

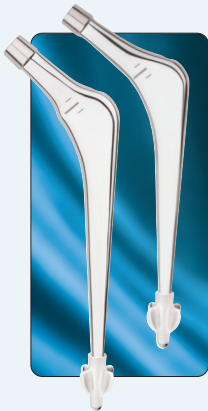


SMITH & NEPHEW

COLLARLESS POLISHED CEMENTED STEM

CPCS

SURGICAL TECHNIQUE



COLLARLESS POLISHED CEMENTED STEM

CPCCS

SURGICAL TECHNIQUE

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

STEM SPECIFICATIONS

SPECIFICATIONS					
Size	Neck Angle	Discal Cross Section	Stem Length	A-P Width	H-L Width
0, 0H	33°/12°	4.5 mm	120 mm	11 mm	26 mm
1, 1H	33°/12°	4.5 mm	135 mm	12 mm	26 mm
2, 2H	33°/12°	4.5 mm	155 mm	13 mm	28 mm
3, 3H	33°/12°	4.5 mm	155 mm	15 mm	30 mm
4, 4H	33°/12°	4.5 mm	155 mm	16 mm	32 mm
5, 5H	33°/12°	4.5 mm	155 mm	17 mm	34 mm

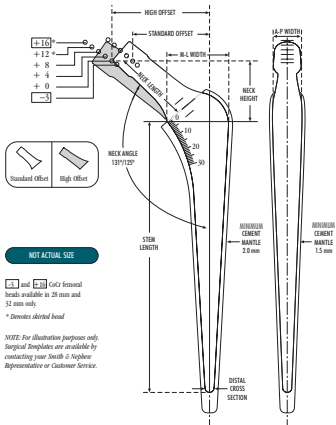
NECK HEIGHT MM						
	When Femoral Head Component Selected Is:					
Size	-3	+0	+4	+8	+12	+16
0	25	25	27	30	33	35
0H	25	25	27	30	32	34
1	24	26	28	31	34	36
1H	24	26	28	31	33	35
2	26	28	30	33	36	38
2H	26	28	30	33	35	37
3	28	30	32	35	37	40
3H	28	30	32	35	37	39
4	30	32	34	37	39	42
4H	30	32	34	36	39	41
5	32	34	36	39	41	44
5H	32	34	36	39	41	43

NECK OFFSET MM						
	When Femoral Head Component Selected Is:					
Size	-3	+0	+4	+8	+12	+16
0	51	53	56	59	62	65
0H	55	57	60	64	67	70
1	52	55	58	61	64	67
1H	59	61	64	68	71	74
2	54	56	59	62	65	68
2H	62	64	67	71	74	77
3	55	58	61	64	67	70
3H	66	68	71	75	78	81
4	57	59	62	65	68	71
4H	66	69	72	76	79	82
5	58	61	64	67	70	73
5H	69	71	74	78	81	84

NECK LENGTH MM						
	When Femoral Head Component Selected Is:					
Size	-3	+0	+4	+8	+12	+16
0	25	28	32	36	40	44
0H	29	32	36	40	44	48
1	27	30	34	38	42	46
1H	32	35	39	43	47	51
2	29	32	36	40	44	48
2H	35	38	41	45	49	53
3	31	34	38	42	46	50
3H	39	42	46	50	54	58
4	35	36	40	44	48	52
4H	41	44	48	52	56	60
5	35	38	42	46	50	54
5H	45	46	50	54	58	62

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

STEM SPECIFICATIONS



NOT ACTUAL SIZE

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

* Denotes skirted head

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

1. Femoral Osteotomy

The level of neck resection should be based on preoperative templating.

Place the template over the X-ray of the hip. After determining the appropriate size stem, determine the level of femoral neck resection based on the lesser trochanter as a landmark.

A graduation scale can be found on the medial aspect of the stem on the template. This scale corresponds to the marks on the osteotomy guide. Make note of how many graduations above the lesser trochanter the osteotomy will take place, as determined by the middle depth mark on the medial aspect of the stem (also identified as the zero mark on the graduation scale).

In the O.R., place the osteotomy guide on the femur by referencing the lesser trochanter at the same graduation mark as noted during templating. Osteotomize the neck (*Figures 1 and 2*).

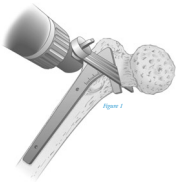


Figure 1

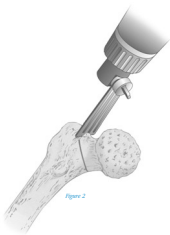


Figure 2

2. Prepare Acetabulum

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

3. Femoral Canal Preparation

Open the medullary canal at the transected neck using the box chisel. Stay posterior and lateral in order to obtain a neutral stem position (Figure 3). Identify and open the femoral canal using the blunt medullary reamer (Figure 4).

The trochanteric reamer is available to help assure a lateral start point and open the metaphysis (Figure 5).

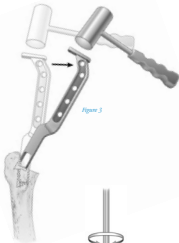


Figure 3



Figure 4



Figure 5

"I frequently use the trochanteric reamer to prevent residual bone in the area of the greater trochanter, and avoid a varus position of the stem."

Knutz Buchler

4. Femoral Broaching

Assemble the broach to the broach handle by placing the broach post in the clamp. Use the thumb to lock the clamp onto the broach. A modular anteversion handle can be assembled to the broach handle to provide version control (Figure 6).

