Surgical Technique

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REDAPT◇

Revision Femoral System

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Smith & Nephew would like to acknowledge the contributions of the following surgeons with whom we designed the REDAPT Revision Femoral System:

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

REDAPT® Revision Femoral System by Smith & Nephew is uniquely designed to address the challenges in today's revision hip arthroplasty: fixation in various bone types, proximal/distal mismatch without compromising stem strength, independent achievement of joint stability, predictable stem position, and surgical efficiency. It all starts with ROCKTITE® flutes which provide rock-solid distal fixation in all bone types.

The adaptable design allows the surgeon to customize the proximal/distal mismatch for the best stem fit without compromising stem strength. Further, the surgeon is able to achieve joint stability through independent adjustment of neck angle, height, offset, and version. Finally, surgeons have shown that REDAPT offers reproducible stem position which is achieved by the combination of ROCKTITE fixation and highly efficient, easy to use instrumentation.

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.

REDAPT Revision Femoral System components are intended for single use only and are to be implanted without bone cement.

Implants

REDAPT implants are designed to provide distal fixation with secondary proximal support allowing the surgeon intra-operative flexibility to achieve the best patient fit. Better fixation and fit should provide better implant stability and outcomes.

REDAPT is a tapered, forged titanium stem with proprietary ROCKTITE distal flutes for improved diaphyseal fixation. REDAPT is available in two stem styles — Proximally Fluted and Modular Sleeved. Together these styles allow the surgeon to address a wide spectrum of revision types.

The Proximally Fluted (PF) stem includes stem and modular neck (Figure 1) and the Modular Sleeved (MS) stem includes stem, proximal sleeve and modular neck (Figure 2). Both styles are available in sizes 12-27 (in 1mm increments) and lengths of 240mm and 300mm.

REDAPT modular sleeves provide secondary proximal support to the distal fixation and enhance implant stability. The titanium conical sleeves are coated with Smith & Nephew STIKTITE® and hydroxyapatite (HA). Sleeves are available in small, medium, and large sizes. An extra small sleeve is available with grit blast finish and HA coating. Implanting the Modular Sleeved stem without a sleeve is not recommended.

REDAPT◇ Proximally Fluted (PF) Stem

Figure 1

Modular neck

- Cobalt chrome
- 12/14 Head taper
- Circulotrapezoidal neck
- 5 Neck options
  - Offset: Standard and high
  - Height: high offset +10
  - Version: anteverted left and right
- Provides 54 head center options
- Compatible with Smith & Nephew heads

Stem

- Forged Titanium tapered, fluted cylinder with proprietary ROCKTITE◇ flutes
- Diameters: 12-27mm (1mm increments)
- Lengths: 240mm and 300mm
  - Stem length is measured from +0 head center at the greater trochanter to distal tip of the stem

REDAPT◇ Modular Sleeved (MS) Stem

Modular sleeve

- Titanium
- HA on grit blast
  – Extra small
- HA on STIKTITE◇ coating
  – Small, medium, large
- 50mm length

Modular neck

- Cobalt chrome
- 12/14 Head taper
- Circulotrapezoidal neck
- 5 Neck options
  – Offset: Standard and high
  – Height: high offset +10
  – Version: anteverted left and right
- Provides 54 head center options
- Compatible with Smith & Nephew heads

Stem

- Forged Titanium tapered stem with proprietary ROCKTITE◇ flutes
- Diameter: 12mm–27mm (1mm increments)
- Lengths: 240mm and 300mm
  – Stem length is measured from +0 head center at the greater trochanter to distal tip of the stem

Figure 2

Modular neck options

Modular necks allow the surgeon to make adjustments for a stable joint. The modular necks are available in five options: standard offset, high offset, high offset +10mm, anteverted left and anteverted right. In combination with all Smith & Nephew head lengths, bidirectional assembly of these five necks allows the surgeon 54 head center options to fine tune offset, leg length and version, thereby achieving optimal fit and function for each patient.

Each neck is made of cobalt chrome with a 12/14 taper for use with compatible cobalt chrome, ceramic and OXINIUM® heads. The circulotrapezoidal neck is designed for increased range of motion. The following table and illustrations show the total offset and height for each REDAPT stem and neck option in a standard orientation (arrow pointed up on the neck).

	Modular neck option (standard is +0 head center)							
	SO Neck		**HO Neck**		**+10 HO Neck**		**ANT Neck**	
Size (mm)	**Height (mm)**	**Offset (mm)**	**Height (mm)**	**Offset (mm)**	**Height (mm)**	**Offset (mm)**	**Height (mm)**	**Offset (mm)**
12-15	33	37	33	45	43	45	33	43
16-27	35	42	35	50	45	50	35	48

PF 15 with HO neck

Sleeved 15 with HO neck

The following table shows the impact on offset, leg length, version and neck angle when making a change in the neck orientation (relative to the standard offset neck with +0 head).

Neck type	Modular neck shaft angle/ orientation		Effect (relative to standard offset neck with +0 head) Offset (mm)	Leg length (mm)	Version (°) Ante+/Retro-
Standard offset	131°		0	0	0
High offset	Varus 125°		+8	0	0
	Valgus 137°		0*	+8	0
High offset +10 (For use with REDAPT® Revision Hip System)	Varus 125°		+8	+10	0
	Valgus 137°		+11	+6	0

Left hip Neck type	Modular neck shaft angle / orientation		Effect (relative to standard offset neck with +0 head) Offset (mm)	Leg Length (mm)	Version (°) Ante+/Retro-
Left anteverted	Varus 125°		+6	0	+10
	Valgus 137°		*0	+6	-10
Right anteverted	Varus 125°		+6	0	-10
	Valgus 137°		*0	+6	+10

Green for left anteverted necks

Red for right anteverted necks

Right hip Neck type	Modular neck shaft angle / orientation		Effect (relative to standard offset neck with +0 head) Offset (mm)	Leg Length (mm)	Version (°) Ante+/Retro-
Right anteverted	Varus 125°		+6	0	+10
	Valgus 137°		*0	+6	-10
Left anteverted	Varus 125°		+6	0	-10
	Valgus 137°		*0	+6	+10

*Note that anything less than 2mm was deemed negligible with regard to offset or leg length adjustment for the purpose of clarity.

Instruments

REDAPT® instruments are designed to maximize surgical efficiency and improve accuracy and reproducibility of implant position during the procedure. This is accomplished by reaming and trialing "over the top" of the distal reamers. Distal and proximal reamers are color-coded to provide easy identification of implant sizes and reduce unnecessary instruments.

Distal reamers allow the surgeon to properly prepare and size the canal for optimal fit of the tapered, fluted distally fixed stem. When used in conjunction with trial bodies and necks, the distal reamers function as intramedullary trials which should provide the surgeon with a more accurate assessment of implant positioning while reducing the number of instruments and trial components. Distal reamers are available in diameters of 10mm to 27mm in 1.0mm increments and lengths of 240mm and 300mm.

The proximal reamers are uniquely designed to be used over the distal reamers. By reaming "over the top" the surgeon is preparing for the proximal aspect of the stem (including if desired the modular sleeve) based on the location of the distal reamer. During canal preparation, "over the top" reaming allows the surgeon to maintain the relative position of the proximal and distal reamed cavities to accept the implant of choice. Proximal reamers are available in sizes which correspond to the Proximally Fluted stem and the extra small, small, medium and large sleeve for each Modular Sleeved stem size.

Proximal reamer color code chart

Distal reamer/ implant size	Color of reamer/ implant	Proximal Reamers by number*												
		Starter	1	2	3	4	5	6	7	8	9	10	11	12
12	Purple	PF		12/13XS	12/13S	12/13M	12/13L							
13	Purple	PF		12/13XS	12/13S	12/13M	12/13L							
14	Black		PF		14/15XS	14/15S	14/15M	14/15L						
15	Black		PF		14/15XS	14/15S	14/15M	14/15L						
16	Blue			PF		16/17XS	16/17S	16/17M	16/17L					
17	Blue			PF		16/17XS	16/17S	16/17M	16/17L					
18	Red				PF		18/19XS	18/19S	18/19M	18/19L				
19	Red				PF		18/19XS	18/19S	18/19M	18/19L				
20	Copper					PF		20/21XS	20/21S	20/21M	20/21L			
21	Copper					PF		20/21XS	20/21S	20/21M	20/21L			
22	Gray						PF		22/23XS	22/23S	22/23M	22/23L		
23	Gray						PF		22/23XS	22/23S	22/23M	22/23L		
24	Brown						PF			24/25XS	24/25S	24/25M	24/25L	
25	Brown						PF			24/25XS	24/25S	24/25M	24/25L	
26	White						PF				26/27XS	26/27S	26/27M	26/27L
27	White						PF				26/27XS	26/27S	26/27M	26/27L

* PF = Proximally fluted

Preoperative planning and templating

Preoperative planning for a revision total hip arthroplasty requires at a minimum a standard set of radiographs, which includes an antero-posterior (A-P) radiograph of the pelvis and a lateral radiograph of the affected hip. Depending on the length of the existing femoral component several additional radiographs may be necessary. Specifically, the A-P and lateral radiographs should include the entire femoral component. On occasion a full-length A-P radiograph of the entire femur may be necessary. As part of the preoperative work-up, the surgeon may consider other imaging modalities such as bone scans and computerized tomography (CT). However, these are not typically necessary for preoperative templating.

