Surgical Technique

smith&nephew

SYNERGY®

Cementless Stem

Comprehensive. Simple. Efficient.

It's easy to understand why SYNERGY Hip System is one of orthopaedics' great success stories. Its rapid adoption by surgeons has been due to the system's significant advances over previous tapered implants, including its unique stem geometry, choice of surface treatments, innovative neck design, true dual offsets and efficient, easy-to-use instrumentation.

The SYNERGY Hip System also provides the surgeon a choice of cementless, cemented and fracture management systems that use the same 2 trays of instrumentation. In addition, the cementless system offers the valuable options of a porous stem, a hydroxyapatite (HA) stem, an HA porous stem and a titanium press-fit stem.

SYNERGY Cementless Stem

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

Introduction

The SYNERGY Tapered Hip System capitalizes on the excellent clinical results of proximal to distal tapered stem designs. The SYNERGY system features a variety of stem designs that provide different methods of stem fixation and that also address different patient demand types. All of the stems in the SYNERGY system are implanted with 1 simple set of surgical instruments.

This surgical technique focuses only on the cementless stems of the SYNERGY Hip System.

SYNERGY cementless femoral stems are available in 4 circumferential surface finishes: porous-coated, HA-coated, Porous Plus HA and a grit blasted. The porous-coated design promotes bone ingrowth and 3-dimensional interlocking between the implant and the bone. The HA-coated stem design features a high shear strength, hydroxyapatite coating that helps promote secure fixation. All are available in standard and high offset versions.

All SYNERGY femoral stems are made from high-strength, forged titanium and feature a 3° proximal to distal taper. Parallel and longitudinally arranged flutes on the stems provide good axial and rotational stability.

The 12/14 taper of SYNERGY stems accepts 22, 26, 28, 32 and 36mm femoral heads in a variety of neck lengths. The circulotrapezoidal neck of SYNERGY stems is smaller in the anterior/posterior direction than most competitive stems and is polished. The smaller A/P neck dimension allows for improved prosthesis range of motion. If impingement of the femoral stem and acetabular component occurs, the polished neck will reduce the amount of debris that is generated. The distal bullet tip of SYNERGY stems has also been polished in order to minimize distal endosteal irritation and reduce the risk of thigh pain.

SYNERGY instrumentation is packaged in 2 sterilization trays. The instruments are arranged in the sterilization trays in the same order required in surgery. This makes for a simple, straightforward surgical technique that is highly reproducible.


Standard Stem
High Offset Stem

Indications

Both cemented and cementless femoral components have demonstrated long-term durability in the treatment of severe arthritic conditions of the hip. An algorithm has been developed that helps define which implant matches each patient's needs. The algorithm takes into consideration patient age, bone stock, disease type and implant cost.

Algorithm for Implant Selection		
	Cementless	Cemented
Age	Under 75	Over 75
Medullary Canal	Funnel Shaped	Cylindrical
Disease	Osteoarthritis	Inflammatory
Cost Type	High-Demand	Low-Demand

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 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. SYNERGY stems gain immediate, rigid fixation through 3-point contact with the femur. This is best appreciated by viewing a lateral postoperative radiograph as shown in Figure 1.

As can be seen in Figure 1, the stem has direct contact with hard cortical bone at 3 points: proximally at the posterior aspect of the femur, anteriorly in the midsection of the stem, and posteriorly above the polished distal tip of the stem.

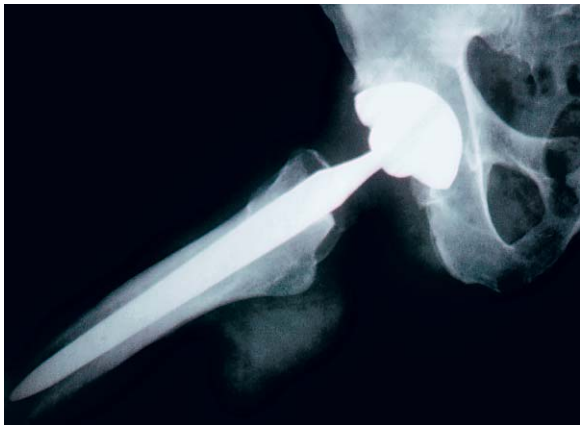


Figure 1
Postoperative lateral radiograph of a porous-coated SYNERGY stem showing 3-point fixation

To determine if a patient has a leg length discrepancy, the anteroposterior 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. This technique is shown in Figure 2.

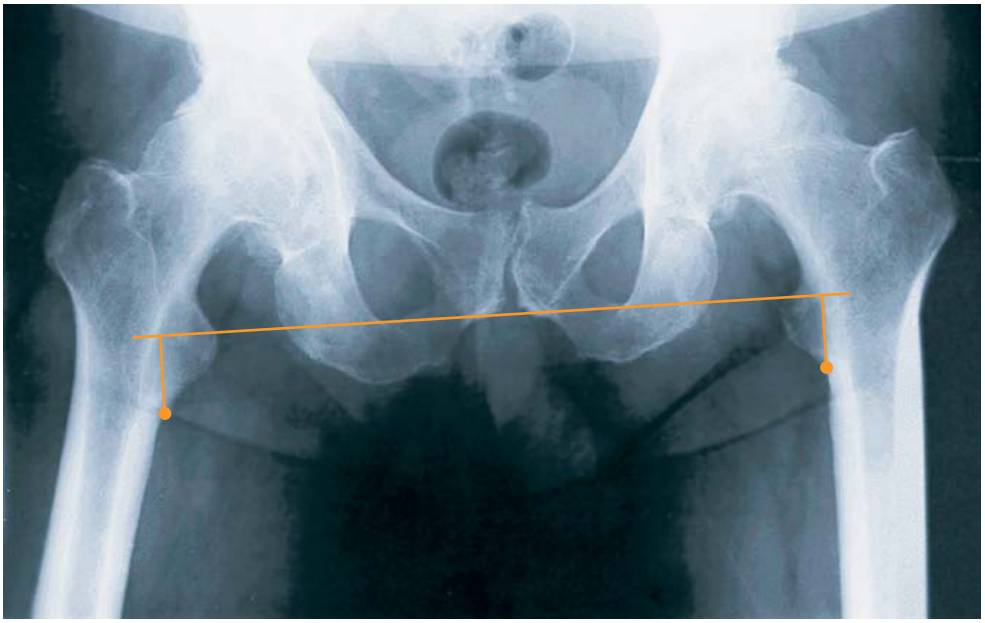


Figure 2
Anteroposterior radiograph demonstrating leg length inequality

Preoperative Planning

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

Intraoperatively, leg length restoration can be verified by measuring the distance between a pin in the iliac wing and a mark on the greater trochanter before hip dislocation. This measurement should be recorded. It is compared later in surgery to a measurement using the same reference points after the implant trials are in place.

