DESIGN RATIONALE

S-ROM®

MODULAR HIP SYSTEM

DePuy
a Johnson & Johnson company

SUCCESS

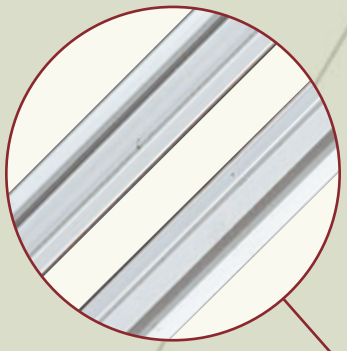
TWENTY YEARS OF PROVEN SUCCESS

The S-ROM® Modular Hip System has been used successfully for more than 20 years in more than 125,000 cases, and its strength and stability have been proven in clinical and laboratory studies.[1] No other modular hip system can boast 98 percent survivorship in primary hip arthroplasties.[2] No other modular hip system can offer up to six neck length/lateral offset options per stem diameter for primary applications. No other modular hip system can offer as much intraoperative versatility.

Lateralized neck options allow offset adjustment without affecting leg length

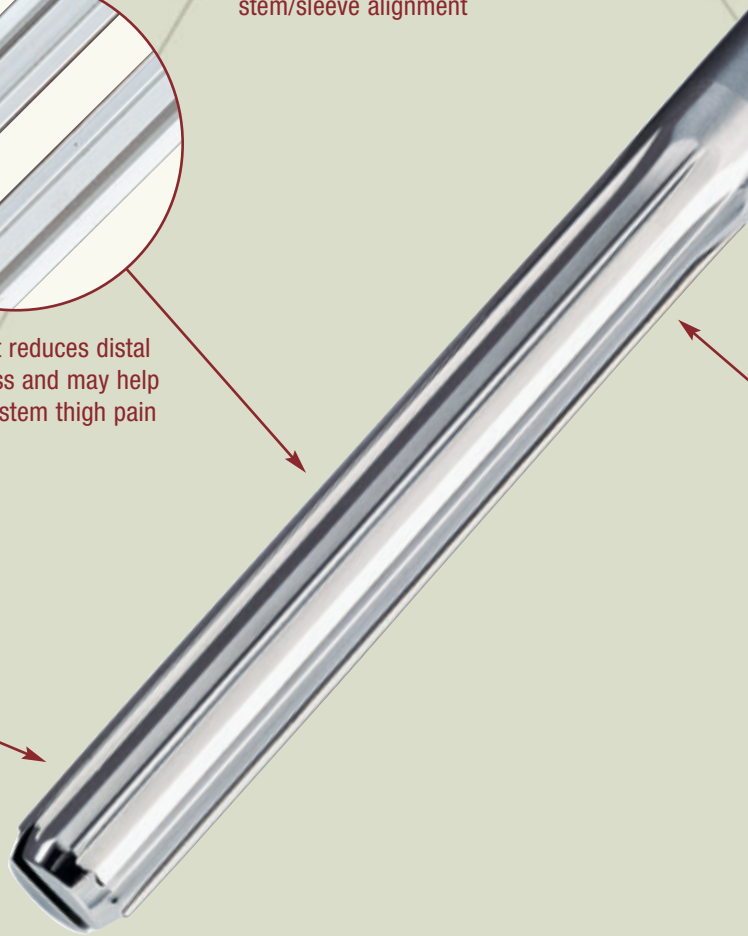
S-ROM
MODULAR HIP SYSTEM

Score marks help address stem/sleeve alignment



Coronal slot reduces distal stem stiffness and may help reduce end-stem thigh pain

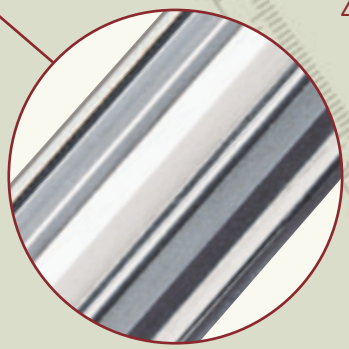
Distal flutes enhance rotational stability



Pinnacle™ acetabular system
with advanced bearing options

Independent neck and sleeve
enables 360 degrees of version

Sleeves are available with proprietary
ZTT™ porous and ZT™ HA coatings



Multiple stem lengths offer a
range of stability options,
especially for fractures and
discontinuities

VERSATILITY

CHOICES IN THE OPERATING ROOM

The modular S-ROM prosthesis is unique. The independent neck and sleeve can accommodate a proximal-distal mismatch while providing ample opportunity for leg length adjustment. The S-ROM stem also allows placement of version to maximize range of motion and resulting hip stability. These features combined with the availability of high-offset stems achieve restoration of patient biomechanics without negatively affecting leg length.

