MINIMALLY INVASIVE CALCAR MILLER SURGICAL TECHNIQUE

S-ROM®

MODULAR HIP SYSTEM

- CLINICALLY PROVEN IMPLANT
- MINIMALLY INVASIVE APPROACH

DePuy
a Johnson & Johnson company

The S-ROM®

MODULAR HIP SYSTEM

In use since 1984... Over 125,000 implanted.

The evolution of minimally invasive (MI) surgical techniques has introduced new complexities to total hip arthroplasty (THA). However, the foundation for clinical success remains unchanged: surgical skill, combined with clinically proven implant systems.

S-ROM®
MODULAR HIP SYSTEM

A DELICATE BALANCE

Patient Demands vs. Clinical Outcomes

How do you as a clinician balance the demands of the potential MI patient with the need to focus on and maintain successful long-term clinical outcomes? Numerous surgeon-authored journal articles have concluded that the rapid adoption of MI surgical techniques may lead to an increased complication rate.[1,2] The answer lies in choosing an MI-enabled implant system that allows you to deliver the technique patients want while addressing the complexities of the minimally invasive environment.

PATIENT'S NEEDS - INITIAL STABILITY

Smaller Incision → Initial Stability → Rehabilitation

Patients may be attracted to MI procedures because they offer the hope of less pain and quicker recovery. Nevertheless, it is important to remember that an implant plays a key role in achieving these objectives. Intimate fit and fill is key to minimizing micromotion for achieving initial fixation, rapid weight bearing and reduced rehabilitation. 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.[3] For exactly this reason, the philosophy of the S-ROM® Total Hip System is to machine the canal in order to achieve an accurate fit that distributes load evenly and encourages rotational stability. Furthermore, in a comparative study regarding initial stem stability, Lee et al. concluded that a cementless hip design must address two key criteria in order to obtain bone ingrowth and maximize initial implant stability. A stem must achieve tight initial distal fit to minimize axial micromotion and minimize rotational micromotion both proximally and distally. The authors also conclude that achieving both proximal fill and concentric distal fit with a one-piece stem is **nearly impossible** due to the disproportionate endosteal geometry of the femur.[4]

The S-ROM instrumentation allows for precise machining of the femoral canal to achieve an accurate fit that distributes load evenly. The patented geometry of the porous coated proximal sleeve, in combination with the ZTT® steps and the distal flutes provide solid axial and rotational stability. All are key elements that can help patients achieve a quicker recovery.

SURGEON'S NEEDS

Intraoperative Flexibility

When performing MI THA surgery, reduced visualization may result in sub-optimal cup positioning which necessitates the need to make last-minute biomechanical adjustments intraoperatively. The S-ROM Modular Hip System offers extensive intraoperative choices for managing component version, while addressing offset and leg length independently.

First, the availability of numerous lateralized neck options, per stem diameter, allows for the adjustment of femoral offset without affecting leg length. In addition, the unique modularity of the S-ROM system allows for a technique known as "sleeve up" and "sleeve down" to adjust leg length while not affecting femoral offset. The ability to manage leg length and offset separately, in combination with the 360 degrees of version offered by the independent neck and sleeve, makes the S-ROM stem well suited for managing hip biomechanics in the challenging MI environment.

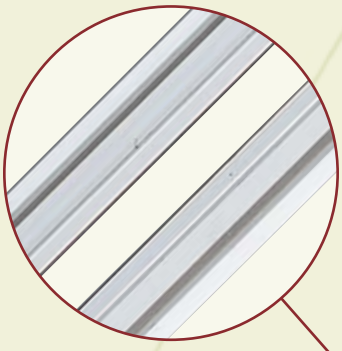
SUCCESS

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.[5] No other modular hip system offers an independent neck and sleeve that allows for 360 degrees of version. No other modular hip system can boast 98 percent survivorship in primary surgeries.[6] No other modular hip system can offer as much intraoperative versatility.

