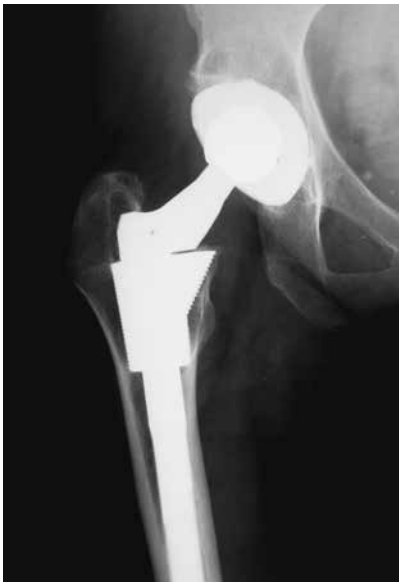
DePuy Synthes
JOINT RECONSTRUCTION
COMPANIES OF Johnson & Johnson

S-ROM® MODULAR HIP SYSTEM

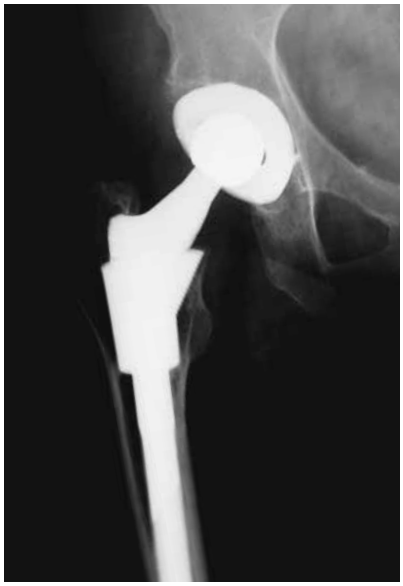
SURGICAL TECHNIQUE

S-ROM®
MODULAR HIP SYSTEM

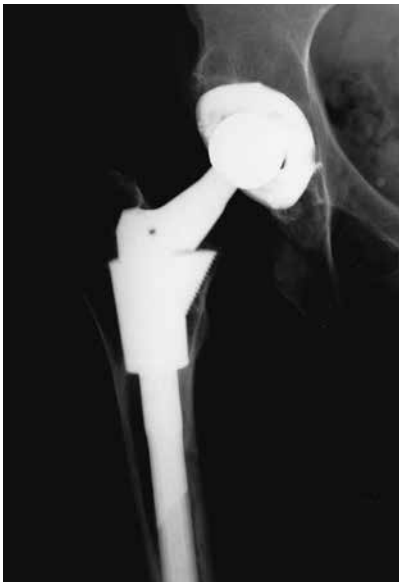
Proven Results



3 years



7 years



10 years

"98% had stable ingrowth…the modular S-ROM femoral prosthesis yielded excellent intermediate-term outcomes."

— 172 hips; 5.3-year average follow-up

Christie, M.J., et al. "Primary Total Hip Arthroplasty with Use of the Modular S-ROM Prosthesis." *The Journal of Bone and Joint Surgery* Dec. 1999: 1707.

"No patient had failure of the implant at the stem-sleeve interface, loss of rotational stability, subsidence, osteolysis."

— 91 patients; 3.5-year average follow-up

Cameron, H.U. "The Three to Six Year Results of a Modular Noncemented Low-Bending Stiffness Hip Implant." *Journal of Arthroplasty* June 1993: 239-243.

"94.8% good to excellent using Harris Hip Score."

— 77 hip replacements; 2- to 5-year follow-up

Smith, J.A., H.K. Dunn and B.J. Manaster. "Cementless Femoral Revision Arthroplasty 2- 5 Year Results with a Modular Titanium Alloy Stem." *Journal of Arthroplasty* Feb. 1997: 194-201.

"At an average of 5.9 years ... 86 percent ..., all of which had had a grade-II or III femoral defect, had an intact and radiographically stable prosthesis. No hip had mechanical failure, uncoupling of the modular components, or fracture of the stem."

Bono, J.V., et al. "Fixation with a Modular Stem in Revision Total Hip Arthroplasty." *The Journal of Bone and Joint Surgery* Sept. 1999: 1326.

"With an aseptic loosening rate of 0% in class I and 1.4% in class II and III, it seems that proximal offloading is possible in most revision cases."

— N=320 pts (109 std, 211 long stems)

Cameron, H. "The Long-Term Success of Modular Proximal Fixation Stems in Revision Total Hip Arthroplasty" *The Journal of Arthroplasty* Vol. 17 No. 4 Suppl. 2002.

Note: *Grades and classes represent the femoral defect classification from the American Academy of Orthopaedic Surgeons*

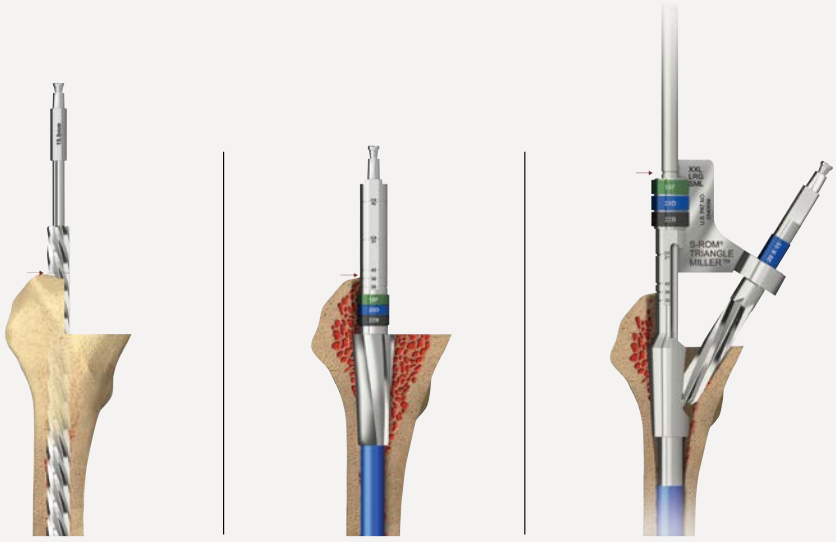
Proven. Versatile. Simple.

S-ROM®
MODULAR HIP SYSTEM

The S-ROM Modular Hip System offers extensive metaphyseal and diaphyseal geometries, making it an excellent stem for the high-demand patient. S-ROM stems have demonstrated clinical success since 1984.

The S-ROM Modular Hip System provides solutions for a variety of surgical scenarios (from primary THA to the most complex revision or the challenges of Development Dysplasia of the Hip) by offering independent neck and sleeve options. The S-ROM system utilizes a straightforward surgical technique involving 1) Distal Reaming, 2) Proximal Reaming and 3) Calcar Reaming. The streamlined S-ROM® MACH1™ instrumentation features color-coding, instrument-implant consistency throughout and a layout that is easy to follow and efficient.

It is as easy as 1, 2, 3!

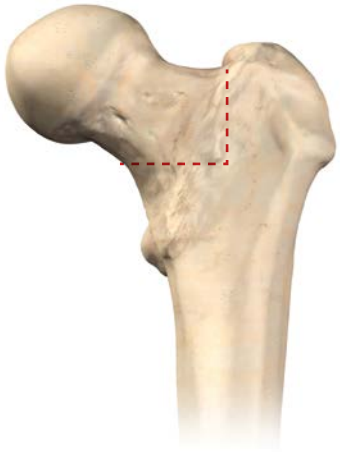


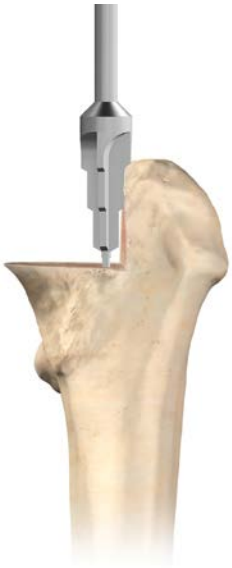
Step 1
Distal Reaming

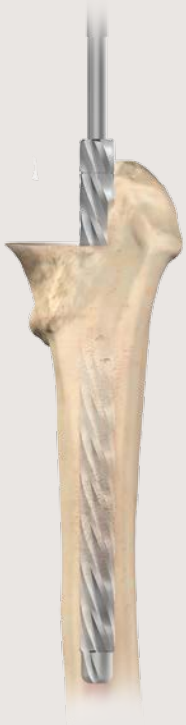
Step 2
Proximal Reaming

Step 3
Calcar Reaming

S-ROM Surgical Technique Quick Reference







Neck Osteotomy (90 degrees)

Perform a preliminary resection of the femoral neck using the biomechanical femoral neck resection template as a guide (not shown). The hole in the neck of the resection template is located at the center of the femoral head.

