S-ROM® NOILES™ Rotating Hinge Knee System

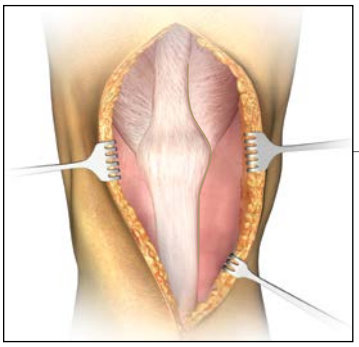
Surgical Technique

DePuy Synthes

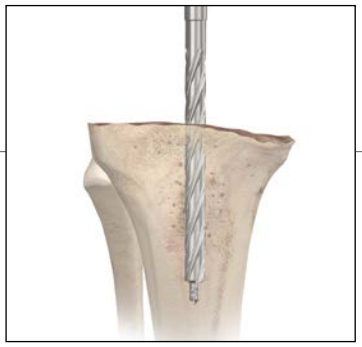
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

Table of Contents

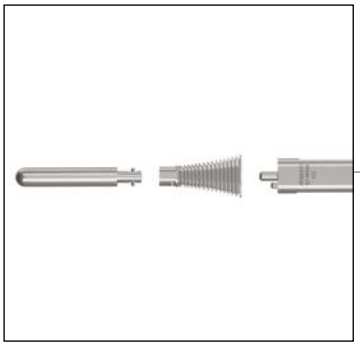
Key Surgical Steps Summary



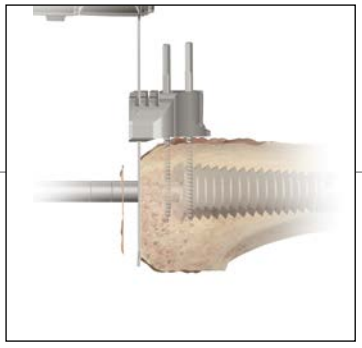
Incision and Exposure



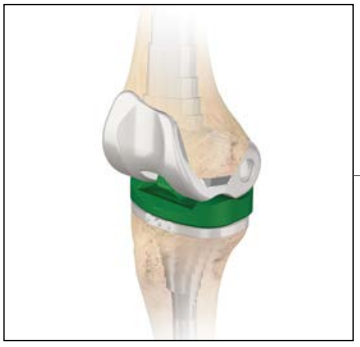
Tibial Medullary Canal Preparation



Femoral Medullary Canal Preparation



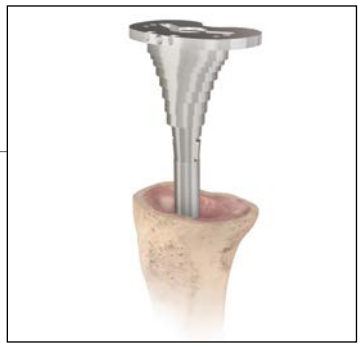
Distal Femoral Resection



Final Trialing

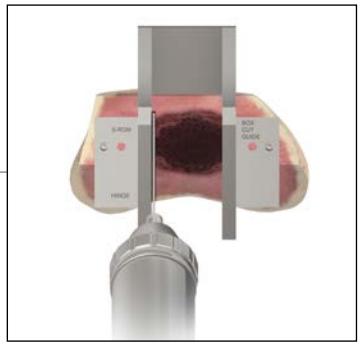
Patella Preparation

Tibial Resection



Tibial Trial Assembly

Femoral Preparation -
A/P and Chamfer Cuts



Femoral Box Cuts

Implantation

S-ROM® NOILES™ Rotating Hinge Knee System

The S-ROM® NOILES™ Rotating Hinge features:

- S-ROM Femoral Components available in three sizes
- 7 degree physiological valgus, fixed in the femoral component
- Deep femoral trochlear groove
- Modular porous sleeves to accommodate bone defects of the Engh Type 2 and Type 3 classification and allow possible bone ingrowth
- Available with both cemented and press-fit slotted stems for both femur and tibia
- Broad, congruent contact areas between femoral and tibial components designed to best distribute surface and sub-surface stresses in the polyethylene
- A rotating hinge that accommodates axial rotation, reducing stresses at the bone cement/implant interfaces

The S-ROM Hinge System Overview

The MBT Revision Knee System is comprised of the following components:

- Tibial Components are available in eight sizes, 1, 1.5, 2, 2.5, 3, 4, 5 and 6
- Tibial Metaphyseal Sleeves are available in 29 mm (cemented or porous), 37 mm, 45 mm, 53 mm and 61 mm sizes (M/L dimension)
- Tibial Wedge Augmentation Components: Step Wedge in 5, 10 and 15 mm thicknesses
- 75, 115 and 150 mm Fluted Universal Stem lengths in 10 to 24 mm diameters in 2 mm increments
- 30 and 60 mm Cemented Universal Stem lengths in 13 mm diameters. 90, 120, 150 Cemented Tapered Universal stem lengths in 13 mm diameters
- Thick Trays are available in three different sizes (2, 3 and 4) and two different thicknesses (+15 mm and +25 mm)
- Accepts Rotating Platform hinged insert from the LPS™ Limb Preservation System, which is compatible with the S-ROM NOILES Rotating Hinge Femoral Component and LPS Femoral Component

The S-ROM Hinge Knee System is comprised of the following components:

- Hinged Femoral Component is available in three sizes, X-Small, Small and Medium
- Femoral Metaphyseal Sleeves are available in 20 mm (cemented only), 31 mm, 34 mm, 40 mm and 46 mm sizes (M/L dimension), and can be used with or without a stem
- 5 and 10 mm Distal Femoral Augments
- 75 mm, 115 mm and 150 mm Fluted Universal Stem lengths in 10 mm to 24 mm diameters in 2 mm increments
- 30 mm and 60 mm Cemented Universal Stem Lengths in 13 mm and 15 mm diameters
- 90 mm, 120 mm, and 150 mm Tapered Cemented Universal Stem lengths in a 13 mm diameter
- 90 mm Tapered Cemented Universal Stem length in a 15 mm diameter (Must be used with a sleeve)

Incision and Exposure

Initial Incision

When possible, follow the scar from the primary procedure (Figure 1). Where parallel incisions are present, the more lateral is usually preferred, as the blood supply to the extensor surface is medially dominant. Where a transverse patellectomy scar is present, the incision should transect it at 90 degrees.

Where there are multiple incision scars or substantial cutaneous damage (burn cases, skin grafting, etc.), one may wish to consult a plastic surgeon prior to surgery to design the incision, determine the efficacy of pre-operative soft tissue expansion and plan for appropriate soft tissue coverage at closure.

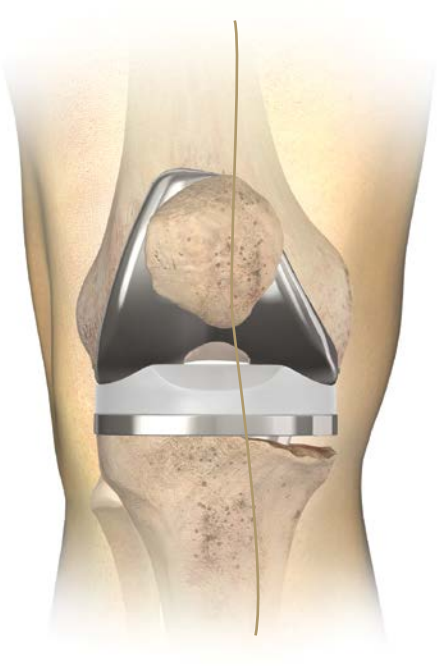


Figure 1

Capsular Incision

The fascial incision extends from the rectus femoris proximal margin to the distal margin of the tibial tubercle following the patella's medial border, maintaining a 3-4 mm cuff for reapproximation of the vastus medialis aponeurosis at closure (Figure 2). Where mobilization of the extensor mechanism and patella is problematic, extend the skin and capsular incisions proximally.

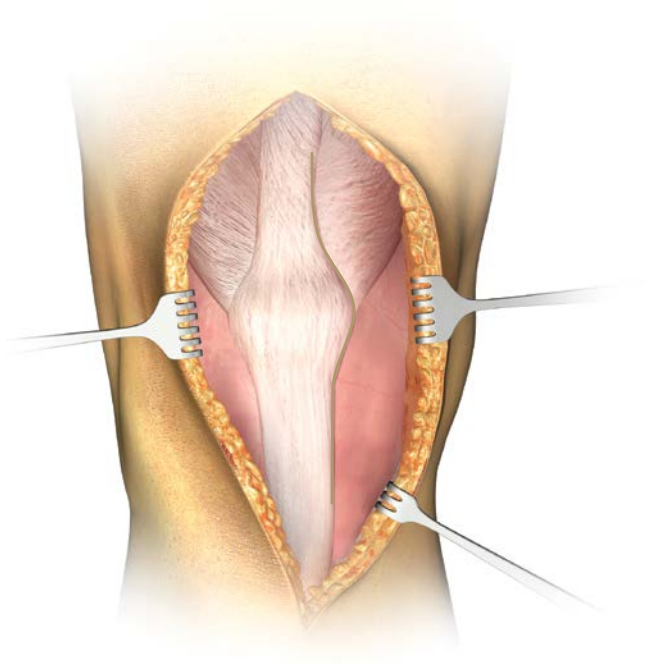


Figure 2

Occasionally an early retinacular release is indicated to assist with patellar eversion. Where eversion difficulties persist, a quadriceps snip, a proximal inverted quadriceps incision (modified V-Y) or a tibial-tubercle osteotomy may be indicated. Perform appropriate ligamentous release based upon pre-operative and intra-operative evaluation. Release fibrous adhesions to re-establish the suprapatellar pouch and medial and lateral gutters (Figure 3). In many revision cases, the posterior cruciate ligament will be absent or non-functional; when this is the situation, excise any residual portion. Exercise care when everting the patella. Frequently, subluxing the patella laterally is adequate. Doing so will help avoid patella tendon avulsion.

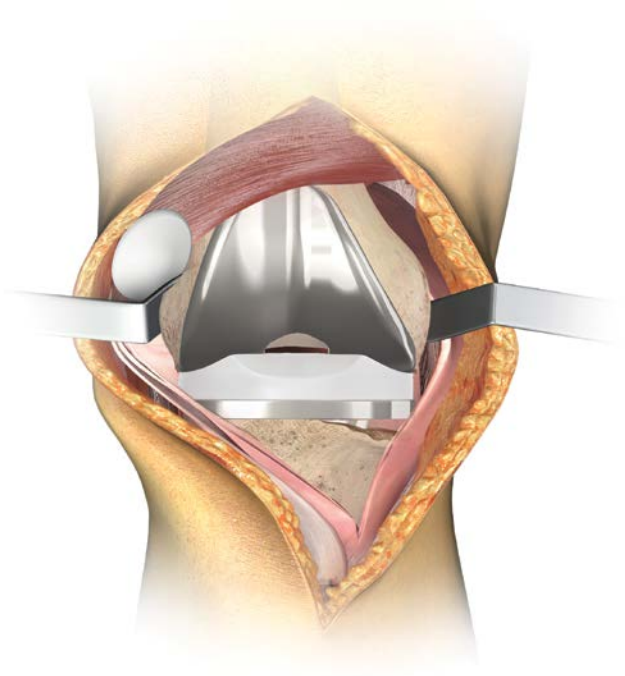


Figure 3

Implant Extraction from the Primary Procedure

Take care to preserve as much bone as possible. To this end, assemble a selection of tools, including thin Osteotomes, an Oscillating Saw, a Gigli Saw, a highspeed Burr and various extraction devices, but many cases will require only the thin Osteotome. Carefully disrupt the bone/cement or bone prosthesis interface before attempting extraction (Figure 4).

Disengage the implanted components and extract as gently as possible, in such manner as to avoid fracture and unnecessary sacrifice of bone stock. Where the entire prosthesis is to be replaced, it is advantageous to remove the femoral component first, as this will enhance access to the proximal tibia. Clear all residual methyl methacrylate with hand (chisels) or power tools.

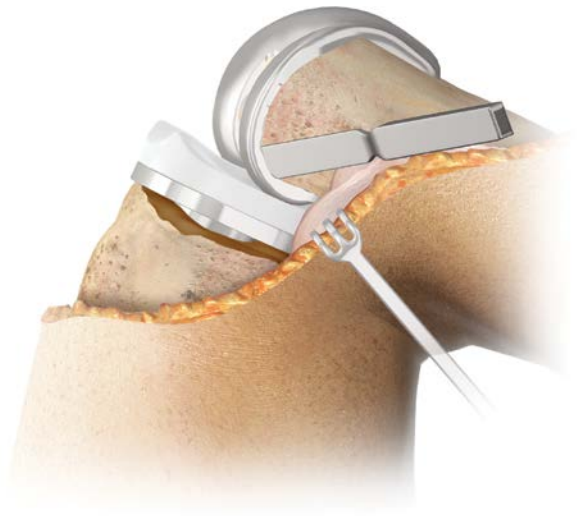


Figure 4

Intra-operative Evaluation

The surgeon should establish two anatomic conditions to facilitate revision arthroplasty: the level of the joint line and the disparity in the flexion and extension gaps.

Joint Line Evaluation

In an average knee in full extension, the true joint line can be approximated in reference to several landmarks.

- It lies 12–16 mm distal to the femoral PCL attachment
- It lies approximately 3 cm distal to the medial epicondyle and 2.5 cm distal to the lateral epicondyle
- It lies distal to the inferior pole of the patella (approximately one finger width)
- Level with the old meniscal scar, if available

Additional pre-operative joint line assessment tools include:

1) Review of original pre-operative roentgenogram of the Total Knee Arthroplasty (TKA)
2) Review of roentgenogram of contralateral knee if non-implanted

Initial Preparation of the Tibia

The Tibial Alignment System
When pre-operative evaluations indicate that Fluted Stem Extensions, Metaphyseal Sleeves or Wedges are required, it is recommended that the proximal tibia be prepared with reference to the position of the I.M. Rod.

Note: **Where a Cemented Stem Extension is indicated, see Appendix 1 (page 48).**

Place the knee in maximal flexion with the patella laterally retracted and the tibia distracted anteriorly and stabilized. Release fibrosis around the tibial border or excise as required to ensure complete visualization of its periphery.

Approximate the location of the medullary canal with reference to pre-operative anterior/posterior (A/P) and lateral X-rays and to the medial third of the tibial tubercle.

Introduce a 9 mm drill into the canal to a depth of 2–4 cm. Avoid cortical contact (Figure 5).

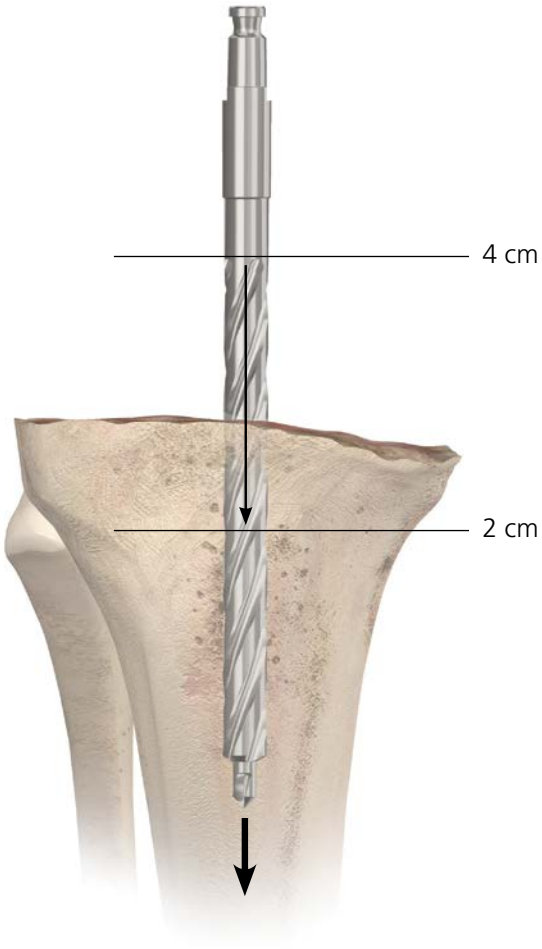


Figure 5

Initial Preparation of the Tibia

Reaming the Medullary Canal

Assemble the Straight Reamer to the T-Handle. *If power reaming, it will be necessary to attach the modified Hudson Adapter to the Straight Reamer.* The shaft of the reamer contains markings in 25.4 mm (1 in) increments. Each marking is numbered to use as a reference when reaming to the appropriate depth. Fluted stem lengths are available in 75, 115 and 150 mm. Determine the length and diameter of the prosthetic Stem Extension with Templates (Cat. No. 2178-30-100) applied to pre-operative X-rays.

Use the Reamer Depth Chart (Figure 6) to determine the appropriate mark on the reamer for canal reaming depth. Another option to determine reamer depth is to measure the trial assembly against the reamer and note the corresponding depth mark for reaming. Sequentially open the canal with progressively larger reamers until firm endosteal engagement is established (Figure 7).

