MIS Intramedullary Instrumentation

For NexGen[®] Cruciate Retaining & NexGen Legacy[®] Posterior Stabilized Knees

Surgical Technique





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Introduction

Successful total knee arthroplasty depends in part on re-establishment of normal lower extremity alignment, proper implant design and orientation, secure implant fixation, and adequate soft tissue balancing and stability. The NexGen Complete Knee Solution and Zimmer Biomet Intramedullary Knee Instrument System are designed to help the surgeon accomplish these goals by combining optimal alignment accuracy with a simple, straight-forward technique.

The instruments and technique assist the surgeon in restoring the center of the hip, knee, and ankle to lie on a straight line, establishing a neutral mechanical axis. The femoral and tibial components are oriented perpendicular to this axis. The instruments promote accurate cuts to help ensure secure component fixation. Ample component sizes allow soft tissue balancing with appropriate soft tissue release.

In addition, implant flexibility offers the opportunity to switch from a cruciate retaining prosthesis to a posterior stabilized prosthesis quickly and easily. The mini-incision TKA technique has been developed to combine the alignment goals of total knee arthroplasty with less disruption of soft tissue. To accommodate this technique, some of the original Intramedullary Instruments have been modified. However, if preferred, a standard incision can be used with the instruments. Prior to using a smaller incision, the surgeon should be familiar with implanting NexGen Components through a standard incision.

Total knee arthroplasty using a less invasive technique is suggested fornonobese patients with preoperativeflexion greater than 90°. Patients with varus deformities greater than 17° or valgus deformities greater than 13° are typically not candidates for the MIS technique.

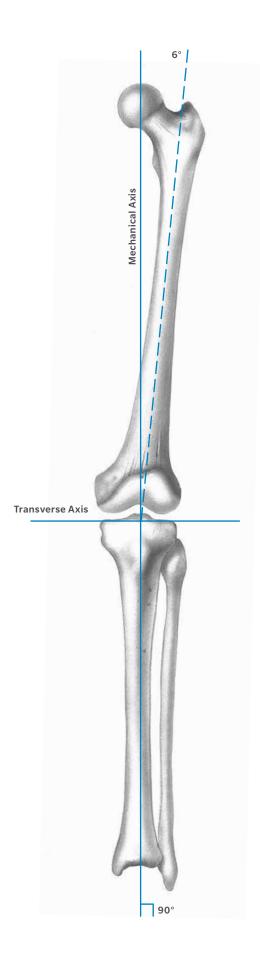
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Preoperative Planning

Use the template overlay (available through your Zimmer Biomet representative) to determine the angle between the anatomic axis and the mechanical axis. This angle will be reproduced intraoperatively. This surgical technique helps the surgeon ensure that the distal femur will be cut perpendicular to the mechanical axis and, after soft tissue balancing, will be parallel to the resected surface of the proximal tibia.

Surgical Approach

The femur, tibia, and patella are prepared independently, and can be cut in any sequence using the principle of measured resection (removing enough bone to allow replacement by the prosthesis). Adjustment cuts may be needed later.



Patient Preparation

To prepare the limb for MIS total knee arthroplasty, adequate muscle relaxation is required. This may be accomplished with a short-acting, nondepolarizing muscle relaxant. The anesthesiologist should adjust the medication based on the patient's habitus and weight, and administer to induce adequate muscle paralysis for a minimum of 30-40 minutes. It is imperative that the muscle relaxant be injected prior to inflation of the tourniquet. Alternatively, spinal or epidural anesthesia should produce adequate muscle relaxation.

If desired, apply a proximal thigh tourniquet and inflate it with the knee in hyperflexion to maximize that portion of the quadriceps that is below the level of the tourniquet.

Once the patient is draped and prepped on the operating table, determine the landmarks for the surgical incision with the leg in extension.

Incision and Exposure

The incision may be made with the leg in extension or flexion depending on surgeon preference. The surgeon can choose a midvastus approach, a subvastus approach, or a medial parapatellar arthrotomy. Also, depending on surgeon preference, the patella can be either everted or subluxed.

The length of the incision is dependent on the size of the femoral component needed. Although the goal of a MIS technique is to complete the surgery with an approximately 10 cm-14 cm incision, it may be necessary to extend the incision if visualization is inadequate or if eversion of the patella is not possible without risk of avulsion at the tibial tubercle. If the incision must be extended, it is advisable to extend it gradually and only to the degree necessary. The advantage of a MIS technique is dependent on maintaining the extensor mechanism insertion.

Make a slightly oblique parapatellar skin incision, beginning approximately 2 cm proximal and medial to the superior pole of the patella, and extend it



Figure 1

approximately 10 cm to the level of the superior patellar tendon insertion at the center of the tibial tubercle (Figure 1). Be careful to avoid disruption of the tendon insertion. This will facilitate access to the vastus medialis obliquis, and allow a minimal split of the muscle. It will also improve visualization of the lateral aspect of the joint obliquely with the patella everted. The length of the incision should be about 50% above and 50% below the joint line. If the length of the incision is not distributed evenly relative to the joint line, it is preferable that the greater portion be distal.

Divide the subcutaneous tissue to the level of the retinaculum.

Note: Using electrocautery to complete the exposure will help minimize bleeding after deflation of the tourniquet, as well as late muscle bleeding.

MIS Midvastus Approach

Make a medial parapatellar incision into the capsule, preserving approximately 1 cm of peritenon and capsule medial to the patellar tendon. This is important to facilitate complete capsular closure.

Split the superficial enveloping fascia of the quadriceps muscle percutaneously in a proximal direction over a length of approximately 6 cm. This will mobilize the quadriceps and allow for significantly greater lateral translation of the muscle while minimizing tension on the patellar tendon insertion.

Split the vastus medialis obliquis approximately 1.5 cm-2 cm (Figure 2).

Use blunt dissection to undermine the skin incision approximately 1 cm-2 cm around the patella.

Slightly flex the knee and remove the deep third of the fat pad.

The patella can be either everted or subluxed. If everting the patella, release the lateral patellofemoral ligament to facilitate full eversion and lateral translation of the patella. Then use hand-held threepronged or two-pronged hooks to begin to gently evert the patella. Be careful to avoid disrupting the extensor insertion. To help evert the patella, slowly flex the joint and externally rotate the tibia while applying gentle pressure. Once the patella is everted, use a standard-size hohmann retractor or two small hohmann retractors along the lateral flare of the tibial metaphysis to maintain the eversion of the patella and the extensor mechanism.

Note: It is imperative to maintain close observation of the patellar tendon throughout the procedure to ensure that tension on the tendon is minimized, especially during eversion of the patella and positioning of the patient.



Figure 2

Remove any large patellar osteophytes.

Release the anterior cruciate ligament, if present. Perform a subperiosteal dissection along the proximal medial and lateral tibia to the level of the tibial tendon insertion. Then perform a limited release of the lateral capsule (less than 5 mm) to help minimize tension on the extensor mechanism.

MIS Subvastus Approach

The subvastus medial arthrotomy has been slightly modified to optimize minimally invasive surgery. It provides excellent exposure for TKA while preserving all four attachments of the quadriceps to the patella. This approach does not require patellar eversion, minimizes disruption of the suprapatellar pouch, and facilitates rapid and reliable closure of the knee joint.

Dissect the subcutaneous tissue down to but not through the fascia that overlies the vastus medialis muscle.

Identify the inferior border of the vastus medialis muscle, and incise the fascia at approximately 5 cm to 8 cm medial to the patellar border (Figure 3) to allow a finger to slide under the muscle belly but on top of the underlying synovial lining of the knee joint. Use the finger to pull the vastus medialis obliquis muscle superiorly and maintain slight tension on the muscle.

Use electrocautery to free the vastus medialis from its confluence with the medial retinaculum, leaving a small cuff of myofascial tissue attached to the inferior border of the vastus medialis.

The tendonous portion of the vastus medialis extends distally to insert at the midpole of the medial border of the patella. Be careful to preserve that portion of the tendon to protect the vastus medialis muscle during subsequent steps. An incision along the inferior border of the vastus medialis to the superior pole of the patella will result in a tear, split, or maceration of the muscle by retractors. Incise the underlying synovium in a slightly more proximal position than is typical with a standard subvastus approach. This will allow a two-layer closure of the joint. The deep layer will be the synovium, while the superficial layer will be the medial retinaculum and the myofascial sleeve of tissue that has been left attached to the inferior border of the vastus medialis.

Carry the synovial incision to the medial border of the patella. Then turn directly inferiorly to follow the medial border of the patellar tendon to the proximal portion of the tibia. Elevate the medial soft tissue sleeve along the proximal tibia in a standard fashion.



Figure 3

Place a bent hohmann retractor in the lateral gutter and lever it against the robust edge of the tendon that has been preserved just medial and superior to the patella. Retract the patella and extensor mechanism into the lateral gutter. If necessary, mobilize the vastus medialis either from its underlying attachment to the synovium and adductor canal, or at its superior surface when there are firm attachments of the overlying fascia to the subcutaneous tissues and skin. Depending on surgeon preference, the fat pad can be excised or preserved.