Another method of leg measurement consists of the surgeon placing the foot of the affected limb on top of the unaffected limb. The relative position of one knee to another is then analyzed. This second method is slightly less accurate than the previously mentioned technique; however, both methods provide a reasonable degree of accuracy in restoring limb length equality.

When determining which size SYNERGY stem to use, the anteroposterior and the lateral radiographs should be templated. 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. This is demonstrated in Figure 3.

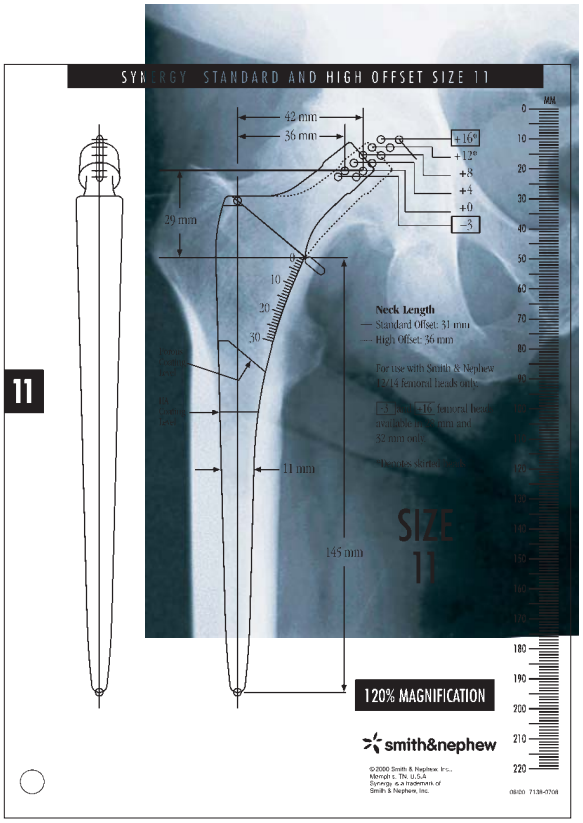


Figure 3
Anteroposterior radiograph demonstrating proper templating of a femur

It is important to check that the stem fits properly into the femur on the lateral radiograph. As stated earlier, it is the lateral radiograph that shows best where 3-point fixation will occur.

A properly implanted porous-coated SYNERGY stem that provides both normal leg length and offset is shown in Figure 4.

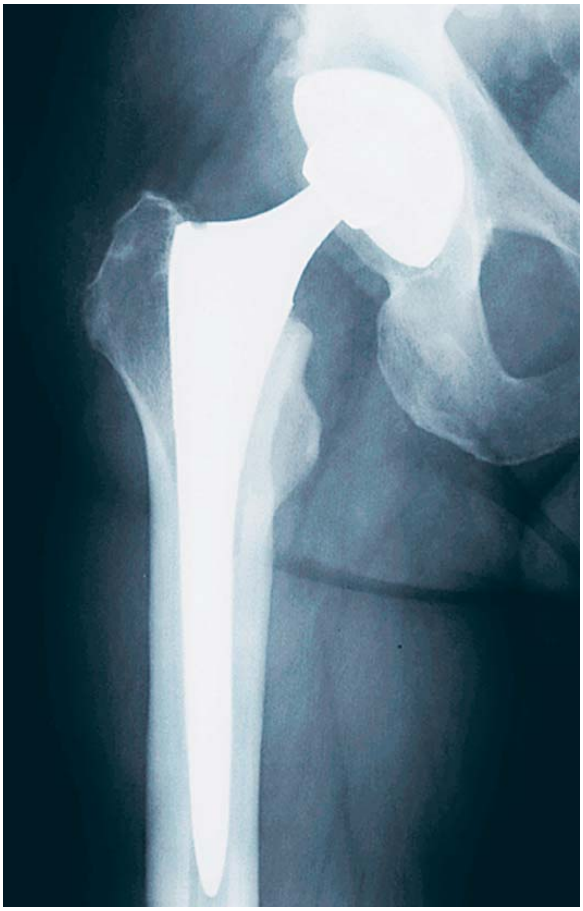


Figure 4
Anteroposterior radiograph of a properly implanted porous-coated SYNERGY stem

Stem Specifications

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

Stem Size	Neck Angle	Conical Cross Section	Stem Length	A-P* Width	M-L* Width
8**	131°	8mm	120mm	12mm	27mm
9	131°	9mm	135mm	13mm	28mm
10	131°	10mm	140mm	14mm	29mm
11	131°	11mm	145mm	15mm	30mm
12	131°	12mm	150mm	16mm	31mm
13	131°	13mm	155mm	17mm	32mm
14	131°	14mm	160mm	18mm	33mm
15	131°	15mm	165mm	19mm	34mm
16	131°	16mm	170mm	21mm	35mm
17	131°	17mm	175mm	22mm	36mm
18	131°	18mm	180mm	23mm	38mm
19**	131°	20mm	185mm	24mm	39mm
20**	131°	21mm	190mm	25mm	40mm

Neck Height mm When Femoral Head Component Selected Is:						
Size	-3	+0	+4	+8	+12	+16
8**	25	27	29	32	35	37
9	26	28	30	33	35	38
10	26	28	31	33	36	39
11	27	29	32	34	37	39
12	28	30	32	35	37	40
13	28	30	33	35	38	41
14	29	31	33	36	39	41
15	30	32	34	37	39	42
16	30	32	35	37	40	43
17	31	33	35	38	41	43
18	32	33	36	39	41	44
19**	32	34	37	39	42	44
20**	33	35	37	40	43	45

