# S-ROM® NOILES™ ROTATING HINGE

Surgical Technique

KNEE
REVISION

DePuy
a Johnson&Johnson company

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## Surgical Technique

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The S-ROM Noiles Rotating Hinge features:

- S-ROM Femoral Component available in three sizes
- Seven degree physiological valgus, fixed in the femoral component
- Deep femoral trochlear groove
- Modular textured sleeves to accommodate bone defects of the Engh Type II and Type III classification and allow possible bone ingrowth
- Slotted tibial and femoral stems to enhance torsional stability and fixation into intact medullary bone
- Broad, congruent contact areas between femoral and tibial components 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 M.B.T. Revision Knee System is Comprised of the Following Components:

- Tibial Components are available in eight sizes
- Tibial Metaphyseal Sleeves are available in 29 mm, 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 inserts from LCS® Complete™, Sigma® RP, LCS® Complete™ Revision and Sigma® TC3 RP inserts
- Accepts Rotating Platform hinged insert from the Orthogenesis LPS™ (Limb Preservation System), which is compatible with the S-ROM® Noiles™ Rotating Hinge (NRH) 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
- Femoral Metaphyseal Sleeves are available in 20 mm, 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 Augmentations
- 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 at a 13 mm diameter
- 30 mm and 60 mm Cemented Universal Stem Lengths in 15 mm diameter (Must be used with a sleeve)
- 90 mm, 120 mm, and 150 mm Tapered Cemented Universal Stem Lengths at a 13 mm diameter
- 90 mm Tapered Cemented Universal Stem Length at a 15 mm diameter (Must be used with a sleeve)

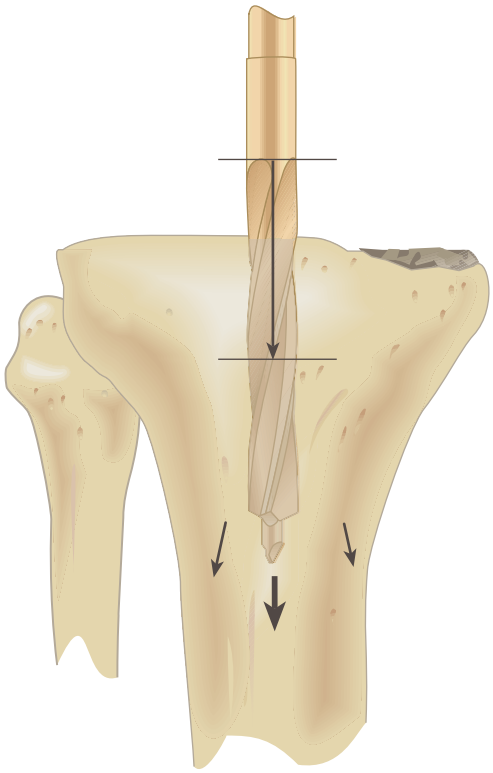


Figure 1

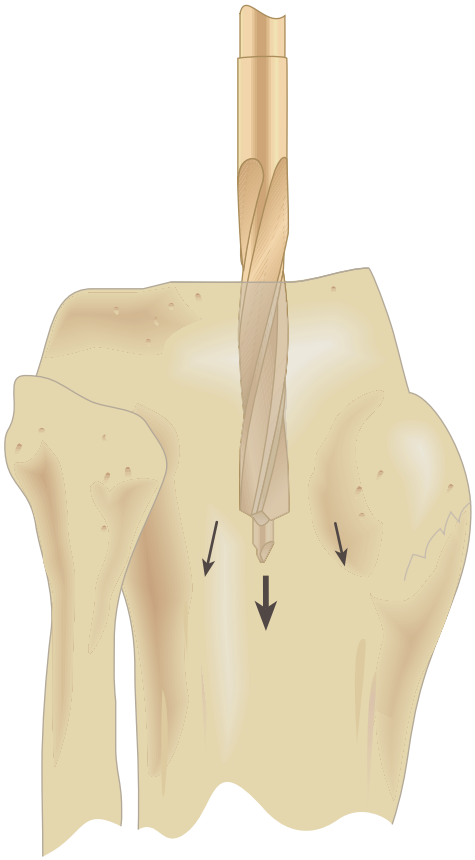


Figure 2

## The Tibial Alignment System

When preoperative evaluation and X-rays 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 IM rod. Where a cemented Universal Stem Extension is indicated, see Appendix 1. 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 preoperative anterior/posterior (A/P) and lateral X-rays and to the medial third of the tibial tubercle. Introduce a 5⁄16 in. (9 mm) drill into the canal to a depth of 2 to 4 cm. Avoid cortical contact [Figures 1 and 2].

## 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. Universal 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 preoperative X-rays.

Utilizing the reamer depth scale and the markings on the straight reamer, ream to the pre-determined depth so the pre-selected marking on the reamer is positioned at the desired tibial resection level. Sequentially open the canal with progressively larger reamers until firm endosteal engagement is established [Figure 3].

*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 flutted 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 somewhat 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 universal fluted stems are available in even sizes (10 through 24 mm). Perform final reaming with an even-sized reamer. Refer to Appendix 1 for cemented universal stem preparation.

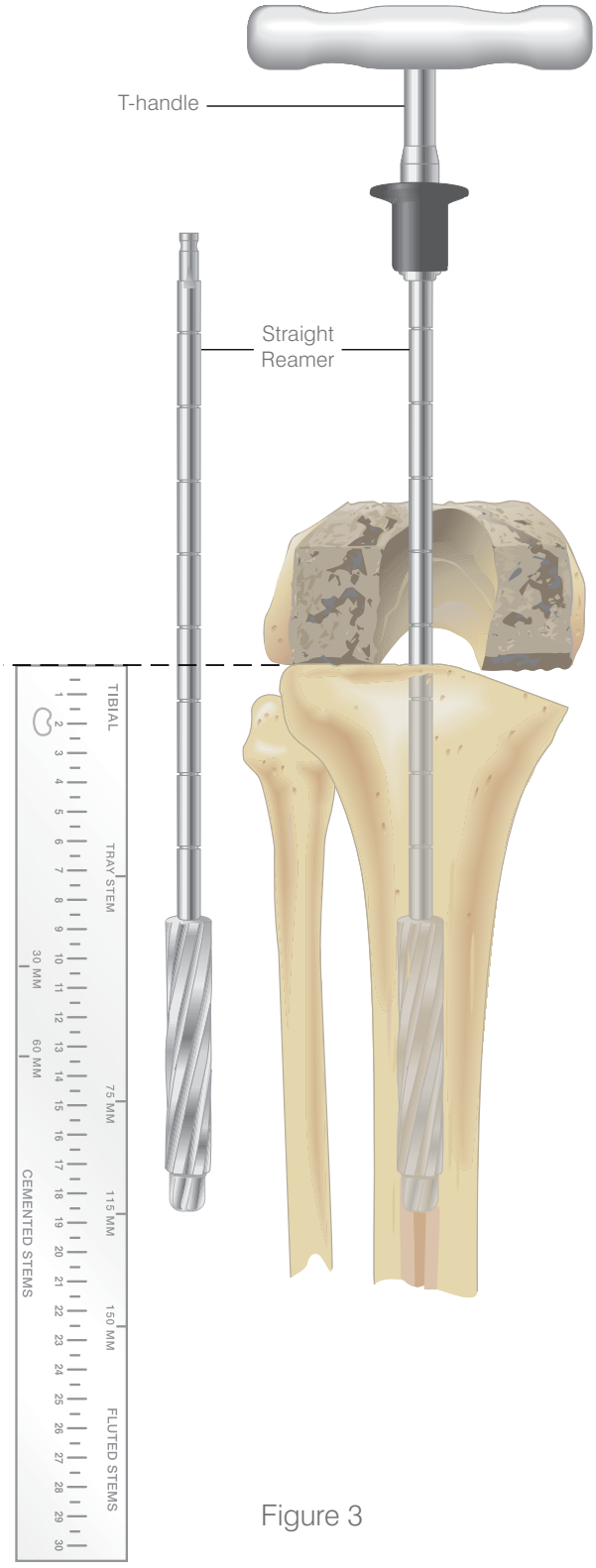



Figure 3

## For Diaphyseal Engaging Stem and Metaphyseal Filling Sleeve

Attach the appropriately sized stem trial to the end of the reamer.

*Note: Assembly of the stem trial may be aided by the pre-attachment of the T-handle.*

Taper ream to the planned proximal tibial resection level [Figure 4].

*Note: Use the "cemented" taper reamer when requiring a cement mantle or when utilizing a sleeve. Use the press-fit tapered reamer when line-to-line fit is desired and a sleeve will not be utilized. 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, intraoperatively determine if a metaphyseal sleeve will be used.

*Note: Metaphyseal sleeves are ideal to provide filling of Engh type II or III defects in revision TKA. The steps also provide progressive loading of the bone with porous coating, which enhances fixation.*

If a metaphyseal sleeve is selected, see page 9 in order to broach the metaphyseal bone. If a metaphyseal sleeve will not be used, see page 7 to prepare for the proximal tibial resection.

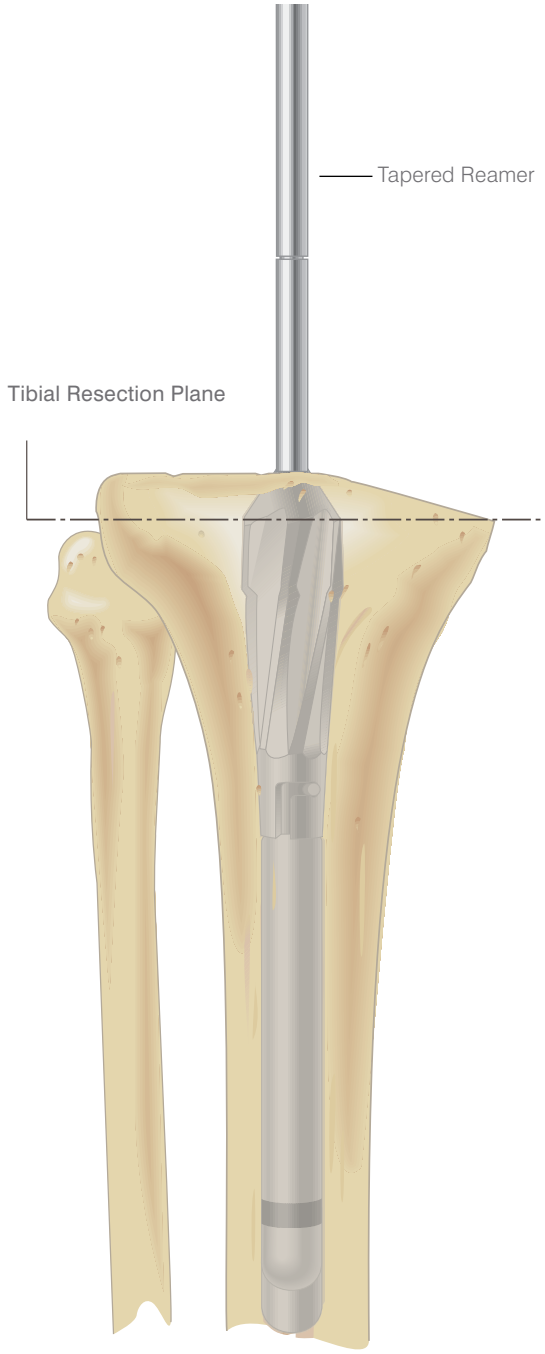



Figure 4

## PROXIMAL TIBIAL RESECTION – TAPERED REAMER

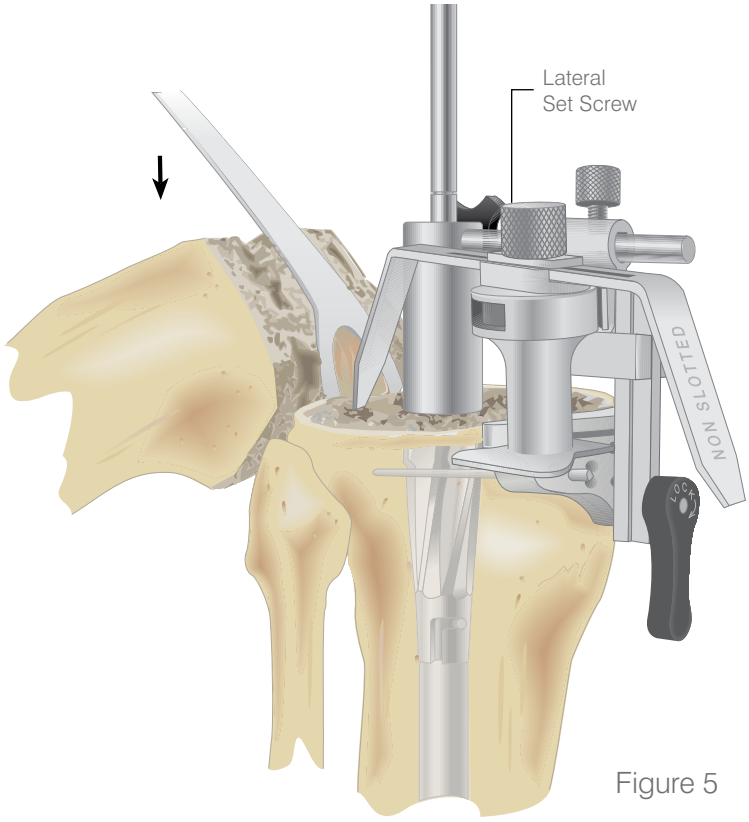



Figure 5

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 total knee arthroplasty, minimize the amount resected: no more than 1-2 mm from the most prominent condyle, managing residual defects of the contralateral condyle 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 5].

Pin the tibial cutting block so a minimal resection is made from the proximal tibia. Utilize the stylus when necessary [Figure 5].

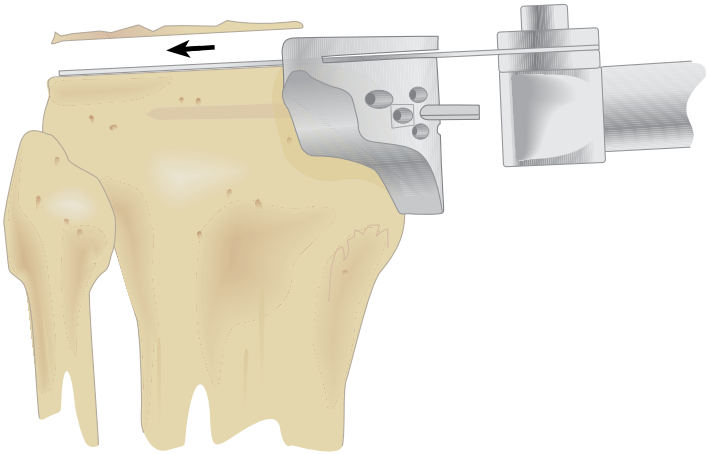


Figure 6

*Note: If a metaphyseal sleeve is to be used, tibial resection using the 2 degree tibial cutting device is unnecessary as the tibial resection will be performed using the tibial sleeve broach. (see page 9, Figure 8) Note: There is a slotted and non-slotted end to the stylus. The difference between the two is 5 mm.*

Remove the I.M. device while leaving the 2 degree cutting block in place. Remove the tapered reamer and resect the proximal tibia [Figure 6] (Maximum saw blade thickness 1.5 mm).

*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.*

## Optional For Sleeve Utilization Only

*Note: The M.B.T. Revision Tibial Tray will accept either a tibial metaphyseal sleeve or a tibial step wedge if using sleeve sizes 37, 45, 53 and 61 mm, but not both. Only the 29 mm sleeve is indicated for use with a tibial step wedge.*

Attach the M.B.T. 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.**

Insert the broach into, then out of, 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. Check for rotational stability. If the broach is unstable or the defect is unfilled, repeat with consecutively larger broaches until the desired fit is achieved [Figure 7]. 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.

**When utilizing a sleeve, resect the tibia off the top of the broach [Figure 8].**

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

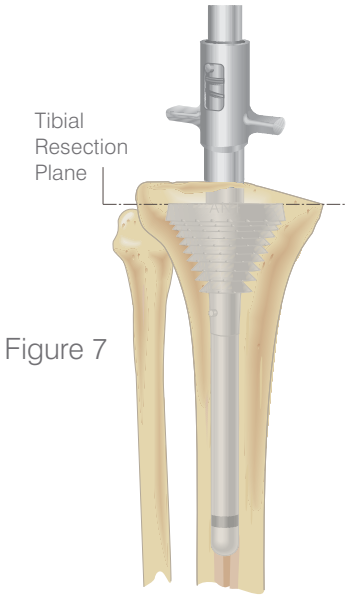



Figure 7

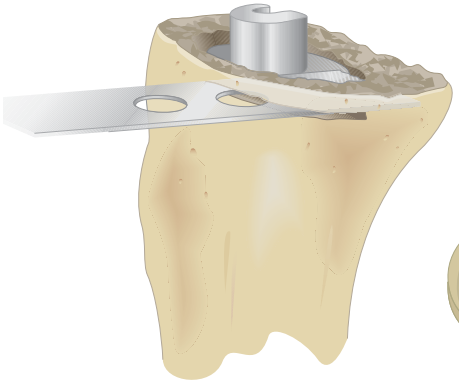


Figure 8

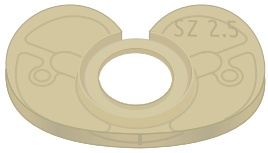



Figure 9

Slide the tibial 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 tibial base plate that will be used. The tibial view plate is transparent to help visualize tibial coverage [Figure 9]. The template matches the implant to aid in orienting the tibial sleeve to the tibial base during assembly.

# FINAL PREPARATION OF THE TIBIA

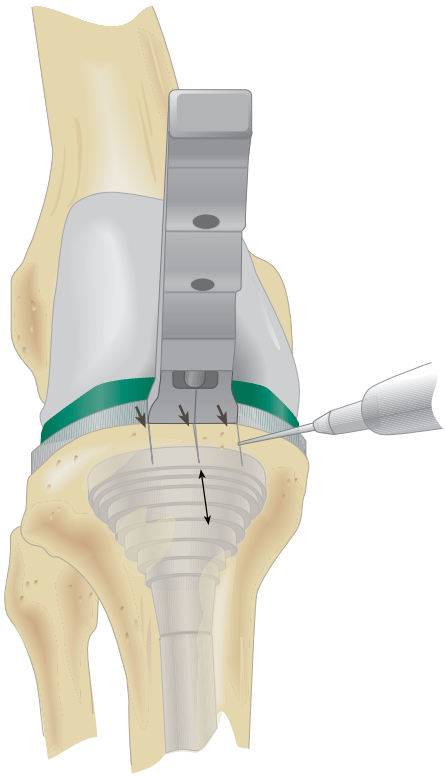


Figure 10

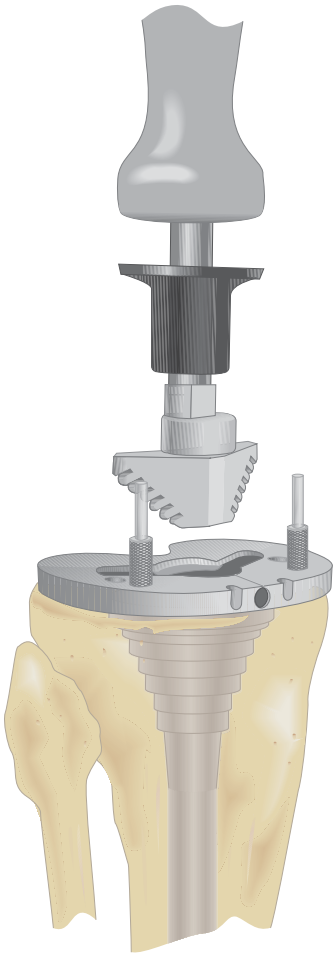


Figure 11

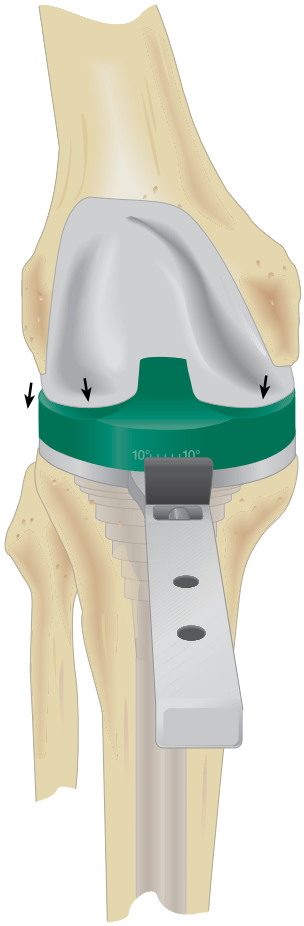


Figure 12

Place the knee in full extension and determine appropriate rotation of the tibial tray [Figure 10].