Flex the knee. The patella will stay retracted in the lateral gutter behind the bent-Hohmann retractor, and the quadriceps tendon and vastus medialis will lie over the distal anterior portion of the femur. To improve visualization of the distal anterior portion of the femur, place a thin knee retractor along the anterior femur and gently lift the extensor mechanism during critical steps of the procedure. Alternatively, bring the knee into varying degrees of extension to improve visualization by decreasing the tension on the extensor mechanism.

MIS Medial Parapatellar Arthrotomy

Minimally invasive total knee arthroplasty can be performed with a limited medial parapatellar arthrotomy. Begin by making a 10 cm-14 cm midline skin incision from the superior aspect of the tibial tubercle to the superior border of the patella. Following subcutaneous dissection, develop medial and lateral flaps, and dissect proximally and distally to expose the extensor mechanism. This permits mobilization of the skin and subcutaneous tissue as needed during the procedure. In addition, with the knee in flexion, the incision will stretch 2 cm-4 cm due to the elasticity of the skin, allowing broader exposure.

The goal of minimally invasive surgery is to limit the surgical dissection without compromising the procedure. The medial parapatellar arthrotomy is used to expose the joint, but the proximal division of the quadriceps tendon should be limited to a length that permits only lateral subluxation of the patella without eversion (Figure 4). Incise the quadriceps tendon for a length of 2 cm-4 cm initially. If there is difficulty displacing the patella laterally or if the patellar tendon is at risk of tearing, extend the arthrotomy proximally along the quadriceps tendon until adequate exposure is achieved.



Figure 4

Surgical Technique



Figure 1a

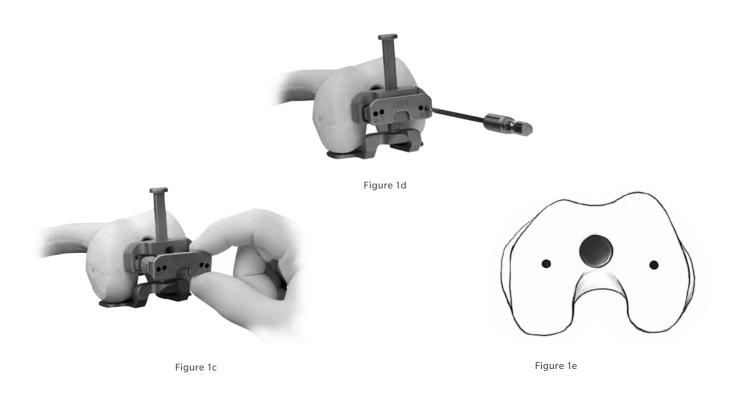


Figure 1b

Step One: Establish External Rotation

Use the 8 mm IM drill w/step to drill a hole slightly medial to the center of the intercondylar notch of the distal femur (Figure 1a), making sure that the drill is parallel to the shaft of the femur in both the anteroposterior and lateral projections. The hole should be approximately one-half to one centimeter anterior to the origin of the posterior cruciate ligament. Medial or lateral displacement of the hole may be needed according to preoperative templating of the A/P radiograph.

The step on the drill will enlarge the entrance hole on the femur to 12 mm. This will reduce intramedullary pressure during placement of subsequent IM guides. Suction the canal to remove medullary contents. Assemble the MIS threaded handle and the external rotation alignment guide (Figure 1b) insert the external rotation alignment guide into the medullary canal until it contacts the distal femur. The body of the External rotation alignment guide should rest against of the most prominent distal condyle and both feet against the cartilage of the posterior condyles.



Step One: Establish External Rotation (cont.)

The external rotation alignment guide can be used to aid in setting 0° , 3° , 5° . or 7° of external rotation of the femoral component in relation to the non-deformed posterior condyles.

There are four external rotation plates: $0^{\circ}/3^{\circ}$ left, $0^{\circ}/3^{\circ}$ right, $5^{\circ}/7^{\circ}$ left, and $5^{\circ}/7^{\circ}$ right. Choose the external rotation plate that provides the desired external rotation for the appropriate knee. The 0° option can be used when positioning will be determined by the A/P axis or the epicondylar axis. Use the 3° option for varus knees. Use the 5° option for knees with a valgus deformity from 10° to 13° . The 7° option requires a standard exposure, and is for knees with patellofemoral disease accompanied by bone loss and valgus deformity greater than 20° .

Attach the selected plate to the external rotation alignment guide (Figure 1c). Use a 3.2 mm drill to drill through the holes in the guide that correspond to the desired external rotation (Figure 1d). This will place two reference holes in the femur for the selected external rotation (Figure 1e). Remove the external rotation plate and attach the MIS threaded handle to remove the external rotation alignment guide. These holes will be used in conjunction with the mini IM alignment guide to set external rotation.

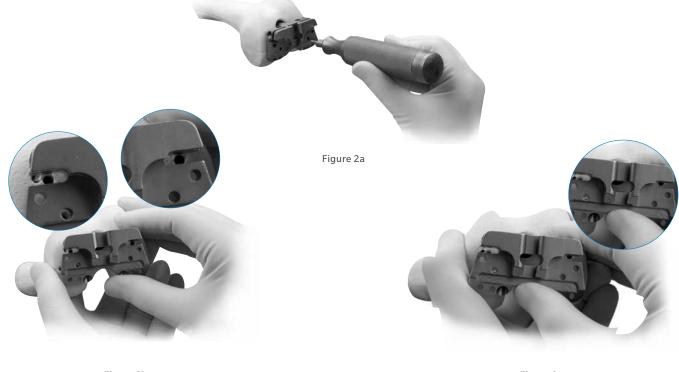


Figure 2b Correct Alignment Figure 2c Wrong Alignment

Step Two: Establish Femoral Alignment

The mini IM alignment guide is available with two intramedullary rod lengths. The rod on the standard instrument is 229 mm (9 inch) long and the rod on the short instrument is 165 mm (6.5 inch) long. Choose the length best suited to the length of the patient's leg which will help provide the most accurate reproduction of the anatomic axis. If the femoral anatomy has been altered, as in a femur with a long-stem hip prosthesis or with a femoral fracture malunion, use the short mini IM alignment guide and use the optional extramedullary alignment technique.

● Note: It is preferable to use the longest intramedullary rod to help ensure the most accurate replication of the anatomic axis. Using the universal handle, insert the mini IM alignment guide into the femur (Figure 2a). The rod is fluted and D-shaped to allow pressure to be released during the insertion. It is important to control rotation of the guide as it approaches the bearing of the medial femoral condyle.

To achieve the desired external rotation of the femoral component, use the alignment holes made in Step One. Line the holes up with the alignment slots on the IM guide (Figures 2b and 2c). If needed to guide insertion, place 3.2 mm (1/8-inch) pins through the alignment slot on the IM guide and into the alignment holes.



Figure 2d

Optional Technique

The external rotation can also be set by referencing the epicondyles. Attach the modular handles to the mini IM alignment guide. Position the handles of the guide referencing the epicondyles or by using the posterior condyles and referencing the posterior aspect of the IM guide (Figure 2d). Once the proper external rotation is achieved, use the universal handle to help align and impact the IM guide until it seats on the most prominent condyle. Ensure that the guide is contacting at least one distal condyle. This will set the proper distal femoral resection.

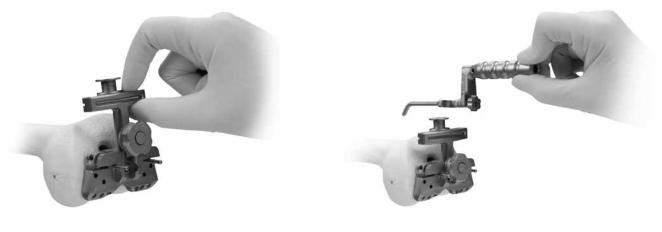


Figure 3a

Figure 3b

Step Three: Cut the Anterior Femoral Condyles

Slightly extend the knee and retract soft tissues to expose the anterior femoral cortex. Clear any soft tissue from the anterior cortex. Ensure that the leg is in less than 90° of flexion (70°-80°). This will decrease the tension of the patellar tendon to facilitate placement of the guide.

Slide the anterior femoral cutting guide onto the mini IM alignment guide (Figure 3a). Slide the mini offset boom under the soft tissue. Ensure that the skin does not put pressure on the boom and potentially change its position. Attach the mini offset boom to the yolk on the anterior femoral cutting guide (Figure 3b). The boom should contact the anterior cortex of the distal femur just proximal to the anterior condyles. With the boom touching this point, the cut will remove the anterior condyles flush with the anterior cortex of the femur. This should reduce the possibility of notching the anterior surface of the femoral cortex. Although this cut will be slightly modified with the femoral finishing guide, it must be accurate for placement of subsequent cutting guides and for measurement.

Note: Excessive skin pressure on the top of the tip of the mini offset boom could compromise the position of the anterior cut.



Figure 3c

Figure 3d

Step Three: Cut the Anterior Femoral Condyles (cont.)

When the mini offset boom is appropriately positioned, lock it by securing the knob (Figure 3c) with a hexhead screwdriver.

Securely tighten the knob on the anterior femoral cutting guide (Figure 3d).

Knees vary somewhat in size and configuration. Use the resection guide to check the location of the bone to be resected. If, on inspection of the instrument positioning, it is felt that excessive resection or notching might occur, the position of the anterior femoral cutting guide can be modified slightly. Loosen the knob and raise the guide so that the tip of the boom is clear of the femoral cortex by 1 mm-2 mm. Then retighten and reset as described above.



