Surgical Technique

smith&nephew

ECHELON®

Primary Hip System

ECHELON◇ Primary Hip System Surgical Technique

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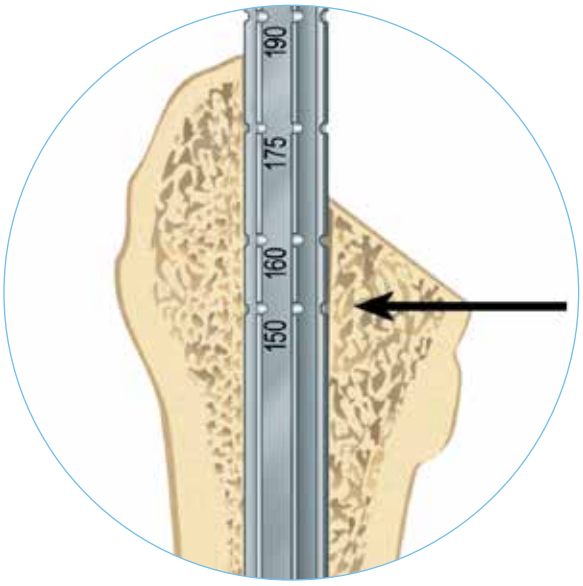
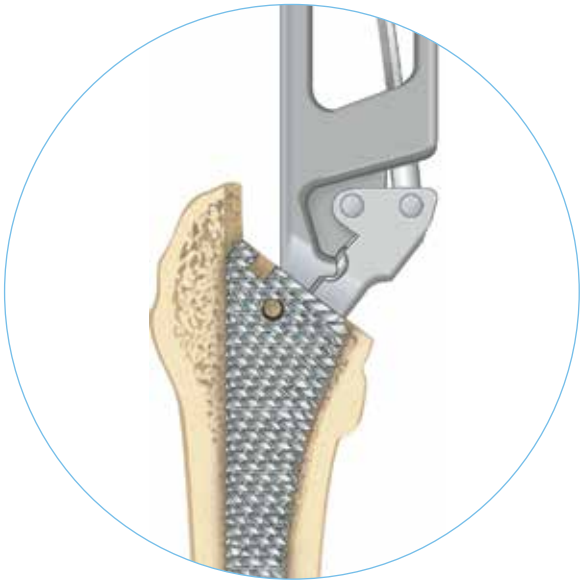
Nota Bene

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.

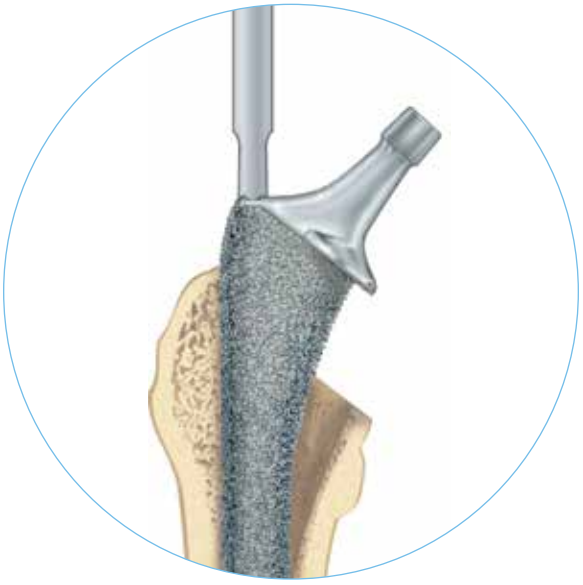
Basic steps



Ream to size



Broach and trial



Implant stem

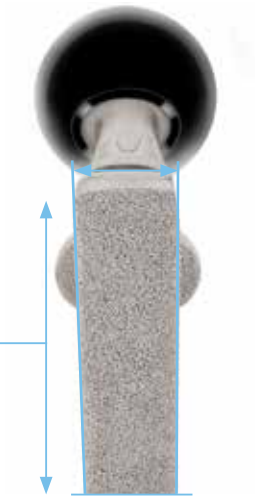
Porous femoral implants

Neck geometry –
Circulotrapezoidal neck provides increased range of motion compared to a circular neck of the same strength. Polished surface improves fatigue strength.

Driving platform –
The ECHELON® implants feature a threaded driving platform with an elliptical slot for rotational and axial implant control during insertion.

Optimized 12/14 taper –
Modular femoral heads are locked onto the stem with an optimized 12/14 taper which contributes to an increased range of motion.

Lateral proximal flare –
ECHELON has a 3° proximal anterior/ posterior flare to improve proximal fill, without preventing implant seating.

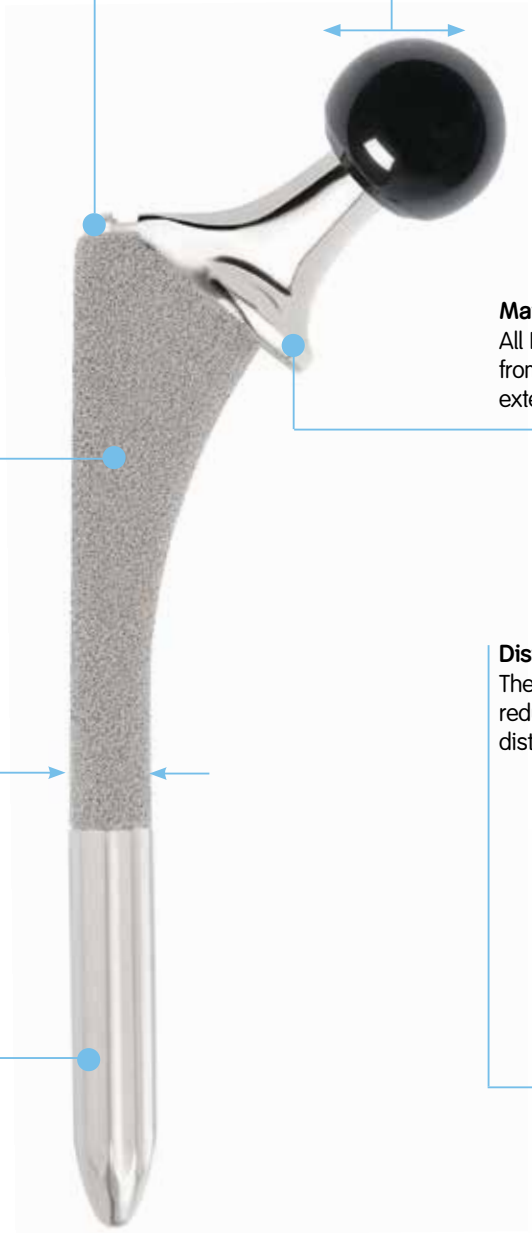


Distal bullet tip –
The bullet tip reduces the stress between the distal implant tip and the bone to minimize end-of-stem thigh pain.

Standard offset

Neck offset options –
Standard and high offset options are available to ensure the appropriate joint tension.

Shoulder relief –
The lateral shoulder is rounded to minimize the risk of fracturing the greater trochanter during stem insertion.

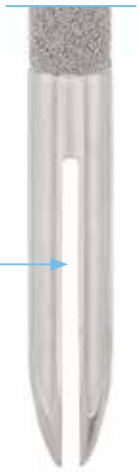


Porous coating –
ROUGHCOAT® porous coating increases the friction between the implant and bone, improving implant stability and providing a porous surface for bone ingrowth.

Material –
All ECHELON® implants are manufactured from Cobalt Chromium allowing for extensive porous coating of the stem.

Size range –
ECHELON Primary stems are offered in 1mm increments to minimize bone removal and provide optimum canal fill.

Distal slot –
The distal slot eases stem insertion, reduces the risk of fracture and reduces distal stem stiffness.



Distal flutes –
The ECHELON system offers distal flutes to increase rotational stability.

High offset

Implant specifications

General specifications

Cobalt chromium material
Neck shaft angle 131°
Standard collar shaft angle 50°
Primary stem length 130-160mm*
Porous-coating length 90-108mm**
The broach is 0.5mm smaller than the implant.
Distal flute diameter is 0.25mm larger than porous coated cylindrical diameter.

* Stem length is measured from the collar to the distal tip
** Porous coating length is measured from the shoulder to the distal end of the coating

Standard offset

High offset

Neck length (mm)

Size	−3		+0		+4		+8		+12		+16	
11	24	—	27	—	31	—	35	—	39	—	43	—
12	24	28	27	31	31	35	35	39	39	43	43	47
13-14	27	33	30	36	34	40	38	44	42	48	46	52
15-17	31	36	34	39	38	43	42	47	46	51	50	55
18-19*	34	39	37	42	41	46	45	50	49	54	53	58

Neck offset (mm)

Size	−3		+0		+4		+8		+12		+16	
11	32	—	34	—	37	—	40	—	43	—	46	—
12	32	38	34	40	37	43	40	46	43	49	46	52
13-14	35	43	37	45	40	48	43	51	46	54	49	57
15-17	38	46	40	48	43	51	46	54	49	57	52	60
18-19*	41	49	43	51	46	54	49	57	52	60	55	63

