Surgical Technique

smith&nephew

REFLECTION◇ INTERFIT◇

Porous-Coated
Acetabular Components

Reflecting the commitment to low wear

Designed with fixation and surgical efficiency in mind, the REFLECTION® Acetabular Cup system minimizes wear and maximizes the integrity of the modular connection. REFLECTION Acetabular Components offer a variety of choices, allowing the surgeon versatility for indication and preference.

The MICROSTABLE® Liner Locking Mechanism and the polished inner surface reflect Smith & Nephew's continued leadership in advanced technology.

Technique described by
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University of California, San Francisco

Nota Bene: This 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.

REFLECTION◇ Acetabular Components
Design features

Liner/shell stability

As shown in many independent studies, the MICROSTABLE◇ Liner Locking Mechanism has the lowest level of liner/shell motion of the shells tested.[1-4] Internal Smith & Nephew testing further demonstrates the superiority of the locking mechanism over competitive designs and Smith & Nephew's commitment to minimize wear due to micromotion.[5]

Polishing

Motion between the liner and shell has been proven to cause wear on the back side of the liner. The rougher the counterface, the more the wear. These facts support the need for a refined finish on the inside of the shell. The polished inner surface of REFLECTION Acetabular Components is a feature that has very low roughness that is within the standard required of femoral heads.[6]

Range of motion

Smith & Nephew understands the issue of impingement, and that range of motion (ROM) is not just dependent on neck design. As a result, REFLECTION liners are designed to allow maximum ROM when combined with Smith & Nephew stems and have been shown to improve ROM over competitive offerings.[7] The overhang, while giving 20° of additional support, maintains a low profile to minimize impingement.

Porous coating

All REFLECTION shells feature RoughCoat porous coating. RoughCoat provides a scratch-fit and enhances initial friction and stability. The 2-3 bead layering has a 20-40% average porosity and 170 microns average pore size. This pore size has been shown to promote bone in-growth.[8] The sintered beads provide a three-dimensional interlock with bone that plasma spray cannot offer.[9]

Hole cover

Having an apex hole in the shell allows easy assessment of cup seating.[10] The watertight apex hole cover has a unique design that seals the shell, which prevents debris transfer as well as minimizes polyethylene creep.[11]

Poly thickness

With a 5mm thick liner for the 46mm OD cup and 7mm for the 50mm cup (for a 28mm femoral head), REFLECTION Acetabular Components meet the challenge of poly thickness.[12,13] Unlike many acetabular cup designs, our poly thickness is not compromised by the locking mechanism. If additional thickness is desired, the lateralized liners can be used, allowing 4mm more thickness at the apex and approximately 2mm additional thickness in the load-bearing area (Table A).

Polyethylene thickness									
	Acetabular cup size								
Femoral head size	42	44	46-48	50-52	54-56	58-60	62-64	66-68	70-76
22mm	6	7	8	10	12	13	15	17	19
26mm	NA	5	6	8	10	11	13	15	17
28mm	NA	NA	5	7	9	10	12	14	16
32mm	NA	NA	NA	5	7	8	10	12	14
36mm	NA	NA	NA	NA	5	6	8	10	12

Table A

REFLECTION® INTERFIT® Porous-Coated Acetabular Components
Design features

Proportional press-fit

Acetabular bone strains and press-fit stability can be influenced by the amount of oversizing (difference between shell size and reamed acetabular cavity). If the same amount of oversizing is used throughout all shell sizes, bone strains and risk of fracture may be higher for smaller acetabula,[14] with a greater risk of inadequate press-fit stability in a larger acetabulum. The REFLECTION INTERFIT shell is designed to address this issue by making the peripheral expansion of the shell proportional; less for a small shell and more for a large component (Table B).

Press-fit stability can also be influenced by variations in shell geometry. The shape of the REFLECTION INTERFIT shell is specifically designed to increase lateral rather than medial acetabular bone strains. The elastic recoil of the bone at the periphery enhances press-fit stability. "Overstuffing" at the dome, however, can create a reaction force that tends to push the shell out of the acetabulum (Figure 1).

Shell size (mm)	Peripheral press-fit (mm)
42	1.50
44	1.50
46	1.55
48	1.60
50	1.65
52	1.70
54	1.75
56	1.80
58	1.85
60	1.90
62	1.95
64	2.00
66	2.05
68	2.10
70	2.15
72	2.20
74	2.25
76	2.30

Table B

Peripheral build-up

The REFLECTION INTERFIT shell is designed to maximize press-fit stability. The periphery of the shell is slightly wider than a hemisphere providing an increased peripheral press-fit when used with hemispherical reamers. The geometry of the REFLECTION INTERFIT shell maximizes peripheral bone strains without increasing medial bone strains.

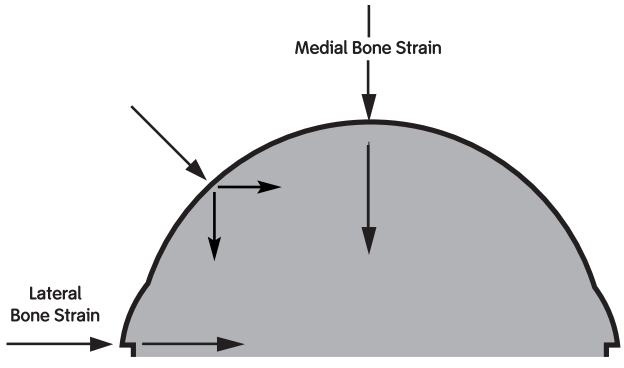


Figure 1

Rim cutout

When a press-fit acetabular shell displaces *in vivo*, it often tilts toward a more vertical position (Figure 2). Bone which overhangs an acetabular shell can contribute to implant stability by preventing the inferior rim of the shell from rotating laterally. The outer rim of the REFLECTION® INTERFIT® shell has a cutout section which is designed to permit bone to overhang the rim without interfering with seating of the polyethylene liner (Figure 3). This effectively creates a low-profile contour which can also facilitate more complete shell seating.

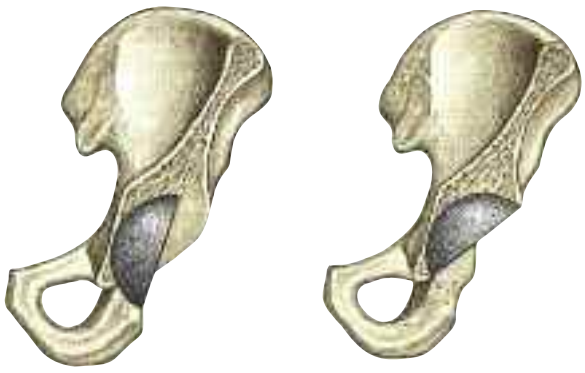


Figure 2
Hemispherical shell displacement Correct alignment

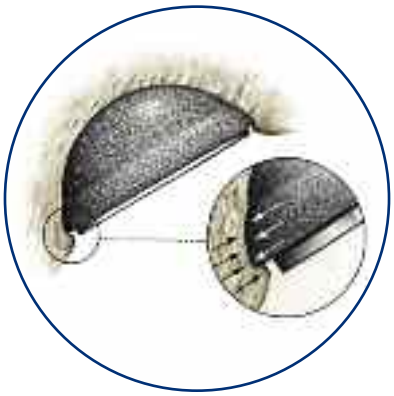


Figure 3

Edge of shell presses against bone. Elastic recoil of bone causes bone to overhang shell rim, resisting vertical displacement.

Screw hole placement

In primary cementless total hip arthroplasty, acetabular screws should be placed superiorly into the thickest bone for maximum fixation and safety. This thick bone, described by Wasielewski, et al, covers a fairly small region of the acetabulum.[14] By placing these three holes in a symmetrical pattern, the cup can easily be oriented properly to place screws in this region for the left or right acetabulum (Figure 4).

