Smith+Nephew

ENGAGE◊

Cementless Partial Knee System

Surgical Technique

Table of Contents

Disclaimer

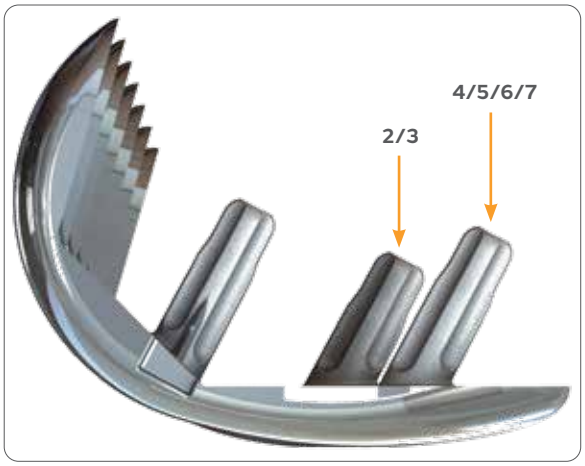
The following technique is for informational and educational purposes only. It is not intended to serve as medical advice. It is the responsibility of treating physicians to determine and utilize the appropriate products and techniques according to their own clinical judgment for each of their patients. For more information on the ENGAGE◊ product, including its indications for use, contraindications, and product safety information, please refer to the product's label and the Instructions for Use packaged with the product.

Note Bena

The technique description herein is made available to the healthcare professional to illustrate the suggested treatment for the unicompartmental procedure. In the final analysis, the preferred treatment is that which addresses the needs of the patient.

Introduction

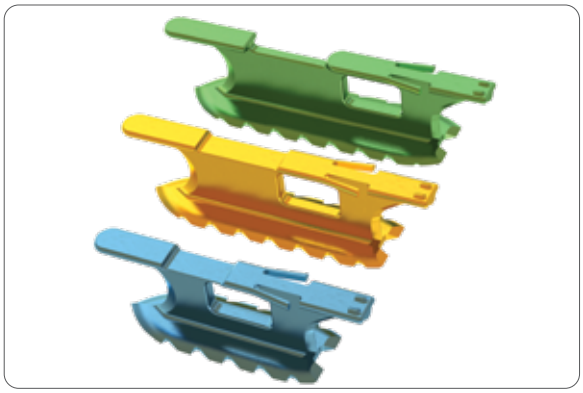
The ENGAGE◊ Cementless Partial Knee System is a unicompartmental knee replacement system that utilizes a ligament-balancing surgical approach designed specifically for the medial compartment. The system provides instrumentation that is designed to allow for precise adjustment of bony resection in order to achieve the desired ligament tension. The system includes Femoral Components, Tibial Trays, Tibial Inserts, and Tibial Anchors to fit the patient population. The Femoral Component includes a porous cobalt chrome coating, while the Tibial Tray includes an engineered ultraporous titanium surface; both of which are designed to promote osseointegration when used without bone cement.



Intraoperative flexibility

Downsizing of the Femoral Components can be achieved by only re-cutting the posterior femoral resection. This allows for ease of flexion gap adjustment, without having to modify the extension gap or recut the tibia. Femoral Components have common peg locations that allow for ease of downsizing, which reduces the instances when re-drilling peg holes is required.

In addition, the posterior and distal condyles have a common thickness across all sizes (7mm) that allows for simplified ligament-balancing. The system also offers both a cementless and cemented technique options that can be selected based on surgeon preference.



Compression of Tibial Tray

The system features ENGAGE◊ Fixation Technology including the ENGAGE Tibial Anchors that, when inserted, draw the Tibial Tray against the prepared tibial bone, creating a compressive force at the prosthesis-to-bone interface.[1] ENGAGE Fixation Technology increases resistance to liftoff.*[,2,3]

ENGAGE Tibial Tray with CONCELOC Porous Technology.

Advanced porous implant surface technology

Both the Tibial Tray and the Femoral Component are porous on 100% of the bone contacting surface to promote cementless biological fixation. Femoral Component's bone contact surfaces are comprised of a sintered porous cobalt chrome coating. The titanium alloy Tibial Tray component is additively manufactured (AM) to include CONCELOC◊ Porous Technology.† CONCELOC consists of irregularly-shaped random interconnected pores that have been optimized based on previous studies evaluating biological fixation of AM components.[4]

Bone-conserving ligament-guided approach

Gap balancing technique that links both flexion and extension gaps to the tibial resection. Tibial resection is in 1mm increments to help fine-tune the overall ligament balance throughout the range of motion.

*Compared to competitive product with press-fit keel

†While the ENGAGE◊ CONCELOC◊ porous surface may be comparable in porosity and pore size range to the CONCELOC Advanced Porous Titanium surface in Smith+Nephew Cementless Total Knee and Revision Acetabular Systems, other technological and performance characteristics, including biomechanical properties, have not been evaluated for equivalence and may not be presumed comparable.

Best Practices for Cementless Partial Knee

Clinical success of a cementless partial knee replacement is predicated upon the presence of a biologically-active bone interface to drive osseointegration of the prosthesis.

- **Limiting Thermal Necrosis:** Heat generation from powered instruments commonly used for bone preparation has been shown to induce thermal necrosis at the bone interface. Thermal injury of bone has been documented to reduce the overall osteogenic potential. Use of saline irrigation directly on the sawblade during tibial and femoral resections will serve to cool the interface, limit thermal necrosis, and help facilitate bone remodeling.[5]
- **Improved Implant Wettability:** Spraying normal (isotonic) saline directly on the implant porous surfaces just prior to implantation may act as a 'wetting-agent' to break the surface tension on the implant. This may improve the initial hydrophilicity and lead to more rapid absorption of blood into the porous structure of the femoral and tibial prostheses.
- **Washing Bone Prior to Implanting:** Avoid excessive washing of the boney interfaces with pressurized means (including pulsed-lavage) prior to implantation of the femoral and tibial components. Pressurized washing can remove key bone proteins and osteocytes responsible for bone remodeling. If washing is necessary, use of bulb syringe is preferred.
- **Drilling Holes in Sclerotic Bone:** If sclerotic bone is encountered after tibial or femoral preparation, placing small drill holes directly into the sclerotic area will facilitate boney bleeding and may support better biologic fixation. If a tourniquet is used, lower the torniquet to assess blood flow. If bone **does not** bleed even after drilling, consider cementing. If eburnated bone is present after making saw-cuts, cement fixation of implants should be utilized. Additionally, hard or sclerotic bone may cause sawblades to deflect (or skive) even when using a captured saw guide. To prevent under-resection of bone, multiple passes of the sawblade over the original resection may be necessary to adequately plane the surface.
- **Use of Antiseptics:** Povidone-Iodine solutions have been shown to inhibit new bone formation. Exposure of the bone interface to antiseptics may negatively impact normal osseointegration of the prosthesis.[6]

Surgical Procedure

Limb Positioning

With the patient lying in the supine position, ensure that the hip and knee can move freely and approximately 110° of knee flexion is able to be achieved. It may be helpful to mark the location of the femoral head with a marking pen, as this information will be useful for varus-valgus limb alignment check in a later step.

Figure 1

Exposure and Osteophyte Removal

Begin with a skin incision centered over the medial compartment to be replaced. Carry the exposure to the joint capsule and incise in either mid-vastus or medial parapatellar fashion. Elevate the soft tissues subperiosteally from the medial tibial plateau only for exposure purposes. The integrity of the superficial MCL should be preserved as excessive release of the medial soft tissues may lead to valgus overcorrection. A pointed self-retaining retractor may be helpful in maintaining exposure of the medial compartment.

After the medial compartment is adequately exposed, osteophytes that exist on the anterior medial tibia, the medial edge of the medial femoral condyle, or the edge of the intercondylar notch may be removed using an osteotome or chisel. Failure to remove osteophytes may affect ligament balancing in flexion and extension.

Figure 2

Proximal Tibial Resection (Step 1)

Assemble the Tibial Ankle Clamp as shown. **(Figure 1)** Ensure the graduated laser marks are visible on the top surface of the Clamp. Assemble Ankle Clamp to the Tibial Resection Guide Rod. **(Figure 2)** Orient the Tower as shown in Figure 2. Select the Slotted (or Non-slotted) Tibial Tower and attach the Tibial Tower to the assembly by threading it in from the top. Ensure orientation as shown in **(Figure 3)**. Continue to turn the thumbscrew until the graduated markings on the Tower are centered about the 0mm mark. This will allow for a maximum range of adjustability when in use.

Note: All images shown in the technique guide display a LEFT Medial partial knee replacement.

The procedure is a mirror image for a RIGHT Medial partial knee.

Figure 3A
Slotted Tibial Tower (Gold)

Figure 3B
Non-Slotted Tibial Tower (Gray)

Figure 4A

Figure 4B

Attach the modular Tibial Cutting Block to the Tibial Tower by sliding it into the slot. **(Figure 4A)** Tighten the screw on the Tibia Tower using the Screwdriver to lock the Cutting Block into place. **(Figure 4B)**

The modular Tibial Cutting Blocks are offered in 0mm, +1mm and +2mm thicknesses and include both Slotted and Non-Slotted versions. It is best to select the 0mm, as more bone can be resected later if needed.

Figure 5

Optional Step: When using the 4mm Blocker pin, with the knee in 90° of flexion, use the thin end of the Tibial AP Sizer Wand to measure the AP dimension of the tibia. **(Figure 5)** This will aid in determining the appropriate insertion depth of the 4mm Blocker Pin.

The System offers two options for tibial resection. Both options have protective measures that prevent over-resection of the sagittal cut. The first option uses the 4mm Blocker Pin. The second option uses a sawblade as a physical stop. Both methods are outlined below.

When using the Non-Slotted Tibial Tower be sure to use corresponding Non-slotted Tibial Cutting Blocks (0mm, +1mm, +2mm). **(Figure 3B)** The Non-Slotted Tower will use a 1.27mm sawblade, or the Angel Wing, left in the transverse (horizontal) cut as physical stop when making the sagittal cut. Place the Tibial Ankle Clamp around the ankle and align the Resection Guide Rod with the axis of the tibia in the sagittal and frontal planes.

Note: The assembled tibial resection instrument has 5° of posterior slope built-in. This amount of slope occurs when the vertical rod is parallel to the axis of the tibia in the sagittal plane. The slope may be adjusted using the distal slider-mechanism built into the Tibial Ankle Clamp.

Figure 6A

Figure 6B

Once osteophytes are removed, with the knee in 90° of flexion, the Angel Wing may be used in the transverse or vertical cutting slot of the guide to provide alignment for initial positioning of the guide. **(Figure 6A/6B)** The preferred location for the sagittal cut is just medial to the ACL attachment. Creating the cut in this location will help to maximize the footprint of the Tibial Tray.

Alternately, if the Non-Slotted Tibial Tower is used the Angel Wing may be placed directly on the Block for initial positioning. **(Figure 6C/6D)**.

Figure 6C

Figure 6D

Figure 7

Once the initial location of the guide is determined, place a 3.2mm Threaded Pin through the lateral pin hole on the Guide Rod to provide initial fixation. **(Figure 7)** Fine adjustment of the transverse and sagittal cuts is possible using the vertical and horizontal adjustment knobs.

Note: 3.2mm Pins are single use only.

A Tibial Stylus may be inserted into the cutting slot to contact the deepest point of the medial compartment of the tibial plateau. **(Figure 8A)** This sets the depth of transverse tibial resection. The stylus is double-ended and offers both +2mm and +4mm resection options based on surgeon preference. Adjust the height of the resection by turning the vertical adjustment knob as necessary. **(Figure 8B)**

Figure 8A

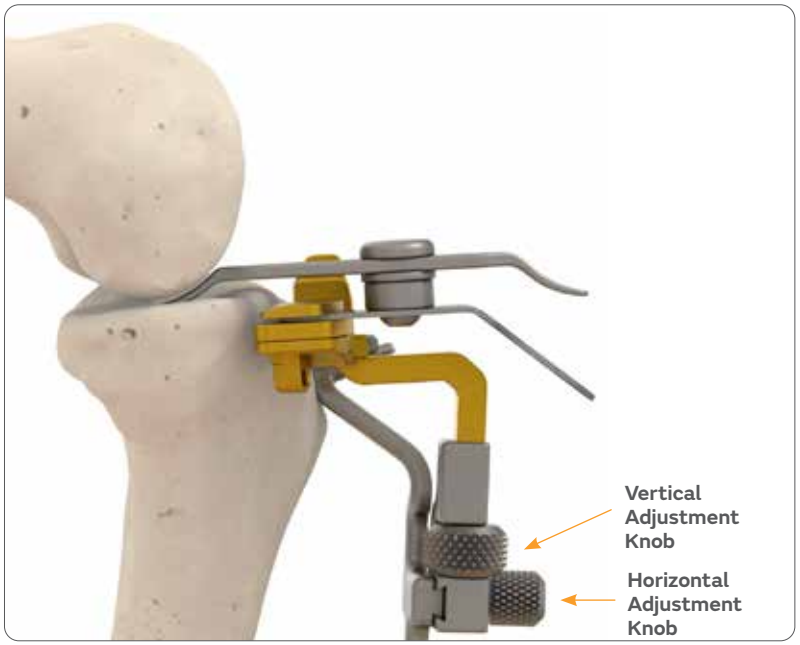


Figure 8B

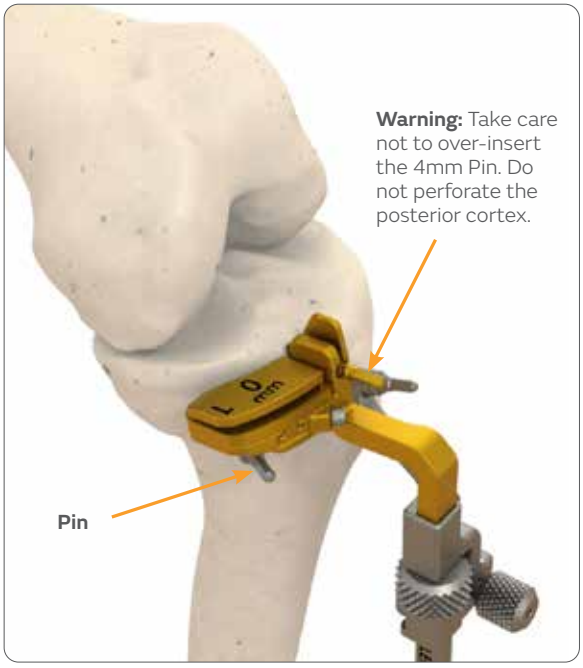


Figure 9A
Slotted Guide (Gold)

Figure 9B
Non-Slotted Guide (Gray)

Utilize the horizontal adjustment knob by loosening and then manually translating the housing as necessary. The knob is captured in the Guide, Do Not Remove. In order to maximize tibial implant coverage, the resection should be adjacent to the medial attachment of the ACL. Rotational alignment should be parallel to the AP axis of the tibial plateau to properly establish the posterior slope.

Once the final resection location is determined, when utilizing the Slotted Tower, a 4mm Blocker Pin is used. The Blocker Pin comes in 45mm length. Gradually insert the Blocker Pin in the corner of the Tibial Tower. Utilizing tactile feedback, ensure the pin does not perforate the posterior cortex. **(Figure 9A)**.

Insert a 3.2mm Threaded Pin into the medial hole on the Tibial Tower for additional stability. **(Figure 9A/B)**

Technique Tip: When using the Slotting Guide, insert the 4mm Blocker Pin to a depth that is less than the AP Measurement **(Figure 5)** of the tibia using the graduated markings on the Blocker Pin to prevent over-insertion. Over-insertion could result in perforation of the posterior cortex and possible impingement of vascular structures or soft tissue.