Determine the appropriate classification for the femoral revision, for example the Paprosky Revision Classification.[1] This will aid in determining the appropriate type, size and position of the revision stem you will need.

As with primary THA preop planning, establishing proper leg length requires assessment of a number of clinical and radiographic parameters. Establishing the proper reference lines requires using a horizontal line between the inferior portion of the teardrop as well as a horizontal line between the inferior margin of the obtruator foramen and ischial tuberosity. Due to the often distorted anatomy in revision cases, utilizing all three reference lines may be necessary.

Similarly, due to bony defects on the femoral side, a combination of anatomic landmarks such as the superior margin of the greater trochanter and inferior margin of the lesser trochanter must be utilized. These obviously need to be compared to similar points in the contralateral side using the A-P radiograph. Any pelvic obliquities and/or spinal deformity must also be taken into account based on radiographic and clinical assessments. The consideration of all relevant factors is necessary to successfully restore the patient's proper leg length.

Surgeon tip The use of simple wooden blocks during the preoperative physical examination of the patient is very useful, as is a discussion of the patient's perceived length elicited during their preop interview.

[1] Paprosky Femoral Revision Classification

The A-P radiograph is also critical in assessing proper femoral offset. If there is a native hip on the contralateral side, the proper offset can be determined by the horizontal distance between the center of rotation of the head and anatomic axis of the femur. If there is a well functioning total hip prosthesis on the contralateral side, a similar assessment can be made using the REDAPT® templates. As noted previously, REDAPT offers several offset, version and leg length options with the modular neck components including standard and high. See the REDAPT neck option chart for more details.

Difficulties sometimes arise when the contralateral hip is deformed or has a malfunctioning THA. Additional problems may be encountered if the ipsilateral acetabulum has failed or has a protrusio deformity. In these cases it is up to the surgeon to determine intraoperatively what the proper offset should be so as to achieve a hip that is stable without impingement in all physiological positions.

Once the bone stock has been assessed and proper leg length and offset has been determined the surgeon should template the femur to determine the appropriate stem size. If there is any compromise in the diaphyseal femoral bone, it is recommended that the implant bypass the deficient bone by approximately 7-12cm.

Once a preliminary estimate of the proper femoral stem size is accomplished, the proper sleeve may be approximated using the templates. REDAPT templates are available in digital and acetate formats (Figure 3). Consult your Smith & Nephew representative for assistance in obtaining templates.

Surgeon tip After the preliminary femoral stem and sleeve sizes are determined, physically draw these on the A-P radiograph in proper position. Drawing is valuable when selecting the proper implant in conjunction with the intraoperative findings so as to establish the proper implant position.

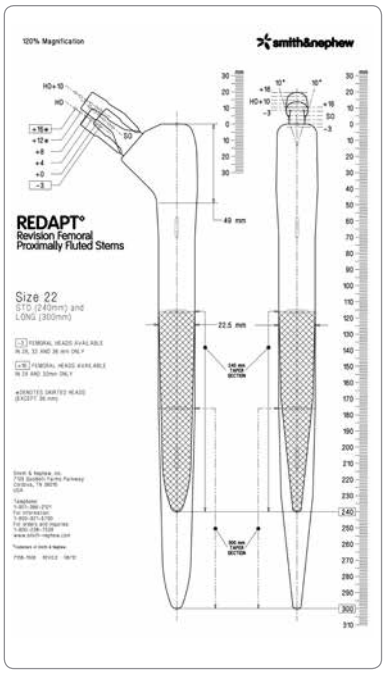
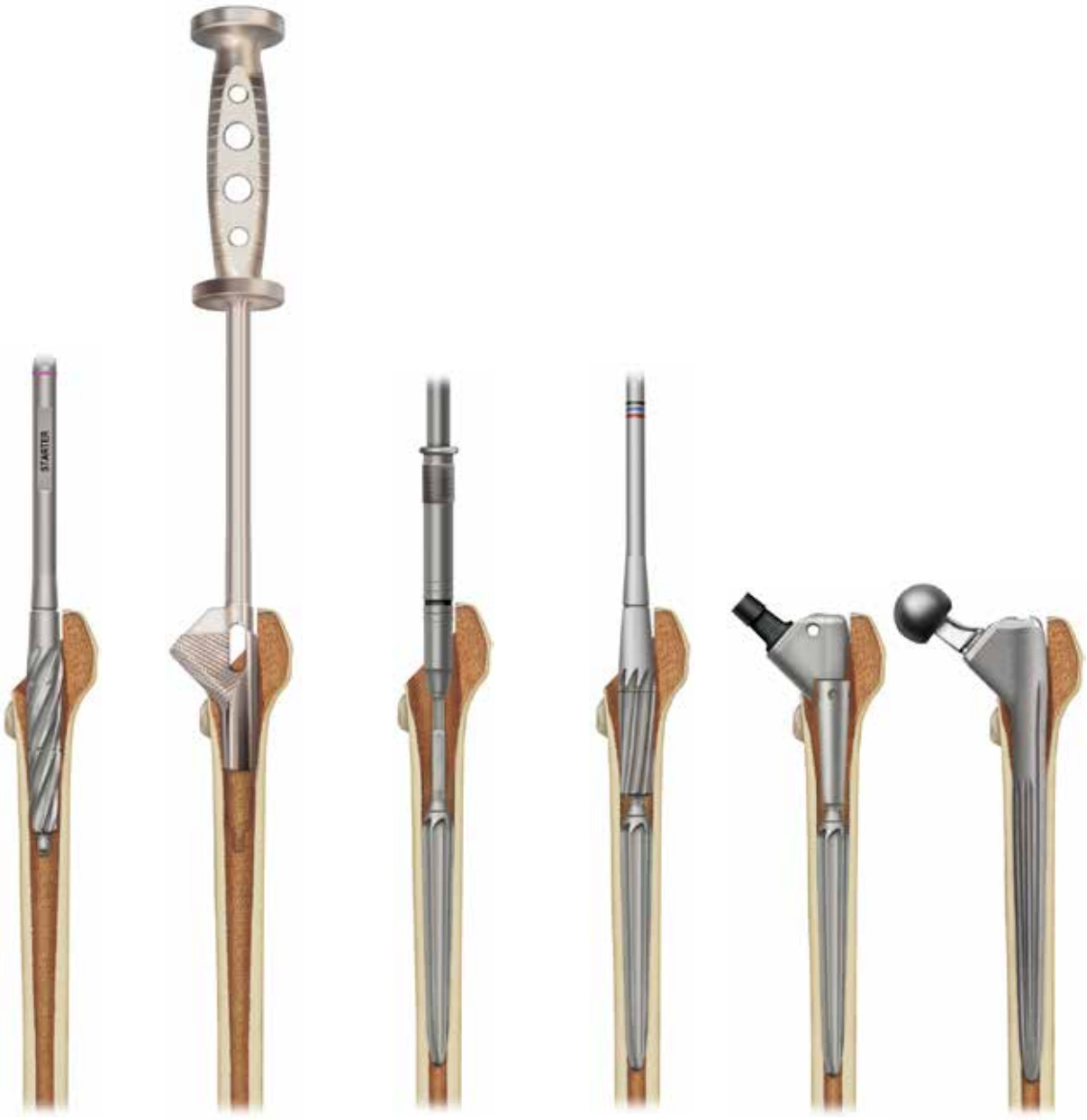


Figure 3

REDAPT◇ Proximally Fluted (PF) Stem

Abbreviated Surgical Technique



Starter ream **Rasp** **Distal ream** **Proximal ream** **Trial** **Implant**

The following technique should be used when implanting the REDAPT Proximally Fluted implants. Before surgery, review instrument sets to ensure all instruments are present and working properly.

Removal of current implant

Remove the current implant and cement (if present) from top of the femoral canal or via an extended trochanteric osteotomy (ETO).

Surgeon tip If using an ETO, place a cable or cerclage wire slightly distal to the osteotomy or the existing stem before reaming, trialing and inserting the stem to minimize risk of propagating a crack or fracture.

Femoral preparation

The starter reamer can be used to open the proximal aspect of the femur to remove bone from the greater trochanteric or medial calcar regions. The presence of this bone will be largely dependent on the stem previously implanted and the stem removal process. Use the starter reamer to remove lateral bone as shown in Figure 4. Removing lateral bone is important for maintaining neutral stem placement.

Caution Align etched depth mark on starter reamer to greater trochanter to ensure proper proximal fit of stem.

Position the medial rasp in the proximal femur as required to achieve appropriate stem version.

Hold the rasp firmly in the desired position and impact it as you would a broach, using a mallet to strike the flat top of the rasp handle.

Note that the platform at the proximal aspect of the rasp indicates where the top of the stem will sit and neutral head position is achieved. Repeat impaction until the rasp is seated at the preferred depth (Figure 5).

Figure 4

Figure 5
Arrow indicates alignment of the greater trochanter and top of PF stem in a neutral head center position

Distal reaming

Select the appropriate reamer for the length of stem chosen: 240mm reamers should be used for 240mm stems and 300mm reamers should be used for 300mm stems.

Attach the quick connect to the appropriate distal reamer(Figure 6).

Set power in forward position and ream the distal femoral canal until desired distal fit is achieved. Begin reaming with a distal reamer that is at least 2mm smaller than the templated size or a reamer that has little or no resistance. To minimize potential risk of reaming through the anterior cortex, direct the reamer from anterior to posterior. Care should be taken to avoid bone or surrounding soft tissue when introducing reamers.

Note Do not strike the quick connect or distal reamers.