ACCOMMODATE

"FIT AND FILL:" ACCOMMODATE A PROXIMAL-DISTAL MISMATCH

No two femurs are shaped exactly alike. This was the finding of an anatomic study in which researchers identified three distinct intramedullary flare shapes.

- The champagne flute (**FIGURES 1A & 1B**)
- The proportional shape
- The stovepipe (**FIGURES 2A & 2B**)

These flares correlate generally with the age, health and activity level of the patient. In the younger, high-demand patient, the diaphysis is characterized by viable cortical bone and may be disproportionately smaller than the metaphysis (the champagne flute shape), creating a size mismatch between the two (champagne flute). In contrast, as patients age, their diaphyseal cortex becomes thinner, resulting in a wider distal canal (stovepipe). To accommodate this variable anatomy, a modular system is required to maximize fit and fill.

CHAMPAGNE FLUTE

FIGURE 1A
PRE-OP

FIGURE 1B
POST-OP

STOVEPIPE

FIGURE 2A
PRE-OP

FIGURE 2B
POST-OP

*The S-ROM approach to fit and fill is **unique** in that the modularity of the stem allows the proximal and distal canals to be sized independently.*

"Fit and fill" are essential elements of the S-ROM Modular Hip System design philosophy. A surgeon's first challenge is filling the distal femoral canal. For younger, high-demand primary patients with a champagne flute shaped canal, a non-modular stem is likely to be undersized proximally if the stem is sized and positioned to fill the distal canal. Moving to the next larger size to achieve adequate proximal fit may compromise proper distal fill. With the S-ROM Modular Hip System, independent fit is exactly what's offered: the stem itself can be sized to fill the distal canal while a larger proximal sleeve is fitted separately.

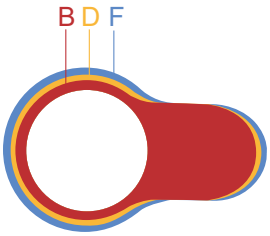
FIT AND FILL

Each S-ROM sleeve can be subdivided into two components:

- For precise fill of the distal canal, standard stem lengths are available in six distal diameters.
- To achieve accurate fit in the metaphysis, each standard stem matches up to **ten** proximal sleeves with varying diameters and calcar triangle sizes.
- Sleeves are available with ZTT™ porous coating and ZT™ HA (hydroxyapatite) coating.

CONE OPTIONS

Three cone sizes available per stem size

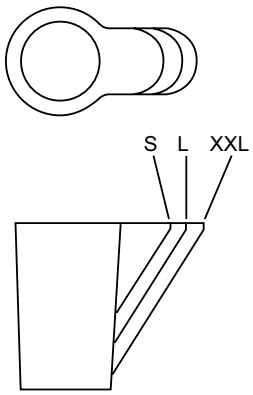


B Cone
Adds 3 mm to proximal diameter of stem
e.g., 18B Outer Diameter equals 21 mm

D Cone
Adds 5 mm to proximal diameter of stem
e.g., 18D Outer Diameter equals 23 mm

F Cone
Adds 7 mm to proximal diameter of stem
e.g., 18F Outer Diameter equals 25 mm

SPOUT OPTIONS



Up to three spout sizes available per cone size

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

Dimensions reflect spout sizes for size 14 sleeve.

RESTORE

RESTORATION OF BIOMECHANICS

- Adjust offset without affecting leg length
- Adjust leg length without affecting offset

The S-ROM Modular Hip System offers extensive intraoperative choices for managing offset and leg length independently.

The availability of lateralized neck options allows for the adjustment of femoral offset without affecting leg length (**FIGURE 3**).

The unique modularity of the S-ROM system also allows for a technique known as "sleeve up" and "sleeve down," to adjust leg length while not affecting femoral offset or compromising fit and fill. Intraoperatively, the surgeon may choose to countersink the proximal sleeve (sleeve down) for shorter leg length or leave the sleeve proud (sleeve up) for greater length, all without affecting offset (**FIGURE 4**).

FIGURE 3

S-ROM 36+0, 36+8 and 36+12 lateralized neck options allow for the adjustment of offset without affecting leg length.

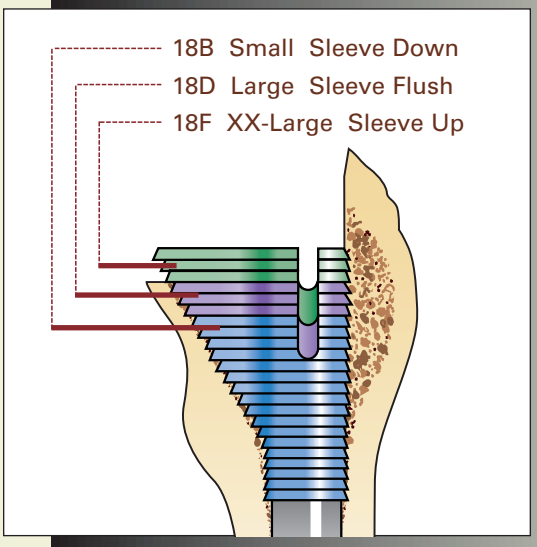


FIGURE 4

Identical spout angles allow multiple sleeve sizes to fit the prepared proximal femur at different heights.