Start the broaching procedure along the mid-axis of the femur with the starter broach and progressively broach to the appropriate femoral stem size. Seat the final broach slightly below the level of the femoral neck resection to facilitate calcar reaming if desired (Figure 7).

The CPCS broach is designed to provide a minimum 2.0 mm cement mantle per side, medially and laterally, and 1.5 mm per side, anteriorly and posteriorly. Additional cement mantle thickness is achieved by pressurizing the cement into the cancellous bone.

The broach is 10 mm longer than the corresponding implant to accommodate the distal centralizer.

Disassemble the broach from the broach handle by placing two fingers (index and middle) in the rectangular slot. Apply pressure to the release bar by squeezing two fingers toward the thumb resting on the medial side of the broach handle (Figure 8).

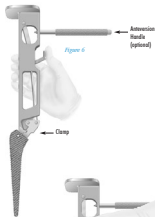


Figure 6

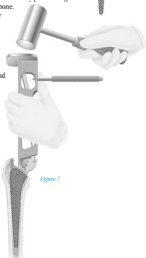


Figure 7



Figure 8

5. Calcar Preparation (optional)

If the femoral neck rejection is asymmetric, with the broach fully seated, remove the broach handle and ream the calcar.

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



6. Trialing

Remove the calcar reamer and place the matching standard or high offset trial neck (as determined by templating) onto the broach post. Select the trial femoral head of desired diameter and length. Reduce the hip to assess stability and to restore leg length. In some cases soft tissue tension may be improved by using the high offset trial neck instead of the standard offset trial neck.

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



Femoral Head And Neck Length Options				
Trial Color	22 mm	26 mm	28 mm	32 mm
Green	—	—	-5	-5
Yellow	+0	+0	+0	+0
Red	+4	+4	+4	+4
White	+8	+8	+8	+8
Blue	+12*	+12*	+12*	+12*
Black	—	—	+16*	+16*

*Denotes offset heads.

7. Selecting Stem & Distal Centralizer

The CPCS hip system was designed to allow the last broach seated in the femur to dictate the size implant to be used.

A distal centralizer, ensures neutral stem alignment, and, if necessary, allows for slight subsidence of the stem by preventing the stem from becoming end-bearing in the cement. Neutral stem alignment provides a minimum 2.0 mm cement mantle per side, medially and laterally and 1.5 mm cement mantle per side, anteriorly and posteriorly. Additional cement mantle thickness can be achieved by cement pressurization and the ensuing cement interdigitation.

Centralizers in 2 mm increments are available in sizes 8-18 mm. Any size centralizer fits on any size stem. To determine the appropriate size centralizer, use the femoral canal sounds.

Using clean gloves, place the distal centralizer over the distal tip of the stem by carefully pushing the centralizer superiorly until snug.



8. Placing The BUCK Cement Restrictor

Attach the broach handle to the broach and remove the broach from the femoral canal.

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

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

Size	Depth
0	140 mm
1	160 mm
2	160 mm
3	160 mm
4	160 mm
5	160 mm



9. Preparing The Femoral Canal

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



10. Drying The Femoral Canal

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

11. Loading Cement

Load cement powder and monomer in Vortex®



12. Mixing

Mix the cement according to manufacturer's instructions. Turn handle clockwise to achieve optimal homogenous mixture.



13. Injecting Cement

Remove the femoral canal suction absorber and use pulsatile lavage and dry. The cement should be introduced promptly to minimize bleeding into the canal. Insert the nozzle of the cement gun to the top of the Buck cement restrictor and inject cement into the canal in retrograde fashion. Continue injecting cement until the canal is completely full and the distal tip of the nozzle is clear of the canal.



14. Pressurizing Cement

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



15. Stem Insertion

Attach the CPCS stem driver handle to the stem driver. The handle can be attached in two positions, horizontal or vertical depending on surgeon preference (Figure 9). A button must be pushed at the end of the handle to either engage or disengage the handle.

Insert the selected femoral stem into the canal by fitting the tip of the locking stem driver into the stem driving platform (Figure 10). The circular disc on the stem driver must be pulled superiorly to engage the tip of the stem driver to the stem driving platform.

While pushing the stem into the canal, place the thumb medial to the stem in order to pressurize the cement and ensure correct alignment (Figure 11). Advance the stem approximately 1cm per second to avoid air inclusions in the stem/cement interface. The stem should be inserted to the appropriate medial depth mark as determined during trial reduction and templating.

Trim away excess cement with Concise™ cement sculps. Carefully remove the stem driver by pulling the circular disc on the stem driver superiorly. Maintain steady pressure with the thumb on the neck taper until the cement is cured.

"During stem insertion and cement pressurization I try to keep blood from mixing with the cement by use of suction and a sponge."

Knutz Buehler



Figure 9



Figure 10

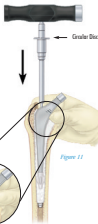


Figure 11

16. Shroud (optional)

The shroud assists in achieving correct leg length and anteversion upon implantation, based on the notes made at templating. The shroud also aids in pressurizing the cement and promotes neutral alignment of the stem in the canal.

By simulating a collar, the shroud helps determine where to stop the insertion of the stem in the canal.

Each stem size has a corresponding shroud.