Surgeon tip Ream until you hear cortical chatter, the reamer contains cortical bone debris, and the reamer does not progress. The reaming technique may be more aggressive than with a cylindrical porous stem.

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

Figure 6

Progressively ream in 1mm increments. Note the color code marked on the shaft of select distal reamers. This color will identify available implant sizes and appropriate instrumentation for subsequent steps.

The size of the PF stem is 0.25mm greater than the equivalently sized reamer, providing a press fit of 0.25mm.

The depth of the reamer is determined by aligning the mark on the quick connect which represents the +0 head center, with the greater trochanter (Figure 7). If the greater trochanter is not available then an alternative anatomical reference must be made. A ruler can be used to measure from the distal end of the osteotomy to the previous location of the greater trochanter. (Ruler not included in instrument set.) Ream consistently to the determined land mark.

Figure 7
Black line on quick connect indicates alignment of greater trochanter or other predetermined landmark

Proximally Fluted (PF) Stem Surgical Technique

Upon achieving desired distal fit, disengage the quick connect and power, apply a T-handle and ensure the reamer does not rotate or translate axially. Leave final distal reamer in the canal and note the size.

Proximal reaming

Select a proximal reamer that offers little or no resistance when placed over the shaft of the final distal reamer. Commence proximal reaming. The proximal reamer will rotate, however the distal reamer will act as a guide and should not advance. Although the distal reamer provides a positive depth stop for the proximal reamer, the surgeon may hear a click or observe that the etched depth mark is aligned to the greater trochanter or other predetermined reference location indicating the proximal reamer has bottomed out (Figure 8). During progressive reaming, pulse lavage may be used to remove bone debris from the canal so it will not impede the proximal reamer from bottoming out on the distal reamer.

Proximal and distal reamers with the same color code represent compatible and available implant options. For example, if the final distal reamer is 17 (blue), the corresponding 17 PF proximal reamer is identified by a blue band located near the chuck end and in the size markings on the shaft of the proximal reamer (Figure 9).

Progressively ream until the PF proximal reamer which corresponds to the distal reamer size is reached. Ream consistently to the determined landmark. Remove the proximal reamer, leaving the distal reamer in position.

Figure 8

Figure 9
Color coding corresponds to the reamer and stem size

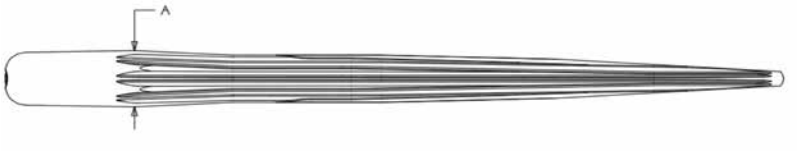
Proximal reamer color code chart

Distal reamer/ implant size	Color of reamer/ implant	Proximal Reamers by number*												
		Starter	1	2	3	4	5	6	7	8	9	10	11	12
12	Purple	PF		12/13XS	12/13S	12/13M	12/13L							
13	Purple	PF		12/13XS	12/13S	12/13M	12/13L							
14	Black		PF		14/15XS	14/15S	14/15M	14/15L						
15	Black		PF		14/15XS	14/15S	14/15M	14/15L						
16	Blue			PF		16/17XS	16/17S	16/17M	16/17L					
17	Blue			PF		16/17XS	16/17S	16/17M	16/17L					
18	Red				PF		18/19XS	18/19S	18/19M	18/19L				
19	Red				PF		18/19XS	18/19S	18/19M	18/19L				
20	Copper					PF		20/21XS	20/21S	20/21M	20/21L			
21	Copper					PF		20/21XS	20/21S	20/21M	20/21L			
22	Gray						PF		22/23XS	22/23S	22/23M	22/23L		
23	Gray						PF		22/23XS	22/23S	22/23M	22/23L		
24	Brown						PF			24/25XS	24/25S	24/25M	24/25L	
25	Brown						PF			24/25XS	24/25S	24/25M	24/25L	
26	White						PF				26/27XS	26/27S	26/27M	26/27L
27	White						PF				26/27XS	26/27S	26/27M	26/27L

* PF = Proximally fluted

The following information illustrates the approximate proximal size of each PF stem.

PF stem size	
Color	**A dimension**
12/13 PF	17.5
14/15 PF	17.5
16/17 PF	19.5
18/19 PF	21.5
20/21 PF	23.5
22/23 PF	25.5
24/25 PF	25.5
26 PF	26.5
27 PF	27.5



Trialing

Assemble trial components over the proximal end of the distal reamer starting with the proximal trial spacer then the trial body and finally with neck trials (Figure 10). Check the proximal spacer and trial body for soft tissue and/or bone debris that may impede the components from seating properly.

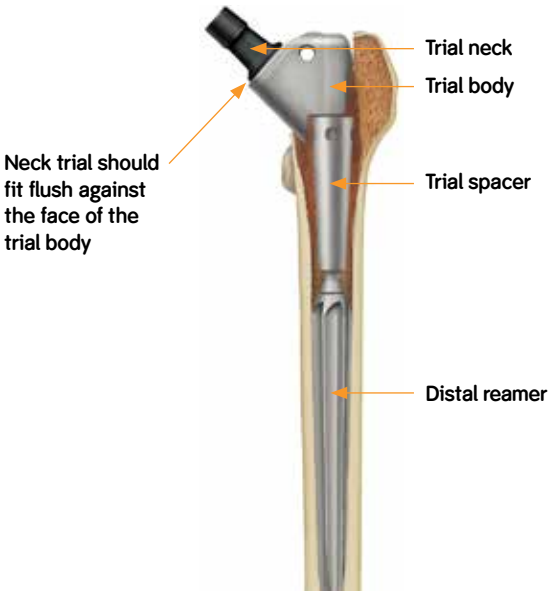


Figure 10

Trial bodies have been designed so that the teeth on the underside of the body mate with the teeth on the proximal spacer when initially placed. When the components are properly mated the screw on the top of the trial body pops up. See Figure 11.

Secure the trial components together by tightening the screw of the trial body with the trial assembly instrument. Advance the trial body screw until it is flush with the top of the trial body. Figure 12 and 13.

Dry the neck pocket and tapered end of the trial neck thoroughly with a sterile cloth or 4x4. Insert the selected trial neck in the desired orientation, Standard or Reverse.

Ensure the arrow on the trial neck component is pointing superiorly for the Standard neck orientation (Figure 14) or inferiorly for the Reverse neck orientation.

Push by hand or, if necessary, tap the trial neck using the head impactor until it is flush with the face of the neck pocket. Do not use excessive force to seat the trial neck.

Attach the selected trial head to the trial neck. Perform trial reduction and range of motion (ROM) exercise to confirm proper seating of implant, assess joint tension, and ensure there is no impingement to the hip. Adjust trial components and position of trial neck to achieve desired leg length, neck offset, and neck version. For version adjustment, loosen trial body screw and rotate trial body to desired position. Use a cautery pen to mark desired position of the implant. Retighten screw and perform trial reduction again to confirm position.

Remove the trial neck by hand or by sliding the neck extractor around the base of the neck from the proximal end and tap lightly.

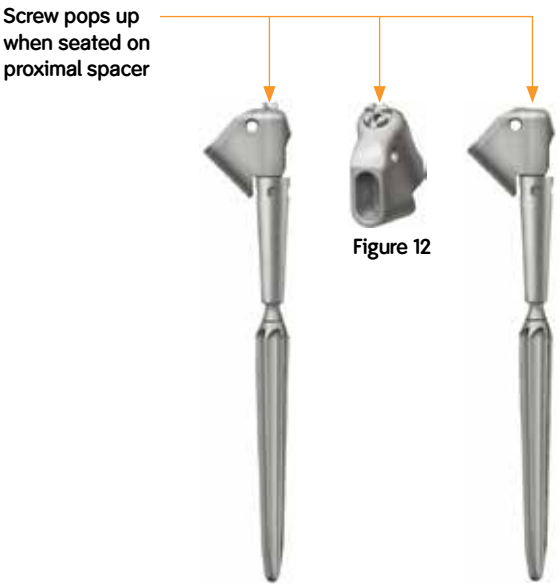


Figure 11

Figure 12

Figure 13

Figure 14

Trial/Reamer removal

Attach trial handle to trial removal hook (Figure 15). To remove the assembled trial components insert the trial removal hook through the cross hole of the trial body (Figure 16). Using gentle force, extract the trial components superiorly, to avoid damage to surrounding tissue.

Important Reamers and trials are not implantable devices and must be removed prior to implant insertion.

If trialing was not performed then the distal reamer component can be removed using the reamer removal tool. Screw the reamer removal cap completely onto the threads of the distal reamer, then place the trial removal hook assembled onto the trial handle through the cross hole in the reamer removal tool and use gentle force to extract superiorly (Figure 17).

If resistance occurs when removing the reamer, unscrew the distal reamer removal cap and assemble the quick connect. Using power or a T-handle reverse the reamer out of the canal.

Note Do not use other devices or instruments to remove reamer as these may damage the threads.

Figure 15

Figure 16

Figure 17

Implant assembly and insertion

Attach the implant driving platform of the stem inserter to the proximal end of the stem implant (Figure 18). To attach, stand the stem inserter upright so that the threaded tip is pointed up. Ensure that the lever handle is open on the stem inserter and screw the implant onto the threaded tip as far as possible. Flip the assembly over so that the stem tip is now pointing down. Engage the frame tines into the slots adjacent to the threaded hole on the stem. Rotate the pommel until the assembly is secure.