Figure 4

Bone depth >35mm

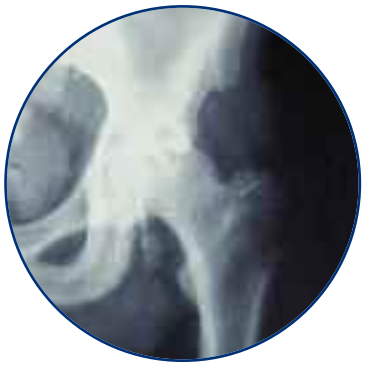
Bone depth >25mm

Screws

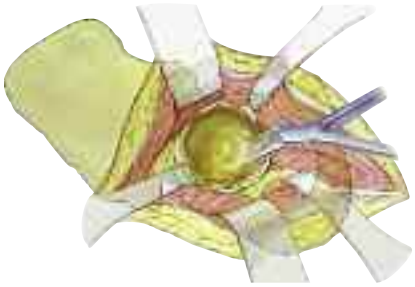
REFLECTION spherical head screws come in a variety of lengths. All are 6.5mm cancellous screws with a 4.0mm minor diameter. The root diameter provides a stronger screw – 56% stronger than one with a 3.2mm root diameter.

REFLECTION◇ INTERFIT◇ Porous-Coated Acetabular Components

Short technique

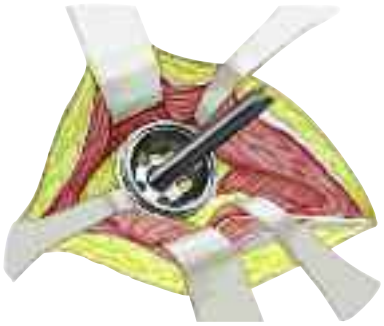


1. Preoperative planning

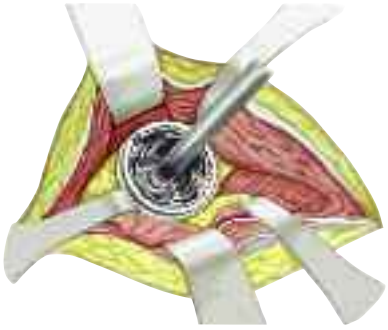


2. Acetabular exposure

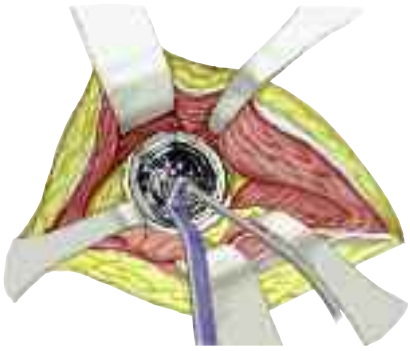
3. Acetabular reaming



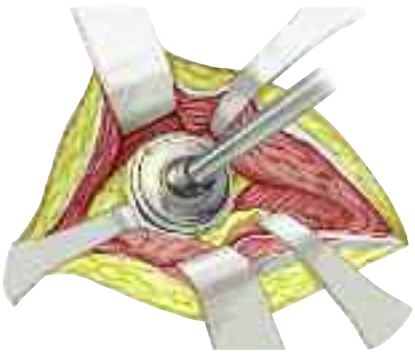
4. Acetabular trialing



5. Acetabular shell insertion



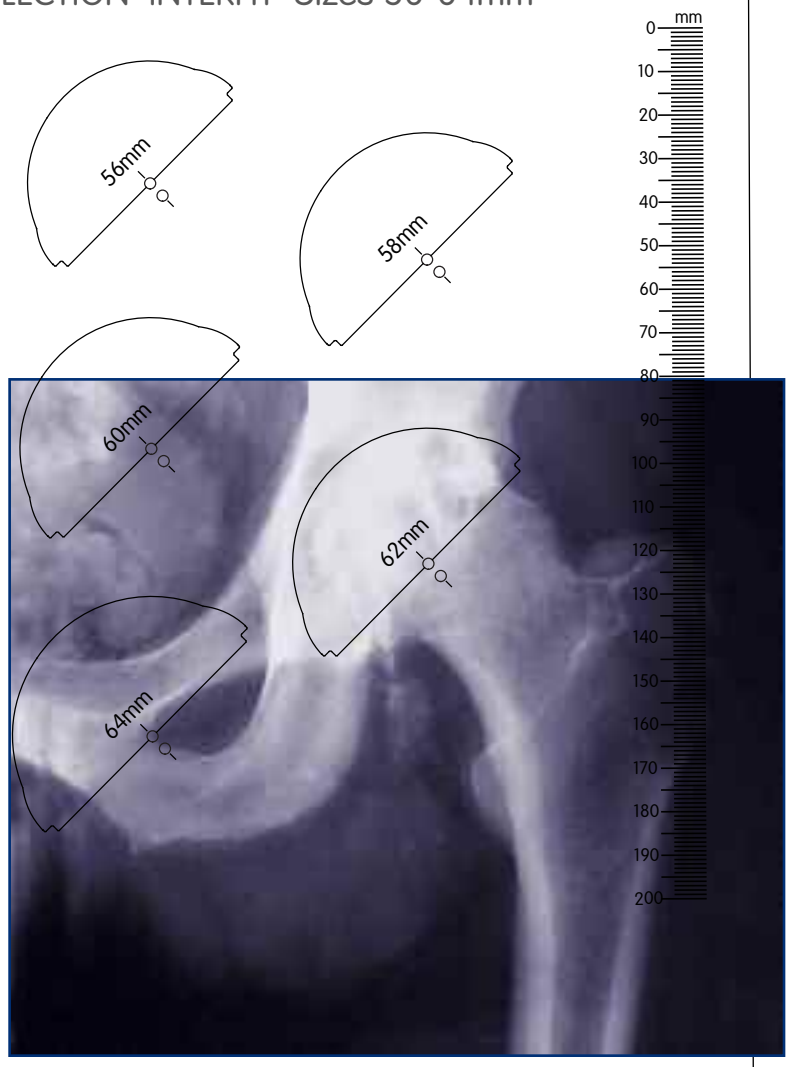
6. Acetabular screw insertion



7. Acetabular liner insertion

Preoperative planning

REFLECTION® INTERFIT® Sizes 56-64mm



120% magnification
Shown with standard and +4mm lateralized liner head centers.

Preoperative X-Rays should include an AP of the pelvis centered over the hips and a lateral of the affected hip.

Templating can be done on the affected side, but it is important that the contralateral hip also be templated to verify the size.

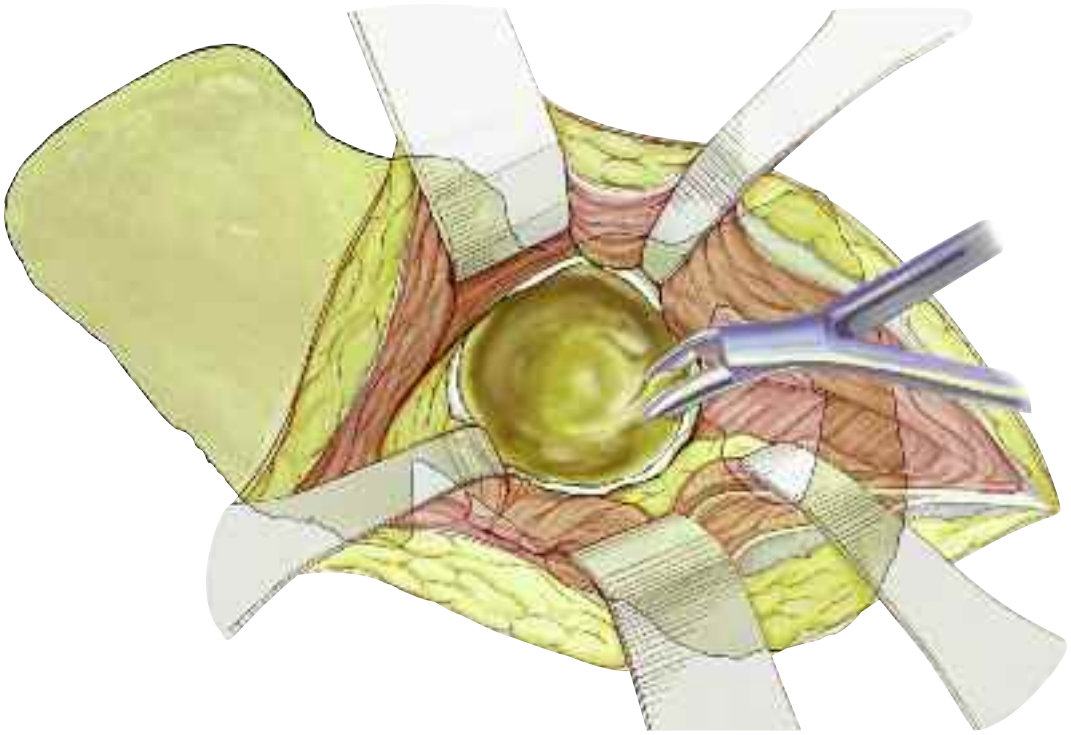
To ensure a congruent fit, the acetabular component should sit against the subchondral bone and the medial aspect of the acetabulum, as indicated by the teardrop.