Figure 3e

Step Three: Cut the Anterior Femoral Condyles (cont.)

Knees vary somewhat in size and configuration. Use the resection guide to check the location of the bone to be resected. If, on inspection of the instrument positioning, it is felt that excessive resection or notching might occur, the position of the anterior femoral cutting guide can be modified slightly. Loosen the knob and raise the guide so that the tip of the boom is clear of the femoral cortex by 1 mm-2 mm. Then retighten and reset as described above. Use a 1.27 mm (0.050-in.) oscillating saw blade to cut the anterior femoral cortex (Figure 3e). Keeping the mini offset boom in place helps ensure that the cutting guide does not move while making the cut.

Unlock and rotate the mini offset boom medially until it clears the medial condyle. Then remove the boom. Remove the anterior femoral cutting guide, but leave the mini IM alignment guide in the femur.



Figure 4a



Figure 4b

Step Four: Cut the Distal Femur

Attach the distal femoral cutting guide to the IM alignment guide. Place the "right" or "left" label up, depending on which knee joint is being replaced. Drop the pivot pin into the pivot hole in the IM alignment guide (Figure 4a). Observe the numbers on the anterior surface of the guide and select the appropriate angle as determined by preoperative radiographs.

Insert a pin through the appropriate angle-setting hole in the cutting guide until it drops into the slot in the IM alignment guide (Figure 4b). This locks the angle and prevents movement of the guide.

Place holding pins through two or three of the pin holes in the anterior surface of the distal femoral cutting guide to secure it further to the femur. Silver spring pins may also be used to secure the guide. The IM alignment guide can either by removed or left in place. The advantage of removal is that one does not have to cut around the rod. If fixation is tenuous, the advantage of leaving the device in place is that additional stability will be provided by the rod and distal pins.

Remove the IM alignment guide with the slaphammer extractor.

Note: For an optional extramedullary alignment technique, see page 19.



Figure 4c

Step Four: Cut the Distal Femur (cont.)

Cut the distal femur through the distal slot labeled "standard cut" in the cutting guide (Figure 4c). This slot removes the same amount of bone that will be replaced by the femoral component. (The correct thickness of bone resection is determined in the previous step by having the IM alignment guide flush against the medial femoral condyle.) Cut both the medial and lateral condyles before removing the guide. A cut made through the slot labeled "3.5 mm Cut" will remove an additional 3.5 mm of bone. This slot can be used if a flexion contracture of at least fifteen degrees exists or if the surgeon needs to resect additional bone for other reasons.

Check the flatness of the distal femoral cut with a flat surface. If necessary, modify the distal femoral surface so that it is completely flat. This is extremely important for the placement of subsequent guides and for proper fit of the implant.

Removing Additional Bone

In some complex cases, such as a knee with a significant flexion contracture or a hypoplastic lateral femoral condyle associated with a valgus deformity, it may be necessary to cut additional bone from the distal femur. The proximal cutting slot labeled "3.5 mm cut" can be used to make this cut.

If there is any question as to how much bone to remove, the "standard cut" slot should be used initially and the cut repeated later if more bone removal is necessary. This situation might arise if, after provisional components have been inserted for trial reduction, it is found that the ligament tightness in extension is excessive after appropriate soft tissue release. This would be an indication for slightly more distal femoral resection (see page 67 of the appendix for distal femoral recutting techniques).



Figure 4d

Optional Technique

An extramedullary alignment system may be used to orient the distal femoral cut. Insert the extramedullary alignment arch onto the distal femoral cutting guide after it has been secured to the IM alignment guide with the pivot pin. Insert a rod through the apex of the arch and pass it proximally toward the hip (Figure 4d). If the proximal tip of the rod points to the center of the femoral head, the distal femoral cutting guide is properly positioned to cut the distal femur exactly perpendicular to the mechanical axis. Pin the cutting guide to the femur and cut the bone.

This technique can be used to double check the intramedullary method and should be used if the 165 mm IM alignment guide is used because the femoral anatomy has been altered.

If the use of extramedullary alignment is anticipated, it is best to identify the center of the femoral head before draping. This can be done by placing a palpable radiopaque marker (e.g. an EKG electrode) over the area where the femoral head is thought to be and then taking an A/P X-ray of the hip. The X-ray will show if the marker needs to be moved. This palpable appliance will then direct positioning of the rod during surgery.

If you prefer to complete tibial cuts prior to completing the femur, refer to page 32.



Figure 5a

Step Five: Size the Femur

To measure the A/P dimension of the distal femur, place the femoral A/P measuring guide flat onto the smoothly cut distal femur (Figure 5a). The feet of the guide should rest on the cartilage of the posterior condyles. Hyperflexion of the knee assists in positioning the feet of the guide against the posterior condyles. In some cases, the proximal tibia may have to be resected first, before the guide can be properly positioned. Lower the gauge and read the proper size on the indicator of the gauge. The gauge should rest on the anterior femoral surface. There are eight sizes labeled "A" through "H". If the reading is between two sizes, with the current inventory of femoral components, the component that is closest to the measured femur may be chosen.



Figure 6a



Figure 6b

Step Six: Finish the Femur

Select the correct size femoral finishing guide as determined by the measurement from the femoral A/P measuring guide. Attach the MIS modular shelf to the finishing guide, and secure it with a hex-head screwdriver (Figure 6a).

Position the guide by setting the ledge of the MIS modular shelf on the cut surface of the anterior femur. This determines the rotation and A/P position of the instrument.

Center the guide mediolaterally on the distal femur (Figure 6b). When the M/L position is set, secure the MIS modular shelf to the anterior femur by inserting one or two short 3.2 mm headed screws, or predrill and insert short-headed holding pins.



Figure 6c



Figure 6d

Step Six: Finish the Femur (cont.)

Use the screw inserter/extractor to insert a 3.2mm headed screw or predrill and insert a hexhead holding pin through the superior pinhole on the beveled medial side of the guide (Figure 6c). Then secure the lateral side in the same manner. If desired, predrill and insert two short-head holding pins through the inferior holes on one or both sides of the guide. For additional stability, use 6.5 mm screws in the peg holes. Remove the screws/pins that secure the MIS modular shelf to the resected anterior surface of the femur (Figure 6d). Loosen the hex-head screw on the MIS modular shelf and remove the shelf from the finishing guide.



Figure 6e

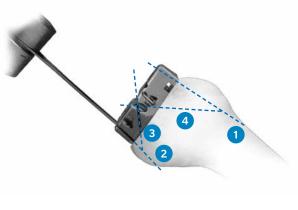


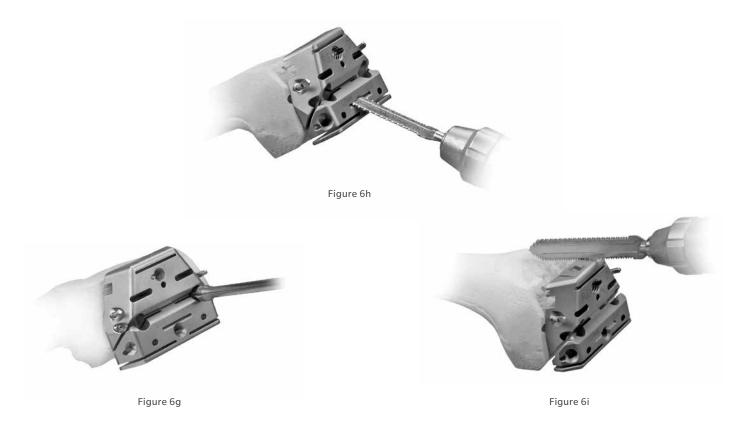
Figure 6f

Step Six: Finish the Femur (cont.)

Use the resection guide through the anterior cutting slot of the finishing guide, and check the medial and lateral sides to be sure the cut will not notch the anterior femoral cortex (Figure 6e).

Use a 1.27 mm (0.050-in.) narrow, oscillating saw blade to cut the femoral profile in the following sequence for optimal stability of the finishing guide (Figure 6f):

Anterior condyles
Posterior condyles
Posterior chamfer
Anterior chamfers



Step Six: Finish the Femur (cont.)

Use the patellar/femoral drill bit to drill the post holes (Figure 6g).

Use the 1.27 mm (0.050-in.) narrow, reciprocating saw blade to cut the base of the trochlear recess (Figure 6h) and score the edges (Figure 6i). Remove the finishing guide to complete the trochlear recess cuts.



Figure 6j Position the MIS notch/chamfer guide flush against the femur

Figure 6k Insert two short headed pins or short screws through the anterior flange

Option One: MIS Notch/Chamfer Trochlear Guide

The MIS notch/chamfer trochlear guide consists of 2 pieces for each size, the MIS notch/chamfer guide and the MIS trochlear guide. Matching sizes must be used.

The MIS notch/chamfer trochlear guide may be used to complete the chamfer cuts, the trochlear groove, the intercondylar box and to drill the peg holes after the anterior and posterior cuts have been made with the MIS femoral finishing guide.

After the anterior and posterior cuts have been made, check the flexion gap and the extension gap using the MIS spacer block. Make the necessary adjustments.