Caution Prior to use, inspect the inserter to ensure that the threads are not damaged and the tip is not bent. Do not over tighten the pommel as this may cause it to lock up during repeated impacting. Close the lever handle to lock the pommel.

Note Take care to protect all taper connections during the attachment of the stem inserter. Consider packing the open neck taper with clean dry sterile gauze to protect it during implantation.

Orient the stem to achieve the desired version. Insert the stem into the femoral canal using hand pressure. Once the stem is in the desired position, use a mallet to seat the stem. Once the stem is implanted, raise the lever on the inserter and unscrew the pommel to release the instrument from the stem.

Dry the neck pocket and tapered end of the trial neck with a sterile cloth or 4x4. Insert the selected trial neck in the desired orientation; Standard or Reverse.

Verify that the neck is in desired orientation (arrow pointed superior or inferior prior to final impaction (Figure 19).

Important Neck trials are not implantable devices and must be replaced with an implant neck.

Impact final neck and head implant components simultaneously with the head/neck impaction tool. Correct selection of the neck length and cup, and stem positioning are important. Muscle looseness and/or mal-positioning of components may result in loosening, subluxation, dislocation, and/or fracture of the component and/or bone. Perform final ROM with implants in position.

Figure 18

Figure 19

Modular Sleeved Stem

Abbreviated Surgical Technique

Distal ream **Proximal ream** **Trial** **Implant**

Modular Sleeved Stem Surgical Technique

The following technique should be used when implanting the REDAPT® Modular Sleeved implants. Before surgery, review instrument sets to ensure all instruments are present and working properly.

Removal of current implant

Remove the current implant and cement (if present) from top of the femoral canal or via an extended trochanteric osteotomy (ETO).

Surgeon tip If using an ETO, place a cable or cerclage wire slightly distal to the osteotomy before reaming, trialing and inserting the stem to minimize risk of propagating a crack or fracture.

Femoral preparation

Distal reaming

Attach the quick connect to the appropriate REDAPT distal reamer (Figure 20).

Figure 20

Ream the distal femoral canal in 1.0mm increments until desired distal fit is achieved. Begin reaming with a distal reamer that is at least 2mm smaller than the templated size or a reamer that has little or no resistance. To minimize potential risk of reaming through the anterior cortex, direct the reamer from anterior to posterior.

Note Do not strike the quick connect or distal reamers.

Surgeon tip Ream until you hear cortical chatter, the reamer contains cortical bone debris, and the reamer does not progress.
The reaming technique may need to be more aggressive than with a cylindrical porous stem.

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

Figure 21

When progressively reaming, note the color code marked on the shaft of select distal reamers. (Figure 21) This color will help identify available implant sizes and appropriate instrumentation for subsequent steps. Each color coded REDAPT distal reamer represents an available stem size.

The size of the distal fluted aspect of the stem is 0.25mm greater than the corresponding sized reamer, providing an automatic press fit of 0.25mm.

The depth of the reamer is determined by aligning the mark on the quick connect which represents the +0 head center, with the greater trochanter (Figure 22). If the greater trochanter is not available then an alternative anatomical reference must be made. A ruler can be used to measure from the distal end of the osteotomy to the previous location of the greater trochanter. (Ruler not included in instrument set.)

Figure 22

Upon achieving desired distal fit, disengage the quick connect and power. Leave final distal reamer in the canal.

Modular Sleeved Stem Surgical Technique

Proximal reaming

Optional Trial Step If the proximal section of the femur has sufficient bone loss an optional trialing step may be useful prior to proximal reaming. See *Trialing* section for more details. Prior to proximal reaming, remove all trial components. Leave distal reamer in the canal. See *Trial and reamer removal* section for additional details.

Select a REDAPT® proximal reamer that offers little or no resistance when placed over the shaft of the final distal reamer. If an ETO is not performed or if the femoral canal is small, the starter reamer may be necessary to remove bone that may impede the function of the proximal reamers. Commence proximal reaming. The proximal reamer will rotate, however the distal reamer will act as a guide and should not advance. Although the distal reamer provides a positive depth stop for the proximal reamer, the etched depth mark will also align to the greater trochanter or other predetermined reference location (Figure 23). Progressively ream using the proximal reamers until the desired proximal fit is achieved.

Proximal and distal reamers with the same color code represent compatible and available implant options. For example, if the final distal reamer is 17 (blue), the corresponding 16/17XS, 16/17S, 16/17M or 16/17L proximal reamers are identified by a blue band located near the chuck end (Figure 24). Refer to Proximal Reamer Color Code chart on page 7 for available options. The following chart shows the proximal and distal width dimensions of the REDAPT sleeves for each size stem as noted in the modular sleeve image to the right.

Figure 23

Figure 24
Color coding corresponds to the reamer and stem size

Modular sleeve

Sleeve sizing chart

Sleeve size corresponding to stem diameter and package/reamer color									STIKTITE® sleeve dimensions		Grit blasted sleeve dimensions	
Color code	Purple	Black	Blue	Red	Copper	Gray	Brown	White	Proximal (mm)	Distal (mm)	Proximal (mm)	Distal (mm)
Stem diameter (mm)	12/13	14/15	16/17	18/19	20/21	22/23	24/25	26/27	A	B	A	B
Sleeve options	12/13 XS										19.9	16.2
	12/13S	14/15XS							21.2	17.5	21.9	18.2
	12/13M	14/15S	16/17XS						23.2	19.5	23.9	20.2
	12/13L	14/15M	16/17S	18/19XS					25.2	21.5	25.9	22.2
		14/15L	16/17M	18/19S	20/21XS				27.2	23.5	27.9	24.2
			16/17L	18/19M	20/21S	22/23XS			29.2	25.5	29.9	26.2
				18/19L	20/21M	22/23S	25XS		31.2	27.5	31.9	28.2
					20/21L	22/23M	24/25S	26/27XS	33.2	29.5	33.9	30.2
						22/23L	24/25M	26/27S	35.2	31.5	—	—
							24/25L	26/27M	37.2	33.5	—	—
								26/27L	39.2	35.5	—	—

Trialing

In some revision cases, medial bone may need to be removed to accommodate the platform of the trial body and the subsequent implant. The osteotomy jig is uniquely designed to address this bone removal. The osteotomy jig will remove 1-2mm of bone below the proximal aspect of the REDAPT stem to ensure proper seating of the implant.

Place the osteotomy jig over the distal reamer and proximal spacer and tighten the screw with the trial assembly tool (Figure 25). Loosen the two thumb screws on the jig. Position the cutting block side marked Lateral, parallel to the lateral aspect of the femur. Orient the jig arm to the desired cutting position. Hand-tighten the thumb screw (A). Orient the position of the medial/ lateral cutting block, relative to the bone, to ensure proper stability of the saw blade. Hand-tighten thumb screw (B). Tighten thumb screws using the trial assembly tool. Insert saw blade into the guide slot and cut.

If a free-hand technique using a rongeur or high speed is preferred, it may be necessary to remove 5-10mm of medial bone to ensure proper trial body and stem position.

Caution When making the osteotomy, take care not to damage the proximal spacer and distal reamer that are located in the femoral canal.

Assemble trial components over proximal end of distal reamer starting with the proximal trial spacer then the trial body and finally with neck components (Figure 26). Check the proximal spacer and trial body for soft tissue and/or bone debris that may impede proper seating of the trial components.

Trial bodies have been designed so that the teeth on the underside of the body mate with the teeth on the proximal spacer when initially placed. When the components are properly mated the screw on the top of the trial body pops up. (See Figure 27, 28 and 29).

Secure the trial components together by tightening the screw of the trial body with the trial assembly instrument.

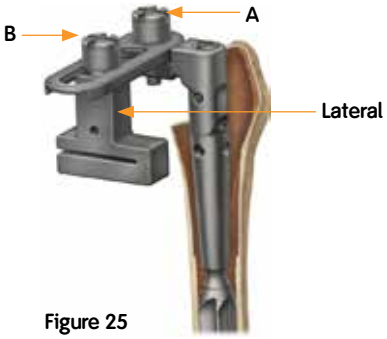


Figure 25

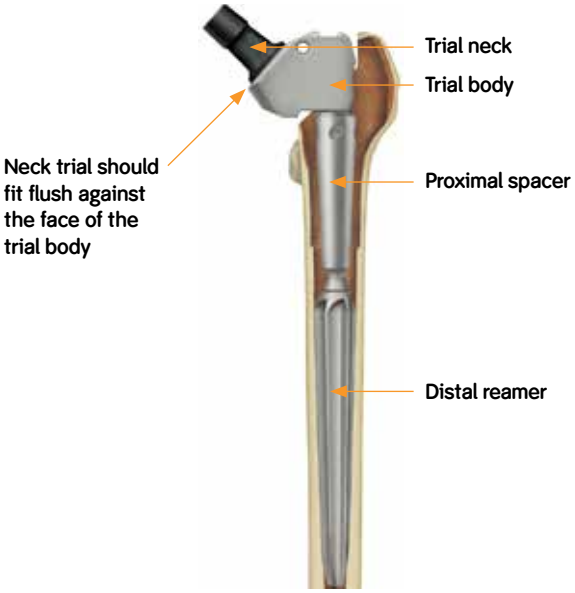


Figure 26

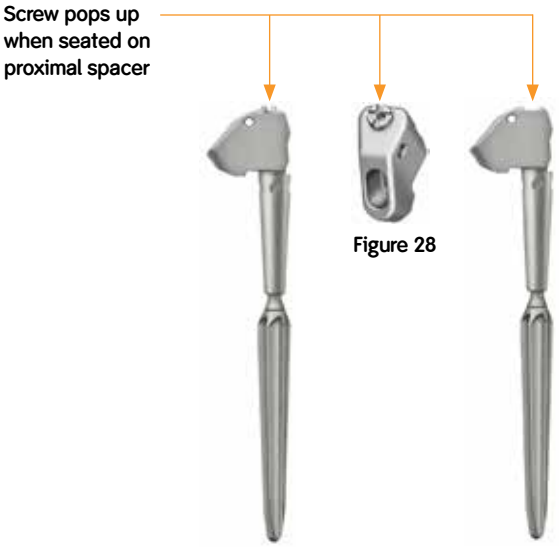


Figure 28

Figure 27

Figure 29

REDAPT® trial components can be adjusted to to achieve the desired leg length, neck offset, and neck version. For version adjustment, loosen the trial body screw and rotate the body to the desired position. Use a cautery pen to mark the desired position of the implant. (Figure 30).

