SIGMA®

Sigma® Revision and M.B.T. Revision Tray

Surgical Technique

KNEE
REVISION

DePuy
a Johnson & Johnson company

Contents

Sigma Revision / M.B.T. Revision Tray Knee Surgery*

Introduction

In total knee arthroplasty (TKA), failure may result from many causes including: wear, aseptic loosening, infection, osteolysis, ligamentous instability, arthrofibrosis and patellofemoral complications. In approaching revision procedures, the surgeon must address such considerations as the planning of an incision in a previously operated site, the condition of the soft tissue, mobilization of the extensor mechanism, extraction of the primary prosthesis and the attendant conservation of bone stock. Among the goals of successful revision arthroplasty are the restoration of anatomical alignment and functional stability, fixation of the revision implants and accurate re-establishment of the joint line. Careful selection of the appropriate prosthesis is of paramount importance. Ideally, the revision knee replacement system will offer the options of adjunctive stem fixation and variable stem positions, femoral and tibial augmentation and various levels of prosthetic constraint.

Preoperative Planning

Revision total knee arthroplasty begins with thorough clinical and roentgenographic evaluation. Physical evaluation includes the examination of the soft tissues, taking into account previous skin incisions, range of motion, motor strength, the condition of all neurovascular structures, ligamentous stability and the integrity of the extensor mechanism.

Biplanar radiographic views are obtained, as are tangential views of the patella and full-length standing bilateral extremity views for the assessment of alignment and bone stock, documentation of the joint line and evaluation of the present implant fixation. Stress views are helpful in evaluating ligamentous instability. CAT and MRI scans may at times be of value in cases of massive bone loss or substantial anatomic distortion from trauma and metabolic bone disorders. Templates are employed to establish replacement implant size and the alignment of bone cuts, to indicate augmentation of skeletal deficits and to confirm the anatomic joint line.

*The Sigma Revision Knee System is intended for cemented use only.

The Sigma Revision 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 Sigma Revision Knee System is Comprised of the Following Components:

- Stabilized Femoral Component is available in seven sizes
- TC3 Femoral Component is available in six sizes
- Modular Femoral Stem, known as the Sigma Femoral Adapter, which allows the use of the Femoral Metaphyseal Sleeves and Universal Stems. Available in 5 and 7 degree valgus angles
- 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
- 4 mm, 8 mm, 12 mm and 16 mm Distal Femoral Augmentations
- 4 mm and 8 mm Posterior Femoral Augmentations
- Three anteroposterior stem positions: 0, +2 mm and -2 mm
- 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)

Surgical Technique

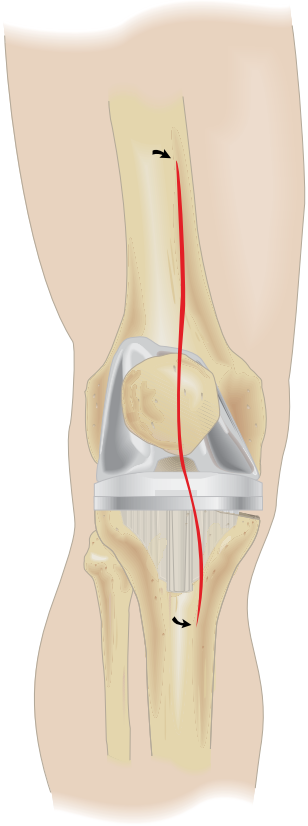


Figure 1

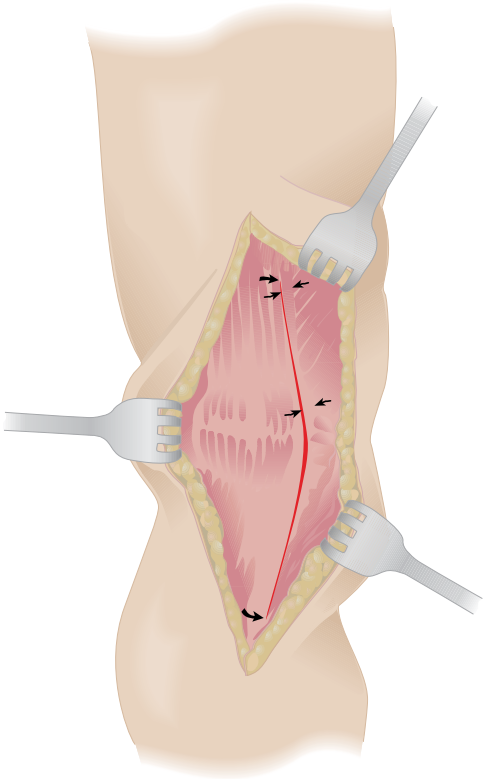


Figure 2

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 preoperative soft tissue expansion and plan for appropriate soft tissue coverage at closure.

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.

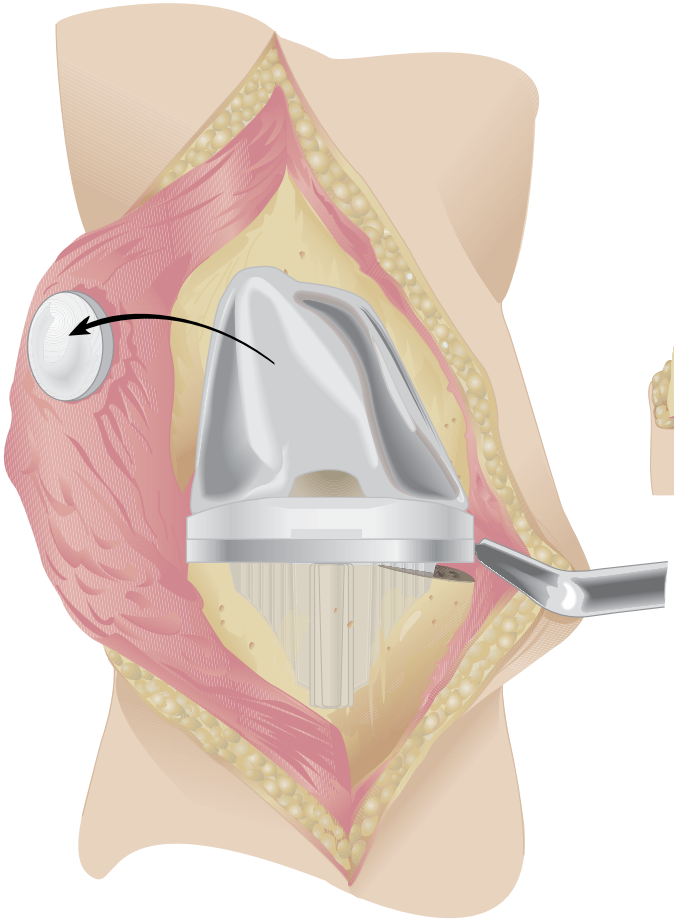


Figure 3

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 preoperative and intraoperative 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 aversion.

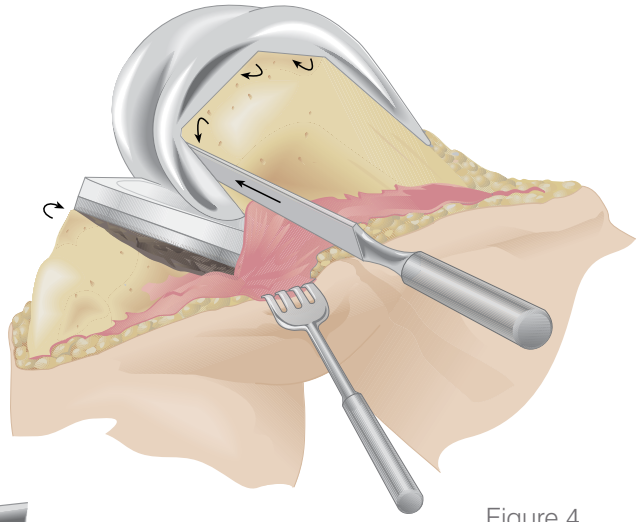


Figure 4

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 high-speed 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.

Intraoperative Evaluation

Recommended Surgical Priority

1. Tibial medullary canal preparation
2. Proximal tibial resection
3. Femoral medullary canal preparation
4. Distal femoral resection
5. Establishment of femoral rotation
6. Anteroposterior, notch and chamfer resection
7. Establishment of tibial rotation
8. Tibial deficit augmentation
9. Final tibial preparation
10. Patellar preparation
11. Implantation of the components

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 (Figure 5).

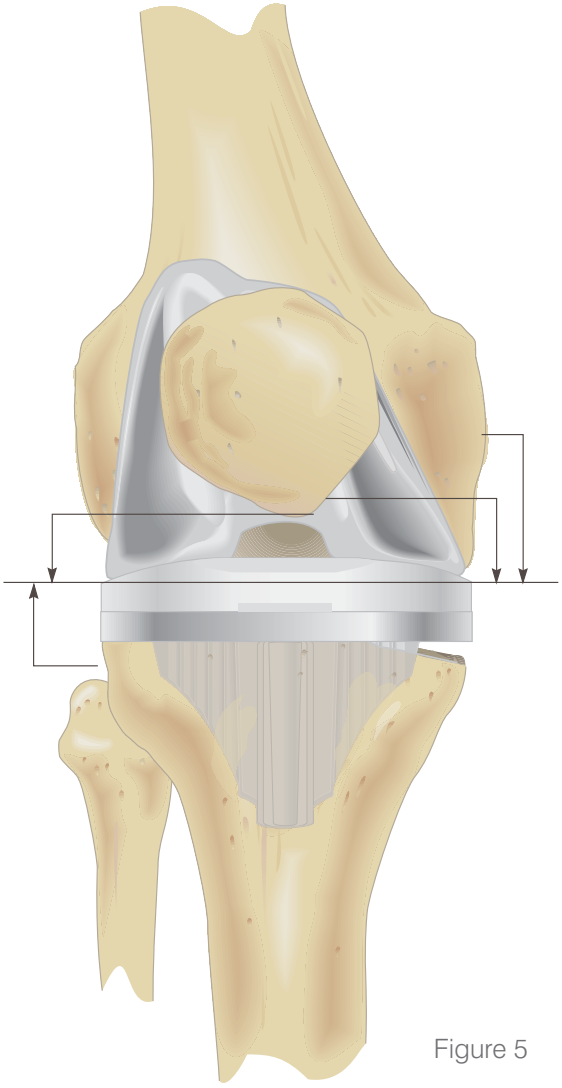


Figure 5

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 preoperative joint line assessment tools include:

1. Review of original preoperative roentgenogram of the TKA
2. Review of roentgenogram of contralateral knee if non-implanted

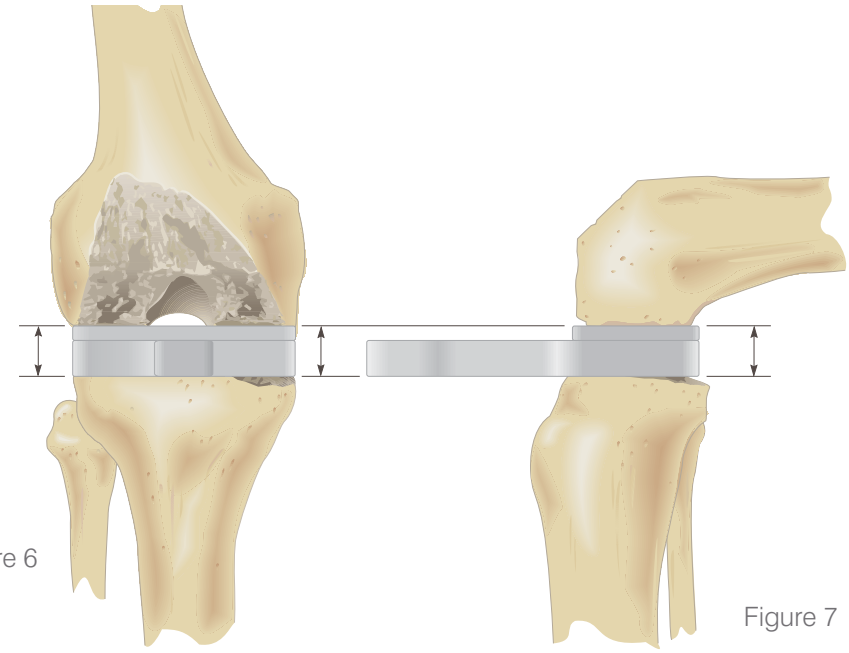


Figure 6

Figure 7

Joint Space Assessment

Joint space is evaluated with spacer blocks to determine the flexion/extension gap relationship and the symmetry of both the flexion and extension gaps, and to indicate if prosthetic augmentation is needed to ensure postoperative equivalence (Figure 6). A 1 mm shim should be used for the extension gap and removed when assessing the flexion gap (Figure 7). This will compensate for the 1 mm component difference between the distal and posterior condyles.

Size the tibia first and initially choose the same size of femoral component. This can then be adjusted to accommodate the following:

Where flexion gap >extension gap:

To decrease flexion gap without affecting extension gap, apply a larger femoral component. This is particularly important where an IM stem extension is indicated, as the stem extension will determine the anteroposterior positioning of the component and the consequent flexion gap.

Where stem positioning will not permit posterior augmentation, assemble a 2 mm offset stem bolt with the arrow pointing anteriorly to the component, translating the femoral component 2 mm posteriorly. (Refer to page 34 for further explanation.)

Where there is insufficient stability, a cemented femoral stem may be substituted, allowing the component to be seated further posteriorly.

Where the joint line is elevated, the preferred correction is posterior femoral augmentation. The alternative—additional distal femoral resection and use of a thicker tibial insert to tighten the flexion gap—is not recommended, as considerable bone stock has been sacrificed in the primary procedure, and it is important that additional resection of the distal femur be avoided. The possible exception is where the joint line is not elevated and minimal distal resection will increase the extension gap toward equivalency with the flexion gap.

Where significant flexion laxity persists despite these maneuvers, consider the use of the TC3 component.

Where extension gap >flexion gap:

To decrease extension gap without affecting flexion gap, augment the distal femur with bone graft or prosthetic augmentation. It is important to note that this will lower the joint line, which is usually desirable as it is generally found to be elevated in revision cases. This will lessen the incidence of postoperative patellar infera.

Initial Preparation of the Tibia

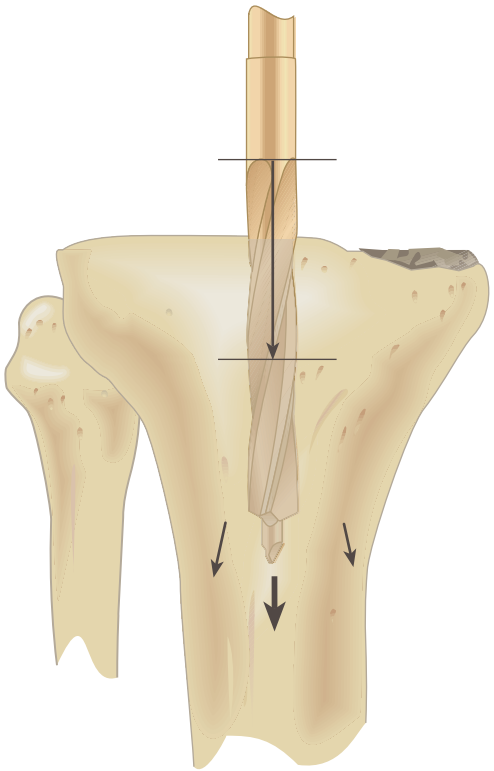


Figure 8

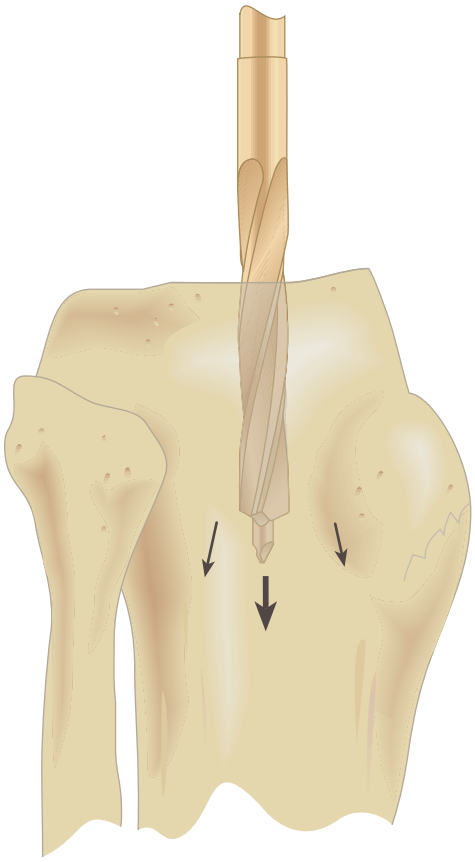


Figure 9

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 I.

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 8 and 9).

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 10).

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.

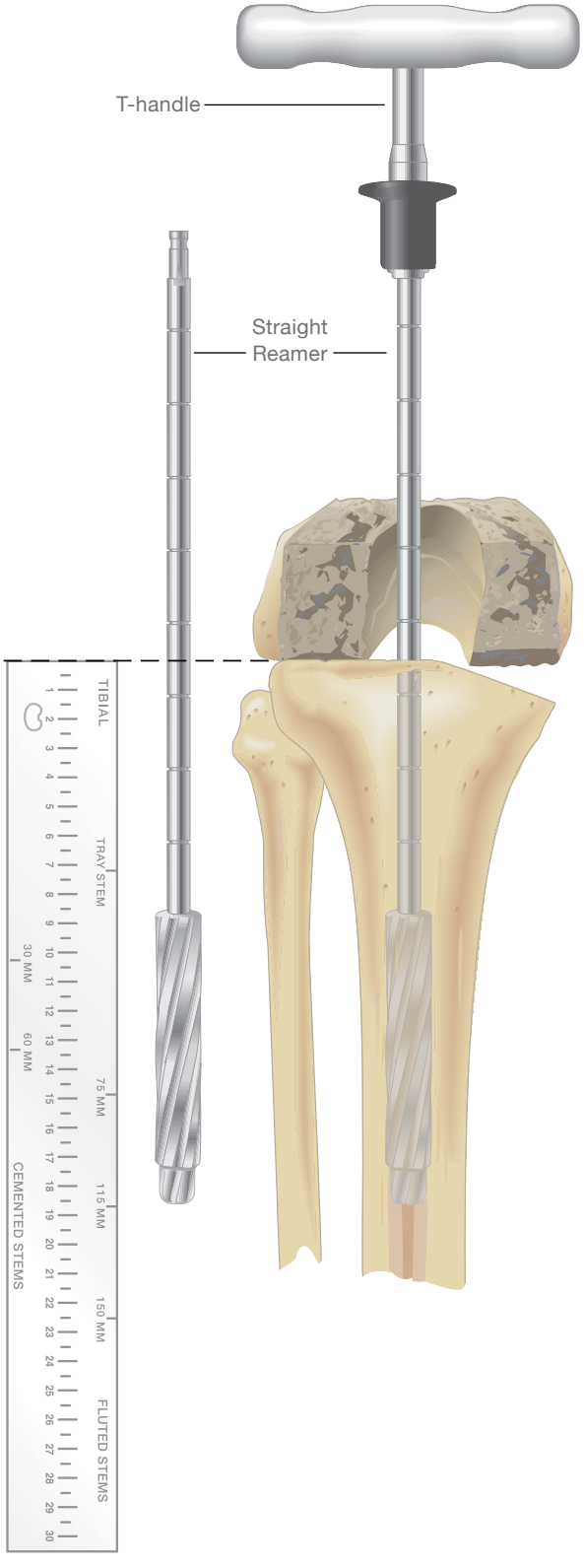


Figure 10

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 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 11).

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 (Figure 11). 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 12 in order to broach the metaphyseal bone.

If a metaphyseal sleeve will not be used, see page 10 to prepare for the proximal tibial resection.

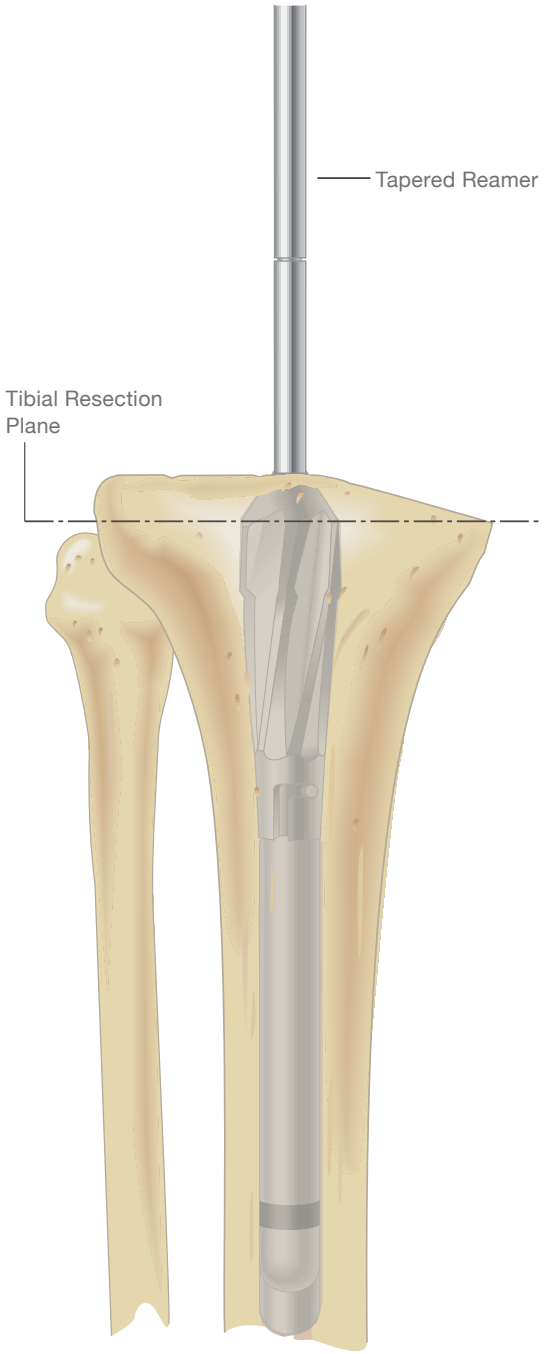


Figure 11

Proximal Tibial Resection – Tapered Reamer

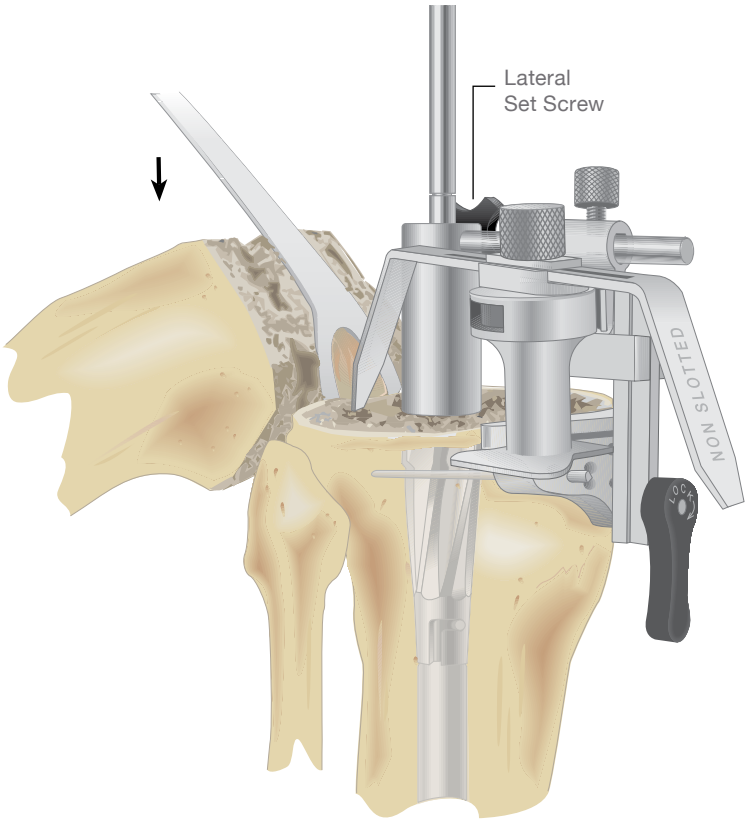


Figure 12

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 12)

Pin the tibial cutting block so a minimal resection is made from the proximal tibia. Utilize the stylus when necessary. (Figure 12)

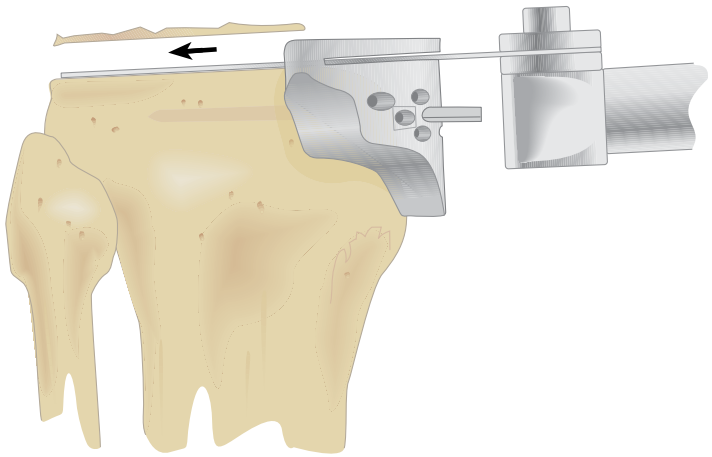


Figure 13

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 13, Figure 15)

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 13) (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.