Mark the appropriate rotation with electrocautery on the anterior tibial cortex at the center and sides of the alignment handle.

Position the tibial tray trial with stem extension and sleeve trial if applicable (sleeve trial allows 20 degrees of rotation) into the prepared tibial canal. 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 11]. The base plate should be positioned to provide the best coverage of the tibial condylar surface.

Disconnect the universal handle, leaving the keel punch in place for trial reduction [Figure 12].

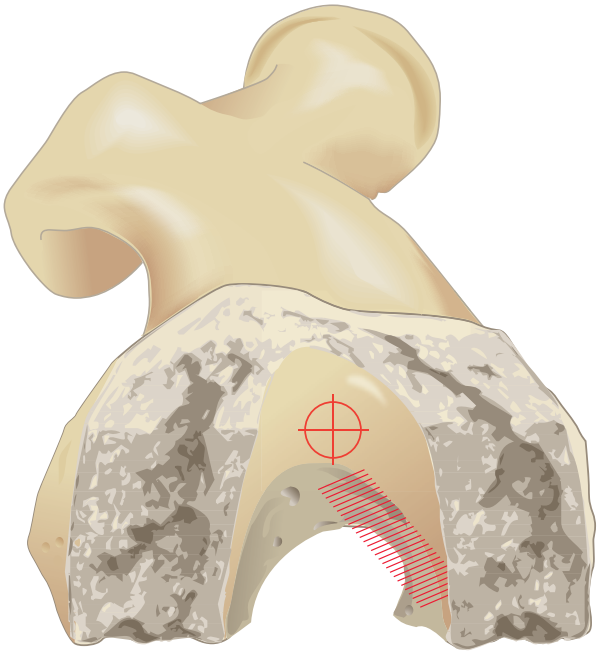


Figure 12

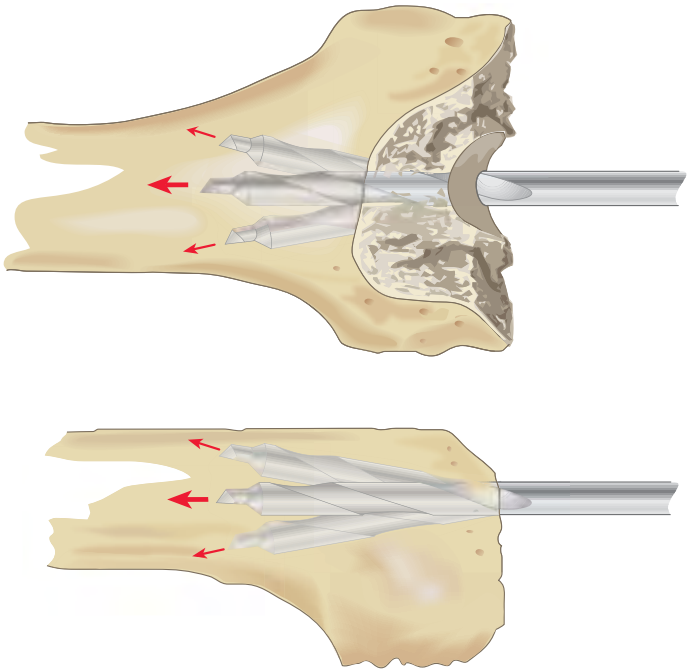


Figure 13

## 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 preoperative roentgenograms. Begin the procedure with the preparation of the medullary canal [Figures 12 and 13]. Enter the medullary canal with a 9 mm drill to a depth of 3-5 cm. 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.

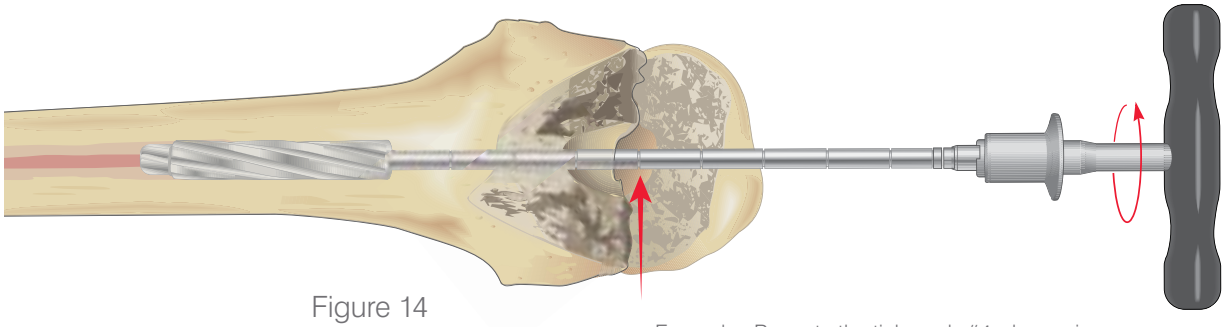


Figure 14

Example: Ream to the tick mark #4 when using S-ROM femur with 31 mm sleeve and 75 mm press-fit stem.

## Reamer Depth Chart

| S-ROM Femur | | Sleeves 20,31,34 mm | Sleeves 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 | 7 |
| | 115 mm | 5 | 5 |
| | 150 mm | 6 | 7 |

Connect the reamer handle to a small diameter M.B.T. revision reamer. If power reaming, it will be necessary to attach the modified Hudson adapter to the straight reamer. Note that the reamer shaft contains markings in 25 mm increments to accommodate the various universal stem/sleeve length combinations [Figure 14]. Use the Reamer Depth Chart to determine reamer depth for each combination of components. Another option to determine reamer depth is to measure the trial assembly against the depth scale ruler.

## The S-ROM Femoral Component accepts:

- Universal fluted stems of 75, 115 and 150 mm in diameters of 10-24 mm.
- Cemented stems available in lengths of 30 and 60 mm lengths and a diameter of 15 mm.
- Cemented tapered stems available in lengths of 90 mm (13 and 15 mm diameter) with sleeve use only, 120 and 150 mm (13 mm diameter only).

*Note: The stem is the same as is currently used with the M.B.T. revision trays.*

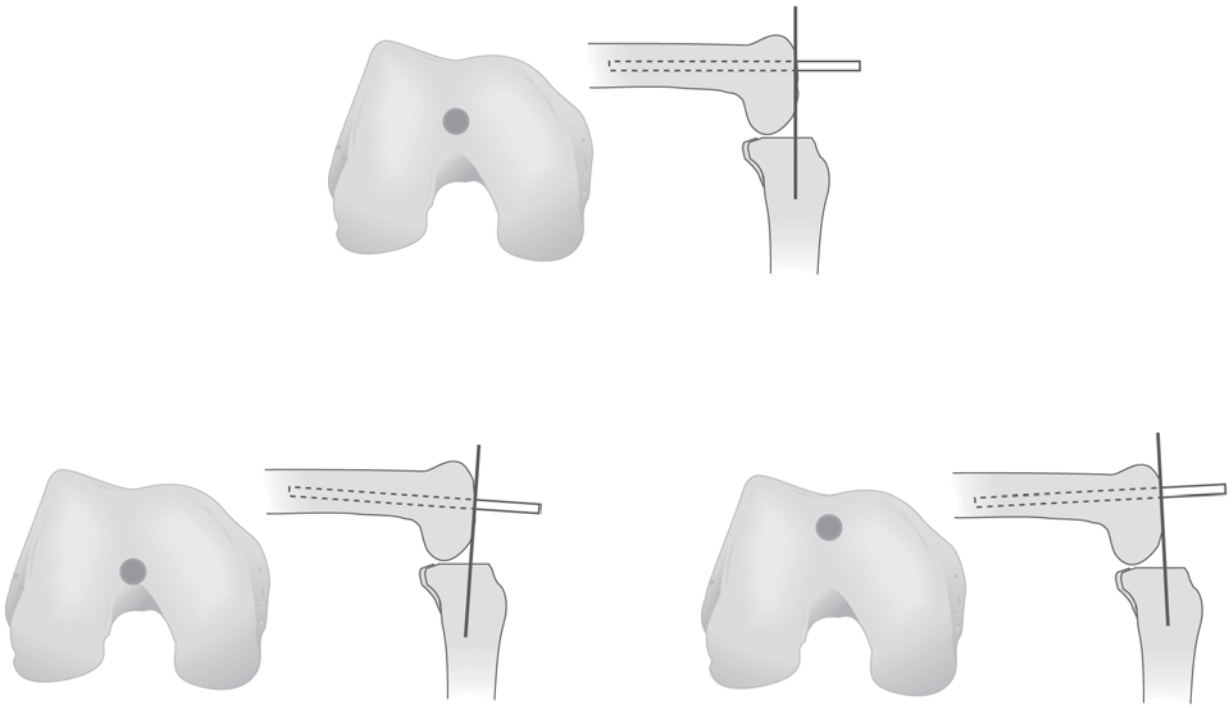


Figure 15

In 1 mm diameter increments, sequentially open the medullary canal with M.B.T. 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 [Figure 15].

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.

## PREPARATION OF THE METAPHYSIS (FOR SLEEVE USE)

Figure 16

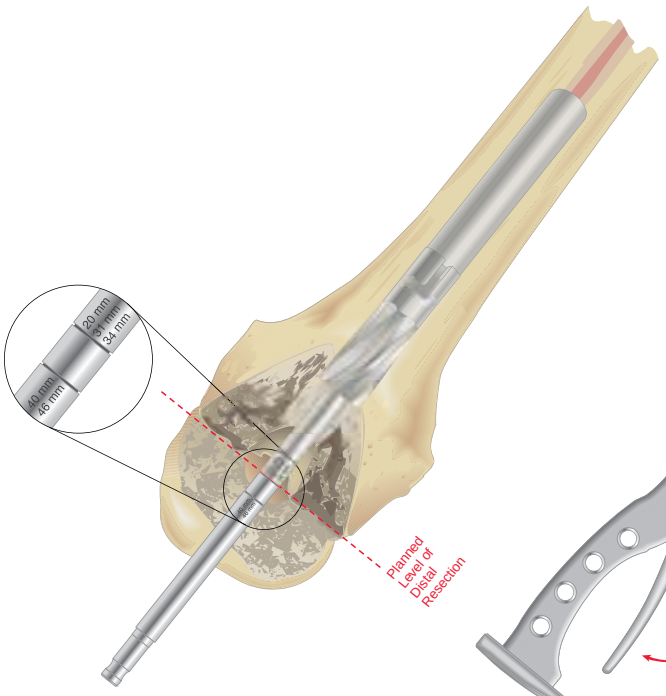



Figure 17

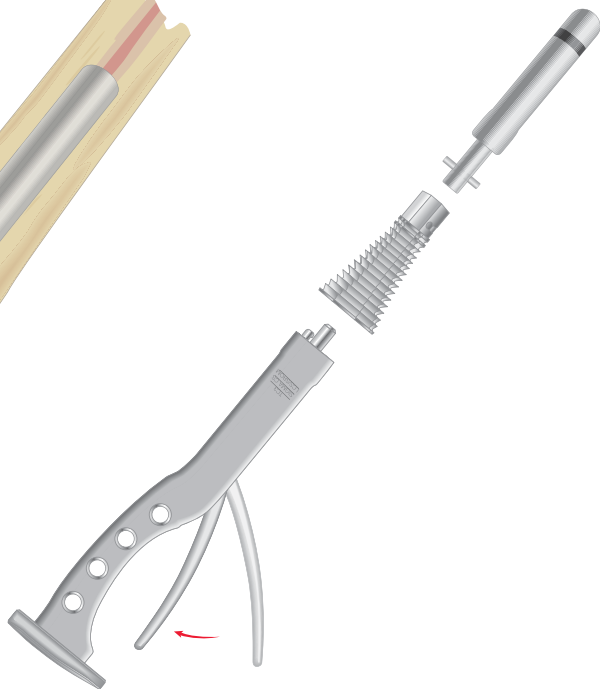


Figure 18

After reaming the intramedullary canal, attach the threaded removable shaft to the broach reamer and then to the appropriate stem trial as determined by straight reaming [Figure 16].

Ream to the appropriate etch mark on the threaded shaft [Figure 17].

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 a 31 mm or larger sleeve is used.

After broach reaming has been completed, attach the 31 mm broach to the broach impactor [Figure 18]. Attach the appropriate stem trial to the broach as determined by straight reaming.

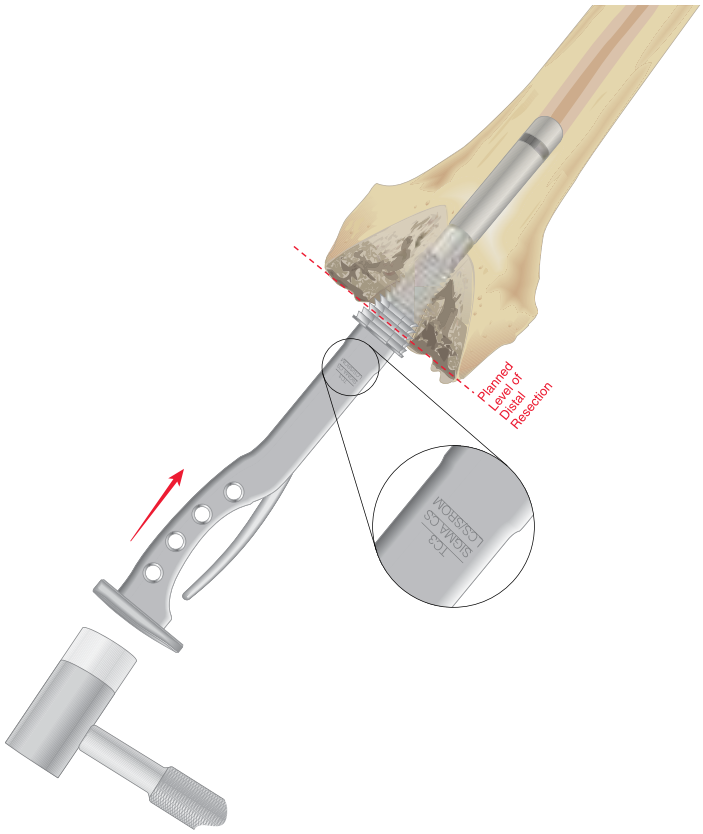



Figure 19

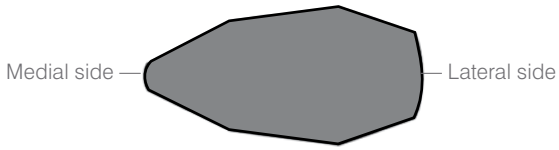



Figure 20

Sequentially broach to the desired dimension of 31, 34, 40 or 46 mm [Figure 19]. When the appropriate etch mark on the broach impactor is at the planned distal resection level, check the broach's rotational stability.

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. 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 20].*

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 21

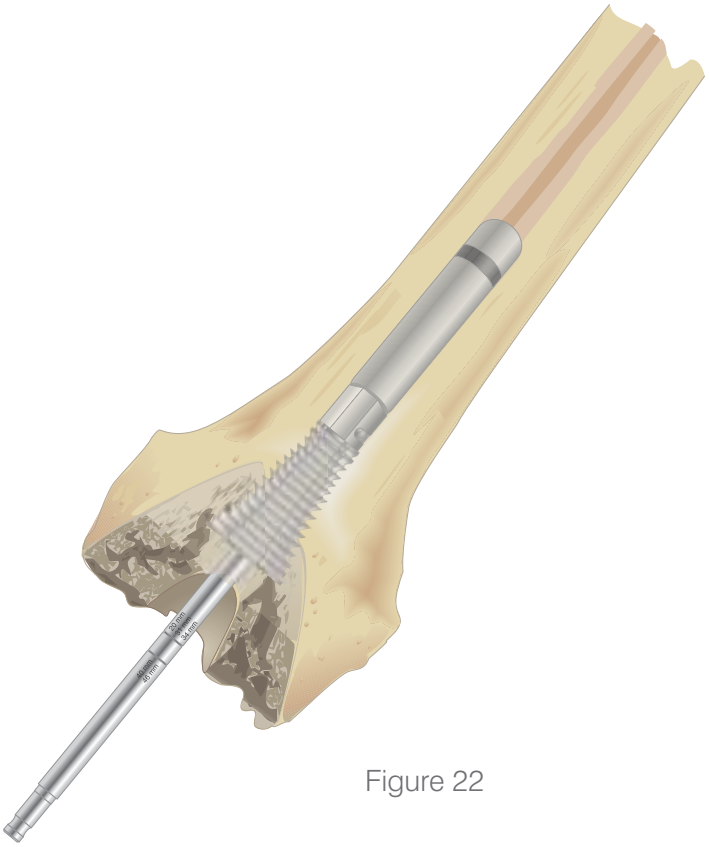



Figure 22

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 22], and continue with the distal, A/P and finishing cuts.

Distal, A/P and finishing cuts will reference off the threaded shaft/broach assembly.

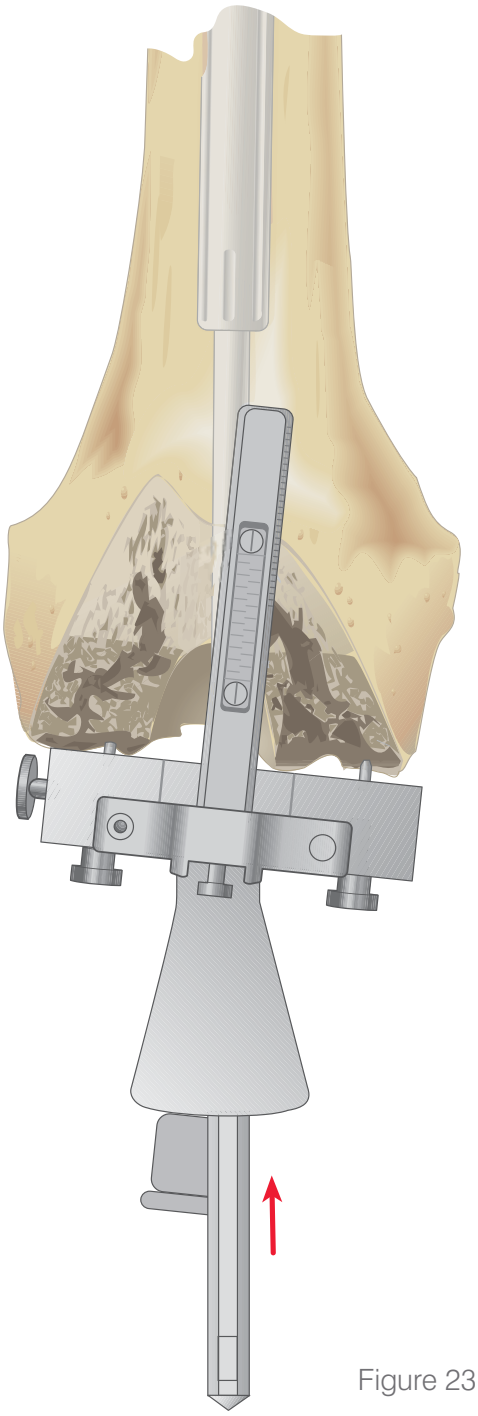


Figure 23

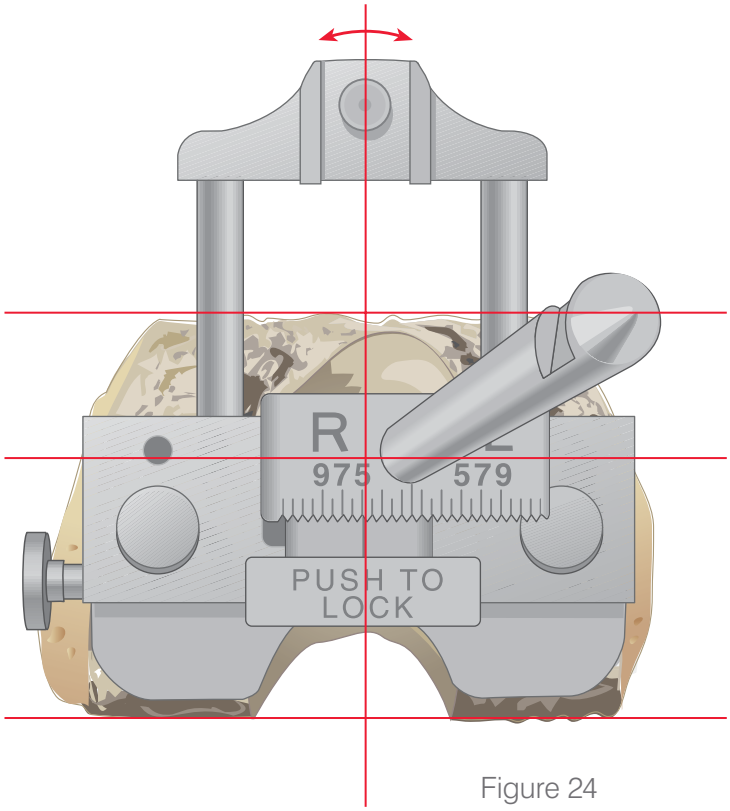



Figure 24

## The Femoral Locating Device

Set the appropriate valgus angle, 7 degrees, and Right/Left knee indication and lock into place on the front of the locating device. The locating device [Figure 23] is placed over the threaded shaft attached to the femoral broach and advanced to contact the distal femur. Center the calibrated outrigger at the trochlea. Make sure it is in its full raised position relative to the prepared anterior surface [Figure 24].