Figure 10A

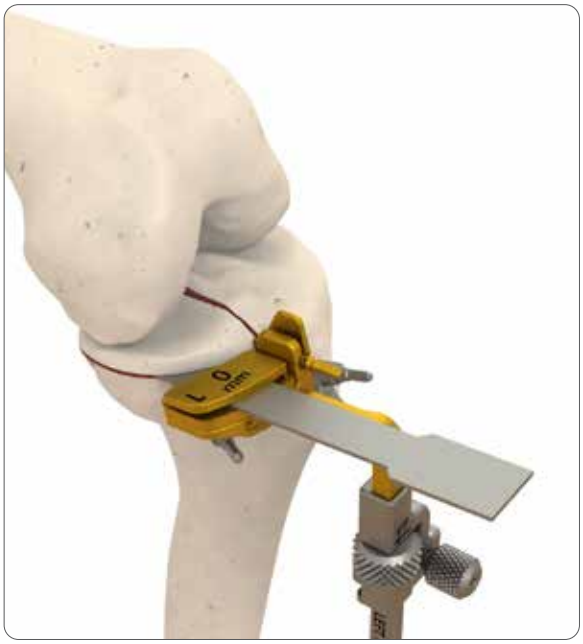


Figure 10B

Method No. 1: Tibial Resection with Tibial Tower using Blocker Pin

With the knee in approximately 90° of flexion, a blunt tipped single-sided reciprocating sawblade should be used for the sagittal resection cut. The blade should pass just medial to the ACL insertion. The blade should cut until it contacts the 4mm Blocker Pin. **(Figure 10A)**

Technique Tip: Make sure the blade is kept parallel to the trajectory of the guide and 4mm Blocker Pin in the sagittal plane to ensure the posterior portion of the cut is not below the projected level of the transverse resection.

Prior to making the transverse resection, a retractor should be used to protect the MCL from the saw blade.

With the knee in 90° of flexion, the transverse resection should be made with a 1.27mm x 12.5/13mm x 90mm oscillating sawblade. **(Figure 10B)** The thickness of the sawblade is important to ensure the cuts are well-controlled via the guide slots throughout the procedure.

Figure 11A

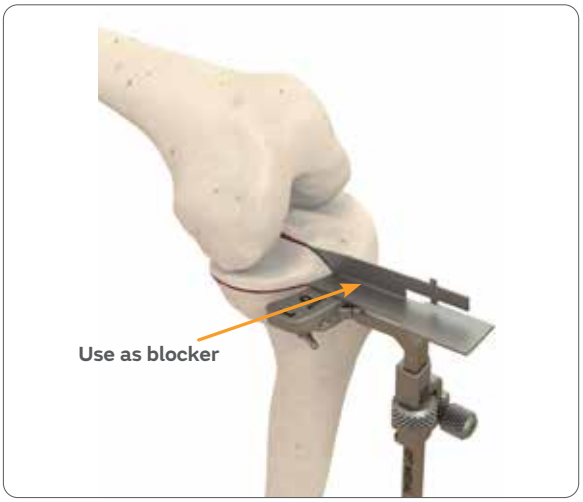


Figure 11B

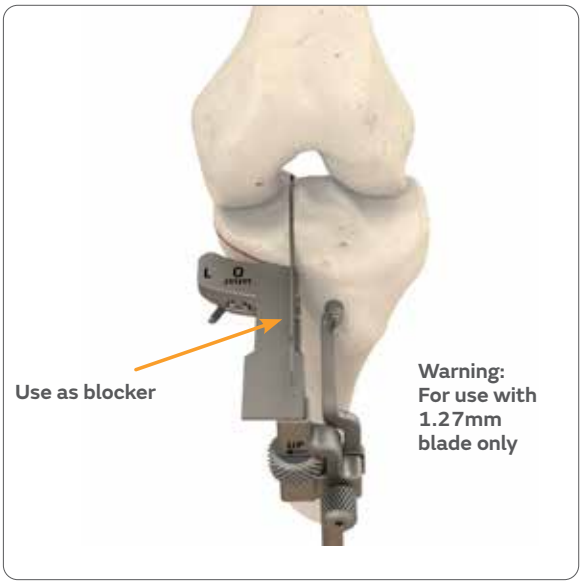


Figure 11C

Method No. 2: Tibial Resection with Non-Slotted Tibial Tower using 1.27mm sawblade or Angel Wing as a blocker

Using the top surface of the Modular Tibial Cutting Block as the guide, use the 1.27mm sawblade to perform the transverse resection **(Figure 11A)**. Ensure the cut traverses slightly more lateral than planned trajectory of the sagittal cut. **(Figure 11B)** Disconnect the blade and leave it in place on the lateral margin of the transverse cut, just below the planned sagittal resection. The 1.27mm blade will serve as a blocker to ensure no over-resection occurs. Alternatively, the Angel Wing may be inserted into the transverse cut and used as a blocker. With a blunt tipped single-sided reciprocating sawblade perform the sagittal resection, until sawblade contacts the blocker.

Technique Tip: Make sure the reciprocating blade is kept parallel to the trajectory of the guide in the sagittal plane to prevent over-resection and notching posteriorly.

The surface of the tibial resection should be assessed visually, and any unresected bone should be removed using the Rasp. **(Figure 12)**

Technique Tip: The Tibial Tray is designed for non-cemented or cemented use. When used in a non-cemented construct, care should be taken to ensure the tibial resection is flat and will allow for intimate contact between the Tibial Tray porous surface and the bone. This will promote a greater degree of osseointegration. In some cases, it may be helpful to use the Rasp at the corner of the two resected surfaces to remove excess bone. Any gap between Tray and bone may result in poor integration. The Rasp has both coarse and fine surfaces.

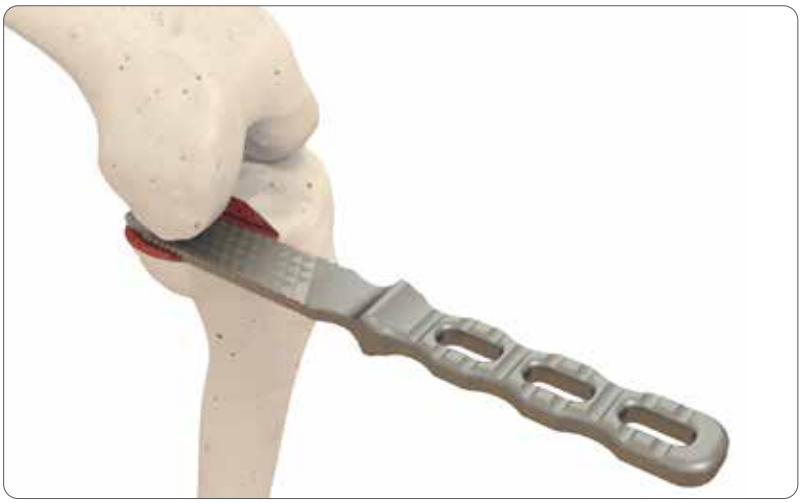


Figure 12

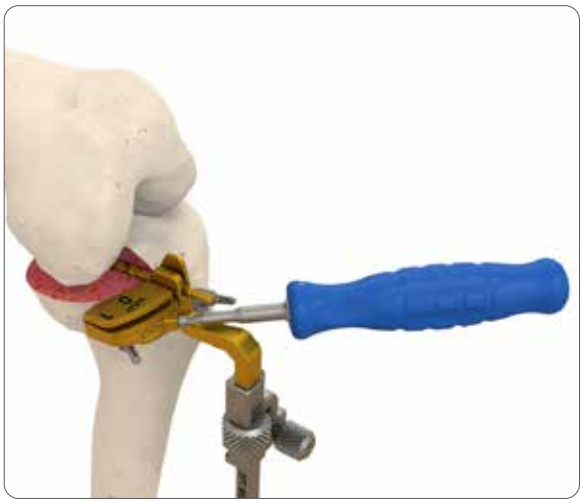


Figure 13

Figure 14

Figure 15

Tibial Resection Assessment (Step 2)

Once the cut is complete, the modular Tibial Cutting Block can be removed by loosening the screw. Screw is captured in Guide, Do Not Remove. **(Figure 13)** This allows for better visualization of the resected tibia. The resected bone may be removed with general surgical instruments (osteotome/kocher) as needed. **(Figure 14)**

With the tibial resection instrumentation still in place, and the knee at 95° of flexion, the thin end of Insert Sizer should be inserted into the joint to assess the ligament tension. The thin end of the Insert Sizer is intended to match the thickness of the final tibial implant including the plastic Tibial Insert. Choose the Sizer that achieves the appropriate amount of ligament tension. **(Figure 15)**

Sizer Height(mm)	Sizer and Trial Color
9	Orange
10	Purple
11	Yellow
13	Green

Figure 16A

Figure 16B

Figure 17

Figure 18

If the 9mm Insert Sizer cannot be inserted, then additional tibial resection may be necessary. Re-install the desired modular Tibial Cutting Block into the Tibial Tower and tighten the screw. **(Figure 16A/16B)** The blocks are available in 0mm, +1mm, and +2mm increments, with (+) corresponding an increase in amount of bony resection.

Note: The resection level of the top of the Guide surface with no Tibial Cutting Block installed is +4mm. Use an oscillating saw to complete the resection. Reassess the ligament tension with the insert sizer and record the thickness/color for optimum ligament tension.

Once the amount of ligament tension is appropriate, remove the 4mm and 3.2mm Pins and the tibial instrumentation can be removed.

Technique Tip: If the 9mm Insert Sizer cannot be inserted, it may be helpful to use the 6/7 or 8/9 Compression Block to measure the size of the gap to determine how much additional bone needs to be removed.

Alternative Method: If the tibial resection instrumentation was removed from the tibia and additional tibial resection is necessary, the Re-Cut Block may be utilized for resecting more tibial bone. **(Figure 17, 18)**

Re-Cut Blocks are offered in +2mm and 2° Posterior Slope versions.

Ligament Balancing and Femoral Resection (Step 3)

After tibial resection is complete, femoral resection should be made with the Tensor Blocks in place. The Tensor Blocks are designed to provide ligament tensioning during resection of the femoral condyle. They are offered in both small and large options and should be selected based on patient anatomy.

Tensor Block thickness should be selected to match the thickness and color of the Insert Sizer used in the previous step.

In addition, optional Tensor Shims are available in 1/2/3/4/5mm thicknesses and are intended to fill any excess space resulting from bone loss or defect that may be present on the distal femoral condyle. Snap the Shim onto the top of the Tensor block as necessary. **(Figure 19)**

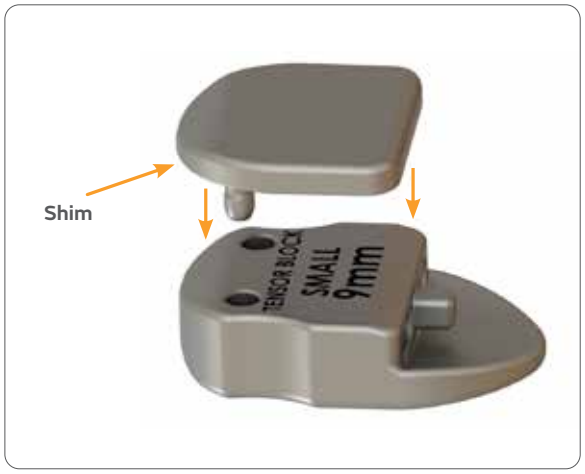


Figure 19

Note: The Tensor Shim should only be installed on the top of the Block as shown in Figure 19. Installation on the bottom of the Block will result in errors in the amount of bony resection and ultimately affect the ligament balancing.

Sizer Height(mm)	Sizer and Trial Color
9	Orange
10	Purple
11	Yellow
13	Green

With the knee in extension, the Tensor Block (with Shim as required) should be inserted using the Quick-connect Handle. **(Figure 20A/20B/20C)** To attach, make sure the Connection-Arm is oriented on the left-hand side when inserting into the Tensor Block. The Tensor Block should sit flat on the tibial resection and contact the lowest point on the distal femur when the knee is in extension. Press button to release the Quick Connect Handle.

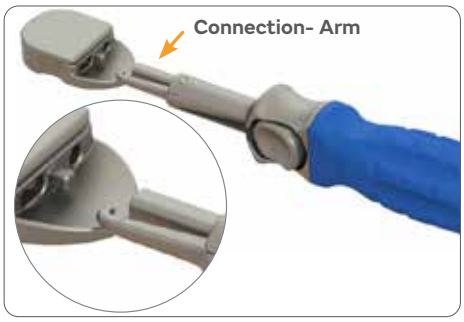


Figure 20A

Figure 20B

Figure 20C

Figure 21

Figure 22

Once inserted, ligament balancing should be assessed by applying a valgus stress to the knee. **(Figure 21)** If excess laxity is present, thicker modular Distal Tensor Shims should be added to the Tensor Block until the joint tension is found to be appropriate. **(Figure 22)** The use of the Tensor Shim allows the user to appropriately re-tension the ligaments and subsequently distalize the femoral resection to account for any bone or cartilage loss that may be present on the distal femur.

Once balancing is complete, the Handle should be disconnected and removed. The Distal Femoral Cutting Block should be inserted into the Tensor Block with the appropriate Shims for ligament balance. **(Figure 23)** 3.2mm Threaded Pins should be utilized to secure the Block to the femur. **(Figure 24A/24B)** Ensure the Distal Femoral Cutting Block is in contact with anterior femur and that the Tensor Block is flat on the tibia.

Note: The Distal Cutting Block comes in both Standard and Long options. It is typical to start with the Long version as it provides the most stability. If this version does not fit the anatomy however, the Standard version can instead be selected.

Figure 23

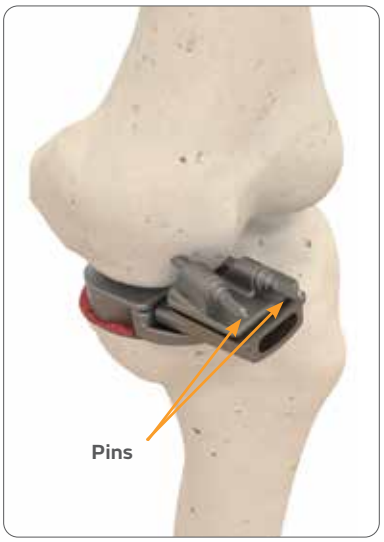


Figure 24A

Figure 24B

Figure 25A

Figure 25B

Prior to making the femoral resection, long limb alignment may be verified using the Extramedullary (EM) Guide with EM Rod and EM Rod with Coupler. **(Figure 25A/25B)** Limb alignment may be adjusted by changing the thickness of the Tensor Shim. Studies of partial knees have shown that a slight under-correction correlates with implant survivorship.[7,8]

Technique Tip: The methods used for adjusting limb alignment are different for a partial knee replacement when compared to a TKA procedure. In a traditional TKA, the angle of tibial and femoral resections results in changes in the post-operative varus/valgus alignment. In a partial knee, the composite thickness of the prosthesis relative the composite thickness of resected bone determines post-operative varus/valgus. As it relates to this system, a thinner Tensor Shim would result in a greater amount of distal femoral bone being resected, thus shifting the alignment more towards varus. A thicker Shim would result in less bony resection, thus more valgus correction.

Figure 26A

Figure 26B

Alternative Method

The EM Rod and EM Rod with Coupler may be used in conjunction with the Insert Sizer for checking long-limb alignment. **(Figure 26A/26B)** Note that the rod will be offset medial with this technique and will not align with the femoral head.

