APEX 3D S™
STEMMED TIBIA

SURGICAL TECHNIQUE GUIDE

APEX 3D S™ Stemmed Tibia

Exclusively foot & ankle
Paragon 28®

PRODUCT DESCRIPTION:

The Paragon 28® APEX 3D S™ Stemmed Tibia Total Ankle Replacement System is a fixed bearing device comprised of a tibial component with additional proximal fixation, a talar component, and a Vitamin E Ultra-High Molecular Weight Polyethylene component. Implants are available in varying sizes and design configurations intended for both primary and revision applications.

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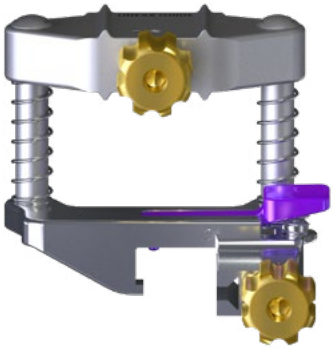
FEATURED IMPLANTS:

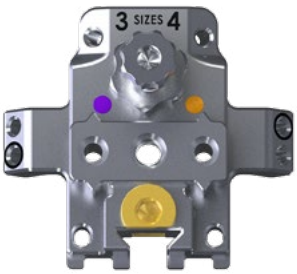
APEX 3D S ARC Tibia Implant

APEX 3D S Flat Tibia Implant

FEATURED INSTRUMENTATION:

Linear Guide
-Secures the Right Angle Drill to the Tibia Docking Fixture





Tibia Docking Fixture
-Secures the Right Angle Drill and Linear Guide to the tibia trial

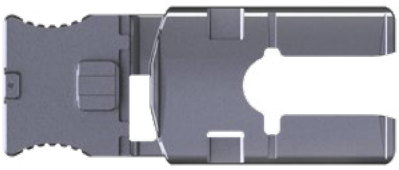
Right Angle Drill
-Prepares the vertical stem location in the tibia

Pilot Drill Bit 

Final Drill Bit 

Drill Bit Caps 

FEATURED INSTRUMENTS:



Modular Tibia Drill Trial
-Available in Arc/Flat

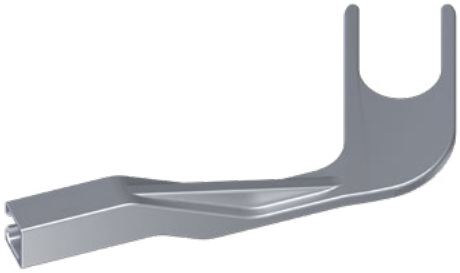
Modular Tibia Trial
-Available in Arc/Flat

Tibia Distraction Paddle

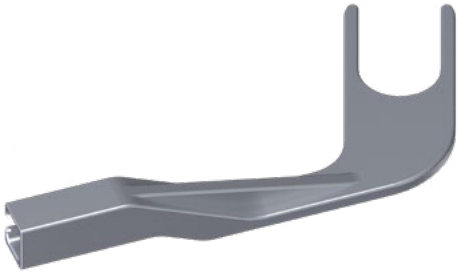
Talus Distraction Paddle

Impaction Protector
-Available in 3 sizes (1-2, 3-4, and 5-6)

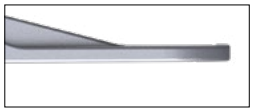
Implantation Paddle



Arc Forked Paddle



Flat Forked Paddle



Flat Paddle

Talar Shim

Manual Right Angle Drill

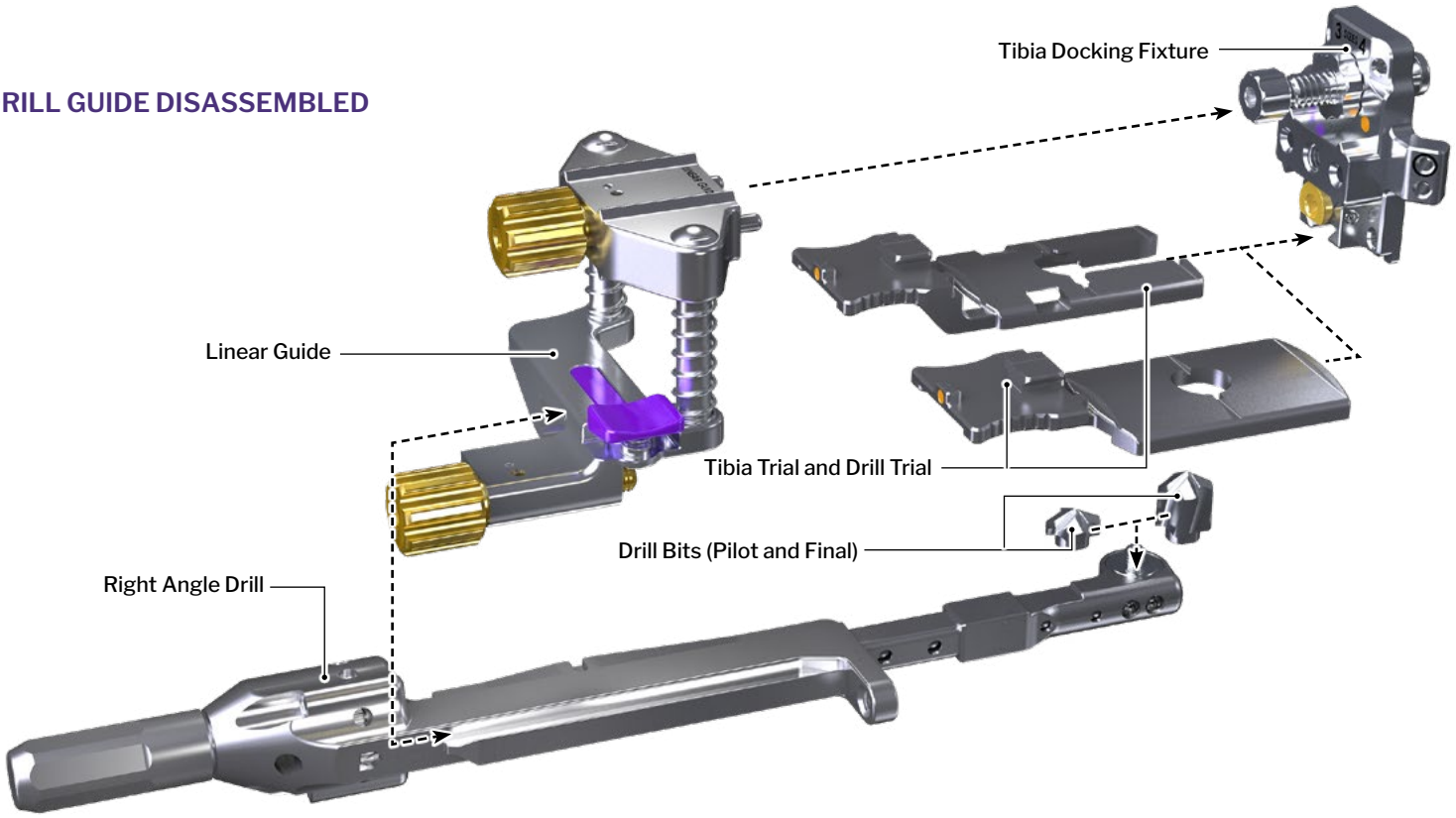
Drill Bit/Pilot Bit Wrench

Trial Holder

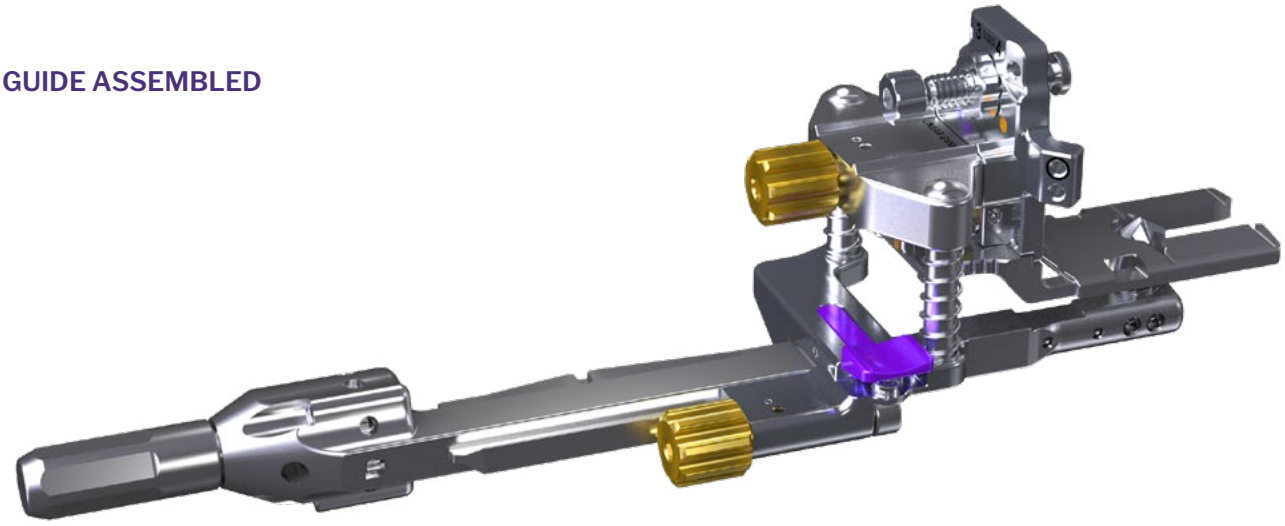
Graft Impactor
-Available in 3 sizes (1-2, 3-4, 5-6)

FEATURED INSTRUMENTS:

DRILL GUIDE DISASSEMBLED

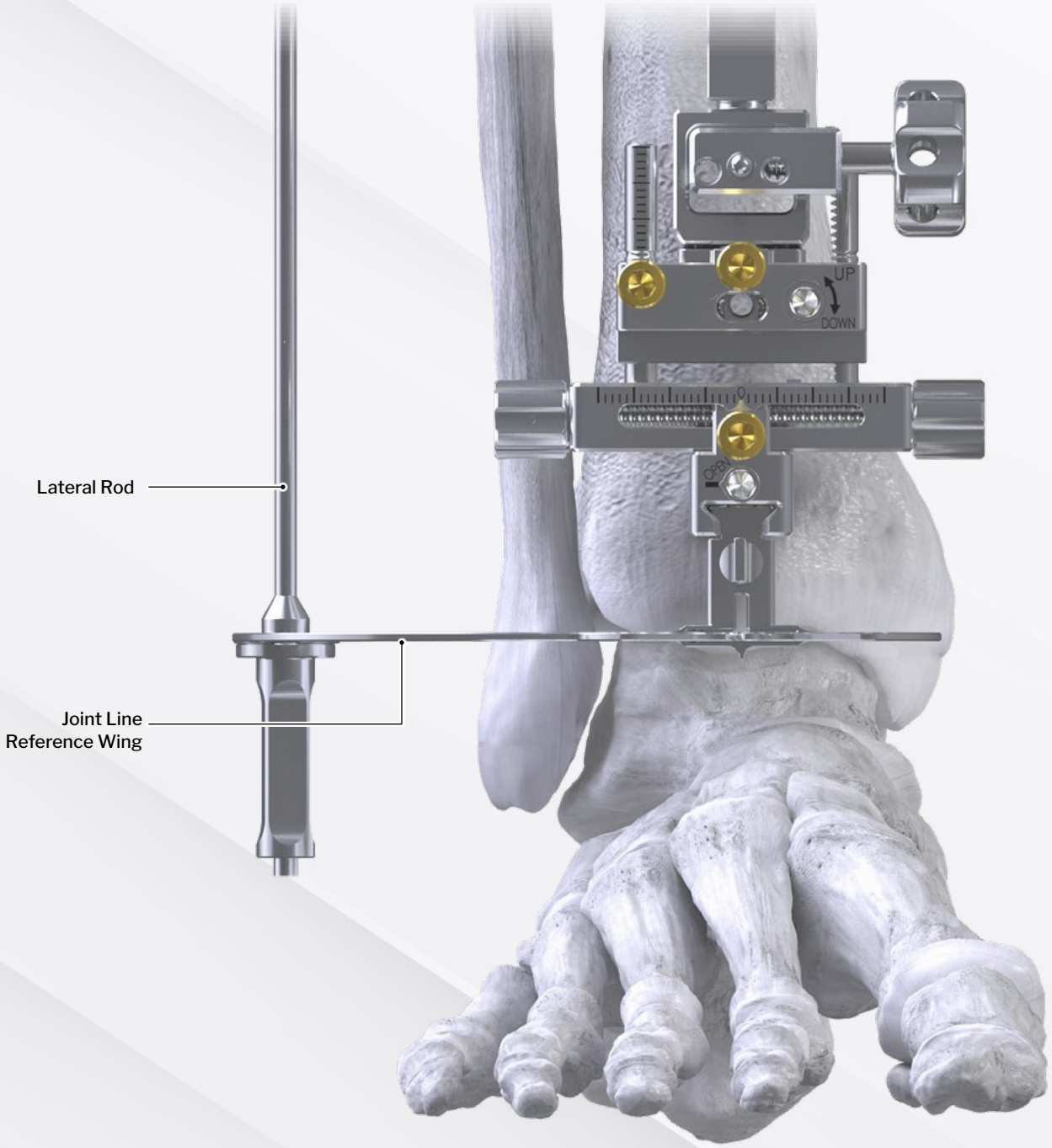


DRILL GUIDE ASSEMBLED



SURGICAL APPROACH

Reference APEX 3D™ Surgical Technique (P10-STG-0001) for the appropriate Surgical Approach Section.

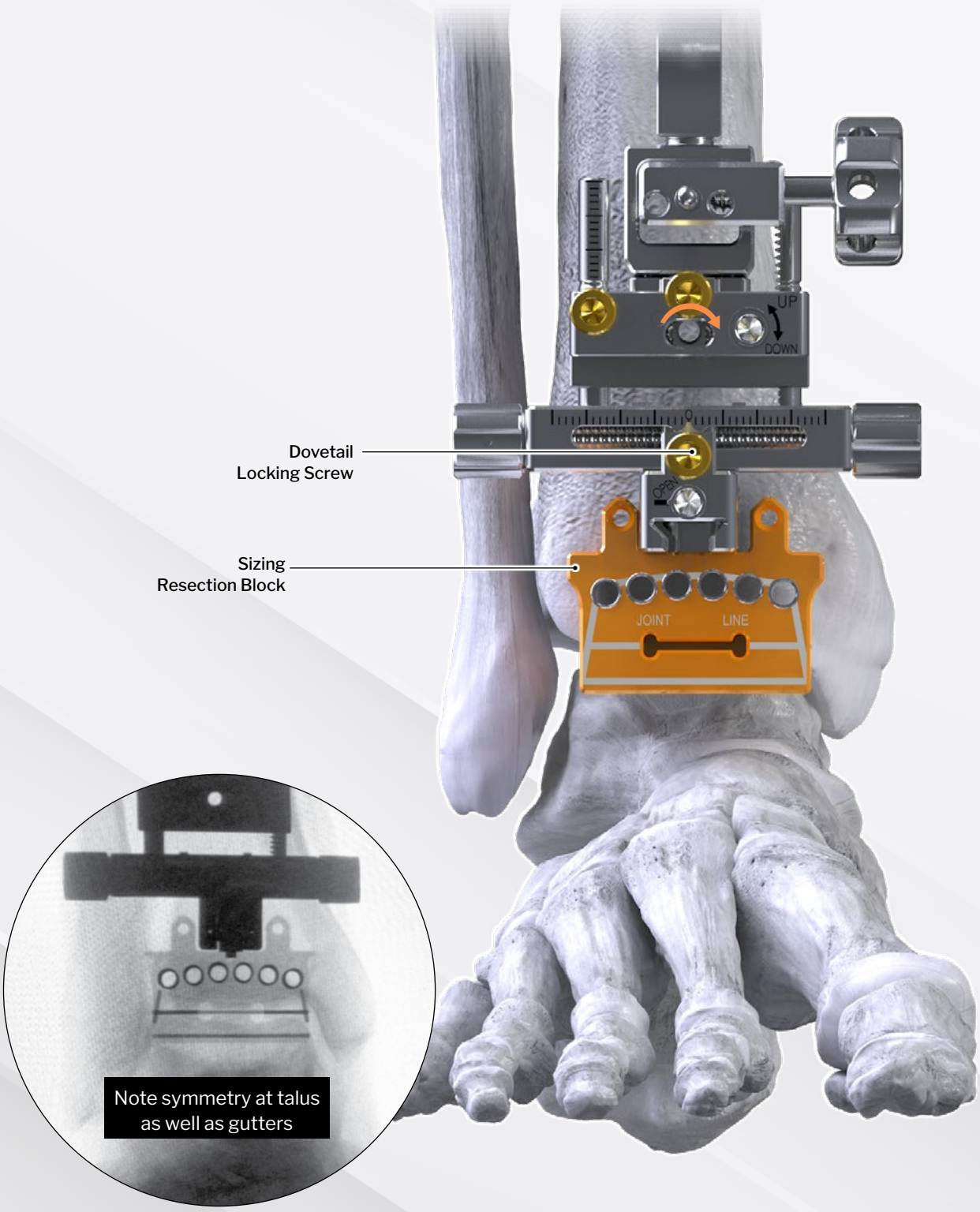


TRADITIONAL ALIGNMENT GUIDE

Reference APEX 3D™ Surgical Technique (P10-STG-0001) for the appropriate Traditional Alignment Guide Section.

