neck Length	28mm	32mm	36mm
-3	71342803	71343203	71343603
+0	71342800	71343200	71343600
+4	71342804	71343204	71343604
+8	71342808	71343208	71343608
+12	71342812	71343212	71343612
+16	71342816	71343216	——

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

Neck Length	22mm	26mm	28mm	32mm
-3	——	——	71302803	71303203
+0	71302200	71302600	71302800	71303200
+4	71302204	71302604	71302804	71303204
+8	71302208	71302608	71302808	71303208
+12	71302212	71302612	71302812	71303212
+16	——	——	71302816	71303216

Alumina Ceramic Femoral Heads 12/14 Taper

Neck Length	28mm	32mm
+0 (short)	71330280	71330320
+4 (medium)	71330284	71330324
+8 (long)	71330288	71330328

ANTHOLOGY® High Offset Neck Cut Guide
Cat. No. 71365920

ANTHOLOGY Standard Offset Neck Cut Guide
Cat. No. 71365704

ANTHOLOGY Neck Cut Guide Sliding Head
Cat. No. 71365921

Box Osteotome
Cat. No. 71364002

ANTHOLOGY Starter Broach
Cat. No. 71365600

ANTHOLOGY Calcar Reamer
Cat. No. 71365702

MI Trial Femoral Head

Neck Length	28mm	32mm	36mm
-3	71369708	71369714	71369720
+0	71369709	71369715	71369721
+4	71369710	71369716	71369722
+8	71369711	71369717	71369723
+12	71369712	71369718	71369724
+16	71369713	71369719	——

ANTHOLOGY Standard Offset Trial Neck

Size	Standard Cat. No.	Size	Standard Cat. No.
1-6	71365701	7-12	71365707

ANTHOLOGY High Offset Trial Neck

Size	High Offset Cat. No.	Size	High Offset Cat. No.
1-6	71365801	7-12	71365807

ANTHOLOGY Trial Head Inserter (Optional)
Cat. No. 71365708

ANTHOLOGY® Primary Hip System

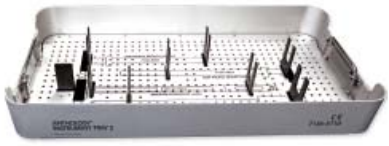
Catalog

Femoral Head Impactor
Cat. No. 71364009

Anteversion Handle
Cat. No. 71364012

ANTHOLOGY Posterior Instrument Set Cat. No. 71365800

ANTHOLOGY Posterior Instrument Tray No. 1
Cat. No. 71365713



ANTHOLOGY Posterior Instrument Tray No. 2
Cat. No. 71365710

Blunt Medullary Reamer
Cat. No. 119657

Low Profile Broach Handle
Cat. No. 71364021

ANTHOLOGY Inserter Posterior Hard
Cat. No. 71365705

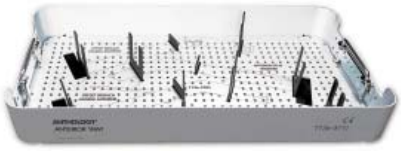
ANTHOLOGY Inserter Posterior Soft
Cat. No. 71365706

ANTHOLOGY® Posterior Broach

Size	Cat. No.	Size	Cat. No.
1	71365601	7	71365607
2	71365602	8	71365608
3	71365603	9	71365609
4	71365604	10	71365610
5	71365605	11	71365611
6	71365606	12	71365612

ANTHOLOGY Anterior Instrument Set Cat. No. 71365700

ANTHOLOGY Anterior Instrument Tray No. 1
Cat. No. 71365711



ANTHOLOGY Anterior Instrument Tray No. 2
Cat. No. 71365712

Offset Broach Handle
Cat. No. 71365703

ANTHOLOGY Inserter Anterior Soft
Cat. No. 71365721

ANTHOLOGY Anterior Broach

Size	Cat. No.	Size	Cat. No.
1	71365201	7	71365207
2	71365202	8	71365208
3	71365203	9	71365209
4	71365204	10	71365210
5	71365205	11	71365211
6	71365206	12	71365212

Important Medical Information
Warnings and Precautions
Total Hip System

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

Materials
Femoral components are cobalt chromium alloy, titanium 6Al-4V alloy or stainless steel. Femoral heads are cobalt chromium alloy, zirconia ceramic, alumina ceramic, OXINIUM® Oxidized Zirconium or stainless steel. Acetabular liners are ultra-high molecular weight polyethylene or alumina ceramic. All poly acetabular components are ultra-high molecular weight polyethylene. Acetabular shells are titanium 6Al-4V alloy. The component material is provided on the outside carton label.