Preparation of the Metaphyseal Bone–Broach

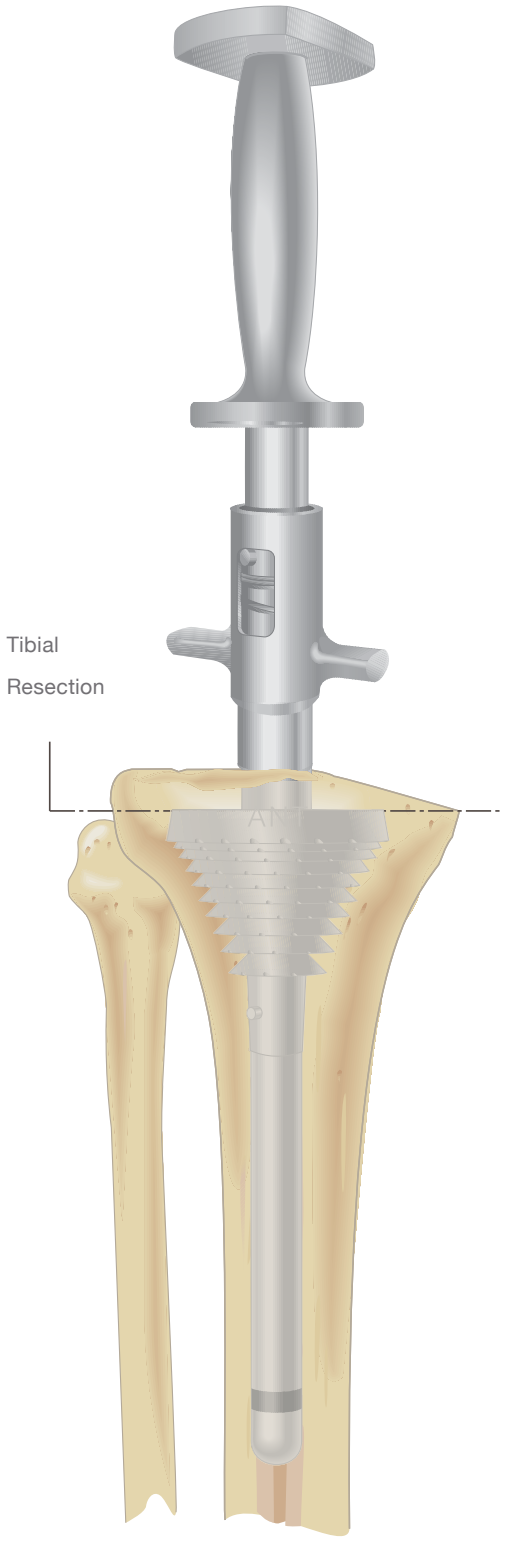


Figure 14

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 14). 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.

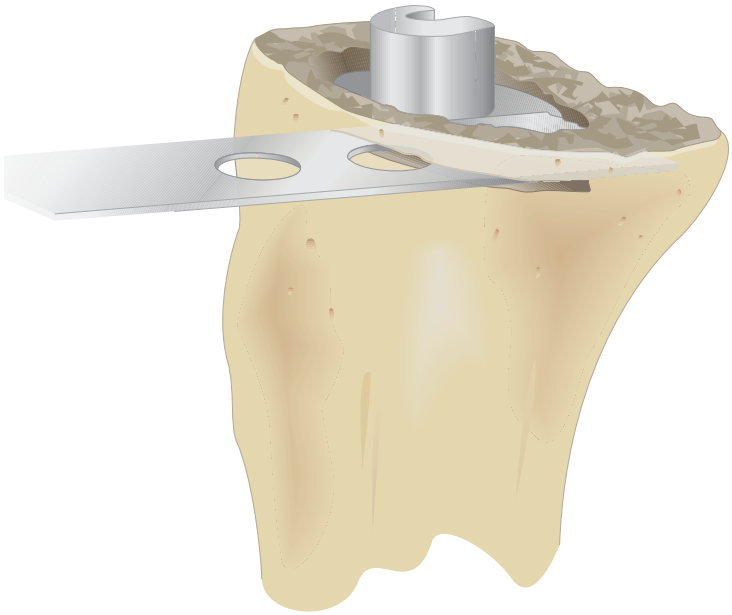


Figure 15

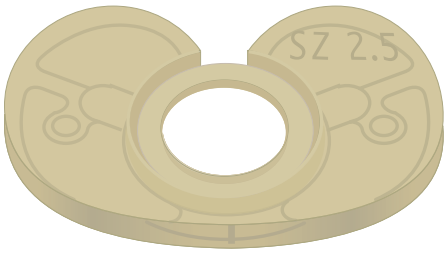


Figure 16

When utilizing a sleeve, resect the tibia off the top of the broach. (Figure 15)

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.

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 16). The template matches the implant to aid in orienting the tibial sleeve to the tibial base during assembly.

Preparation of Femoral Diaphysis

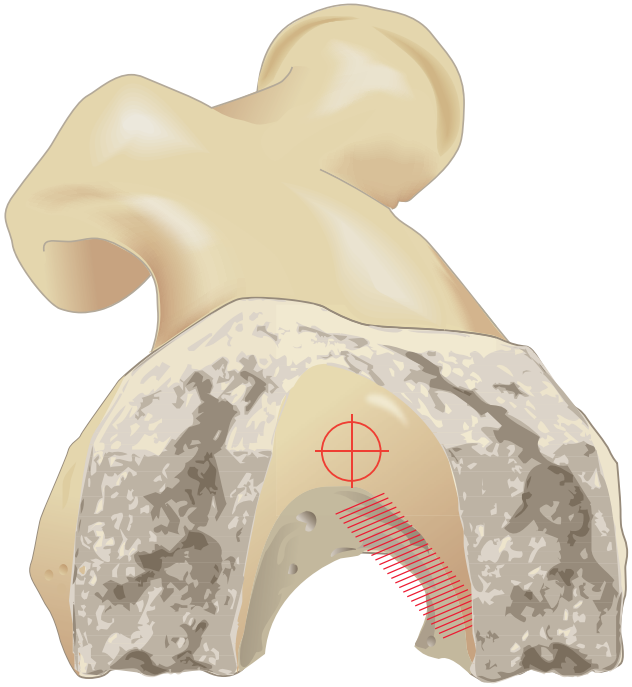


Figure 17a

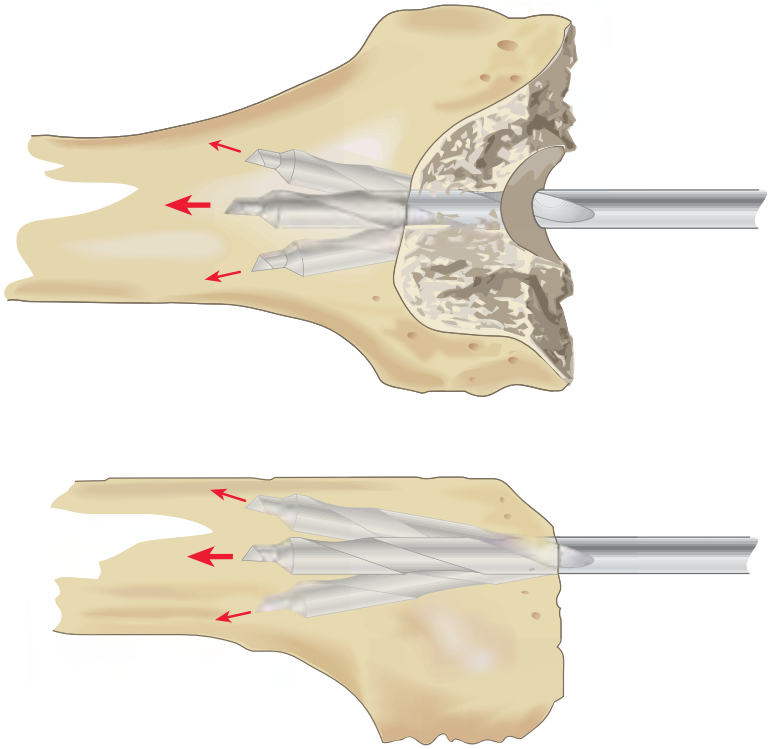


Figure 17b

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 17a and 17b).

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.

Reaming the Medullary Canal

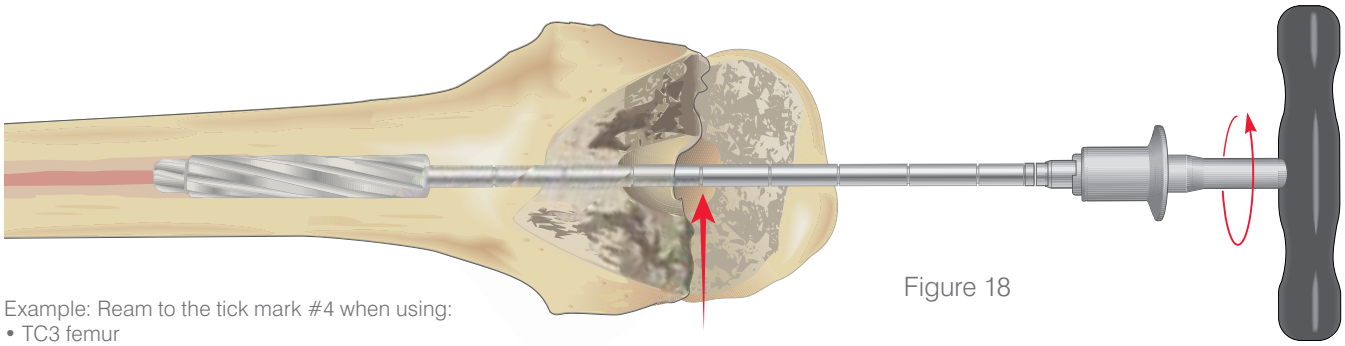


Figure 18

Example: Ream to the tick mark #4 when using:
- TC3 femur
- 60 mm cemented stem
- 46 mm sleeve

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 18). Use the Reamer Depth Chart (Figure 19) 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 P.F.C. Sigma Femoral Component accepts:

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

C/S Femur		Sleeves		
		No Sleeve	20 mm 31 mm 34 mm	40 mm 46 mm
Cemented Stems	30 mm	1	2	2
	60 mm	2	3	3
	90 mm	4	5	5
	120 mm	4	6	6
	150 mm	5	7	7
Universal Slotted Stems	75 mm	2	4	4
	115 mm	4	5	6
	150 mm	5	7	7

TC3 Femur		Sleeves		
		No Sleeve	20 mm 31 mm 34 mm	40 mm 46 mm
Cemented Stems	30 mm	1	2	2
	60 mm	2	3	4
	90 mm	4	5	6
	120 mm	4	6	6
	150 mm	6	7	7
Universal Slotted Stems	75 mm	3	4	4
	115 mm	4	5	6
	150 mm	6	7	7

Figure 19

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.

Do not reverse ream.

It is important that simple cortical contact of the tip not be construed as engagement as it is the fixed relationship of the reamer to the cortices that ensures the secure fit of the appropriate sleeve and subsequently, the corresponding fluted or cemented stem.

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.

Figure 20

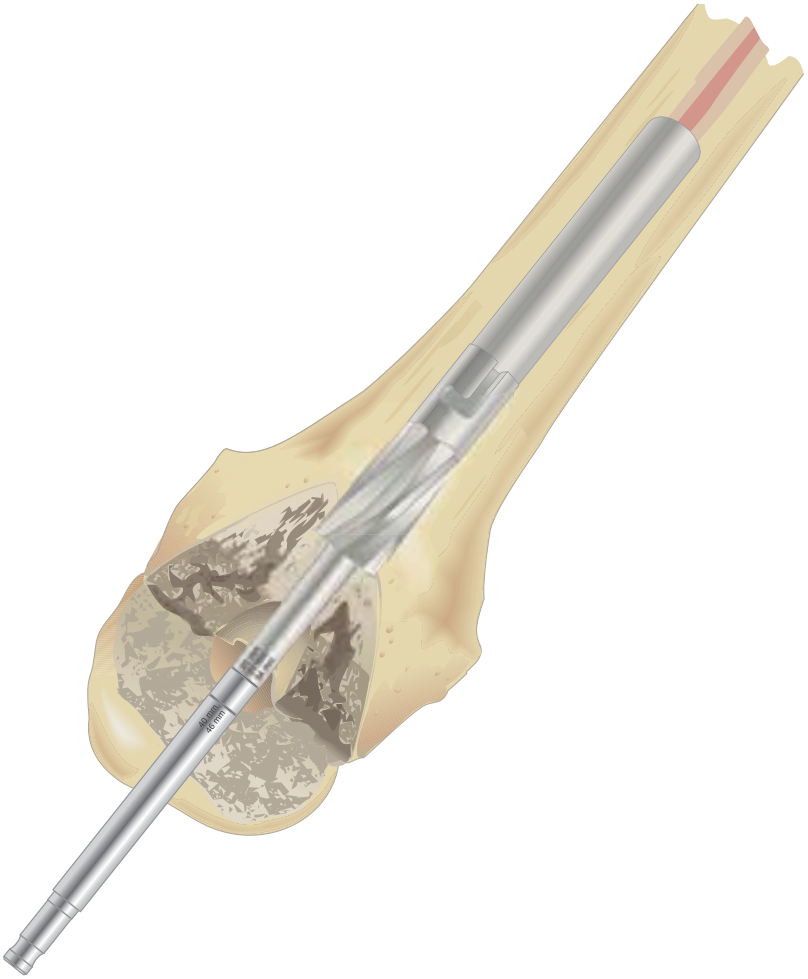


Figure 21

Universal Fluted Stem Use:

As fluted stems are available in even sizes (10 through 24 mm diameters), perform final reaming with the appropriate even-sized reamer.

Note: For stem-only applications, where a fluted stem less than 16 mm in diameter is chosen, use the stem reamer to clear the area around the adapter.

Attach the threaded shaft to the stem reamer and then attach the appropriate stem trial to this assembly (Figure 20). Ream the canal (Figure 21).

For trial and implant assembly with stem-only use, please see page 56 in Appendix 4.

Preparation of the Metaphysis (for Sleeve Use)

Figure 22

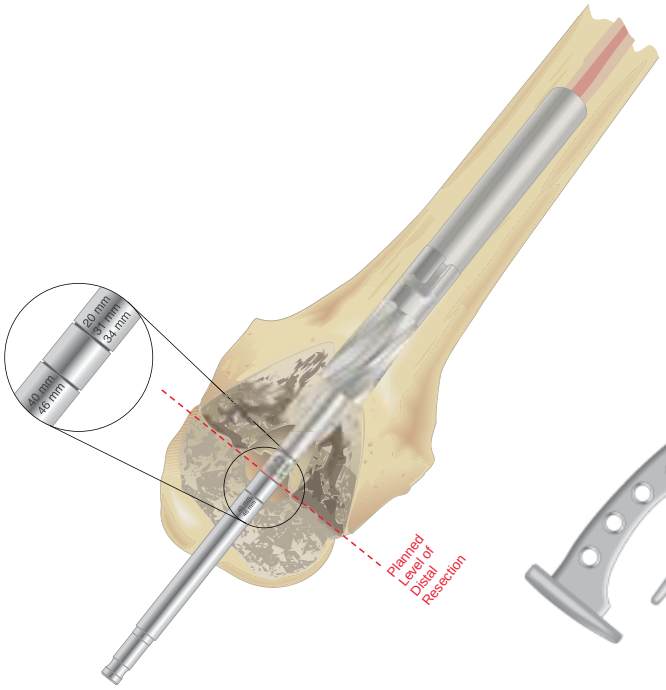


Figure 23

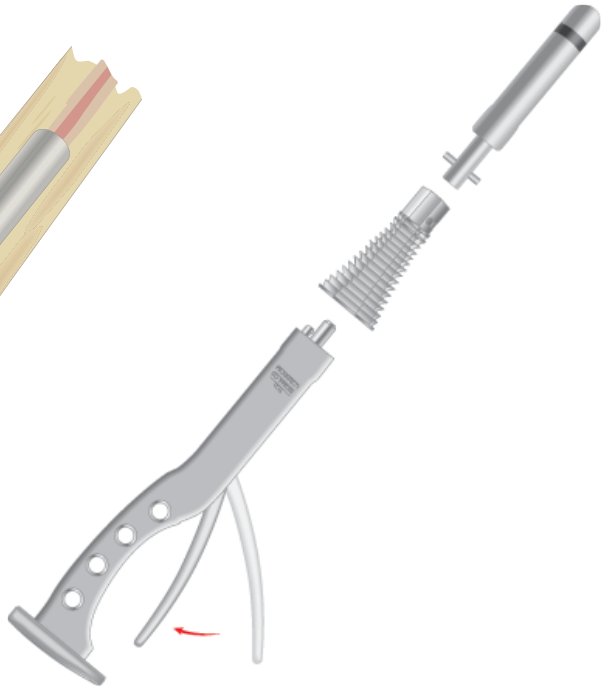


Figure 24

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 22).

Ream to the appropriate etch mark on the threaded shaft (Figure 23).

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 24). Attach the appropriate stem trial to the broach as determined by straight reaming.

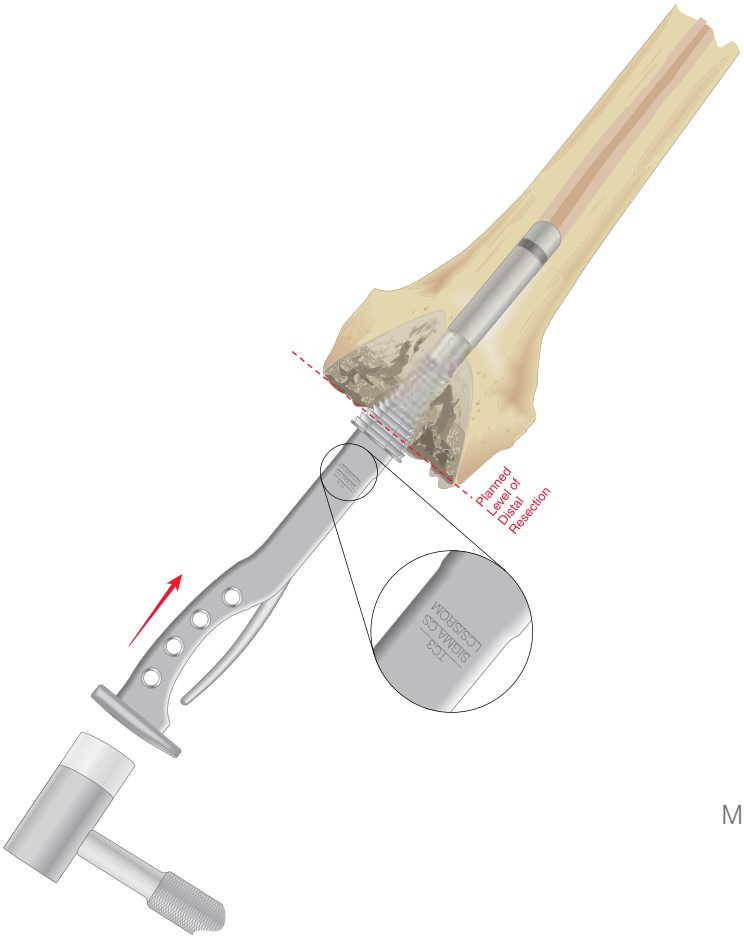


Figure 25

Figure 26

Sequentially broach to the desired dimension of 31, 34, 40 or 46 mm (Figure 25). 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 26).

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.

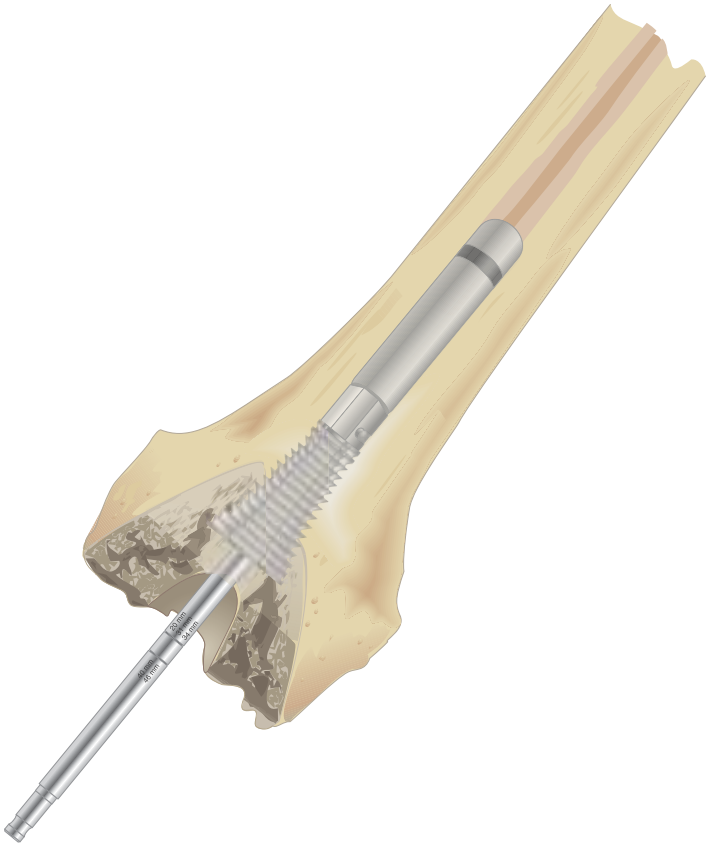


Figure 27

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, as shown in Figure 27, and continue with the distal, A/P and finish cuts.

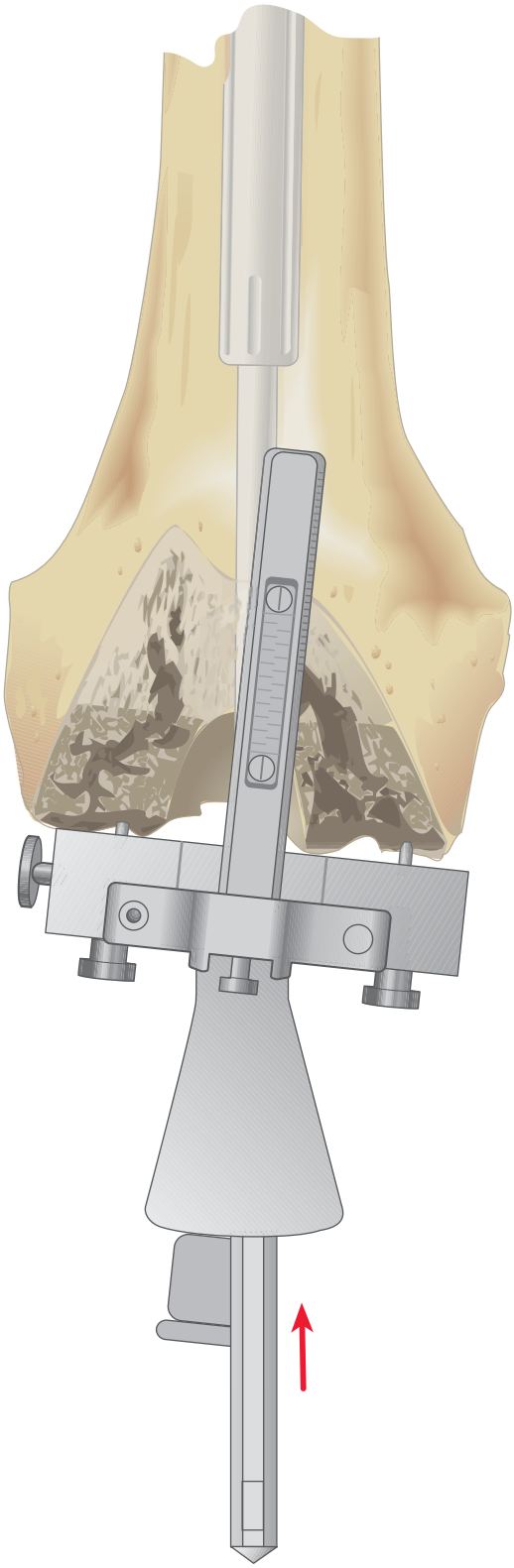


Figure 28

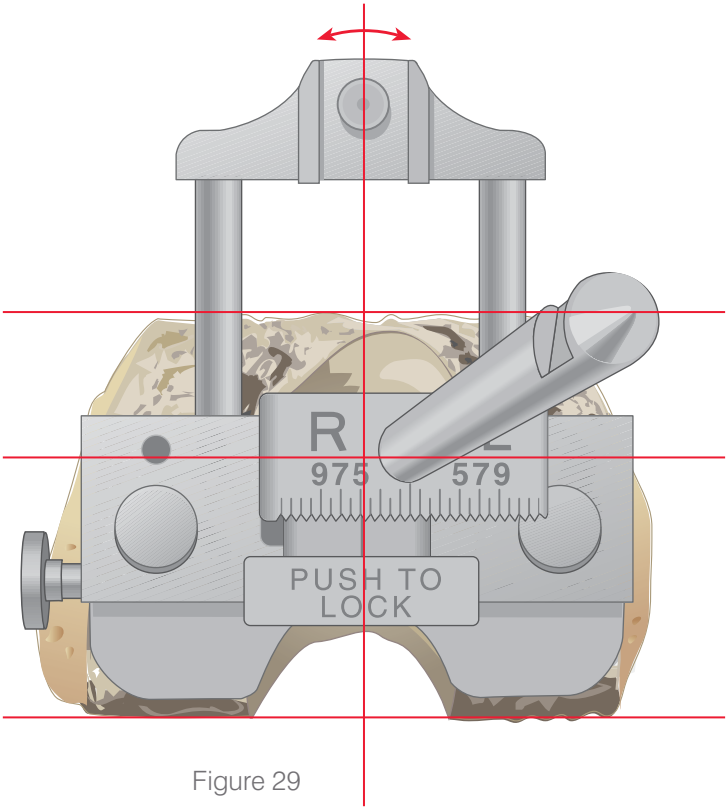


Figure 29

The Femoral Locating Device

Determine the appropriate valgus angle through the application of templates to the preoperative roentgenogram. Set the appropriate valgus angle, 5 degree or 7 degree, and Right/Left knee indication and lock into place on the front of the locating device. Place the locating device (Figure 28) over the M.B.T. Revision Reamer, or 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 29).

