



P.F.C.® SIGMA KNEE SYSTEM

REVISION

SURGICAL TECHNIQUE

SPECIALIST  INSTRUMENTS



REVISION SURGERY
FOR FAILED TOTAL-KNEE
REPLACEMENT

CONSULTING SURGEONS

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INTRODUCTION

In total-knee arthroplasty, 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. Amongst 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.

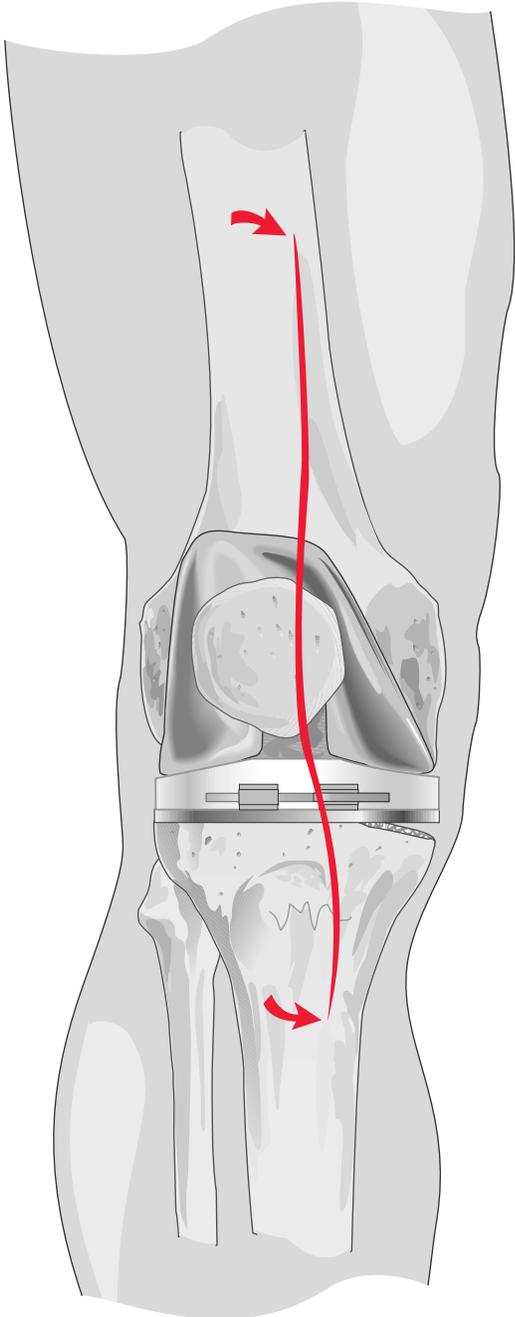
PREOPERATIVE PLANNING

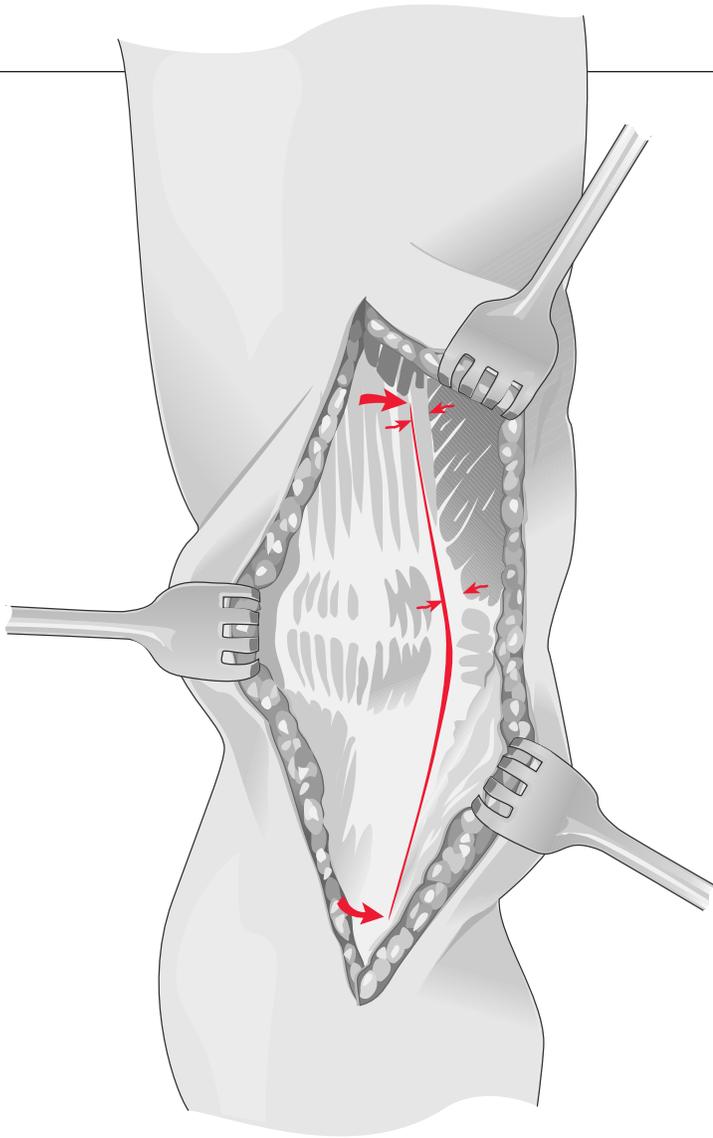
Revision total-knee arthroplasty begins with thorough clinical and roentgenographic evaluation. Physical evaluation includes the examination of the soft tissues, taking into account previous skin incisions, range of motion, motor strength, the condition of all neurovascular structures, ligamentous stability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

INITIAL INCISION

Where possible, the scar from the primary procedure is followed. 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°. 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.



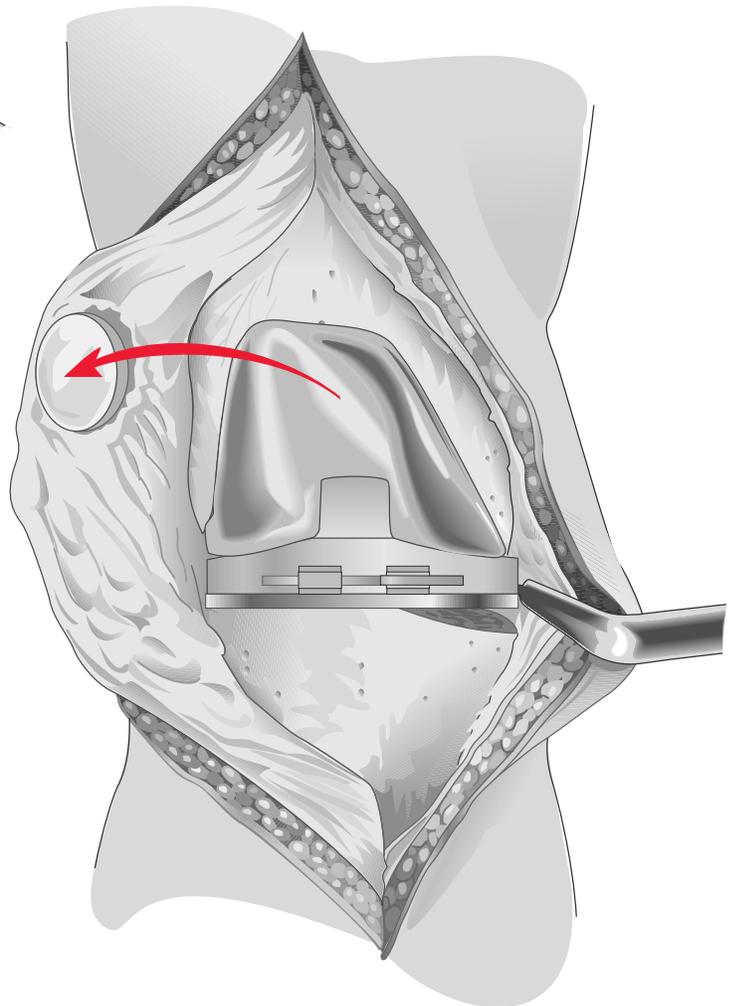


CAPSULAR INCISION

The fascial incision extends from the proximal margin of the rectus femoris to the distal margin of the tibial tubercle following the medial border of the patella, maintaining a $\frac{1}{8}$ " cuff for reapproximation of the vastus medialis aponeurosis at closure. Where mobilization of the extensor mechanism and patella is problematic, the skin and capsular incisions are extended proximally.

Occasionally, an early lateral retinacular release is indicated to assist 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. Appropriate ligamentous release is performed based upon preoperative and intraoperative evaluation. Fibrous adhesions are released to re-establish the suprapatellar pouch and medial and lateral gutters.

In many revision cases, the posterior cruciate ligament will be absent or nonfunctional; any residual portion is excised.



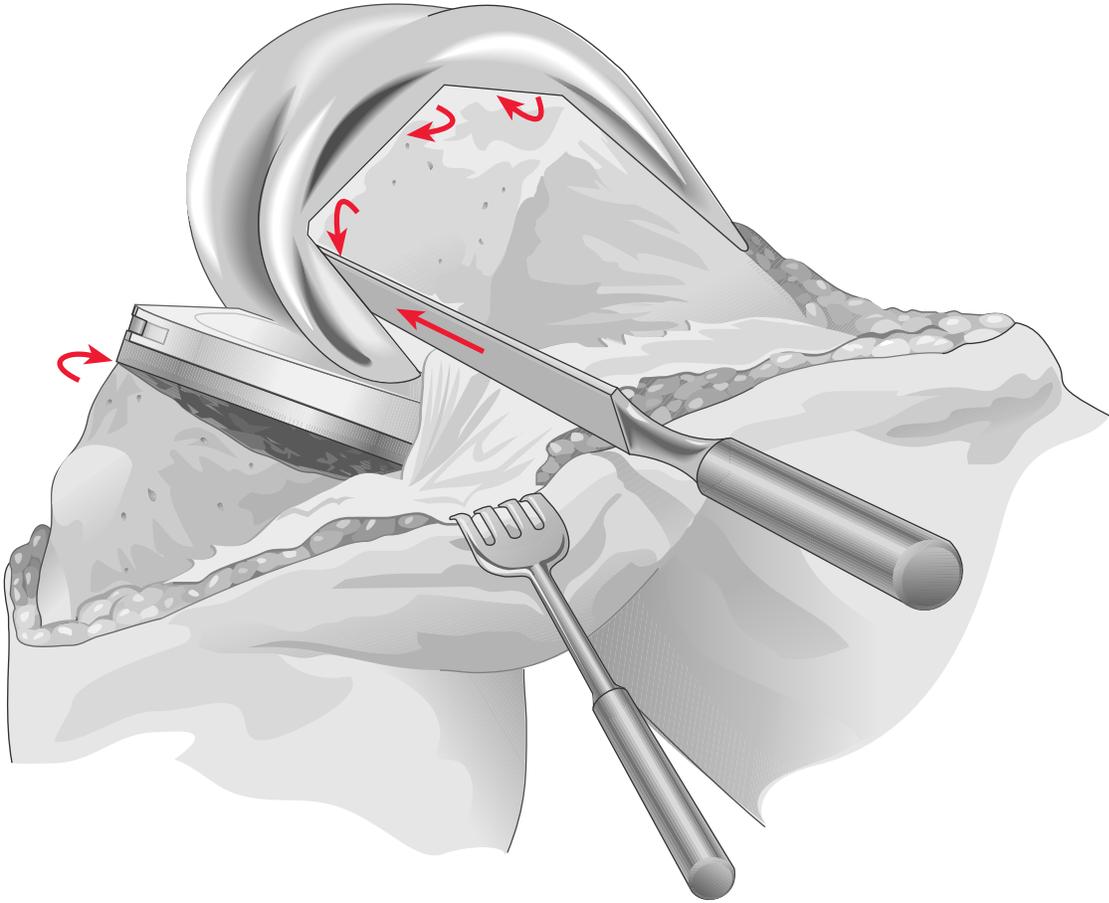
**THE P.F.C.® SIGMA REVISION
KNEE SYSTEM IS COMPRISED OF THE
FOLLOWING COMPONENTS:**

- Stabilized Femoral Component available in seven sizes
- TC3 Femoral Component available in six sizes
- Ability to up/downsize femur to tibia
- 4 mm, 8 mm, 12 mm and 16 mm Distal Femoral Augmentations
- 4 mm and 8 mm Posterior Femoral Augmentations
- Three anteroposterior Femoral Stem Positions: 0, +2 mm and -2 mm
- 125 mm and 175 mm Fluted Femoral Stem Lengths in 10 mm to 24 mm diameters in 2 mm increments at 5° and 7° valgus angles
- 90 mm and 130 mm Cemented Femoral Stem Lengths in 13 mm and 15 mm diameters at 5° and 7° valgus angles
- Three levels of tibial insert constraint: Posterior Stabilized, Stabilized Plus and TC3
- Three types of Tibial Wedge Augmentation Components: Hemi Wedge in 10° and 20° angles; Step Wedge in 10 mm and 15 mm thickness; and Full Wedge in 10° and 15° angles
- 75 mm, 115 mm and 150 mm Fluted Tibial Stem Lengths in 10 mm to 24 mm diameters in 2 mm increments
- 30 mm and 60 mm Cemented Tibial Stem Lengths in 13 mm and 15 mm diameters
- Systematic and simple instrumentation system to accommodate each of the component options and surgical preferences based upon a patented Rod and Sleeve IM alignment system

EXTRACTION OF IMPLANTS FROM THE PRIMARY PROCEDURE

Care is taken to preserve as much bone as possible. To this end, a selection of tools is assembled, including thin osteotomes, an oscillating saw, a Gigli saw, a high-speed burr and various extraction devices, but may cases will require only the osteotome.

The bone/cement or bone/prosthesis interface is carefully disrupted before extraction is attempted. The implanted components are disengaged and extracted 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 tibia. All residual methylmethacrylate is cleared with chisels or power tools.



INTRAOPERATIVE EVALUATION

RECOMMENDED SURGICAL PRIORITY

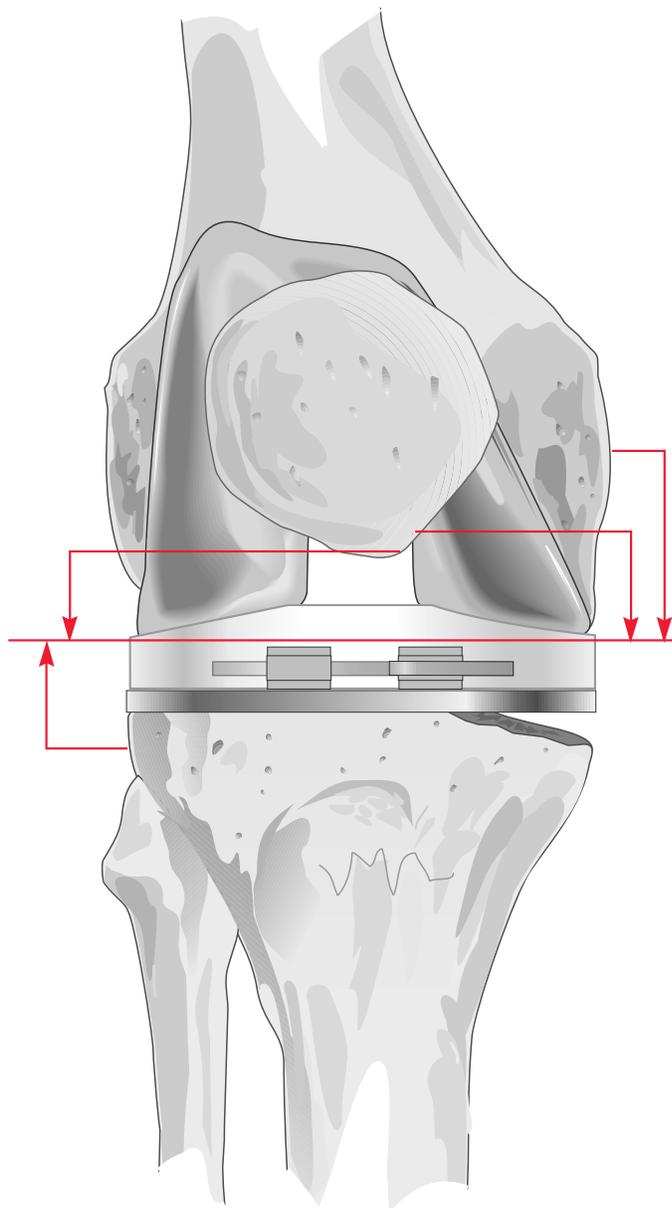
1. Tibial medullary canal preparation
2. Proximal tibial resection
3. Femoral medullary canal preparation
4. Distal femoral resection
5. Establishment of femoral rotation
6. Anteroposterior, notch and chamfer resection
7. Establishment of tibial rotation
8. Tibial deficit augmentation
9. Final tibial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

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 (approx. 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

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. A 1 mm shim should be used for the extension gap and removed when assessing the flexion gap. This will compensate for the 1 mm component difference between the distal and posterior condyles.

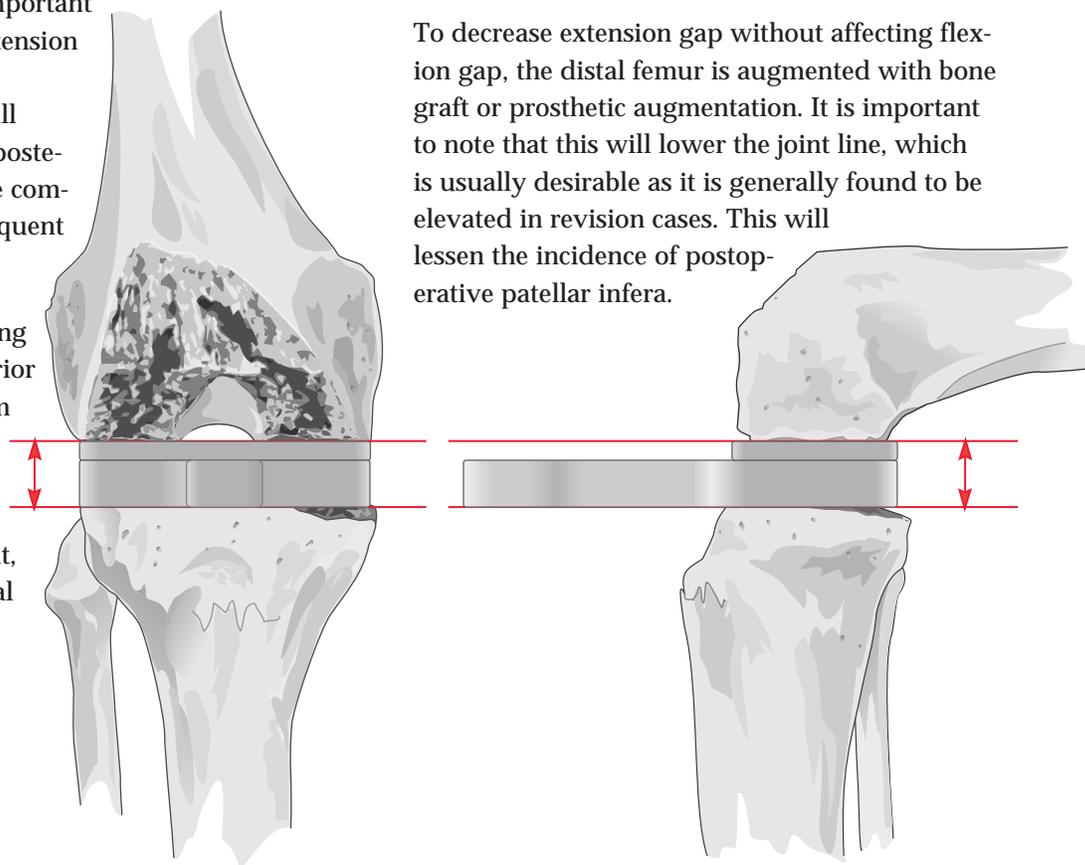
The tibia is sized first, and the same size of femoral component is initially chosen. This can then be adjusted to accommodate the following:

WHERE FLEXION GAP > EXTENSION GAP:

To decrease flexion gap without affecting extension gap, a larger femoral component is applied. 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, a 2 mm offset stem bolt with the arrow pointing anteriorly is assembled to the component, translating the femoral component 2 mm posteriorly.

(Refer to page 29 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, the distal femur is augmented 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.

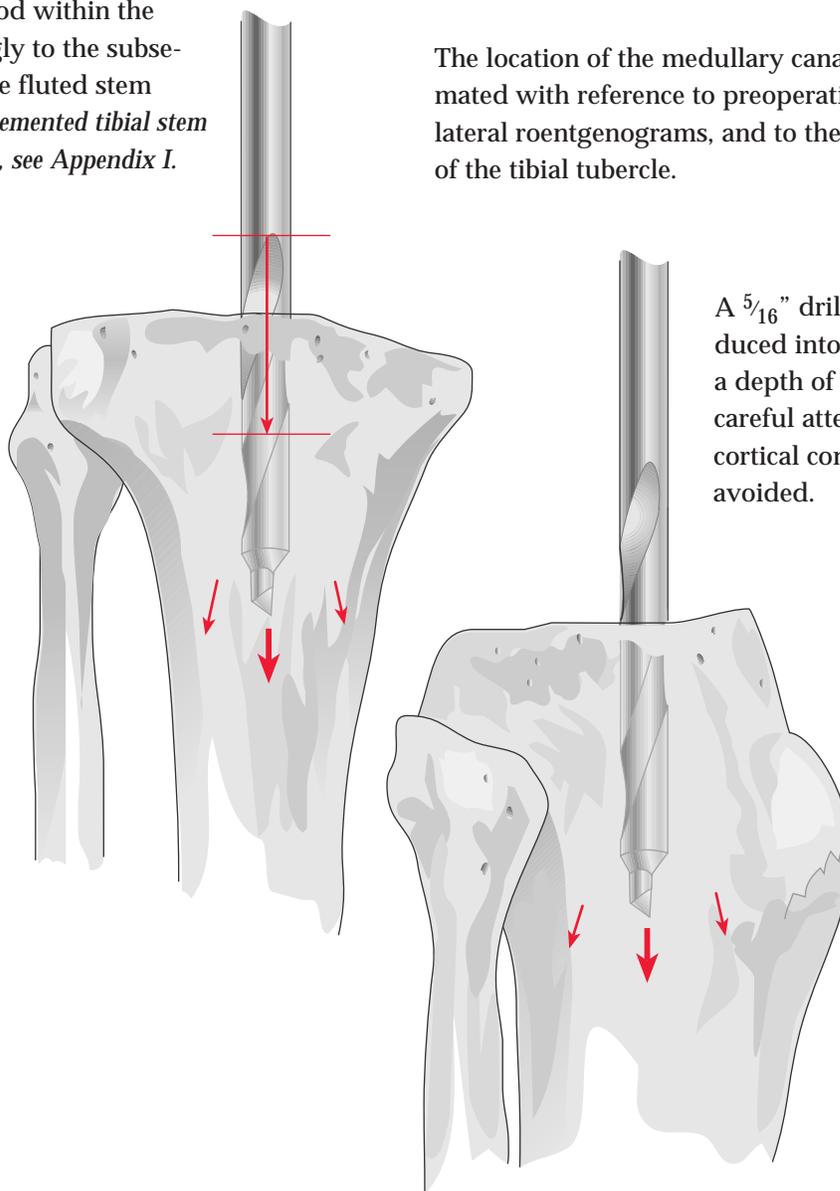
INITIAL PREPARATION OF THE TIBIA

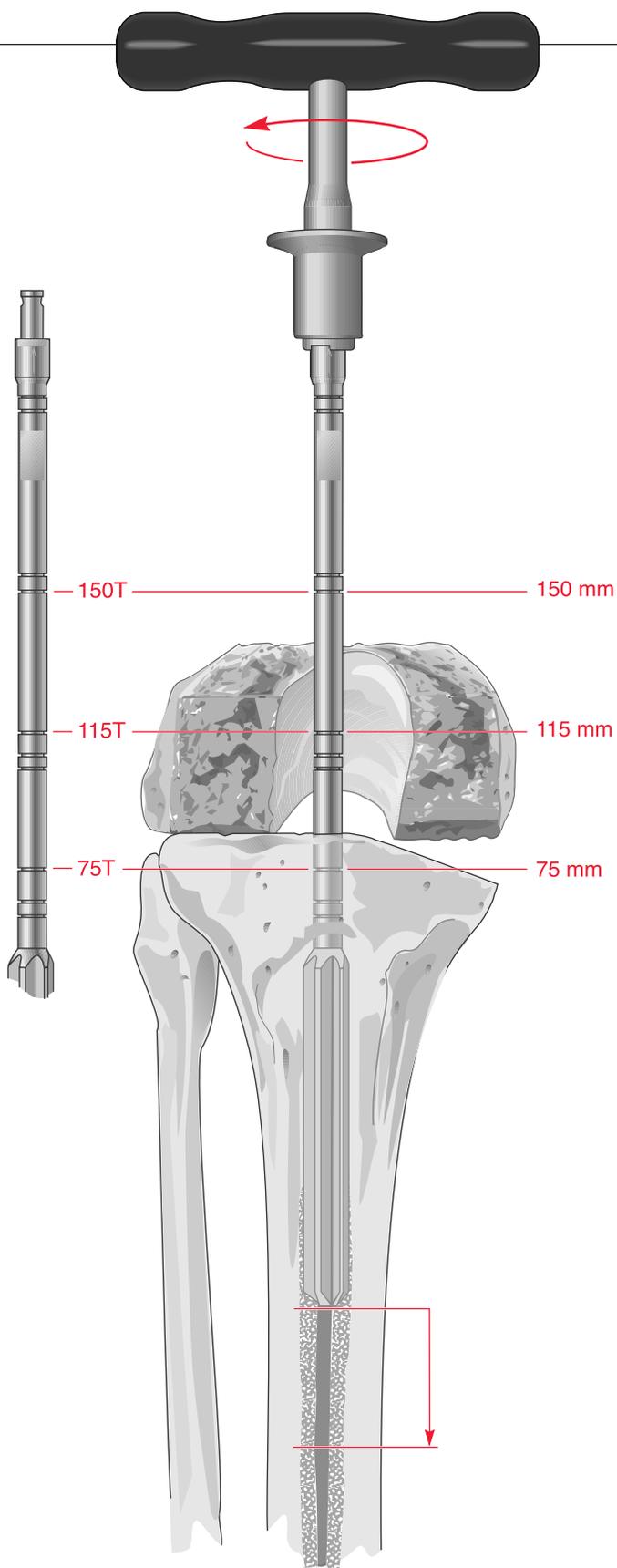
THE INTRAMEDULLARY ROD & SLEEVE TIBIAL ALIGNMENT SYSTEM

When at preoperative evaluation, roentgenographic evaluation demonstrates the condition of the proximal tibia to be such that augmentation and/or a fluted stem extension is indicated, it is recommended that the medullary canal be appropriately prepared and that resection be predicated with reference to the fixed position of the IM rod within the canal and accordingly to the subsequent position of the fluted stem extension. *Where a cemented tibial stem extension is indicated, see Appendix I.*

The knee is placed in maximal flexion with the patella laterally everted and the tibia distracted anteriorly and stabilized. Fibrosis about the tibial border is released or excised as required to ensure complete visualization of its periphery.

The location of the medullary canal is approximated with reference to preoperative A/P and lateral roentgenograms, and to the medial third of the tibial tubercle.





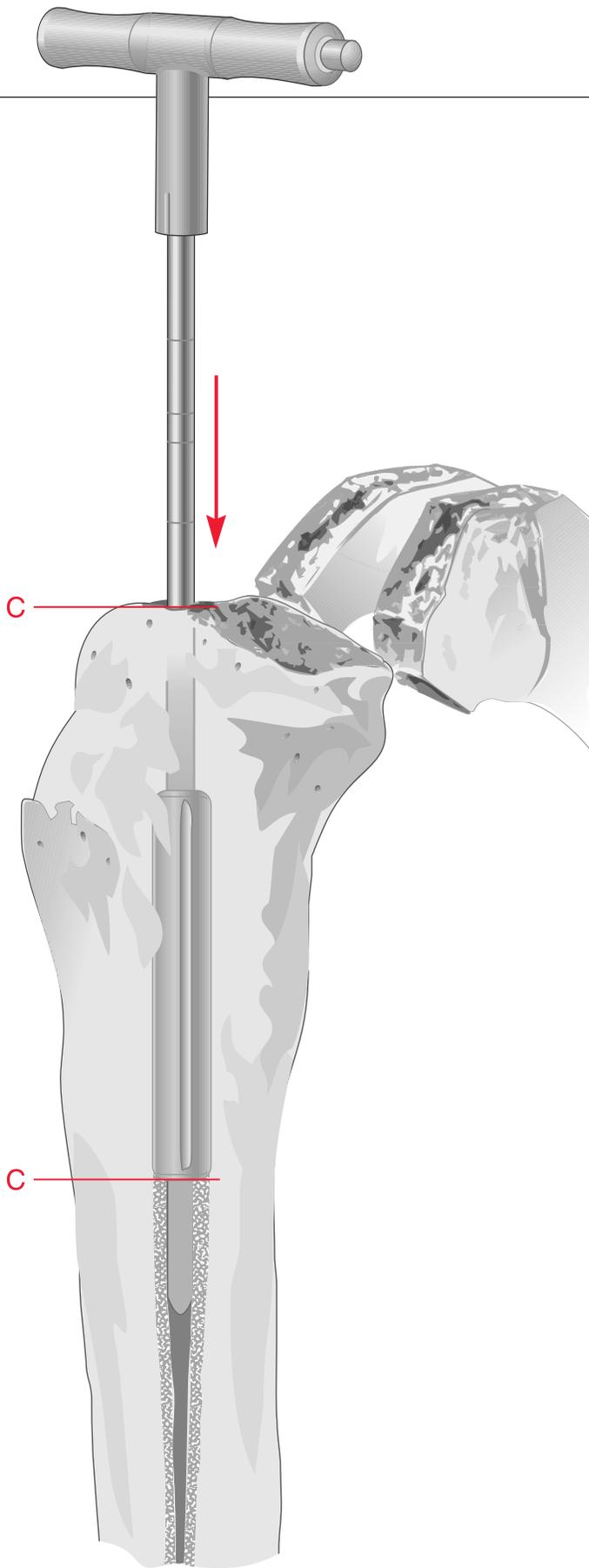
REAMING THE MEDULLARY CANAL

The reamer handle is assembled onto a small diameter Specialist[®] 2 reamer. The shaft contains markings for lengths of both tibial and femoral stems. See illustration for tibial markings. Fluted tibial stem lengths are available in 75 mm, 115 mm and 150 mm. A small-diameter reamer is initially used. The canal is sequentially opened with progressively larger reamers until firm endosteal engagement is established.

The length and diameter of the prosthetic stem extension is initially determined with templates applied to preoperative roentgenograms. The line governing the length of the prosthesis is indicated as shown on the shaft of the reamer and is positioned at the most proximal point of the proximal tibia.

It is important that simple cortical contact 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 stem. It is equally important that osteopenic bone not be overreamed.

The size of the final reamer indicates the size of both the sleeve and the implant stem. As the fluted tibial rods and Specialist 2 revision sleeves are available in even sizes (12 through 24 mm), final reaming is accordingly performed with an even-sized reamer.

