

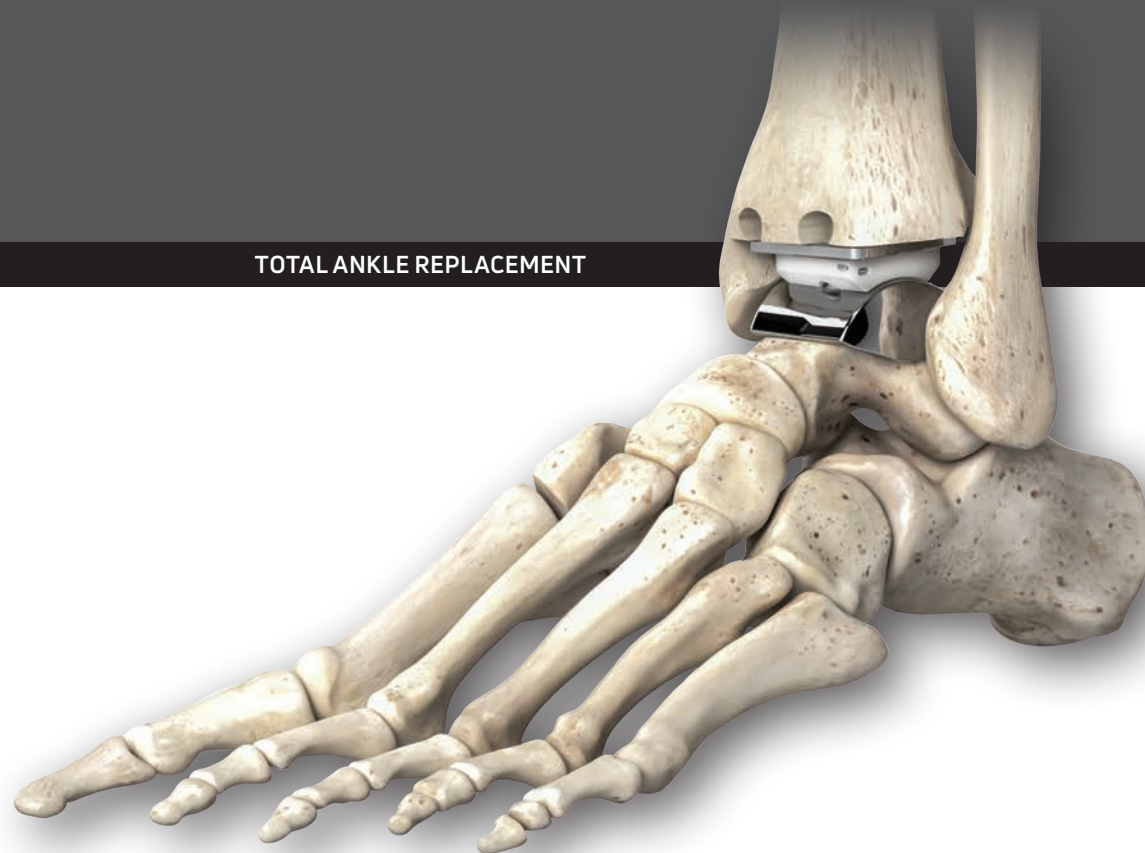
ST

SURGICAL
TECHNIQUE

enovis™

STAR[®] ANKLE

TOTAL ANKLE REPLACEMENT





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Enovis® is a manufacturer of orthopedic implants and does not practice medicine. This surgical technique was prepared in conjunction with licensed health care professionals. The treating surgeon is responsible for determining the appropriate treatment, technique(s), and product(s) for each individual patient.

See package insert for complete list of potential adverse effects, contraindications, warnings and precautions.

A workshop training is recommended prior to performing your first surgery. All non-sterile devices must be cleaned and sterilized before use.

Multi-component instruments must be disassembled for cleaning. Please refer to the corresponding assembly/ disassembly instructions, if applicable. Please remember that the compatibility of different product systems has not been tested unless specified otherwise in the product labeling.

The surgeon must discuss all relevant risks including the finite lifetime of the device with the patient.

This publication sets forth detailed, recommended procedures for using Enovis® devices and instruments. It offers guidance that you should heed, but as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required (900-01-028, 900-01-029, 900-01-030).

A workshop training is recommended prior to performing your first surgery. All non-sterile devices must be cleaned and sterilized before use.

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The surgeon must discuss all relevant risks including the finite lifetime of the device with the patient when necessary.

PLEASE REFER TO IFUs 900-01-028, 900-01-029, 900-01-030, FOR ADDITIONAL LABELING INFORMATION.

INDICATIONS FOR USE

The Scandinavian Total Ankle Replacement (STAR® Ankle) is intended for use as a non-cemented implant to replace a painful arthritic ankle joint due to osteoarthritis, posttraumatic arthritis or rheumatoid arthritis.

CONTRAINDICATIONS

- Active or prior deep infection in the ankle joint or adjacent bones
- Skeletal immaturity
- Bone stock inadequate to support the device including:
- Severe osteoporotic or osteopenic condition or other conditions resulting in poor bone quality
- Avascular necrosis of the talus
- Prior surgery and / or injury that has adversely affected ankle bone quality
- Malalignment or severe deformity of involved or adjacent anatomic structures including:
- Hindfoot or forefoot malalignment precluding plantigrade foot
- Significant malalignment of the knee joint
- Insufficient ligament support
- Neuromuscular disease resulting in lack of normal muscle function in affected ankle
- Lower extremity vascular insufficiency demonstrated by Doppler arterial pressure
- Charcot joint or peripheral neuropathy that may lead to Charcot joint of the affected ankle
- Prior arthrodesis at the ankle joint
- Poor skin and soft tissue quality about the surgical site

WARNINGS/PRECAUTIONS

Only implant the STAR Ankle after adequate training and familiarity with the surgical technique manual, to avoid increased risk of device failure due to improper surgical technique.

Do not use STAR Ankle components in combination with prosthesis components made by other manufacturers, because design, material or tolerance differences may lead to premature device and/or functional failure. Components of the system have been specifically designed to work together.

To ensure proper implantation of the STAR Ankle, use the instrumentation that is supplied with the system in accordance with the surgical technique manual.

The trial prosthesis should not be implanted.

Examine instruments for wear or damage before use. While rare, intra-operative instrument breakage may occur. Instruments that have experienced excessive use of force may be susceptible to breakage.

The safety and efficacy of the STAR Ankle have not been studied on patients weighing > 250 lbs (113kg).

Always confirm that the patient does not have a possible allergy to the implant / prosthesis material before selecting the STAR implant to minimize the risk of an allergic response.

Discard all damaged or mishandled implants. Do not reuse implants and components. Although the implant may appear undamaged, it may have small defects and internal stress patterns which may lead to early failure of the device.

Reuse of instruments designated as single use has been associated with necrosis of bone leading to implant failure. It

may also lead to sepsis and/or communication of potentially lethal viruses.

Single use is defined as use of one implant or instrument on a single patient in a single surgical procedure.

Do not resterilize. Do not use implants or components if the package is damaged or has been opened prior to planned use.

Always exercise care in selecting the proper type and size of the implant. Size and shape of the human bone place restrictions on the size and shape of the implant, potentially limiting device function.

Do not contour or bend an implant because it may reduce its fatigue strength and cause failure under load. Correct handling of the implant is extremely important.

For a minimum of two weeks, a patient should not bear any weight on the implanted STAR Ankle. Certain vigorous activities (e.g., basketball, football) and trauma to the joint replacement may cause early failure of the STAR Ankle. Please refer to the section titled "Post-operative Management."

Appropriate selection, placement and fixation of the STAR Ankle components are critical factors which affect implant service life.

Improper selection, placement and fixation of the implant components may result in early implant failure. As in the case of all prosthetic implants, the durability of these components is affected by numerous biologic, biomechanic and other extrinsic factors which limit their service life. Accordingly, strict adherence to the indications, contraindications, precautions and warnings for this product is essential to potentially maximize service life.

Reuse of implants designated as single use has been associated with sepsis and/or communication of potentially lethal viruses.

Pre-operative planning can provide the opportunity to review a patient's anatomy in order to plan appropriate adjustments to the surgical technique. Review of X-Rays can identify osteophytes, potential deformities, such as varus/valgus orientation, and other elements that may eliminate the patient from consideration for a STAR®, such as generalized Avascular Necrosis (AVN) of the talus.

TECHNIQUE OVERVIEW

Implanting the STAR Ankle consists of a variety of steps intended to allow the surgeon to place and size the implant. A priority is placed on protecting adjacent anatomical structures and minimizing bone resection.

There are six principle cuts made in order to prepare the tibia and talus for the implant. Simple transverse tibial and talar cuts are made, and after sizing the talar component, several precise talar dome cuts are conducted in order for the talar dome component to be seated on top of the talus. The talar component sits on the talus and forms a "cap" on the top and around all four sides. Holes are drilled in the tibia that can serve as anchor points for the tibial component.

Finally, metal components are implanted, and an appropriate polyethylene component is selected, depending on the laxity of the ankle joint. Concomitant procedures may take place either before or after the ankle is replaced, depending upon the need to provide soft tissue balancing for the ankle.

Principal surgical technique steps include:

- Orienting the implant in the axial and coronal planes on the tibia
- Transverse tibial cut
- Orienting the implant on the talus
- Talar dome resection
- Talar component sizing
- Datum positioning
- Talar chamfer & medial/lateral cuts
- Talar keel preparation
- Implant sizing and placement

COMPONENTS

Components needed to use first in the case:

- First cut – reciprocating saw blade with teeth up
- Jacob's chuck with anterior mill assembled to it
- Pin driver with 3.2mm pin assembled to it

Have laid out:

- 3.2mm Pin
- 2.4mm Pins
- Shoulder pin driver equipped with shoulder pins
- Anterior mill (in Jacob's chuck)
- Barrel hole drill
- Talar keel mill

Other items needed:

- Osteotomes (6mm wide, maximum)
- Angled curette
- Rongeurs
- Army/navy

Pull angel wing, T alignment guide, gear key, #3 (or 6mm) talar cut guide, and appropriate (right or left) tibial cut guide are easily accessible.

Ensure the PTCT drill guide can be screwed onto five talar sizers, without cross threading, and no gap between components (handle of sizer not bent).

BACK TABLE LAYOUT

Assemble together:

- Lateral tibial alignment guide
- Lateral tibial alignment rod

Assemble together:

- Tibial alignment guide
- Tibial alignment guide thumbscrew

Then assemble the above with:

- Pin block assembly (lightly lock thumbscrew on rod from assembly)

Use gear key to loosen set screw on pin block assembly, and then assemble:

- Adjustable Slider Block (leave half way out from Pin Block Assembly, at thicker marked line)
- Tighten down set screw on pin block assembly.

⚠ CAUTION: Ensure rounded corners are up on distal portion of the adjustable slider block and that 'funnel' side of the tibial alignment guide lock is down.

APPROACH

A small bump is placed beneath the ipsilateral hip to rotate the ankle so that the line of the medial malleolus is perpendicular to the operating table.

After the foot and ankle have been correctly positioned, the leg is elevated for about 2 minutes, and a thigh high tourniquet is inflated with an appropriate amount of pressure for the size of the patient's leg and foot. The leg should be prepped and draped above the knee to allow the placement of the 3.2mm Tibial Pin.

A longitudinal 20cm incision is centered over the ankle immediately lateral to the anterior tibial tendon. The incision is deepened to the ankle joint while retracting the extensor hallucis longus and the neurovascular bundle laterally.

The superficial branch of the peroneal nerve in the foot is visible and must be retracted carefully to the lateral aspect of the ankle.

It is frequently necessary to sacrifice one small branch of this nerve that innervates the great toe. The tendon sheath of the extensor hallucis longus is now incised in line with the skin incision.

⚠ WARNING: Avoid opening the tendon sheath of the anterior tibial tendon, as this may cause difficulty in closure.

After the tendon sheath of the extensor hallucis longus is opened, the deep peroneal nerve and artery are identified and are gently retracted.

The ankle capsular tissues are incised in line with the skin incision and then are elevated and mobilized exposing the medial malleolus, and lateral malleoli.

If the capsule is of sufficient quality, it should be saved to close over the prosthesis.

⚠ WARNING: Avoid the release of the anterior talofibular ligament as this may lead to lateral instability.