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

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

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

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

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

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

Large taper femoral components mate and lock with either metal heads (26, 28, or 32mm), ceramic heads (28 or 32mm), oxidized zirconium (28, 32, or 36mm), bipolars or unipolar components.

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

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

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

Femoral Heads
Cobalt chromium, stainless steel, oxidized zirconium, and ceramic heads are available in multiple neck lengths for proper anatomic and musculature fit. Heads are highly polished for reduced friction and wear. The following zirconia ceramic heads are available for use only with Small and Large taper femoral components:

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

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

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

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

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

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

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

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

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

Acetabular Components
Acetabular components can be one piece all polyethylene, two-piece component consisting of a titanium shell and a polyethylene liner or a titanium shell and an alumina ceramic liner. Please see Warnings and Precautions for specific information on screws, pegs and hole covers use. Acetabular reinforcement and reconstruction rings are used with an all polyethylene acetabular component. Note: The metal shell and ceramic liner in the Ceramic/Ceramic Acetabular System are not available in the USA.

The BIRMINGHAM HIP® Resurfacing (BHR) prosthesis is a metal-on-metal bearing component consisting of a stemmed femoral head resurfacing component designed for cemented insertion and a hemispherical acetabular cup designed for cementless interference fit into the acetabulum. The acetabular cup has hydroxylapatite coating applied to the external surface and porous coating. Cement should not be used with this type of implant.

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

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

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

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

The BIRMINGHAM HIP Resurfacing (BHR) arthroplasty system is indicated for use for reduction or relief of pain and/or improved hip function in patients who are candidates for a total hip replacement but who have evidence of good femoral bone stock. These patients should also be skeletally mature with the following conditions: noninflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia; inflammatory degenerative joint disease such as rheumatoid arthritis; correction of functional deformity; and are of an age such that total hip revision is likely at some future point.

Acetabular reinforcement and reconstruction rings are intended to be used in primary and revision surgeries where the acetabulum has the deficiencies of the acetabular roof, anterior or posterior pillar, medial wall deficiency, and/or protrusion as a result of the indications listed previously.

Some of the diagnoses listed above and below may also increase the chance of complications and reduce the chance of a satisfactory result.

Contraindications
1. Conditions that would eliminate or tend to eliminate adequate implant support or prevent the use of an appropriately-sized implant, e.g.:
   a. blood supply limitations;
   b. insufficient quantity or quality of bone support, e.g., osteoporosis, or metabolic disorders which may impair bone formation, and osteomalacia; and
   c. infections or other conditions which lead to increased bone resorption.
2. Mental or neurological conditions which tend to impair the patient's ability or willingness to restrict activities.
3. Physical conditions or activities which tend to place extreme loads on implants, e.g., Charcot joints, muscle deficiencies, multiple joint disabilities, etc.
4. Skeletal immaturity.
5. The zirconia ceramic head is contraindicated for use with any other product than an UHMW polyethylene cup or a metal backed UHMW polyethylene cup.
6. The alumina ceramic liner is contraindicated for use with any product other than the metal shell with the correlating inner taper geometry and the appropriate sized alumina ceramic head. The alumina ceramic liner should only be used with the alumina ceramic head.

Contraindications may be relative or absolute and must be carefully weighed against the patient's entire evaluation and the prognosis for possible alternative procedures such as non-operative treatment, arthrodesis, femoral osteotomy, pelvic osteotomy, resection arthroplasty, hemiarthroplasty and others. Conditions presenting increased risk of failure include: osteoporosis, metabolic disorders which may impair bone formation, and osteomalacia.

