SURGICAL TECHNIQUE

S-ROM®

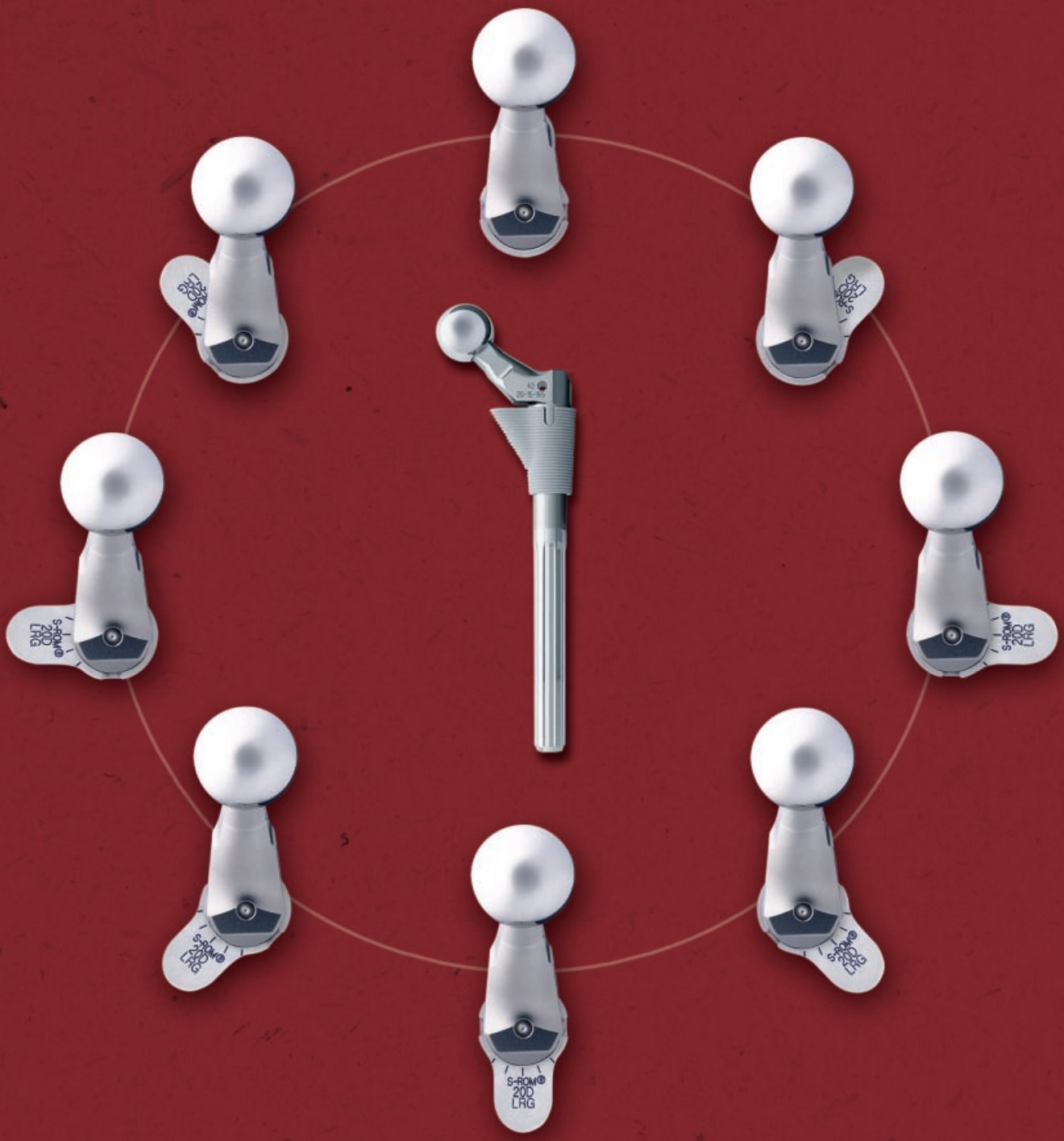
MODULAR HIP SYSTEM

S-ROM MACH 1™ instruments

SINCE 1984

DePuy
a Johnson & Johnson company

PROVEN. VERSATILE. SIMPLE.



S-ROM®

MODULAR HIP SYSTEM

In use since 1984, the S-ROM® Modular Hip System has been successfully implanted in over 100,000 cases. As the only modular hip system with 360 degrees of version, the versatility of its independent neck and sleeve puts more control in the hands of the surgeon, providing solutions for a variety of surgical scenarios, from primary total hip arthroplasty (THA) to the most complex revision or DDH challenge.

Intimate fit is key to the design philosophy of the S-ROM Modular Hip System. The instrumentation allows for precise machining of the canal to achieve an accurate fit that distributes the load evenly and provides rotational stability. In a study that compared an intimate fill with robotically machined femora, Paul et al. found that broaching tore the trabecular bone, whereas femoral canal preparation with reamers was consistently more accurate.[1]

The S-ROM system utilizes a straightforward surgical technique involving distal reaming, proximal reaming and calcar milling. The streamlined instrumentation features enhanced color-coding, ergonomic improvements, instrument-implant consistency throughout and a layout that is easy to follow, thus saving time. Keeping the design philosophy in mind, the new S-ROM® MACH1™ Instruments (pictured below) live up to their name in **M**illing **A**ccurate **C**onsistent **H**ips.