"I use the S-ROM Hip System for all of my primary hip patients because it is the most versatile system on the market. The S-ROM stem allows me to adjust for 360 degrees of version, size the proximal and distal canals independently as well as adjust offset and leg length independently. Therefore, it allows me to tackle virtually every femoral defect I may encounter when performing a primary surgery. My philosophy is that if S-ROM is my stem of choice for my most difficult cases, why wouldn't I want to offer its advantages to all my patients?"

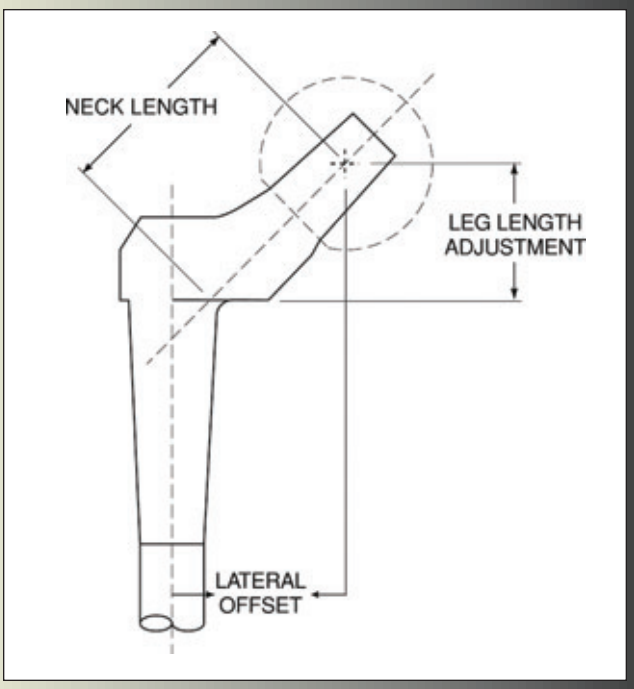
Michael J. Christie, MD

Southern Joint Replacement Institute

Nashville, TN

STANDARD NECK LENGTH OPTIONS

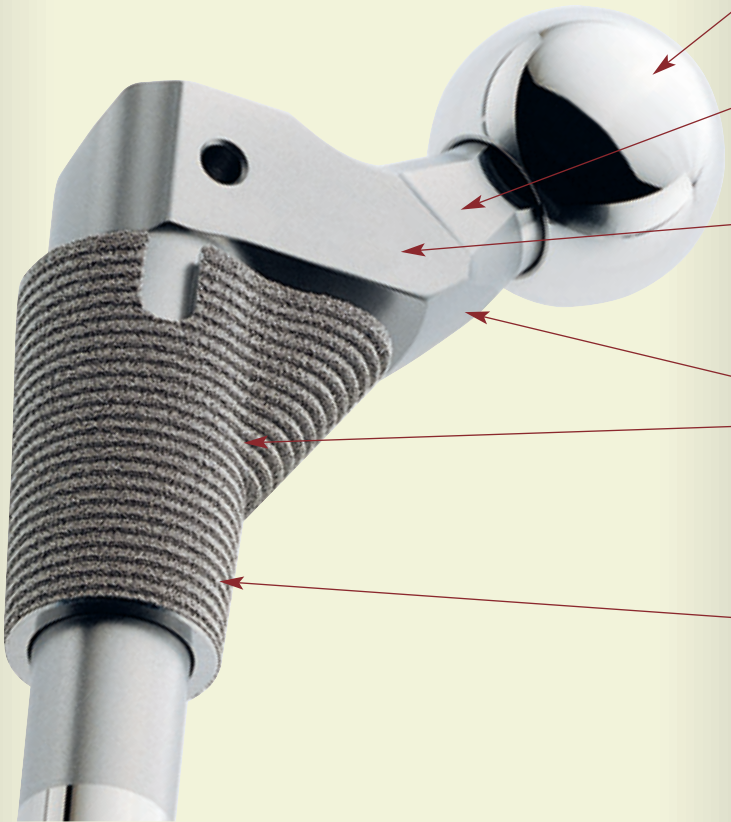
Up to three standard neck lengths and four lateral offset options allow a surgeon to maximize soft-tissue tension without changing head selection.



Neck Sizing Chart — Assume Use of +0 Head
(All necks have an included angle of 135°)

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

The numerous combinations of stems, sleeves and femoral heads allow for the creation of a customized implant that provides maximum fit and fill, proven stability and optimal biomechanics.