Neck Offset mm When Femoral Head Component Selected Is:						
Size	-3	+0	+4	+8	+12	+16
8**	31	34	37	40	43	46
9	32	34	37	40	43	46
9 HO	38	40	43	46	49	52
10	33	35	38	41	44	47
10 HO	39	41	44	47	50	53
11	34	36	39	42	45	48
11 HO	40	42	45	48	51	54
12	34	37	40	43	46	49
12 HO	40	43	46	49	52	55
13	35	37	40	43	46	49
13 HO	41	43	46	49	52	55
14	36	38	41	44	47	50
14 HO	44	46	49	52	55	58
15	37	39	42	45	48	51
15 HO	45	47	50	53	56	59
16	37	40	43	46	49	52
16 HO	45	48	51	54	57	60
17	38	40	43	46	49	52
17 HO	46	48	51	54	57	60
18	39	41	44	47	50	53
18 HO	47	49	52	55	58	61
19**	40	42	45	48	51	54
20**	40	43	46	49	52	55

Neck Length mm When Femoral Head Component Selected Is:						
Size	-3	+0	+4	+8	+12	+16
8**	26	29	33	37	41	45
9	27	30	34	38	42	46
9 HO	31	34	38	42	46	50
10	28	30	34	38	42	46
10 HO	32	35	39	43	47	51
11	28	31	35	39	43	47
11 HO	33	36	40	44	48	52
12	29	32	36	40	44	48
12 HO	33	36	40	44	48	52
13	30	32	36	40	44	48
13 HO	34	37	41	45	49	53
14	30	33	37	41	45	49
14 HO	36	39	43	47	51	55
15	31	34	38	42	46	50
15 HO	37	40	44	48	52	56
16	31	34	38	42	46	50
16 HO	37	40	44	48	52	56
17	32	35	39	43	47	51
17 HO	38	41	45	49	53	52
18	33	36	40	44	48	57
18 HO	38	41	45	49	53	57
19**	33	36	40	44	48	52
20**	34	37	41	45	49	53

* This measurement is for the HA stems. The porous-coated stems have 0.5mm additional thickness

** These stem sizes are only available in the porous-coated version and by special request

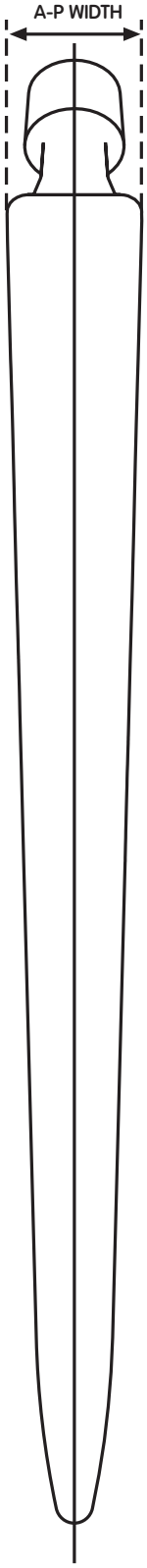
Not Actual Size

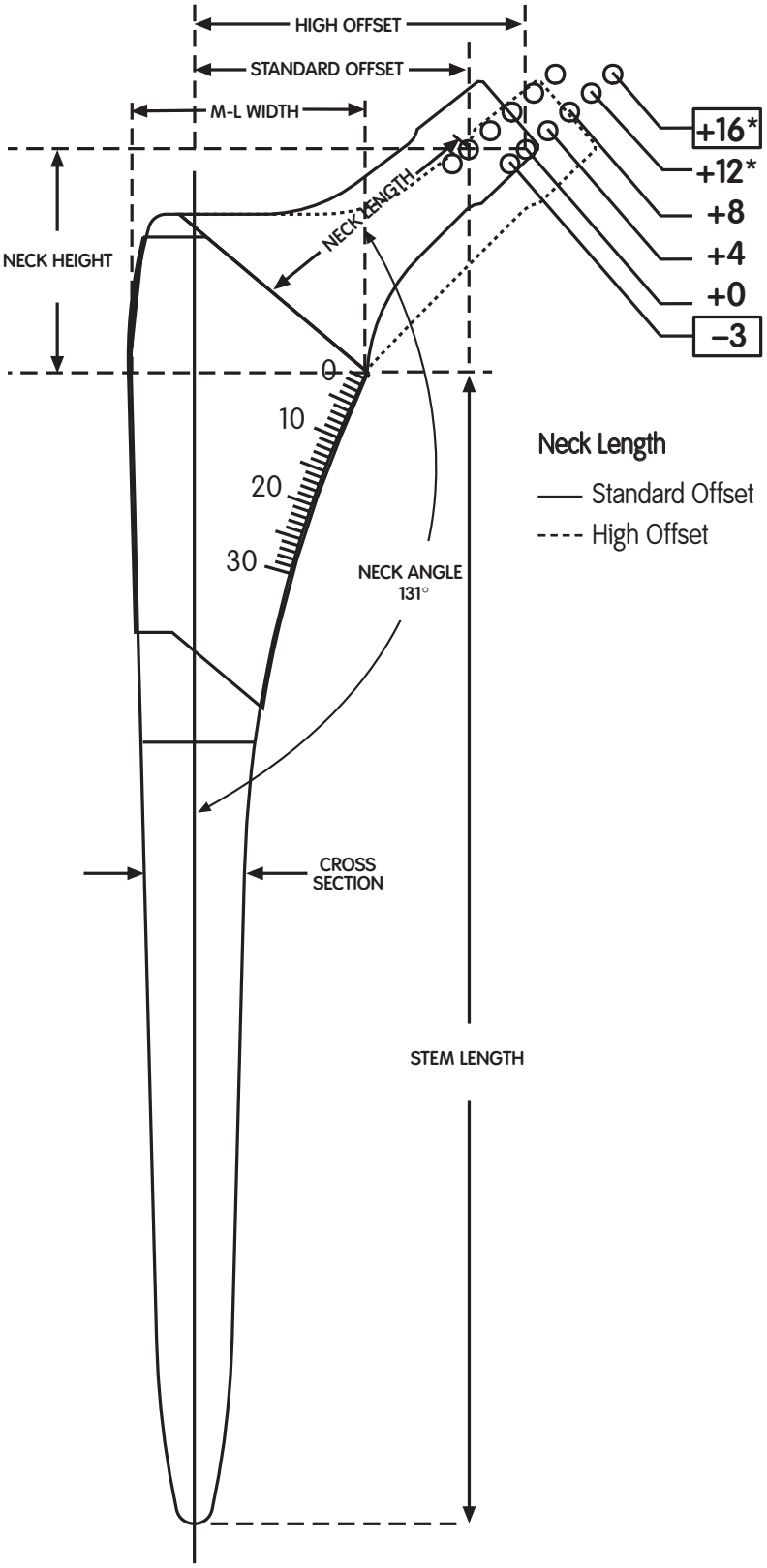
For use with Smith & Nephew 12/14 femoral heads only.