The notch on the medial aspect of the template indicates the most distal point for making the neck resection.

IM Initiator

Open the femoral canal by penetrating the superior femoral cortex with the IM Initiator or box osteotome (not shown). To protect against varus positioning, enter the medullary canal by beginning at the posterior margin of the junction of the neck resection and the complementary cut at the trochanteric fossa.

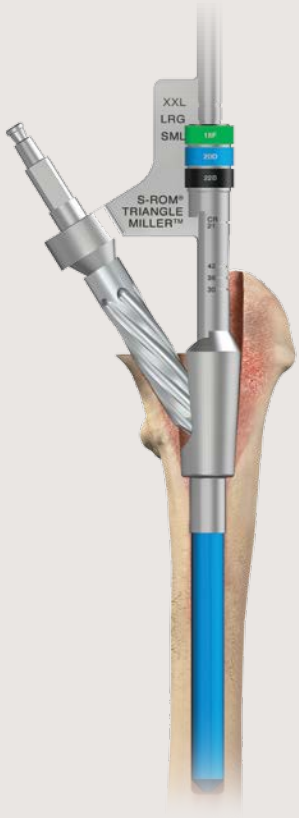
Step 1 – Distal Ream

Begin axial reaming with the end-cutting reamer and work up sequentially until cortical contact is achieved.

In keeping with pre-operative planning, the final straight reamer should be a half-millimeter larger than the minor distal diameter of the selected femoral stem.

The appropriate reamer depth has been established when the witness mark on each distal reamer aligns with the tip of the greater trochanter.

The diameter of the final distal reamer will dictate the color of the instrumentation selected for the remaining surgical steps.



Step 2 – Proximal Ream

Prepare the proximal or "cone" portion of the sleeve implant.

A set of triple-banded, color-coded cone reamers are available for preparing the proximal canal. The proximal diameter of each conical reamer is marked on one side. On the opposite side, the three proximal sleeve sizes (B, D, and F) are marked with the corresponding sleeve configuration. The location of each color band moves from distal to proximal as the proximal diameter increases.

Attach the appropriate color-coded pilot shaft to the distal end of the proximal reamer, and ream until cortical contact is achieved.

Step 3 – Calcar Ream/Mill

Select the appropriate size miller shell based on the final proximal/cone reamer utilized. Attach the appropriate color-coded pilot shaft to the distal end of the miller shell. Numeric markings of the proximal diameter are found on cone reamers and miller shells for cross reference verification.

Use the appropriate size triangle mill/drill to prepare the femur to accommodate the calcar spout of the final sleeve (S, L, or XXL).

Trial

Using the sleeve introducer, insert the appropriate trial sleeve (that matches the cone diameter and spout size reamed). Assemble the trial implant by snapping the chosen neck onto the appropriate size distal stem trial.

Introduce prior to trial reduction. The trial neck can be adjusted in 10-degree increments or "clicks". Use the nut tightener to lock the trial when the desired version is obtained.

Mark version and remove the trials.

Final Implantation

Introduce the sleeve implant with the sleeve introducer. Place the stem introducer onto the femoral implant and implant using the pin punch for version control. The taper is locked when the stem will no longer advance.

This surgical technique was developed in cooperation with:

- James V. Bono, M.D.
  Boston, Massachusetts
- Hugh U. Cameron, M.B.Ch.B., F.R.C.S.(C).
  Toronto, Ontario
- Douglas A. Dennis, M.D.
  Denver, Colorado
- David A. Mattingly, M.D.
  Boston, Massachusetts
- Robert L. Buly, M.D.
  New York, New York
- Michael J. Christie, M.D.
  Nashville, Tennessee
- Wayne M. Goldstein, M.D.
  Chicago, Illinois

Preoperative Planning

Preoperative Planning Goals

Preoperative planning enables the surgeon to prepare for the case and anticipate situations that may arise during surgery. A thorough preoperative plan incorporates elements from the patient's history, physical examination and radiographic analysis.

1. Determine preoperative leg length discrepancy
2. Assess acetabular component size and placement
3. Determine femoral component size, position and fit
4. Assess femoral offset

Radiographs

The first step in accurate templating is obtaining high-quality radiographs using a standardized protocol with known magnification. Use magnification markers attached to the patient's leg at the level of the greater trochanter to verify magnification.

The S-ROM Modular Hip System templates (Cat. No. XRT142) incorporate 15 percent magnification.

Obtain an anterior/posterior (A/P) view of the pelvis with both extremities in 15 degrees of internal rotation to position the head and neck parallel to the coronal plane. A direct lateral radiograph should also be obtained to determine desired femoral fixation.

Determination of Leg Length Discrepancy

To determine preoperative leg length, perform a clinical evaluation in conjunction with a radiographic analysis. Use both to determine intraoperative leg length management.

As an estimate of leg length discrepancy radiographically, draw a reference line along the inferior aspect of the ischial tuberosities (Figure A). Measure the distance from the lesser trochanter landmark to the reference line on each side. The difference between the two is the radiographic leg length discrepancy.

The tip of the greater trochanter may be used as an alternative reference mark in conjunction with the lines along the inferior aspect of the ischial tuberosities.

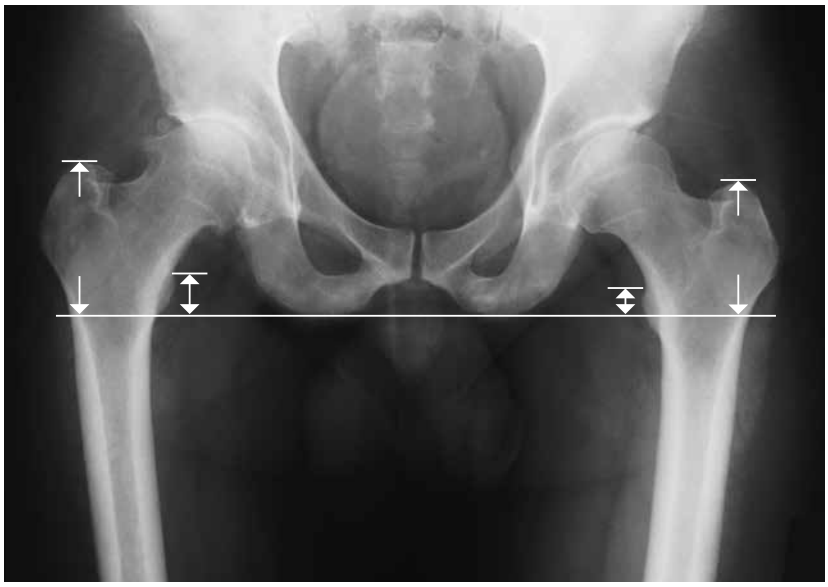


Figure A

Acetabular Cup Size and Position

Most sizing predictions are made on the A/P radiograph of the hip. Determine the optimal position for the acetabular component and predict the size using template overlays. The acetabular teardrop can be referenced as the inferior margin of the acetabular reconstruction.

The goal in cementless acetabular fixation is to maximize bone contact. Once this is determined, mark the intended center of rotation of the bearing surface on the A/P radiograph (Figure B).