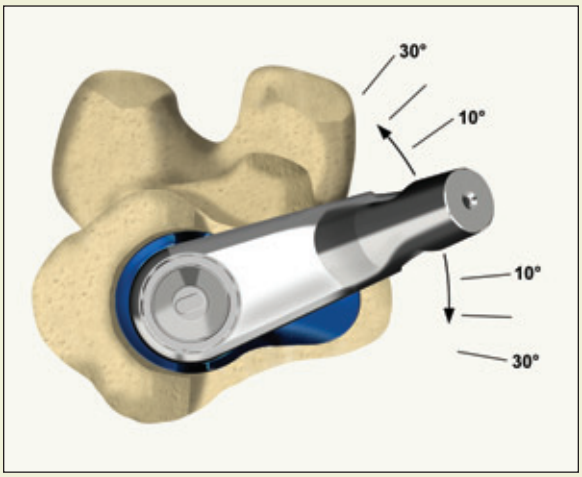


- *Up to five femoral head options per stem range from +0 to +12 in 3 mm increments*
- *Three standard neck lengths (30, 36 and 42) increase both leg length and offset*
- *Availability of +4, +6, +8, +12 offset necks provides additional lateral offset without increasing leg length*
- *The **only** modular hip implant with an independent neck and sleeve, allowing for 360 degrees of version*
- *Up to 10 different sleeve/triangle sizes available per stem*

MANAGE DISLOCATION

RANGE OF MOTION: OPTIMIZING STEM-TO-CUP ALIGNMENT

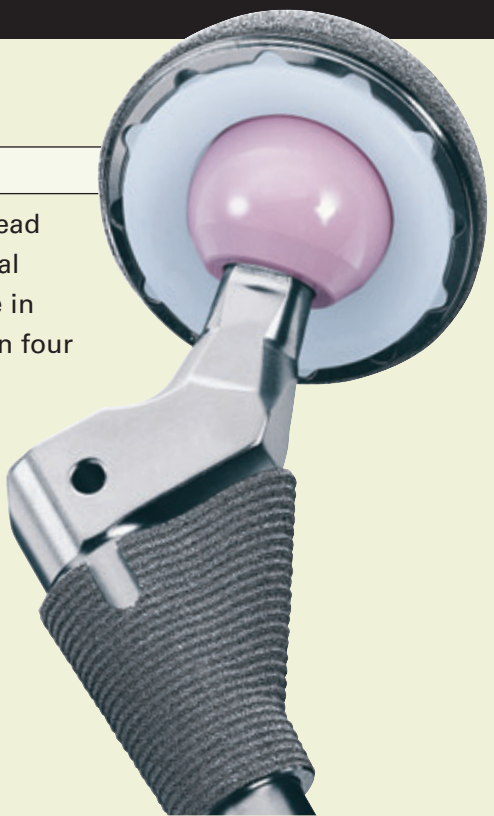
The patented independent neck and sleeve of the S-ROM stem enables the surgeon to address stem-to-cup malalignment to reduce mechanical impingement and resulting dislocation. In a study with 200 cadavers, it was determined that no two femurs are alike when considering depth of isthmus, width of isthmus, neck shaft angle and femoral head offset.[3] With such variety in femoral geometry, it may be difficult to optimize both proximal fixation and range of motion with a non-modular cementless prosthesis. When using a non-modular stem, achieving proper fixation by altering stem version may dictate the angle that the femoral neck mates with the cup. With the S-ROM Modular Hip System, this is no longer an issue. After seating the S-ROM sleeve in the best available bone to achieve proximal fit and stability, the stem can be independently rotated within the sleeve. This flexibility allows the surgeon to re-establish proper stem-to-cup alignment, which optimizes range of motion and hip stability without sacrificing proximal fit.