Note: IM rod and sleeve can be used in place of M.B.T. Revision Reamer.

Distal Resection

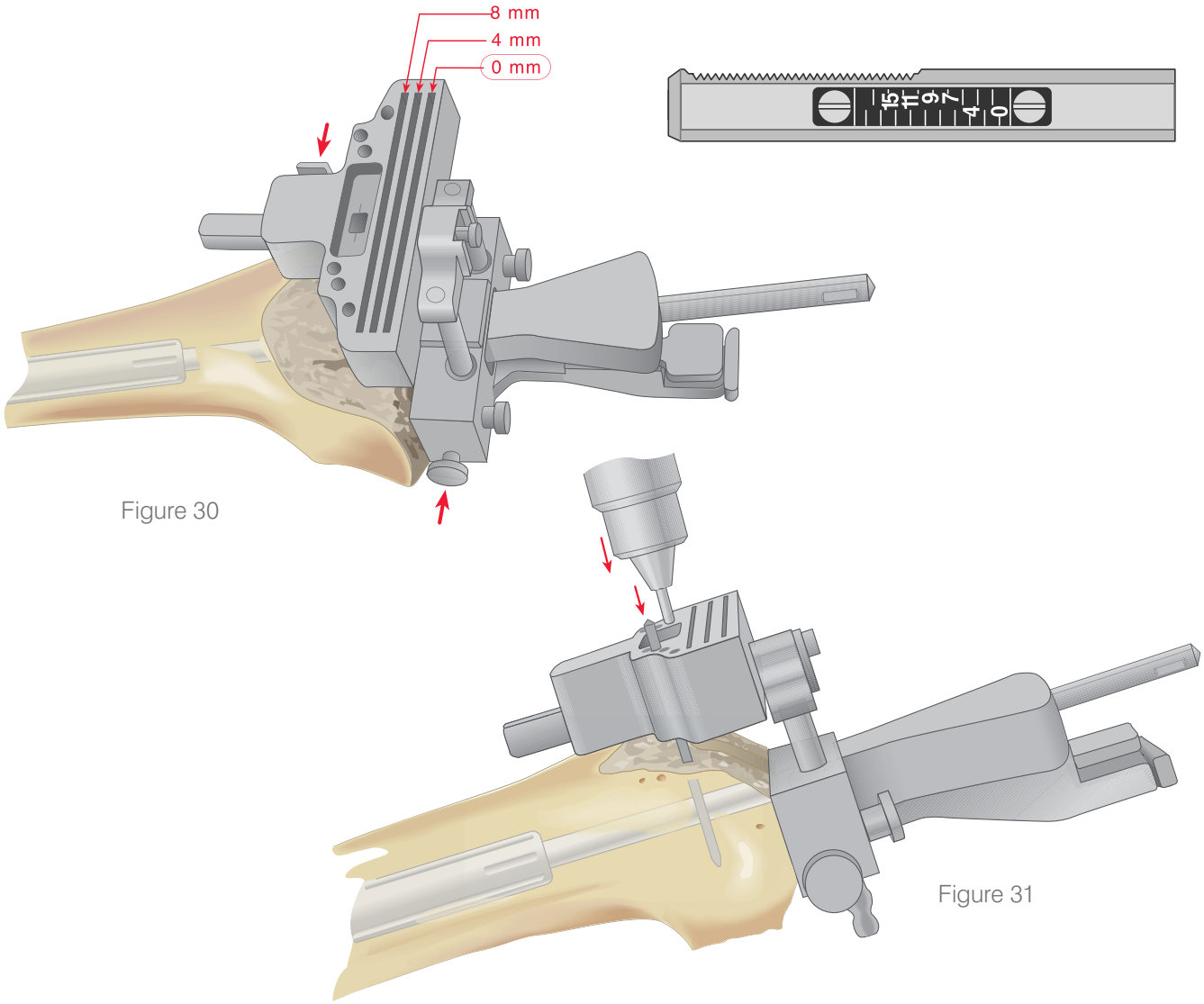


Figure 30

Figure 31

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 30). 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 31).

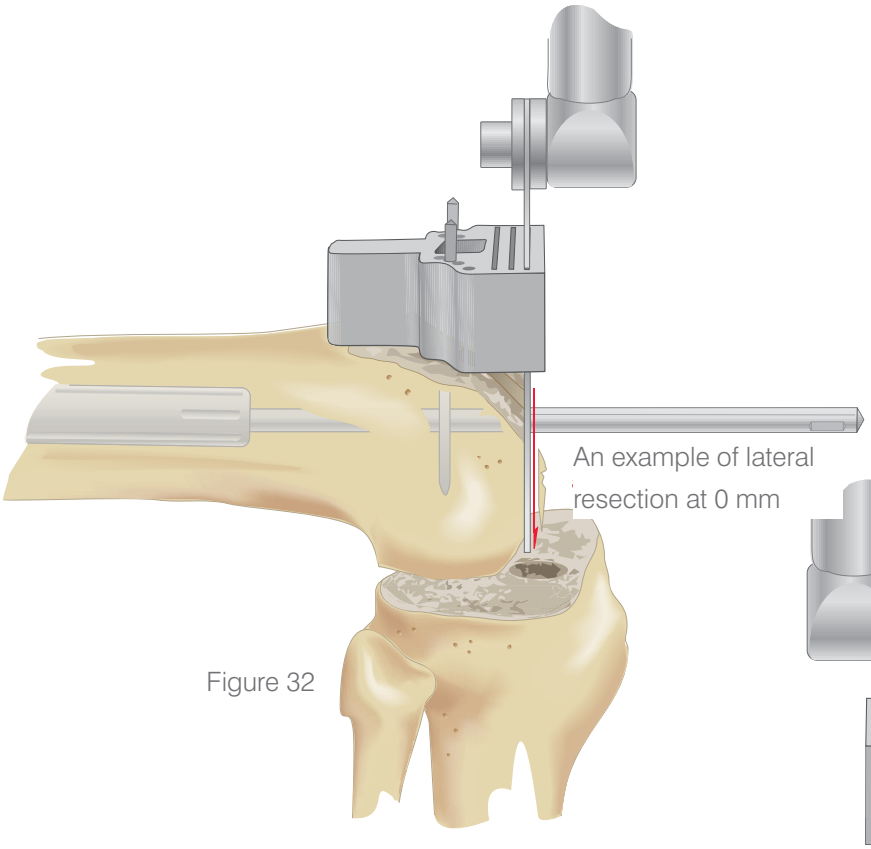


Figure 32

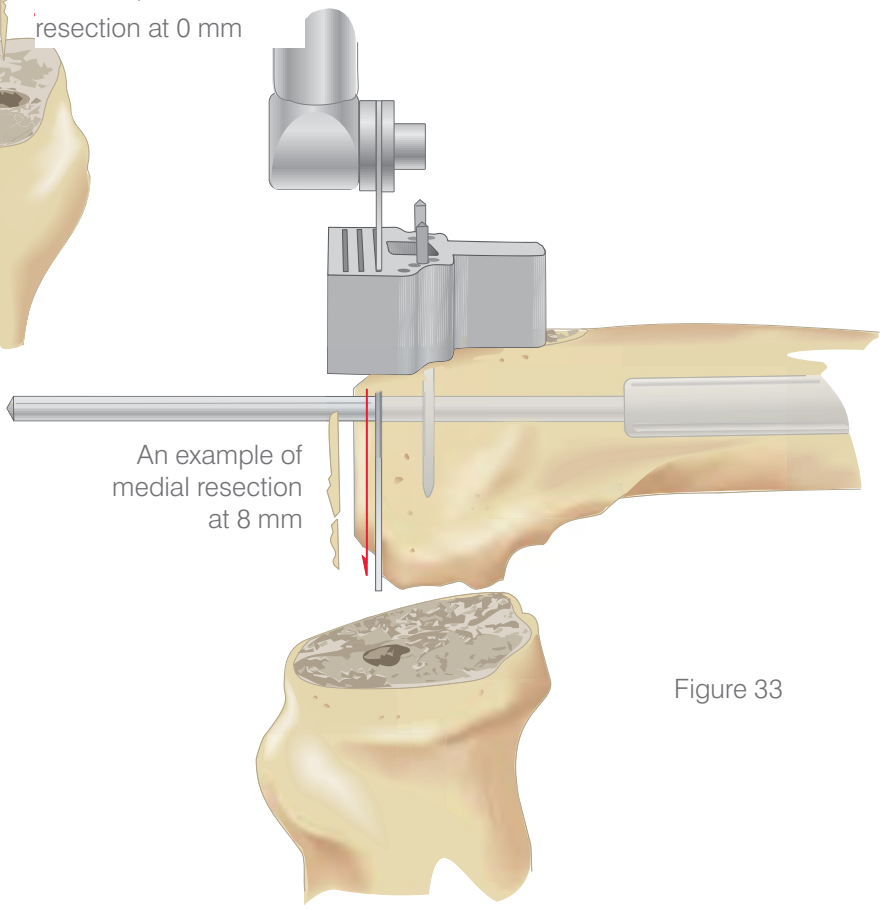


Figure 33

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 32).

Resection is accordingly performed through the slot appropriate for each condyle, using a standard 1.19 mm blade (Figure 33).

Anterior/Posterior Resection

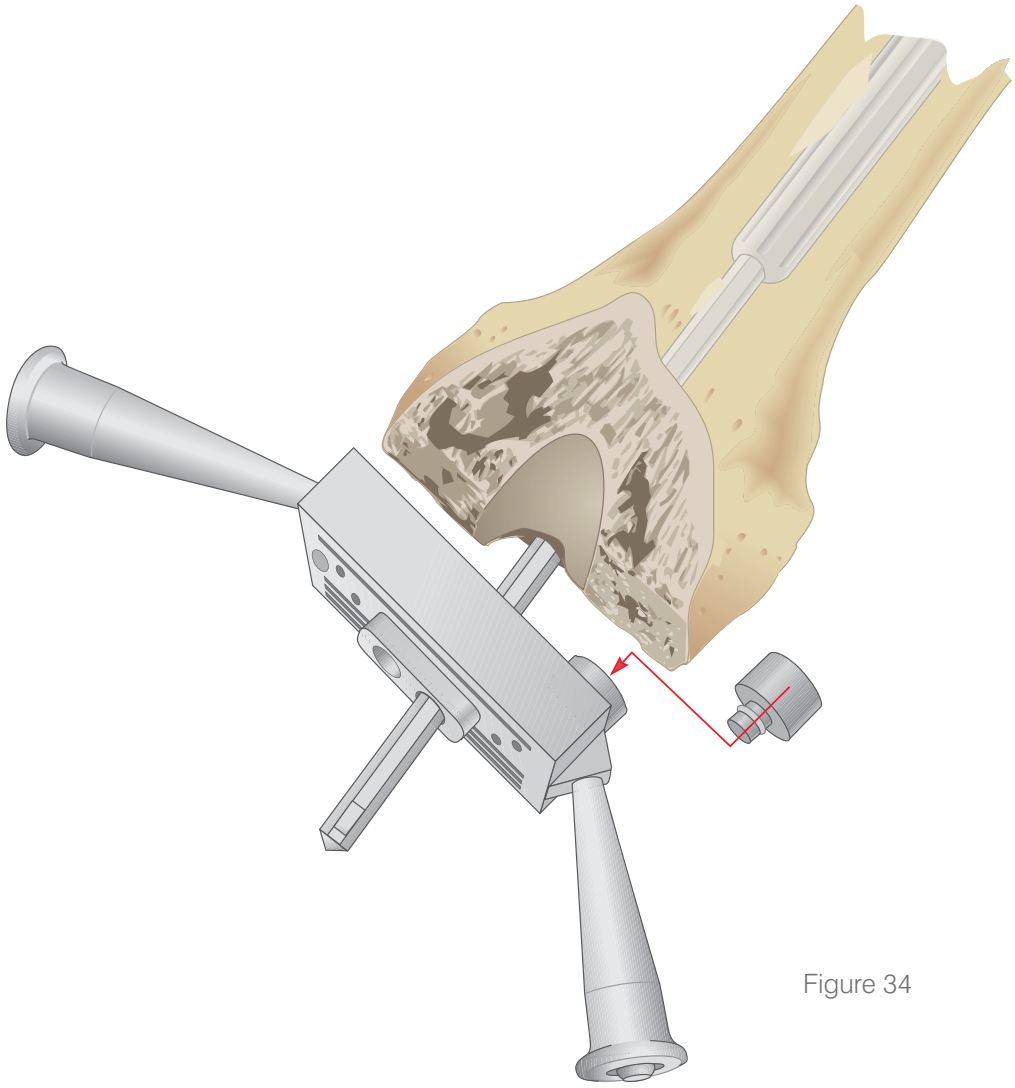


Figure 34

Assemble the appropriate 5 degrees or 7 degrees, 0 mm or ± 2 mm offset bushing, which corrects for the normal stem position at the selected femoral valgus angle and interior bone loss, to the Revision A/P cutting block.

Where indicated, assemble the appropriate distal spacer (4, 8, 12 or 16 mm) to the proximal side of the cutting block to compensate for the condylar discrepancy as determined during spacer block assessment. Assemble the block, in turn, onto the M.B.T. Revision Reamer or threaded shaft through the appropriate Right/Left opening and seat flush to the prepared distal surface (Figure 34).

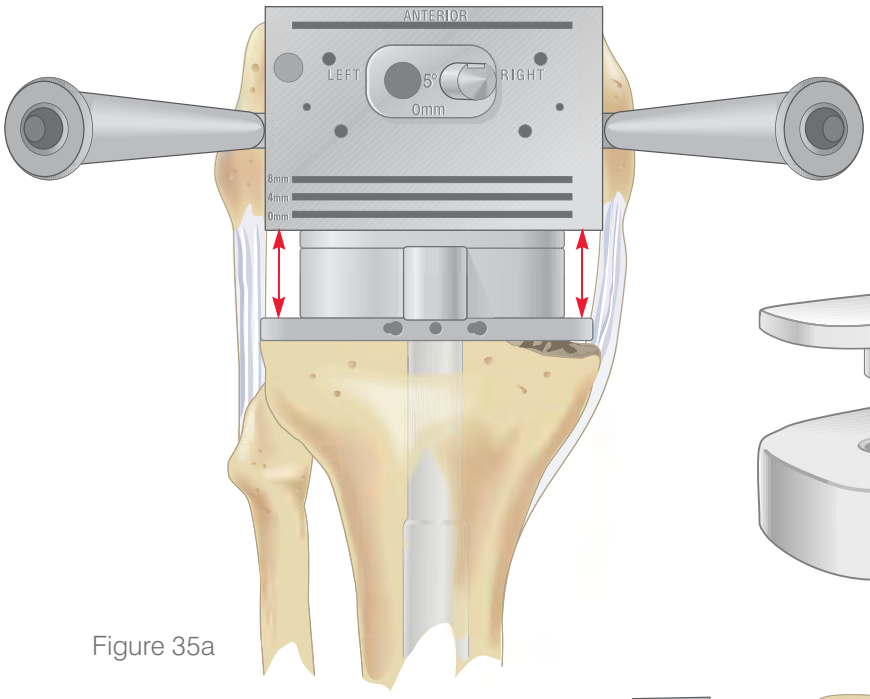


Figure 35a

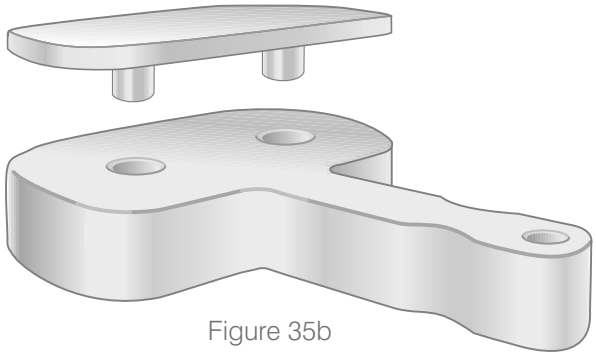


Figure 35b

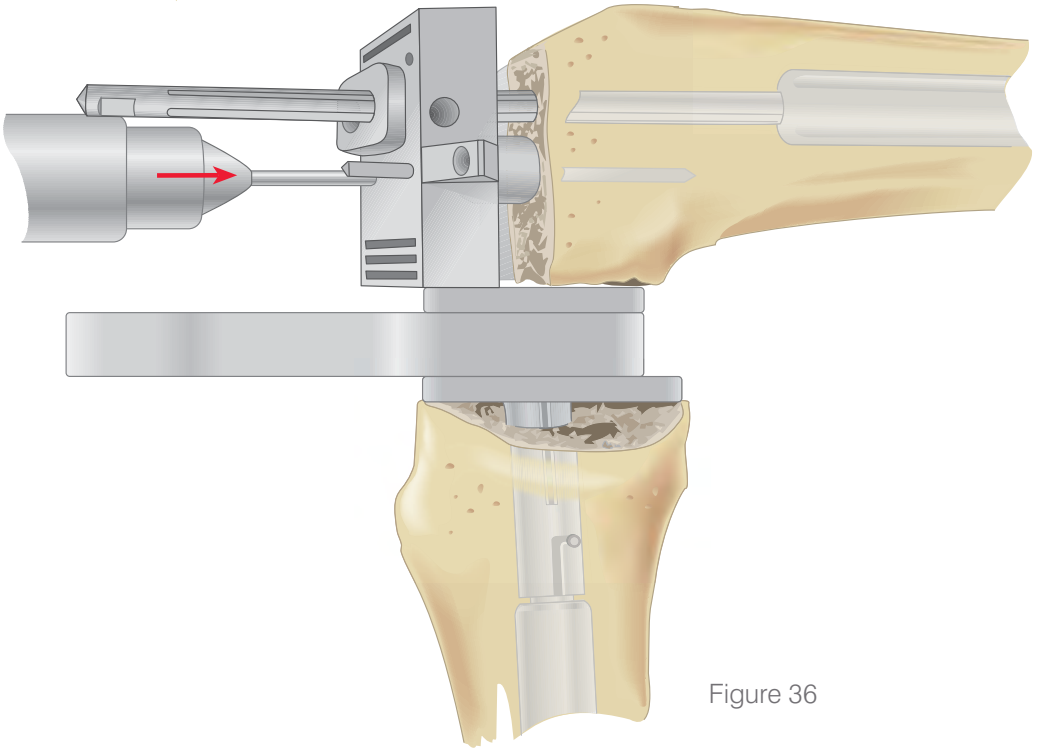


Figure 36

Rotational positioning of the revision A/P cutting block is critical to the establishment of a symmetrical flexion gap and patellofemoral alignment. Rotation is such that the posterior surface of the cutting block is parallel to the resurfaced proximal tibia under tension. Validate symmetry with spacer blocks or laminar spreaders. Where asymmetry exists, additional soft-tissue balancing may be indicated. Confirm positioning by assuring parallel alignment of the cutting block with the transepicondylar axis (Figures 35a and 35b).

With rotation confirmed, secure the cutting block with Steinmann pins introduced through the holes designated ☐ (Figure 36).

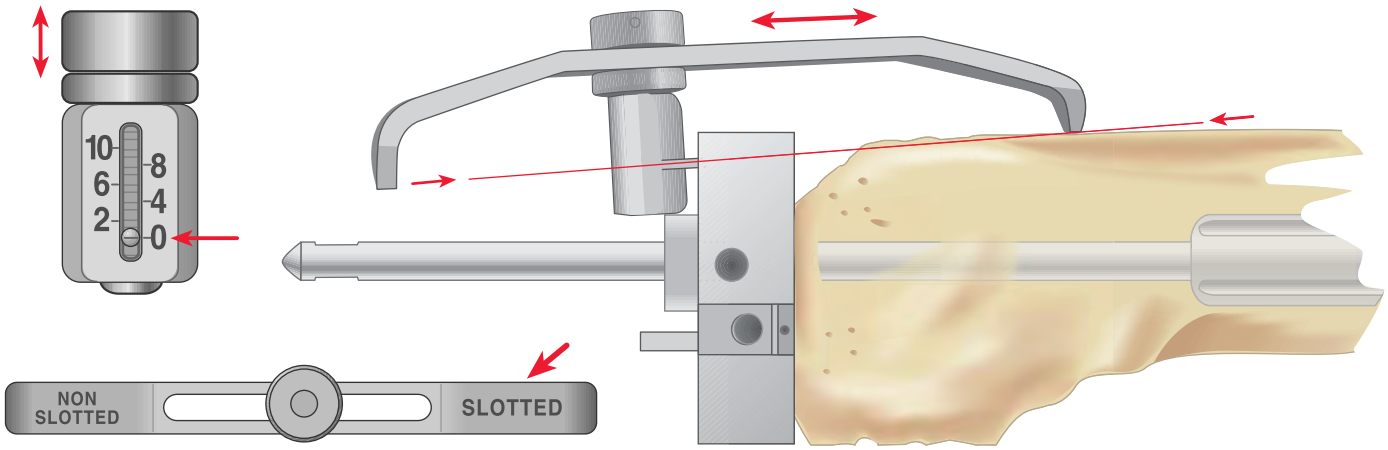


Figure 37

Introduce the foot plate of the stylus into the anterior slot and set the height at 0 mm. The arm of the stylus in contact with the anterior femur should read "Slotted" (Figure 37).

Pass the stylus over the anterior cortex to ensure against femoral notching. Where obstruction is identified, two options are available and are predicated by the flexion gap.

If the flexion gap is loose relative to the extension gap, the next larger size femoral component can be used and the posterior condyles augmented. If the flexion gap is too tight relative to the extension gap, the 0 mm bushing is replaced in the A/P cutting block with the +2/-2 mm bushing in the -2 mm position. This will translate the femoral component 2 mm anteriorly. Where minimal anterior separation is identified, it may be compensated with cement at implantation.

Where the cutting block is correct but the stylus indicates no anterior bone will be removed, it is recommended that the +2/-2 mm bushing be substituted for the 0 mm and placed in the +2 mm position as long as no flexion space tightness exists. This positions the A/P cutting block 2 mm posteriorly, thereby ensuring maximal anterior contact (Figure 38). This decreases the flexion gap by 2 mm.