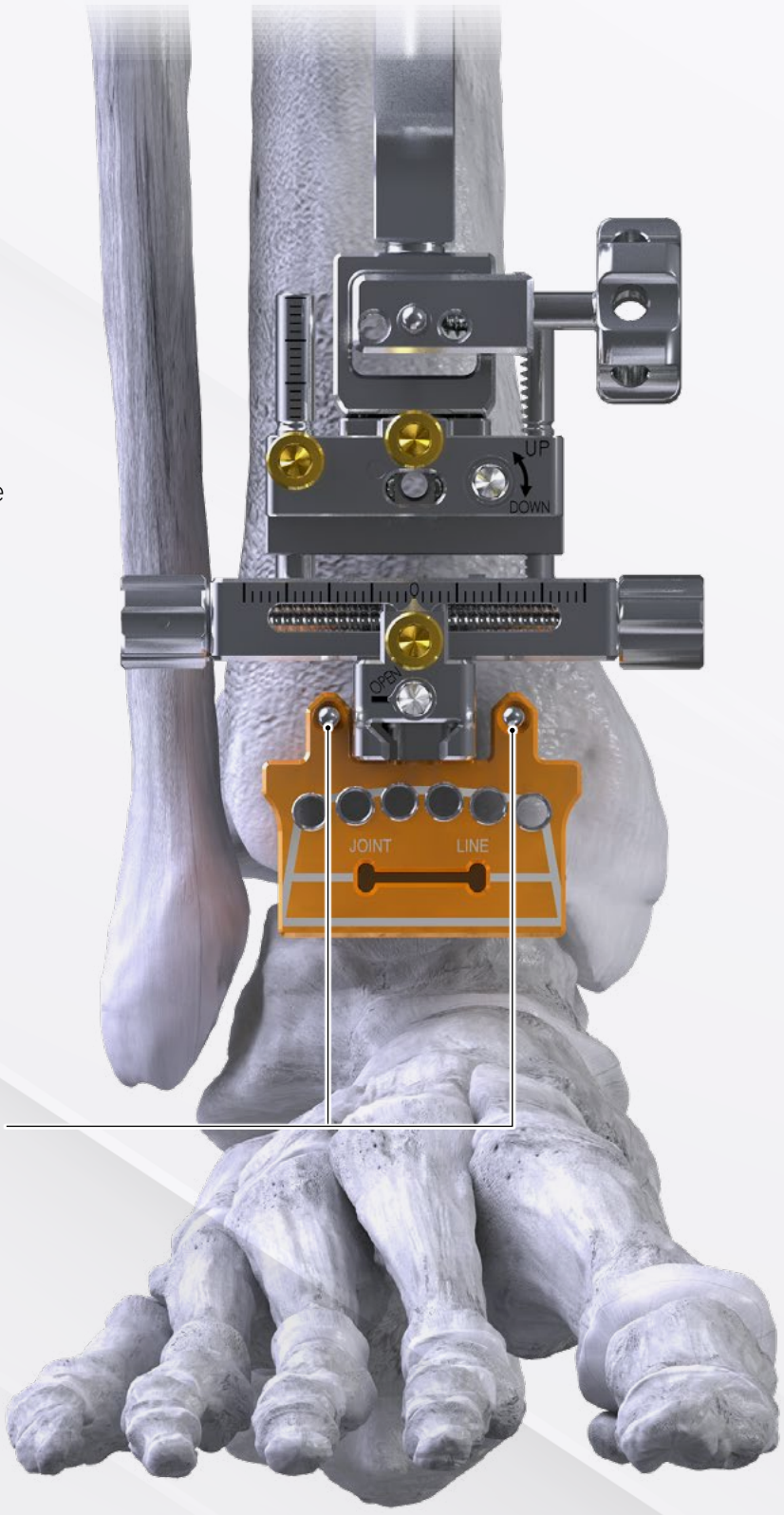
TIBIAL SIZING EVALUATION

Reference APEX 3D™ Surgical Technique (P10-STG-0001) for the appropriate Tibial Sizing Evaluation Section.



FINALIZE AND LOCK POSITION

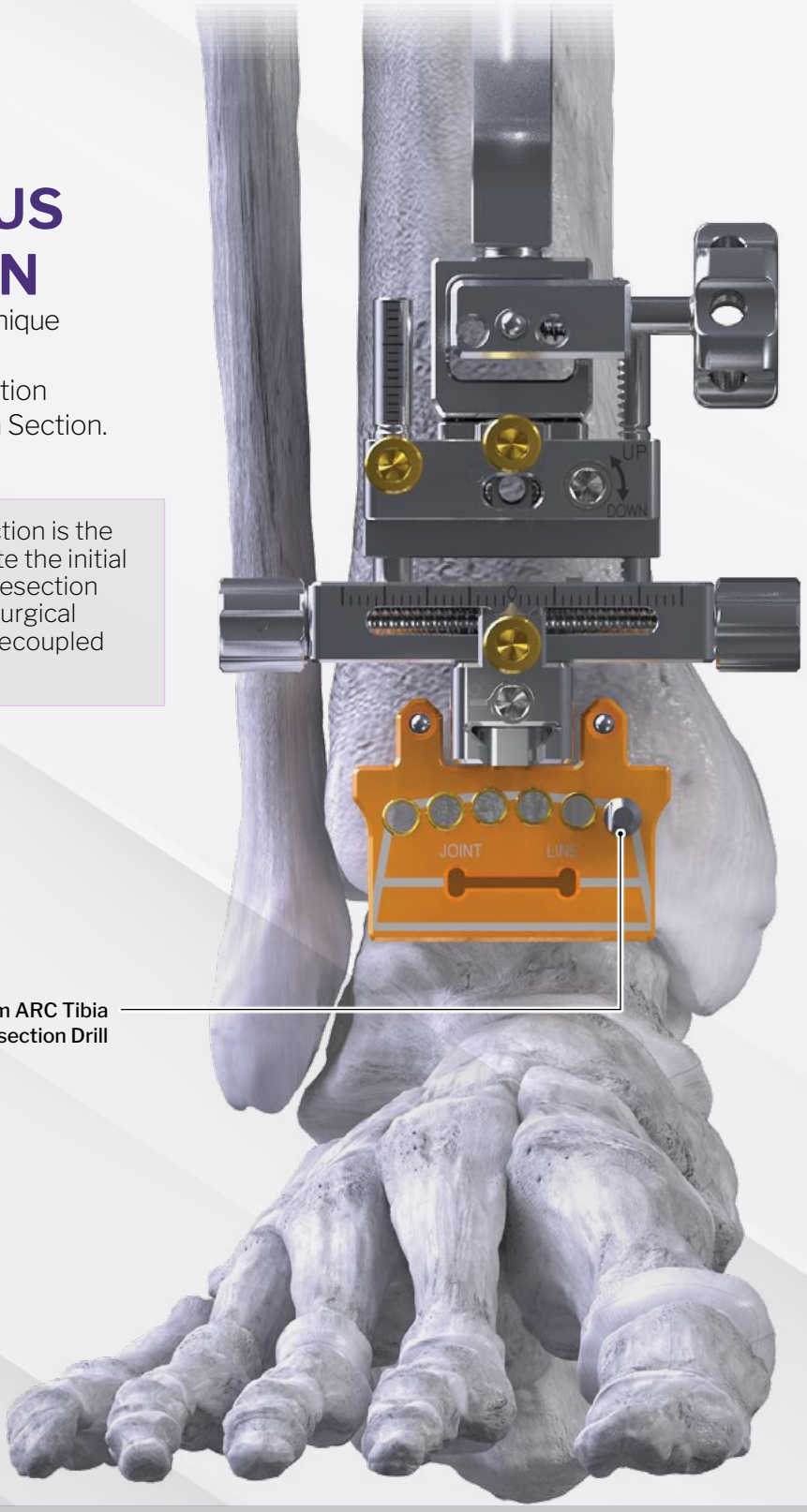
Reference APEX 3D™ Surgical Technique (P10-STG-0001) for the appropriate Finalize and Lock Position Section.



TIBIAL AND TALUS BONE RESECTION

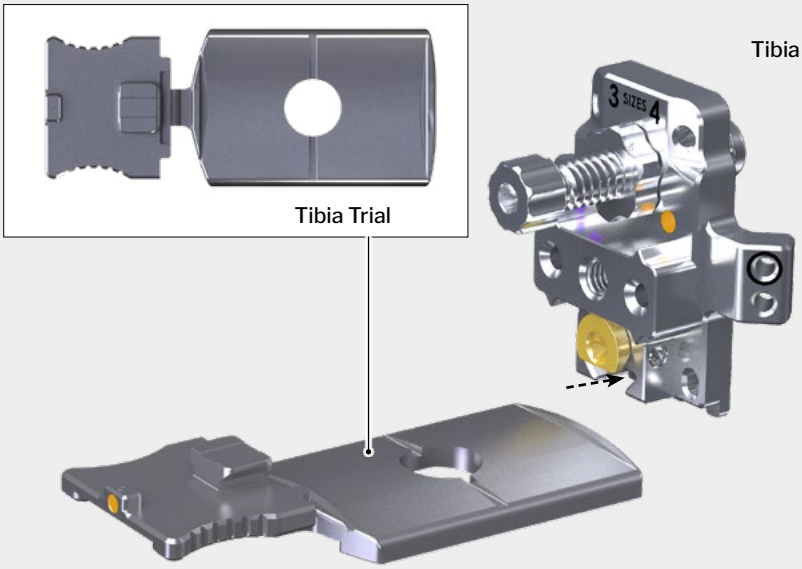
Reference APEX 3D™ Surgical Technique (P10-STG-0001) for the appropriate ARC Tibia / Chamfer Cut Talus Section or the Flat Cut Implant Preparation Section.

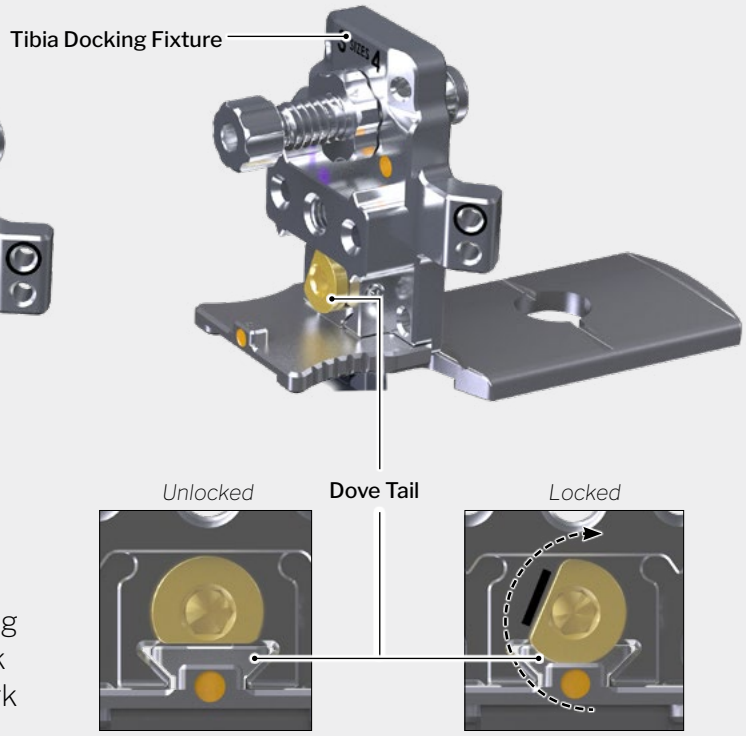
NOTE: If a decoupled Talar Resection is the selected option, **DO NOT** complete the initial talar dorsal cut with the coupled resection block featured in the APEX 3D™ Surgical Technique (P10-STG-0001) For Decoupled Cuts, reference P10-STG-0005.



TIBIAL TRIALING BACK TABLE ASSEMBLY:

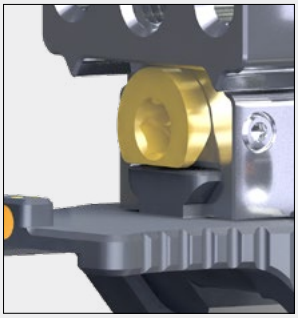
On the back table, assemble the size matched Tibia Docking Fixture and the size matched Tibia Trial by sliding the Tibia Trial into the dove tail of the Tibia Docking Fixture.



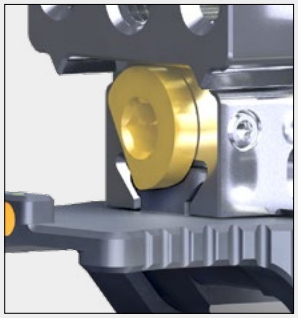


Lock the components into a single construct by turning the cam lock using a provided hex driver. The gold lock collar will cover the trial dovetail and reveal a laser mark line when locked.

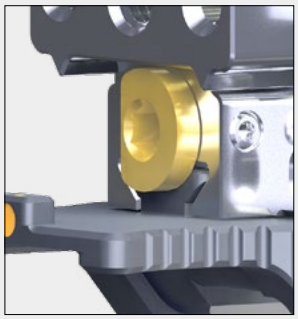
Tray not fully seated

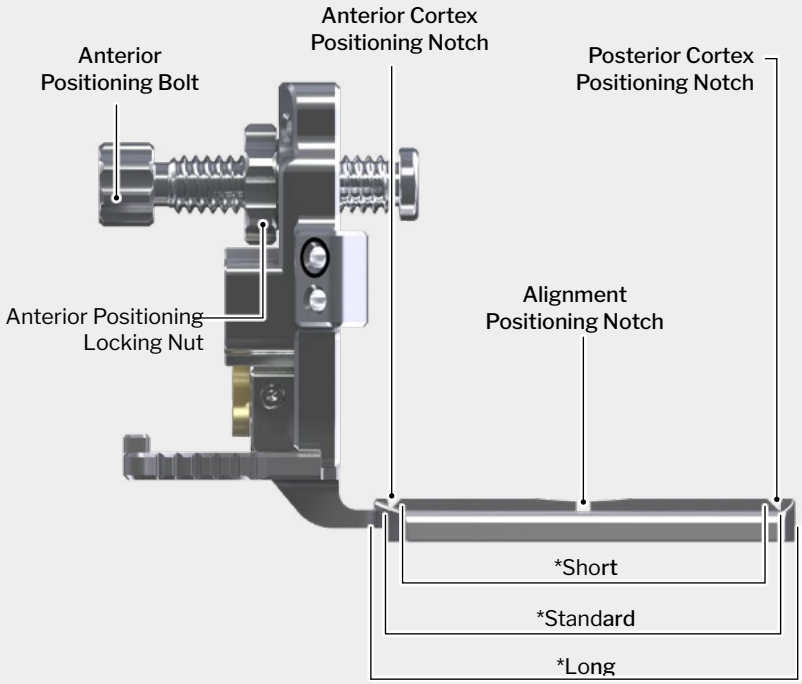


Collar grabs tray with ramp



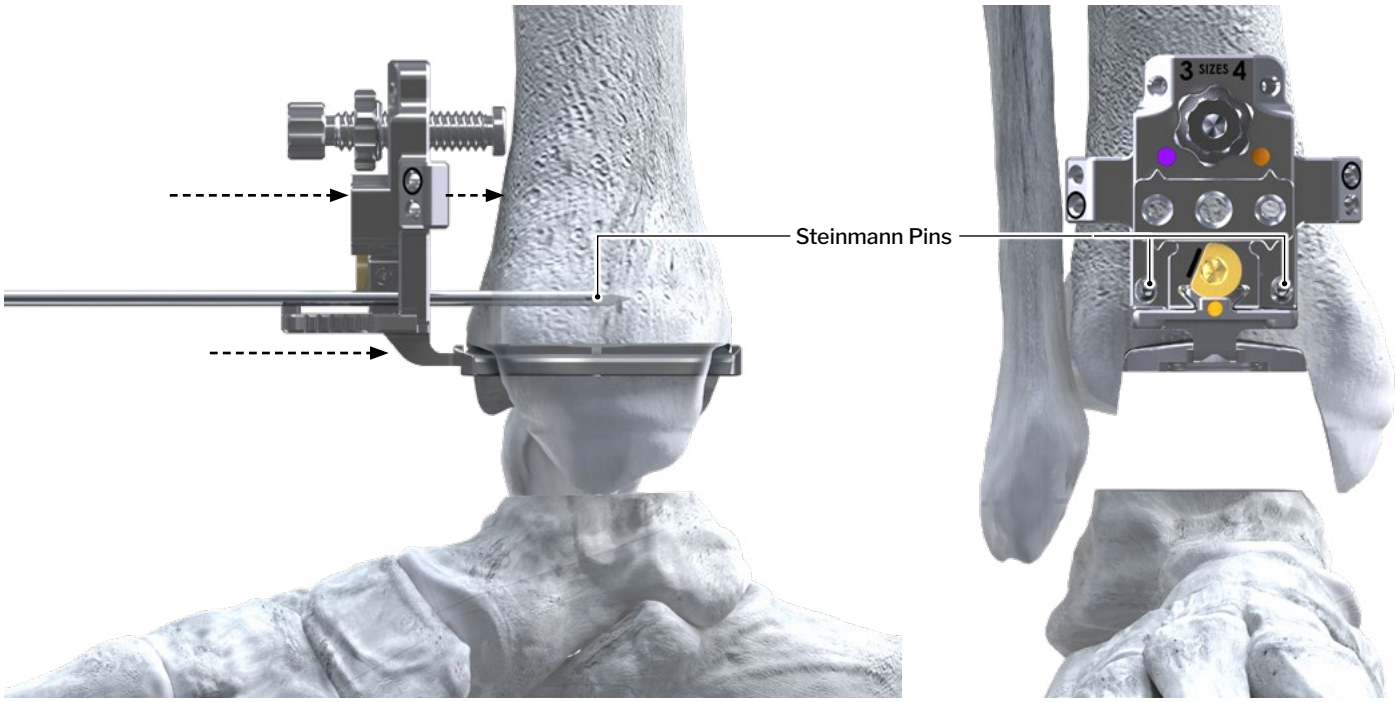
Collar pushes tray in, and cam locks it





TIBIAL TRIALING:

Slide the assembled Tibia Trial Construct over the two (2) Smooth Steinmann Pins that are already in place based on the alignment established according to the technique described in the APEX 3D™ Surgical Technique Guide (P10-STG-0001/P10-STG-0003).