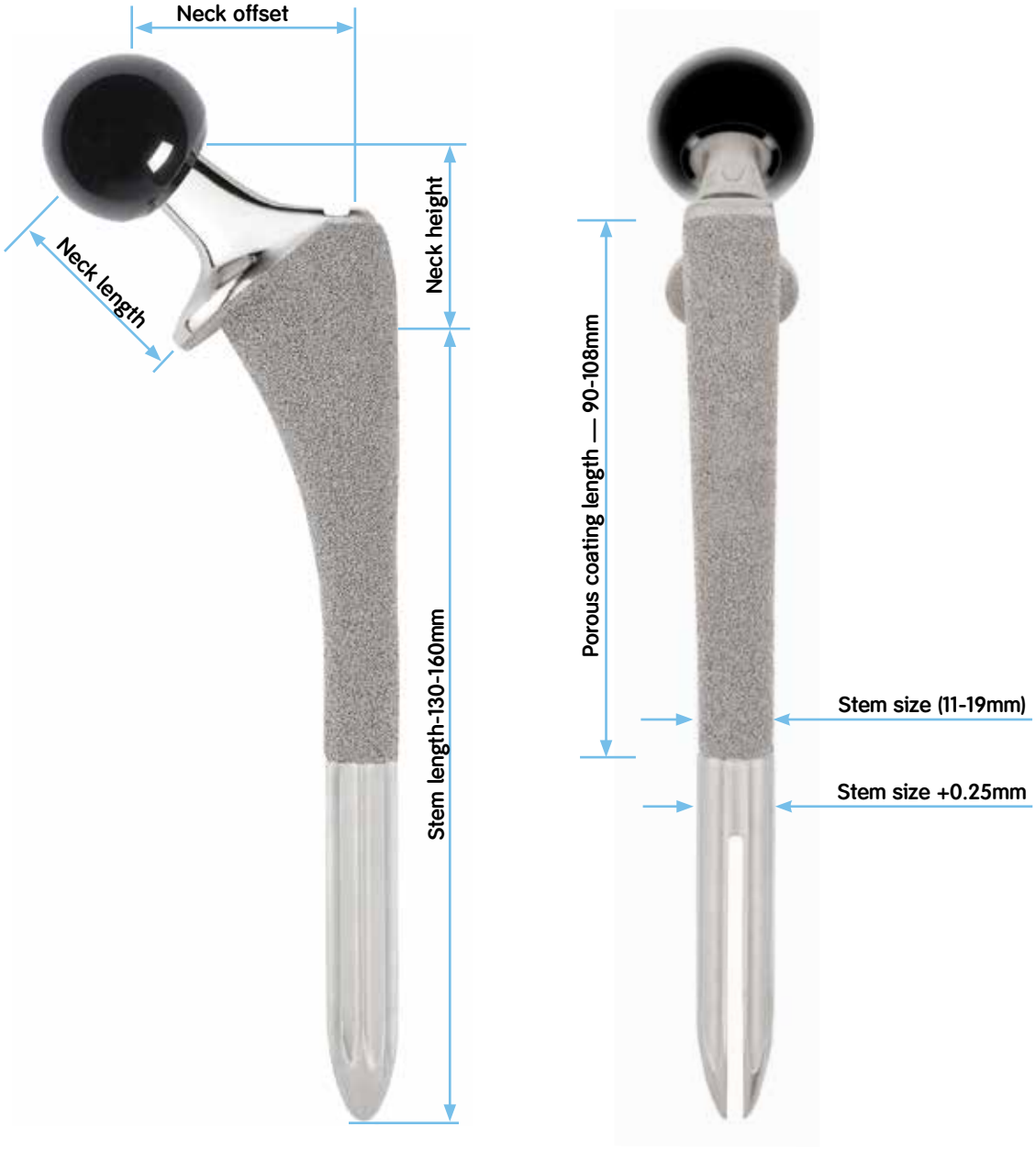
Neck height (mm)

Size	−3		+0		+4		+8		+12		+16	
11	25	—	27	—	30	—	32	—	35	—	37	—
12	25	25	27	27	30	30	32	32	35	35	37	37
13-14	28	28	30	30	33	33	35	35	38	38	40	40
15-17	30	30	32	32	35	35	37	37	40	40	42	42
18-19*	34	34	36	36	39	39	41	41	44	44	46	46

* 18-19 available as special request

Length measurements		
Standard/high offset size	**Stem length**	**Porous coating length**
11-12	130mm	90mm
13-14	140mm	96mm
15-17	150mm	102mm
18-19*	160mm	108mm

*18-19 available as special request



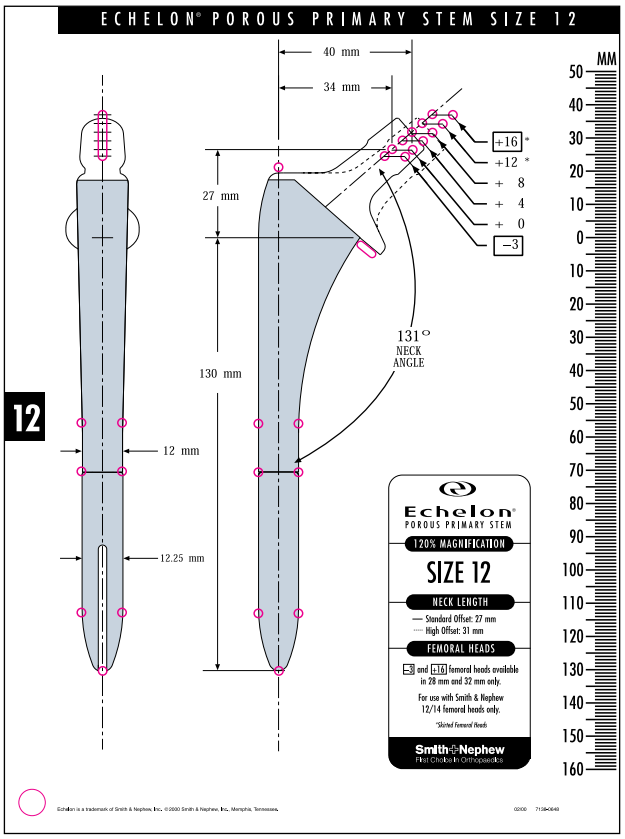
Preoperative planning

Preoperative planning is essential to ensure appropriate implant selection and reaming. It may also be valuable in determining management of leg length discrepancy. Both standard offset and high offset implants are available and templates for these implants should be utilized to determine the optimum offset for each individual patient.

Both an anteroposterior radiograph of the pelvis with the hips in neutral rotation and a lateral hip radiograph optimize preoperative templating. The proximal one-third of the femur should be visible on these radiographs.

In order to determine appropriate offset and management of leg length discrepancy, it is necessary that the femoral templates be utilized in conjunction with acetabular templates appropriate for the implant that has been selected for the acetabular reconstruction.

The femoral templates provided allow for different neck offset options in addition to varying head depths and head diameters to ensure comprehensive selection of implants to deal with variations in femoral and acetabular anatomy.



Femoral neck osteotomy

Step 1

The point of the femoral neck resection should be marked with electrocautery corresponding to both the preoperative templating and the intraoperative measurement. This will confirm that the level of the femoral neck resection is appropriate and will re-establish the desired leg length of the proximal femur.

An osteotomy guide is available for proximal bone resection. Resect the proximal bone by cutting through the angled slot. The osteotomy guide has a vertical scale in 5mm increments to help gauge neck height. Osteotomize the femoral neck (Figures 1A and 1B).

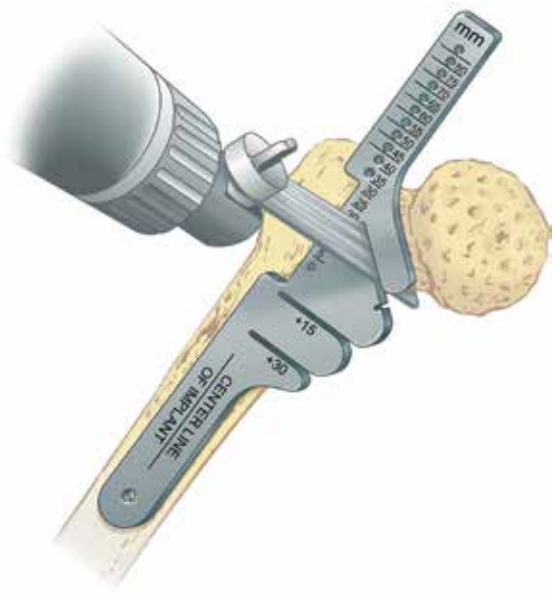


Figure 1A

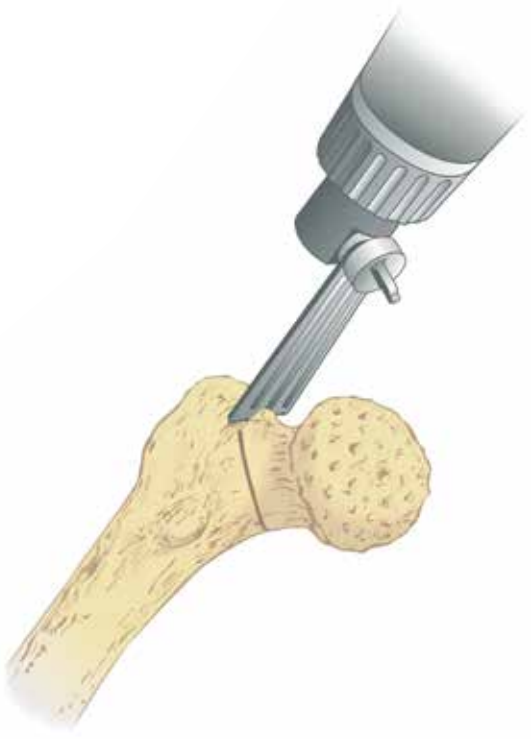


Figure 1B

Acetabular and femoral canal preparation

Step 2

The acetabulum should be prepared in the recommended fashion for the acetabular component to be utilized according to preoperative planning and templating.

Figure 3A

Step 3

Remove remnants of the femoral neck and open the medullary canal using the box osteotome (Figure 3A). Use the canal finder and modular T-handle for initial femoral reaming (Figure 3B).