The center of rotation also should be marked for subsequent reference.

Instrument tip:
The templates have holes that allow you to mark the center of the standard liner or the +4mm lateralized liner.

REFLECTION® INTERFIT® Porous-Coated Acetabular Components

Acetabular exposure



Complete exposure of the acetabulum is required, regardless of the type of approach.

First, resect the acetabular labrum and place a blunt retractor anteriorly.

After identifying the transverse acetabular ligament, divide it inferiorly and place a blunt retractor around the inferior margin of the acetabulum.

Depending on the exposure, a third retractor can be placed posteriorly following the excision of the labrum.

Remove all soft tissue and osteophytes in order to define the medial wall.

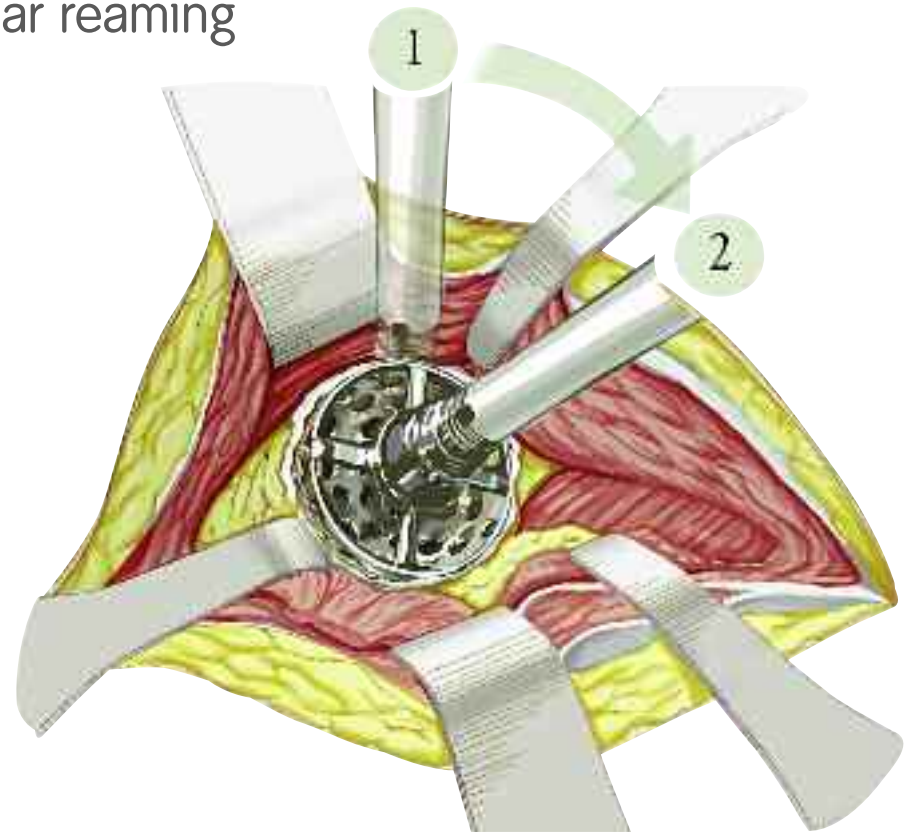
The acetabulum must be medialized to restore the normal center of hip rotation.

Surgical tips:
To minimize the need of assistance, each of the acetabular retractors can be tied directly to a Charnley retractor.

Dividing the transverse acetabular ligament will allow reaming to begin inferiorly, preventing the tendency of the reamer to migrate superiorly.

A medial osteophyte is often present in the fovea, which is usually visible on the preoperative radiographs.

Acetabular reaming



Select an acetabular reamer that is considerably smaller than the templated size of the cup. Generally, a 46mm reamer is suitable.

Position the initial reamer in a vertical direction (1) to ensure the reamer is taken down to the medial wall.

Direct the second reamer and all subsequent reamers in approximately 45° of abduction and 20° of anteversion for final position of the acetabular component (2).

Preserve subchondral bone to provide good support for the prosthesis.

Frequently palpate the posterior and anterior walls of the acetabulum during the reaming process as these walls will determine the largest acetabular size that can be accommodated.

To press-fit porous-coated REFLECTION® INTERFIT® cups, the acetabulum should be reamed to the same size shell inserted. For example, if the final reamer used is a 54mm, then the shell inserted should be a 54mm, providing a line-to-line fit at the dome and a proportional peripheral press-fit.

Surgical tips:
Each successive reamer must be fully seated within the acetabulum. Failure to do so will result in lateralization of the trial and exposure of the porous coating. If lateralization occurs, go back to a smaller reamer and begin again, checking each size to ensure that the reamers are fully seated.

Increasing the reamer size by 2mm is recommended, although in smaller patients 1mm increments may be preferred.

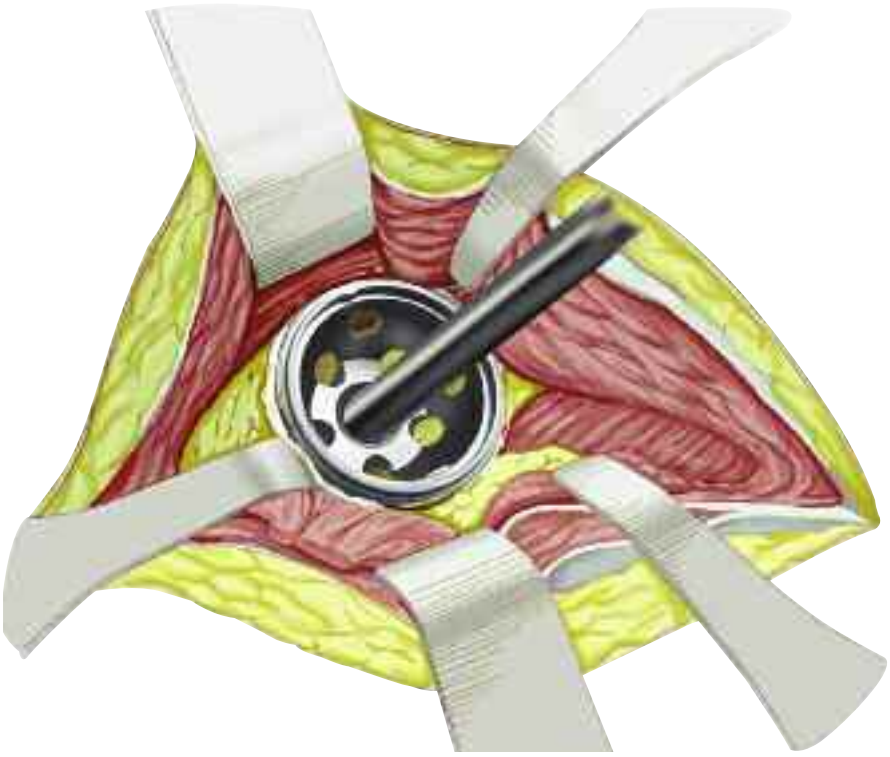
Mark the medial wall with an electrocautery prior to using the last reamer. If the last reamer does not remove the mark, repeat reaming.

Instrument tip:
The REFLECTION reamer has an open back, which helps visualize reaming and allows easy access to bone chips. This style of reamer is hemispherical and when fully seated it should be covered by the rim of the acetabulum.

Gently rock reamer handle back and forth approximately 5° for last size used ONLY to ensure rim is accurate for the desired press fit.

REFLECTION◇ INTERFIT◇ Porous-Coated Acetabular Components

Acetabular trialing



After the preparation of the acetabulum, the trial shell should be inserted to verify size and position of the cup.

If trial reduction using a trial insert is desired at this time, then the preparation of the femur should occur up until the trial reduction stage. The hip should be reduced and leg length, offset, and component position should be assessed.