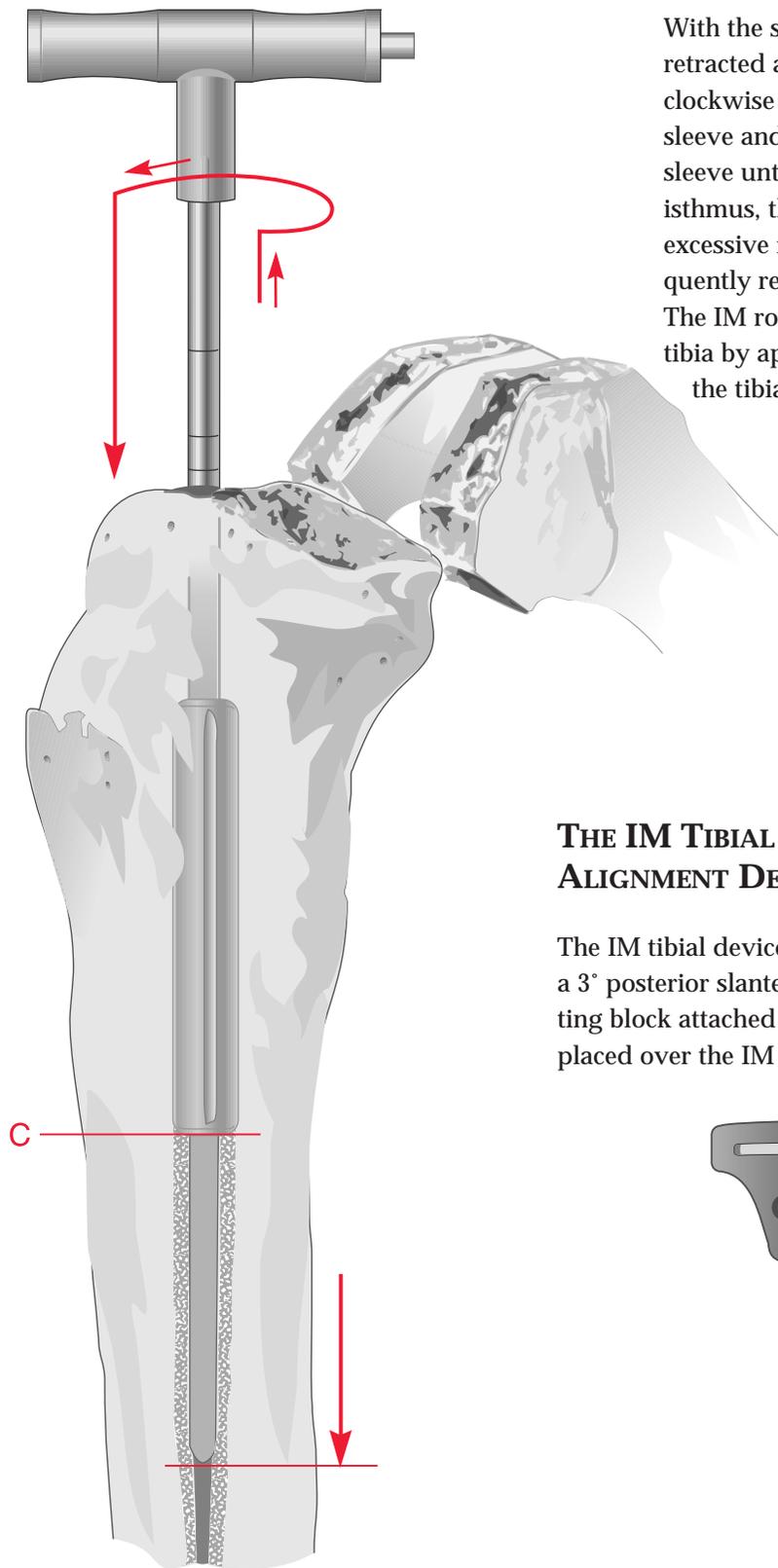


POSITIONING THE ROD AND SLEEVE

The intramedullary rods are provided in three lengths to accommodate various sizes of tibia. The appropriate rod is selected, inserted through the sleeve corresponding to the size of the final reamer and advanced to the distal end. The handle is subsequently assembled to the rod. The sleeve is rotated 180° clockwise on the rod and retracted toward the handle until locked in position. The rod and sleeve assembly are subsequently introduced into the prepared medullary canal and carefully advanced. The sleeve will fit snugly within the reamed canal, but excessive force is not required. Advancement proceeds until the predetermined depth as indicated on the rod is aligned with the proximal surface of the tibia established by the primary procedure. As the depth markings on the IM rod correspond to those of the T-handled reamer, insertion of the sleeve will not exceed the depth reamed.

For Tibial Fluted Stem Lengths

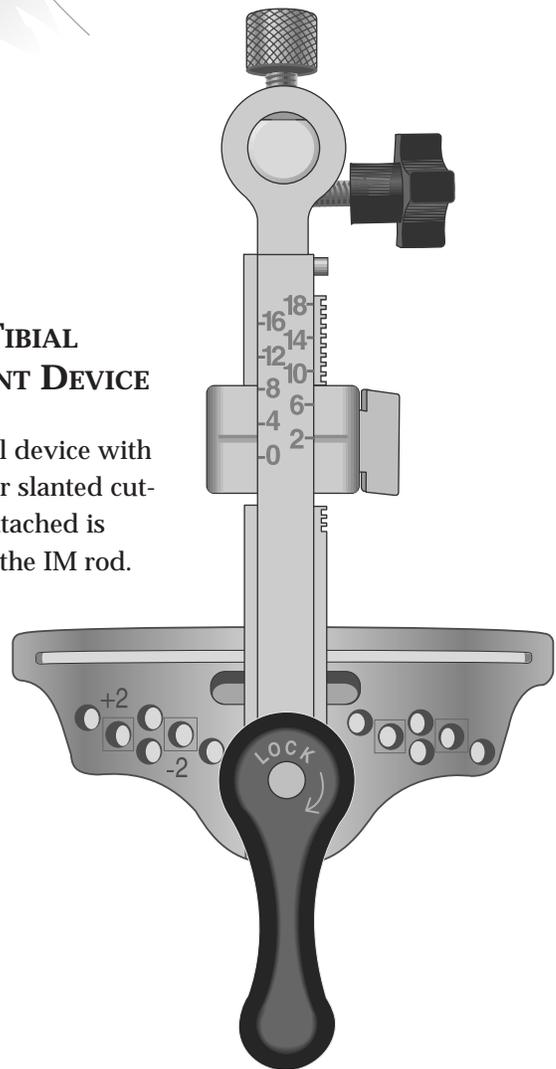
A	75 mm
C	115 mm
E	150 mm



With the sleeve thus engaged, the rod is gently retracted approximately 15 mm and rotated 180° clockwise by the handle to disengage it from the sleeve and enable it to advance beyond the sleeve until its tip is engaged at the diaphyseal isthmus, thereby enhancing stability. Again, excessive force is avoided. The handle is subsequently removed, and the rod remains in place. The IM rod should extend out of the proximal tibia by approximately 12 cm to accommodate the tibial IM device.

THE IM TIBIAL ALIGNMENT DEVICE

The IM tibial device with a 3° posterior slanted cutting block attached is placed over the IM rod.



POSITIONING THE ALIGNMENT DEVICE AND PROVISIONAL ROTATIONAL ALIGNMENT

The cutting guide is positioned on the IM rod and allowed to descend to the proximal tibial surface. As considerable bone stock may have been sacrificed in the primary TKR, the amount resected is held to a minimum: no more than is needed to provide a level surface on the *less* deficient side.

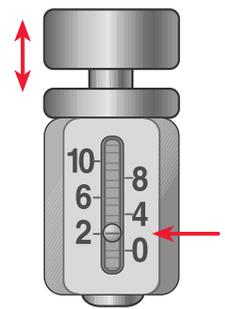
Resection is based upon tibial deficiency and the level of the joint line, with deficiencies compensated with wedges and/or bone grafts. The assembly is locked in position with the lateral

setscrew. The cutting block is advanced to the anterior tibial cortex and locked into position by tightening the knurled knob on the outrigger. Provisional rotational alignment is based on the medial third of the tibial tubercle. The alignment device is secured to the IM rod with the lateral setscrew.

The cylinder foot of the stylus is inserted into the slot of the cutting block and adjusted to the appropriate level. The block is lowered to this level by depressing the level on the right side.

If tibial augmentation is required, bone defect preparation is delayed until after initial trial reduction is performed and exact rotational position of the tibial component confirmed.

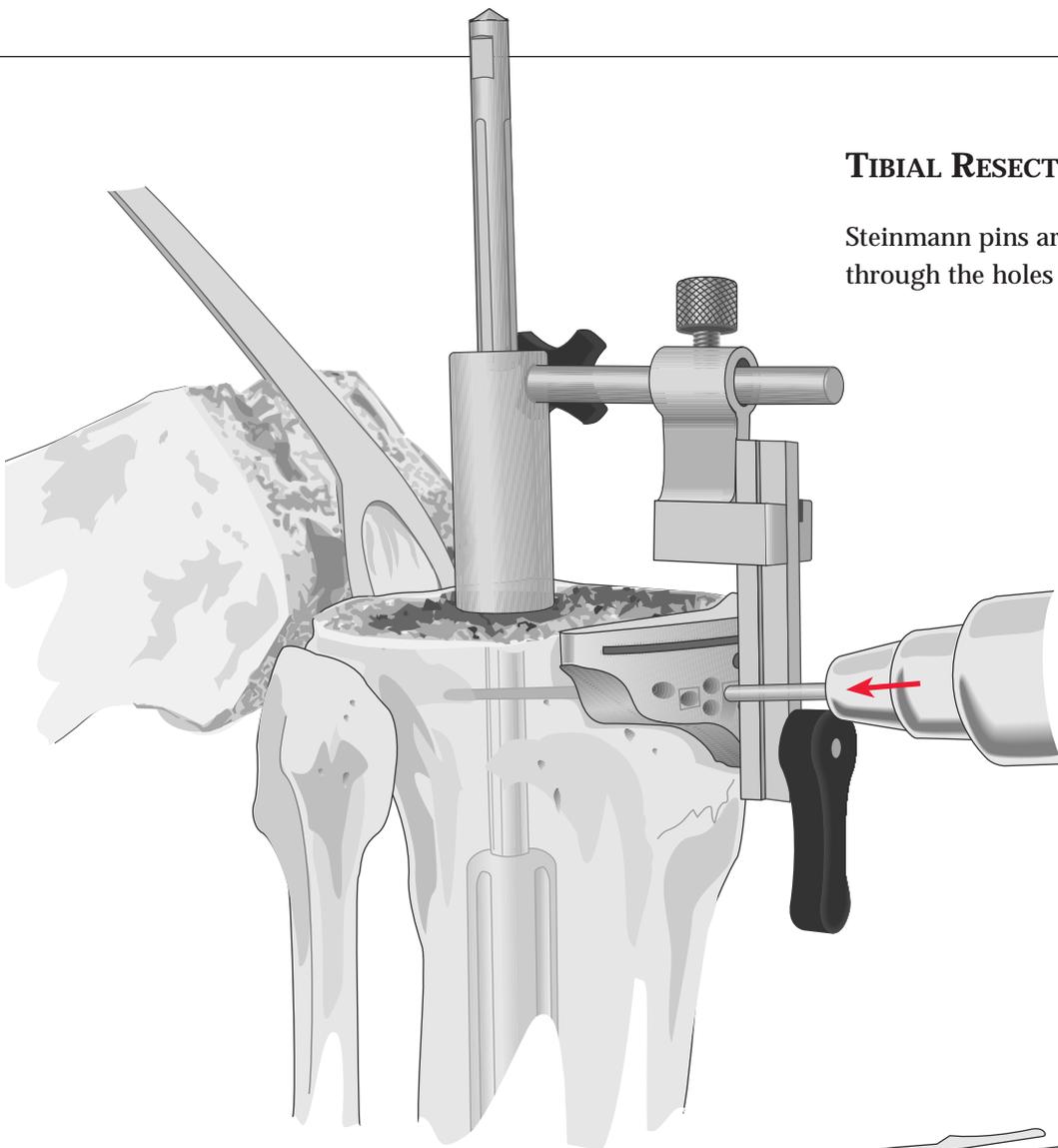
Tibial rotational alignment is confirmed at trial reduction to ensure congruity with the femoral component throughout the complete range of motion.



Stylus Cylinder
Cutting Block set at
the 2 mm level

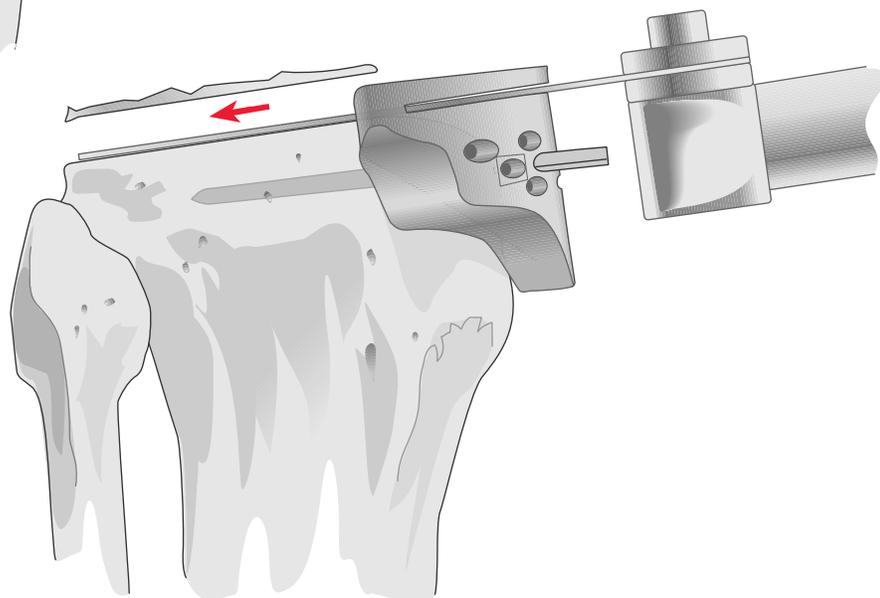
TIBIAL RESECTION

Steinmann pins are introduced bilaterally through the holes designated 0 (boxed).



The IM alignment device is unlocked from the cutting block, and with the IM rod and sleeve is removed from the tibia. Resection is made through the slots with an oscillating saw and a 1.19 mm (.047") blade.

Where full-surface wedge augmentation is indicated, see Appendix II (page 49).



PREPARATION OF THE FEMUR

INTRAMEDULLARY ROD & SLEEVE FEMORAL ALIGNMENT SYSTEM

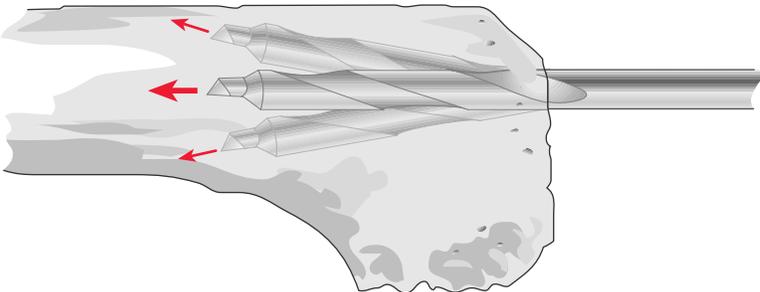
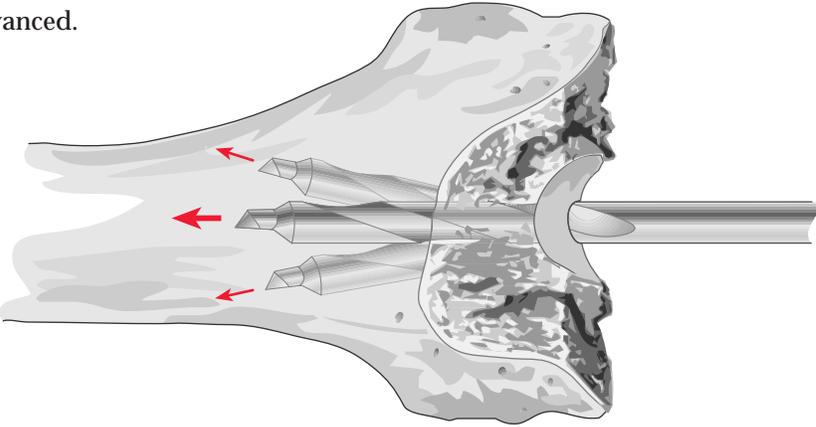
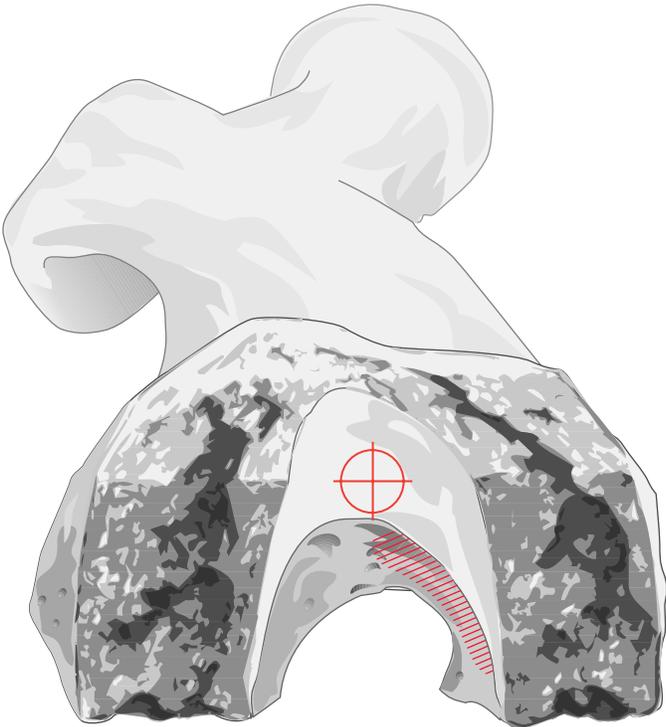
RATIONALE

This technique was designed to predetermine all femoral cut and govern the placement of the femoral component with reference to the fixed position of a P.F.C. Sigma fluted IM rod. The length and diameter of the prosthetic stem extension is determined with templates applied to preoperative roentgenograms. The procedure begins with the preparation of the medullary canal.

The midline of the femoral trochlea is identified 3 mm anterior to the anterolateral margin of the attachment of the posterior cruciate ligament.

The medullary canal is entered with a $\frac{5}{16}$ " drill to a depth of 3-5 cm. Care is taken that the drill avoid the cortices. It is helpful to palpate the distal femoral shaft as the drill is advanced.

Where impedance of the intramedullary rod is anticipated, the entry point is adjusted accordingly.

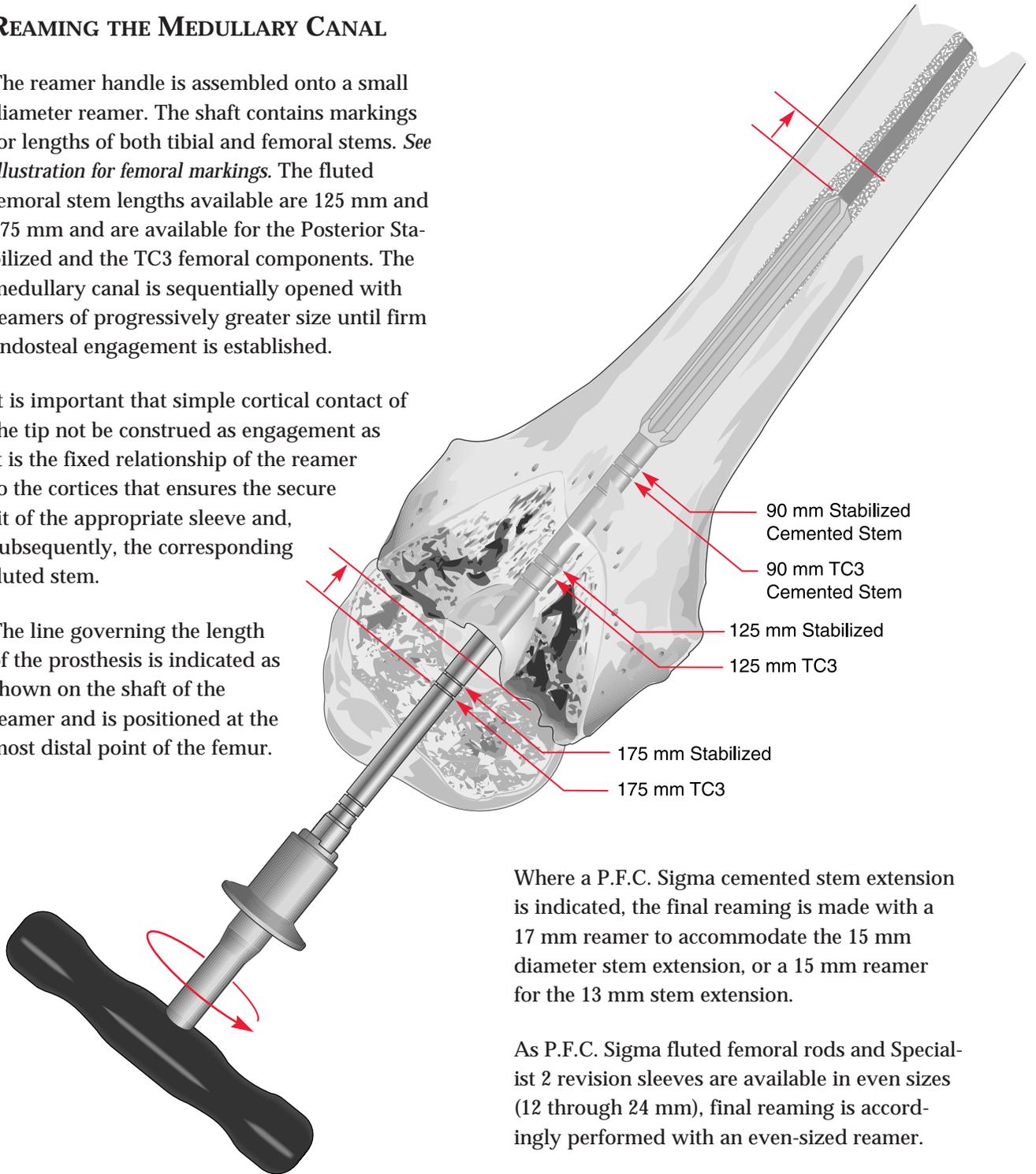


REAMING THE MEDULLARY CANAL

The reamer handle is assembled onto a small diameter reamer. The shaft contains markings for lengths of both tibial and femoral stems. See *illustration for femoral markings*. The fluted femoral stem lengths available are 125 mm and 175 mm and are available for the Posterior Stabilized and the TC3 femoral components. The medullary canal is sequentially opened with reamers of progressively greater size until firm endosteal engagement is established.

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 stem.

The line governing the length of the prosthesis is indicated as shown on the shaft of the reamer and is positioned at the most distal point of the femur.



Where a P.F.C. Sigma cemented stem extension is indicated, the final reaming is made with a 17 mm reamer to accommodate the 15 mm diameter stem extension, or a 15 mm reamer for the 13 mm stem extension.

As P.F.C. Sigma fluted femoral rods and Specialist 2 revision sleeves are available in even sizes (12 through 24 mm), final reaming is accordingly performed with an even-sized reamer.

POSITIONING THE ROD AND SLEEVE

The intramedullary rods are provided in three lengths to accommodate various sizes of femurs. The appropriate rod is selected, inserted through the sleeve corresponding in size to the final reamer, and advanced to the further end. The handle is subsequently assembled to the rod. The sleeve is rotated 180° clockwise on the IM rod and retracted toward the handle until locked in position. The rod and sleeve assembly are subsequently introduced into the prepared medullary canal and carefully advanced.

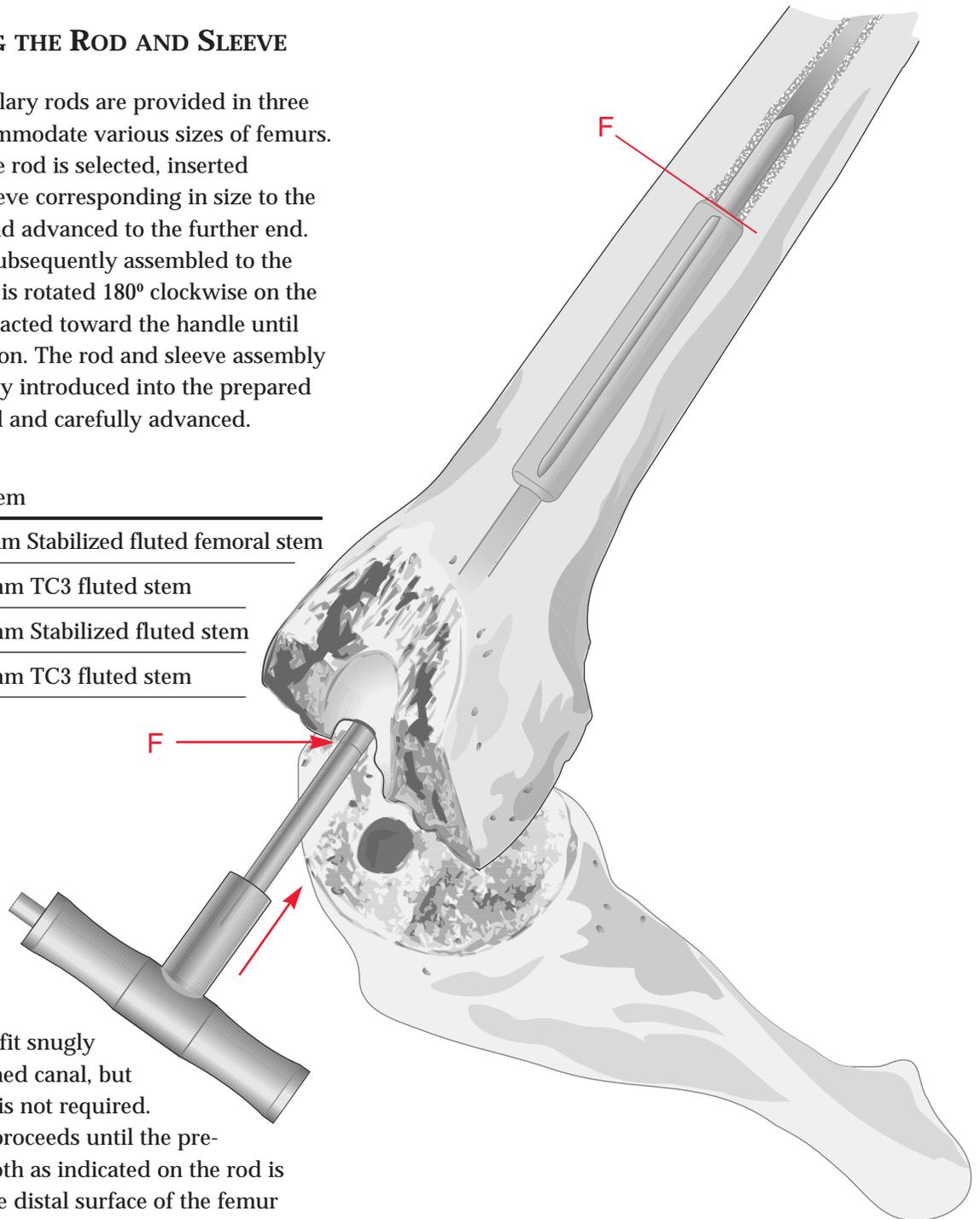
The Femoral Stem

B for the 125 mm Stabilized fluted femoral stem

B for the 125 mm TC3 fluted stem

E for the 175 mm Stabilized fluted stem

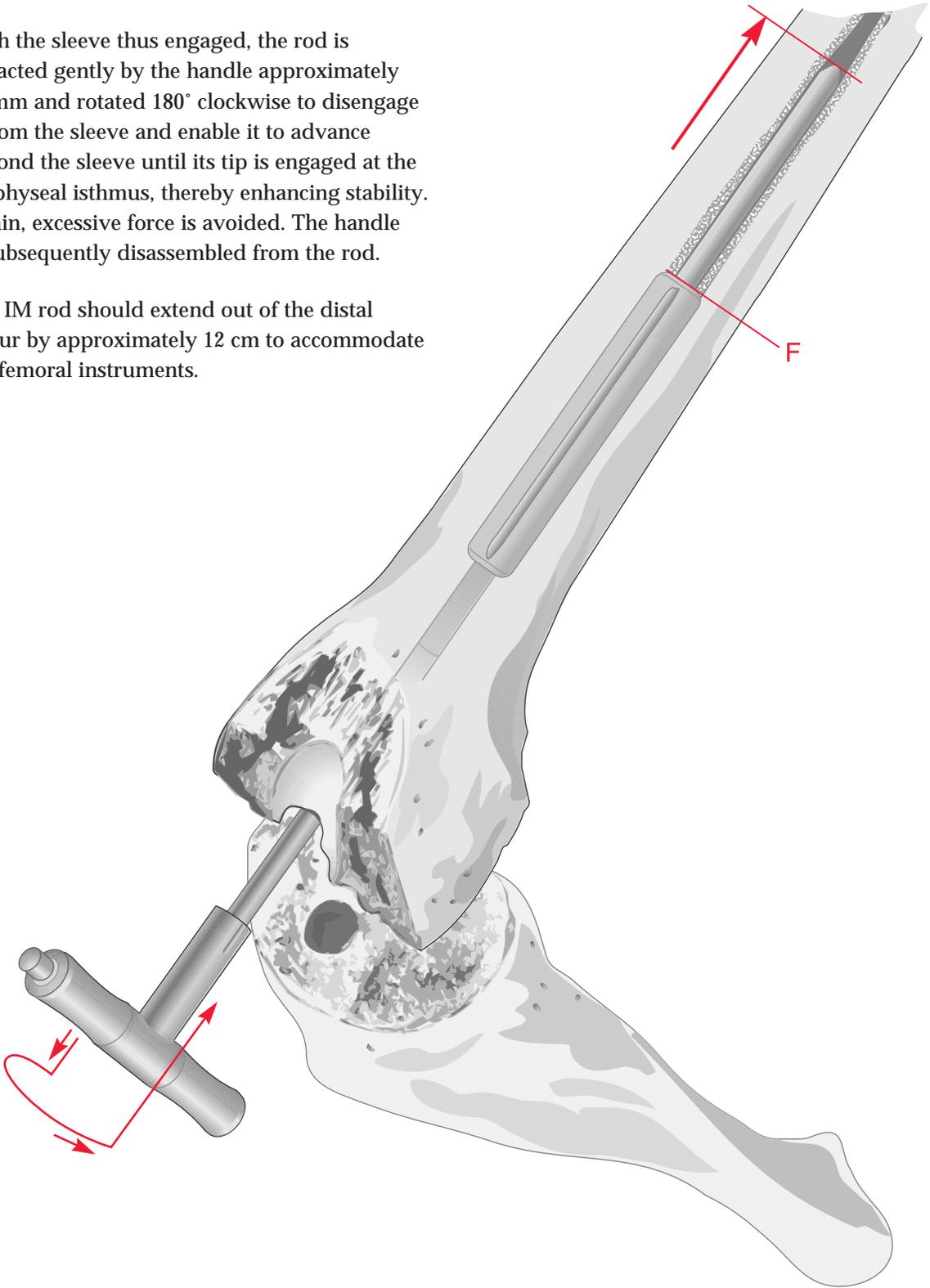
F for the 175 mm TC3 fluted stem

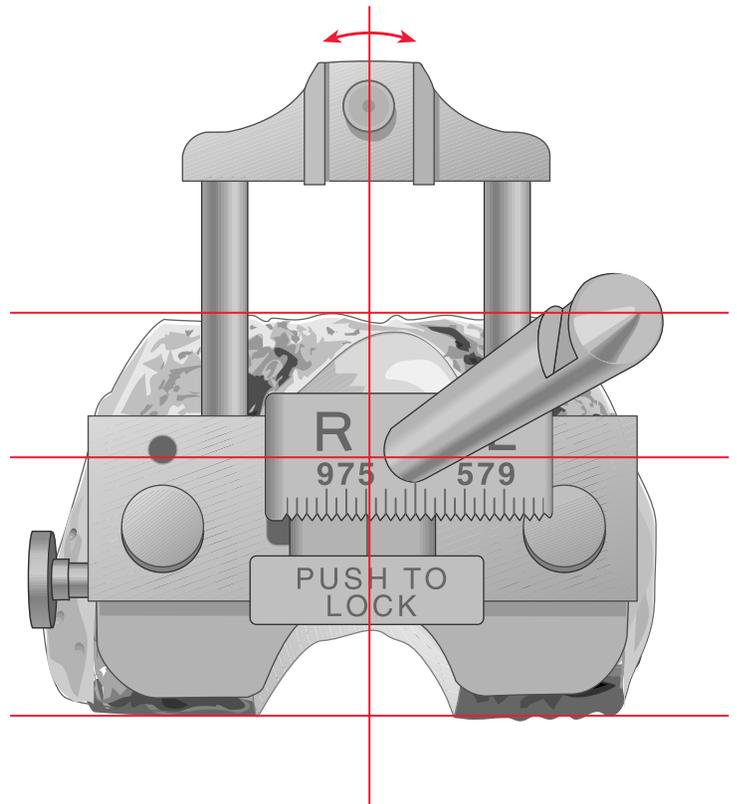
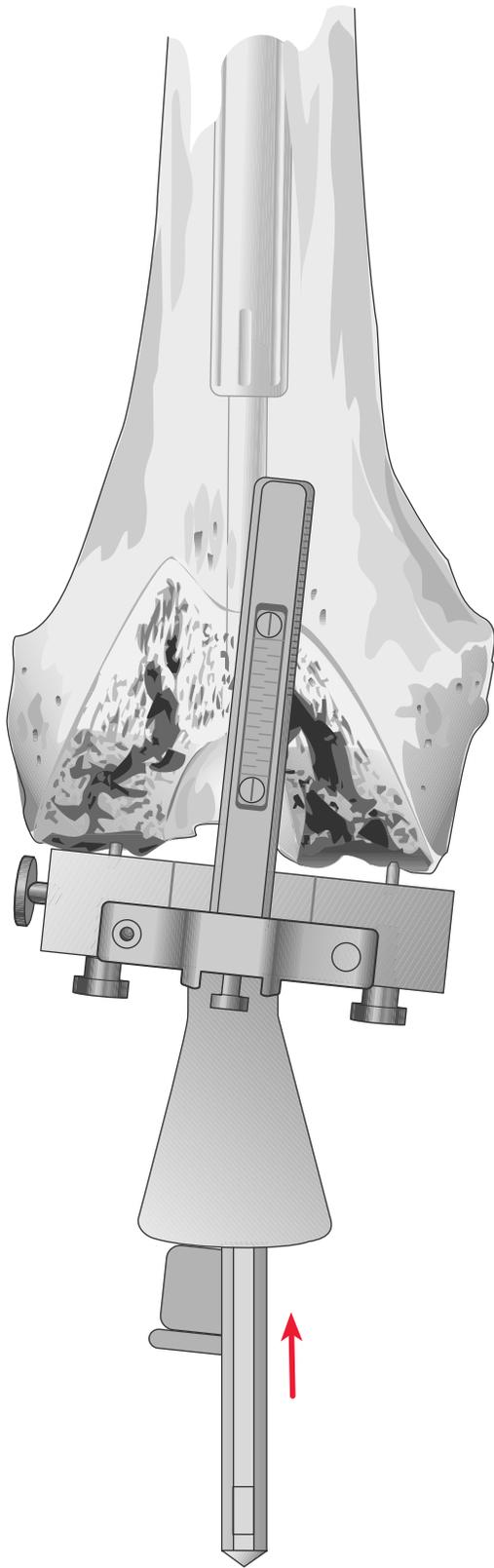


The sleeve will fit snugly within the reamed canal, but excessive force is not required. Advancement proceeds until the pre-determined depth as indicated on the rod is aligned with the distal surface of the femur established by the primary procedure. As the depth markings on the rod correspond to those of the T-handled reamer, insertion of the sleeve will not exceed the depth reamed.