S-ROM® MACH1™ instruments

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

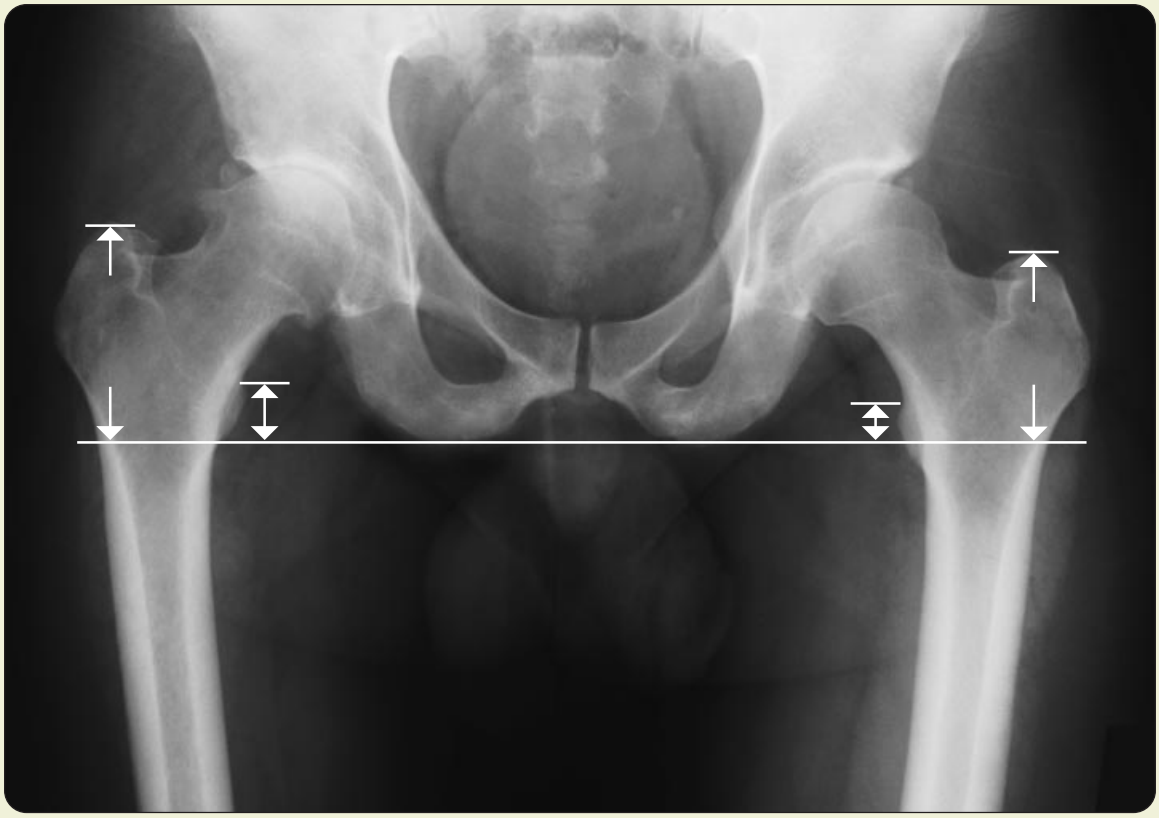


FIGURE A

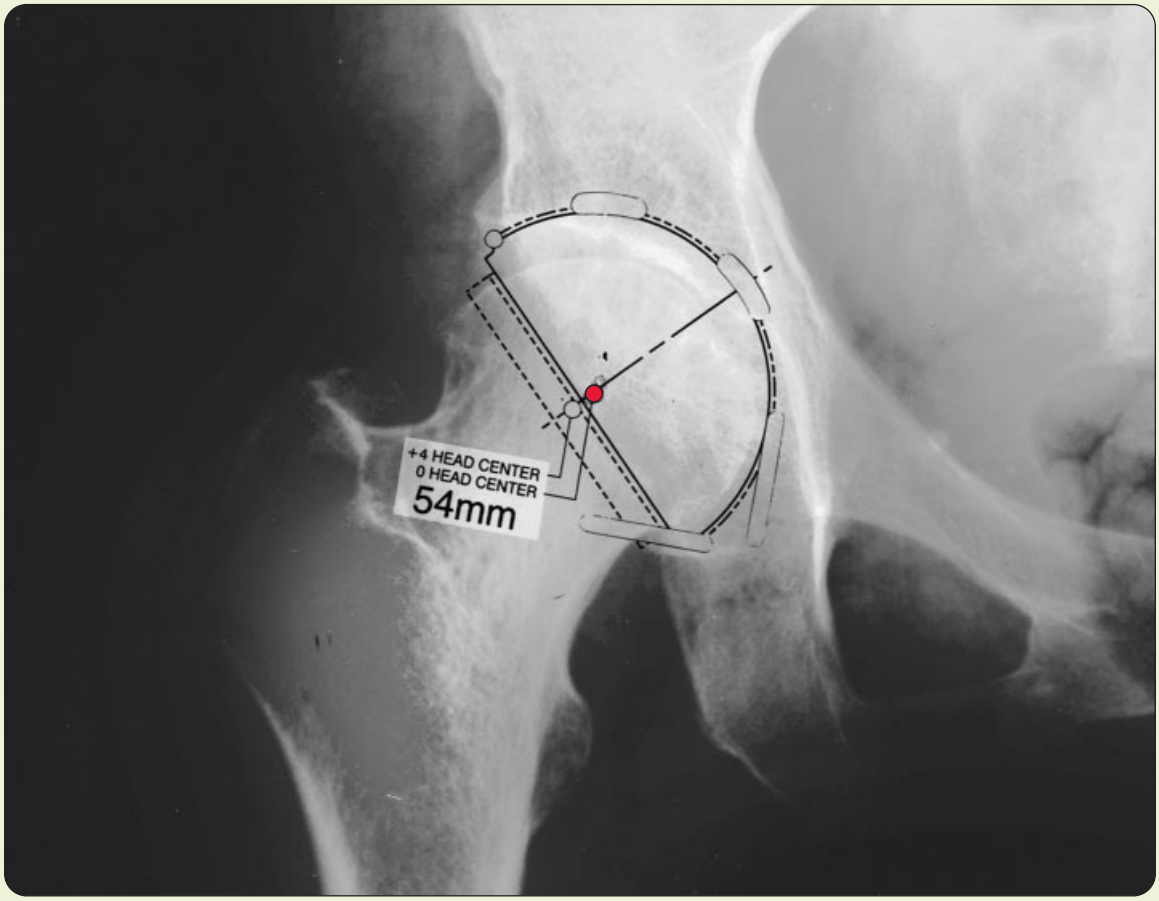


FIGURE B

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 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.

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**).