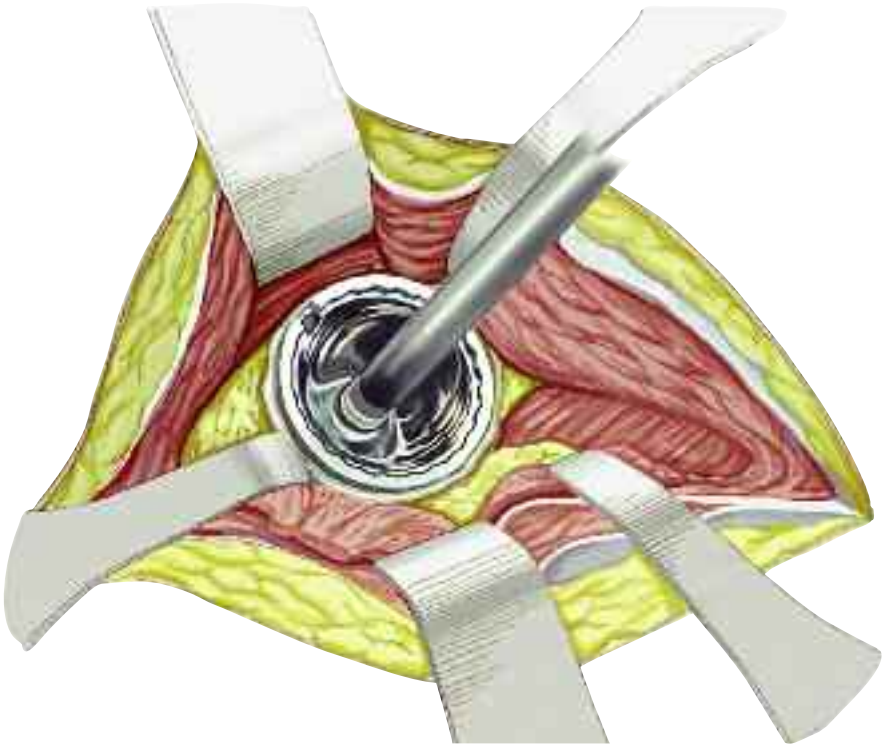
The surgeon should note the appropriate orientation of the acetabular trial to position the cup correctly.

Surgical tips:
The bone at the edge of the trial shell can be marked with an electrocautery to help in final component positioning.

In a relatively normal acetabulum, the final component can be positioned and head coverage adjusted if necessary using overhang liners.

Instrument tip:
The trial shells are the same size as the dome of the REFLECTION INTERFIT cup, but do not have a peripheral build-up. The trial shell should fit concentrically into the reamed acetabulum to ensure the REFLECTION INTERFIT cup will provide peripheral press-fit stability.

Acetabular shell insertion



The size of the REFLECTION® INTERFIT® shell selected should be the same as the largest diameter reamer used. Attach the shell to the cup positioner/impactor and insert it into the acetabulum.

Rotate the X-bar shaft so that it is in line with the liner removal slot. This positions the REFLECTION INTERFIT holes in the superior direction.

Position the X-bar so that the vertical bar is perpendicular to the long axis of the body and the appropriate crossbar aligns with the long axis of the body.

Firmly tap the inserter with a mallet until the cup is fully seated.

Gently toggle the impactor handle to assess the stability and contact of the shell.

Unscrew the impactor handle and look through the impactor hole to judge the distance between the medial wall and the shell.

If the cup is firmly seated, there should be no gap between the shell and the medial wall and no apparent movement in the component.

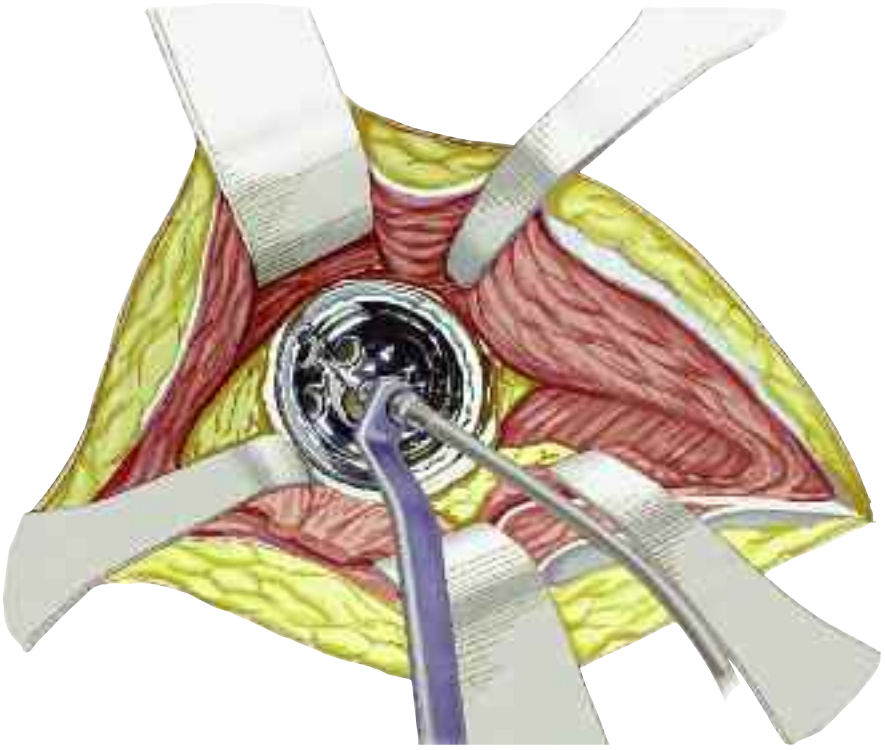
Surgical tip:
A change in pitch as the shell is seated against the medial wall is often not audible. A depth gauge or hemostat should be inserted through the screw holes and apex hole to determine the adequacy of cup seating.

Instrument tips:
The positioner, like the reamer handle, has an easy-to-remove spring to simplify cleaning; however, the spring and nut cannot detach from the shaft, which prevents items from being misplaced.

The positioner references 45° of abduction and 20° of anteversion.

REFLECTION® INTERFIT® Porous-Coated Acetabular Components

Acetabular screw insertion



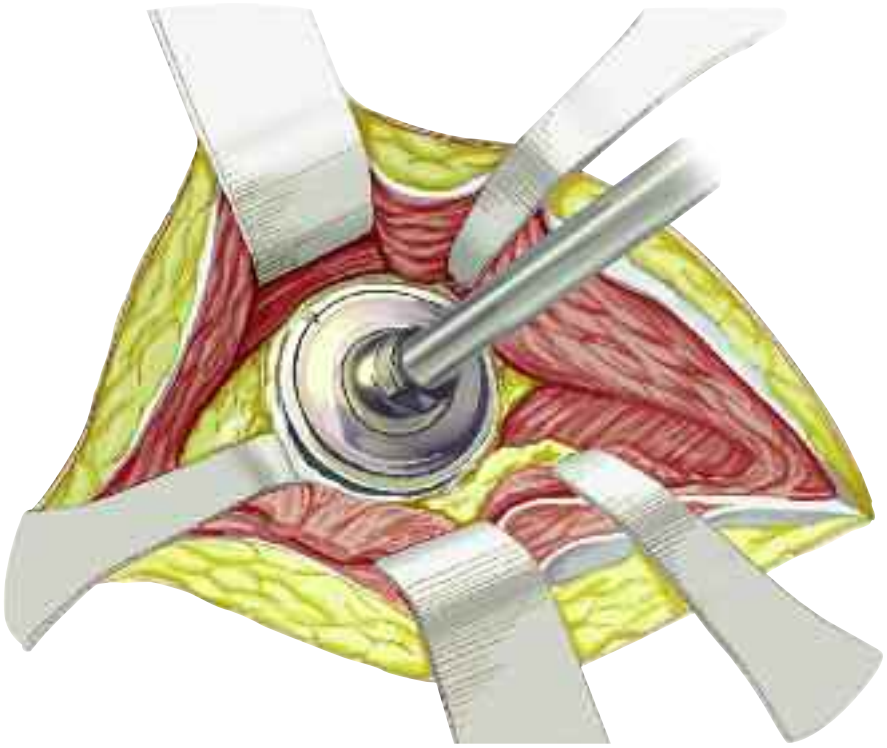
Screw fixation is simple, fast, and the most common method of assuring additional fixation. REFLECTION screws work in compression, which allows the shell to fully seat in the acetabular cavity.

For screw fixation, each screw hole must be predrilled. First, seat the screw drill guide fully into the correct hole in the acetabular shell. The drill guide will position the screw properly, avoiding impingement of the screw head against the shell. After drilling the hole, use the depth gauge to verify appropriate screw length(s).