Note: **Simple cortical contact should not be construed as engagement.**

The fixed relationship of the reamer to the cortices ensures the secure fit of the appropriate reamer and, subsequently, the corresponding fluted stem. It is equally important to not over-ream osteopenic bone. While reaming the proximal tibia, pay close attention to the reamer to assure that it is centrally located to the exposed proximal tibial surface. Eccentric reaming can occur, which could lead to undersizing of the tibial component.

The size of the final reamer indicates the diameter of the implant stem. The fluted stems are available in even sizes (10 through 24 mm). Perform final reaming with an even-sized reamer. The final implant will have a .4 mm press-fit versus the reamer and a .5 mm press-fit versus the Stem Trials.

Note: **Refer to Appendix 1 (page 48) for cemented stem preparation.**

MBT Revision Tray		Reamer Line Depth
Press-Fit Stems	75 mm	2
	115 mm	3
	150 mm	4
Cemented Stems	30 mm	1
	60 mm	2
	90 mm	2.5
	120 mm	3.5
	150 mm	4

Figure 6

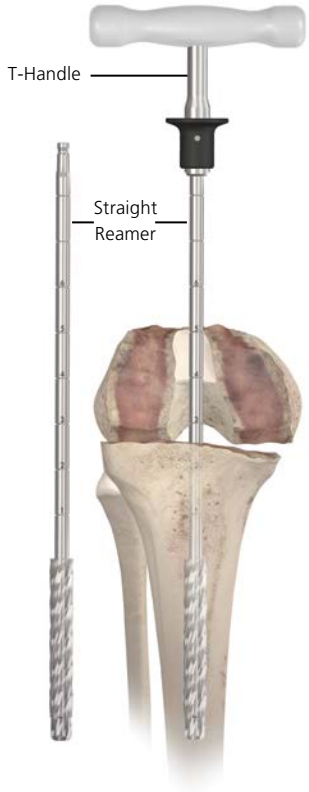


Figure 7

Preparation of the Metaphyseal Bone – Tapered Reamer

For Diaphyseal Engaging Stem and Metaphyseal Filling Sleeve

Attach the appropriately sized Stem Trial to the end of the MBT Revision Tapered Reamer.

Note: **Assembly of the Stem Trial may be aided by the pre-attachment of the T-Handle to the MBT Revision Tapered Reamer.**

Taper ream to the planned proximal tibial resection level (Figure 8). When finished reaming, the notches on the Drill should line up with the planned proximal tibial resection level.

Note: **Use the "cemented" Tapered Reamer when requiring a cement mantle around the cone of the MBT Revision Tray or when utilizing a sleeve. Use the Press-Fit Tapered Reamer when line-to-line fit is desired around the cone of the MBT Revision Tray and a sleeve will not be utilized (Figure 10). Use End-Cutting Primary Reamer (Cat. No. 2178-63-199) when a stem or sleeve will not be used.**

Note: **To avoid Stem Trial disengagement, do not reverse ream.**

At this point, intra-operatively determine if a Metaphyseal Sleeve will be used.

Note: **Metaphyseal Sleeves are ideal to provide filling of Engh Type 2 or 3 defects in revision TKA. The steps of the Metaphyseal Sleeve also provide progressive loading of the bone with porous coating, which enhances fixation.**

If a Metaphyseal Sleeve is selected, see page 16 in order to broach the metaphyseal bone.

If a Metaphyseal Sleeve will not be used, see the following page to prepare for the proximal tibial resection.

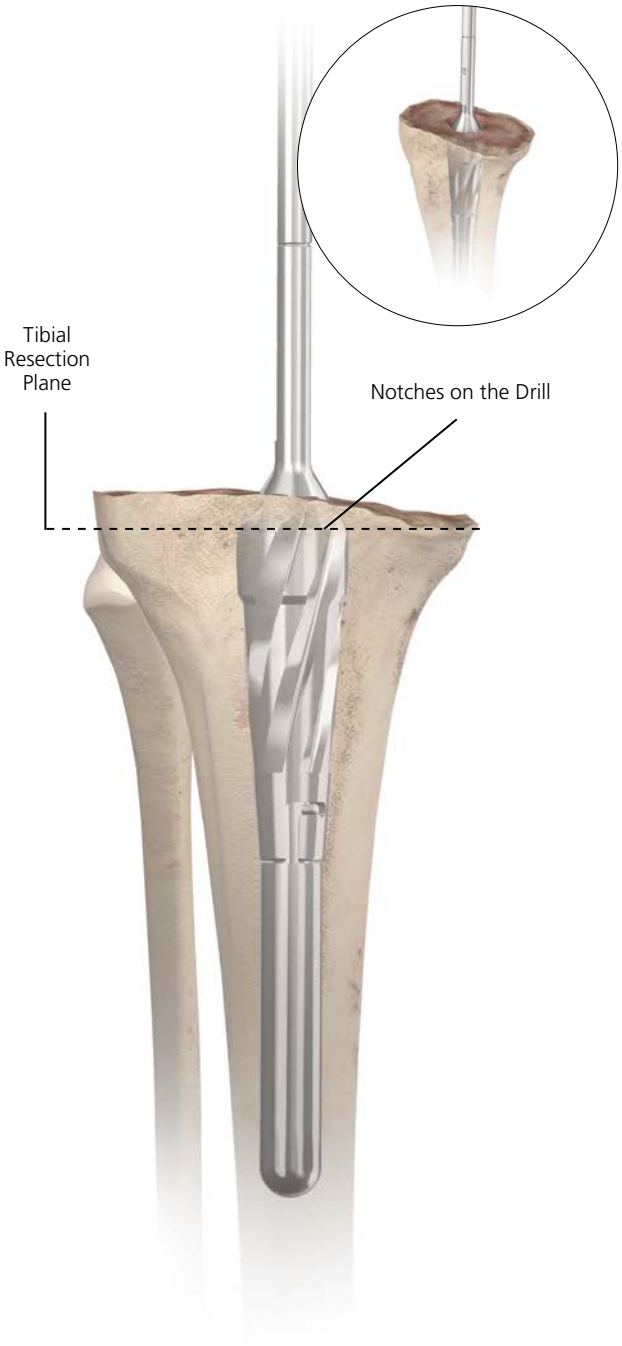


Figure 8

Proximal Tibial Resection – Tapered Reamer

Attach the 2 degree Tibial Cutting Block to the I.M. Tibial Referencing Device. Attach the I.M. Tibial Referencing Device to the shaft of the Tapered Reamer. Position the I.M. Tibial Referencing Device with the pre-attached 2 degree Cutting Block onto the shaft and allow it to descend to the proximal tibial surface. Since considerable bone stock may have been sacrificed in the primary TKA, minimize the amount resected: no more than 1-2 mm from the most prominent tibial aspect, managing residual defects of the contralateral tibial aspect with either prosthetic augment or bone graft.

Resection is based on tibial deficiency and the level of the joint line. Compensate deficiencies with sleeves, wedges and/or bone grafts. Advance the cutting block to the anterior tibial cortex and lock into position by tightening the knurled knob on the outrigger. Preliminary rotational alignment is based on the medial third of the tibial tubercle. Secure the alignment device to the reamer shaft with the lateral Setscrew (Figure 9).

Pin the Tibial Cutting Block so a minimal resection is made from the proximal tibia. Utilize the Stylus when necessary (Figure 9).

Note: **There is a slotted and non-slotted end to the Stylus. The difference between the two is 5 mm.**

Note: **If a Metaphyseal Sleeve is to be used the tibial resection will be performed using the Tibial Sleeve Broach (see page 16, Figure 11).**

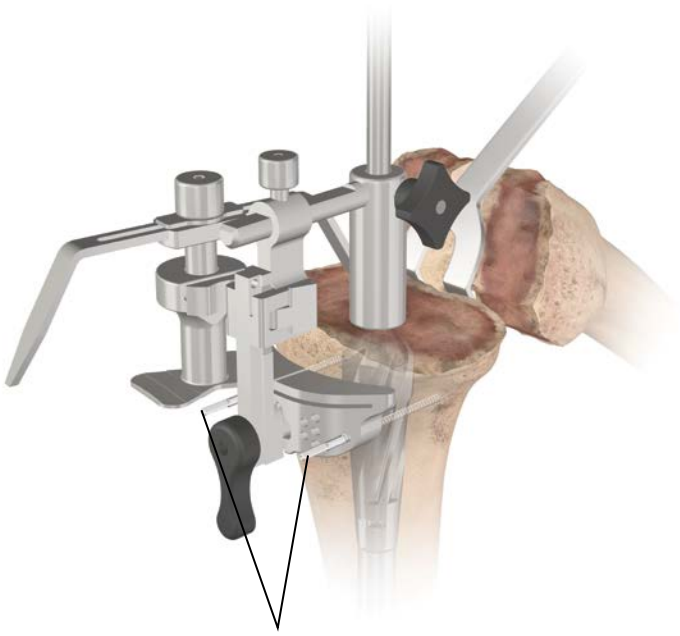


Figure 9

Proximal Tibial Resection – Tapered Reamer

Remove the I.M. device while leaving the 2 degree Cutting Block in place. Remove the Tapered Reamer and resect the proximal tibia (Figure 10).

Note: **At this point determine whether a step wedge is necessary on either the medial or lateral side to augment a defect, or both sides in order to restore the joint line. If a wedge is necessary on one side, it is recommended that the step wedge be prepared after rotational position of both the femoral and tibial components have been determined. For step wedge preparation see Appendix 2 (page 51).**

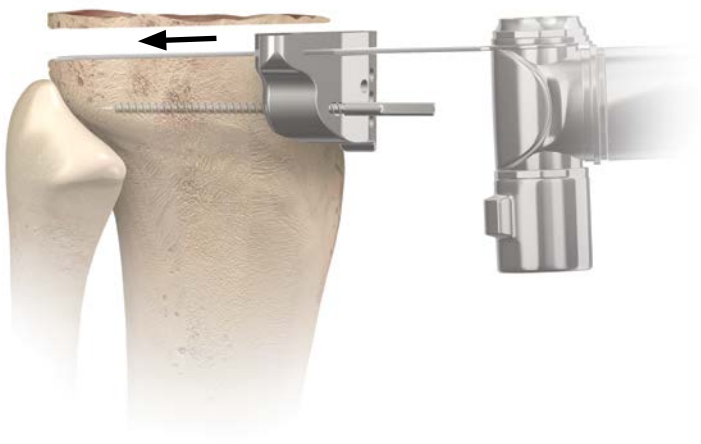


Figure 10

Preparation of the Metaphyseal Bone – Broach

Optional For Sleeve Utilization Only

Note: **The MBT Revision Tibial Tray will accept either a tibial Metaphyseal Sleeve or a tibial Step Wedge. Only the 29 mm Sleeve is indicated for use with a Tibial Step Wedge.**

Attach the MBT Revision Broach Handle to the smallest broach and then attach the appropriately sized Stem Trial. The broaches are asymmetrical, position the "ANT" engraving on the broach anteriorly. Impact the broach into the tibia until the top surface of the broach is at the desired proximal tibial resection level. When broaching the proximal metaphysis, take care to assure the appropriate rotation of the Broach.

Note: **The corresponding tibial sleeve implant allows up to +/- 20 degrees of rotation from the centerline of the MBT Revision Tray.**

Check for rotational stability of the broach. If the broach (not the handle) moves in the canal, it is not rotationally stable.

If the broach is unstable or the defect is unfilled, repeat with consecutively larger broaches until the desired fit is achieved (Figure 11). Remove the Broach Handle, leaving the last broach in place. Any defects remaining can be filled with allograft or autologous bone placed in intimate contact with the sleeve.

Two common tibial broaching techniques:

1) Chase the defect by rotating the broach to fill the defect until reaching rotational stability of the broach. If utilizing this technique the surgeon must be aware that the sleeves are allowed to rotate +/-20 degrees with respect to the MBT Revision Tibial Tray.

2) Align the broach with the medial third of the tibial tubercle and progressively broach until rotational stability of the broach is attained.

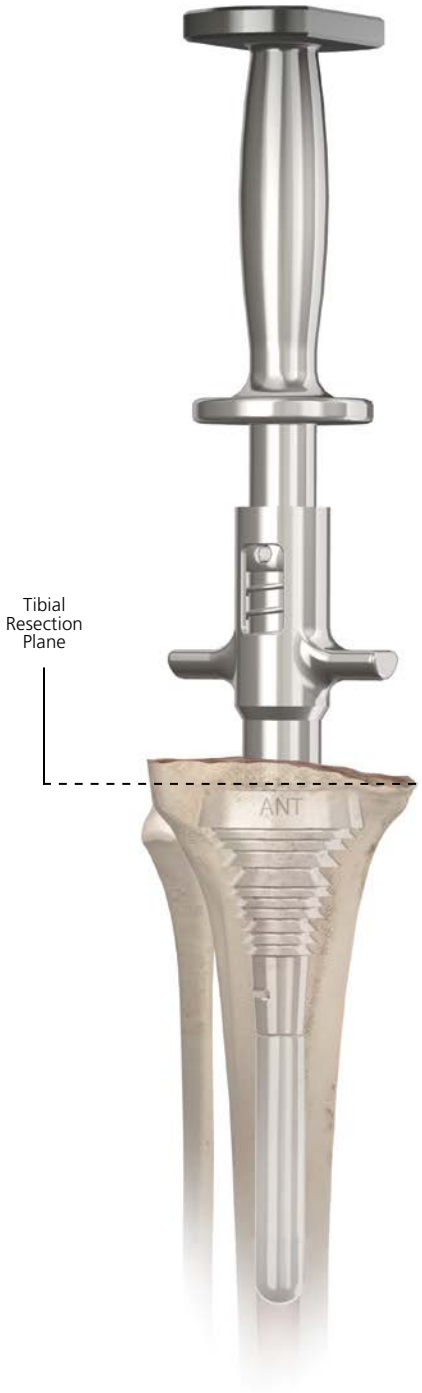


Figure 11

Preparation of the Metaphyseal Bone – Broach

Resect the proximal tibia utilizing the top of the broach as a guide (Figure 12). The top of the broach has a 2 degree slope built in. The proximal cut should be parallel to the top of the broach.

Note: **If a cutting guide is desired for resecting the proximal tibia with the tibial broach in place, assemble the SP2 0 degree Tibial Cutting Block (Cat. No. 96-6320) to the SP2 IM Tibial Guide and slide over the Broach Adapter Outrigger (Cat. No. 2178-01-108). Slide this assembly onto the boss of the seated tibial broach, pin the block, remove the outrigger, and resect through the slot of the cutting block (Figure 13).**

Slide the tibia view plate which best covers the proximal tibial over the broach post. Note the view plate size as it will dictate the size of the MBT Revision Tibial Base Trial that will be used. The tibial view plate is transparent to help visualize tibial coverage (Figure 14). The template matches the implant to aid in orienting the tibial sleeve to the tibial base during assembly.

Figure 12

Figure 13

Figure 14

Tibial Trial Assembly

Assemble the tibial tray trial with the stem extension and sleeve trial, if applicable (Figure 15). Position the Tibial Trial construct into the prepared tibial canal (Figure 16). Assess proximal tibial coverage and rotation of tibial component. The base plate should be positioned to provide the best coverage of the tibial condylar surface.

Note: The MBT Revision Tibial Keel Punch with the Universal Handle may be utilized to assist with seating of the tibial trial construct. Once the tibial trial construct is seated the Keel Punch must be removed in order to accommodate the use of Spacer Blocks.

Leave the trial in place and proceed to femoral preparation, final tibial preparation will occur after femoral preparation is complete.

Note: **A 14 mm or smaller size stem implant can be pulled through the sleeve implant. If the stem is 16 mm or greater it will not pull through the sleeve.**

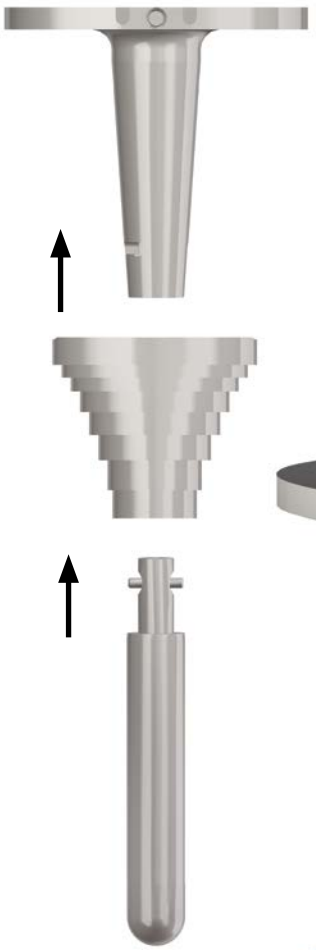


Figure 15

Figure 16

Preparation of Femoral Diaphysis

Intramedullary Femoral Alignment System

This technique is designed to flow in a logical sequence, from reaming the diaphysis, to broaching the metaphysis and cutting the bone. The length and diameter of the stem extension is determined with templates applied to pre-operative roentgenograms.

Begin the procedure with the preparation of the medullary canal (Figures 17 and 18).