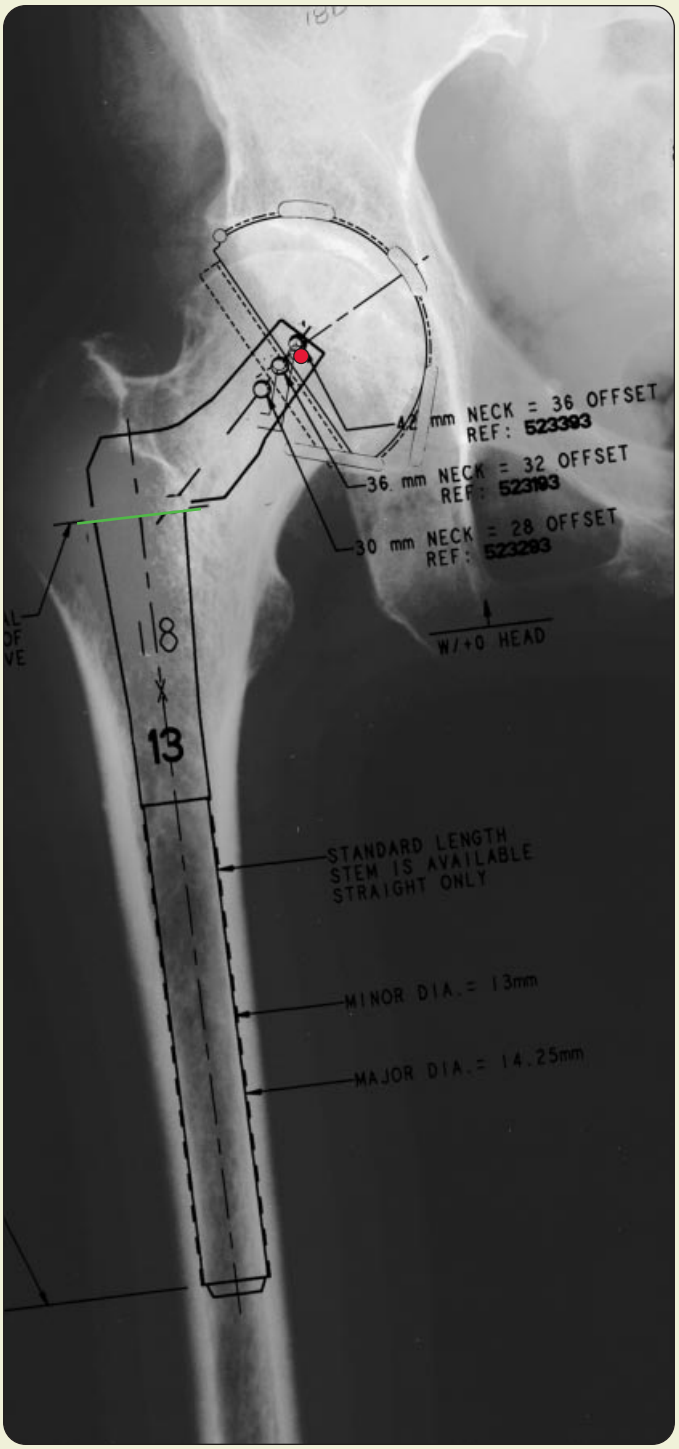


FIGURE C

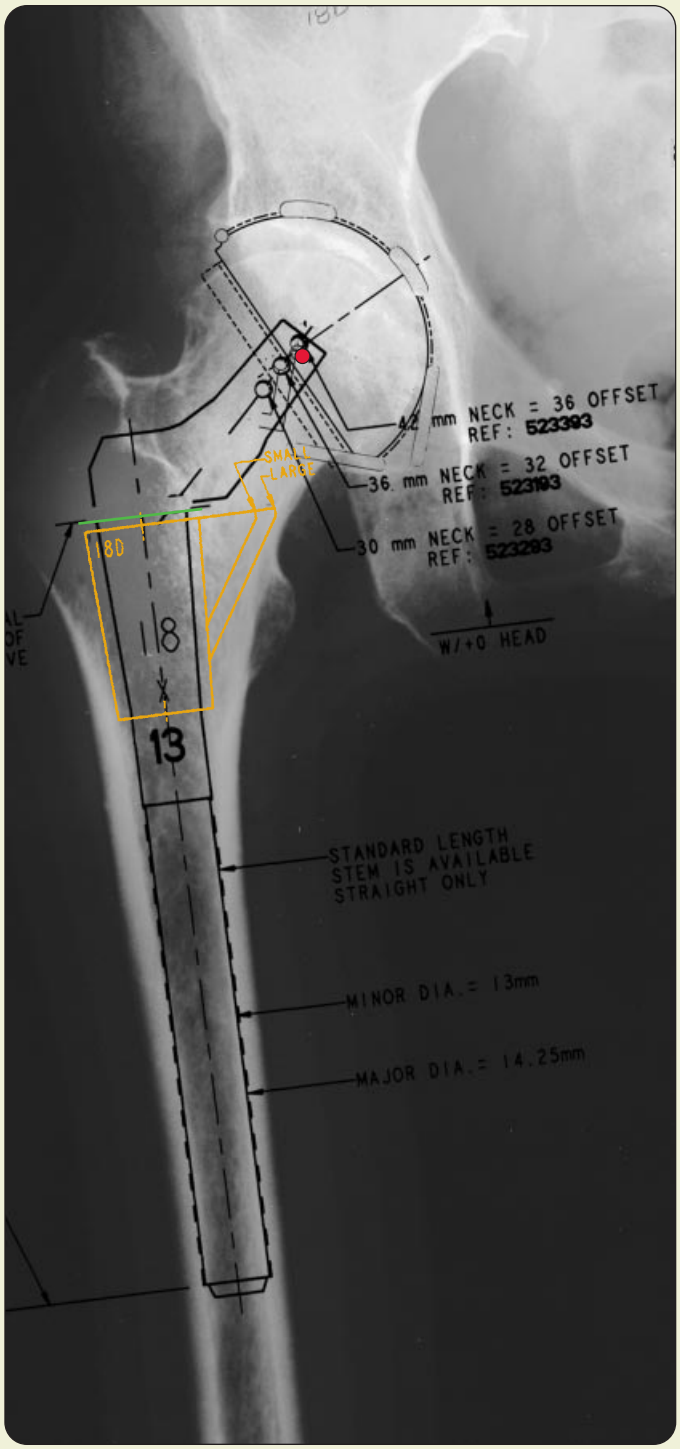


FIGURE D

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**).

1 NECK RESECTION

Perform a preliminary resection of the femoral neck using the biomechanical femoral neck resection template as a guide (**FIGURE 1a**). 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. The device is adjustable and can duplicate a range of lateral offsets, leg lengths and head positions. With S-ROM, a higher, more conservative neck osteotomy may be utilized (**FIGURE 1b**). Final neck preparation is performed later in the procedure.

2 CANAL OPENING

Open the femoral canal by penetrating the superior femoral cortex with the box osteotome and/or stepped starter drill (**FIGURE 2**). Enter the medullary canal by employing the starter drill, beginning at the posterior margin of the junction of the neck resection and the complementary cut at the trochanteric fossa. To protect against varus positioning, the box osteotome can be used to remove additional bone from the medial aspect of the greater trochanter.

3 DISTAL PREPARATION

Sizing begins with the distal stem selected. The distal diameter determines the corresponding proximal stem diameter, which is always 5 mm larger than its distal diameter.

DISTAL REAMER SELECTION FOR STRAIGHT STEMS

Color Code	Stem Size	Final Distal Reamer
Silver	9 x 14 mm	9 or 9.5 mm
Gold	11 x 16 mm	11 or 11.5 mm
Green	13 x 18 mm	13 or 13.5 mm
Blue	15 x 20 mm	15 or 15.5 mm
Black	17 x 22 mm	17 or 17.5 mm
Brown	19 x 24 mm	19 or 19.5 mm

Begin axial reaming with the smallest reamer and work up sequentially 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 (**SEE DISTAL REAMER SELECTION CHART**). Press-fit can be achieved when over-reaming by .5 mm because the distal flutes add 1.25 mm to the specified distal stem diameter on sizes 11 mm and greater (distal stem sizes smaller than 11 mm have 1.0 mm of additional flute height). The appropriate reamer depth has been established when the witness mark on each distal reamer aligns with the tip of the greater trochanter (**FIGURE 3**).

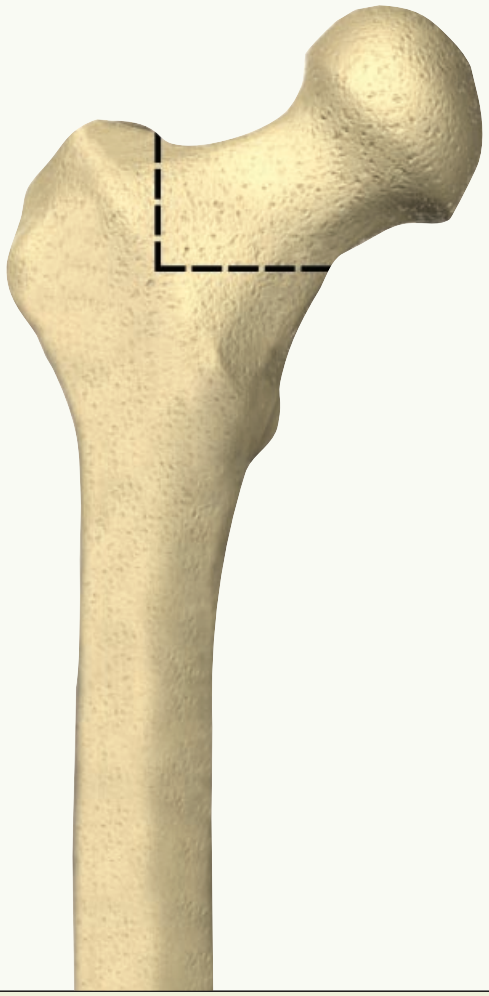
A full complement of side-cutting, blunt-nosed distal reamers is available, starting at 8 mm and growing in half-millimeter increments to 21 mm.