Possible Adverse Effects
1. Wear of the polyethylene and ceramic articulating surfaces of acetabular components may occur. Higher rates of wear may be initiated by the presence of particles of cement, metal, or other debris which can develop during or as a result of the surgical procedure and cause abrasion of the articulating surfaces. Higher rates of wear may shorten the useful life of the prosthesis and lead to early revision surgery to replace the worn prosthetic components.
2. With all joint replacements, asymptomatic, localized, progressive bone resorption (osteolysis) may occur around the prosthetic components as a consequence of foreign-body reaction to particulate wear debris. Particles are generated by interaction between components, as well as between the components and bone, primarily through wear mechanisms of adhesion, abrasion, and fatigue. Secondarily, particles may also be generated by third-body particles lodged in the polyethylene or ceramic articular surfaces. Osteolysis can lead to future complications necessitating the removal or replacement of prosthetic components.
3. Loosening, bending, cracking, or fracture of implant components may result from failure to observe the Warnings and Precautions below. Fracture of the implant can occur as a result of trauma, strenuous activity, improper alignment, or duration of service.
4. Dislocations, subluxation, decreased range of motion, or lengthening or shortening of the femur caused by improper neck selection, positioning, looseness of acetabular or femoral components, extraneous bone, penetration of the femoral prosthesis through the shaft of the femur, fracture of the acetabulum, intrapelvic protrusion of acetabular component, femoral impingement, periarticular calcification, and/or excessive reaming.
5. Fracture of the pelvis or femur: post-operative pelvic fractures are usually stress fractures. Femoral fractures are often caused by defects in the femoral cortex due to misdirected reaming, etc. Intraoperative fractures are usually associated with old congenital deformity, improper stem selection, improper broaching, and/or severe osteoporosis.
6. Infection, both acute post-operative wound infection and late deep wound sepsis.
7. Neuropathies; femoral, sciatic, peroneal nerve, and lateral femoral cutaneous neuropathies have been reported. Temporary or permanent nerve damage resulting in pain or numbness of the affected limb.
8. Wound hematoma, thromboembolic disease including venous thrombosis, pulmonary embolus, or myocardial infarction.
9. Myositis ossificans, especially in males with hypertrophic arthritis, limited pre-operative range of motion and/or previous myositis. Also, periarticular calcification with or without impediment to joint mobility can cause decreased range of motion.
10. Trochanteric nonunion usually associated with early weight bearing and/or improper fixation of the trochanter, when a transtrochanteric surgical approach is used.
11. Although rare, metal sensitivity reactions and/or allergic reactions to foreign materials have been reported in patients following joint replacement.
12. Damage to blood vessels.
13. Traumatic arthrosis of the knee from intraoperative positioning of the extremity.
14. Delayed wound healing.
15. Aggravated problems of the affected limb or contralateral extremity caused by leg length discrepancy, excess femoral medialization, or muscle deficiency.
16. Failure of the porous coating/ substrate interface or hydroxylapatite coating/ porous coating bonding may result in bead separation delamination.
17. Stem migration or subsidence has occurred in conjunction with compaction grafting procedures usually resulting from insufficient graft material or improper cement techniques. Varus stem alignment may also be responsible.