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 track into the femur is in neutral alignment with the femoral axis.

Do not pressurize intramedullary contents with canal finder by inserting too rapidly.

Caution Take care when handling reamers and broaches as they are sharp and may damage surgical gloves and soft tissue.

Figure 3B

Femoral reaming

Step 4

Rigid femoral reamers in 0.5mm increments are available.

The stem size is measured at the maximum diameter of the distal porous coating. The maximum diameter of the flutes is 0.25mm larger than the diameter of the porous coating.

Start reaming with a reamer 4 to 6mm smaller than the templated size or a reamer that has little or no resistance in the femoral canal.

For a line-to-line fit, ream the canal in 0.5mm increments until the last reamer matches the selected implant size. The canal can also be reamed 0.5mm smaller than the size for a tighter distal fit. The final reamer size should be based on bone quality, anatomy and surgeon preference.

Note The flutes on the distal stem are 0.25mm larger than the porous coated diameter. Therefore, reaming line-to-line will produce a 0.25mm press fit in the distal fluted region of the stem.

The stem length is measured from the collar to the distal tip of the implant. Reaming depth is also measured from the collar to the distal tip of the implant (Figure 4A and Figure 4B). Use the implant reaming chart to determine the reaming depth for the porous implants. Seat the reamer to the appropriate depth mark on each reamer.

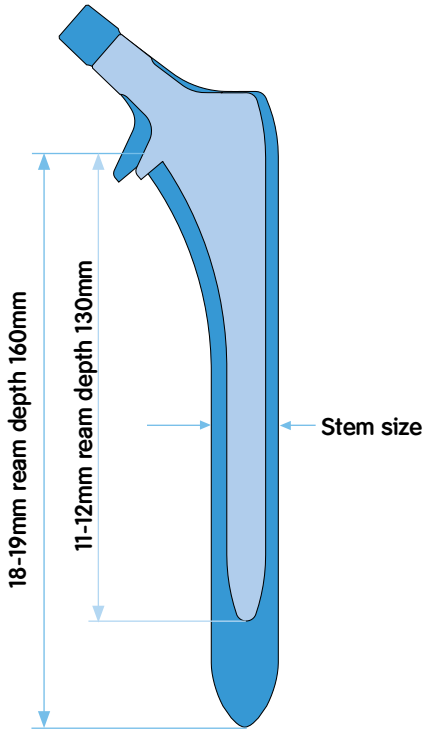


Figure 4A

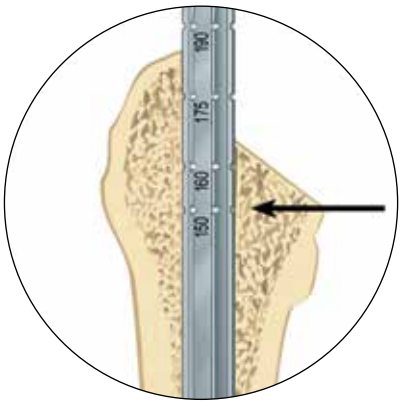


Figure 4B

Note ECHELON® reamers have multiple depth marks. The distal-most mark indicates the Primary stem reaming depth. Other depth markings indicate reaming depths for ECHELON revision implants.

Implant reaming chart

Stem	Ream depth from medial resection level
11-12	130mm
13-14	140mm
15-17	150mm
18-19*	160mm

*18-19 available as special request

Femoral broaching and calcar preparation

Step 5

Attach the broach handle to the femoral broach. Begin broaching two sizes smaller than the size of the last femoral reamer. The broach should be seated to the depth of the medial resection line as shown in Figure 5. The final broach should match the size of the selected implant. The femoral broaches are 0.5mm smaller than the porous coating level of the implant.

Be sure to stay lateral with the smaller broaches to avoid varus broaching.

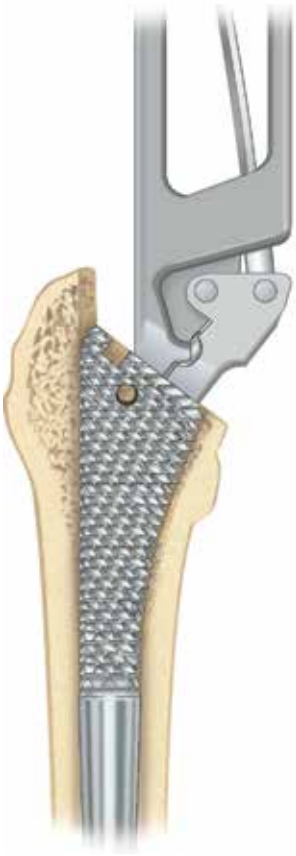


Figure 5

Step 6

A calcar reamer is available. With the final broach fully seated, remove the broach handle. Place the calcar reamer over the broach post and ream the calcar flush with the top of the broach (Figure 6). This will ensure uniform contact between the collar of the prosthesis and the calcar. **This can be verified by placing the trial neck on the broach.**

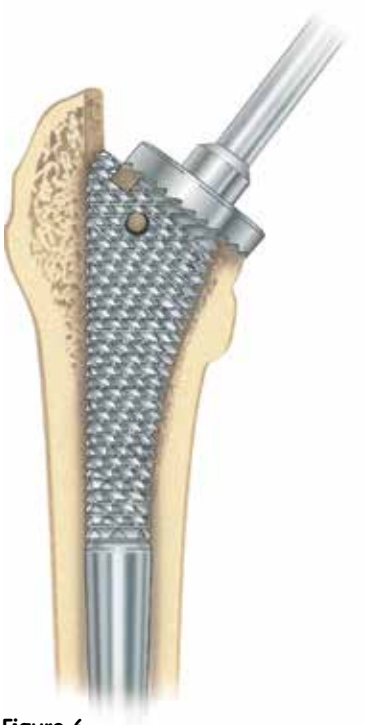


Figure 6

Trialing

Step 7

After calcar reaming, place the matching trial neck onto the broach post (as determined by pre-op templating). Fully engage the desired trial femoral head on the trial neck and reduce the hip to assess stability and range of motion (Figure 7).

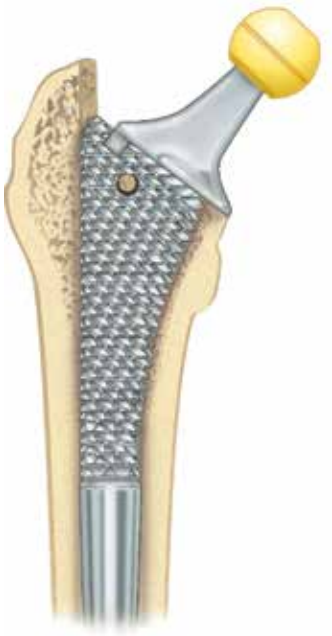


Figure 7

Femoral neck length options						
Global trial head color	**22mm**	**28mm**	**32mm**	**36mm**	**40mm**	**44mm**
Green	—	XS/-3	XS/-3	XS/-3	XS/-3	XS/-3
Rust	S/+0	S/+0	S/+0	S/+0	S/+0	S/+0
Brown	M/+4	M/+4	M/+4	M/+4	M/+4	M/+4
Gray	L/+8	L/+8	L/+8	L/+8	L/+8	L/+8
Blue	XL/+12*	XL/+12*	XL/+12*	XL/+12	XL/+12	XL/+12
Black	—	XXL/+16*	XXL/+16*	—	—	—

*Skirted femoral head

Trial reduction

Step 8

Reduce the hip and evaluate in the following ways:

1 **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 (Figure 8A). Rectus femoris tightness (hip in extension, knee flexed) should be no tighter than pre-op.

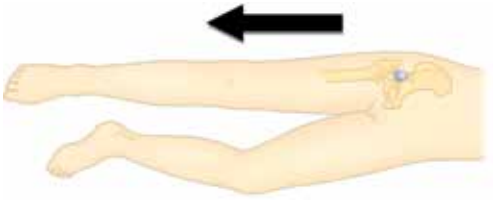


Figure 8A

2 **Anterior Stability** – Place the leg in full abduction, 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 (Figure 8B).

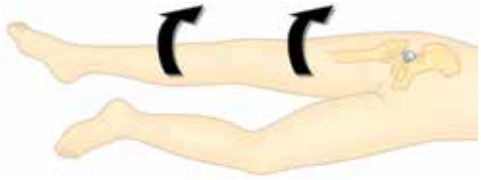


Figure 8B

3 **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 (Figure 8C).

Figure 8C

4 **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 dangerous unstable position that may be adopted by a patient sleeping on their nonoperated side (Figure 8D).

5 **Combined Component Positioning** – Place the leg in neutral extension and adduction. Internally rotate the hip 45°. The cup should cover the "northern hemisphere" of the head. This position is an additional test of the positioning of the components in relation to each other.

Figure 8D

Implant insertion

Step 9

Assemble the threaded stem inserter by inserting the stem inserter pommel through the stem inserter frame. Stand the stem inserter upright so that the threaded tip is pointed up (Figure 9A). Screw the implant onto the threaded tip as far as possible.

Flip the assembly over so that the stem tip is now pointing down (Figure 9B). Engage the frame tine into the slots adjacent to the threaded hole on the stem. Screw the pommel until assembly is secure (Figure 9C). Fully tighten the pommel before impaction.

Stem version can be accurately measured by attaching the anteversion handle to the stem inserter frame. This not only allows accurate visualization of anteversion, but will help control rotation of the stem during impaction.