1 BIOMECHANICAL NECK RESECTION TEMPLATE

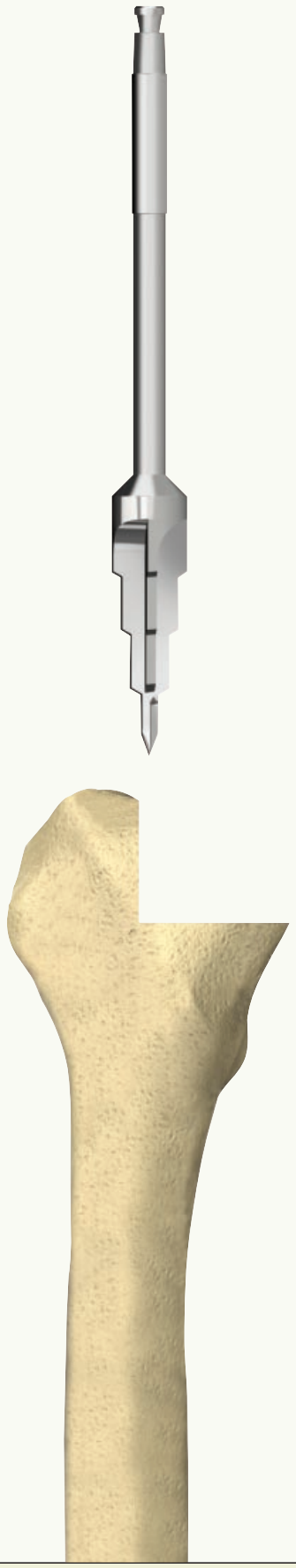
a

1 NECK RESECTION

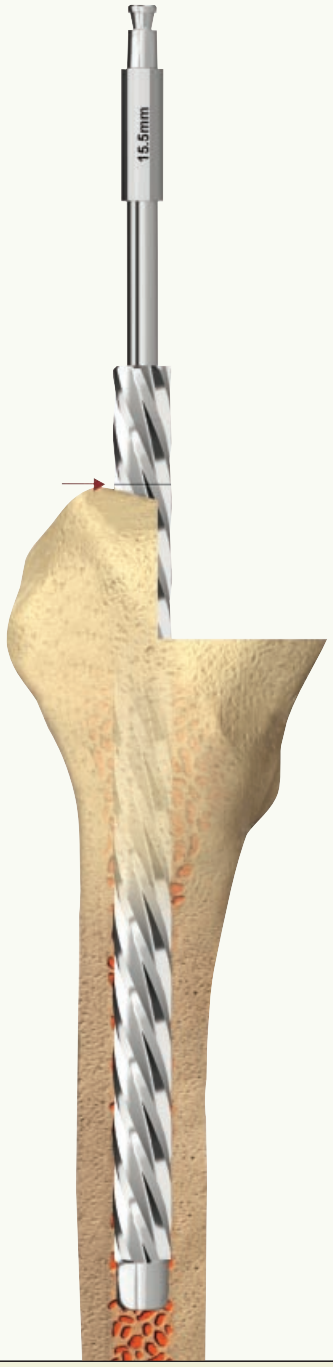
b



2 OPENING THE FEMORAL CANAL



3 DISTAL REAMING

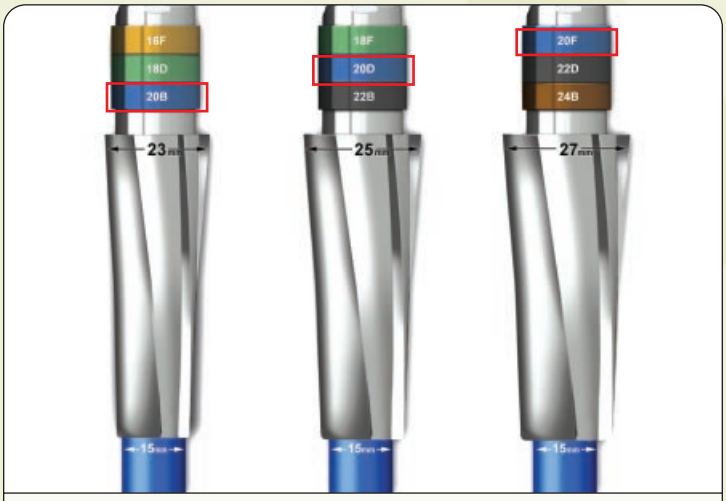


4 CONE SIZING AND REAMING

S-ROM stems have been sized by the inside diameter of the proximal sleeve to assure precise mating of stem and sleeve. The chart below shows the stem's actual distal diameter and how it correlates with a range of proximal sleeve sizes.

CONE SIZING CHART (Additional sizes are available.)

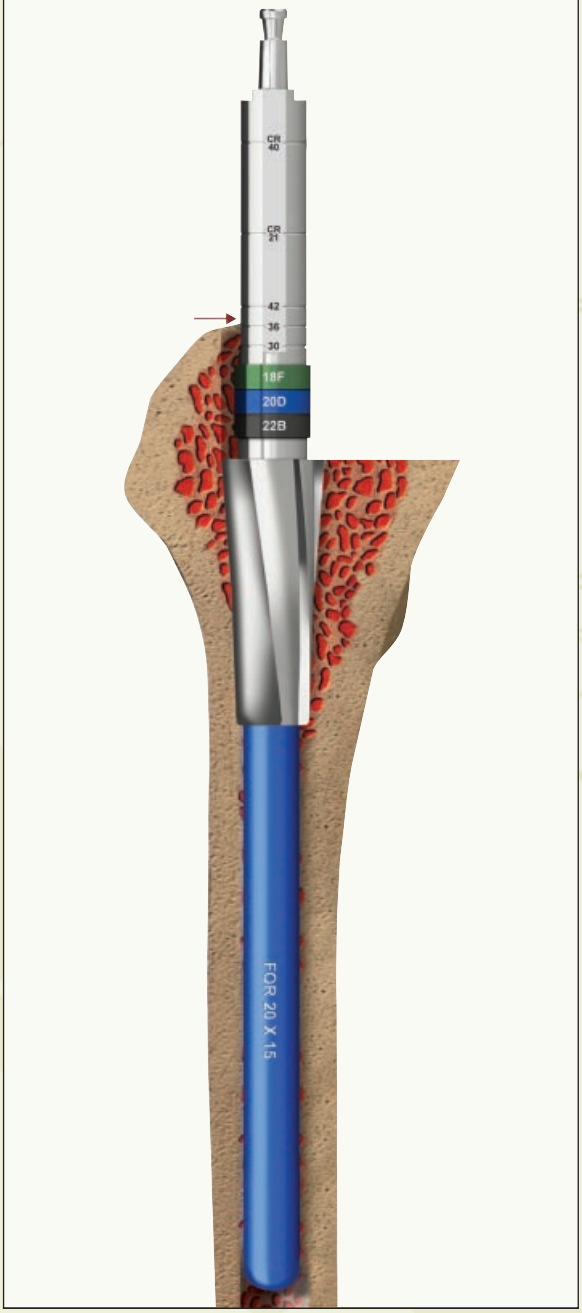
A/P Diameter	19	21	23	25	27
		14F	16F	18F	20F
	14D	16D	18D	20D	22D
	16B	18B	20B	22B	24B
Distal Stem Diameter	9,11	9,11,13	11,13,15	13,15,17	15,17,19



In the example shown above, if the final distal stem is a 15, then cone reamers will begin with the smallest of the "20" proximal series, size 20 B, which adds 3 mm to the A/P diameter. Each successive cone reamer — D and F — will add an additional +2 and +2 mm to the 20 mm dimension. Thus for a "20," the final outer sleeve diameters for B, D and F are 23, 25 and 27 mm respectively.

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 is available for preparing the proximal canal. The A/P diameter of the cone reamer is marked in large print. On the opposite side, the three proximal sleeve sizes are marked with the corresponding sleeve configuration. The location of each color band moves from distal to proximal as the size increases. The distal stem size selected in step 3 dictates the basic proximal or cone size range for the final sleeve (SEE CONE SIZING CHART).

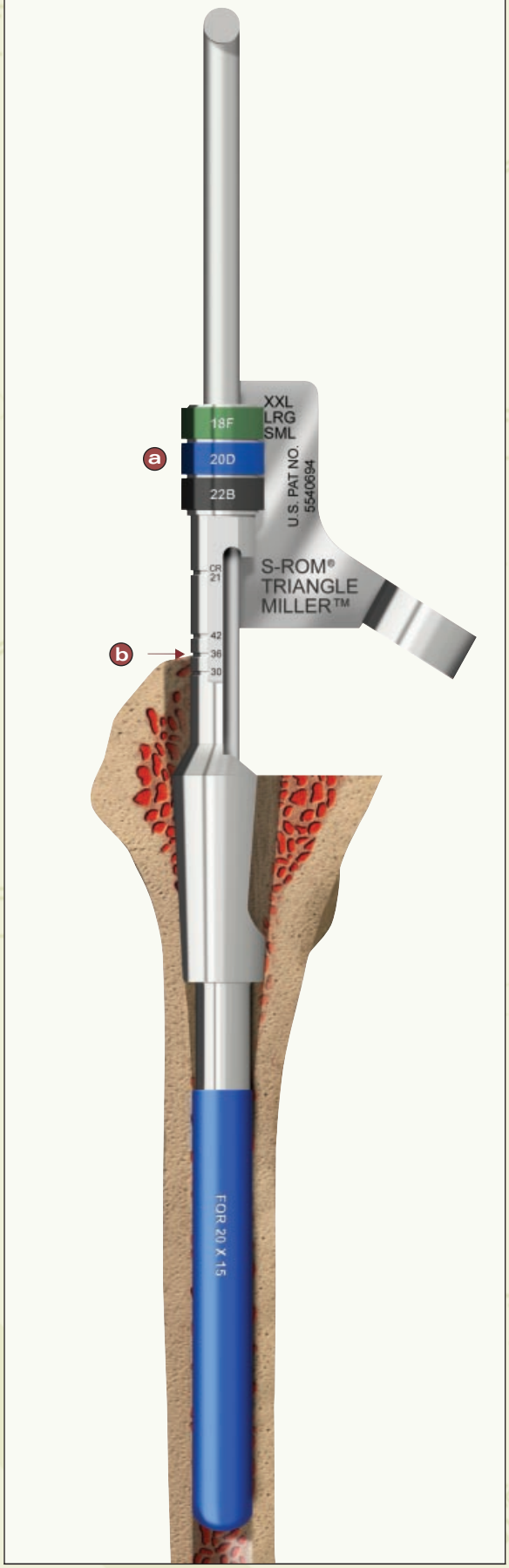
4 CONE REAMING



To cone ream, attach the smallest cone reamer, B, to the pilot shaft marked with the same distal diameter as the final implant.