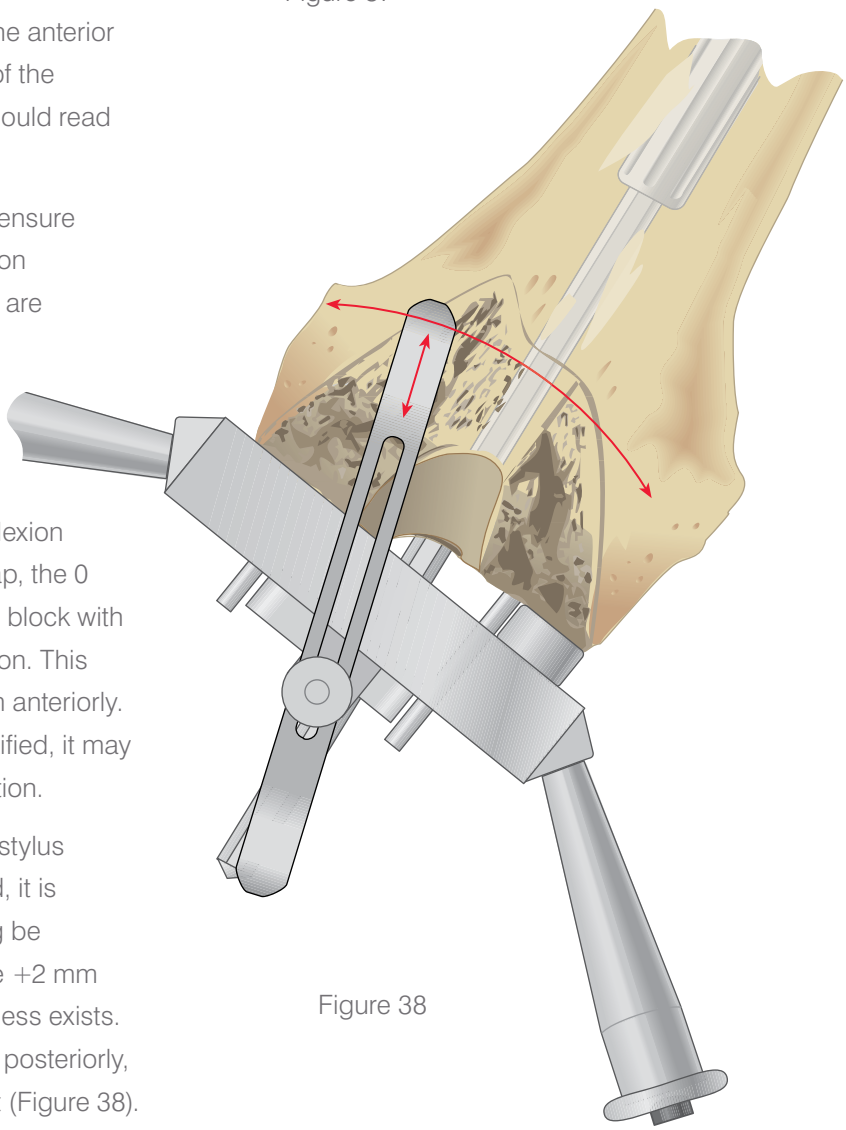


Figure 38

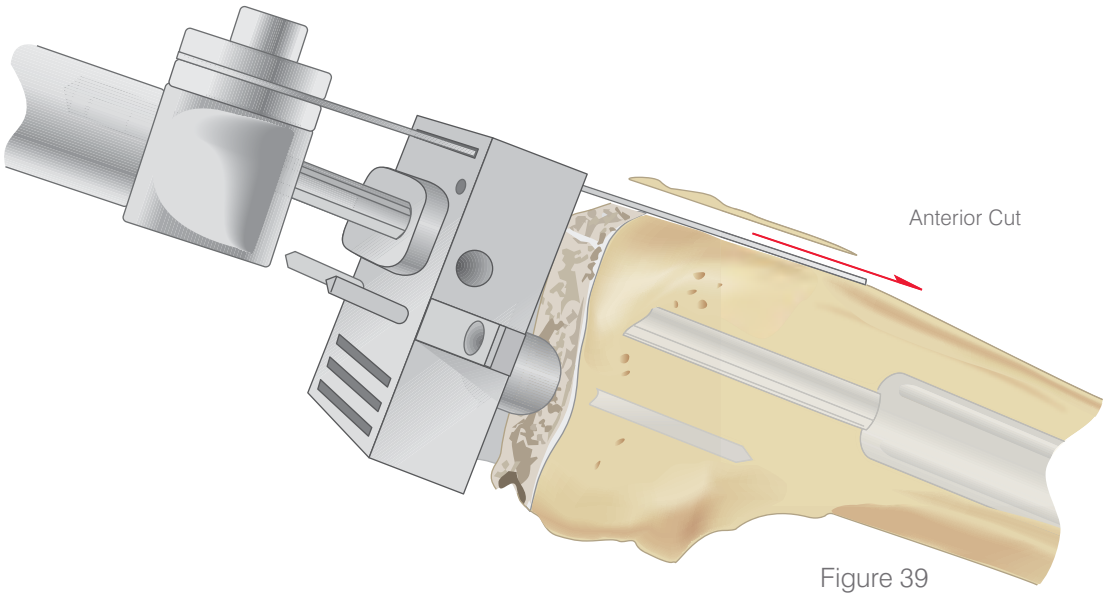


Figure 39

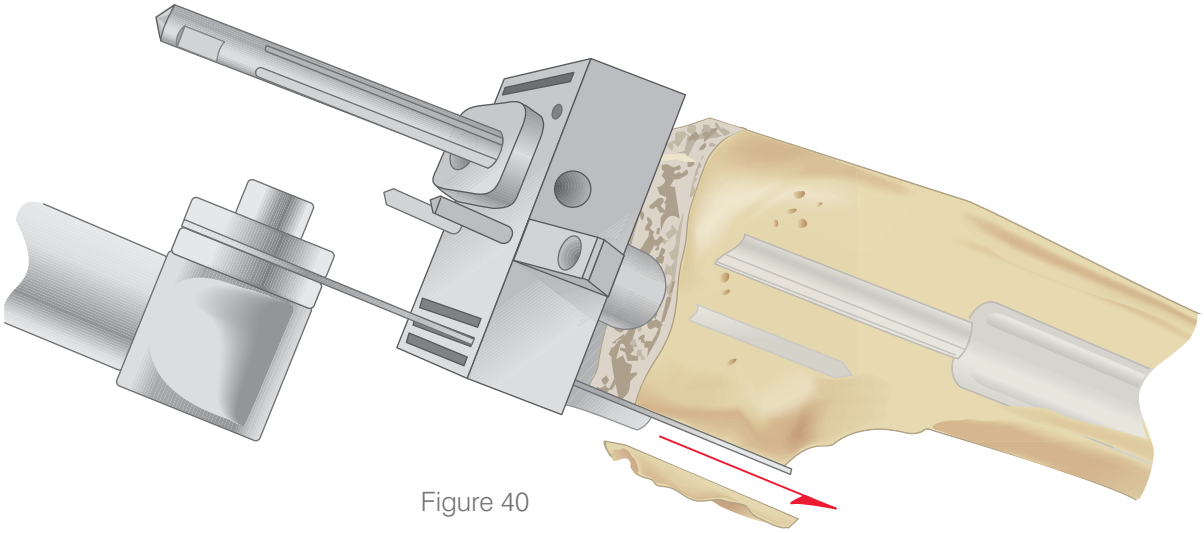


Figure 40

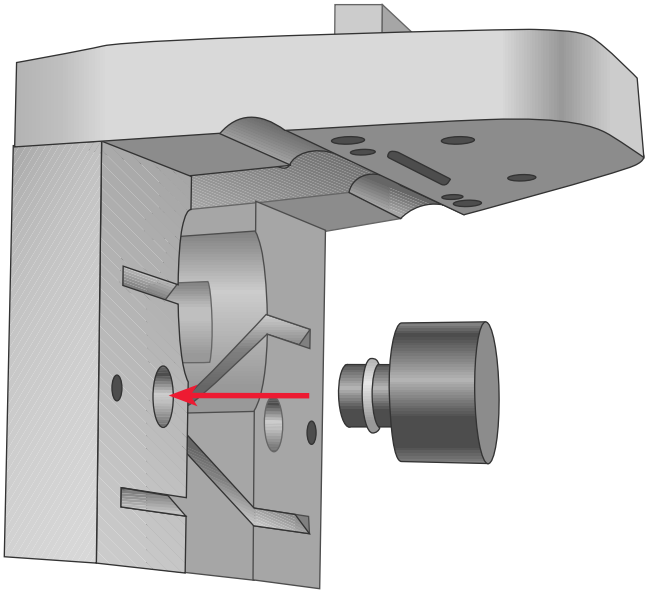
Example of Posterolateral Cut at 4 mm

Remove the stylus assembly. Where unilateral distal augmentation is planned, the appropriate spacer remains positioned between the block and the deficient condyle. Where bilateral distal augmentation is planned, the rigidity of the system is such that only the larger of the indicated spacers need be used. In either case, gain further fixation by affixing Steinmann pins through the anterior holes. Anterior resection is performed through the anterior slot using a 1.19 mm blade (Figure 39).

Posterior resection is through the slot designated 0 or, where there is posterior condylar deficiency, use the appropriate 4 or 8 mm slot to accommodate the projected augmentation (Figure 40).

Notch and Chamfer Resection

Figure 41



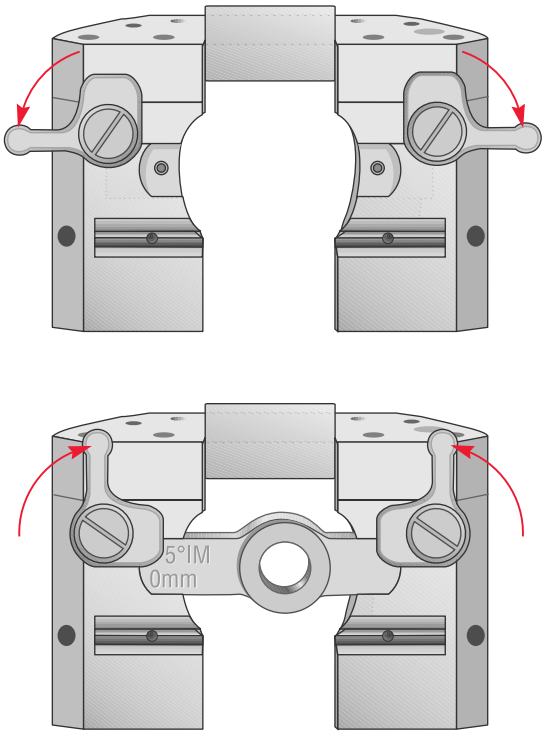


Figure 42

Where distal augmentation is planned, insert the appropriate trial spacer into its receptacle on the notch cutting guide (Figure 41). Select the same trial spacer used on the A/P cutting block.

Select the appropriate notch/chamfer bushing. This corresponds to the bushing that was used on the A/P cutting block, 0 mm, +2 mm or -2 mm. Assemble it onto the notch/chamfer cutting guide with the appropriate Right/Left and 0, +2 or -2 designation facing up and lock into position by rotating the tabs anteriorly to the stop (Figure 42). Leave the tibial tray trial assembly in position and reposition the spacer block. This ensures appropriate rotational orientation, as previously established.

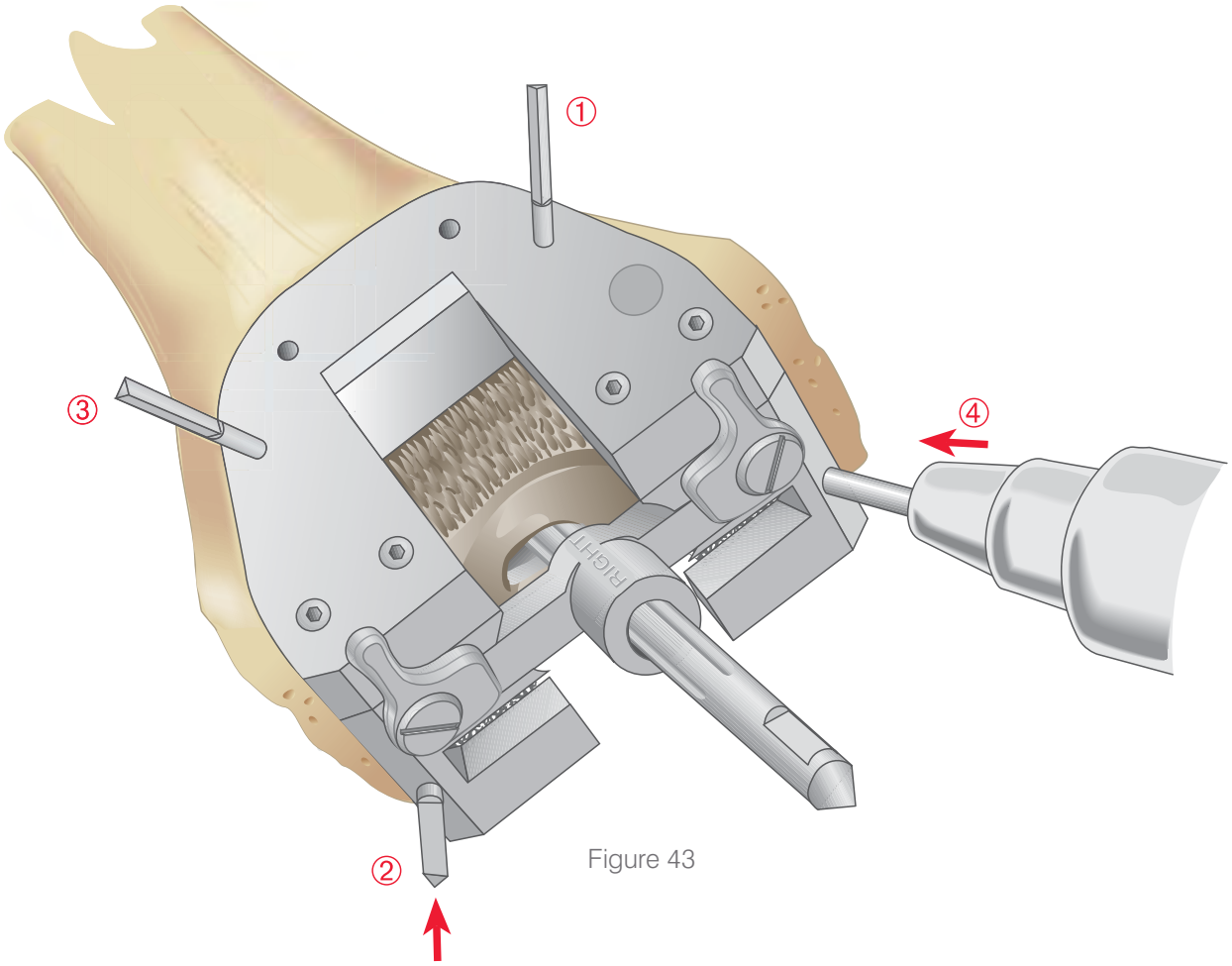


Figure 43

Assemble the notch guide onto the M.B.T. Revision Reamer or threaded shaft and advance to the prepared distal surface.

Introduce Steinmann pins in the sequence displayed: anterior ①, contralateral distal ②, anterior ③ and distal ④ (Figure 43).

Remove the spacer block.

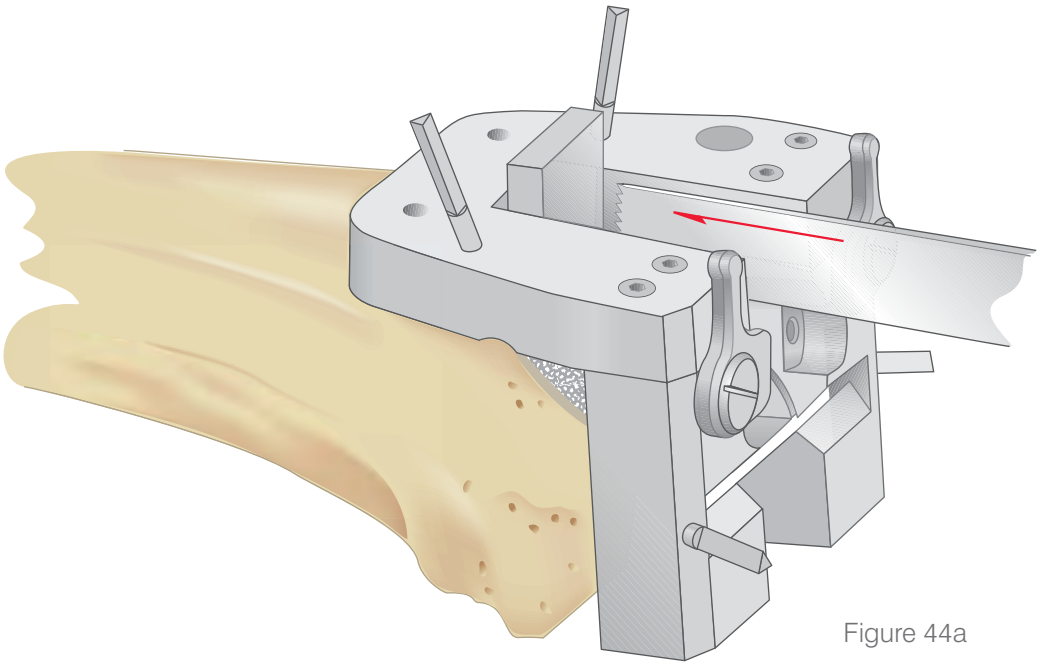


Figure 44a

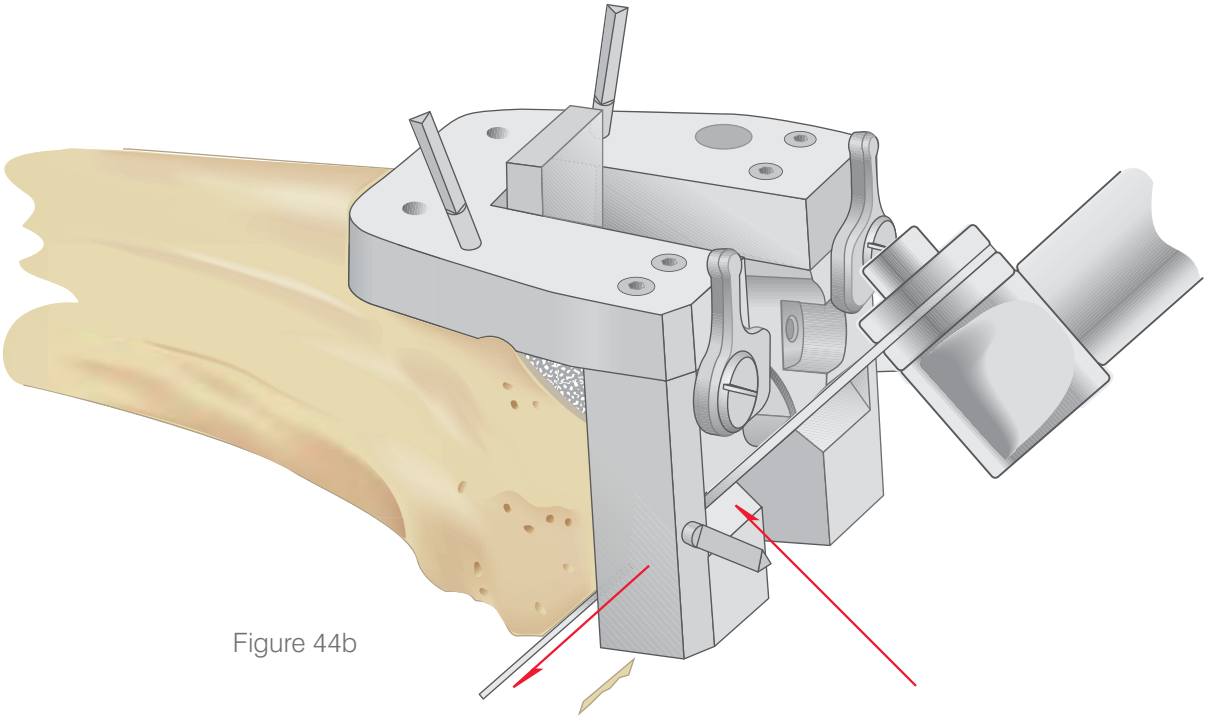


Figure 44b

Make the notch and chamfer cuts with an oscillating saw with the reamer in position (Figures 44a and 44b).

Remove the notch/chamfer bushing. Carefully disengage the M.B.T. Revision Reamer or broach from the reamed canal to preserve the established configuration. Confirm the security of the notch guide.

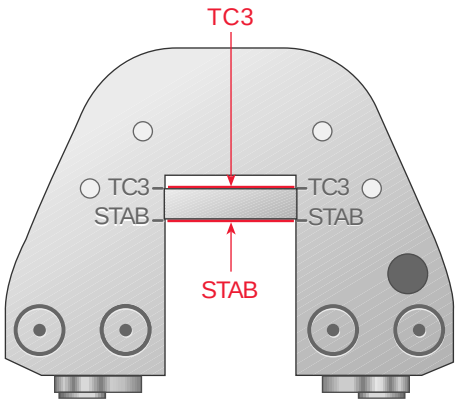


Figure 45

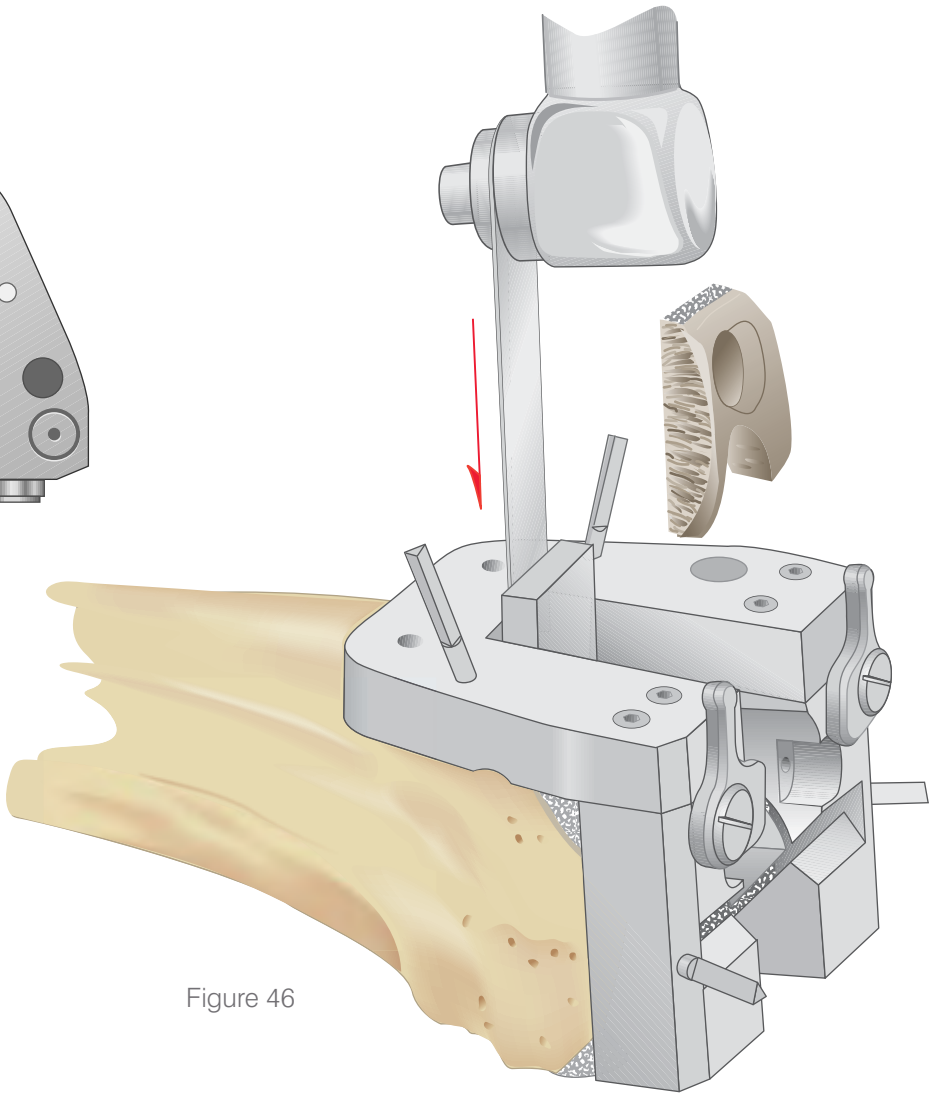


Figure 46

The length of the intercondylar box differs for the P.F.C. Sigma Stabilized and TC3 femoral components. Their respective transverse cut positions are indicated on the anterior surface of the guide: basing the TC3 cut on the proximal surface of the guide bar and the Stabilized (designated STAB) on the distal surface (Figure 45). Perform resection either with an oscillating saw using a 1⁄2'' blade or with an osteotome (Figure 46).

The Trial Femoral Component

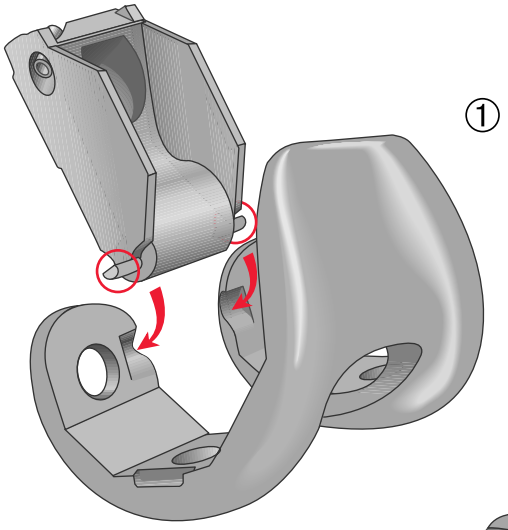


Figure 47

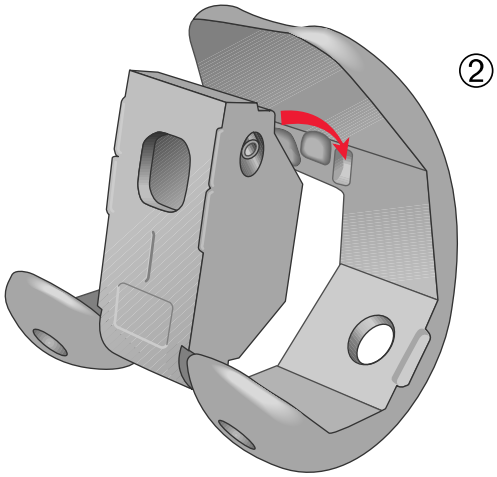


Figure 48

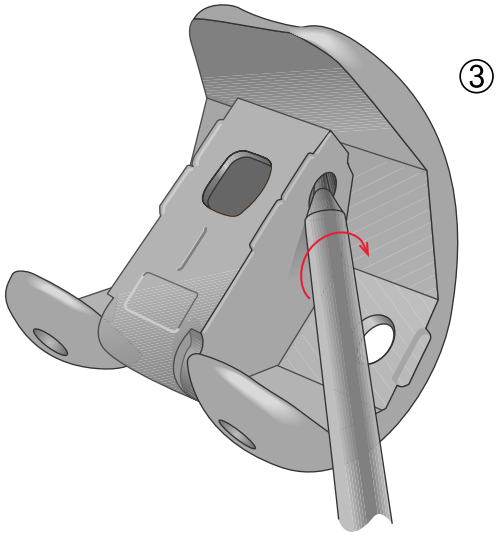


Figure 49

The Femoral Component Box Assembly

1) Place the two outrigger tabs of the box trial into the recesses of the posterior condyles (Figure 47).

2) Insert the two anterior tabs into the recesses of the anterior flange (Figure 48).

3) Turn the angled screw, located in the side of the box, until tight (Figure 49).

Note: Do not overtighten the screw or attempt to remove the screw from the box trial as this will result in damage to the box trial attachment.

Position the femoral trial on the prepared distal femur, and evaluate the accuracy of the cuts.

Where the component tends to rotate posteriorly, the A/P cuts may require adjustment. Where there is lateral rocking, the depth of the notch is inadequate.

Make all appropriate modifications at this time.