Once the body is secure, position the trial neck component into the trial body pocket. Ensure the arrow on the trial neck component is pointing superiorly, which is the standard neck orientation or pointing down in the reverse position as desired. See modular neck chart for additional options. Take care that the ledge of the trial neck fits flush against the face of the trial body.

Attach the selected trial head to the trial neck. Perform range of motion (ROM) exercise to confirm proper seating of implant, assess joint tension, and ensure there is no impingement to the hip. Adjust trial body and neck desired for additional version, offset and length.

Figure 30

Trial/Reamer removal

Attach EMPERION® trial removal handle to trial removal hook (Figure 31). To remove the assembled trial components insert the trial removal hook through the cross hole of the trial neck body (Figure 32). Using gentle force, extract the trial components superiorly.

Important Reamers and trials are not implantable devices and must be removed prior to implant insertion.

If trialing was not performed following the proximal sleeve preparation, then the distal reamer component can be removed by the reamer removal tool. First screw the reamer removal cap completely onto the threads of the distal reamer, then place the trial removal hook assembled onto the trial handle through the cross hole in the reamer removal tool and use gentle force to extract superiorly (Figure 33).

Figure 31

Figure 32

Figure 33

If resistance occurs when removing the reamer, unscrew the distal reamer removal cap and attach the reamer quick connect to the distal reamer. Using power or a T-handle reverse the reamer out of the canal.

Note Do not use other devices or instruments to remove reamer as these may damage the threads.

Implant assembly and insertion

Attach the implant driving platform of the stem inserter to the proximal end of the stem implant. To attach, stand the stem inserter upright so that the threaded tip is pointed up. Ensure that the lever handle is open on the stem inserter and screw the implant onto the threaded tip as far as possible. Flip the assembly over so that the stem tip is now pointing down. Engage the frame tines into the slots adjacent to the threaded hole on the stem. Rotate the pommel until the assembly is secure.

Caution Prior to use, inspect the inserter to ensure that the threads are not damaged and the tip is not bent. Do not over tighten the pommel as this may cause it to lock up during repeated impacting. Close the lever handle to lock the pommel.

Assemble the appropriate size proximal sleeve onto the distal stem by hand (Figure 34). Take care to ensure that all taper surfaces are protected, clean and dry prior to assembling the sleeve in one hand, use the other hand to onto the stem. By holding the sleeve, impact it onto the stem with three surgical hammer impacts on the insertion instrument.

Important Take care to protect the tapered pocket and all taper connections during assembly of the inserter and during stem insertion.

Figure 34

Orient the stem to achieve the desired version. Insert the stem into the femoral canal using hand pressure. Impact the stem/sleeve assembly into the femur using a mallet against the driving platform.

Caution Do not use excessive force to seat the stem. Do not use any other instrument to insert the stem.

Make sure the stem inserter is not impinging on the trochanter (Figure 35). This may cause inadequate stem seating, trochanteric fracture or varus positioning. Assess height and neck pocket orientation as you advance the stem by hand into the desired position. A cautery pen mark made during the trialing step can be used as a reference. Once the stem is in position, impact the stem completely into final position.

Note If stem is not sitting in the desired position, remove inserter and attach the universal joint to the stem and then attach the stem extractor adaptor to the universal joint. Finally, attach the RENOVATION® slap hammer to the extractor adaptor. (Please note that the EMPERION® trial removal handle will also assemble to the universal joint.) Remove the stem by applying backward blows of the slap hammer. Once stem is disengaged, remove the extraction instruments and reattach the stem inserter. Reposition the stem and advance in the desired position.

Figure 35

Figure 36

Once the stem is implanted, raise the lever on the inserter and unscrew the pommel to release the instrument from the stem.

Dry the neck pocket and tapered end of the trial neck with a sterile cloth or 4x4.

Assembly of neck and head

It is recommended that re-trialing be performed using the trial neck and head components (Figure 36). Fine-tuning of offset, leg length, and version can be made with the modular neck and head options. Replace the trial neck with the modular neck implant prior to impaction.

Note Take care to ensure that all taper surfaces are protected, clean and dry prior to assembly.

Verify that the neck is in the desired orientation with the arrow pointed superior or inferior prior to final impaction (Figure 37).

Important Neck trials are not implantable devices and must be replaced with an implant neck.

Impact final neck and head implant components simultaneously with the head/neck impaction tool (Figure 38). 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 the component and/or bone. Perform final ROM with implants in position.

Figure 37

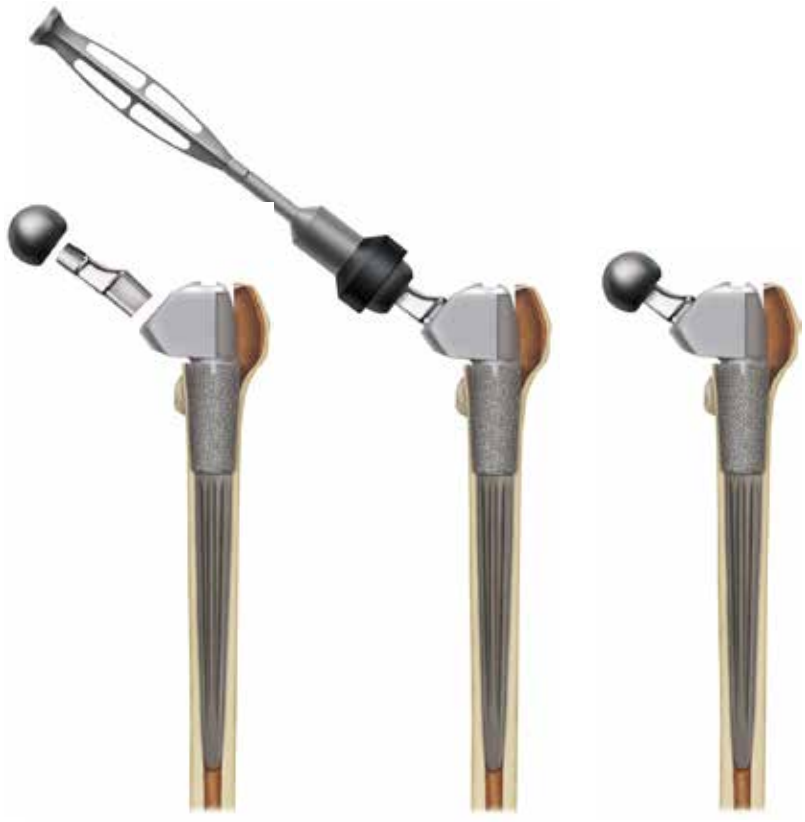


Figure 38

7 Proximal support

Once the final components are implanted, the osteotomy is reduced and secured with cables. In order to reduce the osteotomized bone fragment in its anatomic position, it may be necessary to shape the endosteal surface of the bone fragment with a curette or burr to fit against the lateral position of the femoral component.

Caution The sleeve implant **must** contact bone, bone filler, or secured allograft to provide adequate secondary support.

Reattach the trochanteric segment using ACCORD® Cables (Figure 39) or other appropriate proximal support.

Caution To gain adequate proximal support and reduce the risk of implant failure, the use of adjunctive devices such as cables, cerclage wires, struts, etc. is recommended.