Is it one implant

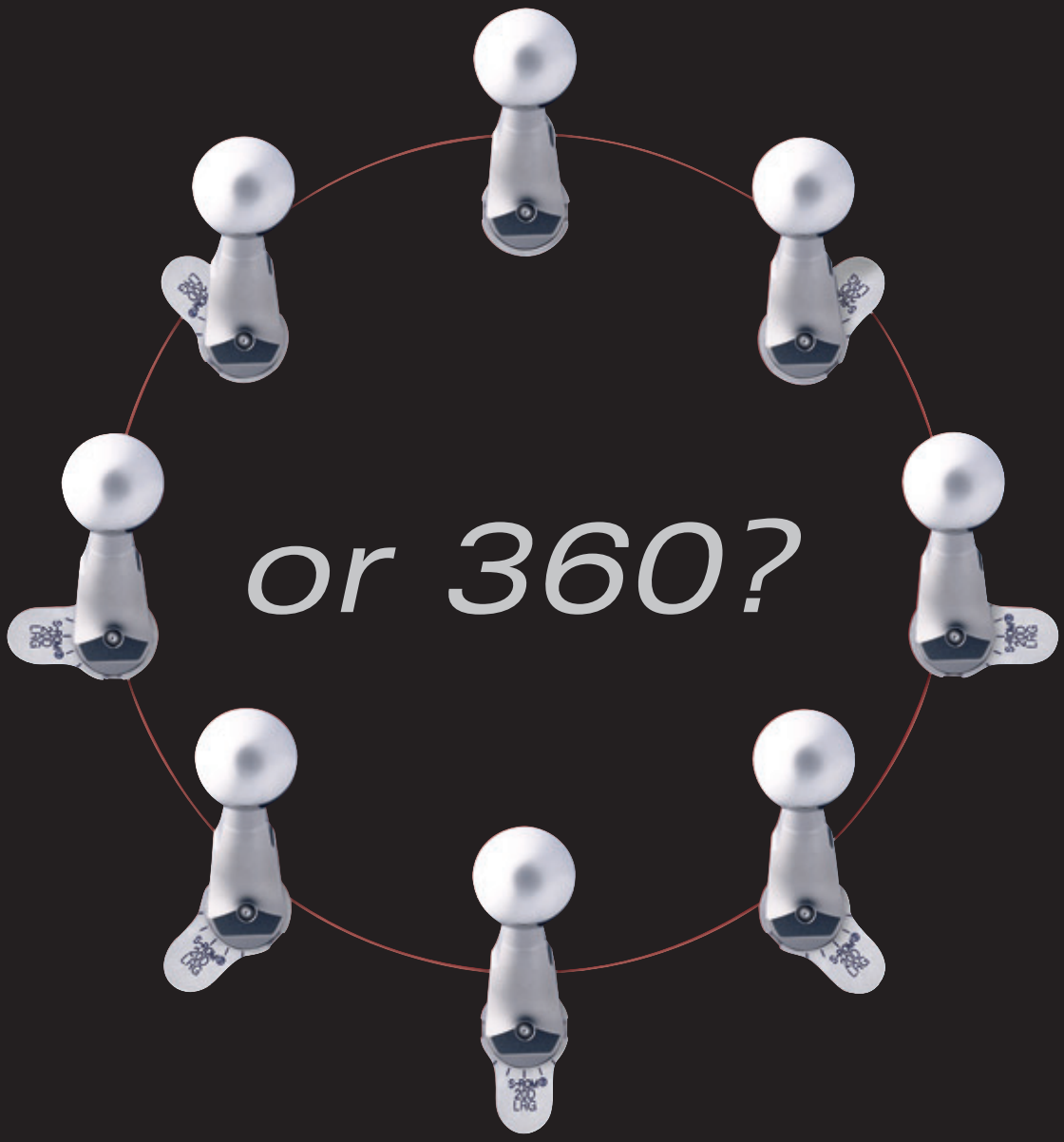
HEAD OPTIONS

The choice of a metal or ceramic femoral head is dependent on the needs of each individual patient. S-ROM femoral heads are available in cobalt chrome and BIOLOX® *delta* ceramic in four different diameters, with five different neck length options. When the numerous head options are combined with the reduced 11/13 S-ROM taper, maximum range of motion is achieved.



"Although there are many biomechanical advantages to the S-ROM Modular Stem, the ability to adjust femoral anteversion after cup placement has become increasingly important when using hard bearing implants where only neutral acetabular liners are available. This permits accurate combined anteversion adjustments to avoid hard bearing impingement while maximizing range of motion and stability for high demand patients."