Enter the medullary canal with a 9 mm drill to a depth of 3-5 cm (Figure 19). Take care that the drill avoids the cortices. It is helpful to palpate the distal femoral shaft as the drill is advanced.

Where impedance of the intramedullary canal is anticipated, adjust the entry point accordingly.

Figure 17

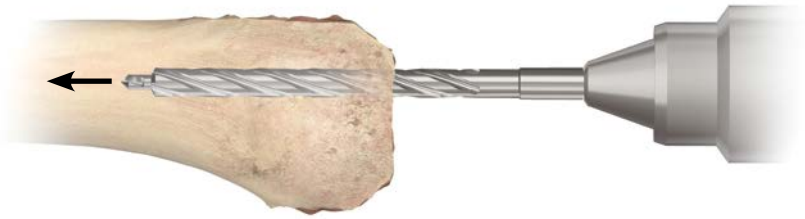


Figure 18

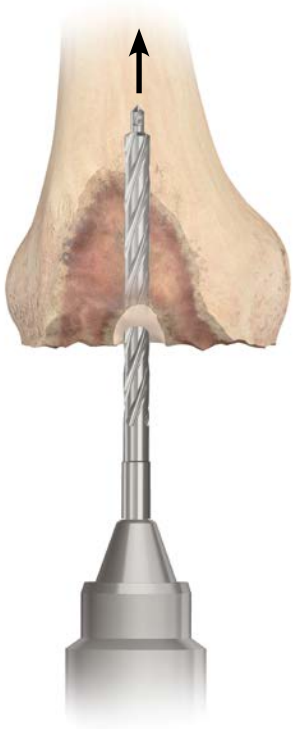


Figure 19

Reaming the Medullary Canal

Connect the Reamer Handle to a small diameter MBT Revision Reamer. If power reaming, it will be necessary to attach the modified Hudson Adapter to the Straight Reamer.

Note: **The reamer shaft contains markings in 25.4 mm increments to accommodate the various Universal Stem/Sleeve length combinations (Figure 20).**

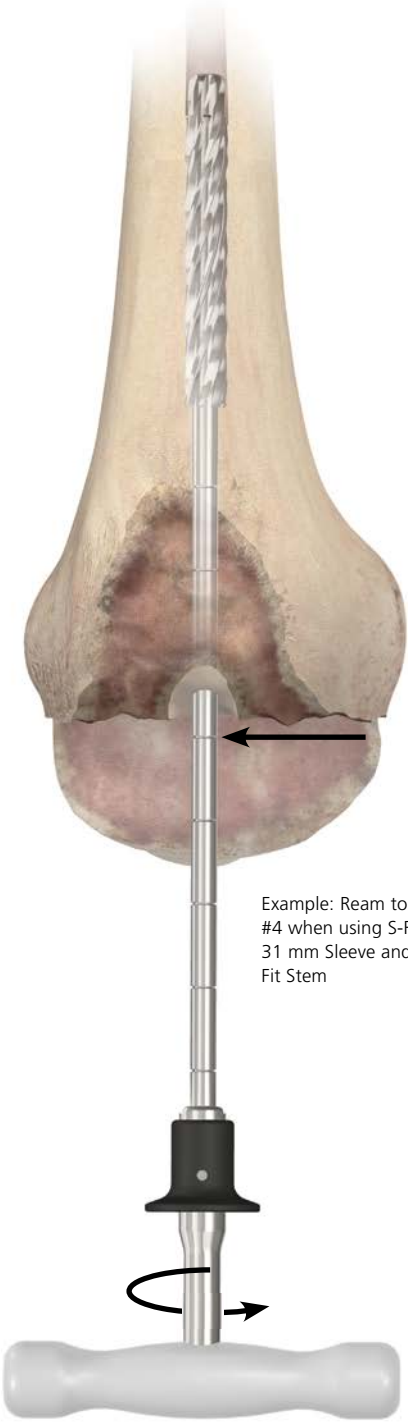
Use the Reamer Depth Chart to determine reamer depth for each combination of components (Figure 21). Another option to determine reamer depth is to measure the trial assembly against the reamer and note the corresponding depth mark for reaming.

You may also determine the length and diameter of the prosthetic stem extension with templates (Cat. No. 2294-99-035: SIGMA® Femoral Adapter Sleeve and Stem Template) applied to pre-operative X-ray. The S-ROM Femoral Components can be found on the S-ROM Templates (XRT-115).

The S-ROM Femoral Component accepts the following stems, only with the use of a femoral sleeve:

- Universal Fluted Stems of 75, 115 and 150 mm in diameters of 10-24 mm in 2 mm increments
- Cemented Stems available in lengths of 30 and 60 mm lengths and a diameter 13 mm or 15 mm
- Cemented Tapered Stems available in lengths of 90 mm (13 mm and 15 mm diameter) and 120 mm and 150 mm (13 mm diameter only)

Note: **The Stem is the same as is currently used with the MBT Revision Trays.**



Example: Ream to the tick mark #4 when using S-ROM Femur with 31 mm Sleeve and 75 mm Press-Fit Stem

Figure 20

Reaming the Medullary Canal

In 1 mm diameter increments, sequentially open the medullary canal with MBT Revision Reamers of progressively greater size until firm endosteal engagement is established.

Take care to ream the canal in line with the femoral axis to avoid putting the implant in flexion.

Note: Do not reverse ream.

It is important that simple cortical contact of the tip not be construed as engagement.

Cemented Stem Use

Where a cemented stem extension is indicated, perform final reaming with a 15 mm diameter reamer for the 13 mm diameter stem extension; similarly a 17 mm diameter reamer is used to accommodate the 15 mm diameter stem extension.

This allows for creation of a cement mantle.

S-ROM Femur		20 mm 31 mm 34 mm	40 mm 46 mm
Cemented Stems	30 mm	2	2
	60 mm	3	3
	90 mm	4	4
	120 mm	5	6
	150 mm	6	7
Press-Fit Stems	75 mm	4	4
	115 mm	5	5
	150 mm	6	7

Figure 21

Preparation of the Metaphysis – Sleeve Use

After reaming the intramedullary canal, attach the Threaded Shaft to the Broach Reamer and then to the appropriate Stem Trial as determined by straight reaming (Figure 22).

Ream to the 20 mm, 31 mm, 34 mm etch mark on the Threaded Shaft (Figure 23).

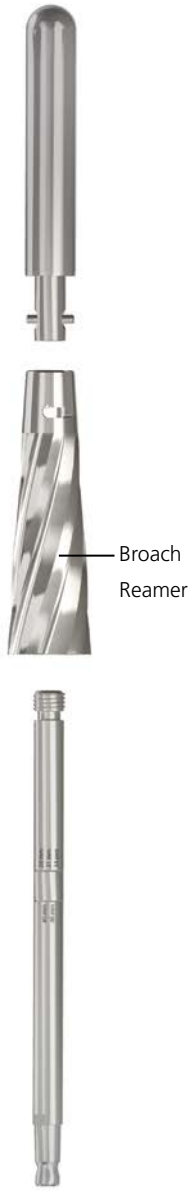


Figure 22

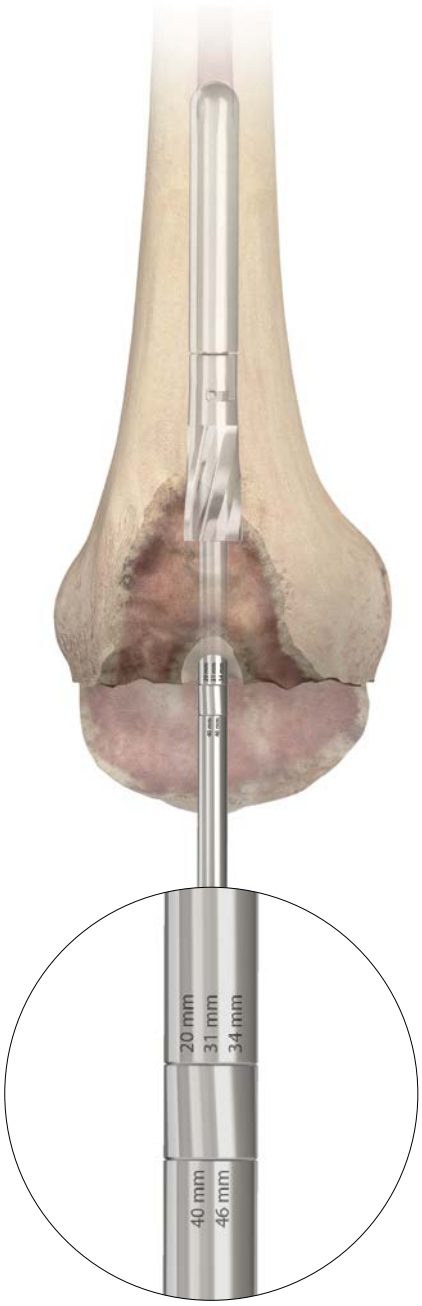


Figure 23

Preparation of the Metaphysis – Sleeve Use

When using the Broach Reamer, the next smaller diameter Stem Trial may be used to allow for easier reaming. The Broach Reamer will be necessary when utilizing a 20 mm sleeve and for the beginning of larger sequential broaching when using a 31 mm or larger sleeve. After broach reaming has been completed, attach the 31 mm broach to the Broach Handle (Figure 24). Attach the appropriate Stem Trial to the broach as determined by straight reaming. Give close attention to the medial orientation of the broach.

Note: **The broach is asymmetrical; and the narrow side of the broach must point medially (Figure 25).**

Note: **When prepping for a 20 mm sleeve, leave the Broach Reamer and threaded shaft in the canal and perform the subsequent femoral cuts off the reamer.**

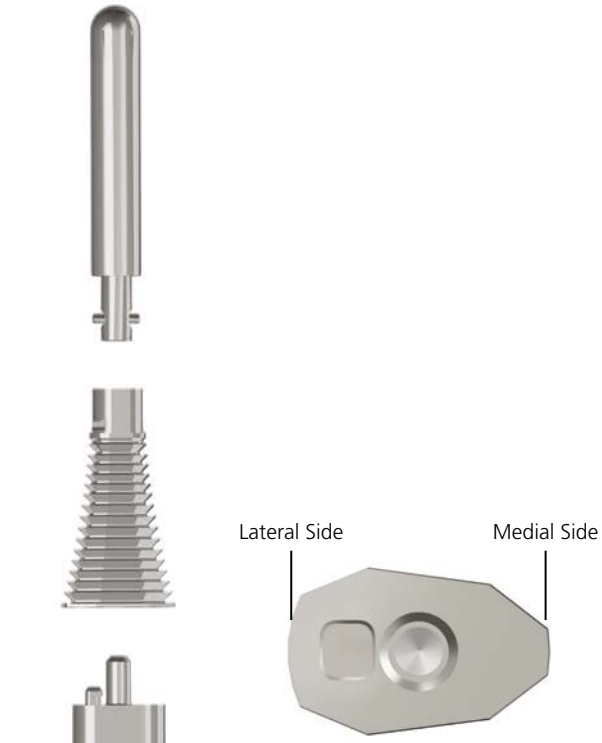


Figure 25

Figure 24

Preparation of the Metaphysis – Sleeve Use

Sequentially broach to the desired dimension of 31, 34, 40 or 46 mm (Figure 26). When the LCS™ COMPLETE Revision Knee System/S-ROM NOILES Rotating Hinge Knee System etch mark on the Broach Handle is at the planned distal resection level, check the broach's rotational stability. If the broach (not the handle) moves in the canal, it is not rotationally stable.

If the stability of the broach is unsatisfactory, move up to the next broach size. The last broach used will be the femoral sleeve size. The broach depth sets the extension gap/joint line.

In patients with a large degree of distal femoral bow, closely monitor the anterior progression of the broach during impaction. Excessive anterior placement of the broach may result in a loose flexion gap.

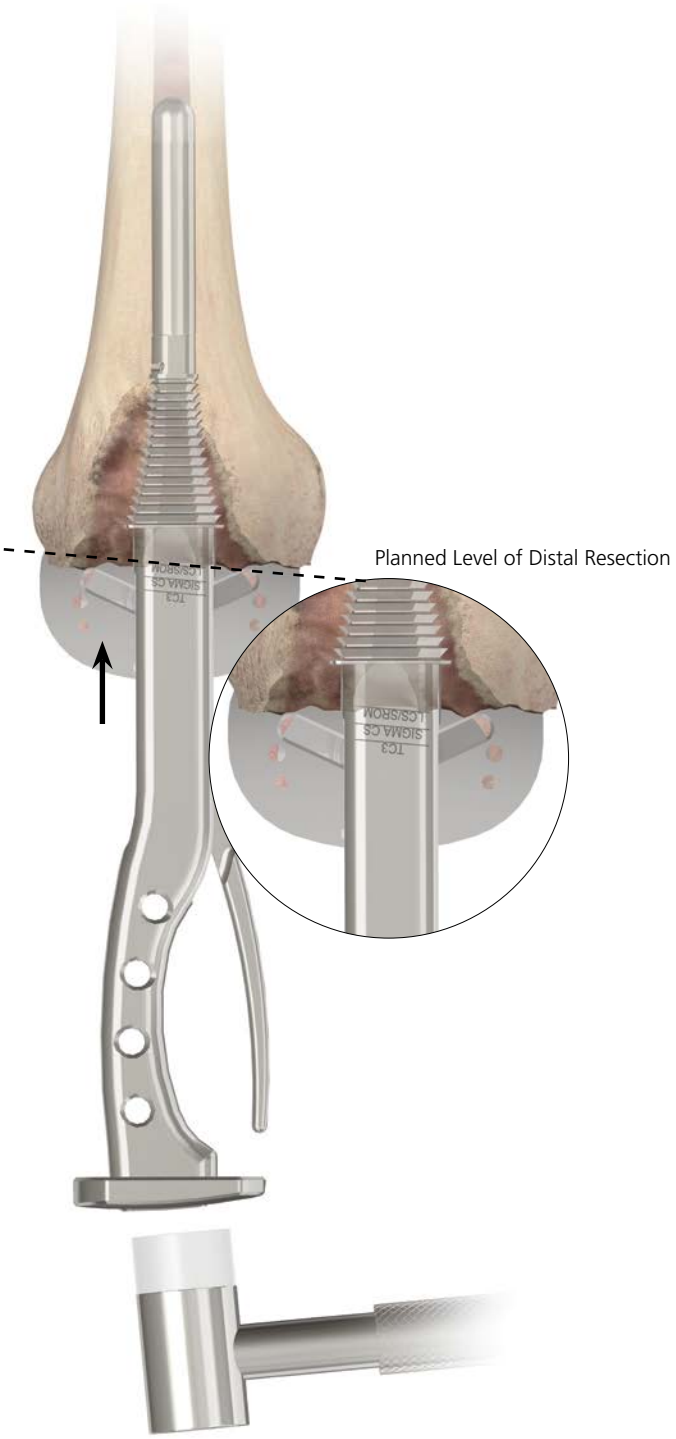


Figure 26

Preparation of the Metaphysis – Sleeve Use

After broaching is complete, remove the Broach Handle from the broach. With the broach seated in the femur, attach the Threaded Shaft to the broach (Figure 27).

Distal, anterior, chamfer, and notch cuts will reference off the Threaded Shaft/Broach assembly.

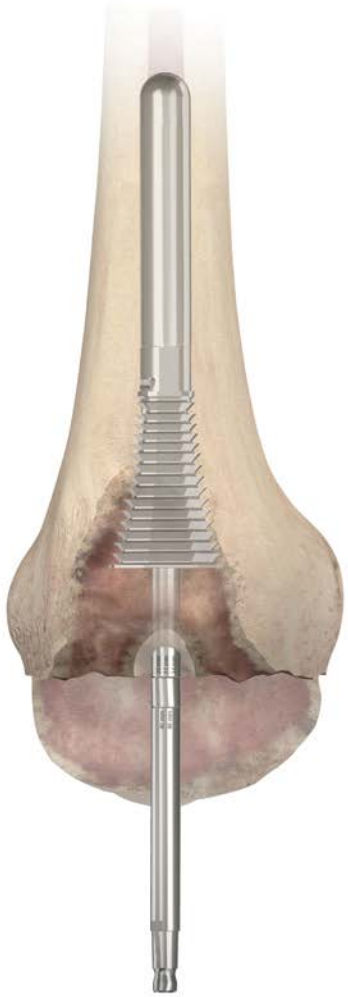


Figure 27

Femoral Preparation – Distal Resection

Distal Resection

Set the valgus angle to 7 degrees and Left/Right on the Distal Femoral Alignment Guide by compressing the two triggers and lock in place by rotating the blue locking lever clockwise. Place the Femoral Alignment Guide on the Threaded Shaft and seat against the distal femur (Figure 28).