Knee in Slight Flexion

Position the appropriate size MIS notch/chamfer guide onto the femur so it is flush against the resected surfaces both distally and anteriorly. Ensure that no soft tissue or osteophytes interfere with instrument positioning. Position the guide mediolaterally (Figure 6j).

Note: The distal mediolateral profile of the MIS notch/chamfer guides, anterior to the tabs, can be used to position the guide referencing the lateral condyle.

Insert two short headed pins or short screws through the anterior flange of the guide to secure the guide in position (Figure 6k).



Figure 6I Secure the MIS notch/chamfer guide to the femur



Figure 6m Cut the sides and base of the intercondylar box

Knee in 90° Flexion

Secure the MIS notch/chamfer guide to the femur distally with two short spring screws or 3.2 mm (1/8-inch) headed screws. Alternatively, insert two headed pins (Figure 6I).

Use a reciprocating saw to cut the sides and base of the intercondylar box (Figure 6m). Protect the tibia with a wide osteotome.

Use the patellar/femoral drill to drill the femoral post holes.

Note: Do not use the LPS-Flex femur peg drill, size A, B with the MIS notch/chamfer guide as there is no stop on the guide for this smaller drill. If using a micro size (A, B) LPS-Flex femoral component, the femoral post holes must be drilled when the anterior and posterior condyle cuts are made using the appropriate size MIS flex femoral finishing guide and the LPS-Flex femur peg drill.



Figure 6n Cut the anterior and posterior chamfers



Figure 6o Apply the matching size MIS trochlear guide with the holes aligned

Knee in 90° Flexion (cont.)

Then use an oscillating saw to cut the anterior chamfer and the posterior chamfer (Figure 6n).

Apply the matching size MIS trochlear guide to the MIS notch/chamfer guide with the holes in the trochlear guide aligned with the threaded holes in the notch/ chamfer guide (Figure 6o).





Figure 6q Cut the sides and base of the trochlear groove

Knee in 90° Flexion (cont.)

Thread the MIS threaded handle through one of the threaded holes to secure the trochlear guide to the MIS notch/chamfer guide (Figure 6p).

Protect the tibia. Use a reciprocating saw through the slots in the trochlear guide to cut the sides and base of the trochlear groove (Figure 6q). Remove the trochlear guide, and insert an osteotome over the resected tibial surface below the trochlear groove. Then use the reciprocating saw to finish the trochlear cuts.

Remove the MIS notch/chamfer guide.

Using the MIS Notch/Chamfer Guide to downsize the femur

If there is a need to downsize the femur, the MIS notch/ chamfer and trochlear guide can be used for sizes C-G standard implants and the notch/chamfer guide can be used for all flex sizes.

Note: Size A, B and H MIS trochlear guides cannot be used for downsizing.

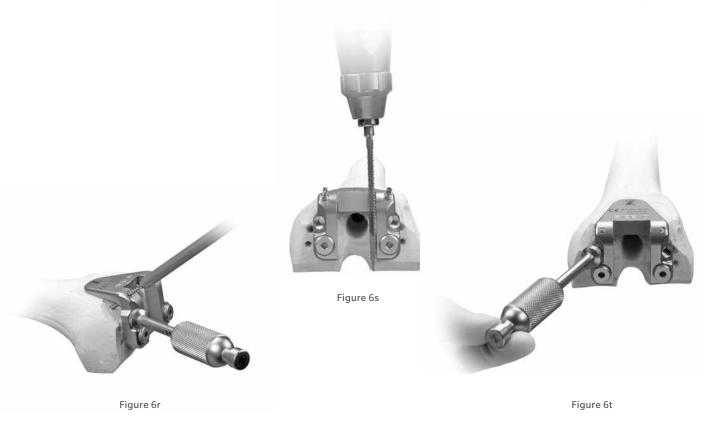
Select the preferred size notch/chamfer guide and pin to the distal femur with two short spring screws or 3.2 mm (1/8-inch) headed screws (48 mm length). Alternatively, insert two hex headed pins. Ensure that the guide is seated on the anterior and distal femur. Use a reciprocating saw to recut the sides of the intercondylar box. Use an oscillating saw to recut the anterior and posterior chamfers. If downsizing for a CR-Flex or LPS-Flex implant, use the posterior surface of the MIS notch/chamfer guide for the posterior cut. If downsizing for a CR or LPS implant, use the MIS threaded handle to attach the matching size MIS trochlear guide to the notch/chamfer guide, and use the posterior surface of the MIS trochlear guide for the posterior cut.

Remove the MIS trochlear and notch/chamfer guides.

Surgeon Notes and Tips

- Although a sequence of femoral cuts has been provided, the cuts may be made in any sequence. It is recommended for the surgeon to complete the cuts in a consistent sequence to help ensure that all cuts are performed. However, the peg holes should be drilled prior to assembling the MIS trochlear guide.
- If the MIS femoral finishing guide is used, the flexion gap should equal the extension gap.
- If the MIS flex femoral finishing guide is used, then the flexion gap will be approximately 2 mm greater.
 For an LPS-Flex implant, use an MIS spacer block with the MIS spacer block flex adapter to check flexion gap.

- An oscillating saw with a narrow blade may also be used, or a reciprocating blade may be used to cut the sides and a chisel or osteotome used to cut the base of the notch.
- Remember that the incision can be moved both medial-to-lateral and superior-to-inferior as needed to gain optimal exposure.
- To facilitate the use of the mobile window, when resecting on the medial side, use retraction on the medial side while relaxing the lateral side. Likewise, when resecting on the lateral side, use retraction on the lateral side while relaxing the medial side.

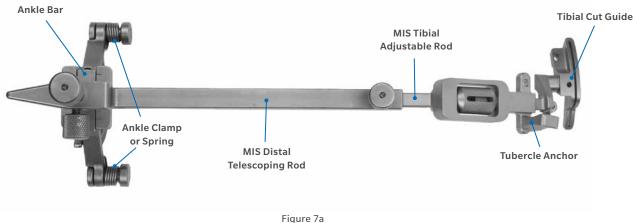


Option Two: MIS QS Notch Guide

Position the appropriate size MIS QS notch guide onto the femur so it is flush against the resected surfaces both distally and anteriorly. The MIS QS notch guide will not contact the anterior chamfer. Use the previously prepared trochlear recess and/or the femoral post holes to position the MIS QS notch guide mediolaterally.

Use the recut guide modular peg with MIS QS notch guides sizes C-H for mediolateral positioning.

Secure the MIS QS notch guide to the femur with two 3.2 mm (1/8-inch) headed screws or predrill and insert two 3.2 mm (1/8-inch) holding pins (Figure 6r). Use a reciprocating saw to cut the sides and the base of the intercondylar notch (Figure 6s). Then remove the MIS QS notch guide (Figure 6t).



MIS Tibial Cut Guide Assembly

Step Seven: Resect Proximal Tibia

This step explains the alignment of the tibial cut to help ensure proper posterior slope and rotation, and the resection of the tibia perpendicular to the mechanical axis. The MIS tibial cut guide assembly is designed to facilitate tibial preparation through a shorter incision and without everting the patella.

Instruments Used

- MIS tibial cut guide assembly
 - MIS tibial cut guide (right or left)
 - MIS tubercle anchor (right or left)
 - MIS tibial adjustable rod
 - MIS distal telescoping rod
 - ankle clamp or spring
 - ankle bar
- resection guide
- MIS tibial depth resection stylus
- osteotome
- various retractors
- kocher clamp
- hex-head screwdriver

- drill/reamer
- MIS screw inserter/extractor
- MIS screws
- assemble the guide

Assemble the Guide

The MIS tibial cut guide assembly consists of instruments for right or left (Figure 5a).

- tibial cut guide
- tubercle anchor
- MIS tibial adjustable rod
- MIS distal telescoping rod
- ankle clamp or spring
- ankle bar



Figure 7b Arrows showing correct alignment



Figure 7c

Step Seven: Resect Proximal Tibia (cont.)

Attach the ankle clamp or optional spring to the ankle bar. Then slide the ankle bar onto the dovetail at the bottom of the MIS distal telescoping rod. Turn the knob opposite the dovetail to temporarily hold the bar in place.

Arrows are etched onto both the MIS tibial adjustable rod and the MIS distal telescoping rod to indicate the correct orientation during assembly. With the arrows aligned, insert the MIS tibial adjustable rod into the distal telescoping rod (Figure 7b). Adjust the length to approximate the length of the patient's tibia and temporarily tighten the thumb screw at the proximal end of the distal rod. Attach the correct right or left tubercle anchor onto the corresponding side of the MIS tibial adjustable rod. For a left knee, the left anchor is inserted into the right hole (Figure 7c).



Figure 7d



Figure 7e

Step Seven: Resect Proximal Tibia (cont.)

For a right knee, the right anchor is inserted into the left hole (Figure 7d).

Be sure that the etched line on the side of the tubercle anchor aligns with the corresponding etched line on the anterosuperior face of the adjustable rod (Figure 7e). ● Note: The tibial cut guide and tubercle anchor are available in left and right configurations. If the incorrect tubercle anchor is used, the cut guide will not fully retract into the adjustable rod and the varus/valgus angle of the tibial cut may be affected.



Figure 7f

Step Seven: Resect Proximal Tibia (cont.)