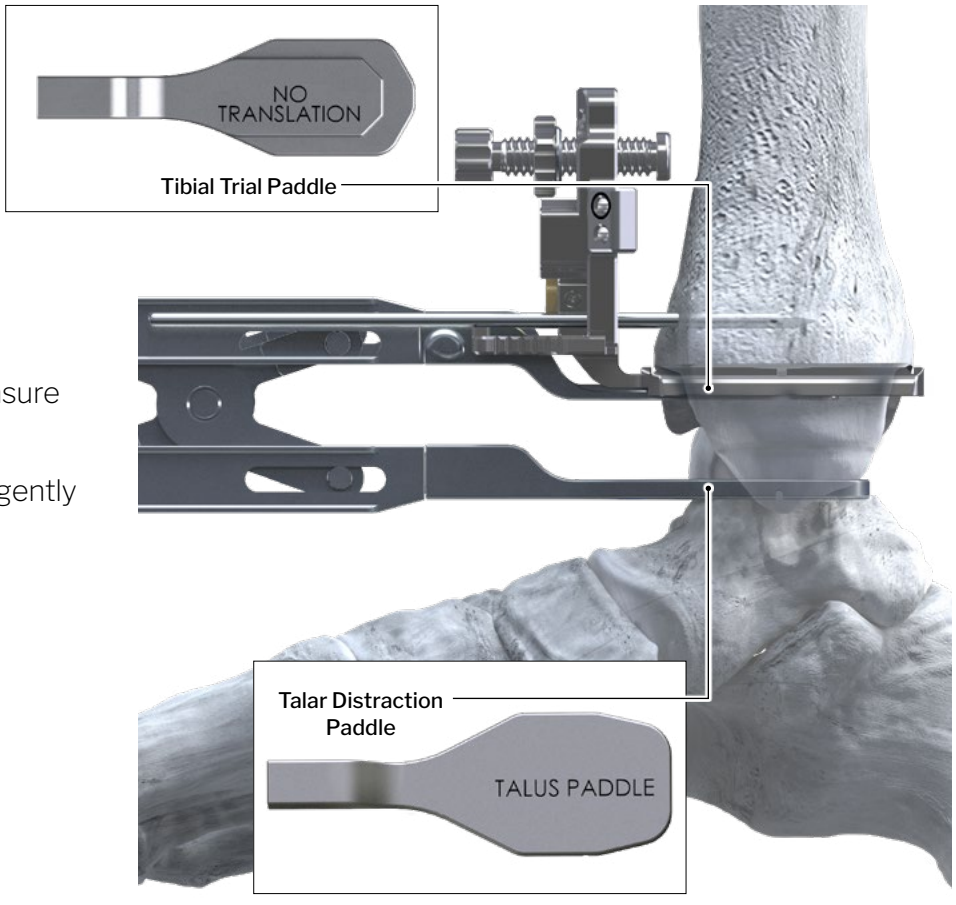
Utilizing the Parallel Distractor (4BAR), attach the constrained modular Tibial Trial Paddle and Talar Distraction Paddle.

Match the connection of the Parallel Distractor's Tibial Trial Paddle to the inferior receiving connection of the Tibia Trial Construct.

To determine appropriate positioning, ensure fluoroscopic markers are aligned.

Under a lateral view, distract the joint by gently squeezing the distractor handle.

Under a lateral view, confirm tibia implant length.

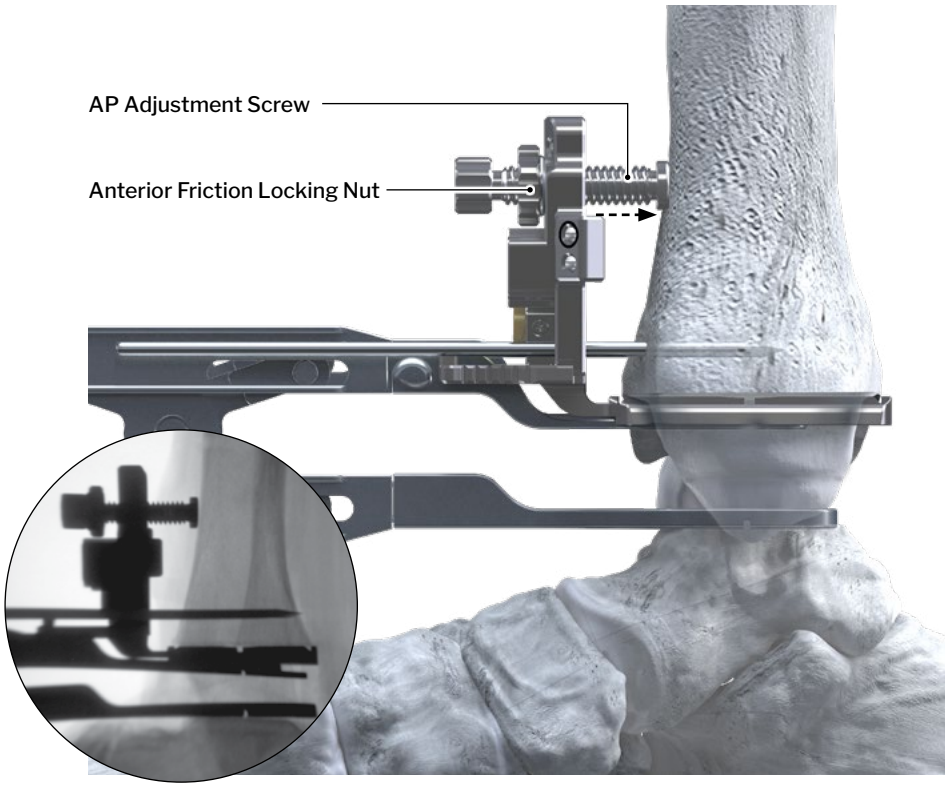


TIBIAL TRIALING:

With the Parallel Distractor loosely retracted in position, fine tune the anterior position of the Tibial Trial Paddle by adjusting the AP positioning bolt with a hex driver.

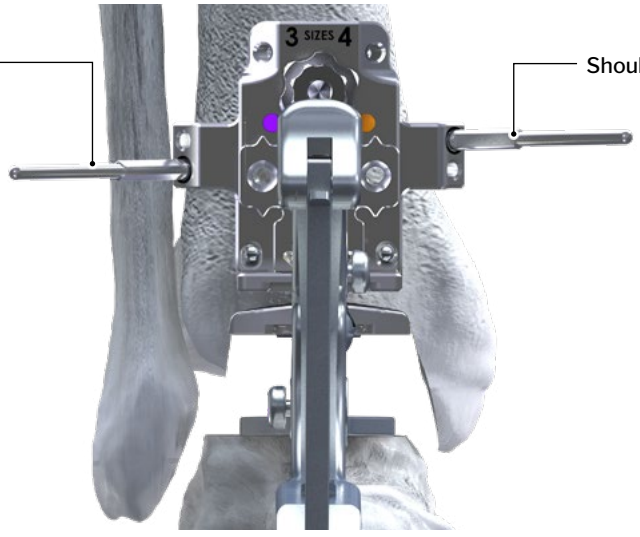
The AP adjustment screw should be adjusted lightly, with low force. High force can cause flex and error in stem placement. Ensure that the trial assembly does not flex out of perpendicularity to the Tibial Docking Fixture from an AP view.

Once appropriate positioning has been achieved, secure the Tibial Trial Paddle's position by advancing the anterior friction locking nut until flush against the trial.

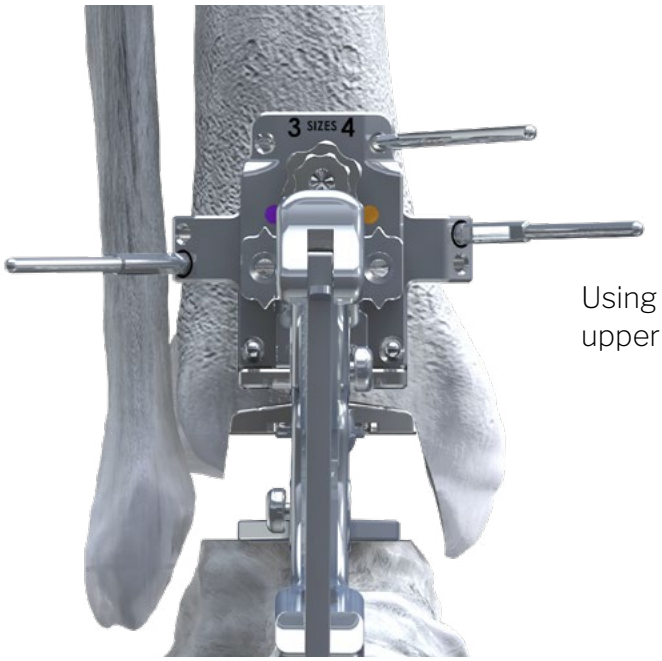


SECURE TIBIAL TRIALING CONSTRUCT:

By hand, place two (2) Short Shank 50 mm Threaded Shoulder Pins into a set of the offset converging pin holes located on the medial and lateral aspect of the Tibial Docking Fixture. Ensure that either both laser marked pin holes are used together, or non-laser marked pin holes are used together.



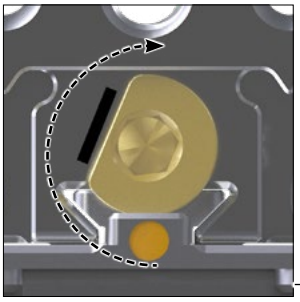
SECURE TIBIAL TRIALING CONSTRUCT:



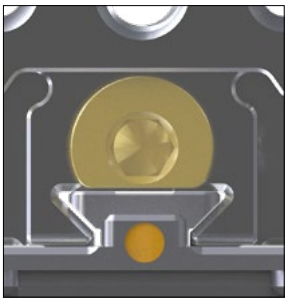
Using power, place 1 Smooth Steinmann Pin in one of the upper holes on the Tibia Docking Fixture.

Remove the distractor, re-check Tibia Trial Construct position under lateral fluoroscopy to confirm position and fit.

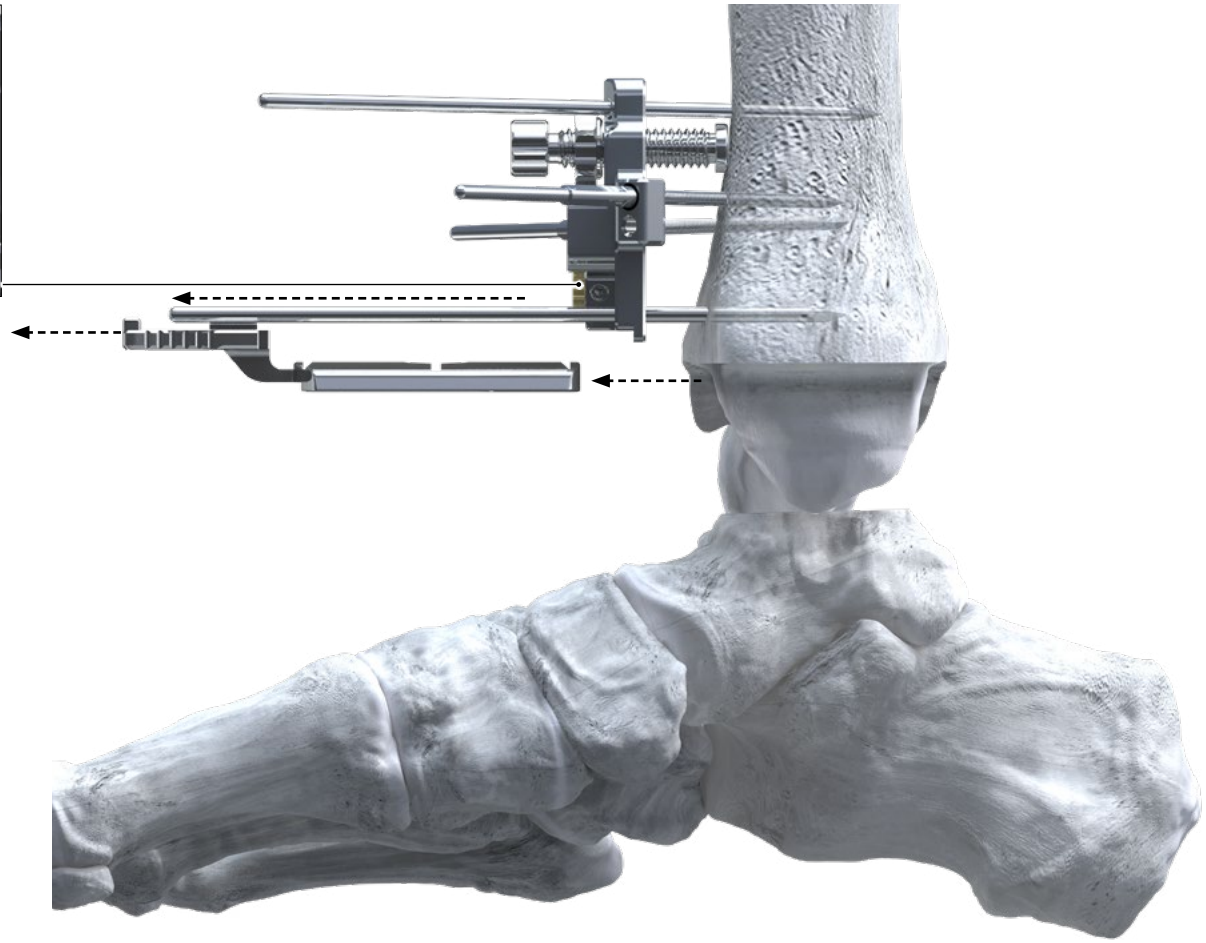
Unlock the cam lock and remove the Tibia Trial by hand or with the trial holder. Remove the two smooth Steinmann Pins.



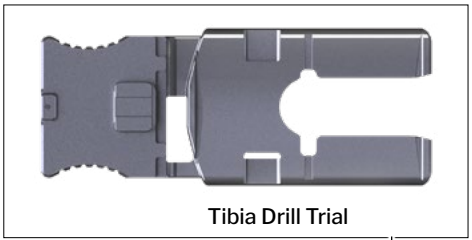
Locked



Unlocked

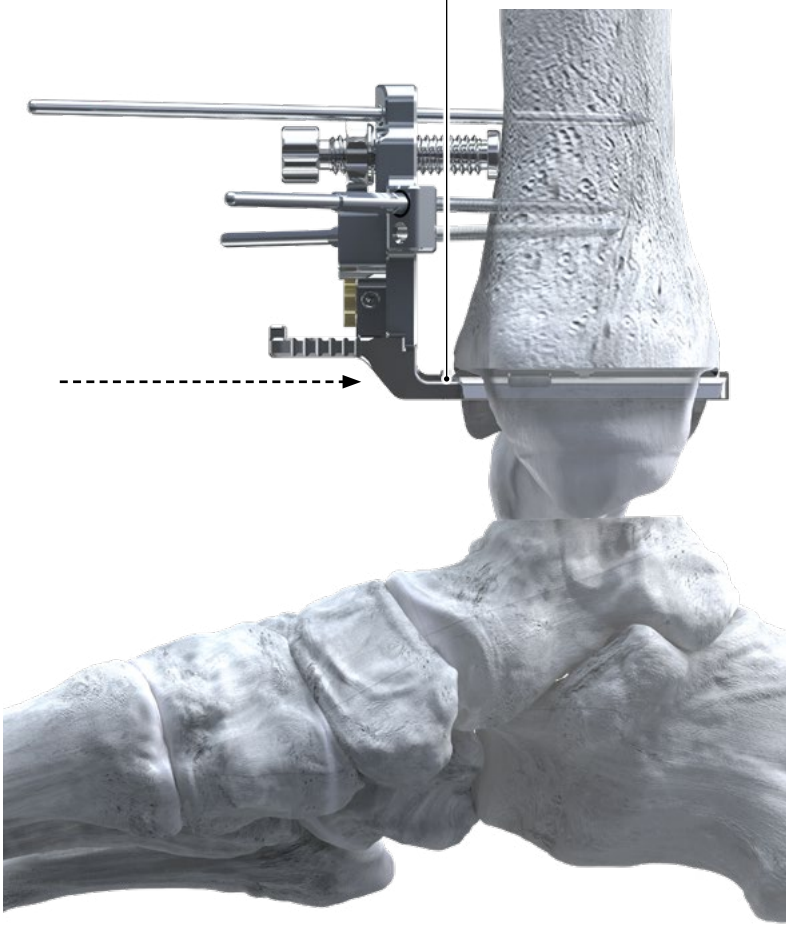


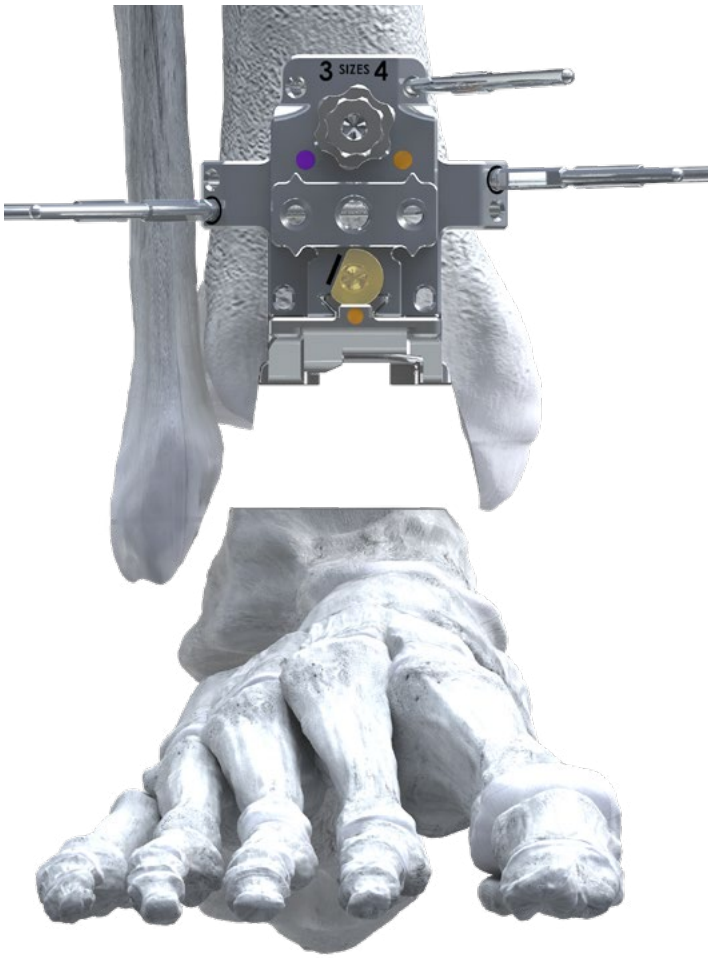
SECURE TIBIAL TRIALING CONSTRUCT:



Tibia Drill Trial

Replace the Tibia Trial with the appropriate size matched Tibia Drill Trial by hand or with the trial holder and secure by turning the cam lock to the lock position.