Figure 27

With the knee in full extension, the distal femoral resection should be made with an oscillating sawblade [1.27mm x 12.5/13mm x 90mm]. **(Figure 27)**

Figure 28A

Figure 28B

Distal Femoral Resection Gap Assessment (Step 4)

With the joint in 5° flexion, place the thick end of Insert Sizer into the joint to confirm the distal femoral resection. **(Figure 28A/28B)** Applying a slight valgus stress will aid in determining the appropriate joint tension. Select the appropriate thickness Insert Sizer until the ligament tension feels adequate. Re-check the flexion gap as needed. Ensure the Sizer sits flush on the resected surfaces of the femur and the tibia when taking the measurement.

Sizer Height(mm)	Sizer and Trial Color
9	Orange
10	Purple
11	Yellow
13	Green

Technique Tip: The thinnest insert size offered is 9mm. This represents the composite thickness of the implant construct including the thinnest tibial component. If the 9mm Insert Sizer (orange) is difficult to insert in extension and you have checked that the posterior horn of the medial meniscus has been completely removed, then additional bone should be resected from the femur using the +2mm Re-Cut Block.

Note: Utilize Sizer thickness and color for all subsequent steps.

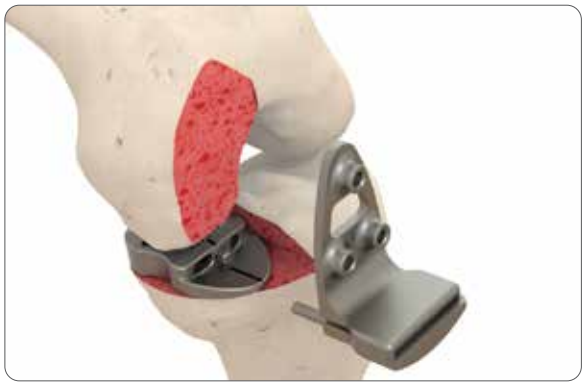


Figure 29A

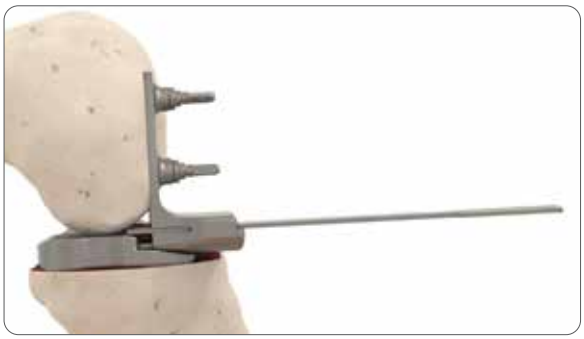


Figure 29B

Figure 30A

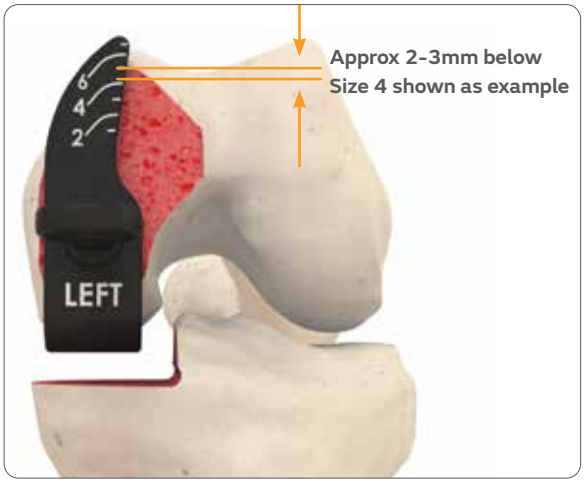


Figure 30B

Alternative Method

If it is determined that the flexion space is tight relative to the extension space, it may be helpful to resect additional bone from the posterior femur. The Femoral Posterior Prep Guide allows one to increase the laxity of the flexion space without taking additional tibial bone. With the knee in flexion, the Tensor Block may be re-inserted. The Posterior Prep Guide is then assembled to the Block **(Figure 29A/29B)** and pushed flush to the distal femoral cut. Once Pins are placed, an additional 1mm of posterior femur may be removed using the saw, thus alleviating the flexion tightness.

Femoral Sizing (Step 5)

Place the Femoral Sizer on the resected femur in flexion. Measure the approximate femoral size by reading graduated markings. **(Figure 30A/30B)** Look at the highest (most anterior) point on the resected femoral surface as a reference, then select the size that is one size below that point. This spacing prevents anterior overhang of the Femoral Component.

Additionally, the Femoral Sizer is an approximate measurement only. Final sizing will occur in the next step with the Posterior Cutting Block.

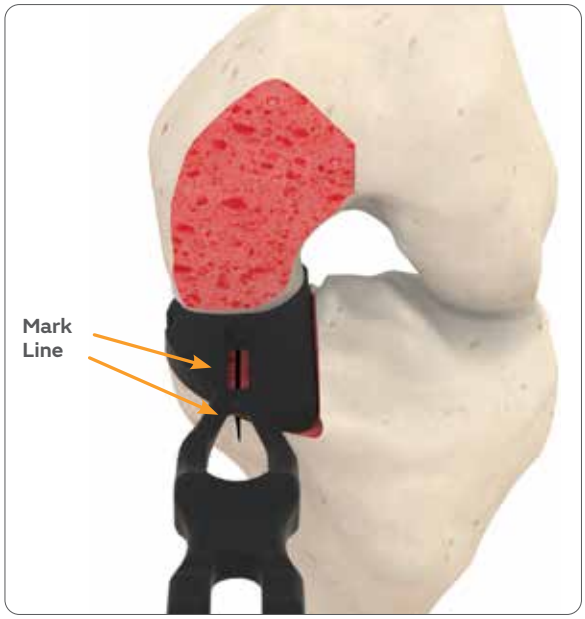


Figure 31A

Figure 31B

Tibial and Femoral Alignment Marking (Step 6)

Appropriate M/L alignment of the femoral and tibial components reduces the chances of edge loading of the tibial bearing and may improve implant tracking.

The ENGAGE◊ Partial Knee System allows for precise M/L positioning and improved femoral-to-tibial component tracking throughout the range of motion via the Tibial Marking Guides. Previous studies have demonstrated that aligning the contact point of the femoral prosthesis with the **central weight bearing line** of the tibia results in better alignment of the components and improved patient outcomes.[9]

With the knee in flexion, place the Tibial Centerline Marking Guide over the resected tibia. Align the Guide with the medial border to maximize cortical coverage, while ensuring the long axis of the Guide is parallel with the sagittal plane. Using a Viscot Medical 1460SRL Sterile marking pen, mark the centerline on the tibial resection and the adjacent anterior tibia through the slot. **(Figure 31A/31B)**

The centerline of the tibial component is transferred to the femur via the Femoral Marking Tower.

With the knee in 95° flexion, insert the thin end of the Insert Sizer and visually align the central slot of the Insert Sizer with the markings on the tibia **(Figure 32)** created in the previous step. Assemble the Femoral Marking Tower to the Sizer and slide forward to contact the distal femoral cut surface. **(Figure 33A, next page)**

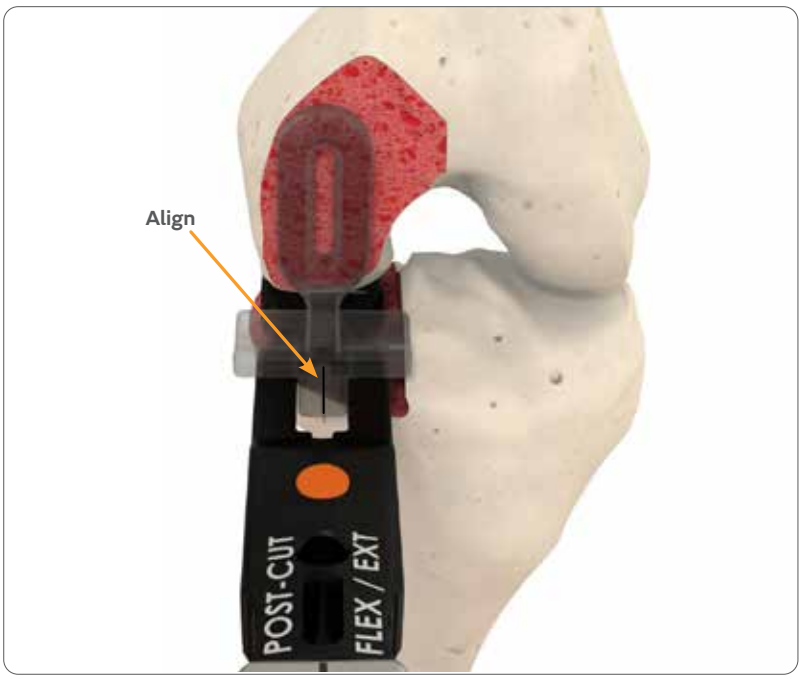


Figure 32

Figure 33A

Using a Viscot Medical 1460SRL marking pen, place a vertical mark on the femoral distal resection using the Marking Tower as a guide. **(Figure 33B)** This mark represents the approximate centerline of the Femoral Component in flexion.

Figure 33B

Figure 34A

With the knee in extension, install the thick end of the Insert Sizer into the joint. Visually align the central slot of the Insert Sizer with the existing markings on the tibia. Using the center groove on the Insert Sizer, apply a mark to the anterior femur. **(Figure 34A/34B)** This mark corresponds to the approximate M/L location of where the Femoral Component will contact the Tibial Insert in extension.

The marks will provide a guide for placing the Posterior Cutting Block in a later step.

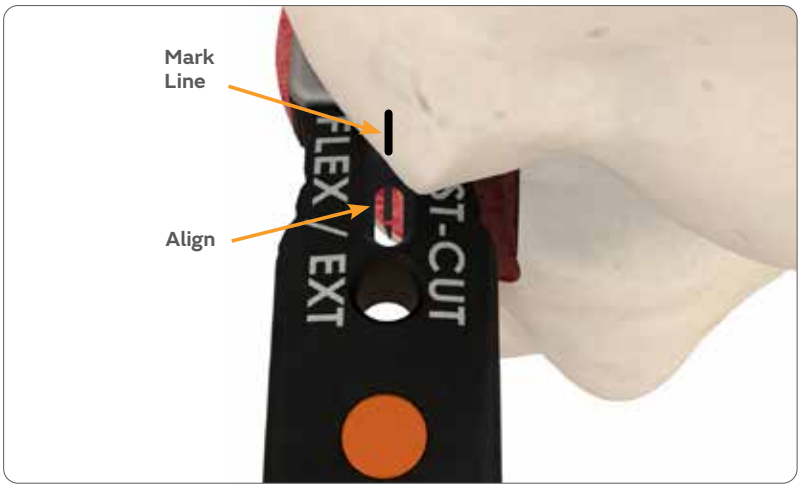


Figure 34B

Posterior Femoral Resection and Peg Drilling (Step 7)

Select the same Tensor Block For Rotation thickness and color that matches the thickness measured with the Insert Sizer in the previous steps. This ensures the flexion and extension spaces are balanced. The Tensor Block For Rotation are all color-coded to match the Insert Sizer thicknesses.

Technique Tip: Remove any remaining posterior meniscus prior to inserting the Tensor Block For Rotation. The meniscus may impinge upon the Tensor Block, preventing it from being fully inserted. This could prevent the Posterior Cutting Block from sitting flush on the Distal Femoral Cut.

With the joint in 95° of flexion, insert the Tensor Block for Rotation using the Quick-Connect Handle into the joint space. **(Figure 35/36A/36B)** Lift the femur anteriorly (superiorly) with the Tensor Block in place to ensure that there is no gapping and the flexion space is appropriately tensioned.

Technique Tip: Align the centerlines on the Tensor Block with the centerlines created on the tibia and distal femur. This will help to locate the Tensor Block in the correct central position.

Figure 35

Figure 36A

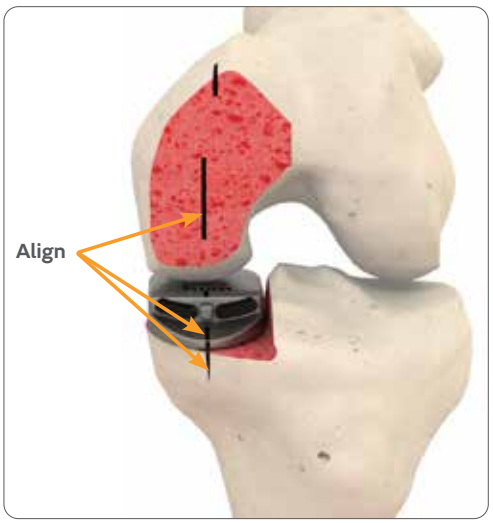


Figure 36B

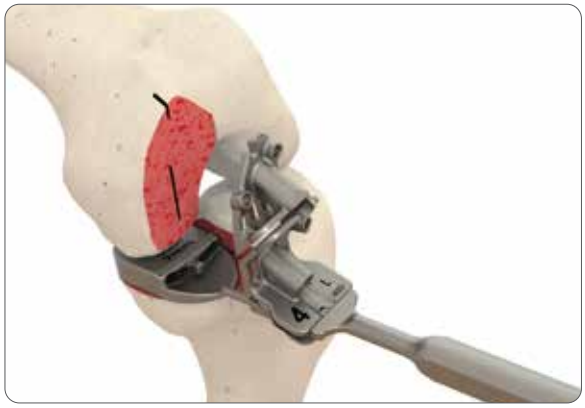


Figure 37

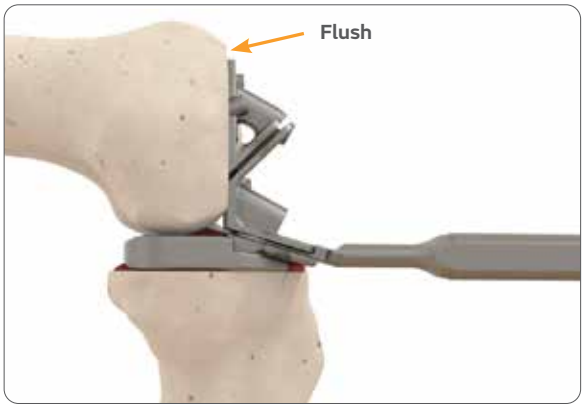


Figure 38

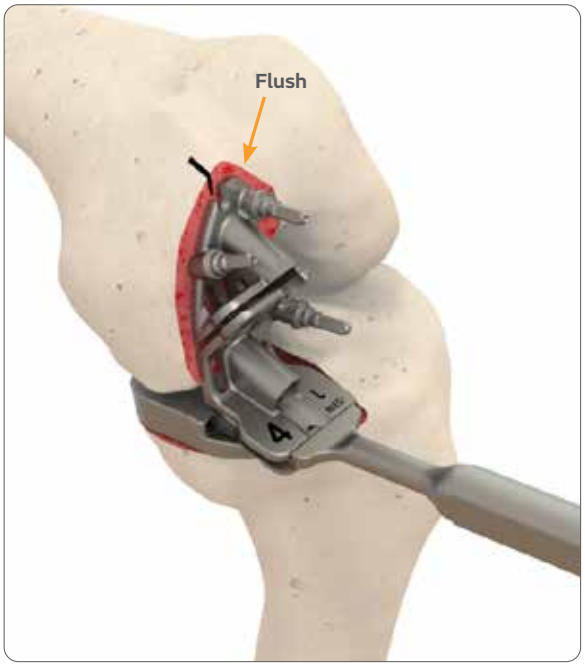


Figure 39

Remove the Quick-Connect Handle from the Tensor block. Next, attach the Posterior Cutting Block Handle to the Posterior Cutting Block by inserting it into the posterior cutting slot **(Figure 37)**. Insert the Posterior Cutting Block into the Tensor Block **(Figure 38)**.