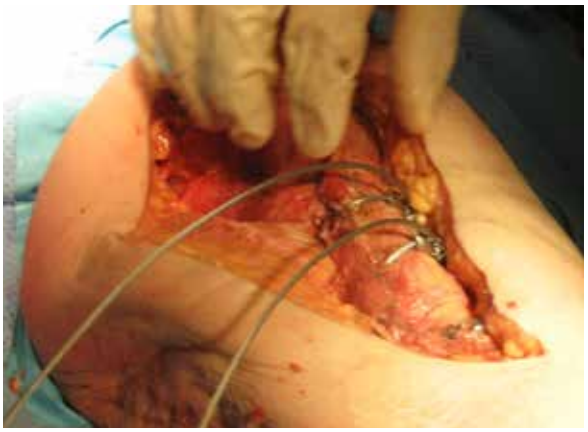
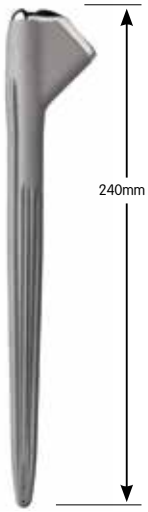


Figure 39

Catalog information

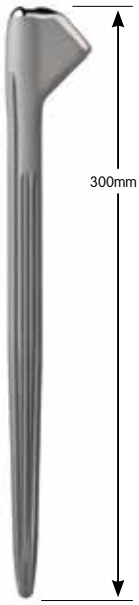
REDAPT® Proximally Fluted Revision Stem – 240mm Length

Catalog Item	Description
7135-4312	Mod PF Revision Stem-240mm Size 12
7135-4313	Mod PF Revision Stem-240mm Size 13
7135-4314	Mod PF Revision Stem-240mm Size 14
7135-4315	Mod PF Revision Stem-240mm Size 15
7135-4316	Mod PF Revision Stem-240mm Size 16
7135-4317	Mod PF Revision Stem-240mm Size 17
7135-4318	Mod PF Revision Stem-240mm Size 18
7135-4319	Mod PF Revision Stem-240mm Size 19
7135-4320	Mod PF Revision Stem-240mm Size 20
7135-4321	Mod PF Revision Stem-240mm Size 21
7135-4322	Mod PF Revision Stem-240mm Size 22
7135-4323	Mod PF Revision Stem-240mm Size 23
7135-4324	Mod PF Revision Stem-240mm Size 24
7135-4325	Mod PF Revision Stem-240mm Size 25
7135-4326	Mod PF Revision Stem-240mm Size 26
7135-4327	Mod PF Revision Stem-240mm Size 27



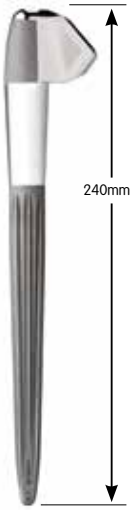
REDAPT Proximally Fluted Revision Stem – 300mm Length

Catalog Item	Description
7135-4328	Mod PF Revision Stem-300mm Size 12
7135-4329	Mod PF Revision Stem-300mm Size 13
7135-4330	Mod PF Revision Stem-300mm Size 14
7135-4331	Mod PF Revision Stem-300mm Size 15
7135-4332	Mod PF Revision Stem-300mm Size 16
7135-4333	Mod PF Revision Stem-300mm Size 17
7135-4334	Mod PF Revision Stem-300mm Size 18
7135-4335	Mod PF Revision Stem-300mm Size 19
7135-4336	Mod PF Revision Stem-300mm Size 20
7135-4337	Mod PF Revision Stem-300mm Size 21
7135-4338	Mod PF Revision Stem-300mm Size 22
7135-4339	Mod PF Revision Stem-300mm Size 23
7135-4340	Mod PF Revision Stem-300mm Size 24
7135-4341	Mod PF Revision Stem-300mm Size 25
7135-4404	Mod PF Revision Stem-300mm Size 26
7135-4405	Mod PF Revision Stem-300mm Size 27



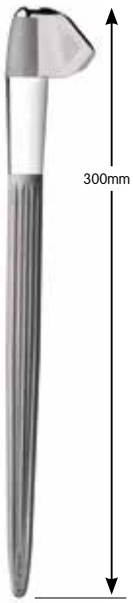
REDAPT° Modular Sleeved Revision Stem – 240mm Length

Catalog Item	Description
7135-4407	REDAPT MS Revision Stem-240mm Size 12
7135-4408	REDAPT MS Revision Stem-240mm Size 13
7135-4409	REDAPT MS Revision Stem-240mm Size 14
7135-4360	REDAPT MS Revision Stem-240mm Size 15
7135-4361	REDAPT MS Revision Stem-240mm Size 16
7135-4362	REDAPT MS Revision Stem-240mm Size 17
7135-4363	REDAPT MS Revision Stem-240mm Size 18
7135-4364	REDAPT MS Revision Stem-240mm Size 19
7135-4365	REDAPT MS Revision Stem-240mm Size 20
7135-4366	REDAPT MS Revision Stem-240mm Size 21
7135-4367	REDAPT MS Revision Stem-240mm Size 22
7135-4368	REDAPT MS Revision Stem-240mm Size 23
7135-4369	REDAPT MS Revision Stem-240mm Size 24
7135-4370	REDAPT MS Revision Stem-240mm Size 25
7135-4371	REDAPT MS Revision Stem-240mm Size 26
7135-4372	REDAPT MS Revision Stem-240mm Size 27



REDAPT Modular Sleeved Revision Stem – 300mm Length

Catalog Item	Description
7135-4374	REDAPT MS Revision Stem-300mm Size 12
7135-4375	REDAPT MS Revision Stem-300mm Size 13
7135-4376	REDAPT MS Revision Stem-300mm Size 14
7135-4377	REDAPT MS Revision Stem-300mm Size 15
7135-4378	REDAPT MS Revision Stem-300mm Size 16
7135-4379	REDAPT MS Revision Stem-300mm Size 17
7135-4380	REDAPT MS Revision Stem-300mm Size 18
7135-4381	REDAPT MS Revision Stem-300mm Size 19
7135-4382	REDAPT MS Revision Stem-300mm Size 20
7135-4383	REDAPT MS Revision Stem-300mm Size 21
7135-4384	REDAPT MS Revision Stem-300mm Size 22
7135-4385	REDAPT MS Revision Stem-300mm Size 23
7135-4386	REDAPT MS Revision Stem-300mm Size 24
7135-4387	REDAPT MS Revision Stem-300mm Size 25
7135-4388	REDAPT MS Revision Stem-300mm Size 26
7135-4389	REDAPT MS Revision Stem-300mm Size 27



Catalog information

REDAPT® Modular Sleeves (with HA)

Catalog Item	Description
Extra Small (XSM)	
7135-4213	REDAPT Mod Sleeve 12-13 XSM Grit-blast w/HA
7135-4215	REDAPT Mod Sleeve 14-15 XSM Grit-blast w/HA
7135-4217	REDAPT Mod Sleeve 16-17 XSM Grit-blast w/HA
7135-4219	REDAPT Mod Sleeve 18-19 XSM Grit-blast w/HA
7135-4221	REDAPT Mod Sleeve 20-21 XSM Grit-blast w/HA
7135-4223	REDAPT Mod Sleeve 22-23 XSM Grit-blast w/HA
7135-4225	REDAPT Mod Sleeve 24-25 XSM Grit-blast w/HA
7135-4227	REDAPT Mod Sleeve 26-27 XSM Grit-blast w/HA
Small (SM)	
7135-4031	REDAPT Mod Sleeve SM 12-13-STIKTITE w/HA
7135-4032	REDAPT Mod Sleeve SM 14-15-STIKTITE w/HA
7135-4033	REDAPT Mod Sleeve SM 16-17-STIKTITE w/HA
7135-4034	REDAPT Mod Sleeve SM 18-19-STIKTITE w/HA
7135-4035	REDAPT Mod Sleeve SM 20-21-STIKTITE w/HA
7135-4036	REDAPT Mod Sleeve SM 22-23-STIKTITE w/HA
7135-4037	REDAPT Mod Sleeve SM 24-25-STIKTITE w/HA
7135-4038	REDAPT Mod Sleeve SM 26-27-STIKTITE w/HA
Medium (MED)	
7135-4041	REDAPT Mod Sleeve MED 12-13-STIKTITE w/HA
7135-4042	REDAPT Mod Sleeve MED 14-15-STIKTITE w/HA
7135-4043	REDAPT Mod Sleeve MED 16-17-STIKTITE w/HA
7135-4044	REDAPT Mod Sleeve MED 18-19-STIKTITE w/HA
7135-4045	REDAPT Mod Sleeve MED 20-21-STIKTITE w/HA
7135-4046	REDAPT Mod Sleeve MED 22-23-STIKTITE w/HA
7135-4047	REDAPT Mod Sleeve MED 24-25-STIKTITE w/HA
7135-4048	REDAPT Mod Sleeve MED 26-27-STIKTITE w/HA
Large (LG)	
7135-4051	REDAPT Mod Sleeve LG 12-13-STIKTITE w/HA
7135-4052	REDAPT Mod Sleeve LG 14-15-STIKTITE w/HA
7135-4053	REDAPT Mod Sleeve LG 16-17-STIKTITE w/HA
7135-4054	REDAPT Mod Sleeve LG 18-19-STIKTITE w/HA
7135-4055	REDAPT Mod Sleeve LG 20-21-STIKTITE w/HA
7135-4056	REDAPT Mod Sleeve LG 22-23-STIKTITE w/HA
7135-4057	REDAPT Mod Sleeve LG 24-25-STIKTITE w/HA
7135-4058	REDAPT Mod Sleeve LG 26-27-STIKTITE w/HA

7135-4061	Modular Neck High Offset +10 Neck Height
7135-2111	Standard Offset Neutral Modular Neck
7135-2112	High Offset Neutral Modular Neck
7135-2116	Left Anteverted Modular Neck
7135-2117	Right Anteverted Modular Neck