Figure 9A

Figure 9B

Figure 9C

Implant insertion

Step 10

Insert the implant into the canal with hand pressure and verify proper implant version. Use firm mallet blows to seat the implant to the desired level (Figure 10).

Caution Do not use the Stem Inserter Pommel as a stand alone instrument, either for stem insertion or removal

Note Once the implant flutes have engaged the bone, the implant version cannot be changed without removing the implant. The implant can be removed by striking the underside of the threaded stem driver with a mallet.

Surgeon tip When using a porous coated cylindrical stem, some surgeons prefer to know the exact dimensions of the reamers and implants used. In these situations, surgeons may use a ring gauge to measure the reamers and implants to within 0.5mm. Based on those measurements, they may adjust their reaming to tailor implant fit.

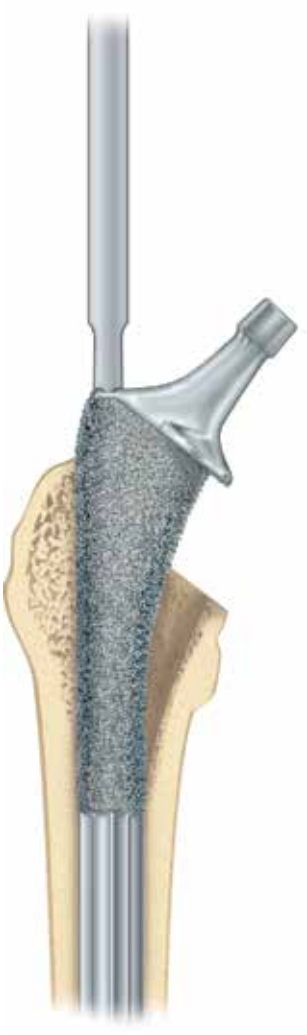


Figure 10

Implant trialing and femoral head assembly

Step 11

Once the implant is fully seated, perform a final trial reduction to determine appropriate neck length. Place the desired trial femoral head on the implant and reduce the hip to assess stability and range of motion (Figure 11).

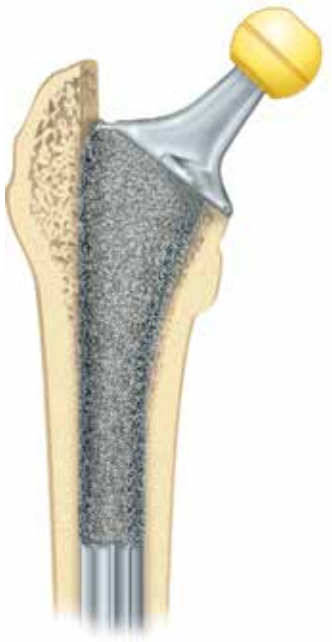


Figure 11

Step 12

Clean and dry the taper with a sterile cloth, place the prosthetic femoral head on the neck taper and firmly impact several times with a femoral head impactor and a mallet (Figure 12).

Figure 12

Conclusion

Irrigate the wound and maintain appropriate hemostasis. If desired, repair the hip capsule and overlying tendons. Close the deep fascial layers, subcutaneous tissue and skin.

Catalog information

Standard offset

High offset

Femoral Implants

Size	Standard offset	High offset
11	7134-1011	—
12	7134-1012	7134-1022
13	7134-1013	7134-1023
14	7134-1014	7134-1024
15	7134-1015	7134-1025

Size	Standard offset	High offset
16	7134-1016	7134-1026
17	7134-1017	7134-1027
18*	7134-1018	7134-1028
19*	7134-1019	7134-1029

*18 and 19 available upon request

OXINIUM® 12/14 Taper Femoral Heads

Neck length	22mm	26mm	28mm	32mm	36mm
–3	—	—	7134-2803	7134-3203	7134-3603
+0	7134-2200	7134-2600	7134-2800	7134-3200	7134-3600
+4	7134-2204	7134-2604	7134-2804	7134-3204	7134-3604
+8	7134-2208	7134-2608	7134-2808	7134-3208	7134-3608
+12	7134-2212	7134-2612	7134-2812	7134-3212	7134-3612
+16	—	—	7134-2816	7134-3216	—

*7134-2340 OXINIUM 40mm Modular Femoral Head

*7134-2344 OXINIUM 44mm Modular Femoral Head

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

Neck length	28mm	32mm	36mm
+0 (short)	71330280	71330320	71332084
+4 (medium)	71330284	71330324	71332085
+8 (long)	71330288	71330328	71332086

Biolox *delta* Ceramic Femoral Heads 12/14 Taper

Neck length	28mm	32mm	36mm
+0 (short)	76539160	76539165	71346004
+4 (medium)	76539161	76539166	71346005
+8 (long)	76539162	76539167	71346006

Catalog information

CoCr 12/14 Taper Femoral Heads

Cobalt Chromium – ASTM F 799

Neck length	22mm	26mm	28mm	32mm	36mm
–3	—	—	7130-2803	7130-3203	7130-3603
+0	7130-2200	7130-2600	7130-2800	7130-3200	7130-3600
+4	7130-2204	7130-2604	7130-2804	7130-3204	7130-3604
+8	7130-2208	7130-2608	7130-2808	7130-3208	7130-3608
+12	7130-2212	7130-2612	7130-2812	7130-3212	7130-3612
+16	—	—	7130-2816	7130-3216	—

*7134-2640 CoCr 40mm Modular Femoral Head

*7134-2644 CoCr 44mm Modular Femoral Head

Global Femoral Head Trial 12/14 Taper

Length	Neck Color	22mm	28mm	32mm	36mm	40mm	44mm
XS/-3	Green	—	7510-0843	7510-0849	7510-0855	7510-0868	7510-0873
S/+0	Rust	7510-0839	7510-0844	7510-0850	7510-0856	7510-0869	7510-0874
M/+4	Brown	7510-0840	7510-0845	7510-0851	7510-0857	7510-0870	7510-0875
L/+8	Gray	7510-0841	7510-0846	7510-0852	7510-0858	7510-0871	7510-0876
XL/+12	Blue	7510-0842	7510-0847	7510-0853	7510-0859	7510-0872	7510-0877
XXL/+16	Black	—	7510-0848	7510-0854	—	—	—

Titanium Modular Neck Sleeve 12/14 Taper

Neck length		Neck length	
-4	71344245	+4	71344248
+0	71344247	+8	71344249

Use with 40mm and 44mm Oxinium and CoCr Femoral Heads

Box Osteotome
Cat. No. 7136-4002

T-handle
(2 per set)
Cat. No. 7136-4006

Anteversion Handle
(2 per set)
Cat. No. 7136-4012

Osteotomy Guide
Cat. No. 7136-4100

Femoral Canal Finder
Cat. No. 7136-4001

Broach Handle
(2 per set)
Cat. No. 7136-4007

Proximal Reamer
Cat. No. 7136-4015

Catalog information

Trial Neck

Size	Standard offset	High offset
11	7136-7201	—
12	7136-7201	7136-7221
13-14	7136-7202	7136-7222
15-17	7136-7203	7136-7223
18-19	7136-7204	7136-7224

Stem Inserter Pommel

Cat. No. 7136-4011

Stem Inserter Frame

Cat. No. 7136-4008

Broach

Cat. No.	Size	Cat. No.	Size
7136-7010	10	7136-7016	16
7136-7011	11	7136-7017	17
7136-7012	12	7136-7018	18
7136-7013	13	7136-7019	19
7136-7014	14	7136-7020	20
7136-7015	15		

Calcar Reamer

Cat. No. 7136-4004

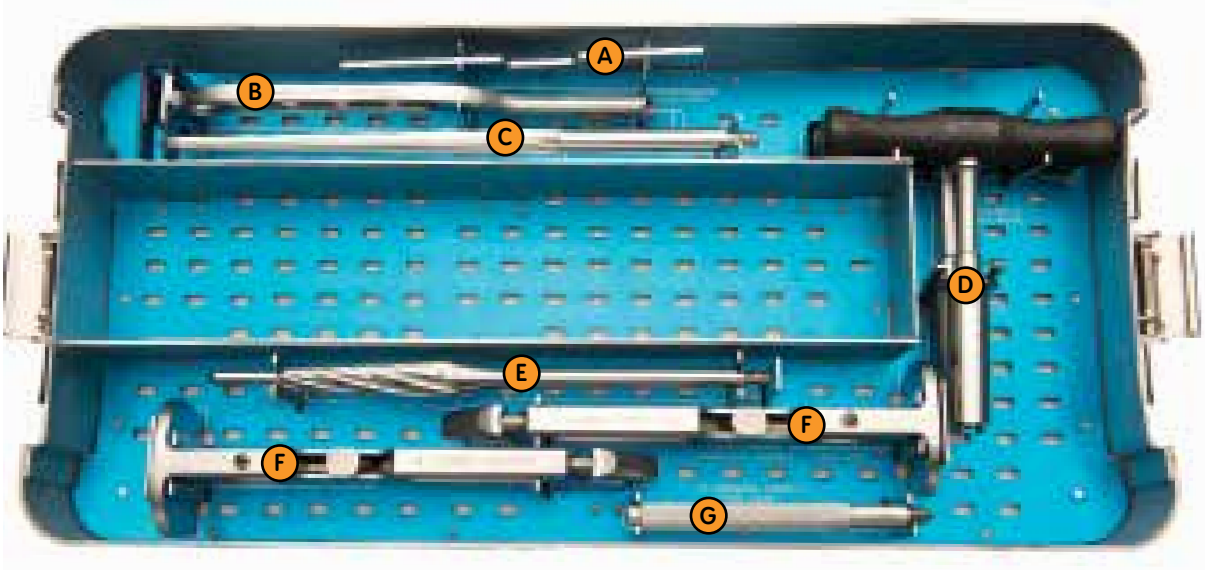
Femoral Head Impactor

Cat. No. 7136-4009

ECHELON◇ Primary Instrument Set (Cat. No. ECH002)