Advance the cone reamer until the witness marking on the desired neck length — 30, 36 or 42 mm — aligns with the tip of the greater trochanter (FIGURE 4). Successively larger cone reamers D and F are used 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.

5 CALCAR TRIANGLE MILLING



5 CALCAR PREPARATION

Use the triangle miller to prepare the femur to accommodate the calcar triangle 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.

a Select a miller shell that corresponds in size to the final cone reamer used in step 4 (**SEE CONE SIZING CHART**). Numeric markings of the A/P diameter are found on cone reamers and miller shells for cross reference verification (**FIGURE 5a**).

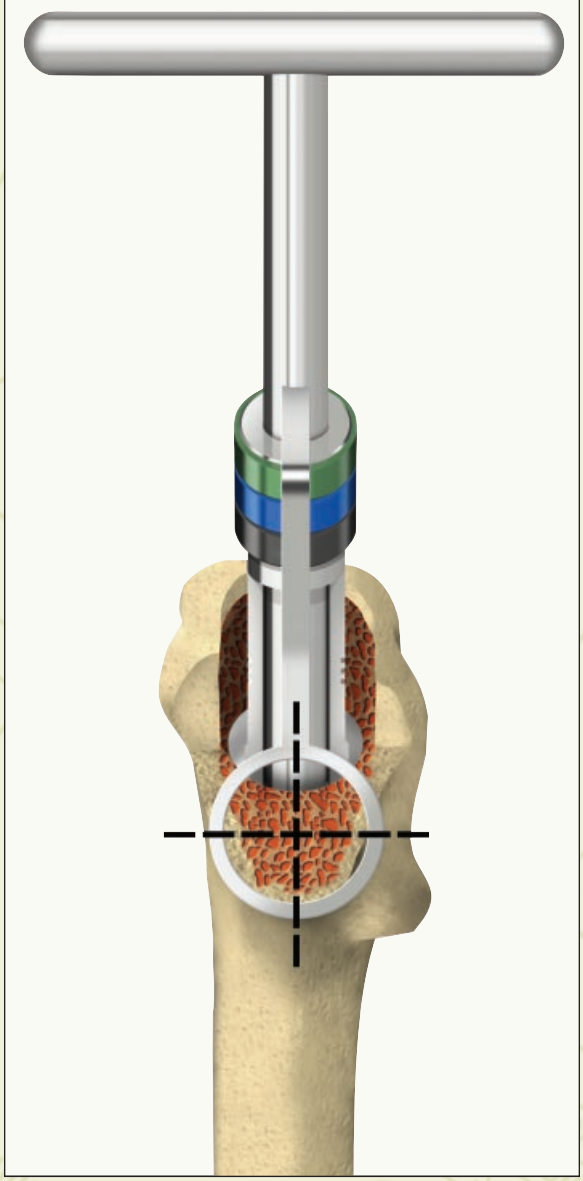
b After attaching the miller shell and the miller frame to the same size pilot shaft that was used in step 4, gently lower the triangle miller. Align the desired neck length witness mark with the tip of the greater trochanter (**FIGURE 5b**).

5 CALCAR PREPARATION continued

c The ring of the miller frame can now be rotated so that it targets the best available host bone (FIGURE 5c).

5 CALCAR TRIANGLE MILLING

c



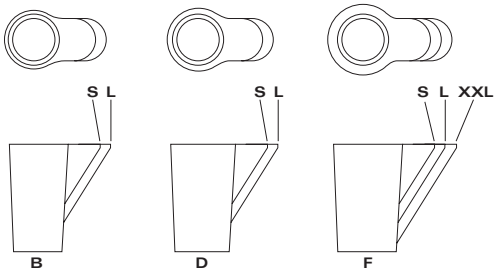
The final element that must be machined is the spout or triangle of the proximal sleeve. The triangle indicates the extension of the triangle from the outside diameter (OD) of the cone. Triangle sizing comes in Small, Large or XX-Large, as shown below. The extent of the triangle on the ZTT sleeve is proportional to the diameter of the stem.

TRIANGLE MILLING 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



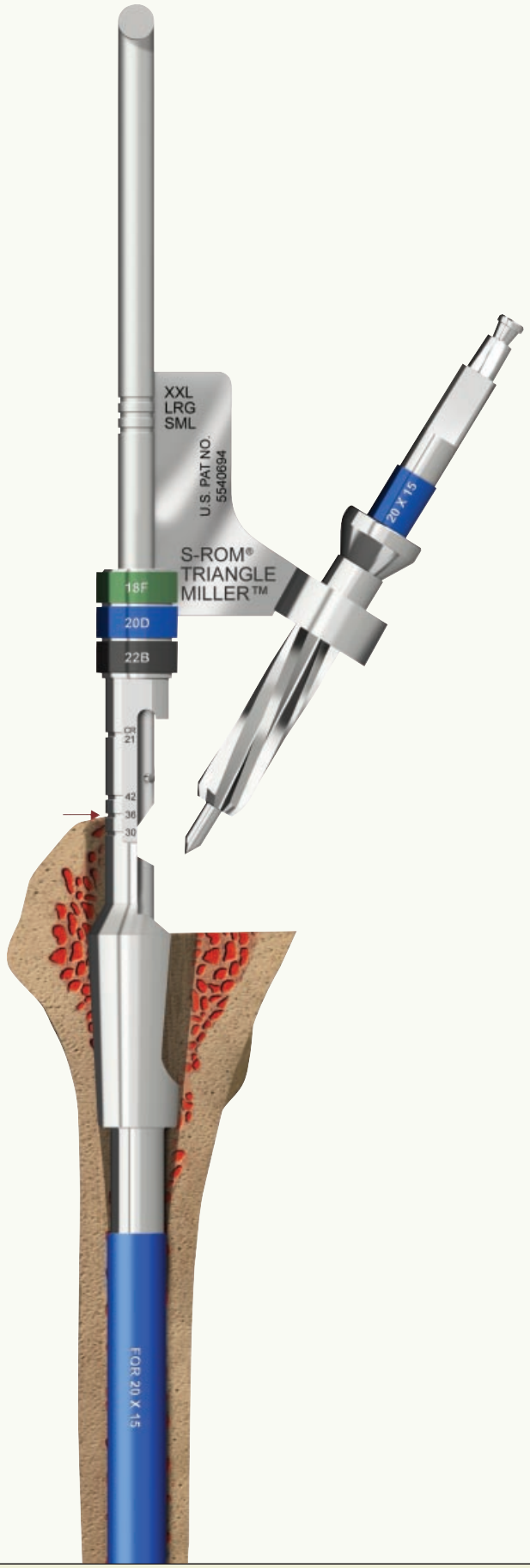
d Select a miller cutter that corresponds to the proximal size of the selected stem (11 x 16, 13 x 18, 15 x 20, 17 x 22 or 19 x 24 mm) (FIGURE 5d).

e Pass the miller cutter through the ring and load the cutter tip into the pilot hole. Lower the miller frame so that the miller cutter makes contact with the cancellous bone to be milled (FIGURE 5e).

f Mill until desired cortical bone has been exposed. Then note the size indicated where the markings on the miller frame align with the top of the miller shell to determine the appropriate sleeve spout size (FIGURE 5f).