REDAPT® Distal Reamers – 240mm Length

Catalog Item	Description
7135-5001	REDAPT Distal Reamer 240mm Size 10
7135-5003	REDAPT Distal Reamer 240mm Size 11
7135-5005	REDAPT Distal Reamer 240mm Size 12
7135-5007	REDAPT Distal Reamer 240mm Size 13
7135-5009	REDAPT Distal Reamer 240mm Size 14
7135-5011	REDAPT Distal Reamer 240mm Size 15
7135-5013	REDAPT Distal Reamer 240mm Size 16
7135-5015	REDAPT Distal Reamer 240mm Size 17
7135-5017	REDAPT Distal Reamer 240mm Size 18
7135-5019	REDAPT Distal Reamer 240mm Size 19
7135-5022	REDAPT Distal Reamer 240mm Size 20
7135-5024	REDAPT Distal Reamer 240mm Size 21
7135-5026	REDAPT Distal Reamer 240mm Size 22
7135-5028	REDAPT Distal Reamer 240mm Size 23
7135-5030	REDAPT Distal Reamer 240mm Size 24
7135-5032	REDAPT Distal Reamer 240mm Size 25
7135-5034	REDAPT Distal Reamer 240mm Size 26
7135-5036	REDAPT Distal Reamer 240mm Size 27

Color indicator on reamer shaft corresponds to available implant sizes

REDAPT® Distal Reamers – 300mm Length

Catalog Item	Description
7135-5038	REDAPT Distal Reamer 300mm Size 10
7135-5042	REDAPT Distal Reamer 300mm Size 11
7135-5044	REDAPT Distal Reamer 300mm Size 12
7135-5046	REDAPT Distal Reamer 300mm Size 13
7135-5048	REDAPT Distal Reamer 300mm Size 14
7135-5051	REDAPT Distal Reamer 300mm Size 15
7135-5053	REDAPT Distal Reamer 300mm Size 16
7135-5055	REDAPT Distal Reamer 300mm Size 17
7135-5057	REDAPT Distal Reamer 300mm Size 18
7135-5059	REDAPT Distal Reamer 300mm Size 19
7135-5062	REDAPT Distal Reamer 300mm Size 20
7135-5064	REDAPT Distal Reamer 300mm Size 21
7135-5066	REDAPT Distal Reamer 300mm Size 22
7135-5068	REDAPT Distal Reamer 300mm Size 23
7135-5071	REDAPT Distal Reamer 300mm Size 24
7135-5073	REDAPT Distal Reamer 300mm Size 25
7135-5075	REDAPT Distal Reamer 300mm Size 26
7135-5077	REDAPT Distal Reamer 300mm Size 27

Color indicator on reamer shaft corresponds to available implant sizes

Catalog information

REDAPT® Proximal Reamers

Catalog Item	Description
7135-5079	REDAPT Proximal Reamer-Starter and Size PF 12/13
7135-5081	REDAPT Proximal Reamer #1-11XS PF14/15
7135-5082	REDAPT Proximal Reamer #2-11S 12/13XS PF16/17
7135-5083	REDAPT Proximal Reamer #3-11M 12/13S 14/15XS PF18/19
7135-5084	REDAPT Proximal Reamer #4-11L 12/13M 14/15S 16/17XS PF20/21
7135-5085	REDAPT Proximal Reamer #5-12/13L 14/15M 16/17S 18/19XS PF22+
7135-5086	REDAPT Proximal Reamer #6-14/15L 16/17M 18/19S 20/21XS
7135-5087	REDAPT Proximal Reamer #7-16/17L 18/19M 20/21S 22/23XS
7135-5088	REDAPT Proximal Reamer #8-18/19L 20/21M 22/23S 24/25XS
7135-5089	REDAPT Proximal Reamer #9-20/21L 22/23M 24/25S 26/27XS
7135-5091	REDAPT Proximal Reamer #10-22/23L 24/25M 26/27S
7135-5092	REDAPT Proximal Reamer #11-24/25L 26/27M
7135-5093	REDAPT Proximal Reamer #12-27L

7135-5079

7135-5083

General Instruments

Catalog Item	Description
7135-5094	REDAPT® Reamer Quick Connect
7135-5095	REDAPT Trial Body-Proximally Fluted Size 12-15
7135-5096	REDAPT Trial Body-Proximally Fluted Size 16-27
7135-5097	REDAPT Trial Body-Sleeved Size 12-15
7135-5098	REDAPT Trial Body-Sleeved Size 16-27
7135-5106	REDAPT Proximal Spacer Trial
7135-5107	REDAPT Stem Extractor Universal Joint
7135-5108	REDAPT Stem Extractor Adaptor
7135-5109	REDAPT Reamer Removal Cap
7135-5112	REDAPT Osteotomy Jig for Sleeved Stem
7135-5113	REDAPT Medial Rasp
7135-4174	Trial Body Assembly Tool
7136-0093	Mini Head/neck impactor
7136-0094	Mini Neck Extractor
7136-0917	EMPERION® Trial Removal Hook
7136-0919	EMPERION Sleeve/Stem Separator
7136-0920	EMPERION Trial Removal Handle
7136-4006	T-Handle
7136-4012	Anteversion Handle
7136-4036	EMPERION Sleeve Implant Removal Tool
7136-5705	ANTHOLOGY® Stem Inserter (Posterior Hard)
7135-0384	Radiopaque Trial Neck-Standard Offset
7135-0385	Radiopaque Trial Neck High Offset
7135-0386	Radiopaque Trial Neck Anteverted Left
7135-0387	Radiopaque Trial Neck Anteverted Right
7135-5111	Radiopaque Trial Neck High Offset+10mm

7135-5094

7135-5113

7135-5095

7135-4174

7135-5096

7135-5106

7135-5107

7135-5108

7135-5109

7135-5112

Catalog information

REDAPT Implant Sets

Catalog Item	Description
7135-0000	Proximally Fluted 240mm Implant Set
7135-1700	Proximally Fluted 300mm Implant Set
7135-2930	Proximally Fluted Large Size Set
7135-1300	Modular Sleeve 240mm Implant Set
7135-1400	Modular Sleeve 300mm Implant Set
7135-1500	Modular Sleeve Large Size Set
7135-1600	Large Sleeves Implant Set

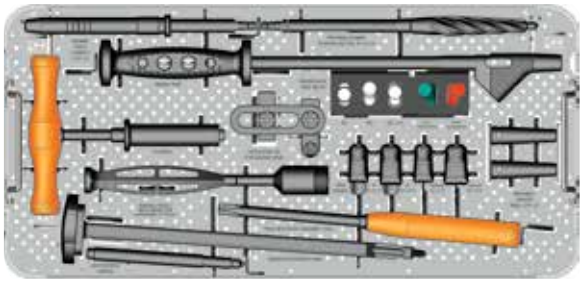
REDAPT Instrument Sets

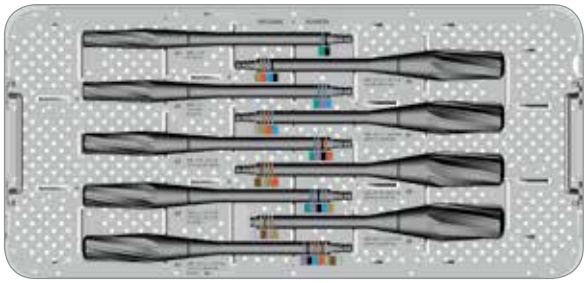
Catalog Item	Description
7135-2000	Full Instrument Set
7135-2900	300mm Reamers Set
7135-2910	240mm Outlier Reamer Set
7135-2920	300mm Outlier Reamer Set

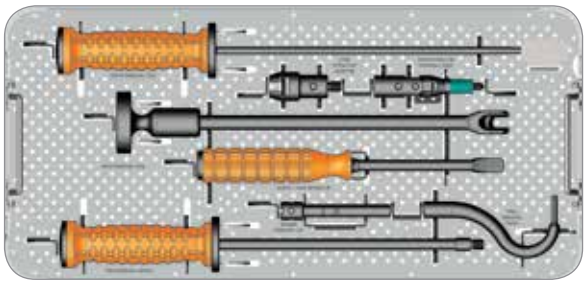
Detailed set descriptions are available upon request.

REDAPT° Instrument Trays

Catalog Item	Description
7135-4201	Common Instrument Tray
7135-4203	Proximal Reamer Tray
7135-4204	240mm Distal Reamer Tray
7135-4205	300mm Distal Reamer Tray
7135-4206	240mm Large Reamer Tray
7135-4207	300mm Large Reamer Tray
7135-4210	Extraction Tray



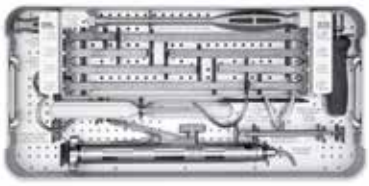




Catalog information

ACCORD® Cable System

Catalog Item	Description
7136-0005	Instrument Set



Catalog Item	Description
7134-5000	Implant Set Includes: all titanium small & standard grips 3 titanium fracture management plates 12 cobalt chrome cables w/clamp 12 cobalt chrome cables for grips/plates

RENOVATION® Removal Instrument Set

Catalog Item	Description
7136-7575	Instrument Set

Total Hip Systems
Important Medical Information

Important Note
Total hip arthroplasty (THA) 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. **Caution: Federal Law (U.S.A) restricts the subject total hip arthroplasty devices to sale by or on the order of a physician.**

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, zirconia ceramic or stainless steel (SS). Acetabular liners are ultra-high molecular weight polyethylene (UHMWPE), cobalt chromium (CoCr) alloy, 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 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 for use in the U.S.**

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, hydroxyapatite (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, which are available with 10/12, 12/14, and 14/16 tapers, mate and lock directly with Smith & Nephew, Inc. femoral heads having the same sized taper. Certain femoral heads may require taper sleeves for attachment to the femoral stem taper. See chart 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. See the following Sleeve Compatibility Chart for the appropriate combinations. Failure to utilize the proper sleeve — head combination may lead to implant failure resulting in revision surgery. Never place more than one taper sleeve on a femoral component, as this combination will increase stresses on implant and may lead to failure resulting in revision surgery.