David Mattingly, MD
Longwood Orthopaedic Associates, Inc.
Chestnut Hill, MA



STABILITY

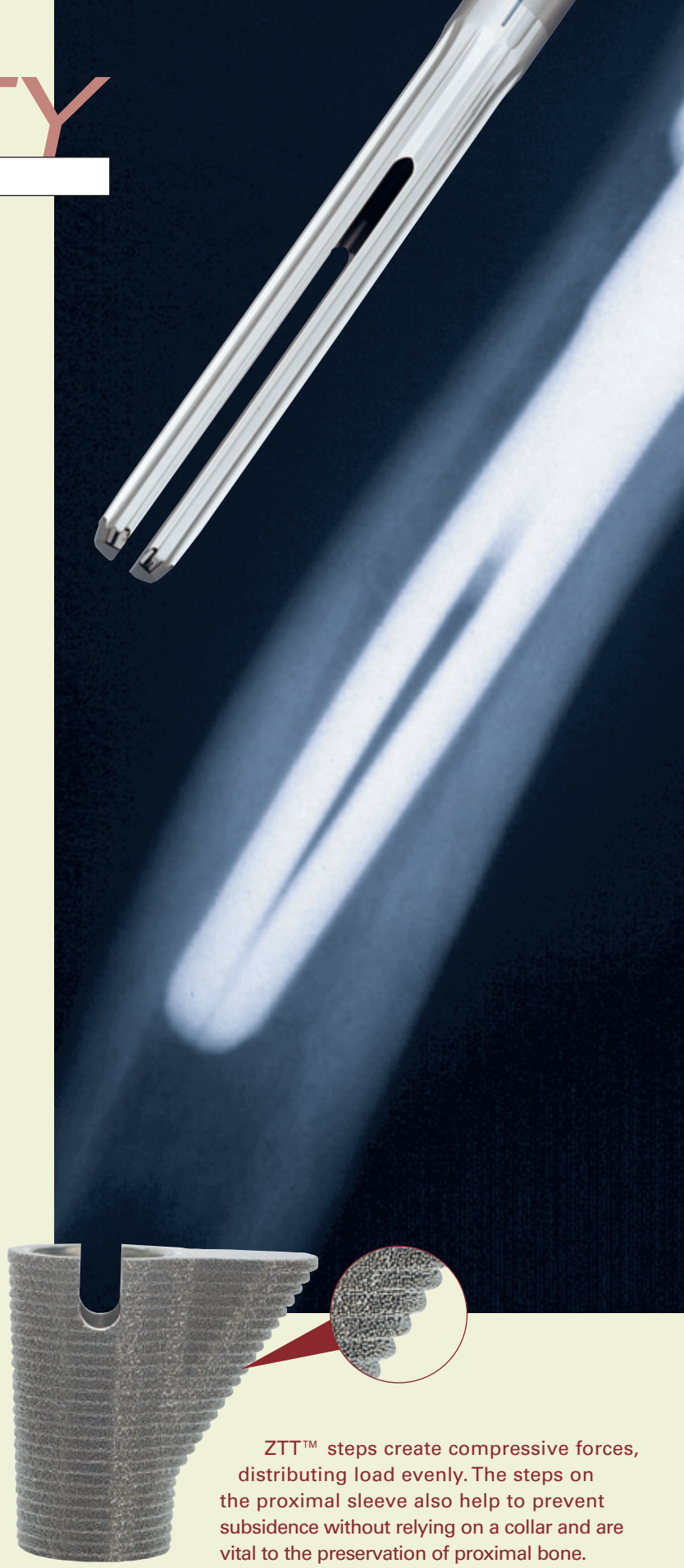
STABILITY BY DESIGN

For the high-demand patient, rotational stability is key to the success of a cementless implant. With the S-ROM Modular Hip System, this stability is achieved through a combination of key design elements, including the proximal sleeve geometry and distal flutes.

The S-ROM titanium alloy stem with its deep coronal slot fits tight within the diaphysis. The distal portion of the femoral stem has polished flutes that add up to 1.25 mm to the minor diameter of the stem.* These flutes cut into the distal cortices of the prepared femoral canal and further increase the rotatory resistance of the assembled prosthesis. They are designed to achieve rotational stability without fixation, thus avoiding distal impingement and preventing thigh pain.[3]

S-ROM Proximal Sleeves combine a conical shape and an extended triangle, which can be placed in the best available bone. Because the stepped design converts shear forces into compressive loads, the ZT™ and ZTT™ sleeves reference the Greek "zeta tau," meaning "zero shear." The combination of the extended triangle and ZT™ steps results in a well-fixed, proximal sleeve that both provides torsional stability and prevents subsidence. Available in a wide variety of sizes, the S-ROM Proximal Sleeve comes in a choice of ZTT™ porous-coated or ZT™ HA-coated surfaces.

*Stem sizes smaller than 13 mm have 1.0 mm flute height.



ZTT™ steps create compressive forces, distributing load evenly. The steps on the proximal sleeve also help to prevent subsidence without relying on a collar and are vital to the preservation of proximal bone.