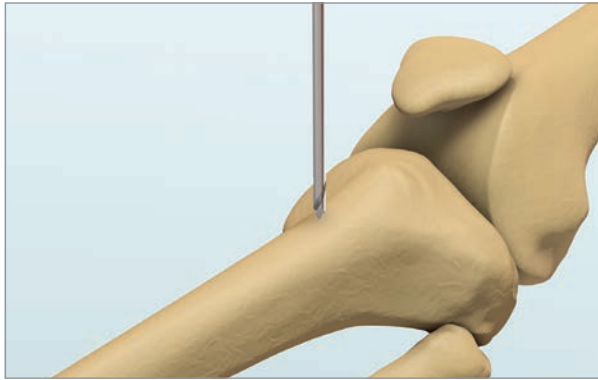
The ankle joint is distracted slightly, and hypertrophic synovium, intraarticular loose bodies or periarticular spurs are resected. Osteophytes on the anterior distal tibia are removed to visualize the tibial plafond.

⚠ CAUTION: Self-retaining retractors should be avoided when possible, to eliminate excess pressure on the skin edges.

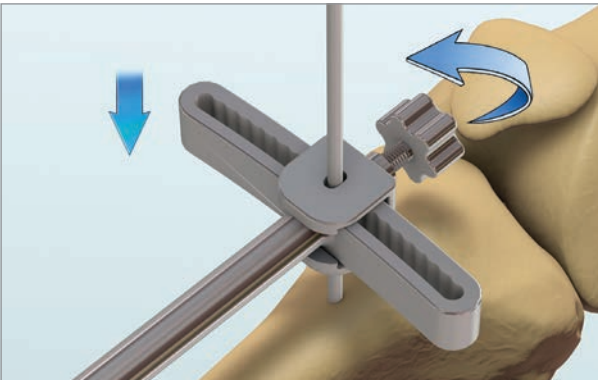
⚠ CAUTION: Hand retractors should be frequently repositioned to minimize the risk of tissue trauma.

STEP 1: SETUP

Make a mark at the level of the tibial tubercle. Place an osteotome in the medial gutter. Create a stab incision over the mark. Insert a 3.2mm self-drilling pin into the tibial tubercle, parallel to the osteotome in the gutter in the axial plane, but in slight plantarflexion.

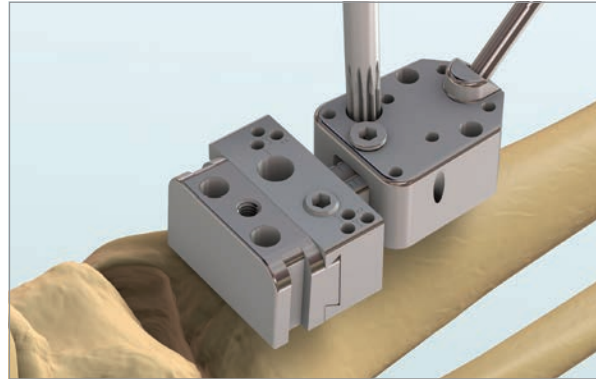


1.2 Position the proximal portion of the previously assembled Tibial Alignment Guide over the pin, at a height of one fingerbreadth above the tibia proximal to the knee (if measuring distal to the knee, use two fingerbreadths), and tighten the proximal screw to lock the guide superiorly.

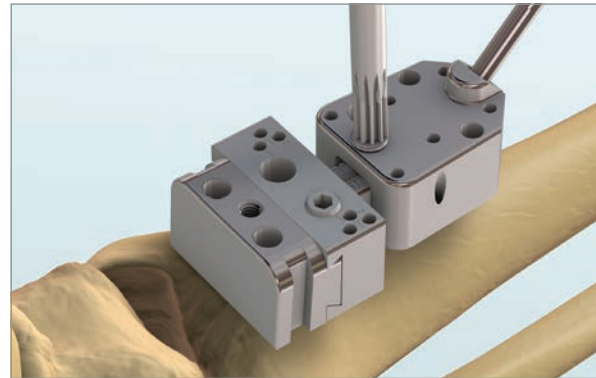


ADJUSTING THE PIN BLOCK

1.3 The gear key is used to both lock into position, and adjust the pin block. The diagram illustrates which holes manipulate each of the components.

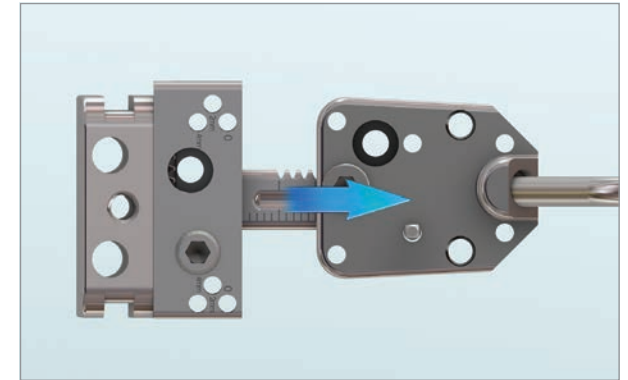


Adjustment Gear



Locking Screw

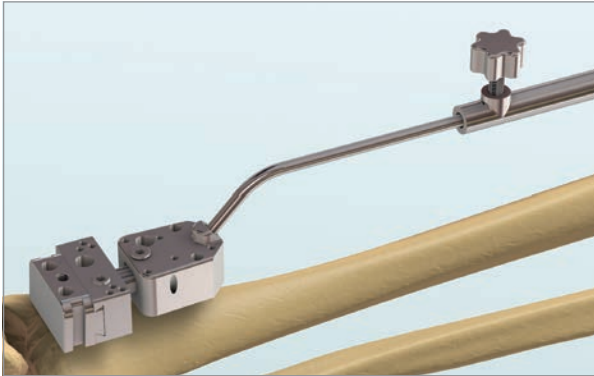
1.4 Extend the pin block assembly to allow for a one-centimeter gap between the proximal and distal blocks.



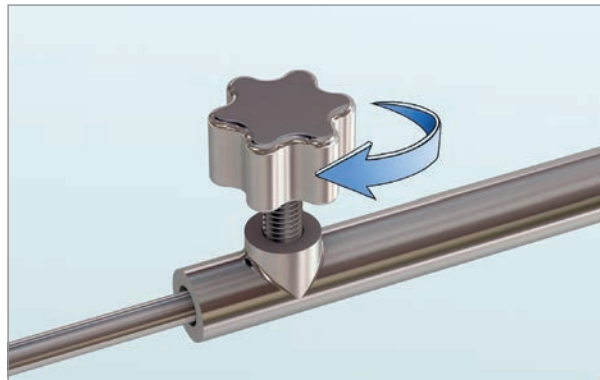
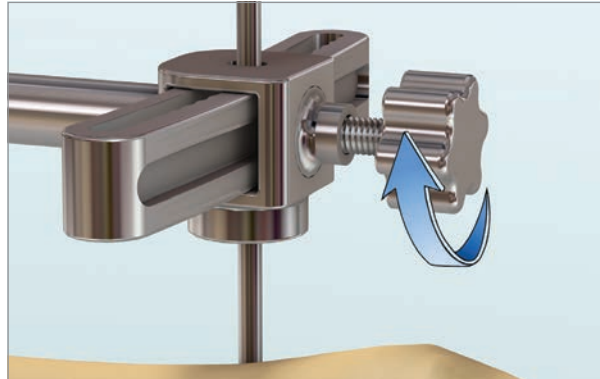
1.5 Adjust the distal aspect of the tibial alignment guide (roughly at the level or above the plafond) proximal to the tibial plafond to allow for a cut just proximal to the articular surface.



1.6 Generally align the Tibial Alignment Guide over the crest of the tibia.

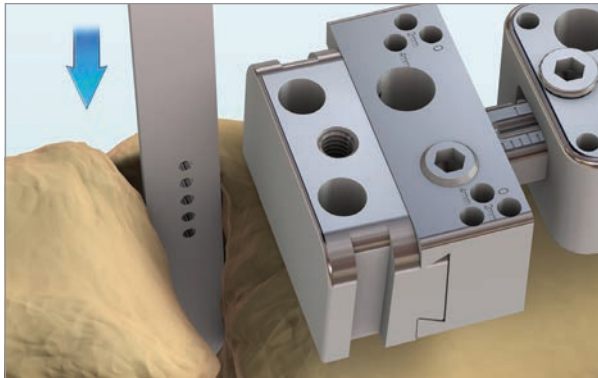


1.7 Hand tighten the proximal and middle screws of the tibial alignment guide.

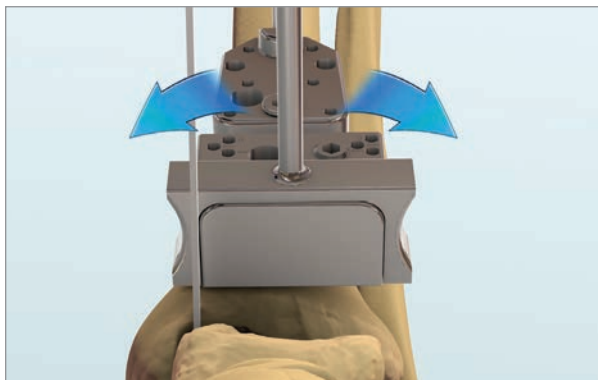


STEP 2: AXIAL PLANE ALIGNMENT

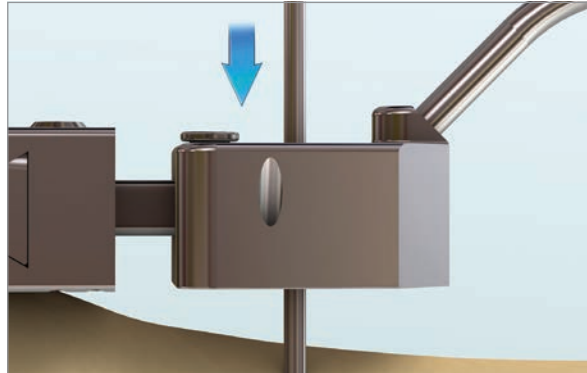
2.1 Place an Osteotome in the medial gutter. Place the "T" Alignment Guide over the distal end of the Adjustable Slider Block.



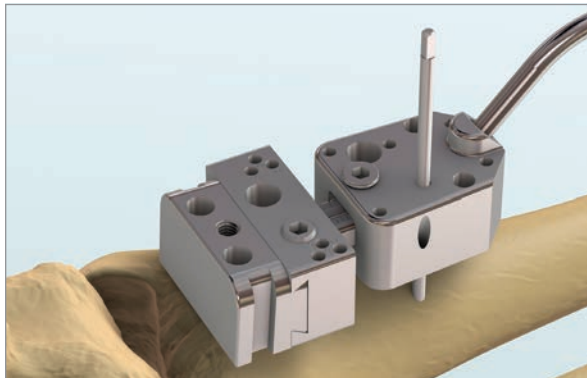
2.2 Release the middle thumb screw on the tibial alignment guide and adjust the rotation to ensure the shaft of the "T" Alignment Guide is parallel with the osteotome.



2.3 Put one pin in the superior Pin Block Assembly, only penetrating the first cortex of the tibia to allow varus/valgus and tibial cut slope adjustment. This locks the axial plane alignment.

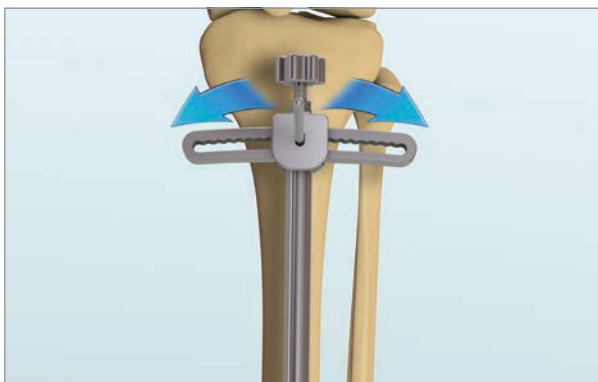


2.4 Remove the "T" Alignment Guide and osteotome.

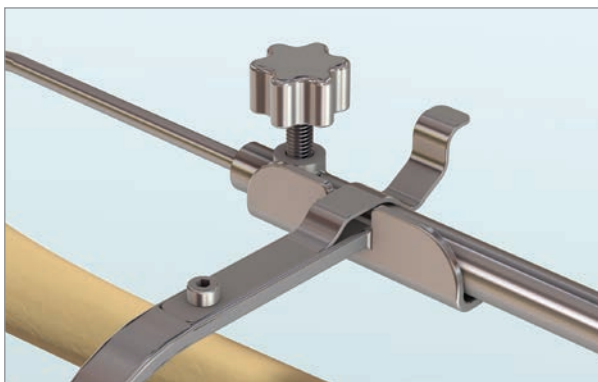


STEP 3: CORONAL & SAGITTAL PLANE ALIGNMENT

3.1 Adjust the coronal plane alignment by loosening, and rotating the guide medially or laterally on the 3.2mm tibial tubercle pin. Hand tighten the set screw after final positioning.