-3 femoral heads available in 28, 32 and 36mm only.

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

* Denotes skirted heads (except 36mm)

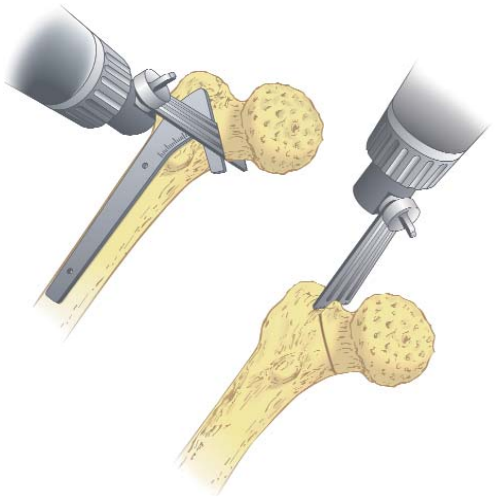




NOTE: For illustration purposes only. Surgical templates are available by contacting your Smith & Nephew representative or Customer Service.

Short Technique

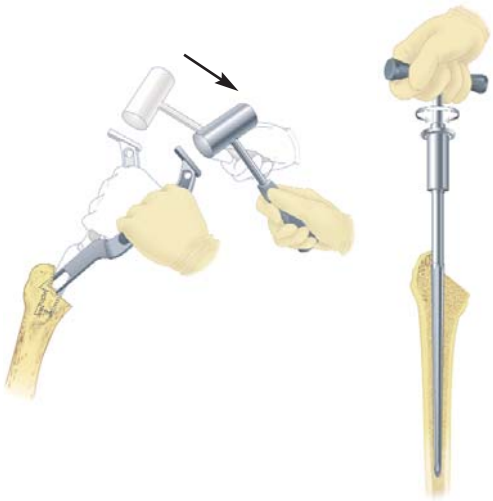
1. Femoral Osteotomy



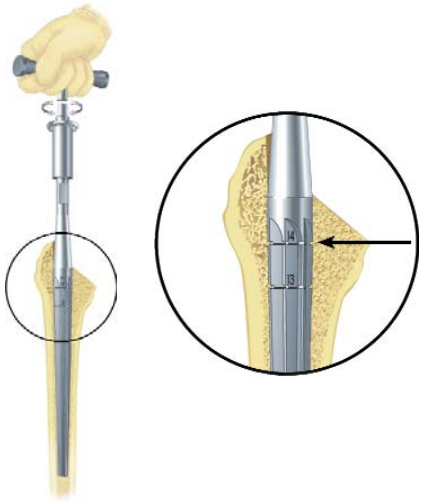
2. Acetabular Preparation

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

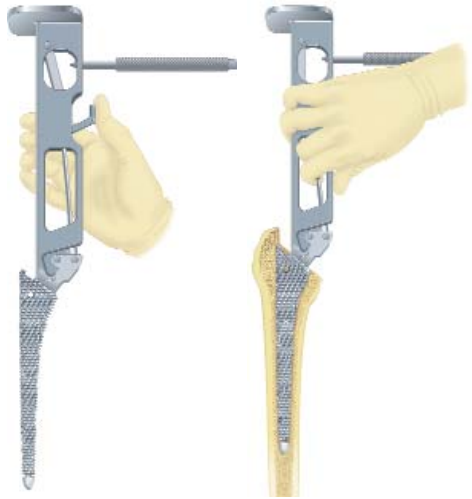
3. Canal Preparation



4. Femoral Reaming

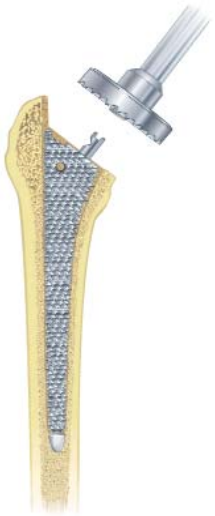


5. Broach Assembly/Disassembly

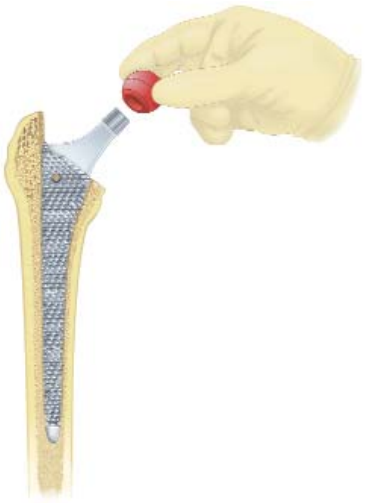


6. Femoral Broaching

7. Calcar Preparation (optional)



8. Trialing

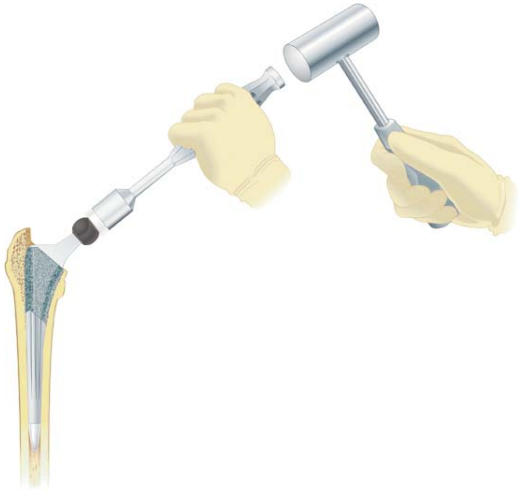


9. Stem/Impactor Assembly

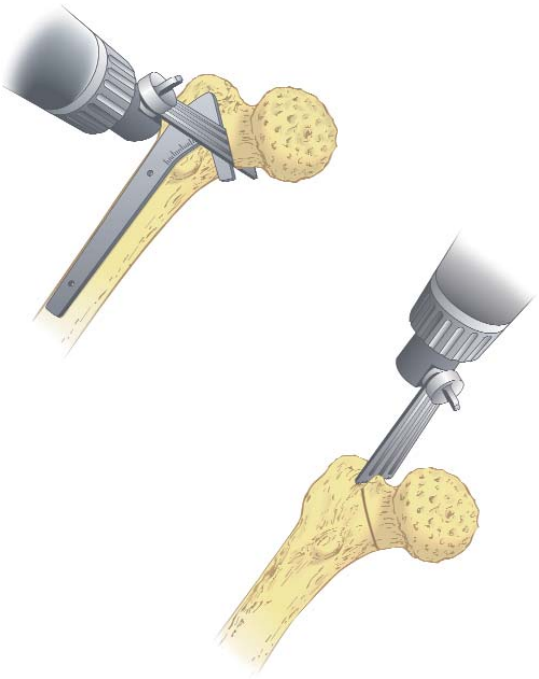
10. Stem Insertion

11. Final Trial Reduction

12. Femoral Head Assembly

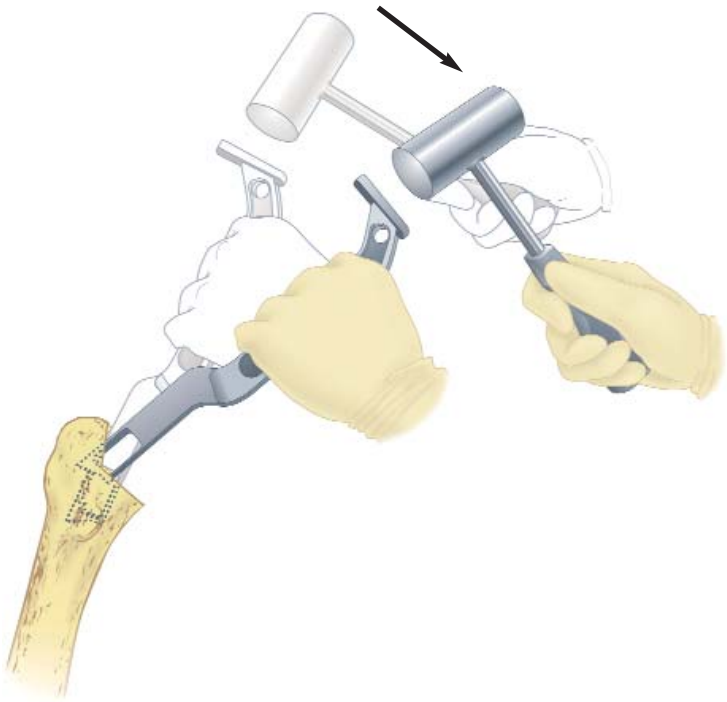


Surgical Technique



Femoral Osteotomy