With the sleeve thus engaged, the rod is retracted gently by the handle approximately 15 mm and rotated 180° clockwise to disengage it from the sleeve and enable it to advance beyond the sleeve until its tip is engaged at the diaphyseal isthmus, thereby enhancing stability. Again, excessive force is avoided. The handle is subsequently disassembled from the rod.

The IM rod should extend out of the distal femur by approximately 12 cm to accommodate the femoral instruments.



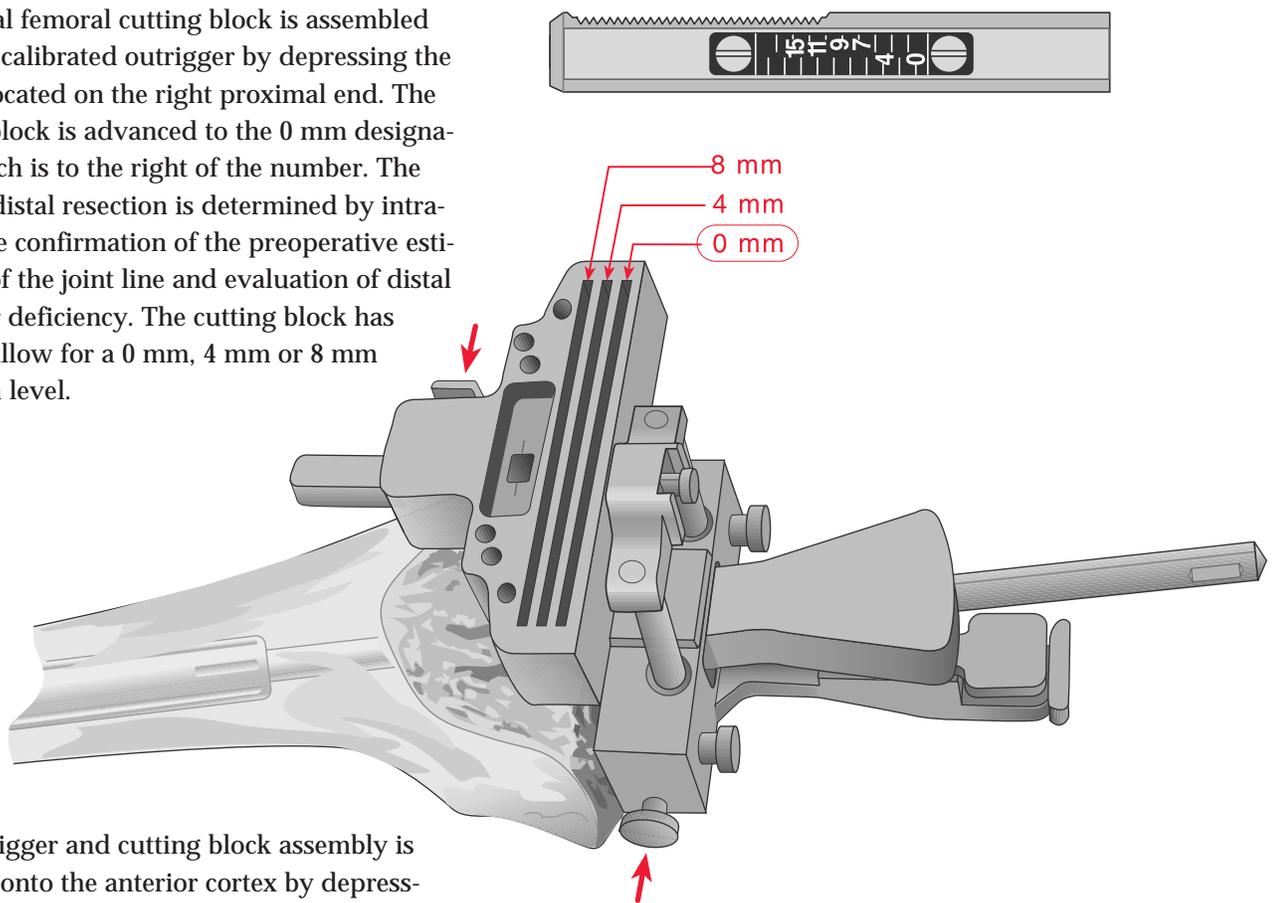


THE FEMORAL LOCATING DEVICE

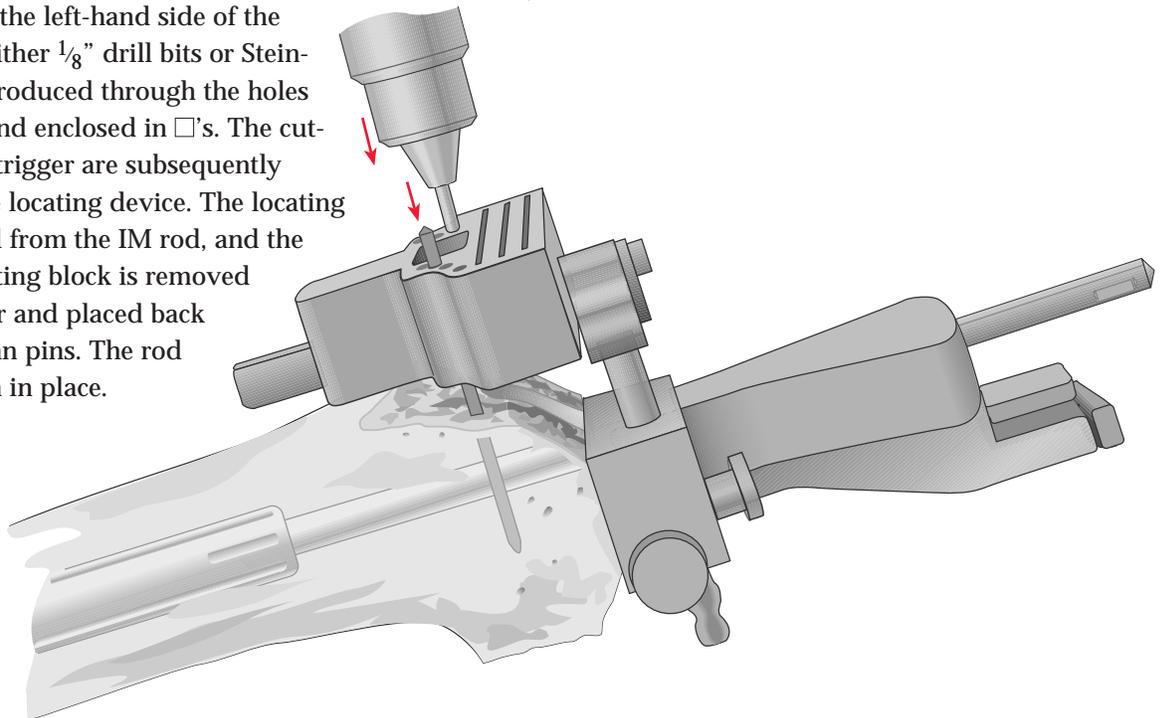
The appropriate valgus angle is determined through the application of templates to the preoperative roentgenogram. The appropriate valgus angle, 5° or 7°, and Right/Left knee indication is set and locked into place on the front of the locating device. The locating device is placed over the IM rod and advanced to contact the distal femur. The calibrated outrigger will be centered at the trochlea and must be in its full raised position relative to the prepared anterior surface.

DISTAL RESECTION

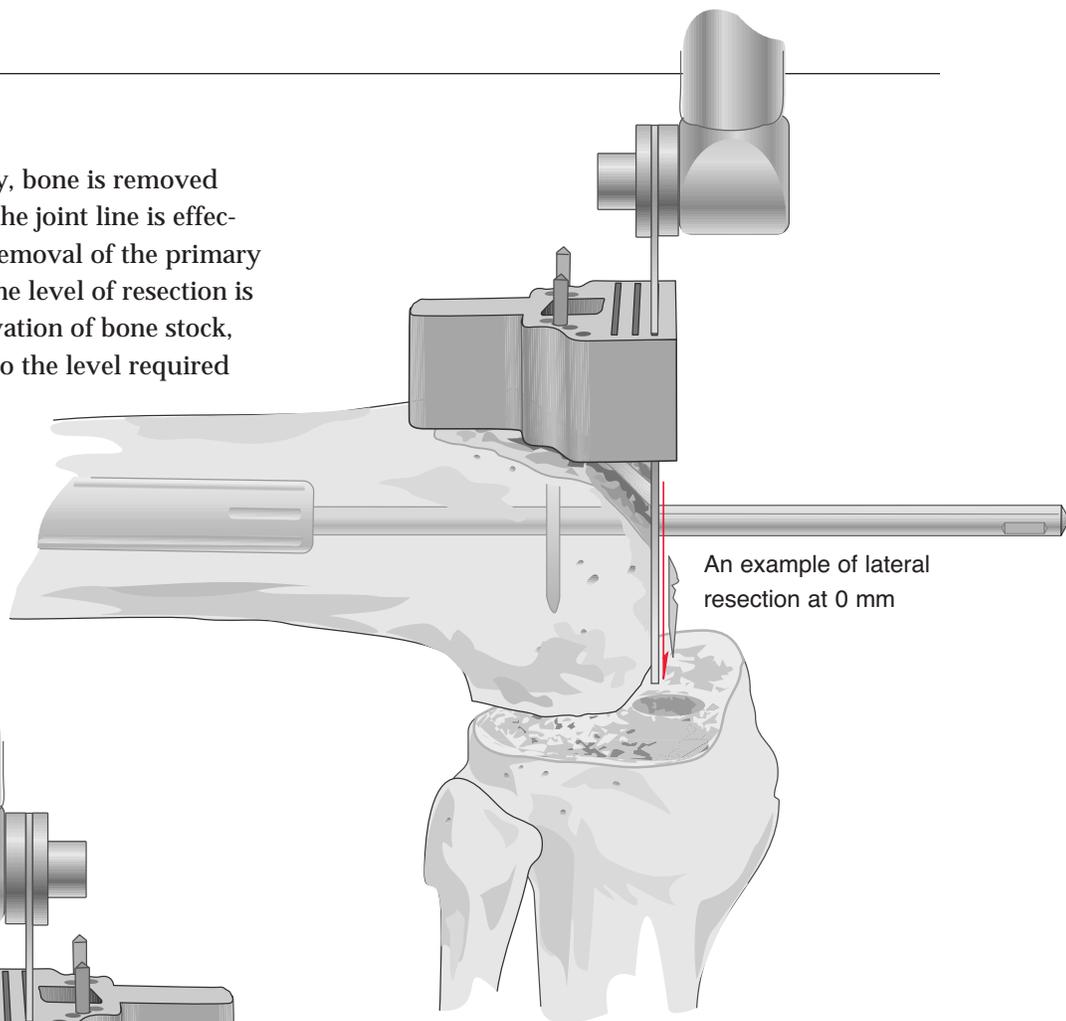
The distal femoral cutting block is assembled onto the calibrated outrigger by depressing the button located on the right proximal end. The cutting block is advanced to the 0 mm designation which is to the right of the number. The level of distal resection is determined by intra-operative confirmation 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.



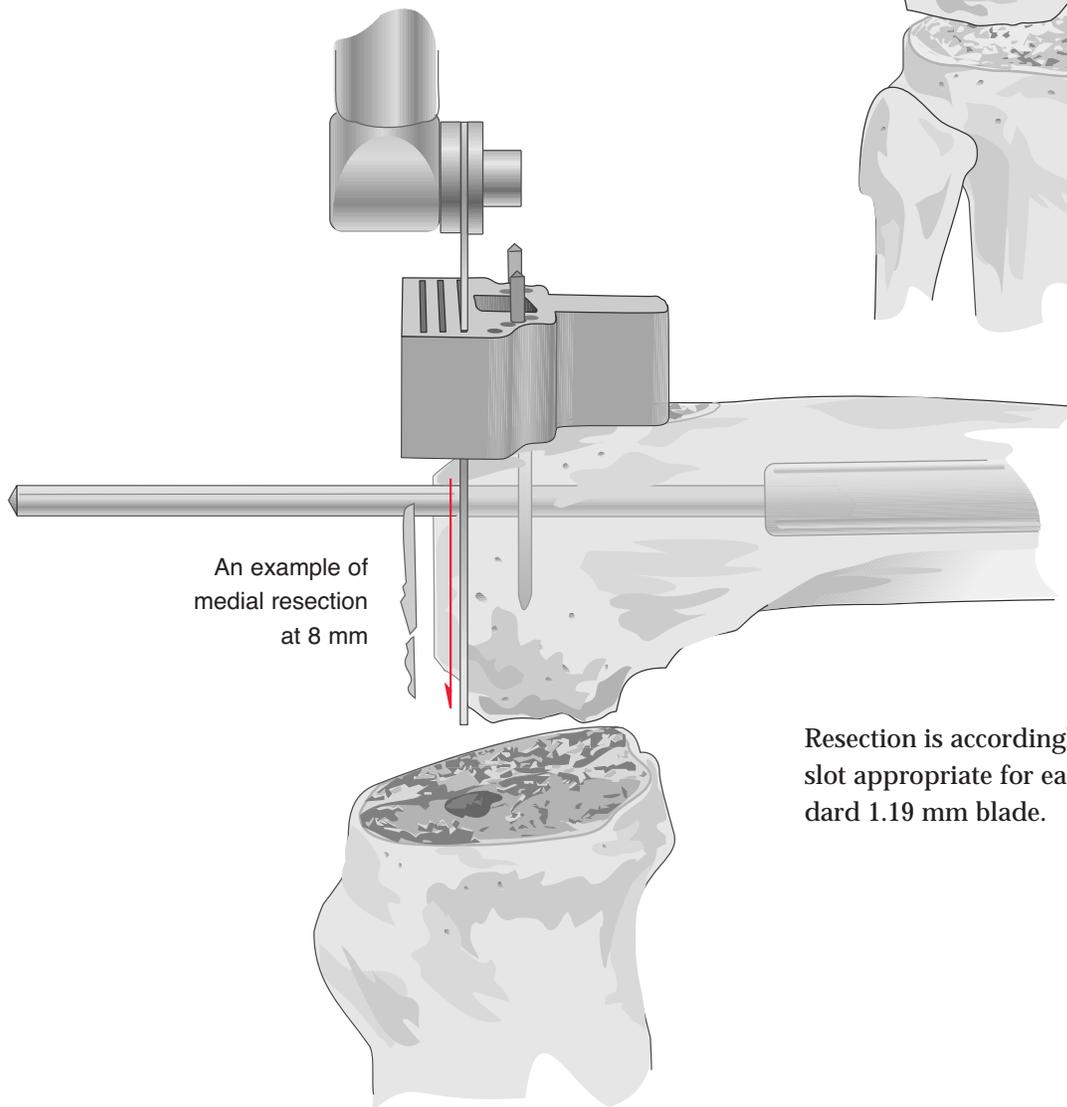
The outrigger and cutting block assembly is lowered onto the anterior cortex by depressing the button on the left-hand side of the locating device. Either $\frac{1}{8}$ " drill bits or Steinmann pins are introduced through the holes designated zero and enclosed in □'s. The cutting block and outrigger are subsequently removed from the locating device. The locating device is removed from the IM rod, and the distal femoral cutting block is removed from the outrigger and placed back over the Steinmann pins. The rod and sleeve remain in place.



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 predicated 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.



An example of lateral resection at 0 mm

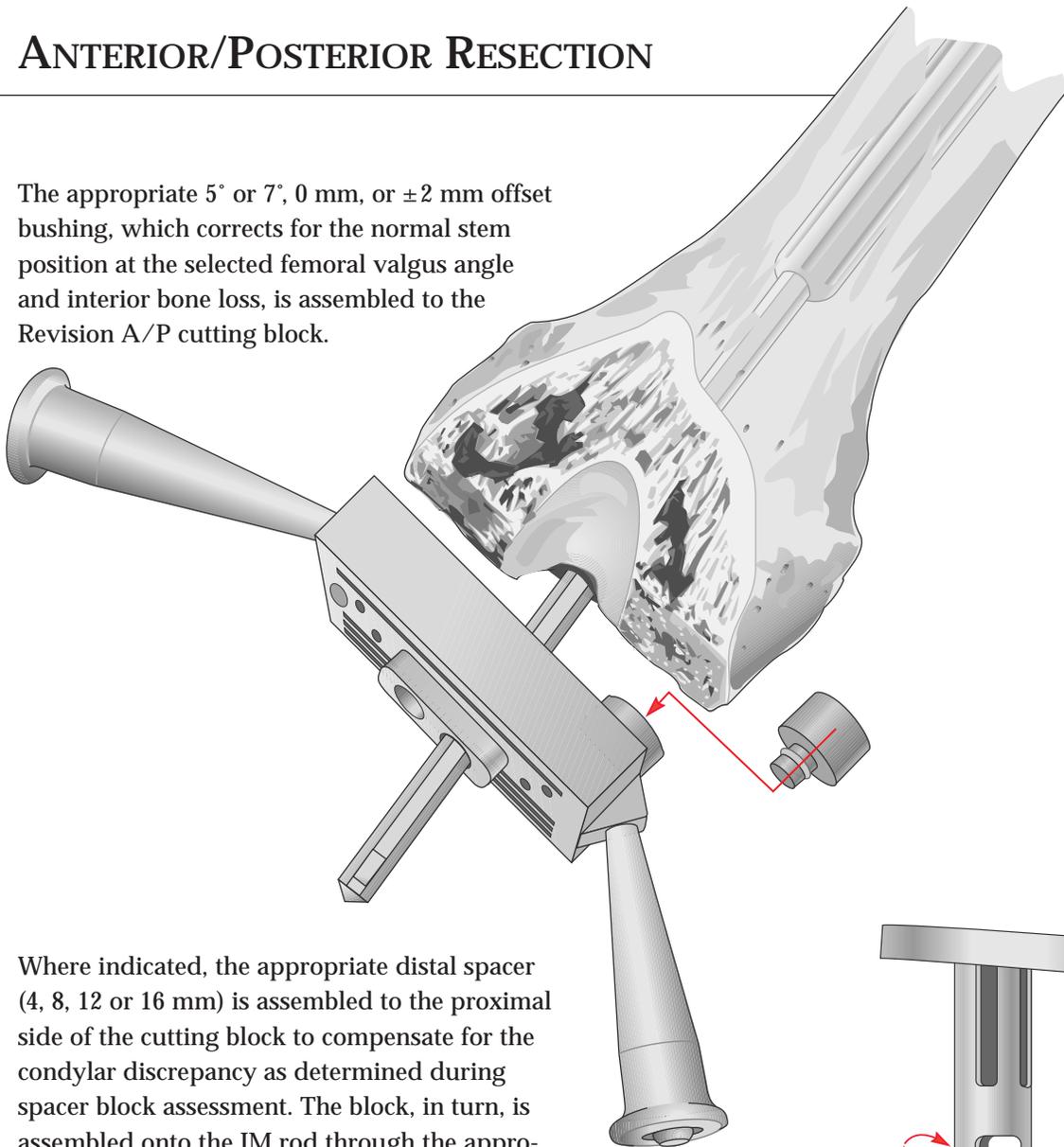


An example of medial resection at 8 mm

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

ANTERIOR/POSTERIOR RESECTION

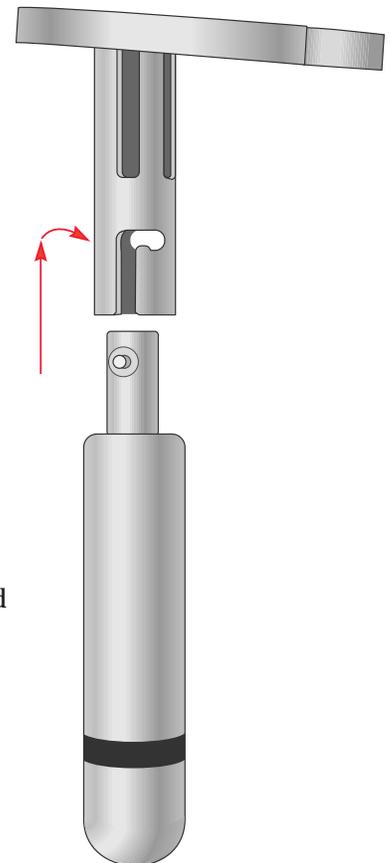
The appropriate 5° or 7°, 0 mm, or ±2 mm offset bushing, which corrects for the normal stem position at the selected femoral valgus angle and interior bone loss, is assembled to the Revision A/P cutting block.

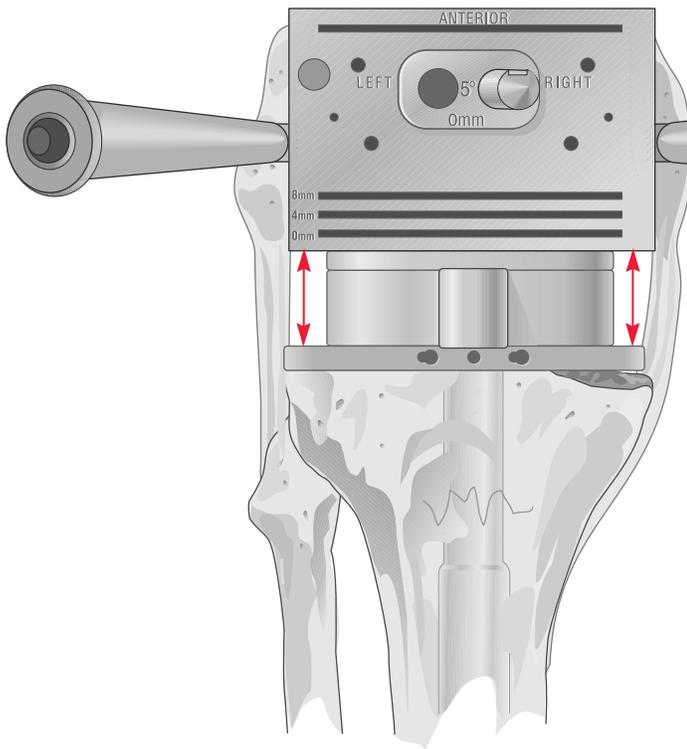


Where indicated, the appropriate distal spacer (4, 8, 12 or 16 mm) is assembled to the proximal side of the cutting block to compensate for the condylar discrepancy as determined during spacer block assessment. The block, in turn, is assembled onto the IM rod through the appropriate Right/Left opening and seated flush to the prepared distal surface.

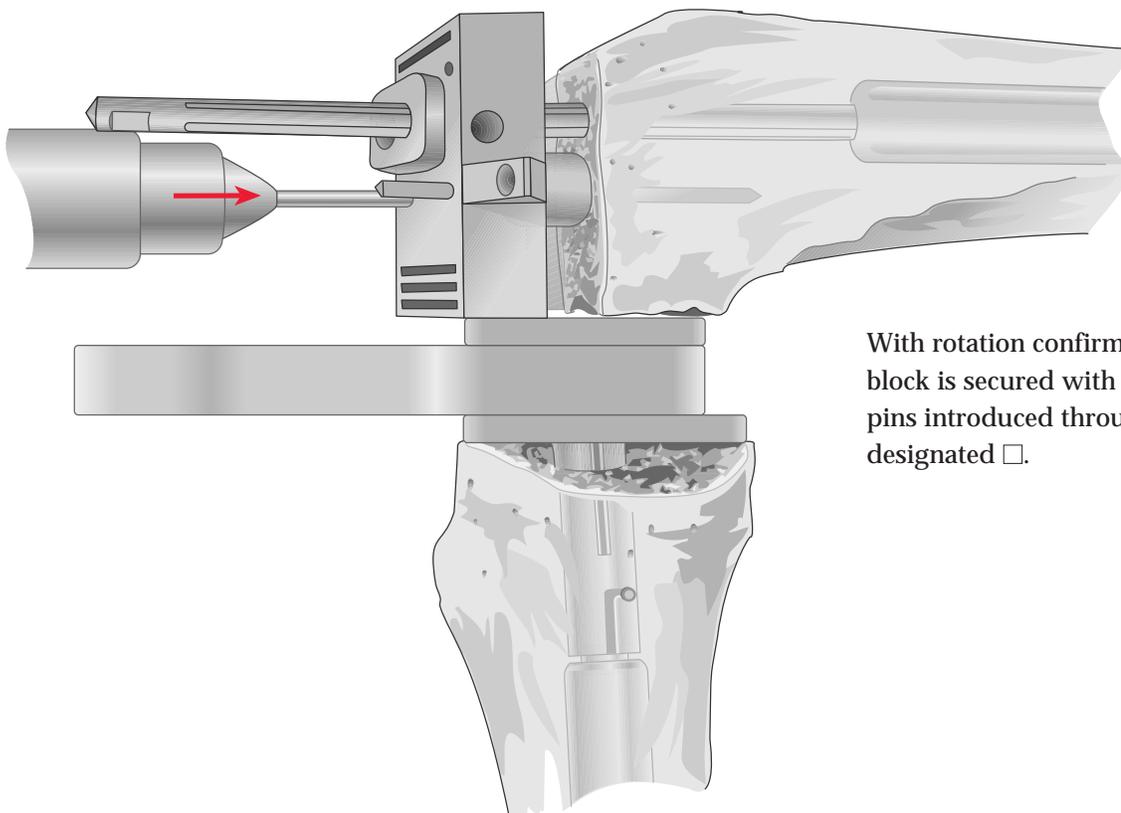
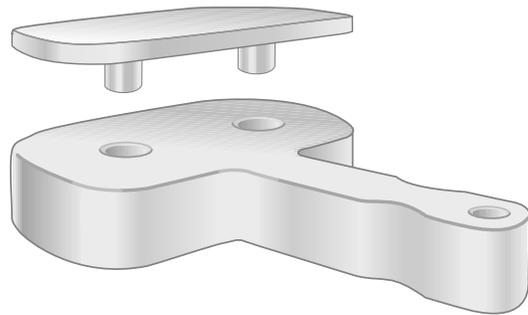
ROTATIONAL ALIGNMENT OF THE A/P AND CHAMFER CUTTING DEVICES

The appropriate trial fluted stem is assembled to the trial tibial tray and positioned within the prepared medullary canal.



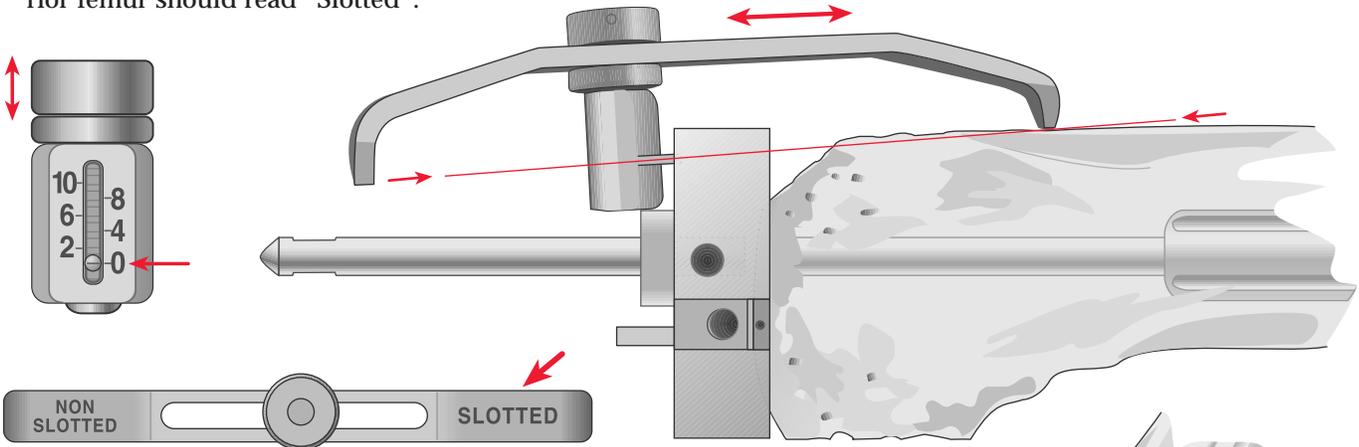


Rotational positioning of the revision A/P cutting block is critical to the establishment of a symmetrical flexion gap and patellofemoral alignment. Rotation is such that the posterior surface of the cutting block is parallel to the resurfaced proximal tibia under tension. Symmetry is validated with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



With rotation confirmed, the cutting block is secured with Steinmann pins introduced through the holes designated □.

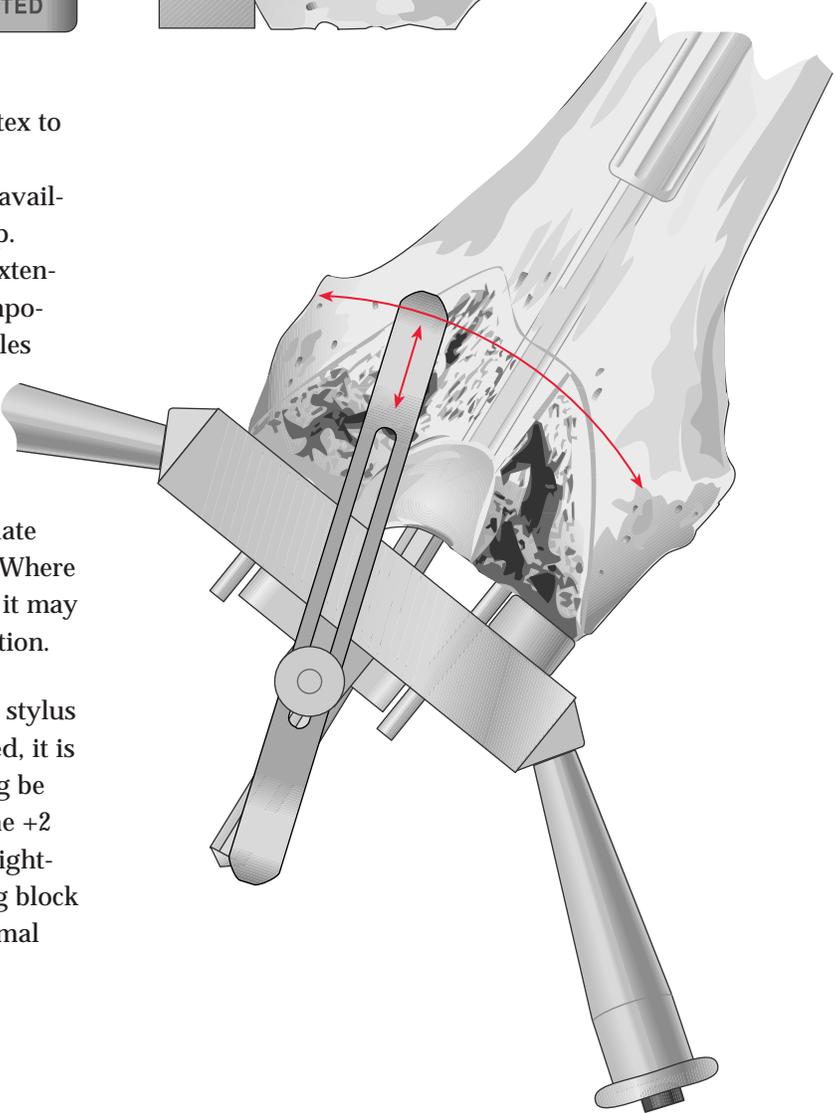
The foot plate of the stylus is introduced into the anterior slot and the height is set at 0 mm. The arm of the stylus in contact with the anterior femur should read "Slotted".



The stylus is passed 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.