S-ROM®
MODULAR HIP SYSTEM

Score marks help address stem cup alignment



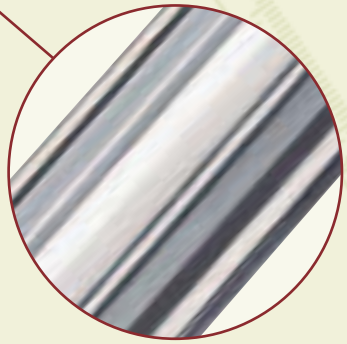
Coronal slot reduces distal stem stiffness and may help reduce end-stem thigh pain

Distal flutes enhance rotational stability

Pinnacle™ acetabular cup system with advanced bearing options

Independent neck and sleeve enables 360 degrees of version

Sleeves are available with ZTT and ZT™ HA coatings



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

TECHNIQUE

INTUITIVE THREE-STEP SURGICAL TECHNIQUE

Distal Reaming → Promixal Reaming → Calcar Milling

The S-ROM system utilizes an intuitive and straightforward surgical technique involving three easy steps: distal reaming, proximal reaming and calcar milling. The distal reaming and proximal reaming steps are performed along the femoral axis and are relatively simple with regard to a small incision. In contrast, the calcar milling step has been more difficult to perform through a small incision due to its size and angle of approach. The new S-ROM MI calcar miller was designed to work more in-line with the femoral axis to make the calcar milling step more conducive to a minimally invasive surgical approach.

The enhancements to the calcar miller enable the S-ROM implant, an implant with 20 years of clinical use, to meet the evolving needs of current MI surgeons.

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, the surgeon reams the distal canal using straight reamers. During this process, the final reamer prepares a canal that is 0.5 mm larger than the minor diameter of the femoral stem to be implanted.