The point of the femoral neck resection should be marked with electrocautery corresponding to both the preoperative templating and the intraoperative measurement. Prior to the resection of the femoral head, assemble the broach, trial neck and trial femoral head corresponding to the implant that was templated. Place this trial stem on the femur to verify that the center of the prosthetic head aligns with the center of the femoral head. This will confirm that the level of the femoral neck resection is appropriate and will re-establish the desired leg length and offset of the proximal femur. Osteotomize the femoral neck.

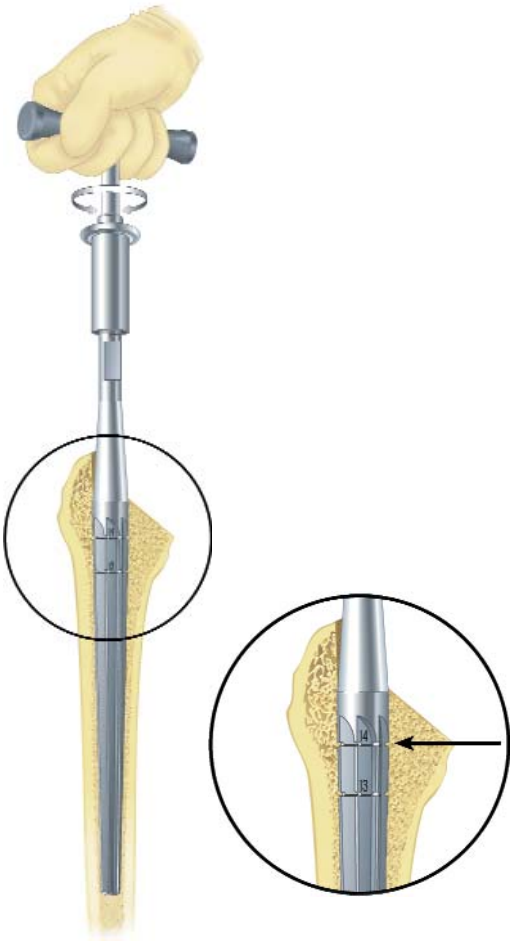
Prepare Acetabulum
If acetabular reconstruction is required, prepare the acetabulum using the surgical technique for the intended acetabular component.



Open Femoral Canal
Remove remnants of the femoral neck and open the medullary canal using the box osteotome.

Femoral Canal Preparation
Use the canal finder and modular T-handle for initial femoral reaming.

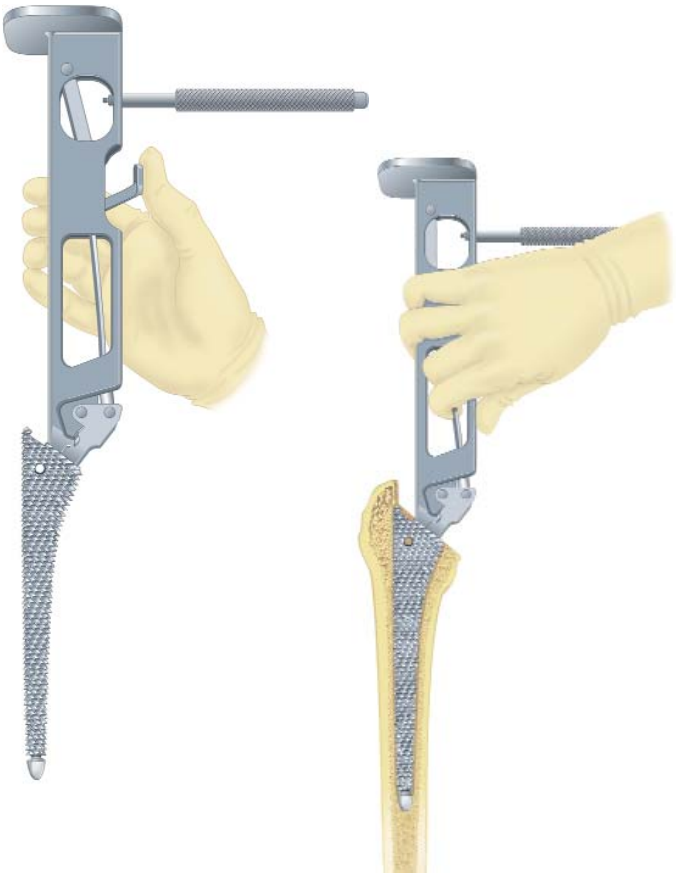
NOTE: It is important to stay lateral with both the box osteotome and canal finder. Care should be taken to ensure that the initial reaming tract into the femur is in neutral alignment with the femoral axis.