Insert the correct right or left tibial cut guide into the adjustable rod and rotate the thumb wheel counterclockwise until the threads engage (Figure 7f). Continue to rotate the thumb wheel until the guide is approximately midway through its range of travel. This will allow the depth of the tibial resection to be adjusted after the assembly is secured to the bone via the tubercle anchor.



Figure 7g



Figure 7h

Position the Guide

Place the spring arms of the ankle clamp around the ankle proximal to the malleoli and loosen the anterior knob that provides mediolateral adjustment at the ankle. If preferred, the ankle spring may be used instead of the ankle clamp.

Loosen the knob on the proximal end of the distal telescoping rod and adjust the length of the guide until the tibial cut guide is positioned at the approximate depth of cut. With the tibial cut guide and tubercle anchor contacting the bone, move the tibial cut guide mediolaterally to align the rod with the medial third of the tibial tubercle (Figure 7g). This will usually place

the proximal end of the adjustable rod so it is centered below the intercondylar eminence. The tibial cut guide will contact the tibia at an oblique angle and the lowprofile portion of the cutting head will fit under the patellar tendon. The tubercle anchor is shaped to fit between the patellar tendon and the base of the cutting head.

Note: Be sure that only the low-profile portion of the cutting head extends beneath the patellar tendon (Figure 7h).

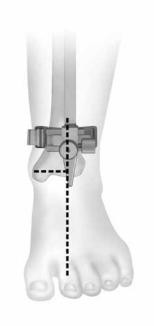


Figure 7i

Position the Guide (cont.)

When correctly aligned, the distal telescoping rod and adjustable rod should be parallel to the tibia in the coronal and sagittal planes. To help avoid rotational malalignment of the rod, check its position from a direct anterior view, ie, stand at the foot of the operating table.

Adjust the distal end of the MIS distal telescoping rod by moving the slide at the foot of the rod medially or laterally until the guide is aligned with the mechanical axis of the tibia. The end of the MIS distal telescoping rod should be positioned about 5 mm-10 mm medial to the midpoint between the palpable medial and lateral malleoli. The tip should point to the second toe (Figure 7i). When the proper M/L position is achieved, tighten the anterior knob to secure the MIS distal telescoping rod to the ankle bar. Loosen the knob on the side of the distal end of the MIS distal telescoping rod. Then use the slide adjustment to align the rod in the sagittal plane so it is parallel to the anterior tibial shaft. This will create a 7° posterior tibial slope. If more or less slope is desired, use the slide adjustment to obtain the desired slope. Then tighten the knob. If there is a bulky bandage around the ankle, adjust the rod to accommodate the bandage. This will help ensure that the tibia will be cut with the proper slope.



Figure 7j



Figure 7k

Position the Guide (cont.)

Insert an MIS screw near the tibial tubercle through the hole in the tubercle anchor (Figure 7j).

● Note: The tubercle anchor position does not determine the varus/valgus of the tibial cut.

Then use the resection guide through the cutting slot to assess the slope of the cut (Figure 7k).



Figure 7I

Figure 7m

Figure 7n

Set the Final Resection Level

With the tibial cut guide flush against the anteromedial edge of the tibia, insert the MIS tibial depth resection stylus into the hole on the top of the tibial cut guide. For a minimal cut, swing the 2 mm arm of the stylus over the defective tibial condyle. Adjust the tibial cut guide up or down by rotating the thumb wheel until the tip of the 2 mm stylus rests on the surface of the condyle (Figure 7I). This will position the tibial cut guide to remove 2 mm of bone below the tip of the stylus.

Alternatively, swing the 10 mm arm of the MIS tibial depth resection stylus over the least involved tibial condyle. Adjust the tibial cut guide until the tip of the 10 mm arm rests on the surface of the condyle (Figure 7m). This will position the tibial cut guide to remove 10 mm of bone below the tip of the stylus.

These two points of resection will usually not coincide. The surgeon must determine the appropriate level of resection based on patient age, bone quality, and the type of prosthetic fixation planned.

Note: The grooves on the stem of the tibial cut guide represent 2 mm increments (Figure 7n).



Figure 7o



Figure 7p

Set the Final Resection Level (cont.)

Use the hex-head screwdriver to tighten all of the screws on the tibial assembly to maintain position.

Insert an MIS screw through the medial oblong hole on the cutting head (Figure 7o). This hole is angled to facilitate screw insertion. Place another MIS screw through the central anterior hole on the cutting head (Figure 7p).



Resect the Proximal Tibia

Use a 1.27 mm (0.050-in) oscillating saw blade through the slot on the tibial cut guide to cut the proximal surface of the tibia flat (Figure 7q). After cutting through the medial side and as far as possible into the lateral side, remove the cut guide assembly. Extend the knee and retract soft tissue on the lateral side.

Note: Take care to protect the patellar tendon when cutting the lateral side. Use a kocher clamp to remove the tibial bone fragment. Then trim any remaining bone spikes and meniscus on the posterior and lateral aspects of the resected tibial surface.

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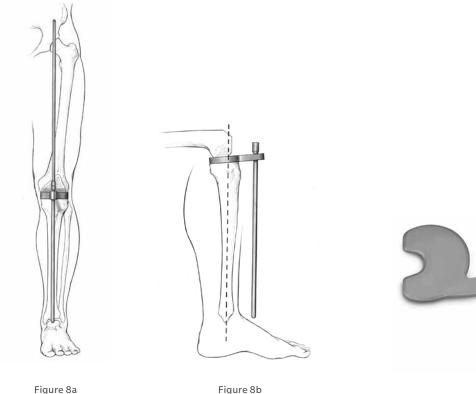


Figure 8c

Step Eight: Check Flexion/Extension Gaps

Use the spacer/alignment guides to check the flexion and extension gaps. With the knee in extension, insert the thinnest appropriate spacer/alignment guide between the resected surfaces of the femur and tibia (Figure 8a). Insert the alignment rod into the guide and check the alignment of the tibial resection (Figure 8b). If necessary insert progressively thicker spacer/ alignment guides until the proper soft tissue tension is obtained.

Then flex the knee and check ligament balance and joint alignment in flexion. When using the MIS flex femoral finishing guide, the flexion gap will be approximately 2 mm greater than the extension gap. For example, if the extension gap is 10 mm, the flexion gap will be 12 mm. To account for this difference, the appropriate MIS CR-Flex spacer adapter or MIS LPS-Flex spacer adapter (Figure 8c) should be placed on top of the spacer/alignment guide that was used in extension to accurately check ligament balance in flexion. The combined construct will equal the total posterior condylar thickness of the final implant. If the tension is significantly greater in extension than in flexion, re-cut the distal femur using the appropriate instrumentation. This will enlarge the extension space.

If the tension is significantly less in extension than in flexion, either downsize the femur or perform additional ligament releases.

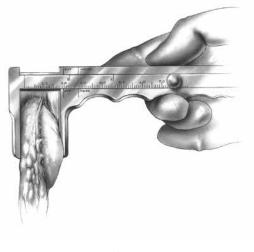


Figure 9a

Step Nine: Prepare the Patella

Sharply dissect through the prepatellar bursa to expose the anterior surface of the patella. This will provide exposure for affixing the anterior surface into the patellar clamp.

Remove all osteophytes and synovial insertions from around the patella. Be careful not to damage tendon insertions on the bone. Use the patellar caliper to measure the thickness of the patella (Figure 9a). Subtract the implant thickness from the patella thickness to determine the amount of bone that should remain after resection.

Patella Thickness – Implant Thickness = Bone Remaining

Implant Thicknesses

	Micro	Standard
26 mm	7.5 mm	_
29 mm	7.5 mm	8.0 mm
32 mm	8.0 mm	8.5 mm
35 mm	8.0 mm	9.0 mm
38 mm	_	9.5 mm
41 mm	_	10.0 mm

● Note: At least 11 mm of total bone will remain to allow for implant pegs if the patella reamer is used.

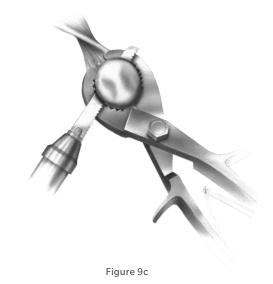




Figure 9b

Resect the Patella

Universal Saw Guide Technique

Apply the universal patellar saw guide in line with the patellar tendon. Push the patella up between the jaws of the saw guide. Level the patella within the saw guide jaws and use the thumbscrew to tighten the guide.

The amount to be resected across the top of the saw guide jaws should be approximately the same on all sides. Check to be sure that the 10 mm gauge does not rotate beneath the anterior surface of the patella. If the gauge hits the anterior surface of the patella as it is rotated, this indicates that at least 10 mm of bone stock will remain after the cut (Figure 9b). Cut the patella flat so that a smooth surface remains (Figure 9c).



Figure 9d

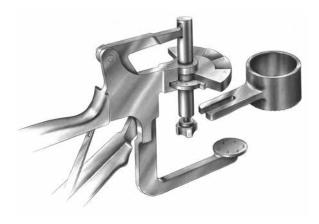


Figure 9e

Patellar Reamer Technique Total Surfacing Procedure

Use the patellar reamer surfacing guides as templates to determine the appropriate size guide and reamer. Choose the guide which fits snugly around the patella, using the smallest guide possible (Figure 9d). If the patella is only slightly larger than the surfacing guide in the mediolateral dimension, use a rongeur to remove the medial or lateral edge until the bone fits the guide. Insert the appropriate size patellar reamer surfacing guide into the patella reamer clamp (Figure 9e). Turn the locking screw until tight.