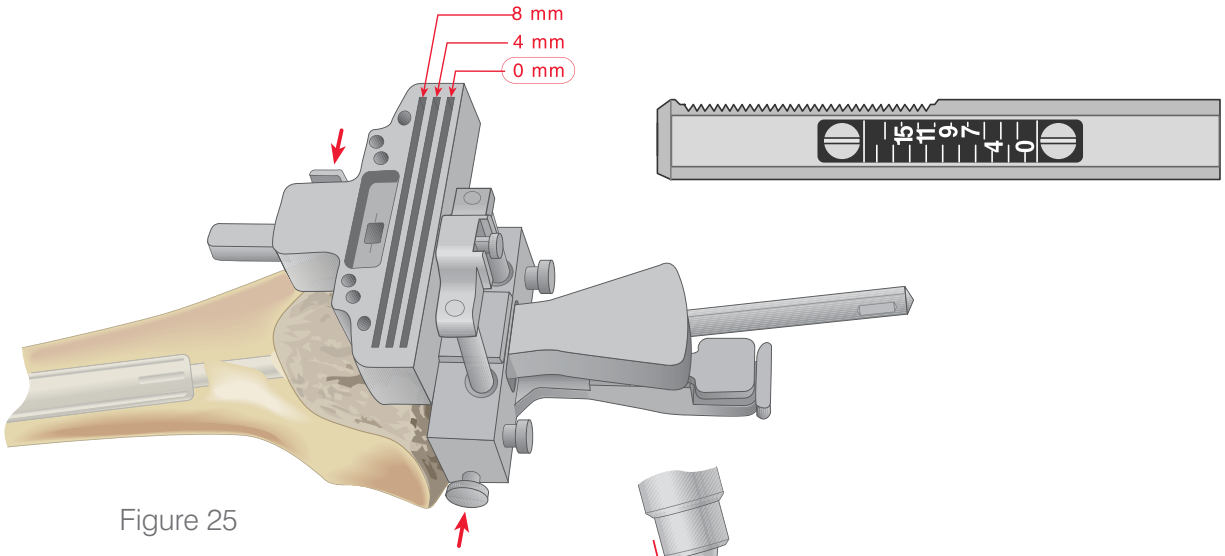



Figure 25

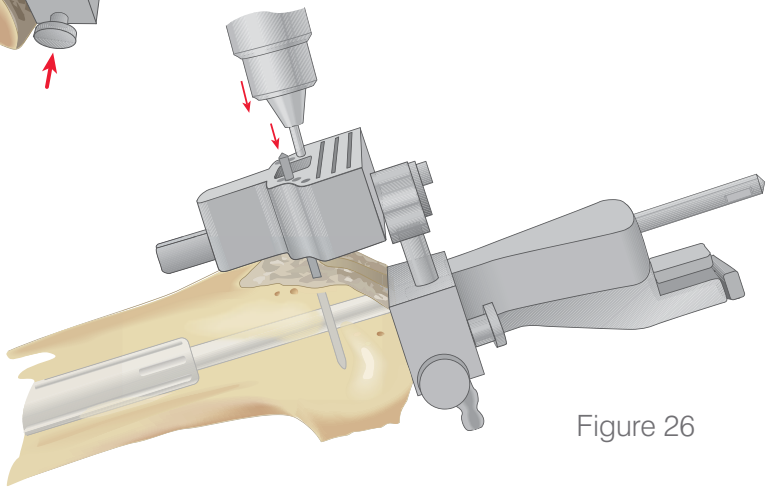
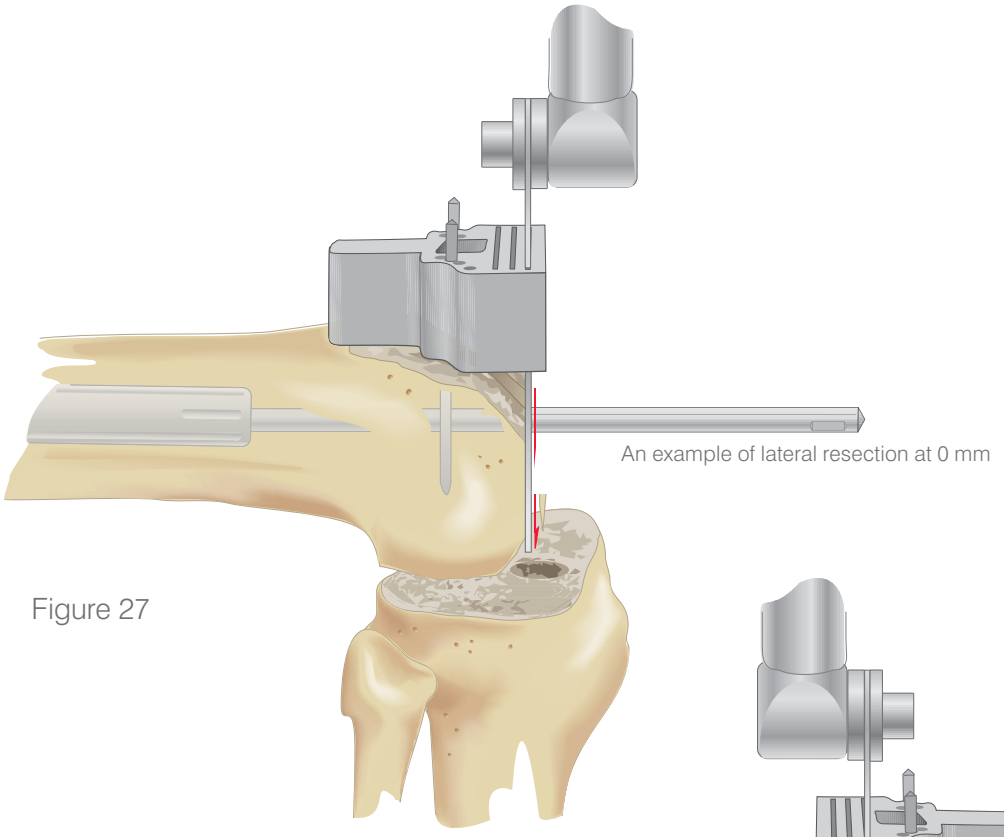


Figure 26

Assemble the distal femoral cutting block onto the calibrated outrigger by depressing the button located on the right proximal end. Advance the cutting block to the 0 mm designation, which is to the right of the number. Determine the level of distal resection by intraoperative confirmation of the preoperative estimation of the joint line and evaluation of distal condylar deficiency. The cutting block has slots to allow for a 0 mm, 4 mm or 8 mm resection level.

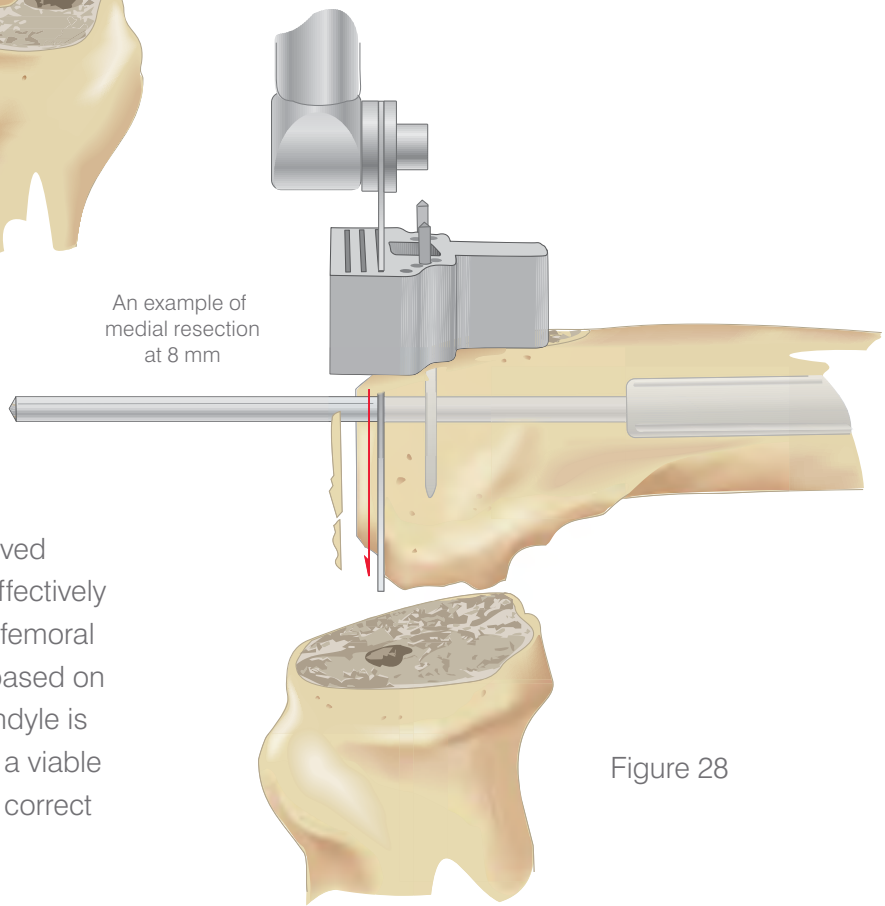
Lower the outrigger and cutting block assembly onto the anterior cortex by depressing the button on the left-hand side of the locating device [Figure 25]. Introduce either 1⁄8" drill bits or Steinmann pins through the holes designated zero and enclosed in □'s. Remove the locating device and outrigger by depressing the button located on the right proximal end of the distal cutting block and pulling the entire assembly (femoral locating device and outrigger) distally over the M.B.T. revision reamer or threaded shaft [Figure 26].

## DISTAL RESECTION



An example of lateral resection at 0 mm

Figure 27



An example of medial resection at 8 mm

Figure 28

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 [Figure 27].

Resection is accordingly performed through the slot appropriate for each condyle, using a standard 1.19 mm blade [Figure 28].

- The femoral cutting guide is size specific (2 blocks – xs/small and medium). Determine the femoral component size by preoperative 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 appropriate cutting size over the threaded shaft. Use corresponding hole depending on left or right knee.

- Place the guide into neutral rotation by aligning the anterior cortex parallel with the anterior portion of the guide. Also use the femoral epicondylar axis as the rotational reference.

  *Note: If distal augmentation will be used, there should be a gap of 5 or 10 mm between the cutting guide and the distal condyle(s) of the affected side(s).*

- Achieve fixation of the cutting guide with 1/8" drill points, introduced through the holes designated on the front of the block and side (if additional fixation is needed). These pins will need to be temporarily removed later to complete the resections.

- Attach the removable handles to the cutting guide (optional).

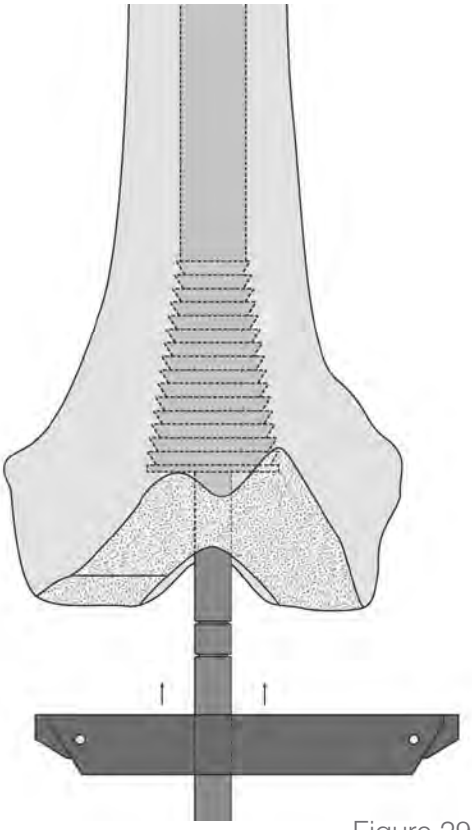


Figure 29

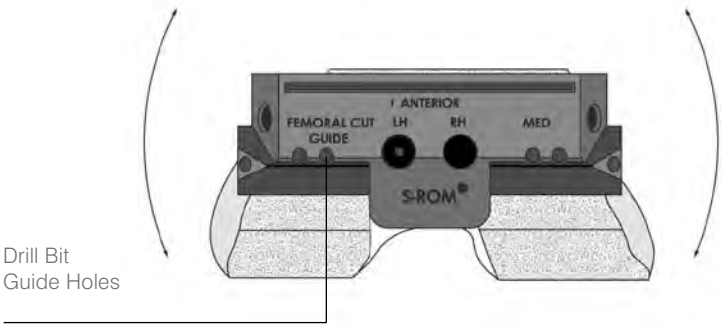



Figure 30

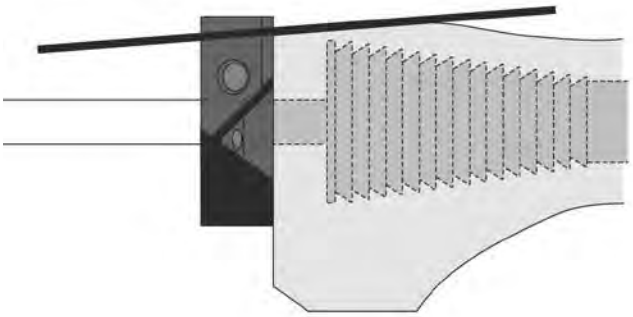


Figure 31

- Make the anterior cut [Figure 31]. Proceed to make the anterior chamfer cut through the captive slot. If the block was previously pinned, temporarily remove one pin at a time while making the resection.
- Make the posterior chamfer cut by holding the saw blade flush with the cutting guide. Again, if 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” drill point on each side of the guide. These will be used to position the box cut guide.
- Remove the femoral cutting guide and femoral broach/stem assembly while leaving the 1/8” drill points in place.

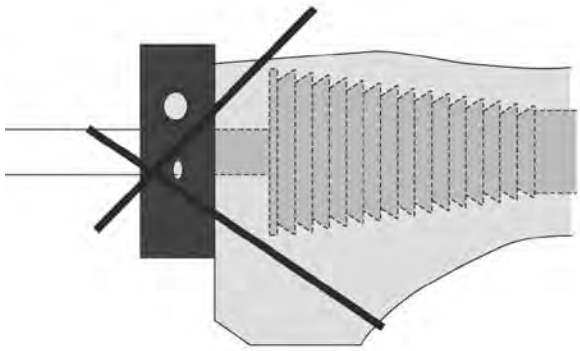


Figure 32

- Use 5 or 10 mm box cut guide spacers if distal augmentation blocks will be used [Figure 33].

- Slide the hinge femoral box cut guide over the 1⁄8” drill points 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 points before positioning the box cut guide [Figure 33]. Attach removable handles to the box cut guide for additional stability.

  Four additional 1⁄8” drill holes are provided on the anterior surface of the box cut guide; 1⁄8” drill points 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 as illustrated above [Figure 34].

- Use a narrow saw blade (12.7 mm or 0.5”), placed on the sloped guide surface, to remove the bone block of the center box [Figure 35].

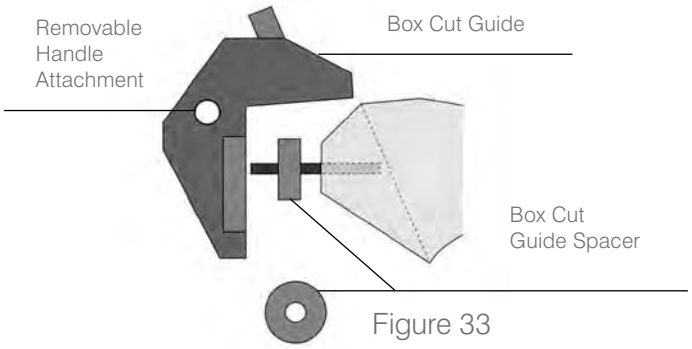



Figure 33

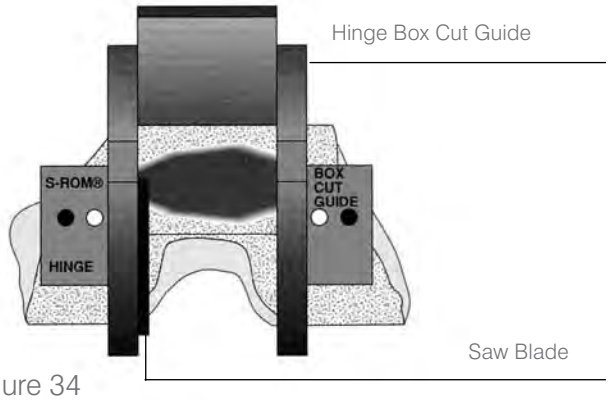



Figure 34

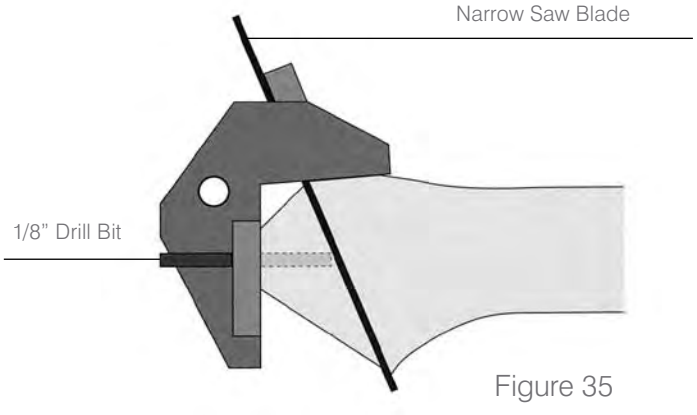



Figure 35

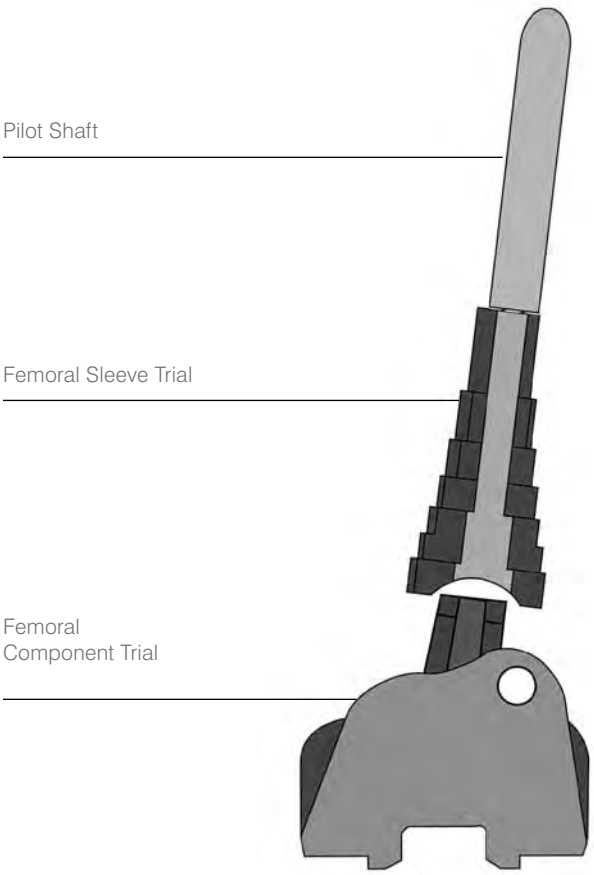



Figure 36

- Connect the pilot shaft into the appropriate femoral sleeve trial. The diameter of the pilot shaft 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 36].