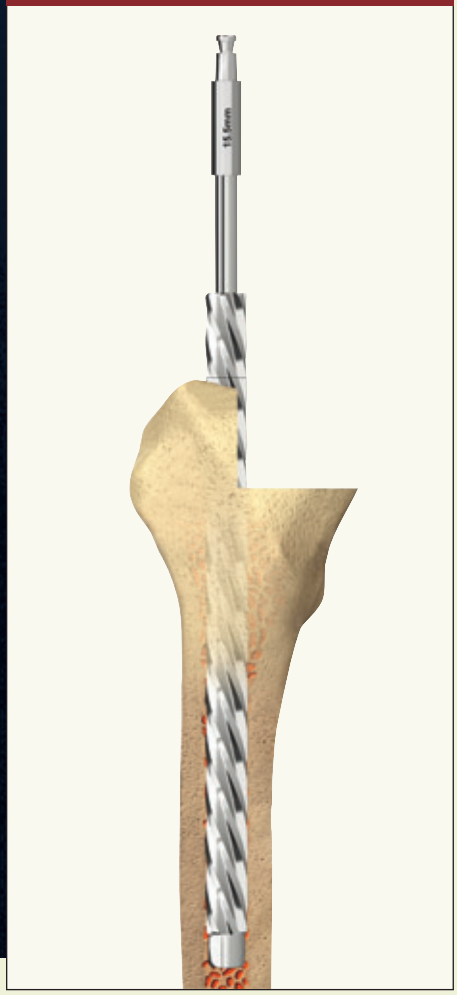
TECHNIQUE

INTUITIVE AND STRAIGHTFORWARD TECHNIQUE

The "fit and fill" philosophy is instrumental to the S-ROM design. Intimate fit of all components is achieved through precise preparation of the intramedullary canal. 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.[4] For exactly this reason, the philosophy of the S-ROM Modular Hip System is to machine the canal in order to achieve an accurate fit that distributes load evenly and encourages rotational stability.

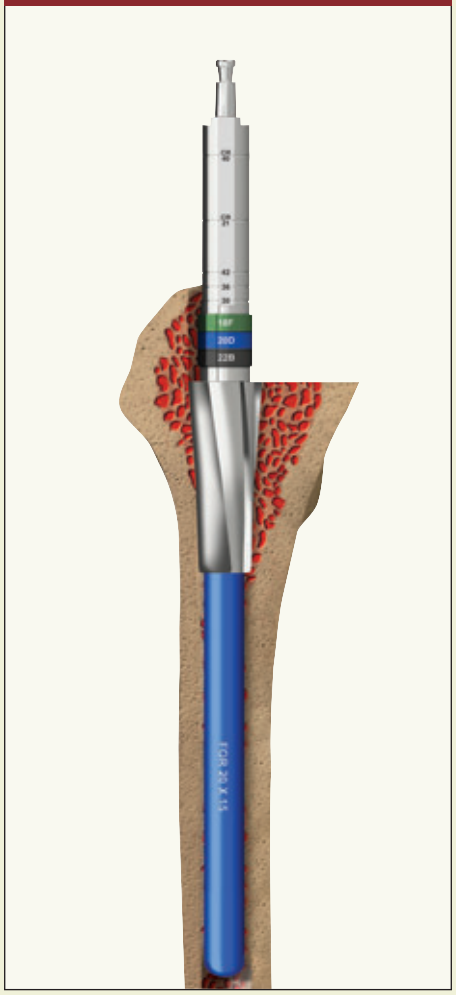
Implanting an S-ROM stem is straightforward involving three basic steps:

STEP 1: DISTAL REAMING



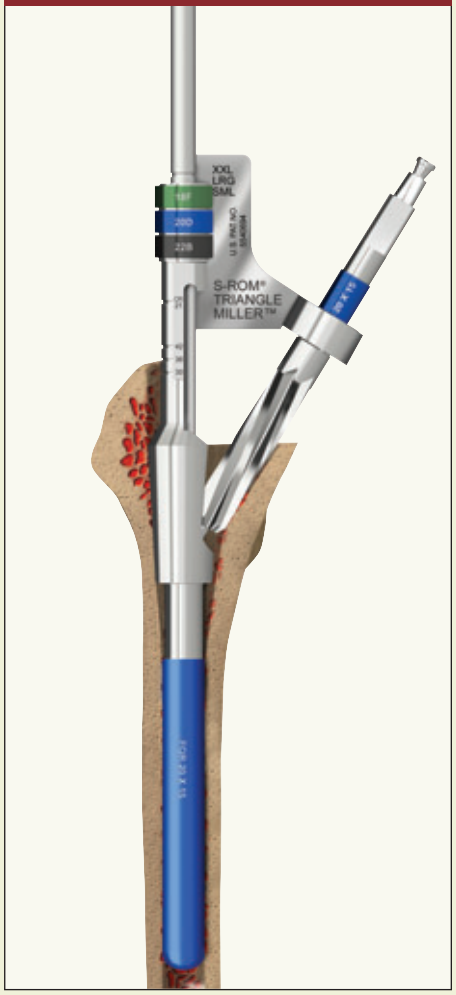
Precise canal preparation requires a surgical technique that is intuitive as well as exact. First, ream the distal canal using straight reamers. During this process, the final reamer prepares a canal that is equivalent to or 0.5 mm larger than the minor diameter of the femoral stem to be implanted.

STEP 2: PROXIMAL REAMING



Proximal reaming is then accomplished by using progressively larger reamers. The first proximal reamer used corresponds to the last distal reamer used in Step 1. The final reamer used determines the diameter of the proximal sleeve and corresponds to the correct sleeve size. Each distal diameter correlates with up to four proximal diameters, providing opportunities for superb fit and fill.