5 CALCAR TRIANGLE MILLING

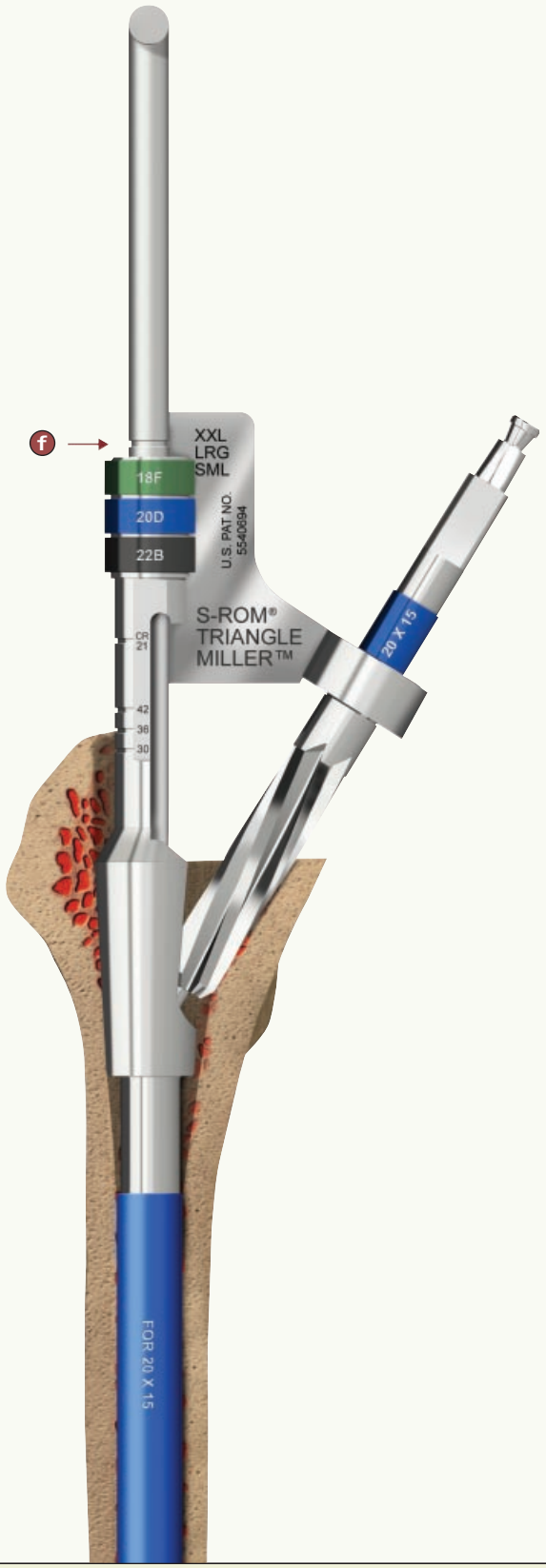
d



5 CALCAR TRIANGLE MILLING

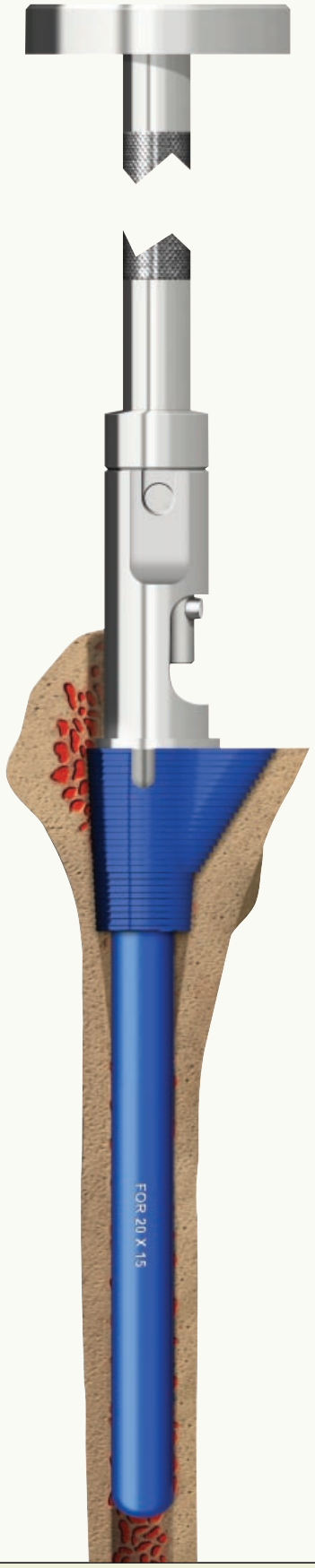
e

f



6 TRIAL SLEEVE

a

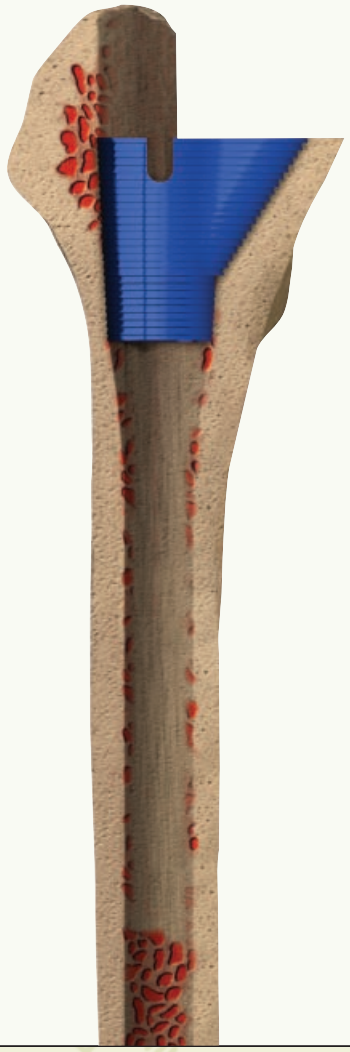


6 TRIAL SLEEVE

Secure the introducer handle onto the 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 (add 5 mm) and a large triangle (extends 13.5 mm). Proximal sleeve trials are color coded, which match its designated stem. Attach the pilot shaft onto the sleeve introducer and slide on the sleeve. Gently impact the sleeve into the prepared metaphysis (**FIGURE 6a**). Seat the trial sleeve completely and withdraw the introducer handle (**FIGURE 6b**). At this point, evaluate the sleeve in relation to its final position.

6 TRIAL SLEEVE

b



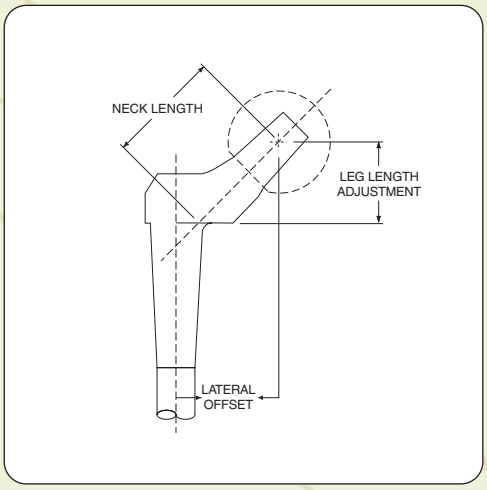
7 NECK TRIALING, TRIAL INSERTION AND VERSION ADJUSTMENT

Restoring patient biomechanics is achieved with a wide range of neck options.