17. Stem Insertion Using The Shroud

Advance the stem approximately 1 cm per second to avoid air inclusions in the stem/cement interface. Push the stem into the canal until the shroud is resting on the medial calcar (*Figure 12*).

Trim away excess cement with Concise[®] cement sculps. Carefully remove the stem driver by pulling the circular disc on the stem driver superiorly. Maintain steady pressure with the thumb on the neck taper until the cement is cured.

After the cement is fully polymerized remove the shroud from the stem. Careful attention must be paid to cement that may have attached to the shroud. Make sure any cement is cleared away from the shroud before it is removed.

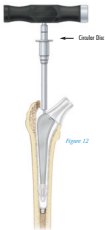


Figure 12

18. Final Trial Reduction

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



19. Femoral Head Assembly

Clean and dry the neck taper with a clean cloth. Place the prosthetic femoral head on the neck taper and firmly impact with a head impactor and a mallet.

NOTE: Care should be taken not to use Cobalt-Chromium heads on stainless steel stems. To distinguish the material, the stainless steel femoral heads have a notch at their taper opening, while the stainless steel stems have a notch in the middle of the taper.



CPCS FEMORAL STEM & HEAD COMPONENTS


CPCS
Primary Standard Offset Stems

Forged Cobalt Chromium – ASTM F 759

Size	Stem Length	Implant Cat. No.	Breach/Trial Cat. No.	Trial Neck Cat. No.
0	120 mm	7131-2340	7136-3400	7136-5110
1	135 mm	7131-2341	7136-3401	7136-5111
2	135 mm	7131-2342	7136-3402	7136-5112
3	135 mm	7131-2343	7136-3403	7136-5113
4	135 mm	7131-2344	7136-3404	7136-5114
5	135 mm	7131-2345	7136-3405	7136-5115


CPCS
Primary Standard Offset Stems

Stainless Steel

Size	Stem Length	Implant Cat. No.	Breach/Trial Cat. No.	Trial Neck Cat. No.
0	120 mm	7131-2380	7136-3400	7136-5110
1	135 mm	7131-2381	7136-3401	7136-5111
2	135 mm	7131-2382	7136-3402	7136-5112
3	135 mm	7131-2383	7136-3403	7136-5113
4	135 mm	7131-2384	7136-3404	7136-5114
5	135 mm	7131-2385	7136-3405	7136-5115


CPCS
Primary High Offset Stems

Forged Cobalt Chromium – ASTM F 759

Size	Stem Length	Implant Cat. No.	Breach/Trial Cat. No.	Trial Neck Cat. No.
0H	120 mm	7131-2370	7136-3400	7136-2600
1H	135 mm	7131-2371	7136-3401	7136-2601
2H	135 mm	7131-2372	7136-3402	7136-2602
3H	135 mm	7131-2373	7136-3403	7136-2603
4H	135 mm	7131-2374	7136-3404	7136-2604
5H	135 mm	7131-2375	7136-3405	7136-2605


CPCS
Primary High Offset Stems

Stainless Steel

Size	Stem Length	Implant Cat. No.	Breach/Trial Cat. No.	Trial Neck Cat. No.
0H	120 mm	7131-2390	7136-3400	7136-2600
1H	135 mm	7131-2391	7136-3401	7136-2601
2H	135 mm	7131-2392	7136-3402	7136-2602
3H	135 mm	7131-2393	7136-3403	7136-2603
4H	135 mm	7131-2394	7136-3404	7136-2604
5H	135 mm	7131-2395	7136-3405	7136-2605

CPCS FEMORAL STEM & HEAD COMPONENTS


**Zirconia 12/14 Taper
Femoral Heads**

Neck Length	22 mm	26 mm	28 mm
+0	—	7152-0820	7152-0828
+4	7152-0422	7152-0426	7152-0428
+8	7152-0822	7152-0826	7152-0828


CPCS Distal Centralizers

Cat. No.	O.D.
7151-2400	0 mm
7151-2408	8 mm
7151-2410	10 mm
7151-2412	12 mm
7151-2414	14 mm
7151-2416	16 mm
7151-2418	18 mm


**CoCr 12/14
Femoral Heads**

Cobalt Chromium – ASTM F 799

Neck Length	22 mm	26 mm
-5	—	—
+0	7130-2200	7130-2600
+4	7130-2204	7130-2604
+8	7130-2208	7130-2608
+12	7130-2212	7130-2612
+16	—	—

Neck Length	28 mm	32 mm
-5	7130-2805	7130-3205
+0	7130-2800	7130-3200
+4	7130-2804	7130-3204
+8	7130-2808	7130-3208
+12	7130-2812	7130-3212
+16	7130-2816	7130-3216

**SST 12/14
Femoral Heads**

Stainless Steel

Neck Length	22 mm	26 mm
-5	—	—
+0	7129-2200	7129-2600
+4	7129-2204	7129-2604
+8	7129-2208	7129-2608
+12	7129-2212	7129-2612
+16	—	—

Neck Length	28 mm	32 mm
-5	7129-2805	7129-3205
+0	7129-2800	7129-3200
+4	7129-2804	7129-3204
+8	7129-2808	7129-3208
+12	7129-2812	7129-3212
+16	7129-2816	7129-3216