Trial Assembly - Sleeve and Stem Use

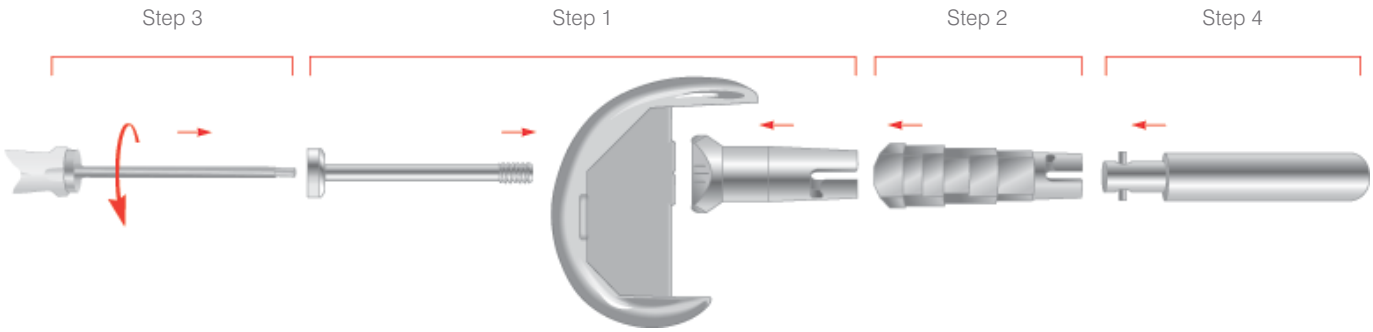


Figure 50

For trial assembly with sleeve-only use, please see page Appendix 5, page 60. Trial assembly order (with sleeve and stem use, see Figure 50):

- Thread sleeve bolt trial through trial femur and trial femoral adapter
- Place trial sleeve over adapter trial
- Loosely tighten assembly with hex head screwdriver, or by spinning sleeve
- Add stem trial to trial assembly
- Add posterior and distal augment trials, if needed
- Seat trial assembly on femur
- Once sleeve trial has achieved proper orientation, tighten securely with hex head screwdriver

After distal, A/P and finish cuts are completed, select the appropriate P.F.C. Sigma Femoral Adapter trial, 5 or 7 degrees, corresponding to the bushing used on the A/P cutting block and the notch chamfer guide. Assemble the trial for either a right or left orientation and assemble with the appropriate orientation markings facing the posterior aspect of the trial femoral component. Pass the appropriate P.F.C. Sigma Femoral Adapter sleeve bolt trial, neutral or +/-2 mm, corresponding to the bushing selected for the A/P cutting block and notch/chamfer guide, through the hole in the box of the distal femur and through the P.F.C. Sigma Femoral Adapter trial (Figure 50 - Step 1).

Note: Once bolt trial is through cemented trial box, use finger to hold bolt trial and spin femoral adapter trial to engage. Depending on the femoral size and sleeve size, this can also be done with the femoral sleeve.

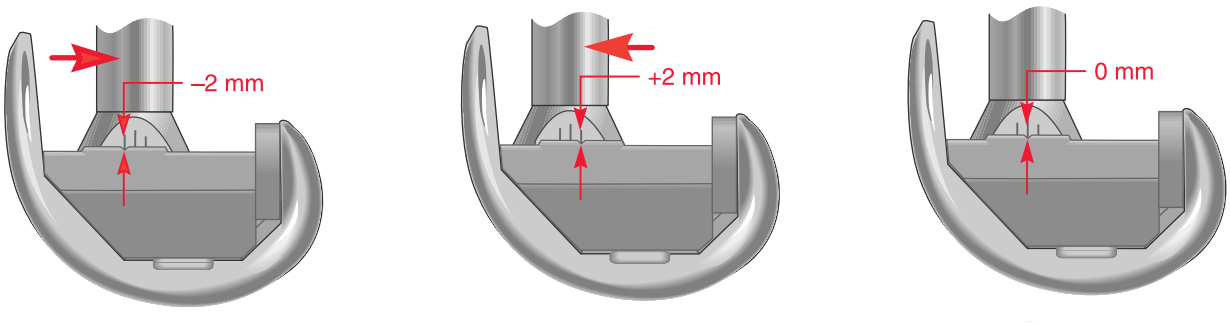
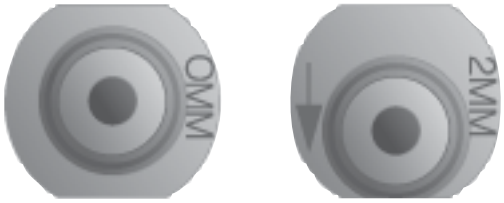


Figure 51

Neutral (non-offset)
P.F.C. Sigma Femoral
Adapter Sleeve trial bolt



Offset (+2/-2 mm)
P.F.C. Sigma Femoral
Adapter Sleeve trial bolt

Figure 52

Note: Leave the adapter femoral trial construct loose until the sleeve trial is added.

If using the +2/-2 mm trial bolt, the arrow is pointing to the direction in which the femoral adapter is located relative to the neutral position (Figure 51). If using the +2 mm position, shift the adapter 2 mm towards the anterior flange. If using the -2 mm position, locate the femoral adapter 2 mm posterior to the neutral position.

There are three visual checks to ensure the proper assembly: (1) the arrow on the bolt trial is pointing to the desired position (Figure 52); (2) align the lateral side of the adapter trial and the box trial and (3) position the adapter trial on the trial femoral component such that the angle and the orientation markings are visible from the posterior aspect of the trial femoral component.

Note: Trial bolt lengths are different for adapter/sleeve use than for adapter/stem-only use.

Tighten by turning the sleeve trial to initially engage the bolt trial thread. This mechanical connection to the adapter/femoral trial construct helps to ensure that the parts do not disassociate during use.

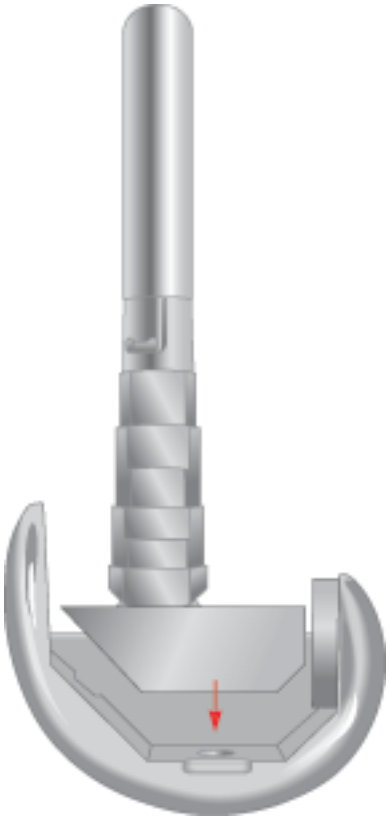


Figure 53

Figure 54

Make sure to properly orient the sleeve trial with the narrow side facing medially. Use the hex head screwdriver to loosely secure the assembly, as shown in Step 3 of Figure 50. Assemble the appropriate stem trial to the sleeve trial, as shown in Step 4 of Figure 50.

Note: Please consult the anteroposterior width chart on Appendix 6B page 65 to determine sleeve/femur compatibility and the distance between the anterior flange and the anterior aspect of the sleeve.

Where augmentation is employed, assemble the appropriate trial distal and posterior augmentation components to the trial femur (Figure 53). Seat the femoral trial in the femur.

The sleeve trial will achieve the rotation and orientation of the final broach used.

After the sleeve trial is seated firmly in the metaphysis, securely tighten the bolt trial with the hex head screwdriver.

Etch lines have been added to the medial side of the adapter trial for more accurate assessment of the sleeve's rotation during the final implant assembly (Figure 54).

Final Preparation of the Tibia

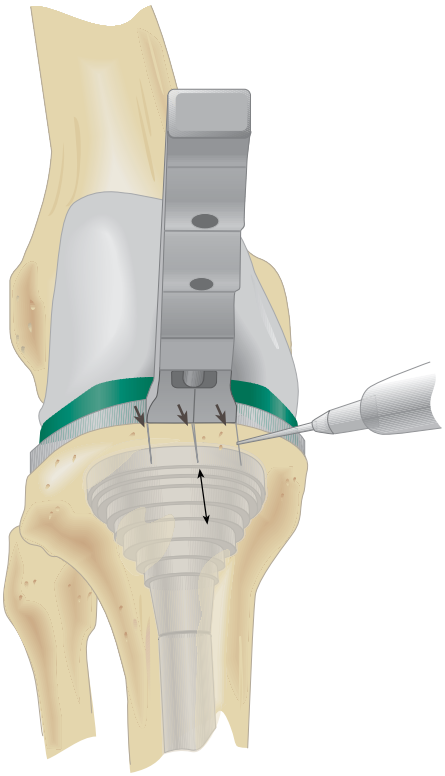


Figure 55

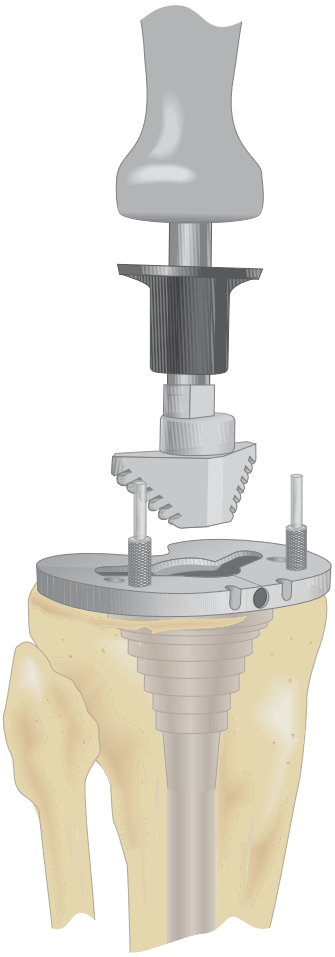


Figure 56

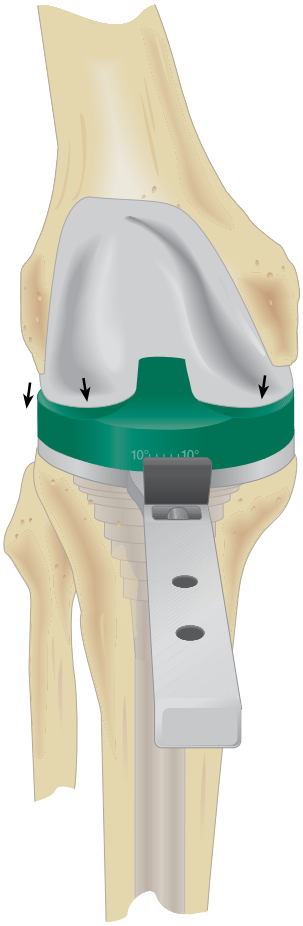


Figure 57

Place the knee in full extension and determine appropriate rotation of the tibial tray (Figure 55).

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 56). 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 57).

Assembling the Prosthesis

Figure 58

Figure 59

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 58). 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 59).

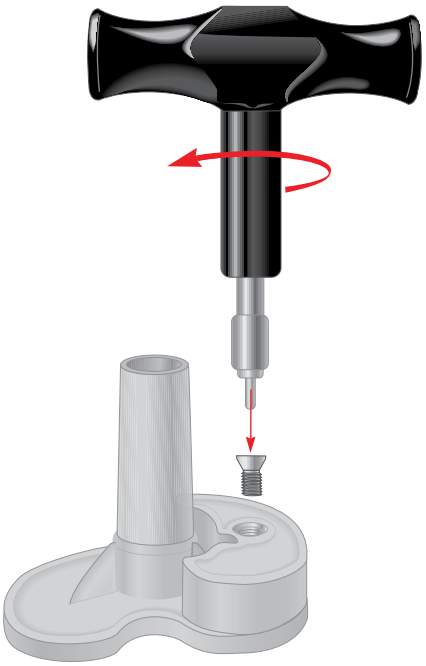


Figure 60

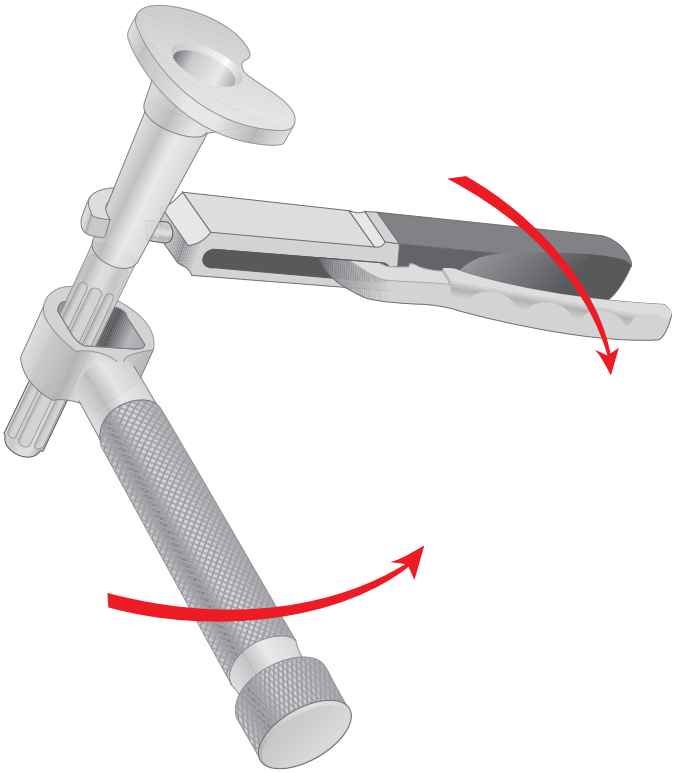


Figure 61

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 60).

Stem Component Assembly

Attach the stem extension to the prosthetic tray using the two appropriate wrenches to ensure full engagement (Figure 61).

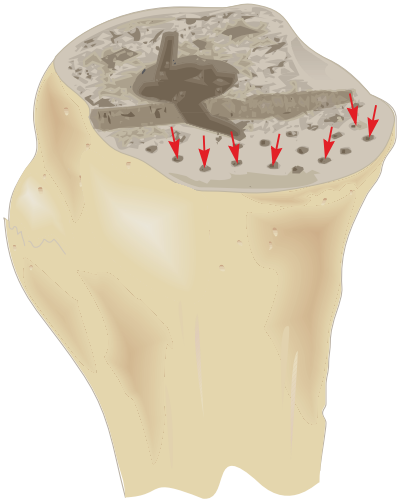


Figure 62

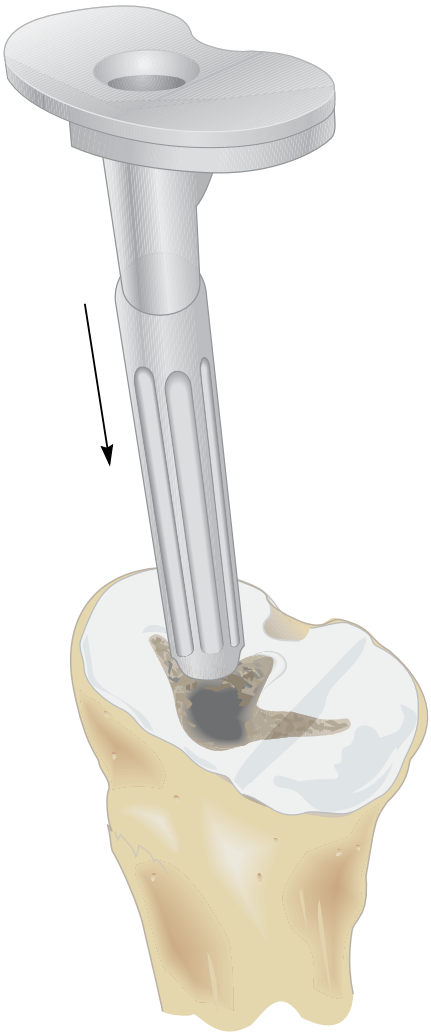


Figure 63

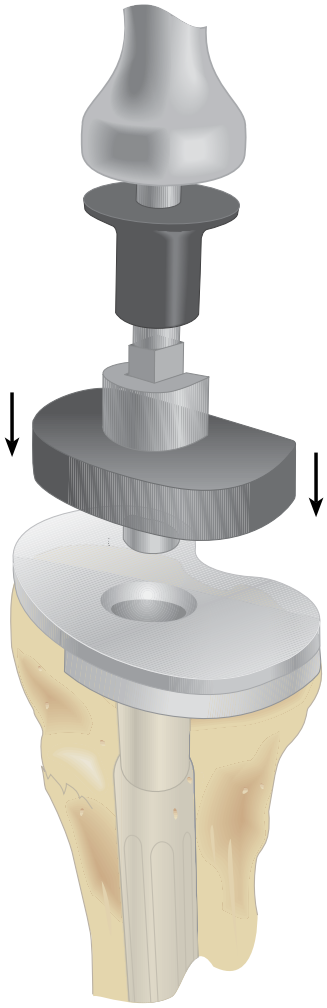


Figure 64

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 62). 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 sleeve is used, ensure the medullary canal remains free of cement. Clear all extruded cement with a curette (Figures 63 and 64).

Trial Reduction

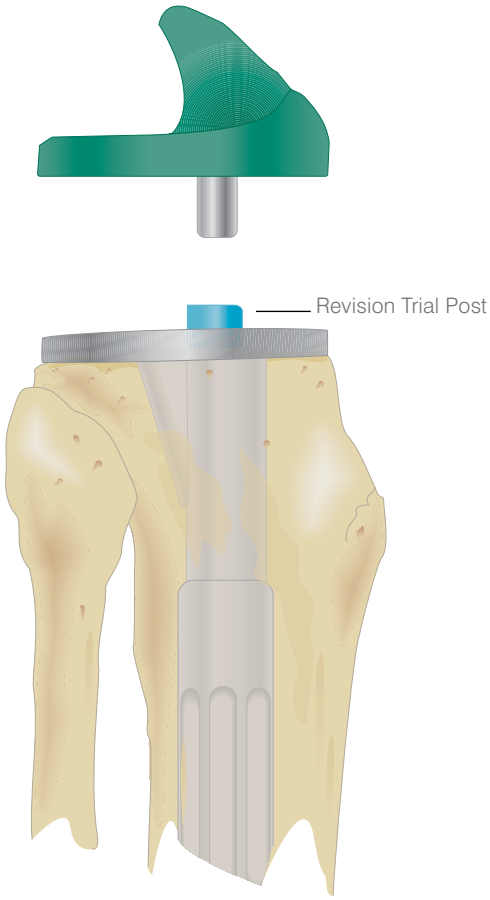


Figure 65

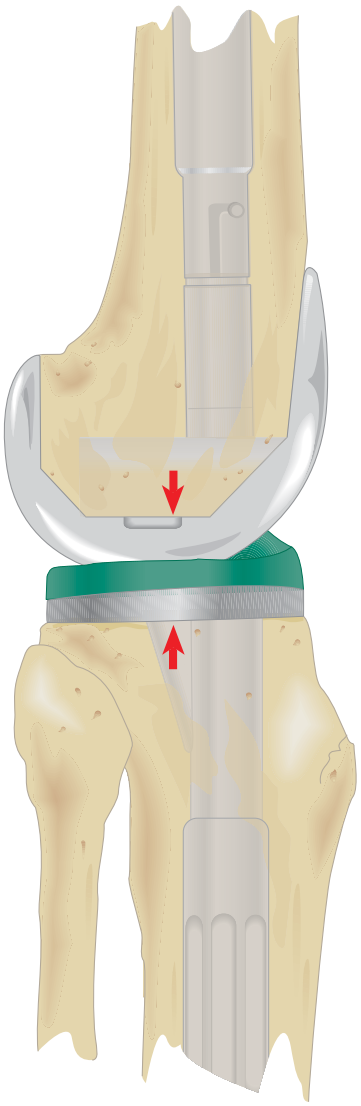


Figure 66

When femoral rotation is known, place the revision stem extension into the cone of the M.B.T. Revision implant. Seat the appropriate trial insert in the trial post/tray (Figure 65). The trial femoral component remains in place. Fully extend the knee to maintain pressure as the cement polymerizes (Figure 66). After cement polymerization, cement the femoral component.

Note: With constrained femoral and tibial components in trial reduction, it may be appropriate to cement the tibial tray implant and the femoral implant using the insert trial. This will allow visibility of final rotation.

Implant Assembly - Sleeve and Stem Use

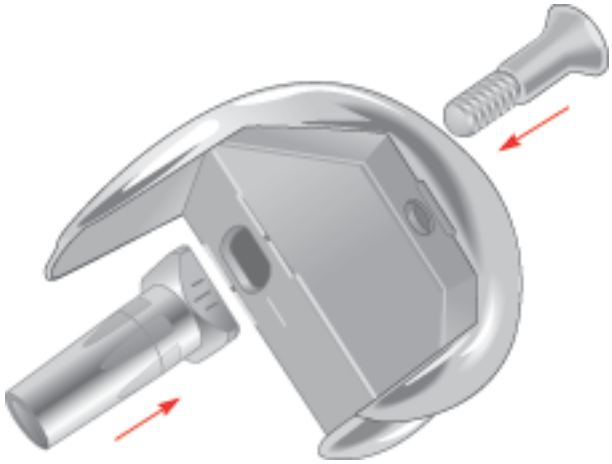


Figure 67

Remove the trial components in reverse order and clean the site thoroughly using pulse lavage before implantation. Before prostheses implantation proceeds, attach all augments, sleeves and modular stems to the femoral and tibial components. Implant assembly order (with sleeve and stem use):

- Femoral Adapter-to-femur
- Add posterior and distal augments if necessary
- Sleeve-to-stem
- Sleeve-to-Femoral Adapter

Pass the appropriate P.F.C. Sigma Femoral Adapter bolt, neutral or +/-2 mm, corresponding to the bushing selected for the A/P cutting block and notch/chamfer guide, through the hole in the box of the distal femur and into the P.F.C. Sigma Femoral Adapter (Figure 67).

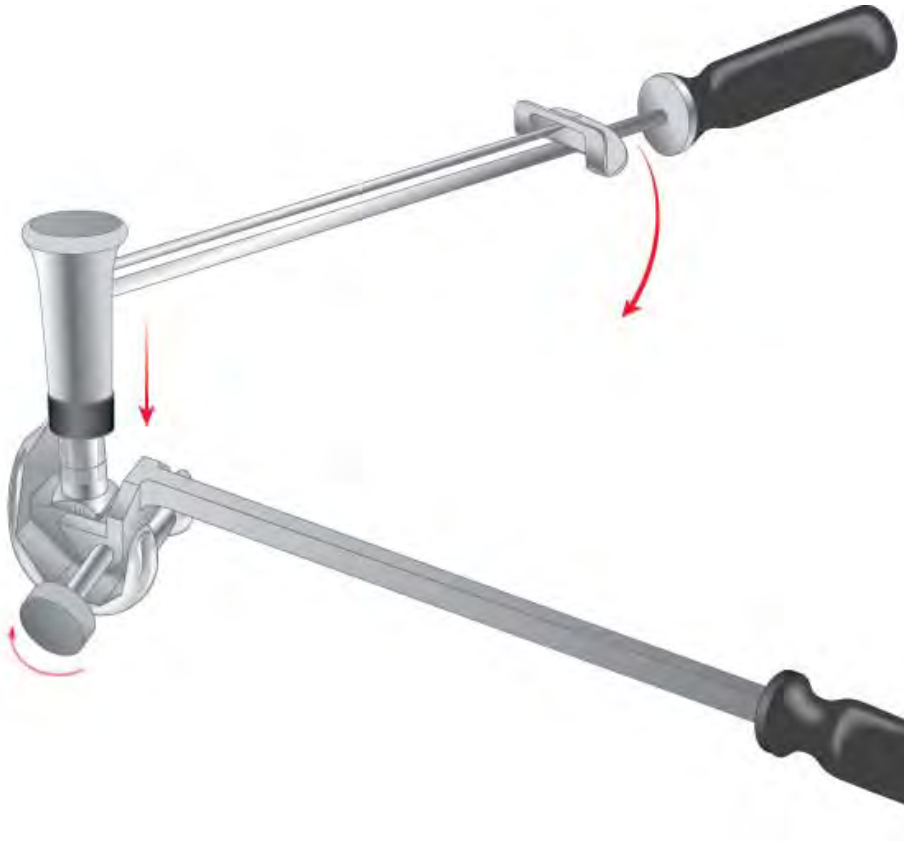


Figure 68

Figure 69

Tighten the construct until the base of the adapter is flush with the femoral box. The three A/P etch marks on the base of the adapter implant should face laterally.

Note: The P.F.C. Femoral stem bolt is not compatible with the P.F.C. Sigma Femoral Adapter, as it is approximately 7 mm longer than the P.F.C. Sigma Femoral Adapter bolt and will prevent the adapter from sitting flush on the femoral box.

Attach the P.F.C. Sigma Femoral Adapter holding clamp to the femoral implant and tighten it. The clamp provides the second moment arm needed to assemble the parts. Place the torque wrench over the P.F.C. Sigma Femoral Adapter implant and move it clockwise to tighten the adapter to the femoral implant (Figure 68). The torque wrench has a deflection beam, which indicates when sufficient torque has been applied (Figure 69).

Note: Torque the assembly to the 270 in. lb mark on the torque wrench to ensure assembly strength (Figure 69).

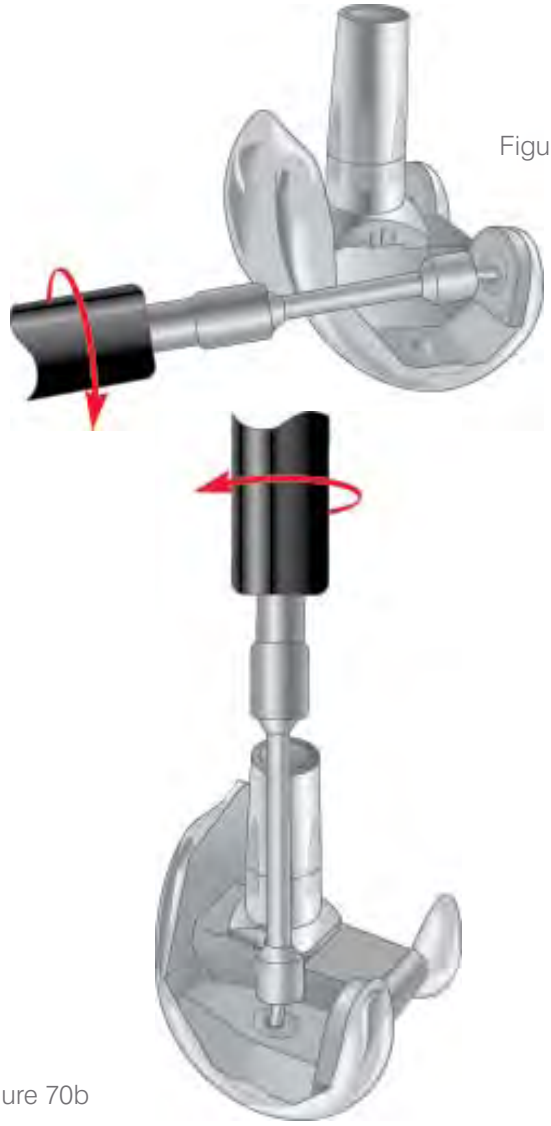


Figure 70a

Figure 70b

Attach the augments using the wobble bits included in the augment package. Attach the femoral augments to the femoral component using the augment T-handle provided (Figures 70a and 70b).