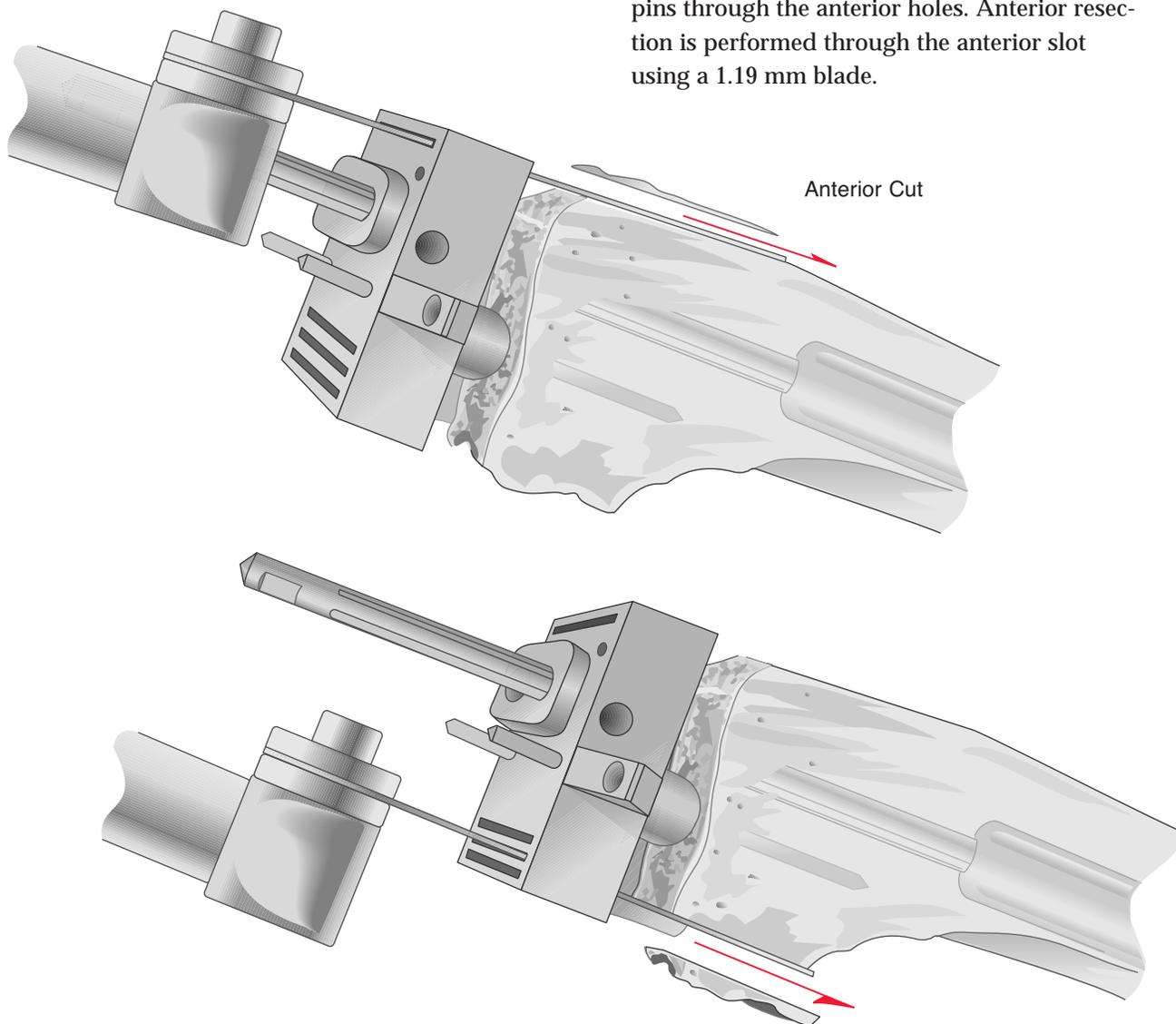
Where the cutting block is correct but the stylus indicates no anterior bone will be removed, it is recommended that the +2/-2 mm bushing be substituted for the 0 mm and placed in the +2 mm position as long as no flexion space tightness exists. This positions the A/P cutting block 2 mm posteriorly, thereby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

This decreases the flexion gap by 2 mm.



The stylus assembly is removed. 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, further fixation is gained by affixing Steinmann pins through the anterior holes. Anterior resection is performed through the anterior slot using a 1.19 mm blade.



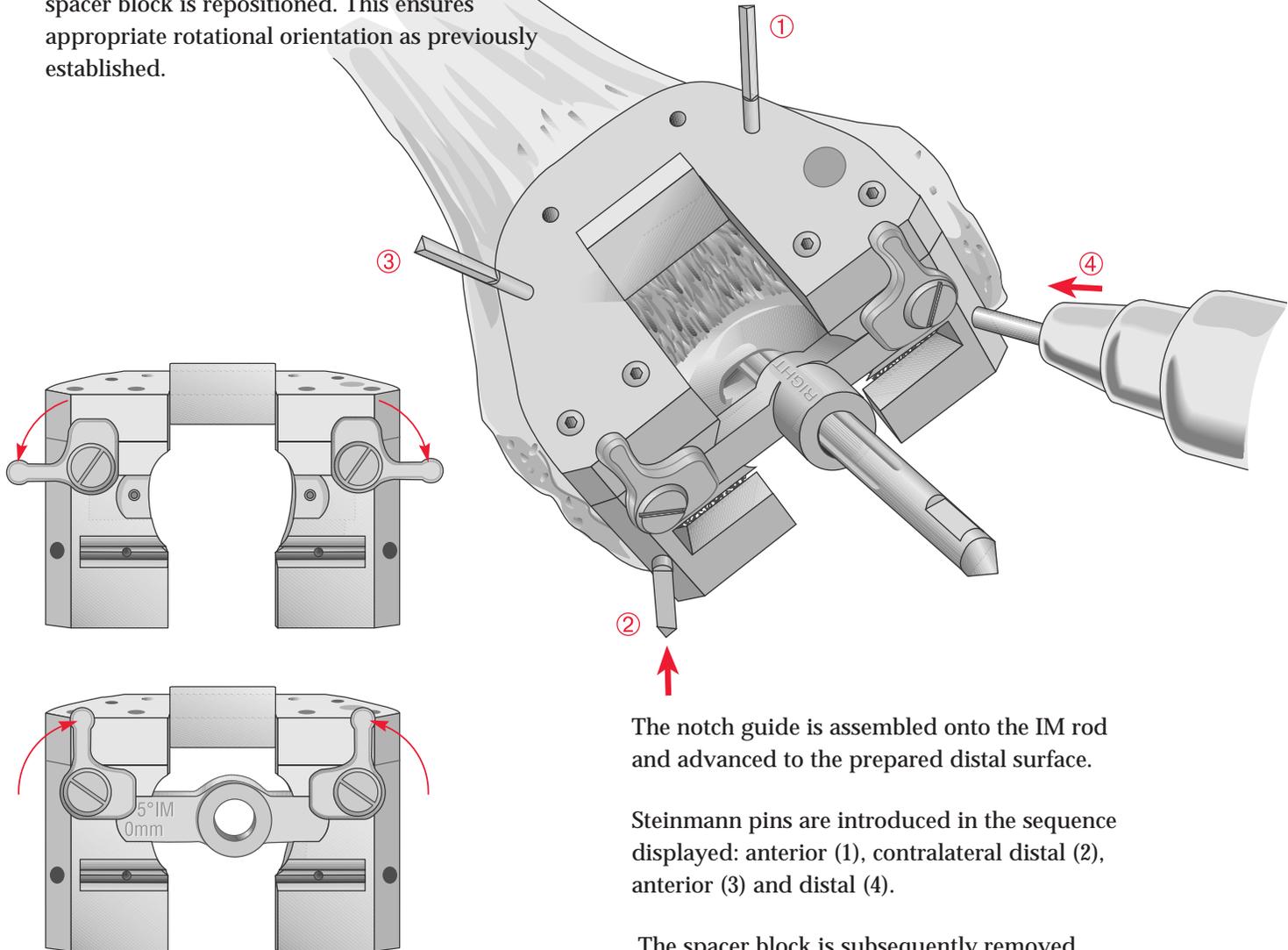
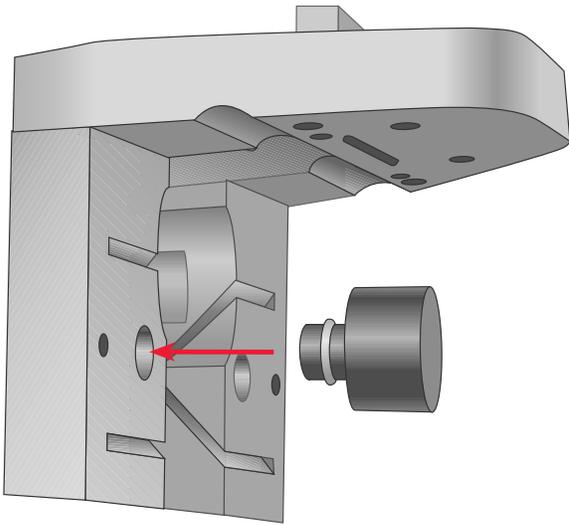
An Example of Posterolateral Cut at 4 mm

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

NOTCH AND CHAMFER RESECTION

Where distal augmentation is planned, the appropriate trial spacer is inserted into its receptacle on the notch cutting guide. The trial spacer selected should be the same as was used on the A/P cutting block.

The appropriate notch/chamfer bushing is selected. This corresponds to the bushing that was used on the A/P cutting block, 0 mm, +2 mm or -2 mm. It is assembled onto the notch/chamfer cutting guide with the appropriate Right/Left and 0, +2 or -2 designation facing up and locked into position by rotating the tabs anteriorly to the stop. The tibial tray trial assembly remains in position and the spacer block is repositioned. This ensures appropriate rotational orientation as previously established.

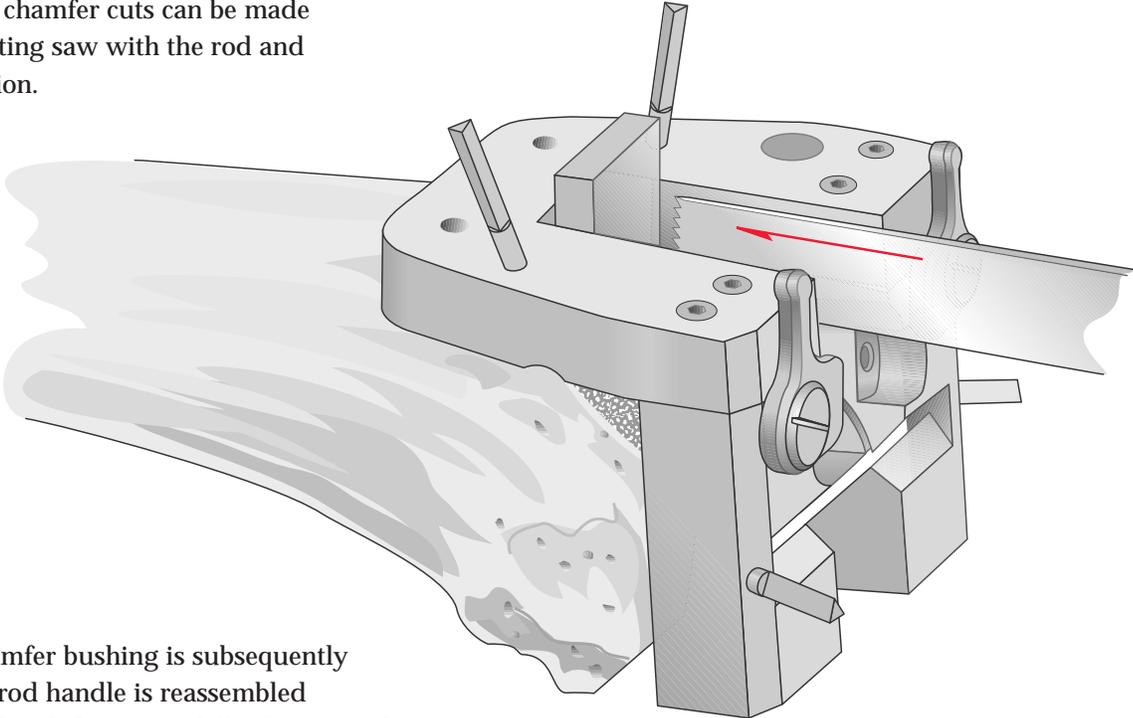


The notch guide is assembled onto the IM rod and advanced to the prepared distal surface.

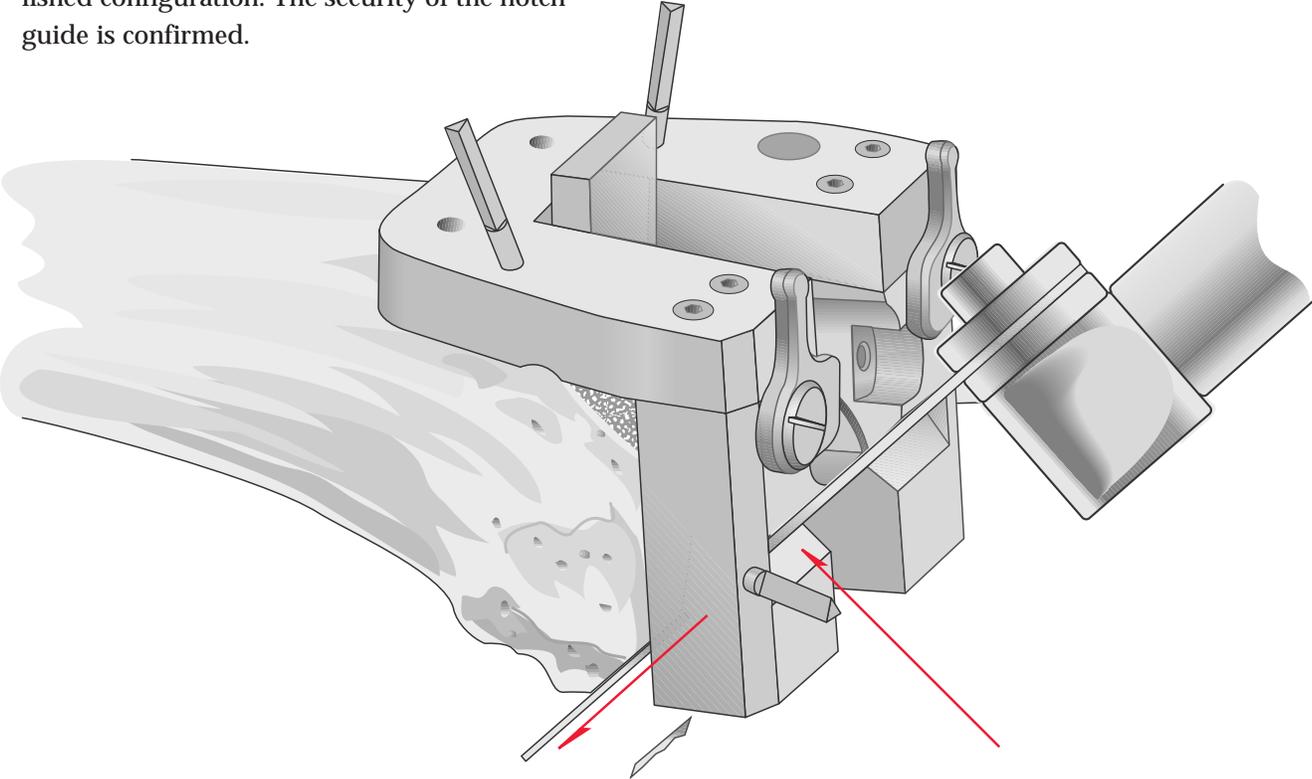
Steinmann pins are introduced in the sequence displayed: anterior (1), contralateral distal (2), anterior (3) and distal (4).

The spacer block is subsequently removed.

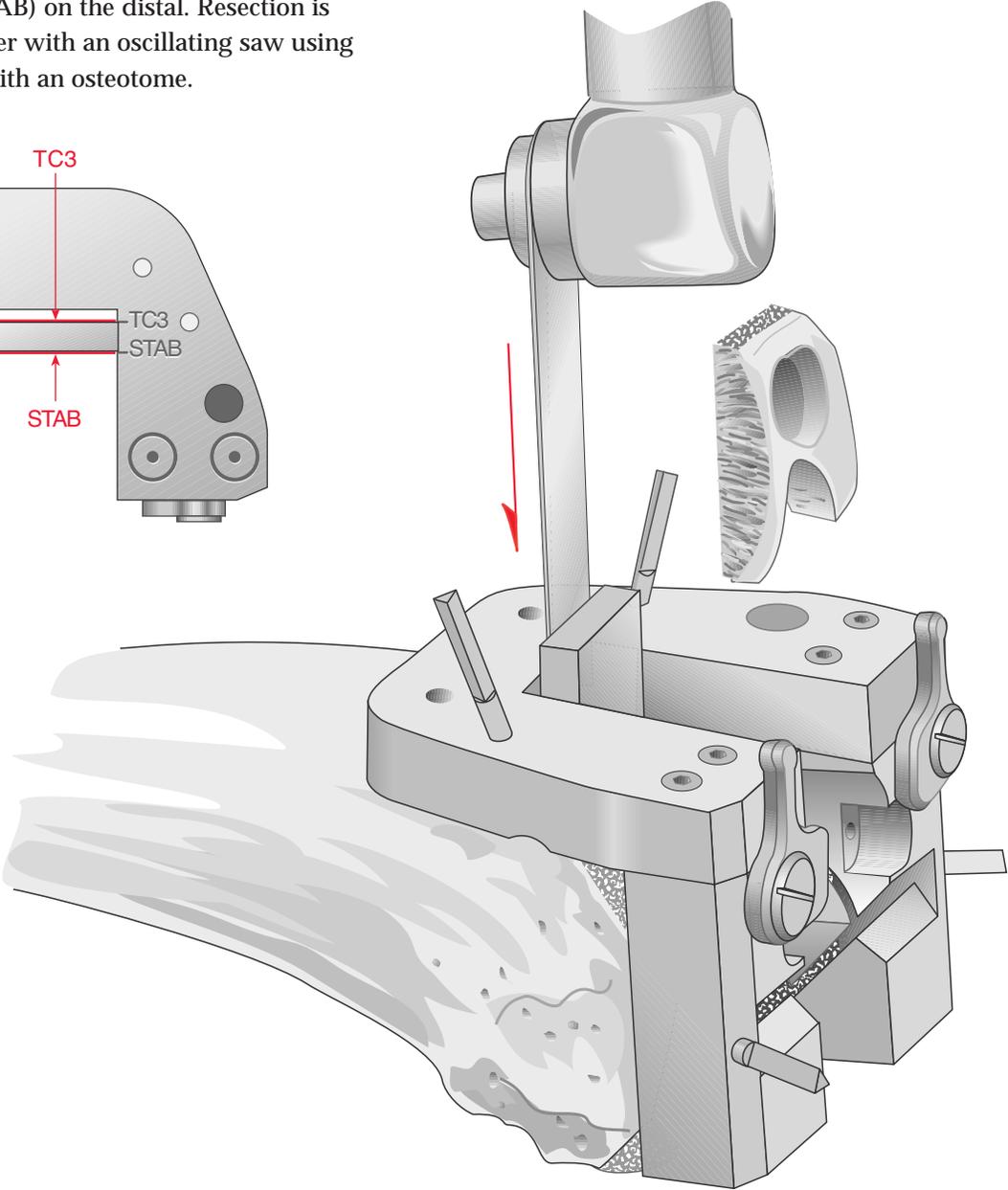
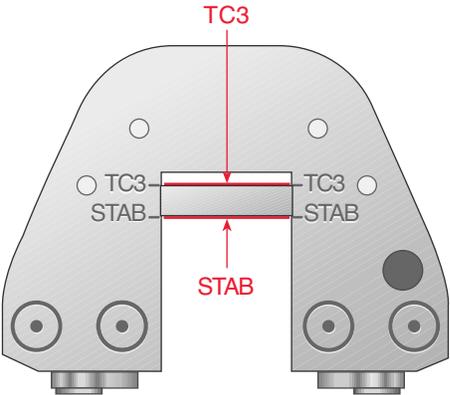
The notch and chamfer cuts can be made with an oscillating saw with the rod and sleeve in position.



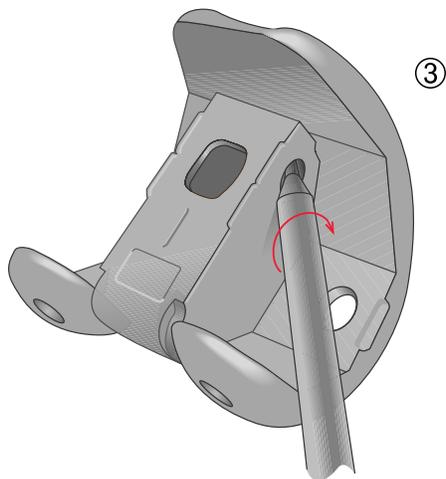
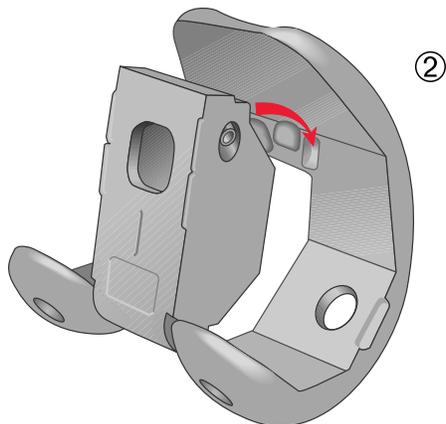
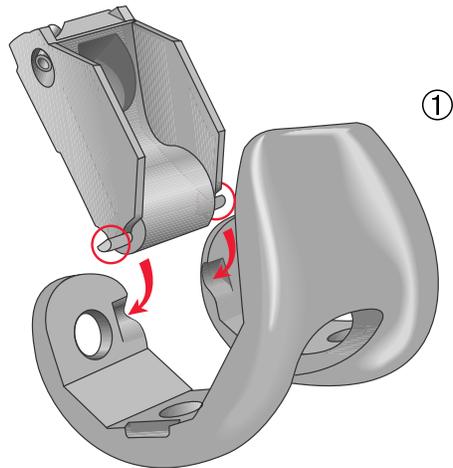
The notch/chamfer bushing is subsequently removed. The rod handle is reassembled and the IM rod and sleeve carefully disengaged from the reamed canal to preserve the established configuration. The security of the notch guide is confirmed.



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, the Stabilized (designated STAB) on the distal. Resection is performed either with an oscillating saw using a 1/2" blade or with an osteotome.



THE TRIAL FEMORAL COMPONENT



THE FEMORAL COMPONENT BOX ASSEMBLY

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

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

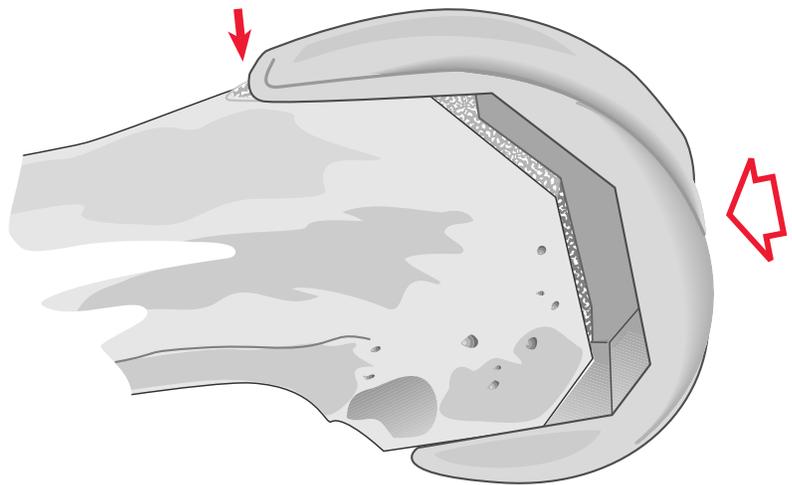
3) Turn the angled screw, located in the side of the box, until tight.

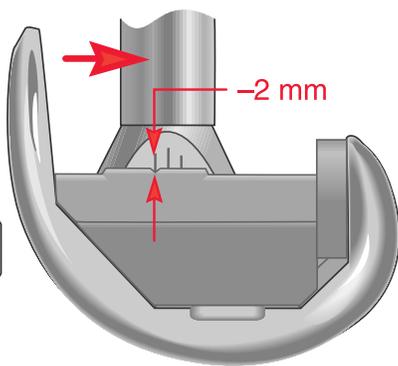
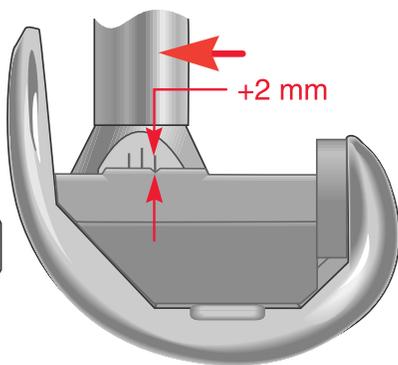
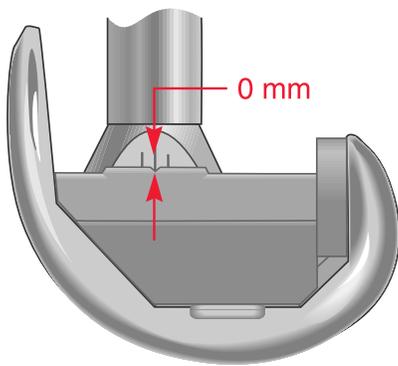
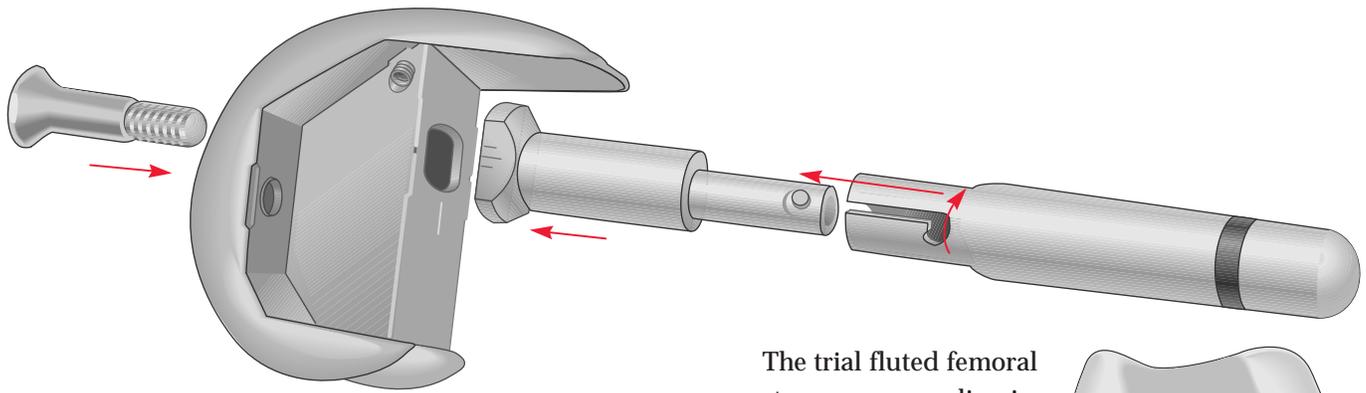
Note: Do not over tighten the screw or attempt to remove the screw from the box trial as this will result in damage to the box trial attachment.

The femoral trial is positioned on the prepared distal femur, and the accuracy of the cuts is evaluated.

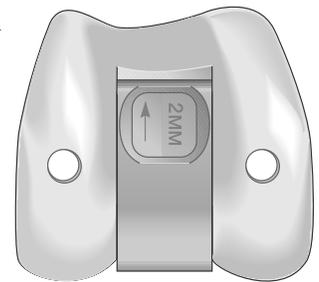
Where the component tends to rotate posteriorly (rocking into flexure) the A/P cuts may require adjustment. Where there is lateral rocking, the depth of the notch is inadequate.

All appropriate modifications are made at this time.





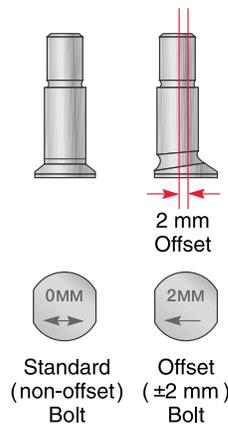
The trial fluted femoral stem, corresponding in size to the final reamer employed and to the established depth, is assembled to the trial femoral component. The appropriate bolt, 0 or +2/-2, corresponding to the bushing



Arrow indicates magnitude and direction of offset.

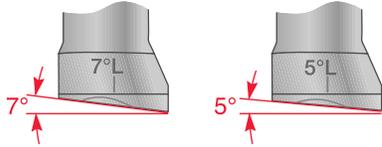
selected for the A/P cutting block and notch/chamfer guide is passed through the hole in the box of the distal femur. As illustrated, if the +2/-2 bolt is used, the arrow is pointing to the direction in which the stem will be placed. When the arrow is pointing to the anterior part of the femoral component, the stem is located 2 mm anterior to the 0 mm position, resulting in the femoral component shifting 2 mm posterior relative to the stem position. This is referred to as the

+2 mm position. Subsequently, if the arrow is pointing to the posterior part of the femoral component, the stem is located 2 mm posterior to the 0 mm position, resulting in the femoral component shifting 2 mm anterior relative to the stem position. This is referred to as the -2 mm position.

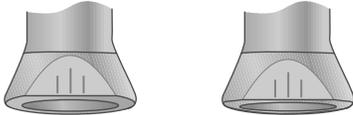


2 Stem Collar Angles:

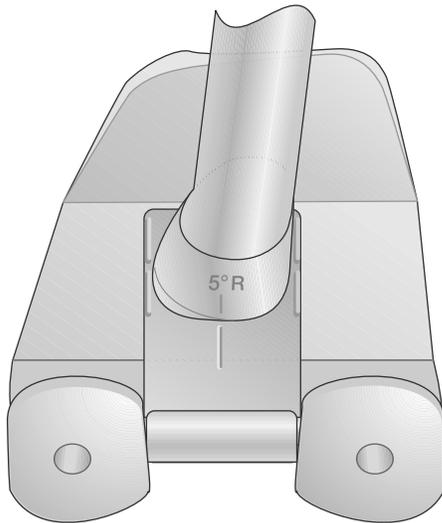
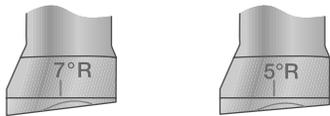
Left orientation marks



Marks for verifying offset position



Right orientation marks



Orientation system to verify angulation and left/right orientation.

The appropriate trial femoral stem collar assembly, 5° or 7°, corresponding to the bushing used on the A/P cutting block and the notch/chamfer guide is selected. The collar swivels to adjust for either a right or left orientation and is assembled with the markings facing the posterior trial femoral component. The bolt is introduced through the femoral box trial and into the trial femoral stem assembly, and is tightened with the trial femoral stem assembly wrench.

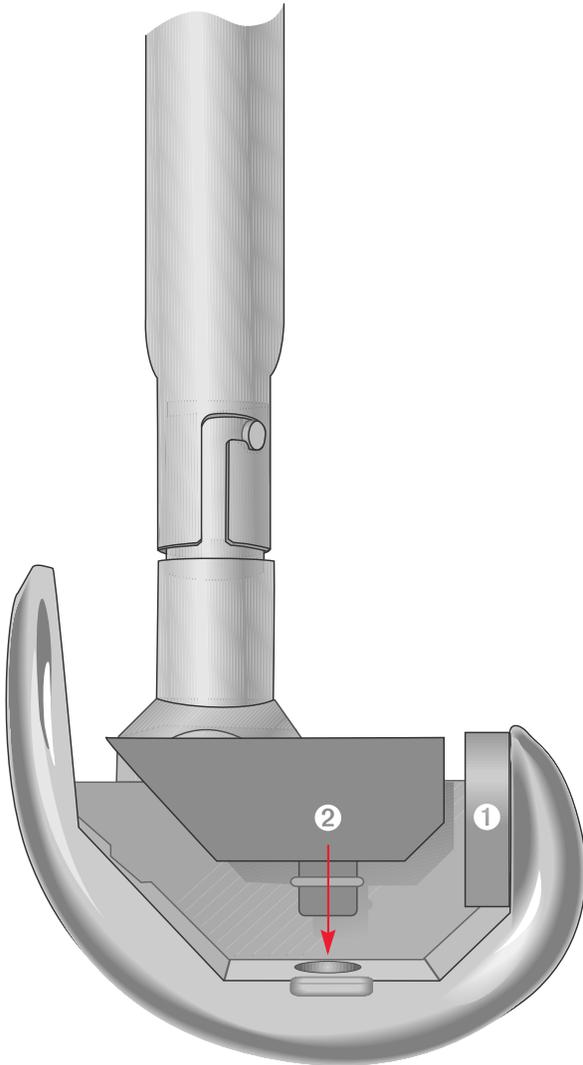
To ensure the proper assembly, there are three visual checks: (1) the arrow on the bolt is pointing to the desired position; (2) the lateral side of the collar and the box trial are aligned, as illustrated on page 29; and (3) the collar is positioned on the trial femoral component such that the angle and the orientation are viewed from the posterior trial femoral component.

The trial fluted femoral stem, corresponding in size to the final reamer employed and to the established depth, is assembled to the trial femoral component.

Where augmentation is employed, the appropriate trial distal and posterior augmentation components are assembled to the trial. The trial component is gently impacted into position allowing for possible discrepancy between the stem and prepared canal.

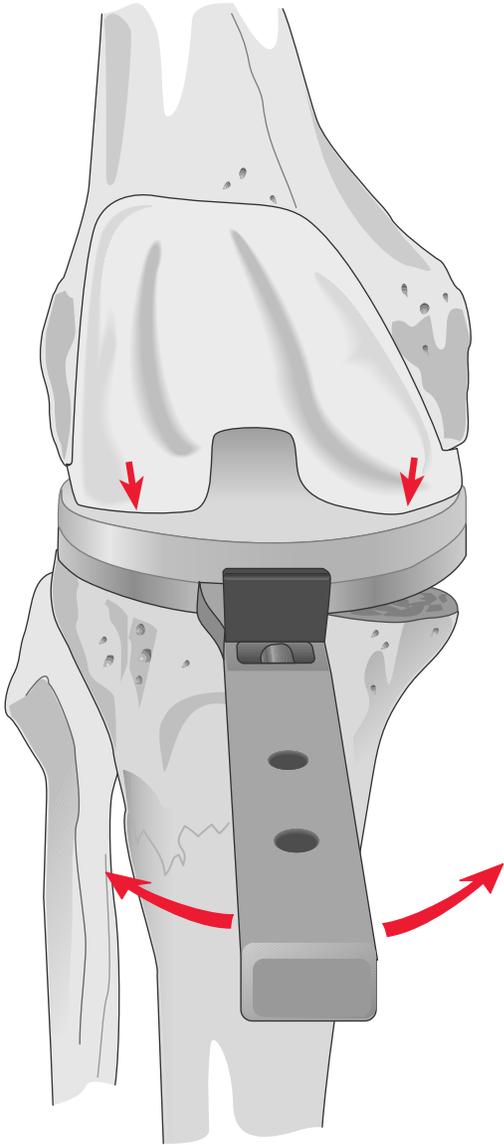
A trial tibial tray is selected such that the prepared surface is adequately covered without peripheral overhang. Where slight overhang is unavoidable, it should be posterolateral. Where a fluted tibial stem is indicated, the trial stem corresponding in size to the final reamer and the established depth is assembled to the trial tibial tray. The trial polyethylene insert is selected that will provide maximum range of motion and satisfactory stability and restoration of the anatomic joint line. Ligamentous balance is re-evaluated and accordingly corrected.