CPCS INSTRUMENTATION



CPCS Primary Instrument Tray
Cat. No. 7136-3528

Small Exterior Carrying Case

Not Shown
Cat. No. 7112-9401

Lid for Exterior Carrying Case

Not Shown
Cat. No. 7112-9402

CPCS Primary Shroud Tray

Not Shown
Cat. No. 7136-2711



Osteotomy Guide

Cat. No.	Size
7136-4000	Sizes 1-5



Broach Handle

Cat. No. 7136-4007



Box Chisel

Cat. No.	Size
7136-4002	Small



Anteversion Handle

Cat. No. 7136-4012



Blunt Medullary Reamer

Cat. No. 11-9657



Trochanteric Reamer

Cat. No. 7136-4005



Broaches/Trials

Cat. No.	Size
7136-3399	Starter
7136-3400	0
7136-3401	Size 1
7136-3402	Size 2
7136-3403	Size 3
7136-3404	Size 4
7136-3405	Size 5

CPCS INSTRUMENTATION



Calcar Reamers

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



CPCS Femoral Stem Driver

Cat. No. 7136-2631



Femoral Head Impactor

Cat. No. 7136-4009



CPCS Inserter Handle

Cat. No. 7136-2630



CPCS Trial Necks

Size	Primary Standard Offset		Primary High Offset	
	Cat. No.	Size	Cat. No.	Size
0	7136-2700	0H	7136-2705	
1,2	7136-2701	1H,2H	7136-2704	
3,4,5	7136-2702	3H,4H,5H	7136-2705	

CPCS Shroud

Size	Primary Collared		Primary High Offset	
	Cat. No.	Size	Cat. No.	Size
0	7192-7208	0H	7192-7209	
1	7192-7204	1H	7192-7209	
2	7192-7205	2H	7192-7210	
3	7192-7206	3H	7192-7211	
4	7192-7207	4H	7192-7212	
5	7192-7208	5H	7192-7213	



Trial 12/14 Taper Femoral Heads

Neck Length	Color Code	22 mm	*26 mm	*28 mm	32 mm
-5	Green	—	—	7135-2803	7135-3205
+0	Yellow	7135-2200	7135-2600	7135-2800	7135-3200
+4	Red	7135-2204	7135-2604	7135-2804	7135-3204
+8	White	7135-2208	7135-2608	7135-2808	7135-3208
+12	Blue	7135-2212	7135-2612	7135-2812	7135-3212
+16	Black	—	—	7135-2816	7135-3216

*Space allowed for 28 mm and 32 mm heads in instrument tray

Femoral Sounds

Cat. No.	Size
7136-3508	8-9mm
7136-3510	10-11mm
7136-3512	12-13mm
7136-3514	14-15mm
7136-3516	16-17mm
7136-3518	18-19mm

CEMENT & ACCESSORIES

PREP-IM® Kit

Cat. No. 12-1000

Kit contains the following:

Cat. No.	Description
12-9418	Buck Cement Restrictor, 18.5 mm
12-9419	Buck Cement Restrictor, 25 mm
11-0005	Femoral Canal Brush, 19 mm
11-1000	Concise Cement Sculp Kit
11-0057	Femoral Canal Suction Absorber, 19 mm
—	Disposable Cement Restrictor Tool (available in kit only)



Femoral Pressurizers

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

Buck Femoral
Cement Restrictor
Insertion

Cat. No. 11-2428



Vent Opening Tool

Cat. No. 11-0028



Buck Cement Restrictor

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



Femoral Canal Brush

Cat. No.	O.D.
11-0005	19 mm
11-0055	12.5 mm

Concise™ Cement
Sculps KitCat. No. 11-1000
(one of each)MixOR® Vacuum Mixing
System with Syringe

Cat. No. 7127-0020

Femoral Canal
Suction Absorber

Cat. No.	Size
11-0057	19 mm
11-0058	25 mm

Femoral Cement
Compressor

Cat. No. 11-1454



CEMENT & ACCESSORIES



**Disposable
Femoral Cement
Compressor Cap**

Cat. No. 11-1435



**MixOR Pump
and Hose Kit**

Cat. No. 7127-0040

**MixOR Hose Only
(not shown)**

Cat. No. 7127-0040

**MixOR Pump Only
(not shown)**

Cat. No. 7127-0042



Injector™ Gun

Cat. No. 7127-2000



Vortex™ Vacuum Mixer

Cat. No. 7127-0070



VersaBond®

Cat. No. 7127-1140

**VersaBond
Sample**

Cat. No. 7127-0094



**Connector,
Schraeder**

Cat. No. 7127-0050



Connector, Drager

Cat. No. 7127-0051



Connector, D.I.S.S.

Cat. No. 7127-0052



**Handpiece with
Zimmer Coupling**

Cat. No. 7127-7000



**Powerhose with
Zimmer Coupling**

Cat. No. 7127-7001



Hip with Suction

Cat. No. 7127-7004



Hip without Suction

Cat. No. 7127-7005

IMPORTANT MEDICAL INFORMATION

Warnings and Precautions Total Hip System

IMPORTANT NOTE

Total hip replacement arthroplasty has become a successful procedure for relieving pain and restoring function to patients who are disabled from hip arthralgia. The goals of total hip replacement are to decrease pain, restore function, and increase mobility.