Use the screw forceps to hold the screw. Attach the ball joint or flexible screwdriver shaft to the end of the screw. Then introduce the screw into the hole and screw it into place using the ratcheting screwdriver handle. Make sure the screw is fully seated within the screw hole so that it will not impinge on the acetabular shell/liner.

Surgical tip:
Screws have been shown to be a reliable method of assuring fixation; however, it is important to avoid neurovascular complications by proper screw placement, avoiding the anterior/superior or anterior/inferior quadrants.

Acetabular liner insertion



Trial reduction should be performed with the final shell and broach in place to appropriately assess head length, stem offset, and liner style and position stem type (standard or high offset), neck length, and liner type (neutral, +4mm, overhang). Every attempt should be made to avoid the use of "skirted" modular heads.

Before inserting the acetabular polyethylene liner, lavage any unused holes and insert the hole covers. Using the angled hole cover inserter, place screw hole covers over any remaining screw holes and then impact with the peg impactor. Cover the apex hole with the watertight threaded hole cover. Using the straight screwdriver, screw in the hole cover until it stops and is flush with the inner diameter of the shell.

For the liner insertion, place the appropriate liner impactor head on the end of the cup positioner and ensure that the splines on the liner are aligned with the splines on the shell.

Firmly impact the inserter with the mallet until the liner is fully seated.

Inspect the liner/shell interface for proper seating.

Surgical tips:
If there is continual difficulty inserting the liner, recheck the lock mechanism to assure that no soft tissue is obstructing it. Then chill the liner in cold saline for 2 or 3 minutes and fully seat the liner into the shell.

Use an instrument such as a hemostat to assure proper locking of the polyethylene insert. A properly locked liner will not toggle; however, due to the unique, non-damaging lock mechanism, the liner can be pulled out. If the liner is not locked in place, even low loads will toggle it.

Instrument tips:
The liner requires an impaction force between 120 and 200 pounds which increases with the diameter of the shell.

The liner can be removed and repositioned 3 times without compromising the locking mechanism of the liner. To remove, insert the removal tool fully into the removal slot and pry the liner loose.

The threaded trial liners are designed to screw into the shell, which provides more stability in trialing.

REFLECTION® Acetabular Components

Catalog

REFLECTION XLPE Acetabular Liners

0° Liner Cat. No	20° Liner Cat. No.	I.D. (mm)	O.D. (mm)	Liner Size
7133-3351	7133-3301	22	42	B
7133-3352	7133-3302	22	44	C
7133-3353	7133-3303	22	46-48	D
7133-3354	7133-3304	22	50-52	E
7133-3355	7133-3305	22	54-56	F
7133-3356	7133-3306	22	58-60	G
7133-3357	7133-3307	22	62-64	H
7133-3358	7133-3308	22	66-68	J
7133-3359	7133-3309	22	70-76	K
7133-3362	7133-3312	26	44	C
7133-3363	7133-3313	26	46-48	D
7133-3364	7133-3314	26	50-52	E
7133-3365	7133-3315	26	54-56	F
7133-3366	7133-3316	26	58-60	G
7133-3367	7133-3317	26	62-64	H
7133-3368	7133-3318	26	66-68	J
7133-3369	7133-3319	26	70-76	K
7133-3373	7133-3323	28	46-48	D
7133-3374	7133-3324	28	50-52	E
7133-3375	7133-3325	28	54-56	F
7133-3376	7133-3326	28	58-60	G
7133-3377	7133-3327	28	62-64	H
7133-3378	7133-3328	28	66-68	J
7133-3379	7133-3329	28	70-76	K
7133-3384	7133-3334	32	50-52	E
7133-3385	7133-3335	32	54-56	F
7133-3386	7133-3336	32	58-60	G
7133-3387	7133-3337	32	62-64	H
7133-3388	7133-3338	32	66-68	J
7133-3389	7133-3339	32	70-76	K
7133-3395	7133-3345	36	54-56	F
7133-3396	7133-3346	36	58-60	G
7133-3397	7133-3347	36	62-64	H
7133-3398	7133-3348	36	66-68	J
7133-3399	7133-3349	36	70-76	K

REFLECTION XLPE Lateralized (+4mm) Liners

0° Liner Cat. No	20° Liner Anteverted Cat. No.	I.D. (mm)	O.D. (mm)	Liner Size
7133-3451	7133-3401	22	42	B
7133-3452	7133-3402	22	44	C
7133-3453	7133-3403	22	46-48	D
7133-3454	7133-3404	22	50-52	E
7133-3455	7133-3405	22	54-56	F
7133-3456	7133-3406	22	58-60	G
7133-3457	7133-3407	22	62-64	H
7133-3458	7133-3408	22	66-68	J
7133-3459	7133-3409	22	70-76	K
7133-3462	7133-3412	26	44	C
7133-3463	7133-3413	26	46-48	D
7133-3464	7133-3414	26	50-52	E
7133-3465	7133-3415	26	54-56	F
7133-3466	7133-3416	26	58-60	G
7133-3467	7133-3417	26	62-64	H
7133-3468	7133-3418	26	66-68	J
7133-3469	7133-3419	26	70-76	K
7133-3473	7133-3423	28	46-48	D
7133-3474	7133-3424	28	50-52	E
7133-3475	7133-3425	28	54-56	F
7133-3476	7133-3426	28	58-60	G
7133-3477	7133-3427	28	62-64	H
7133-3478	7133-3428	28	66-68	J
7133-3479	7133-3429	28	70-76	K
7133-3484	7133-3434	32	50-52	E
7133-3485	7133-3435	32	54-56	F
7133-3486	7133-3436	32	58-60	G
7133-3487	7133-3437	32	62-64	H
7133-3488	7133-3438	32	66-68	J
7133-3489	7133-3439	32	70-76	K
7133-3495	7133-3445	36	54-56	F
7133-3496	7133-3446	36	58-60	G
7133-3497	7133-3447	36	62-64	H
7133-3498	7133-3448	36	66-68	J
7133-3499	7133-3449	36	70-76	K

REFLECTION® Acetabular Liners

0° Liner Cat. No.	20° Liner Cat. No.	I.D. (mm)	O.D. (mm)	Liner Size
7174-2042	7174-2242	22	42	B
7174-2044	7174-2244	22	44	C
7174-2046	7174-2246	22	46-48	D
7174-2050	7174-2250	22	50-52	E
7174-2054	7174-2254	22	54-56	F
7174-2058	7174-2258	22	58-60	G
7174-0644	7174-2644	26	44	C
7174-0646	7174-2646	26	46-48	D
7174-0650	7174-2650	26	50-52	E
7174-0654	7174-2654	26	54-56	F
7174-0658	7174-2658	26	58-60	G
7174-0846	7174-2846	28	46-48	D
7174-0850	7174-2850	28	50-52	E
7174-0854	7174-2854	28	54-56	F
7174-0858	7174-2858	28	58-60	G
7174-0862	7174-2862	28	62-64	H
7174-0866	7174-2866	28	66-68	J
7174-0870	7174-2870	28	70-76	K
7174-0250	7174-3250	32	50-52	E
7174-0254	7174-3254	32	54-56	F
7174-0258	7174-3258	32	58-60	G
7174-0262	7174-3262	32	62-64	H
7174-0266	7174-3266	32	66-68	J
7174-0270	7174-3270	32	70-76	K

REFLECTION Liner Impactor Head

Cat. No.	Size (mm)
7136-2222	22
7136-2226	26
7136-2228	28
7136-2232	32
7136-3622	36

Positioner/Impactor Replacement Tip
Cat. No. 7136-2109

REFLECTION Trial Shells

Cat. No.	O.D. (mm)	Cat. No.	O.D. (mm)
Standard Size Trial Shells		**Small Size Trial Shells**	
7136-2345	45	7136-2340	40
7136-2346	46	7136-2341	41
7136-2347	47	7136-2342	42
7136-2348	48	7136-2343	43
7136-2349	49	7136-2344	44
7136-2350	50		
7136-2351	51	**Large Size Trial Shells**	
7136-2352	52	7136-2365	65
7136-2353	53	7136-2366	66
7136-2354	54	7136-2367	67
7136-2355	55	7136-2368	68
7136-2356	56	7136-2369	69
7136-2357	57	7136-2370	70
7136-2358	58	7136-2371	71
7136-2359	59	7136-2372	72
7136-2360	60	7136-2373	73
7136-2361	61	7136-2374	74
7136-2362	62	7136-2375	75
7136-2363	63	7136-2376	76
7136-2364	64		