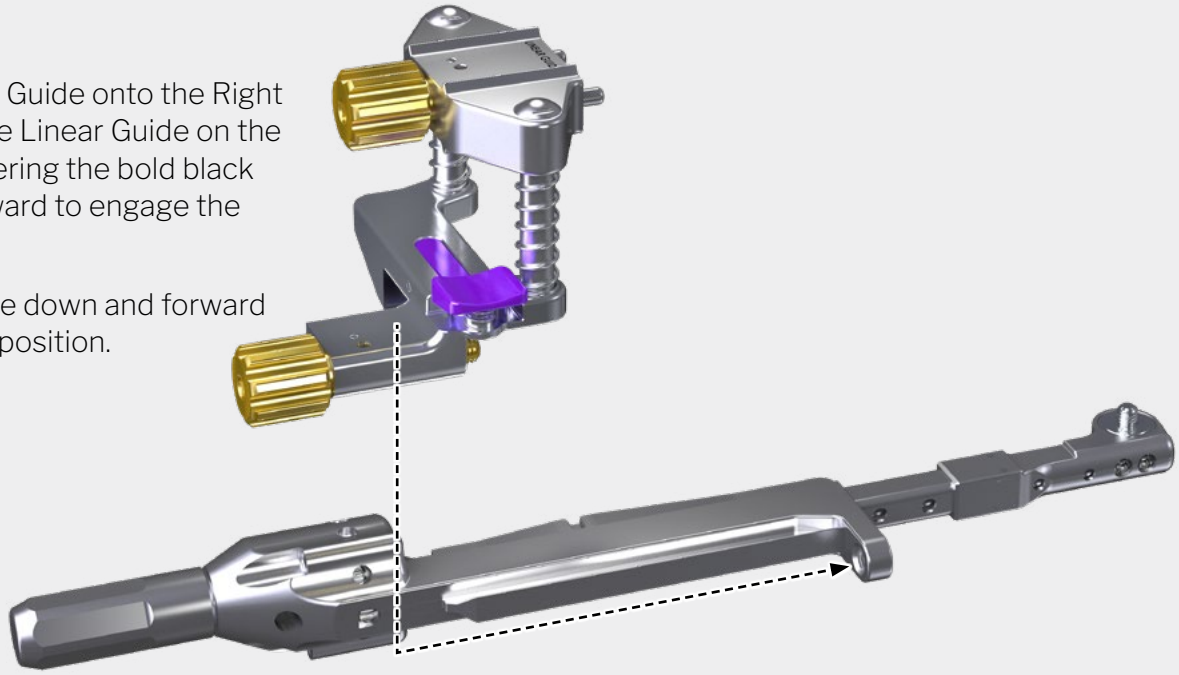


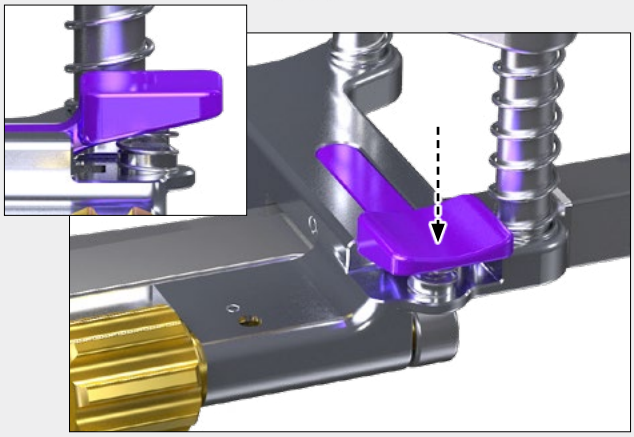


TIBIAL VERTICAL DRILLING ASSEMBLY BACK TABLE ASSEMBLY:

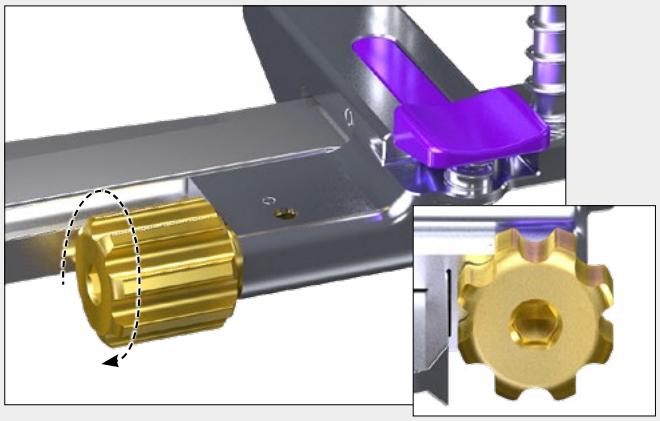
Assemble the Linear Guide onto the Right Angle Drill placing the Linear Guide on the Right Angle Drill covering the bold black line, then slide it forward to engage the Right Angle Drill.

Slide the Linear Guide down and forward onto the Drill to lock position.





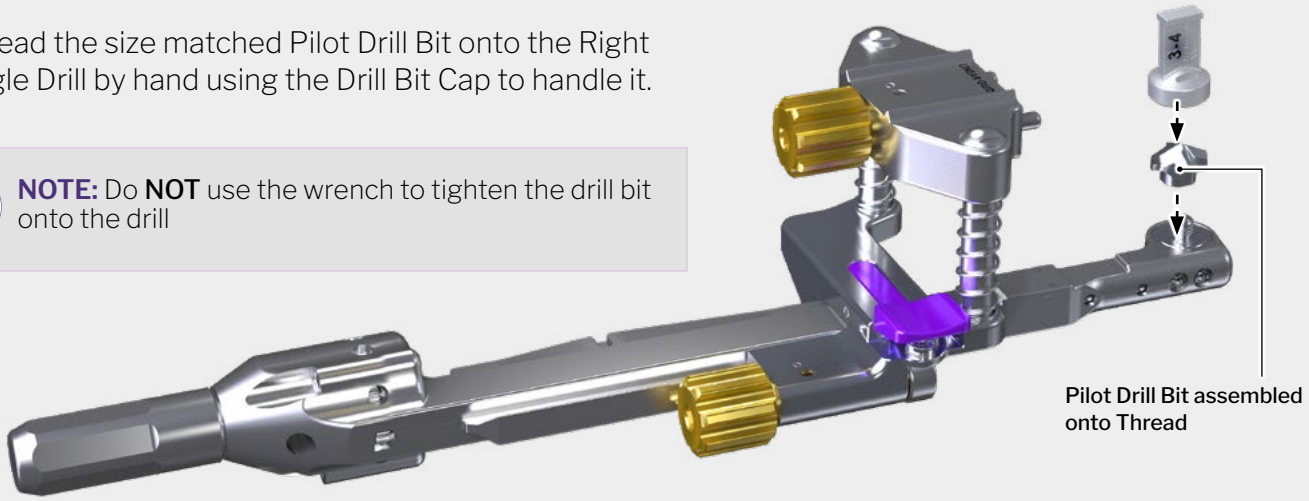
Press down on the purple lever to advance the Linear Guide until it seats into the position closest to the Drill Bit.



Thread in the bottom knob by hand or with a hex driver to lock position of the Linear Guide.

Thread the size matched Pilot Drill Bit onto the Right Angle Drill by hand using the Drill Bit Cap to handle it.

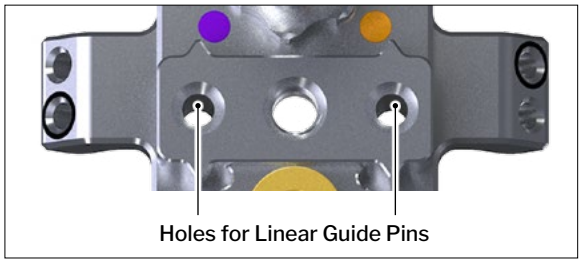
NOTE: Do **NOT** use the wrench to tighten the drill bit onto the drill



Pilot Drill Bit assembled onto Thread

TIBIAL VERTICAL DRILLING:

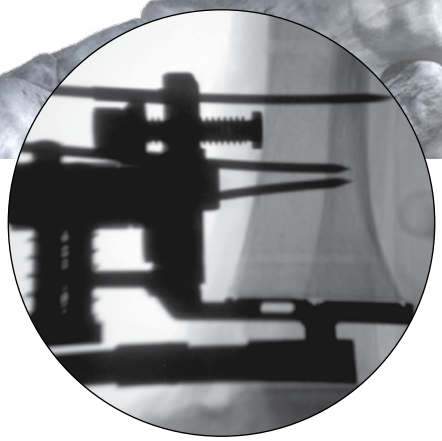
Insert Right Angle Drill Assembly into the resected space. Guide the pins on the top of the Linear Guide into the holes on the Tibial Trial Construct.



Compress the Linear Guide and secure it to the Tibia Docking Fixture by tightening the Top Locking Knob of the Linear Guide. Lock the Bottom Locking Knob of the Linear Guide. Do not over tighten the Locking Knobs.

Confirm Linear Guide is flush to the Tibia Docking Fixture.

Using Fluoroscopy, check the Drill position. Connect the Right Angle Drill to power using the provided Adaptor.

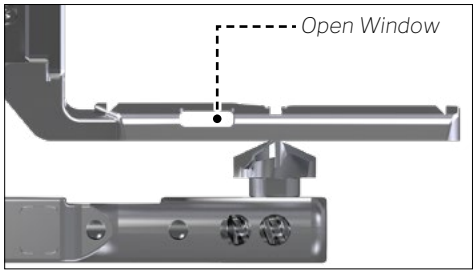


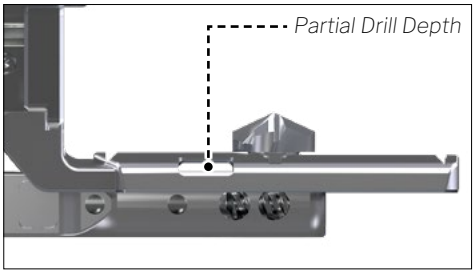
NOTE: ML view will ensure that the Drill tip is centered on the Tibia Drill Trial.

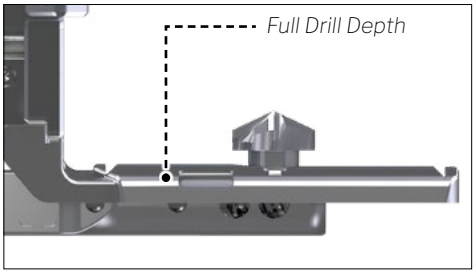
TIBIAL VERTICAL DRILLING:

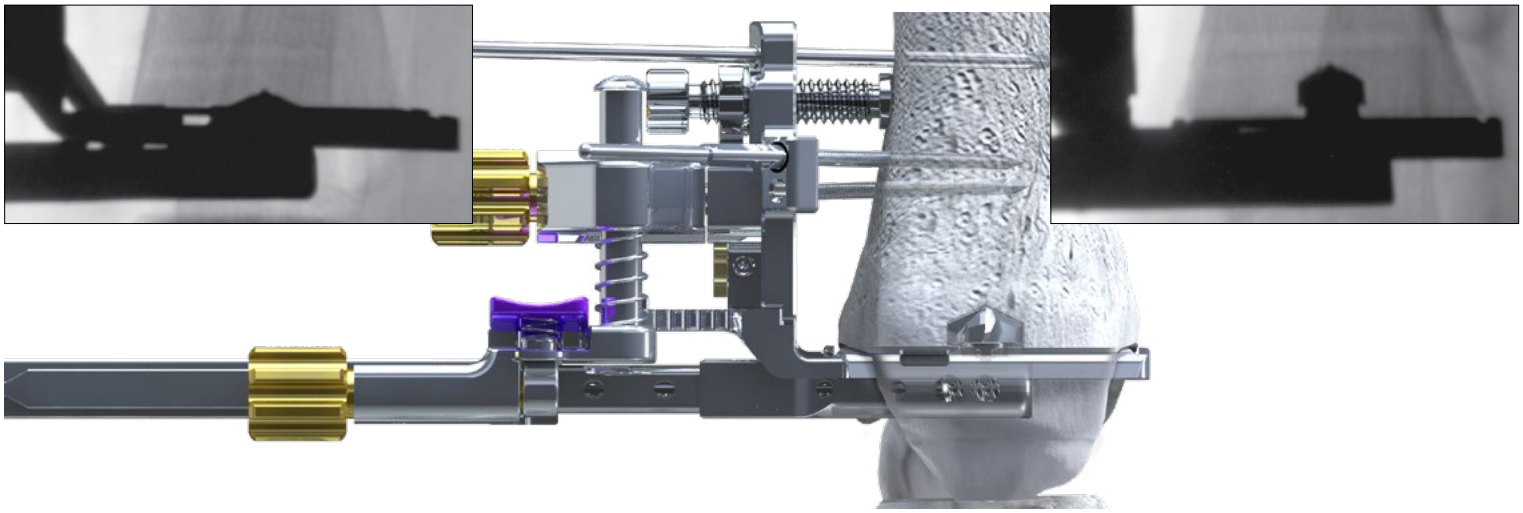
Under power, drill the pilot hole. The Drill can be advanced vertically into the distal tibia by any of the following methods:

- **DRILLING SHOULD BE COMPLETED IN DRILL MODE ON THE DRILL**
- Hand Compression of the Linear Guide
- Distracting a lamina spreader placed under the Drill Head
- Distracting using distraction paddles placed under the Drill Head

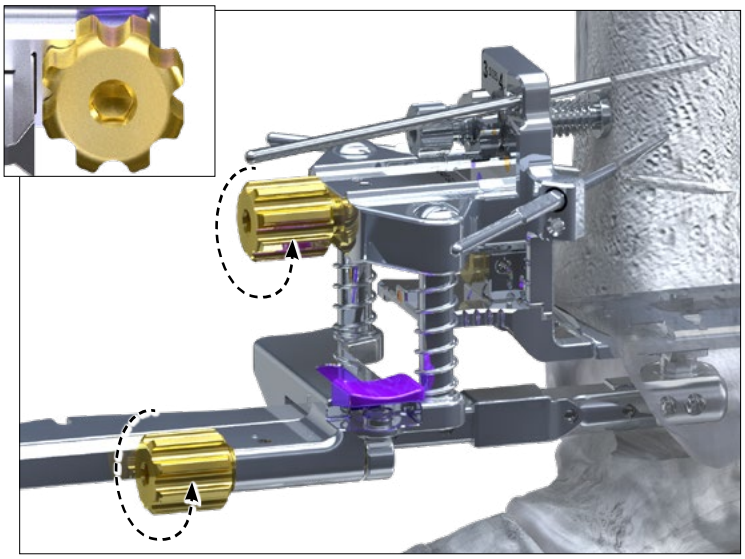




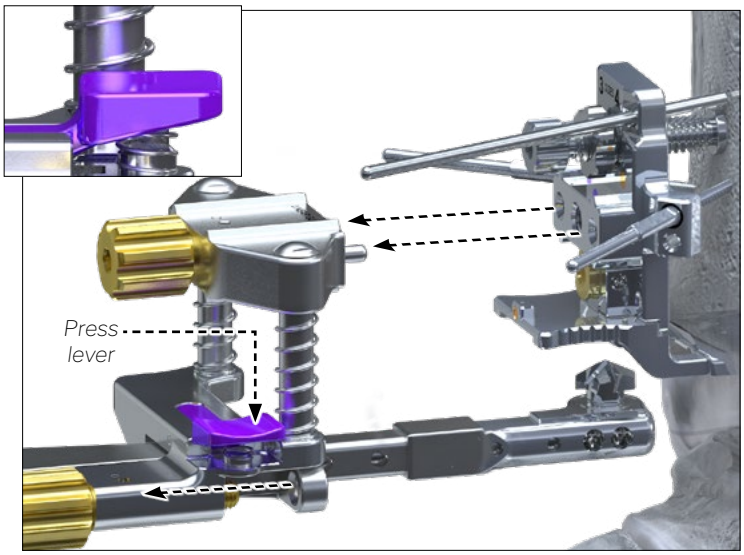




Confirm the Drill is seated correctly under fluoroscopy. The Drill is fully seated when the window on the Tibia Drill Trial is closed and/or the shoulders on the Drill Bit should be visible in the bone above the Drill Guide.