ECHELON Starter Tray

Cat. No. 7136-6001

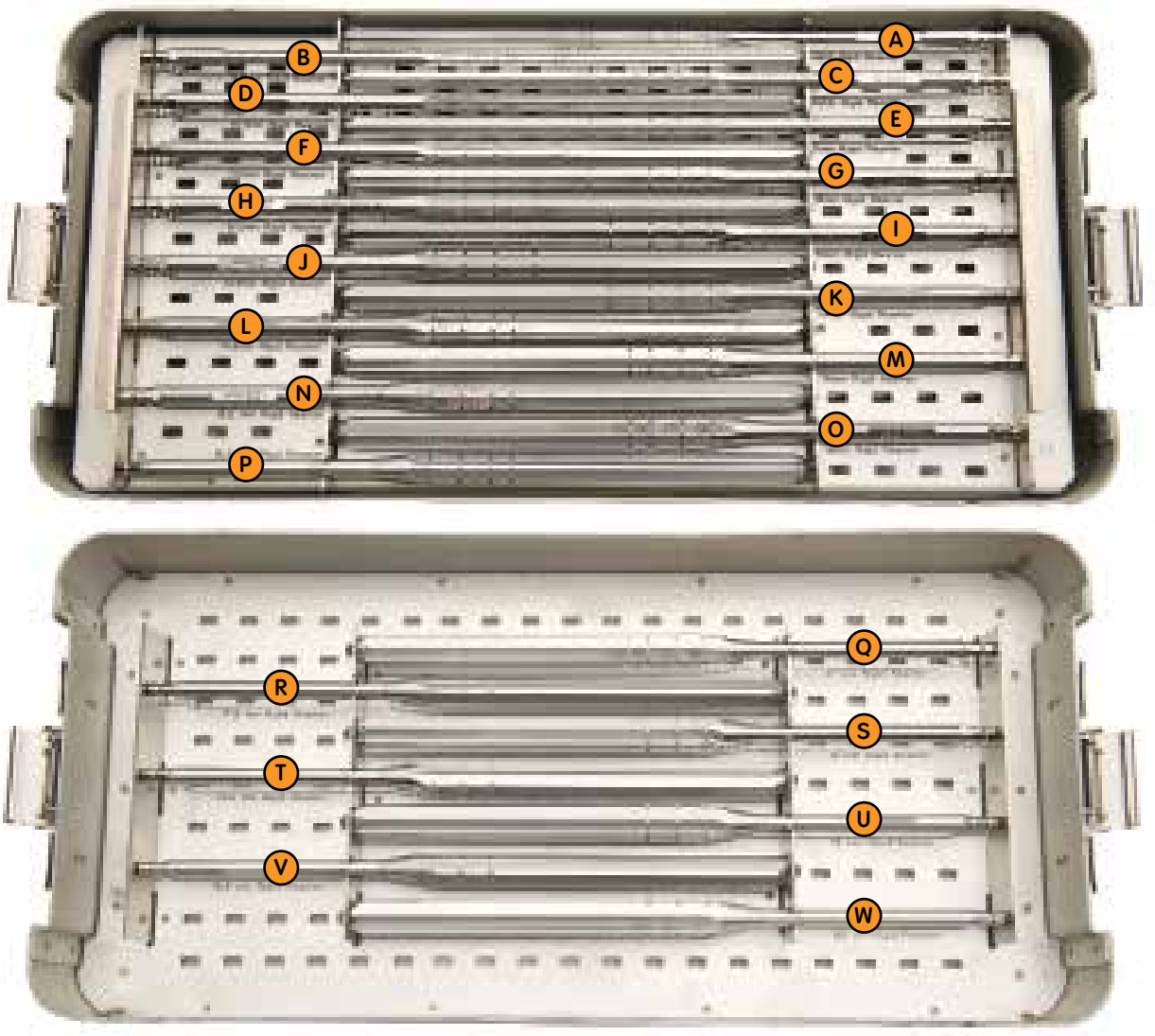


Cat. No.	Description	Ref.
7136-4100	Osteotomy Guide	A
7136-4002	Box Osteotome	B
7136-4001	Femoral Canal Finder	C
7136-4006	T-Handle (2 per set)	D
7136-4015	Proximal Reamer	E
7136-4007	Broach Handle (2 per set)	F
7136-4012	Anteversion Handle (2 per set)	G

ECHELON◇ Primary Instrument Set (Cat. No. ECH002)

ECHELON Rigid Reamer Tray

Cat. No. 7136-6002

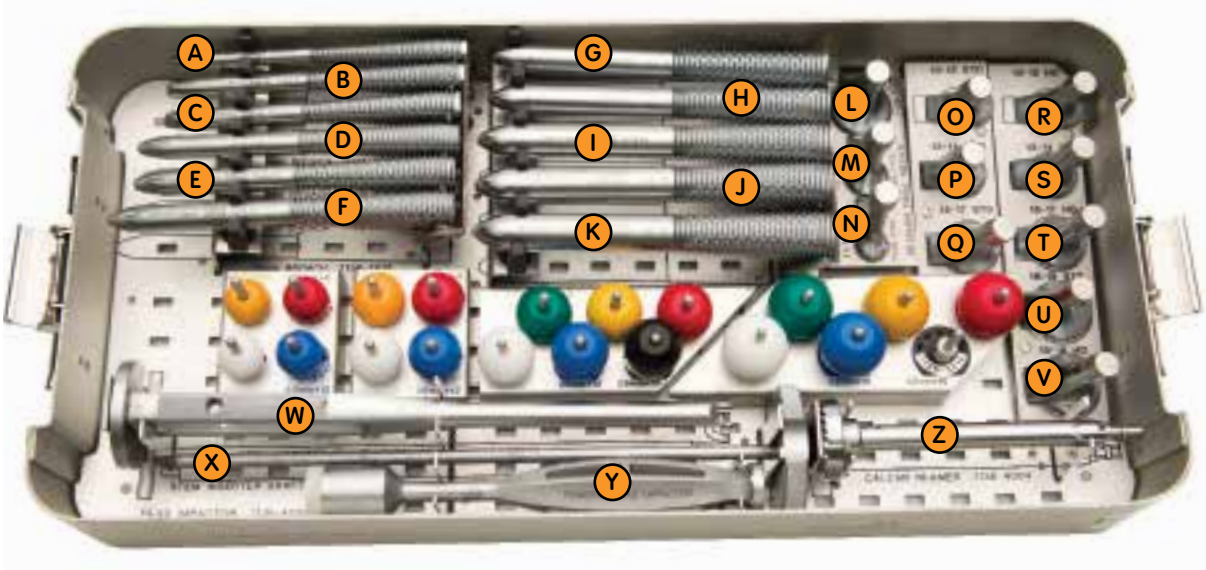


Cat. No.	Description	Ref.
7135-0090	Rigid Reamer, Size 9 mm	A
7135-0095	Rigid Reamer, Size 9.5 mm	B
7135-0100	Rigid Reamer, Size 10 mm	C
7135-0105	Rigid Reamer, Size 10.5 mm	D
7135-0110	Rigid Reamer, Size 11 mm	E
7135-0115	Rigid Reamer, Size 11.5 mm	F
7135-0120	Rigid Reamer, Size 12 mm	G
7135-0125	Rigid Reamer, Size 12.5 mm	H
7135-0130	Rigid Reamer, Size 13 mm	I
7135-0135	Rigid Reamer, Size 13.5 mm	J
7135-0140	Rigid Reamer, Size 14 mm	K
7135-0145	Rigid Reamer, Size 14.5 mm	L

Cat. No.	Description	Ref.
7135-0150	Rigid Reamer, Size 15 mm	M
7135-0155	Rigid Reamer, Size 15.5 mm	N
7135-0160	Rigid Reamer, Size 16 mm	O
7135-0165	Rigid Reamer, Size 16.5 mm	P
7135-0170	Rigid Reamer, Size 17 mm	Q
7135-0175	Rigid Reamer, Size 17.5 mm	R
7135-0180	Rigid Reamer, Size 18 mm	S
7135-0185	Rigid Reamer, Size 18.5 mm	T
7135-0190	Rigid Reamer, Size 19 mm	U
7135-0195	Rigid Reamer, Size 19.5 mm	V
7135-0200	Rigid Reamer, Size 20 mm	W

ECHELON® Broach Tray

Cat. No. 7136-6003



Cat. No.	Description	Ref.
7136-7010	Broach, Size 10	A
7136-7011	Broach, Size 11	B
7136-7012	Broach, Size 12	C
7136-7013	Broach, Size 13	D
7136-7014	Broach, Size 14	E
7136-7015	Broach, Size 15	F
7136-7016	Broach, Size 16	G
7136-7017	Broach, Size 17	H
7136-7018	Broach, Size 18	I
7136-7019	Broach, Size 19	J
7136-7020	Broach, Size 20	K
7136-7103	Revision Trial Neck, Size 18-22	L
7136-7102	Revision Trial Neck, Size 13-17	M
7136-7101	Revision Trial Neck, Size 11-12	N
7136-7201	Trial Neck, Size 10-12, Standard Offset	O
7136-7202	Trial Neck, Size 13-14, Standard Offset	P
7136-7203	Trial Neck, Size 15-17, Standard Offset	Q
7136-7221	Trial Neck, Size 12, High Offset	R
7136-7222	Trial Neck, Size 13-14, High Offset	S
7136-7223	Trial Neck, Size 15-17, High Offset	T
7136-7204	Trial Neck, Size 18-19, Standard Offset	U
7136-7224	Trial Neck, Size 18-19, High Offset	V
7136-4008	Stem Inserter Frame	W
7136-4011	Stem Inserter Pommel	X
7136-4009	Femoral Head Impactor	Y
7136-4004	Calcar Reamer	Z

Total Hip Systems

CAUTION: *Federal law (USA) restricts the subject total hip arthroplasty devices to sale by or on the order of a physician.*

Device Descriptions

Total Hip Systems

The Total Hip Systems consist of femoral components, modular necks, proximal sleeves, taper sleeves, acetabular components, fixation screws and pegs, hole covers, centralizers, and femoral heads. Components may be grit blasted, porous coated, hydroxyapatite (HA) coated, or HA porous coated. All implantable devices are for single use only.