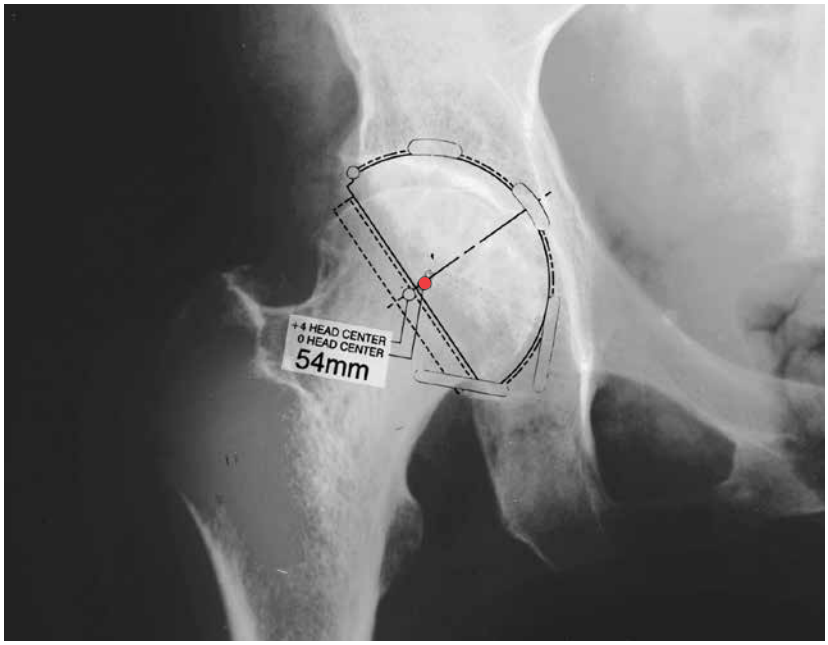


Figure B

Preoperative Planning, continued

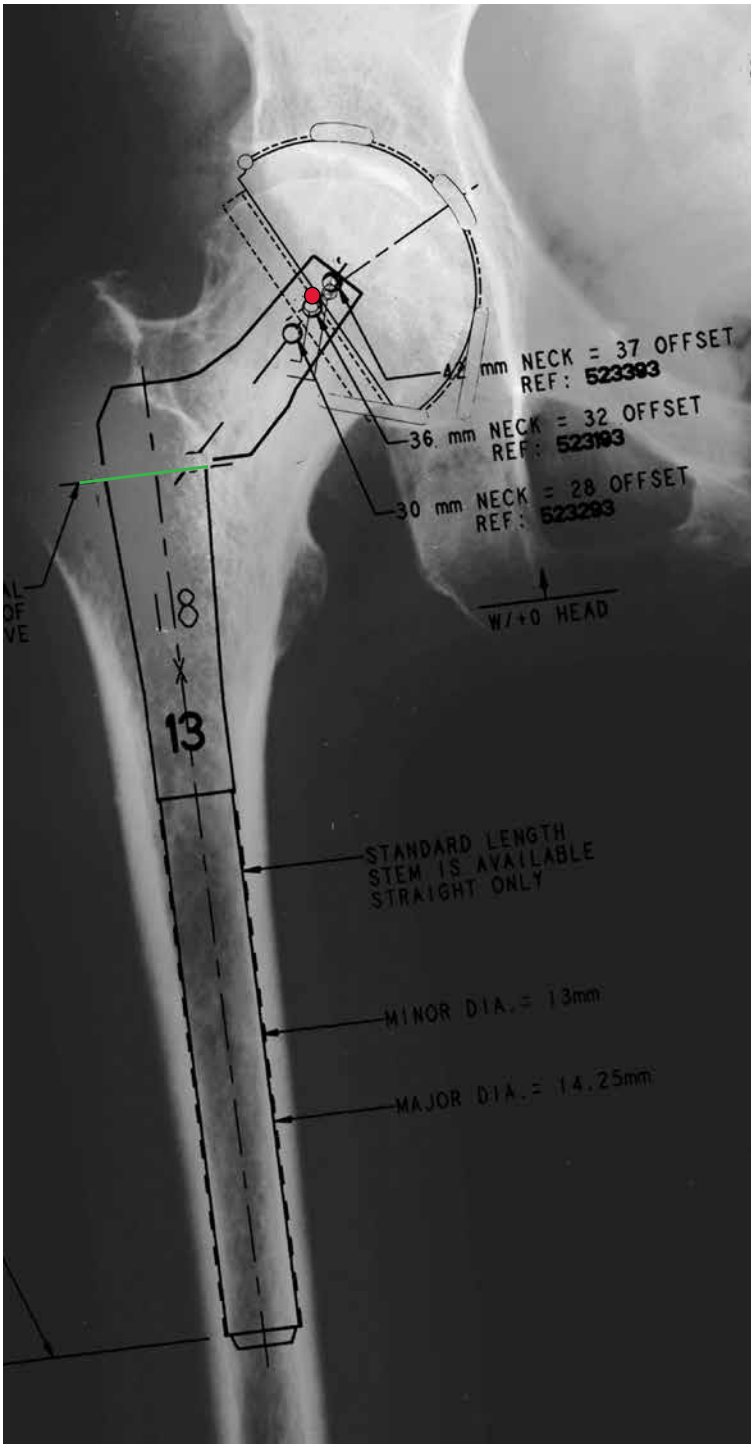


Figure C

Cementless Femoral Component Selection

Select the femoral component template size that will fit the distal femur and equalize leg lengths (Figure C). The distal stem diameter determines the range of possible ZTT™ sleeves that can be used proximally. The appropriate ZTT sleeve will allow for proximal fit and fill for stable fixation.

The femoral template should be in line with the long axis of the femur and the neck resection line drawn at the point where the selected stem provides the desired amount of leg length (Figure C). The vertical distance between the planned center of rotation of the acetabular component and the center of rotation of the femoral head constitutes the distance the leg length will be adjusted. The level of neck resection depends on the stem size and the desired leg length, with the goal of using a non-skirted modular head to optimize range of motion prior to prosthetic impingement.

A lateral radiograph should also be obtained as part of preoperative planning. To help properly position the template on the lateral radiograph, estimate the distance between the tip of the greater trochanter and the neck resection line of the stem using the A/P radiograph. Verify that the stem size chosen in the A/P plane also fits in the lateral plane. The lateral radiograph of a properly sized implant will typically exhibit appropriate fixation.

Sleeve Selection

Overlay the ZTT sleeve template cone size that corresponds to the selected stem and provides adequate proximal bone fill (Figure D). Position the sleeve template using the centerline of the stem, the centerline of the sleeve and the horizontal resection line. The ZTT sleeve is estimated most accurately from the lateral endosteum (i.e., the metaphyseal A/P diameter).

Offset Requirements

The S-ROM cementless femoral components are available in a range of offsets and calcar options. Through templating and intraoperative trialing, determine which option restores proper offset by matching the cup's center of rotation with the desired head center of rotation (Figure D).