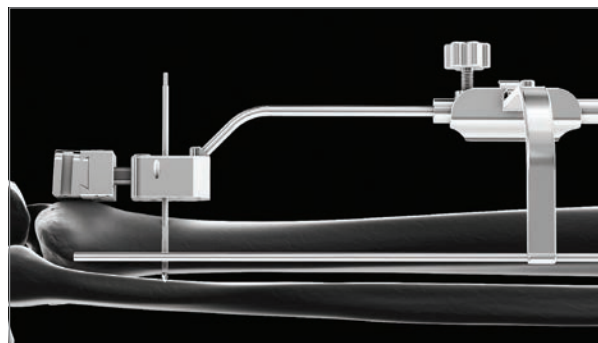
3.2 Attach the Parallel Alignment Guide to the mid-portion of the Tibial Alignment Guide.



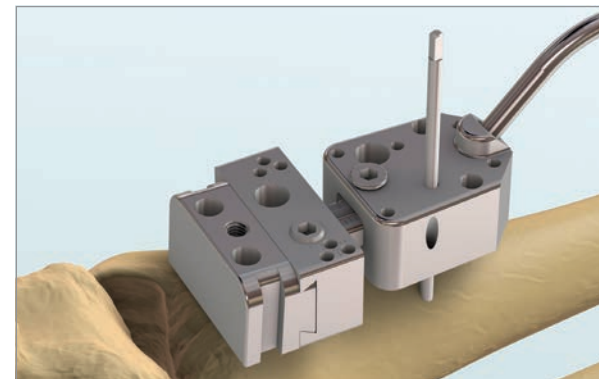
3.3 Align the tibial alignment guide to be parallel to the tibial diaphysis in both the coronal and sagittal planes. Confirm with fluoroscopy.

Alignment can be adjusted by changing the position of the Tibial Alignment Guide with respect to the pins in place. For example, raising the proximal portion of the Tibial Alignment Guide on the 3.2mm pin will close the anterior angle of the tibial cut in the sagittal plane.

NOTE: When the Tibial Alignment Guide is parallel from a lateral view to the intramedullary canal, the tibial cut angle is 3° open anterior, with the typical anatomic patient being 7°-10° open anterior.



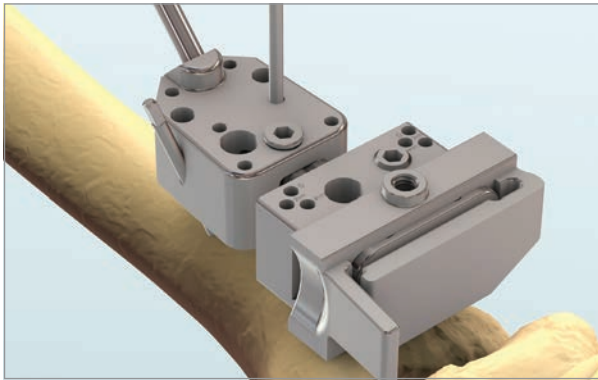
3.4 Drive the initial pin that was earlier placed in the Pin Block Assembly to the far cortex to lock the slope of the cut in the sagittal plane.



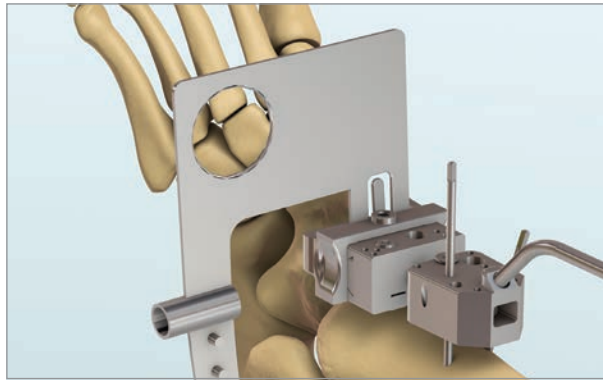
3.5 Remove the Parallel Alignment Guide.

STEP 4: TIBIAL CUT

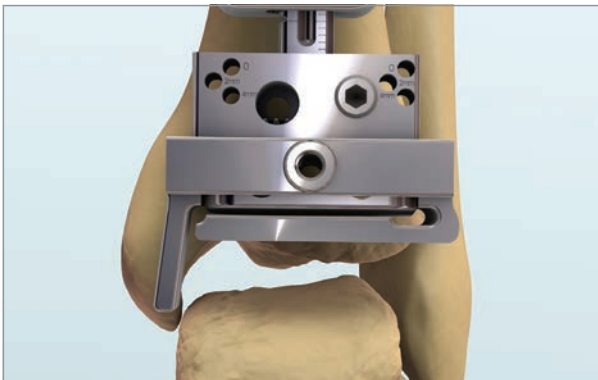
4.1 Attach the Tibial Cut Guide onto the Adjustable Slider Block and secure it in place with the Gear Key.



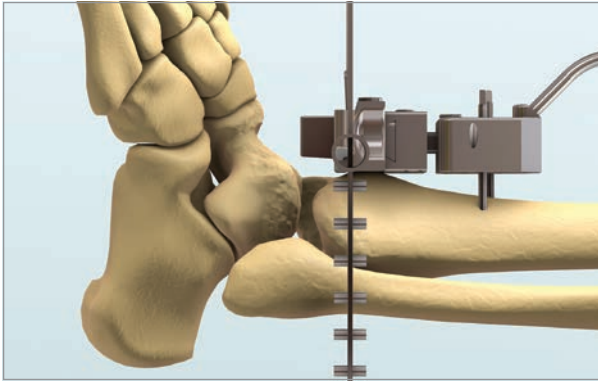
The Pegs are spaced 10mm apart, so can be used to generally determine the depth of the cut from an A/P perspective.



4.2 Insert the Angel Wing into the cutting slot of the Tibial Cut Guide. The Angel Wing has seven pegs extending five millimeters superior and inferior from the central blade.

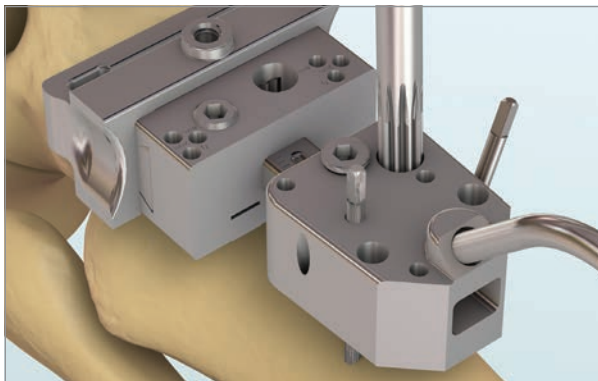


4.3 The Angel Wing design accounts for the amount of bone resected by the saw blade, when measuring the cut.



4.4 Use the Gear Key on the set screw and adjustment within the Pin Block Assembly to loosen and align the Adjustable Slider Block such that the inferior tip of the closest peg is aligned with the most superior aspect of the distal tibial plafond.

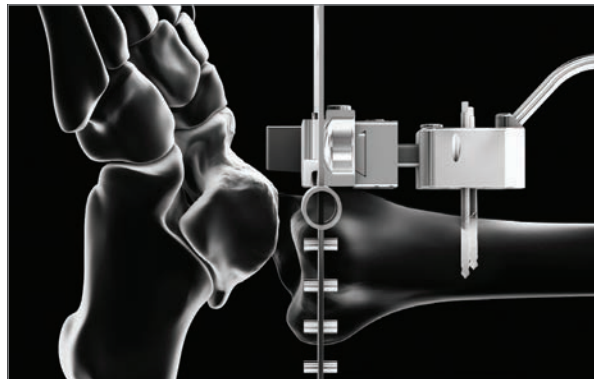
NOTE: With this default setting, a maximum of five millimeters of distal tibial bone will be removed.



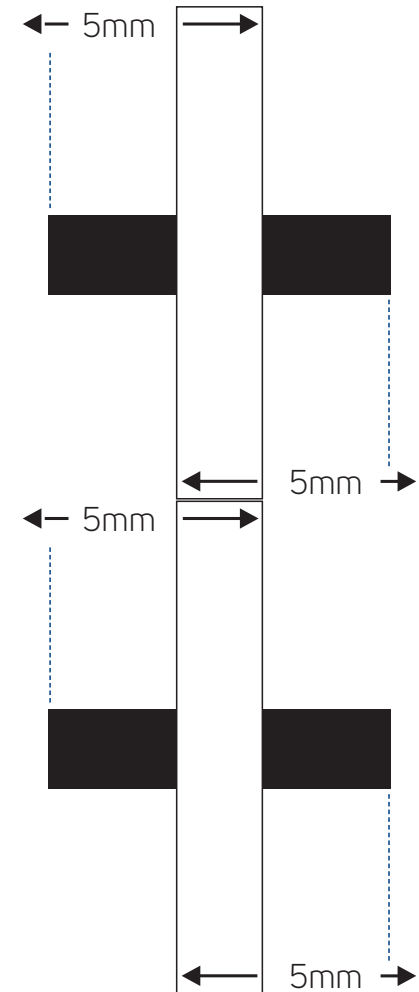
Fluoroscopy is properly positioned when the lateral view of the wide section of the wing is a thin single line also known as a "True Lateral View."

NOTE: The Angel Wing mimics the thickness of the saw blade.

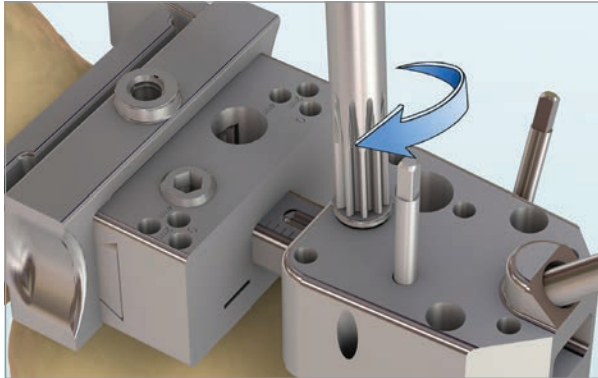
CAUTION: Double check the "Slope" of the tibial cut in the sagittal plane. Make additional adjustments as needed. The default setting of the cut guides is to provide 3° open slope.



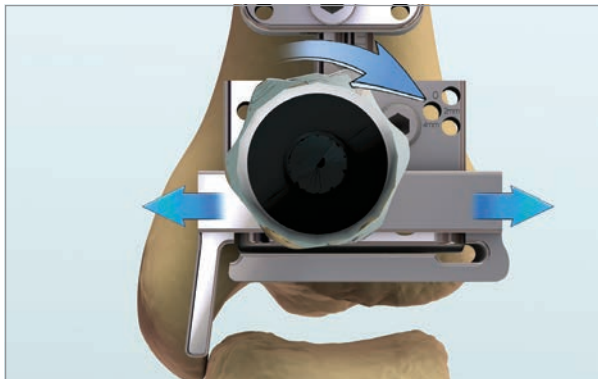
BLADE/WING



4.5 Tighten the set screw to lock the resection level of the Tibial Alignment Guide. Now secure the guide in the oblique holes using the 2.4mm pins.

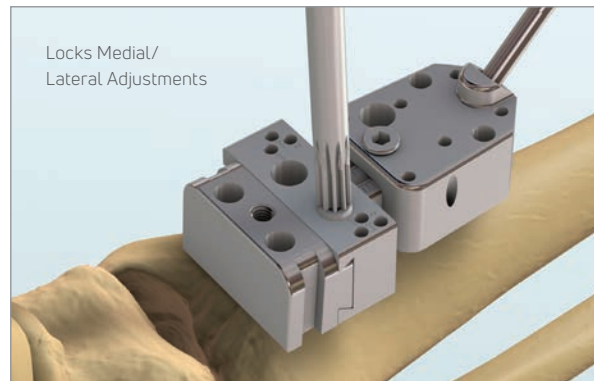


4.6 Remove the Angel Wing.



4.7 Make medial and lateral adjustments with the gear key.

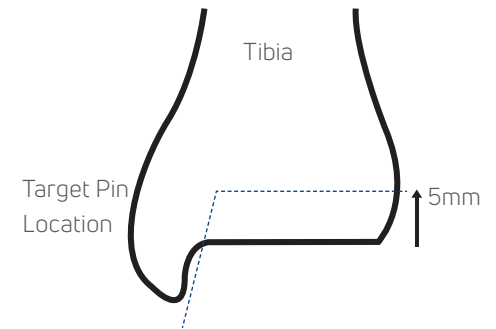
⚠ CAUTION: Using the Gear Key for this adjustment minimizes the risk of notching either the medial and lateral malleoli during tibial resection.