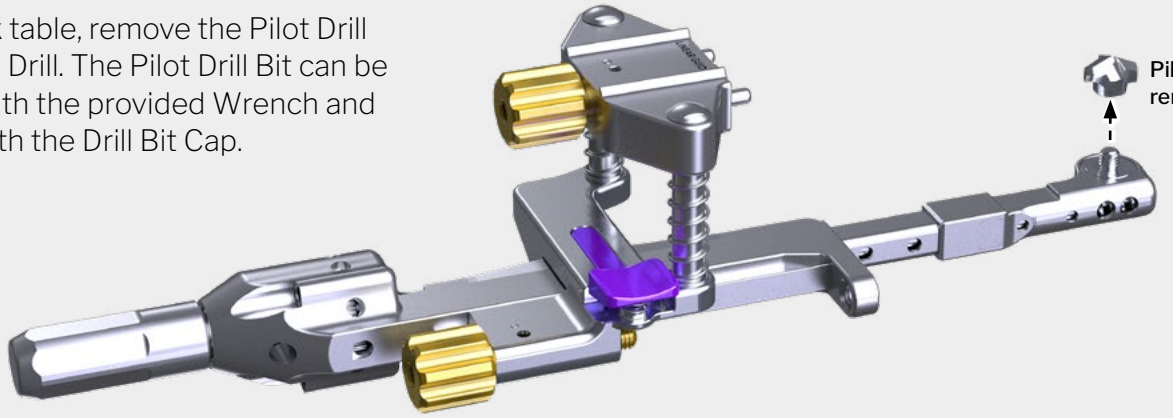
After confirming proper pilot hole drilling, release the Drill by unthreading the top and bottom locking knobs of the Linear Guide.



Press down on the purple lever and bring the Linear guide back to the retracted position. Slide the Drill out of the joint space.

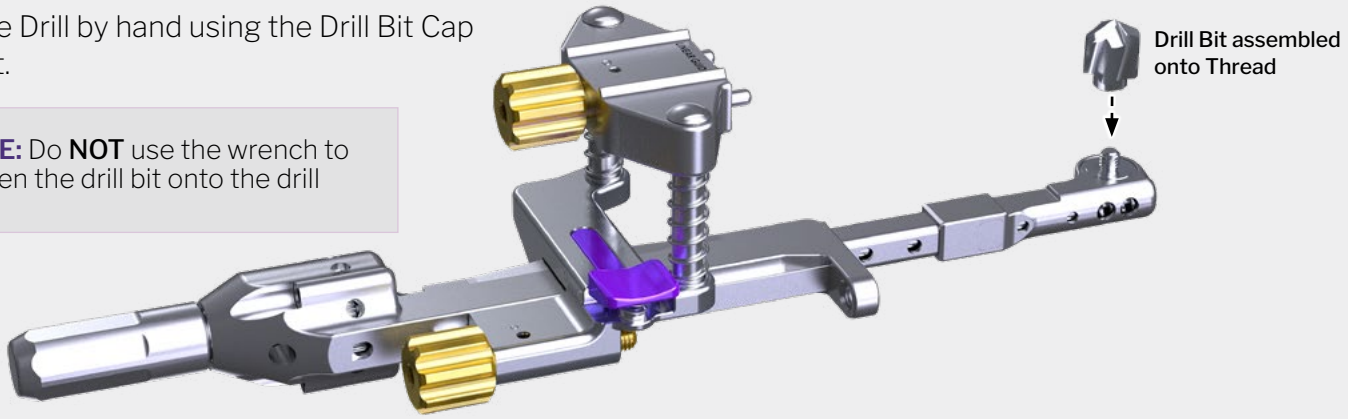
TIBIAL VERTICAL DRILLING ASSEMBLY BACK TABLE ASSEMBLY:

On the back table, remove the Pilot Drill Bit from the Drill. The Pilot Drill Bit can be loosened with the provided Wrench and removed with the Drill Bit Cap.

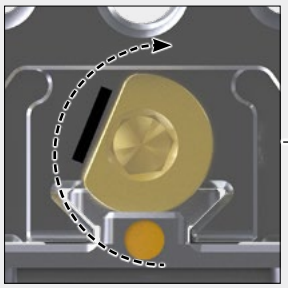


Thread the size matched Final Drill Bit onto the Right Angle Drill by hand using the Drill Bit Cap to handle it.

NOTE: Do **NOT** use the wrench to tighten the drill bit onto the drill

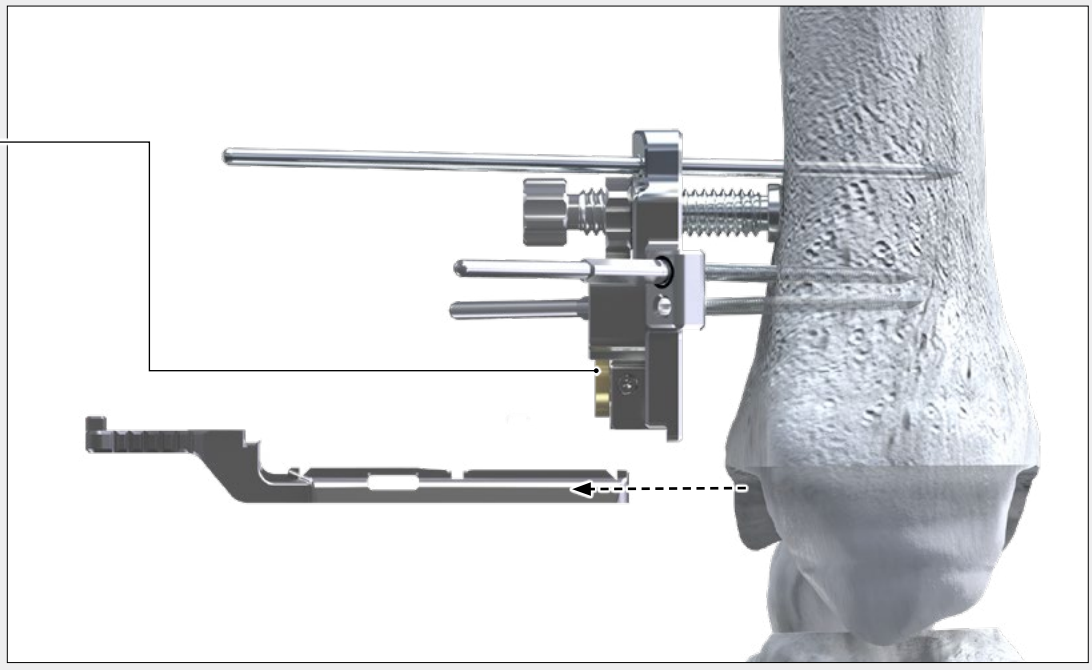


Remove the Tibial Drill Trial from the docking fixture by unlocking the cam lock collar with the 3.5 Hex Driver and removing the Drill Trial by hand or with the Trial Handling Tool.



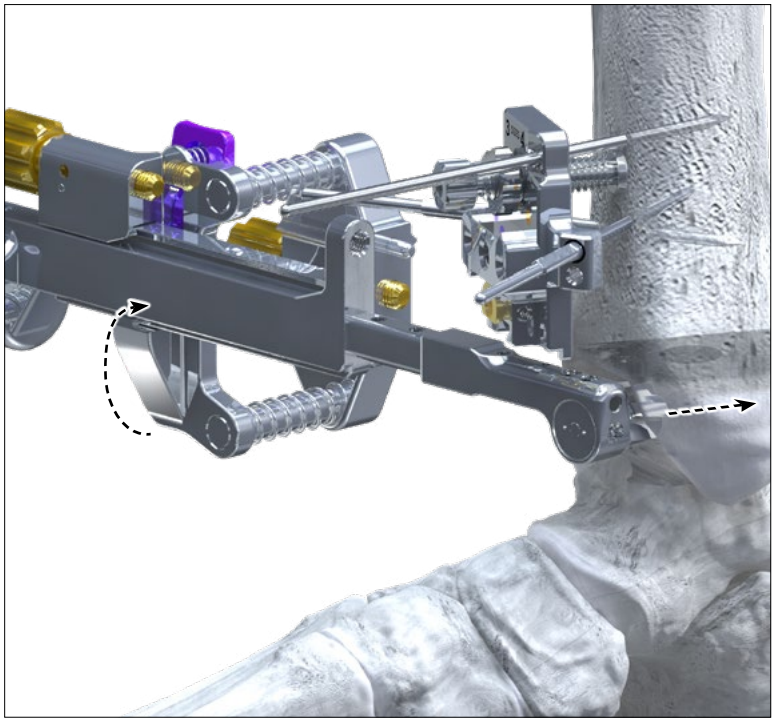
Locked

Unlocked

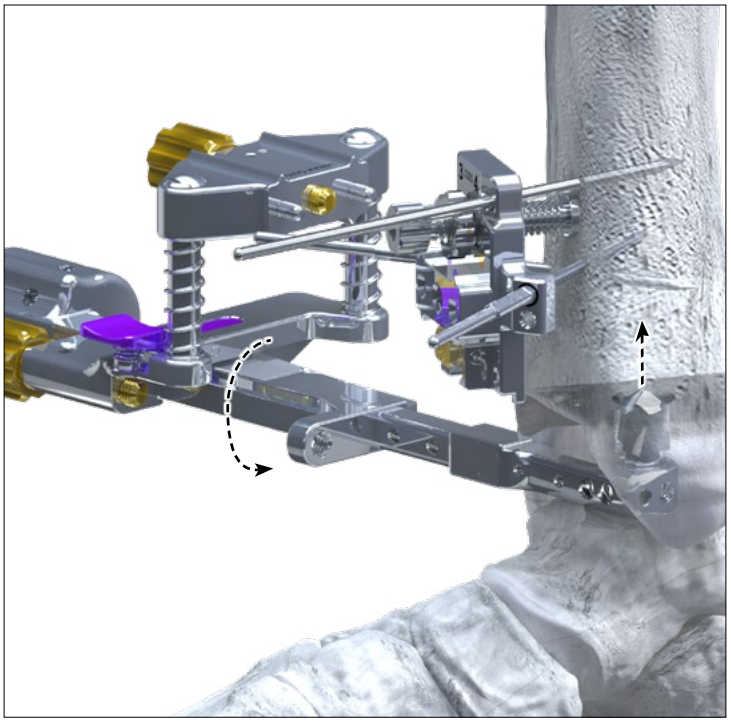


TIBIAL VERTICAL DRILLING:

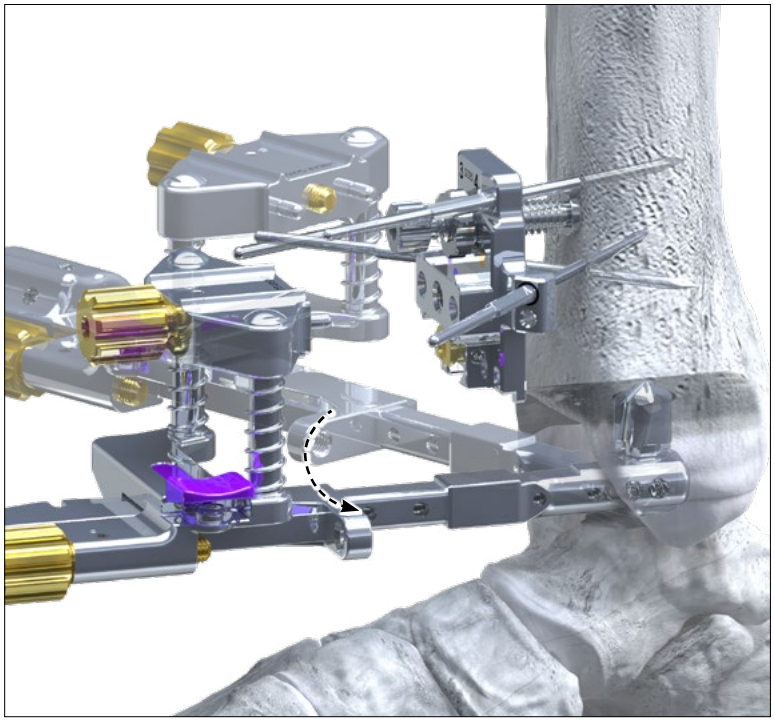
Ensure the Linear Guide is attached to the Right Angle Drill and is in the retracted position prior to inserting the Drill back into the resected space.



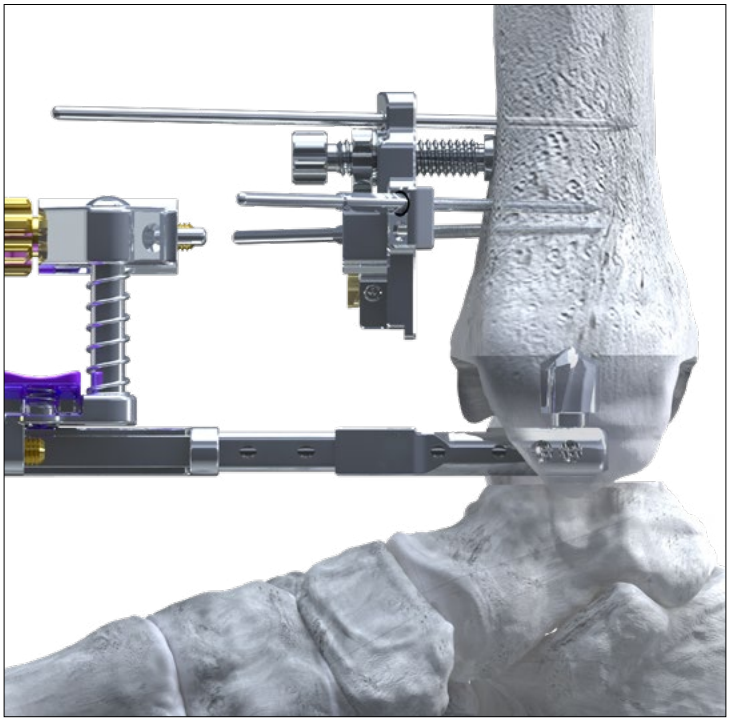
Holding the Drill with the left hand, orient the tip of the Drill so that the flat side is facing anterior and the Drill Bit is facing posterior.



Place the Drill in the joint space with the remaining portion of the Drill on the medial or lateral side of the limb.



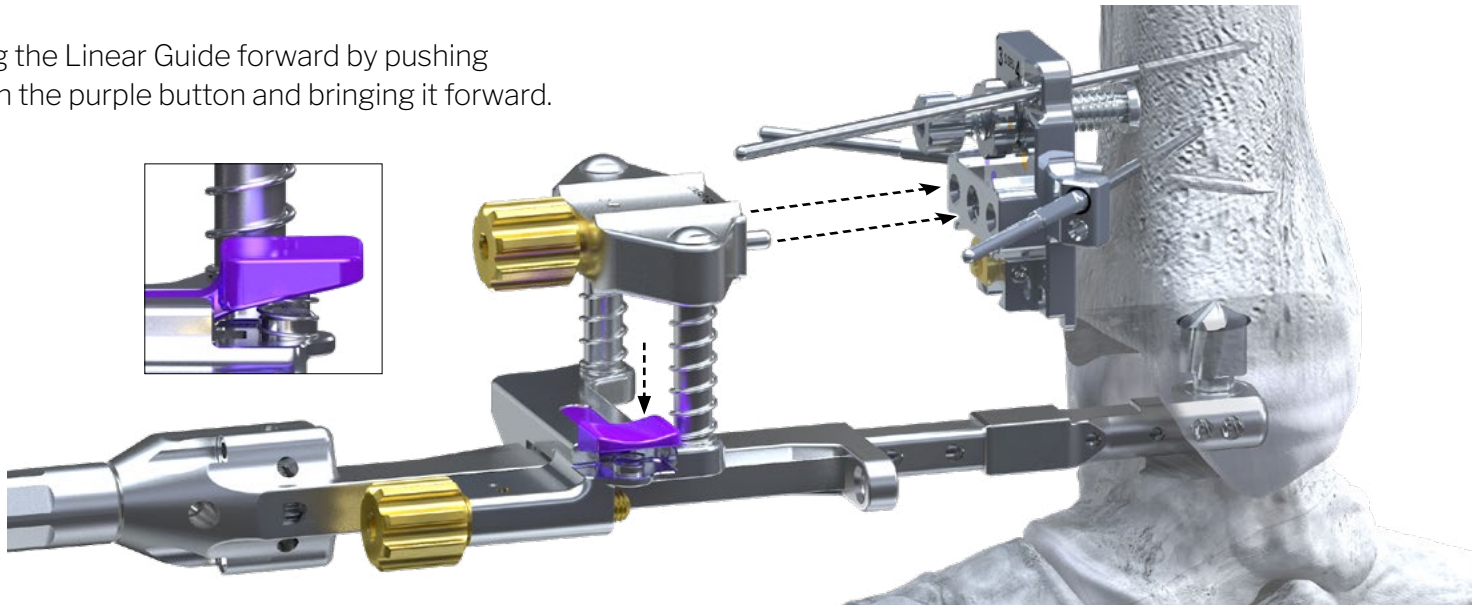
Rotate the Drill Bit 90° so that the Drill enters the pilot hole and rotate the remaining portion of the assembly to be aligned with the anterior face of the limb.



The Final Drill Bit should slide into the pilot drill location. Distraction tools can be used as needed to help with placement of the Drill.