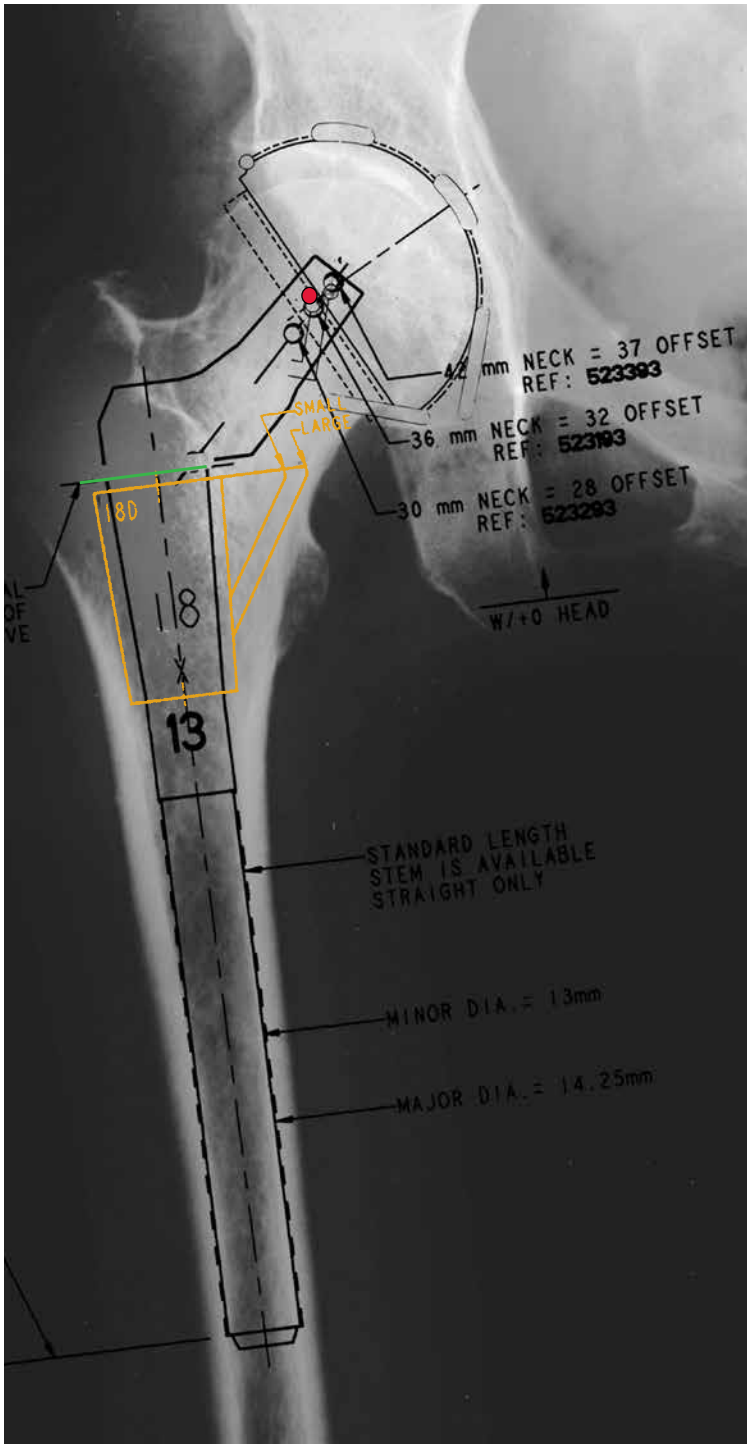


Figure D

Femoral Preparation

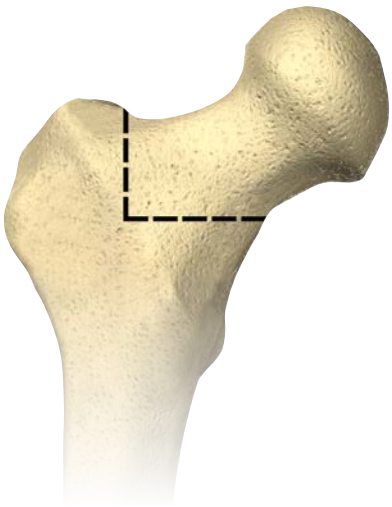


Figure 1
Neck resection

Figure 2
Biomechanical femoral neck resection template

Figure 3
Opening the femoral canal

Neck Osteotomy

With S-ROM, a higher, more conservative, perpendicular neck osteotomy may be utilized. It is recommended that preoperative templating be used to make the neck cut (Figure 1).

Additionally, a preliminary resection of the femoral neck can be performed using the biomechanical femoral neck resection template (Cat. No. 2576-00-004) as a guide (Figure 2). The hole in the neck of the resection template is located at the center of the femoral head (28mm). The notch on the medial aspect of the template indicates the most distal point for making the neck resection. The device is adjustable and can duplicate a range of lateral offsets, leg lengths and head positions. Final neck preparation can be performed later in the procedure (during calcar reaming).

Opening Canal

Open the femoral canal by penetrating the superior femoral cortex with the IM initiator (Cat. No. 2576-00-006) (Figure 3). Start the IM initiater at the junction of the neck resection and the complementary cut at the trochanteric fossa. To protect against varus positioning, the circular box osteotome (not shown) (Cat. No. 2576-00-002) can be used to remove additional bone from the medial aspect of the greater trochanter.

Distal Ream – Step 1

Distal Preparation

The distal diameter determines the corresponding proximal stem diameter, which is always 5 mm larger than its distal diameter. The final distal diameter reamed will also dictate the color-coded instrumentation needed for the remainder of the case (Table 1).

Begin axial reaming with the smallest reamer in your set (8 mm for the standard set and 6 mm for the DDH set) in conjunction with the T-handle attachment. The smallest reamer in each set is end cutting, whereas all consecutive sizes are blunt-nosed side-cutting only. Continue to ream sequentially with increasing reamer diameters until cortical contact is achieved. In keeping with preoperative planning, the final straight reamer should correspond to, or be a half millimeter larger than, the minor diameter of the selected femoral stem (Table 1). The appropriate reamer depth has been established when the witness mark on each distal reamer aligns with the tip of the greater trochanter (Figure 4).

Press-fit can be achieved when over-reaming by .5 mm because the distal flutes add 1.25 mm total to the specified distal stem minor diameter on sizes 13 mm and greater. Distal stem sizes of 7, 8, 9, & 11 mm have 1.0 mm total of additional flute diameter (Table 1). The 6 mm DDH distal stem has 0.75 mm of additional flute diameter.

Caution: Before moving past any one of the final distal reamer diameters listed in Table 1, make sure you are comfortable reaching the next largest final distal reamer diameter.
For example, if you distally ream past 13.5 mm, be confident that the anatomy will allow you to reach to a minimum of 15.5 mm.

Table 1

DISTAL REAMER SELECTION FOR STRAIGHT STEMS			
Color Code	Stem Size	Final Distal Reamer	Distal Flute Outer Diameter
Silver	9 x 14 mm	9 or 9.5 mm	10 mm
Gold	11 x 16 mm	11 or 11.5 mm	12 mm
Green	13 x 18 mm	13.5 mm	14.25 mm
Blue	15 x 20 mm	15.5 mm	16.25 mm
Black	17 x 22 mm	17.5 mm	18.25 mm
Brown	19 x 24 mm	19.5 mm	20.25 mm

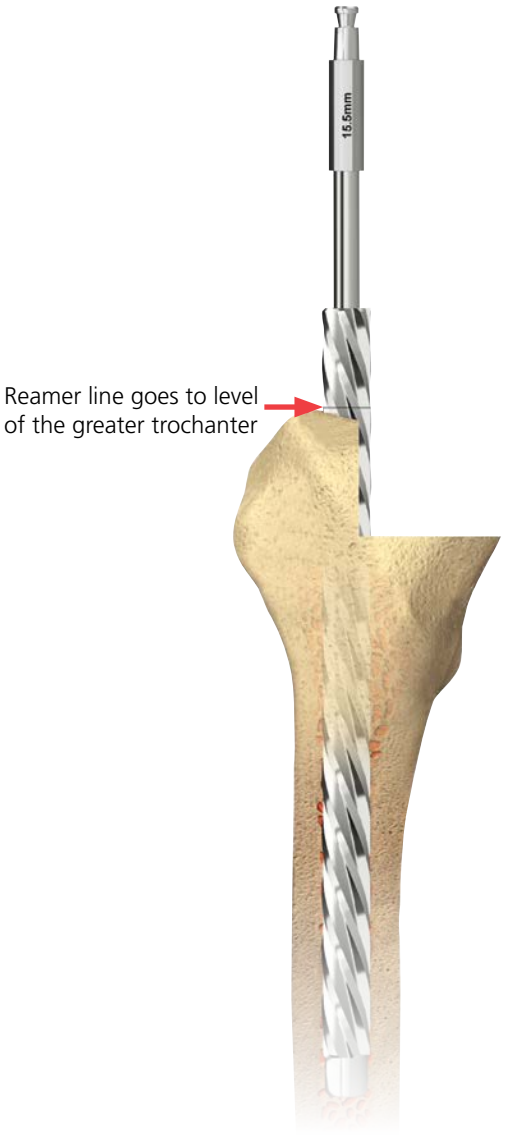


Figure 4
Distal reaming

Proximal Ream – Step 2

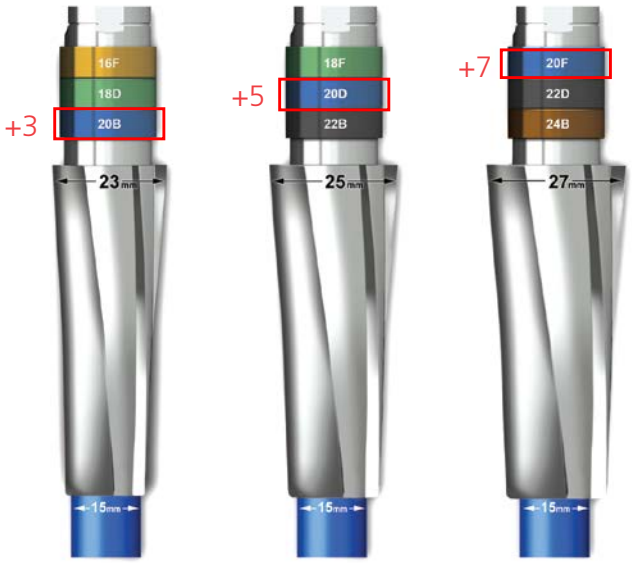


Figure 5

The three proximal reamers available for the 15 mm x 20 mm stem

Caution: You must always place the appropriate size color-coded pilot shaft on the distal end of the proximal reamers.