Balance of flexion and extension gaps and restoration of the anatomic joint line are confirmed. The knee is carried through a range of motion to evaluate stability. Where indicated, the next greater size insert is substituted to enhance stability. The patella should track normally with the capsule open, without tendency to tilt. The knee is fully extended and overall alignment and stability confirmed.

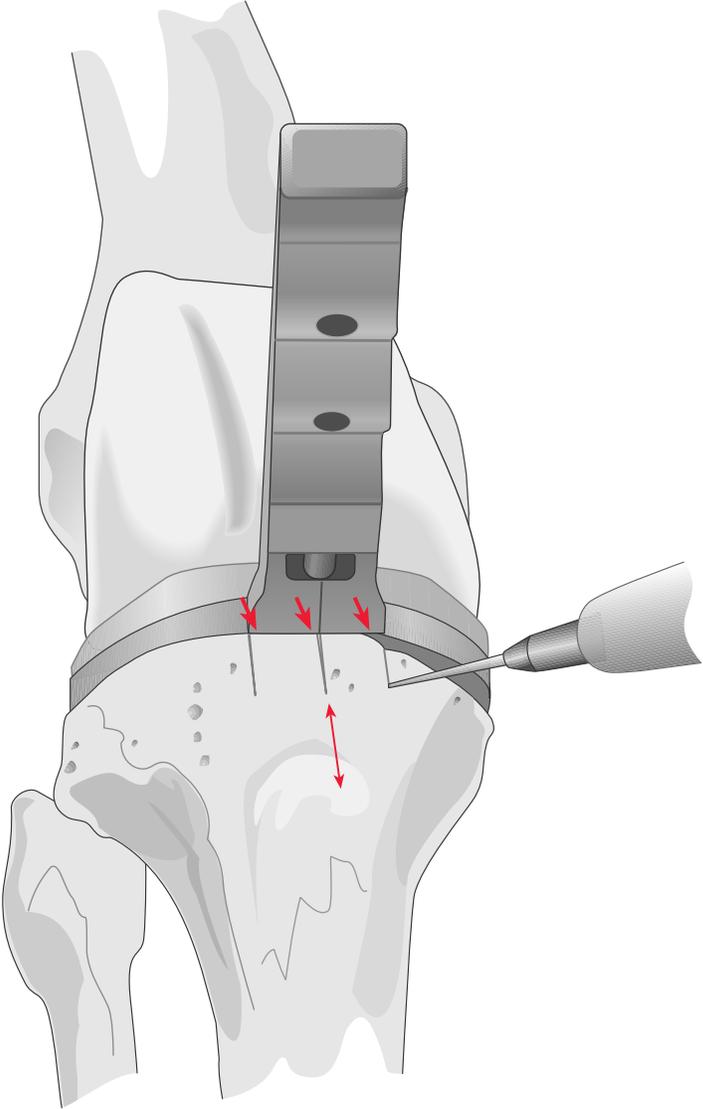


FINAL PREPARATION OF THE TIBIA

The knee is placed in full extension and appropriate rotation of the tibial tray determined. The tibial alignment handle is attached to the tray and rotated into congruency with the femoral trial.



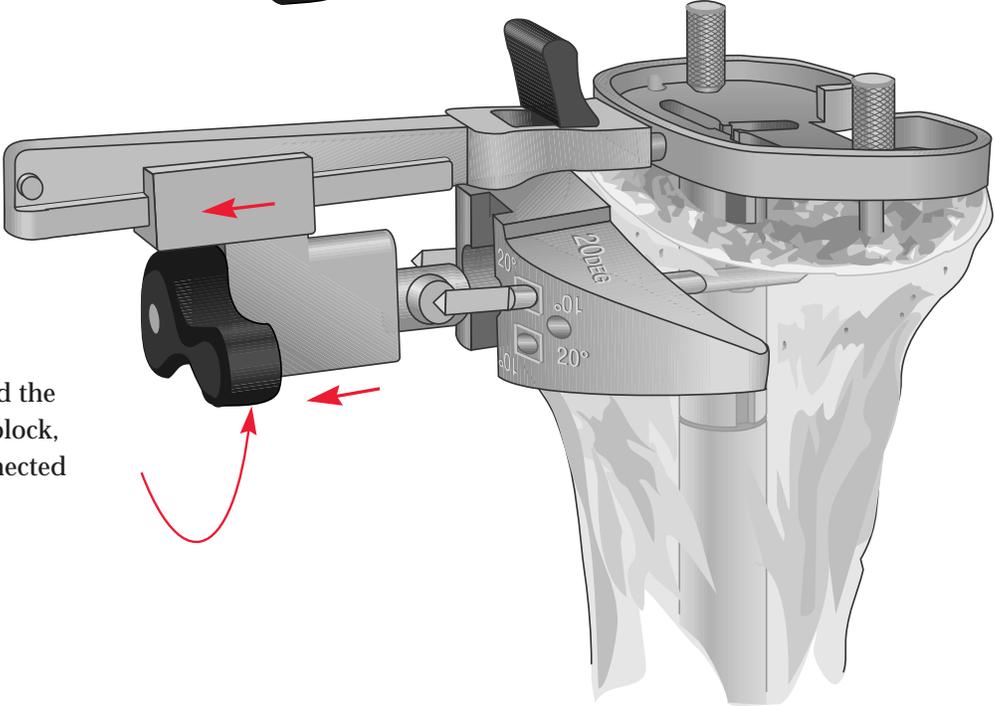
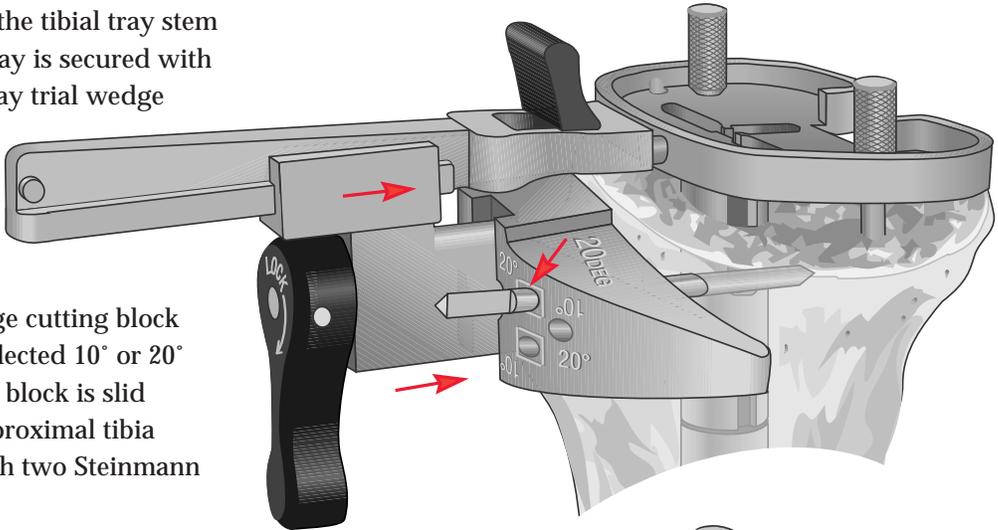
Appropriate rotation is inscribed with electrocautery on the anterior tibial cortex at the center and sides of the alignment handle.



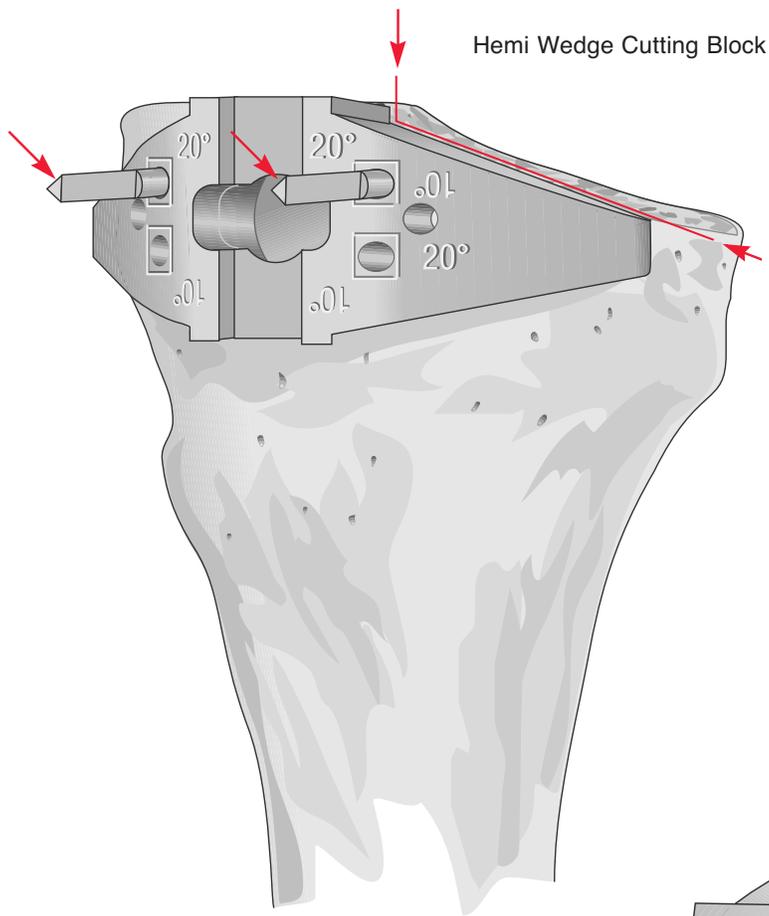
STEP OR HEMI WEDGE AUGMENTATION

Resection for supplementary tibial augmentation may be based on the established position of the trial tray. The femoral trial is removed to provide greater access. Rotational alignment of the tibial tray stem trial is confirmed. The tray is secured with two fixation pins. The tray trial wedge cutting attachment with the appropriate step wedge or hemi wedge cutting guide is attached to the trial tray.

Note that the hemi wedge cutting block is assembled with the selected 10° or 20° markings facing up. The block is slid forward to the anterior proximal tibia and secured in place with two Steinmann pins through the □'s.



The block is unlocked and the assembly slid out of the block, and the handle is disconnected from the trial tray.

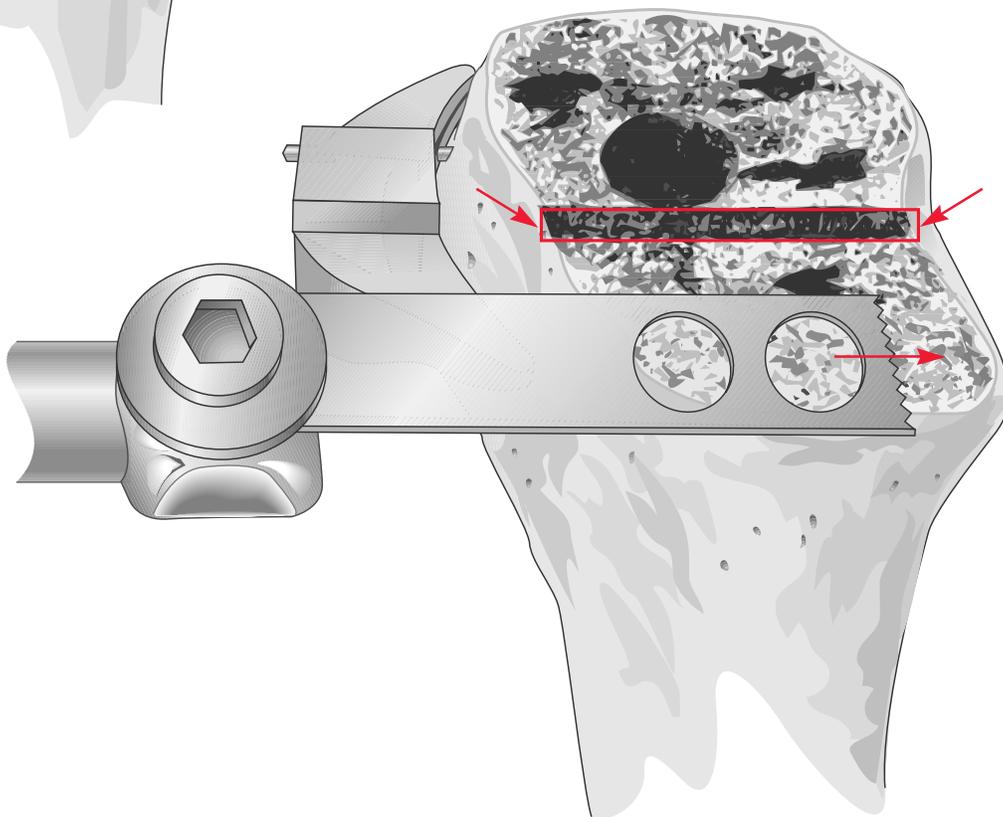


Hemi Wedge Cutting Block

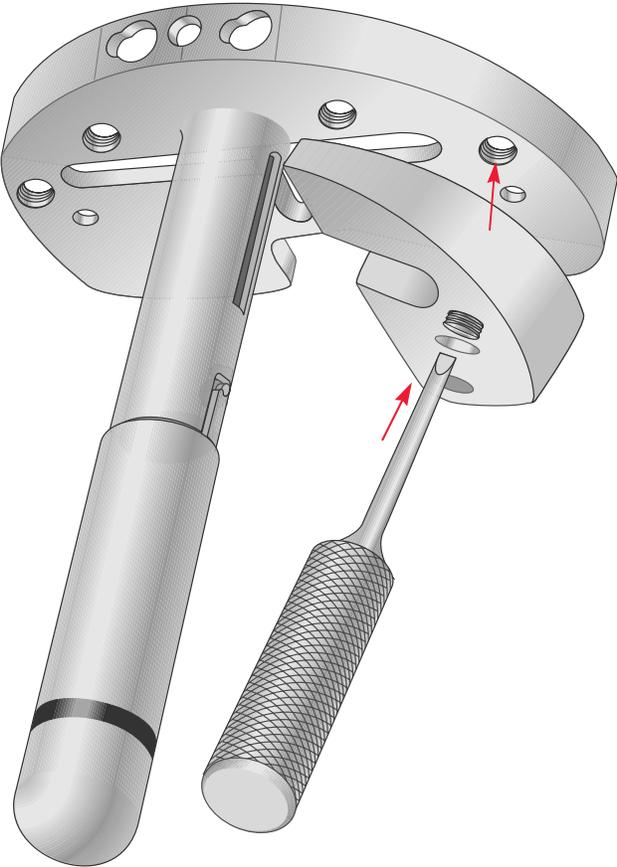
The hemi wedge or the step wedge cutting block is positioned on the pins such that the appropriate cutting surface (10° or 20° for the hemi wedge, 10 or 15 mm for the step) is at the deficient condyle.

The condyle is accordingly trimmed with an oscillating saw such that the cut does not extend beyond the central riser. The block and pins are subsequently removed.

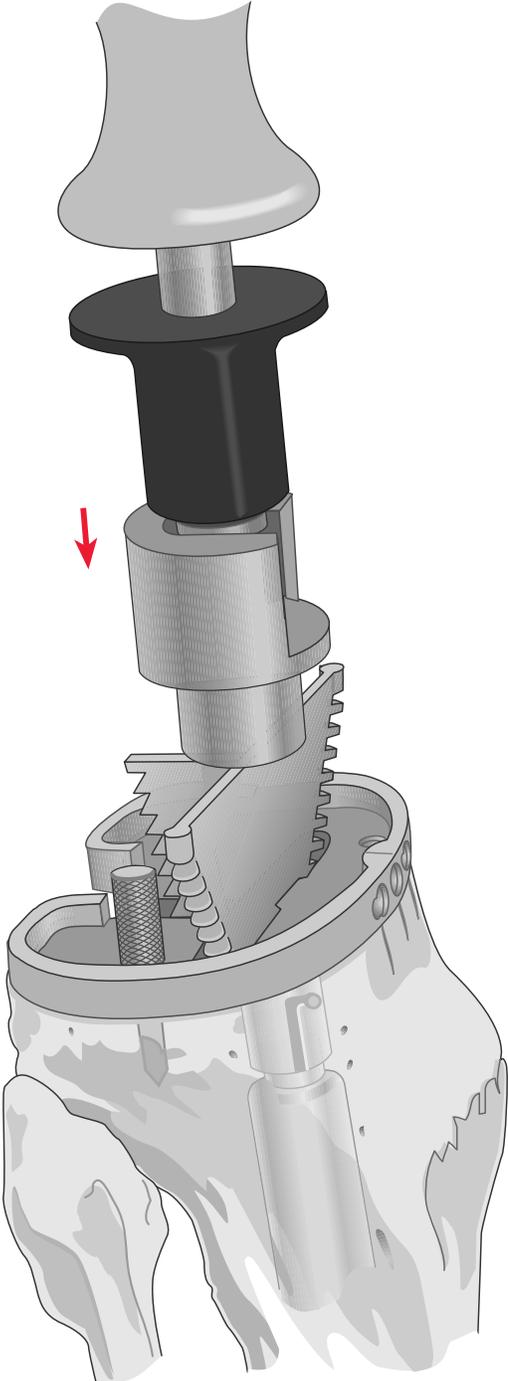
Step Wedge Cutting Block



The trial wedge and/or the trial stem are assembled to the appropriate trial tibial tray, which is subsequently introduced into the prepared site. Minimal correction is performed with a bone file where indicated to ensure maximal contact.

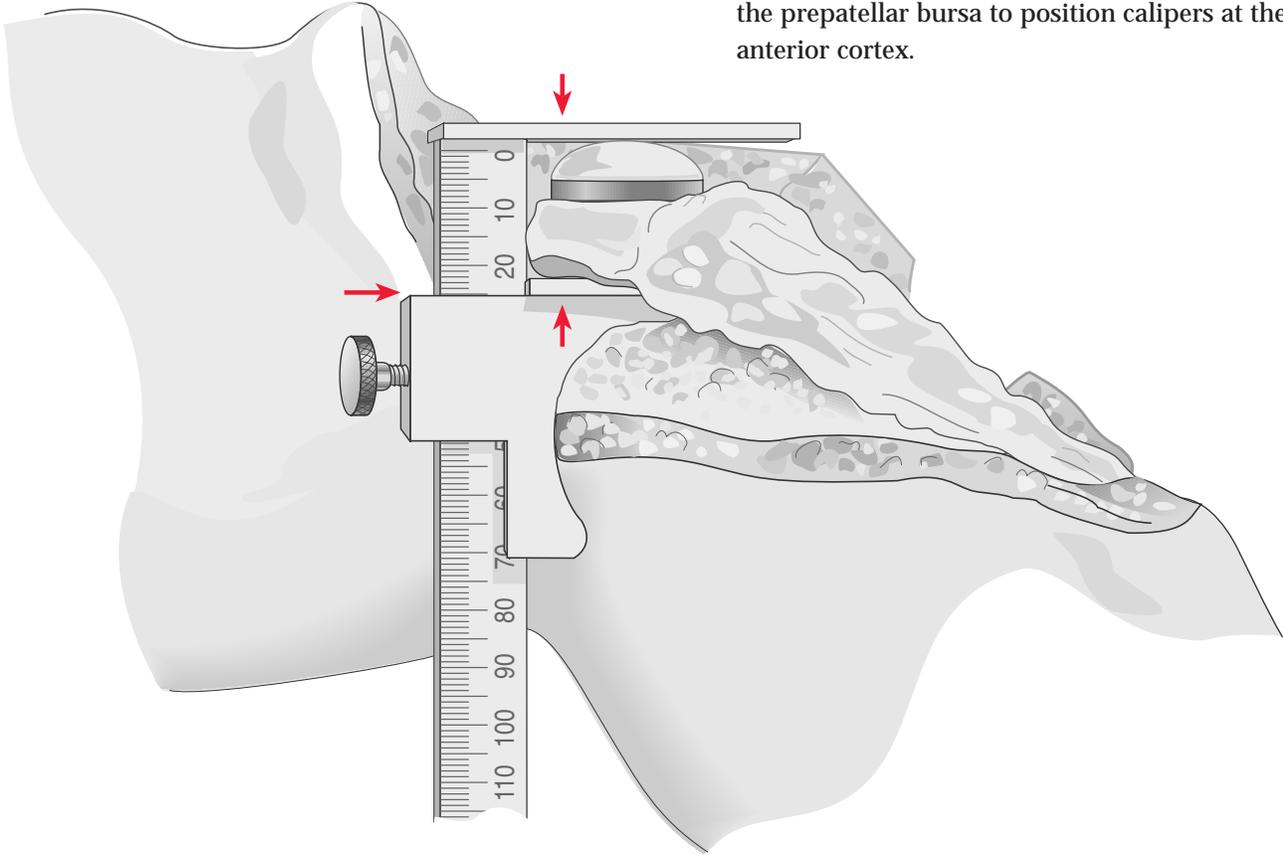


Positioning, alignment and security of the tray assembly is confirmed. If there is old cement or sclerotic bone present, relieve this first through the trial tray with a saw blade or burr prior to punching. The Specialist 2 tibial keel punch is appropriately positioned at the tray and cancellous bone interface and impacted into the keel configuration. The punch is carefully extracted and the tray assembly is subsequently withdrawn.



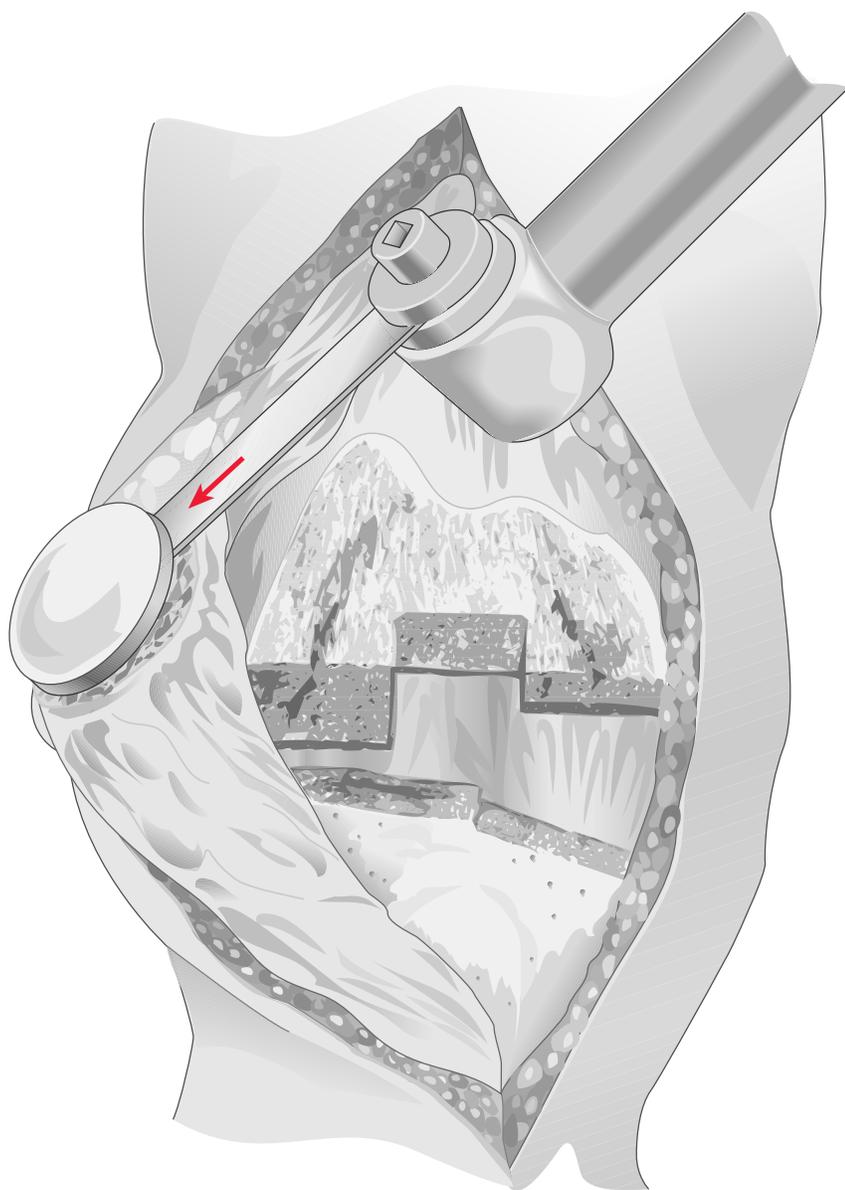
PREPARATION OF THE PATELLA

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. Sufficient soft tissue is freed at the prepatellar bursa to position calipers at the anterior cortex.



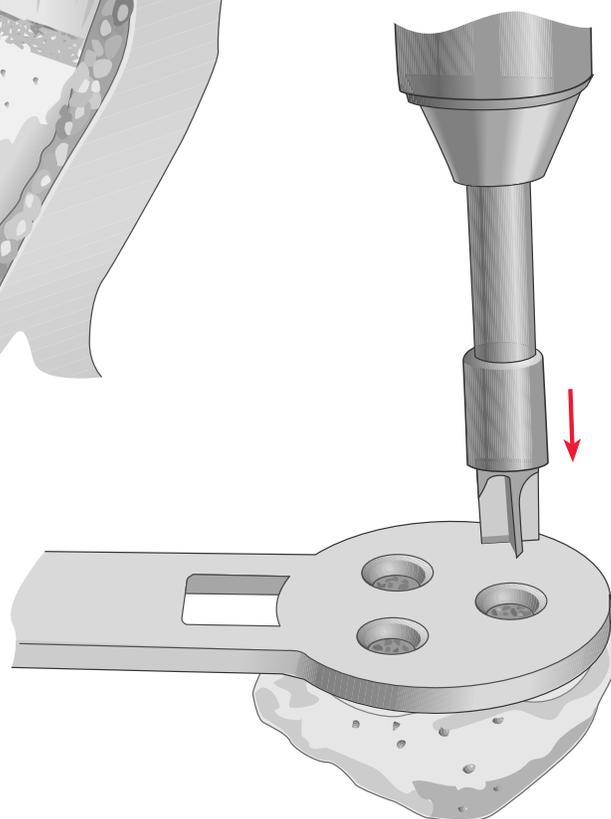
Where residual bone stock is adequate, implantation of the replacement prosthesis is essentially routine. Where inadequate, patelloplasty may be indicated.

NB: The normal anteroposterior patellar dimension is 22–24 mm in the female, 24–26 in the male.



Meticulous disruption of the bone/prosthesis interface is essential. It is performed with thin osteotomes and thin oscillating saw blades. Excessive leverage is avoided to minimize possible fracturing.

The patellar template that most adequately covers the prepared surface is positioned along the horizontal axis of the patella and is firmly engaged. The three holes for the fixation pegs of the component are fashioned with the appropriate drill. Depth is governed by the collar.

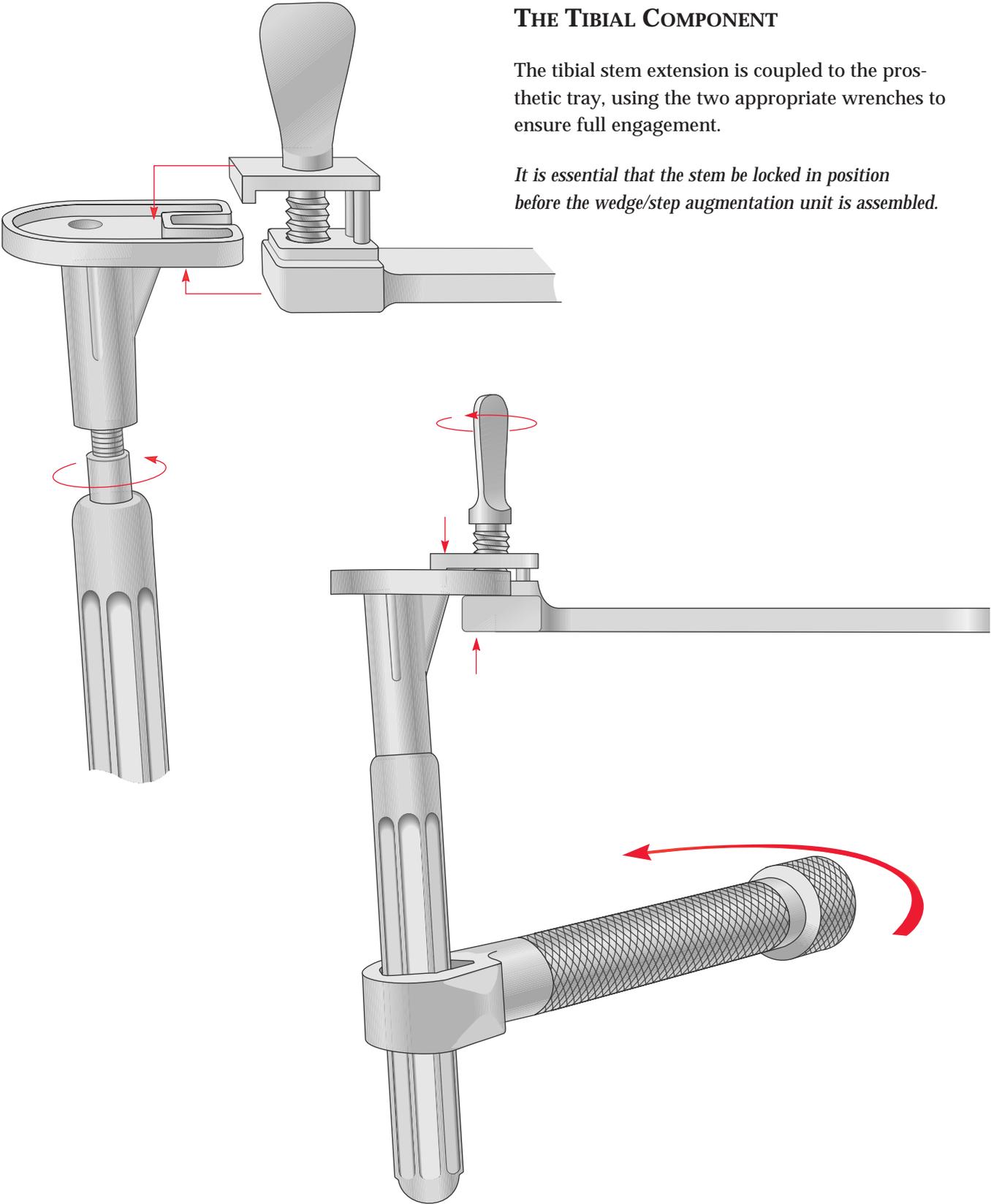


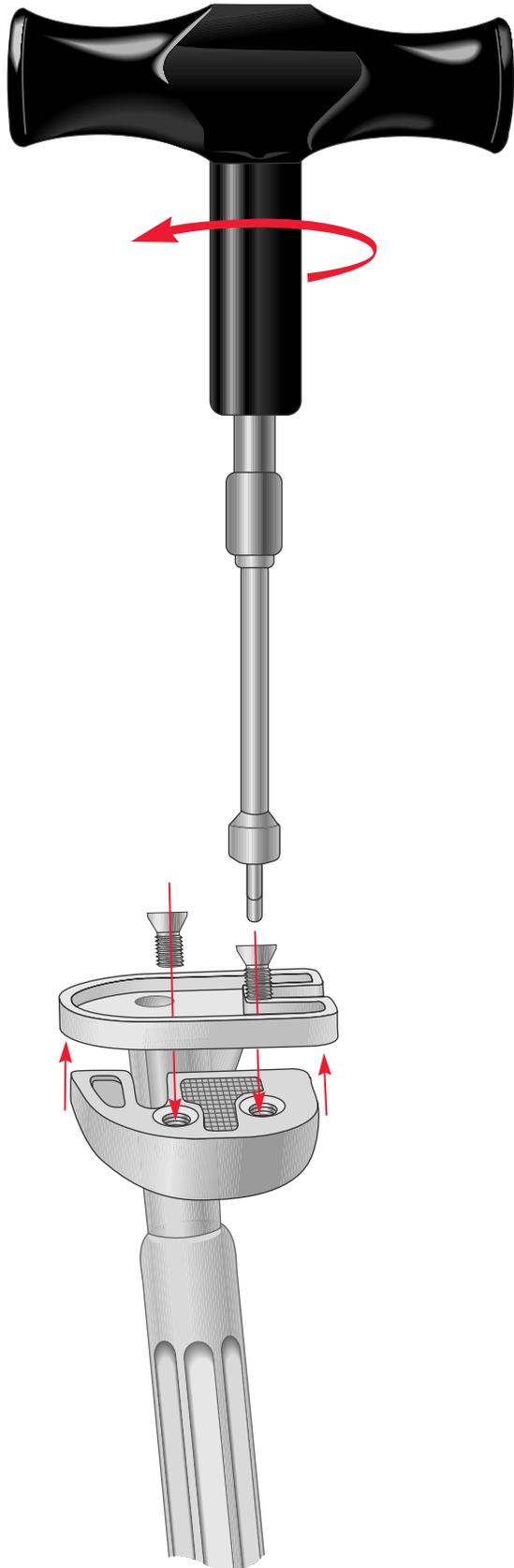
ASSEMBLING THE PROSTHESIS

THE TIBIAL COMPONENT

The tibial stem extension is coupled to the prosthetic tray, using the two appropriate wrenches to ensure full engagement.