It may be necessary to use the T-handle extension in conjunction with the T-handle to attach the augments.

Assembly Rules for Femoral Augmentation

1. For Size 1.5 Femoral Components

- Distal augmentation component augments in 4, 8 and 12 mm thicknesses.
- Assemble last.

2. For Size 4n PS Femoral Components

- Use size 2 distal and posterior augments

3. For 4 mm/8 mm Augments

- They are fully interchangeable.
- If using 4 mm or 8 mm distal with posterior augment, install distal first.

4. For 12 mm/16 mm Distal Augment:

- Use 16 mm distal augment with TC3 femoral only.
- Femoral stem is indicated.
- On size 2, 2.5 and 3 femoral component, use 4 mm posterior.
- On size 4, 5 femoral component, may use 4 or 8 mm posterior.
  (Note: No size 6 augments available - use size 5 augment with size 6 femur).
- If using with posterior augment, install posterior augment first.

Figure 71

Fully seat the augments on the component before tightening the screw thread mechanism.

The augment assembly sequence chart is shown in Figure 71.

For implant assembly with sleeve-only use, please see Appendix 5 page 62.

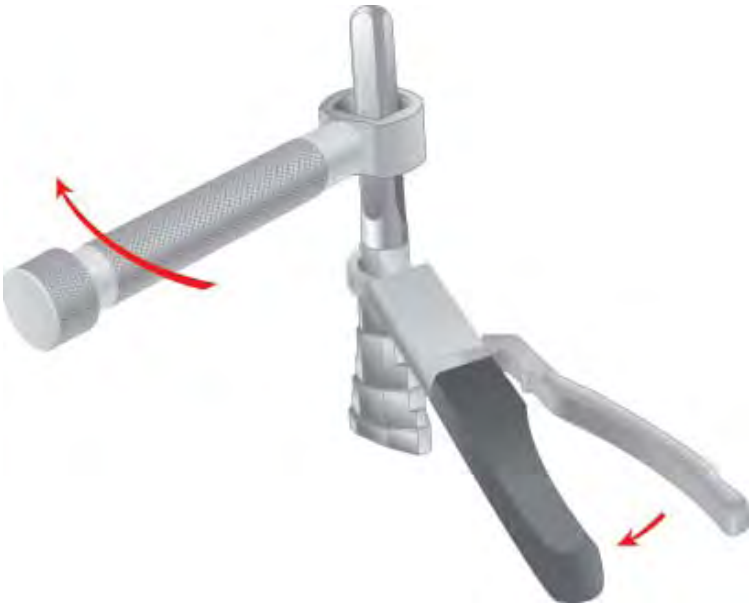


Figure 72

Figure 73

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 72.

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.

Use the etch marks on the medial side of the adapter implant to assist in recreating sleeve rotation established during trial phase (Figure 73).

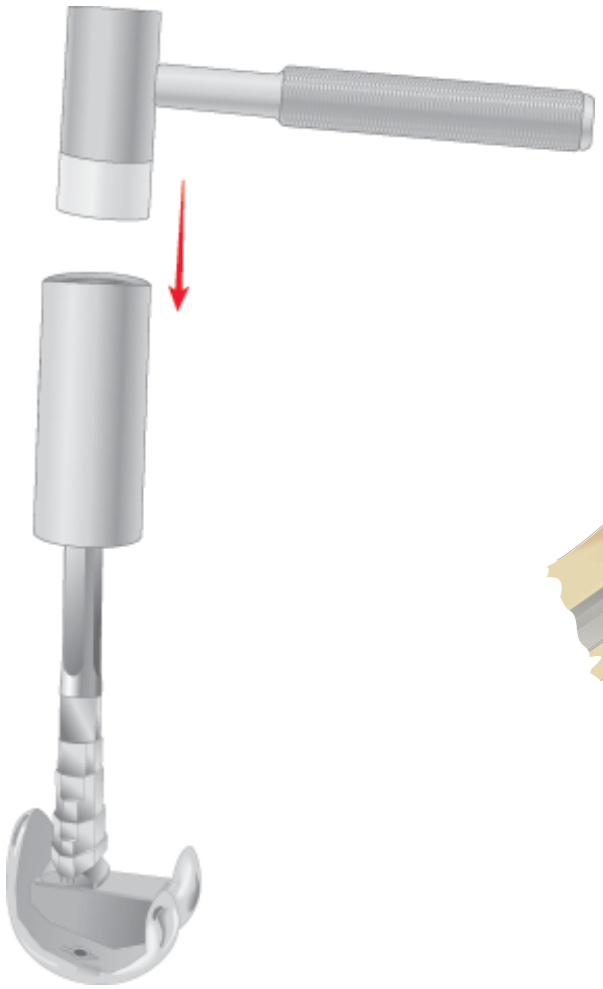


Figure 74

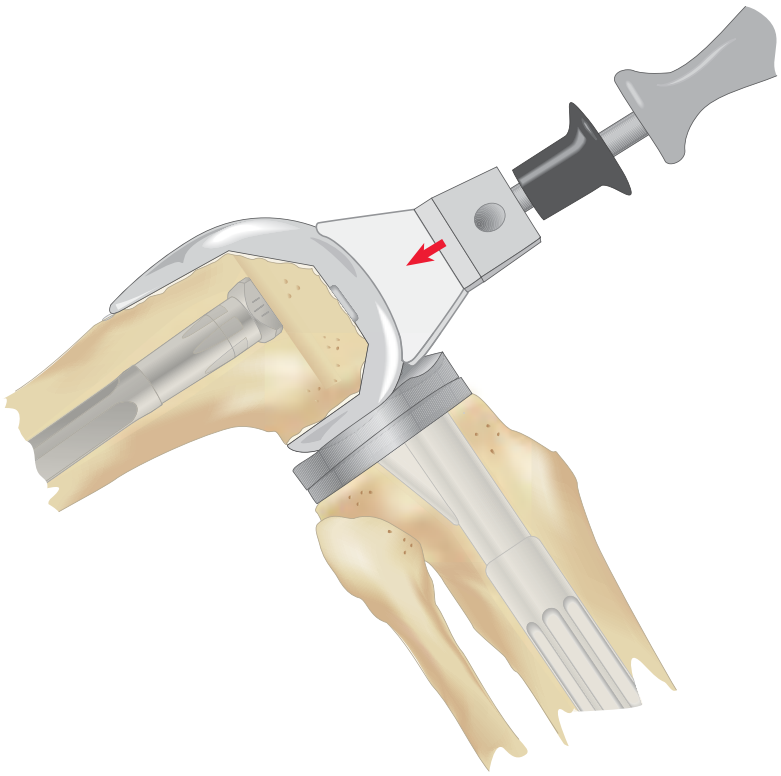


Figure 75

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 74).

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)
- Sigma Fixed Bearing or Rotating Platform CS or TC3 inserts

Implant the femoral component using the Femoral Impactor (Figure 75).

Preparation of the Patella

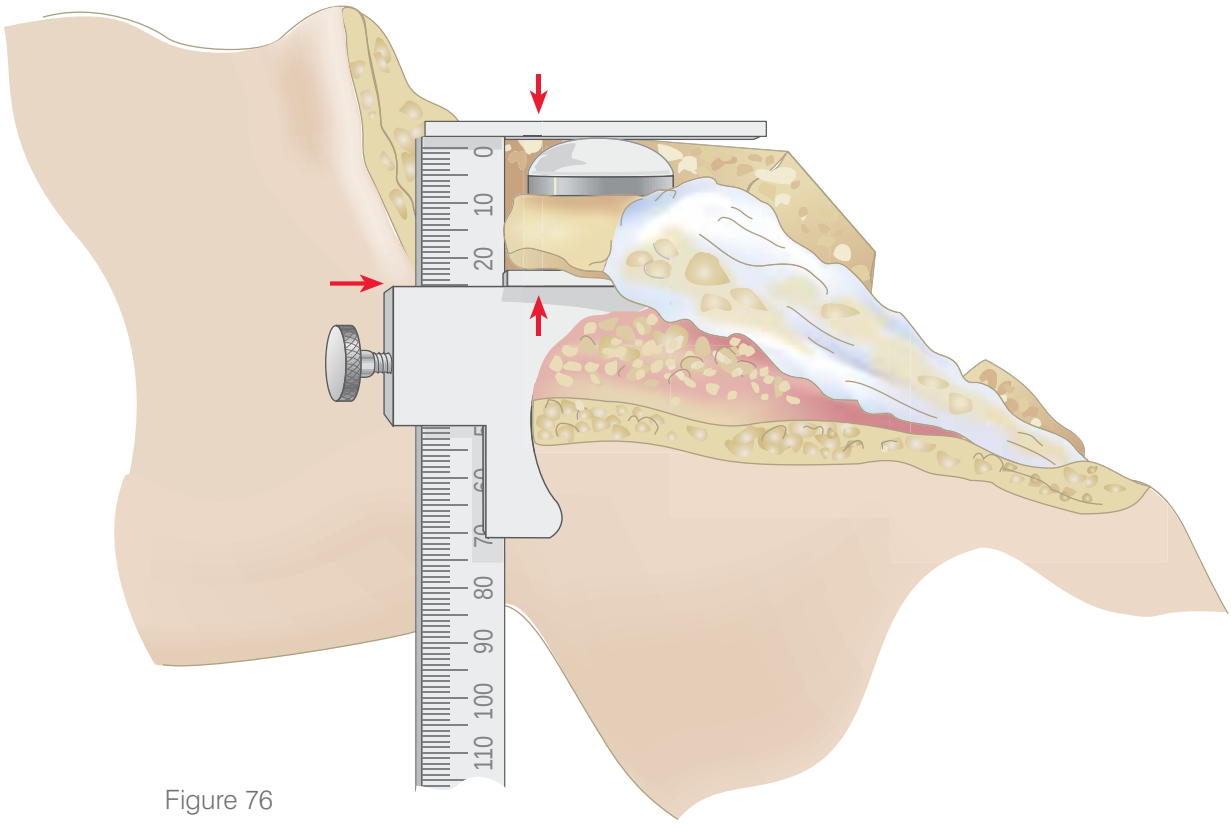


Figure 76

Where replacement of the patellar component is indicated, it is important that the anteroposterior dimension be maintained and that adequate bone stock be preserved. Problems arise from inadequate, excessive or uneven resection resulting in abnormal anteroposterior dimension to the complex, subsequent patellar tilt and implant wear. Free sufficient soft tissue at the prepatellar bursa to position calipers at the anterior cortex.

Where residual bone stock is adequate, implantation of the replacement prosthesis is essentially routine. Where inadequate, patelloplasty may be indicated.

Note: The normal anteroposterior patellar dimension is 22–24 mm in the female, 24–26 in the male (Figure 76).

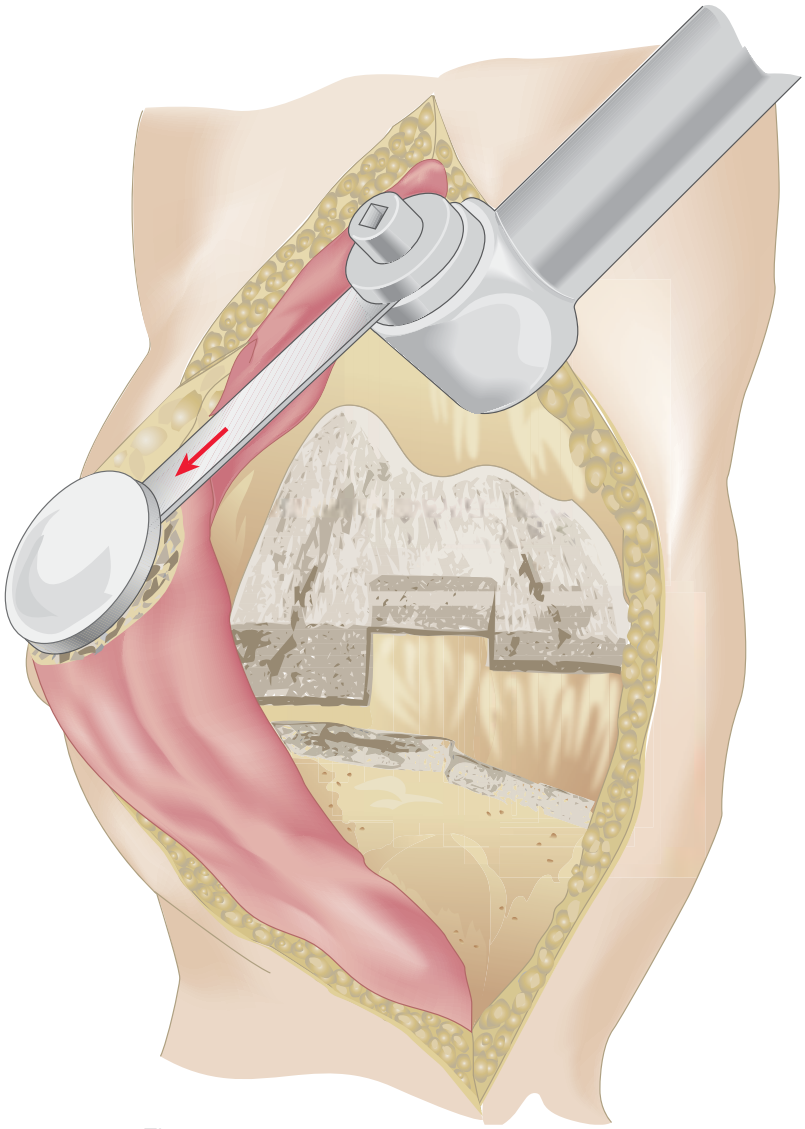


Figure 77

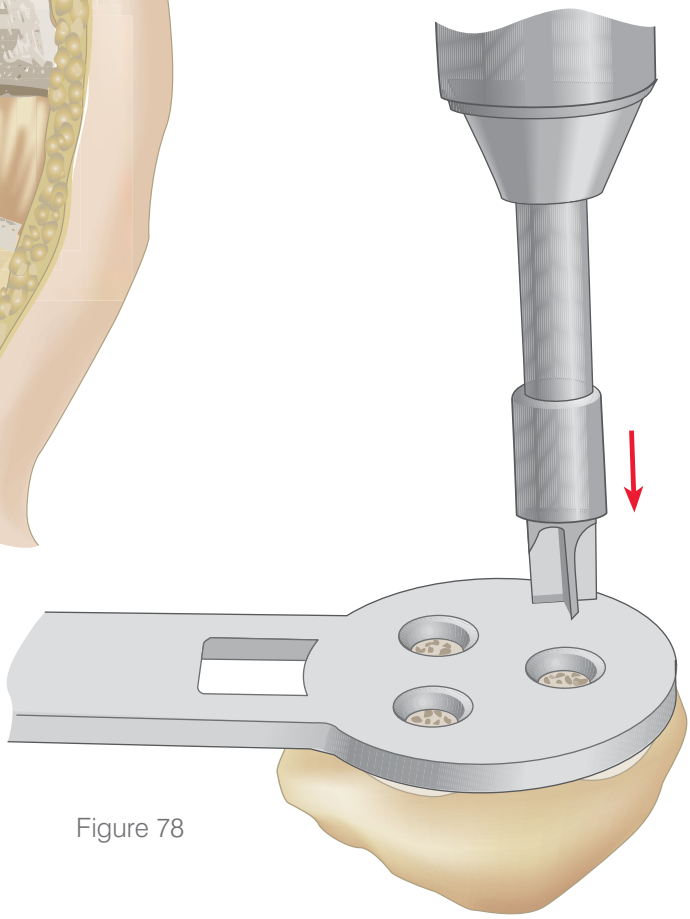


Figure 78

Meticulous disruption of the bone/prosthesis interface is essential. It is performed with thin osteotomes and thin oscillating saw blades (Figure 77). Avoid excessive leverage to minimize possible fracturing.

Position the patellar template that most adequately covers the prepared surface along the horizontal axis of the patella and firmly engaged. Fashion the three holes for the fixation pegs of the component with the appropriate drill (Figure 78). Depth is governed by the collar.

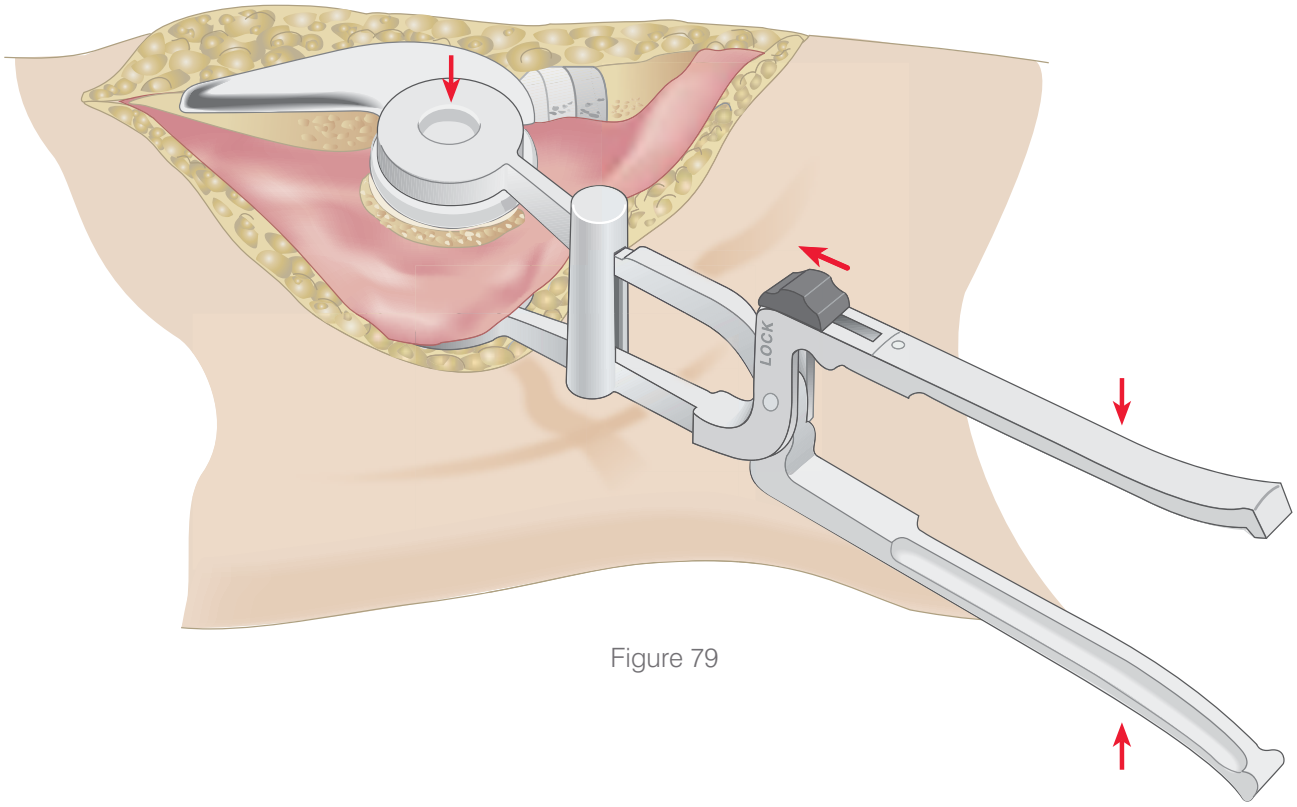


Figure 79

Implanting the Patellar Component

Perform patellar implantation when convenient.

Cleanse the site with pulsatile lavage and apply methyl methacrylate. Insert the component into the prepared holes and position the patellar clamp.

The clamp is designed to fully seat and stabilize the implant. Position it with the silicone O-ring centered over the articular surface of the implant and the metal backing plate against the anterior patellar cortex, avoiding skin entrapment. When snug, the handles are closed and held by the ratchet until polymerization is complete (Figure 79). Avoid excessive compression as it can fracture osteopenic bone. Remove all extruded cement with a curette.

The Cemented Tibial Stem Extensions

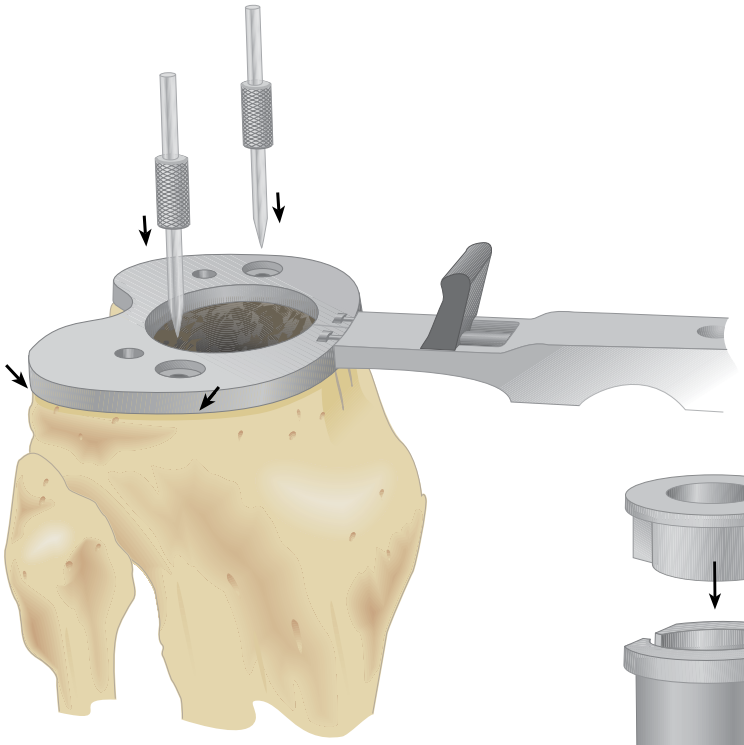


Figure 1

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).

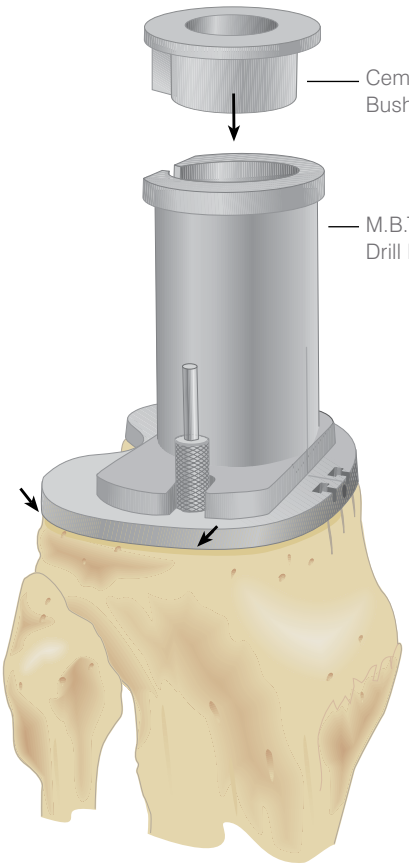


Figure 2

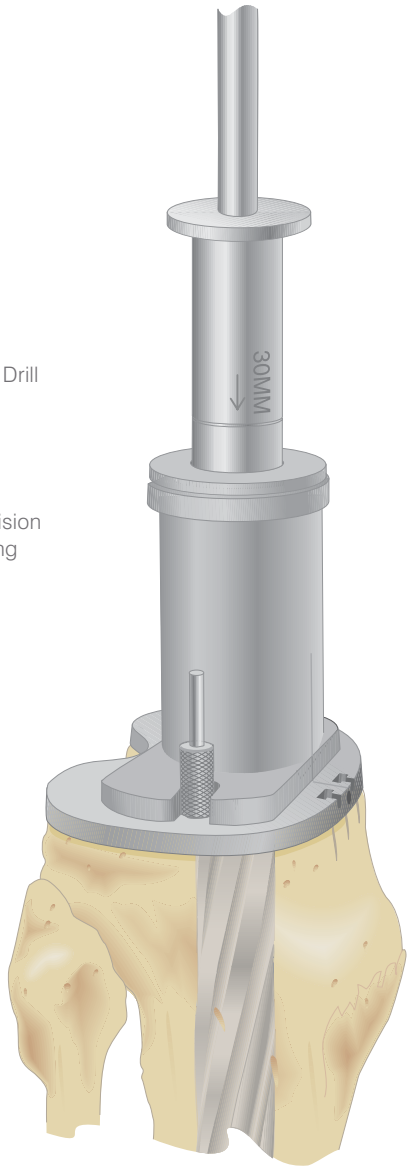


Figure 3

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 4

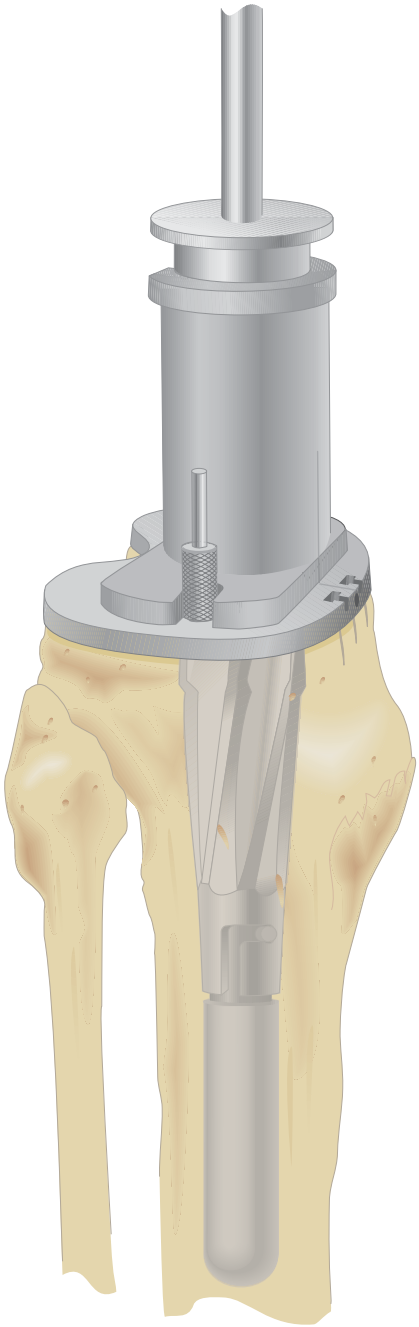


Figure 5

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.