Compatible Sleeve Combinations

Femoral Stem Taper	Sleeves to be used with the following femoral heads:					
	40, 44mm Modular OXINIUM® heads	**40, 44mm 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

Sleeve	Material	Description / Part Numbers
A	Ti-6Al-4V	Ti 12/14 Modular Sleeve
		-4: 71344245, +0: 71344247, +4: 71344248, +8: 71344250
B	CoCr	CoCr 12/14 Modular Sleeve
		-4: 74222100, +0: 74222200, +4: 74222300, +8: 74222401
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

* Modular CoCr heads are intended for hemi-arthroplasty use in the U.S. In the U.S., refer to the separate package insert provided with these components.
**** BH Modular Heads are not available for use in the U.S.**

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.

Femoral Heads
Cobalt chromium, stainless steel, oxidized zirconium, and ceramic heads are available in multiple neck lengths for proper anatomic and musculature fit. Heads may be available in 10/12, 14/16, and 12/14 tapers. Certain modular heads and unipolar heads may require taper sleeves for attachment to the femoral stem taper. See Compatible Sleeve Combination Charts in the Taper Sleeves section for details. 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 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	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 for use in the U.S.

The following CoCr BIRMINGHAM HIP® (BH) modular heads†† should be used only with BIRMINGHAM HIP acetabular cups and R3 metal acetabular liners. In the U.S., refer to the separate package insert provided with these components.

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

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

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 U.S., 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 for use in the U.S.** For R3 metal liners available for use with the BIRMINGHAM HIP Resurfacing (BHR) System in the U.S., refer to the separate package insert provided with these components.

Note: 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. **Stainless Steel (SS) heads are not available for use in the U.S.**

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. 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 lead to 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 cement. Reference product labeling and literature for specific applications.

The REDAPT® revision hip system (formerly MDF) is intended to be used without cement. In the EU, REDAPT 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

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, osteolysis, 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. **In the U.S., refer to the separate package insert provided with the ceramic acetabular liners.**
6 **In revision surgery, inadequate proximal implant support is contraindicated.** The literature shows 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.
7 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.

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

Possible Adverse Effects of the Device (In Primary and Revision THA)

1 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.
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, metal, or ceramic articular surfaces. Osteolysis can lead to future complications necessitating the removal or replacement of prosthetic components.
3 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.
4 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.
5 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.
6 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 resulting in revision surgery.
7 Implant migration or subsidence resulting in revision surgery has occurred in conjunction with compaction grafting procedures usually resulting from insufficient graft material, improper cement techniques, and/or varus stem alignment.
8 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.
9 Temporary or permanent device related noise such as clicking, squeaking, popping, grating, or grinding, which may lead to implant failure and revision surgery.
10 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 any Total Hip Arthroplasty Surgery, Primary and Revision

1 Infection, both early, post-operative superficial and early, post-operative deep wound infection and late periprosthetic infection.
2 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.
3 Wound hematoma, thromboembolic disease including venous thrombosis, or pulmonary embolus. Some studies have shown an increased risk of thromboembolic disease including venous thrombosis with cemented THA as compared to uncemented THA.
4 Myositis ossificans, especially in males with hypertrophic arthritis, limited preoperative range of motion and/or previous myositis. Also, periarticular calcification with or without impediment to joint mobility can cause decreased range of motion.
5 Trochanteric nonunion usually associated with early weight bearing and/or improper fixation of the trochanter, when a transtrochanteric surgical approach is used.
6 Damage to blood vessels.
7 Accidental patient burns from cautery device.
8 Delayed wound healing.
9 Aggravated problems of the affected limb or contralateral extremity caused by leg length discrepancy, excess femoral medialization, or muscle deficiency.

WARNINGS AND PRECAUTIONS

Preoperative

1 The patient should be warned of surgical risks, and made aware of possible adverse effects.
2 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.
3 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.
4 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.
5 Improper selection, placement, positioning, and fixation of the implant components may result in unusual stress conditions and subsequent early failure/fracture of the components.
6 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.
7 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.
8 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, as this may compromise fixation and lead to failure.
9 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.
10 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.
11 The surgeon should be familiar with the appropriate surgical technique. Refer to medical or manufacturer literature for specific product information, which is available upon request. Failure to follow the appropriate surgical technique may result in implant failure or revision surgery.
12 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.
13 Do not cold water quench ceramic components and never sterilize ceramic heads while fixed on the stem taper, as this may induce additional stresses on component which may cause implant failure, resulting in revision surgery. (See Sterilization section, below.)
14 OXINIUM® oxidized zirconium femoral heads and cobalt chrome femoral heads are designed to articulate with conventional UHMWPE or 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 or R3 metal 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 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.**
15 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, resulting in revision surgery.
16 Do not use Smith & Nephew 36mm -3 heads with SL-PLU.S.® Hip Stems and SLR-PLU.S. Hip Stems or any of the +16 heads with any PLU.S. Hip Stem. Use of these unapproved combinations may result in implant failure and revision surgery.
17 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, 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, resulting in revision surgery.
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 and stability verified. Failure to do so may result in implant failure and revision surgery.
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 Eight of the "Preoperative" section of "Warnings and Precautions."
4 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.
5 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.
6 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.
7 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.
8 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.
9 Take care, when positioning and drilling 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 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. Failure to comply may result in implant failure and revision surgery.
10 REFLECTION three hole (SP3), multi-hole (SPM), peripheral hole (SPR), INTERFIT® and R3 Shells accept both REFLECTION spherical head screws and Universal 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 Three 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.

11 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.

12 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.

13 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.

14 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 in cement product labeling. During curing of the cement, care should be taken to prevent movement of the implant components. Failure to do so may cause implant failure and revision surgery.

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. Do not assemble a ceramic head on a used taper, as the 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 cracks, scratches, looseness, and other signs of damage, and replace if necessary. The head/neck component should be changed only when clinically necessary. Failure to comply may result in implant failure and revision surgery.

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 and result in revision surgery.

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 are technically demanding and difficult to exercise, with 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. 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.

21 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 or painful or restricted motion.

22 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.

23 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 which may lead to revision surgery.

24 To minimize the risk of acetabular shell loosening in uncemented applications, surgeons should consider using orthopedic bone fixation devices such as bone screws, spikes, pegs, fins, or other bone fixation devices. To minimize loosening risk for cemented acetabular shells, care should be taken to prevent movement of the implant components while cement is curing.

25 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.

26 For computer assisted surgery systems, it is extremely important to correctly select input parameters (e.g. bony landmarks). Operators of this equipment should be familiar with the anatomy relevant to the procedure. Failure to provide proper input could cause problems such as violation of critical anatomical structures and malpositioned implants, which may lead to revision surgery.

27 Trial instrumentation may be provided for intraoperative assessment of final implant fit. **Do NOT implant trial components.**

28 Do not implant HA-coated devices in bone cement.

29 Inappropriate use of taper sleeves may lead to implant failure resulting in revision surgery. Select the appropriate sleeve based on the Compatible Sleeve Combinations Charts located in the Description of System section of this document.

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, which may result in subluxation or dislocation.

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 as prescribed by the physician should be structured to regain muscle strength around the hip and a gradual increase of activities.

5 Continued periodic x-rays as prescribed by the physician 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.

8 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 compromising the durability of the implants.

9 Post-operative subluxation may result in higher wear and implant damage.

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 or past the expiration date, return the component to Smith & Nephew, Inc. Use of damaged or expired product increases the risk of infection which may lead to revision surgery.

Healthcare provider should have a full understanding of the product labeling information including but not limited to the following: Instructions For Use (IFU) document and manufacturer provided surgical techniques and other relevant product materials.

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.

Hip implant components, disposable or single-use instruments should not be reused due to risks of breakage, failure, or patient infection. 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 available from customer service or via Smith & Nephew website, for further information on cleaning instructions and validated sterilization procedures.

Recommended Steam Sterilization Cycle Parameters
- Dynamic Air Removal (Prevacuum) Steam Cycle: 132ºC (270ºF) – 4 minutes or 135ºC (275ºF) – 3 minutes; Minimum drying time: wrapped instruments – 15 minutes, containerized devices – 30 minutes.
- Gravity Displacement Steam Cycle: 132°C (270°F) – 15 minutes for wrapped instruments and 30 minutes for containerized devices; Minimum drying time – 30 minutes.
- Immediate Use Steam Sterilization or Flash Steam Cycle (Reusable instruments only): 132°C (270°F) for 15 minutes in a Gravity Displacement Cycle or 4 minutes in a Dynamic Air Removal (Prevacuum) Cycle.
- United Kingdom Steam Cycle: 134°C (273°F) – 3 minutes; Minimum vacuum drying – 30 minutes. (Note: The procedure outlined in HTM 2010 should be followed).

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.

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. 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 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 1-800-238-7538 for calls within the continental U.S.A and 1-901-396-2121 for all international calls.

Manufacturing facilities and EC representative:

Smith & Nephew Inc.
1450 Brooks Road
Memphis, TN 38116 U.S.A
Telephone: 1-901-396-2121

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

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 cemented use only

 – For uncemented use only

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Notes

Smith & Nephew, Inc.
7135 Goodlett Farms Parkway
Cordova, TN 38016
USA

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