It is essential that the stem be locked in position before the wedge/step augmentation unit is assembled.

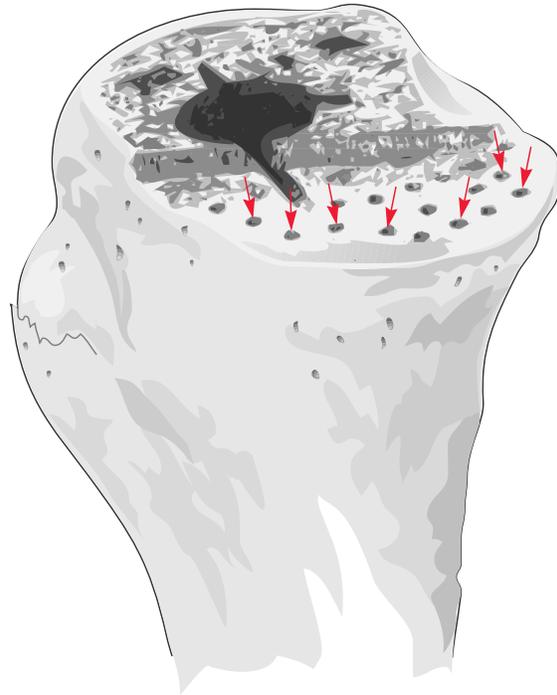




Where wedge augmentation is indicated, the appropriate polyethylene plugs are removed from the Modular Plus tibial tray with the plug puller.

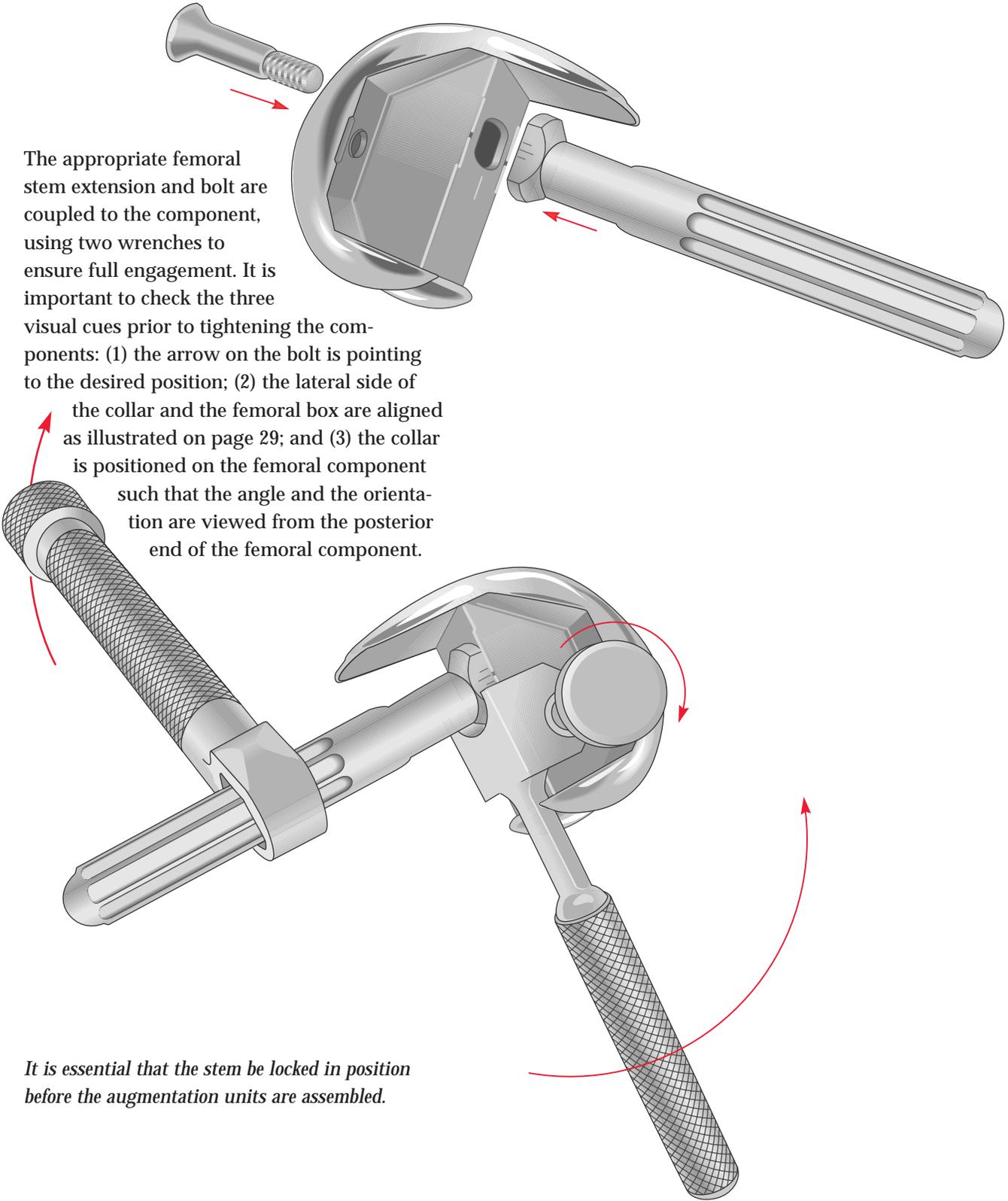
The designated wedge is assembled to the tray and secured by the appropriate screws, which are carefully tightened with the large T-handled torque driver until an audible click is discerned, ensuring a full and permanent interlock.

Where the prepared tibial surface is eburnated, it may be perforated with small drill holes to facilitate penetration of methyl methacrylate. Residual small cavity bone defects are packed with cancellous autograft, if available, or allograft.



THE FEMORAL COMPONENT ASSEMBLY

The appropriate femoral stem extension and bolt are coupled to the component, using two wrenches to ensure full engagement. It is important to check the three visual cues prior to tightening the components: (1) the arrow on the bolt is pointing to the desired position; (2) the lateral side of the collar and the femoral box are aligned as illustrated on page 29; and (3) the collar is positioned on the femoral component such that the angle and the orientation are viewed from the posterior end of the femoral component.



It is essential that the stem be locked in position before the augmentation units are assembled.

Where augmentation is employed, the following sequence must be followed:

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.

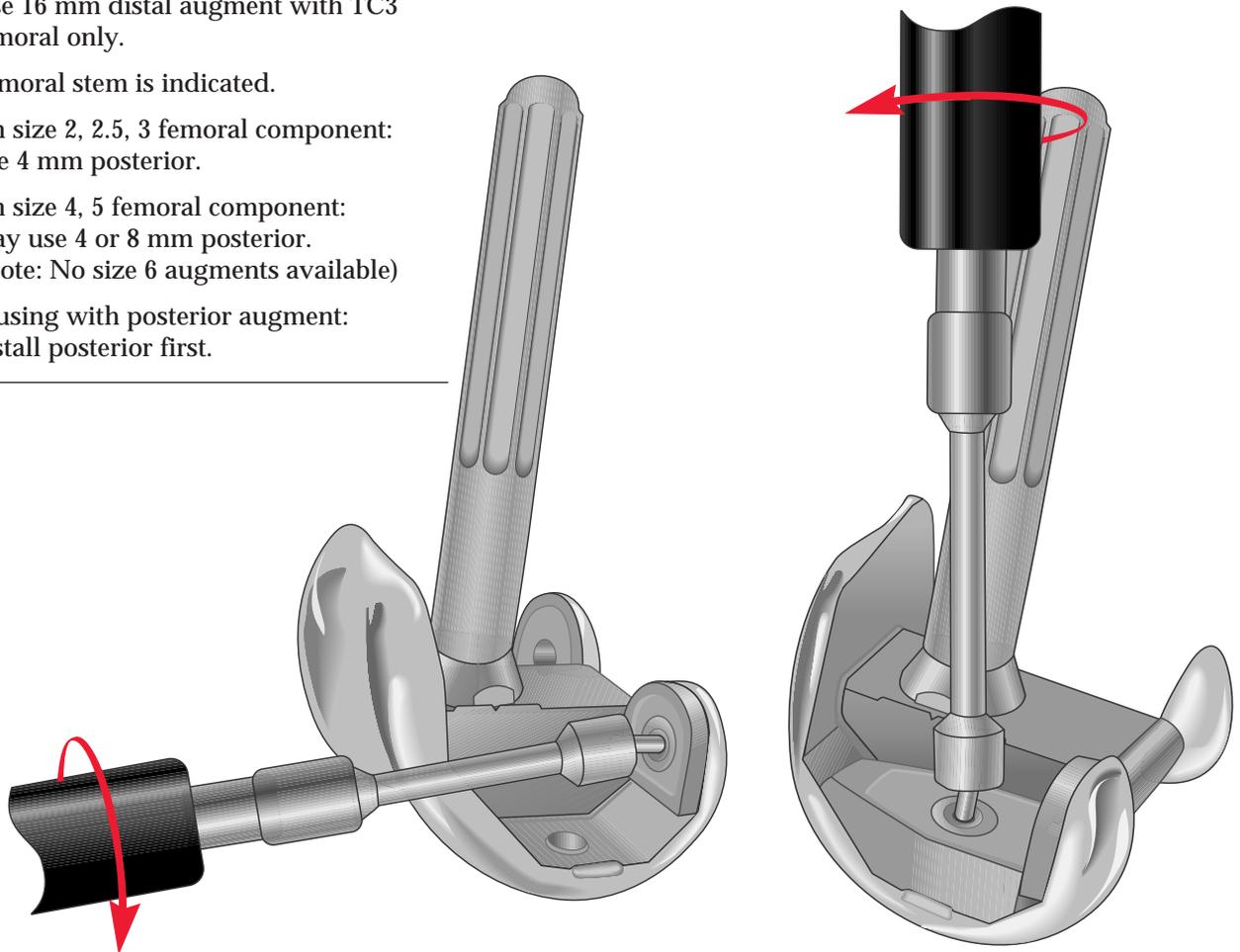
2. For 4 mm/8 mm Augments:

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

3. For 12 mm/16 mm Distal Augment:

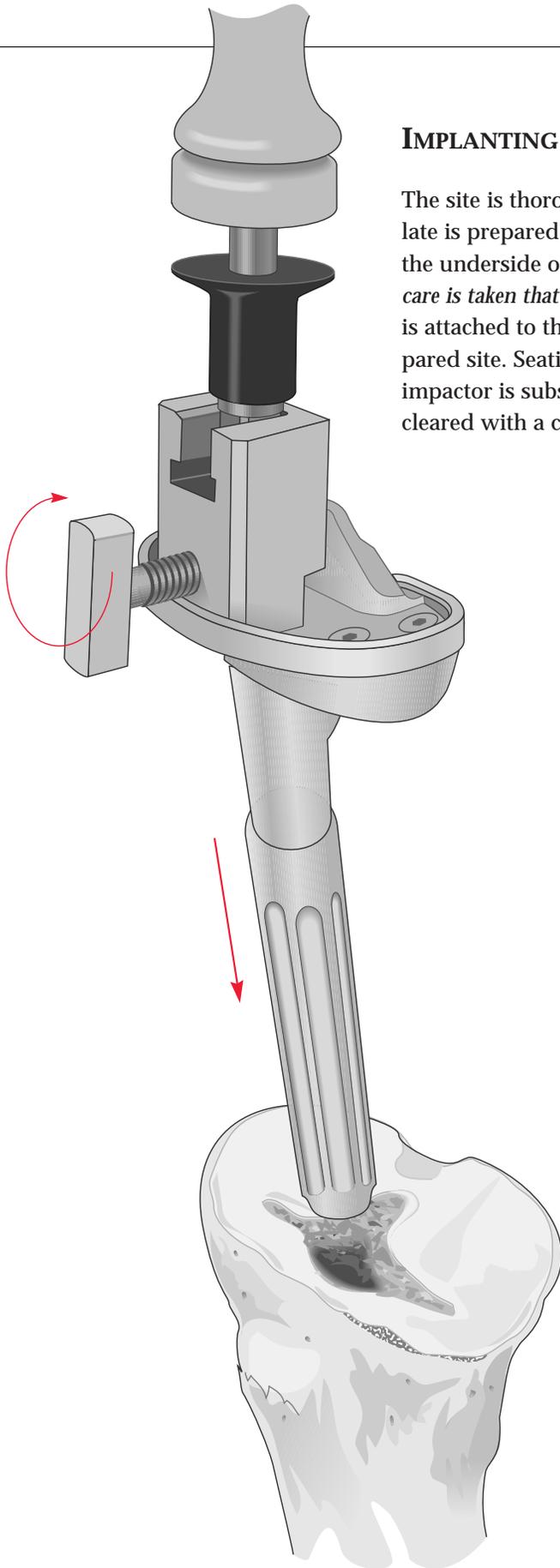
- Use 16 mm distal augment with TC3 femoral only.
- Femoral stem is indicated.
- On size 2, 2.5, 3 femoral component: use 4 mm posterior.
- On size 4, 5 femoral component: may use 4 or 8 mm posterior. (Note: No size 6 augments available)
- If using with posterior augment: install posterior first.

Each augmentation component is packaged with a disposable, single-use wobble hex bit. Position the augmentation component in the femoral component, place the wobble hex bit into the hex head of the augment screw and place the torque driver onto the wobble hex bit. The torque driver is used to apply a compressive force while tightening the screw. The driver is turned until an audible click is discerned, ensuring a full and permanent interlock.

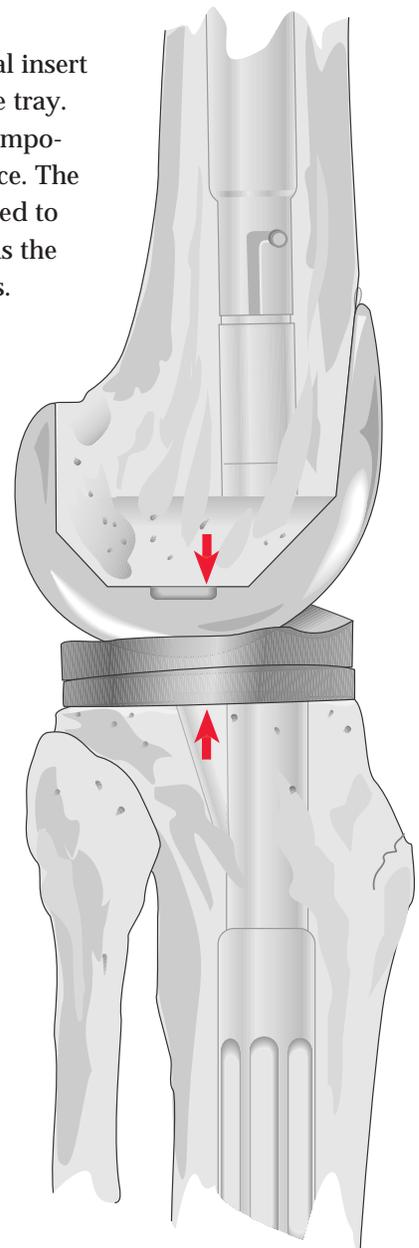


IMPLANTING THE TIBIAL COMPONENT

The site is thoroughly cleansed with pulsatile lavage. Methylmethacrylate is prepared and applied to the proximal tibial surface or directly to the underside of the tibial tray component. Where a fluted stem is used, *care is taken that the medullary canal remain free of cement.* The implant tray is attached to the universal tibial impactor and inserted into the prepared site. Seating is established with several strikes of a mallet. The impactor is subsequently detached from the tray. All extruded cement is cleared with a curette.

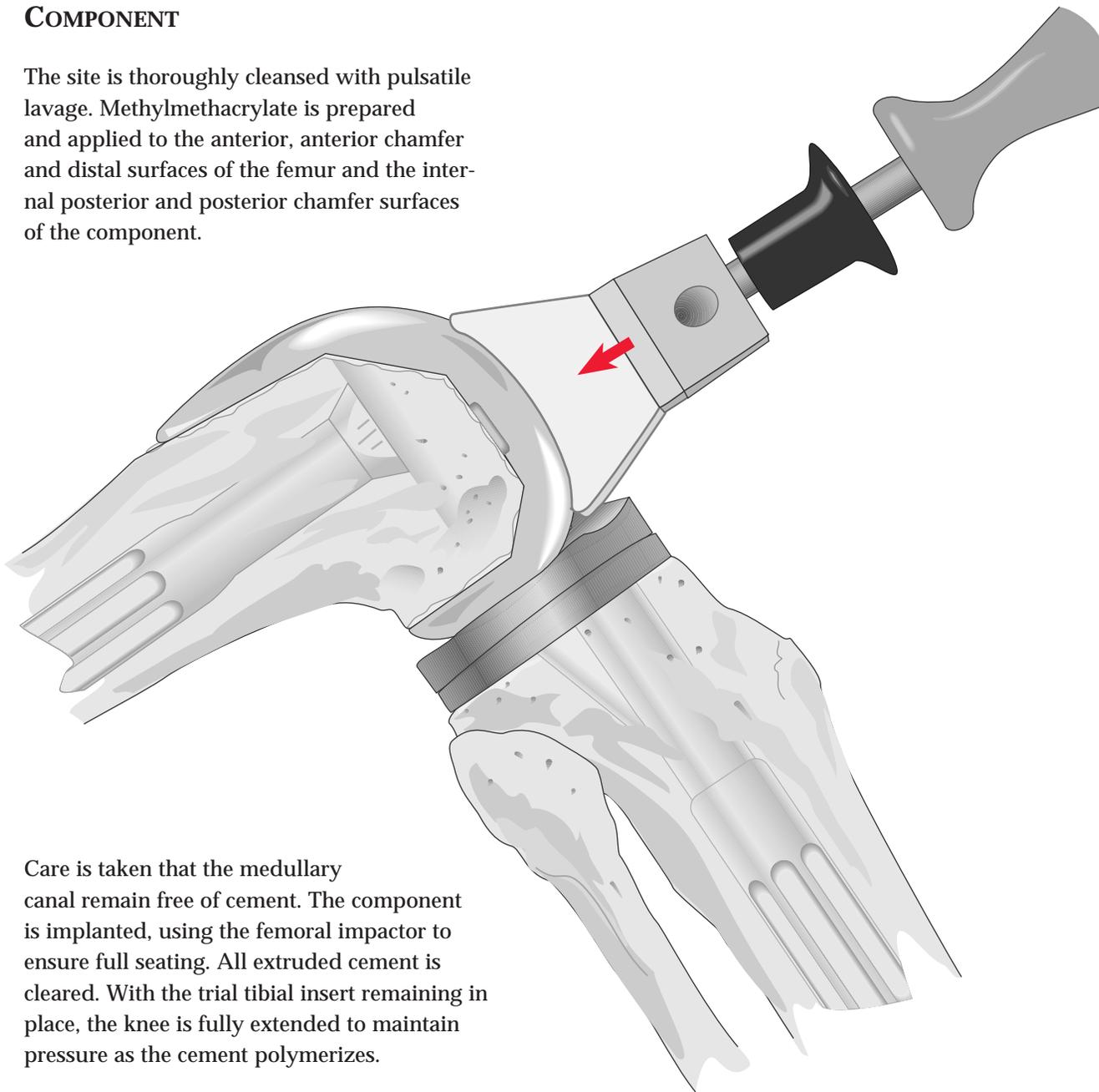


The appropriate trial insert is fully seated in the tray. The trial femoral component remains in place. The knee is fully extended to maintain pressure as the cement polymerizes.



IMPLANTING THE FEMORAL COMPONENT

The site is thoroughly cleansed with pulsatile lavage. Methylmethacrylate is prepared and applied to the anterior, anterior chamfer and distal surfaces of the femur and the internal posterior and posterior chamfer surfaces of the component.



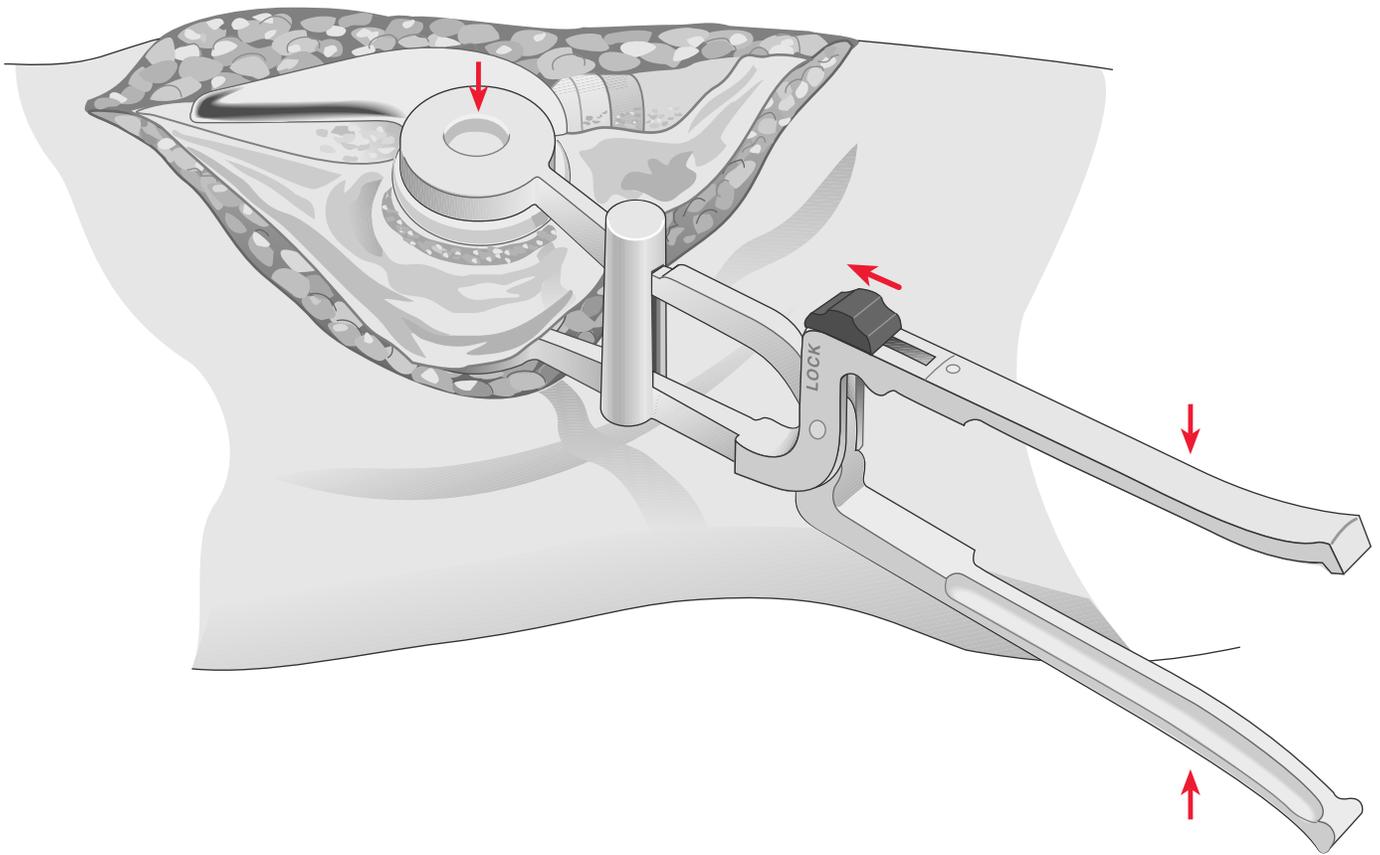
Care is taken that the medullary canal remain free of cement. The component is implanted, using the femoral impactor to ensure full seating. All extruded cement is cleared. With the trial tibial insert remaining in place, the knee is fully extended to maintain pressure as the cement polymerizes.

IMPLANTING THE PATELLAR COMPONENT

Patellar implantation is performed when convenient.

The site is cleansed with pulsatile lavage and methylmethacrylate applied. The component is inserted into the prepared holes and the patellar clamp positioned.

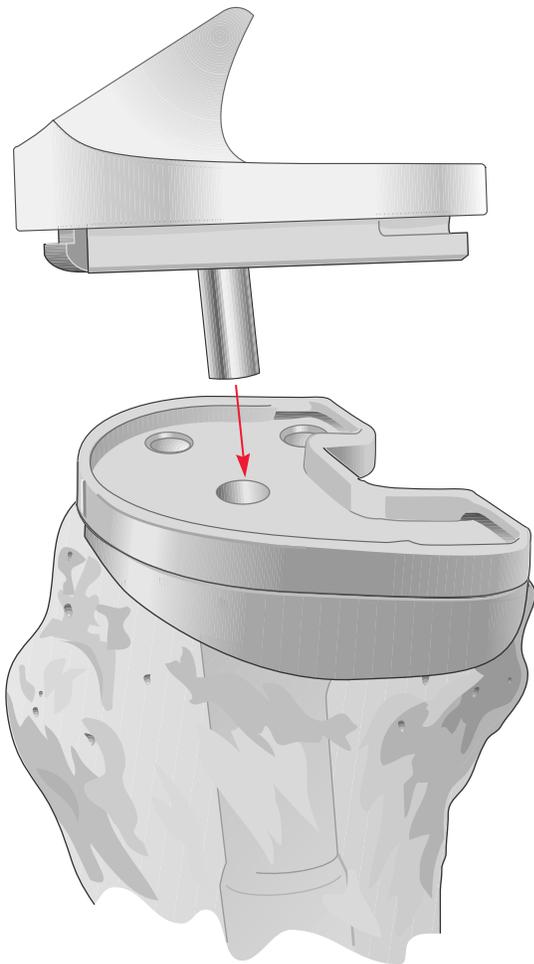
The clamp is designed to fully seat and stabilize the implant. It is positioned with the silicone O-ring centered over the articular surface of the implant and the metal backing plate against the anterior patellar cortex, *avoiding skin entrapment*. When snug, the handles are closed and held by the ratchet until polymerization is complete. Excessive compression is avoided as it can fracture osteopenic bone. All extruded cement is removed with a curette.



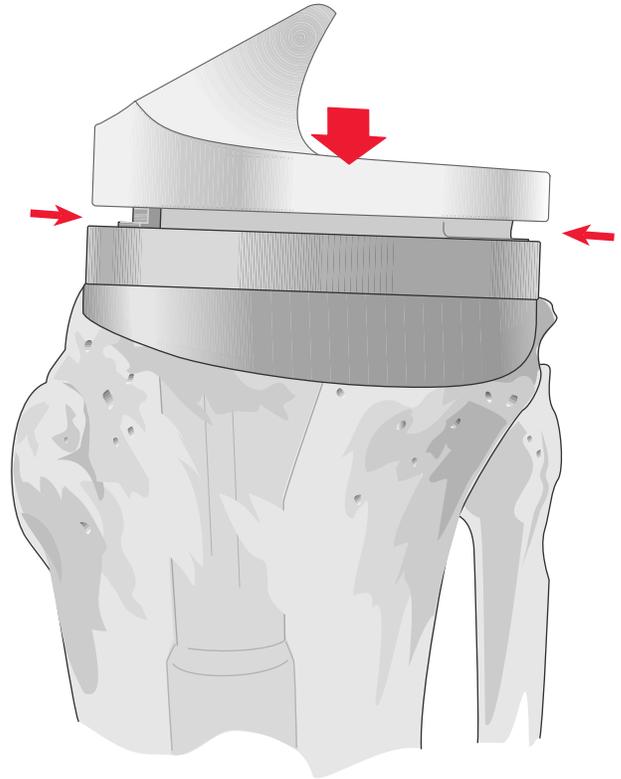
THE TIBIAL INSERT

Reduction is performed. Where indicated, an appropriate replacement trial insert is substituted.

The trial insert is subsequently removed and the permanent insert introduced into the implanted tibial tray. Its metal post, which is assembled on the Stabilized Plus and the TC3 insert, is inserted into the central hole.



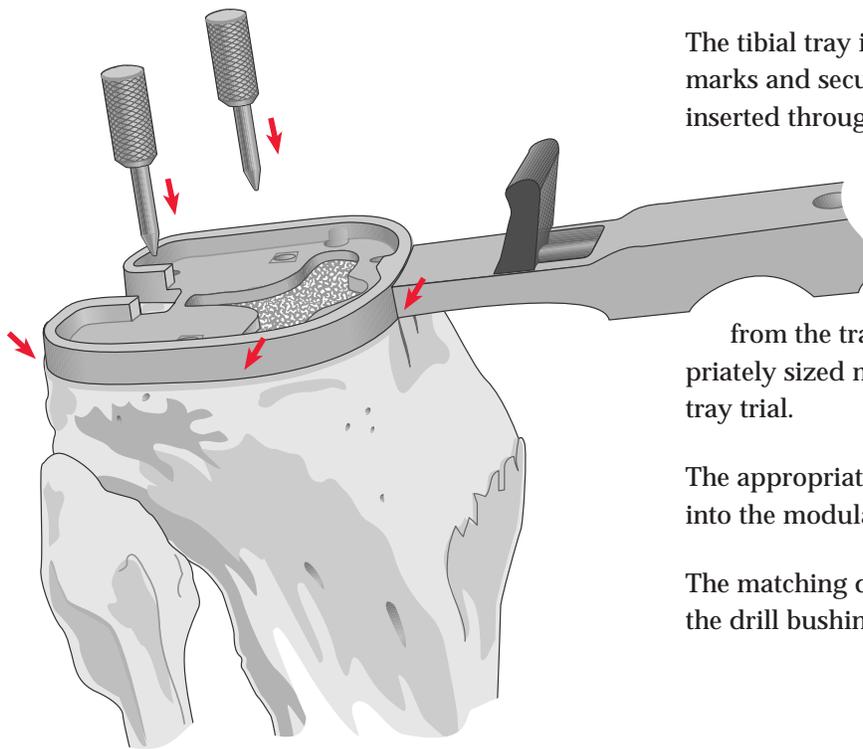
The anterior and posterior margins are simultaneously deflected past the lip of the tray and into position by tapping with a poly tibial component impactor. Seating is confirmed by circumferential inspection.



CLOSURE

At closure, the knee is put through a range of motion from full extension to full flexion to confirm patellar tracking and the integrity of capsular closure, with specific attention to extensor mechanism balance.

THE CEMENTED TIBIAL AND FEMORAL STEM EXTENSIONS



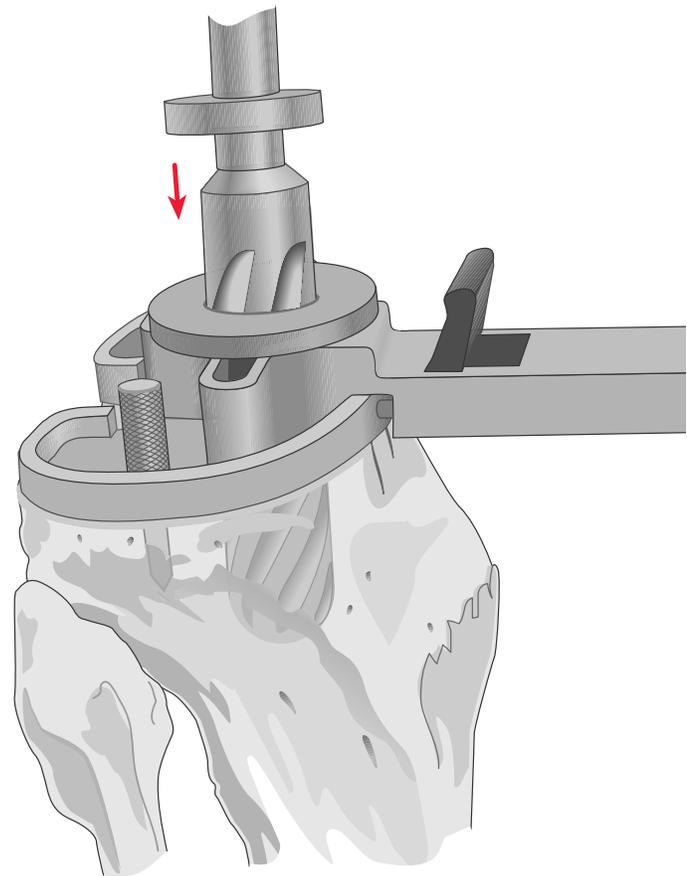
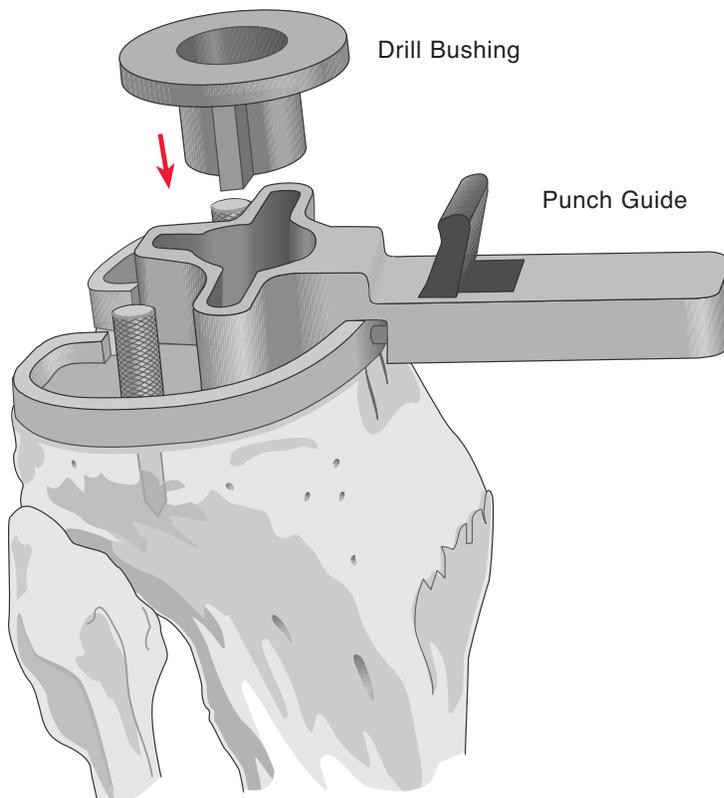
The tibial tray is aligned with the rotation marks and secured with two fixation pins inserted through the holes designated □.