REFLECTION Trial Shell Handle
Cat. No. 7136-2297

REFLECTION Positioner/Impactor
Cat. No. 7136-2299

REFLECTION Liner Removal Tool
Cat. No. 7136-2296

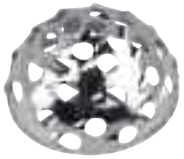
REFLECTION® Acetabular Components Catalog

REFLECTION Screw-in Trial Liners

0° Liner Cat. No.	20° Liner Cat. No.	I.D. (mm)	O.D (mm)	Liner Size
7136-2243	7136-2242	22	42	B
7136-2245	7136-2244	22	44	C
7136-2247	7136-2246	22	46-48	D
7136-2251	7136-2250	22	50-52	E
7136-2255	7136-2254	22	54-56	F
7136-2259	7136-2258	22	58-60	G
7136-2263	7136-2262	22	62-64	H
7136-2267	7136-2266	22	66-68	J
7136-2271	7136-2270	22	70-76	K
7136-2645	7136-2644	26	44	C
7136-2647	7136-2646	26	46-48	D
7136-2651	7136-2650	26	50-52	E
7136-2655	7136-2654	26	54-56	F
7136-2659	7136-2658	26	58-60	G
7136-2663	7136-2662	26	62-64	H
7136-2667	7136-2666	26	66-68	J
7136-2671	7136-2670	26	70-76	K
7136-2847	7136-2846	28	46-48	D
7136-2851	7136-2850	28	50-52	E
7136-2855	7136-2854	28	54-56	F
7136-2859	7136-2858	28	58-60	G
7136-2863	7136-2862	28	62-64	H
7136-2867	7136-2866	28	66-68	J
7136-2871	7136-2870	28	70-76	K
7136-3251	7136-3250	32	50-52	E
7136-3255	7136-3254	32	54-56	F
7136-3259	7136-3258	32	58-60	G
7136-3263	7136-3262	32	62-64	H
7136-3267	7136-3266	32	66-68	J
7136-3271	7136-3270	32	70-76	K
7136-3655	7136-3654	36	54-56	F
7136-3659	7136-3658	36	58-60	G
7136-3663	7136-3662	36	62-64	H
7136-3667	7136-3666	36	66-68	J
7136-3671	7136-3670	36	70-76	K

REFLECTION Lateralized Screw-in Trial Liners (+4mm)

0° Liner Cat. No.	20° Liner Anteverted Cat. No.	I.D. (mm)	O.D (mm)	Liner Size
7136-2235	7136-2238	22	42	B
7136-2236	7136-2239	22	44	C
7136-2249	7136-2248	22	46-48	D
7136-2253	7136-2252	22	50-52	E
7136-2257	7136-2256	22	54-56	F
7136-2261	7136-2260	22	58-60	G
7136-2265	7136-2264	22	62-64	H
7136-2269	7136-2268	22	66-68	J
7136-2273	7136-2272	22	70-76	K
7136-2636	7136-2635	26	44	C
7136-2649	7136-2648	26	46-48	D
7136-2653	7136-2652	26	50-52	E
7136-2657	7136-2656	26	54-56	F
7136-2661	7136-2660	26	58-60	G
7136-2665	7136-2664	26	62-64	H
7136-2669	7136-2668	26	66-68	J
7136-2673	7136-2672	26	70-76	K
7136-2849	7136-2848	28	46-48	D
7136-2853	7136-2852	28	50-52	E
7136-2857	7136-2856	28	54-56	F
7136-2861	7136-2860	28	58-60	G
7136-2865	7136-2864	28	62-64	H
7136-2869	7136-2868	28	66-68	J
7136-2873	7136-2872	28	70-76	K
7136-3253	7136-3252	32	50-52	E
7136-3257	7136-3256	32	54-56	F
7136-3261	7136-3260	32	58-60	G
7136-3265	7136-3264	32	62-64	H
7136-3269	7136-3268	32	66-68	J
7136-3273	7136-3272	32	70-76	K
7136-3657	7136-3656	36	54-56	F
7136-3661	7136-3660	36	58-60	G
7136-3665	7136-3664	36	62-64	H
7136-3669	7136-3668	36	66-68	J
7136-3673	7136-3672	36	70-76	K



REFLECTION® Reamer Domes

Cat. No.	Size (mm)	Cat. No.	Size (mm)
Standard Size Domes		**Small Size Domes**	
7136-2742	42	7136-2738	38
7136-2743	43	7136-2739	39
7136-2744	44	7136-2740	40
7136-2745	45	7136-2741	41
7136-2746	46		
7136-2747	47	**Large Size Domes**	
7136-2748	48	7136-2765	65
7136-2749	49	7136-2766	66
7136-2750	50	7136-2767	67
7136-2751	51	7136-2768	68
7136-2752	52	7136-2769	69
7136-2753	53	7136-2770	70
7136-2754	54	7136-2771	71
7136-2755	55	7136-2772	72
7136-2756	56	7136-2773	73
7136-2757	57	7136-2774	74
7136-2758	58	7136-2775	75
7136-2759	59	7136-2776	76
7136-2760	60		
7136-2761	61		
7136-2762	62		
7136-2763	63		
7136-2764	64		

Watertight Hole Cover
Cat. No. 7133-0001

REFLECTION Ratchet Handle
Cat. No. 7136-2294

REFLECTION Reamer Handle
Cat. No. 7136-2279

Power Adapters
Cat. No. 7136-2781
Cat. No. 7136-2782
Cat. No. 7136-2783

REFLECTION X-Bar
Cat. No. MT-2201

REFLECTION Main Instrument Tray
(Shown with instruments)
Cat. No. 7136-2280

REFLECTION Primary Reamer Tray
(Shown with instruments)
Cat. No. 7136-2281

REFLECTION Large Reamer/Trial Tray
Cat. No. 7136-2284

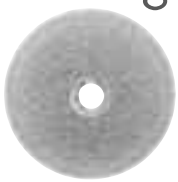
REFLECTION Small Reamer/Trial Tray
Cat. No. 7136-2286

REFLECTION Trial Shell Tray
Cat. No. 7136-2282

REFLECTION Jumbo Reamer/Trial Tray
Cat. No. 7136-2285

REFLECTION Additional Trial Liner Tray
Cat. No. 7136-2283

REFLECTION◇ INTERFIT◇ Porous-Coated Acetabular Components Catalog



INTERFIT NO HOLE

Cat. No.	O.D. (mm)	Liner Size	Liner I.D. (mm)
7133-4042	42	B	22
7133-4044	44	C	22, 26
7133-4046	46	D	22, 26, 28
7133-4048	48	D	22, 26, 28
7133-4050	50	E	22, 26, 28, 32
7133-4052	52	E	22, 26, 28, 32
7133-4054	54	F	22, 26, 28, 32, 36
7133-4056	56	F	22, 26, 28, 32, 36
7133-4058	58	G	22, 26, 28, 32, 36
7133-4060	60	G	22, 26, 28, 32, 36
7133-4062	62	H	22, 26, 28, 32, 36
7133-4064	64	H	22, 26, 28, 32, 36
7133-4066	66	J	22, 26, 28, 32, 36
7133-4068	68	J	22, 26, 28, 32, 36

INTERFIT MULTI-HOLE

Cat. No.	O.D. (mm)	Liner Size	Liner I.D. (mm)
7133-5050	50	E	22, 26, 28, 32
7133-5052	52	E	22, 26, 28, 32
7133-5054	54	F	22, 26, 28, 32, 36
7133-5056	56	F	22, 26, 28, 32, 36
7133-5058	58	G	22, 26, 28, 32, 36
7133-5060	60	G	22, 26, 28, 32, 36
7133-5062	62	H	22, 26, 28, 32, 36
7133-5064	64	H	22, 26, 28, 32, 36
7133-5066	66	J	22, 26, 28, 32, 36
7133-5068	68	J	22, 26, 28, 32, 36
7133-5070	70	K	22, 26, 28, 32, 36
7133-5072	72	K	22, 26, 28, 32, 36
7133-5074	74	K	22, 26, 28, 32, 36
7133-5076	76	K	22, 26, 28, 32, 36