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

Preoperative

1. Use extreme care in handling and storage of implant components. Cutting, bending, or scratching the surface of components can significantly reduce the strength, fatigue resistance, and/or wear characteristics of the implant system. These, in turn, may induce internal stresses that are not obvious to the eye and may lead to fracture of the component. Implants and instruments should be protected from corrosive environments such as salt air during storage. Do not allow the porous surfaces to come in contact with cloth or other fiber-releasing materials.
2. Allergies and other reactions to device materials, although infrequent, should be considered, tested for (if appropriate), and ruled out preoperatively.
3. Fixation and expected longevity of components expected to be left in place at revision surgery should be thoroughly assessed.
4. Surgical technique information is available upon request. The surgeon should be familiar with the technique. Refer to medical or manufacturer literature for specific product information.
5. Intraoperative fracture or breaking of instruments can occur. Instruments which have experienced extensive use or excessive force are susceptible to fracture. Instruments should be examined for wear, or damage, prior to surgery.
6. Do not cold water quench ceramic components and never sterilize ceramic heads while fixed on the stem taper. (See sterilization section, below.)
7. Select components such that the zirconia ceramic and oxidized zirconium heads always articulate with a UHMW polyethylene cup or a metal backed UHMW polyethylene cup and alumina heads articulate with UHMW polyethylene or alumina liners. Zirconia ceramic, oxidized zirconium, and alumina heads should never articulate against metal because severe wear of the metal will occur.
8. Select only Smith & Nephew femoral components that indicate their use with ceramic heads. This is important because the taper on the stem is machined to tightly mate and lock with the ceramic head thus preventing rotation of the ceramic head on the stem. Also, an improperly dimensioned taper could result in fracture of the ceramic head.
9. The zirconia ceramic head is composed of a new ceramic material with limited clinical history. Although mechanical testing demonstrates that when used with a polyethylene acetabula component the yttria stabilized zirconia ball produces a relatively low amount of particulates, the total amount of particulate remains undetermined. Because of the limited clinical and preclinical experience, the biological effect of these particulates can not be predicted.
10. Alumina ceramic should never articulate against metal because severe wear could occur.
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 +12mm or +16mm 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 25mm of the tip of the base stem.
6. Matrix Small taper stem sizes 8S - 10L must have a minimum neck length of +8mm when used with a bipolar component; and small taper stem sizes 12S - 16L must have a minimum neck length of +4mm when used with a bipolar component.
7. Modular heads and femoral components should be from the same manufacturer to prevent mismatch of tapers.
8. Stainless steel heads and stainless steel stems should only be used together. Neither should be used with other metal components.
9. Use only REFLECTION® Liners with REFLECTION Shells.
10. Clean and dry stem taper prior to impacting the femoral head or taper sleeve. The modular femoral head component must be firmly seated on the femoral component to prevent disassociation.
11. Take care, when positioning and drilling screw and peg holes, to avoid penetration of the inner cortex of the pelvis, penetration of the sciatic notch, or damage to vital neurovascular structures. Perforation of the pelvis with screws that are too long can rupture blood vessels causing the patient to hemorrhage. Do not place a screw in the center hole of the acetabular prosthesis. Placement of drills and screws in the anterior or medial portions of the prosthesis is associated with a high risk of potentially fatal vascular injury. Bone screws must be completely seated in the holes of the shell to allow proper locking for the acetabular component liner. If the tapered pegs need to be removed from the shell after impaction of the pegs, do not reuse the pegs or the peg shell holes. Use new pegs and different shell holes, or a new shell if necessary.
12. **Use only reflection titanium spherical head bone screws, universal cancellous bone screws, tapered pegs, and hole covers** with the REFLECTION Acetabular Components. REFLECTION SP3, FSO and INTERFIT® 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, and tapered screw-hole covers, not pegs. REFLECTION Peripheral Hole Screws should only be used with REFLECTION Peripheral Hole Shells. Locking Head Pegs and REFLECTION SP Screw Hole Covers are only for use with SP3 Shells. Tapered pegs can only be used with REFLECTION V Shells. The threaded center hole in REFLECTION Shells only accepts the threaded hole cover, not screws or pegs. The INTERFIT threaded hole cover is only for use with REFLECTION INTERFIT, SP3, Spiked and No Hole Shells. The REFLECTION threaded hole cover can be used with all REFLECTION shells. Refer to product literature for proper adjunctive fixation and hole cover usage.
13. Prior to seating modular components, surgical debris including tissue must be cleaned from the surfaces. Debris, including bone cement, may inhibit the component locking mechanism. If the shell is to be cemented in place, remove extraneous cement with a plastic sculps tool to ensure proper locking of the liner. During liner insertion, make sure soft tissue does not interfere with the shell/liner interface. Chilling the liner reduces the impaction force required to seat the liner. Modular components must be assembled securely to prevent disassociation. Debris inhibits the proper fit and locking of modular components which may lead to early failure of the procedure. Failure to properly seat the acetabular liner into the shell can lead to disassociation of the liner from the shell.
14. Avoid repeated assembly and disassembly of the modular components which could compromise the critical locking action of the locking mechanism.
15. Care is to be taken to assure complete support of all parts of the device embedded in bone cement to prevent stress concentration which may lead to failure of the procedure. During curing of the cement, care should be taken to prevent movement of the implant components.
16. If the head is removed from a femoral component that will be left in place at revision surgery, it is recommended that a metal head be used. A ceramic head may fracture from irregularities on the femoral component taper.
17. If components are to be left in place at revision surgery, they should first be thoroughly checked for signs of looseness, etc. and replaced if necessary. The head/neck component should be changed only when clinically necessary.
18. Once removed from the patient, implants previously implanted should never be reused, since internal stresses which are not visible may lead to early bending or fracture of these components.
19. With the congenitally dislocated hip, special care should be taken to prevent sciatic nerve palsy. Also, note that the femoral canal is often very small and straight and may require an extra-small straight femoral prosthesis; however, a regular-sized prosthesis should be used when possible. Note that the true acetabulum is rudimentary and shallow. A false acetabulum should not ordinarily be utilized as a cup placement site for anatomical and biomechanical reasons.
20. With rheumatoid arthritis, especially for those patients on steroids, bone may be extremely osteoporotic. Care should be taken to prevent excessive penetration of the acetabular floor or fracture of the medial acetabular wall, femur, or greater trochanter.
21. Revision procedures for previous arthroplasty, Girdlestone, etc., are technically demanding and difficult to exercise. Common errors include misplacement of the incision, inadequate exposure or mobilization of the femur, inadequate removal of ectopic bone, or improper positioning of components. Postoperative instability as well as excessive blood loss can result. In summary, increased operative time, blood loss, increased incidence of pulmonary embolus and wound hematoma can be expected with revision procedures.
22. Prior to closure, the surgical site should be thoroughly cleaned of cement, bone chips, ectopic bone, etc. Ectopic bone and/or bone spurs may lead to dislocation or painful or restricted motion. Range of motion should be thoroughly checked for early contact or instability.
23. Proper positioning of the components is important to minimize impingement which could lead to early failure, premature wear, and/or dislocation.
24. In order to minimize the risks of dislocation and loosening of the shell-acetabular bone or shell-bone cement interface that may occur when using a metallic shell intended for biological fixation or cemented use only, surgeons should consider providing immediate resistance to tensile forces between the metallic shell and the acetabular bone or bone cement interface through the use of orthopedic bone fixation devices such as bone screws, spikes, screw threads, pegs, fins, or other bone fixation devices.
25. Physicians should consider component malposition, component placement, and the effect on range of motion when using modular heads (with sleeves or skirts) and extended liners.
26. 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.