Important Step: Once inserted, align the Posterior Cutting Block so it is completely flush with the surface of the distal femoral resection. **(Figure 39)**

Critical Note: The flexion angle of the knee may need to be adjusted slightly until the Posterior Cutting Block is flush on the femoral resection while the Tensor Block is flush on the tibia resection. Any gaps could lead to a shift in femoral cuts, leading to poor femoral implant fit and gap balancing. 3.2mm Pins are single use only.

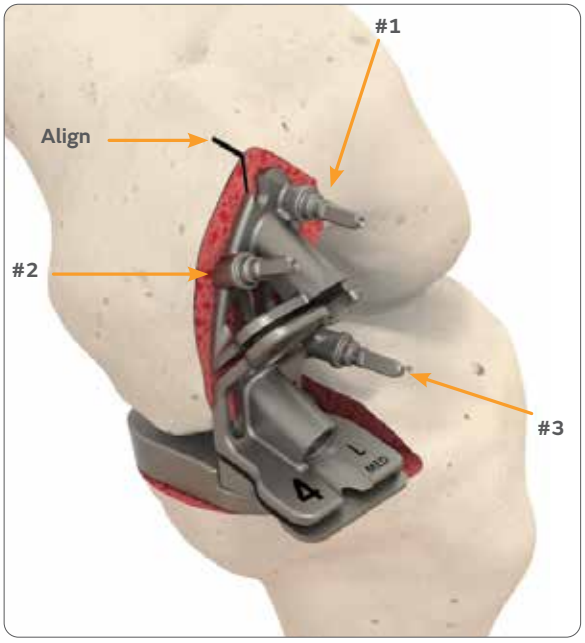


Figure 40A

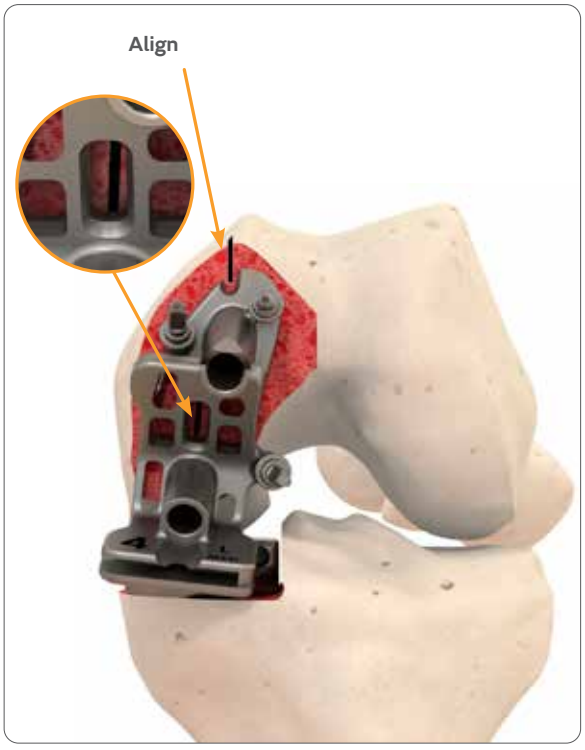


Figure 40B

Technique Tip: The Posterior Cutting Block matches the shape of the distal section of femoral prosthesis. The M/L positioning of the Block should be assessed prior to placing any pins. Visually examine the margins of the Block to ensure there is a rim of exposed bone anteriorly and medially to the Block. **(Figure 40B)** Reposition the construct as necessary to maximize femoral coverage without inducing component overhang on the medial or lateral margins. If this is not possible, a smaller sized Cutting Block should be selected. It is important to ensure that the Cutting Block is sitting flat on the surface of the femoral resection surface prior to placing the 3.2mm Threaded Pins.

Femoral anatomy varies from patient-to-patient. To achieve increased femoral coverage and improved femorotibial tracking throughout the range of motion, it may be beneficial to rotate the Femoral Component slightly to match the shape of the resected femur.

When the Posterior Cutting Block is used in conjunction with the Tensor Block for Rotation, up to an additional 5° of external (or internal) rotation of the Posterior Cutting Block is possible.

Using the markings created on the anterior and distal femur as a guide, align the Cutting Block by translating and rotating it to align the marks in the anterior notch and central window of the block. **(Figure 40B)** The anterior mark should align with the anterior notch in the Cutting Block, while the distal mark should fall within the vertical window when appropriately aligned. The anterior mark determines the location of the Femoral Component in extension, while the distal mark position the Femoral Component in flexion. Once the location is confirmed and the Block is flush against the distal cut bone, place the 3.2mm Threaded Pin in the order shown in **Figure 40A**. A 'lug-nut method' for tightening the pins is recommended. Place the first two pins so the heads are not completely flush, then place the third pin all the way down. Come back and complete tightening on pins one and two.

Note: The markings are designed to serve as additional guide for visual verification of component positioning only. Femoral coverage and component M/L overhang should be assessed as the final means for positioning.

Figure 41

Figure 42

Figure 43
Cut Posterior 1st

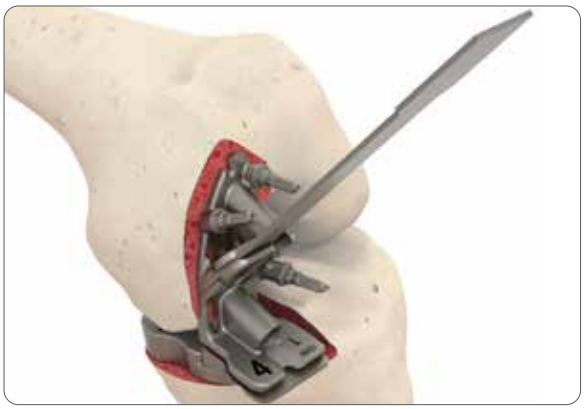


Figure 44
Cut Chamfer 2nd

Once the Posterior Cutting Block has been pinned to the femur and bone apposition/alignment have been confirmed, drill the posterior peg hole and anterior peg hole using Femoral Drill with power **(Figure 41/42)**. Continue until the drill shoulder contacts the stop on the Cutting Block to ensure the correct depth has been achieved.

Using 1.27mm x 12.5/13mm x 90mm oscillating sawblade, first resect the posterior femoral condyle. **(Figure 43)** followed by the chamfer resection. **(Figure 44)** Using a sawblade with correct thickness is important to ensure the cuts are well-controlled via the guide slots throughout the procedure.

Thoroughly inspect the resected surfaces as well as along the edge of the inter-condylar notch. The Rasp may be used to clean up any remaining bone that was not removed with the saw. The resected surfaces should be flat and clear of debris to ensure a tight fit with the Femoral Component. Irrigation should be used as necessary to clear out any bone that may have entered the drill holes.

Note: Take care to avoid damage to the MCL and ACL during resection. A retractor may be used to protect the MCL as necessary.

Warning: For use with 1.27mm blade only.

Technique Tip: A tight fit of the femoral prosthesis to the bone is important for promoting osseointegration. Following the femoral preparation steps in the order described above will facilitate more repeatable cuts and ultimately a better fit.

Posterior Femoral Resection Gap Assessment (Step 8)

After completing the femoral resection, a final check of the ligament tension may be necessary. Install the thick end of the Insert Sizer with the joint in approximately 110° of flexion to verify posterior gap. **(Figure 45A/45B)** Ensure that the Insert Sizer is flush against both the posterior femoral cut and tibial resection. Applying a slight valgus stress will aid in determining the appropriate ligament tension.

Next with the joint in approximately 5° flexion, as a final check, place the thick end of the same Insert Sizer into the joint to re-confirm the distal femoral resection. **(Figure 46A/46B)** Adjust the joint flexion until resection surfaces are sitting flush on the Sizer. The knee should feel balanced using the Insert Sizer in flexion and extension.

If the knee does not feel balanced in flexion and extension utilize the same Insert Sizer, refer to the Knee Balancing Algorithm. **(Page 50)**

Figure 45A

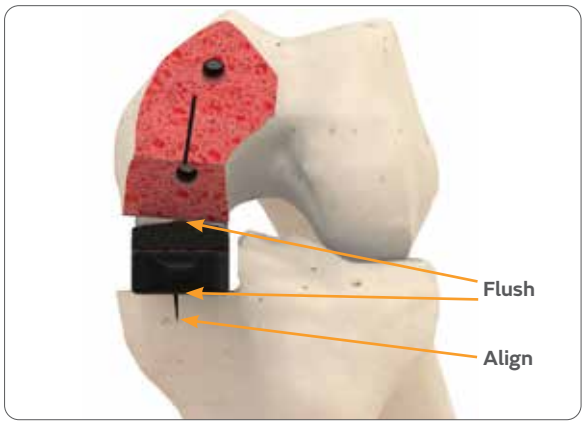


Figure 45B

Figure 46A

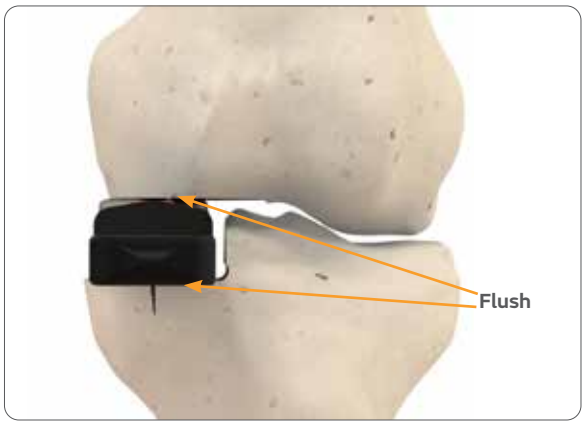


Figure 46B

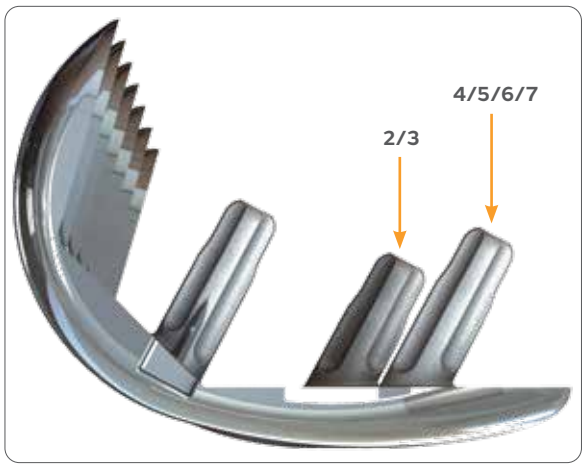


Figure 47

Femoral Downsizing

If the ligament tension in flexion is determined to be too tight, but the ligament tension in extension remains appropriate, it is possible to resect additional posterior femur and downsize the Femoral Component.

Re-cutting the posterior resection only will allow for the next smaller size to be implanted onto the resected surfaces, without effecting the gap balance. The Femoral Downsizing Guide allows for approximately 1.3mm (approximate thickness of the sawblade) of additional bone being resected posteriorly when moving to the next smaller size. The resulting posterior joint laxity is increased proportionally.

Technique Tip: The ENGAGE Partial Knee System is designed for simple downsizing compatibility, with Femurs having common peg positions. Sizes 2/3 all have the same peg locations, while 4/5/6/7 have commonality. **(Figure 47)** Additionally, all femur sizes have constant thicknesses for the distal and posterior condyles (7mm total including the coating thickness).

There are two types of Downsizing Guides. When downsizing from a Size 3 or from Sizes 5 through 7, use the 2-3 / 5-8 Downsizing Guide. Place the Guide on the distal and posterior femoral resections to locate the Guide **(Figure 48A/48B/48C)** and ensure flush contact on both surfaces.

Technique Tip: As an option, the Compression Block of the appropriate thickness may be used to ensure intimate contact between the existing posterior cut and the Downsizing Guide. Prior to placing the pins, place the Compression Block below the Guide to compress the guide against the posterior femoral cut. **(Figure 48B)**

Once the Guide is stable and the 3.2mm pins have been installed, place the oscillating saw into the slot and recut the posterior femur. This will remove enough bone to allow for the next smaller size Femoral Component to be used.

Downsizing Guide - 2-3 / 5-8

Figure 48A

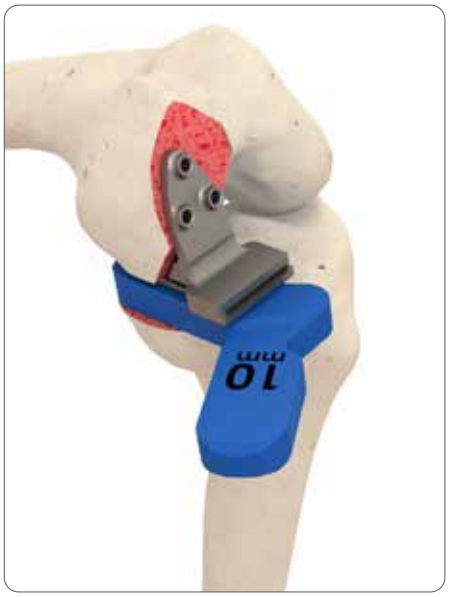


Figure 48B

Figure 48C

When down-sizing from Size 4 to a Size 3, use the Size 4 Only Femoral Downsizing Guide. **(Figure 49A/49B/49C/49D)** Insert the alignment pegs into the holes until the Guide is flush with the distal femoral resection. Insert 3.2mm Threaded Pins until the Guide is stable.

When down-sizing from the Size 4 to the Size 3, a new peg hole must also be drilled using Size 4 Only Femoral Downsizing Guide. Once the guide is stable, using the femoral drill, plunge through the central hole on the Guide until the drill stop is in contact with the Guide. Only Size 4 Only Downsizing Guide requires the peg drilling step. Next place the oscillating saw in the slot and recut the posterior femur. In this case, it may be beneficial to pack auto-graft into the previous anterior peg hole to provide additional stability, prior to placing the final femoral implant.

If knee balancing has still not been achieved, follow tips in Knee Balancing Algorithm. **(Page 48)**

Downsizing Guide - Size 4 Only

Figure 49A

Figure 49B

Figure 49C

Figure 49D

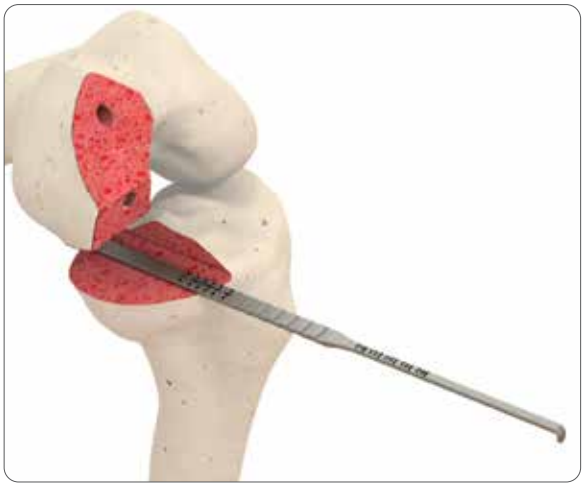


Figure 50A

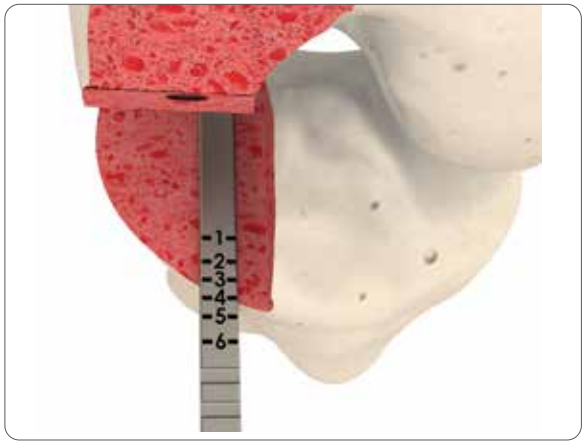


Figure 50B

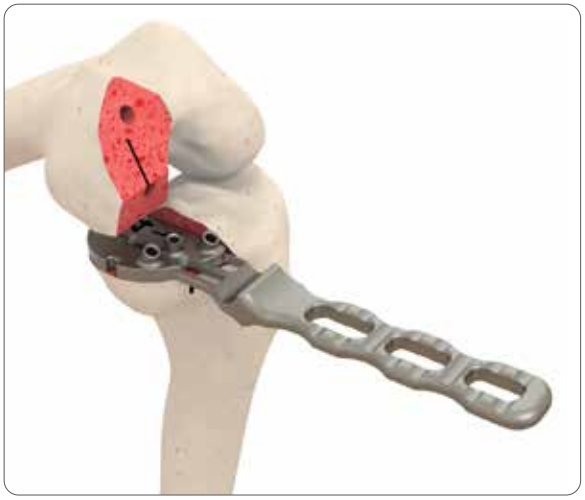


Figure 51

Tibial Preparation (Step 9)

The Tibial Tray size may be approximated using the Tibial AP Sizer Wand. Using the thick end of the AP Sizer as shown. **(Figure 50A/50B)** This provides an initial AP measurement; final sizing should be done with the Tibial Sizer.