INTERFIT THREE HOLE

Cat. No.	O.D. (mm)	Liner Size	Liner I.D. (mm)
7133-6042	42	B	22
7133-6044	44	C	22, 26
7133-6046	46	D	22, 26, 28
7133-6048	48	D	22, 26, 28
7133-6050	50	E	22, 26, 28, 32
7133-6052	52	E	22, 26, 28, 32
7133-6054	54	F	22, 26, 28, 32, 36
7133-6056	56	F	22, 26, 28, 32, 36
7133-6058	58	G	22, 26, 28, 32, 36
7133-6060	60	G	22, 26, 28, 32, 36
7133-6062	62	H	22, 26, 28, 32, 36
7133-6064	64	H	22, 26, 28, 32, 36
7133-6066	66	J	22, 26, 28, 32, 36
7133-6068	68	J	22, 26, 28, 32, 36

REFLECTION Spherical Head Screws

Cat. No.	Length (mm)
7133-2515	15
7133-2520	20
7133-2525	25
7133-2530	30
7133-2535	35
7133-2540	40
7133-2545	45
7133-2550	50
7133-2560	60
7133-2570	70

REFLECTION® Mallet
Cat. No. 7136-2106

REFLECTION Ball Joint Screwdriver
Cat. No. 7136-2295

REFLECTION Depth Gauge
Cat. No. 7136-2012

REFLECTION Flexible Screwdriver Shaft
Cat. No. 7136-2290

REFLECTION Captured Flexible Screwdriver Shaft
Cat. No. 7136-2291

REFLECTION Straight Screwdriver Shaft
Cat. No. 7136-2293

REFLECTION Captured U-Joint Screwdriver Shaft
Cat. No. 7136-2292

REFLECTION Screw Drill Guide
Cat. No. 7136-2919

REFLECTION Screw Forceps
Cat. No. 7136-2298

REFLECTION Hole Cover Inserter
Cat. No. 73-2133

REFLECTION Angled Peg Impactor
Cat. No. 73-2117

Flexible Screw Drills

Cat. No.	Length (mm)
7136-2915	15
7136-2925	25
7136-2935	35
7136-2950	50

Important Medical Information
Total Hip System

Important Note

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

Materials

Femoral components are cobalt chromium alloy, titanium 6Al-4V alloy or stainless steel. Femoral heads are cobalt chromium alloy, OXINIUM© oxidized zirconium, BIOLOX® forte alumina ceramic, BIOLOX delta alumina/zirconia ceramic or stainless steel. Acetabular liners are ultra-high molecular weight polyethylene (UHMWPE), cobalt chromium (CoCr) alloy, BIOLOX forte alumina ceramic, or BIOLOX delta alumina/zirconia ceramic. All poly acetabular components are UHMWPE. Acetabular shells are titanium 6Al-4V alloy or cobalt chromium (CoCr). The component material is provided on the outside carton label.

Note: BIOLOX delta ceramic liners are not available in the US.

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

Description of System

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

Femoral Components

Femoral components are available in a variety of sizes. Porous coated components are coated for biological ingrowth and are intended to be used without cement. Modular femoral components are available with an oval taper to accept Smith & Nephew, Inc. CoCr modular necks and/or a Morse type taper to accept proximal sleeves. Non-porous femoral components can feature PMMA centralizers that help produce a uniform thickness of cement.

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

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

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

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

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

Taper Sleeves

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

Modular Necks

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

Femoral Heads

Cobalt chromium, stainless steel, oxidized zirconium, and ceramic heads are available in multiple neck lengths for proper anatomic and musculature fit. Heads are highly polished for reduced friction and wear.

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

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

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

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

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

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

*Not available in the US.

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

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

*BH Modular Heads are not available in the US.

Acetabular Components

Acetabular components can be one-piece all polyethylene, or two-piece, consisting of a titanium shell and either a UHMWPE liner, BIOLOX forte ceramic liner, BIOLOX delta ceramic liner or CoCr metal liner. For BIOLOX forte ceramic liners available for use with the REFLECTION© Ceramic Acetabular System in the US, refer to the separate package insert provided with these components. See Warnings and Precautions for specific information on screws, pegs and hole covers use. Acetabular reinforcement and reconstruction rings are used with an all polyethylene acetabular component. Note: BIOLOX delta ceramic liners are not available in the US. For R3 metal liners available for use with the BIRMINGHAM HIP Resurfacing (BHR) System in the US, refer to the separate package insert provided with these components.

Note: 10 Mrad cross-linked UHMWPE acetabular liners may be used with metal (CoCr), oxidized zirconium, BIOLOX forte ceramic heads or BIOLOX delta ceramic heads.

Femoral components and femoral heads are designed for use with any Smith & Nephew polyethylene acetabular component or polyethylene-lined, metal-backed acetabular component having an appropriately-sized inside diameter. Acetabular liners are designed for use only with acetabular shells from the same product family (i.e. REFLECTION liners can only be used with REFLECTION shells; R3 liners can only be used with R3 shells).

INDICATIONS, CONTRAINDICATIONS, AND ADVERSE EFFECTS

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

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

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

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

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

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

Contraindications

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

Contraindications may be relative or absolute and must be carefully weighed against the patient's entire evaluation and the prognosis for possible alternative procedures such as non-operative treatment, arthrodesis, femoral osteotomy, pelvic osteotomy, resection arthroplasty, hemiarthroplasty and others.

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

Possible Adverse Effects

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

Warnings and Precautions

The patient should be warned of surgical risks, and made aware of possible adverse effects. The patient should be warned that the device does not replace normal healthy bone, that the implant can break or become damaged as a result of activity or trauma, and that it has a finite expected service life and may need to be replaced in the future. Do not mix components from different manufacturers unless specially approved by the manufacturer of the components. For purposes of product inter-compatibility, products manufactured and labeled by entities formerly known as Plus Endoprothetik, Intraplant, Precision Implants and Plus Orthopedics (now Smith & Nephew Orthopaedics AG) may be considered as the same manufacturer, Smith & Nephew. Additional Warnings and Precautions may be included in component literature.

Preoperative

1. Use extreme care in handling and storage of implant components. Cutting, bending, or scratching the surface of components can significantly reduce the strength, fatigue resistance, and/or wear characteristics of the implant system. These, in turn, may induce internal stresses that are not obvious to the eye and may lead to fracture of the component. Implants and instruments should be protected from corrosive environments such as salt air during storage. Do not allow the porous surfaces to come in contact with cloth or other fiber-releasing materials.
2. Allergies and other reactions to device materials, although infrequent, should be considered, tested for (if appropriate), and ruled out preoperatively.
3. Fixation and expected longevity of components expected to be left in place at revision surgery should be thoroughly assessed.
4. Surgical technique information is available upon request. The surgeon should be familiar with the technique. Refer to medical or manufacturer literature for specific product information.
5. Intraoperative fracture or breaking of instruments can occur. Instruments which have experienced extensive use or excessive force are susceptible to fracture. Instruments should be examined for wear, or damage, prior to surgery. Single use devices should not be reused due to risks of breakage, failure or patient infection.
6. Do not cold water quench ceramic components and never sterilize ceramic heads while fixed on the stem taper. (See sterilization section, below.)
7. OXINIUM© oxidized zirconium femoral heads and cobalt chrome femoral heads are designed to articulate with UHMWPE bearing surfaces. BIOLOX forte ceramic femoral heads and BIOLOX delta ceramic femoral heads articulate with UHMWPE liners or cups, BIOLOX forte ceramic liners or BIOLOX delta ceramic liners. OXINIUM oxidized zirconium femoral heads, cobalt chrome femoral heads, BIOLOX forte ceramic femoral heads and BIOLOX delta ceramic femoral heads should never articulate against metal because severe wear of the bearing surfaces may occur. BHR resurfacing heads and Birmingham Hip CoCr modular heads articulate with Birmingham Hip acetabular cups or R3 metal liners. Note: BIOLOX delta ceramic liners and Birmingham Hip CoCr modular heads are not available in the US.
8. Select only Smith & Nephew femoral components that indicate their use with ceramic heads. This is important because the taper on the stem is machined to tightly mate and lock with the ceramic head thus preventing rotation of the ceramic head on the stem. Also, an improperly dimensioned taper could result in fracture of the ceramic head.
9. Alumina ceramic should never articulate against metal because severe wear could occur.
10. The SL-PLUS© Stems, SL-PLUS Lateralized Stems, SLR-PLUS© Stems and SL-PLUS MIA Stems are compatible with Smith & Nephew ball heads, including Unipolar and Bipolar, with the exception of +16 offset all sizes. Do not use the Smith & Nephew +16 heads with SL-PLUS Stems and SLR-PLUS Stems.
11. If a computer assisted surgery system is used, consult the applicable software and hardware reference manuals provided by the manufacturer to ensure proper operation of this equipment.