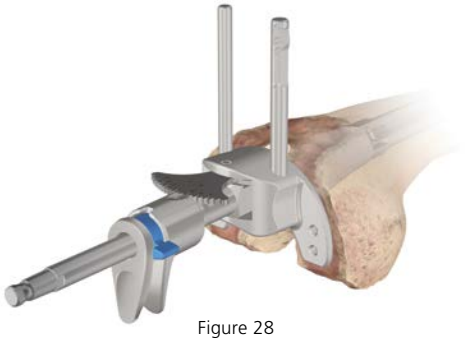


Figure 28

Rotate the knob on the Femoral Resection Guide counterclockwise until the arrow is pointing to the padlock symbol. Slide the Distal Femoral Connector into the Femoral Resection Guide. Rotate the knob on the Femoral Resection Guide clockwise. Every click moves the Revision Distal Cutting Block 1 mm proximal or distal. Turn the knob clockwise from 15 all the way down to 0 (which is the padlock symbol). This will set the block up for a 0 mm resection (Figure 29).

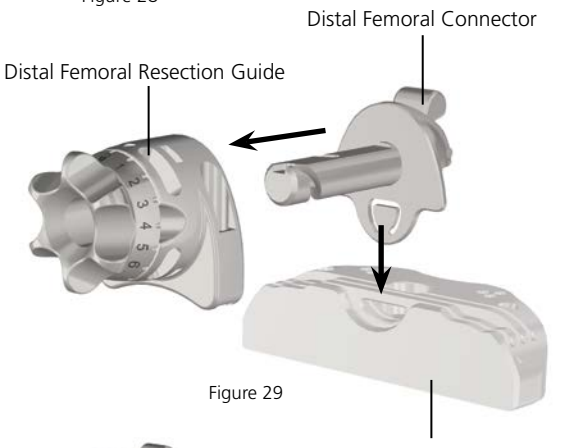


Figure 29

Slide the revision Distal Cutting Block onto the Distal Femoral Block attachment. The tang on the block connector will slide into the 0 mm cutting slot on the cutting block. The trigger should engage in the hole behind the 0 mm slot (Figure 30).

Note: **An open resection will resect 4 mm less femur. When a 0 mm open resection is desired, the dial should be set to 4 mm.**

Position the resection guide over the two legs of the Distal Femoral Alignment Guide until the Distal Cutting Block touches the anterior femur (Figure 31).

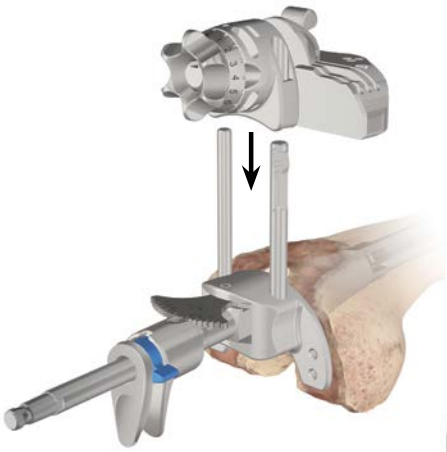


Figure 30

Note: **The Revision Distal Block is equipped with 0, 4, and 8 mm saw slots. Please keep in mind that if the resection level is not at 0 (the padlock symbol) this will alter the resection. If the resection knob is set at 2, for instance, the saw slots will perform 2, 6, and 10 mm resections.**

Figure 31

Femoral Preparation – Distal Resection

Rest the Femoral Alignment Guide against the most prominent distal condyle. If no distal augments are needed, proceed with pinning the distal resection block and making the distal cuts through the 0 mm resection slot (Figures 32 and 33).

If it is determined that a 5 mm or a 10 mm Distal Augment will be needed on only one condyle, perform a 0 mm clean-up cut first on the prominent condyle. Then turn the dial on the Femoral Resection Guide to 5 mm or 10 mm and make the cut on the other condyle through the 0 mm resection slot.

Note: **Do not use the saw slots on the Distal Block to make augment cuts. The augment slots on this block are set up in 4 mm increments instead of the needed 5 mm increments for the S-ROM Knee System.**

Note: **When adding 5 or 10 mm Distal Augments to both sides of the femur, it may be necessary to re-evaluate the depth the sleeve was broached to, based upon the addition of augments. If the augments require the broach to be distalized, rebroaching should occur with a larger broach in order to distalize the sleeve in the canal without losing press-fit.**

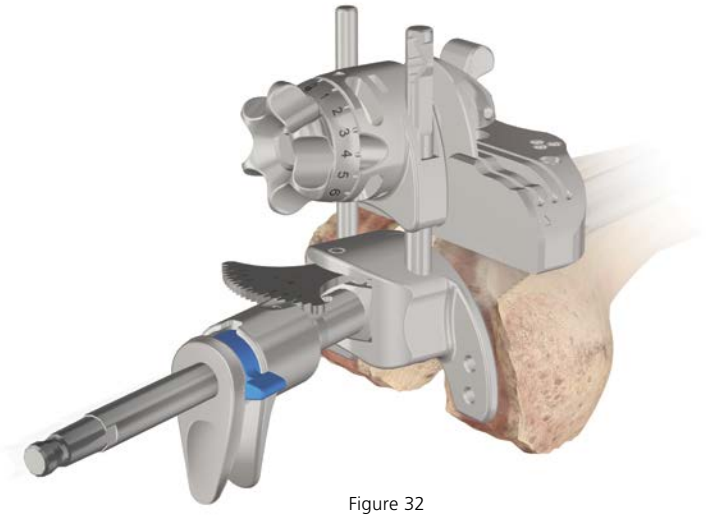


Figure 32

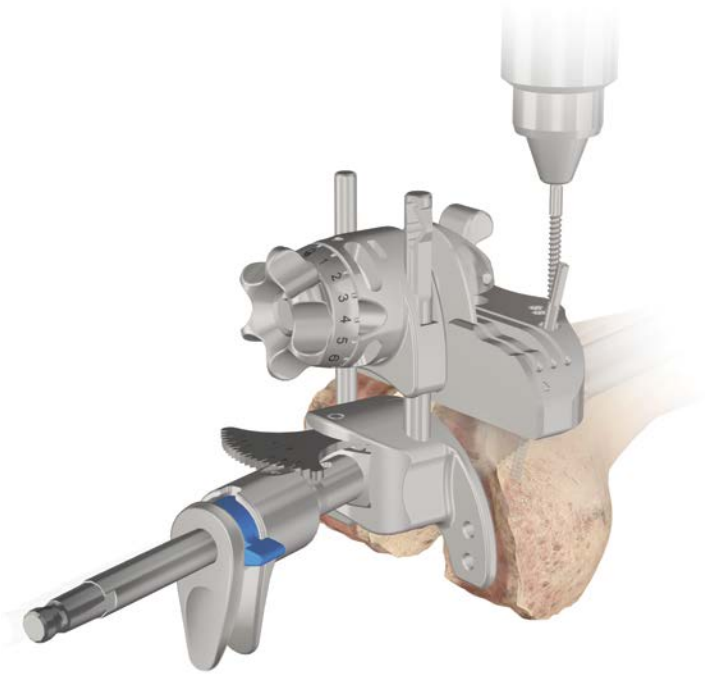


Figure 33

Femoral Preparation – Distal Resection

Once the pins are in place, unlock the Distal Cutting Block from the Distal Femoral Connector, using your thumb and index finger to release the attachment. Slide the Femoral Resection Guide upwards on the Alignment Guide legs until the block connector disengages from the Cutting Block and in one motion remove the Femoral Alignment Guide by pulling the instruments distally over the Threaded Shaft (Figure 34).

In many cases, little, if any, bone is removed from the distal femur as the joint line is effectively elevated with the removal of the primary femoral component. As the level of resection is based on the preservation of bone stock, each condyle is cut only to the level required to establish a viable surface, with augmentation employed to correct imbalance.

The resection is then performed through the slot appropriate for each condyle, using a standard 1.19 mm thick blade (Figure 35).

Note: **If a ½ in. wide Standard Saw Blade is used it can complete both medial and lateral distal femoral cuts with the entire jig still in place.**

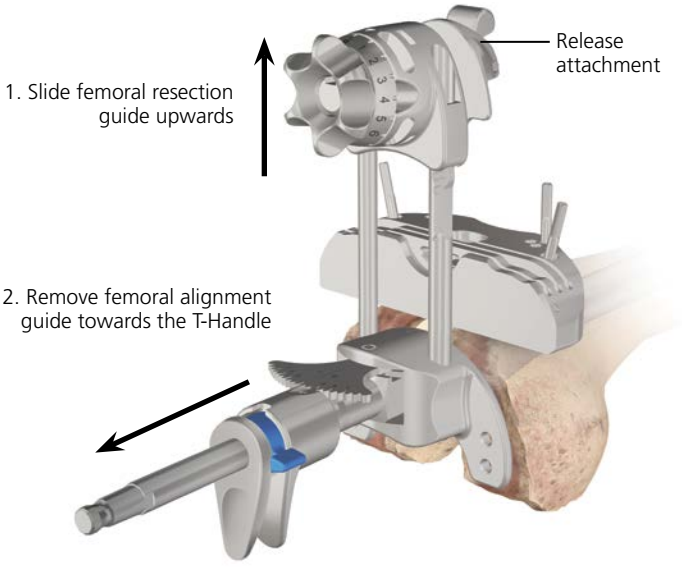


Figure 34

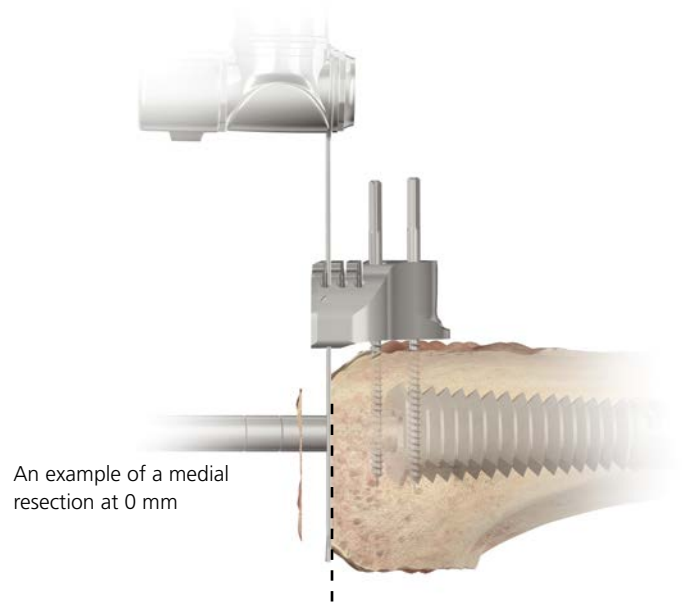


Figure 35

Femoral A/P and Chamfer Cuts

The Femoral Cutting Guide is size specific (two blocks – X-Small/Small and Medium). Determine the femoral component size by pre-operative templating and comparing the Femoral Component Trial to the size of the femur. Use the size which gives the best medial/lateral (M/L) coverage.

Slide the appropriately sized cutting guide over the Threaded Shaft. Use the corresponding hole for a left or a right knee (Figure 36).

Place the guide into neutral rotation by aligning the anterior cortex parallel with the anterior portion of the guide. The SIGMA® Revision Knee Angel Wing (part number: 96-6530) may be helpful in this step. Also use the femoral epicondylar axis as the rotational reference.

Note: **If distal augmentation will be used, use 5 or 10 mm Box Cut Guide Spacers on the appropriate condyle(s). Establish the proper rotation of the A/P block first, then pin through one each of the medial and lateral pin holes. Remove the block from the pins, then put the appropriate spacer(s) over the pins before replacing the A/P block. These spacers should rest between the cutting guide and the distal condyle(s) to fill these gaps appropriately (part numbers: 5 mm - 63-3305A and 10 mm - 63-3306A).**

Achieve fixation of the cutting guide with 1/8 in. drill pins, introduced through the convergent holes on the side of the block. These Pins will need to be temporarily removed later to move to the notch guide (Figure 37).

Attach the Removable Handles to the cutting guide (optional).

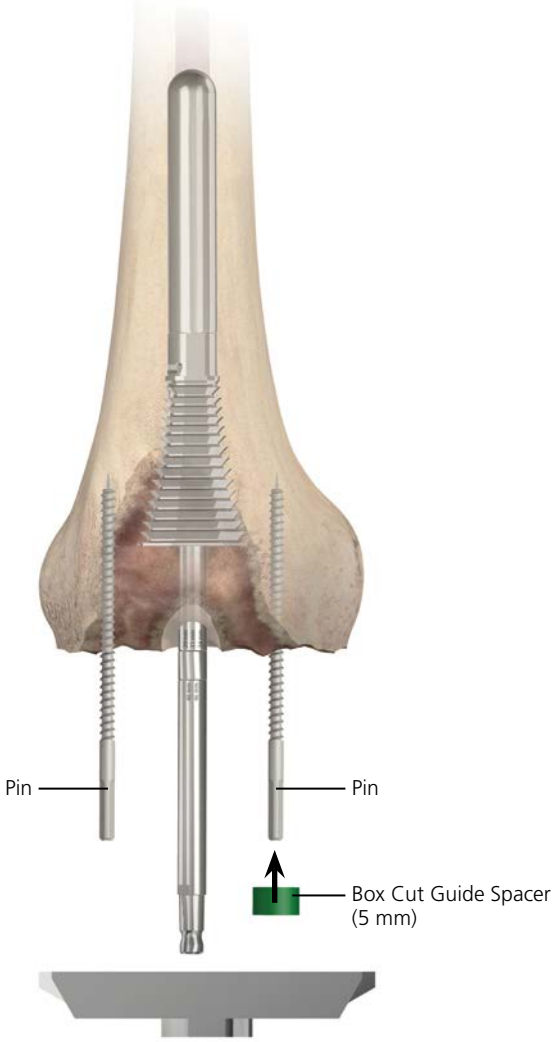


Figure 36

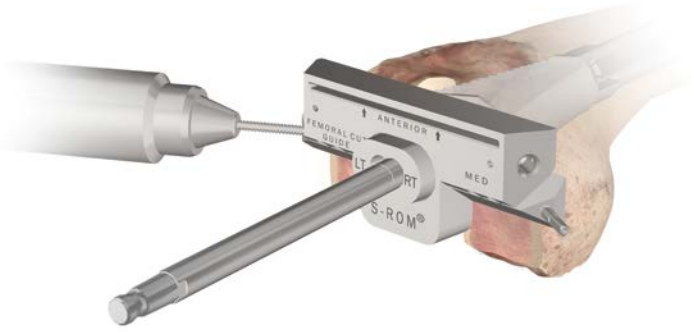


Figure 37

Femoral A/P and Chamfer Cuts

Make the anterior cut (Figure 38) first. Proceed to make the anterior chamfer cut through the captured slot. If the block was previously pinned, temporarily remove one pin at a time while making the resection.

Make the posterior chamfer cut (Figure 39) by holding the saw blade flush with the cutting guide. If anterior pins are being used for fixation, remove the pin while resecting, then replace. Care should be taken to avoid damaging posterior soft tissue.

If not previously pinned, place at least one 1/8 in drill pin on each side of the guide. These will be used to position the Box Cut Guide. Next, remove the convergent pins.

Finally, remove the femoral cutting guide, leaving the 1/8 in. drill pins in place (Figure 40).

Note: **It may be easier to remove the threaded shaft first, before trying to slide the blocks off the pins.**

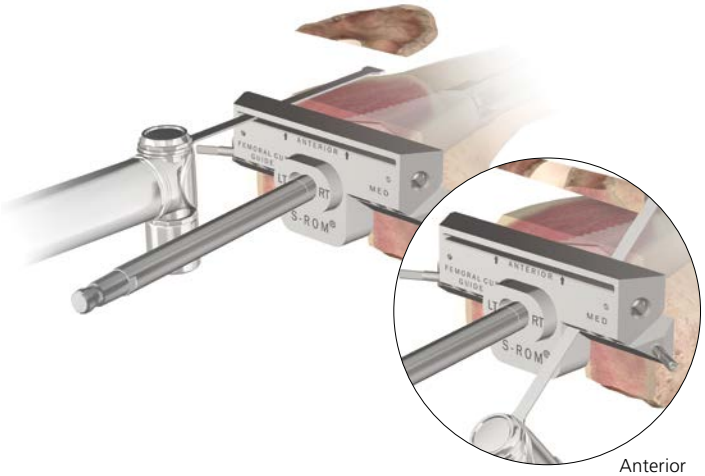


Figure 38

Figure 39

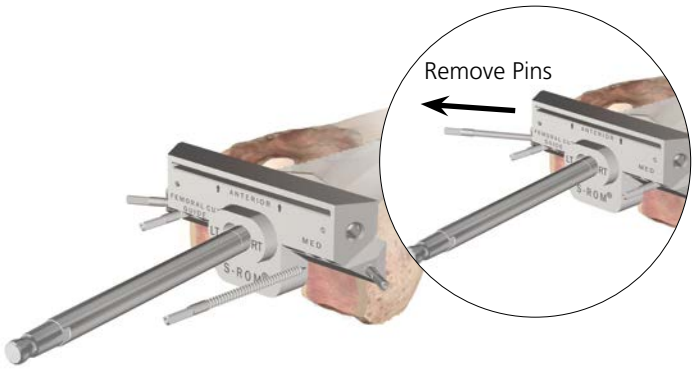


Figure 40

Femoral Box Cuts

Use 5 or 10 mm Box Cut Guide Spacers if distal Augmentation Blocks will be used (Figure 41).