Femoral Reaming
Continue to enlarge the femoral canal sequentially using the femoral reamers. Each reamer is marked with 2 or 3 lines. Stop reaming when the mark on the reamer associated with the templated stem size is even with the medial femoral neck resection or endosteal bone resistance is encountered. If reaming becomes difficult before reaching the templated stem size, consider using a stem size smaller than the templated stem size.

NOTE: It is important to stay lateral with the femoral reamers to ensure that the canal is being opened in neutral alignment with the femoral axis.

OPTIONAL: If utilizing fully toothed broaches, a broach-only technique can be performed.

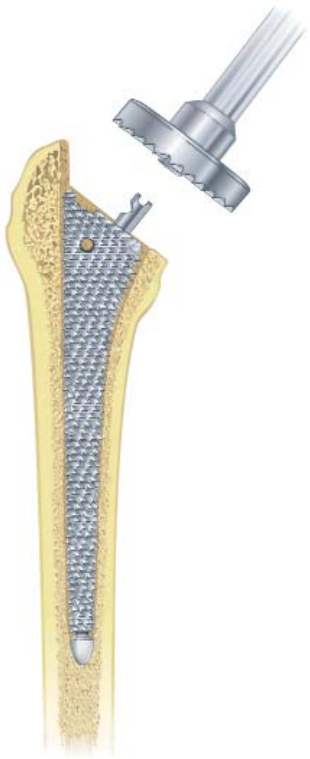


Broach Assembly/Disassembly
Assemble the broach to the broach handle by placing the broach post in the clamp. Use the thumb to lock the clamp onto the broach. A modular anteversion handle can be assembled to the broach handle to provide version control.

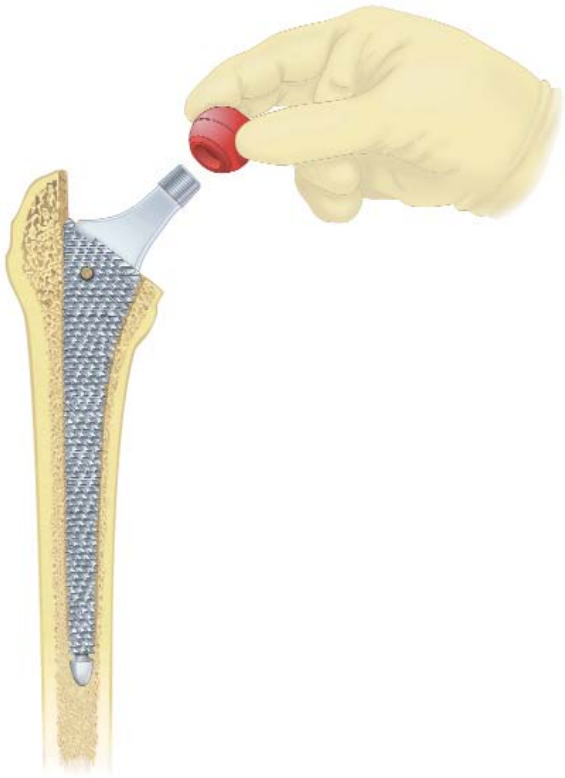
Disassemble the broach from the broach handle by placing 2 fingers (index and middle) in the rectangular slot. Apply pressure to the release bar by squeezing the 2 fingers toward the thumb resting on the medial side of the broach handle frame.

Femoral Broaching
Start the broaching procedure along the axis of the femur with a broach at least 2 sizes smaller than the last reamer used. Sequential broaching should then be carried out to the templated stem size. Stop broaching when the top of the last broach is slightly below the level of the resected femoral neck to facilitate calcar reaming.

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. 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 for optimal implant collar/femoral neck contact.

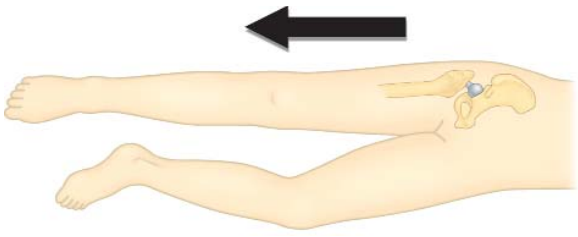


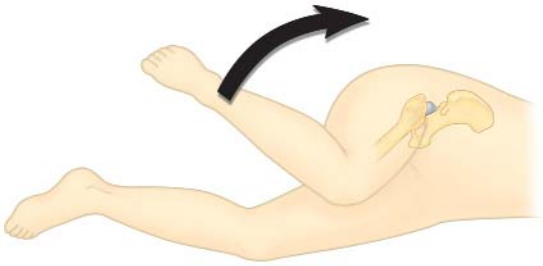
Trial Reduction
Place the standard or high offset trial neck (as determined by templating) onto the broach post. Select the trial femoral head of desired diameter and neck length. Measure the distance between the mark at the lesser trochanter and the center of the trial femoral head. This number should correspond to the preoperative and intraoperative measurements. Adjustments in neck length and/or offset can be made at this time.

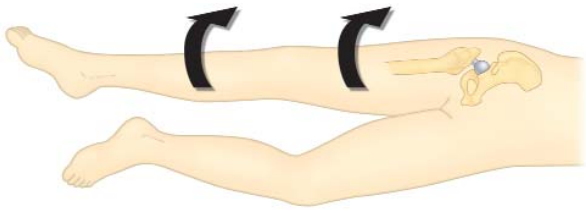
If trialing for a unipolar or bipolar, trial according to the appropriate technique for the selected device.