Materials

Femoral components are manufactured from cobalt chromium alloy, titanium 6Al-4V alloy, or stainless steel (SS). Femoral heads are manufactured from cobalt chromium alloy, OXINIUM® oxidized zirconium, BIOLOX® *forte* alumina ceramic, BIOLOX *delta* alumina/zirconia ceramic, zirconia ceramic, or stainless steel. Acetabular liners are manufactured from ultra-high molecular weight polyethylene (UHMWPE), BIOLOX *forte* alumina ceramic, or BIOLOX *delta* alumina/zirconia ceramic. In the U.S., refer to the separate package insert provided with the ceramic acetabular liners. All poly acetabular components are manufactured from UHMWPE. Acetabular shells are manufactured from titanium 6Al-4V alloy or cobalt chromium (CoCr) alloy. BIRMINGHAM HIP® acetabular cups are cobalt chromium (CoCr) alloy. The component material is provided on the outside carton label. **Note:** BIOLOX *delta* ceramic liners are not available for use in the U.S.

Some of the alloys needed to produce orthopedic implants contain metallic components that may be carcinogenic in tissue cultures or in an 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.

Femoral Components

Femoral components are available in a variety of sizes. Porous coated components are coated for biological ingrowth and are intended for use without cement. Modular femoral components are available with an oval taper to accept Smith & Nephew CoCr modular necks and/or a Morse-type taper to accept proximal sleeves. Non-porous femoral components can feature poly(methyl methacrylate) (PMMA) centralizers that help produce a uniform cement thickness. Femoral components, available with 10/12, 12/14, and 14/16 tapers, mate and lock directly with Smith & Nephew femoral heads having the same size taper. Certain femoral heads may require taper sleeves for attachment to the femoral stem taper. Refer to the table in the taper sleeve section for details.

Taper Sleeves

A taper sleeve may be required when mating femoral stems with specific types of femoral heads. Refer to the sleeve compatibility table for the appropriate combinations. Failure to utilize the proper sleeve to head combination may lead to implant failure and may result in revision surgery. Never place more than one taper sleeve on a femoral component, this combination will increase stresses on the implant and may lead to failure and may result in revision surgery.

Modular Necks

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

Compatible Sleeve Combinations

Femoral Stem Taper	40, 44 mm Modular OXINIUM Heads	40, 44 mm Modular CoCr Heads	Modular CoCr Heads*	BH Modular CoCr Heads**	TANDEM® CoCr & OXINIUM Unipolar Heads	14/16 OXINIUM and CoCr Heads
12/14	A	A	B	B	C	-
14/16	-	-	-	-	D	No sleeve required
10/12	-	-	-	-	E	F

* Modular CoCr heads are made from CoCr alloy and are intended for hemiarthroplasty use in the U.S. Refer to the separate package insert provided with the components.

** BH Modular Heads are not available for use in the U.S. These heads can only be used with uncemented SYNERGY® Femoral Stems.

Sleeve	Material	Description/Part Numbers
A	Ti-6Al-4V	Ti 12/14 Modular Sleeve -4: 71344245, +0L: 71344247, +4: 71344248, +8: 71344250
B	CoCr	CoCr 12/14 Modular Sleeve -4: 74222100, +0: 74222200, +4: 74222300, +8: 74222400
C	Ti-6Al-4V	12/14 TANDEM Unipolar Sleeve -3: 71326603, +0: 71326600, +4: 71326604, +8: 71326608, +12: 71326613
D	Ti-6Al-4V	14/16 TANDEM Unipolar Sleeve +0: 126600, +4: 126604, +8: 126608, +12: 126613
E	Ti-6Al-4V	10/12 TANDEM Unipolar Sleeve +4: MH0304, +8: MH0308, +12: MH0312, +16: MH0317
F	Ti-6Al-4V	10/12 to 14/16 Taper Conversion Sleeve +0: MH0001, +12: MH0003

Femoral Heads

For proper anatomic and musculature fit, cobalt chromium, stainless steel, oxidized zirconium, and ceramic heads are available in multiple neck lengths. Heads are available in 10/12, 12/14, and 14/16 tapers. Certain modular heads and unipolar heads may require taper sleeves for attachment to the femoral stem taper. Refer to the Compatible Sleeve Combinations table in the Taper Sleeves section for details. Heads are highly polished for reduced friction and wear. Femoral components and femoral heads are designed for use with any Smith & Nephew polyethylene acetabular component or polyethylene-liner, metal-backed acetabular component having an appropriately-sized inside diameter.

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

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

* Used with REFLECTION® BIOLOX *forte* Ceramic Acetabular Liners in the U.S.

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

*** Used with R3 BIOLOX *forte* Ceramic Acetabular Liners in the U.S.

In the U.S., refer to the separate package insert provided with the ceramic acetabular liners.

BIOLOX *delta*

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

† Not available for use in the U.S.

The following CoCr BIRMINGHAM HIP (BH) modular heads†† should be used only with BIRMINGHAM HIP acetabular cups.

BIRMINGHAM HIP Modular Heads

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

†† BH Modular Heads are not available for use in the U.S.

Acetabular Components

Acetabular components can be one-piece all polyethylene or CoCr (BIRMINGHAM HIP only), or two-piece, consisting of a titanium shell and either a UHMWPE liner, BIOLOX *forte* ceramic liner, or BIOLOX *delta* ceramic liner. For BIOLOX *forte* ceramic liners available for use with the REFLECTION Ceramic Acetabular System in the U.S., refer to the separate package insert provided with the components. Refer to the Warnings and Precautions section for specific information on the use of screws, pegs, and hole covers. Acetabular reinforcement and reconstruction rings are used with an all polyethylene acetabular component.

Note: BIOLOX *delta* ceramic liners are not available for use in the U.S.

Note: The 10 Mrad cross-linked UHMWPE acetabular liners may be used with metal (CoCr and SS), oxidized zirconium, BIOLOX *forte* ceramic heads, or BIOLOX *delta* ceramic heads. **Note:** Stainless steel heads are not available for use in the U.S.

Acetabular liners are designed for use only with acetabular shells from the same product family (i.e., REFLECTION liners can only be used with REFLECTION shells; R3 liners can only be used with R3 shells). The use of other combinations may cause implant failure and may result in revision surgery.

Indications

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

Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis, arthritis secondary to a variety of diseases and anomalies, and congenital dysplasia; treatments of nonunion, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; endoprosthesis, femoral osteotomy, or Girdlestone resection; fracture-dislocation of the hip; and correction of deformity.

Total hip systems may be indicated for use (i) with bone cement, (ii) without bone cement, or (iii) for use with or without bone cement. Refer to the product labeling and literature for specific applications.

The REDAPT® Revision Hip System (formerly *MDF*) is intended to be used without cement. In the EU, the REDAPT Revision Hip System is indicated for revision surgery only.

The R3 Acetabular System is for single use only and is intended for cementless use.

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 may increase the risk of complications and reduce the chance of a satisfactory result. Specifically, an increased risk of complications for revision surgery for any reason has been documented in the literature. Patient selection factors such as age, weight, and activity level can negatively affect implant longevity and increase the risk of revision surgery. Literature has shown a higher likelihood of revision in younger, heavier, or more active patients. Specifically, the risk of complications is greater in obese and morbidly obese patients.

Contraindications

- Conditions that would eliminate or tend to eliminate adequate implant support or prevent the use of an appropriately-sized implant, e.g.:
  - blood supply limitations;
  - insufficient quantity or quality of bone support, e.g., osteoporosis, or metabolic disorders which may impair bone formation, and osteomalacia; and
  - infections or other conditions which may lead to increased bone resorption.
- Mental or neurological conditions which may tend to impair the patient's ability or willingness to restrict activities.
- Physical conditions or activities which tend to place extreme loads on implants, e.g., Charcot joints, muscle deficiencies, multiple joint disabilities, etc.
- Skeletal immaturity.
- The alumina ceramic liner is contraindicated for use with any product other than the metal shell with the correlating inner taper geometry and the appropriately-sized alumina ceramic head. In the U.S., refer to the separate package insert provided with the ceramic acetabular liners.
- In revision surgery, inadequate proximal implant support is contraindicated. There is an increased risk of implant failure in revision cases where proximal support is not achieved, poor bone quality exists, and smaller sized implants are utilized. The lower the implant fixation point in the femur (distance from the head center) the greater the risk of implant fracture and/or re-revision.
- Morbid obesity.

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.