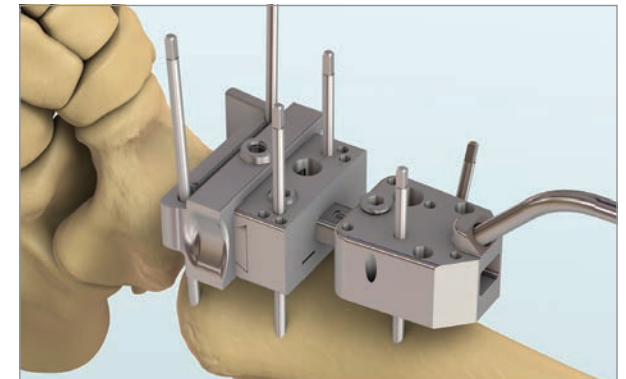
4.8 Insert two 2.4mm pins into the inferior portion of the Pin Block Assembly to lock the amount of tibial resection.

📋 NOTE: Use the holes marked "0" (the most proximal). Doing so will enable a 2mm adjustment simply by repositioning the Adjustable slider Block from the "0" holes to the "2" holes if a recut is needed.

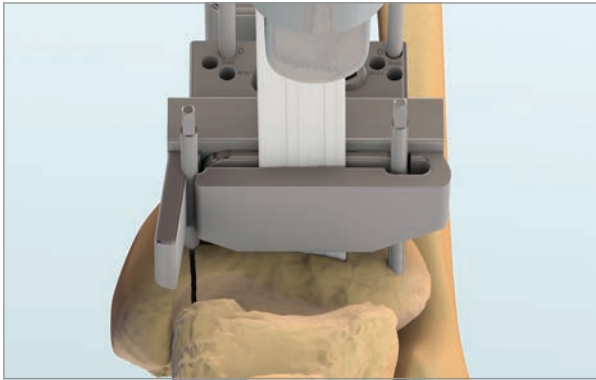
4.9 Insert medial and lateral pins into their slots in the saw guide to protect the medial malleolus and fibula from notching or cutting.



⚠ CAUTION: Ensure the pins are seated deeply enough to avoid interfering with the saw in order to properly conduct the tibial cuts.

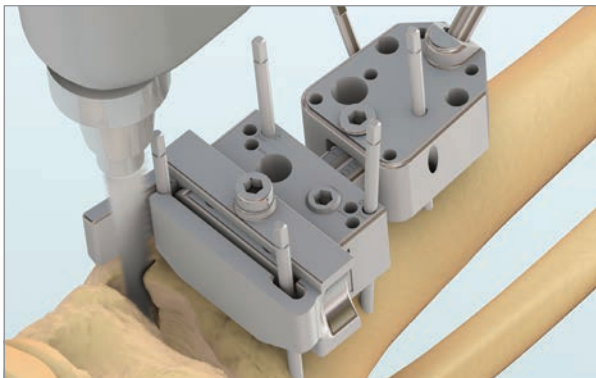


4.10 With the oscillating saw, using a pecking motion to determine proper depth, make a transverse distal tibial cut within the Tibial Cut Guide.



4.11 With the reciprocating saw, make an upward, proximally-oriented cut with a pecking motion along the inner edge of the medial malleolus.

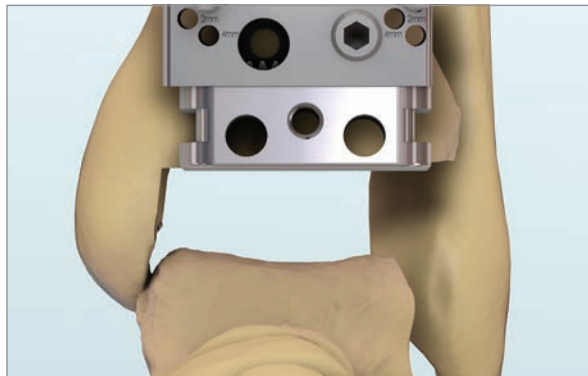
⚠ CAUTION: Care should be taken to not overcut the tibial bone.



4.12 Remove the pins from the Tibial Cut Guide, unlock it from the Pin Block Assembly and remove the Tibial Cut Guide.

4.13 Using osteotomes, rongeurs, or other surgical instruments, remove all resected tibia bone.

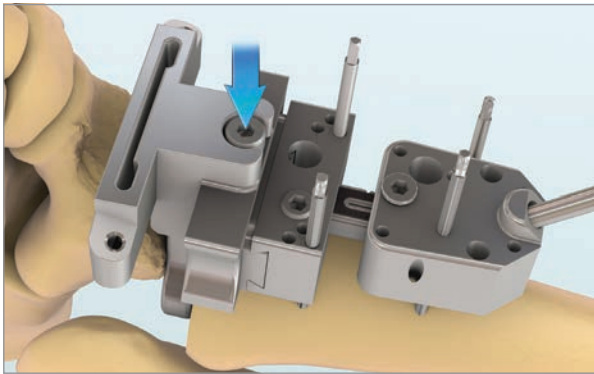
⚠ CAUTION: If pressure is applied to either the internal surfaces of the medial malleolus or lateral malleolus, this may cause fracturing. This fracturing would be increased if either of these surfaces are notched by aggressive cutting of the tibia.



STEP 5: TALAR PREP & RESECTION

NOTE: For patients with deformities, it may be appropriate to mobilize the talus by cleaning out both lateral and medial gutters.

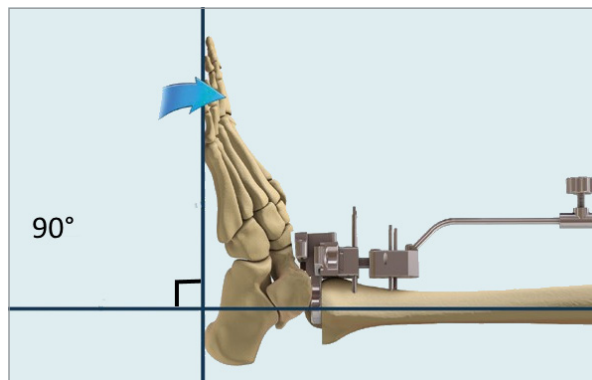
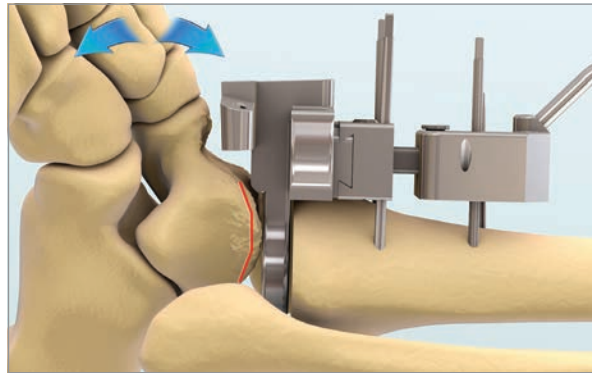
5.1 Insert the Number 3 (or 6mm) Talar Cut Guide onto the Tibial Alignment Guide, and lock in place by tightening with the set screw. With the Talar Cut Guide in this position, a maximum of 4mm of bone will be removed from the talar dome.



5.2 The Talus should be neutrally positioned (90° perpendicular) to the long axis of the tibia.

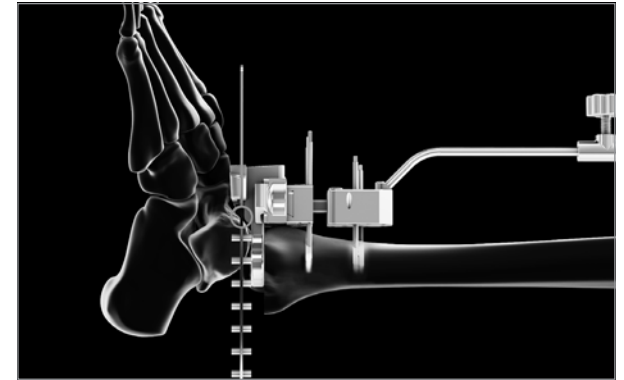
CAUTION: Excessive dorsiflexion will rotate the talar component anteriorly while excessive plantarflexion will rotate it posteriorly. Proper orientation protects the talar neck from inadvertent weakening from the anterior chamfer cut.

CAUTION: Ensure the talus is touching the paddle face for an adequate amount of resection.

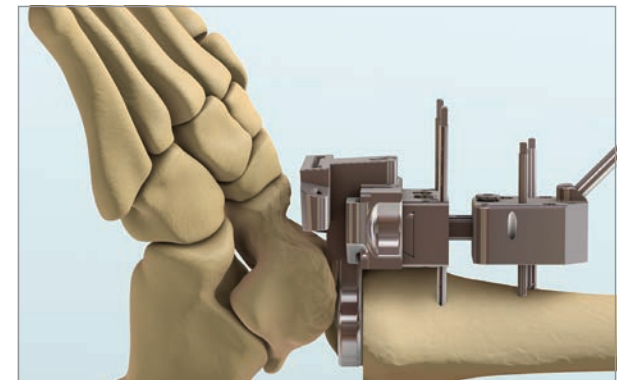


5.3 The foot should be in a neutral or slightly valgus orientation.

5.4 Insert the Angel Wing to verify the orientation angle of the talar cut and amount of the resection.

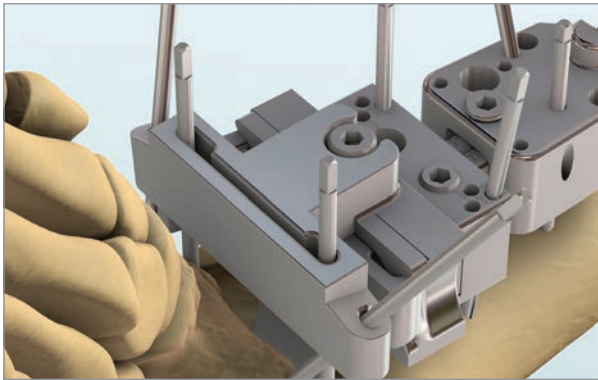


5.5 Insert medial and lateral fixation pins into the Talar Cut Guide while holding the foot in a neutral alignment.



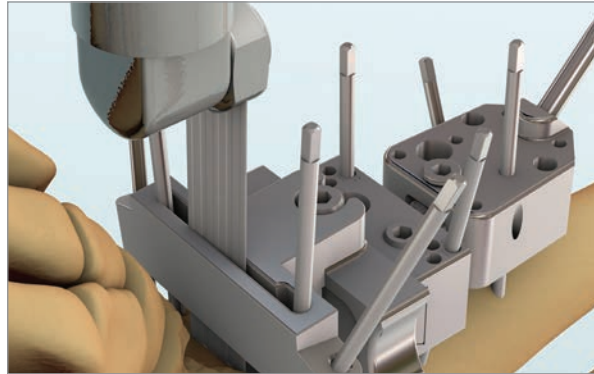
5.6 Insert medial and lateral pins into the Talar Cutting Guide slots to protect the malleoli. Use a mallet to begin placement of the pins and ensure proper orientation of the alignment.

NOTE: Improper alignment may cause the pins to bind in the holes of the Talar Cut Guide.



5.7 Using the oscillating saw, make the transverse distal talar cut.

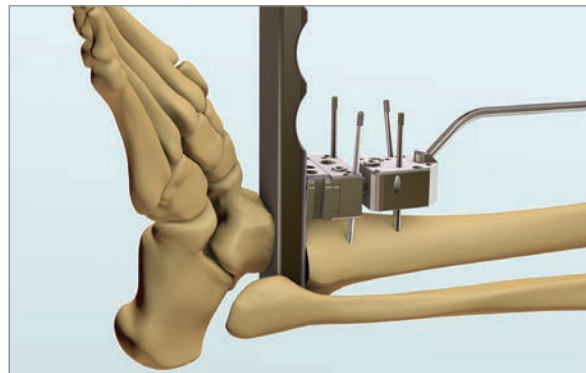
5.8 Remove the pins from the Talar Cut Guide, unlock it from the Pin Block Assembly and remove the Number 3 (6mm) Talar Cut Guide.