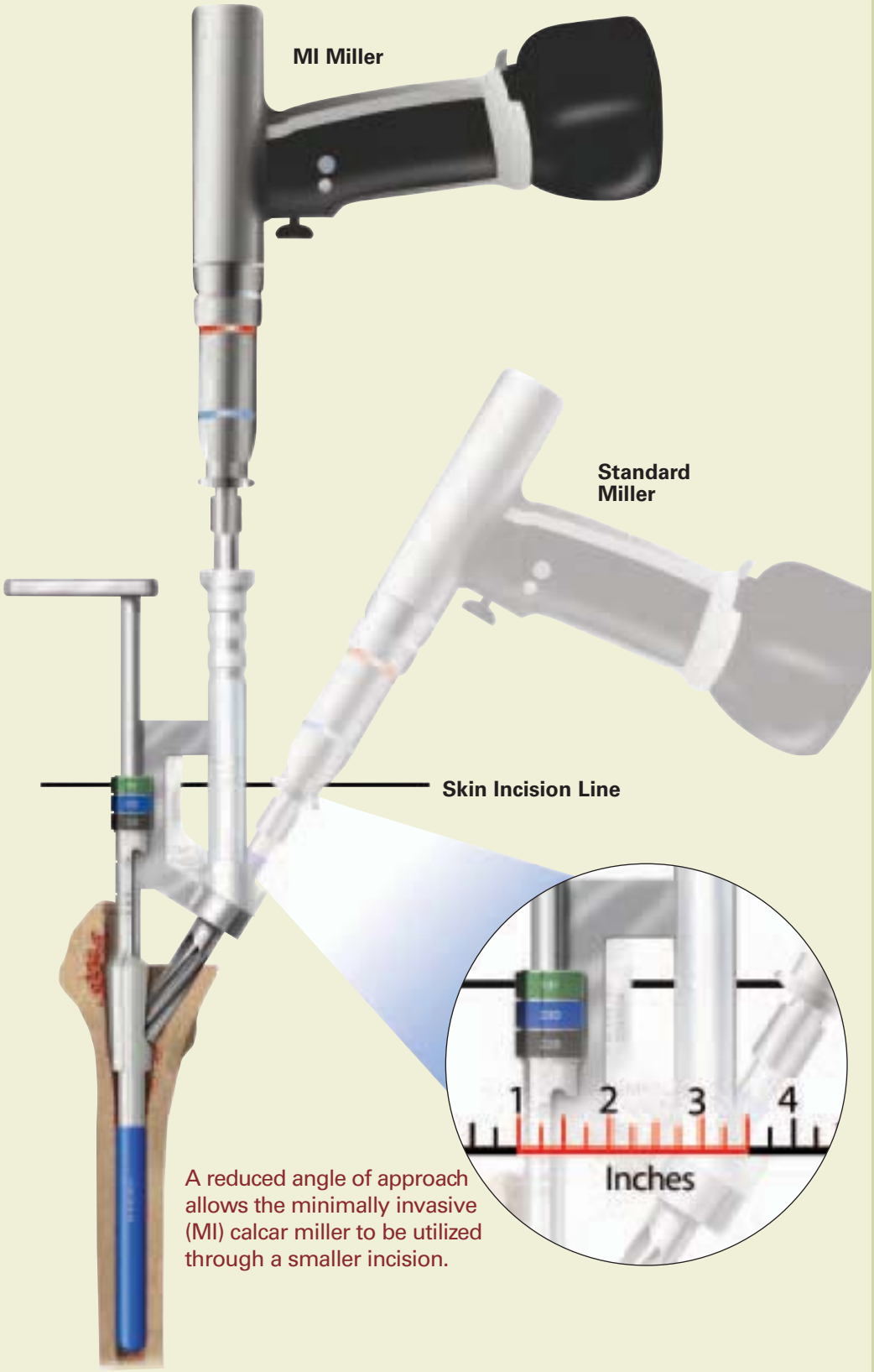
STEP 2: PROXIMAL REAMING

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 spout.
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.

MI CALCAR MILLING



A reduced angle of approach allows the minimally invasive (MI) calcar miller to be utilized through a smaller incision.

CALCAR PREPARATION

Use the calcar miller to prepare the femur to accommodate the spout of the final sleeve. In most instances, the spout is placed in the medial proximal femur. However, because the placement does not dictate the neck version, the spout can be rotated 360 degrees to place the sleeve in optimal bone.

Select a miller shell that corresponds in size to the final proximal reamer used in the previous step. Numeric markings of the A/P diameter are found on reamers and miller shells for cross reference verification **(Figure 1)**.

FIGURE 1:

After attaching the calcar miller shell to the same size pilot shaft that was used for cone reaming, gently lower the miller shell into the femoral canal. Align the desired neck length witness mark with the tip of the greater trochanter **(Figure 1)**.

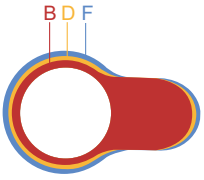
"FIT AND FILL"

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

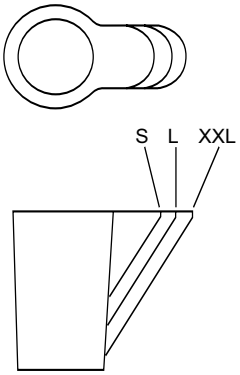


B Cone
Adds 3 mm to promixal diameter of stem
e.g., 18B Outer Diameter equals 21 mm

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

F Cone
Adds 7 mm to promixal 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

FIGURE 2A:

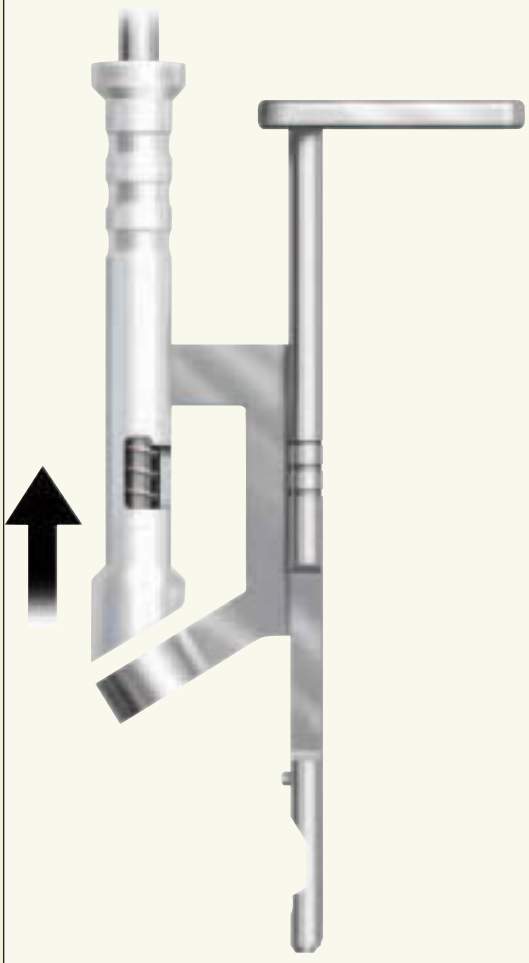
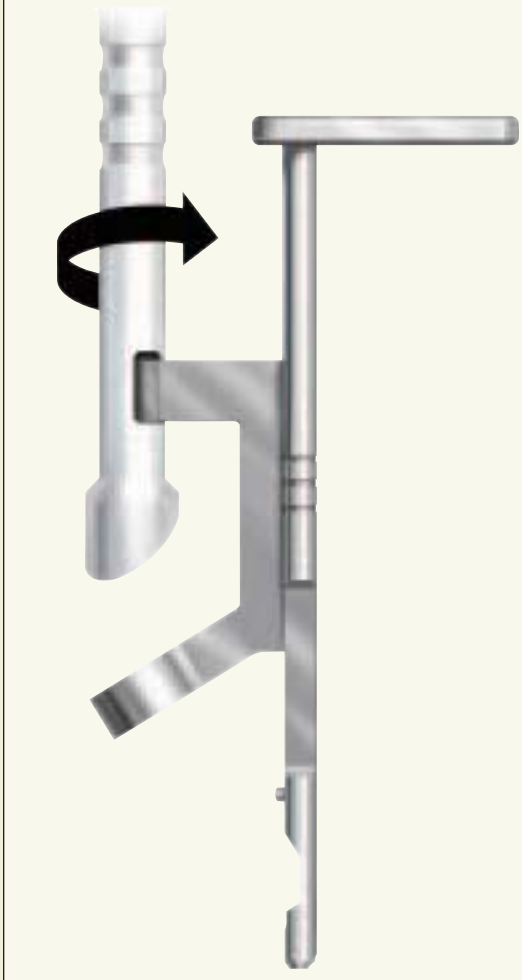