NOTICE

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

Component	Material	Material Reference
Femoral Components	5455/52 or Co-Cr Mo	ASTM F158 and ISO 5832-2 or ASTM F137 and ISO 5832-2 or ASTM F178 and ISO 5832-2 or ASTM F137 and ISO 5832-2
Acetabular shell	5455/52	ASTM F158 and ISO 5832-2 or ASTM F137 and ISO 5832-2
Acetabular liner	5455/52	ASTM F158 and ISO 5832-2
Acetabular liner	Alumina Ceramic	ASTM F162 and ISO 6033
Femoral cement	PMMA PMMA PMMA	ISO standards
Acetabular cement	PMMA PMMA	ISO standards
Acetabular cement shell	PMMA	ISO standards
Eye-welding wire	Co-Cr Mo Stainless Steel	ASTM F158 and ISO 5832-2
Acetabular Reinforcement Ring	Co-Cr Mo	ASTM F158 and ISO 5832-2
Acetabular Reinforcement Ring	Co-Cr Mo	ASTM F158 and ISO 5832-2
Acetabular Reinforcement Ring	Co-Cr Mo	ASTM F158 and ISO 5832-2
Femoral Heads	5455/52 or Ceramic or Ceramic	ASTM F158 and ISO 5832-2 or ISO 12088 or ASTM F162 and ISO 6033

Femoral Ceramic components and porous Co-Cr Mo components are coated with commercially pure (C.P.) titanium beads (ASTM F 67 and ISO 5842/2) and Co-Cr Mo beads (ASTM F 75), respectively. Hydrophobic coatings include: (1) ZPT/PT (1:10) beads applied either on a grit finished or porous surface; (2) Ti-6Al beads applied on either a grit finished or porous surface; (3) Ti-6Al beads applied on porous surfaces and ceramic-titanium implants are not available in the USA.

Some of the alloys needed to produce arthroplasty implants contain certain metallic components that may be carcinogenic in tissue culture or inhaled organisms under any unusual circumstances. Conditions have been stated in the scientific literature as to whether or not these alloys may be carcinogenic to implanted components. Studies conducted to evaluate this issue have not identified conclusive evidence of such phenomenon, in spite of the volume of implants in use.

DESCRIPTION OF SYSTEM

The Total Hip System consists of femoral component, proximal pain, liner sleeve, distal sleeve, acetabular component, fixation sleeve and peg, liner cover, cementation, and femoral head. Components may be grit finished, porous coated, hydroxyapatite (HA) coated, or HA porous coated. All available 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 pain and distal sleeve, respectively. Non porous femoral component can feature PMMA cementation that help produce a uniform biofilm of cement.

Femoral components are available with a Small Length (54/52), or 12/16 long design.

Small length femoral components made and lock directly with a 22 mm neck or cementless head. The Small length also makes with a large sleeve which, in turn, makes with either metal or ceramic heads (28, 28, or 32 mm), bipolar or unipolar components.

Large length femoral components made and lock with either metal heads (28, 28, or 32 mm), ceramic heads (28 or 32 mm), bipolar or unipolar components.

Femoral components with a 12/16 long make and lock with either metal heads (22, 28, 28, or 32 mm), ceramic heads (22, 28, 28, or 32 mm), bipolar or unipolar components.

Small, Large, and 12/16 long femoral component liners are machined to mate and lock with ceramic heads. Thick protruding ridges of the ceramic head on the stem, which would cause wear of the stem liner.

Distal Sleeve

A distal sleeve is required to be implanted on the Small length femoral component prior to implanting a femoral head size 28, 28, or 32 mm. A large sleeve is required to attach a ceramic head. Unipolar liner sleeves are available in Small, Large, and 12/16 lengths. Please place more than one liner sleeve on a femoral component.

Femoral Heads

Collar diameter (22, 28, 28, and 32 mm) and ceramic (22, 28, 28, and 32 mm) heads are available in multiple neck lengths for proper alignment and modulation. 8. Heads are highly polished for reduced friction and wear. The following ceramic femoral heads are available for use only with Small and Large liner femoral components:

Ceramic	Head Diameter	Neck Length
42/1916	22 mm	Long 4 mm
42/1918	22 mm	3.5 Long 3 mm
42/1918	28 mm	Standard 2 mm
42/1919	28 mm	Long 4 mm
42/1920	28 mm	3.5 Long 3 mm

Note: 32 mm head with a 3 mm neck length are not available for use with the small length stems.

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

Ceramic	Head Diameter	Neck Length
7132/0022	22 mm	Long 2 mm
7132/0026	22 mm	3.5 Long 3 mm

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

The following zirconia ceramic heads are available for use only with 12/16 length femoral components:

Ceramic	Head Diameter	Neck Length
7132/0028	28 mm	Standard 0 mm
7132/0028	28 mm	Long 4 mm
7132/0028	28 mm	3.5 Long 3 mm
7132/0028	28 mm	2 mm
7132/0028	28 mm	Long 4 mm
7132/0022	22 mm	3.5 Long 3 mm
7132/0022	22 mm	3.5 Long 3 mm

The following alumina ceramic heads are available for use only with 12/16 length femoral components:

Alumina	Head Diameter	Neck Length
7132/0040	28 mm	0 mm
7132/0040	28 mm	4 mm
7132/0020	22 mm	0 mm
7132/0020	22 mm	4 mm
7132/0020	22 mm	0 mm
7132/0020	22 mm	4 mm

The alumina 28mm H-head size is not for use with a Co-Cr Mo liner in the USA.

Acetabular Components

Acetabular components can be one piece of 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 cement, pegs and hole covers etc. Acetabular reinforcement and reconstruction rings are used with all polyethylene acetabular component. Note: the metal shell and ceramic liner in the Ceramic/Ceramic Acetabular System are not available in the USA.