Adverse Events In Primary and Revision Surgery

- Wear of the polyethylene, metal, 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 earlier revision surgery to replace the worn prosthetic components.
- 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, metal, or ceramic articular surfaces. Osteolysis can lead to future complications necessitating the removal or replacement of prosthetic components.
- Failure to observe the warnings and precautions, trauma, strenuous activity, implant alignment, patient non-compliance, involuntary muscular disorders, improper or duration of service increase the risk of loosening, bending, cracking, or fracture of implant components, which may lead to revision surgery.
- Failure of the implant porous coating/substrate interface or hydroxyapatite coating/porous coating bonding may result in bead separation or delamination, which may lead to increased third body wear and may result in revision surgery.
- Implant migration or subsidence that has resulted in revision surgery and has occurred in conjunction with compaction grafting procedures usually as a result of insufficient graft material, improper cement techniques, and/or varus stem alignment.
- Implant loosening or fracture, particularly of smaller sized or high offset implants, is more likely to occur in patients who are young, physically active, and/or heavy, which may lead to implant failure and revision surgery.
- Temporary or permanent device related noise such as clicking, squeaking, popping, grating, or grinding, which may lead to implant failure and revision surgery.
- Although rare, metal sensitivity reactions and/or allergic reactions to foreign materials have been reported in patients following joint replacement, which have required device removal.

Potential Complications Associated with Total Hip Arthroplasty Surgery, Primary or Revision

- Infection, both early, post-operative superficial and early, post-operative deep wound infection and late periprosthetic infection.
- 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.
- Wound hematoma, thromboembolic disease including venous thrombosis, or pulmonary embolus. There may be an increased risk of thromboembolic disease including venous thrombosis with the cemented THA compared to the uncemented THA.
- Myositis ossificans, especially in males with hypertrophic arthritis, limited preoperative range of motion and/or previous myositis. Periarticular calcification with or without impediment to joint mobility can cause decreased range of motion.
- Trochanteric nonunion usually associated with early weight bearing and/or improper fixation of the trochanter, when a transtrochanteric surgical approach is used.
- Damage to blood vessels.
- Accidental patient burns from cautery device.
- Delayed wound healing.
- Aggravated problems of the affected limb or contralateral extremity caused by leg length discrepancy, excess femoral medialization, or muscle deficiency.

Warnings and Precautions

Preoperative

- Do not use if package is damaged. Do not use if the product sterilization barrier or its packaging is compromised.
- Contents are sterile unless package is opened or damaged. DO NOT RESTERILIZE. For single use only. Discard any open, unused product. Do not use after the expiration date.
- U.S. Federal law restricts this device to sale by or on the order of a physician.
- Hazards associated with reuse of these devices include, but are not limited to, patient infection and/or device malfunction.
- Prior to use, inspect the device to ensure it is not damaged. Do not use a damaged device.
- The healthcare provider should have a full understanding of the product labeling information including, but not limited to, the following: Instructions For Use (IFU), surgical techniques, and other relevant product materials that have been provided by the manufacturer.
- 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 trauma or activity including heavy labor for occupation or recreation.
- The patient should be warned that the implant has a finite expected service life and may need to be replaced in the future. Patients should be warned that the longevity of the implant may depend on their weight and level of activity.
- The patient should be warned of the brittle nature of the ceramic components and the possibility of failure of the device leading to additional surgery in the future.
- Improper selection, placement, positioning, and fixation of the implant components may result in unusual stress conditions and subsequent early failure/fracture of the components.
- The surgeon should be thoroughly familiar with the implants, instruments, and surgical procedure prior to performing surgery. Certain insertion techniques may be different than those known for conventional hip systems, and are specifically designed to avoid potential implant failures.
- Do not mix components from different manufacturers unless specially approved by the manufacturer of the components. Failure to comply may result in implant failure and revision surgery. For purposes of product inter-compatibility, products manufactured and labeled by entities formerly known as Plus Endoprothetik, Intraplant, Precision Implants, and Plus Orthopedics (now Smith & Nephew Orthopaedics AG) may be considered as the same manufacturer, Smith & Nephew unless otherwise stated. Additional warnings and precautions may be included in component literature.
- Handle and store the implant components with extreme care. Cutting, bending, or scratching the surface of components can significantly reduce the strength, fatigue resistance, and/or wear characteristics of the implant system. These 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, as this may compromise fixation and lead to failure.
- Allergies and other reactions to device materials, although infrequent, should be considered, tested for (if appropriate), and ruled out preoperatively. A reaction may lead to revision surgery.
- Fixation and expected longevity of components expected to be left in place at revision surgery should be thoroughly assessed. Damage to and/or disruption of the implant during revision surgery may lead to implant failure.
- Refer to medical or manufacturer literature for specific product information. Failure to follow the appropriate surgical technique may result in implant failure or revision surgery.
- 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 and proper operation prior to surgery. Failure to do so may result in injury to the surgical team and/or the patient. Single use devices should not be reused due to risks of breakage, failure, or patient infection and revision surgery.
- OXINIUM oxidized zirconium femoral heads and cobalt chrome femoral heads are designed to articulate with conventional UHMWPE or cross-linked polyethylene (XLPE) bearing surfaces. BIOLOX *forte* femoral heads and BIOLOX *delta* femoral heads articulate with conventional UHMWPE or XLPE bearing surfaces, BIOLOX *forte* ceramic liners, or BIOLOX *delta* ceramic liners. BHR resurfacing heads and BH cobalt chrome modular heads articulate with BH acetabular cups. OXINIUM oxidized zirconium femoral heads, cobalt chrome femoral heads, BIOLOX *forte* ceramic femoral heads and BIOLOX *delta* ceramic femoral heads should never articulate against metal bearing surfaces because severe wear of the metal bearing surfaces may occur. OXINIUM oxidized zirconium femoral heads and cobalt chrome femoral heads should never articulate against BIOLOX *delta* or BIOLOX *forte* ceramic liners because severe wear of the bearing surfaces may occur. **Note:** BIOLOX *delta* ceramic liners and BIRMINGHAM HIP CoCr modular heads are not available for use in the U.S.
- Select only Smith & Nephew femoral components for use with Smith & Nephew ceramic heads. The taper on the stem/neck is machined to tightly mate and lock with the ceramic head. An improperly dimensioned taper could result in disassociation or fracture of the ceramic head, and may result in revision surgery.
- Do not use Smith & Nephew 36 mm -3 heads with SL-PLUS® Hip Stems and SLR-PLUS Hip Stems or any of the +16 heads with any PLUS Hip Stem. Use of these unapproved combinations may result in implant failure and revision surgery.
- 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 may increase the risk of dislocations, subluxation, decreased range of motion, or lengthening or shortening of the femur, which may lead to revision surgery.
- Congenital deformity, improper implant selection, improper broaching or reaming, osteoporosis, bone defects due to misdirected reaming, trauma, strenuous activity, improper implant alignment or placement, patient non-compliance, etc. can increase risk of femoral or pelvic fractures.

Intraoperative

- 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, activity levels, weight, bone and muscle conditions, any prior surgery and anticipated future surgeries, etc. Generally, the component with the largest cross-section 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, resulting in revision surgery.
- 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 and stability verified. Failure to do so may result in implant failure and revision surgery.
- Care should be taken not to scratch, bend (with the exception of the reconstruction rings) or cut implant components during surgery. Refer to the "Preoperative" section of the Warnings and Precautions. Carefully examine the ceramic components for signs of damage that may have occurred during shipping or in prior in-hospital handling. Do not implant damaged components.
- A +12 mm or +16 mm femoral head should not be used with any small taper stems. These unapproved combinations will increase stresses which must be borne by the stem and may result in implant failure and revision surgery.
- Modular heads, modular necks, modular sleeves, and femoral components should be from the same manufacturer unless specially approved by the manufacturer of the components to prevent mismatch. Failure to comply may result in implant failure and revision surgery.
- Stainless steel heads and stainless steel stems should only be used together. Neither should be used with other metal components. These unapproved metal combinations may corrode causing implant failure and revision surgery.
- Use only REFLECTION Liners with REFLECTION Shells. Use only R3 liners with R3 shells. Failure to comply may result in implant failure and revision surgery.
- Clean and dry all taper connections prior to impacting for assembly. The modular femoral head, neck and/or sleeve components must be firmly seated on the femoral component to prevent disassociation, excess fretting wear, implant failure, and revision surgery.
- Care should be taken to position and drill the screw and peg holes to avoid penetration of the inner cortex of the pelvis, penetration of the sciatic nerve, or damage to other vital neurovascular structures. Perforation of the pelvis with screws that are too long can rupture blood vessels and cause 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. Failure to comply may result in implant failure and revision surgery. REFLECTION 3-hole (SP3), multi-hole (SPM), peripheral hole (SPR), INTERFIT® and R3 shells accept both REFLECTION spherical head screws and niversal cancellous bone screws. REFLECTION INTERFIT shells accept the modified REFLECTION screw hole covers. REFLECTION peripheral hole screws should only be used with REFLECTION SPR shells. Locking head pegs and REFLECTION locking head screw hole Covers are only for use with REFLECTION SP3. The threaded center hole in REFLECTION shells only accepts threaded hole covers, not screws or pegs. The INTERFIT threaded hole cover is only for use with REFLECTION INTERFIT, spiked and no hole shells. The REFLECTION threaded hole cover can be used with all REFLECTION and R3 shells. The R3 screw hole cover can be used with R3 and REFLECTION 3-hole shells. Refer to product literature for proper adjunctive fixation and hole cover usage. Failure to comply may result in implant failure and revision surgery.
- Modular components must be assembled securely to prevent disassociation. Prior to seating modular components, surgical debris including blood, bone, tissue, and bone cement must be cleaned from the surfaces. Debris may inhibit the component locking mechanism leading to implant failure and revision surgery.
- 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.
- Avoid repeated assembly and disassembly of the modular components which could compromise the critical locking action of the locking mechanism, resulting in component failure and revision surgery. Do not assemble and then disassemble the ceramic head and the metal femoral stem. This may cause damage to the locking and taper joints. Once the head is impacted, the ridges machined into the metal stem taper become deformed. If the ceramic head is removed, the metal stem taper cannot be reused with a ceramic head.
- Care should be taken to ensure proper cement mixing, an adequate cement mantle, and the complete support of all parts of the device embedded in bone cement, to prevent stress concentration which may lead to failure of the procedure. Specific cement mixing and handling instructions can be found on the cement product labeling. When the cement cures, care should be taken to prevent movement of the implant components. Failure to comply may result in implant failure and revision surgery.
- If the head is removed from a femoral component that will be left in place during a revision surgery, it is recommended that a metal head be used. Do not assemble a ceramic head on a used taper, the ceramic head may fracture from irregularities on the femoral component taper. If broken ceramic material is encountered, remove all loose identifiable fragments and thoroughly irrigate and suction the operative site.
- If components are to be left in place during a revision surgery, they should be thoroughly checked for cracks, scratches, looseness, and other signs of damage, and replaced if necessary. The head/neck component should be changed only when clinically necessary. Failure to comply may result in implant failure and revision surgery.
- Hazards associated with reuse of this device include, but are not limited to, patient infection, fracture of the device, and/or device malfunction.
- With a congenitally dislocated hip, special care should be taken to prevent sciatic nerve palsy. **Note:** 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:** 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.
- 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.
- Revision for previous arthroplasty procedures is technically demanding and difficult to exercise and has higher complication rates, as shown in literature. Increased operative time, increased blood loss, increased incidence of pulmonary embolus and wound hematoma, and a higher risk of infection can be expected with revision procedures.

