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**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, proximal avascular, slipped capital femoral epiphysis, and disability due to previous failure.

**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 POL Y-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 LUMEX. The femoral head size and the inner diameter of the acetabular component must correspond.

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**WARNING:**
Ceramic femoral heads are comprised 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.

**ADVERSE EVENTS:**
Peripheral neuropathy, deep wound infection, and heterotopic bone formation have been reported following hip replacements. Subclinical bone damage has also been reported. Osteolysis, subluxation, muscle and fatous tissue laxity, and loosening may also occur.

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SUCCESS

TWO DECADES OF 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.1 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.

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.

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**SUCCESS**

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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.

“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.

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.

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.
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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).

“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

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.

**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.

<table>
<thead>
<tr>
<th>Neck Style</th>
<th>Neck Length (mm)</th>
<th>Lateral Offset (mm)</th>
<th>Leg Length Adjustment (mm)</th>
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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.

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More and Better Intraoperative Options

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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. 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.

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.”

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Is it one implant or 360?
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.

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.
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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.

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**ESSENTIAL PRODUCT INFORMATION**

**S-ROM® MODULAR HIP SYSTEM**

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