Select the appropriate punch guide, drill bushing, drill and modular keel punch system. Remove the alignment handle

from the tray trial and assemble the appropriately sized modular tray punch guide to the tray trial.

The appropriately sized drill bushing is seated into the modular tray punch guide.

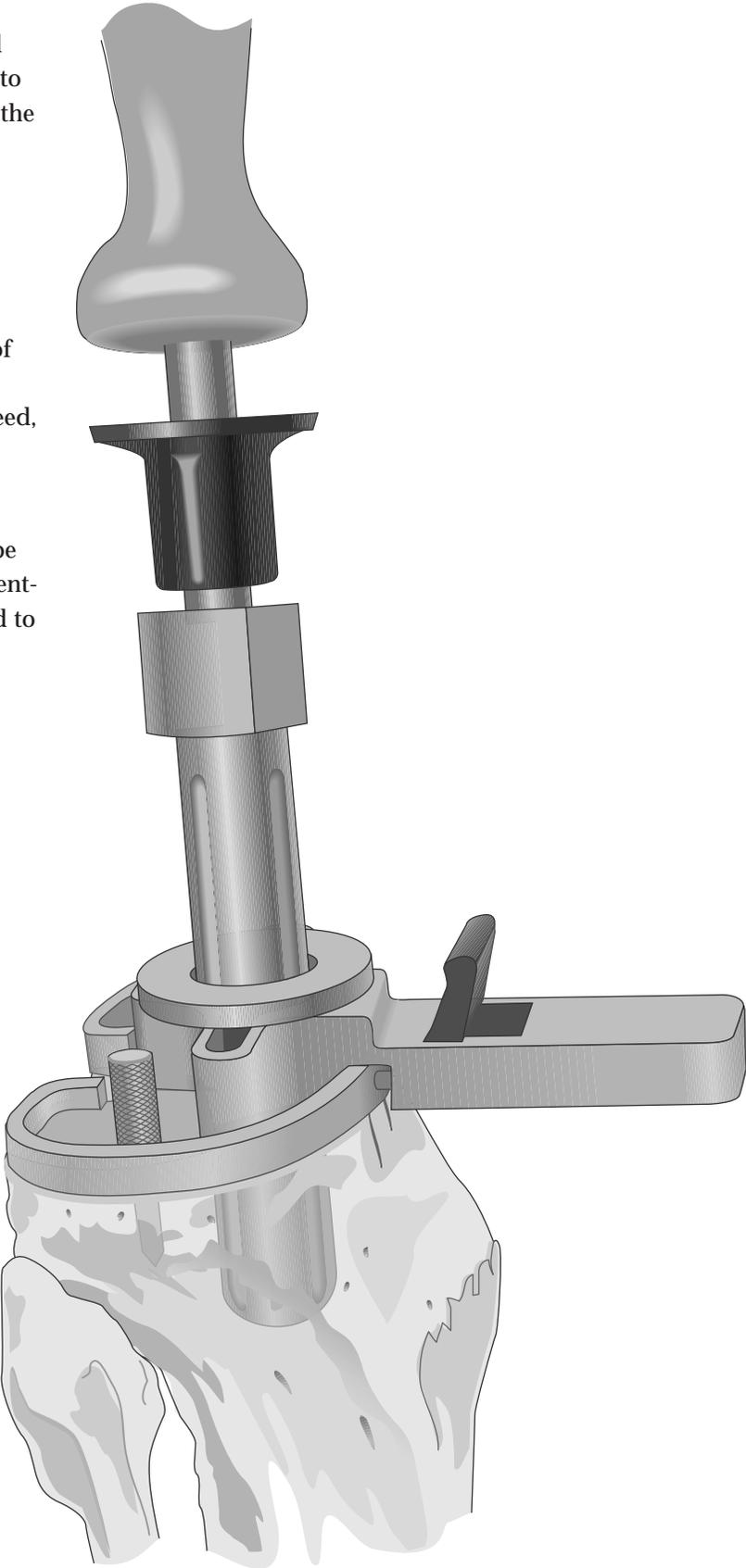
The matching drill is fully advanced through the drill bushing into the cancellous bone.

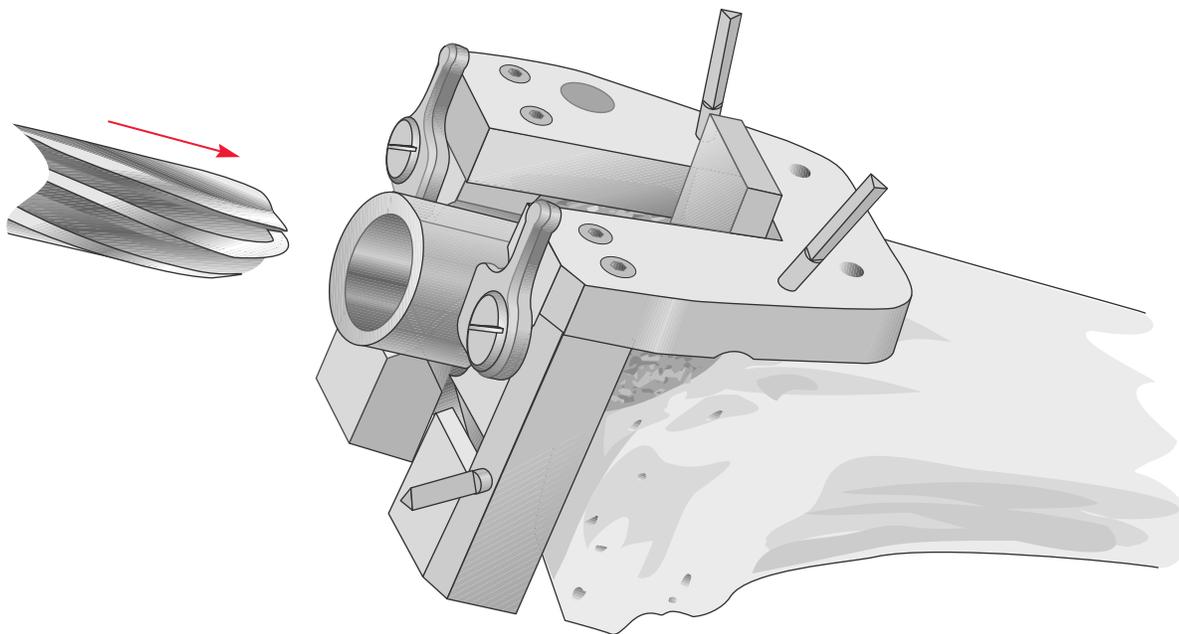


The appropriate 30 mm or 60 mm cemented stem punch in 13 mm or 15 mm is attached to the universal handle and is introduced into the drill bushing. The punch is gently impacted until the shoulder of the punch is in contact with the guide.

The appropriately sized modular tray keel punch is subsequently positioned through the guide and impacted until the shoulder of the punch is in contact with the guide. The modular tray keel punch is subsequently freed, taking care that the punch configuration be preserved.

It is recommended that a cement restrictor be placed at the appropriate level prior to cementing the component. A cement gun is utilized to fill the canal with methylmethacrylate.





THE CEMENTED FEMORAL STEM EXTENSIONS

Smooth, non-fluted modular stems are available in 5° and 7° angles, 13 mm and 15 mm diameters, 90 mm and 130 mm lengths and three stem positions, 0 mm, +2 mm and -2 mm. See page 29 for an explanation of stem positioning and trial assembly. See page 40 for implant assembly.

With the notch/chamfer guide positioned on the distal femur, select the appropriate cemented stem drill bushing with the same anteroposterior stem position as that selected for the A/P cutting block. There are twelve available as follows:

Select the appropriate diameter femoral stem drill and advance the drill to the desired depth according to the markings on the drill. The drill is advanced to the first mark on the drill for a 90 mm depth and seated against the bushing for a 130 mm depth.

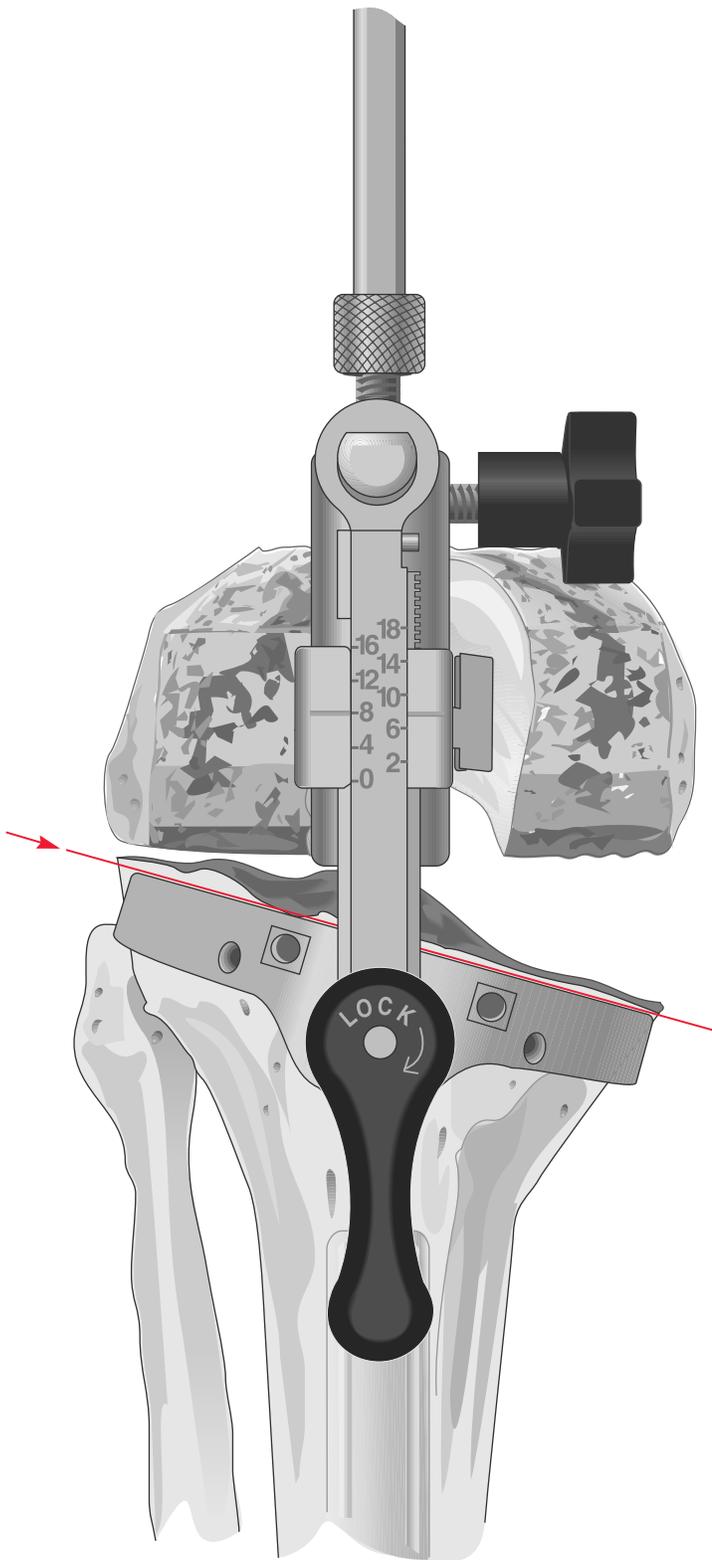
At implantation, the intramedullary canal should be clean, dry and plugged with a cement restrictor at the appropriate depth. A pressurized cement gun is used to deliver the methylmethacrylate into the femoral canal.

5 degrees	7 degrees
13 mm +2mm Left/-2 Right	13 mm +2mm Left/-2 Right
13 mm +2mm Right/-2 Left	13 mm +2mm Right/-2 Left
13 mm 0 mm Offset	13 mm 0 mm Offset
15 mm +2mm Left/-2 Right	15 mm +2mm Left/-2 Right
15 mm +2mm Right/-2 Left	15 mm +2mm Right/-2 Left
15 mm 0 mm Offset	15 mm 0 mm Offset

FULL WEDGE AUGMENTATION RESECTION

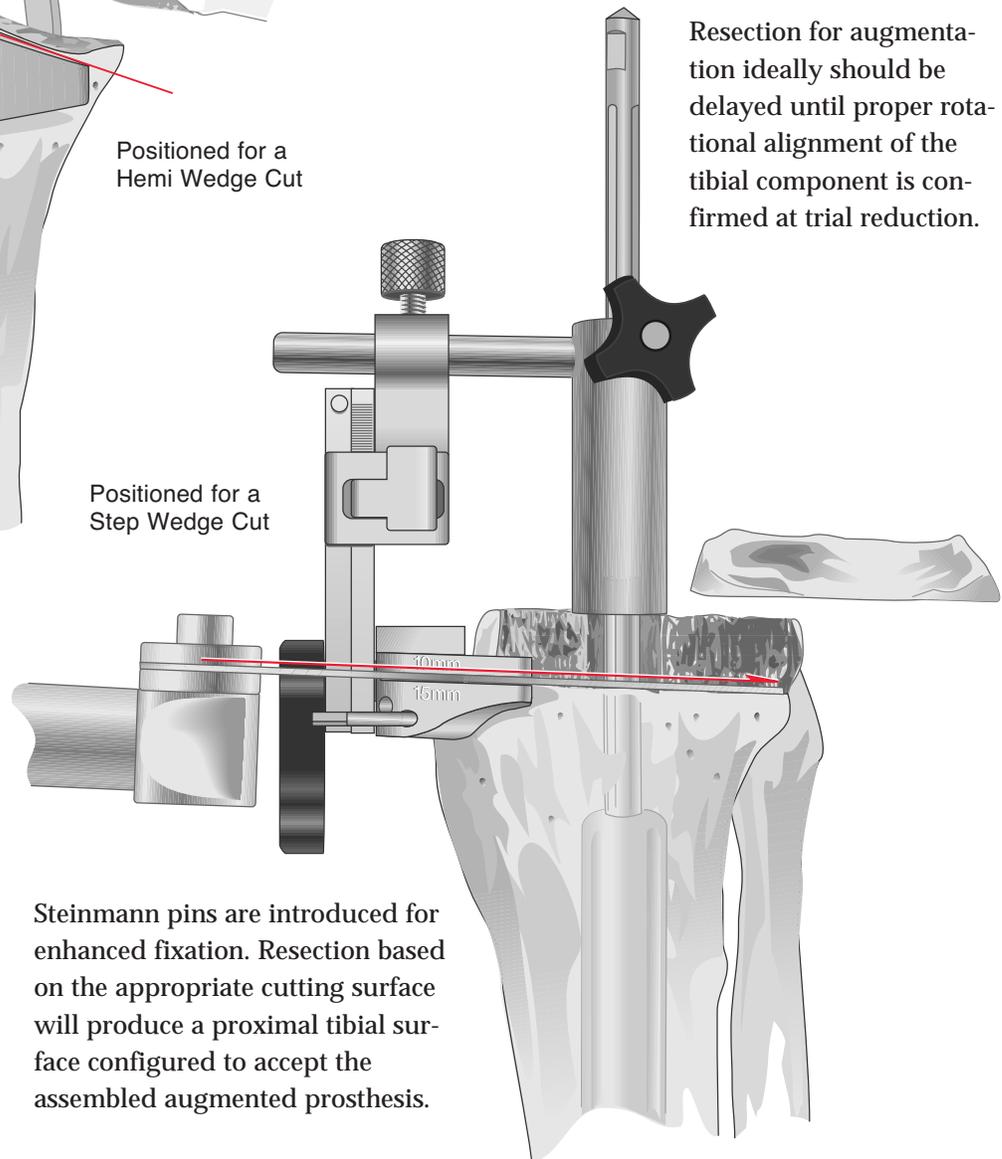
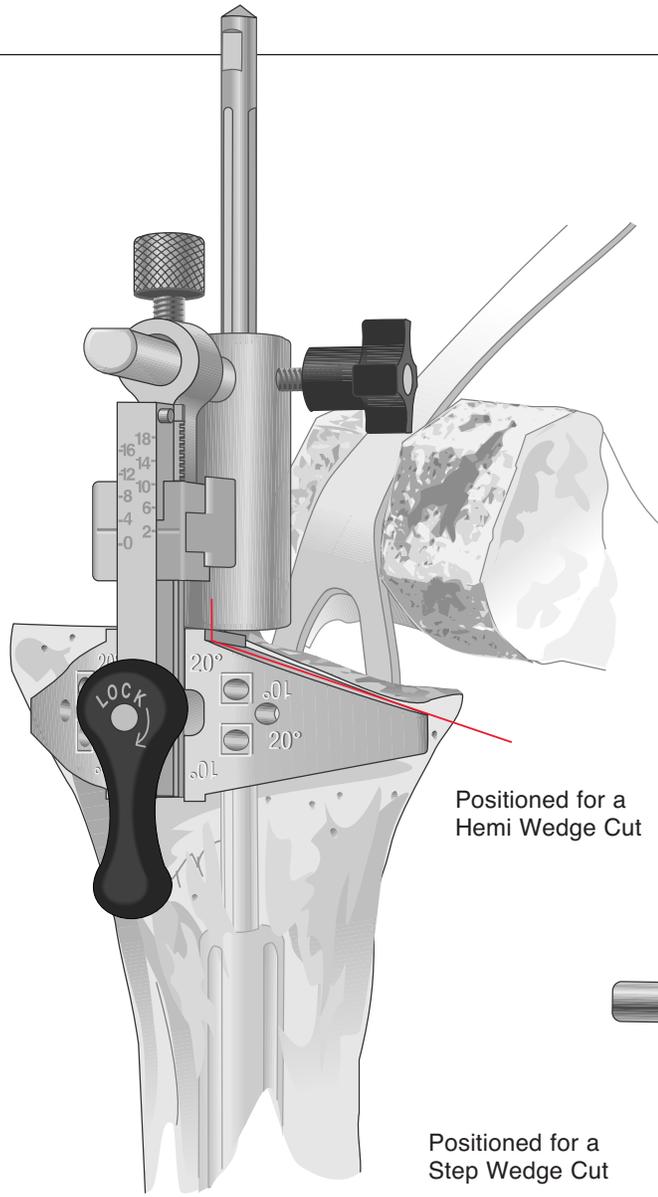
Where a full-surface wedge is indicated, preliminary tibial resection is not required. The appropriate full-wedge cutting guide is assembled to the outrigger of the alignment assembly and adjusted to the level which will yield a viable implantation surface with the sacrifice of minimal bone. Rotational alignment is confirmed. The cutting guide is advanced to the anterior cortex and affixed with Steinmann pins.

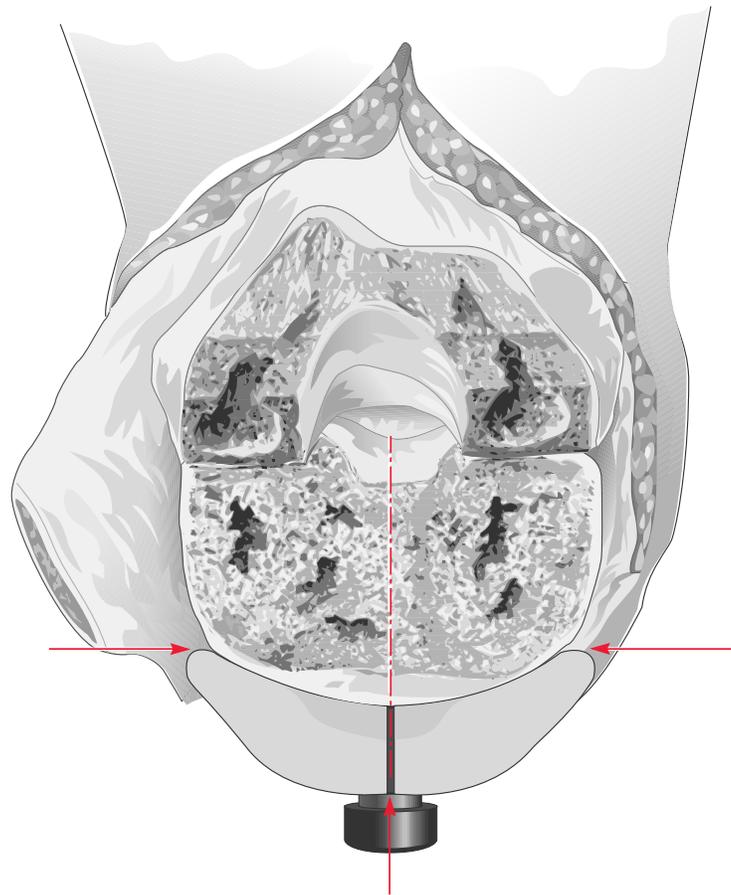
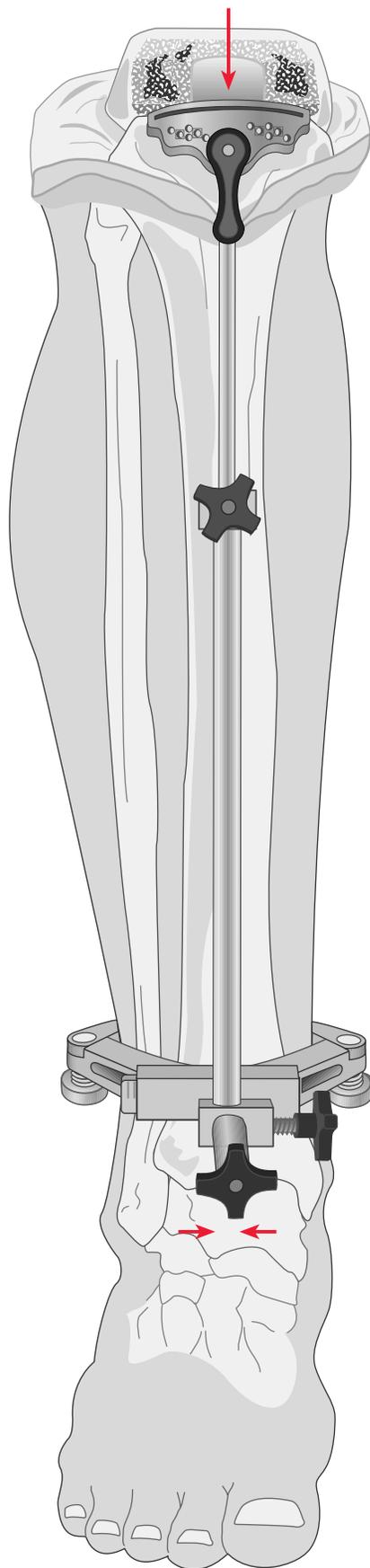
The alignment assembly, rod and sleeve are carefully disengaged from the medullary canal. Resection is performed with care taken that the blade of the oscillating saw be maintained flush to the cutting surface.



STEP AND HEMI WEDGE AUGMENTATION RESECTION

The IM system was designed to control wedge or step cuts directly from the tibial alignment device. The Steinmann pins are withdrawn and the cutting block removed. The alignment device remains locked in position on the IM rod. The wedge/step cutting block is assembled to the outrigger with the appropriate cutting surface (10° or 20° for the hemi, 10 or 15 mm for the step) positioned at the more deficient condyle at the same outrigger level employed for the proximal tibial resection.



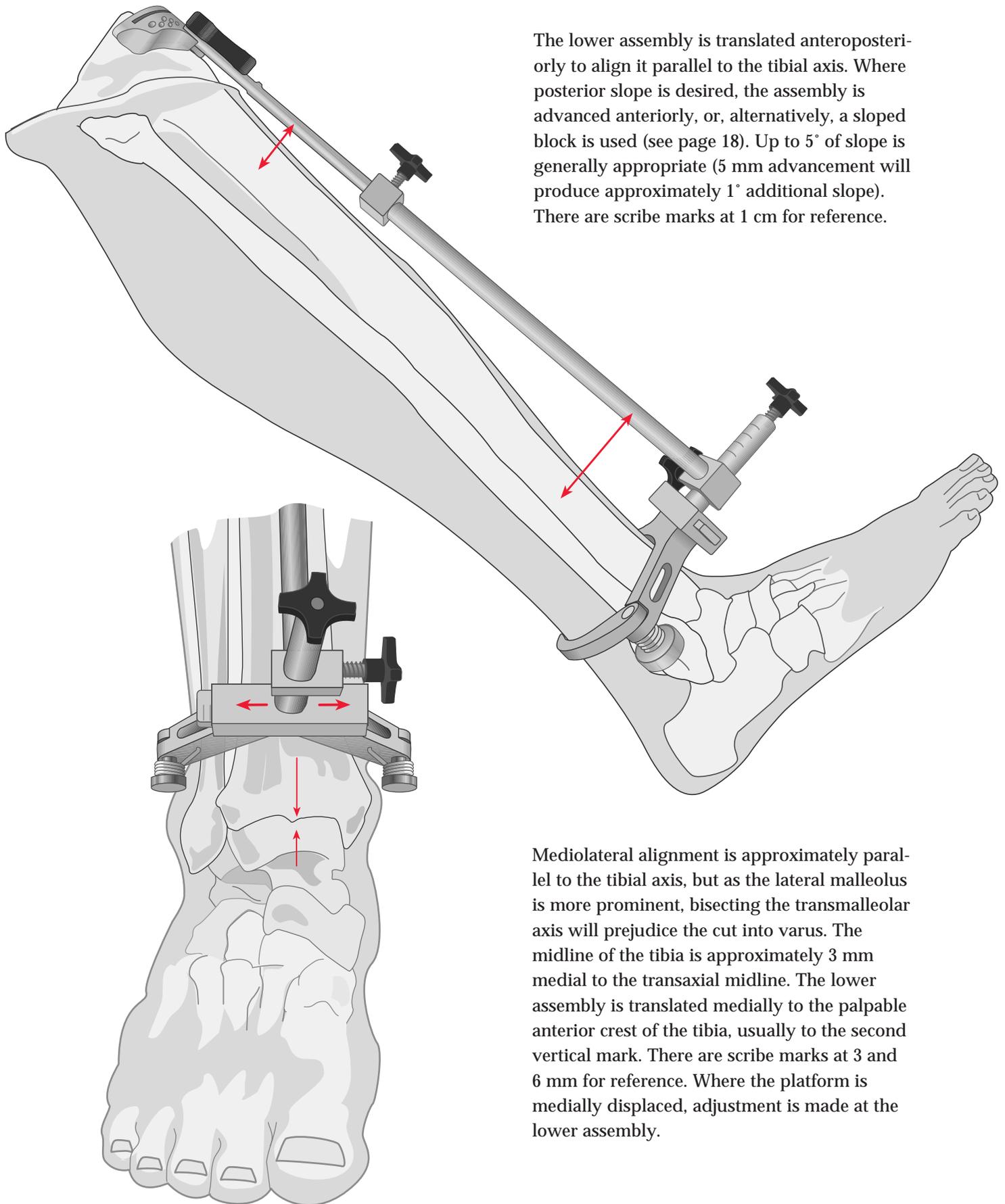


Where it is determined at intraoperative evaluation that the condition of the proximal tibia is such that a fluted stem extension is indicated, mediolateral positioning and the requisite 3° posterior slope are more accurately established with the intramedullary alignment system. Where such is not the case, the external tibial alignment guide may be used for proximal tibial resection.

The external tibial alignment device is positioned with the malleolar clamp immediately proximal to the malleoli.

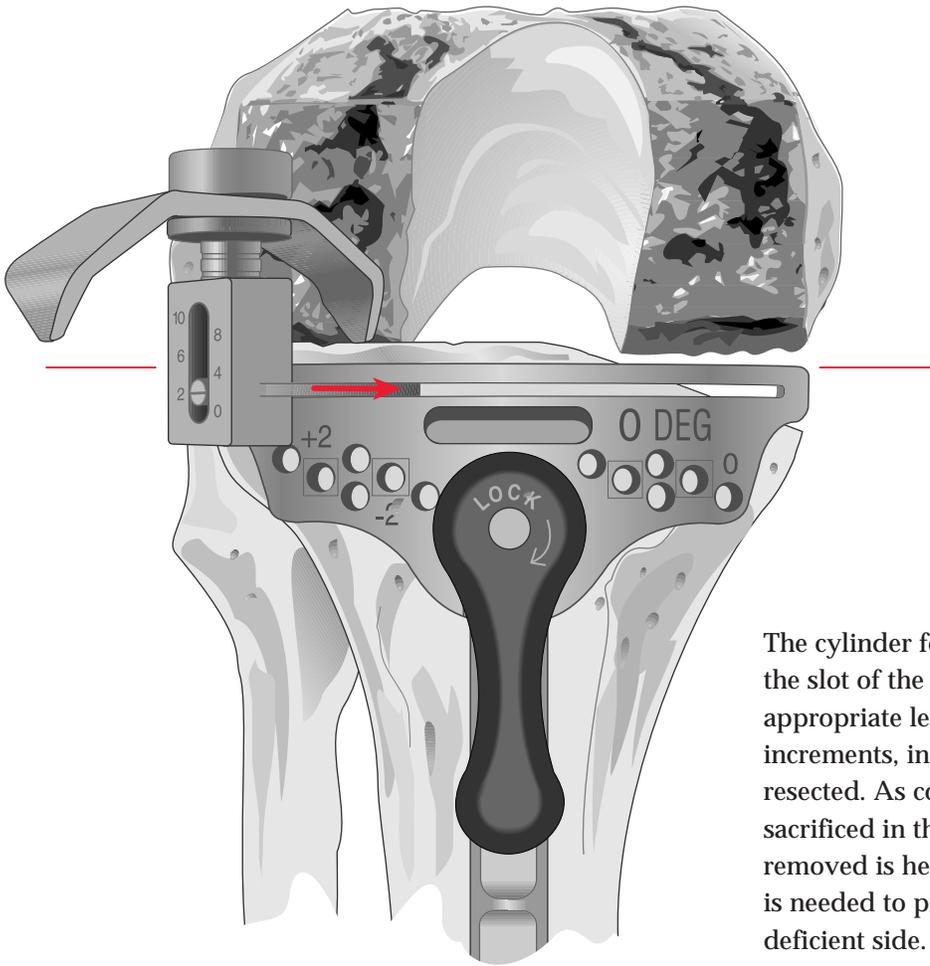
The upper rod is aligned with the medial third of the tibial tubercle, the cutting guide positioned at the anterior cortex.

LOWER ALIGNMENT



The lower assembly is translated anteroposteriorly to align it parallel to the tibial axis. Where posterior slope is desired, the assembly is advanced anteriorly, or, alternatively, a sloped block is used (see page 18). Up to 5° of slope is generally appropriate (5 mm advancement will produce approximately 1° additional slope). There are scribe marks at 1 cm for reference.