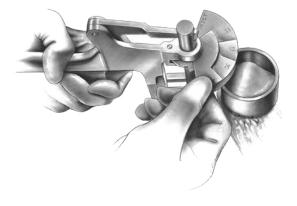


Figure 9f

Figure 9g

Patellar Reamer Technique Total Surfacing Procedure (cont.)

Apply the patellar reamer clamp at a 90° angle to the longitudinal axis with the patellar reamer surfacing guide encompassing the bearing of the patella. Squeeze the clamp until the anterior surface of the patella is fully seated against the fixation plate (Figure 9f). Turn the clamp screw to hold the instrument in place. The anterior surface must fully seat upon the pins and contact the fixation plate. Turn the depth gauge wing on the patellar reamer clamp to the proper indication for the correct amount of bone that is to remain after reaming (Figure 9g).

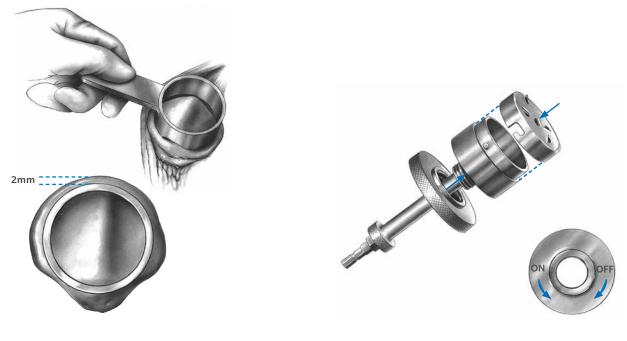


Figure 9h

Figure 9i

Patellar Reamer Technique Total Surfacing Procedure (cont.)

Attach the appropriate size patellar reamer blade to the appropriate size patellar reamer shaft. Use only moderate hand pressure to tighten the blade.

Note: Patella reamers that use the pilot drill can also be used.

Do not overtighten the blade. Insert the patellar reamer shaft into a drill/reamer. Insert the reamer assembly into the patellar reamer surfacing guide. Raise the reamer slightly off the bone and bring it up to full speed. Advance it slowly until the prominent high points are reamed off the bone. Continue reaming with moderate pressure until the step on the reamer shaft bottoms out on the depth gauge wing of the patellar reamer clamp. Remove the reamer clamp assembly.

Proceed to "Finish the Patella" on page 48.

Insetting Technique

Use the patellar reamer insetting guides as templates to determine the appropriate size guide and reamer. Choose the guide which will allow approximately 2 mm between the superior edge of the patella and the outer diameter of the guide (Figure 9h).

Insert the appropriate size patellar reamer insetting guide into the patellar reamer clamp. Turn the locking screw until tight. Apply the patellar reamer clamp at a 90° angle to the longitudinal axis with the patellar reamer insetting guide on the bearing. Squeeze the clamp until the anterior surface of the patella is fully seated against the fixation plate. Turn the clamp screw to hold the instrument in place. The anterior surface must fully seat on the pins and contact the fixation plate.

Turn the clamp wing to the "inset" position.

Attach the appropriate size patellar reamer blade to the appropriate size patellar reamer shaft (Figure 9i). Use only moderate hand pressure to tighten the blade. **Do not overtighten the blade.**

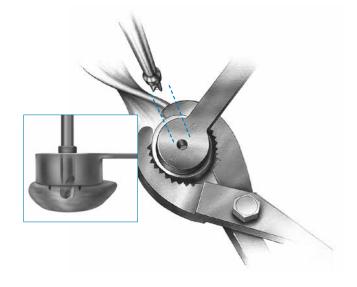


Figure 9k



Figure 9j

Insetting Technique (cont.)

Insert the patellar reamer shaft into a drill/reamer.

Use the patellar reamer depth stops to control the amount of bone to be removed based on the thickness of the implant chosen.

● Note: If using a primary porous patella with Trabecular Metal[™] Material, all implants are 10 mm thick.

The depth gauge wing on the patellar reamer clamp can be used instead of the stops to control the amount of bone remaining, rather than the amount of bone removed.

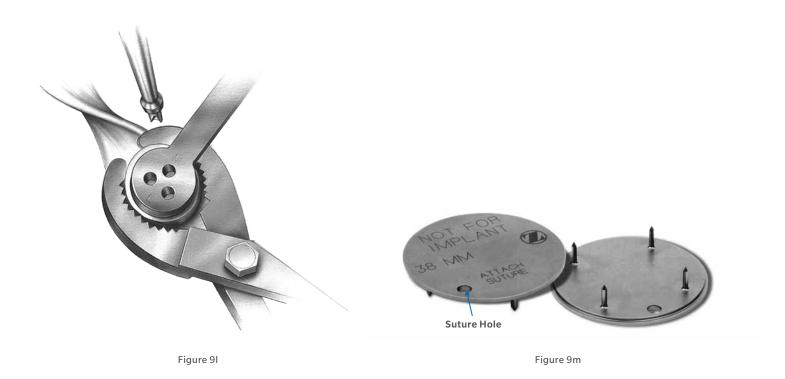
Insert the reamer assembly into the patellar reamer insetting guide. Raise the reamer slightly off the bone and bring it up to full speed. Advance it slowly until the prominent high points are reamed off the bone. Continue reaming with moderate pressure. Remove the reamer clamp assembly.

Finish the Patella

NexGen Primary Porous Patella with Trabecular Metal Material

Center the appropriate patellar drill guide over the resected patella surface with the handle on the medial side of the patella and perpendicular to the tendon. Press the drill guide firmly in place so that the teeth fully engage and the drill guide sits flat on the bone surface (Figure 9j). Drill the peg hole making sure the drill stop collar contacts the top of the drill guide (Figure 9k).

Note: The primary porous patellar clamp may be used to fully seat the drill guide on hard sclerotic bone surfaces.



NexGen All-Polyethylene Patella

Center the appropriate patellar drill guide over the patella with the handle on the medial side of the patella and perpendicular to the tendon. Holding the drill guide firmly in place, drill the three peg holes using the patellar/femoral drill bit (Figure 9I).

Patella Protectors

- Note: If the patella will not be resurfaced, be careful to avoid injury to the patella during surgery.
- Note: The patella protectors are not recommended for use in an insetting technique.

There are 3 sizes of patella protectors available to cover the patella while completing the remaining bone resections. Choose the size that best covers the patella – 26 mm, 32 mm, or 38 mm. Handle with care; the spikes may be sharp.

A suture needs to be placed through the hole in the patella protector (Figure 9m). Loosely tie a suture through the hole on the patella protector. Attach a hemostat to the end of the suture material. Leave an adequate amount of suture material to position the hemostat away from the incision.

Patella Protectors (cont.)

After the initial patella cut is completed, use thumb pressure to press the patella protector against the bone. If the bone is particularly hard, apply the patellar clamp against the patella protector. Squeeze the clamp until the patella protector is fully seated against the bone.

The patella protector should be part of the instrument count before closing the wound. It is not intended for implantation. Completely remove the suture material at the end of the operation and before sending the instrument for cleaning.

Surgeon Notes and Tips

• The suture placed through the hole in the patella protector provides a tether for finding and removing the patella protector.

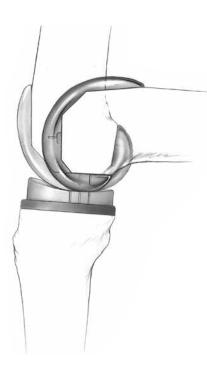


Figure 10a



Figure 10b

Step Ten: Perform a Trial Reduction

After preparing the tibia, select the appropriate pegged or stemmed tibial sizing plate/provisional that provides the desired tibial coverage. Check the size matching chart (for the style of NexGen Knee implant) for component matching instructions.

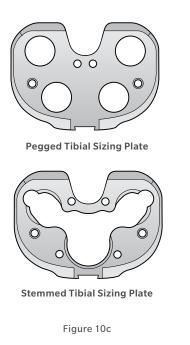
Insert the femoral provisional, patellar provisional, tibial sizing plate/provisional, and bearing provisional.

Flex and extend the knee with theprovisionals in place. Check the rangeof motion and ligament stability. Perform any necessary soft tissue releases. With proper soft tissue balancing complete the tibial component tends to seat itself in the position where it best articulates with the femur (Figure 10a)

Note: During the trial reduction, observe the relative position of the femoral provisional on the tibial bearing provisional by using the lines on both provisionals. The lines can be used to determine if posterior rollback is occurring, whether the PCL is functional, and if the femoral component will contact the tibial bearing in the proper location. If the PCL is properly balanced, the femoral provisional should sit near the anterior or center lines on the tibial bearing provisional in extension and near the posterior line in flexion.

If the femoral provisional sits posterior to the lines, the PCL may be too tight or the bearing may be too thick. If the femoral provisional sits anterior to the lines, the PCL may be too loose.