Place the appropriate Tibial Sizer on the resected tibial surface to measure the tibia. Place the instrument initially farther posterior than the expected final position and place flush on the resected tibia. Gradually slide the instrument anteriorly, until you feel the hook make contact with the posterior aspect of bone. Visually verify the Sizer is laying flat on the bone. Align the medial and anterior surface of the tibia so they appear flush with the edges of the Sizer. Ensure the Sizer DOES NOT overhang anteriorly or medially, as it would lead to mis-sizing of the tibial component (and Tibial Anchor) and could result in possible soft tissue impingement. **(Figure 51/52)** Previous studies have shown excessive overhang of Tibial Trays used in partial knee replacement have led to poorer clinical outcomes.[10,11] Keep in mind location of the Sizer represents the final location of the Tibial Tray.

The centerline mark on the tibia may be used as an aid in positioning of the Tibial Sizer. Align the mark on the tibial resection with the slot in the Sizer. This method should only be used as a general guide however, as final sizing and positioning should be done to achieve optimal tibial coverage.

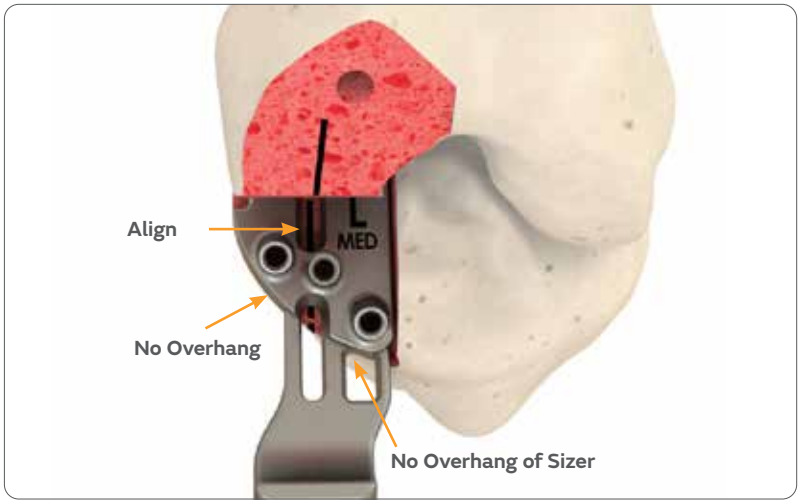


Figure 52

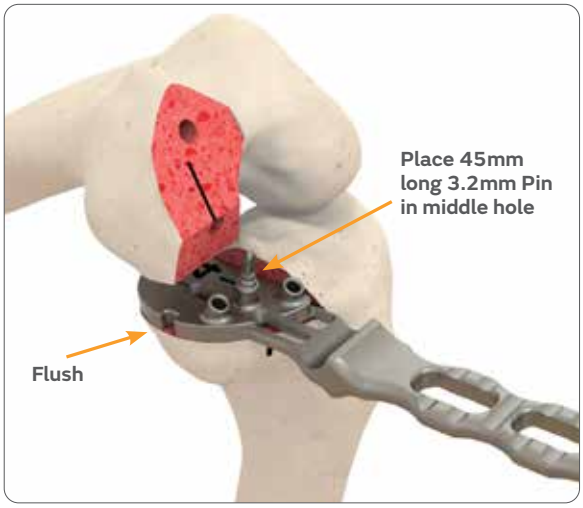


Figure 53

Once the sizing and location are confirmed, maintain stable downward pressure on the Sizer so it remains flush on the back edge of the tibia. Place the 45mm long 3.2mm Pin through the middle hole on the Sizer to stabilize the instrument. Only the 45mm long 3.2mm Pin may be used in this location, a longer pin may perforate the tibial cortex. Confirm the final location of the Sizer has not shifted during Pin insertion. The final location of the Tibial Tray will match the location and fit of the Sizer. Ensure the Tibial Sizer is flush with the tibial cut surface, especially posteriorly. **(Figure 53)** Readjust the positioning as necessary.

Note: The fit of the Sizer represents the fit of the final implant, so any gap that exists at the device-to-bone interface should be resolved prior to proceeding to the next step.

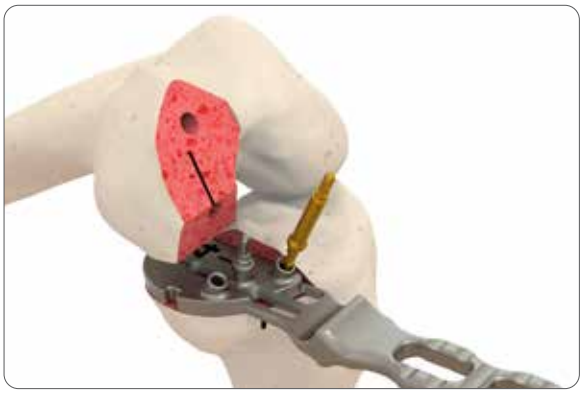


Figure 54

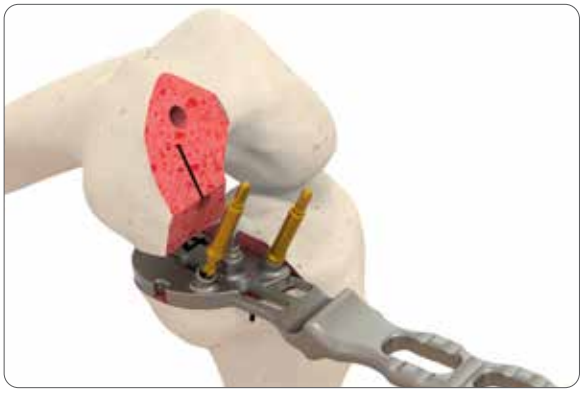


Figure 55

With the Tibial Sizer pinned in place, prepare the first peg hole with the Tibial Drill and leave in place. **(Figure 54)** Next, with a second Tibial Drill, prepare the second peg hole. **(Figure 55)**

Implant Trialing and Range of Motion (Step 10)

With the knee in flexion, align the pegs on the Tibial Tray Trial with the holes on the tibia and provide downward finger pressure for initial placement. Utilize impaction on the Curved Impactor for final Trial Tray placement. **(Figure 56A/56B)** Impact around Tray surface and especially posteriorly. Ensure the Tibial Trial is flush with the resection tibial surface and no gaps are present with visual inspection. Utilize the Angel Wing as a feeler gage to inspect posteriorly. **(Figure 57)** If a gap exists, re-adjust as necessary.

Note: Avoid excessive impaction of the of the Tibial Tray trial. Excessive impaction loads could lead to fracture of the resected tibia.

Align the Femoral Trial pegs with the holes on the femur and apply finger pressure to insert. Seat with the Femoral Impactor. Use impaction until the Femoral Trial is flush and in contact on all bony resection surfaces. **(Figure 58)**

Figure 56A

Figure 56B

Figure 57

Figure 58

Select the appropriate Insert Trial size and thickness to match the corresponding earlier gap measurements. The Insert Trials are color coded to match the Insert Sizer color utilized previously. **(Figure 59A)** Place the Insert Trial into the Tibial Tray Trial utilizing the Insert Impactor as needed. **(Figure 59B)** Manipulate the knee through the desired range of motion to assess joint stability. A Tension Gauge may be used to assess the ligament balance. The Gauge includes 1mm and 2mm thicknesses and may be placed between the Femoral Trial and Insert Trial to assess laxity in both flexion and extension. 1-2mm of gap is the recommended laxity to achieve optimum ligament balancing. **(Figure 59C)**.

Figure 59A

Figure 59B

Figure 59C

Figure 60A

Figure 60B

If a different Insert Trial thickness is needed, utilize the Removal Hook to swap out for a different thickness. **(Figure 60A/60B)** To use, insert the hook and pivot down until the catch presses against the anterior face of the Insert Trial. Lift and pull to remove Insert Trial.

Note: The trials are True-To-Size and represent the final thickness and fit of the actual implants.

Sizer Height(mm)	Sizer and Trial Color
9	Orange
10	Purple
11	Yellow
13	Green

Once the sizes are confirmed, remove the trials. The Femoral Trial is removed with the Slap Hammer. **(Figure 61A)** To engage the Slap Hammer, insert the tip into the Femoral Trial and rotate 90º. **(Figure 61B)**

The Tibial Tray Trial can be removed with the Quick-Connect Handle as needed. **(Figure 62A/62B)** The connection arm should be oriented vertically to attach. **(Figure 62B)**

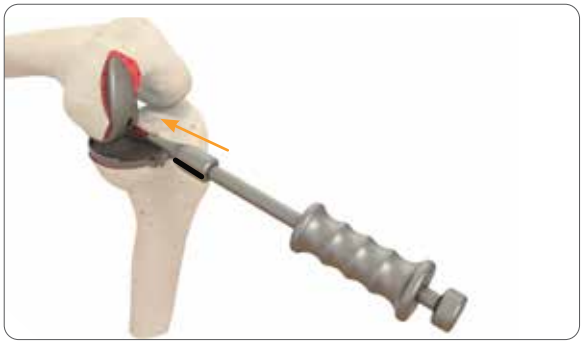


Figure 61A

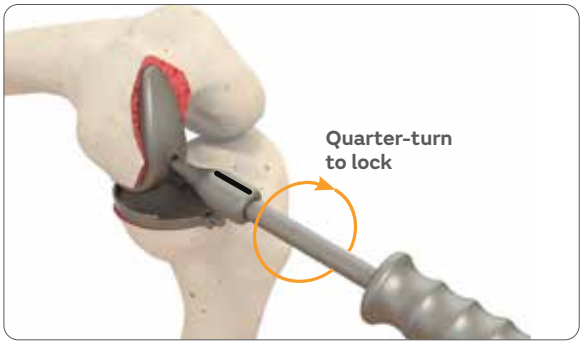


Figure 61B

Figure 62A

Figure 62B

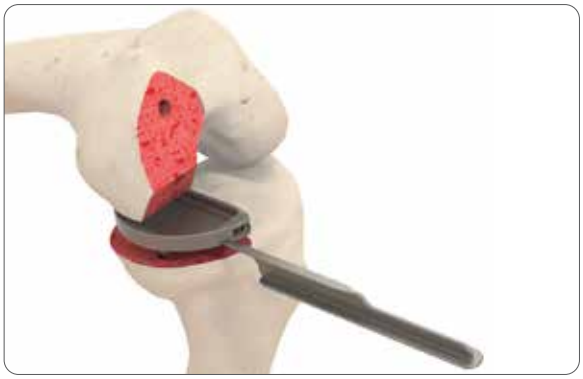


Figure 64A

Figure 64B

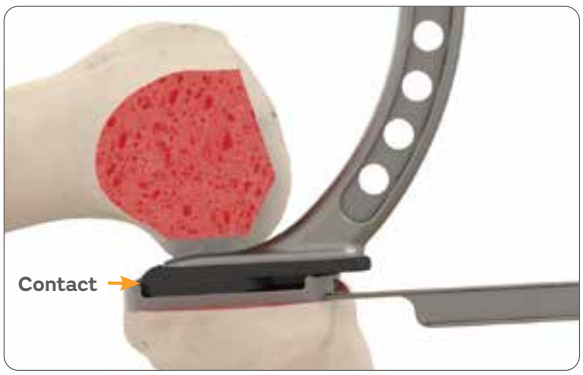


Figure 64C

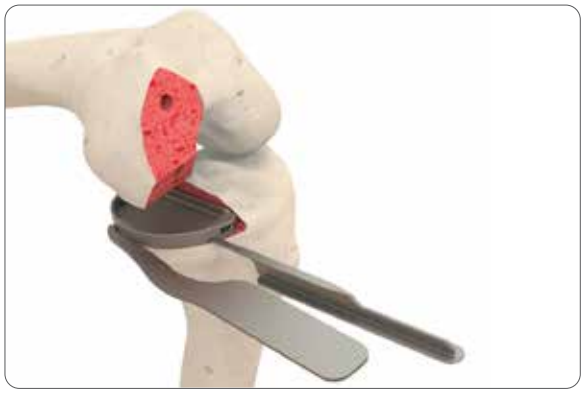


Figure 65

Tibial Tray and Tibial Anchor Implantation (Step 11)

Cementless Technique

Prior to implanting the tray, slide the thin end of the Guide Rail into the Tibial Tray. The Guide Rail helps simplify the attachment of the Anchor Guide. In the event that bone slurry is used on the porous surfaces of the implant, the Guide Rail may also be used to keep the slurry from migrating into the anchor channel during tibial tray impaction. With the knee in flexion, align the pegs on the Tibial Tray with the holes on the tibia and provide downward finger pressure for initial placement. Utilize impaction on the Curved Impactor for final implant placement. **(Figure 64A/64B)** Ensure the Tibial Tray is flush with the resected tibia and no gaps are present with visual inspection and utilizing the Angel Wing as a feeler gage to inspect posteriorly. **(Figure 65)** Continue impaction as necessary until Tray is flush. Ensure to impact around Tray surface and especially posteriorly. Intimate contact between the prosthesis and the tibial resection will facilitate osseointegration.

Technique Tip: Be sure to slide the impaction surface of the Impactor all the way posterior, so it engage on the back edge of the Tray. **(Figure 64 C)**. This will ensure impaction forces are distributed throughout the Tray.

Note: As mentioned in the Best Practices, prior to implanting the tray it is recommended that the porous surface be sprayed with saline to break the surface tension and help improve the absorptive properties of porous structure.