- Slide the sleeve/shaft assembly into the prepared cavity in the femoral canal to allow the assembly to self align with the broached surfaces.

  *Note: The narrow side of the sleeve trial points medially.*

- 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 37].

  *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.*

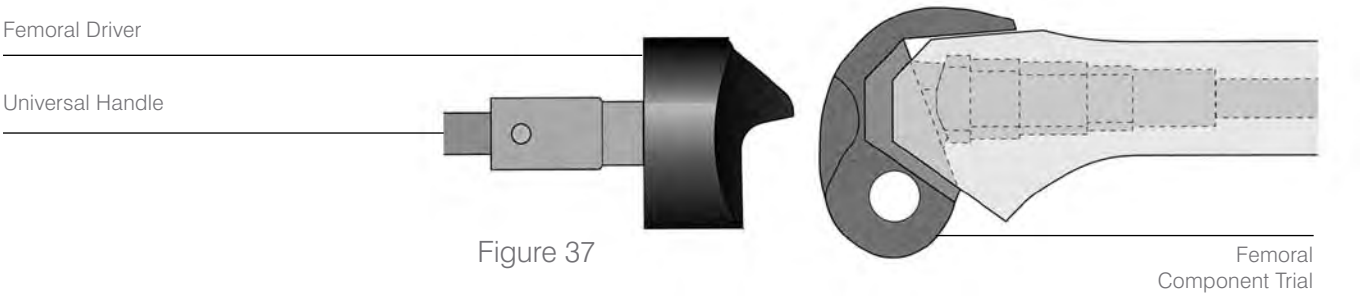



Figure 37

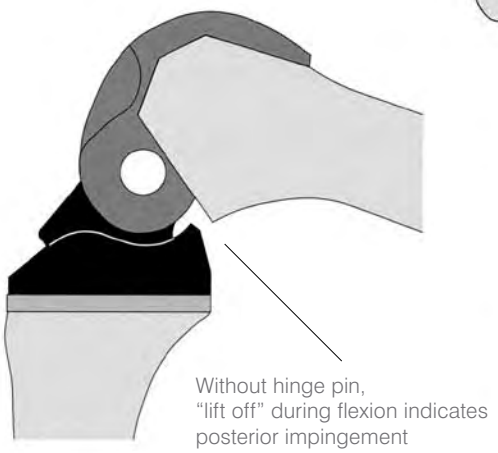



Figure 38

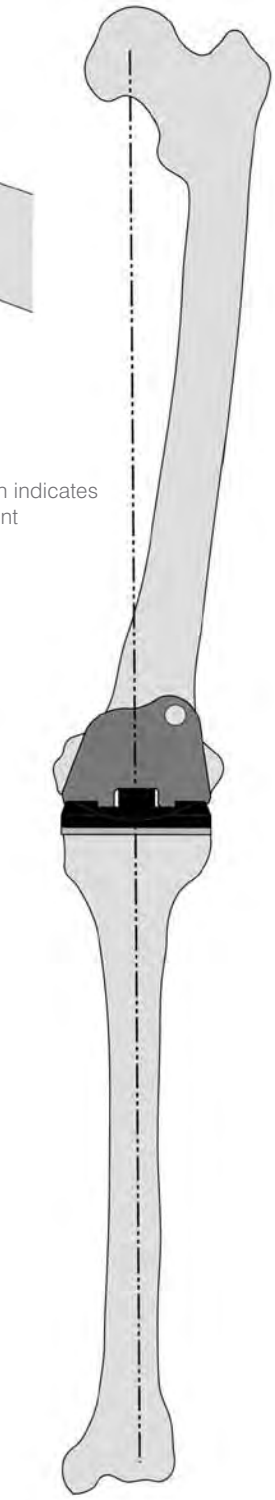


Figure 39

- Slide the condyles of the femoral trial into the plateau trial. Do not insert the hinge pin trial [Figure 38].
- With the leg in full extension, evaluate the resection of the mechanical axis. The center of the femoral head, knee and talus should all be in line [Figure 39].
- The knee should be stable throughout the full range of motion.
- If the condyles lift off the plateau during flexion, check the posterior area for soft tissue, osteophyte or bone impingement.
- Insert the hinge pin trial and repeat the range of motion check.
- Check ligament tension and leg length.
- Revision of the tibial or femoral resection may be required if satisfactory stability cannot be achieved. Accomodate 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 luxation of the tibial plateau out of the modular tibial base. In this instance, fit the patient with a postoperative brace, limiting flexion to 90 degrees and no more for at least three months. This helps soft tissue establishment of flexion tension. Consult package insert.*

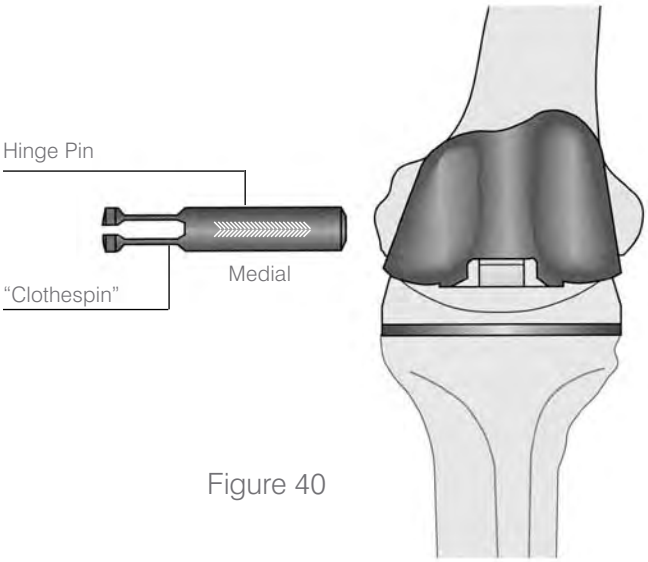



Figure 40

- Put the condyles of the femoral component into the corresponding recesses in the tibial plateau. Recheck range of motion and stability. Look for lift off due to impingement. Clear all cement around the implants.

- Insert the hinge pin through the hole on the medial side of the femoral component. Orient the rectangular head of the hinge pin with the rectangular recess in the femoral component [Figure 40].

- 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 41].

- Test the knee through full range of motion.

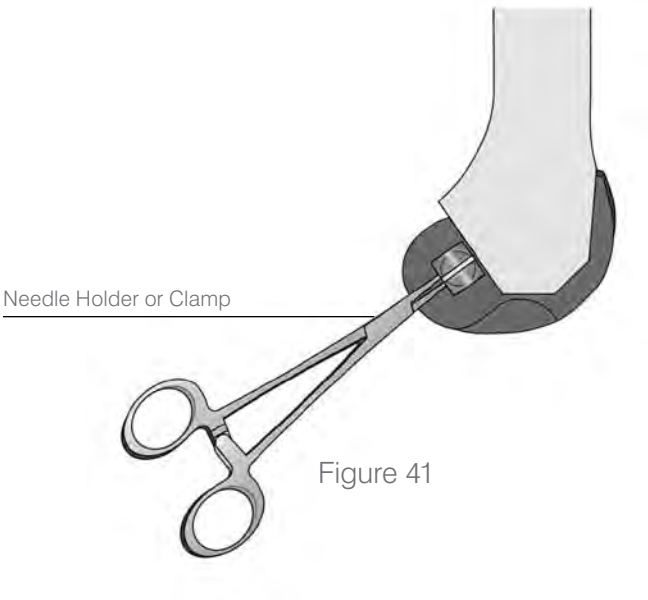



Figure 41

## 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 M.B.T. 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 42]. The sleeve can rotate 20 degrees internally or externally.

Using the sleeve impactor and a mallet, impact the sleeve onto the M.B.T. revision tray. Deliver several strikes to engage the two components [Figure 43].

Figure 42

Figure 43

## Wedge Assembly

*Note: To aid wedge assembly, attach wedge prior to 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 44].

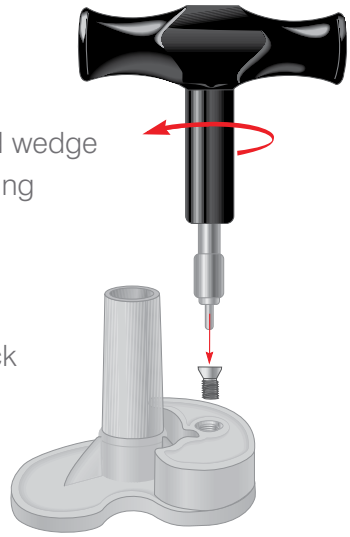


Figure 44

## Stem Component Assembly

Attach the tibial stem extension to the prosthetic tray using the two appropriate wrenches to ensure full engagement [Figure 45].

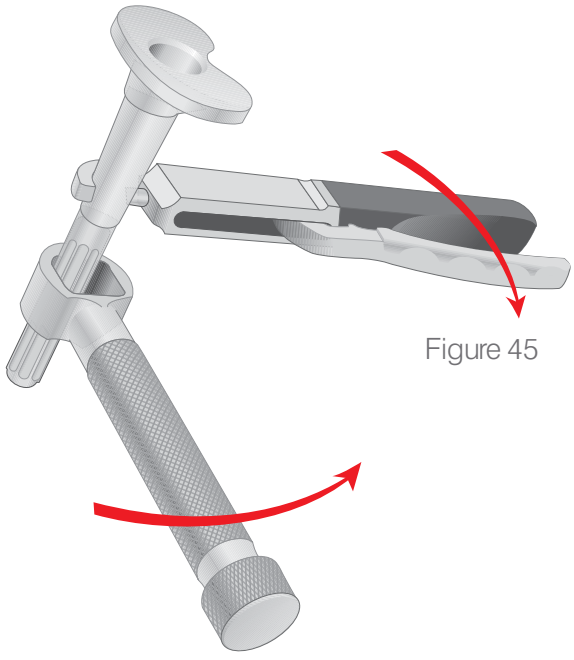


Figure 45

## Implanting the Tibial Component

Thoroughly cleanse the site with pulsatile lavage. Where the prepared tibial surface is eburnated, perforate with small drill holes to facilitate penetration of methyl methacrylate [Figure 46]. Pack residual small cavitory bone defects with cancellous autograft, if available, or allograft. Apply methyl methacrylate cement to the proximal tibial surface or directly to the underside of the tibial tray component.

When a fluted stem or a fluted stem with a metaphyseal filling sleeve is used, ensure the medullary canal remains free of cement. Clear all extruded cement with a curette [Figures 47 and 48].

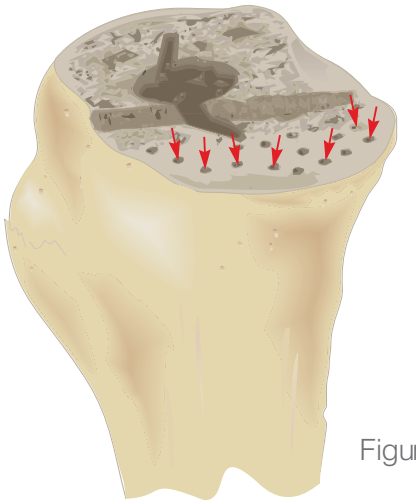


Figure 46

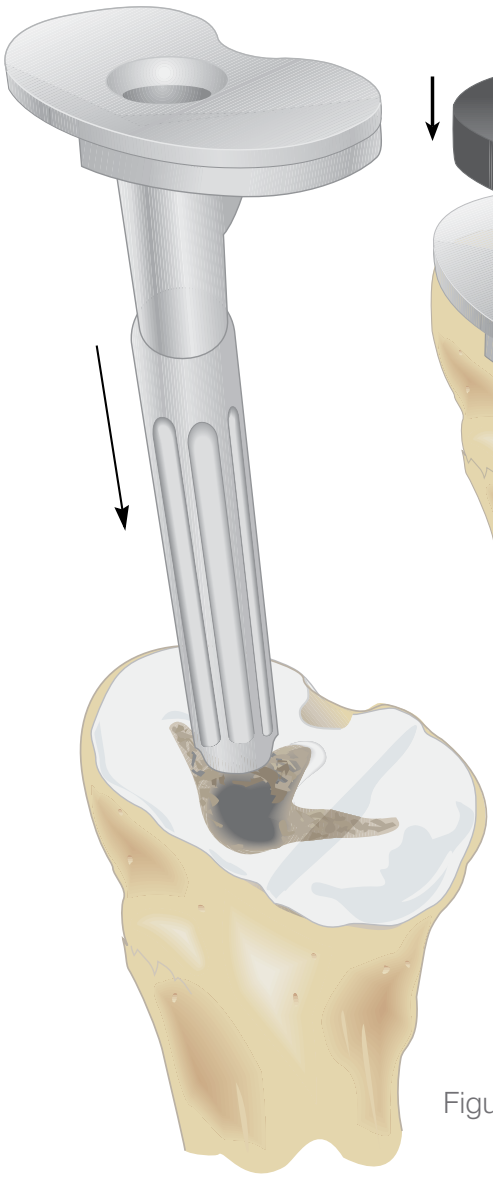


Figure 47

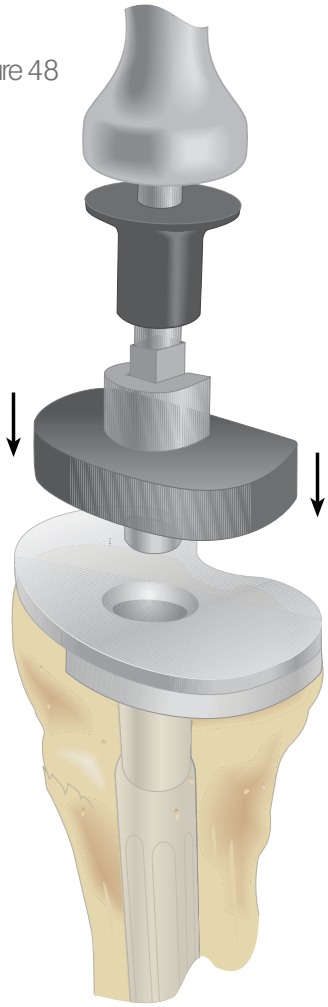


Figure 48

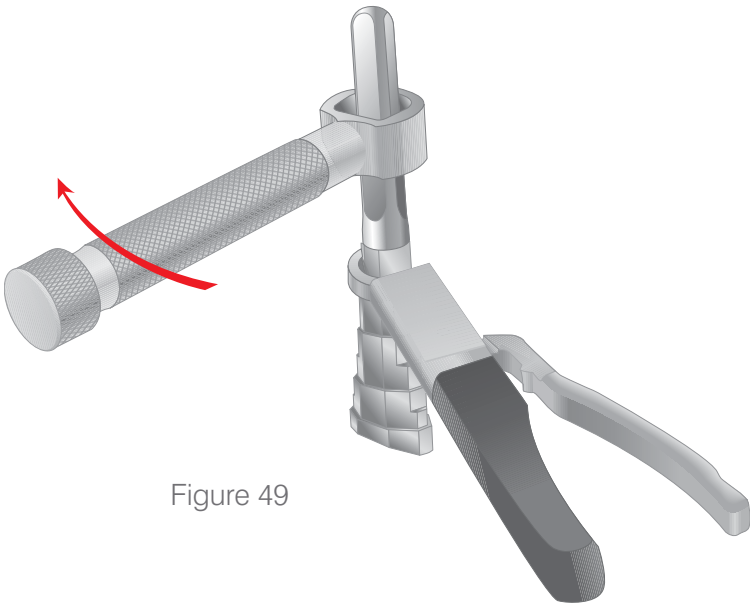


Figure 49

To attach the universal stem to the revision 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. Tighten as shown in Figure 49.

Apply sufficient force to both wrenches to ensure that the stem is secure.
Place the femoral component on a firm, stable surface. Place the appropriate sleeve and stem construct on top of the femoral component.

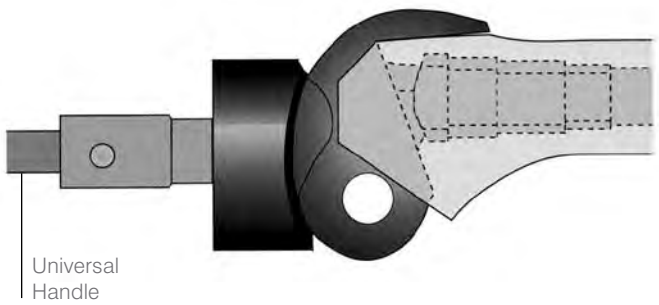



Figure 50

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.

*Note: The femoral stem/sleeve impactor has two uses, one end for use of a sleeve without a stem extension and one end for a sleeve and stem combination.*

The definitive components are implanted in the following order:

- Tibial tray (with stem, sleeve or wedges)
- Femoral component (with stem, sleeve and augments)
- LPS Hinged insert

Implant the femoral component using the femoral impactor [Figure 50].

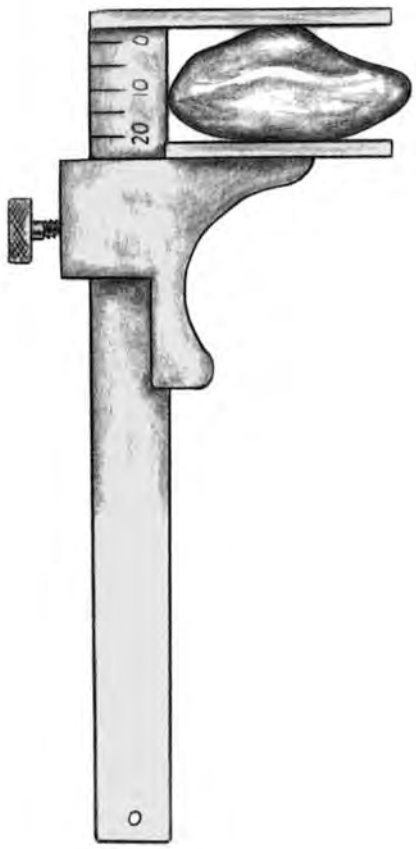



Figure 51

- Measure and record the overall thickness of the patella using a caliper [Figure 59].
- Resect approximately 7 mm of bone from the posterior patella surface using an oscillating saw [Figure 52].
- Measure and record the thickness of the resected/removed bone in order to properly duplicate the original thickness [Figure 53].

Figure 52

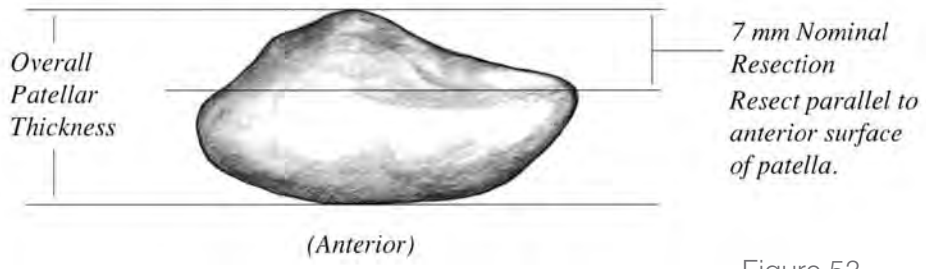



Figure 53

- Patella domes are available in four diameters [Figure 54]. Select a patella trial with the diameter that best matches the patient's patella [Figure 55].
- 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 55].