Postoperative

1. Postoperative directions and warnings to patients by physicians, and patient care, are extremely important. Gradual weight bearing is begun after surgery in ordinary total hip arthroplasty. However, with trochanter osteotomy or certain complex cases, weight-bearing status should be individualized with the non or partial weight-bearing period extended.
2. Patients should be warned against unassisted activity, particularly use of toilet facilities and other activities requiring excessive motion of the hip.
3. Use extreme care in patient handling. Support should be provided to the operative leg when moving the patient. While placing the patient on bedpans, changing dressings, and clothing, and similar activities, precautions should be taken to avoid placing excessive load on the operative part of the body.
4. Postoperative therapy should be structured to regain muscle strength around the hip and a gradual increase of activities.
5. Periodic X-rays are recommended for close comparison with immediate postoperative conditions to detect long-term evidence of changes in position, loosening, bending and/or cracking of components or bone loss. With evidence of these conditions, patients should be closely observed, the possibilities of further deterioration evaluated, and the benefits of early revision considered.
6. Prophylactic antibiotics should be recommended to the patient similar to those suggested by the American Heart Association for conditions or situations that may result in bacteremia.

Packaging and Labeling
Components should only be accepted if received by the hospital or surgeon with the factory packaging and labeling intact. If the sterile barrier has been broken, return the component to Smith & Nephew, Inc.

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

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

- Prevacuum Cycle: 4 pulses (Maximum = 26.0 psig (2.8 bars) & Minimum = 10.0 inHg (339 millibars)) with a minimum dwell time of 4 minutes at 270°F to 275°F (132°C to 135°C), followed by a 1 minute purge and at least 15 minutes of vacuum drying at 10 inHg (339 millibars) minimum.
- For the United Kingdom, sterilization should be carried out in accordance with HTM 2010. The recommended prevacuum sterilization cycle is: Evacuation to 100mBar for 2-3 minutes, Negative Pressure pulsing (5): 800mBar-100mBar, Positive Pressure pulsing (5): 2.2Bar – 1.1 Bar, Sterilization exposure: 3 minutes at 134°-137°C, Drying vacuum 40mBar for 5-10 minutes. Note: mBar absolute.
- Gravity Cycle: 270°F to 275°F (132°C to 135°C) with a minimum dwell time at temperature of 10 minutes, followed by a 1 minute purge and at least 15 minutes of vacuum drying at 10 inHg (339 millibars) minimum.

Smith & Nephew does not recommend the use of low temperature gravity cycles or flash sterilization on implants. Do not resterilize femoral prostheses with ceramic heads seated on the stem. Do not steam autoclave femoral prostheses with proximal or distal centralizers attached. If resterilization is required for femoral prostheses with proximal or distal centralizers attached, use ethylene oxide gas.

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

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

Sterilant	Temp.	Humidity	Maximum Pressure	Concentration	Exposure Time
100% EtO	131°F (55°F)	40-80% (70% Target)	10 PSIA (689 millibar)	725 mg/l	60-180 minutes

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

Ceramic Components
Do not resterilize ceramic femoral heads or liners.

Information
For further information, please contact Customer Service at 1-800-238-7538 for calls within the continental USA and 1-901-396-2121 for all international calls.

Manufacturing facilities and EC representative:

Smith & Nephew Orthopaedics
1450 Brooks Road
Memphis, TN 38116 USA
Tel.: 1-901-396-2121

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.

H_2O_2 – hydrogen peroxide sterilization

81019184 Rev. 0 6/04

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

www.smith-nephew.com

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

Printed in USA
06/06 45860101