Table 2

CONE SIZING CHART CONE SIZING CHART (mm)					
Proximal Reamer Diameter	19	21	23	25	27
Available Sleeves		14F	16F	18F	20F
	14D	16D	18D	20D	22D
	16B	18B	20B	22B	24B
Distal Stem Diameter	9, 11	9, 11, 13	11, 13, 15	13, 15, 17	15, 17, 19

Upon completion of distal reaming, prepare the proximal or "cone" portion of the final sleeve to be implanted. A set of triple banded, color-coded cone reamers are available for preparing the proximal canal (Figure 5). The proximal diameter of each conical reamer is marked in large print. On the opposite side, the three proximal sleeve sizes (i.e., 23mm, 25 mm, & 27 mm) are marked with the corresponding sleeve configuration (i.e., 20 B, 20 D, & 20 F, respectively). The location of each color band moves from distal to proximal as the proximal diameter increases. After attaching the color-coded pilot shaft to the distal end of the conical reamer, advance the reamer until the witness marking of the desired neck length (either 30, 36 or 42 mm) aligns with the tip of the greater trochanter (Figure 6). Consecutively proximally ream until cortical contact is achieved in the proximal femur. Contact will be felt first in the anterior femur in the subtrochanteric region. **Do not drive the reamer in reverse**.

In the example shown in Figure 5, the final distal diameter revealed that this patient required a 15 mm distal stem corresponding to the blue instrumentation in the MACH1 instruments. Therefore, the three proximal reamers with blue bands, as well as the blue pilot shafts were selected (Figure 5). Pilot shafts MUST be screwed into the distal end of the proximal reamers before the reamer may be introduced into the femur.

Table 2 shows the stems (proximal reamer diameter at the top and the distal stem diameters at the bottom) and how these stems correlate with the available proximal sleeve sizes. Distal diameters of 6, 7 & 8 mm DDH stems are not shown.

Begin proximal reaming with the smallest of the reamers. In the case of a 15 mm X 20 mm stem, the first proximal reamer used is the 20 B. Note that the first proximal reamer has the color band most distal and is always denoted as B, adding +3 mm to the proximal diameter. If the surgeon feels that more cancellous bone should be removed, a 20 D proximal reamer would be used, adding +5 mm to the proximal diameter. Note that the blue band is now in the middle of the proximal reamer for the D option. Lastly, should the surgeon need to remove even more proximal bone, a 20 F reamer would be selected that would add +7 mm to the proximal diameter. For the F proximal reamer, the color band is most proximal on the reamer.

To summarize, for a 15 mm x 20 mm stem, blue instruments are selected, the final proximal sleeve diameters for B, D and F are 23, 25 and 27 mm respectively.

Alternative Technique: Depending on the osteotomy cut and the ability to visualize the greater trochanter, you may opt to simply line up the top of the proximal reamer with the osteotomy surface as shown by a blue arrow in Figure 6. Trialing would then be critical for selecting the final implants that best restore leg length and femoral offset.

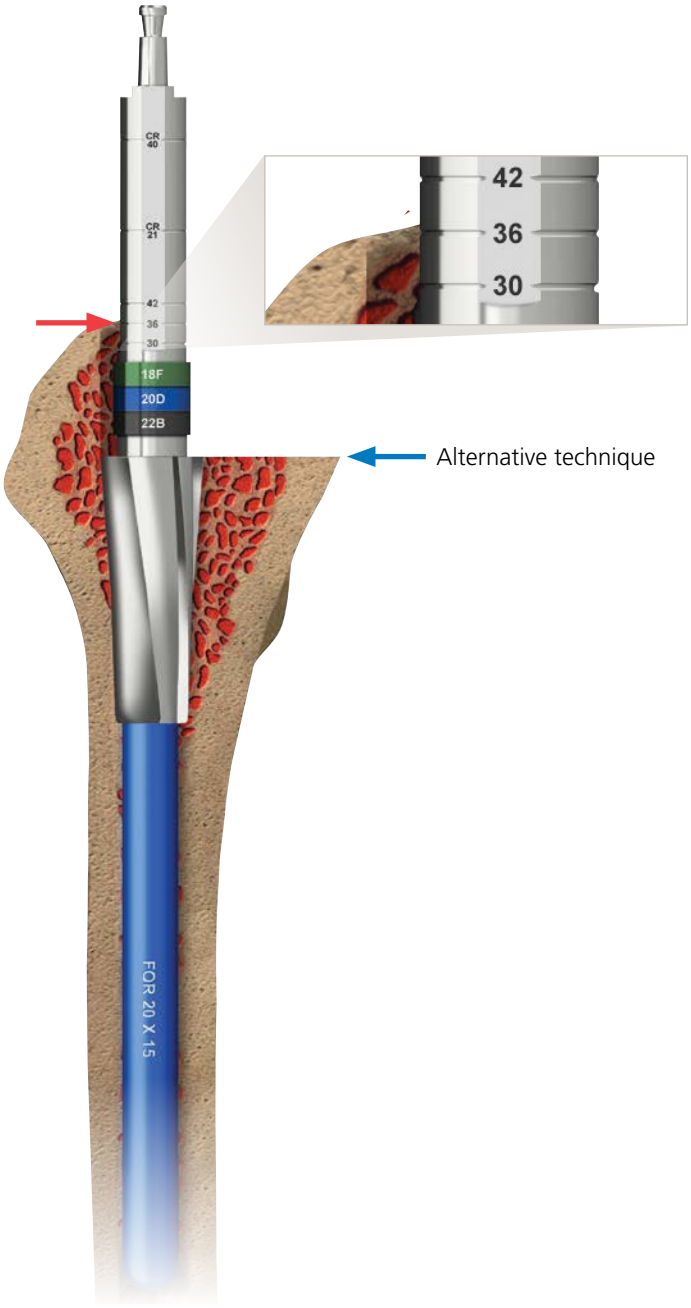


Figure 6

Cone reaming

Calcar Ream / Mill – Step 3

Lastly, the spout or triangle of the proximal sleeve must be machined. Spout sizing comes in Small, Large or XX-Large. The spout size on the ZTT sleeve is proportional to the diameter of the stem.

Use the triangle miller to prepare the femur to accommodate the calcar spout of the final sleeve. In most instances, the final triangle is placed in the medial proximal femur. However, because the placement does not dictate the neck version, the triangle can be rotated 360 degrees to place the sleeve in optimal bone. SPA sleeves (without a spout) are also available in this system to accommodate unusual anatomies. Cone preparation will not be necessary if using a SPA sleeve.

Select the miller shell that has the identical color band pattern as was present on the final cone reamer used in the proximal reaming step (Figure 7). Numeric markings of the proximal diameter are found on cone reamers and miller shells for cross reference verification.

After attaching the miller shell and the miller frame to the appropriate pilot shaft, gently lower the triangle miller. Align the desired neck length witness mark with the tip of the greater trochanter (Figure 7).

The ring of the miller frame can be rotated so that it targets the best available host bone (Figure 8).

Caution: You must always place the appropriate color-coded pilot shaft on the distal end of the triangle miller frame.

Alternative Technique: You can line up the top of the miller frame bevel to the level of the osteotomy surface as shown by the blue arrow in Figure 7 to ensure that the sleeve will fit in the proximal femur. Trialing will be critical for selecting the final implant components that best restore leg length and femoral offset.