STEP 3: CALCAR MILLING



Calcar (i.e., triangle) milling completes the preparation of the proximal femur, enabling the surgeon to mill the appropriate size triangle.

This machined preparation of the femoral canal—unique to the S-ROM System—supports the fit of precisely sized components and may aid in reducing hoop stresses.

ESSENTIAL PRODUCT INFORMATION S-ROM® MODULAR HIP SYSTEM

Modular Femoral Stem Prosthesis*

Standard-Length Stems, Standard Necks (Sterile)

Cat. No.	Stem Size (mm) DIST x PROX 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

Standard-Length Stems, Standard Necks and Lateral Necks (Sterile)

Cat. No.	Stem Size (mm) DIST x PROX 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
523193	13 x 18 x 160	36 + 12
523194	15 x 20 x 165	36 + 12
523195	17 x 22 x 165	36 + 12

Proximal Femoral Sleeves*

ZTT Porous Coated (Sterile)		ZT Hydroxyapatite Coated (Sterile)	
Cat. No.	Description	Cat. No.	Description
550104	14D-LRG	550121	16B-SML
550103	14D-SML	550122	16B-LRG
550102	14B-LRG	550124	16D-SML
550101	14B-SML	550125	16D-LRG
550506	14F-LRG	550127	16F-SML
521463	16B-SML	550128	16F-LRG
521465	16B-LRG	550129	16F-XXL
550513	16D-SML	550145	18B-SML
550514	16D-LRG	550146	18B-LRG
550515	16F-SML	550148	18D-SML
550516	16F-LRG	550149	18D-LRG
550520	16F-XXL	550151	18F-SML
521483	18B-SML	550152	18F-LRG
521485	18B-LRG	550153	18F-XXL
550523	18D-SML	550109	20B-SML
550524	18D-LRG	550110	20B-LRG
550525	18F-SML	550112	20D-SML
550526	18F-LRG	550113	20D-LRG
550530	18F-XXL	550115	20F-SML
521403	20B-SML	550116	20F-LRG
521405	20B-LRG	550117	20F-XXL
550533	20D-SML	550133	22B-SML
550534	20D-LRG	550134	22B-LRG
550535	20F-SML	550136	22D-SML
550536	20F-LRG	550137	22D-LRG
550540	20F-XXL	550139	22F-SML
521423	22B-SML	550140	22F-LRG
521425	22B-LRG	550141	22F-XXL
550543	22D-SML	550157	24B-SML
550544	22D-LRG	550158	24B-LRG
550545	22F-SML	550160	24D-SML
550546	22F-LRG	550161	24D-LRG
550550	22F-XXL	550163	24F-SML
550561	24B-SML	550164	24F-LRG
550562	24B-LRG	550165	24F-XXL
550564	24D-SML		
550565	24D-LRG		
550567	24F-SML		
550568	24F-LRG		
550569	24F-XXL		

* Additional sizes are available.

BIOLOX *delta* Ceramic Femoral Heads

28 mm	
Cat. No.	Neck Length
1365-28-210	+0
1365-28-220	+3
1365-28-230	+6
32 mm	
Cat. No.	Neck Length
1365-32-210	+0
1365-32-220	+3
1365-32-230	+6
36 mm	
Cat. No.	Neck Length
1365-36-210	+0
1365-36-220	+3
1365-36-230	+6

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
1365-26-000	-3
1365-31-000	+0
1365-32-000	+3
1365-33-000	+6
1365-34-000	+9
1365-36-000	+12

"M" Heads are precision polished for use with Ultamet™ metal inserts or Marathon® cross-linked polyethylene.

REFERENCES

1. Krygier, J.J., Bobyn, J.D., et al. "Strength, stability, and wear analysis of a modular titanium femoral hip prosthesis tested in fatigue." *Orthopaedic Research Laboratory*, Montreal General Hospital, Montreal, Canada.
2. Christie, M.J., et al. "Primary Total Hip Arthroplasty with Use of the Modular S-ROM Prosthesis." *Journal of Bone & Joint Surgery*, Dec. 1999: 1707.
3. Noble, P.C., et al. "The Anatomic Basis of Femoral Component Design." *CORR* 235, October 1988: 148-165.
4. Paul, H.A., et al. "Development of a Surgical Robot for Cementless Total Hip Arthroplasty." *CORR* 285, Dec. 1992: 57-66.

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.

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:

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.

S-ROM femoral heads with +12 neck length extension are contraindicated for use with the POLY-DIAL™ constrained liner. Use of the Alumina ceramic head without the preassembled taper adaptor is contraindicated. The ceramic femoral heads are indicated for use only with acetabular shells composed of UHMWPE or metal-backed UHMWPE. The femoral head size and the inner diameter of the acetabular components must correspond. SPA proximal sleeves are indicated for cemented use only. ZT, ZT HA, 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.

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

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