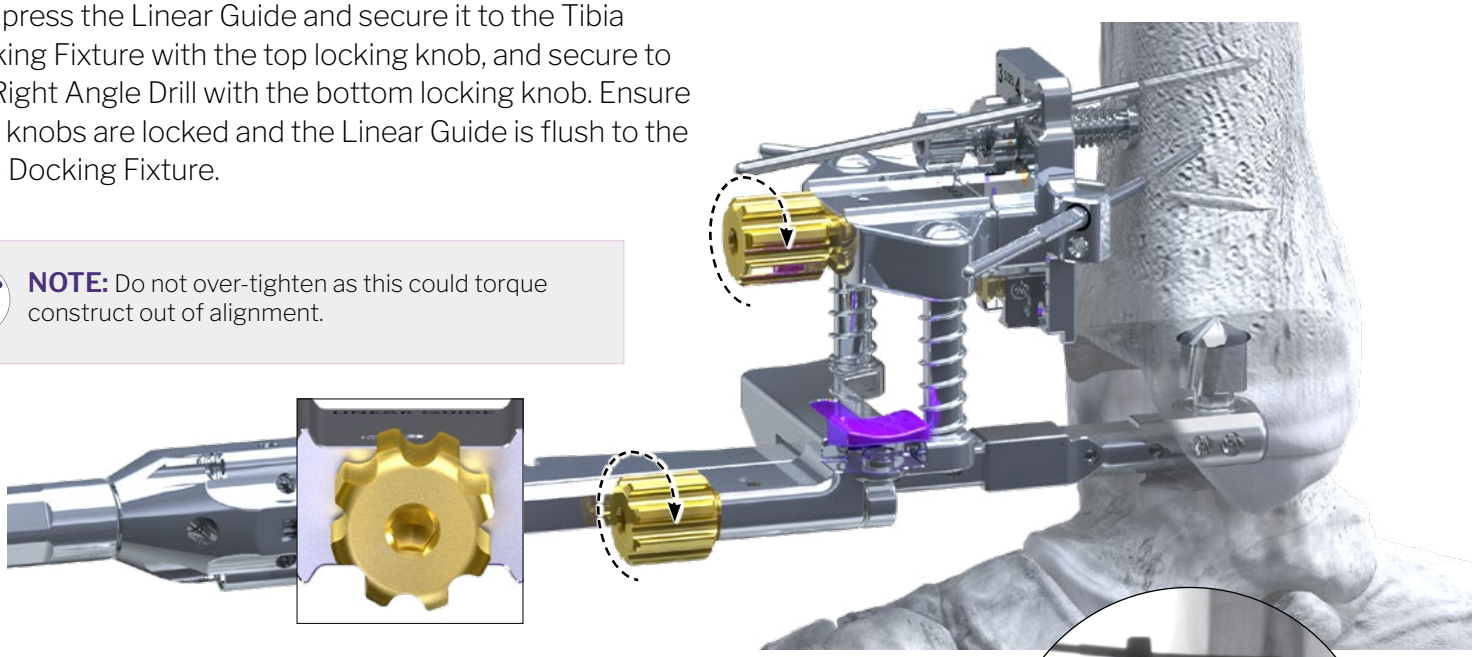
TIBIAL VERTICAL DRILLING:

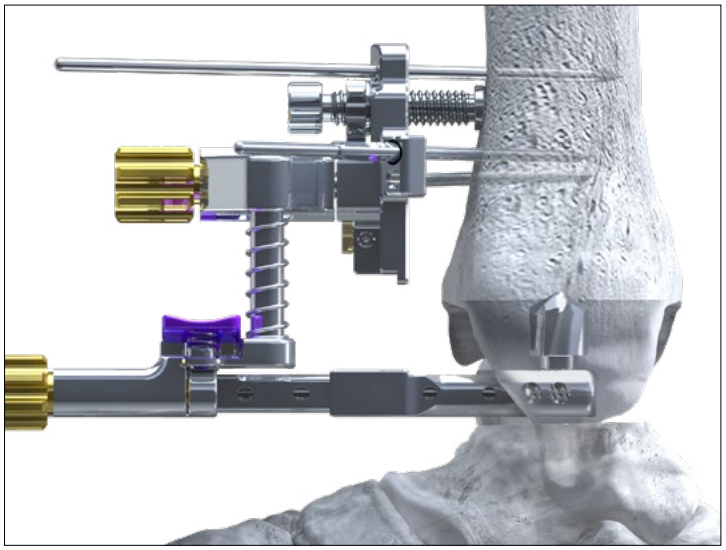
Bring the Linear Guide forward by pushing down the purple button and bringing it forward.

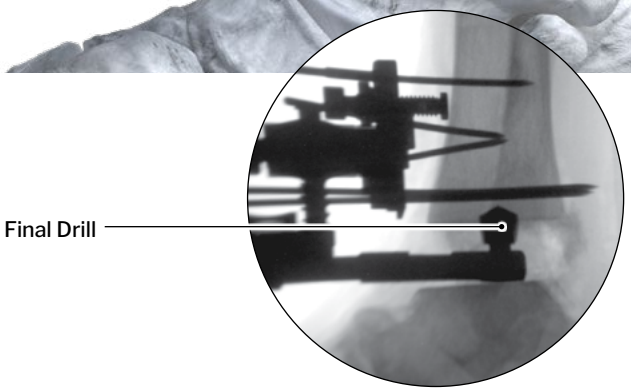


Compress the Linear Guide and secure it to the Tibia Docking Fixture with the top locking knob, and secure to the Right Angle Drill with the bottom locking knob. Ensure both knobs are locked and the Linear Guide is flush to the Tibia Docking Fixture.

NOTE: Do not over-tighten as this could torque construct out of alignment.





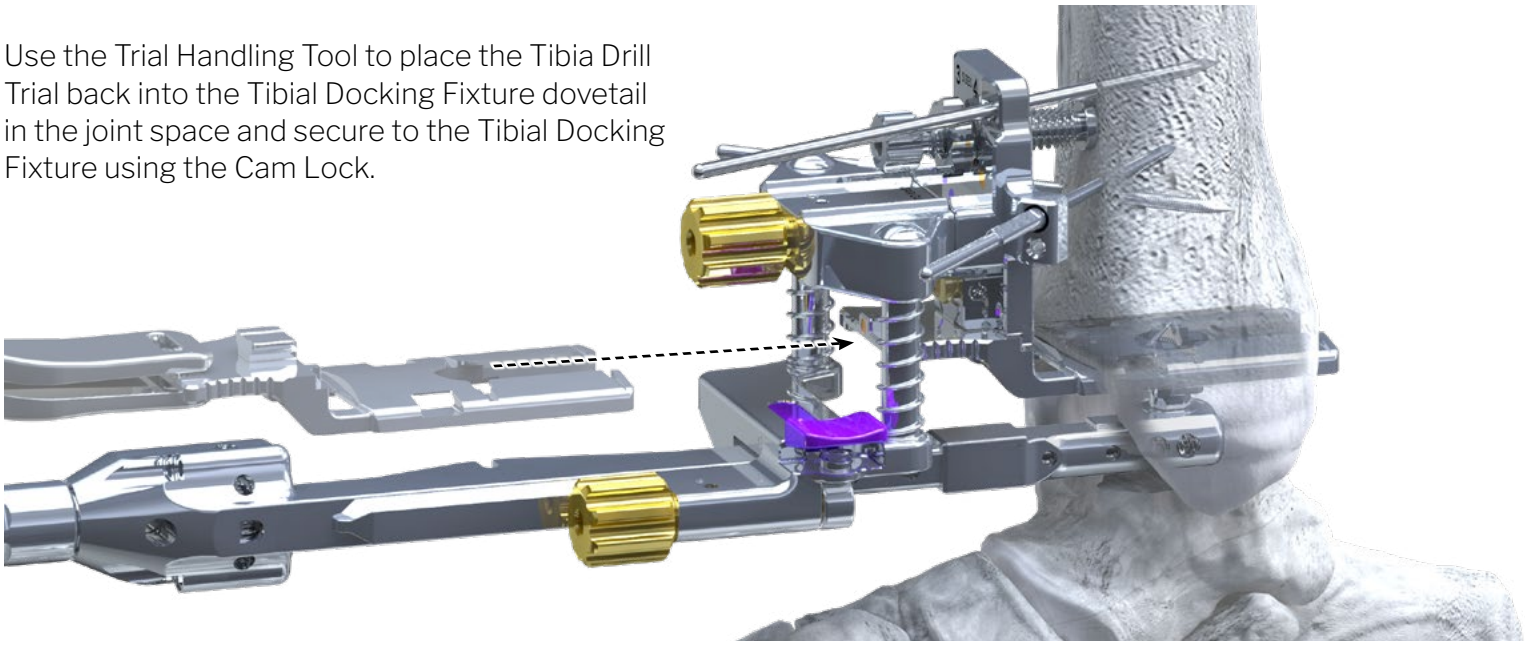


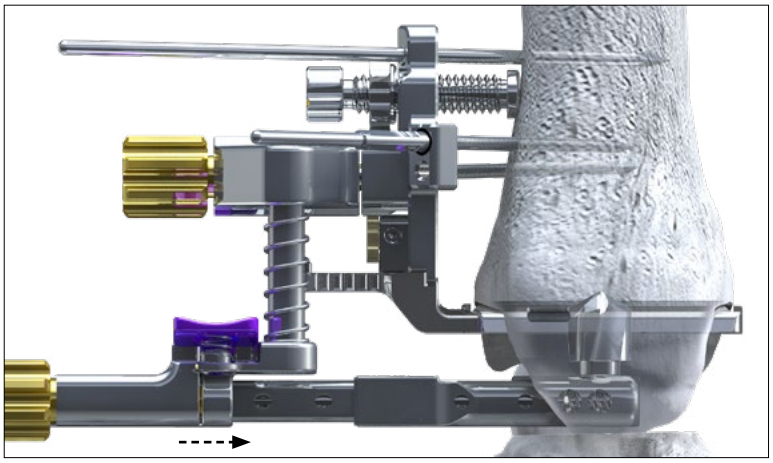
Confirm Drill position using fluoroscopy. The flutes on the Drill may distort the view.

NOTE: If the Drill visually looks non perpendicular, ensure the two lock knobs on the Linear Guide are secure.

TIBIAL VERTICAL DRILLING:

Use the Trial Handling Tool to place the Tibia Drill Trial back into the Tibial Docking Fixture dovetail in the joint space and secure to the Tibial Docking Fixture using the Cam Lock.

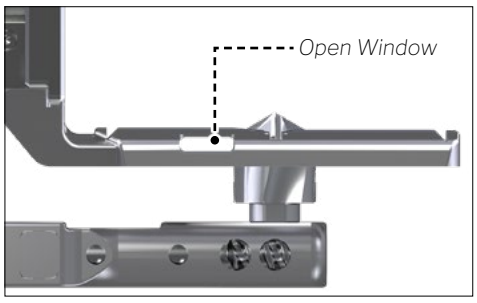


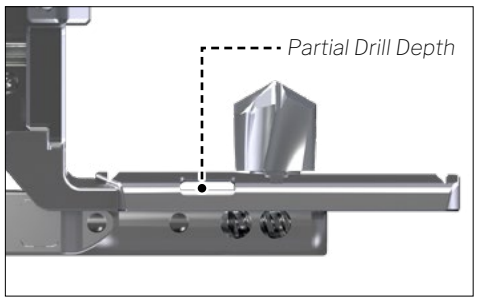


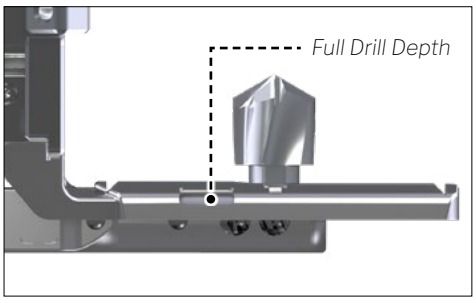
Confirm Drill position using fluoroscopy.
The flutes on the Drill may distort the view.

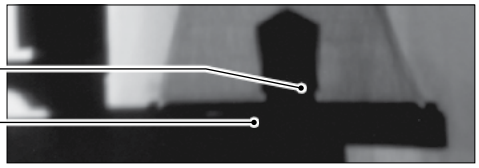
Under power, advance the Drill vertically into the distal tibia by any one of the following:

- **DRILLING SHOULD BE COMPLETED IN DRILL MODE ON THE DRILL**
- Hand Compression of the Linear Guide
- Distracting a lamina spreader placed under the Drill Head
- Distracting parallel using distraction paddles placed under the Drill Head



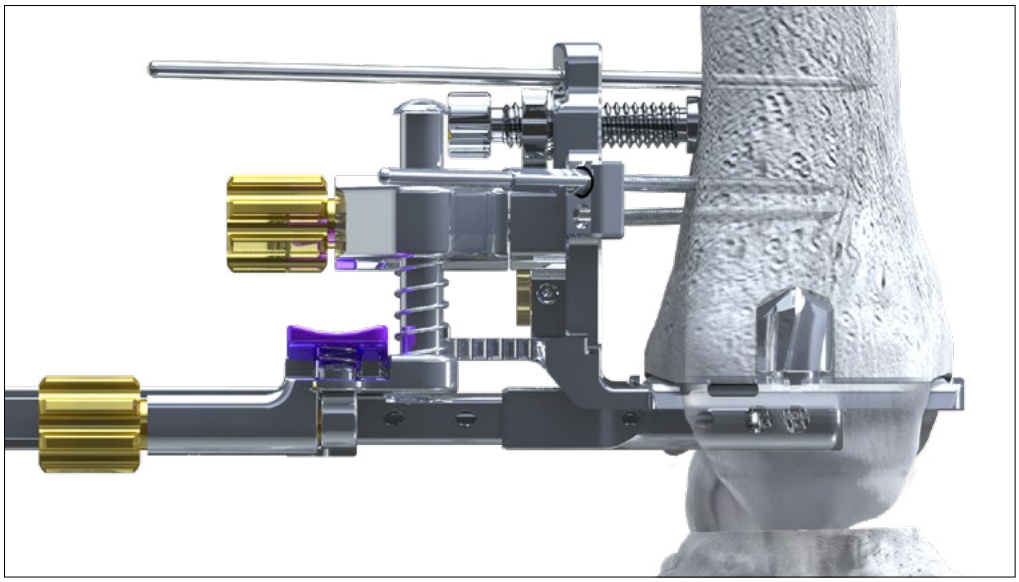




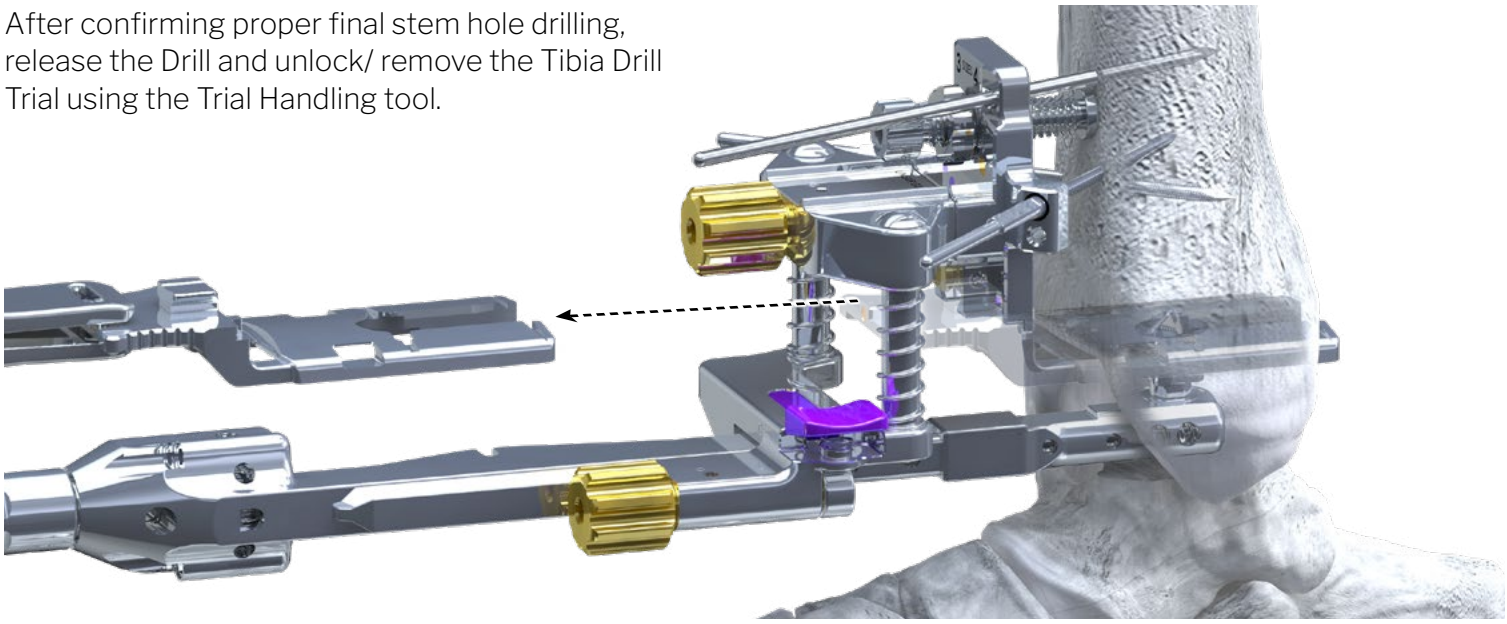


TIBIAL VERTICAL DRILLING:

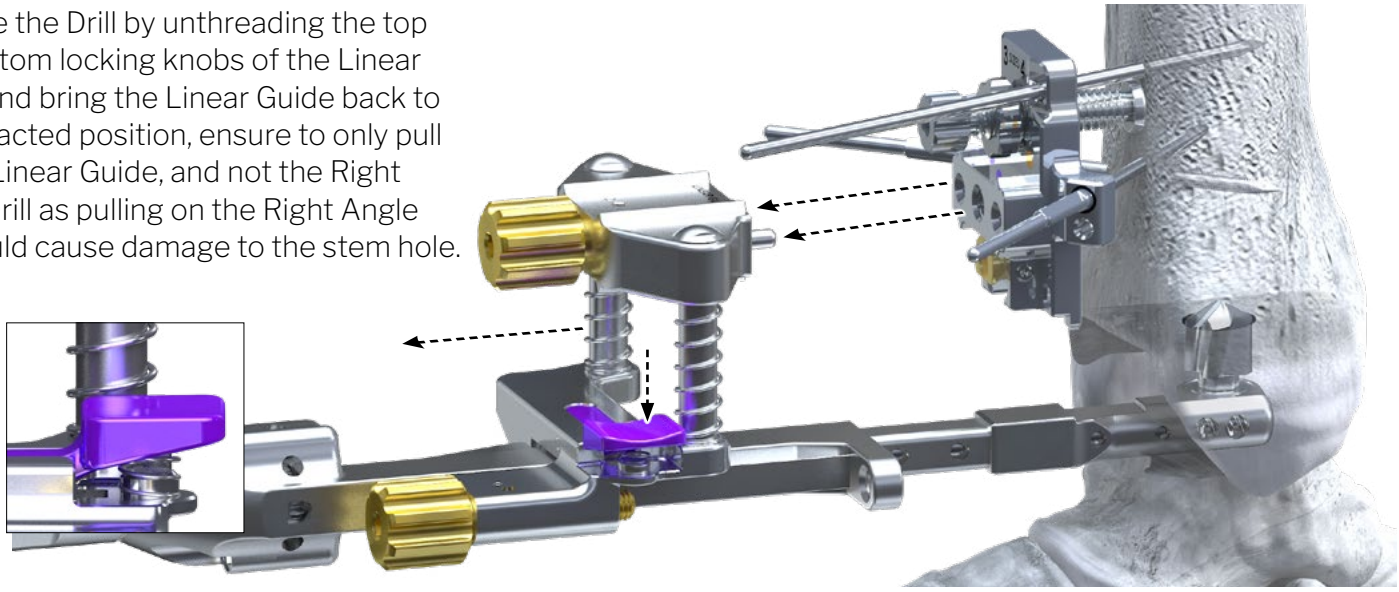
Confirm the Drill depth under fluoroscopy. The Drill is fully seated when the window on the Tibia Drill Trial is closed.