After this self-centering process has occurred, mark the position of the component with methylene blue or electrocautery (Figure 10b). Then remove the provisional components. The femoral extractor can be used to remove the femoral provisional.



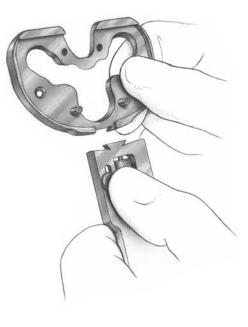


Figure 10d

Tibial Position based on Anatomic Landmarks

The position of the tibial component can also be determined based on anatomic landmarks prior to trial reduction. Select the appropriate pegged or stemmed tibial sizing plate/provisional that provides the desired tibial coverage (Figure 10c). Please refer to the NexGen[®] MIS Tibial Component Cemented Surgical Technique (97-5950-002-00) for complete product information and instructions for the MIS tibial component.

Attach the universal handle to the selected tibial sizing plate/provisional by depressing the button on the handle and engaging the dovetail on the handle with the dovetail on the sizing plate/provisional and secure it by tightening the thumbscrew (Figure 10d).



Figure 10e

Tibial Position based on Anatomic Landmarks (cont.)

Generally, the handle aligns with the anterior aspect of the tibia. Rotate the sizing plate/provisional so the handle points at, or slightly medial to, the tibial tubercle (Figure 10e). The alignment rod can be used to aid in double checking varus/valgus alignment. Pin the plate in place with two short head holding pins.

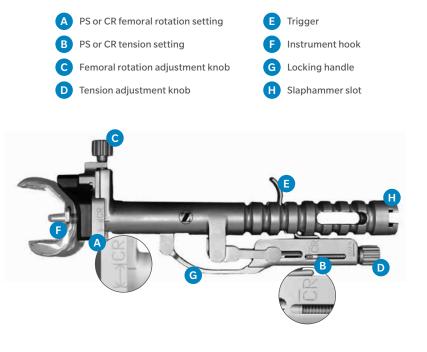


Figure 11a

Figure 11b

Step Eleven: Perform Trial Reduction

In this step, a trial reduction is performed to check component position, patellar tracking, ROM, and joint stability.

The tibial sizing plate is in place.

Knee in 70-90° Flexion

Place the collateral retractor laterally, an army-navy retractor anteriorly, and a rake retractor on the meniscal bed medially.

Insertion of Femoral Provisional using Optional MIS Femoral Inserter/Extractor

Determine type of NexGen implant or provisional being used – posterior stabilized (PS) or cruciate retaining (CR). Refer to the side of the instrument, labeled PS or CR (see (A) & (B)) which corresponds with the implant or provisional type (Figure 11a).

Initially adjust femoral rotation setting and tension setting. For the femoral rotation setting, a good starting point is between the lines of the implant type (A). For the tension setting, start with the two lines aligned (B).

Open locking handle (G) to attach implant or provisional. Attach implant or provisional by positioning the instrument hook (Figure 11b).



Figure 11c

Figure 11d

Figure 11e

Insertion of Femoral Provisional using Optional MIS Femoral Inserter/Extractor (cont.)

If needed, turn adjustment knob (C) to achieve desired rotation of the femoral component (Figure 11c).

Turn tension adjustment knob (D) to increase (tighten) or decrease (loosen) the clamping force (Figure 11d).

Close locking handle to secure instrument to implant or provisional (Figure 11e).

Align implant or provisional onto prepared bone, impact end (H).

Open locking handle by pressing trigger (E) to release instrument from implant or provisional.

If preferred, the femoral provisional may be positioned by hand.

Translate the femoral provisional laterally until the lateral peg of the provisional aligns with the drill hole in the lateral femoral condyle. Push the provisional in place beginning laterally, then medially. Be sure that soft tissue is not trapped beneath the provisional component.



Figure 11f

Knee in Extension

Check to ensure that the femoral provisional is flush against the resected surface on the medial condyle. Then retract the lateral side and check to make sure it is flush on the lateral side. The femoral provisional should be centered mediolaterally on the distal femur.

Attach the appropriate tibial bearing provisional and perform a trial reduction. Check ligament stability in extension and in 30°, 60°, and 90° flexion. Attempt to distract the joint in flexion to ensure that it will not distract. If a posterior stabilized component is used, hyperflex the knee and check to make sure that the spine still engages the cam.

Insert the patellar provisional onto the resected patellar surface. Perform a ROM to check patellar tracking.

When component position, ROM, and joint stability have been confirmed, remove all provisional components.

Removal of Femoral Provisional using Optional MIS Femoral Inserter/Extractor

Ensure (A) and (B) are still set properly for provisional type being used (PS or CR).

Position instrument hook under provisional (F) (Figure 11f).

Turn tension adjustment knob (D) to tighten or loosen as needed.

Close locking handle (G).

Attach slaphammer (H), extract.

Surgeon Notes and Tips

 In performing the trial reduction and during implantation of the femoral provisional or prosthesis, make certain that no portion of the quadriceps or soft tissue is pinned beneath the component.

Step Twelve: Implant Components

In this step, the final components are implanted, and the tibial bearing is secured to the implanted tibial base plate. When using cemented components, it is recommended to use two batches of cement.

After the implants have been chosen, make a final check to ensure that the femoral, tibial base plate, and tibial components match. If using a cemented component, mix the first batch of cement. The cement should have a doughy consistency when ready for use.

Tibial Base Plate

If a stemmed tibial base plate will be used with a stem extension, attach the desired stem extension to the stem and strike it once with a mallet. If a 10 mm-14 mm thick tibial bearing will be used, insert the locking screw for the stem extension.

If a stemmed tibial base plate will be used without a stem extension, consider the need for a taper plug. If a 17 mm or 20 mm bearing will be used, a stem extension or taper plug is required. A taper plug also can be used with the 10 mm-14 mm tibial bearing. If it is planned to use a 14 mm bearing or if the flexion and extension gaps are not balanced, consider using the taper plug in case the final reduction reveals that it is necessary to switch to a 17 mm or 20 mm bearing. Furthermore, if the bearing should ever require revision with a 17 mm or 20 mm thick component, the taper plug is already in place and revision of the tibial base plate may not be necessary. Assemble the taper plug onto the tibial plate by striking it several times with a mallet to allow the ring on the taper to deform.

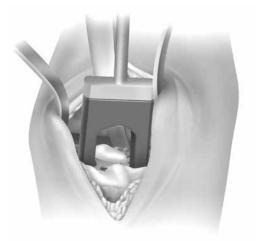


Figure 12a Use the Tibial Impactor to impact the tibial base plate.

Tibial Base Plate (cont.)

Position the PCL retractor posteriorly, the collateral soft tissue protector laterally, and the collateral retractor medially. Sublux the tibia anteriorly. Place a layer of cement on the underside of the tibial base plate, around the keel, on the resected tibial surface, and in the tibial IM canal. Position the tibial base plate onto the tibia and use the tibial impactor to impact it until fully seated (Figure 12a). Thoroughly remove any excess cement in a consistent manner.

Femoral Component

Mix a second batch of cement. Attach the femoral component to the femoral impactor/extractor.

Knee in 70-90° Flexion

Place the collateral retractor laterally, an army-navy retractor anteriorly, and a rake retractor on the meniscal bed medially.

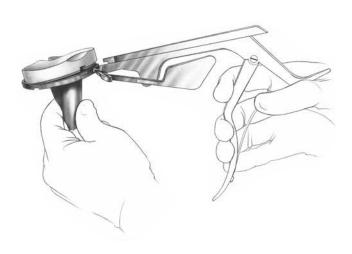
Place a layer of cement on the underside of the prosthesis and in the holes drilled in the femur.

Attach the femoral/impactor/extractor to the femoral component. Insert the femoral component onto the distal femur by translating the component laterally until the lateral peg aligns with the drill hole in the lateral femoral condyle. Take care to avoid scratching the implant component surfaces. Disposable, plastic tibial plate protectors (available at later date) may be temporarily inserted onto the tibial base plate to protect the implant surfaces during insertion of the femoral component. Remove the tibial plate protector after the femur is seated. Be sure tat soft tissue is not trapped beneath the implant. Use a mallet to impact the component until fully seated.

Remove the femoral impactor/extractor, and the retractors. Check the medial and lateral sides to make sure the femoral component is fully impacted. Remove any excess cement in a thorough and consistent manner.

Alternatively, push the component in place by hand beginning laterally, then medially.

Patellar Component NexGen Primary Porous Patella with Trabecular Metal Material Knee in 70°-90° flexion.



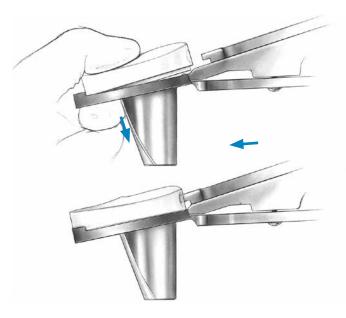


Figure 12c

Figure 12b

After the implants have been chosen, make one last check to ensure that the femoral, tibial, and bearing components match.