NECK SIZING CHART — ASSUMES USE OF +0 HEAD
(All necks have an included angle of 135 degrees)

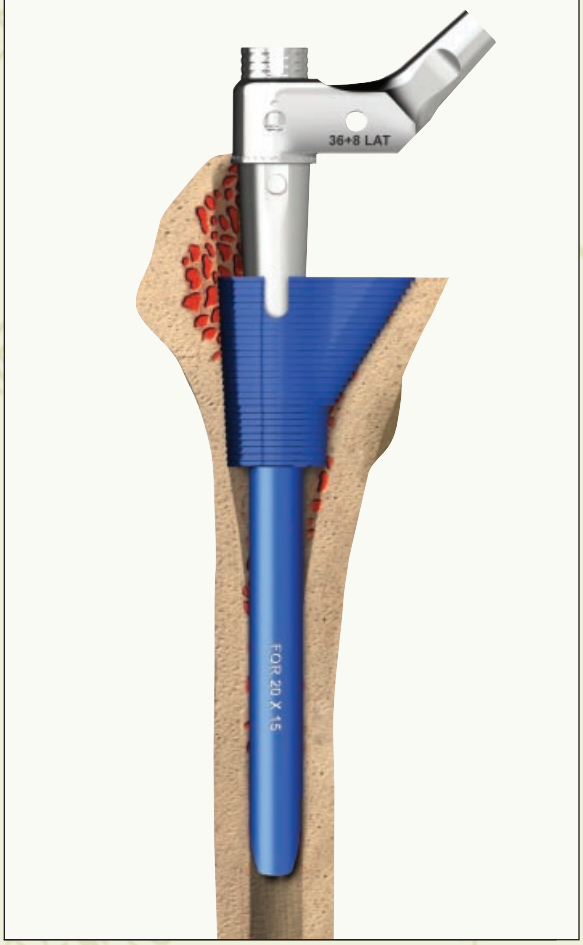
Neck Style	Neck Length (mm)	Lateral Offset (mm)	Leg Length Adjustment (mm)
Standard	30	28	21
Standard	36	32	25
Standard	42	37	30
Standard + 4 Lat	30	32	21
Standard + 6 Lat	36	38	25
Standard + 8 Lat	36	40	25

Assemble the trial implant by snapping the chosen neck onto the appropriate size distal stem trial (**FIGURE 7a**). Align the laser marks in neutral initially. Introduce prior to trial reduction. The trial neck can be adjusted in 10-degree increments until desired version is obtained (**FIGURE 7b**). Trial reduction can also be performed with Long, X-Long and XX-Long distal stem trials. For revision trials, assemble by sliding the proximal body trial over the shaft of the distal stem trial and snap on the chosen neck.



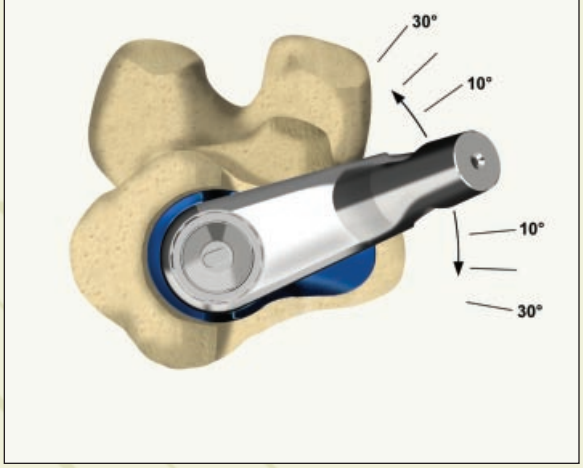
7 TRIAL INSERTION

a



7 VERSION ADJUSTMENT

b



8 SLEEVE INSERTION

a

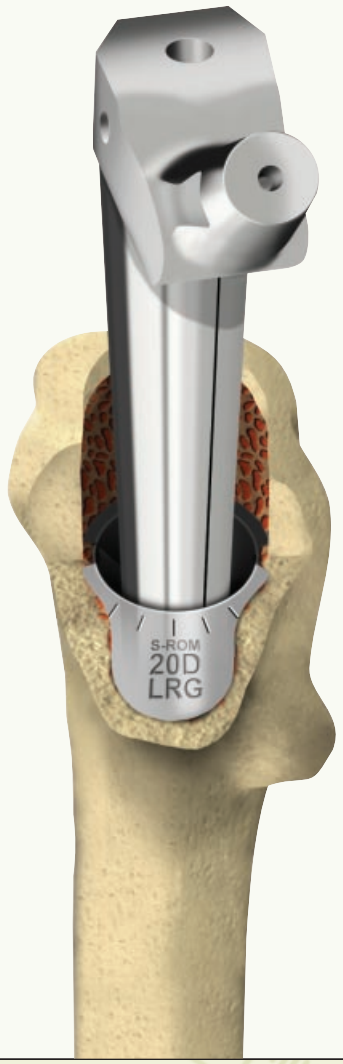
8 INSERTION

Place the proximal sleeve implant onto the sleeve introducer assembly and gently impact the sleeve into the metaphysis (**FIGURE 8a**).

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 8b**). 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 8b**). Use these orientation lines on the stem and sleeve to ensure that the final implant alignment is consistent with trial alignment.

8 STEM INSERTION

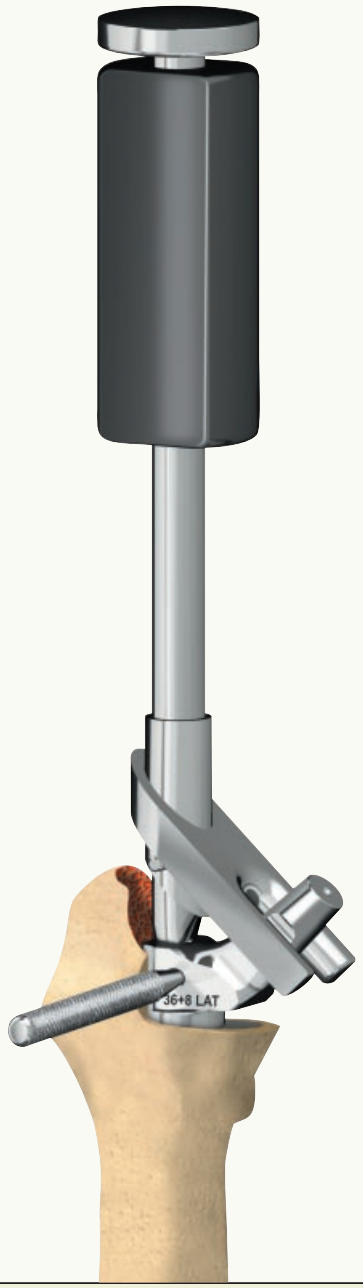
b



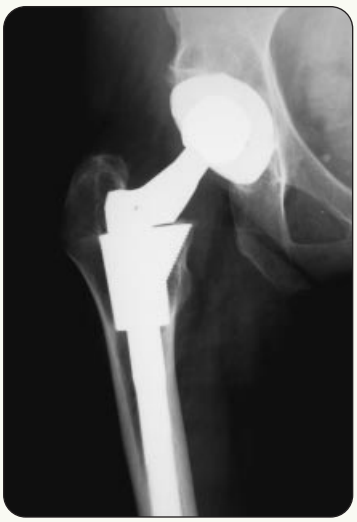
Place the stem introducer handle onto the femoral implant and insert the pin punch into the rotational alignment hole in the femoral neck (**FIGURE 8c**). Using the pin punch as a version control guide, impact the femoral implant until securely seated. The taper is locked when the stem will no longer advance and 2-3 mm remains between the inferior aspect of the femoral neck and the superior aspect of the implant sleeve.

8 STEM INSERTION

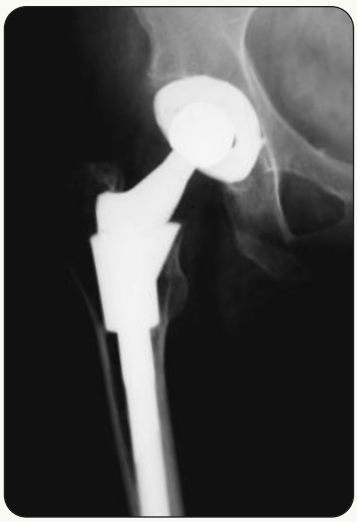
C



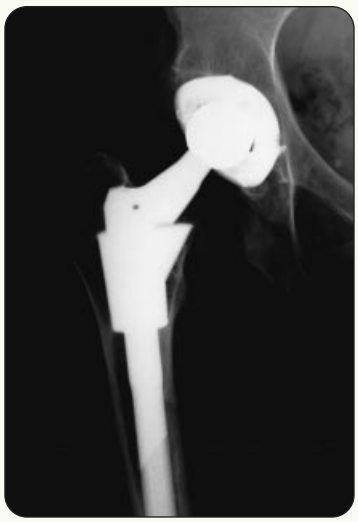
PROVEN RESULTS



3 YEARS



7 YEARS



10 YEARS

Radiographs courtesy of Dr. M. Christie

"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." *Journal of Bone and Joint Surgery* Dec. 1999: 1707.