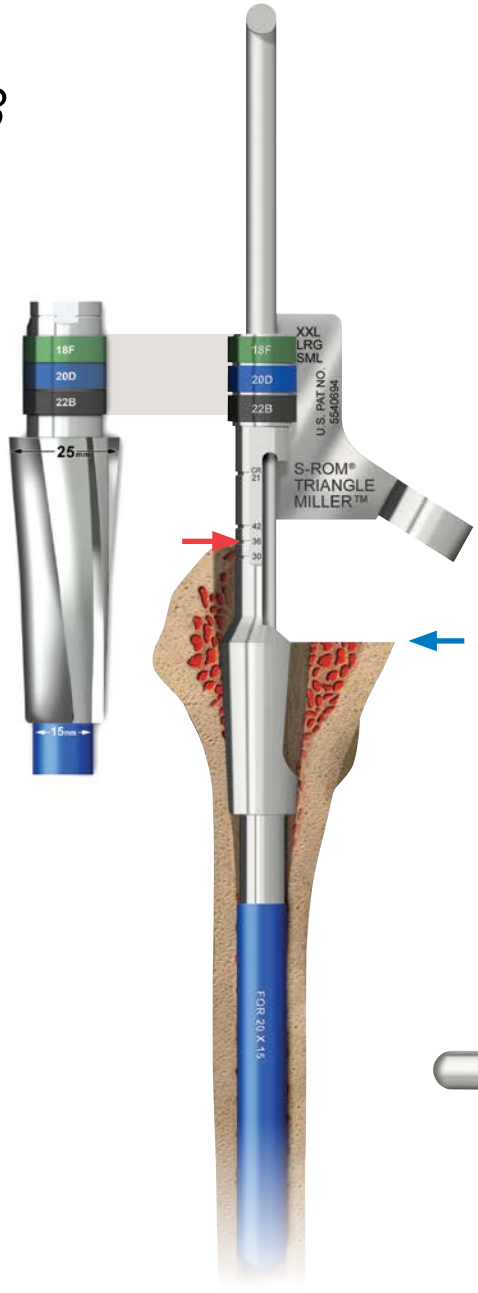


Figure 7

Positioning of triangle miller shell

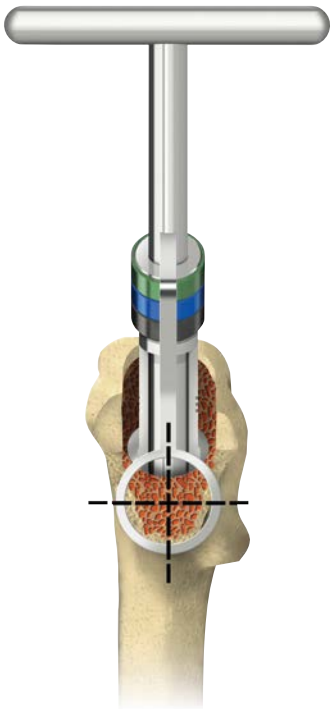


Figure 8

Positioning of triangle miller frame

Figure 9
Calcar reaming

Recess to the top of the groove in the triangle miller for the desired spout size as shown by the red arrow in Figure 9. If using a B or D cone, be careful to not allow the triangle milling to go to XXL, since XXL spouts are not available for these cone sizes.

Select the appropriate size miller drill that corresponds to the color-coding used throughout the procedure.

Pass the miller drill through the ring and load the drill tip into the guide hole before starting the drill. Lower the miller frame so that the miller drill makes contact with the cancellous bone to be milled (Figure 9).

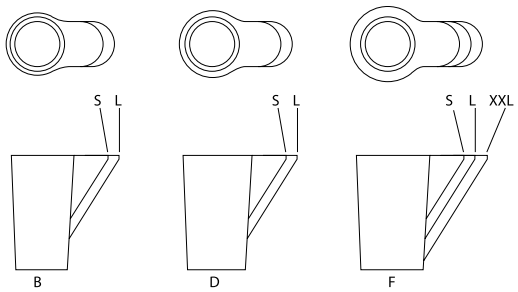
Mill on power until desired cortical bone has been exposed. To determine the final spout size (Small, Large, or XXL), make note of the size indicated where the markings on the miller frame align with the top of the miller shell as shown by the red arrow in Figure 9.

TRIANGLE SPOUT SIZING CHART

Small
Extends 9.5 mm from the cone

Large
Extends 13.5 mm from the cone

XX-Large
Extends 17.5 mm from the cone



Caution: Before proceeding from one spout size to the next, confirm that there is enough calcar bone to accommodate 4 mm of additional reaming to reach the next spout size (i.e., Small to Large or Large to XXL). Please review the Triangle Spout Sizing Chart for more detail.

Trial

Trial Sleeve

Secure the sleeve introducer handle (Cat. No. 53-5801) onto the appropriate size sleeve introducer corresponding to the selected sleeve size. As an example, a proximal sleeve trial designated 20 D large is a sleeve that will fit a 15 x 20 stem with a D outer diameter (adding 5 mm to the proximal diameter) and a large spout (extending 13.5 mm). Proximal sleeve trials are color coded. Attach the appropriate colored pilot shaft onto the sleeve introducer and slide on the sleeve.

Note: The trial sleeve is not secured / retained on the sleeve introducer so care must be taken to prevent the trial sleeve from falling off the introducer.

Gently impact the trial sleeve into the prepared metaphysis (Figure 10). Seat the trial sleeve completely and withdraw the introducer handle (Figure 11). At this point, evaluate the sleeve in relation to its final position.

Caution: Make sure that the bolt on the sleeve introducer handle is facing toward the spout. If the bolt cannot be seen, the handle could disconnect from the sleeve introducer attachment.

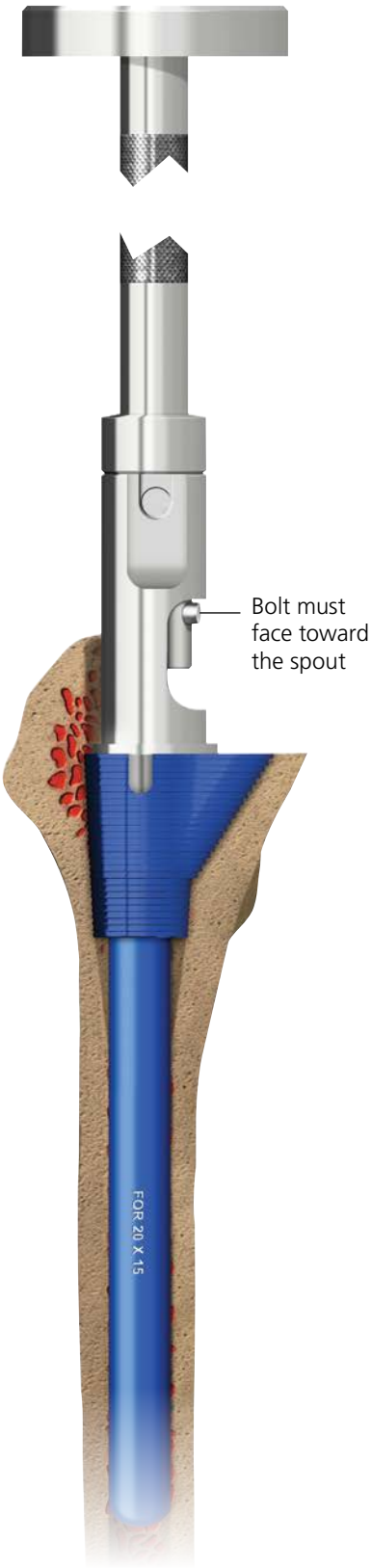


Figure 10
Trial sleeve insertion

Figure 11
Trial sleeve position

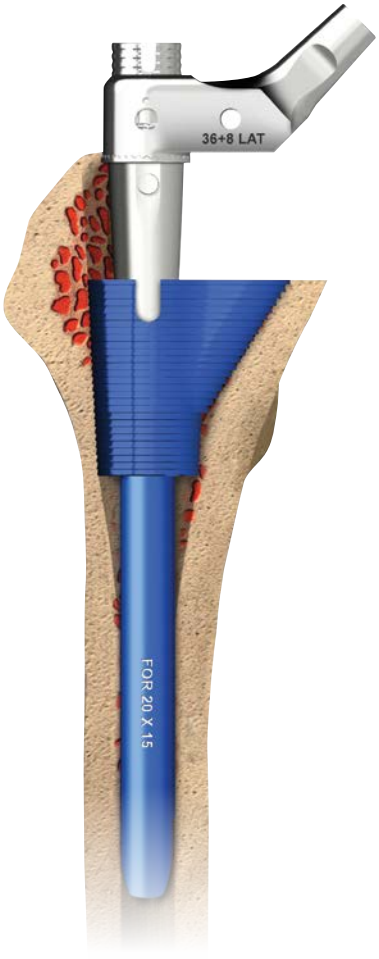
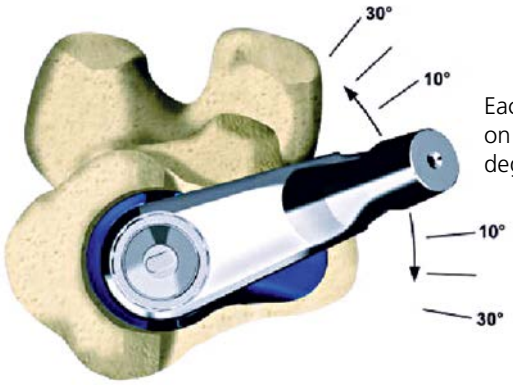


Figure 13
Trial stem insertion



Each click on trial is 10 degrees

Figure 14
Version adjustment

Note: To record version, a Bovie may be utilized on an anatomic landmark.