Intraoperative

1. The general principles of patient selection and sound surgical judgment apply. The correct selection of the implant is extremely important. The appropriate type and size should be selected for patients with consideration of anatomical and biomechanical factors such as patient age and activity levels, weight, bone and muscle conditions, any prior surgery and anticipated future surgeries, etc. Generally, the largest cross-section component which will allow adequate bone support to be maintained is preferred. Failure to use the optimum-sized component may result in loosening, bending, cracking, or fracture of the component and/or bone.
2. Correct selection of the neck length and cup, and stem positioning, are important. Muscle looseness and/or malpositioning of components may result in loosening, subluxation, dislocation, and/or fracture of components. Increased neck length and varus positioning will increase stresses which must be borne by the stem. The component should be firmly seated with the component insertion instruments.
3. Care should be taken not to scratch, bend (with the exception of the Reconstruction Rings) or cut implant components during surgery for the reasons stated in Number One of the "Pre-Operative" section of "Warnings and Precautions."
4. A +12 mm or +16 mm femoral head should not be used with any Small taper stems.
5. MATRIX© Small taper stem sizes 8S - 10L must have a minimum neck length of +8 mm when used with a bipolar component; and Small taper stem sizes 12S - 16L must have a minimum neck length of +4 mm when used with a bipolar component.
6. Modular heads, modular necks, modular sleeves and femoral components should be from the same manufacturer unless specially approved by the manufacturer of the components to prevent mismatch.
7. Stainless steel heads and stainless steel stems should only be used together. Neither should be used with other metal components.
8. Use only REFLECTION Liners with REFLECTION Shells. Use only R3 Liners with R3 Shells.
9. Clean and dry all taper connections prior to impacting for assembly. The modular femoral head, neck and/or sleeve components must be firmly seated on the femoral component to prevent disassociation.
10. Take care, when positioning and drilling screw and peg holes, to avoid penetration of the inner cortex of the pelvis, penetration of the sciatic notch, or damage to vital neurovascular structures. Perforation of the pelvis with screws that are too long can rupture blood vessels causing the patient to hemorrhage. Do not place a screw in the center hole of the acetabular prosthesis. Placement of drills and screws in the anterior or medial portions of the prosthesis is associated with a high risk of potentially fatal vascular injury. Bone screws must be completely seated in the holes of the shell to allow proper locking for the acetabular component liner. If the tapered pegs need to be removed from the shell after impaction of the pegs, do not reuse the pegs or the peg shell holes. Use new pegs and different shell holes, or a new shell if necessary.
11. REFLECTION Three Hole, FSO, INTERFIT© and R3 Shells accept both REFLECTION spherical head screws and Universal cancellous bone screws. REFLECTION FSO and INTERFIT Shells accept the Modified REFLECTION screw hole covers. The REFLECTION V Shell only accepts Universal Cancellous, REFLECTION screws, tapered screw-hole covers and tapered, pegs. REFLECTION Peripheral Hole Screws should only be used with REFLECTION Peripheral Hole Shells. Locking Head Pegs and REFLECTION Locking Head Screw Hole Covers are only for use with REFLECTION Three Hole Shells. The threaded center hole in REFLECTION Shells only accepts threaded hole covers, not screws or pegs. The INTERFIT threaded hole cover is only for use with REFLECTION INTERFIT, Spiked and No Hole Shells. The REFLECTION threaded hole cover can be used with all REFLECTION and R3 shells. The R3 screw hole cover can be used with R3 and REFLECTION Three Hole shells. Refer to product literature for proper adjunctive fixation and hole cover usage.
12. Prior to seating modular components, surgical debris including tissue must be cleaned from the surfaces. Debris, including bone cement, may inhibit the component locking mechanism. If the shell is to be cemented in place, remove extraneous cement with a plastic sculps tool to ensure proper locking of the liner. During liner insertion, make sure soft tissue does not interfere with the shell/liner interface. Chilling the liner reduces the impaction force required to seat the liner. Modular components must be assembled securely to prevent disassociation. Debris inhibits the proper fit and locking of modular components which may lead to early failure of the procedure. Failure to properly seat the acetabular liner into the shell can lead to disassociation of the liner from the shell.
13. Avoid repeated assembly and disassembly of the modular components which could compromise the critical locking action of the locking mechanism.
14. Care is to be taken to assure complete support of all parts of the device embedded in bone cement to prevent stress concentration which may lead to failure of the procedure. During curing of the cement, care should be taken to prevent movement of the implant components.
15. If the head is removed from a femoral component that will be left in place at revision surgery, it is recommended that a metal head be used. A ceramic head may fracture from irregularities on the femoral component taper.
16. If components are to be left in place at revision surgery, they should first be thoroughly checked for signs of looseness, etc. and replaced if necessary. The head/neck component should be changed only when clinically necessary.
17. Once removed from the patient, implants previously implanted should never be reused, since internal stresses which are not visible may lead to early bending or fracture of these components. Reuse may also increase the risk of patient infection.
18. With the congenitally dislocated hip, special care should be taken to prevent sciatic nerve palsy. Also, note that the femoral canal is often very small and straight and may require an extra-small straight femoral prosthesis; however, a regular-sized prosthesis should be used when possible. Note that the true acetabulum is rudimentary and shallow. A false acetabulum should not ordinarily be utilized as a cup placement site for anatomical and biomechanical reasons.
19. With rheumatoid arthritis, especially for those patients on steroids, bone may be extremely osteoporotic. Care should be taken to prevent excessive penetration of the acetabular floor or fracture of the medial acetabular wall, femur, or greater trochanter.
20. Revision procedures for previous arthroplasty, Girdlestone, etc., are technically demanding and difficult to exercise. Common errors include misplacement of the incision, inadequate exposure or mobilization of the femur, inadequate removal of ectopic bone, or improper positioning of components. Postoperative instability as well as excessive blood loss can result. In summary, increased operative time, blood loss, increased incidence of pulmonary embolus and wound hematoma can be expected with revision procedures.
21. Prior to closure, the surgical site should be thoroughly cleaned of cement, bone chips, ectopic bone, etc. Ectopic bone and/or bone spurs may lead to dislocation or painful or restricted motion. Range of motion should be thoroughly checked for early contact or instability.
22. Proper positioning of the components is important to minimize impingement which could lead to early failure, premature wear, and/or dislocation.
23. In order to minimize the risks of dislocation and loosening of the shell-acetabular bone or shell-bone cement interface that may occur when using a metallic shell intended for biological fixation or cemented use only, surgeons should consider providing immediate resistance to tensile forces between the metallic shell and the acetabular bone or bone cement interface through the use of orthopedic bone fixation devices such as bone screws, spikes, screw threads, pegs, fins, or other bone fixation devices.
24. Physicians should consider component malposition, component placement, and the effect on range of motion when using modular heads (with sleeves or skirts) and extended liners.
25. For computer assisted surgery systems, it is extremely important to correctly select input parameters (e.g. bony landmarks). Operators of this equipment should be familiar with the anatomy relevant to the procedure. Failure to provide proper input could cause problems such as violation of critical anatomical structures and malpositioned implants.
26. Do not implant HA-coated devices in bone cement.

Postoperative

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

Magnetic Resonance Imaging (MRI) Safety

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

Packaging and Labeling

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

Sterilization

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

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

Recommended Steam Sterilization Cycle Parameters

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

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

Retrieval and Analysis of Removed Implants

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

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

INFORMATION

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

Manufacturing facilities and EC representative:

Smith & Nephew Inc.
1450 Brooks Road
Memphis, TN 38116 U.S.A.
Tel.: 901-396-2121

Smith & Nephew Orthopaedics GmbH
Alemannenstrasse 14
78532 Tuttlingen, Germany
Tel.: 07462/208-0
Fax: 07462/208-135

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

H_2O_2 – hydrogen peroxide sterilization

 – For cemented use only

 – For uncemented use only

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