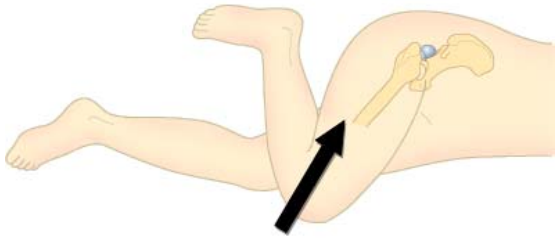
Femoral Head and Neck Length Options					
Trial Color	22mm	26mm	28mm	32mm	36mm
Green	—	—	-3	-3	-3
Yellow	+0	+0	+0	+0	+0
Red	+4	+4	+4	+4	+4
White	+8	+8	+8	+8	+8
Blue	+12*	+12*	+12*	+12*	+12
Black	—	—	+16*	+16*	—

* Denotes skirted heads









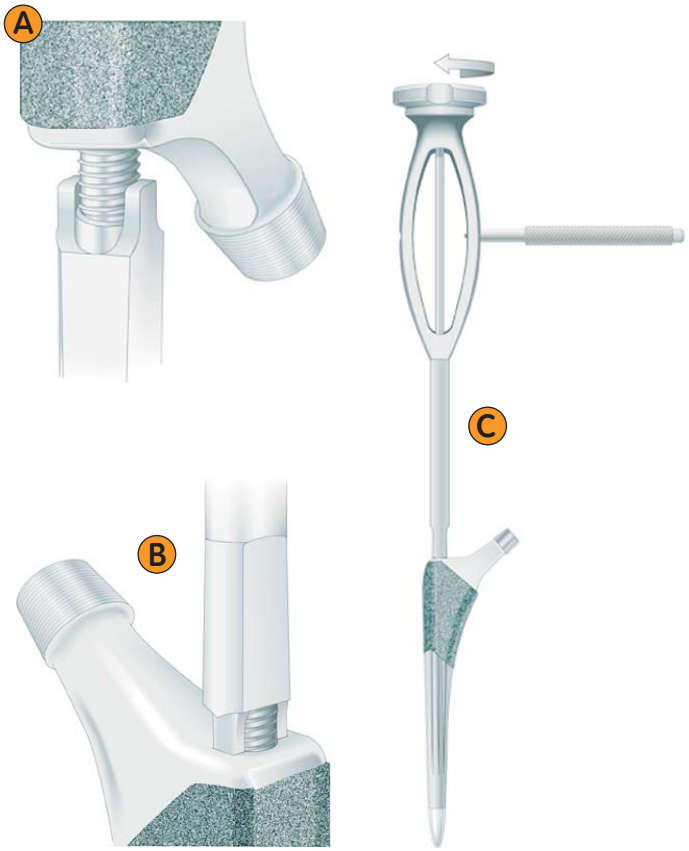
Trial Reduction
Reduce the hip and evaluate in the following ways:

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.

Anterior stability
Place the leg in full adduction, full extension 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 neutral adduction and 90° flexion. Gradually rotate internally. 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 nonoperated side.



Stem/Impactor Assembly
Place the stem inserter pommel through the stem inserter frame and stand upright so that the threaded tip is pointed up (A). Screw the implant onto the threaded tip as far as possible.

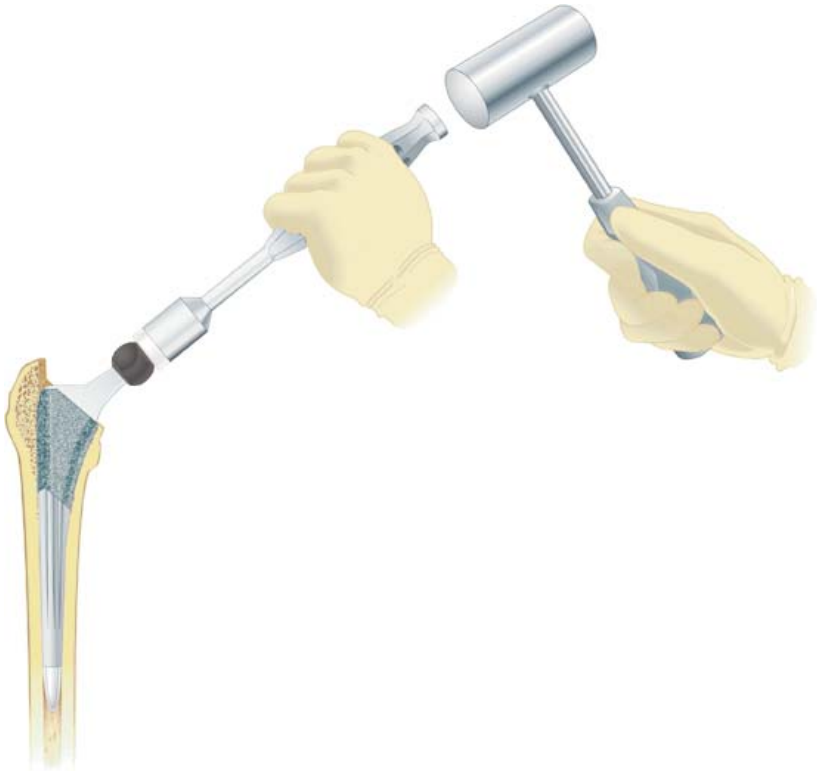
Flip the assembly over so that the stem tip is now pointing down (B). Engage the frame tines into the slots adjacent to the threaded hole on the stem. Screw the pommel until assembly is secure (C).

Stem Insertion
Insert the selected femoral stem into the canal. 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 reaming and broaching steps.