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

INDICATIONS, CONTRAINDICATIONS, AND ADVERSE EFFECTS

My components are indicated for individuals undergoing primary and revision surgery where either treatment or devices have failed in relieving hip discomfort as a result of trauma or non-traumatic degenerative joint disease (DJD), or any of its complete diagnosis of osteoarthritis, osteoarthritis, traumatic arthritis, slipped capital scapulae, head-on, fracture of the pelvis, and traumatic arthritis.

My 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 system, in which case, the patient should be warned of an ablate normal degree of infection post-operatively. Prevalence of revision, femoral neck fracture and acetabular fractures of the proximal femur with load treatment that are contraindications using other techniques, malalignment, femoral dislocation, Chondroblast reaction, fracture dislocation of the hip, and correction of deformity.

Acetabular reinforcement and reconstruction rings are intended to be used in primary and revision surgeries where the acetabulum has the deficiencies of the acetabular roof, anterior or posterior lip, medial wall softening, anterior-posterior rim as a result of the previous failed primary total hip replacement, femoral neck fracture and acetabular fractures of the proximal femur and before any increase the chance of complications and reduce the chance of a satisfactory result.

Contraindications

1. Conditions that would minimize or tend to minimize adequate implant support or prevent the use of an appropriately sized implant.
2. A blood supply deficiency.
3. Insufficient quality or quality of bone support, e.g., osteoporosis, or metabolic disorders which may impair bone formation, and osteoporosis and
4. Infections or other conditions which tend to increase bone resorption.
5. Mental or neurological conditions which tend to impair the patient's ability or willingness to accept activities.
6. Physical conditions or activities which tend to place undue loads on implants, e.g., Channel joints, muscle deformations, multiple joint dislocations, etc.
7. Bacterial immunity.
8. The alumina ceramic head is contraindicated for use with any other product than an UHMW polyethylene cup or a metal backed UHMW polyethylene cup.
9. The alumina ceramic liner is contraindicated for use with any product other than the metal shell with the acetabular liner layer 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 progress for possible alternative procedures such as non-operative treatment, arthroscopy, femoral resection, pelvic osteotomy, retractor arthroplasty, hemipelvectomy and others.

Conditions preventing increased risk of failure include osteoporosis, metabolic disorders which may impair bone formation, and osteoporosis.

Possible Adverse Effects

1. Wear of the polyethylene and ceramic articulating surfaces of acetabular components may occur. Greater 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 damage of the articulating surfaces. Higher rates of wear may develop the rest of the procedure, and lead to early revision surgery to replace the worn polyethylene components.
2. With all joint replacements, asymptomatic, localized, progressive bone resorption (osteolysis) may occur around the prosthetic components. A consequence of long-term 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. Secondary particles may also be generated by full-body particles lodged in the polyethylene or ceramic articulating surfaces. Osteolysis can lead to future complications including 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 before. Fracture of the implant can occur as a result of trauma, abnormal stress activity, improper alignment, or duration of service.
4. Osteolysis, subsidence, increased range of motion, or lengthening or shortening of the femur caused by improper neck extension, positioning, loosening of acetabular or femoral components, relaxation, bone penetration of the femoral proximal through the shell of the femur, fracture of the acetabulum, inadequate production of acetabular component, femoral impingement, prosthetic substitution, or failed cementation.
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 malaligned cementing, etc. High-velocity fractures are usually associated with all congenital defects, improper stem selection, improper handling, and/or stress osteoporosis.
6. Infection, both acute postoperative wound infection and late deep wound sepsis.
7. Neuropraxia, femoral, sciatic, peroneal nerve and lateral femoral cutaneous neuropraxia 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 embolism, or myocardial infarction.
9. Synovial conditions, especially in males with hyperostotic arthritis, limited preparation range of motion and proximal femoral impingement. Also, particulate substitution with or without impingement to joint mobility can cause decreased range of motion.
10. Thrombotic thrombocytopenic usually associated with weight bearing and/or improper fixation of the liner, when a haemostatic surgical approach is used.
11. Although rare, metal sensitivity reactions and/or allergic reactions to X-ray materials have been reported in patients following joint replacement.
12. Damage to blood vessels.

- Traumatic arthritis of the knee from intraoperative positioning of the extremity.
- Delayed wound healing.
- Aggravated problems of the affected limb or contralateral extremity caused by leg length-inequality, excessive flexion or immobilization, or muscle debility.
- Failure of the porous coating substrate interface or hydroxyapatite coating/pore coating bonding may result in bone separation/osteolysis.
- Deep migration or subluxation has occurred in conjunction with compression grafting procedures usually resulting from insufficient graft material or improper cement technique. Visual stem alignment may also be important.

WARNINGS AND PRECAUTIONS

The patient should be warned of surgical risks, and made aware of possible anesthesia effects. The following information is provided so that the device does not replace correct health care. But the implant can break or become damaged as a result of abnormal activity or trauma, and that it has a finite expected service life and may need to be replaced in the future. Do not use components from different manufacturers. Complete Warnings and Precautions may be included in component literature.