Tapered Cemented Stems

Ream the canal with a reamer two sizes larger than the stem. For example, 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 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).

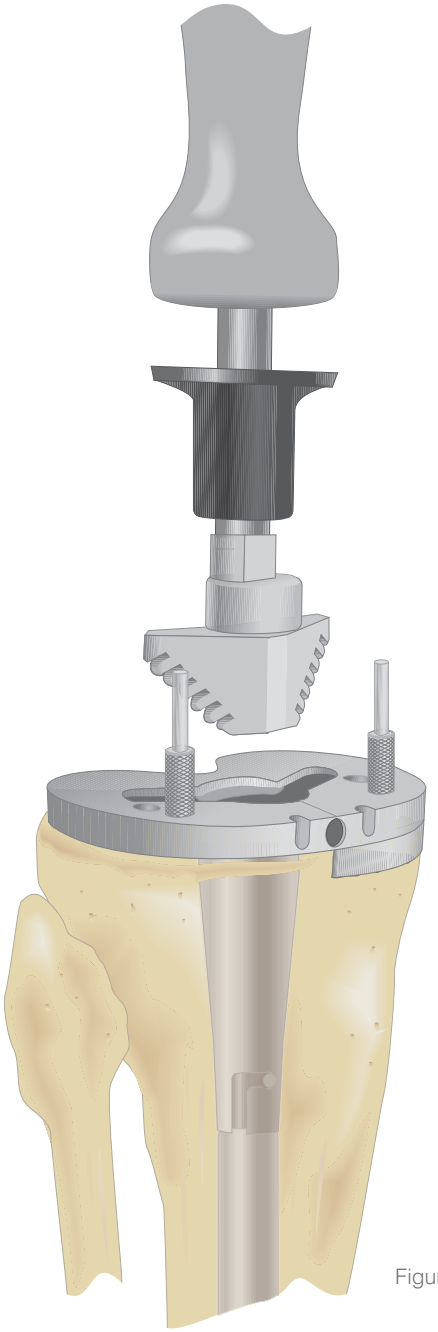


Figure 6

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.

Step Wedge Preparation

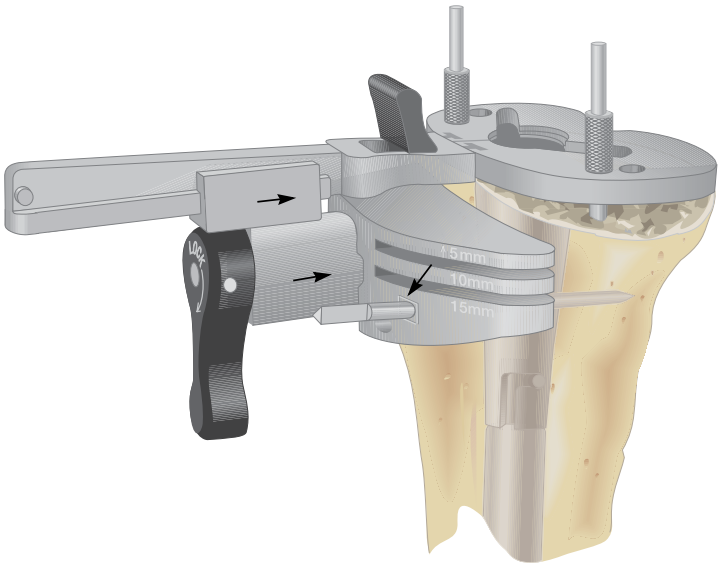


Figure 1

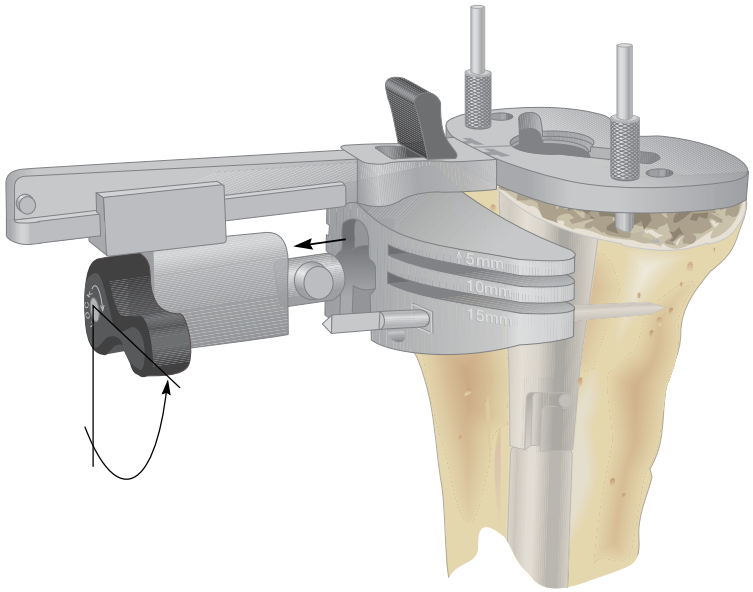


Figure 2

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 1).

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 2).

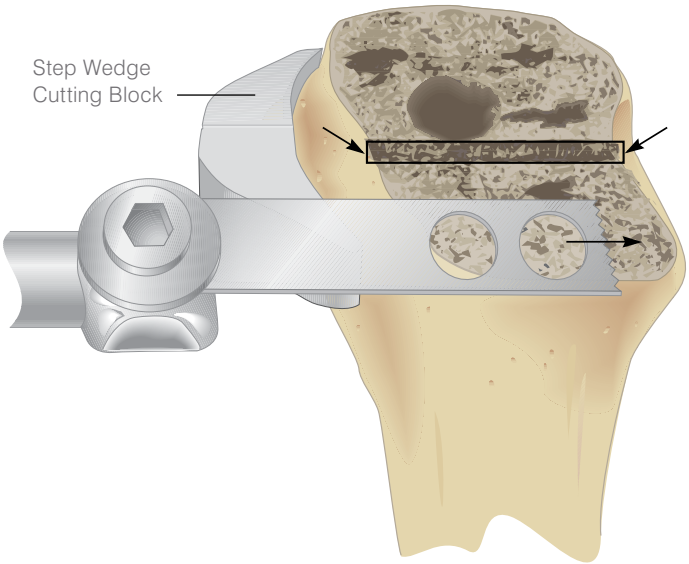


Figure 3

Figure 4

Trim the tibia accordingly with an oscillating saw so the cut does not extend beyond the central riser. Remove the block and pins (Figure 3).

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 4).

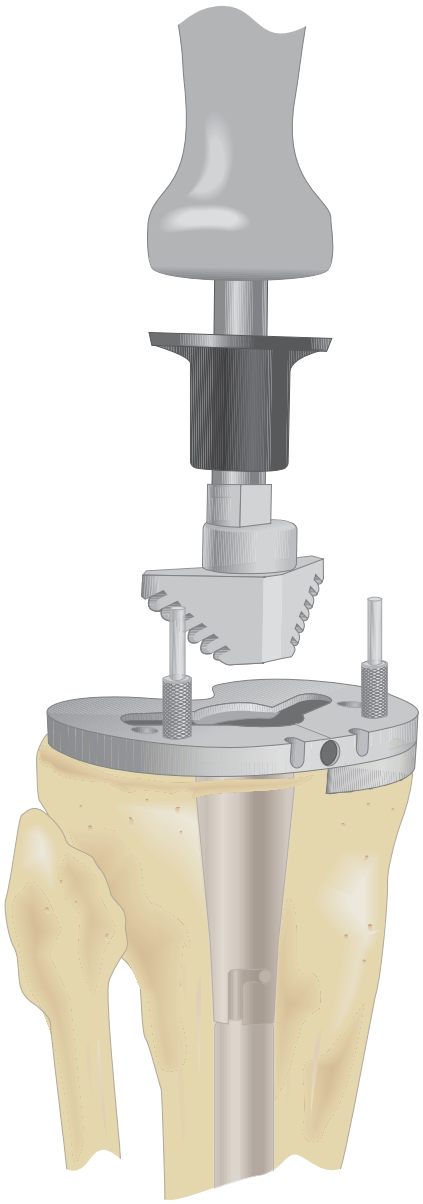


Figure 5

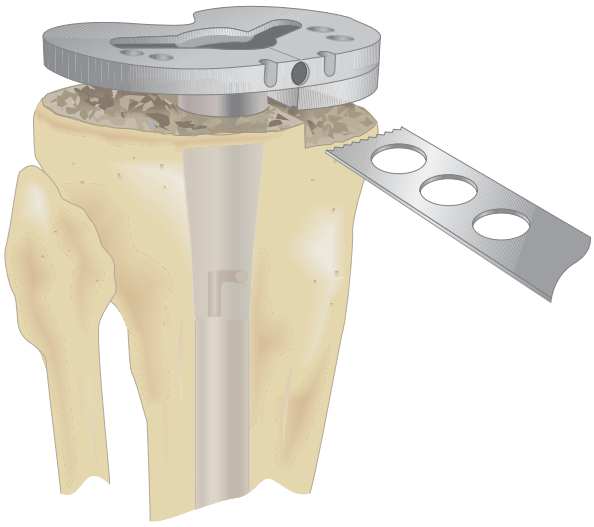


Figure 6

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 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).

Thick Tray Preparation

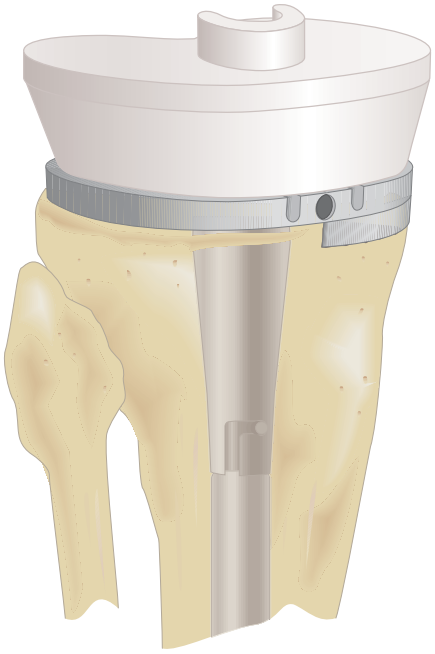


Figure 1

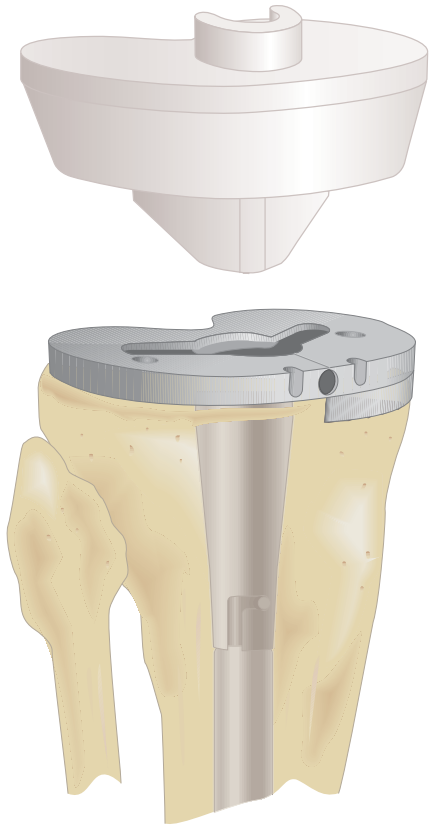


Figure 2

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 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 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.

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 M.B.T. thick tray instrument set.

Appendix: Femoral Trial Assembly - Stem-Only Use

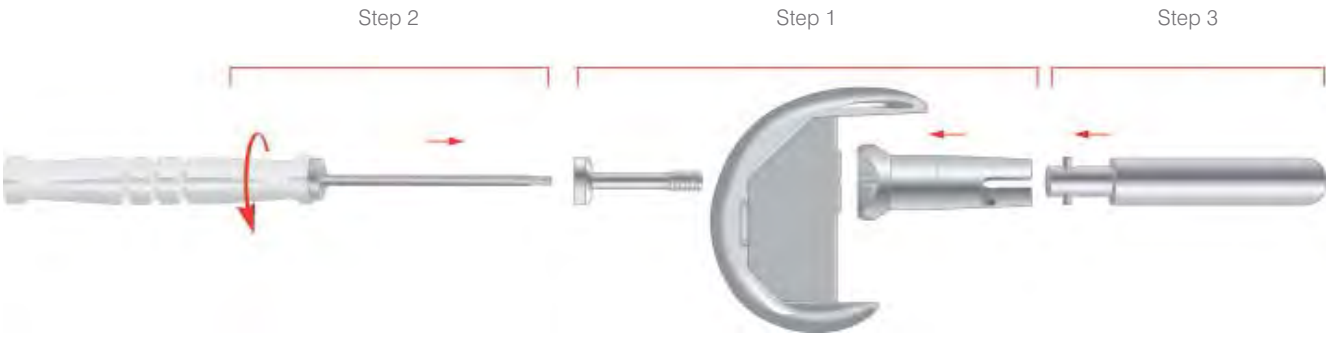


Figure 1

Trial assembly order (with stem-only use, Figure 1):

- Thread the stem bolt trial through the trial femur and trial femoral adapter and tighten (Steps 1 and 2)
- Add stem trial to trial assembly (Step 3)
- Add posterior and distal augment trials

Pass the appropriate P.F.C. Sigma Femoral Adapter stem bolt trial, neutral or +/-2 mm, corresponding to the bushing selected for the A/P cutting block and notch/chamfer guide, through the hole in the box of the distal femur. Thread the bolt trial through the P.F.C. Sigma Femoral Adapter trial (Figure 1 - Step 1).

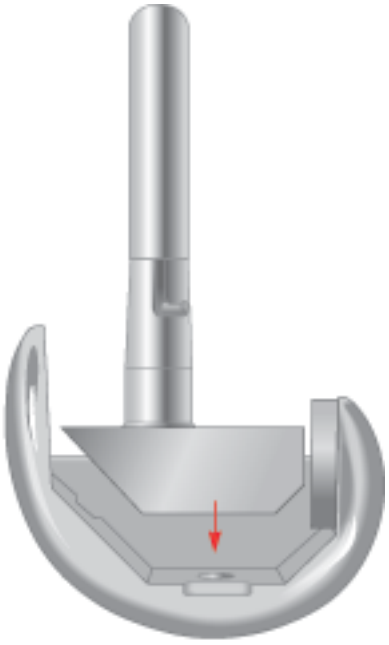


Figure 2

Note: Trial bolt lengths are different for adapter/sleeve use than for adapter/stem-only use.

Secure the adapter trial to the femoral trial by tightening the trial bolt with hex head screwdriver (Figure 1 - Step 2 on page 56). Assemble the stem trial, corresponding in size to the final diameter of the M.B.T. Revision reamer employed and to the established depth, to the femoral component/P.F.C. Sigma Femoral Adapter trial assembly (Figure 1 - Step 3 on page 56).

Where augmentation is employed, assemble the appropriate trial distal and posterior augmentation components to the trial femur (Figure 2). Gently impact the trial component assembly into position with the femoral impactor.

Femoral Implant Assembly - Stem-Only Use

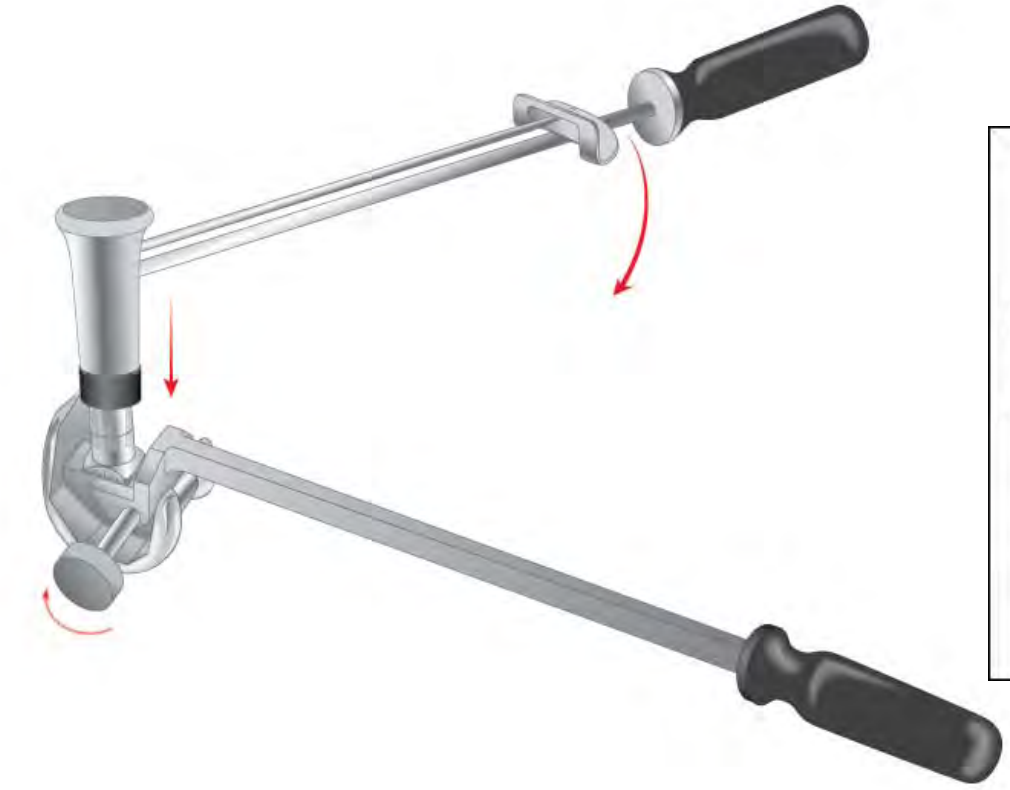


Figure 3

Figure 4

Implant assembly order (with stem-only use):

- Femoral adapter to femur
- Stem implant to femoral adapter
- Add posterior and distal augments if necessary

Attach the P.F.C. Sigma Femoral Adapter holding clamp to the femoral implant and tighten it. The clamp provides the second moment arm needed to assemble the parts. Place the torque wrench over the P.F.C. Sigma Femoral Adapter implant and move it clockwise to tighten the adapter to the femoral implant (Figure 3).

The torque wrench has a deflection beam, which indicates when sufficient torque has been applied (Figure 4).

Note: Torque the assembly to the 270 in. lb mark on the torque wrench to ensure implant longevity (Figure 4).

Note: The P.F.C. Femoral stem bolt is not compatible with the P.F.C. Sigma Femoral Adapter, as it is approximately 7 mm longer than the P.F.C. Sigma Femoral Adapter bolt and will prevent the adapter from sitting flush on the femoral box.

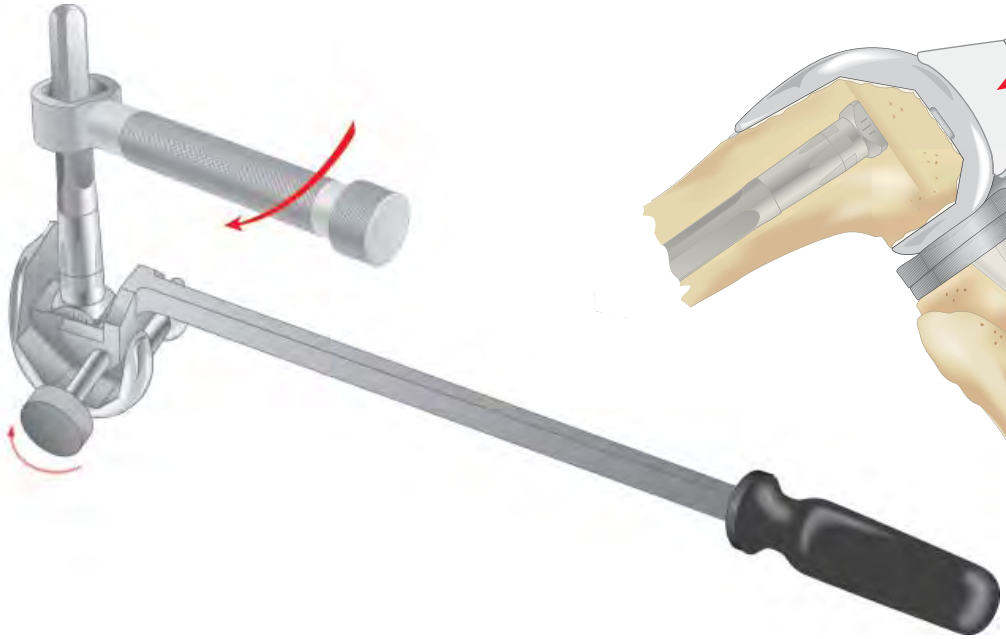


Figure 5

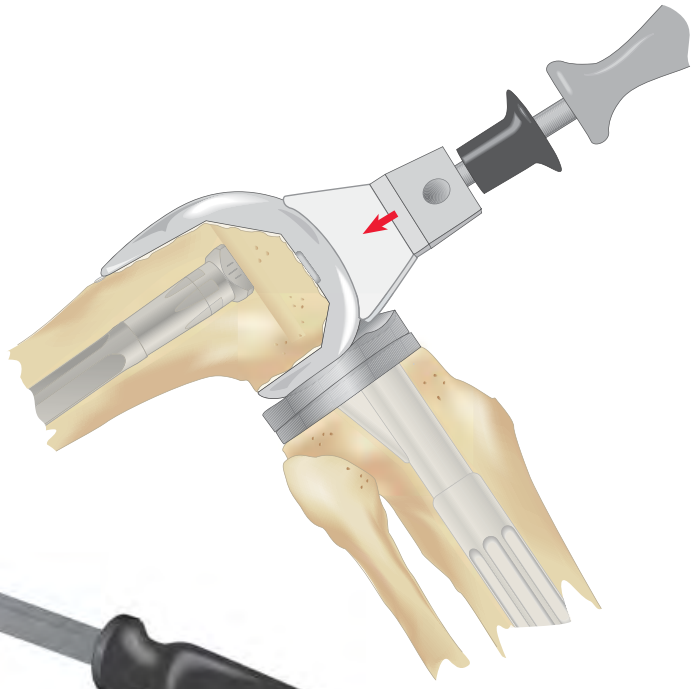


Figure 6

To attach the universal stem to the P.F.C. Sigma Femoral Adapter, thread the stem onto the adapter.

With the P.F.C. Sigma Femoral Adapter holding clamp in place, use the stem extension wrench to grasp the universal stem. Tighten as shown in Figure 5.

Apply sufficient force to both the P.F.C. Sigma Femoral Adapter holding clamp and stem extension wrench to ensure that stem is secure.

Implant the femoral component using the femoral impactor (Figure 6).

Femoral Trial Assembly - Sleeve-Only Use

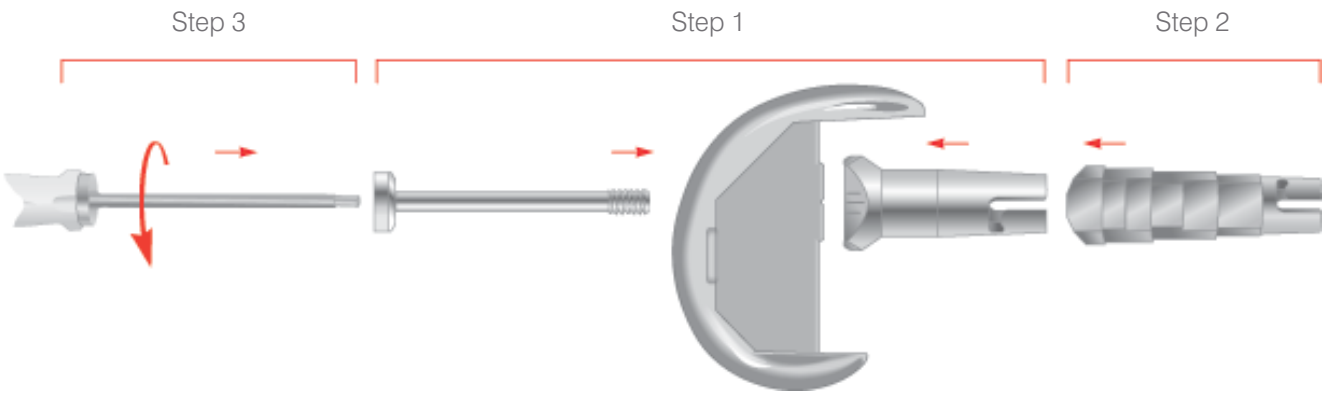


Figure 1

Trial assembly order (with sleeve-only use, Figure 1)

- Thread the bolt trial through the trial femur and trial femoral adapter
- Trial sleeve placed over adapter trial
- Loosely tighten assembly with hex head screwdriver, or by spinning sleeve
- Add posterior and distal augment trials if needed
- Seat trial assembly in femur
- Once sleeve trial has achieved proper orientation, tighten securely with hex head screwdriver

Pass the appropriate P.F.C. Sigma Femoral Adapter sleeve bolt trial, neutral or +/-2 mm, corresponding to the bushing selected for the A/P cutting block and notch/chamfer guide, through the hole in the box of the distal femur. Thread the bolt trial through the P.F.C. Sigma Femoral Adapter trial (Figure 1 - Step 1).