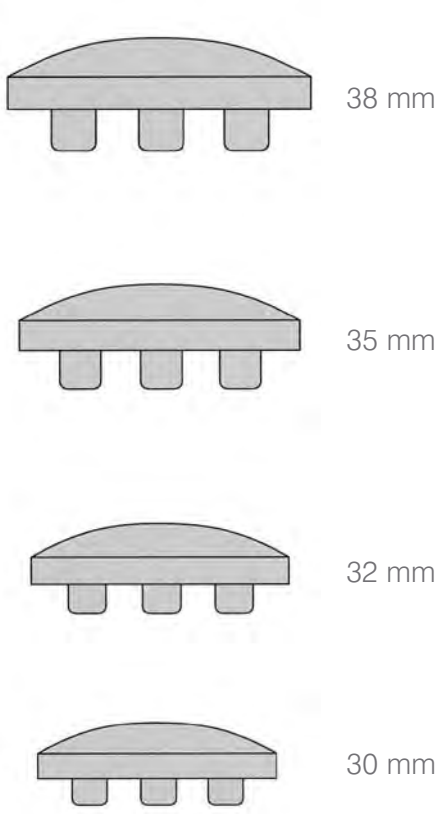



Figure 54

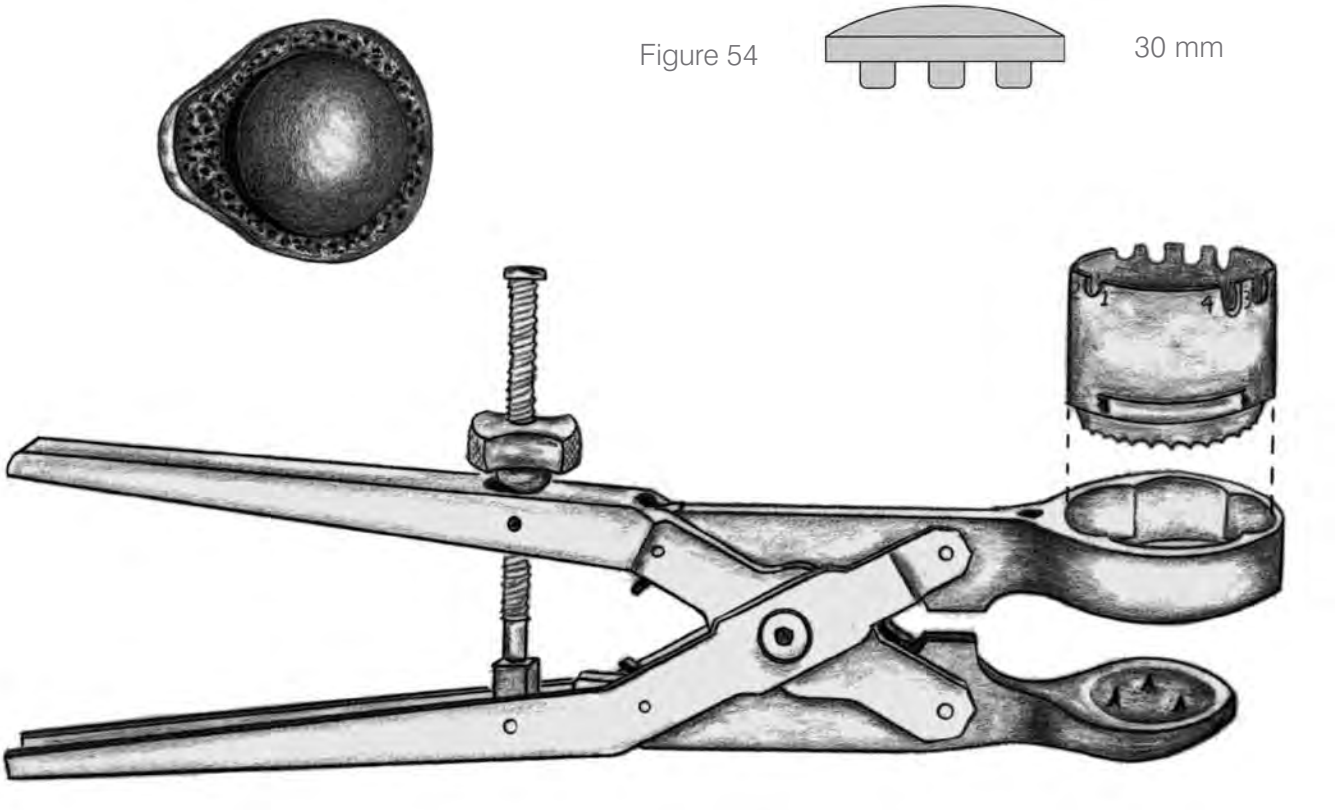


Figure 55

- Clamp the patella restraining instrument assembly onto the patella. Lock into position by turning the thumb nut clockwise [Figure 56].

- 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 2 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 bone prior to reaming. Ream until the patella reamer flange makes contact with the patella reamer bushing.

| Table 2 | | | | |
|---|---|---|---|---|
| Thickness of selected patella component | | Measured thickness of bone resected and removed | | Select Slot number |
| 9 mm | - | 7 mm | = | 2 |

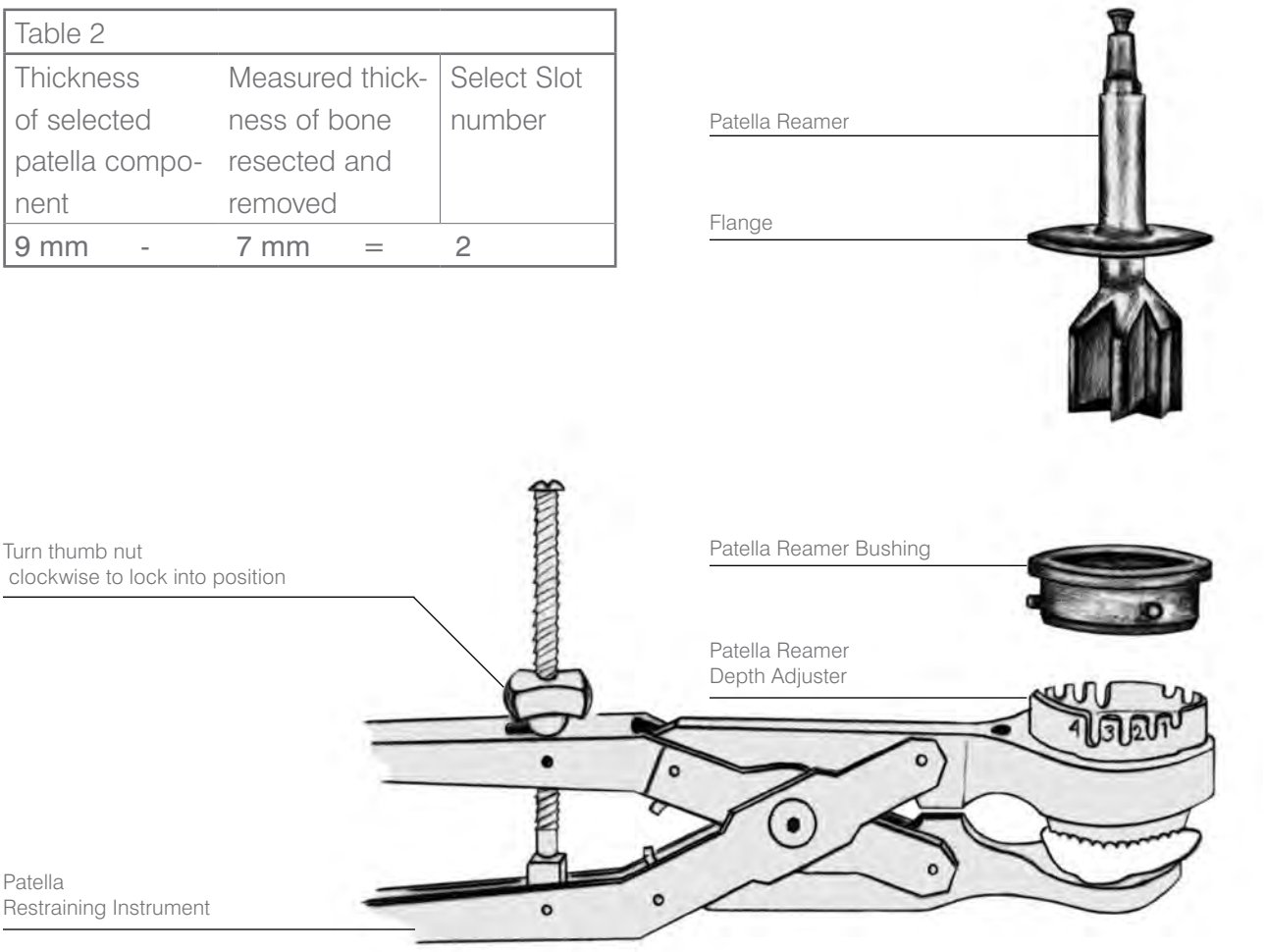



Figure 56

- 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 57].

- Select the 3⁄16” 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 58].

  Optional: Select the 1⁄8” 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.

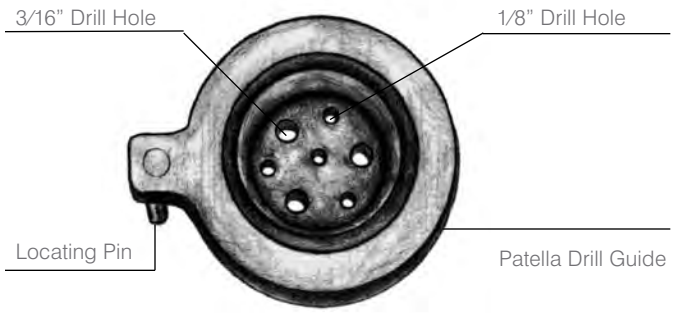



Figure 57

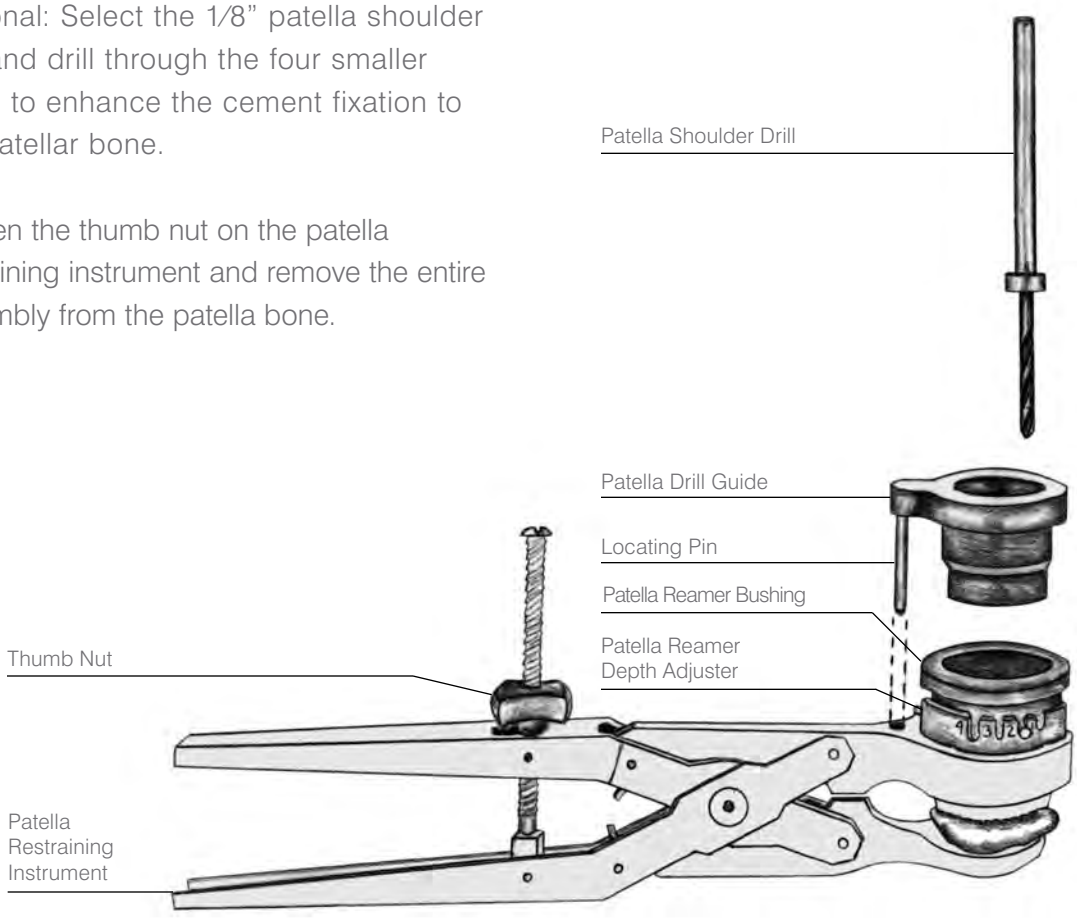



Figure 58

- Place the appropriate diameter patella trial into the prepared patella bone. Measure 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 59].

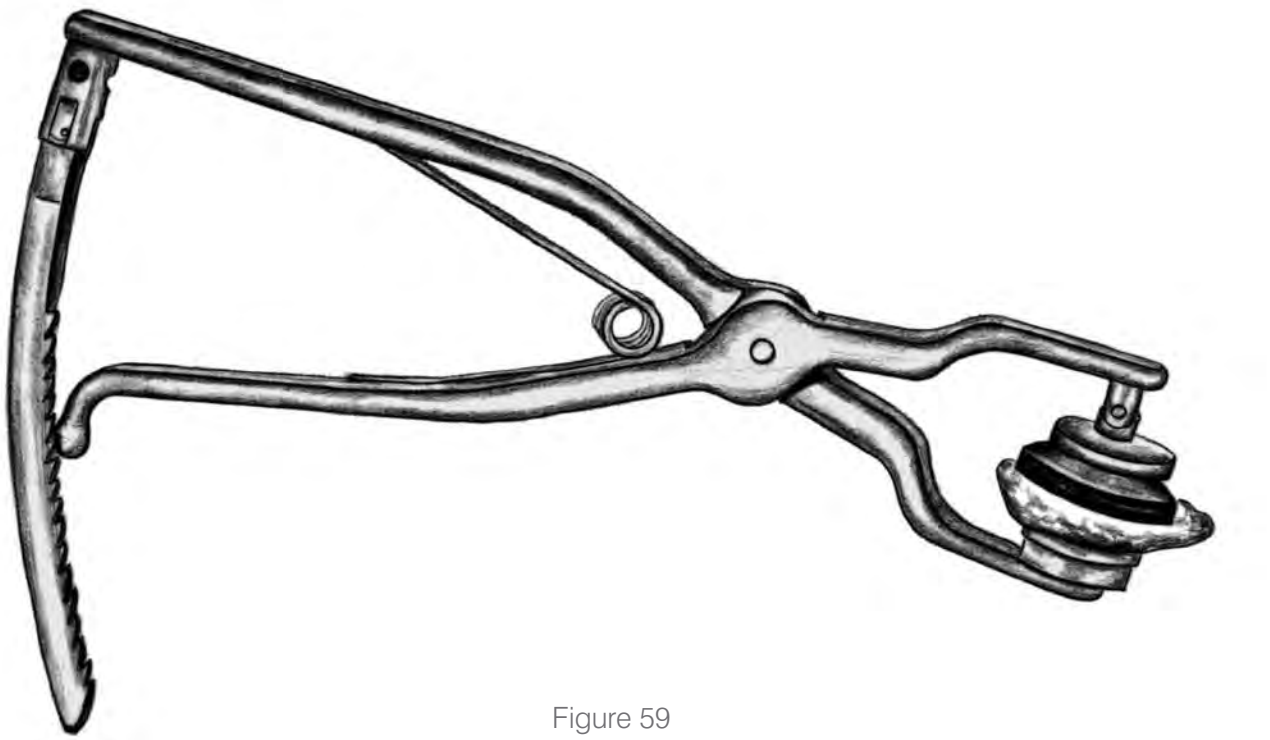


Figure 59

## Cemented Stem Reamer

Align the tibial tray and secure with two fixation pins inserted through the holes designated [Figure 1].

Seat the M.B.T. revision drill bushing onto the tibia trial. Place in the posterior holes.

Place the cemented drill bushing into the M.B.T. 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 M.B.T. revision drill bushing in place [Figure 3].

*Note: Only a 13 mm diameter cemented stem should be used in conjunction with the M.B.T. revision tray to avoid a step off at the stem/tray junction.*

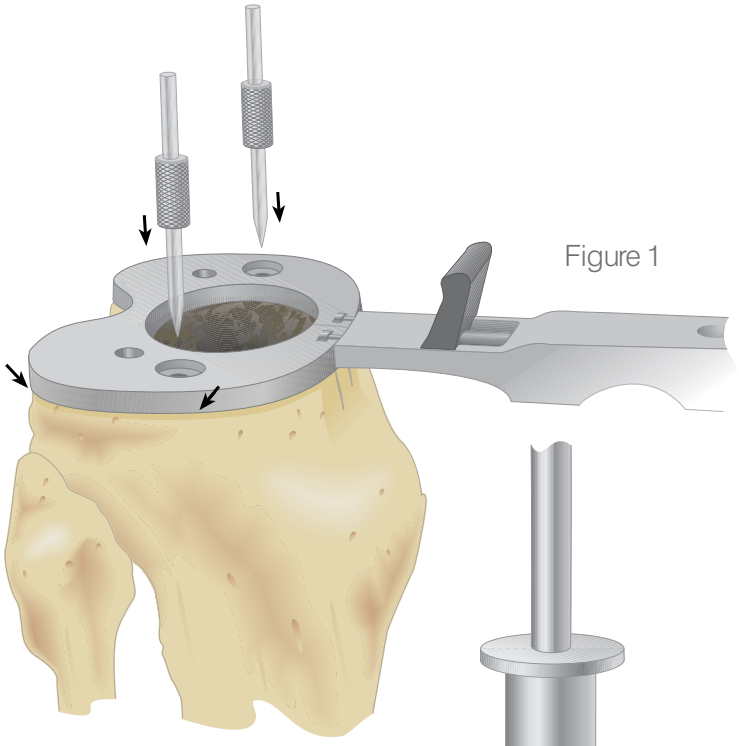


Figure 1

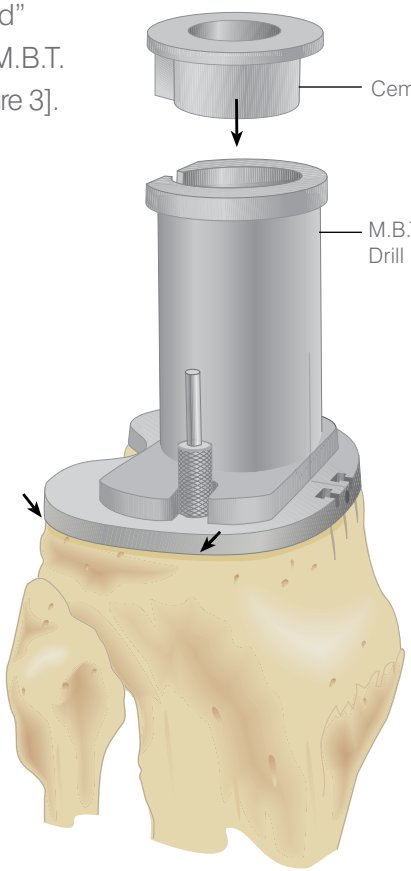



Figure 2

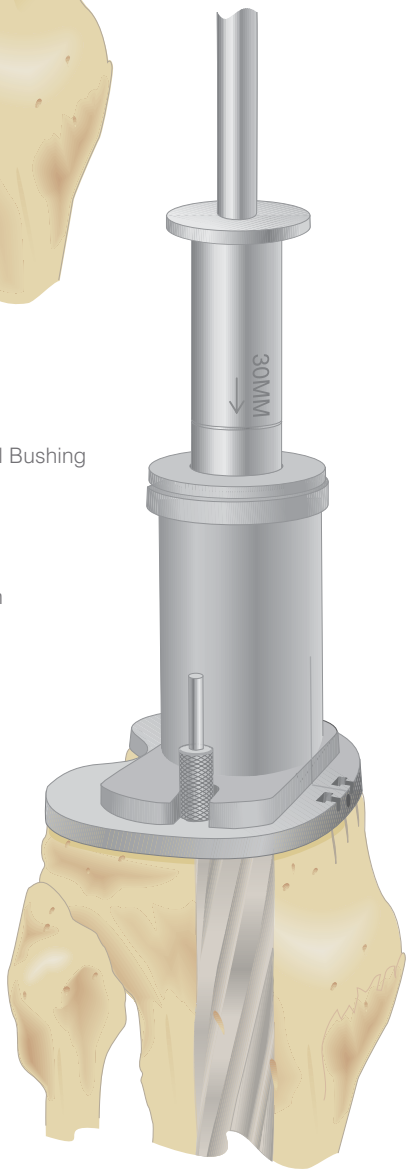



Figure 3

## 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 M.B.T. revision drill bushing [Figure 5].

Note: To avoid stem trial disengagement, do not reverse ream.