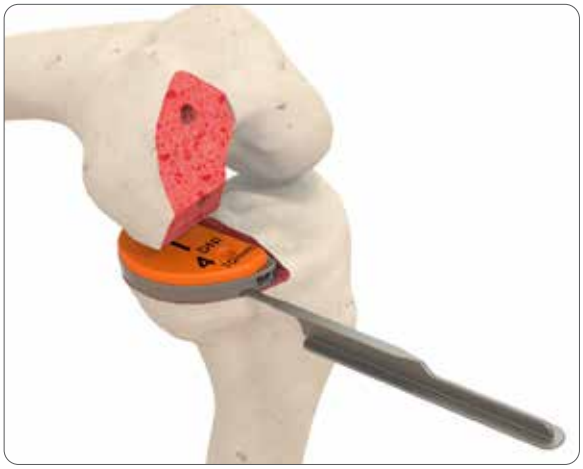


Figure 66A

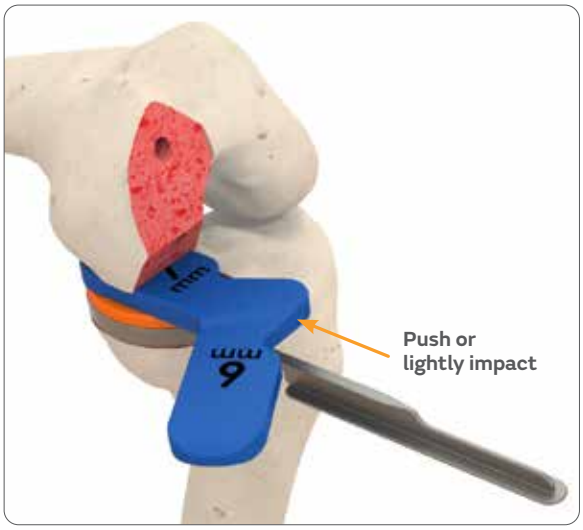


Figure 66B

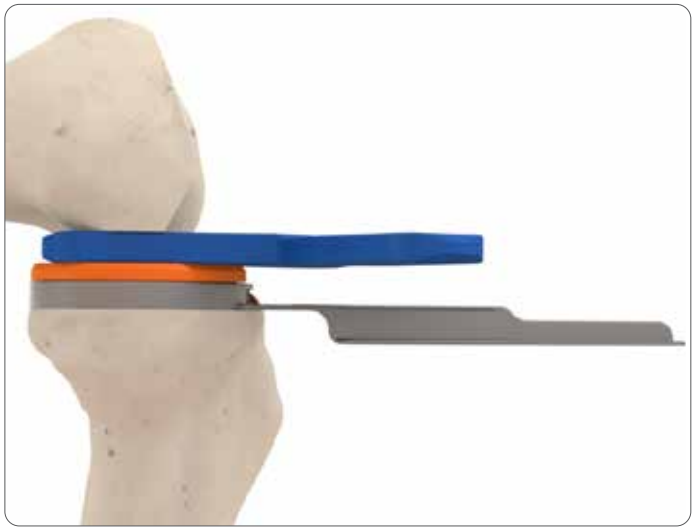


Figure 66C

With the leg in flexion, insert the desired Tibial Insert Trial. Next, while maintaining approximately 110° of flexion, select the appropriate thickness Compression Block and insert between the Insert Trial and the posterior femoral resection to create a tight fit. **(Figure 66A/66B/66C)** It is important to verify that the posterior femoral resection is parallel with the top of the Insert Trial when inserting the Compression Block. Push the compression block as far back as it will go until it stops. It may be helpful to lightly impact the Compression Block into place using the mallet to create a tightly fit construct. Increase the thickness of the Compression Block as necessary until there is no motion of the construct and the Tibial Tray is held tightly against the resected tibia. Blocks are offered in double-ended 6/7, 8/9 and 10/11 options. If the desired stability is not achieved, use a thicker Insert Trial and repeat the process.

Note: The Compression Block is intended to stabilize the Tibial Tray during Tibial Anchor preparation and insertion and is independent of the previous ligament balancing steps. Achieving a tightly fit construct provides a stable environment for Tibial Anchor insertion

Align the Anchor Guide with the Tibial Guide Rail. The T-slot in the Anchor Guide should slide easily over the Guide Rail until the Anchor Guide interfaces with the Tibial Tray. To prevent cross-threading, turn the screw initially by hand. **(Figure 67A, 67B, 67C)** Final tightening should be achieved using the Screwdriver. **(Figure 68)** Once the Anchor Guide is securely attached, remove the Guide Rail from the Tray and Anchor Guide prior to moving to the next step.

Note: Inspect the pockets on the front surface of the Tray to ensure they are free of debris prior to attaching the Anchor Guide. If debris is present, flush as necessary. Removing all debris will ensure the Guide is able to fully attach and does not loosen.

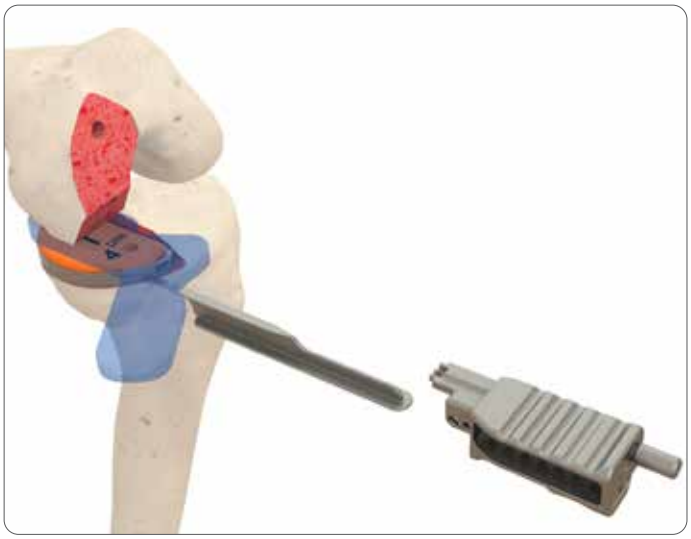


Figure 67A

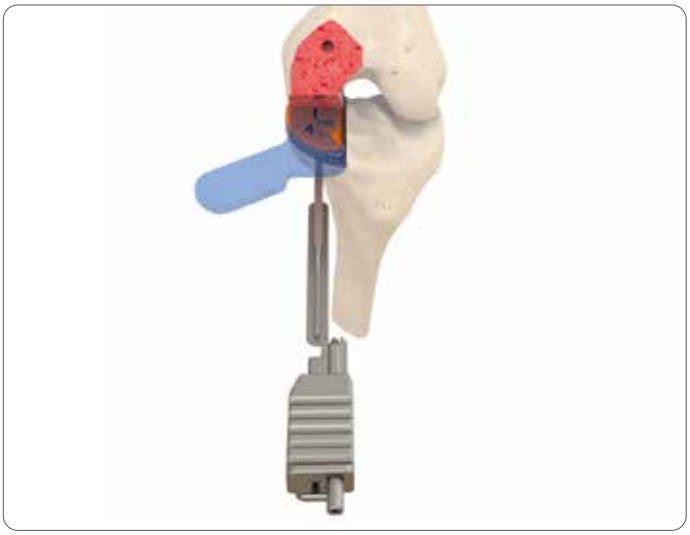


Figure 67B

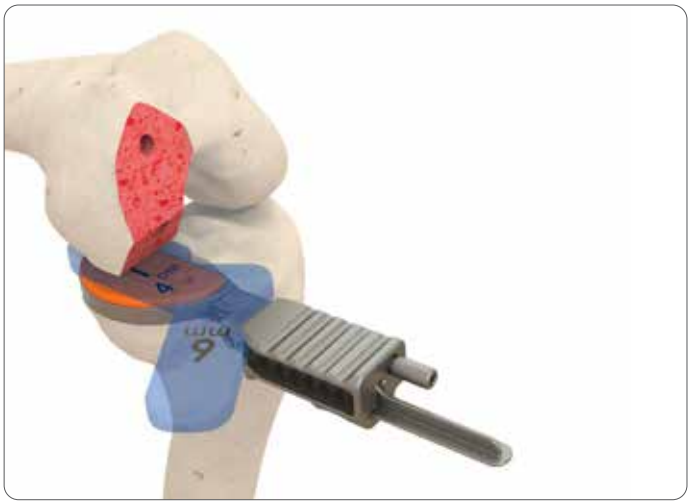


Figure 67C

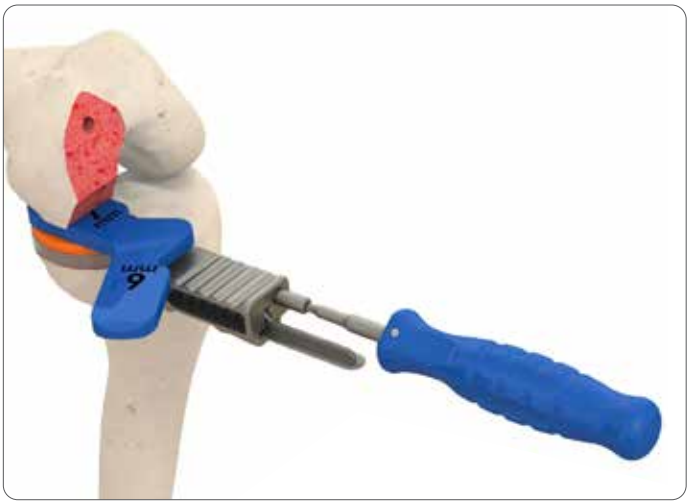


Figure 68

Technique Tip: Select the Anchor Guide based on the desired Tray size. Sizes 1, 2, and 3 Tibial Trays utilize the 1/2/3 Anchor Guide (gray), while Trays 4/5/6 use the 4/5/6 Anchor Guide (gold).

Tibial Tray Size	Anchor Guide Size	Anchor Guide Color
1	1/2/3	Gray
2		
3		
4	4/5/6	Gold
5		
6		

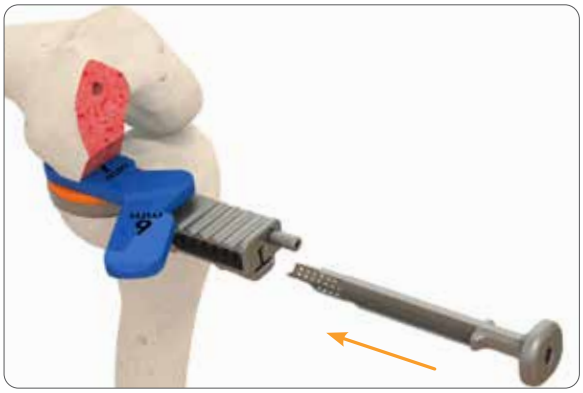


Figure 69

Verify the Tray position prior to the pilot cutting step. After the pilot cut is made the Tray position is fixed.

With the knee in flexion and the Compression Block still securely in place, insert the Pilot Cutter into the mating slot on the Anchor Guide. **(Figure 69)** While applying light finger pressure in the superior direction on the Anchor Guide, impact the Pilot Cutter into the tibia until the depth stop is reached. **(Figures 70A and 70B)** After the depth stop is reached, discontinue impacting, as further impaction may damage the instruments.

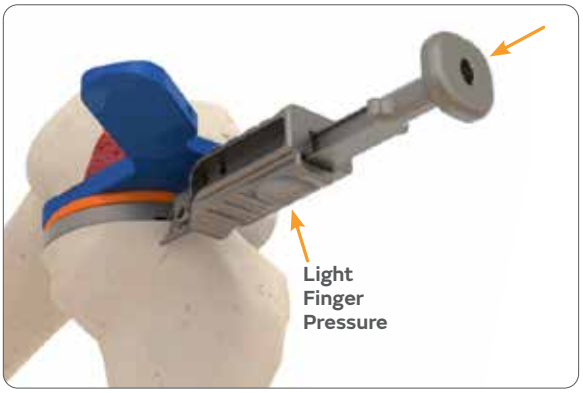


Figure 70A

Note: The Pilot Cutter creates a channel for the Anchor that extends just beyond the anterior cortex. The Pilot Cutter is sharp. Handle with care during insertion and removal

Figure 70B

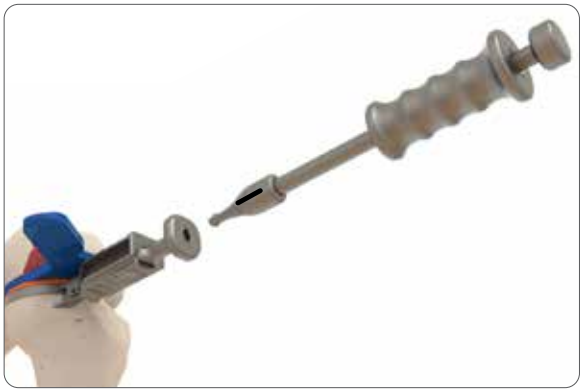


Figure 71

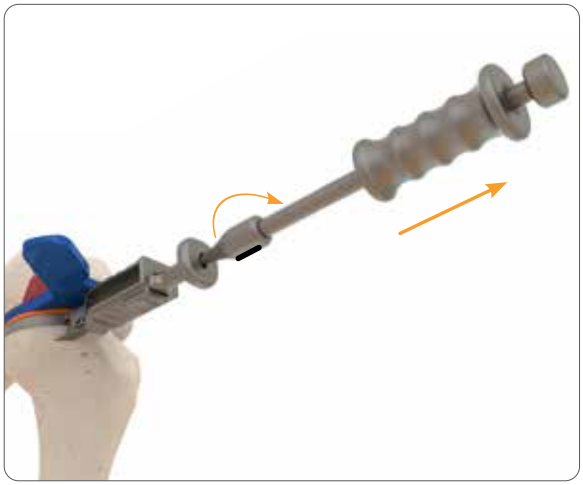


Figure 72

While stabilizing the Anchor Guide with one hand, use the Slap hammer to remove the Pilot Cutter from the bone. **(Figure 71, Figure 72)**

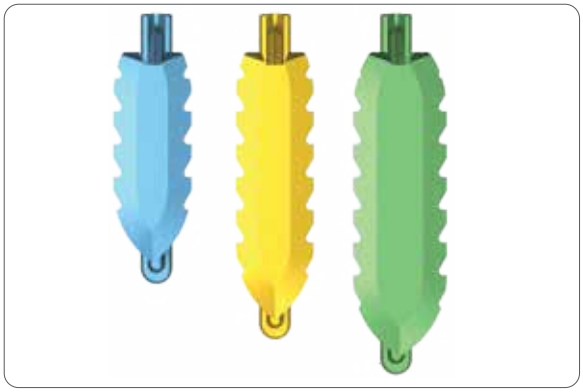


Figure 73

Select the appropriate Tibial Anchor to match the size of the Tibial Tray per the table below. The Anchors are color-coded for error-proofing. **(Figure 73)** The Tibial Anchor should not be used in conjunction with bone cement.

Tibial Anchor Sizing

Anchor Size	Tibial Tray Size
1-2	1
	2
3-4	3
	4
5-6	5
	6

Figure 74

Figure 75A

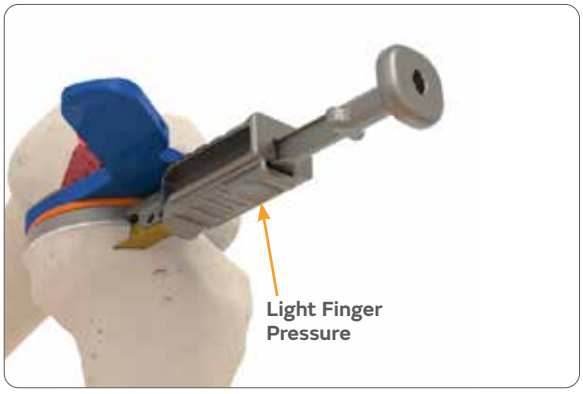


Figure 75B

Install the Tibial Anchor into the slot of the Anchor Guide. **(Figure 74)** With slight superior finger pressure on the Anchor Guide, impact the Anchor Tamp to install the Tibial Anchor. **(Figure 75A)** Install the Anchor Tamp and impact until the depth stop is reached. **(Figure 75B)** The built-in depth stop ensures the Anchor is fully inserted and locked into the Tray. **(Figure 77, next page)** Once the depth stop is reached, do not over impact the Tamp, as further impaction may damage the instruments.