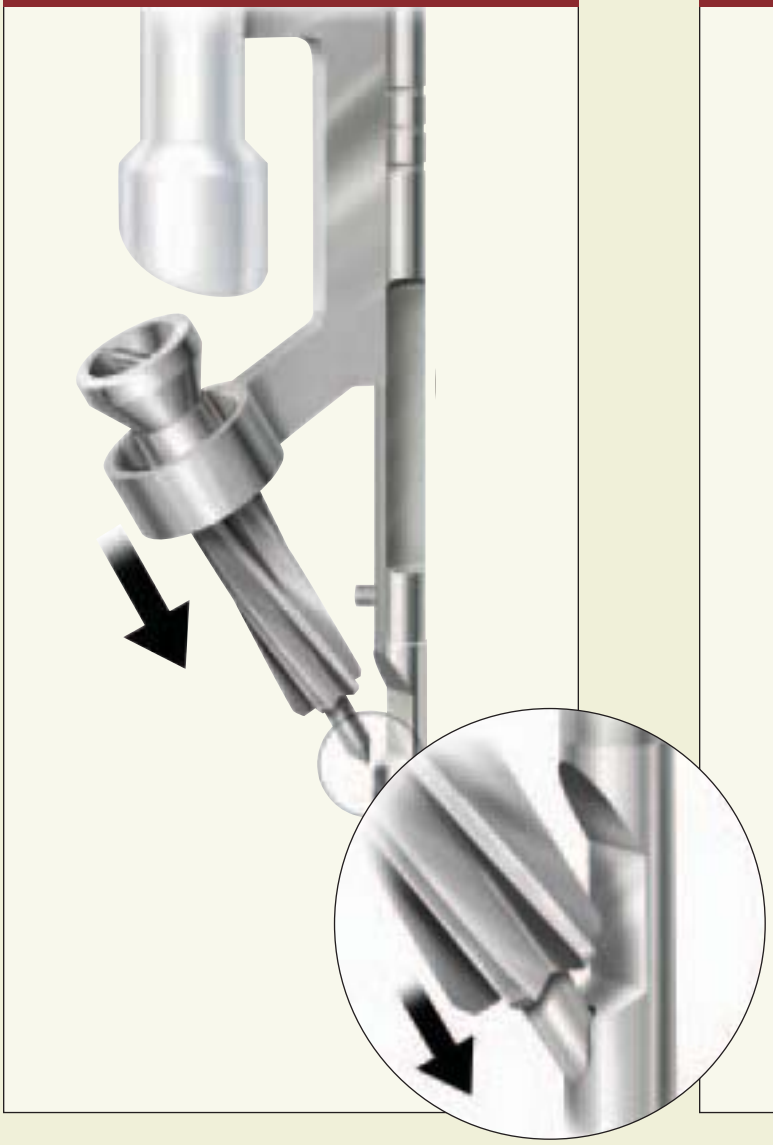
FIGURE 2B:



Select a calcar 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).