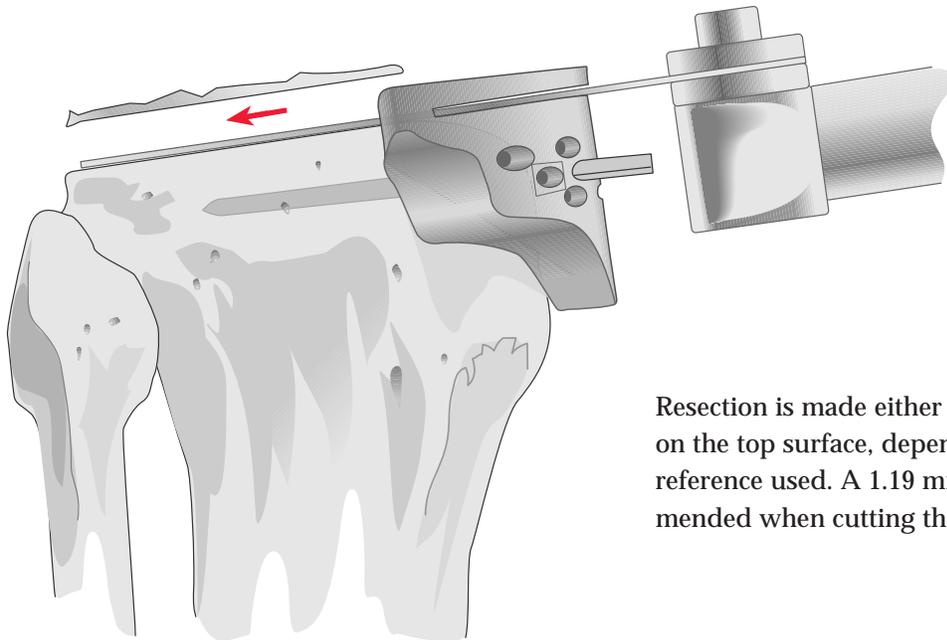
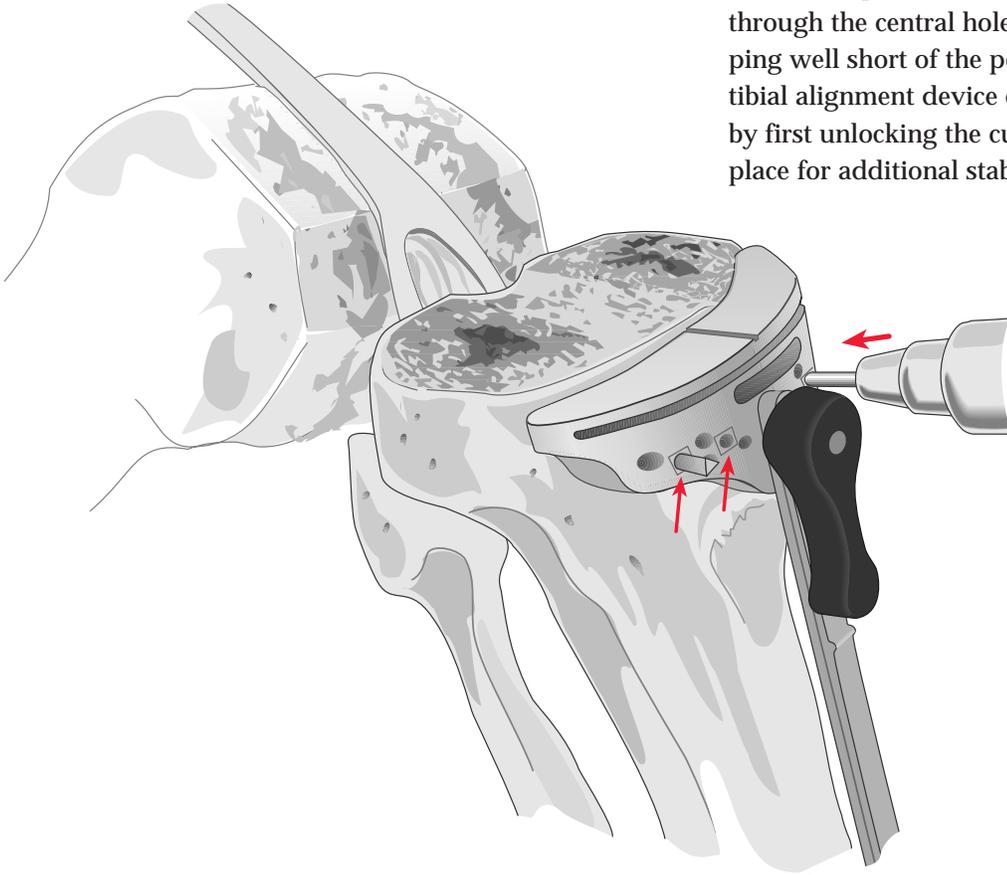
Mediolateral alignment is approximately parallel to the tibial axis, but as the lateral malleolus is more prominent, bisecting the transmalleolar axis will prejudice the cut into varus. The midline of the tibia is approximately 3 mm medial to the transaxial midline. The lower assembly is translated medially to the palpable anterior crest of the tibia, usually to the second vertical mark. There are scribe marks at 3 and 6 mm for reference. Where the platform is medially displaced, adjustment is made at the lower assembly.



The cylinder foot of the stylus is inserted into the slot of the cutting block and adjusted to the appropriate level. It is calibrated in 2 mm increments, indicating the amount of bone to be resected. As considerable bone may have been sacrificed in the primary TKR, the amount removed is held to a minimum: no greater than is needed to provide a level surface on the less deficient side. A setting of 2 mm is recommended. The platform level is adjusted such that the stylus rests upon the lowest point of the less deficient side and is secured by tightening the large anterior knob.

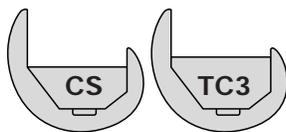
Where the stem is employed following preparation with the external alignment system, it may be necessary to revise the tibial cut to obtain maximal contact at the bone/tray interface, as the posterior inclination of the tray is ultimately governed by the fixed position of the stem.

Steinmann pins or 1/8" drill bits are introduced through the central holes into the tibia, stopping well short of the posterior cortex. The tibial alignment device can either be removed by first unlocking the cutting block, or left in place for additional stability.

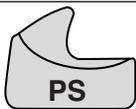


Resection is made either through the slot or on the top surface, depending upon the stylus reference used. A 1.19 mm saw blade is recommended when cutting through the slots.

FEMORAL REVISION AND TIBIAL INSERT COMPATIBILITY



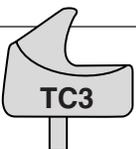
		FEMORAL COMPONENTS						
		SIZE 1.5 53AP/57ML	SIZE 2 56AP/60ML	SIZE 2.5 59AP/63ML	SIZE 3 61AP/66ML	SIZE 4 65AP/71ML	SIZE 5 69AP/73ML	SIZE 6 74AP/78ML
		CS TC3	CS TC3	CS TC3	CS TC3	CS TC3	CS TC3	CS TC3
TIBIAL INSERTS								
SIZE 1.5								
41AP/61ML	PS SP	■ ■	■ ■					
	TC3		■ ■					
SIZE 2								
43AP/64ML	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						■ ■	■ ■



PS POSTERIOR STABILIZED
8, 10, 12.5, 15, 17.5, 20, 22.5, 25 (mm)

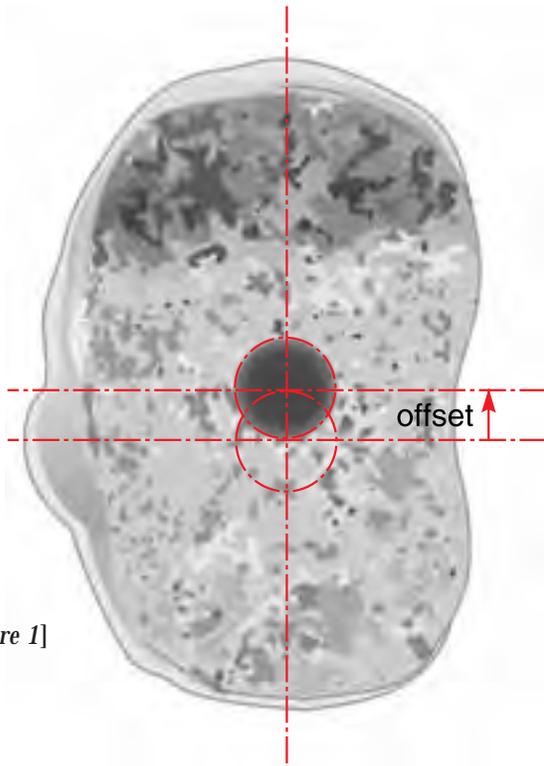


SP STABILIZED PLUS
10, 12.5, 15, 17.5, 20, 22.5, 25, 30 (mm)

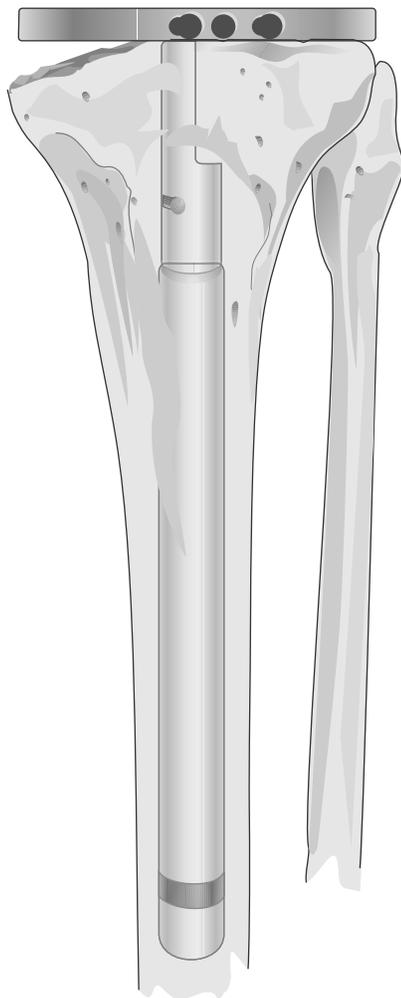


TC3
10, 12.5, 15, 17.5, 20, 22.5, 25, 30 (mm)

OFFSET TIBIAL TRAY PREPARATION FOR FLUTED STEMS



[figure 1]



[figure 2]

The need for an offset tibial tray component is determined either through roentgenographic evaluation or assessed intra-operatively. The P.F.C. Offset Tibial Tray accepts all fluted and cemented stems, as well as mechanically attached wedges.

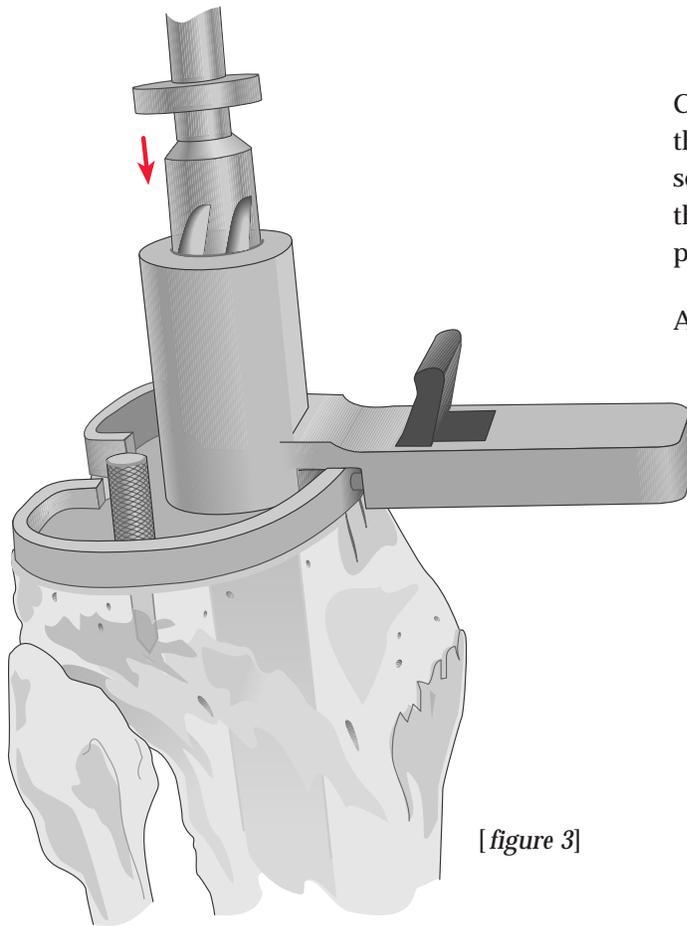
Use a trial offset tibial tray if, upon completion of the preparation of the proximal tibia, the canal location appears to be offset from the center of the proximal tibia. The offset tray is available in sizes 1.5 through 5 with left and right offsets which vary anatomically by size as follows:

Size	Offset
1.5	4 mm
2	4 mm
2.5	4 mm
3	4 mm
4	4.5 mm
5	4.5 mm

[fig. 1]

Assemble the trial stem to the appropriate trial tibial tray and subsequently introduce it into the prepared site. Perform minimal correction with a bone file where indicated to ensure maximal contact. [fig. 2]

Refer to the “Final Preparation of the Tibia” section of the *Revision Surgery for Failed Total Knee Replacement* to review rotational alignment procedure and tibial augment preparation.



[figure 3]

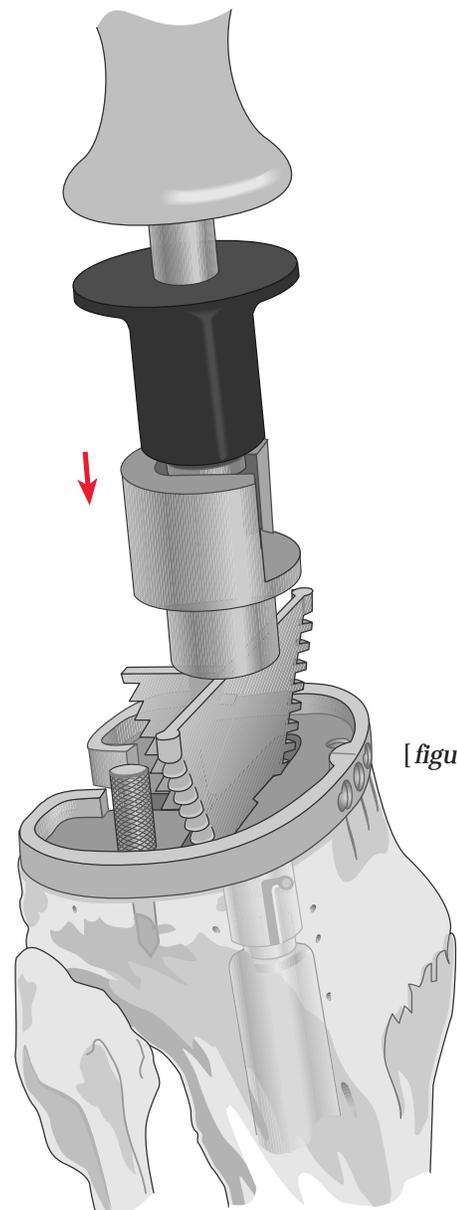
Confirm the position, alignment and security of the tray assembly. If old cement or sclerotic bone is present, relieve this first through the trial tray with a saw blade or burr prior to punching.

Assemble the appropriate tall offset drill bushing onto the trial offset tibial tray and fully advance the matching drill through the drill bushing into the cancellous bone.

[fig. 3]

The Specialist 2 tibial keel punch is appropriately positioned at the trial offset tray and cancellous bone interface. Impact through the keel configuration and carefully extract the punch.

[fig. 4]



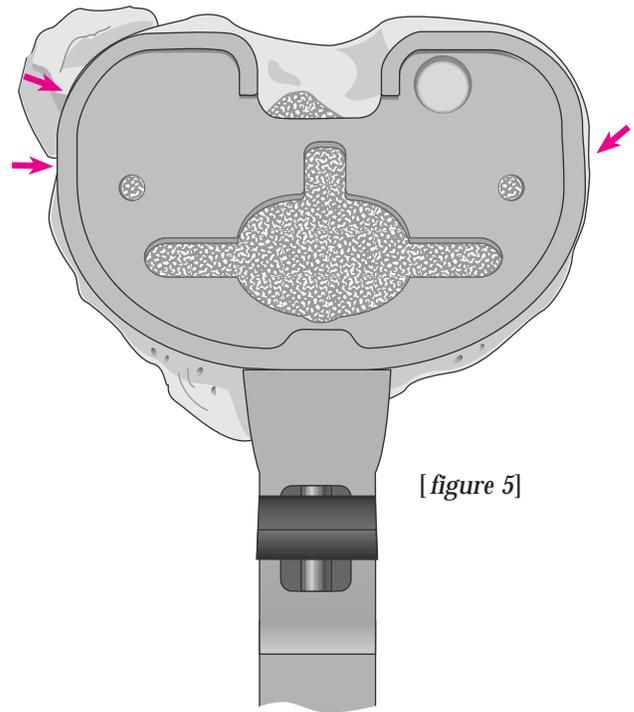
[figure 4]

OFFSET TIBIAL TRAY PREPARATION IN PRIMARY TKA OR WHEN USING A CEMENTED STEM

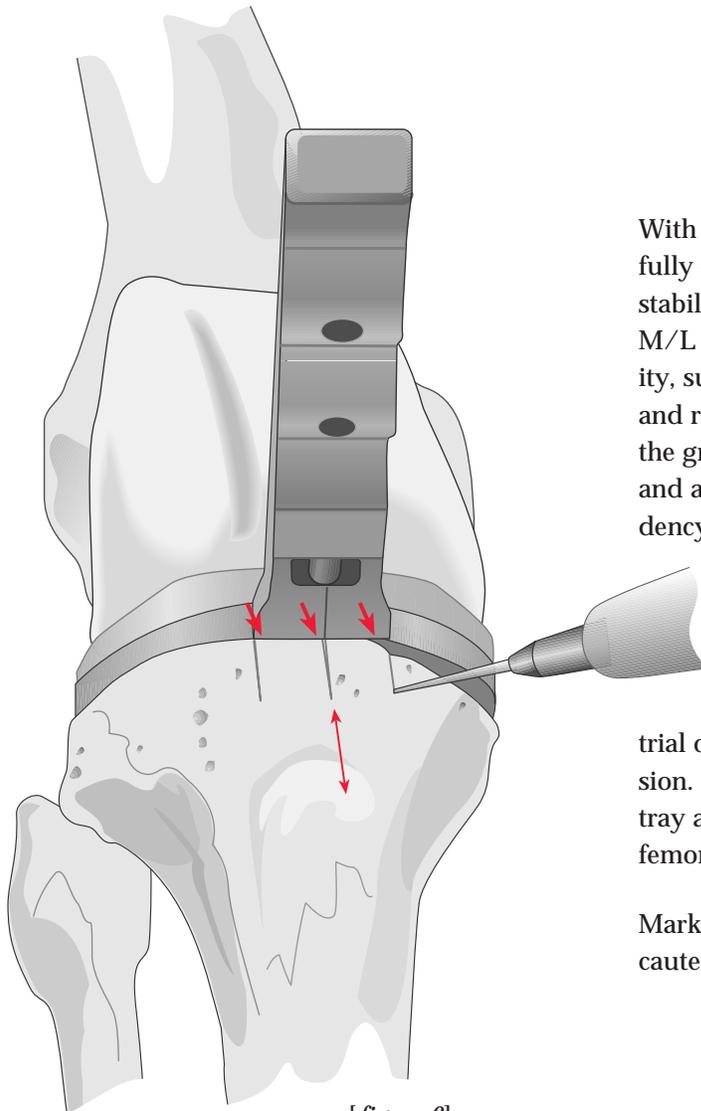
With the knee in maximal flexion, sublux the tibia anteriorly with the tibial retractor. Select the trial offset tibial tray that provides the greatest coverage of the prepared surface without overhang anterior to the midcoronal plane.

Assemble the trial offset tibial tray to the alignment handle and place it onto the resected tibial surface.

Insert the appropriate color-coded nylon trial into the tray. [fig. 5]



[figure 5]



[figure 6]

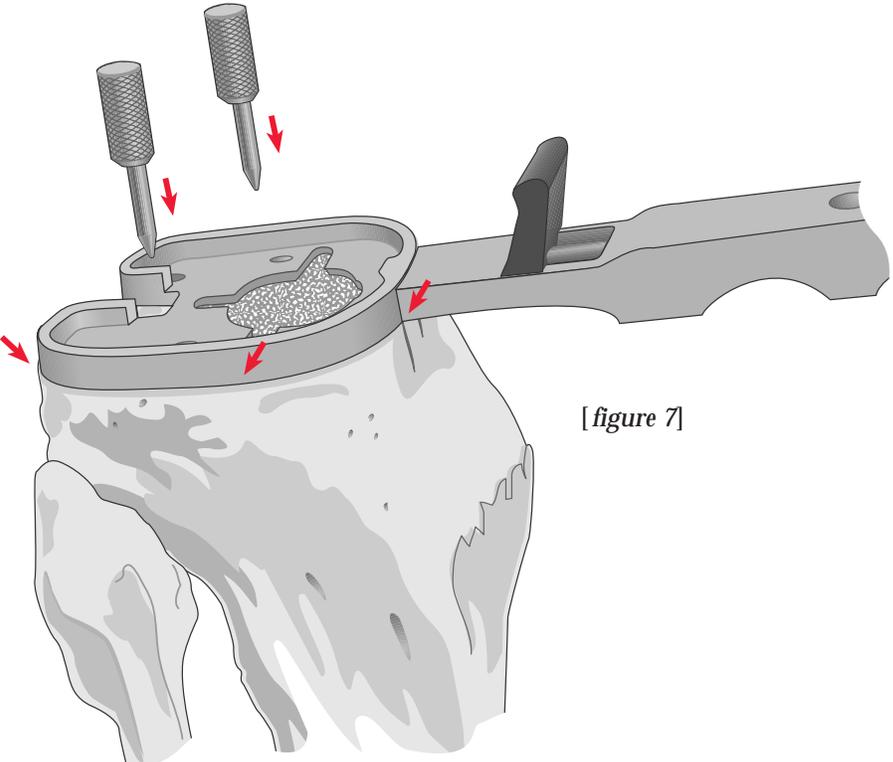
With all trial prostheses in place, carefully and fully extend the knee, noting medial and lateral stability and overall alignment in the A/P and M/L plane. If there is any indication of instability, substitute the next greater size tibial insert and repeat reduction. Select the insert that gives the greatest stability in flexion and extension and allows full extension. Where there is a tendency for lateral subluxation or patellar tilt in the absence of medial patellar influence (thumb pressure), lateral retinacular release is indicated.

Adjust the rotational alignment of the trial offset tibial tray with the knee in full extension. Use the alignment handle to rotate the tray and trial insert into congruency with the femoral trial.

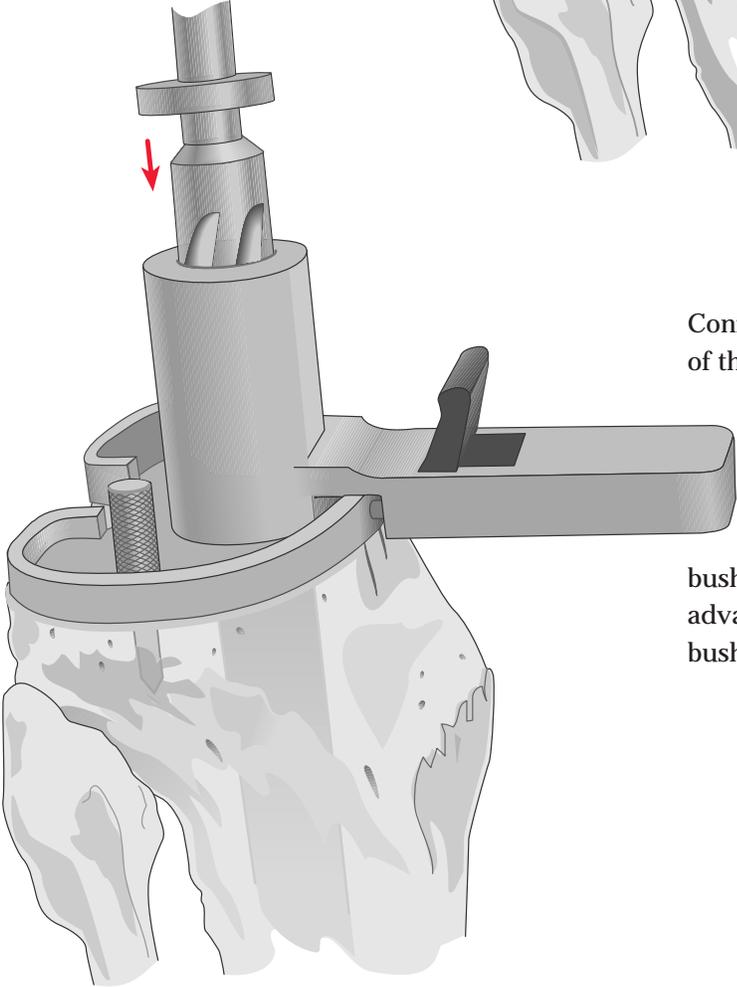
Mark the appropriate position with electrocautery on the anterior tibial cortex. [fig. 6]

With the knee in full flexion and the tibia subluxed anteriorly, establish proper rotational alignment with the electrocautery marks.

Secure the tray with two short fixation pins inserted through the holes designated □. [fig. 7]



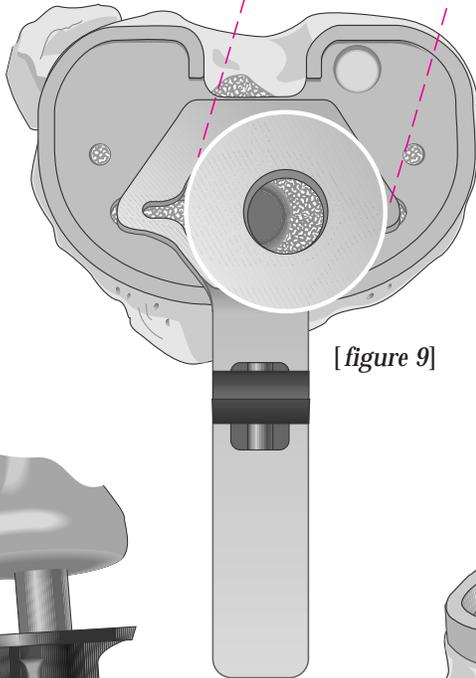
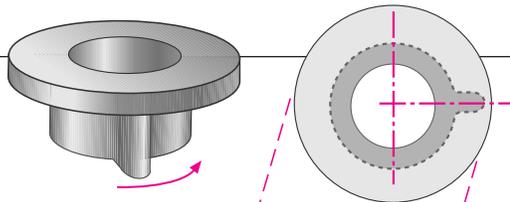
[figure 7]



Confirm the position, alignment and security of the tray assembly. If old cement or sclerotic bone is present, relieve this first through the trial tray with a saw blade or burr prior to punching.

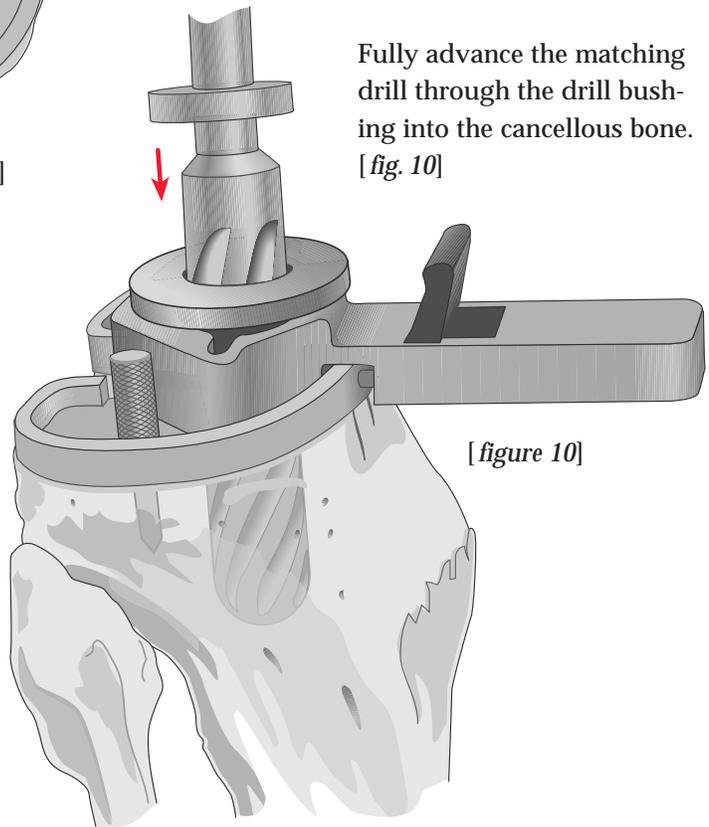
Assemble the appropriate tall offset drill bushing onto the trial offset tibial tray and fully advance the matching drill through the drill bushing into the cancellous bone. [fig. 8]

[figure 8]



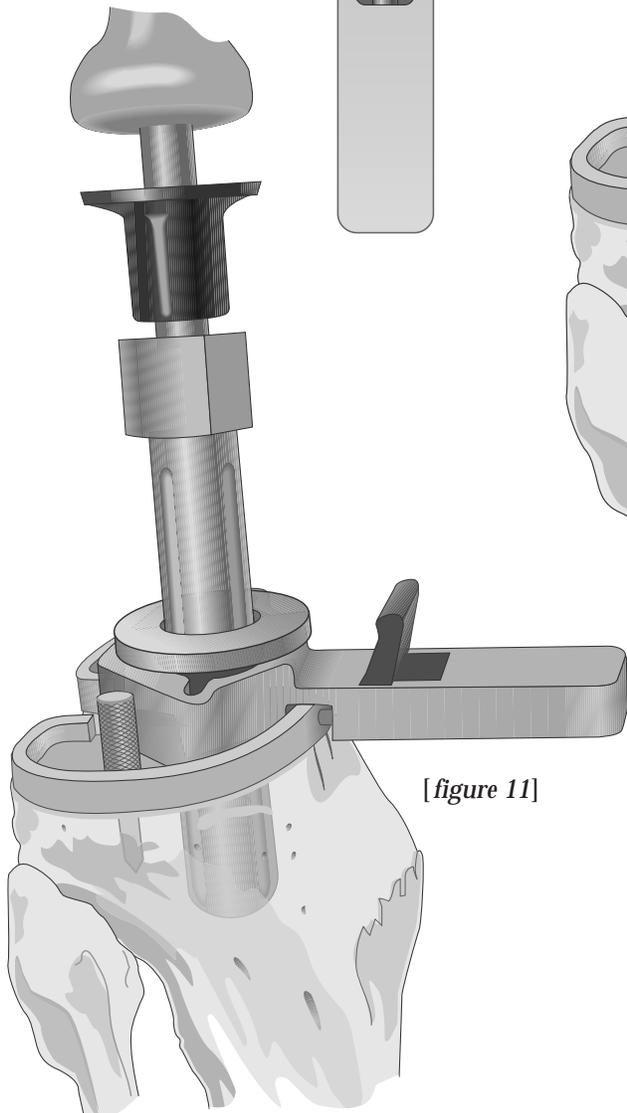
[figure 9]

Seat the appropriately sized drill bushing into the offset tray punch guide. Position the tab on the bushing toward the desired medial or lateral offset. [fig. 9]



[figure 10]

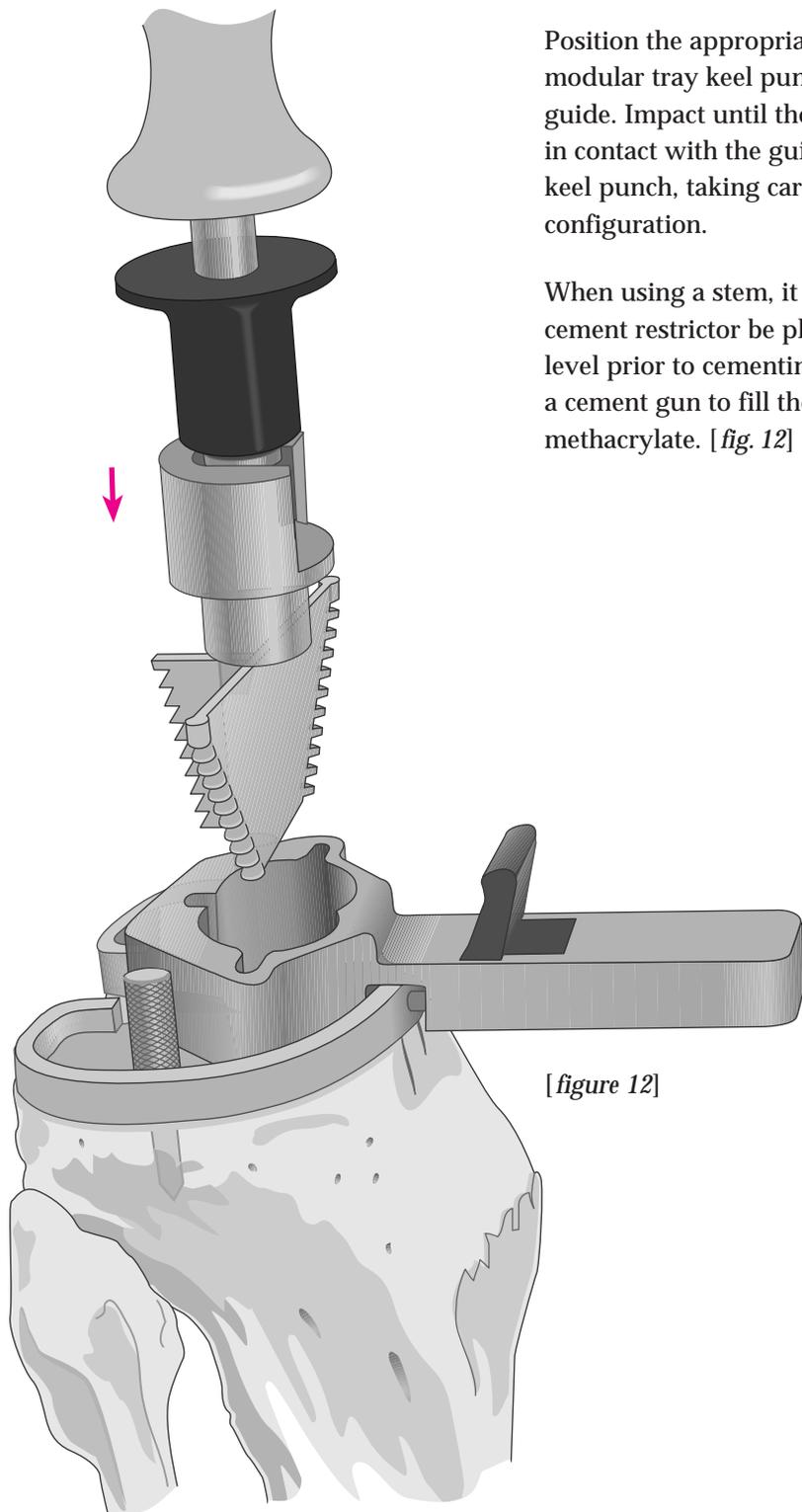
Fully advance the matching drill through the drill bushing into the cancellous bone. [fig. 10]



[figure 11]

Attach the appropriate 30 mm or 60 mm cemented stem punch, available in 13 mm or 15 mm diameters, to the universal handle and introduce it into the drill bushing. Gently impact until the shoulder of the punch is in contact with the guide. [fig. 11]

Note: Skip this step if a stem is not to be used.



Position the appropriately sized Specialist 2 modular tray keel punch through the offset guide. Impact until the shoulder of the punch is in contact with the guide. Free the modular tray keel punch, taking care to preserve the punch configuration.

When using a stem, it is recommended 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. [fig. 12]

[figure 12]

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.jnjgateway.com.



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