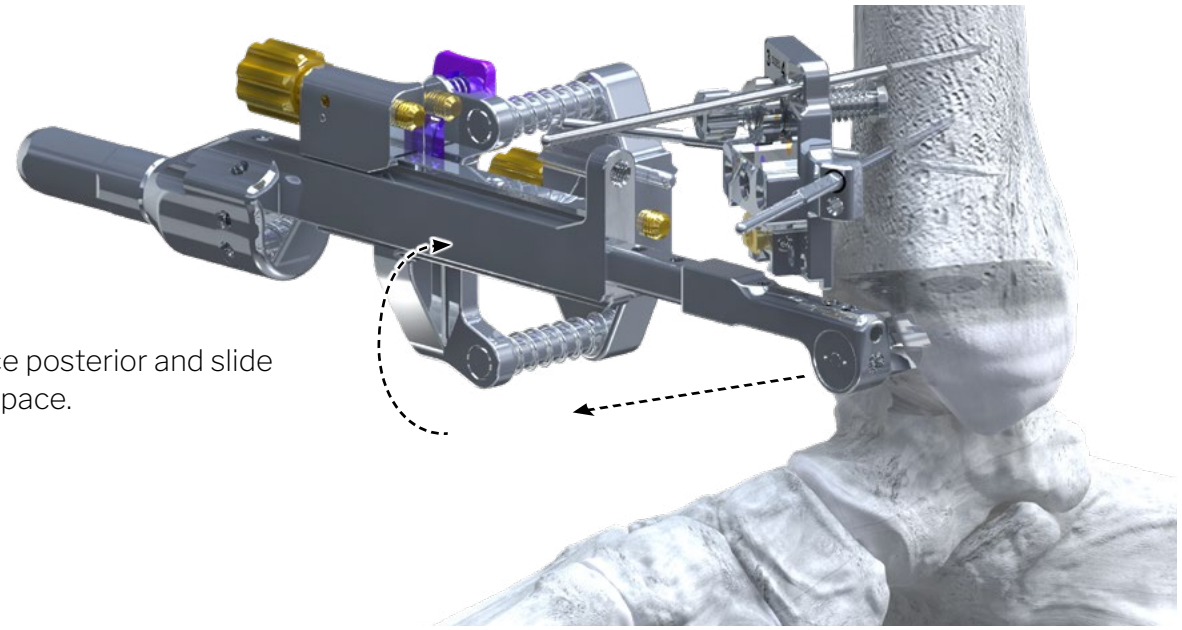
After confirming proper final stem hole drilling, release the Drill and unlock/ remove the Tibia Drill Trial using the Trial Handling tool.



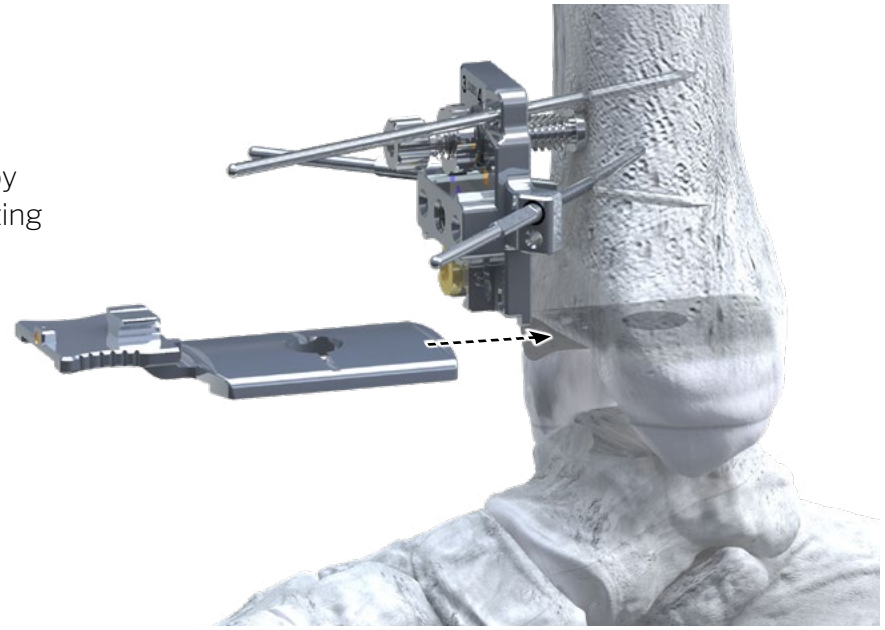
Remove the Drill by unthreading the top and bottom locking knobs of the Linear Guide and bring the Linear Guide back to the retracted position, ensure to only pull on the Linear Guide, and not the Right Angle Drill as pulling on the Right Angle Drill could cause damage to the stem hole.



TIBIAL VERTICAL DRILLING:

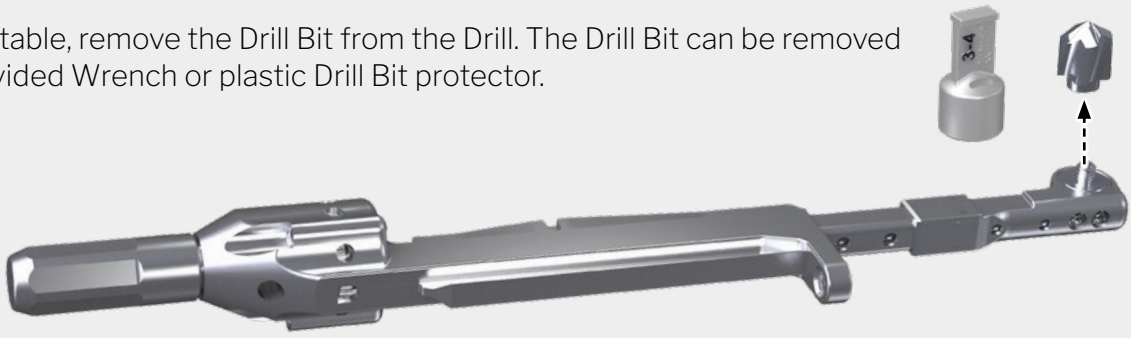


Rotate the Drill Bit to face posterior and slide the Drill out of the joint space.



Replace the Tibia Drill Trial with the Tibia Trial by hand or with the Trial Handling Tool by connecting it to the Tibial Docking Fixture.

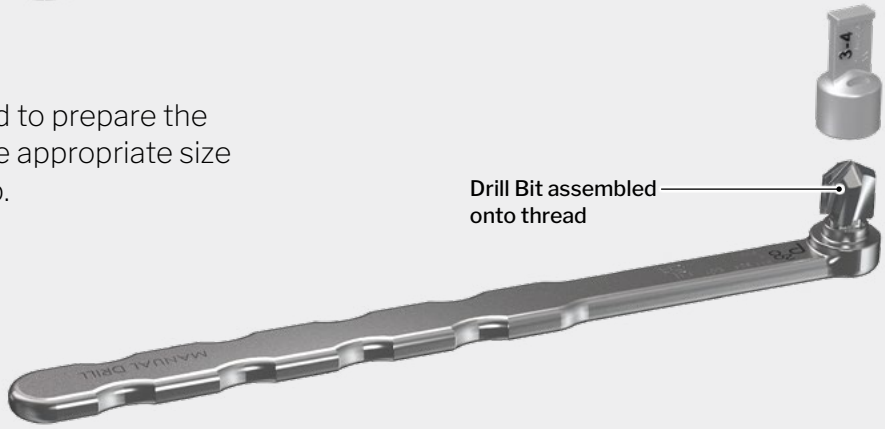
On the back table, remove the Drill Bit from the Drill. The Drill Bit can be removed with the provided Wrench or plastic Drill Bit protector.

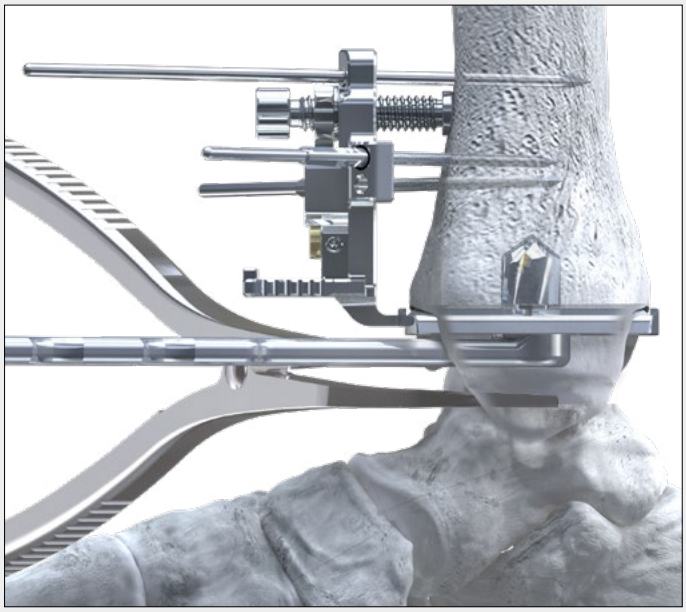


TIBIAL VERTICAL DRILLING MANUAL DRILLING:

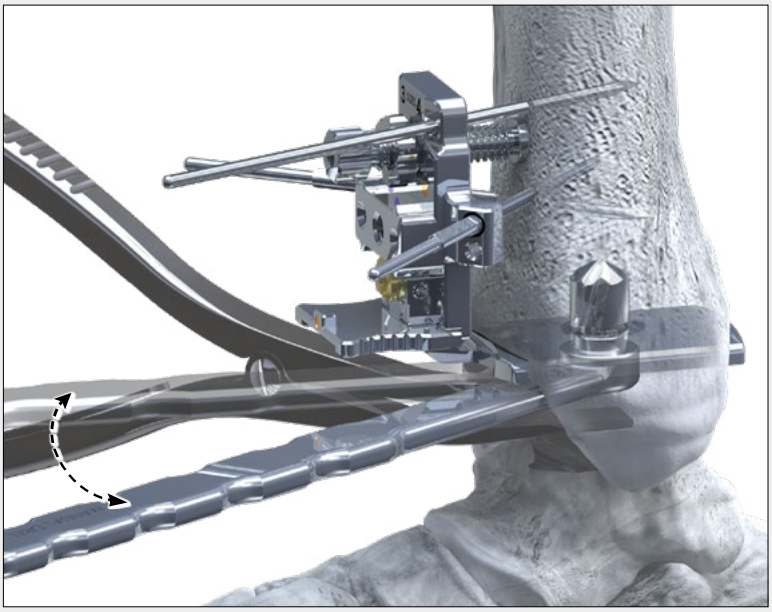
OPTIONAL: MANUAL DRILL

If necessary, a Manual Drill can be used to prepare the tibia. To use the Manual Drill, attach the appropriate size matched Drill Bit using the Drill Bit Cap.





Place the Drill into the joint space and align with the pilot hole and drill through the Tibia Trial.



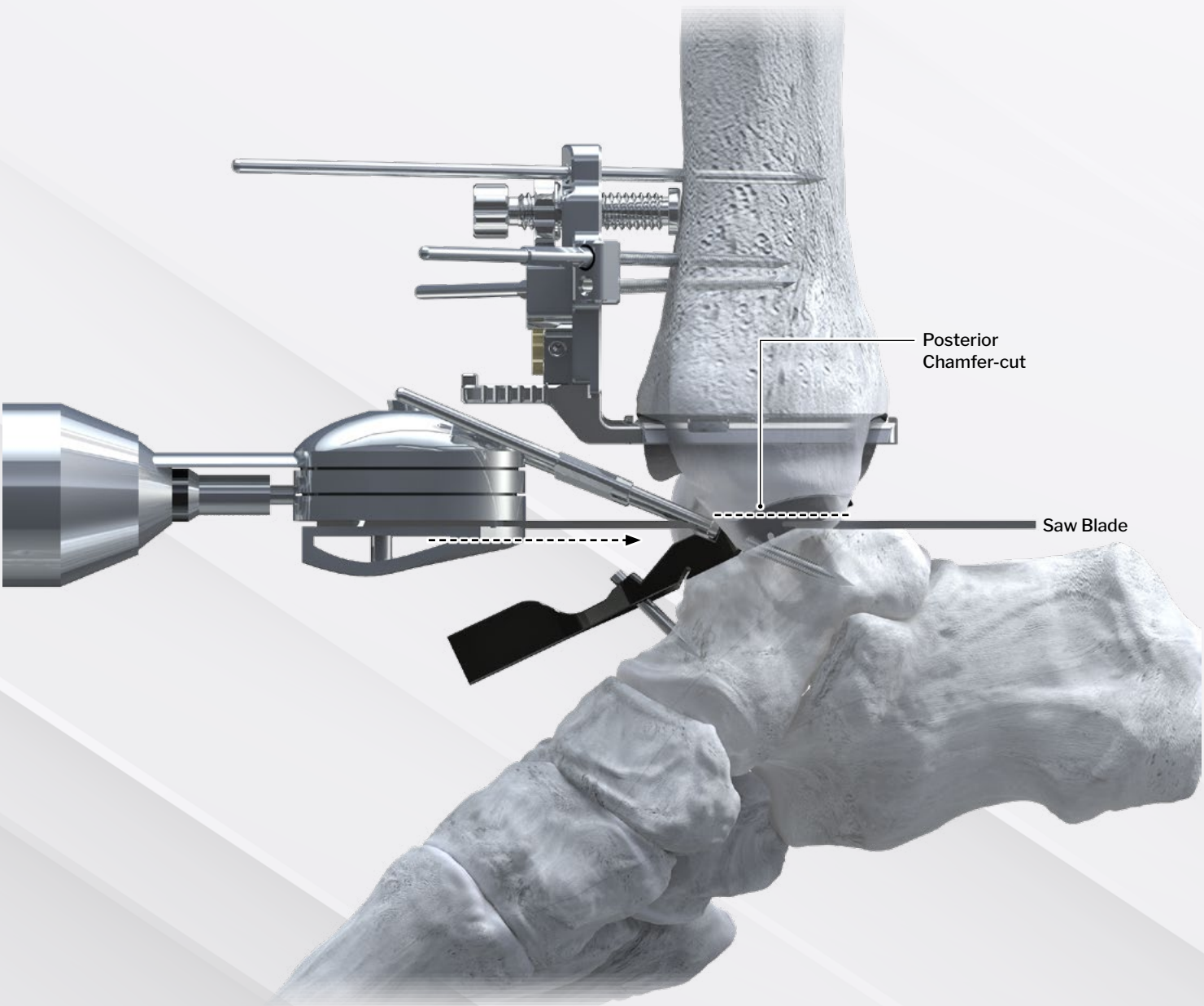
Use a Lamina Spreader to provide in-line distraction to advance the Drill as the surgeon repeatedly turns the Drill clockwise and counterclockwise to drill the bone.

NOTE: Take care to maintain parallelism with the face of the Manual Drill and the tibia resection cut visually or with fluoroscopy.

Confirm the Drill is seated correctly under fluoroscopy. When the Drill bottoms out on the Tibia Trial, remove the Tibia Trial and finish drilling until the Drill is fully seated.