5.9 Insert the 12mm end of the Joint Space Evaluator between the cut surfaces of the tibia and talus.

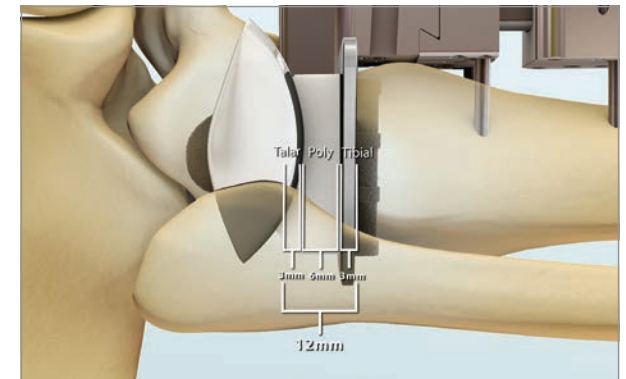
NOTE: Improper alignment may cause the pins to bind in the holes of the Talar Cut Guide.

If the Joint Space Evaluator does not fit easily in the joint space, additional bone will have to be cut, at the surgeon's discretion. This will typically be done on the tibia. Additional tibial bone can be removed by re-attaching the Tibial Cut Guide to the Adjustable Slider Block.



5.10 Remove the Tibial Alignment Guide and corresponding 2.4mm pins.

NOTE: If the talar dome is unevenly cut, it may be necessary to flatten the surface of the talus in order to properly use the Post Talar Cut Template (PTCT) to size the talar component.



STEP 6: TALAR COMPONENT SIZING

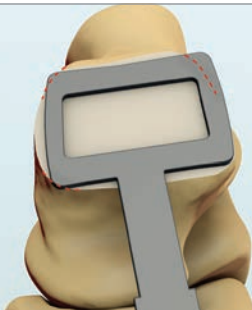
6.1 Insert the Post Talar Cut Template (PTCT) onto the cut surface of the talus. The template determines the correct talar component size. The outer outline of the template corresponds to the outer outline of the talar component.

⚠ CAUTION:

- For optimal sizing, the outer surface of the PTCT should match the outer edge of the talar bone.
- One side of the Post Talar Cut Template is for the left ankle, and the other is for the right ankle.

⚠ WARNING:

If template selected is too large, it will cause overlap in the gutters.

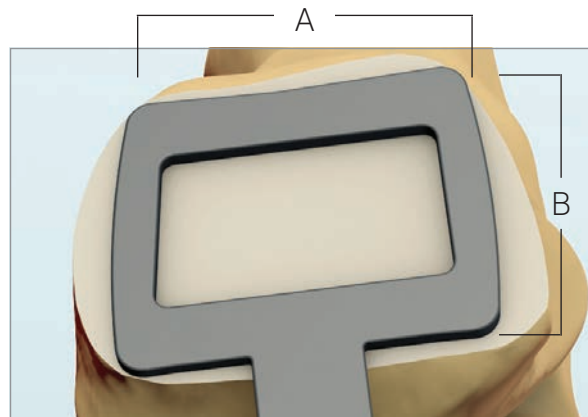
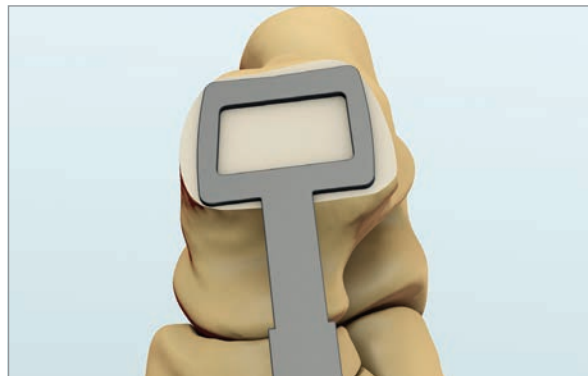


⚠ WARNING:

If template selected is too small, it will cause too much bone to be removed.



SIZE	A (MM)	B (MM)
XXSMALL	28	29
XSMALL	30	31
SMALL	34	35
MEDIUM	36	35
LARGE	38	35



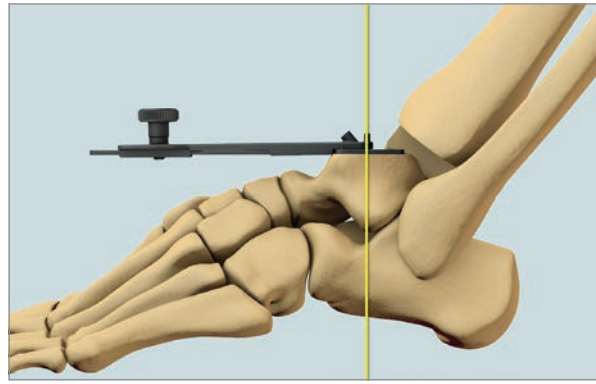
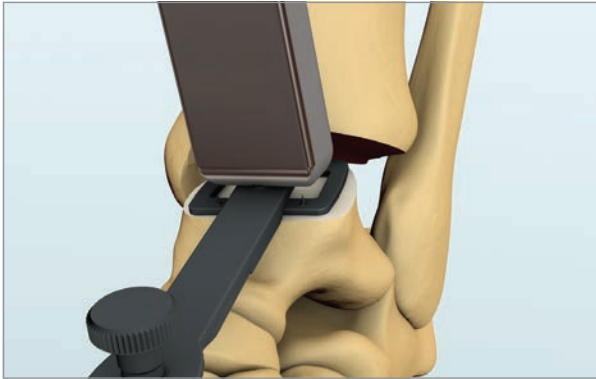
6.2 Once the appropriate PTCT is determined, attach the drill guide onto the PTCT.



6.3 Rotational alignment of the sizer is determined by aligning the shaft of the PTCT toward the second metatarsal. Note the size on the Post Talar Cut Template. The size of the datum used in future steps will conform to the appropriate size of the PTCT. Approximately center the PTCT on the surface of the talus.

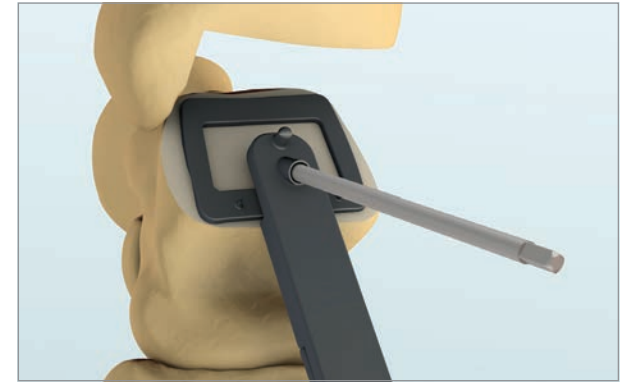


6.4 The post of the drill guide should be centered over the lateral process. Anterior/Posterior positioning of the template is achieved by using the c-arm to align the midpoint of the template to the center of rotation of the talus.



6.5 Once template alignment is properly positioned, insert a 2.4mm pin through the drill guide.

6.6 Loosen the thumbscrew on the PTCT Drill Guide and remove. Separately, remove the PTCT, leaving the pin in the talus.



NOTE: Use the Joint Space Distractor to clamp the PTCT to the top of the talus.

CAUTION: Pay particular attention that there is no gap between the PCTC and the top of the talus especially posteriorly.

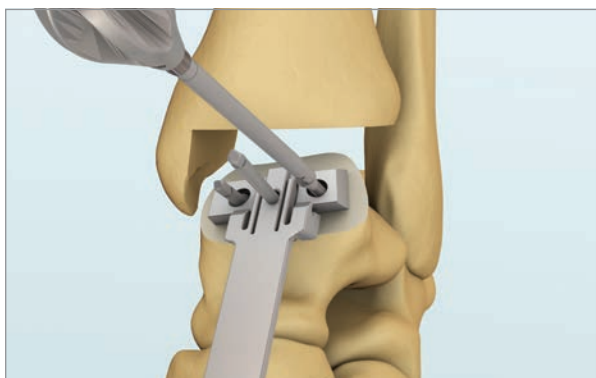


STEP 7: DATUM POSITIONING

NOTE: X-Small and XX-Small sizes skip Step 7. Datum is integrated into the A/P and M/L cut guides.

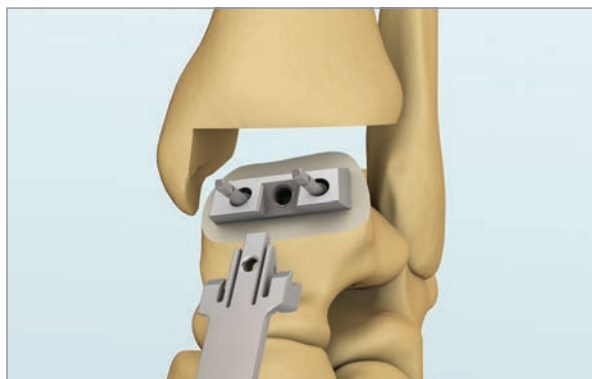


7.1 Select a Datum that matches the size of the previously determined PTCT onto the Datum Holder. Slide the Datum mounted on its holder over the 2.4mm pin in the talus. Align the handle of the Datum Holder with the 2nd metatarsal.

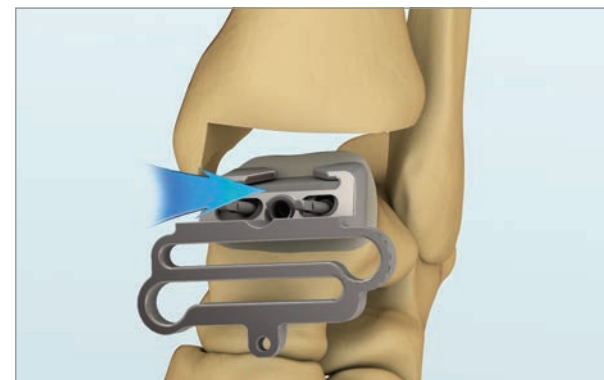


7.2 Secure the Datum to the talus with 15mm Drill Tip Pins (w/shoulder) using the Pin Driver. Should this provide insufficient purchase, 20mm length pins are also available from the sterile Instrument set.

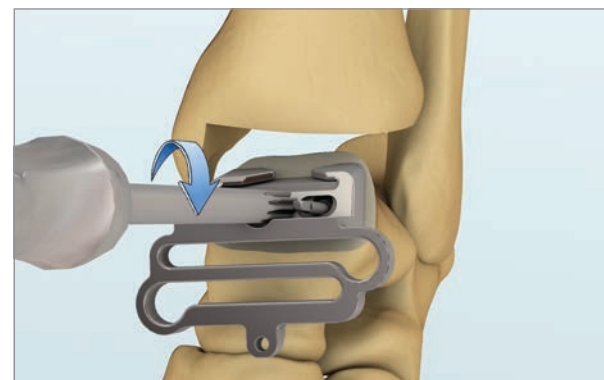
CAUTION: If power is used with the Pin Driver, care should be taken to ensure final tightening is done manually.



7.3 Remove the 2.4mm Pin and then the Datum Holder.

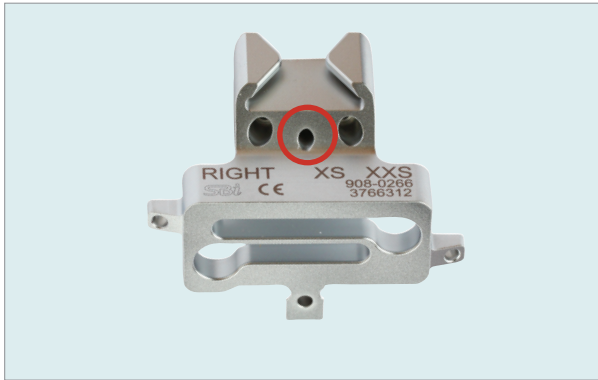


7.4 Insert the Talar A/P Cut Guide onto the Datum and secure it with its locking bolt.



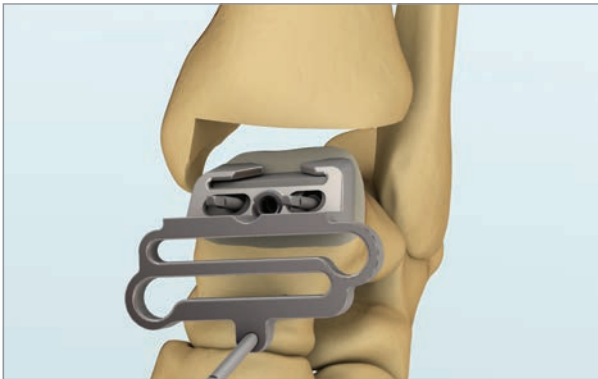
STEP 8: TALAR CIRCUMFERENTIAL CUTS

XS/XXS - Talar A/P Cut Guide is placed over the centering 2.4mm pin, and secured to the Talus with the shoulder pins.