Slide the Hinge Femoral Box Cut Guide over the 1⁄8 in. drill pins placed in the previous step or align with the lines marked off the Femoral Cutting Guide. If Distal Augmentation Blocks will be used, slide 5 or 10 mm Box Cut Guide Spacers over the drill pins before positioning the Box Cut Guide.

Four additional 1⁄8 in. drill holes are provided on the anterior surface of the Box Cut Guide; 1⁄8 in. drill pins are recommended for additional stability.

Holding the saw blade flat against the inner surface of the Box Cut Guide, make the side cuts for the center box (Figure 42).

Use a narrow saw blade (12.7 mm or 0.5 in), placed on the sloped guide surface, to remove the bone block of the center box (Figure 43).

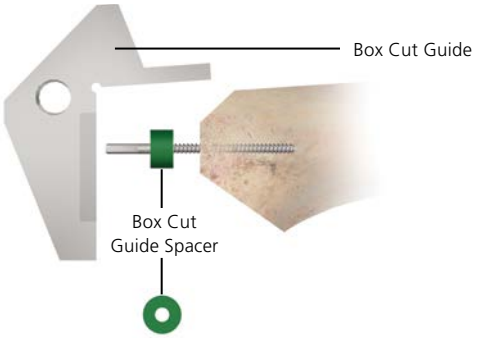


Figure 41

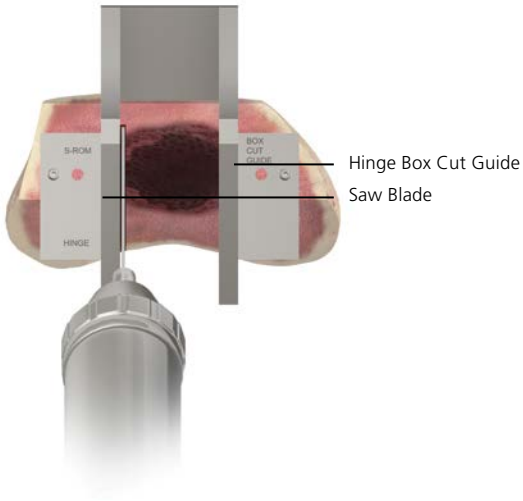


Figure 42

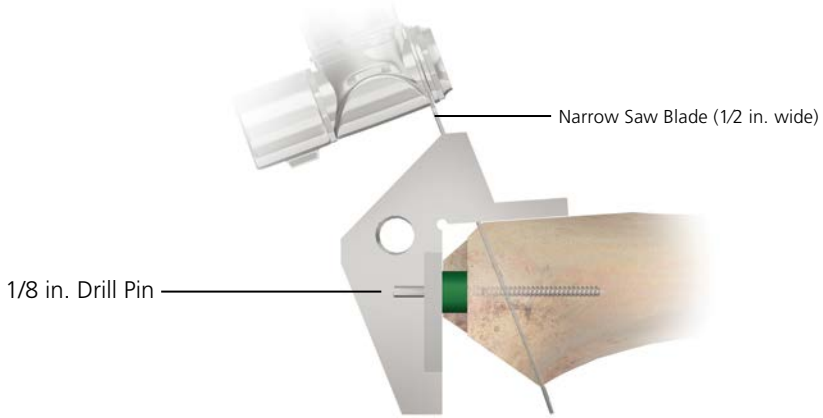


Figure 43

Final Preparation of the Tibia

Assess proximal tibial coverage and rotation of tibial component. Impact the appropriate Keel Punch (utilize the cemented Keel Punch if a cement mantle is desired or the Press-Fit Keel Punch if line-to-line contact is desired) (Figure 44). The base plate should be positioned to provide the best coverage of the tibial condylar surface.

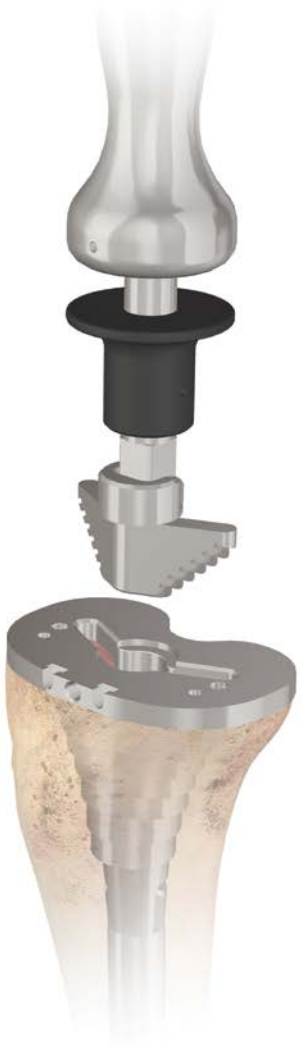


Figure 44

Femoral Trial Insertion

Two femoral Augmentation Blocks are available for the S-ROM NOILES Rotating Hinge Total Knee System. They are 5 and 10 mm Distal Blocks. One size fits all, i.e. X-Small, Small and Medium hinge femoral components. If distal augmentation is required, attach the Augmentation Block Trial(s) with bone wax to the Femoral Component Trial (Figure 45).

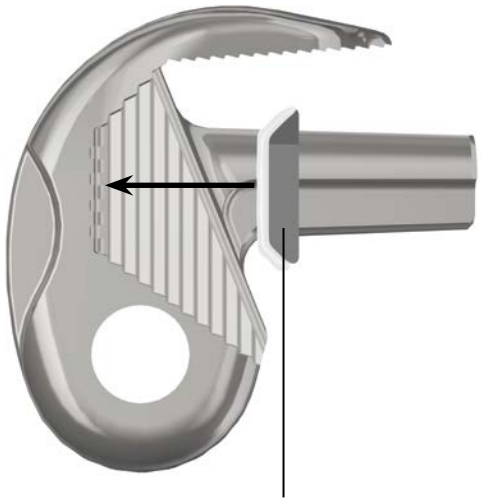


Figure 45

Implant Cat. No.	Femoral Location	Use with S-ROM NOILES Rotating Hinge Femoral Size	Augment Thickness	Trial Cat. No.
623805	Distal	All Sizes	5 mm	633785
623810	Distal	All Sizes	10 mm	633790

Femoral Trial Insertion

Connect the Stem Trial into the appropriate Femoral Sleeve Trial. The diameter of the Stem Trial will be the same as the final Straight Reamer used; the size of the Femoral Sleeve Trial will be the same as the final Femoral Broach used (Figure 46).

Slide the Sleeve/Stem Trial assembly into the prepared cavity in the femoral canal to allow the assembly to self align with the broached surfaces (Figure 47).

Note: **The narrow side of the Sleeve Trial points medially.**

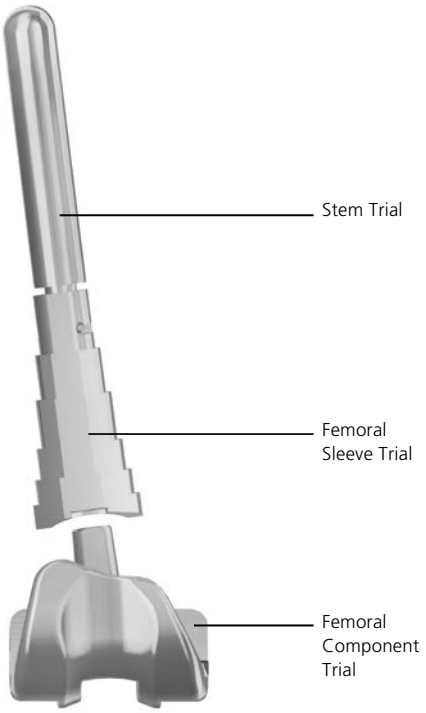


Figure 46

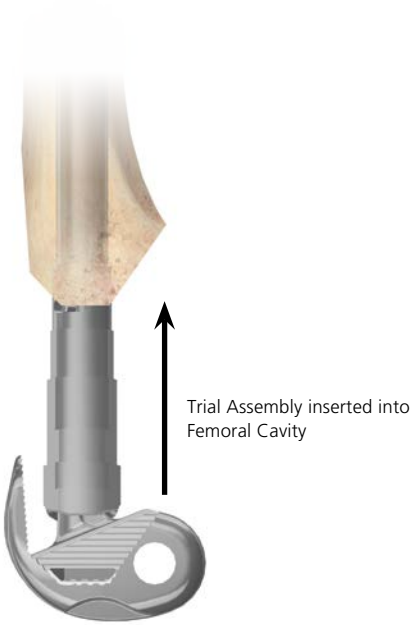


Figure 47

Femoral Trial Insertion

Slide the Femoral Component Trial onto the resected femur, aligning the anterior cut with the posterior aspect of the patellar flange. After the Femoral Component Trial engages the Femoral Sleeve Trial, impact using the Femoral Driver on the Universal Handle. Check accuracy of the bone cuts. Revise or rebroach if necessary (Figure 48).

Note: **If Distal Augmentation Blocks will be used, fix Distal Augment Block Trials to the Femoral Trial with bone wax before impacting the Trial onto the femur.**

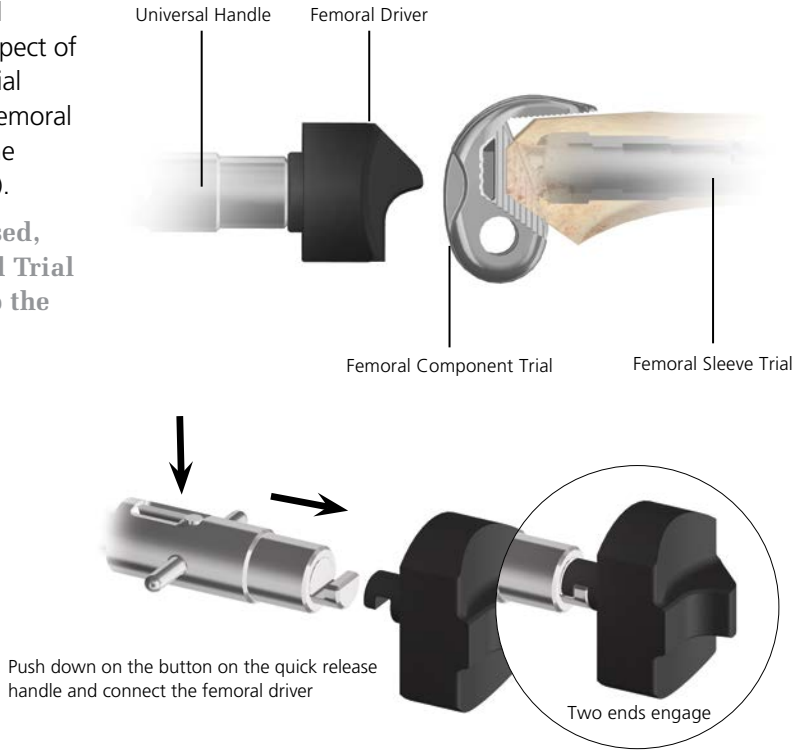


Figure 48

Trial Reduction

Slide the condyles of the Femoral Trial into the Plateau Trial. If the insert trial lifts off the tibial baseplate during flexion, check the posterior area for soft tissue, osteophyte or bone impingement (Figure 49).

It is easier to insert the Hinge Pin Trial prior to placing the insert trial into the tibial baseplate. The Hinge Pin Trial can be inserted either medially or laterally (Figure 49).

With the leg in full extension, evaluate the mechanical axis. The center of the femoral head, knee and talus should all be in line (Figure 50).

The knee should be stable throughout the full range of motion (Figure 51).

Check ligament tension and leg length.

Revision of the tibial or femoral resection may be required if satisfactory stability cannot be achieved. Accommodate additional bone resection with rebroaching.

Remove the femoral trials and ensure that the rotational alignment of the assembly is preserved. This is used as a reference when assembling the modular implant.

Note: **In patients with severe soft tissue loss, flexion of the knee beyond 90 degrees may cause distraction and subluxation of the tibial plateau out of the modular tibial base. In this instance, fit the patient with a post-operative brace, limiting flexion to 90 degrees and no more for at least three months. This helps soft tissue establishment of flexion tension. Consult Instructions for Use.**

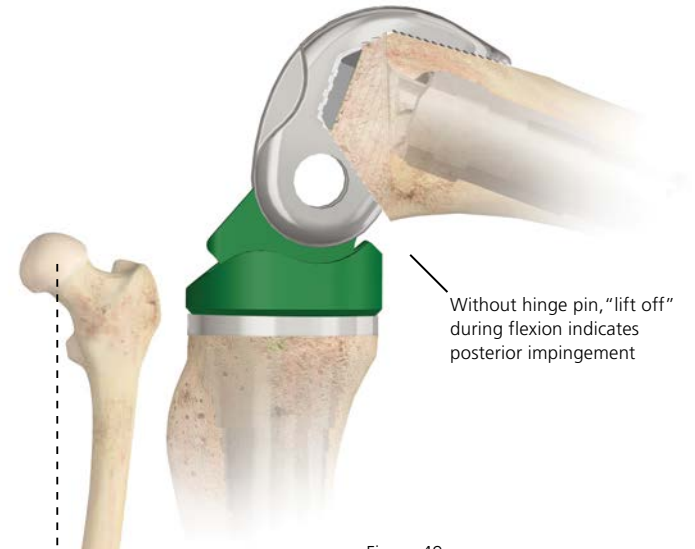


Figure 49

Figure 50

Figure 51

Implant Assembly – Tibia

Tibial Sleeve Assembly

Note: **It is imperative to assemble the Sleeve prior to stem attachment.**

Note: **Sleeves and Step Wedges can only be used together if using a 29 mm Sleeve.**

Remove trial component in one piece (use as guide for assembly of implants).

Place the MBT Revision Tray on a firm, stable, padded surface. Set the Tibial Sleeve in an orientation that matches the prepared canal. Matching the orientation of the Tray/Sleeve Trial is helpful in determining appropriate rotation of the final tibial tray/sleeve implant (Figure 52). The sleeve can rotate 20 degrees internally or externally.

Using the Sleeve Impactor and a Mallet, impact the sleeve onto the MBT Revision Tray. Deliver several strikes to engage the two components (Figure 53).

Stem Component Assembly

Attach the Stem Extension to the prosthetic tray using the two appropriate Wrenches to ensure full engagement (Figure 54).

Figure 52

Figure 53

Figure 54

Cementing Technique

During cementing of implants, movement of the components should be minimized while the cement is curing.

Prepare the sclerotic bone to ensure a continuous cement mantle with good cement interdigitation of 2 mm - 4 mm. This can be done by drilling holes and cleansing the bone with pulsatile lavage, taking care to dry the bone afterwards. Pack residual small cavity bone defects with cancellous autograft, allograft,or synthetic bone substitutes.

Apply a thick layer of cement to the bone, the implant surface or to both.

Caution: **Blood lamination can reduce the mechanical properties of the cement; therefore, it is vital to choose cement that reaches its working phase quickly. If applying cement to both the implant and bone, implantation should be completed early in its dough state to ensure good cement-cement adhesion and reduce the risk of dry laminations; which can weaken the cement.**

Caution: **Application of the cement to the roughened implant surface early in the dough state has been demonstrated to increase the fixation strength of the cement to the implant.2**

For additional reference see the Guidance for Cementing Total Knee Replacements document.

Tibial Implantation

Implanting the Tibial Component

Thoroughly cleanse the site with pulsatile lavage. Perforate with small drill holes on the prepared tibial surface to facilitate penetration of methyl methacrylate (Figure 55). Pack residual small cavitory bone defects with cancellous autograft, if available, or allograft.

Apply methyl methacrylate cement to the proximal tibial surface (Figure 56) or directly to the underside of the tibial tray component.

When a Fluted Stem or a Fluted Stem with a Metaphyseal Sleeve is used, ensure the medullary canal remains free of cement. Clear all extruded cement with a Curette.

Seat the Tibial Implant construct into the prepared tibia by impacting the RP Tray Impactor and Universal Handle assembly (Figure 57).