Bearing Insertion

The bearing inserter applies both downward and rearward forces to aid in the insertion of the bearing onto the tibial base plate. Push the lever on the inserter fully to either side place the bearing onto the tibial base plate, engaging the dovetails (Figure 12b). Steady the surface on the base plate with one hand by applying downward pressure near the posterior cruciate cutout. Engage the hook on the inserter with the mating slot in the front of the base plate and close the lever with your index finger. This should lock the inserter to the base plate. Squeeze the handles of the inserter to seat the bearing (Figure 12c). Open the lever and remove the inserter. **Insert an bearing only once. Never reinsert the same bearing onto a tibial base plate.**

Bearing Insertion (cont.)

Apply cement to the Trabecular Metal surface and the post of the patellar component while in a doughy consistency. Locate the drilled post hole and use the primary porous patellar clamp to insert and secure the patella in place. Fully open the jaws of the clamp and align the teeth to the anterior surface of the patella and the plastic ring to the posterior surface of the implant. Use the clamp to apply a significant amount of pressure to the implant to fully seat the implant on the patellar surface. Then remove excess cement.

Note: If the implant post begins to engage at an angle, the implant should be removed and repositioned perpendicular to the resected surface. Insert the patella again and reclamp, applying an even distribution of pressure on the patellar surface.

NexGen All-polyethylene Patella Knee in 70-90° Flexion

Apply cement to the anterior surface and pegs of the patellar component while in a doughy consistency. Locate the drilled peg holes and use the patellar clamp to insert and secure the patella in place. Fully open the jaws of the clamp and align the teeth to the anterior surface of the patella and the plastic ring to the posterior surface of the implant. Use the clamp to apply a significant amount of pressure to the implant to fully seat the implant on the patellar surface. Then remove excess cement.



Figure 12d Insert the tibial bearing onto the tibial base plate.

Net-Shape Molded Prolong Polyethylene

Figure 12e

Tibial Bearing Knee in 70-90° Flexion

Use the bearing insertion instrument to attach the appropriate tibial bearing onto the tibial base plate (Figure 12d).

Technique for 17 mm and Thicker Tibial Bearing Assemblies

A secondary locking screw is required for the 17 mm and thicker tibial bearing components if using a flex femoral component. Therefore, stemmed tibial base plates with either a stem extension or taper plug must be used with these thicker components (Figure 12e). This assists in lift off resistance at higher flexion positions.

Note: The pegged plate cannot be used with the 17 mm or thicker Net-Shape molded or Prolong[®] Highly Crosslinked Polyethylene bearing.

Technique for 17 mm and Thicker Tibial Bearing Assemblies (cont.)

With the Prolong Highly Crosslinked Polyethylene Bearing component (17 mm and 20 mm only), the metal locking clip and screw are packaged separately from the tibial bearing container, but in the same box. Before inserting the tibial bearing, insert the metal locking clip into the anterior slot of the compartment. The rail should be aligned with the space in the slot. There is an arrow on the superior side of the locking clip that indicates the correct direction for insertion. The purpose of the rail is to prevent the clip from being assembled incorrectly. The metal locking clip should glide easily into the slot. The clip is properly seated when a click is heard. For the molded tibial bearing, the metal locking clip is preassembled into the component. A taper plug also can be used with the 10 mm to 14 mm bearing components. If you plan to use a 14 mm component or the flexion and extension gaps are not balanced, consider using the taper plug in case, during final reduction, it would be necessary to use a 17 mm or thicker component. Then, if the bearing should ever require revision with a 17 mm or thicker component, the taper plug is already in place and revision of the tibial plate component may not be necessary.

For Back Table Assembly:

- Assemble the stem extension or the taper plug onto the tibial plate by striking it with a mallet once for the stem extension or several times for the taper plug to allow the ring on the taper plug to deform.
- 2. Place the tibial plate onto the holding fixture, which is an integral part of the instrument case.
- 3. Use the bearing Inserter to insert the bearing onto the tibial plate.
- 4. With the bearing in place, insert the secondary locking screw (packaged with the bearing).
- 5. Use the LCCK deflection beam torque wrench with the 4.5 mm hex driver bit attached to torque the screw to 95 in.-lbs. Alternatively, if using a stem extension, use the tibial plate wrench to assist when torquing the screw. Do not over or under torque.

For In Vivo Assembly:

If preferred, 17 mm or thicker bearing can be inserted after the tibial plate has been implanted.

 Assemble the stem extension or the taper plug onto the tibial plate by striking it with a mallet once for the stem extension or several times for the taper plug to allow the ring on the taper plug to deform.

It is recommended to secure the taper plug/stem extension using a replacement stem extension locking screw: 00-5980-090-00 (available as a separate sterile item) before implanting the tibial component. This screw will hold the taper plug/ stem extension in place when the tibial plate is impacted.

2. Implant the tibial plate*. Remove the replacement stem extention locking screw and discard. If bone cement is being used, wait for the cement to completely cure before inserting the bearing. A bearing provisional may be inserted to use as space while the cement cures.

For In Vivo Assembly (cont.):

- 3. Remove the bearing provisional and insert the bearing onto the plate using the bearing inserter.
- 4. Select the tibial plate wrench that matches the size of the implant to be assembled. Place the end of the wrench over the tibial plate. Ensure that the wrench is in line with the base of the tibial plate.
- 5. Place the locking screw (packaged with the bearing) through the hole in the bearing.
- 6. Use the LCCK deflection beam torque wrench attached to the 4.5 mm hex driver bit to torque the screw to 95 in.-lbs.

*For cemented applications, apply a layer of bone cement to the underside of the tibial plate, around the keel, on the resected tibial surface and in the tibial IM canal. Remove the excess cement.

Recheck the ROM and stability of the knee.

Surgeon Notes and Tips

- Take care that the retractors not inadvertantly dislodge the tibial base plate, particularly on the posterolateral corner.
- Verify that the femoral component is fully seated before closing the wound.
- Confirm that no portion of the quadriceps mechanism has been pinned beneath the femoral component.



Figure 12f

Surgical Support Team Tips

- The cement may need to be prepared in two separate batches to implant the components.
 - Place cement onto the tibial bone, position the implant, and impact into place. Remove excess cement.
 - Place cement onto the femoral component, then position the implant and impact into place. Remove all excess cement in a consistent manner.
- After the tibial base plate component has been implanted, ensure that the tibial base plate component has not been dislodged when the femur is subluxed anteriorly to implant the femoral component.

If desired, apply cement to the Trabecular Metal material and post while in a doughy consistency. Locate the drilled post hole and use the primary porous patellar clamp to insert and secure the patella in place. Fully open the jaws of the clamp and align the teeth to the anterior surface of the patella and the plastic ring to the posterior surface of the implant. Use the clamp to apply a significant amount of pressure to the implant to fully seat the implant on the patellar surface (Figure 12f). Remove excess cement. The primary porous patella can be used uncemented.

Note: If the implant post begins to engage at an angle, the implant should be removed and repositioned perpendicular to the resected surface. Insert the patella again and reclamp, applying an even distribution of pressure on the patellar surface.

Apply cement to the anterior surface and pegs of the patellar component while in a doughy consistency. Locate the drilled peg holes and use the patellar clamp to insert and secure the patella in place. Fully open the jaws of the clamp and align the teeth to the anterior surface of the patella and the plastic ring to the posterior surface of the implant. Use the clamp to apply a significant amount of pressure to the implant to fully seat the implant on the patellar surface. Remove excess cement.

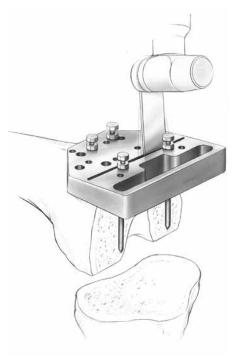


Figure A

Step Thirteen: Close Incision

Freely irrigate the wound with the solution of choice. A drain may be placed intracapsularly. Then close the wound with sutures, and apply a bandage.

Appendix One

Recutting the Distal Femur

The distal femoral recutting guide provides quick, reproducible results to recut 3 mm or 5 mm of bone.

Extend the skin incision as necessary. Lay the guide on the anterior cut surface of the femur with the engraving facing up. Place pins through the appropriate holes for the amount of additional resection desired (3 mm or 5 mm) and slide the guide proximal so the pins contact the existing distal cut surface. Pin the recutting guide in place with standard pins or silver spring pins and recut through the slot (Figure A).

Optional Technique

Reinsertion of the IM alignment guide coupled with the distal femoral cutting guide makes this resection simple, accurate, and adjustable for the removal of the amount of bone necessary for appropriate ligament tension. When reinserting the IM alignment guide and the distal femoral cutting guide, be sure they reference the same point as the first cut. If the IM alignment guide touches the distal femur, an erroneous additional 12 mm could be removed using the optional slot. Reestablish the original reference point by reinserting a saw blade and touching the blade against the cut distal surface. Pin the guide in place and make the cut through the "Optional 3.5 mm Cutting Slot" leaving the IM alignment guide in place. After recutting the distal femur, reinsert the correct size of femoral finishing guide coupled with the femoral holding pegs and repeat the chamfer and condyle cuts. The guide can be placed in the proper A/P position by inserting a 1.27 mm (0.050-in.) saw blade through the anterior slot and resting the blade on the existing anterior cut surface. This will position the guide in the same A/P location as the original cuts.

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This documentation is intended exclusively for physicians and is not intended for laypersons. Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advise in whole or in part.

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