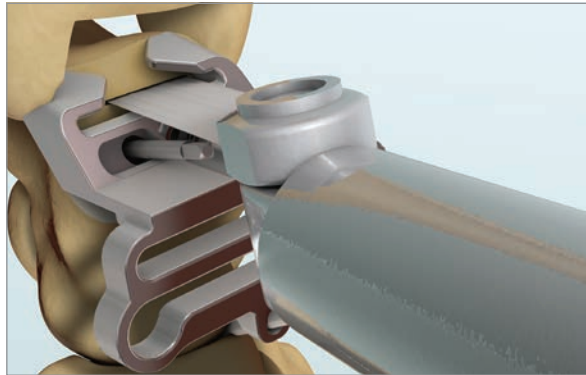


8.1 Place a 2.4mm drill pin in the distal section of the A/P Cut Guide to secure it.

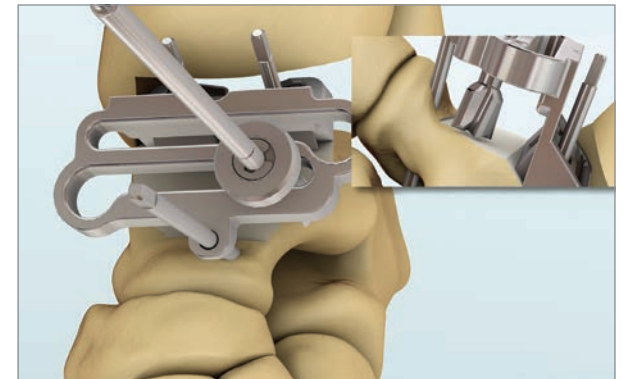
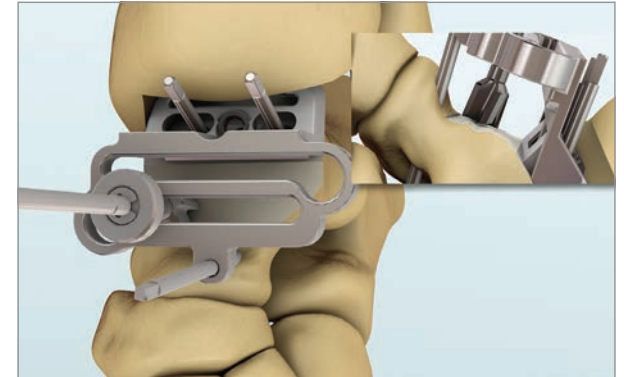
⚠ CAUTION: Be careful not to penetrate into the subtalar joint.



8.2 With an oscillating saw, make the posterior talar cut through the posterior guide of the Talar A/P Cut Guide.



8.3 Using the Anterior Chamfer Reamer begin with the distal cut slot and proceeding with the proximal cut slot, prepare the anterior surface of the talus through the superior and inferior slots of the Talar A/P Cut Guide with a pecking and sweeping motion.



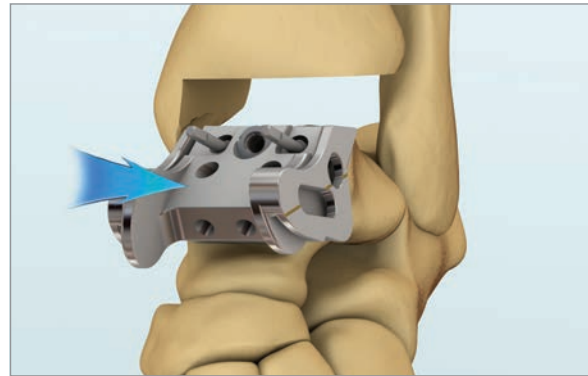
8.4 Remove the pin from the Talar A/P Cut Guide, unlock it from the Datum, and remove the Talar A/P Cut Guide from the Datum.

⚠ CAUTION: Make sure all loose bone is removed from the anterior surface of the talus, and the surface is smooth so as to not interfere with Talar M/L Cut Guide in the next steps.

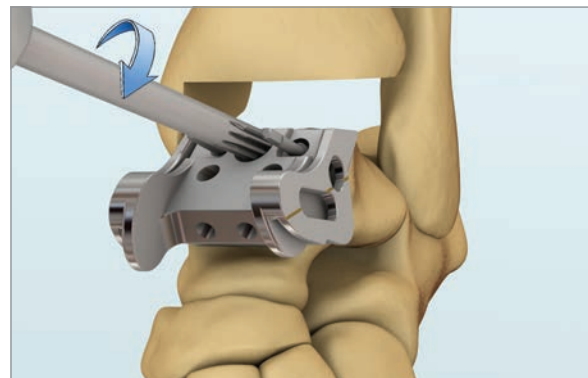


XS/XXS - Place a 2.4mm Drill Pin back into the center hole of the guide. Remove the two shoulder bolts. Remove the A/P Cut Guide. Insert the Talar M/L Cut Guide onto the centering 2.4mm pin and secure it with the two shoulder pins.

8.5 Insert the Talar medial/lateral Cut Guide onto the Datum. Secure it with its locking bolt.



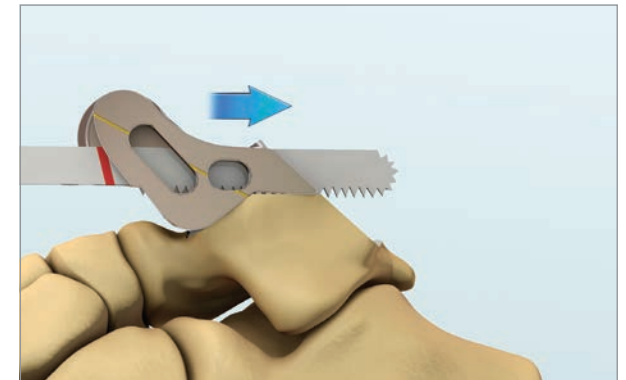
NOTE: For additional fixation support, with osteopenic bone, for example, additional pins or shoulder pins can be utilized in the Talar M/L Cut Guide.



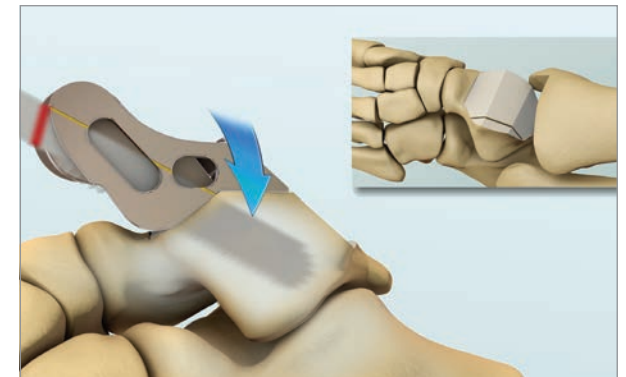
Use the Joint Space Distractor to clamp the M/L Cut Guide to the top of the talus.

⚠ CAUTION: Pay particular attention that there is no gap between the M/L Cut Guide and the top of the talus especially posteriorly.

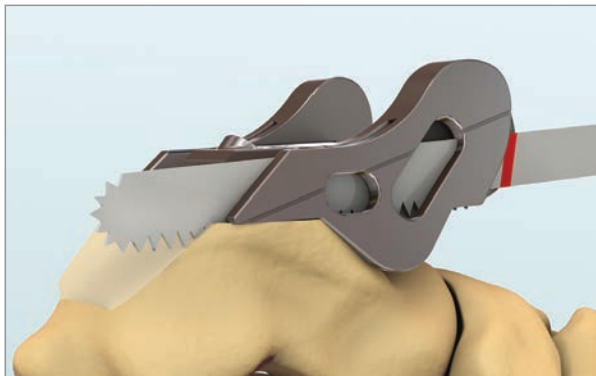
8.6 The reciprocating blade is inserted into the guide until the laser mark and last cutting tooth are flush with the front edge of the guide. The saw is then started and rotated by dropping the tip of the saw blade until the top edge of the blade is even with the engraved line on the side of the guide. This insures the proper depth of resection while avoiding resecting down into the sub-talar joint.



8.7 The blade is then drawn anteriorly until the teeth meet the bottom edge of the anterior chamfer face.



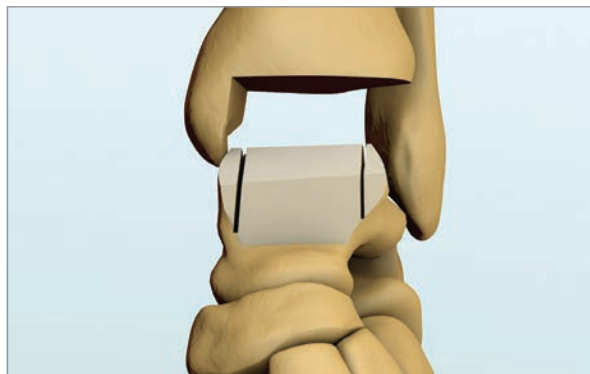
8.8 The same motion is repeated on the other side.



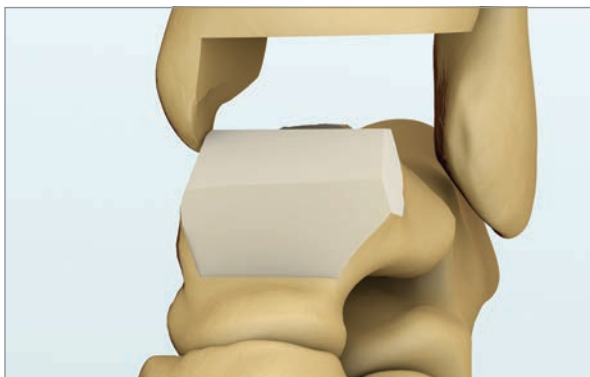
8.9 Remove the Talar M/L Cut Guide, Datum, and fixation pins from the talus. Take care to fully engage the Pin Driver on the Drill Tip Pins by rotating the Driver until the square end of the Pin seats deeply inside the Pin Driver.

⚠ CAUTION: If using power, ensure full engagement before applying power.

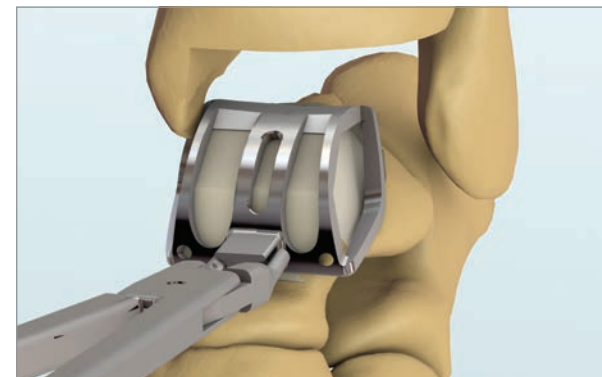
📌 NOTE: The M/L talar cut bone is most easily removed by using a 6mm osteotome at 90° to the cut surface, rather than prying the bone away from the center of the talus.



8.10 Using an osteotome, remove the medial/lateral cut section of the talus. Approximately 10mm medial and 15mm lateral gutter bone must be removed.

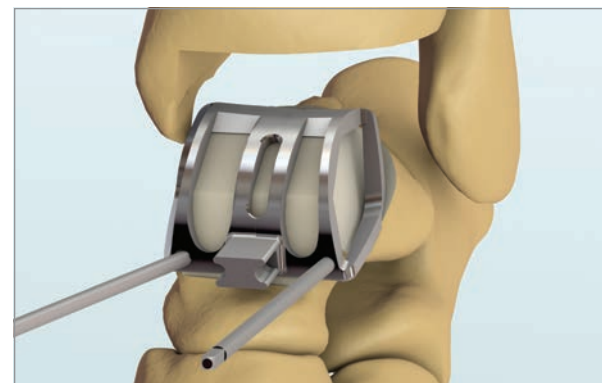


8.11 Using forceps, place the Talar Window Trial over the talus. The Talar Window Trial is used to ensure that all talar cuts are complete and accurate, and all loose bone has been removed.