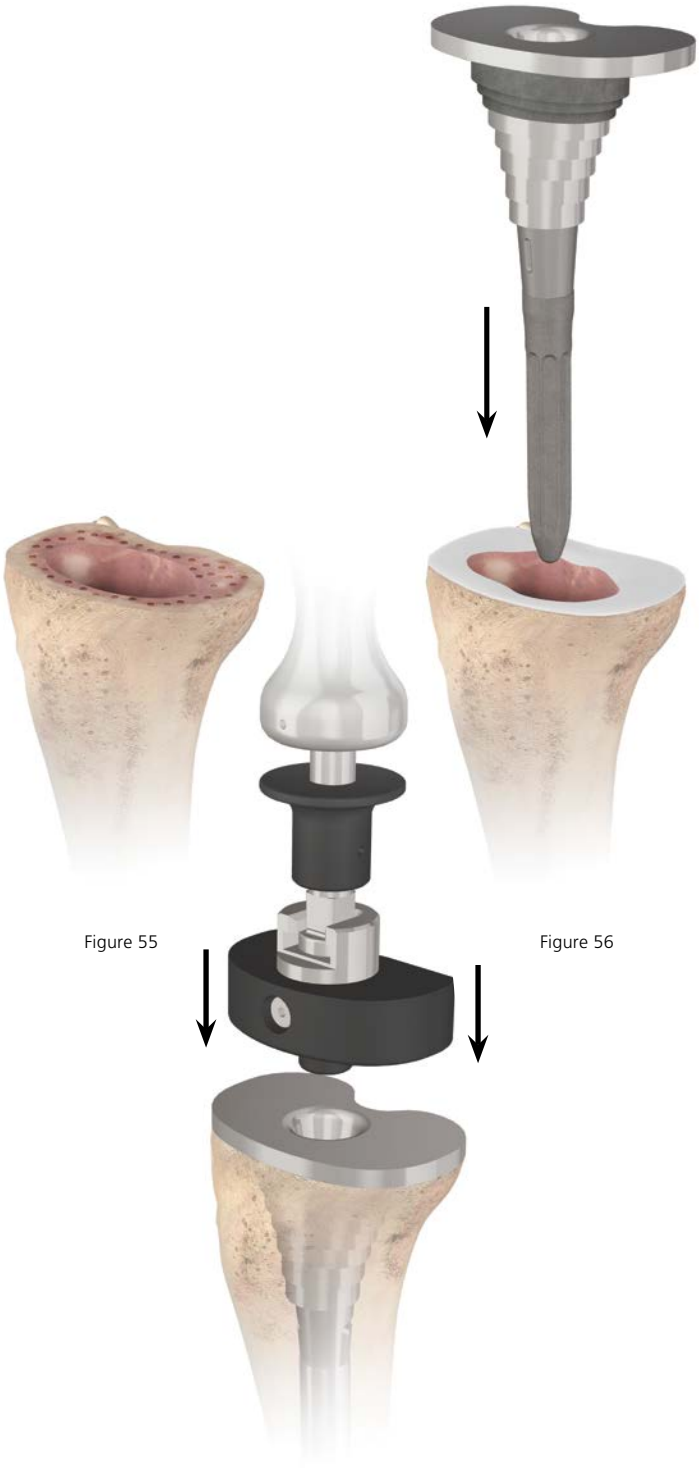


Figure 55

Figure 56

Figure 57

Implant Assembly - Sleeve and Stem Use
Implant assembly order (with Sleeve and Stem use):

- Add distal augments if necessary
- Attach stem to sleeve
- Attach sleeve construct to femoral construct

Implantation
After assembling the femoral components, prepare one package of bone cement according to instructions.

Apply cement to the augmentation block(s) on the side which contacts the femoral component, and to the corresponding surface(s) of the femoral component (Figure 58).

Attach the augmentation block(s) to the femoral component. Use an Augment Block Clamp to secure to the femoral component until the cement is fully cured.

Note: **When distal augmentation blocks are used with the S-ROM NOILES Rotating Hinge Femoral Component, place the Augment Block Clamp into the distal condylar "pocket" of the femoral component (Figure 59).**

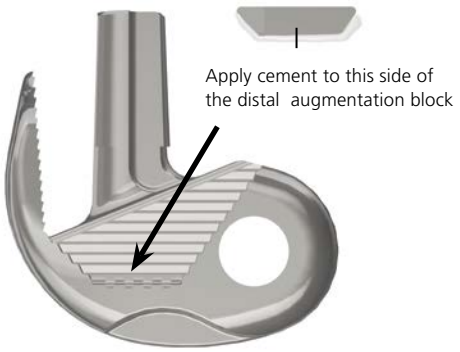


Figure 58

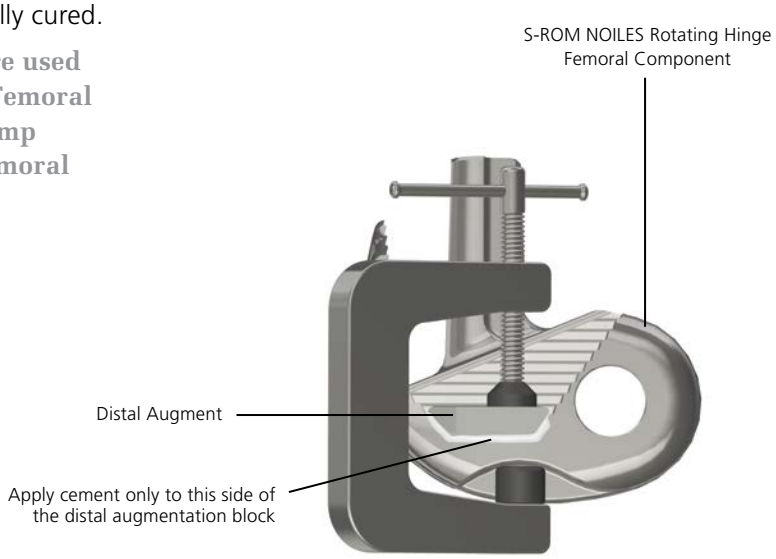


Figure 59

Implant Assembly – Sleeve and Stem Use

To attach the Universal Stem to the Universal Femoral Sleeve, thread the stem onto the sleeve. Grasp the sleeve with the Tibial Sleeve Clamp and use the Stem Extension Wrench to grasp Universal Stem and tighten (Figure 60).

Apply sufficient force to both Wrenches to ensure that the Stem is secure.

Place the femoral component with the Femoral Adapter on a firm, stable surface. Place the appropriate sleeve and stem construct on top of the Femoral Adapter assembly (Figure 61). Use the sleeve and femoral construct trial to help set the final sleeve and femur implant rotation.

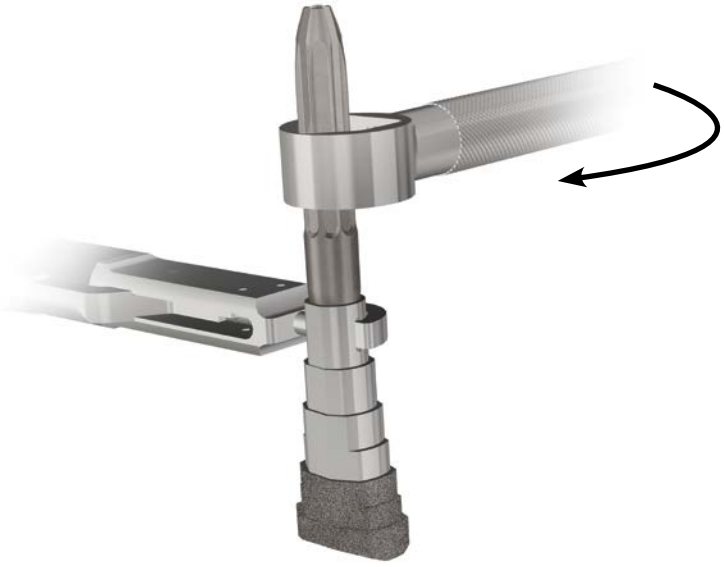


Figure 60

Figure 61

Implant Assembly – Sleeve and Stem Use

Slide the Femoral Stem/Sleeve Impactor on top of the stem and forcefully apply three strikes with a Mallet to engage the two component assemblies (Figure 62).

The definitive components are implanted in the following order:

- Tibial tray (with stem, sleeve or wedges)
- Femoral component (with stem, sleeve and augments)
- LPS Limb Preservation System Hinged Insert

Implant the femoral component using the Femoral Impactor (Figure 63).

Figure 62

Figure 63

Bearing and Hinge Pin Insertion

After the femoral component and tibial tray have been cemented into place, do one final check with the trial inserts. Once the proper thickness has been verified, introduce the actual implant into the sterile field.

Note: **Take extreme care when opening the LPS Limb Preservation System Universal Insert to hold onto the bushings to ensure they do not fall out.**

Put the condyles of the femoral component into the corresponding recesses in the tibial plateau.

Insert the Hinge Pin through the hole on the medial or lateral side of the femoral component. Orient the rectangular head of the Hinge Pin with the rectangular recess in the femoral component (Figure 64).

Squeeze the "clothespin" of the Hinge Pin together and insert the Hinge Pin into the femoral component. Make sure the Hinge Pin is securely locked in place (Figure 65).

Place the LPS Limb Preservation System Universal Insert post into the cone of the MBT Revision Implant (Figure 66).

Test the knee through full range of motion (Figure 67).

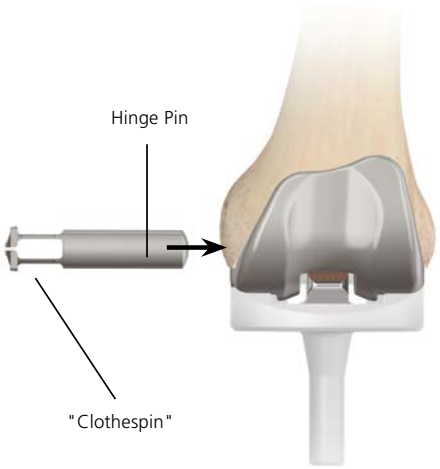


Figure 64

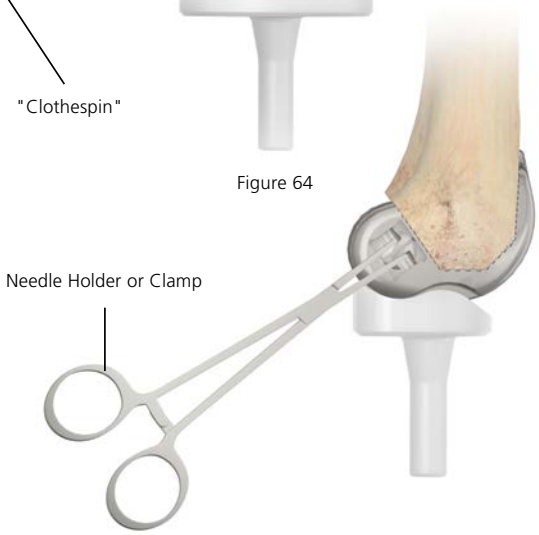


Figure 65

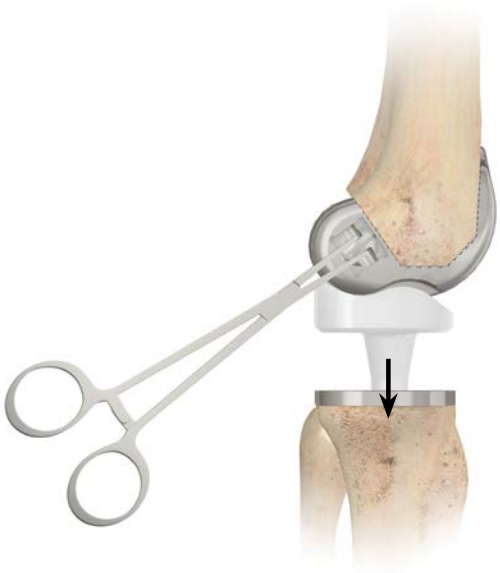


Figure 66

Figure 67

Initial Patellar Resection

Assess and record the overall thickness of the patella using a Caliper (Figure 68).

Resect approximately 7 mm of bone from the posterior patella surface using an Oscillating Saw.

Assess and record the thickness of the resected/removed bone in order to properly duplicate the original thickness.

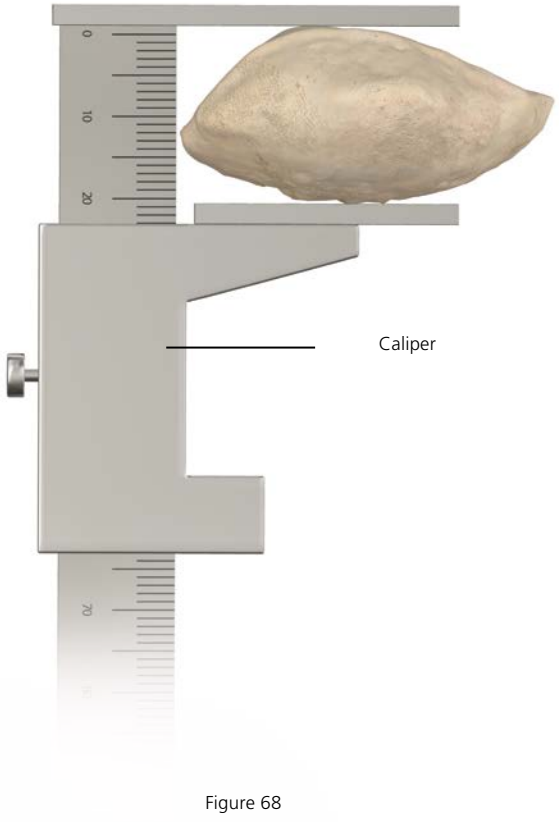


Figure 68

Initial Patellar Resection

Patella Domes are available in four diameters (Figure 70). Select a patella trial with the diameter that best matches the patient's patella (Figure 69).

Select the Patella Reamer Depth Adjuster that is the same diameter as the patella trial.

Insert the Patella Reamer Depth Adjuster into the Patella Restraining Instrument. Rotate the depth adjuster 120 degrees clockwise to lock into position (Figure 70).

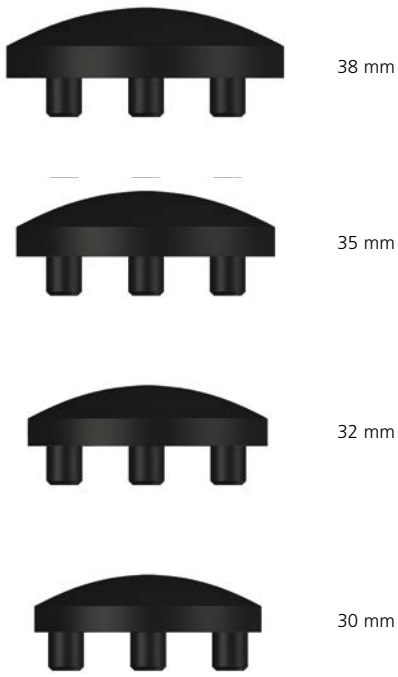


Figure 69

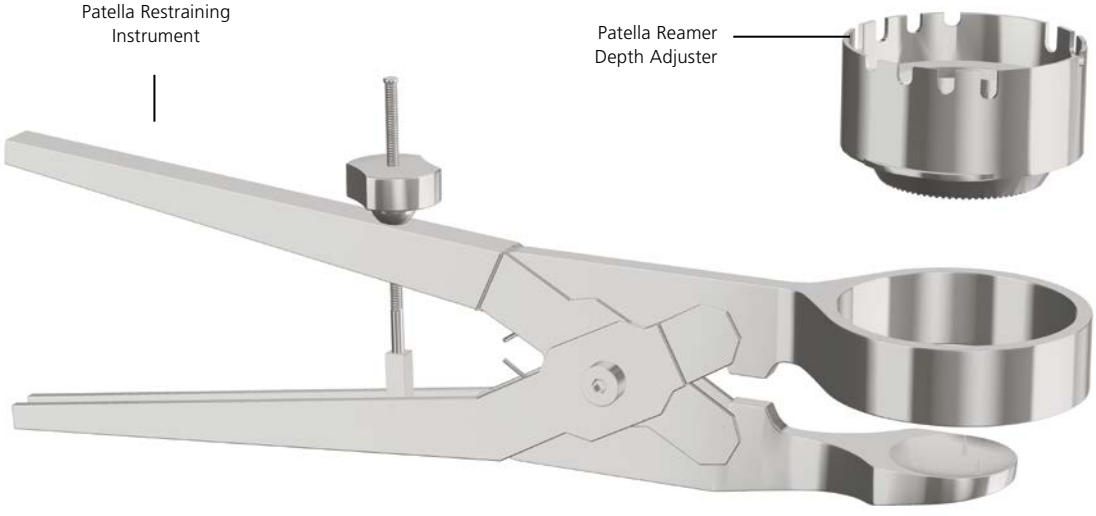


Figure 70

Patella Reaming

Clamp the Patella Restraining Instrument assembly onto the patella. Lock into position by turning the Thumb Nut clockwise (Figure 71).

Insert the Patella Reamer Bushing into the appropriate set of slots on the Patella Reamer Depth Adjuster. Slots on the depth adjuster are marked 1, 2, 3 and 4, which indicate the reaming depth in millimeters. To determine the correct slot, use the formula shown in (Table 1) as a guide.

Select the Patella Reamer that matches the diameter of the patella component to be used and insert through the Patella Reamer Bushing into the Patella Reamer Depth Adjuster. Ensure that the Patella Reamer is making full contact with the bone prior to reaming. Ream until the Patella Reamer flange makes contact with the Patella Reamer Bushing.