Total Hip Systems *continued*

CAUTION: *Federal law (USA) restricts the subject total hip arthroplasty devices to sale by or on the order of a physician.*

Intraoperative *continued*

Common errors include misplacement of the incision, inadequate exposure or mobilization of the femur, inadequate removal of ectopic bone, improper positioning of components, or inadequate proximal support of the femoral component. Studies have indicated a higher risk of implant fatigue fracture in cases with inadequate proximal bone stock or where extended trochanteric osteotomies have been performed. In these cases, it is imperative that adjunctive reinforcement procedures such as bone grafting, cortical strut allografts, cables, and trochanteric plates are utilized to provide adequate proximal support to the femoral component. The use of larger prostheses may also reduce the risk of avoiding prosthetic fatigue fracture. Although these adjunctive reinforcement procedures may minimize the risk of implant failure, they do not ensure a predictable clinical result.

- Prior to closure, the surgical site should be thoroughly cleaned of cement, bone chips, ectopic bone, or other foreign matter. Ectopic bone and/or bone spurs may lead to dislocation and painful or restricted motion.
- Range of motion should be thoroughly assessed for early impingement or joint instability. Postoperative instability (i.e., dislocation) is a leading complication associated with revision surgery and may result in additional surgery.
- Proper positioning of the components is important to minimize impingement which could lead to early failure, premature wear, device related noise, and/or dislocation, all of which may lead to revision surgery.
- To minimize the risk of acetabular shell loosening in uncemented applications, surgeons should consider the use of orthopedic bone fixation devices such as bone screws, spikes, pegs, fins, or other bone fixation devices. To minimize the risk of loose cemented acetabular shells, care should be taken to prevent movement of the implant components while the cement cures.
- Physicians should consider component malposition, component placement, and the effect on range of motion and stability when using modular heads (with sleeves or skirts) and overhang liners.
- 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, which may lead to revision surgery.
- Trial instrumentation may be provided for the intraoperative assessment of the final implant fit. Do NOT implant trial components.
- Do not implant HA-coated devices in bone cement.
- Inappropriate use of taper sleeves may lead to implant failure which may lead to revision surgery. Select the appropriate sleeve based on the Compatible Sleeve Combinations Charts located in the Device Description section of this document.

Postoperative

- Postoperative warnings, precautions, and patient care instructions presented by the physician are extremely important. Gradual weight bearing begins after surgery in ordinary total hip arthroplasty procedures. However, with the trochanter osteotomy or certain complex cases, the weight bearing status should be individualized with the non or partial weight bearing period extended.
- Patients should be warned against unassisted activity, particularly use of toilet facilities and other activities requiring excessive motion of the hip, as they may result in subluxation or dislocation.
- Handle patients with extreme care. 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 an excessive load on the operative leg.
- Postoperative therapy, prescribed by the physician, should be structured to regain muscle strength around the hip and to attain a gradual increase of activities.
- Periodic x-rays, prescribed by the physician, are recommended for comparison to immediate postoperative conditions to detect long-term evidence of changes in position, loosening, bending, and/or cracking of components or loss of bone. If these conditions are evident, patients should be closely observed, the possibilities of further deterioration evaluated, and the benefits of early revision considered.
- If the ceramic head must be revised for any reason and the hip stem is firmly fixed, the revision should be made with a CoCr head and corresponding polyethylene liner and metal shell. If the REFLECTION Ceramic Liner requires revision, both the ceramic liner and the REFLECTION Acetabular Shell cannot be reassembled to any liner. If the R3 poly liner requires revision, and the R3 Acetabular Shell is well-fixed, a new R3 poly liner may be assembled to the existing R3 acetabular shell. If fractured ceramic material is encountered intraoperatively, remove all loose, identifiable fragments and thoroughly irrigate and suction the operative site.
- Prophylactic antibiotics should be recommended to the patient, similar to those suggested by the American Heart Association, for conditions or situations which may result in bacteremia.
- Normal daily activity may be resumed at the physician's direction. Patients should be advised to seek a medical opinion(s) before entering potentially adverse environments that could affect the performance of the implant, such as electromagnetic or magnetic fields, including a magnetic resonance environment.
- The patient should be advised to report any pain, decrease in range of motion, swelling, fever, squeaking, clicking, popping, grating, or grinding noises, and unusual incidences. Patient reports of squeaking, clicking, popping, grating, or grinding should be carefully evaluated as they may indicate position changes in the components which may compromise the durability of the implants.
- Postoperative subluxation may result in higher wear and implant damage.

Cleaning and Sterilization

Cleaning

Refer to the document "Instructions for care, maintenance, cleaning and sterilization of Smith & Nephew orthopaedic devices." This document, reference number 71381339, is available from customer service or via the Smith & Nephew website.

Sterilization

Refer to the product label for the method of sterilization. If not specifically labeled sterile, components are supplied non-sterile and must be cleaned and sterilized prior to surgery. Refer to the document, "Recommendations for decontamination instructions for care, maintenance, cleaning, and sterilization of Smith & Nephew orthopaedic devices," which is available from customer service or via the Smith & Nephew website, for further information regarding the cleaning instructions and the validated sterilization procedures.

Recommended Steam Sterilization Cycle Parameters for Reusable Instruments

- ***Dynamic Air Removal (Prevacuum) Steam Cycle:***
  Exposure temperature: 132°C (270°F); **Exposure time:** 4 minutes
  Exposure temperature: 135°C (275°F); **Exposure time:** 3 minutes
  Minimum drying time: Wrapped devices - 15 minutes
  Containerized devices - 30 minutes
- ***Gravity Displacement Steam Cycle:***
  Exposure temperature: 132°C (270°F)
  Exposure time: 15 minutes for instruments not in a containment device
  30 minutes* for devices in a containment device
  Minimum drying time: 30 minutes
  This sterilization cycle is not considered by the United States Food and Drug Administration (US FDA) to be a standard sterilization cycle. Users should only use sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization containers) that have been cleared by the US FDA for the selected sterilization cycle specifications (time and temperature).
- ***Immediate Use Steam Sterilization or Flash Steam Cycle:***
  Exposure temperature: 132°C (270°F)
  Exposure time: Dynamic air removal (pre-vacuum): 4 minutes

For Non-US Customers

- ***United Kingdom Steam Cycle:***
  Pre-vacuum Cycle
  Exposure temperature: 134°C (273°F)
  Exposure time: 3 minutes
  Vacuum drying time: 30 minutes
- ***World Health Organization (WHO) Steam Cycle:***
  Exposure temperature: 134°C (273°F)
  Exposure time: 18 minutes
  Vacuum drying time: 30 minutes

Note: Sterilization evacuation and pulsing should be carried out in accordance with HTM 2010.

Magnetic Resonance Imaging (MRI) Safety

Smith & Nephew hip systems have not been reviewed by the FDA for safety and compatibility in the MR environment. Hip system components have not been tested for heating or migration in the MR environment. Known risks of exposing implant devices to the MR environment include displacement, torque, and radio frequency induced heating. Implant devices may also create image artifacts in MR scans.

Retrieval and Analysis of Harvested Implants

The most important part of surgical implant retrieval is preventing damage that would render scientific examination useless. Special care should be given to protect the implant from damage during handling and shipment. Specifically, for conventional polyethylene or XLPE, use alternative sterilization method other than steam autoclave. Follow internal hospital procedures for the retrieval and analysis of implants harvested during surgery. When handling the harvested implants, use precautions to prevent spread of bloodborne pathogens.

Information

For further information on the medical devices, the information presented herein, or assistance in returning product contact Customer Service at (800) 238-7538 for calls within the continental USA and (901) 396-2121 for all international calls.

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Explanation of symbols used in labeling:

H_2O_2	–	Hydrogen peroxide sterilization
ID	–	Inner diameter
OD	–	Outer diameter
S/+0	–	Short
M/+4	–	Medium
L/+8	–	Long
SO	–	Standard offset
H or HO	–	High offset


– For use with bone cement


– For use without bone cement

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