Preoperative

- Use extreme care in handling and storage of implant components. Cutting, bending, or twisting the surface of components can significantly reduce the strength, fatigue resistance, and/or wear characteristics of the implant system. These items 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 corrosion environments such as salt or distilled water. Do not allow the porous surfaces to come in contact with salt or other flame-retarding materials.
- Abrasive and other reactions to device materials, although infrequent, should be considered, limited (if appropriate), and ruled out preoperatively.
- Position and extend length of components exposed to be left in place to minimum surgery depth as thoroughly as possible.
- Surgical technique information is available upon request. The user should be familiar with the technique. Refer to medical or manufacturer literature for specific product information.
- Intraoperative fracture or breaking of instruments can cause instruments which have experienced excessive use or excessive heat are unsuitable for fracture. Instruments should be examined for wear, or damage, prior to surgery.
- Do not add solid waste, Spanish ceramic components, or other debris onto ceramic heads or/and on the stem layer. (See sterilization section, below.)
- Detail components such that the Zirconia ceramic heads always align with a UHMW polyethylene cup or a metal backed UHMW polyethylene cup. Zirconia ceramic should never articulate against metal femoral cement core of the metal or shell.
- Detail only Smith & Nephew femoral components that indicate the user with ceramic heads. This is important because the layer on the stem is required to lightly mate and finish with the ceramic head thus preventing violation of the ceramic head on the stem. Use an irregularly dimensioned layer could result in fracture of the ceramic head.

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 zirconia ceramic head produces a relatively low amount of particulates, the full amount of particulate remains undetermined. Because of the limited clinical and preclinical experience, the biological effect of these particulates can not be predicted.

Aluminum ceramic should never articulate against metal femoral cement core.

Postoperative

- The general principles of patient education and sound nursing 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, lean and muscle conditions, any prior surgery and anticipated future surgeries, etc. Generally, the largest size available 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.
- Careful selection of the neck length and angle, and stem positioning are important. Bone loss and/or malpositioning of components may result in loosening, malrotation, dislocation, and/or fracture of components. Increased neck length and correct positioning will increase stresses which may be borne by the bone. The component should be firmly seated with the cement injection instruments.
- Care should be taken not to scratch, bend (with the exception of the Removable Ring) or cut implant components during surgery for the reasons stated in Number One of the "Preoperative" section of "Warnings and Precautions."
- A 1/2 inch or a 1/8 inch femoral head should not be used with any 3/4 inch stem.
- Distal stems should not be used to bridge normal defects that be within 23 mm of the tip of the knee stem.

- Stable Small Head stem sizes are 1/2, must have a minimum neck length of 18 mm when used with a bipolar component, and Small Head stem sizes 1/2-1/8, must have a minimum neck length of 4 mm when used with a bipolar component.
- Modular heads, and femoral components should be from the same manufacturer to prevent misalignment of parts.
- Clean and dry the stem prior to inserting the femoral head or layer stems. The modular femoral head component must be firmly seated on the femoral component to prevent disassembly.
- Take care, when positioning and filling some and peg holes, to avoid penetration of the inner cortex of the pelvis, penetration of the acetabulum, or through the distal epiphysis of the femur. Penetration 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 acetabulum. Placement of drills, and screws in the anterior or medial portions of the acetabulum, is associated with a high risk of posteriorly directed vascular injury. These screws must be completely seated in the holes of the shell to allow proper loading for the acetabular component. If the tapered pegs need to be modified, refer to the shell after preparation of the pegs. Do not make the pegs of the pegs drill holes. Use new pegs and different shell holes, or a new shell if necessary.

USE ONLY REFLECTOR™ TITANIUM BONE SCREWS, UNIVERSAL CANCELLOUS BONE SCREWS, IMPROVED PEGS, AND THE ANTERIOR OR MEDIAL PORTIONS OF THE PROSTHESIS, IS ASSOCIATED WITH ONE OF OPTIMA™ TITANIUM BONE SCREWS AND UNIVERSAL CANCELLOUS BONE SCREWS with the Opti Peg Acetabular Component. The Reflector Ident™ and the Reflector Peg System (PES) shells, and the Reflector Acetabular Component, femoral, and tapered screw/rod covers, not peg. Tapered pegs can only be used with Reflector II shells. The threaded hole cover in Reflector shells only accepts the standard hole cover, not screws or pegs. The shell's threaded hole cover can only be used with Reflector Ident™. The Reflector threaded hole cover can be used with both Reflector and Opti shells. Refer to product literature for proper application of the femoral and hole cover usage.

Prior to using modular components, surgical debris including metal should be observed for any debris that may be present. If any metal may remain in place, remove extensive cement with a plastic scalpel blade before proper loading of the liner. During the operation, make sure the femur does not fracture with the use of the Reflector. Chilling the liner reduces the injection time required to seal the stem. Modular components must be assembled correctly to prevent dislocation. Details include the proper fit of the components. The components which may lead to early failure of the prosthesis. Failure to properly seal the acetabular liner into the shell can lead to observation of the liner from the shell.

Acid regulated assembly and disassembly of the modular components which could compromise the initial locking action of the locking mechanism. Do not use force to assemble or disassemble.

Care is to be taken to insure complete support of all parts of the femur embedded in bone cement to prevent stress concentration which may lead to failure of the prosthesis. During curing of the cement, care should be taken to prevent movement of the implant components.

Components are to be left in place in revision surgery. They should not be thoroughly checked for signs of loosening, etc. and replaced if necessary. The head/neck component should be changed only when clinically necessary.

Care removed from the patient, implants previously implanted should never be used, non-removable stems which are not made may lead to early bending or fracture of these components.