Trial Stem

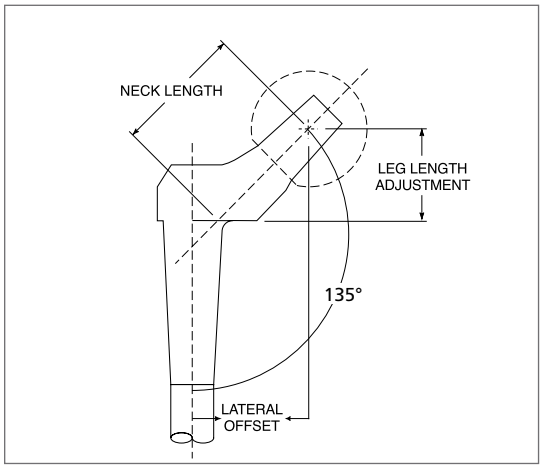
Restoring patient biomechanics is achieved with a wide range of neck options (Table 3).

Table 3

NECK SIZING CHART — ASSUMES USE OF +0 HEAD (All necks have an included angle of 135 degrees)			
Neck Style	Neck Length (mm)	Lateral Offset (mm)	Leg Length Adjustment (mm)
Standard	30	28	21
Standard	36	32	25
Standard	42	37	30
Standard + 4 Lat	30	32	21
Standard + 6 Lat	36	38	25
Standard + 8 Lat	36	40	25
Standard + 12 Lat	36	44	25

Figure 12 shows the neck shaft angle and how neck length, lateral offset, and leg length adjustment are measured.

Figure 12



Assemble the trial implant by snapping the chosen neck onto the appropriate size distal stem trial. Align the lateral laser marks in neutral initially and introduce the trial neck and trial stem construct into the femoral canal (Figure 13). The trial neck can be adjusted in 10-degree increments until desired version is obtained (Figure 14). Tighten the trial neck to the trial stem using the nut tightener (Cat. No. 2576-52-100). Trial reduction can also be performed with Long, X-Long and XX-Long distal stem trials.

Tip: The opposite end of the nut tightener will thread onto the stem trial for extraction, should that be necessary.

Final Implantation

You can separate the trial sleeve and trial stem using the stem-sleeve separator (Cat. No. 53-6450). Remove the trial stem and use the sleeve extractor (not shown), (Cat. No. 2576-00-016) to remove the trial sleeve. The sleeve extractor works by being placed on an extreme angle to catch the distal lip of the sleeve.

Place the proximal sleeve implant onto the sleeve introducer assembly and gently impact the sleeve into the metaphysis (Figure 15).

Again, note that the sleeve is not secured/ retained on the sleeve introducer assembly.

Introduction of the femoral implant into the femoral canal can be done by hand initially until the distal flutes begin to make cortical contact (Figure 16). A witness mark located on the medial aspect of the femoral implant can be aligned with the corresponding radial laser markings on the superior aspect of the sleeve implant to determine anteversion. Each radial mark on the sleeve represents 20 degrees (Figure 16). Use these orientation lines on the stem and sleeve to ensure that the final implant alignment is consistent with trial alignment.

Figure 15
Sleeve insertion

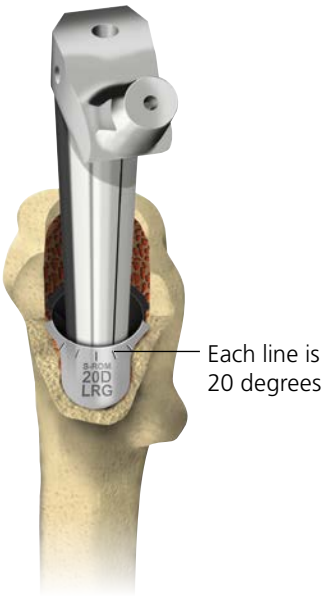


Figure 16
Stem insertion

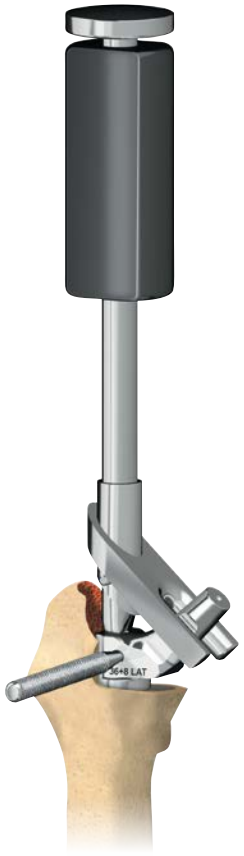
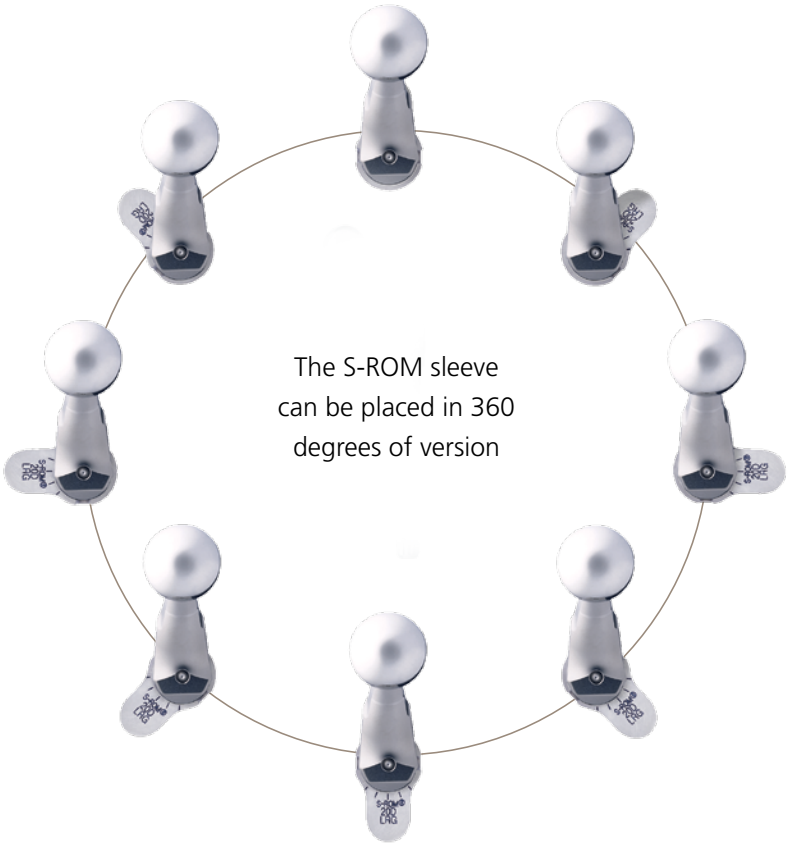


Figure 17
Stem insertion

Place the stem introducer handle (Cat. No. 53-2029) onto the femoral implant and insert the pin punch (Cat. No. 53-1500) into the rotational alignment hole in the femoral neck (Figure 17). Using the pin punch as a version control guide, impact the femoral implant until securely seated. The taper is locked when the stem will no longer advance and 2-3 mm remains between the inferior aspect of the femoral neck and the superior aspect of the implant sleeve.

Confirm the final placement of the S-ROM implants using the neck resection guide and/or preoperative templates.