Note: If an Anchor is dropped outside the sterile field or becomes damaged in any way, it should be replaced with a NEW Anchor. Be sure to select the appropriately sized Anchor to match the Tray size.

Remove the Anchor Guide before removing the Compression Block and Insert Trial from the Tray.

Note: If the Anchor Guide Screw becomes damaged or worn it may be removed and replaced. Contact your sales representative or distributor.

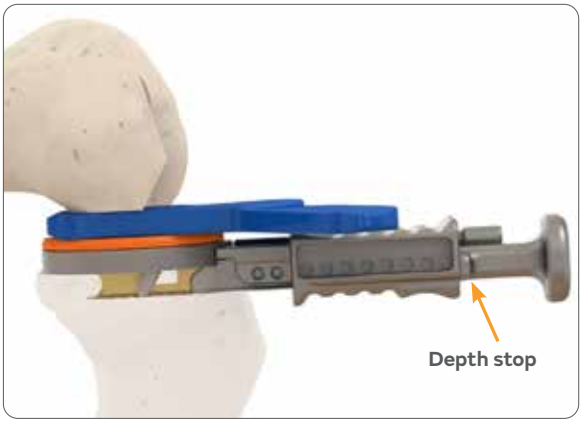


Figure 76

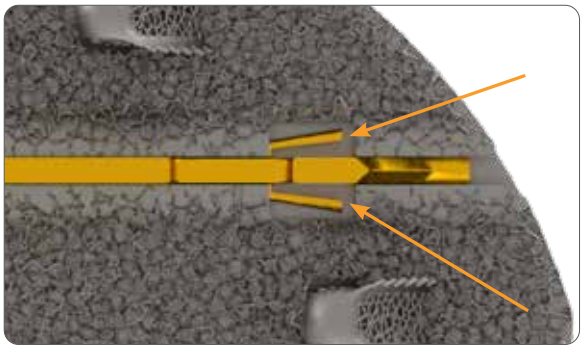


Figure 77A

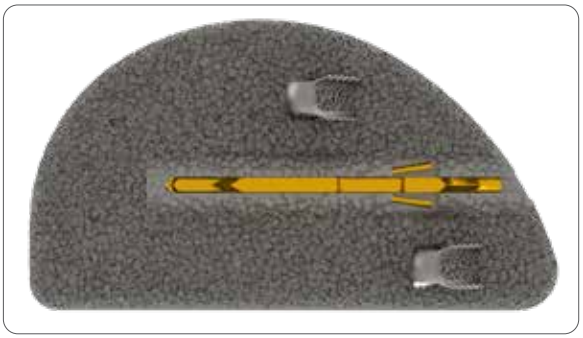


Figure 77B

The Tibial Anchor locking mechanism consists of two deformable tabs that mate with pockets interior to the Tibial Tray. The Anchor locking tabs snap into the pockets to engage the Tray. **(Figure 77A/77B)** This occurs when the Tamp is fully inserted and bottoms out on the Anchor Guide. **(Figure 76)**

Warning: If a Tibial Anchor is removed after it is inserted into the bone [see Implant Removal Technique], another Anchor should NOT be reinserted in its place. The Tibial Tray must be cemented using the standard cementing technique described.

Cemented Technique

Prior to application, use pulsed lavage to cleanse the bone surface. Utilizing standard cementing technique, apply a layer of cement to the bone contacting surface of the Tibial Tray. Apply cement to the tibial resection and align the pegs to drill holes in the tibia to position the Tray. Apply finger pressure to initially seat the Tray. Complete the insertion of the Tray using impaction with the Curved Impactor. Any extra bone cement should be removed from the edges of the tibia using general surgical instruments. Prior to moving onto the next step, confirm all cement has been cleared from the proximal pocket of the Tibial Tray and from the anterior threaded connection feature.

Note: The Tibial Anchor should not be used when cement is used for tibial fixation

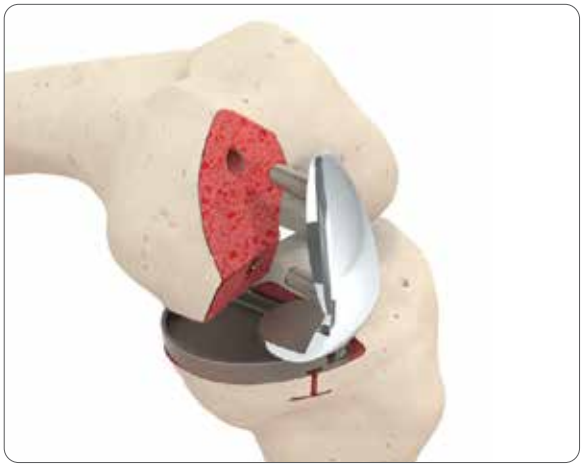


Figure 78A

Figure 78B

Figure 78C

Femoral Insertion (Step 12)

Cementless Technique

With the knee in deep flexion, place the femoral implant pegs into the drilled holes on the femur. Apply finger pressure to initially seat the implant.

The femur design includes stepped-peg geometry that aligns the implant with the drilled holes using a line-to-line fit initially at the hole interface diameter. **(Figure 78A/78B)** Once the implant is correctly aligned with the holes, use the Femoral Impactor to further advance the implant and generate press-fit on the pegs. Continue impaction until the prosthesis is flush against the bone and the final implant positioning is achieved. **(Figure 78C)**

Visually verify there are no gaps present on the bone-to-implant interface. Intimate bone contact will facilitate osseointegration of the prosthesis.

Note: As mentioned in the Best Practices, prior to implanting the femur it is recommended that the porous surface be sprayed with saline to break the surface tension and help improve the absorptive properties of porous structure.

Cemented Technique

Prior to application, use pulsed lavage to cleanse the bone surface. Utilizing standard cementing technique, apply a layer of cement to the bone contacting surfaces of the Femoral Component. Avoid contact between the polished articulation surface of the femoral prosthesis and the cement. Apply cement to the prepared femoral surface and place the implant using impaction with Femoral Impactor. Any extra bone cement should be removed from the edge of the femur using general surgical instruments. Prior to moving onto the next step, confirm all excess cement has been cleared from the articular surface.

Tibial Insert (Step 13)

Final Insert Trialing

Install the selected Insert Trial into the Tibial Tray and take the knee through a range of motion. Ensure that the knee is balanced using the Tension Gauge. **(Figure 79)** 1-2mm of laxity is recommended. Remove the Insert Trial with the Hook.

Figure 79

Insert Locking

Ensure that there is no debris or soft tissue on the superior surface of the Tibial Tray. The Insert has a posterior lip that will slide into the groove on the Tibial Tray. Use the Insert Impactor **(Figure 80A/80B/80C)** in the horizontal orientation shown to push the Insert posteriorly until it stops. (Step 1-Push Horizontally) Once the Insert stops on the posterior lip, with the Impactor in the vertical orientation (Step 2-Lock Vertically), lightly impact to lock the Insert into the Tray. **(Figure 80D/80E/80F)**

Step 1 - Push Horizontally

Figure 80A

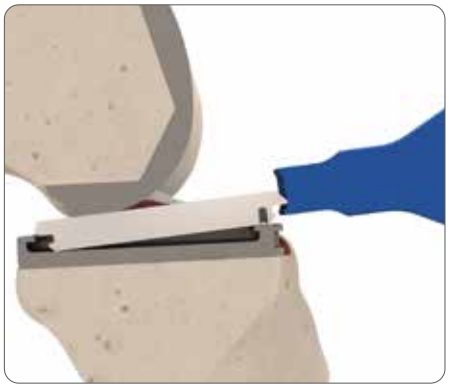


Figure 80B

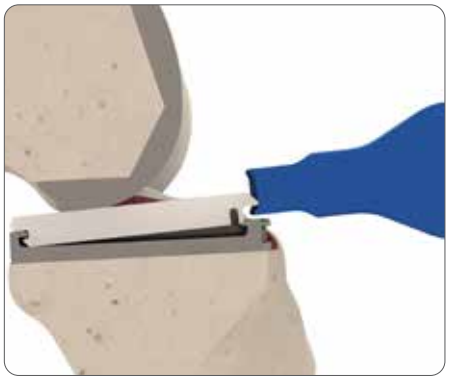


Figure 80C

Step 2 - Lock Vertically

Figure 80D

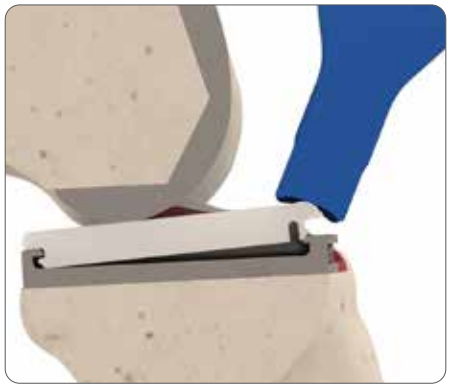


Figure 80E

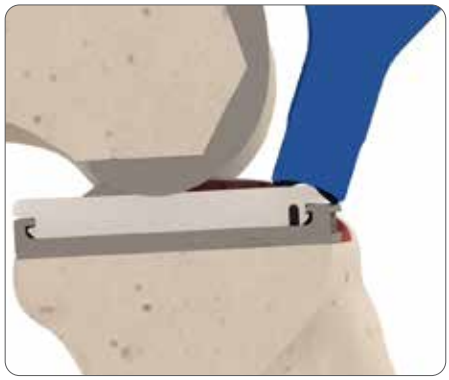


Figure 80F

Note: If the Insert appears angled relative to the front surface of the Tray, it will not properly engage and lock (Fig 80I). When the Insert is in the correct orientation, it will be parallel to the top surface of the Tibial Tray **(Fig 80J)**.

A single impact with the Mallet should be sufficient to lock the Insert. If it is difficult to lock the Insert, it may not be installed correctly. (Figure 80G/80I) Remove the Insert, then remove any loose tissue or debris on the Tray surfaces or in posterior or anterior grooves. If the Insert is removed, a new Insert should be used in its place. An Insert should not be re-used once it is removed. Once the Insert is installed, the implant installation is complete. **(Figure 81)**

Note: The poly Insert must be pushed all the way posterior so the tongue and groove mate together at the back of the Tray. When this occurs, the chamfer on the front end of the Insert will contact the chamfer on the Tibial Tray. **(Figure 80C/80E)**. If the Insert is not properly installed, it will sit proud of the Tibial Tray anteriorly and there will be a gap. A vertical impact force to lock the Insert should not be applied when in this position, as it may damage the locking mechanism.

Incorrect

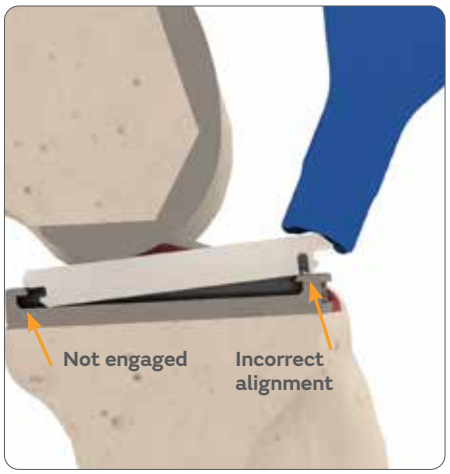


Figure 80G

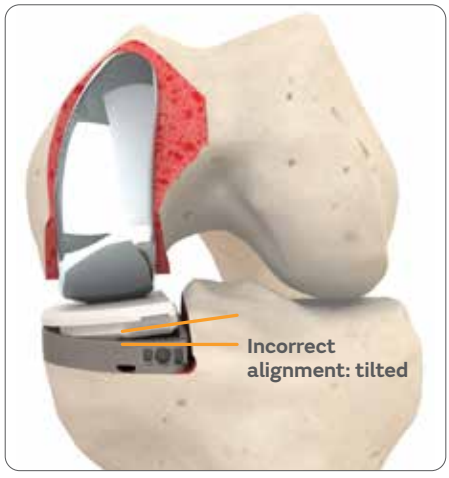


Figure 80I

Correct

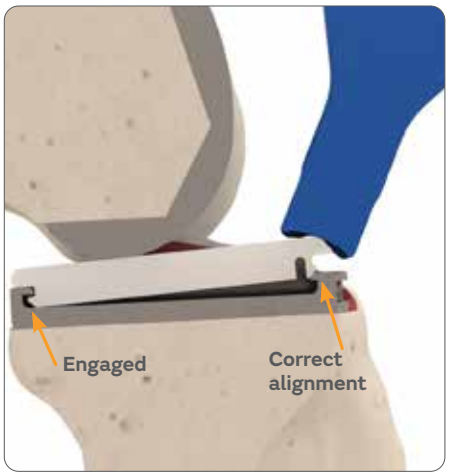


Figure 80H

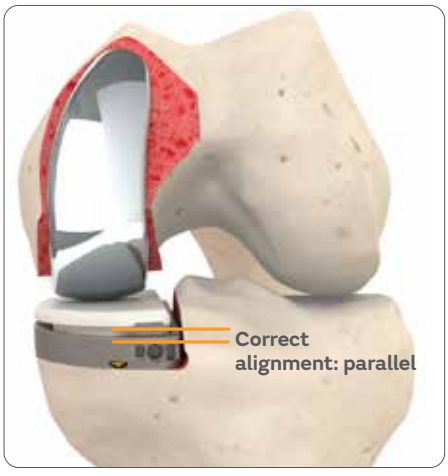


Figure 80J

Figure 81

Implant Removal Technique

If it becomes necessary to remove the implant component from the patient, the ENGAGE◊ Partial Knee System includes specific instrumentation for removal.

Tibial Anchor Removal: Attach the Anchor Revision Guide to the Tibial Tray using the threaded attachment mechanism. **(Figure 82A/82B)** Use the Screwdriver for tightening of the instrument to the Tray. **(Figure 83)**

Note: Similar to the Anchor Guide, the Removal Guide is sized to match the Tray. Use the 1/2/3 Removal Guide (Gray) with the Size 1, 2, or 3 Tibial Tray and the 4/5/6 Removal Guide (Gold) with Size 4, 5, or 6 Tibial Tray.

Tibial Tray Size	Anchor Guide Size	Anchor Guide Color
1	1/2/3	Gray
2		
3		
4	4/5/6	Gold
5		
6		

Figure 82A

Figure 82B

Figure 83

Once attached, align the dovetail boss on the Anchor Removal Cutter with the mating channel in the Removal Guide. **(Figure 84A/84B)** Install the Removal Cutter using impaction until the depth stop is reached. Once the stop is reached do not continue impacting. **(Figure 84C)** Remove the Cutter using the Slap Hammer. **(Figure 85)** Next, install the Anchor Removal Chisel into the Guide (similar to the previous step) until depth stop is reached. **(Figure 87A)**. Remove with Slap Hammer. Repeat this step multiple times until Chisel goes in with minimal impaction force.