Thickness of selected patella component	Thickness of bone resected and removed	Select Slot number
9 mm	**7 mm**	**2**

Table 1

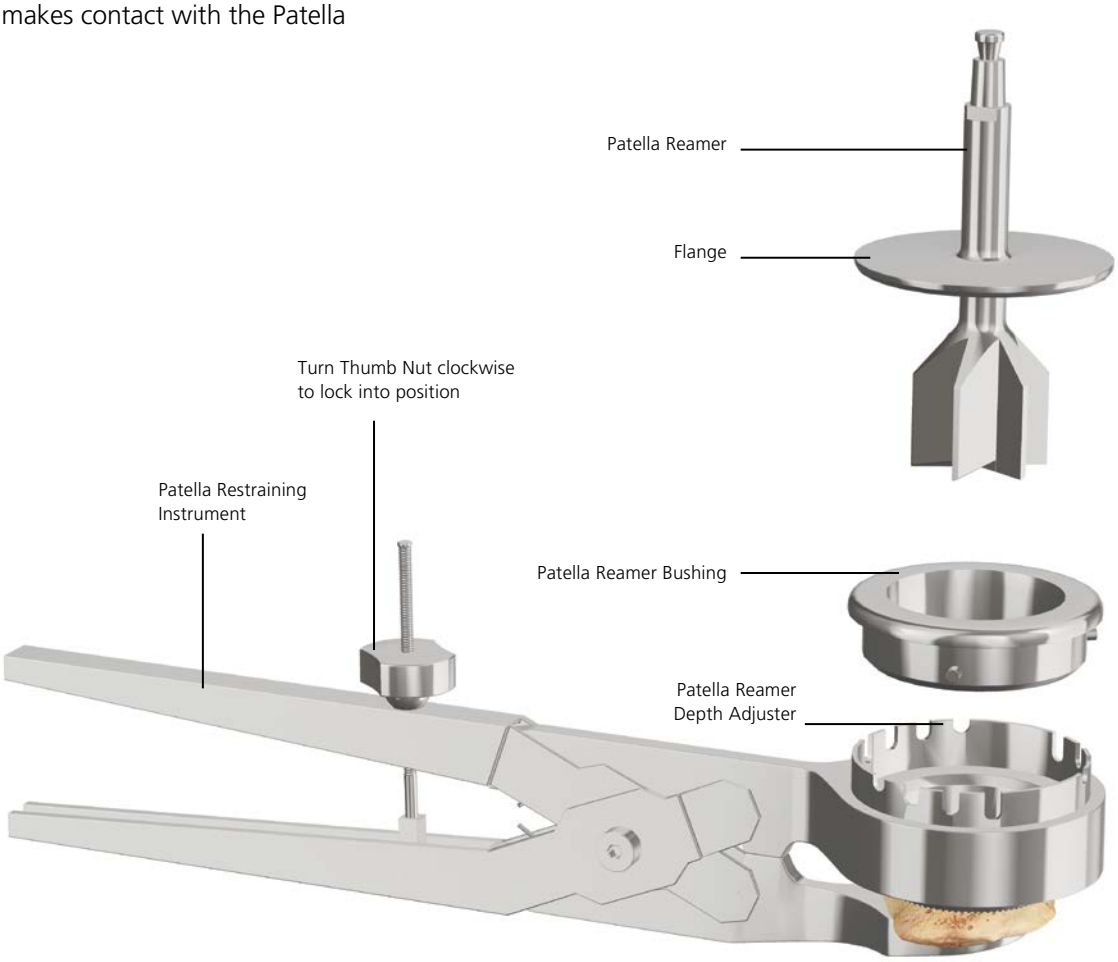


Figure 71

Patella Drilling

Remove the Patella Reamer and insert the Patella Drill Guide into the Patella Reamer Bushing. The Locating "Pin" on the Drill Guide will insert into the hole in the Patella Restraining Instrument (Figure 72).

Select the 3⁄16 in. Patella Shoulder Drill and prepare the three patella peg holes by drilling through the three larger holes in the Patella Drill Guide.

The depth of the holes drilled is correct for the length of the pegs on the selected Patella Button (Figure 73). Optional: Select the 1⁄8 in. Patella Shoulder Drill and drill through the four smaller holes to enhance the cement fixation to the patellar bone. Loosen the Thumb Nut on the Patella Restraining Instrument and remove the entire assembly from the patella bone.

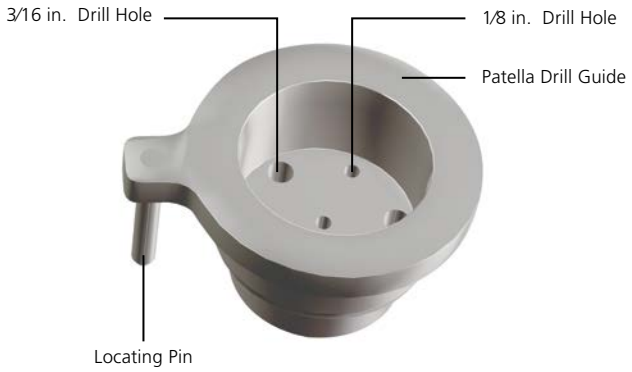


Figure 72

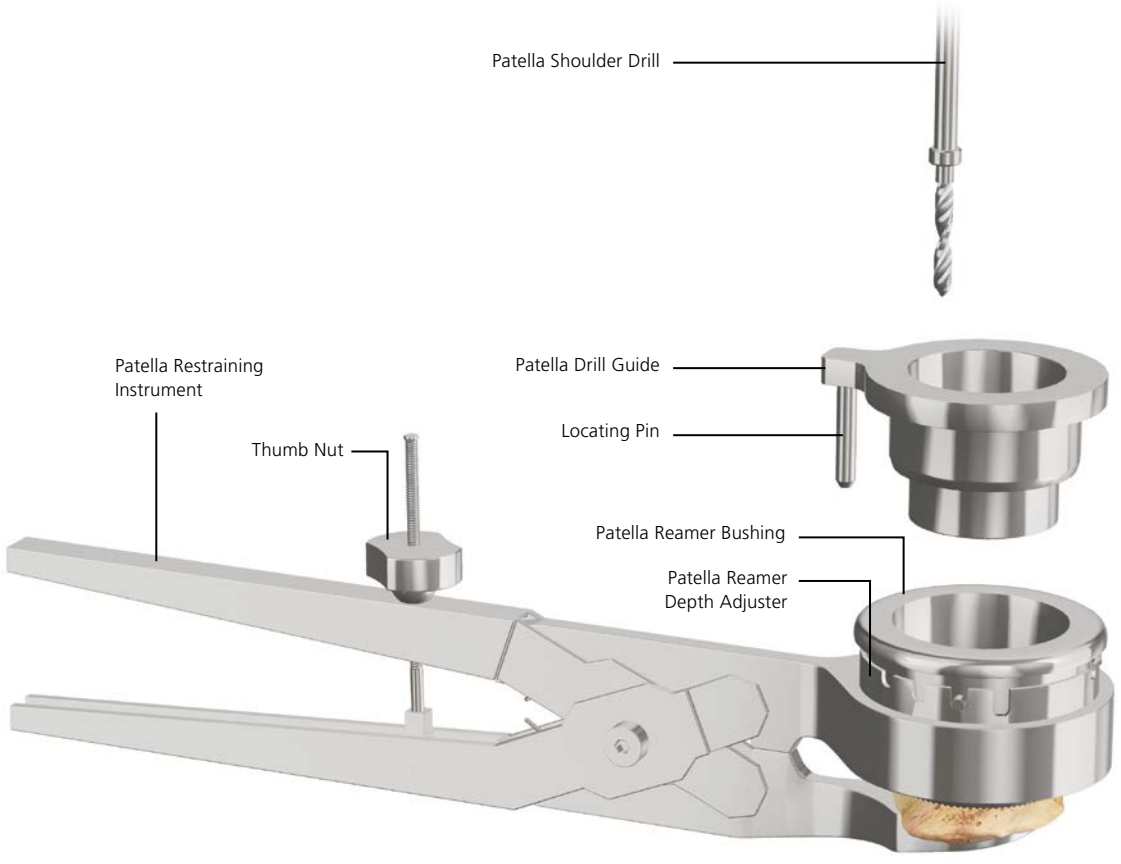


Figure 73

Place the appropriate diameter Patella Trial into the prepared patella bone. Assess the overall thickness of the patella construct to ensure that it is the desired thickness, i.e. equal to or 1-2 mm less than the original patella thickness. A "no-thumbs" trial reduction and patella tracking evaluation can now be performed.

Note: **If the reconstructed patella is too thick, repeat the reaming and drilling steps using the number 2, 3 or 4 slot on the Patella Reamer Depth Adjuster. If a greater thickness must be removed, take additional resection from the patella. The reaming and drilling steps must be repeated. (Take care to make sure the patella bone is not cut too thin. Maintain at least 10 mm of patella bone to prevent drill or peg penetration of the anterior cortex).**

The appropriately sized Patella Dome may now be cemented into place. A Patella Cement Clamp is provided for this purpose (Figure 74).

Figure 74

Appendix 1: The Cemented Tibial Stem Extensions

Cemented Stem Reamer

Align the Tibial Tray and secure with two Fixation Pins inserted through the holes designated (Figure 1). Seat the MBT Revision Drill bushing onto the tibia trial. Place in the posterior holes.

Place the Cemented Drill Bushing into the MBT Revision Drill Bushing (Figure 2).

Use the "cemented" reamer to ream to the predetermined selected depths for tray only or the Tray with a 30 or 60 mm cemented stem.

Remove the reamer and "cemented" bushing, leaving the tray trial and MBT Revision Drill Bushing in place (Figure 3).

Note: Only a 13 mm diameter cemented stem should be used in conjunction with the MBT Revision Tray to avoid a step off at the stem/tray junction.

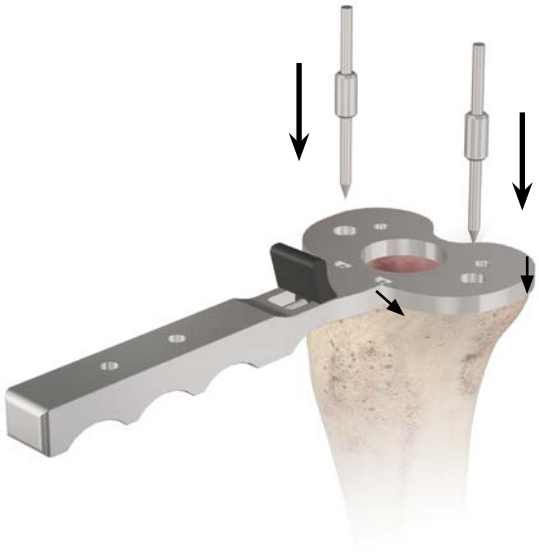


Figure 1

Figure 2

Figure 3

Appendix 1: The Cemented Tibial Stem Extensions

Tapered Reamer
Assemble the Revision Reamer Adapter onto the Cemented Tapered Reamer.

Next, attach the modified Hudson Adapter to the Tapered Reamer, if power reaming.

Attach the appropriately sized Cemented Stem Trial

(13 x 30 mm or 13 x 60 mm) to the Tapered Reamer, if utilizing a cemented stem extension (Figure 4). Ream until the Revision Reamer Adapter is flush with the MBT Revision Drill Bushing (Figure 5).

Note: **To avoid Stem Trial disengagement, do not reverse ream.**

Figure 4

Figure 5

Appendix 1: The Cemented Tibial Stem Extensions

Tapered Cemented Stems

Note: **Tapered Cemented Stem sizes 13 x 90/120/150 mm are compatible with MBT Revision Trays.**

Ream the canal with a reamer two sizes larger than the stem. Ream the medullary canal with a 15 mm reamer to implant a 13 mm Tapered Cemented Stem, which allows for a 1 mm circumferential cement mantle at the proximal end of the stem. The cement mantle will be greater around the distal end of the Cemented Tapered Stem (3 mm per side).

This provides the following benefits:

- Thicker cement mantle distally helps assure that a circumferential mantle is present and reduces the possibility of thin or non-existent cement coverage of the stem distally
- Stresses are greatest at the tip of the stem. A larger cement mantle is advantageous in dissipating these stresses. Thinner cement mantles are more prone to breakdown when exposed to higher stresses

Tibial Keel Preparation

Place the knee in full extension and determine appropriate rotation of the Tibial Tray. Mark the appropriate rotation with electrocautery on the anterior tibial cortex at the center and sides of the Alignment Handle.

Assemble the appropriate Stem Trial to the MBT Revision Tray Trial and seat in the prepared bone bed. Impact the Cemented Keel Punch (Figure 6).

Disconnect the Universal Handle leaving the Keel Punch in place for trial reduction (if appropriate).

It is recommended that a Cement Restrictor be placed at the appropriate level prior to cementing the component. Use a Cement Gun to fill the canal with methyl methacrylate.

Figure 6

Appendix 2: Step Wedge Preparation

Step Wedge Augmentation

Resection for supplementary tibial augmentation may be based on the established position of the Trial Tray. Remove the Femoral Trial to provide greater access. Confirm rotational alignment of the Tibial Tray Trial. Secure the Tray with two Fixation Pins.

Attach the Tray Trial Wedge cutting attachment with the Step Wedge Cutting Guide to the Trial Tray. The Step Wedge Cutting Block allows for a 5, 10 or 15 mm Step Wedge preparation as necessary. Slide the block forward to the anterior proximal tibia and secure in place with two Steinmann Pins through the holes marked with ☐ (Figure 1).

Unlock the block and slide the assembly out of the block. Disconnect the handle from the Trial Tray (Figure 2).

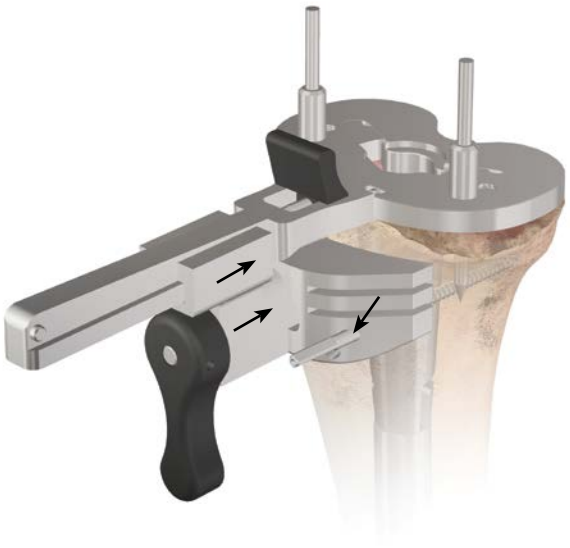


Figure 1

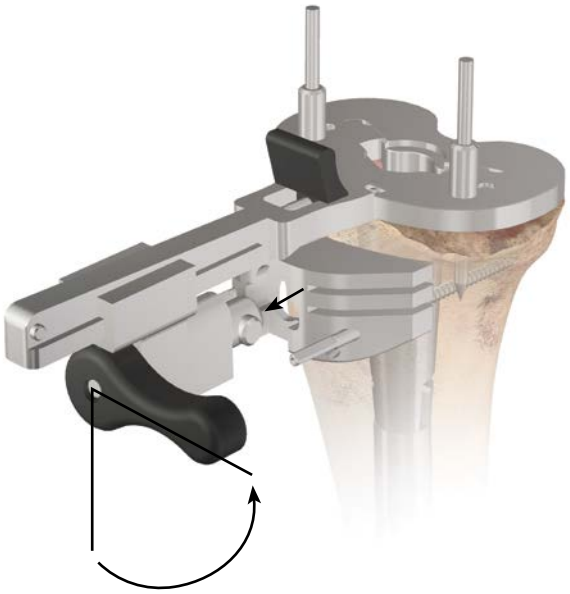


Figure 2

Appendix 2: Step Wedge Preparation

Trim the tibia accordingly with an Oscillating Saw so the cut does not extend beyond the central riser (Figure 3). Remove the Block and Pins.

Assemble the Trial Wedge to the appropriate Tibial Tray Trial (Figure 4) and introduce into the prepared site. Perform minimal correction with a Bone File where indicated to ensure maximal contact.

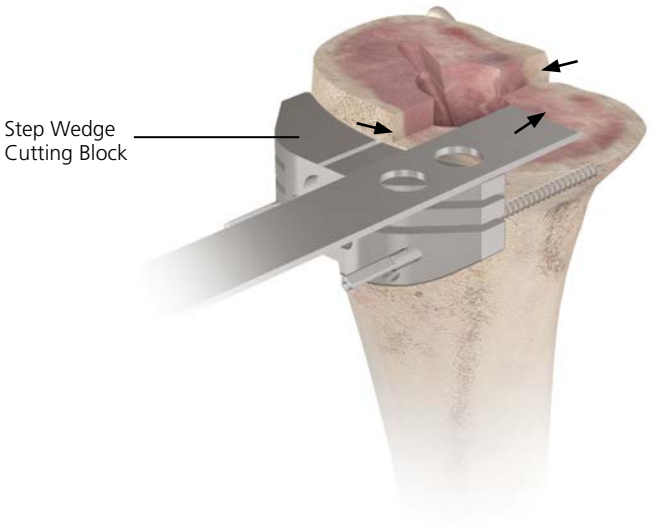


Figure 3

Figure 4

Appendix 2: Step Wedge Preparation

Confirm positioning, alignment and security of the tray assembly. If there is old cement or sclerotic bone, remove this first with a saw blade or burr prior to punching. Position the MBT Revision Tibial Keel Punch at the tray and cancellous bone interface and impact into the keel configuration. Leave the punch in place and perform a final trial reduction if necessary (Figure 5).