"When tight proximal fixation is combined with tight distal fixation excellent resistance to torsional load can be achieved with S-ROM."

Ohl, M.D., et al. "Torsional Fixation of a Modular Femoral Hip Component." *CORR* Feb. 1993: 135-141.

"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.

"The modularity provides intraoperative customization to address many problems encountered in primary and revision hip surgery."

Bono, J. "S-ROM Modular Total Hip Replacement." *Operative Techniques in Orthopaedics* Vol. 11, No. 4, 2001.

"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.

"The ability to handle a variety of bone morphologies with a stem that provides stability and ingrowth . . . the S-ROM stem is a potent tool in the armamentarium of the surgeon."

Buly, R. "The S-ROM Stem for Revision Total Hip Arthroplasty." *Techniques in Orthopaedics* Vol. 16, No. 3, 2001.

"Average 5.9 years Grade II or III femoral defect. No hip had mechanical failure, uncoupling of the modular components or fracture."

Bono, J.V., et al. "Fixation with a Modular Stem in Revision Total Hip Arthroplasty." *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.

Modular Femoral Stem Prosthesis*
Standard-Length Stems, Standard Necks (Sterile)

Cat. No.	Stem Size (mm) PROX x DIST x LENGTH	Neck Length (mm)
523292	11 x 16 x 150	30
523192	11 x 16 x 150	36
523293	13 x 18 x 160	30
523193	13 x 18 x 160	36
523393	13 x 18 x 160	42
523194	15 x 20 x 165	36
523394	15 x 20 x 165	42
523195	17 x 22 x 165	36
523395	17 x 22 x 165	42
523196	19 x 24 x 175	36
523396	19 x 24 x 175	42

Modular Femoral Stem Prosthesis*
Standard-Length Stems, Standard Necks and Lateral Necks (Sterile)

Cat. No.	Stem Size (mm) PROX x DIST x LENGTH	Neck Length (mm)
563516	11 x 16 x 150	30 + 4
563517	11 x 16 x 150	36 + 6
563518	13 x 18 x 160	30 + 4
523418	13 x 18 x 160	36 + 8
523420	15 x 20 x 165	36 + 8
523422	17 x 22 x 165	36 + 8
523424	19 x 24 x 175	36 + 8

Proximal Femoral Sleeves*
ZTT Porous Coated (Sterile)

Cat. No.	Description
550506	14F-LRG
521463	16B-SML
521465	16B-LRG
550513	16D-SML
550514	16D-LRG
550515	16F-SML
550516	16F-LRG
550520	16F-XXL
521483	18B-SML
521485	18B-LRG
550523	18D-SML
550524	18D-LRG
550525	18F-SML
550526	18F-LRG
550530	18F-XXL
521403	20B-SML
521405	20B-LRG
550533	20D-SML
550534	20D-LRG
550535	20F-SML
550536	20F-LRG
550540	20F-XXL
521423	22B-SML
521425	22B-LRG
550543	22D-SML
550544	22D-LRG
550545	22F-SML
550546	22F-LRG
550550	22F-XXL
550561	24B-SML
550562	24B-LRG
550564	24D-SML
550565	24D-LRG
550567	24F-SML
550568	24F-LRG
550569	24F-XXL

Proximal Femoral Sleeves*
ZTT Hydroxyapatite Coated (Sterile)

Cat. No.	Description
550121	16B-SM
550122	16B-LRG
550124	16D-SML
550125	16D-LRG
550127	16F-SML
550128	16F-LRG
550129	16F-XXL
550145	18B-SML
550146	18B-LRG
550148	18D-SML
550149	18D-LRG
550151	18F-SML
550152	18F-LRG
550153	18F-XXL
550109	20B-SML
550110	20B-LRG
550112	20D-SML
550113	20D-LRG
550115	20F-SML
550116	20F-LRG
550117	20F-XXL
550133	22B-SML
550134	22B-LRG
550136	22D-SML
550137	22D-LRG
550139	22F-SML
550140	22F-LRG
550141	22F-XXL
550157	24B-SML
550158	24B-LRG
550160	24D-SML
550161	24D-LRG
550163	24F-SML
550164	24F-LRG
550165	24F-XXL

S-ROM Femoral Heads

22.225 mm

Cat. No.	Neck Length
52-2022	+0

28 mm

Cat. No.	Neck Length
52-2028	+0
87-5953	+3
52-2029	+6
87-5954	+9
52-2030	+12

32 mm

Cat. No.	Neck Length
52-2032	+0
87-5955	+3
52-2033	+6
87-5956	+9
52-2034	+12

28 mm "M" Heads

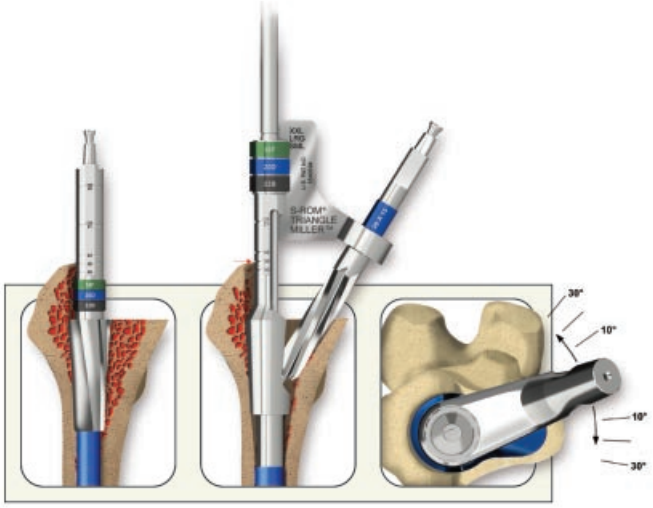
Cat. No.	Neck Length
1365-16-500	+0
1365-17-500	+3
1365-18-500	+6

36 mm "M" Heads

Cat. No.	Neck Length
1365-31-000	+0
1365-32-000	+3
1365-33-000	+6
1365-34-000	+9
1365-35-000	+12

*Additional sizes are available.

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. With demonstrated clinical success since 1984, S-ROM stems have been proven in well over 100,000 cases.

ESSENTIAL PRODUCT INFORMATION

IMPORTANT

This Essential Product Information summary 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 indicated for: a severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis or congenital hip dysplasia; avascular necrosis of the femoral head; acute traumatic fracture of the femoral head or neck; failed previous hip surgery; and certain cases of ankylosis.

CONTRAINDICATIONS

THA is contraindicated in cases of: active local or systemic infection; loss of musculature, neuromuscular compromise or vascular deficiency in the affected limb, rendering the procedure unjustifiable; poor bone quality; Charcot's or Paget's disease.

WARNINGS AND PRECAUTIONS

The following conditions tend to adversely affect hip replacement implants: excessive patient weight, high levels of patient activity, likelihood of falls, poor bone stock, metabolic disorders, disabilities of other joints. The following are the most frequent adverse events after THA: change in position, loosening or fracture of components, dislocation, infection, tissue reaction.

REFERENCE

1. Paul, H.A., et al. "Development of a Surgical Robot for Cementless Total Hip Arthroplasty." *Clinical Orthopedics and Related Research* 285 Dec. 1992: 57-66.

For more information about the S-ROM Modular Hip System, visit our web site at **www.jnjgateway.com**.

DePuy
a Johnson&Johnson company

DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, IN 46581-0988
USA
Tel: +1 (800) 366 8143
Fax: +1 (574) 267 7196

DePuy International Ltd
St Anthony's Road
Leeds LS11 8DT
England
Tel: +44 (113) 270 0461
Fax: +44 (113) 272 4101

5M0303
0601-36-050 (Rev. 3)

Printed in USA.