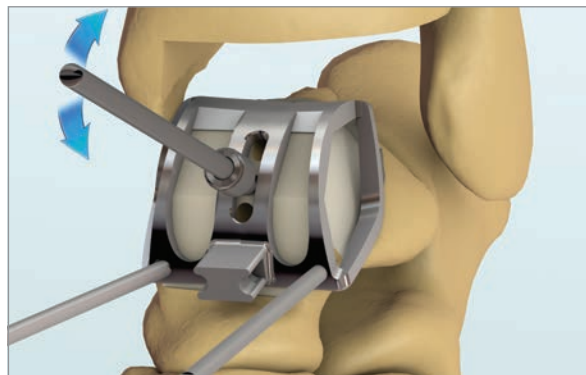
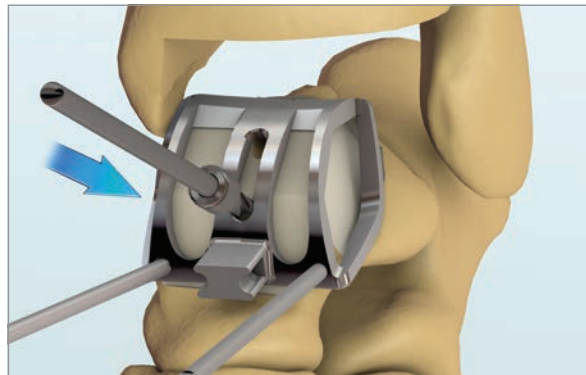
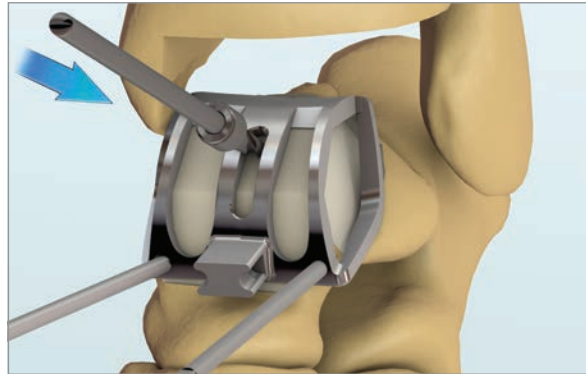
8.12 Use a mallet to begin placement of the 2.4mm fixation pins and ensure proper orientation and alignment.

⚠ CAUTION: Improper alignment may cause the pins to bind in the holes of the Talar Window Trial.

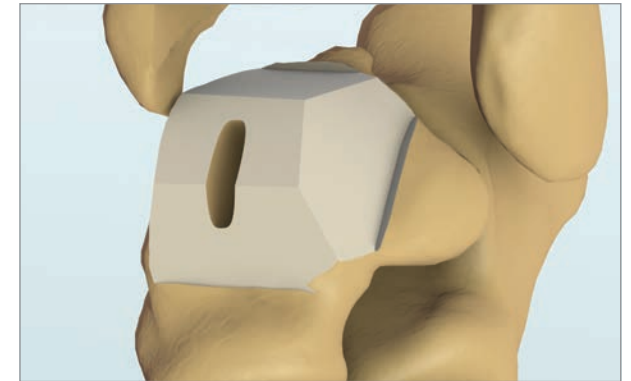


8.13 Insert the Talar Keel Mill into the center slot of the Talar Window Trial, and drill an anterior hole, a posterior hole, and center hole. Connect the holes by sweeping the drill in the slot.

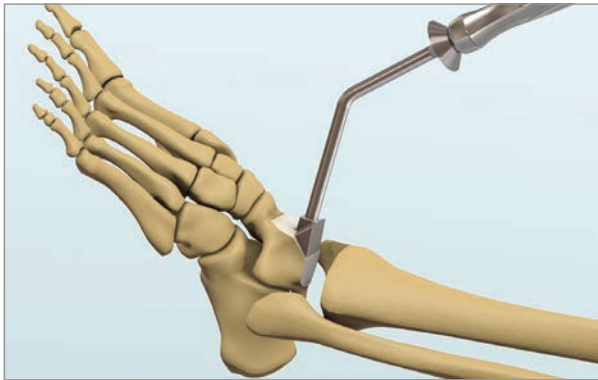
NOTE: Raise the drill as close to the tibia as possible, then pull the mill forwards; this will ensure that an anterior window is created in the anterior cut surface of the talus.



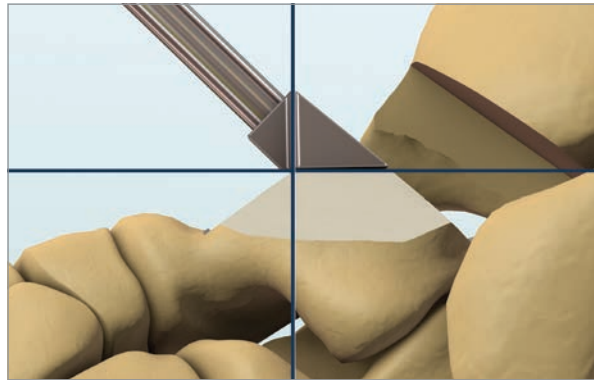
8.14 Remove the Talar Keel Mill, fixation pins, and Talar Window Trial.



8.15 Insert the Keel Broach into keel slot to check the talar cuts.

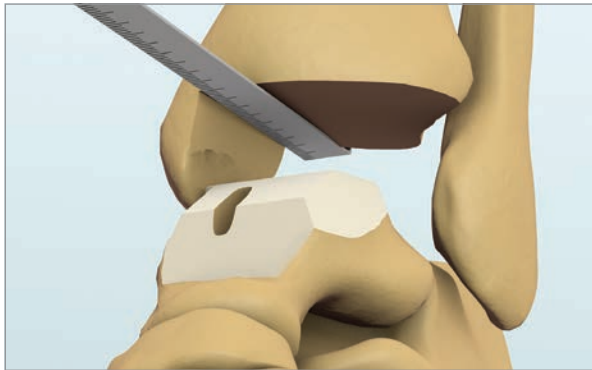


8.16 The back angled surface of the keel broach should line up with the posterior talar cut, and the vertical face should line up with the intersection of the anterior and superior talar cuts.

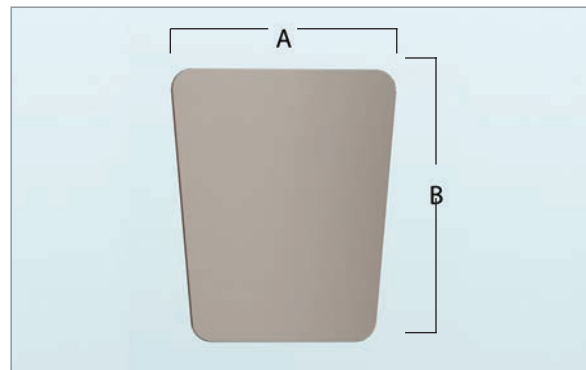
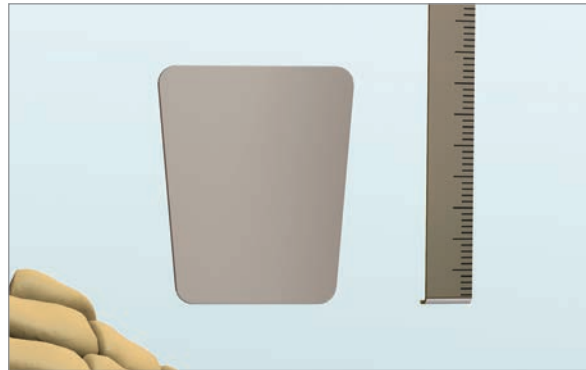


STEP 9: IMPLANT SIZING AND PLACEMENT

9.1 To obtain the correct size for the tibial component, hook the edge of the ruler to the posterior edge of the tibial surface.



9.2 Obtain anterior/posterior dimension medially and laterally on the tibia, and select corresponding tibial component based on the reference chart below.



Size	A (mm)	B (mm)
X-Small	30	30
Small	32	30
Medium	32.5	35
Large	33	40
X-Large	33.5	45

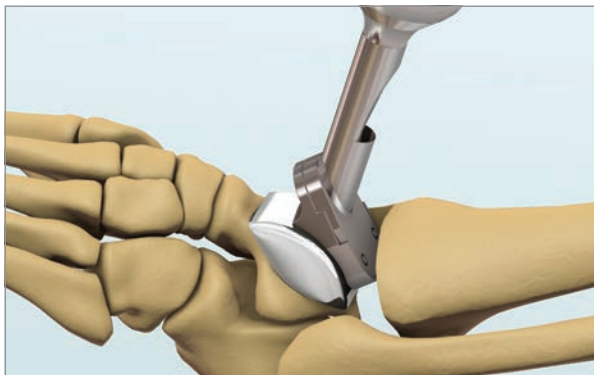
9.3 Insert corresponding Barrel Hole Guide (BHG) to confirm adequate space. The black laser on the inferior portion of the Barrel Hold Guide mimics the actual implant's size. Depth and tibial surface coverage can be confirmed on fluoroscopy.

NOTE:

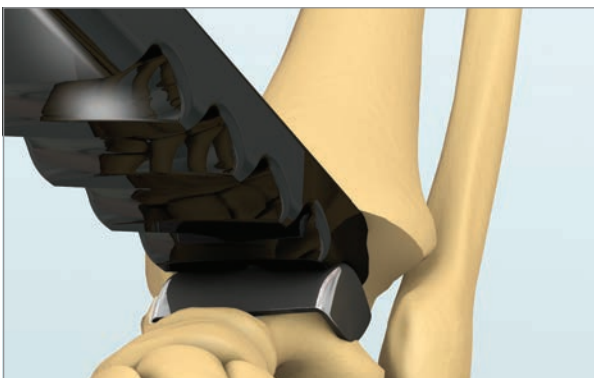
- Note how deeply inserted the BHG is – the tibial component will be implanted as deeply as the flange of the BHG is positioned in relation to the tibia.
- Gapping, due to bone fragments can also be identified with fluoroscopy. Look for incongruence or gaps between the Barrel Hole Guide and the cut surface of the Tibia.



9.4 Insert the talar component onto the prepared talus. The notched end of the Joint Space Evaluator can be used on the anterior edge of the talar component to aid in impacting the talar component in place. Seat the talar component with the talar impactor.



9.5 Use the Joint Space Evaluator 9mm end to ensure the talar component is properly seated. Fluoroscopy can be used to determine proper A/P positioning of the talar component.



9.6 Next, insert the Tibial Barrel Hole Wedge between the tibia and the talar component. The poly ensures that the Barrel Hole Guide (BHG) is flush against the prepared tibial surface and to protect the bearing surface while inserting.

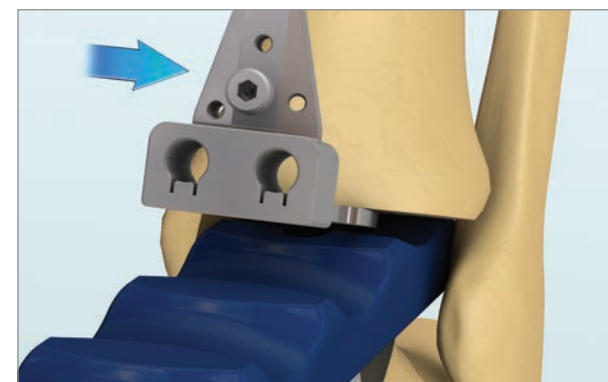
⚠ CAUTION: The Tibial Component should have maximum cortical coverage to resist subsidence. A small amount of overhang anteriorly and posteriorly is acceptable.



9.7 Place the BHG against the prepared surface of the tibial cut. Ensure alignment of the BHG with the talar component.

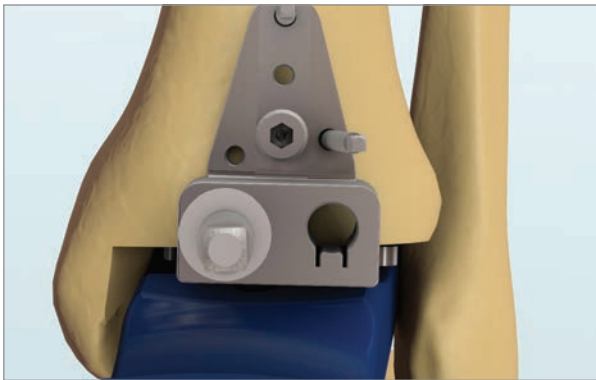
⚠ CAUTION: Fluoroscopy should be used to ensure the BHG is flush with the cut tibial surface.