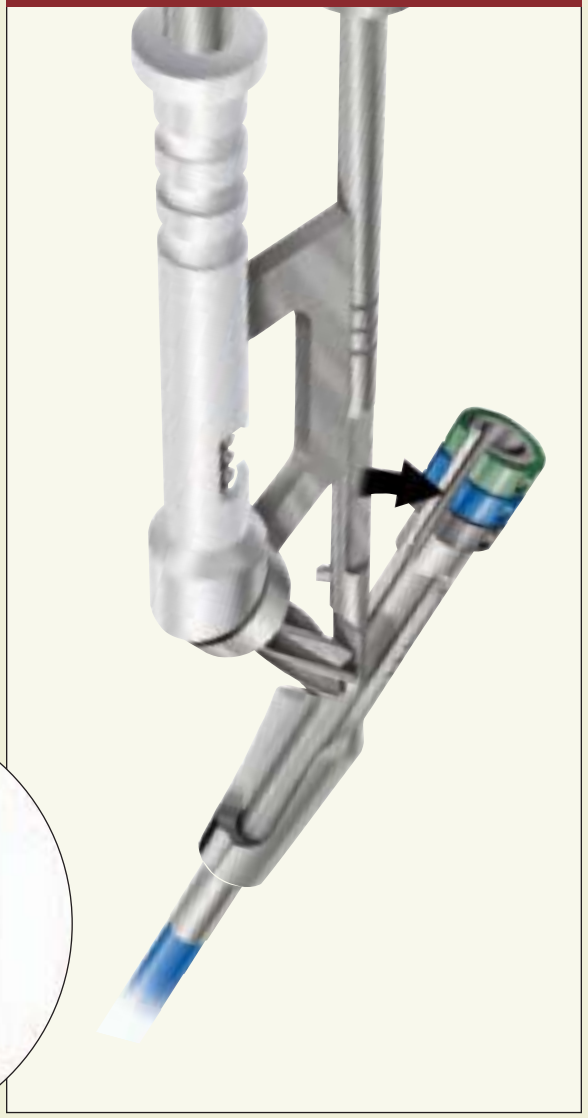
Place the plastic milling sleeve in the open position by sliding the sleeve upward and rotating it counterclockwise **(Figures 2A and 2B)**.

FIGURE 3:



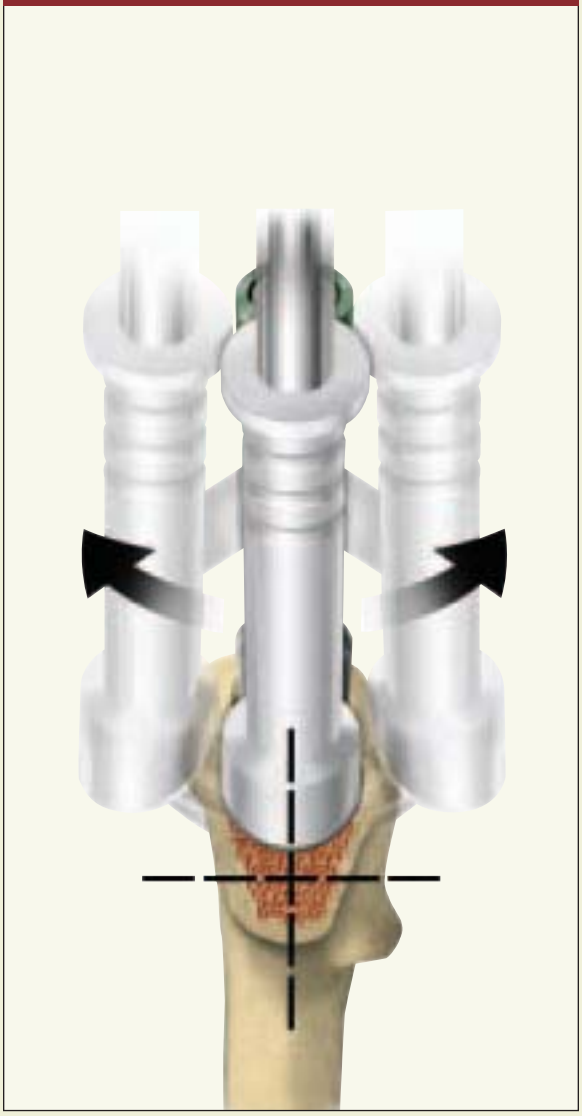
Pass the calcar miller cutter through the top of the ring and load the cutter tip into the pilot hole on the calcar milling frame. Place the plastic milling sleeve in the closed position by rotating it clockwise, before releasing **(Figure 3).**

FIGURE 4:



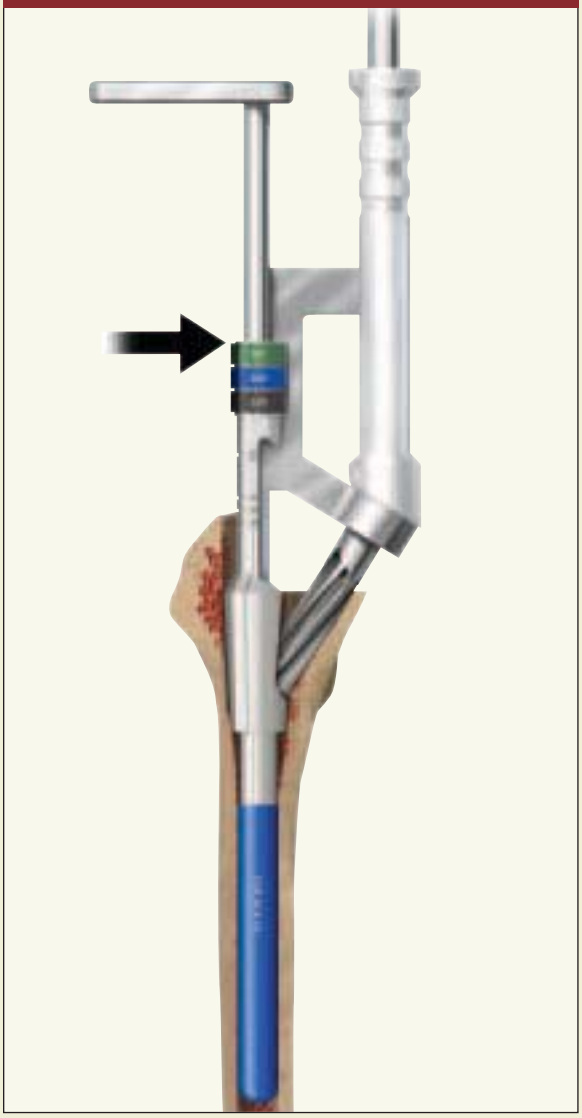
Insert the assembled calcar miller frame and cutter into the miller shell. While holding the miller frame at an angle, insert the distal tip of the frame into the miller shell, before sliding the recessed portion of the miller frame through the groove in the miller shell **(Figure 4).**

FIGURE 5:



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

FIGURE 6:



Lower the calcar miller frame so that the miller cutter makes contact with the cancellous bone to be milled **(Figure 6)**.

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 (S, L, XXL).

S-ROM® TOTAL HIP PROSTHESES SYSTEM

IMPORTANT:

This Essential Product Information is for the S-ROM Hip components that are shown in this Surgical Technique which are used with the S-ROM Instrumentation. 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.

S-ROM MI Triangle Miller Ordering Information

Catalog Number	Description	
2576-08-000	Minimally Invasive Calcar Miller Frame	
2576-08-012	S-ROM MI Calcar Milling Reamer Size	12
2576-08-014	S-ROM MI Calcar Milling Reamer Size	14
2576-08-016	S-ROM MI Calcar Milling Reamer Size	16
2576-08-018	S-ROM MI Calcar Milling Reamer Size	18
2576-08-020	S-ROM MI Calcar Milling Reamer Size	20
2576-08-022	S-ROM MI Calcar Milling Reamer Size	22
2576-08-024	S-ROM MI Calcar Milling Reamer Size	24
2576-05-000	S-ROM MI Calcar Milling Case Complete	
2576-05-100	S-ROM MI Calcar Milling Case Lid	
2576-05-200	S-ROM MI Calcar Milling Outer Case	

REFERENCES

1. Goldstein WM, et al. Minimal-incision total hip arthroplasty. *JBJS*. 85A, Supplement 4 2003:33-38.
2. Woolson ST, et al. Comparison of primary total hip replacements performed with a standard incision or a mini-incision. *JBJS*. 86A, July 2004: 1353-1358.
3. Paul HA, et al. Development of a surgical robot for cementless total hip arthroplasty. *CORR* 285, December 1992: 57-66.
4. Lee, T., et al. "Initial Stability Comparison of Modular Hip Implants in Synthetic Femurs." *Orthopedics,* 21 Aug. 1998: 885-888.
5. 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.
6. Christie, M.J., et al. "Primary Total Hip Arthroplasty with use of the Modular S-ROM Prosthesis". *JBJS*, Dec. 1999:1707.

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) 387 7800
Fax: +44 (113) 387 7890

2.5M1204
0612-04-503

Printed in USA.