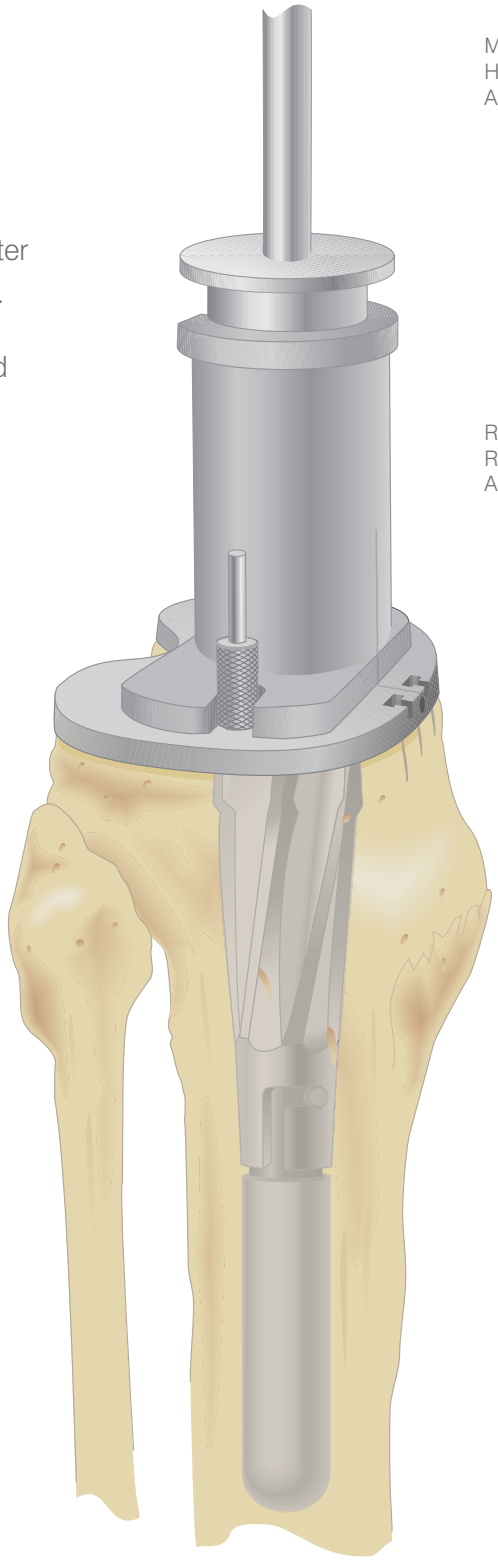


Figure 5

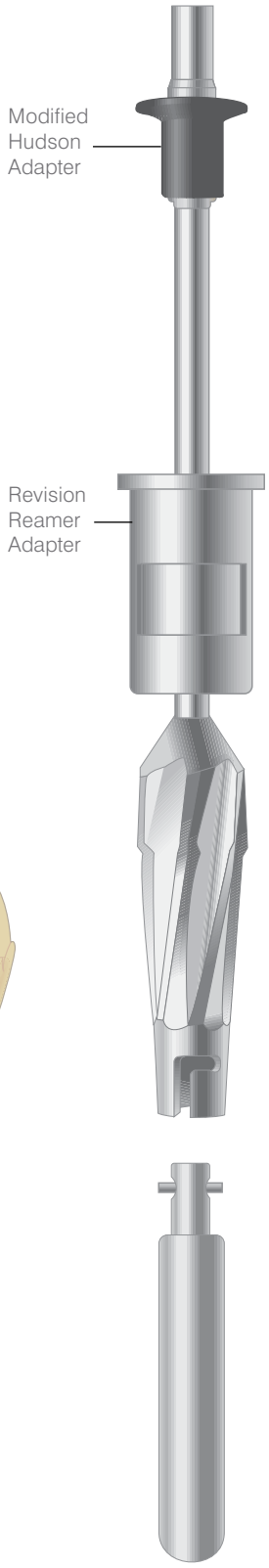



Figure 4

## 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 M.B.T. revision tray trial and seat in the prepared bone bed.

Impact the cemented keel punch if a cement mantle is desired or the press-fit keel punch if line-to-line contact is desired [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.

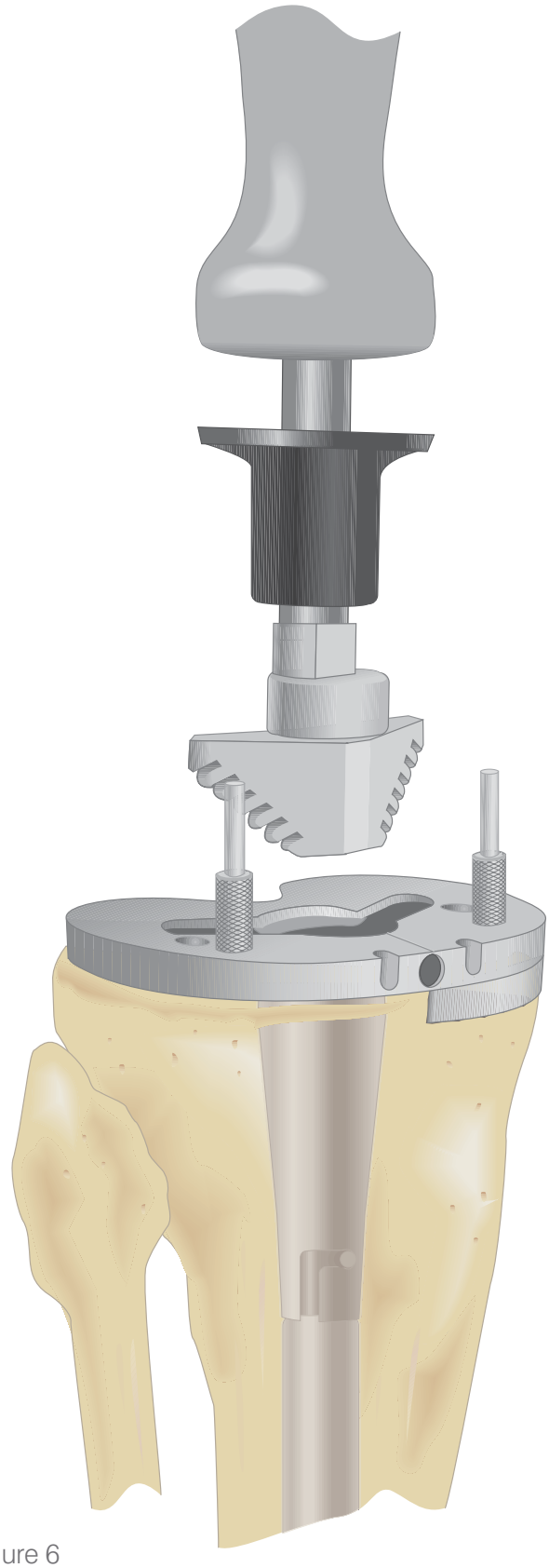


Figure 6

## 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 stem 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. Slide the block forward to the anterior proximal tibia and secure in place with two Steinmann pins through the holes marked with □ [Figure 7].

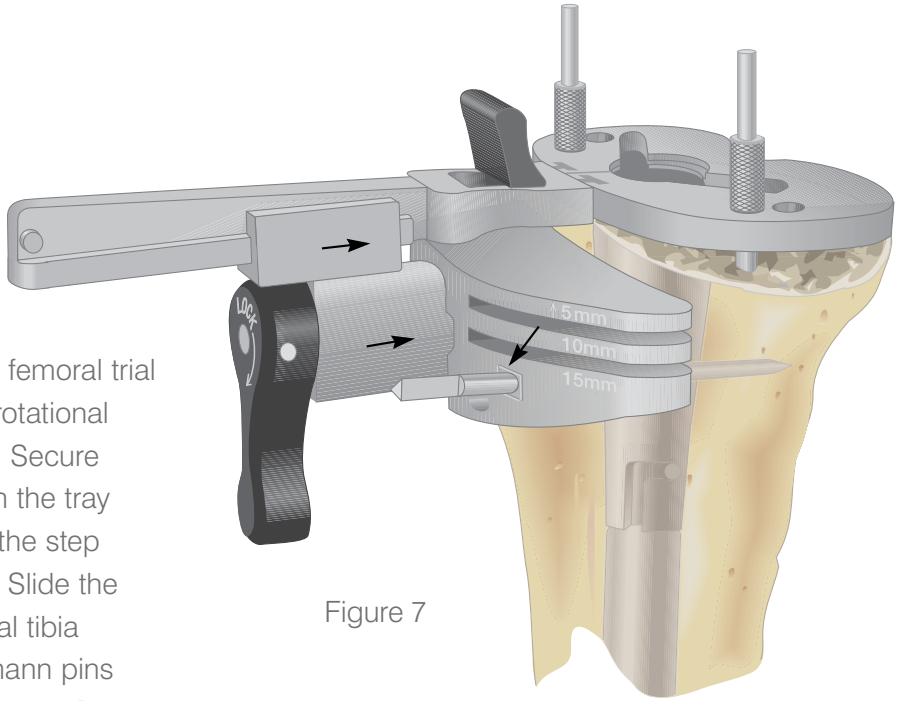



Figure 7

Unlock the block and slide the assembly out of the block. Disconnect the handle from the trial tray.

Position the step wedge cutting block on the pins so the appropriate cutting surface (5, 10 or 15 mm step) is at the deficient condyle [Figure 8].

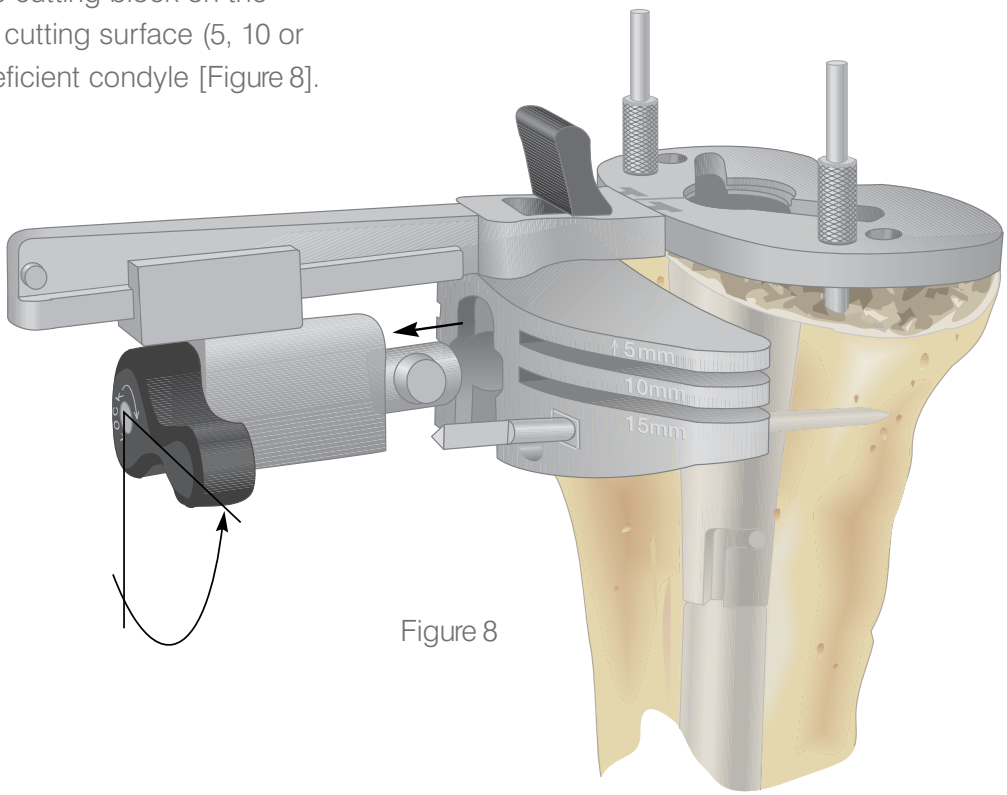



Figure 8

Trim the tibia accordingly with an oscillating saw so the cut does not extend beyond the central riser. Remove the block and pins [Figure 9].

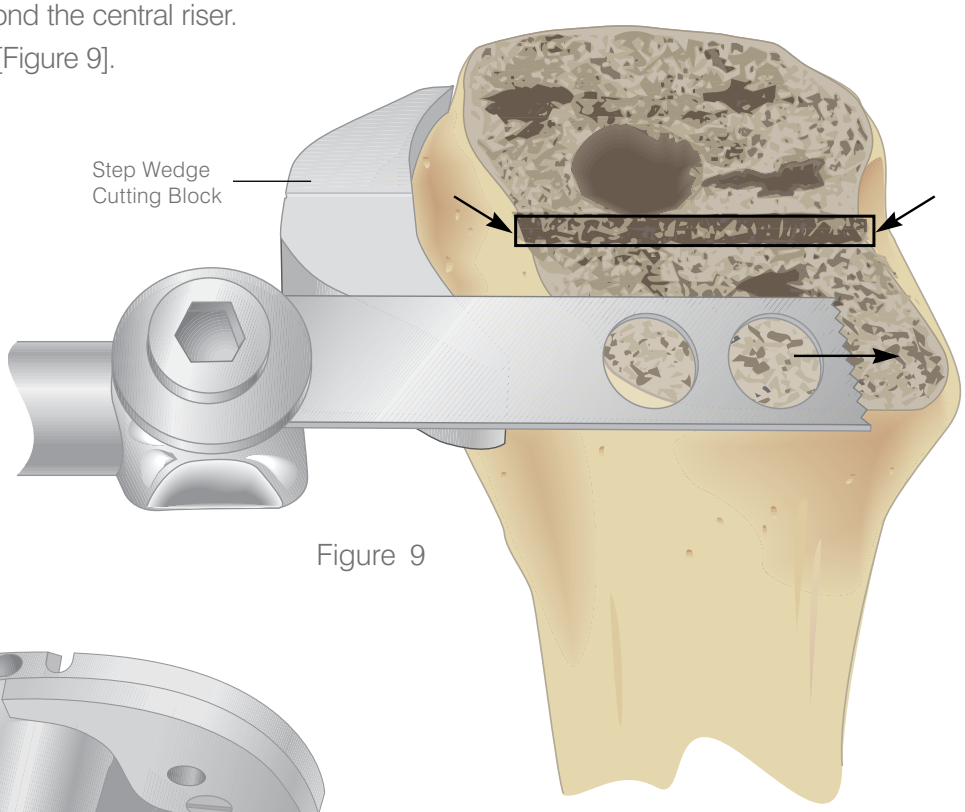



Figure 9

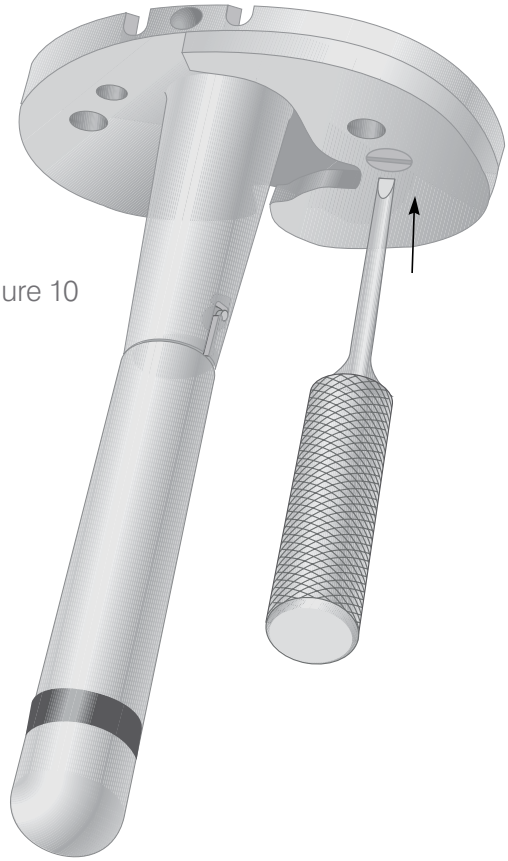


Figure 10

Assemble the trial wedge to the appropriate tibial tray trial and introduce into the prepared site. Perform minimal correction with a bone file where indicated to ensure maximal contact [Figure 10].

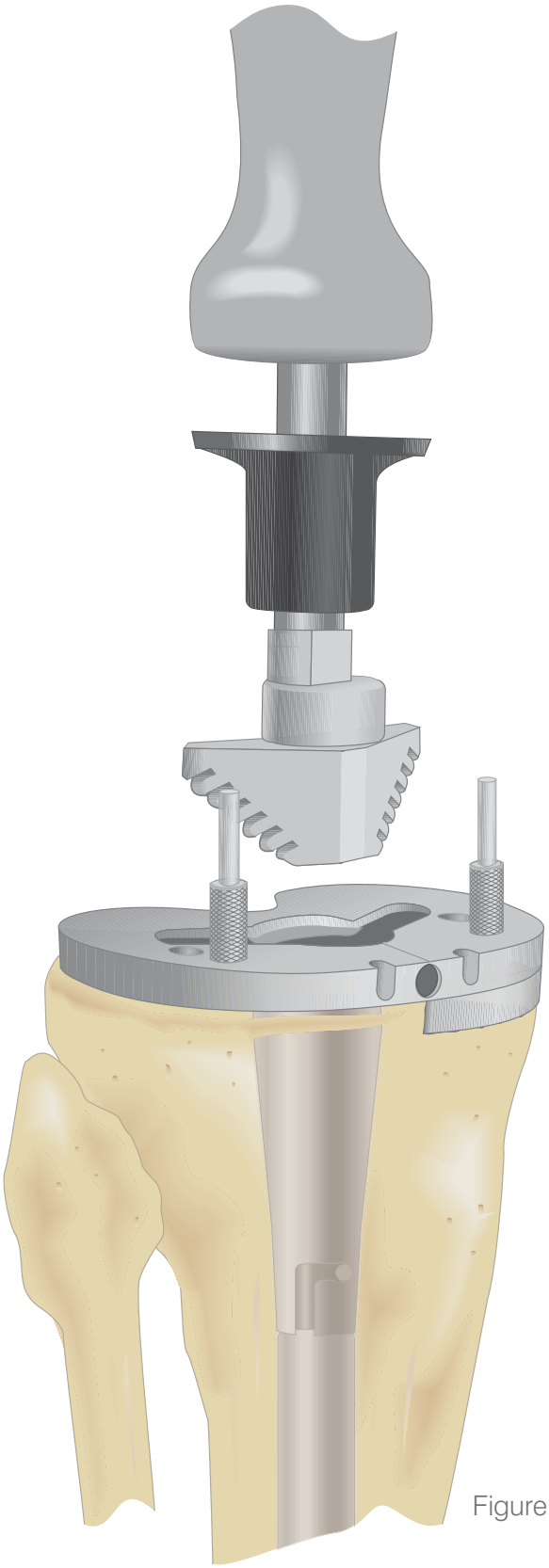


Figure 11

Confirm positioning, alignment and security of the tray assembly. If there is old cement or sclerotic bone, relieve this first through the trial tray with a saw blade or burr prior to punching. Position the M.B.T. 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 11].