Note: **Utilize the "cemented" Keel Punch when a cement mantle is desired.**

Alternative Step Wedge Preparation

This is a "free-hand" resection. Assemble the Wedge Trial and Stem Trial to the Tibial Tray Trial. Position the device slightly proximal to the planned resection level. Make a conservative "free-hand" wedge resection and then check cuts with the Trials (Figure 6).

Wedge Implant Assembly

Note: **To aid wedge implant assembly, attach wedge prior to attaching the stem attachment.**

Assemble the designated wedge to the tray and secure using the appropriate screw. Carefully tighten with the large T-Handle Torque Driver until an audible "click" is discerned, ensuring a full and permanent interlock (Figure 7).

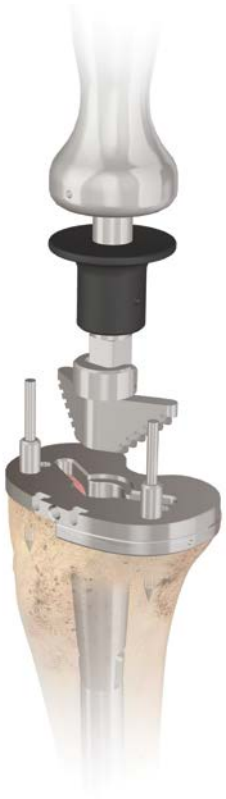


Figure 5

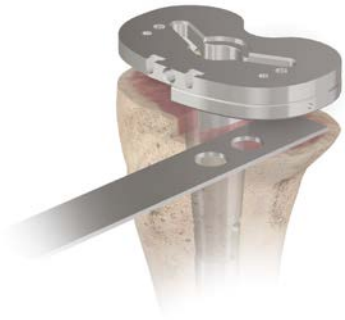


Figure 6

Figure 7

Appendix 3: Thick Tray Preparation

After impacting the cement or Press-Fit Keel Punch, remove the Keel Punch. Insert the MBT Thick Tray Trial Adapter (15 or 25 mm) onto the Tibial Tray Trial (Figures 1 and 2).

Note: **The Tibial Tray Trial must be used with the Thick Tray Adapters as the two pieces equal the appropriate sizing – 15 or 25 mm.**

Perform the final trial reductions utilizing the same technique as the standard MBT Revision Tray. Implant assembly and implantation is also the same as with the standard MBT Revision Tray. If utilizing a Wedge, refer to the Step Wedge Preparation in Appendix 2.

Note: **A Tibial Wedge can be used with all Thick Tray sizes, except for size 2. Due to the taper, use size 2 Tibial Wedges with size 4 MBT Revision Thick Trays, and use size 1 Tibial Wedges with size 3 MBT Revision Thick Trays. Sleeves may be used with all Thick Trays.**

Note: **Due to the taper, trial with appropriate tray trial size. For example, a size 4 Thick Tray tapers down to a size 2. Use the size 2 Tray Trial with the size 4 Thick Tray Adapter. The size 3 Thick Tray tapers down to a size 1. And the size 2 Thick Tray tapers down to a size 0. The size 0 Tray Trial can be found in the MBT Thick Tray Instrument Set.**

Figure 1

Figure 2

Implant Listing

S-ROM Femoral Components
(hinge pin is packaged with the femur)

62-3401L	Medium Left S-ROM Femur
62-3401R	Medium Right S-ROM Femur
62-3411L	Small Left S-ROM Femur
62-3411R	Small Right S-ROM Femur
62-3421L	X-Small Left S-ROM Femur
62-3421R	X-Small Right S-ROM Femur

S-ROM Femoral Augments

62-3805	Distal Augment, 5 mm (used on all femur sizes)
62-3810	Distal Augment, 10 mm (used on all femur sizes)

Universal Femoral Sleeves

1294-53-205	20 mm Cemented Femoral Sleeve
1294-53-215	31 mm Distally Porous Femoral Sleeve
1294-53-216	31 mm Fully Porous Femoral Sleeve
1294-53-225	34 mm Distally Porous Femoral Sleeve
1294-53-226	34 mm Fully Porous Femoral Sleeve
1294-53-235	40 mm Distally Porous Femoral Sleeve
1294-53-236	40 mm Fully Porous Femoral Sleeve
1294-53-245	46 mm Distally Porous Femoral Sleeve
1294-53-246	46 mm Fully Porous Femoral Sleeve

Universal Press-Fit Stems

86-7410	75 mm x 10 mm Universal Fluted Stem
86-7412	75 mm x 12 mm Universal Fluted Stem
86-7414	75 mm x 14 mm Universal Fluted Stem
86-7416	75 mm x 16 mm Universal Fluted Stem
86-7418	75 mm x 18 mm Universal Fluted Stem
86-7419	75 mm x 20 mm Universal Fluted Stem
86-7420	75 mm x 22 mm Universal Fluted Stem
86-7421	75 mm x 24 mm Universal Fluted Stem
86-7424	115 mm x 10 mm Universal Fluted Stem
86-7426	115 mm x 12 mm Universal Fluted Stem
86-7428	115 mm x 14 mm Universal Fluted Stem
86-7430	115 mm x 16 mm Universal Fluted Stem
86-7432	115 mm x 18 mm Universal Fluted Stem
86-7433	115 mm x 20 mm Universal Fluted Stem
86-7434	115 mm x 22 mm Universal Fluted Stem
86-7435	115 mm x 24 mm Universal Fluted Stem
86-7438	150 mm x 10 mm Universal Fluted Stem
86-7440	150 mm x 12 mm Universal Fluted Stem
86-7442	150 mm x 14 mm Universal Fluted Stem
86-7444	150 mm x 16 mm Universal Fluted Stem
86-7446	150 mm x 18 mm Universal Fluted Stem
86-7447	150 mm x 20 mm Universal Fluted Stem
86-7448	150 mm x 22 mm Universal Fluted Stem
86-7449	150 mm x 24 mm Universal Fluted Stem

Implant Listing

Universal Femoral Sleeves

86-6401	30 mm x 13 mm Cemented Stem (used on MBT Revision Trays size 3 and smaller)
86-6402	60 mm x 13 mm Cemented Stem (used on MBT Revision Trays size 3 and smaller)
86-6403	30 mm x 15 mm Cemented Stem (used on MBT Revision Trays size 4 and larger)
86-6404	60 mm x 15 mm Cemented Stem (used on MBT Revision Trays size 4 and larger)
86-6468	90 mm x 13 mm Cemented Tapered Stem
86-6469	90 mm x 15 mm Cemented Tapered Stem
86-6498	120 mm x 13 mm Cemented Tapered Stem
86-6499	150 mm x 13 mm Cemented Tapered Stem

S-ROM Patella

62-1630	30 mm S-ROM Dome Patella
62-1632	32 mm S-ROM Dome Patella
62-1635	35 mm S-ROM Dome Patella
62-1638	38 mm S-ROM Dome Patella

LPS Universal Inserts (compatible with S-ROM and LPS femurs, must match femur size-to-size)

1987-27-112	X-Small 12 mm LPS Universal Insert
1987-27-114	X-Small 14 mm LPS Universal Insert
1987-27-116	X-Small 16 mm LPS Universal Insert
1987-27-118	X-Small 18 mm LPS Universal Insert
1987-27-121	X-Small 21 mm LPS Universal Insert
1987-27-123	X-Small 23 mm LPS Universal Insert
1987-27-126	X-Small 26 mm LPS Universal Insert
1987-27-128	X-Small 28 mm LPS Universal Insert
1987-27-131	X-Small 31 mm LPS Universal Insert
1987-27-212	Small 12 mm LPS Universal Insert
1987-27-214	Small 14 mm LPS Universal Insert
1987-27-216	Small 16 mm LPS Universal Insert
1987-27-218	Small 18 mm LPS Universal Insert
1987-27-221	Small 21 mm LPS Universal Insert
1987-27-223	Small 23 mm LPS Universal Insert
1987-27-226	Small 26 mm LPS Universal Insert
1987-27-228	Small 28 mm LPS Universal Insert
1987-27-231	Small 31 mm LPS Universal Insert
1987-27-312	Medium 12 mm LPS Universal Insert
1987-27-314	Medium 14 mm LPS Universal Insert
1987-27-316	Medium 16 mm LPS Universal Insert
1987-27-318	Medium 18 mm LPS Universal Insert
1987-27-321	Medium 21 mm LPS Universal Insert
1987-27-323	Medium 23 mm LPS Universal Insert
1987-27-326	Medium 26 mm LPS Universal Insert
1987-27-328	Medium 28 mm LPS Universal Insert
1987-27-331	Medium 31 mm LPS Universal Insert

Implant Listing

MBT Revision Tray

Cat. No.	Size (mm)	A/P	M/L	Stem Length	Tray Thickness
1294-35-110	1	39.0	59.2	61.8	4.8
1294-35-115	1.5	40.7	61.8	61.8	4.8
1294-35-120	2	42.6	64.6	61.8	4.8
1294-35-125	2.5	44.2	67.1	61.8	4.8
1294-35-130	3	45.8	69.6	61.8	4.8
1294-35-140	4	49.3	74.9	61.8	4.8
1294-35-150	5	53.1	80.6	61.8	4.8
1294-35-160	6	57.2	86.8	61.8	4.8
1294-35-215	2+15	42.6	64.6	61.8	15
1294-35-225	2+25	42.6	64.6	61.8	25
1294-35-315	3+15	45.8	69.6	61.8	15
1294-35-325	3+25	45.8	69.6	61.8	25
1294-35-415	4+15	49.3	74.9	61.8	15
1294-35-425	4+25	49.3	74.9	61.8	25

MBT Revision Sleeve

Cat. No.	Size (mm)	A/P	M/L	Height
1294-54-000	29	26	29	40
1294-54-140 (Cemented)	29	26	29	40
1294-54-100	37	27	37	40
1294-54-110	45	27	45	40
1294-35-120	53	31	53	40
1294-35-130	61	34	61	40

Implant Listing

MBT Revision Augments

Cat. No.	Size (mm)	Cat. No.	Size (mm)
1294-56-110	1-5	1294-56-130	3-5
1294-56-111	1-10	1294-56-131	3-10
1294-56-112	1-15	1294-56-132	3-15
1294-56-115	1.5-5	1294-56-135	4-5
1294-56-116	1.5-10	1294-56-136	4-10
1294-56-117	1.5-15	1294-56-137	4-15
1294-56-120	2-5	1294-56-140	5-5
1294-56-121	2-10	1294-56-141	5-10
1294-56-122	2-15	1294-56-142	5-15
1294-56-125	2.5-5	1294-56-145	6-5
1294-56-126	2.5-10	1294-56-146	6-10
1294-56-127	2.5-15	1294-56-147	6-15

Note: **If a tibial sleeve is used, MBT Revision Augments are only compatible with the 29 mm sleeve.**

Compatibility Chart

			LPS XX-Small Femoral Component	LPS X-Small Femoral Component and S-ROM X-Small Femoral Component	S-ROM Small Femoral Component	S-ROM Medium Femoral Component
	Tray No.	**M/L**	**56.6**	**66.7**	**66.7**	**71.2**
MBT Revision Tray Size 1	1294-35-110	59.2	✓			
MBT Revision Tray Size 1.5	1294-35-115	61.8	✓			
MBT Revision Tray Size 2	1294-35-120	64.6	✓	✓	✓	
MBT Revision Tray Size 2.5	1294-35-125	67.1	✓	✓	✓	
MBT Revision Tray Size 3	1294-35-130	69.6	✓	✓	✓	✓
MBT Revision Tray Size 4	1294-35-140	74.9	✓	✓	✓	✓
MBT Revision Tray Size 5	1294-35-150	80.6	✓	✓	✓	✓
MBT Revision Tray Size 6	1294-35-160	86.8	✓	✓	✓	✓

■ signifies preferred match

LPS Universal Inserts must match S-ROM or LPS Femoral Component size-to-size.
For example, XX-Small femoral component = XX-Small polyethylene; Small femoral component = Small polyethylene, etc.

S-ROM MODULAR TOTAL KNEE SYSTEM | NOILES ROTATING HINGE KNEE SYSTEM

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 AND USAGE:

The S-ROM NOILES Rotating Hinge Knee is indicated for use with PMMA bone cement in primary or revision cases in patients:

- who have reached skeletal maturity and
- for whom the surgeon has decided to resect both cruciate ligaments or whose cruciate ligaments are absent or incompetent and
- who exhibit insufficiency of lateral/collateral ligaments and other soft supporting tissue due to the following conditions:
  - Rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, and arthritis secondary to a variety of diseases and anomalies
  - Failure of a previous knee reconstruction procedure
  - Trauma

CONTRAINDICATIONS:

1. Active infection or history of general infections or local infectious disease.
2. Vascular insufficiency, muscular atrophy or neuromuscular disease in the affected limb.
3. Advanced loss of osteochondral structure that would preclude proper fixation of the prosthesis.
4. Tumors of the supporting bone structure, systemic and metabolic disorders leading to progressive deterioration of solid bone support.
5. Drug or alcohol addiction, or limiting neuropathic disease.
6. Skeletal immaturity.
7. Obesity or very active lifestyle that can produce loads on the prosthesis that can lead to failure of the fixation of the device or device itself.
8. Allergic reaction to the implant materials.
9. Inadequate flexor and extensor mechanism necessary to achieve a functional prosthetic joint.

WARNINGS:

Improper prosthesis selection or alignment, inadequate fixation, use where contraindicated or in patients whose medical, physical, mental, or occupational conditions will likely result in extreme stresses to the implant, may result in premature failure due to loosening, fracture, or wear.

Post-operative care is extremely important. The patient should be instructed on the limitations of the device and should be cautioned regarding load bearing, ranges of motion, and activity levels permissible. Early motion and load bearing should be carefully controlled.

The S-ROM Tibial Base, Tibial Sleeve, Tibial Stem Extension, and Tibial Augmentation Blocks may not be used with the NOILES Posterior Stabilized Knee.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

PRECAUTIONS:

The S-ROM NOILES Rotating Hinge Knee is designed to articulate from 6 degrees hyperextension to 110 degrees flexion. If, due to grossly inadequate soft tissue integrity, flexion beyond 90 degrees causes luxation of the plateau assembly out of the tibial base, the patient must have a knee brace posto-peratively to limit flexion to 90 degrees. In such cases, the surgeon should consider closing the wound with the knee in full extension.The size of the tibial plateau assembly must correspond with the size of the femoral component. The size of the tibial augmentation block must correspond to the size of thetibial base. Femoral sleeves are required when using femoral stem extensions. A femoral plug is required with the femoral sleeve when a femoral stem extension is not used. A tibial cap is required with the tibial sleeve when a tibial stem extension is not used. Tibial augmentation blocks cannot be used when tibial sleeves are being used.

An implant should never be reused. Any implant, once used, should be discarded. Even though it appears undamaged, it may have small defects and/or internal stress patterns that may lead to failure. Likewise, a new implant should be handled carefully to avoid damage that could compromise the integrity of the device and cause early failure or loosening.

The wear rate of prosthesis contact surfaces is greatly accelerated if loose fragments of bone cement become detached and act as an abrasive in the bearing surfaces. When using bone cement, care should be taken to remove all excess cement from the periphery of the implant.

*DePuy Synthes Joint Reconstruction Single Use devices have not been designed to undergo or withstand any form of alteration, such as disassembly, cleaning or re-sterilization, after a single patient use. Reuse can potentially compromise device performance and patient safety.

ADVERSE EFFECTS:

Fracture may occur due to improper preparation of the implant site or if excessive force is used during seating of the implant. Transient peroneal palsy has been reported following total knee arthroplasty, especially after correction of severe flexion or valgus deformities.

Patients have complained of persistent pain and stiffness following total knee arthroplasty. In addition, patellar tendon rupture, femoral-tibial subluxation or dislocation, and persistent ligamentary laxity have been reported with the use of total knee implants. Infection and loosening have been reported following total joint arthroplasty, as have wear and failure due to fracture of knee prosthesis components.

Histological reactions have been reported as an apparent response to exposure to a foreign material. The actual clinical significance of these reactions is unknown.

Serious adverse side effects may necessitate surgical intervention.

Limited Warranty and Disclaimer: DePuy Synthes products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

Please also refer to the package insert(s) or other labeling associated with the devices identified in this surgical technique for additional information.

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

Some devices listed in this surgical technique may not have been licensed in accordance with Canadian law and may not be for sale in Canada. Please contact your sales consultant for items approved for sale in Canada.

Not all products may currently be available in all markets.

DePuy Synthes

PART OF THE Johnson&Johnson FAMILY OF COMPANIES

DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, IN 46582
USA
Tel: +1 (800) 366-8143
Fax: +1 (800) 669-2530

DePuy (Ireland)
Loughbeg Ringaskiddy
Co. Cork
Ireland
Tel:+35 (321) 491-4278
Fax: +35 (321) 491-4199

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

CE 0086

www.depuysynthes.com

DSUS/JRC/0414/0052 Rev. 2 | DSEM/JRC/0118/0995