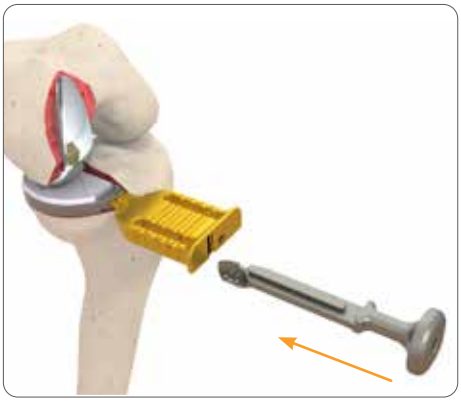


Figure 84A

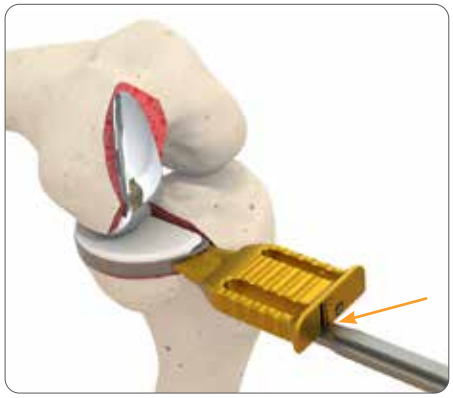


Figure 84B

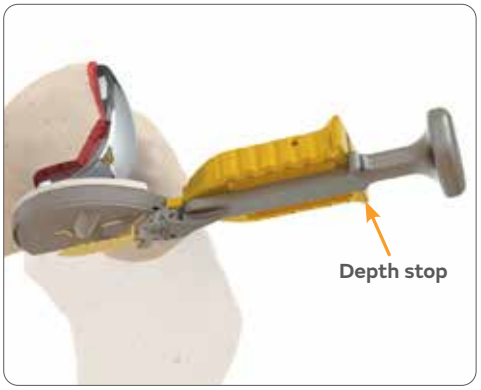


Figure 84C

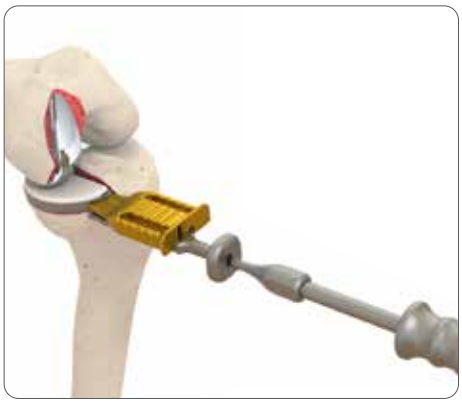


Figure 85

Figure 86

Figure 87A

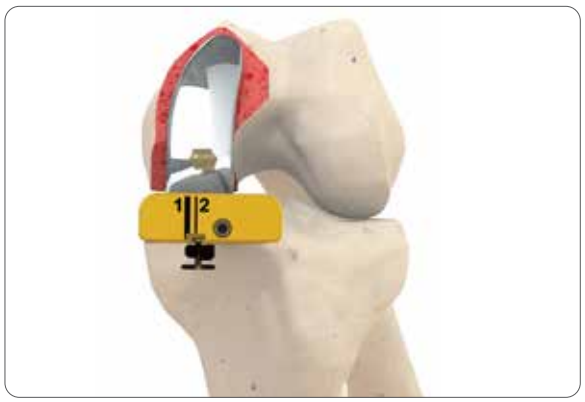


Figure 87B

Figure 88A

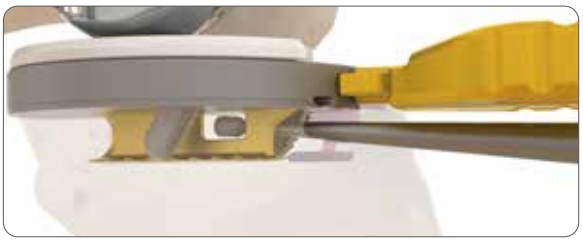


Figure 88B

The Chisel creates a pathway for the Anchor Removal Tool to be inserted. **(Figure 87B)**

Prior to inserting the Anchor Removal Tool, use a standard small angled curette to clear any remaining bone from the window feature in the anchor **(Figure 88A/B)**

Prior to use, ensure the Anchor Removal Tool is in the fully extended position by turning the T-handle counter-clockwise until it stops. When the instrument is fully extended, the entire large arrow marking is visible to the user. **(Figure 89)** Insert the dovetail boss of the Anchor Removal Tool into the matching channel on the Removal Guide. **(Figure 90)** With hand pressure, insert the tip of the Removal Tool into the channel created with the Chisel. Push Removal Tool into Guide until the black handle makes contact with the Guide. **(Figure 91)**

Note: If the Removal Tool is not in the fully extended position prior to use, it will fail to grasp the Anchor and remove it from the implant. It must be fully extended initially.

Figure 89

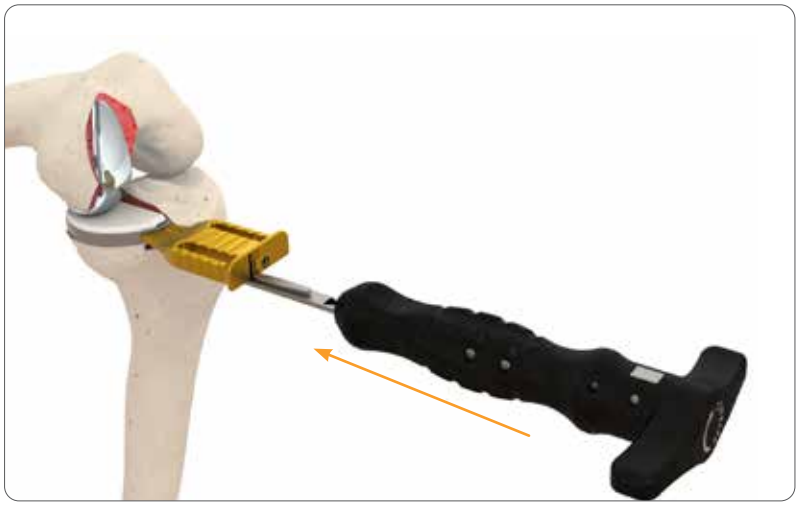


Figure 90

When fully inserted the Removal Tool handle will contact the proximal surface Removal Guide. The Removal Tool will automatically align with the #1 line on the Guide when fully inserted. **(Figure 91A/91B/91C)**. While stabilizing the Removal Guide in one hand, apply light hand pressure to the Removal Tool to pivot from the #1 Position to the #2 Position as marked on the proximal surface of the Guide. **(Figure 92)** The distal hook on the instrument is now engaged with the Anchor, at which point the Anchor is ready for removal. **(Figure 92)**

Note: Avoid applying excessive lateral forces to the Removal Tool handle when pivoting to the #2 Position. Excessive lateral forces (including impact with a mallet) may lead to instrument failure or tibial fracture.

Position 1

Figure 91A

Figure 91B

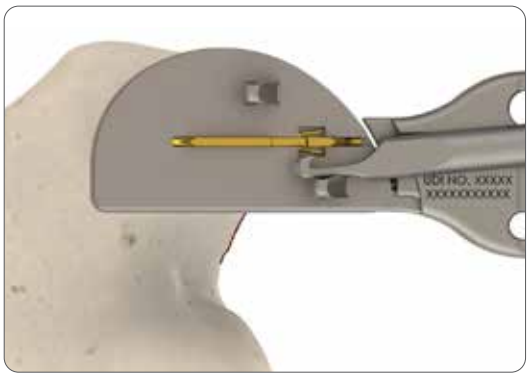


Figure 91C

Position 2

Figure 92A

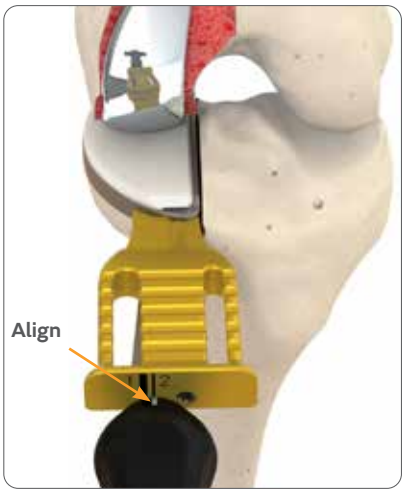


Figure 92B

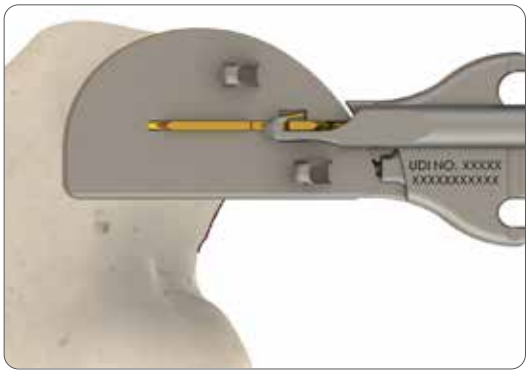


Figure 92C

While grasping the main handle firmly in one hand, rotate the T-handle of the Removal Tool clockwise to extract the Anchor. **(Figure 93)** This retraction will deform the Anchor locking tabs and disengage the Anchor locking mechanism from the Tray. Continue to rotate the handle until the Anchor is pulled completely from the bone. **(Figure 94A/94B)** At this point, disassemble the Anchor Removal Tool from the Guide.

Note: Once an Anchor is removed from the tibial construct, a new Anchor should not be implanted in its place and the Tray should be implanted utilizing cement.

Figure 93

Figure 94A

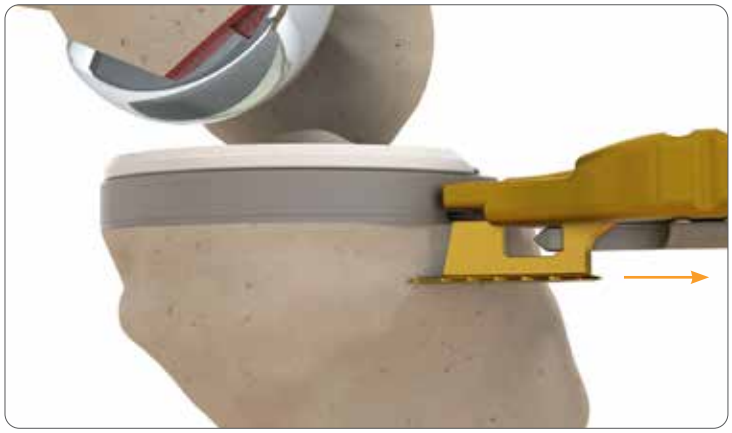


Figure 94B

If the Tray is ingrown with bone, it may be possible to remove the Tray using a standard surgical osteotome or powered saw and resecting just below the Tray.

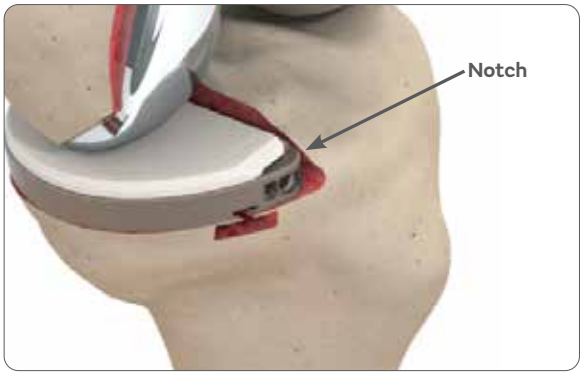


Figure 95

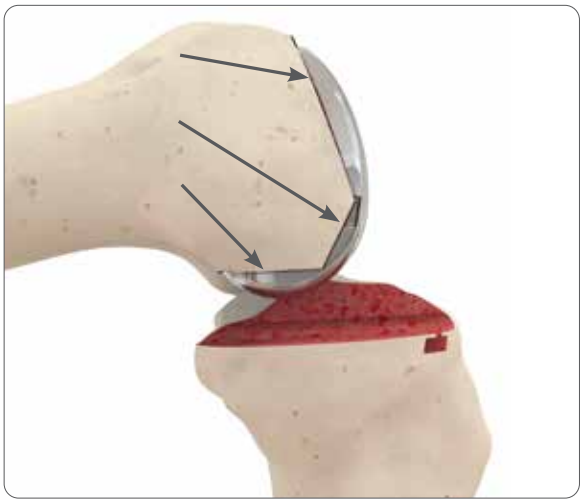


Figure 96A

Figure 96B

Note: Once the Tibial Tray is removed, it should not be re-used. A new Tray should be implanted utilizing cement.

Insert Removal

The insert may be unlocked from the Tray using a small osteotome. Place the osteotome in the anterior notch of the Insert, located just above the Tibial Tray and impact the osteotome to disengage the locking mechanism. **(Figure 95)** Use standard instrumentation to remove the unlocked Insert.

Note: Once an Insert is unlocked and removed, it should not be re-used. A new Insert must be used.

Tibial Tray Size	Anchor Guide Size	Anchor Guide Color
1	1/2/3	Gray
2		
3		
4	4/5/6	Gold
5		
6		

Femoral Removal

Standard osteotomes may be used at the implant-to-bone interface to free the component. **(Figure 96A/96B)**

Knee Balancing Algorithm

After completing the posterior resection of the femur, the ligament balance of the knee should be verified in flexion and extension using the Insert Sizer. If balance has not been achieved, follow the steps outlined in the table below.

Flexion	Extension	Method
Good	Good	Proceed to next step.
Good	Too loose	Up-size the Tibial Insert thickness until the extension gap is balanced and Use Femoral Downsizing Guide to resect posterior femur to downsize Femoral Component to balance the flexion gap.
Too tight	Good	Use the Femoral Posterior Prep Guide to cut an additional 1mm from the posterior femur. Alternatively, if the posterior and chamfer resections have been made on the femur, use the Femoral Downsizing Guide to cut posterior femur to downsize Femoral Component OR recut the tibia to add more posterior slope using the 2° SLOPE Re-Cut Block to balance the flexion gap. The Femoral Downsizing Guide increases laxity in flexion by approx. 1mm by removing additional posterior femur.
Too loose	Good or Too tight	In this very rare circumstance, you will need to up-size the Insert thickness to bring the flexion gap into balance, while simultaneously taking additional distal femur to loosen the extension space. To do so utilize the +2mm Recut Block to recut the distal femur. Check the gap in extension with the Insert Sizer. The +2mm Re-Cut Block may be re-used multiple times until the gap feels balanced in flexion and extension. If the posterior and chamfer resections have been completed, recut the femoral chamfer by using the original size Posterior Cutting Block. With the knee in flexion, pack the existing peg holes with bone graft. Then place a saw blade through the posterior cutting slot of the Posterior Cutting Block. Position the Posterior Cutting Block against the distal cut and shift the Block anteriorly until the saw blade touches the existing posterior cut. This will give you the correct position relative to the existing cuts. Recut the chamfer only and then re-drill the 2 peg holes. Cement may be used in the peg holes to supplement the femoral fixation.
Too tight	Too tight	Downsize the Tibial Insert thickness if possible, OR recut the tibia.
Too tight	Too loose	Recut the tibia to add more posterior slope using the 2 degree Recut Block OR use the Femoral Posterior Prep Guide to cut an additional 1mm from the posterior femur, then up-size the Tibial Insert thickness. Alternatively, if the posterior and chamfer resections have been made on the femur, use the Femoral Downsizing Guide to cut posterior resection and downsize Femoral Component then up-size the Tibial Insert thickness. The Femoral Downsizing Guide increases laxity in flexion by approx. 1mm by removing additional posterior femur.
Too loose	Too loose	Up-size the Tibial Insert thickness.

System Compatibility

The system includes a large range of sizes to fit the normal patient population. The system is designed so all sizes of femur are interchangeable with any size Tibial Tray and Tibial Insert combination.

Note: Tibial Anchors are size-matched to each Tibial Tray. One Anchor size covers two Tibial Tray sizes. For example, the Size 1 and Size 2 Tray both use Size 1-2 Tibial Anchor. A different Tibial Anchor size should not be used with a size 1 or size 2 Tibial Tray. The Anchors are color-coded by size as well as laser marked for size compatibility.

Tibial Anchor Sizing

Anchor Size	Tibial Tray Size
1-2	1
	2
3-4	3
	4
5-6	5
	6

Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Smith+Nephew representative or distributor if you have questions about the availability of Smith+Nephew products in your area.

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