*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 12].

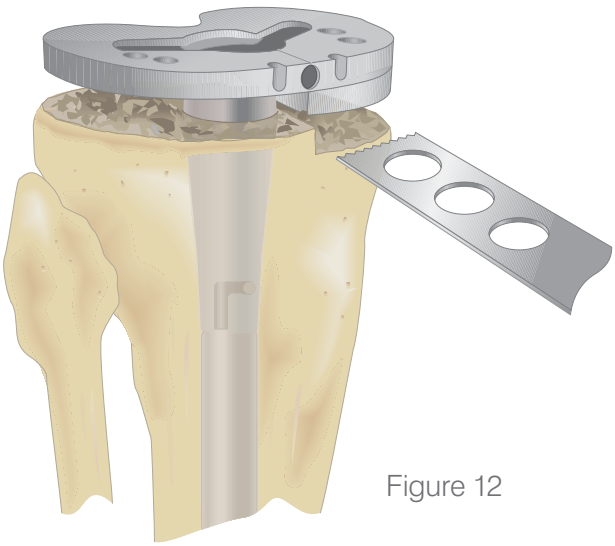


Figure 12

After impacting the cement or press-fit keel punch, remove the keel punch. Insert the M.B.T. thick tray trial adapter (15 or 25 mm) onto the tibial tray trial [Figures 13 and 14].

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 M.B.T. revision tray. Implant assembly and implantation is also the same as with the standard M.B.T. 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. Sleeves may be used with all thick trays.

Figure 13

Figure 14

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.

| Implant Cat. No. | Femoral Location | Use With S-ROM Noiles Rotating Hinge Femoral Size | Augmentation Thickness | Trial Cat. No |
|---|---|---|---|---|
| 623805 | Distal | all sizes | 5 mm | 633785 |
| 623810 | Distal | all sizes | 10 mm | 633790 |

## Trial Reduction

- Slide the femoral sleeve trial assembly into the femoral canal. Insert only as deep as the distal resection.

- Using bone wax, attach the augmentation block trial(s) as appropriate to the femoral component trial [Figure 15].

- Proceed with the trial insertion.

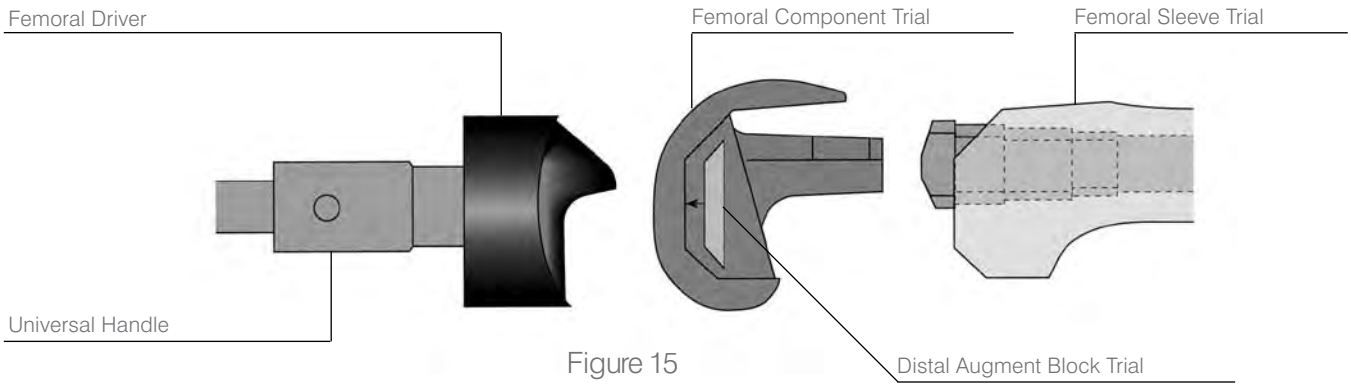



Figure 15

## 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 16].
- 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 17].*

- The remainder of the mixed cement may be used to implant the patella and tibial component while the blocks are setting.

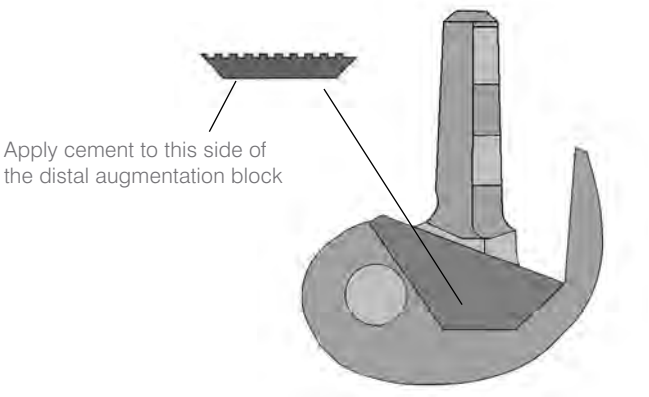



Figure 16

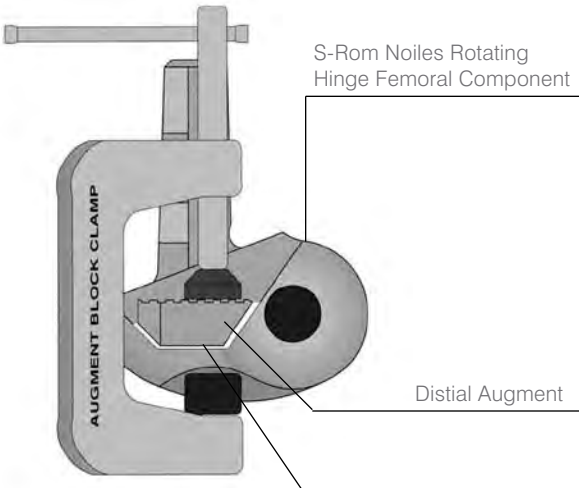



Figure 17

## M.B.T. 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 |

## M.B.T. Revision Sleeve

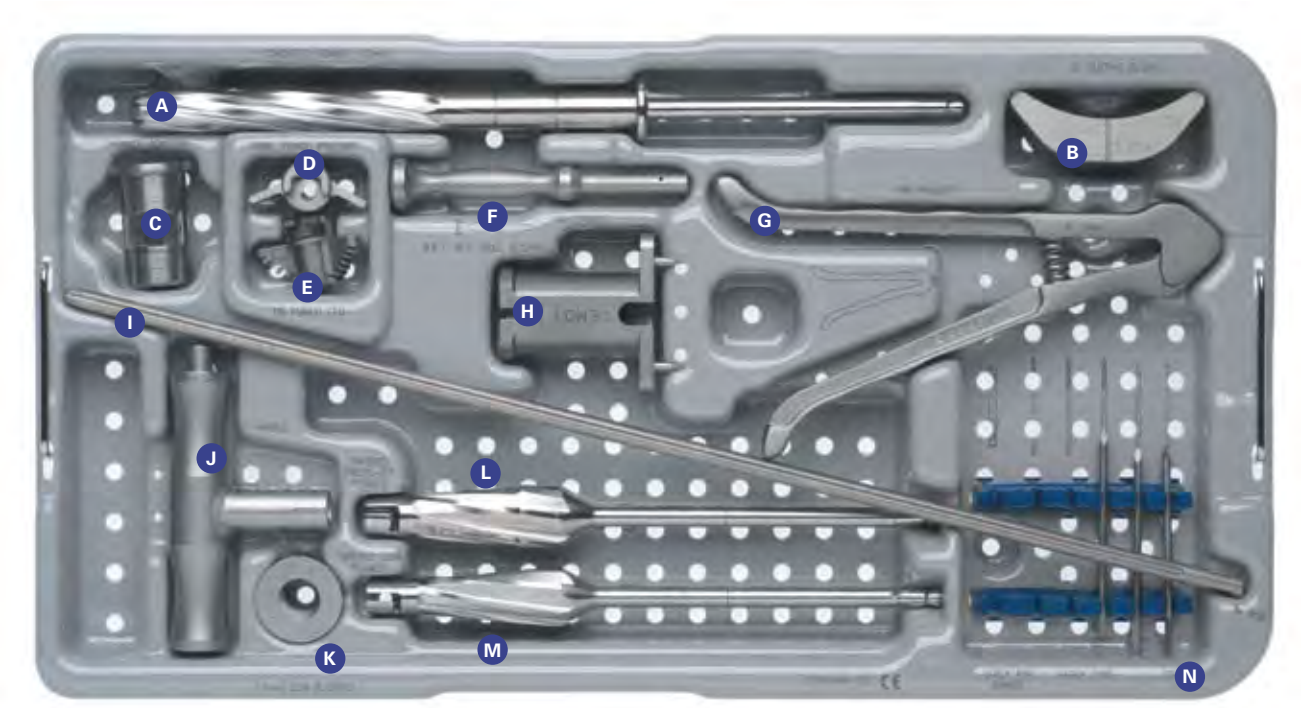
| Cat. No. | Size (mm) | A/P | M/L | Height |
|---|---|---|---|---|
| 1294-54-000 | 29 | 26 | 29 | 40 |
| 1294-54-140 (Cemented) | 29 | 26 | 29 | 40 |
| 1294-54-100 | 37 | 27 | 37 | 40 |
| 1294-54-110 | 45 | 27 | 45 | 40 |
| 1294-54-120 | 53 | 31 | 53 | 40 |
| 1294-54-130 | 61 | 34 | 61 | 40 |

## M.B.T. 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 |

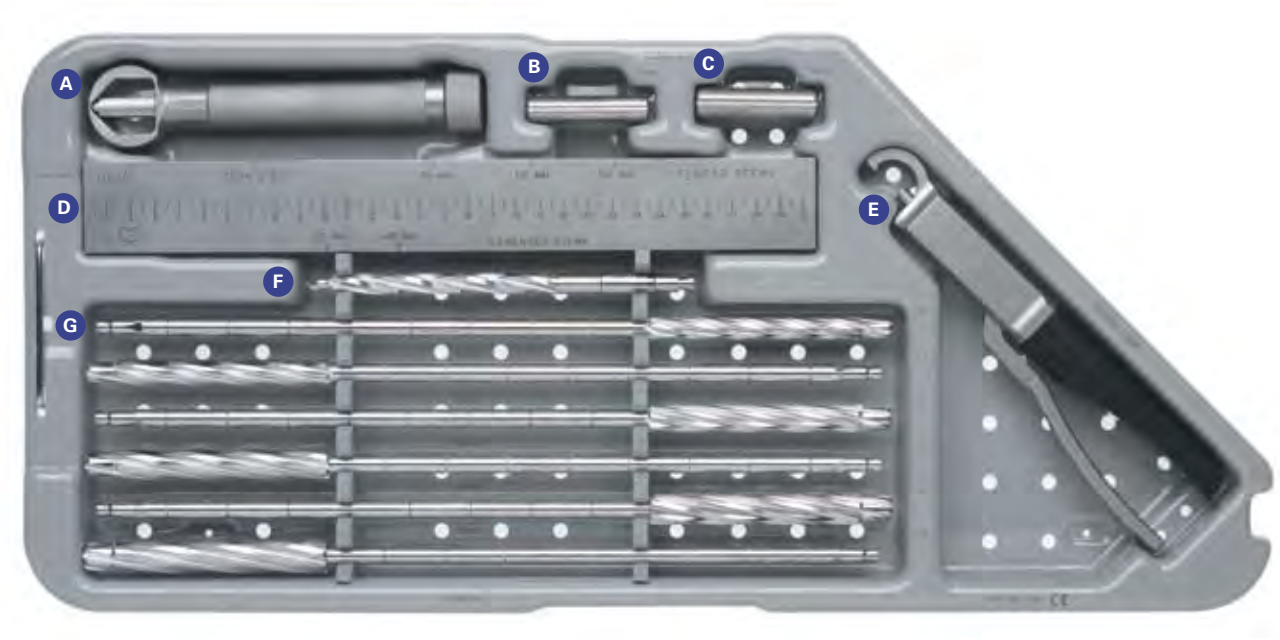
| | | | Orthogenesis LPS XX-Small Femur | Orthogenesis LPS X-Small Femur and S-ROM X-Small Femur | S-ROM Small Femur | S-ROM Medium Femur |
|---|---|---|---|---|---|---|
| | **Tray No.** | **M/L** | **56.6** | **66.7** | **66.7** | **71.2** |
| M.B.T. Revision Tray Size 1 | 1294-35-110 | 59.2 | | | |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

LPS inserts must match S-ROM or LPS femrurs size-to-size. For example, xx small femur = xx small polyethylene; small femur = small polyethylene, etc.




| | Description | Size | Cat. No. |
|---|---|---|---|
| A | Cemented Stem Reamer | 13 mm | 2178-63-185 |
| B | 2-Degree Cutting Block | | 2178-40-086 |
| C | Reamer Adapter | | 2178-63-128 |
| D | Tibial Punch Press-fit | | 2178-63-118 |
| E | Tibial Punch Cemented | | 2178-63-120 |
| F | Pin Holder | .125 in. | 2490-94-000 |
| G | SP2 Pin Puller | | 96-6515 |
| H | Drill Bushing | | 2178-63-100 |
| I | SP2 I.M. Rod | 400 mm | 96-6120 |
| J | I.M. Rod Handle | | 99-2011 |
| K | Cemented Bushing | 13 mm | 2178-63-196 |
| L | Tapered Press-fit Reamer | | 2178-63-104 |
| M | Tapered Cemented Reamer | | 2178-63-106 |
| N | Steinmann Pins | | 86-9117 |


| | Description | Size | Cat. No. |
|---|---|---|---|
| A | 2-Degree Broach | 29 mm | 2178-63-109 |
| B | 2-Degree Broach | 37 mm | 2178-63-111 |
| C | 2-Degree Broach | 45 mm | 2178-63-113 |
| D | 2-Degree Broach | 53 mm | 2178-63-115 |
| E | 2-Degree Broach | 61 mm | 2178-63-117 |
| F | Sleeve Trial | 29 mm | 2294-54-000 |
| G | Sleeve Trial | 37 mm | 2294-54-100 |
| H | Sleeve Trial | 45 mm | 2294-54-110 |
| I | Sleeve Trial | 53 mm | 2294-54-120 |
| J | Sleeve Trial | 61 mm | 2294-54-130 |
| K | M.B.T. Revision Tibial Broach Handle | | 96-6521 |
| L | I.M. Tibial Alignment Device | | 96-6315 |
| M | Tibial Stylus | | 2178-40-045 |
| N | Sleeve Impactor | | 2178-63-124 |
| O | Femoral Sleeve/Stem Impactor | | 2178-63-126 |
| P | Universal Handle | | 96-6520 |
| Q | Tray Impactor | | 96-5383 |
| R | View Plates | **Size** | **Cat. No.** |
| | | 1 | 2178-65-110 |
| | | 1.5 | 2178-65-115 |
| | | 2 | 2178-65-120 |
| | | 2.5 | 2178-65-125 |
| | | 3 | 2178-65-130 |
| | | 4 | 2178-65-140 |
| | | 5 | 2178-65-150 |
| | | 6 | 2178-65-160 |




| | Description | Size | Cat. No. |
|---|---|---|---|
| A | Press-fit Rod Wrench | | 86-5189 |
| B | Sleeve Guide | 12 mm | 2178-63-187 |
| C | Sleeve Guide | 14 mm | 2178-63-188 |
| D | Reamer Depth Scale | | 2178-63-102 |
| E | Revision Femoral/Tibial/Sleeve Clamp | | 2178-63-134 |
| F | I.M. Initiator Drill Tibial | 9 mm | 2189-03-000 |
| G | M.B.T. Revision Reamers | **Size** | **Cat. No.** |
| | | 10 mm | 2178-63-170 |
| | | 11 mm | 2178-63-171 |
| | | 12 mm | 2178-63-172 |
| | | 13 mm | 2178-63-173 |
| | | 14 mm | 2178-63-174 |
| | | 15 mm | 2178-63-175 |


| | Description | Size | Cat. No. |
|---|---|---|---|
| A | M.B.T. Revision Reamers | 16 mm | 2178-63-176 |
| | | 17 mm | 2178-63-177 |
| | | 18 mm | 2178-63-178 |
| | | 19 mm | 2178-63-179 |
| | | 20 mm | 2178-63-180 |
| | | 21 mm | 2178-63-181 |
| | | 22 mm | 2178-63-182 |
| | | 23 mm | 2178-63-183 |
| | | 24 mm | 2178-63-184 |
| B | Reamer T-handle | | 2178-63-137 |
| C | Hudson Adapter | | 2178-63-136 |
| D | I.M. Rod Sleeve Guide | 16 mm | 2178-63-189 |
| E | I.M. Rod Sleeve Guide | 18 mm | 2178-63-190 |
| F | I.M. Rod Sleeve Guide | 20 mm | 2178-63-191 |
| G | I.M. Rod Sleeve Guide | 22 mm | 2178-63-192 |
| H | I.M. Rod Sleeve Guide | 24 mm | 2178-63-193 |
| I | I.M. Rod Sleeve Guide | 26 mm | 2178-63-194 |

# REVISION STEM TRIALS & INSTRUMENTS STERILIZATION TRAY


| | Description | Size | Cat. No. |
|---|---|---|---|
| A | Revision Femoral/Tibial/Sleeve Clamp | | 2178-63-134 |
| B | Tibial Cemented Stem Trial | 13 x 60 2-3 | 86-6502 |
| C | Tibial Cemented Stem Trial | 13 x 30 1.5-3 | 86-6501 |
| D | Stem Trial Extractor | | 86-5226 |
| E | Fluted Tibial Rod Trials | **Size** | **Cat. No.** |
| | | 10 x 75 | 86-6874 |
| | | 12 x 75 | 86-6875 |
| | | 14 x 75 | 86-6876 |
| | | 16 x 75 | 86-6877 |
| | | 18 x 75 | 86-6878 |
| | | 20 x 75 | 86-6878 |
| | | 22 x 75 | 86-6880 |
| | | 24 x 75 | 86-6881 |

| | Description | Size | Cat. No. |
|---|---|---|---|
| F | Fluted Tibial Rod Trials | 10 x 115 | 86-6882 |
| | | 12 x 115 | 86-6883 |
| | | 14 x 115 | 86-6884 |
| | | 16 x 115 | 86-6885 |
| | | 18 x 115 | 86-6886 |
| | | 20 x 115 | 86-6887 |
| | | 22 x 115 | 86-6888 |
| | | 24 x 115 | 86-6889 |
| G | Fluted Tibial Rod Trials | 10 x 150 | 86-6890 |
| | | 12 x 150 | 86-6891 |
| | | 14 x 150 | 86-6892 |
| | | 16 x 150 | 86-6893 |
| | | 18 x 150 | 86-6894 |
| | | 20 x 150 | 86-6895 |
| | | 22 x 150 | 86-6896 |
| | | 24 x 150 | 86-6897 |