⚠ WARNING: If gapping occurs, it is possible that additional bone fragments are present, and need to be removed. Secure the BHG to the tibia with two 2.4mm fixation pins.



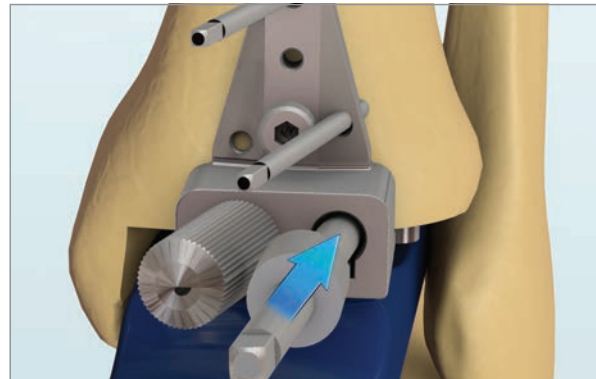
9.8 Drill the first hole with a 6.5mm Barrel Hole Drill with hand slightly dropped toward the foot to prevent the drill from skiving downward posteriorly.

⚠ CAUTION: Ensure the hole is drilled all the way so that the positive stop on the drill meets the Barrel Hole Guide.



9.9 Remove the drill bit, and insert the Barrel Hole Plug in the drilled hole to ensure precise spacing as the second hole is drilled.

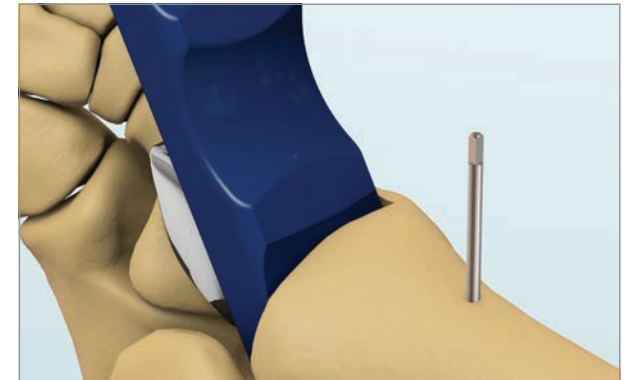
⚠ CAUTION: Drill the second hole, being sure to drill all the way to the positive stop on the drill.



9.10 Use the Key Hole Broach to remove the thin section of bone between the hole and the cut tibial surface. Then, the Barrel Hole Plug should be inserted in the second hole, and the first hole should be prepared with the Key Hole Broach.



9.11 Remove the fixation pins and BHG, leaving the proximal pin to guide orientation during impaction.



9.12 Select a tibial component that matches the size of the BHG. Mount the tibial component onto the tibial inserter, locking it with the thumb screw.

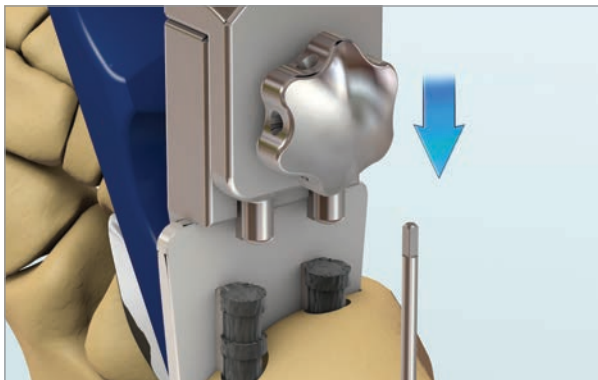


9.13 Insert the mounted tibial component into the prepared tibial barrel holes, ensuring alignment with proximal pin.

⚠ CAUTION: Drop hands toward foot while impacting to ensure barrels remain seated in prepared channels. Place the foot in maximum plantarflexion.

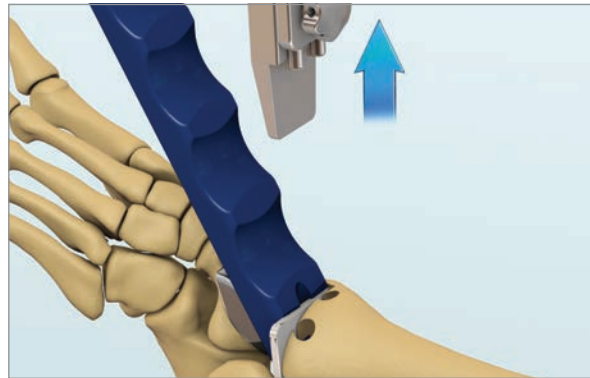
Impact the tibial component until the barrels are fully inserted in the tibia.

📋 NOTE: Due to the slope of the bone of the anterior tibia, the tibial tray may protrude 1mm from the current anterior edge of the anterior tibia. However, due to the poor soft tissue envelope of the ankle, too much protrusion is to be avoided.



9.14 Loosen the thumbscrew on the tibial inserter, and remove the Tibial Inserter. Fluoroscopy can be used to determine proper implant depth. Use the notched side of the Joint Spacer Evaluator to impact the tibial component to its final depth. Place the smallest Trial Bearing between the tibial and talar components.

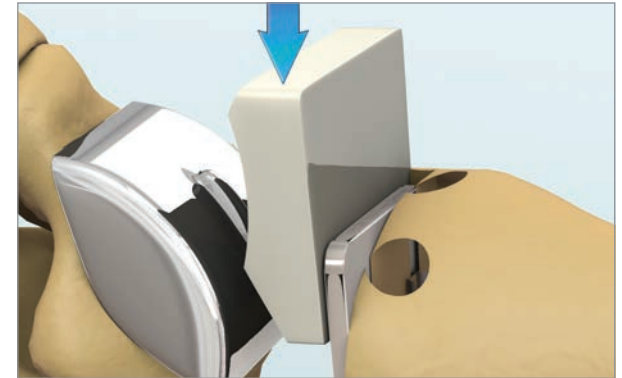
📋 NOTE: A 2.4mm pin can be used to loosen the thumbscrew on the Tibial Inserter in case it is put on too tightly.



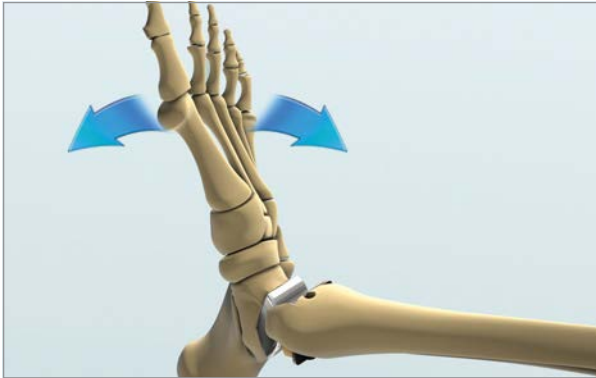
9.15 To assess bearing size, place the trial bearing in the joint space. If the trial forceps is used:

⚠ WARNING: Be careful not to scratch the polished bearing surfaces.

⚠ CAUTION: Do not twist the forceps to assess varus / valgus, as this can stress the forceps metal tips.

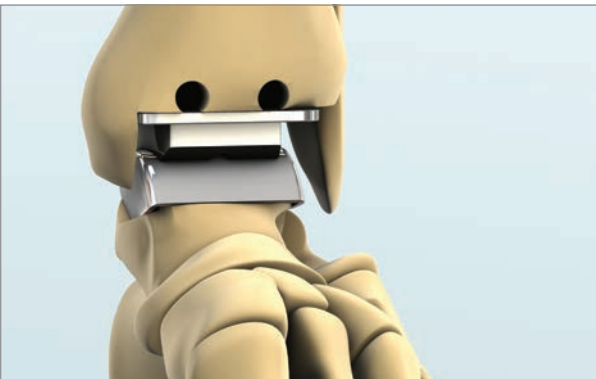


9.16 Once the trial bearing is in place, assess the ankle stability and assess the Trial Bearing size.



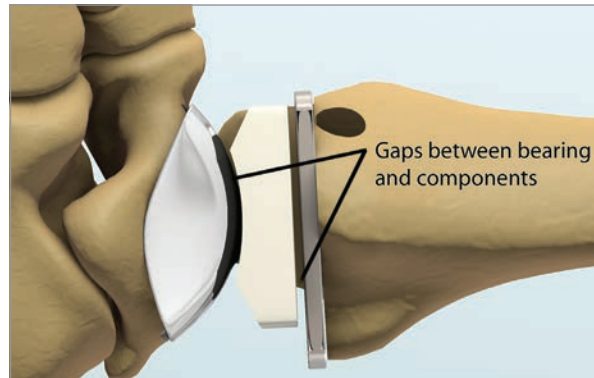
9.17 If a gap of more than a millimeter is seen anywhere between the trial bearing and metal components, try the next thicker size.

⚠ CAUTION: If a gap occurs only on one side, ligament balancing may be necessary.

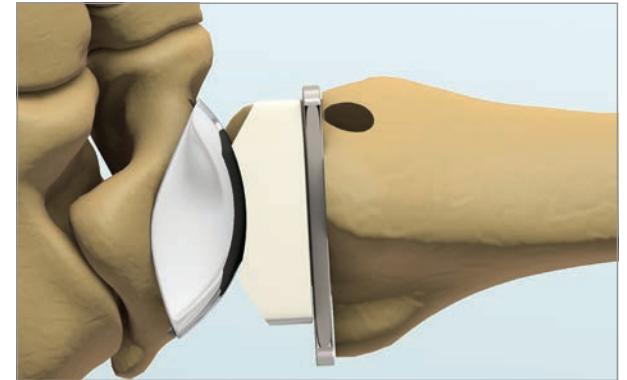


9.18 If satisfactory results are obtained, replace the trial bearing with the appropriate final mobile bearing.

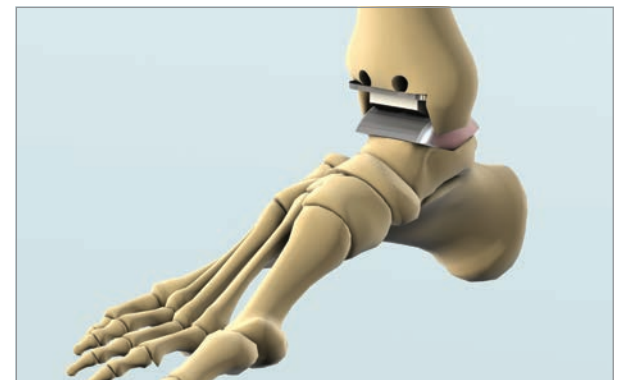
NOTE: If the trial bearing is difficult to remove, plantarflex the foot to move the bearing anteriorly and shuck the heel to better release the trial.



9.19 Fill the two barrel holes with bone graft and tamp to compact the material.



9.20 Perform any adjunct procedures, and then close the incision in layers.



POST-OPERATIVE MANAGEMENT

For a minimum of two weeks a patient should not bear any weight on the implanted STAR® ankle. The patient should keep 'toes above the nose' as much as possible while limiting all physical activities. Partial weight-bearing may begin at 2 to 3-weeks post-operative and gradually increase until the patient is fully weight-bearing at 4 to 6-weeks post-operative.

MOBILE BEARING REMOVAL

The polyethylene component may be removed with towel clamp to grip the sides. For tight joints, should polyethylene replacement be required, this component can also be drilled into, taking care to not damage any of the metal components. After drilling with a small drill, the shoulder pins can be used to lock into the polyethylene and remove the component.

TIBIAL COMPONENT REMOVAL

A Tibial Component Remover is included in the system. The Tibial plastic end of the Barrel Impactor can be removed (by unscrewing the large knob), and replaced with the Tibial Extractor. The Tibial Extractor can be inserted into the joint space and the distal lip hook over the posterior of the Tibial component. Be sure to remove bones covering the anterior aspect of the barrels. A thin, flexible osteotome may be required to free the implant from the bone.

TALAR COMPONENT REMOVAL

An osteotome can be used to disengage the Talar Component from the talus. For a well fixed Talar Component, an osteotome can be used to carefully separate the Talar Component from bone.



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MKT0190301 Rev C

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