To avoid the completely dislocated hip, special care should be taken to prevent acute knee flexion. Also, note that the femoral neck is often very small and slightly flared. Use an extra small straight hip prosthesis, however, a regular straight prosthesis may be used when possible. Note that the low acetabulum is supplementary and shallow. A later acetabulum should not ordinarily be utilized as a support surface for anatomical and biomechanical reasons.

With abnormal arthritis, especially for those patients on steroids, there may be reduced vascularity. Care should be taken to insure maximum penetration of the acetabular liner or fracture of the metal acetabular wall, femur, or greater fracture.

Revision procedures for previous all-hip prostheses, etc., are technically demanding and difficult to execute. Certain errors should be avoided to prevent subsequent problems or malfunctions of the femur. Inadequate removal of implant bone or improper positioning of components, supplementary instability as well as excessive blood loss can result. In summary, increased operative time, blood loss, increased treatment of soft tissue, and blood and wound hemostasis can be expected with revision procedures.

Prior to return, the surgical site should be thoroughly cleaned of cement, bone chips, and debris, etc. Etiology: bone and/or bone chips may be taken to dislocate or partial or reduced motion. Range of motion should be flexibly checked to verify correct or stability.

When using a ceramic liner and metal shell, proper shell and liner alignment and positioning are critical to implant performance. If the ceramic liner and shell are not fully seated or are aligned incorrectly after final inspection, it will be necessary to re-drill the shell and liner and/or the shell and liner components. In improper shell and liner alignment and positioning, it may increase the chance of subsequent liner fracture or other component failure. Refer to the surgical technique

- for specific information on shell assembly and the implantation method.
- Proper positioning of the components is important to minimize impingement should occur lead to early failure, premature wear, and/or dislocation.

Postoperative

- Postoperative directions and warnings to patients by physicians, and patient care, are extremely important. Careful weight bearing is urged after surgery to minimize limb rigidity/contracture. However, with fracture reduction or other complex cases, weight-bearing should be individualized with the case or partial weight bearing period indicated.
- Patients should be warned against unassisted activity, particularly use of toilet facilities, and other activities requiring maximum motion of the hip.
- Use extreme care in patient handling. Support should be provided to the operation leg when moving the patient. WDM placing the patient on the stretcher, changing dressings, and sitting, and other activities, movements should be taken to avoid placing excessive load on the operative part of the body.
- Postoperative therapy should be adjusted to regain muscle strength around the hip and a gradual increase of activities.
- Periods of rays are recommended for close comparison with immediate postoperative conditions to detect long term evidence of changes or problems of loosening, migration, or other changes or bone loss. With evidence of these conditions, patients should be closely observed; the possibilities of further evaluation evaluated; and the benefits of early review considered.
- Psychiatric status should be monitored in the patient similar to that suggested by the American Heart Association for conditions or situations that may result in bacteremia.

PACKAGING AND LABELING

Components should only be assembled if returned by the hospital or surgeon with the factory packaging and labeling intact.

STERILIZATION/RESTERILIZATION

Most implants are supplied sterile and have been packaged in protective bags. The method of sterilization is noted on the package label. All call altered sterilized components have been exposed to a minimum of 20 minutes of gamma irradiation. If not specifically stated on the label, 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.

Material

Nonporous or non-FA coated metal components may be fully sterilized only if required, if necessary by steam autoclaving in appropriate protective wrapping after removal of all original packaging and labeling. Pored the stems, particularly metal surfaces, from contact with metal or other hard objects which could damage the product. The following procedures are recommended for these devices:

- Nonporous: Cycle 4 (Autoclave) - 20.0 psi (2.0 bar) & Minimum - 10.0 min (200 minutes) with a minimum dwell time of 5 minutes at 270°F to 275°F (130°C to 135°C), followed by a 1 minute purge and hold for 15 minutes of vacuum drying at 10.0 psi (2.0 bar) minimum.
- Cycle 2 (Dry Heat) - 270°F (130°C) with a minimum dwell time of 10 minutes of 10 minutes, followed by a 1 minute purge and a hold 15 minutes of vacuum drying at 10.0 psi (2.0 bar) minimum.

Smith & Nephew does not recommend the use of low temperature gas-lytic or low steam sterilization on implants.

Do not sterilize femoral prostheses with ceramic heads coated on the stem.

If porous acetabular or FA-coated implants are inadvertently contaminated, the use of the steam autoclave is not appropriate or recommended. DO NOT RESTERILIZE porous acetabular or FA-coated implants. The porous coating requires special cleaning procedures.

Plastic Components

Plastic components may be sterilized by ethylene oxide gas. The following parameters are recommended as starting points for cycle validation:

Exposure Temperature	Exposure Time	Relative Humidity	Exposure Distance	Exposure Time
100°C (212°F)	100 hr	40-60%	60 cm	60-90
110°C (230°F)	100 hr	40-60%	60 cm	60-90

Minimum recommended starting point for validation is 12 hours at 120°F (50°C) with 50% relative humidity. Contact your manufacturer for more specific instructions.

Ceramic Components

Do not sterilize ceramic femoral heads on stems.

INFORMATION

For further information, please contact Customer Service at (800) 238-7328 or call within the continental USA and (907) 386-2711 for all other national calls.

Authorized CE Representative: Smith & Nephew Orthopaedics GmbH, Tuttlingen, Germany.

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



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