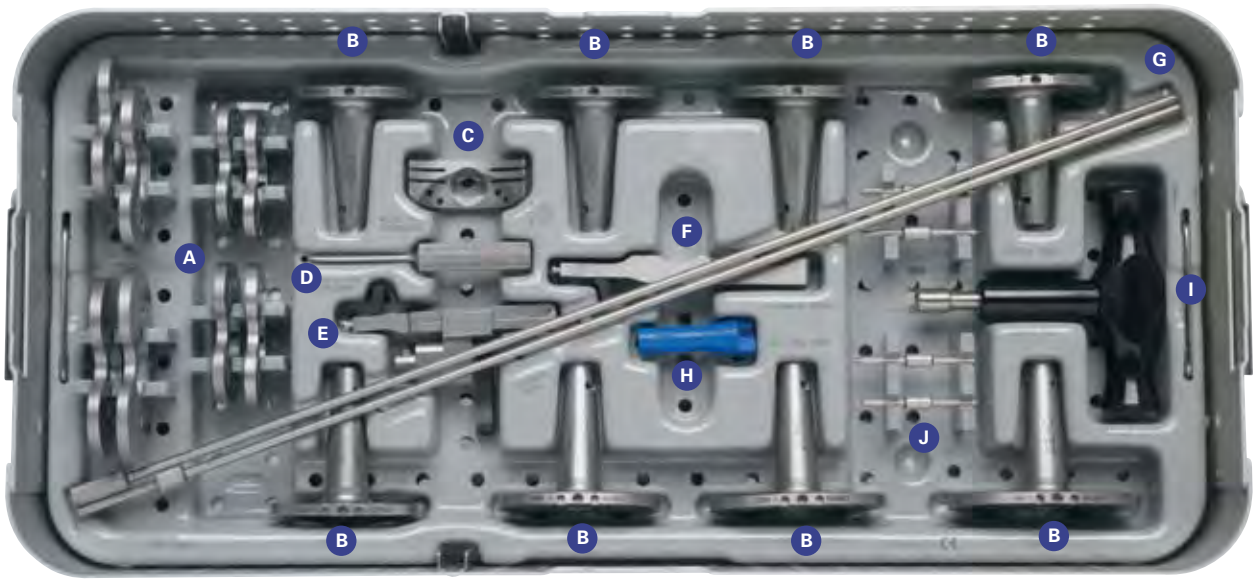

| | Description | Size | Cat. No. |
|---|---|---|---|
| A | Press-fit Rod Wrench | | 86-5189 |
| B | Tibial Cemented Stem Trial | 13 x 60 2-3 | 86-6502 |
| C | Tibial Cemented Stem Trial | 13 x 30 1.5-3 | 86-6501 |
| D | Fluted Tibial Rod Trials | **Size** | **Cat. No.** |
| | | 10 x 75 | 86-6874 |
| | | 12 x 75 | 86-6875 |
| | | 14 x 75 | 86-6876 |
| | | 16 x 75 | 86-6877 |
| | | 18 x 75 | 86-6878 |
| | | 20 x 75 | 86-6878 |
| | | 22 x 75 | 86-6880 |
| | | 24 x 75 | 86-6881 |

| | Description | Size | Cat. No. |
|---|---|---|---|
| E | Fluted Tibial Rod Trials | 10 x 115 | 86-6882 |
| | | 12 x 115 | 86-6883 |
| | | 14 x 115 | 86-6884 |
| | | 16 x 115 | 86-6885 |
| | | 18 x 115 | 86-6886 |
| | | 20 x 115 | 86-6887 |
| | | 22 x 115 | 86-6888 |
| | | 24 x 115 | 86-6889 |
| F | Fluted Tibial Rod Trials | 10 x 150 | 86-6890 |
| | | 12 x 150 | 86-6891 |
| | | 14 x 150 | 86-6892 |
| | | 16 x 150 | 86-6893 |
| | | 18 x 150 | 86-6894 |
| | | 20 x 150 | 86-6895 |
| | | 22 x 150 | 86-6896 |
| | | 24 x 150 | 86-6897 |

# M.B.T. REVISION TRAY TRIALS & WEDGE INSTRUMENTS STERILIZATION TRAY


| | Description | Size | Cat. No. |
|---|---|---|---|
| A | M.B.T. Step Wedge Trials | 5 mm | |
| | | 1 | 2294-56-110 |
| | | 1.5 | 2294-56-115 |
| | | 2 | 2294-56-120 |
| | | 2.5 | 2294-56-125 |
| | | 3 | 2294-56-130 |
| | | 4 | 2294-56-135 |
| | | 5 | 2294-56-140 |
| | | 6/7 | 2294-56-145 |
| B | M.B.T. Step Wedge Trials | 10 mm | |
| | | 1 | 2294-56-111 |
| | | 1.5 | 2294-56-116 |
| | | 2 | 2294-56-121 |
| | | 2.5 | 2294-56-126 |
| | | 3 | 2294-56-131 |
| | | 4 | 2294-56-136 |
| | | 5 | 2294-56-141 |
| | | 6/7 | 2294-56-146 |

| | Description | Size | Cat. No. |
|---|---|---|---|
| C | M.B.T. Step Wedge Trials | 15 mm | |
| | | 1 | 2294-56-112 |
| | | 1.5 | 2294-56-117 |
| | | 2 | 2294-56-122 |
| | | 2.5 | 2294-56-127 |
| | | 3 | 2294-56-132 |
| | | 4 | 2294-56-137 |
| | | 5 | 2294-56-142 |
| | | 6/7 | 2294-56-147 |

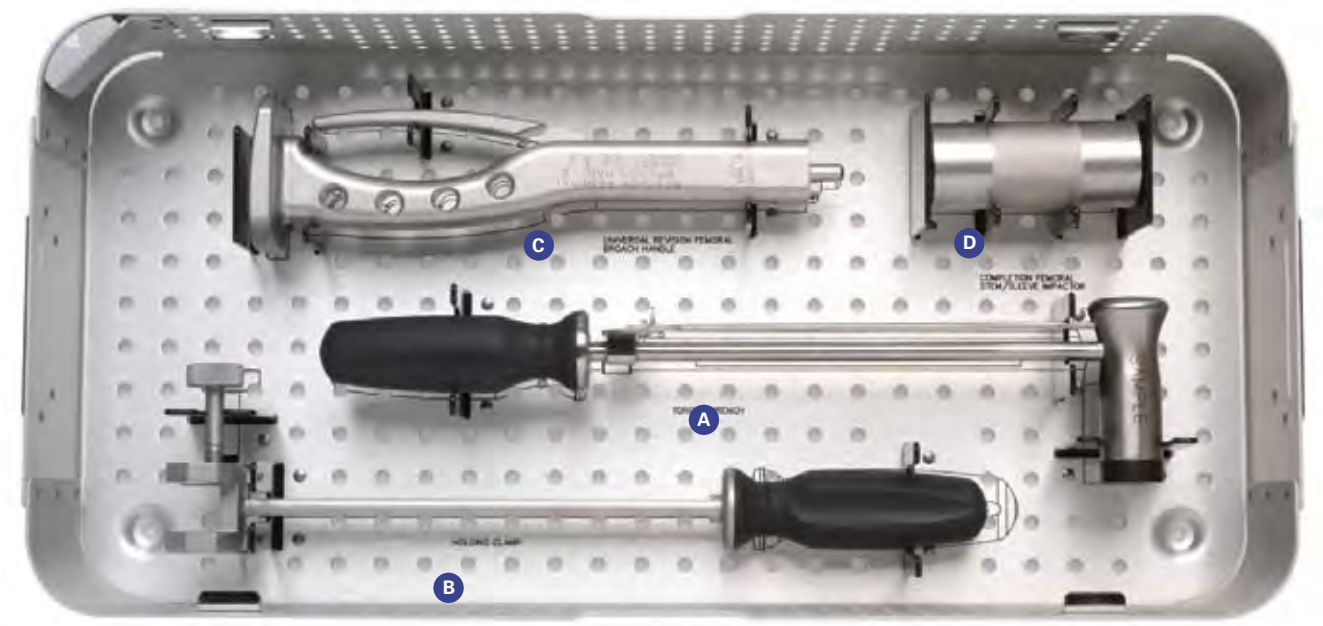



| Description | Size | Cat. No. |
|---|---|---|
| A M.B.T. Tibial Trials | | |
| | 1 | 2294-36-110 |
| | 1.5 | 2294-36-115 |
| | 2 | 2294-36-120 |
| | 2.5 | 2294-36-125 |
| | 3 | 2294-36-130 |
| | 4 | 2294-36-140 |
| | 5 | 2294-36-150 |
| | 6 | 2294-36-160 |
| B Tray Trials with Stem | **Size** | **Cat. No.** |
| | 1 | 2294-35-111 |
| | 1.5 | 2294-35-115 |
| | 2 | 2294-35-120 |
| | 2.5 | 2294-35-125 |
| | 3 | 2294-35-130 |
| | 4 | 2294-35-140 |
| | 5 | 2294-35-150 |
| | 6 | 2294-35-160 |

| Description | Size | Cat. No. |
|---|---|---|
| C Cut Block | | 2178-63-122 |
| D Screw Driver | | 86-0277 |
| E Wedge Cut Attachment | | 2178-63-130 |
| F Alignment Handle | | 96-6330 |
| G Alignment Rods | | 99-1016 |
| H Trial Post | | 2178-63-132 |
| I Torque Driver | | 86-0284 |
| J Fixation Pins | | 2178-30-123 |

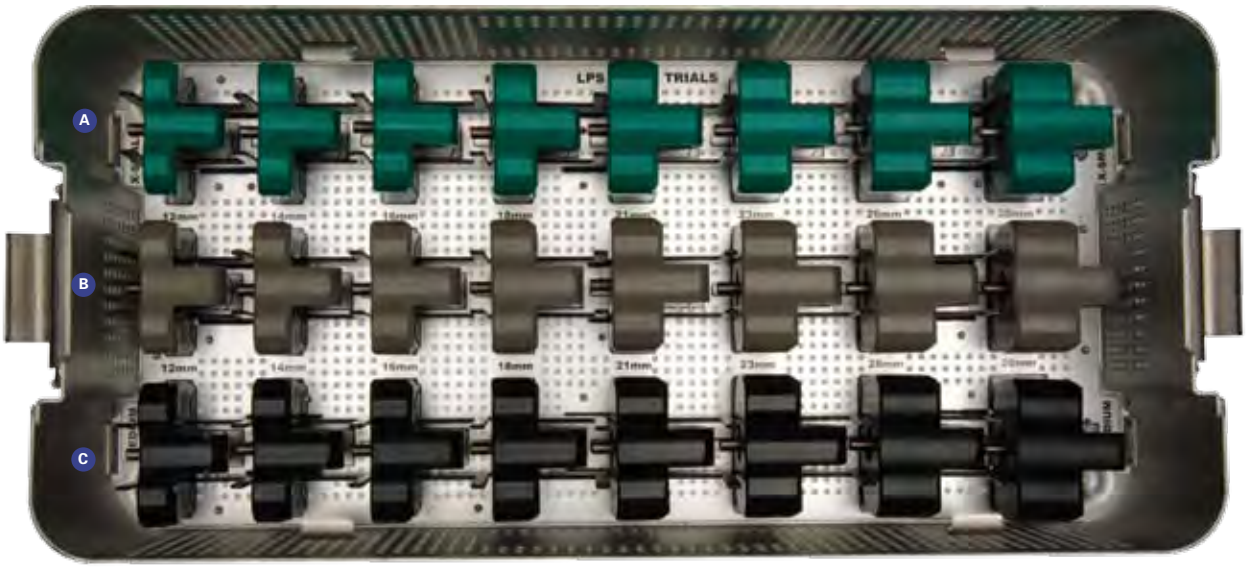
# SIGMA FEMORAL ADAPTER INSTURMENTS
# TOP TRAY - CAT. NO. 69 - 70


| | Description | Cat. No. |
|---|---|---|
| A | Universal Revision Femoral Broach Reamer | 96-1671 |
| B | P.F.C. Sigma Femoral Adapter Removable Shaft | 96-1670 |
| C | Universal Revision Femoral Broach, 31 mm | 96-1683 |
| D | Universal Revision Femoral Broach, 34 mm | 96-1684 |
| E | Universal Revision Femoral Broach, 40 mm | 96-1685 |
| F | Universal Revision Femoral Broach, 46 mm | 96-1686 |
| G | Completion Revision Femoral Tapered Reamer | 2178-60-030 |
| H | P.F.C. Sigma Femoral Adapter Stem Bolt Trial, 2 mm Offset | 96-1779 |
| I | P.F.C. Sigma Femoral Adapter Stem Bolt Trial, Neutral | 96-1780 |
| J | P.F.C. Sigma Femoral Adapter Sleeve Bolt Trial, 2 mm Offset | 96-2777 |
| K | P.F.C. Sigma Femoral Adapter Sleeve Bolt Trial, Neutral | 96-1777 |
| L | P.F.C. Sigma Femoral Adapter Trial, 5 Degree | 96-1774 |
| M | P.F.C. Sigma Femoral Adapter Trial, 7 Degree | 96-1778 |
| N | LCS/P.F.C. Sigma Complete Femoral Sleeve Trial 20 mm | 2294-53-100 |
| O | LCS/P.F.C. Sigma Complete Femoral Sleeve Trial 31 mm | 2294-53-110 |
| P | LCS/P.F.C. Sigma Complete Femoral Sleeve Trial 34 mm | 2294-53-120 |
| Q | LCS/P.F.C. Sigma Complete Femoral Sleeve Trial 40 mm | 2294-53-130 |
| R | LCS/P.F.C. Sigma Complete Femoral Sleeve Trial 46 mm | 2294-53-140 |

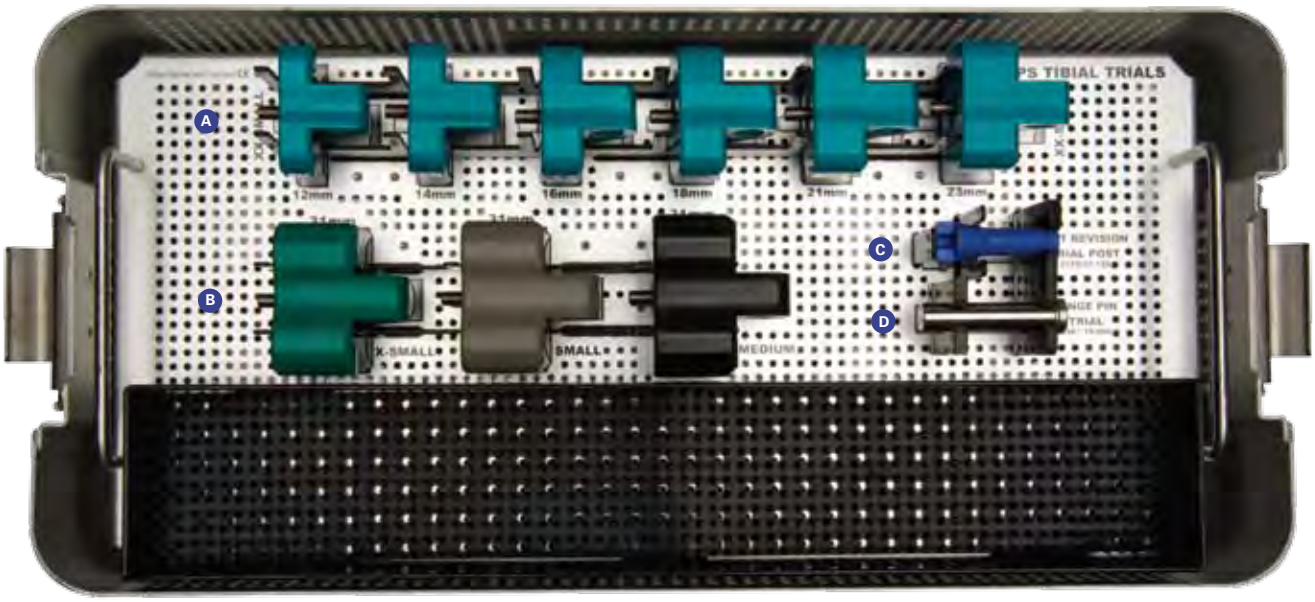



| | Description | Cat. No. |
|---|---|---|
| A | P.F.C. Sigma Femoral Adapter Torque Wrench | 96-1673 |
| B | P.F.C. Sigma Femoral Adapter Holding Clamp | 96-1674 |
| C | Universal Revision Femoral Broach Handle | 96-1682 |
| D | Completion Femoral Stem/Sleeve Impactor | 2178-63-126 |

# LPS HINGE INSERT TRIALS




| Description | | Cat. No. |
|---|---|---|
| A Xsm Hinged Insert Trials | LPS Hinge Insert Trial 12 mm, Xsm | 2987-22-112 |
| | LPS Hinge Insert Trial 14 mm, Xsm | 2987-22-114 |
| | LPS Hinge Insert Trial 16 mm, Xsm | 2987-22-116 |
| | LPS Hinge Insert Trial 18 mm, Xsm | 2987-22-118 |
| | LPS Hinge Insert Trial 21 mm, Xsm | 2987-22-121 |
| | LPS Hinge Insert Trial 23 mm, Xsm | 2987-22-123 |
| | LPS Hinge Insert Trial 26 mm, Xsm | 2987-22-126 |
| | LPS Hinge Insert Trial 28 mm, Xsm | 2987-22-128 |
| B Sm Hinged Insert Trials | LPS Hinge Insert Trial 12 mm, Sm | 2987-22-212 |
| | LPS Hinge Insert Trial 14 mm, Sm | 2987-22-214 |
| | LPS Hinge Insert Trial 16 mm, Sm | 2987-22-216 |
| | LPS Hinge Insert Trial 18 mm, Sm | 2987-22-218 |
| | LPS Hinge Insert Trial 21 mm, Sm | 2987-22-221 |
| | LPS Hinge Insert Trial 23 mm, Sm | 2987-22-223 |
| | LPS Hinge Insert Trial 26 mm, Sm | 2987-22-226 |
| | LPS Hinge Insert Trial 28 mm, Sm | 2987-22-228 |
| C Med Hinged Insert Trials | LPS Hinge Insert Trial 12 mm, Med | 2987-22-312 |
| | LPS Hinge Insert Trial 14 mm, Med | 2987-22-314 |
| | LPS Hinge Insert Trial 16 mm, Med | 2987-22-316 |
| | LPS Hinge Insert Trial 18 mm, Med | 2987-22-318 |
| | LPS Hinge Insert Trial 21 mm, Med | 2987-22-321 |
| | LPS Hinge Insert Trial 23 mm, Med | 2987-22-323 |
| | LPS Hinge Insert Trial 26 mm, Med | 2987-22-326 |
| | LPS Hinge Insert Trial 28 mm, Med | 2987-22-328 |




| | Description | Cat. No. | |
|---|---|---|---|
| A | XXSm Hinged Insert Trials | LPS Hinge Insert Trial XX-Sm 12 mm | 2987-22-012 |
| | | LPS Hinge Insert Trial XX-Sm 14 mm | 2987-22-014 |
| | | LPS Hinge Insert Trial XX-Sm 16 mm | 2987-22-016 |
| | | LPS Hinge Insert Trial XX-Sm 18 mm | 2987-22-018 |
| | | LPS Hinge Insert Trial XX-Sm 21 mm | 2987-22-021 |
| | | LPS Hinge Insert Trial XX-Sm 23 mm | 2987-22-023 |
| B | 31mm Hinged Insert Trials | LPS Hinge Insert Trial 31 mm, Xsm | 2987-22-131 |
| | | LPS Hinge Insert Trial 31 mm, Sm | 2987-22-231 |
| | | LPS Hinge Insert Trial 31 mm, Med | 2987-22-331 |
| C | MBT Rev Trial Post | | 2178-63-132 |
| D | LPS Hinge Pin Trial | | 2987-15-000 |

## 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 NOILES Rotating Hinge Knee is indicated for use with PMMA bone cement in primary or revision cases in patients:

- who have reached skeletal maturity
- 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,
  - or trauma

## Contraindications

Infections; vascular insufficiency, muscular atrophy or neuromuscular disease; loss of osteochondral structure that would preclude proper fixation of the prosthesis; tumors, systemic and metabolic disorders leading to deterioration of bone support; drug or alcohol addiction or limiting neuropathic disease; skeletal immaturity; 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; allergic reaction to the implant materials; 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.
The S-ROM tibial base, tibial sleeve, tibial stem extension, and tibial augmentation blocks may not be used with the NOILES Posterior Stabilized Knee.

## Precautions

The NOILES Rotating Hinge Knee is designed to articulate from 6° hyperextension to 110° flexion. If, due to grossly inadequate soft tissue integrity, flexion beyond 90° causes luxation of the plateau assembly out of the tibial base, the patient must have a knee brace postoperatively to limit flexion to 90°. 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 the tibial 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.
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.

## 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.

## REFERENCES

1. Jones, R. E., “Management of the Bone-Deficient Knee Management of Complex Revision Problems with a Modular Total Knee System” Orthopedics, Sept. 1996: 802-804.

2. Jones, R.E. , R.L. Barrack, “Modular, Mobile-Bearing Hinge Total Knee Arthroplasty,” Presented at 2001 AAOS.

The S-ROM Noiles Rotating Hinge Knee has been cleared for cemented application.

For more information about the S-ROM Noiles Rotating Hinge Knee, visit our web site at **www.jnjgateway.com/sromknee**.

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