Stem Removal Note: It is critical to first unlock the taper between the stem and the sleeve using the stem-sleeve separator (Cat. No. 53-6450). To extract the stem, use the slap hammer instrumentation found in the S-ROM Long Trials & Extraction Instruments case. To assemble the slap hammer, slide the handle (53-1207) into the side of the weight (53-1205), place the weight through the shaft (53-1206). Screw the extractor stem loop (53-4400) onto the end of the slide hammer shaft. Place the extractor stem loop over the head/neck of the stem until the loop engages the trunion/head. Using appropriate force slide the slide hammer weight up impacting the handle stop of the slide hammer shaft until the stem is dislodged.

Implant Ordering Information

STEM DIAMETER & LENGTHS		FEMORAL NECKS STANDARD			FEMORAL NECKS LATERALIZED				FEMORAL NECKS CALCAR REPLACEMENT & LATERALIZED		
Neck Length		**30**	**36**	**42**	**30 +4**	**36 +6**	**36 +8**	**36 +12**	**36 +21**	**36 +21 +4**	**36 +21 +8**
Lateral Offset w/ +0 Femoral Head		**28**	**32**	**37**	**32**	**38**	**40**	**44**	**32**	**36**	**40**
Leg Adjustment Length		**21**	**25**	**30**	**21**	**25**	**25**	**25**	**46**	**46**	**46**
12x6	N Standard	**115mm** 523206									
12x7	N Standard	**115mm** 523207									
14x8	N Standard	**130mm** 523208									
14x9	N Standard	**130mm** 523291 **150mm** 523251	**130mm** 523191		**130mm** 563514						
	N,L,R Long		**205mm** 526514N 526514L 526514R		**205mm** 563214N 563214L 563214R				**205mm** 526614N		
16x11	N Standard	**150mm** 523292	**150mm** 523192		**150mm** 563516	**150mm** 563517			**150mm** 526676		
	N,L,R Long		**205mm** 526516N 526516L 526516R		**205mm** 563216N 563216L 563216R					**205mm** 563016N 563016L 563016R	
	N,L,R X-Long									**240mm** 563036N 563036L 563036R	
	N,L,R XX-Long									**300mm** 563056N 563056L 563056R	
18x13	N Standard	**160mm** 523293	**160mm** 523193	**160mm** 523393	**160mm** 563518		**160mm** 523418	**160mm** 563618	**160mm** 526678		
	N,L,R Long		**215mm** 526518N 526518L 526518R	**215mm** 526418N 526418L 526418R			**215mm** 563118N 563118L 563118R				**215mm** 563018N 563018L 563018R
	N,L,R X-Long						**255mm** 563138L 563138R				**255mm** 563038N 563038L 563038R
	N,L,R XX-Long						**315mm** 563158L 563158R				**315mm** 563058N 563058L 563058R
20x15	N Standard		**165mm** 523194	**165mm** 523394			**165mm** 523420	**165mm** 563620	**165mm** 526680		
	N,L,R Long		**225mm** 526520N 526520L 526520R	**225mm** 526420N 526420L 526420R			**225mm** 563120N 563120L 563120R				**225mm** 563020N 563020L 563020R
	N,L,R X-Long						**270mm** 563140L 563140R				**270mm** 563040N 563040L 563040R
	N,L,R XX-Long						**325mm** 563160L 563160R				**325mm** 563060N 563060L 563060R

STEM DIAMETER & LENGTHS		FEMORAL NECKS STANDARD			FEMORAL NECKS LATERALIZED				FEMORAL NECKS CALCAR REPLACEMENT & LATERALIZED		
Neck Length		**30**	**36**	**42**	**30 +4**	**36 +6**	**36 +8**	**36 +12**	**36 +21**	**36 +21 +4**	**36 +21 +8**
Lateral Offset w/ +0 Femoral Head		**28**	**32**	**37**	**32**	**38**	**40**	**44**	**32**	**36**	**40**
Leg Adjustment Length		**21**	**25**	**30**	**21**	**25**	**25**	**25**	**46**	**46**	**46**
22x17	N Standard		**165mm** 523195	**165mm** 523395			**165mm** 523422	**165mm** 563622	**165mm** 526682		
	N,L,R Long		**230mm** 526522N 526522L 526522R	**230mm** 526422N 526422L 526422R			**230mm** 563122N 563122L 563122R				**230mm** 563022N 563022L 563022R
	N,L,R X-Long						**275mm** 563142L 563142R				**275mm** 563042N 563042L 563042R
	N,L,R XX-Long						**325mm** 563162L 563162R				**325mm** 563062N 563062L 563062R
24x19	N Standard		**175mm** 523196	**175mm** 523396			**175mm** 523424	**175mm** 563624	**175mm** 526684		
	N,L,R Long			**230mm** 526424N 526424L 526424R			**230mm** 563124N 563124L 563124R				**230mm** 563024N 563024L 563024R
	N,L,R X-Long						**275mm** 563144L 563144R				
26x21	N Standard		**175mm** 523197					**175mm** 563626			

PROXIMAL SLEEVES ZTT™ / ZTT™ SPA

Size	Small	Large	XX Large	SPA
12B	550570	550571		
12D	550572	550573		
14B	550501	550502		535342
14D	550503	550504		535344
14F	550505	550506		
16B	521463	521465		535362
16D	550513	550514		535364
16F	550515	550516	550520	535366
18F Oversized	550717	550718	550721	

Size	Small	Large	XX Large	SPA
18B	521483	521485		535382
18D	550523	550524		535384
18F	550525	550526	550530	535386
20F Oversized	550727	550728	550731	
20B	521403	521405		
20D	550533	550534		
20F	550535	550536	550540	
22F Oversized	550737	550738	550741	

Size	Small	Large	XX Large	SPA
22B	521423	521425		
22D	550543	550544		
22F	550545	550546	550550	
24F Oversized	550747	550748	550751	
24B	550561	550562		
24D	550564	550565		
24F	550567	550568	550569	
24D Undersized	550770	550771	550772	
24F Undersized	550777	550778	550779	

Essential Product Information

Important
This Essential Product Information sheet does not include all of the information necessary for selection and use of a device. Please see full labeling for all necessary information.

Indications
Total Hip Arthroplasty (THA) is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. The components of the S-ROM Total Hip System are indicated for use in total hip replacement procedures for patients suffering severe pain and disability due to structural damage in the hip joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, and nonunion of femoral fractures. Use of the prosthesis is also indicated for revision of previous hip arthroplasty and for patients with congenital hip dysplasia, protrusio acetabuli, slipped capital femoral epiphysis, and disability due to previous fusion. The ZTT Porous Coated Proximal Sleeves and SPA Porous Coated Proximal Sleeves are indicated for cemented application only.

Contraindications
Use is contraindicated in cases with active or recent joint sepsis, insufficient bone stock, marked atrophy or deformity in the upper femur, skeletal immaturity, or where loss of musculature or neuromuscular disease would render the procedure unjustifiable.

Warnings and Precautions
S-ROM femoral heads with +12 neck length extension cannot be used with the POLY-DIAL™ constrained liner. Any S-ROM ceramic femoral head that has been impacted or dropped should be discarded and another ceramic femoral head used. If a ceramic femoral head is removed from the femoral stem after assembly, a new head should be used. The removed head should be discarded and under no circumstances be reused. Do not use ceramic heads with constrained acetabular liners. The femoral head size and the inner diameter of the acetabular components must correspond. ZT and ZTT oversized proximal sleeves must be used with S-ROM stems having a nominal proximal diameter 2 mm smaller than the nominal diameter of the sleeve. For all other S-ROM proximal sleeves, the nominal proximal stem diameter must correspond with the nominal diameter of the sleeve. The trochanter screws and washers must be used together with the S-ROM 36+21 calcar replacement neck femoral stem.

Adverse Events
Peripheral neuropathy, deep wound infection, and heterotopic bone formation have been reported following hip replacements. Subclinical nerve damage has also been reported. Dislocation, subluxation, muscle and fibrous tissue laxity, and loosening may also occur.

The ceramic femoral heads are composed of new ceramic materials with limited clinical histories. Because of the limited clinical and preclinical experience, the long-term biological effects of these particulates are unknown. Histological reactions have been reported as an apparent response to exposure to a foreign material.

S-ROM MACH 1 instruments™

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CAUTION: USA Law restricts these devices to sale by or on the order of a physician.

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0601-36-050 (Rev. 8) 0.5M 11/13