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

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

SYNERGY Porous-Coated Stem
Titanium 6Al-4V

Size	Length	Standard Cat. No.	High Offset Cat. No.
8*	120mm	7130-6608	—
9	135mm	7130-6609	7130-6109
10	140mm	7130-6610	7130-6110
11	145mm	7130-6611	7130-6111
12	150mm	7130-6612	7130-6112
13	155mm	7130-6613	7130-6113
14	160mm	7130-6614	7130-6114
15	165mm	7130-6615	7130-6115
16	170mm	7130-6616	7130-6116
17	175mm	7130-6617	7130-6117
18	180mm	7130-6618	7130-6118
19*	185mm	7192-6107	—
20*	190mm	7192-6108	—

* Available by special request

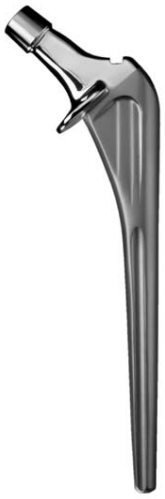
SYNERGY HA-Coated Stem
Titanium 6Al-4V

Size	Length	Standard Cat. No.	High Offset Cat. No.
9	135mm	7130-6709	7130-6409
10	140mm	7130-6710	7130-6410
11	145mm	7130-6711	7130-6411
12	150mm	7130-6712	7130-6412
13	155mm	7130-6713	7130-6413
14	160mm	7130-6714	7130-6414
15	165mm	7130-6715	7130-6415
16	170mm	7130-6716	7130-6416
17	175mm	7130-6717	7130-6417
18	180mm	7130-6718	7130-6418

Catalog

SYNERGY Porous Plus HA Stem

Size	Length	Standard Cat. No.	High Offset Cat. No.
9	135mm	7130-9009	7130-9109
10	140mm	7130-9010	7130-9110
11	145mm	7130-9011	7130-9111
12	150mm	7130-9012	7130-9112
13	155mm	7130-9013	7130-9113
14	160mm	7130-9014	7130-9114
15	165mm	7130-9015	7130-9115
16	170mm	7130-9016	7130-9116
17	175mm	7130-9017	7130-9117
18	180mm	7130-9018	7130-9118



SYNERGY Cemented Stem
Forged CoCr

Size	Length	Standard Cat. No.	High Offset Cat. No.
9	110mm	7131-6009	7131-6209
10	115mm	7131-6010	7131-6210
11	120mm	7131-6011	7131-6211
12	125mm	7131-6012	7131-6212
13	130mm	7131-6013	7131-6213
14	135mm	7131-6014	7131-6214
15	140mm	7131-6015	7131-6215
16	140mm	7131-6016	7131-6216
17	140mm	7131-6017	7131-6217

CONQUEST FX° Stem
CoCr

Size	Length	Standard Cat. No.
9	125mm	7131-6509
10	130mm	7131-6510
11	135mm	7131-6511
12	140mm	7131-6512
13	145mm	7131-6513
14	150mm	7131-6514
15	150mm	7131-6515
16	150mm	7131-6516
17	150mm	7131-6517
18	150mm	7131-6518

SYNERGY Ti-Press Fit Stem
Titanium

Size	Standard Cat. No.
9	7130-6809
10	7130-6810
11	7130-6811
12	7130-6812
13	7130-6813
14	7130-6814
15	7130-6815
16	7130-6816
17	7130-6817
18	7130-6818

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	—

CoCr Femoral Heads 12/14 Taper

Cobalt Chromium – ASTM F 799

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

Catalog

Femoral Instrumentation Tray No. 1

Cat. No. 7136-6201

Osteotomy Guide

Cat. No. 7136-4000

Box Osteotome

Size	Cat. No.
Small	7136-4002
Large	7136-4003

Canal Finder

Cat. No. 7136-4001

T-Handle

Cat. No. 7136-4006

Tapered Reamer

Size	Cat. No.
8-9-10	7136-6209
11-12	7136-6211
13-14	7136-6213
15-16	7136-6215
17-18	7136-6217

Broach Handle

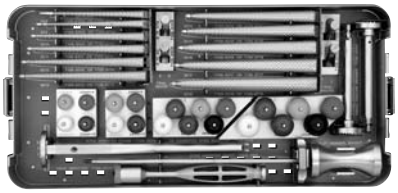
(2 Per Set)

Cat. No. 7136-4007

Anteversion Handle

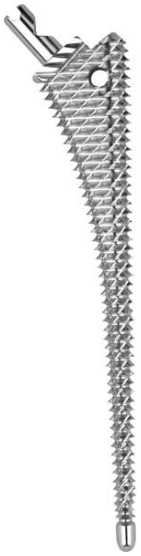
Cat. No. 7136-4012

Catalog



Femoral Instrumentation Tray No. 2

Cat. No. 7136-6203



Fully Toothed Broach

Size	Cat. No.
8	7136-6708
9	7136-6709
10	7136-6710
11	7136-6711
12	7136-6712
13	7136-6713
14	7136-6714
15	7136-6715
16	7136-6716
17	7136-6717
18	7136-6718

Stem Inserter Frame

Cat. No. 7136-4008

Stem Inserter Pommel

Cat. No. 7136-4011

Trial Neck

Size	Standard Cat. No.	High Offset Cat. No.
8-13	7136-6408	7136-6508
14-18	7136-6414	7136-6514

Calcar Reamer

Size	Cat. No.
Small	7136-4004
Large	7136-4005

Catalog

Femoral Head Impactor
Cat. No. 7136-4009

Slap Hammer Weight
Cat. No. 7136-4010

Trial Femoral Head 12/14 Taper

Neck Length	Color Code	22mm Optional	26mm Optional	28mm	32mm Optional	36mm Optional
-3	Green	——	——	7135-2803	7135-3203	7134-3603
+0	Yellow	7135-2200	7135-2600	7135-2800	7135-3200	7134-3600
+4	Red	7135-2204	7135-2604	7135-2804	7135-3204	7134-3604
+8	White	7135-2208	7135-2608	7135-2808	7135-3208	7134-3608
+12	Blue	7135-2212	7135-2612	7135-2812	7135-3212	7134-3612
+16	Black	——	——	7135-2816	7135-3216	——

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 U.S.A.

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 U.S.A.

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 U.S.A.

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: The BHR prosthesis is not available in the U.S.A.

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 acetabular component the yttria stabilized zirconia ball produces a relatively low amount of particulates, the total amount of particulate remains undetermined. Because of the limited clinical and preclinical experience, the biological effect of these particulates can not be predicted.
10. Alumina ceramic should never articulate against metal because severe wear could occur.
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°C)	40-80% (70% Target)	10 PSIA (689 millibar)	725 mg/l	60-180 minutes

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

Ceramic Components

Do not resterilize ceramic femoral heads or liners.

INFORMATION

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

Manufacturing facilities and EC representative:

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Alemannenstrasse 14
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Tel.: 07462/208-0
Fax: 07462/208-135

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

H_2O_2 – hydrogen peroxide sterilization

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