Note: Trial bolt lengths are different for adapter/sleeve use than for adapter/stem-only use.

When preparing the femoral trial for use with a sleeve, assemble the sleeve trial, corresponding in size to the final broach employed, to the femoral component/ P.F.C. Sigma Femoral Adapter trial assembly. Tighten by turning the sleeve trial to initially engage the bolt trial thread.

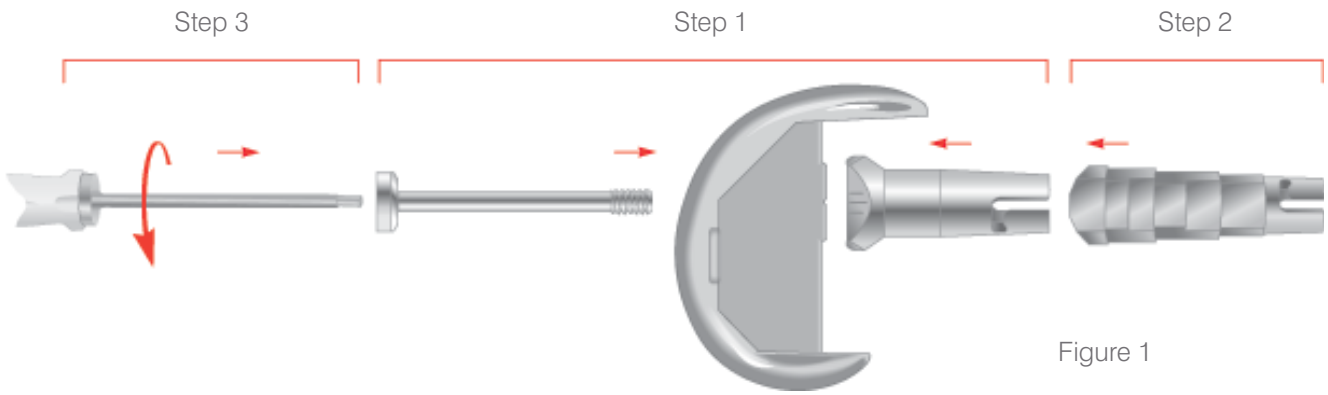


Figure 1

(continued)

Make sure to properly orient the sleeve trial with the narrow side facing medially. Use the hex head screwdriver to loosely secure the assembly (Figure 1 - Step 3). This mechanical connection to the adapter/femoral trial construct helps to ensure that the parts do not disassociate during use.

Note: Please consult the anteroposterior width chart on page 65 of the Appendix to determine the sleeve/femur compatibility and the distance between the anterior chamfer and the anterior aspect of the sleeve.

Where augmentation is employed, assemble the appropriate trial distal and posterior augmentation components to the trial femur.

Seat the femoral trial in the femur. The sleeve trial will achieve the rotation and orientation of final broach used.

After the sleeve trial is seated securely in the metaphysis, securely tighten the bolt trial with the hex head screwdriver. Etch lines have been added to the medial side of the adapter trial and sleeve trials for a more accurate assessment of the sleeve's rotation during final implant assembly.

Femoral Implant Assembly - Sleeve-Only Use

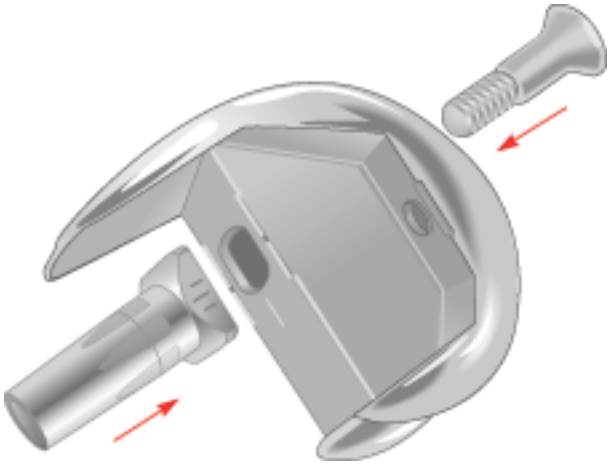


Figure 2

Figure 3

Implant assembly order (with sleeve-only use):

- Femoral adapter-to-femur
- Add posterior and distal augments if necessary
- Sleeve-to-femoral adapter

Pass the appropriate P.F.C. Sigma Femoral Adapter bolt, neutral or +/-2 mm, corresponding to the bushing selected for the A/P cutting block and notch/chamfer guide, through the hole in the box of the distal femur and into the P.F.C. Sigma Femoral Adapter (Figure 2).

Note: The P.F.C. Femoral stem bolt is not compatible with the P.F.C. Sigma Femoral Adapter, as it is approximately 7 mm longer than the P.F.C. Sigma Femoral Adapter bolt and will prevent the adapter from sitting flush on the femoral box.

Attach the P.F.C. Sigma Femoral Adapter holding clamp to the femoral implant and tighten it. The clamp provides the second moment arm needed to assemble the parts. Place the torque wrench over the P.F.C. Sigma Femoral Adapter implant and move it clockwise to tighten the adapter to the femoral implant (Figure 3).

Figure 4

Figure 5

The torque wrench has a deflection beam, which indicates when sufficient torque has been applied (Figure 4). Remove the P.F.C. Sigma Femoral Adapter holding clamp.

Note: Torque the assembly to the 270 in. lb mark on the torque wrench to ensure implant longevity (Figure 4).

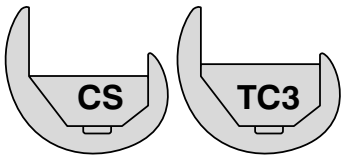
Place the femoral component with the femoral adapter on a firm, stable surface. Place the appropriate sleeve on top of the adapter.

Slide the femoral stem/sleeve impactor on top of the sleeve and forcefully apply three strikes with a mallet to engage the two components (Figure 5).

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

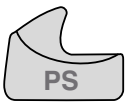
Implant the femoral component using the femoral impactor.

Femoral Revision and Tibial Insert Compatibility

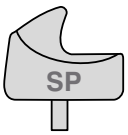


Tibial Inserts		Femoral Components													
		SIZE 1.5 53AP/57ML		SIZE 2 56AP/60ML		SIZE 2.5 59AP/63ML		SIZE 3 61AP/66ML		SIZE 4 65AP/71ML		SIZE 5 69AP/73ML		SIZE 6 74AP/78ML	
		CS	TC3	CS	TC3	CS	TC3	CS	TC3	CS	TC3	CS	TC3	CS	TC3
SIZE 1.5 41AP/61ML	PS SP	■	■	■	■										
	TC3		■		■										
SIZE 2 43AP/64ML	PS SP	■	■	■	■	■	■	■	■						
	TC3		■		■		■		■						
SIZE 2.5 45AP/67ML	PS SP			■	■	■	■	■	■						
	TC3				■		■		■						
SIZE 3 47AP/71ML	PS SP			■	■	■	■	■	■	■	■				
	TC3					■		■		■		■			
SIZE 4 51AP/76ML	PS SP							■	■	■	■	■	■		
	TC3								■		■		■		
SIZE 5 55AP/83ML	PS SP									■	■	■	■	■	
	TC3										■		■		
SIZE 6 59AP/89ML	PS SP											■	■	■	

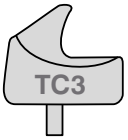
Fixed



Posterior Stablized
8, 10, 12.5, 15, 17.5, 20, 22.5, 25 (mm)



Stablized Plus
10, 12.5, 15, 17.5, 20, 22.5, 25, 30 (mm)



TC3
10, 12.5, 15, 17.5, 20, 22.5, 25, 30 (mm)

Rotating Platform

Posterior Stabilized
10, 12.5, 15, 17.5, 20, 22.5, 25 (mm)

TC3 RP
10, 12.5, 15, 17.5, 20, 22.5, 25, 30 (mm)

Sigma Revision Anteroposterior Chart (With Sleeve Use)

The following chart shows the distance (mm) between the anterior flange of a femoral component and the sleeve, based on the size of the component and the anteroposterior option chosen. Fields with an X denote that the sleeve, femur and offset option is not possible.

Femoral Size and A/P Position

Size of sleeve (M/L)	1.5 Ant	1.5 Neut	1.5 Post	2 Ant	2 Neut	2 Post	2.5 Ant	2.5 Neut	2.5 Post	3 Ant	3 Neut	3 Post
20 mm	0.9	2.7	4.7	1.8	3.8	5.8	2.6	4.6	6.6	3.2	5.2	7.2
31 mm	2.1	4.5	5.8	2.7	5.0	7.0	3.8	5.8	7.8	4.6	6.7	8.6
34 mm	X	3.4	4.6	2.1	4.4	5.9	3.2	5.2	7.0	3.6	5.7	7.6
40 mm	X	2.4	3.9	1.2	3.2	5.6	2.0	3.9	6.0	2.7	4.6	6.5
46 mm	X	2.6	3.6	X	2.6	4.8	1.5	3.6	5.5	2.4	4.6	6.4

Femur Size and A/P Position

Size of sleeve (M/L)	4 Ant	4 Neut	4 Post	5 Ant	5 Neut	5 Post	6 Ant	6 Neut	6 Post
20 mm	4.9	6.9	8.9	6.4	8.4	10.4	8.5	10.5	12.5
31 mm	6.3	8.3	10.2	7.8	9.7	11.8	9.9	11.9	13.9
34 mm	5.3	7.3	9.3	6.8	8.9	10.8	8.8	10.9	13.0
40 mm	4.2	6.1	8.1	5.6	7.6	9.6	7.8	9.9	11.8
46 mm	4.3	6.2	8.2	5.7	7.6	9.6	7.9	9.9	11.7

Femoral Augmentation

Trials & Inserts – Cat. No. 96-6585

	Description	Cat. No.
A	Plug Puller	86-5151
B	Mod Plus Torque Driver Extension	96-6301
C	Mod Plus Torque Driver	86-0284

		Size	Size Thickness	Cat. No.
D	Distal Augment Trials	1.5	4 mm	96-1800
		1.5	8 mm	96-1802
		1.5	12 mm	96-1810
		2	4 mm	96-1820
		2	8 mm	96-1822
		2	12 mm	96-1830
		2	16 mm	96-1832
		2.5	4 mm	96-1840
		2.5	8 mm	96-1842
		2.5	12 mm	96-1850
		2.5	16 mm	96-1852
		3	4 mm	96-1860
		3	8 mm	96-1862
		3	12 mm	96-1870
		3	16 mm	96-1872
		4	4 mm	96-1880
		4	8 mm	96-1882
		4	12 mm	96-1890
		4	16 mm	96-1892
		5	4 mm	96-1900
		5	8 mm	96-1902
		5	12 mm	96-1910
		5	16 mm	96-1912
E	Posterior Augmentation Trials			
		1.5	4 mm	96-1806
		2	4 mm	96-1826
		2	8 mm	96-1828
		2.5	4 mm	96-1846
		2.5	8 mm	96-1848
		3	4 mm	96-1866
		3	8 mm	96-1868
		4	4 mm	96-1886
		4	8 mm	96-1888
		5	4 mm	96-1906
		5	8 mm	96-1908

Femoral Revision Tray

Base Tray – Cat. No. 96-6582

	Description		Cat. No.
A	Femoral Notch guide	**Size**	**Cat. No.**
		2 mm	96-6252
		2.5 mm	96-6251
		3 mm	96-6253
		4 mm	96-6254
		5 mm	96-6255
B	Femoral Locating Device Outrigger		96-6112
C	Femoral Locating Device		96-6110
D	Femoral Notch Guide Bushings	96-6531 – 96-6548 (1mm increments)	
E	Femoral Box Trials - STB	**Size**	**Cat. No.**
		2 mm	96-1042
		2.5 mm	96-1048
		3 mm	96-1043
		4 mm	96-1044
		5 mm	96-1045
F	Femoral Box Trials - TC3	**Size**	**Cat. No.**
		2 mm	96-1052
		2.5 mm	96-1058
		3 mm	96-1053
		4 mm	96-1054
		5 mm	96-1055
G	Femoral Box Trial Screw Driver		96-6295

Femoral Revision Tray

Insert – Cat. No. 96-6582

A	Removable Handles		96-6147
B	Femoral Revision A/P Cutting Blocks	**Size**	**Cat. No.**
		2	96-6172
		2.5	96-6171
		3	96-6173
		4	96-6174
		5	96-6175
C	Steinmann Pins		86-9117
D	Distal Femoral Cutting Block		96-6115
E	Femoral Distal Augment Spacers	**Size**	**Cat. No.**
		4 mm	96-6165
		8 mm	96-6166
		12 mm	96-6167
		16 mm	96-6168
F	Femoral A/P Revision Guide shings		**Cat. No.**
	Offset	**Size**	
	0	5°	96-6177
	+2/-2	5°	96-6178
	0	7°	96-6182
	+2/-2	7°	96-6183
G	Stylus		96-6335

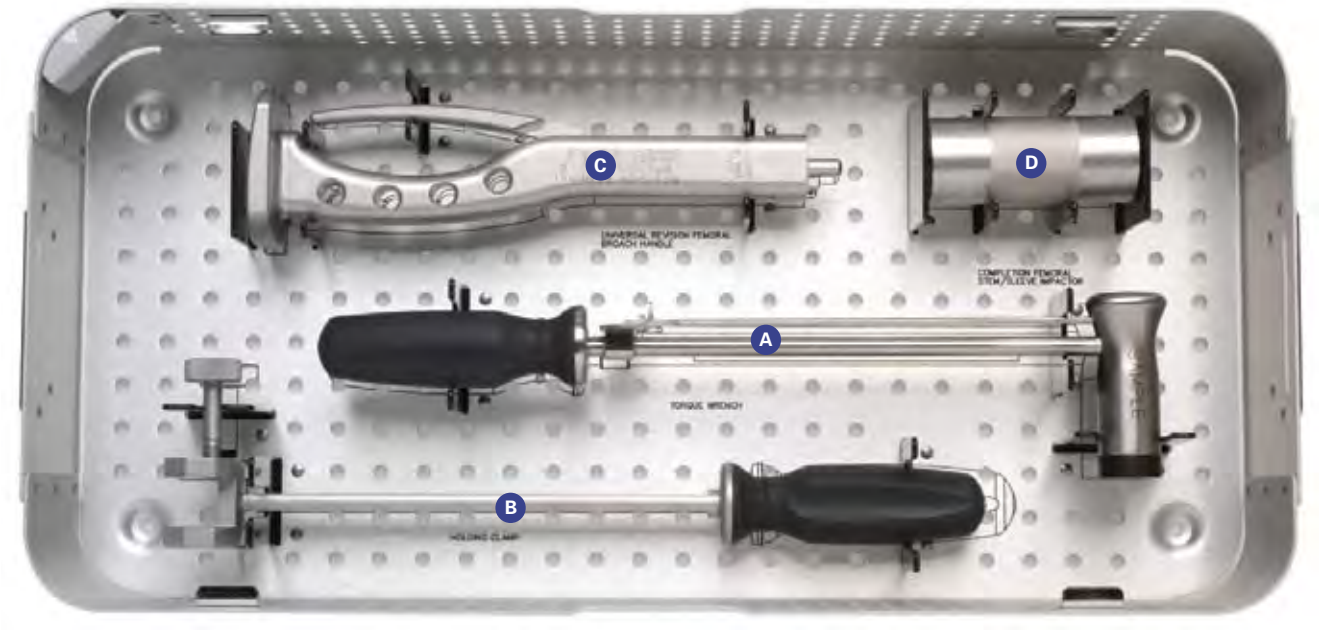
Sigma Femoral Adapter Instruments

Top Tray – Cat. No. 96-1689

	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

Sigma Femoral Adapter Instruments

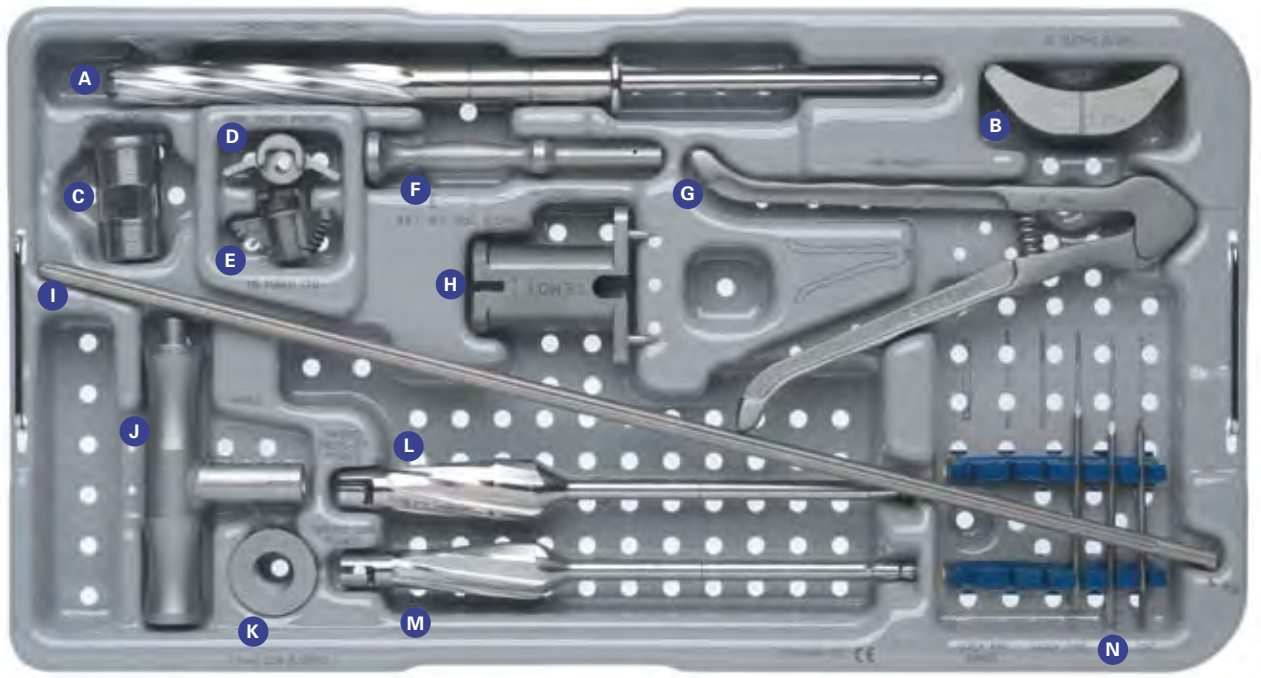
Bottom Tray – Cat. No. 96-1689



	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

M.B.T. Revision Prep Sterilization

Top Insert – Cat. No. 2178-64-100



	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

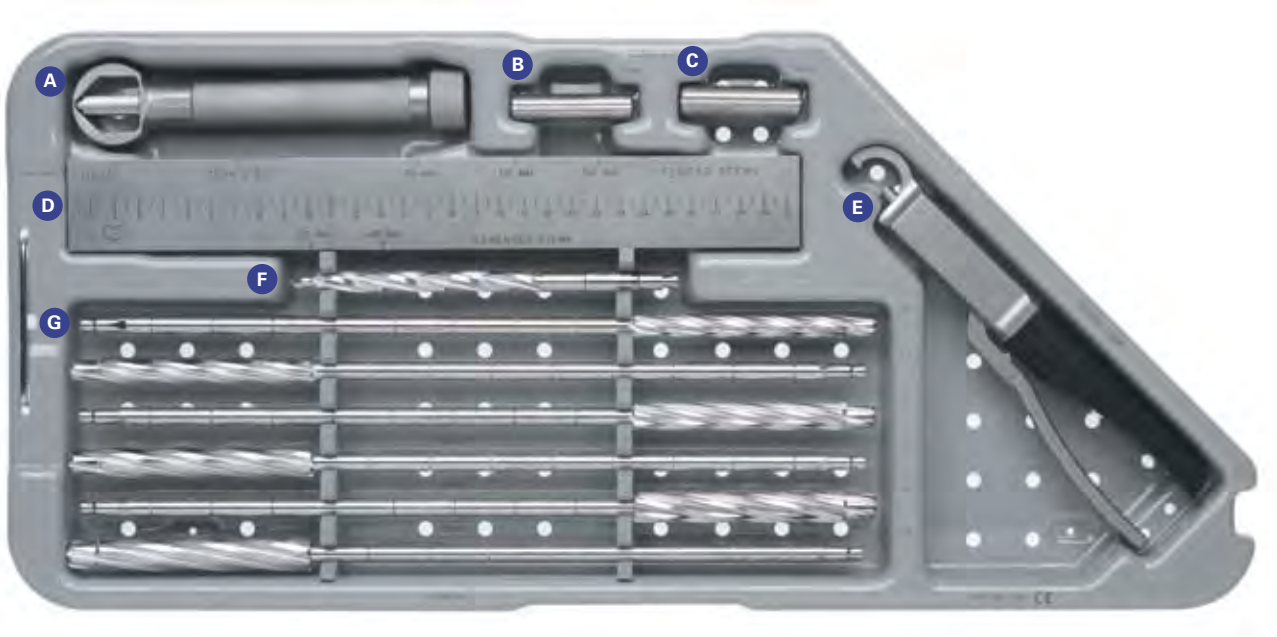
M.B.T. Revision Prep Sterilization

Base and Bottom Insert – Cat. No. 2178-64-100

	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

Revision Reamers Sterilization Tray

Top Insert – Cat. No. 2178-64-105



	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	2178-56-6045
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

Revision Reamers Sterilization Tray

Base and Bottom Insert Cat. No. 2178-64-105

	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

Top Insert – Cat. No. 2178-64-110

	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	86-6889
		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

Revision Stem Trials & Instruments Sterilization Tray

Base and Bottom Insert – Cat. No. 2178-64-110

	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	86-6889
		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

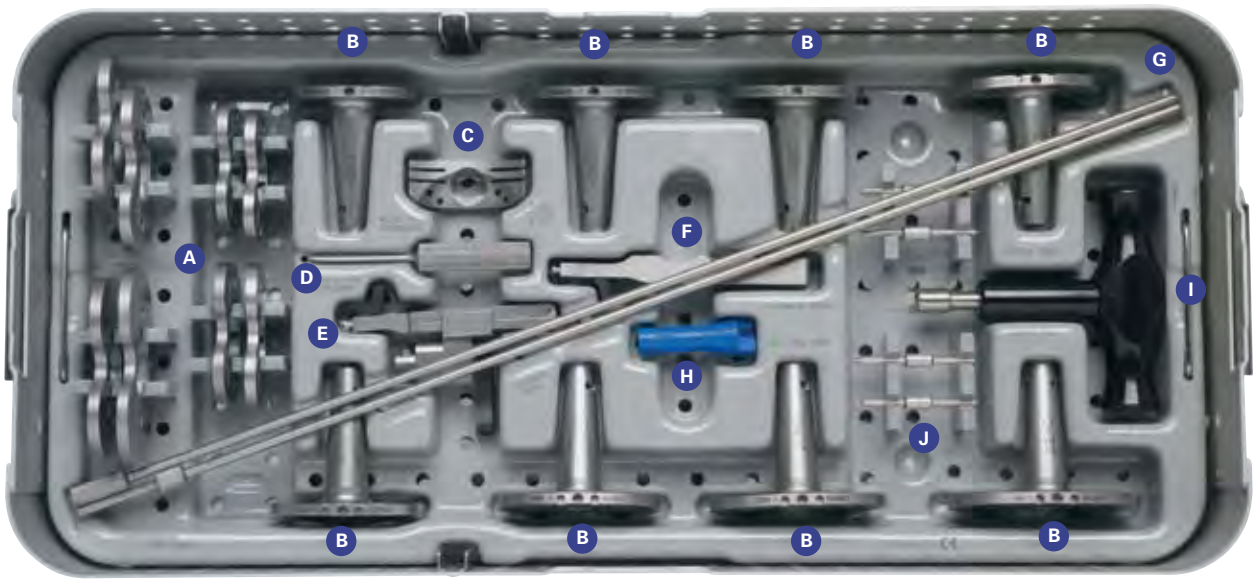
Top Insert – Cat. No. 2178-64-115

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

M.B.T. Revision Tray Trials & Wedge Instruments Sterilization Tray

Base and Bottom Insert – Cat. No. 2178-64-115



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

Notes

Total and Unicompartmental Knee Prostheses

Important

This essential product information does not include all of the information necessary for selection and use of a device. Please see full labeling for all necessary information.

Indications

Total knee arthroplasty (TKA) and unicompartmental knee replacement are intended to provide increased patient mobility and reduce pain by replacing the damaged knee joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. TKA is indicated for: a severely painful and or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis or a failed previous implant. Unicompartmental knee replacement is indicated in these conditions if only one side of the joint (medial or lateral) is affected.

Contraindications

TKA and unicompartmental knee replacement are contraindicated in cases of: active local or systemic infection; loss of musculature, neuromuscular compromise or vascular deficiency in the affected limb, rendering the procedure unjustifiable; poor bone quality; or severe instability secondary to advanced loss of osteochondral structure or the absence of collateral ligament integrity. Unicompartmental knee replacement is contraindicated in patients with over 30 degrees of fixed varus or valgus deformity.

Warnings and Precautions

Components labeled for “Cemented Use Only” are to be implanted only with bone cement. The following conditions tend to adversely affect knee replacement implants: excessive patient weight, high levels of patient activity, likelihood of falls, poor bone stock, metabolic disorders, disabilities of other joints.

Adverse Events

The following are the most frequent adverse events after knee arthroplasty: change in position of the components, loosening, bending, cracking, fracture, deformation or wear of one or more of the components, infection, tissue reaction to implant materials or wear debris; pain, dislocation, subluxation, flexion contracture, decreased range of motion, lengthening or shortening of leg caused by improper positioning, looseness or wear of components; fractures of the femur or tibia.

For more information about DePuy products, visit our web site at www.depuyknees.com

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