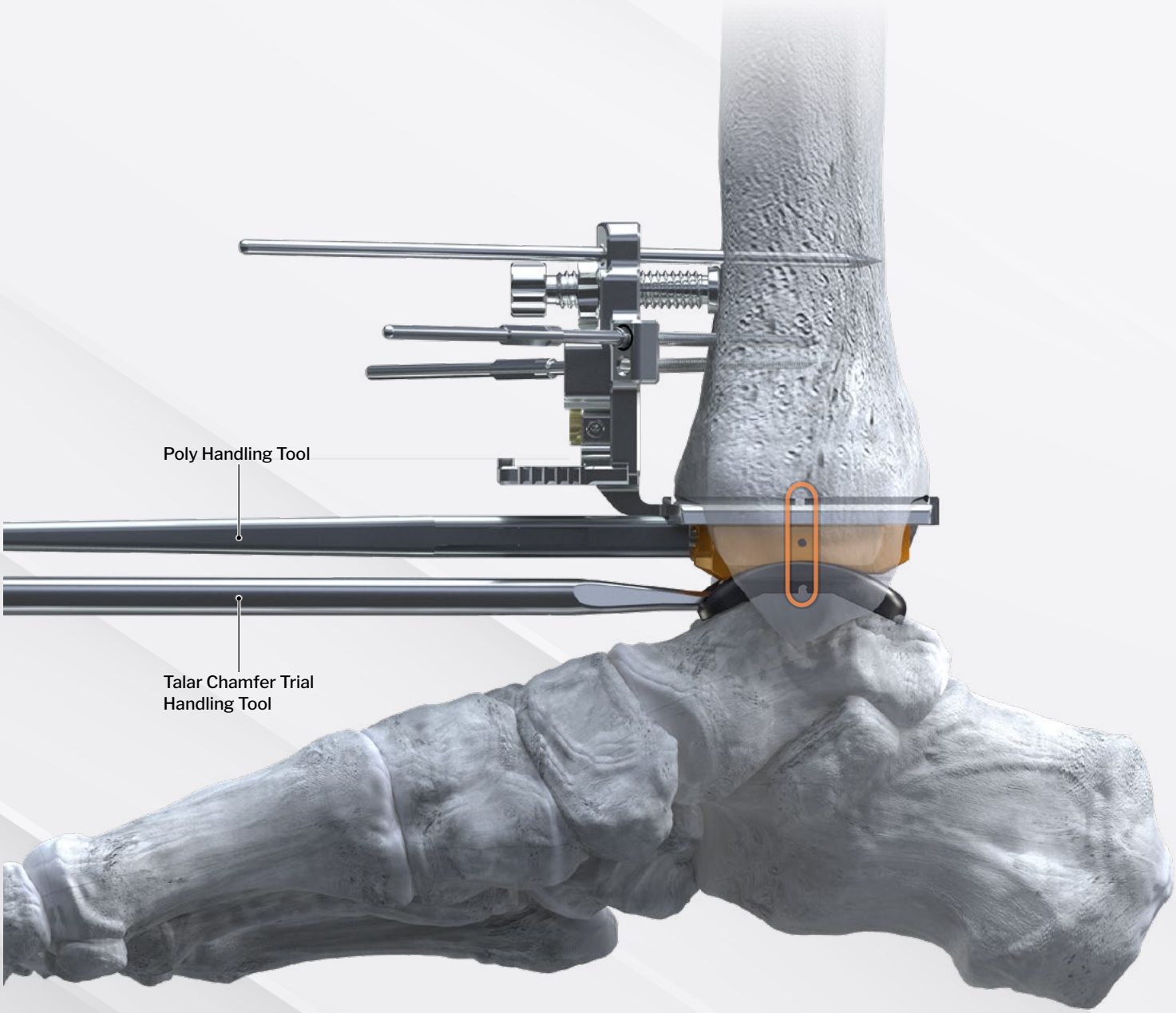
TALAR BONE PREPARATION

Reference APEX 3D™ Surgical Technique (P10-STG-0001) for the appropriate Talar Resection: Chamfer Talus Preparation or Flat Talus Preparation.

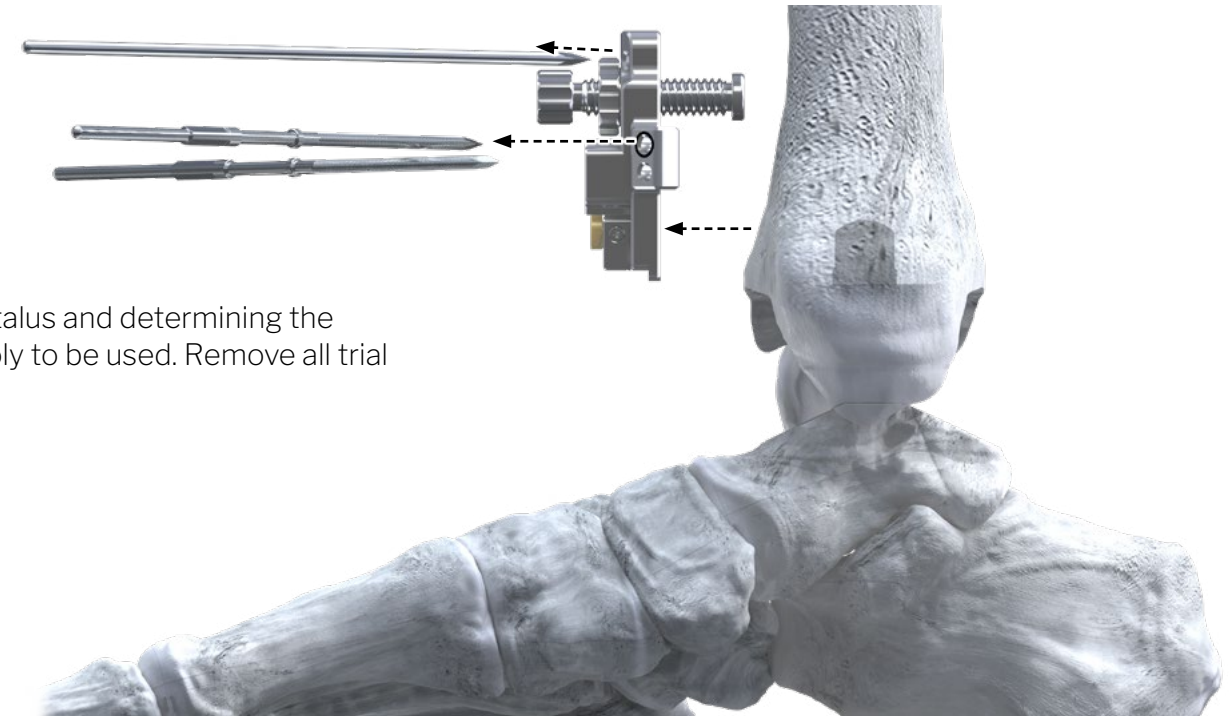


POLY TRIAL PLACEMENT

Reference APEX 3D™ Surgical Technique (P10-STG-0001) for the appropriate Poly Trialing Section.



FINAL TIBIAL IMPLANTATION:

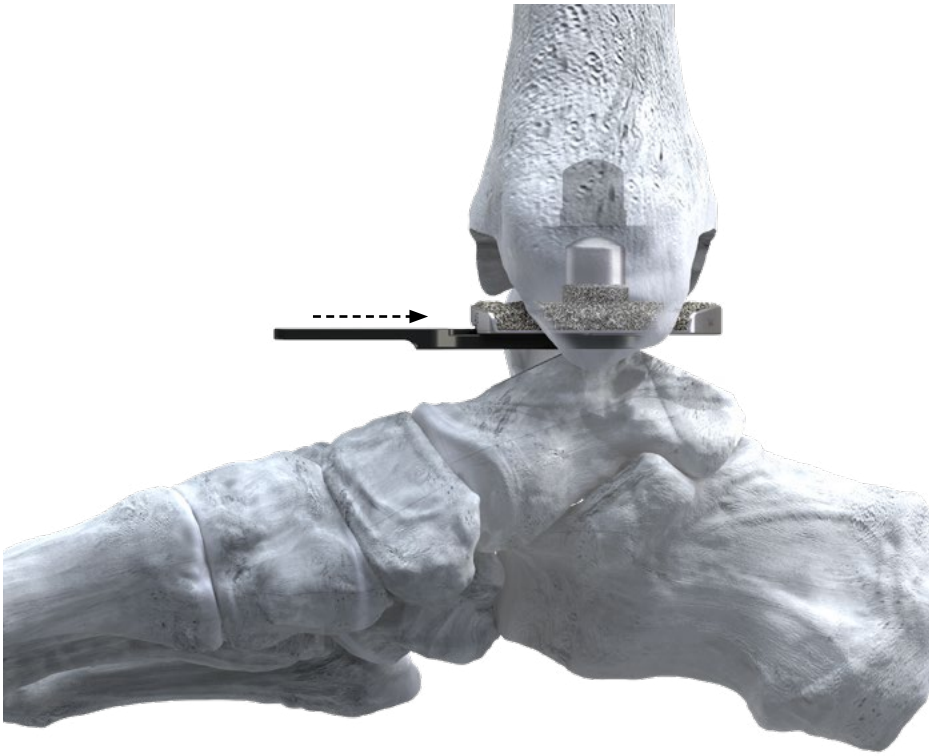


After preparing the talus and determining the appropriate sized poly to be used. Remove all trial instrumentation.

Do not apply bone cement to the vertical stem.

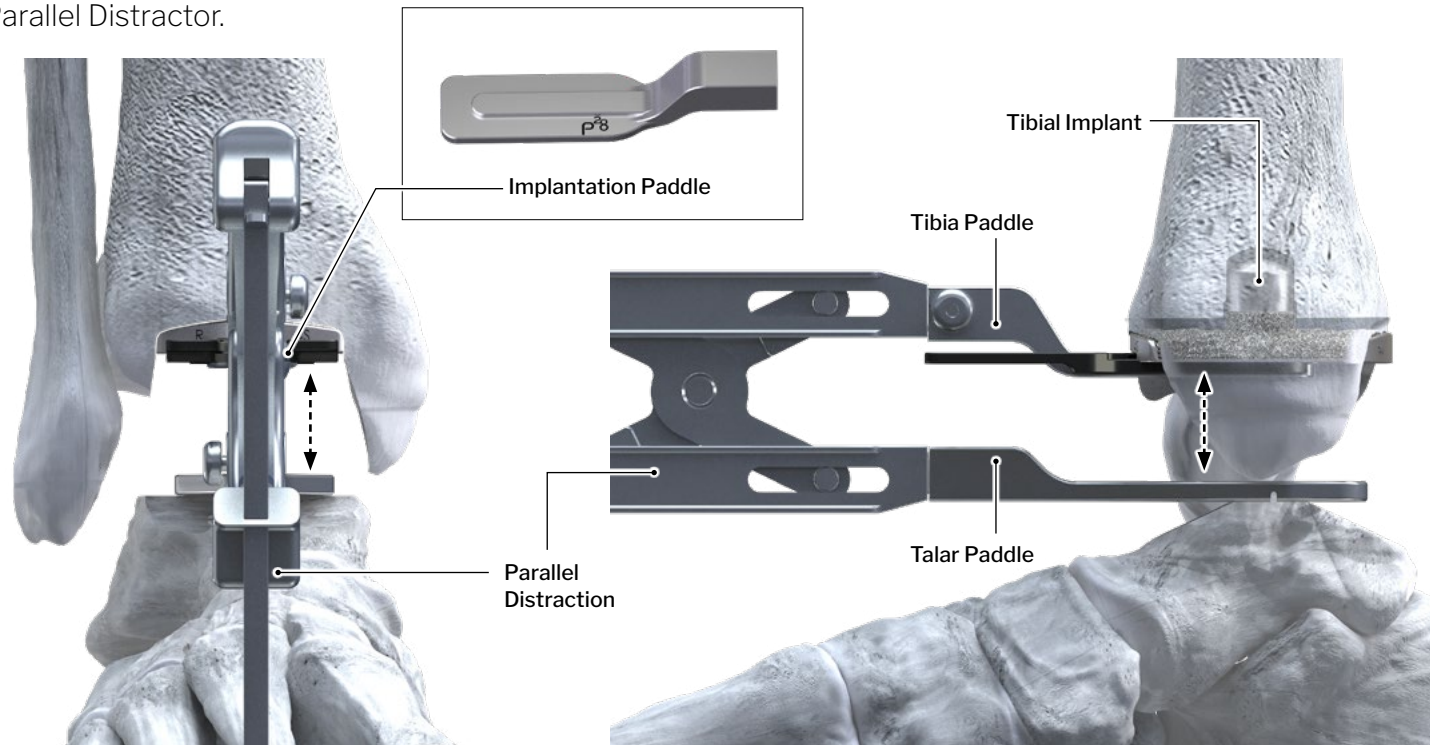
Attach final Tibia Implant onto the size matched Impaction Protector. By hand, slide the implant into the resected spaced using the Impaction Protector handles. The implant should slide into the prepared hole. Advance vertically until resistance is felt.

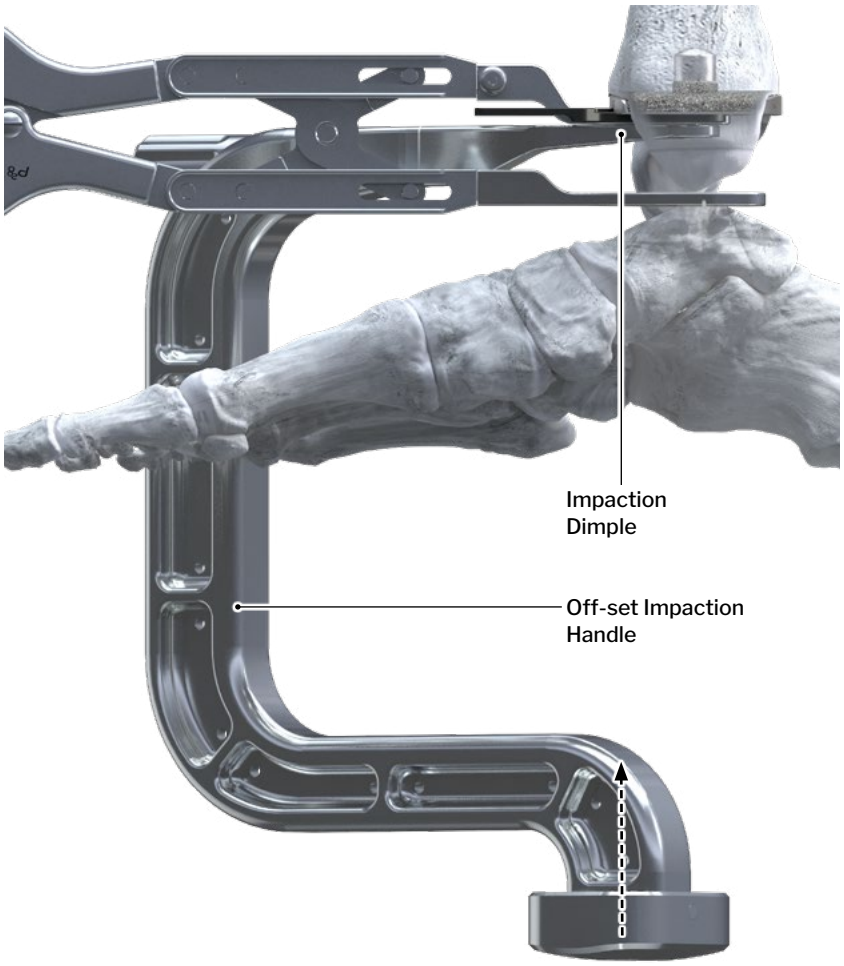
NOTE: Bone can be protected with either the Talar Shim or the Forked Distraction Paddles. Use the appropriate paddle for the style of tibia implant being implanted.



FINAL TIBIAL IMPLANTATION:

Attach the Implantation Paddle and the Talar Paddle to the Parallel Distractor. Insert the Parallel Distractor into the joint space. Fully insert the Implantation Paddle in the recess of Tibia Impaction Protector. Distract the Parallel Distractor.

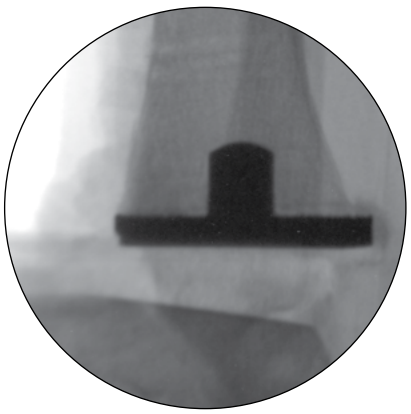


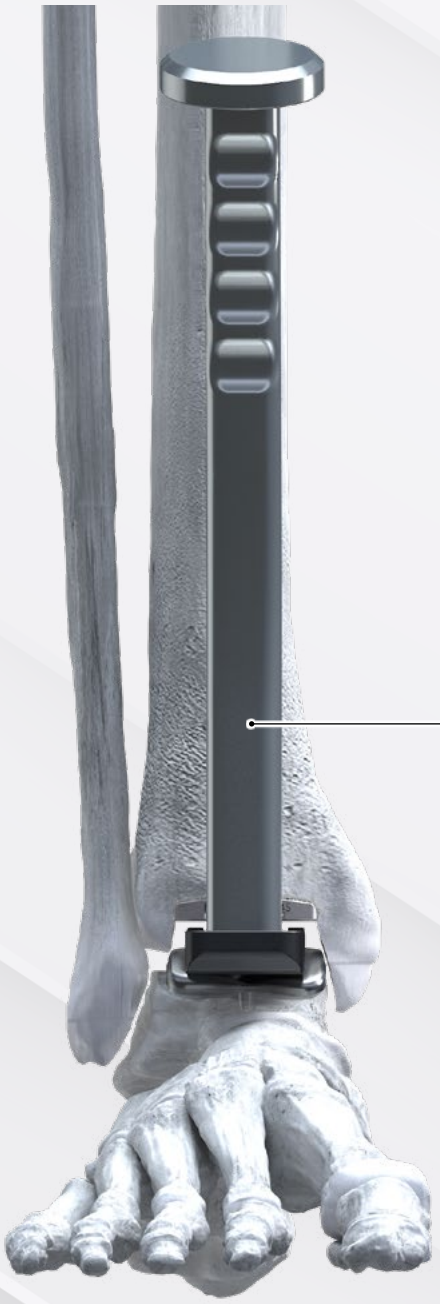


Insert impaction Coin or Dimple, aligning with the impaction paddle recess.

Strike the Offset Impaction Handle with the mallet to fully seat the Tibial Implant.

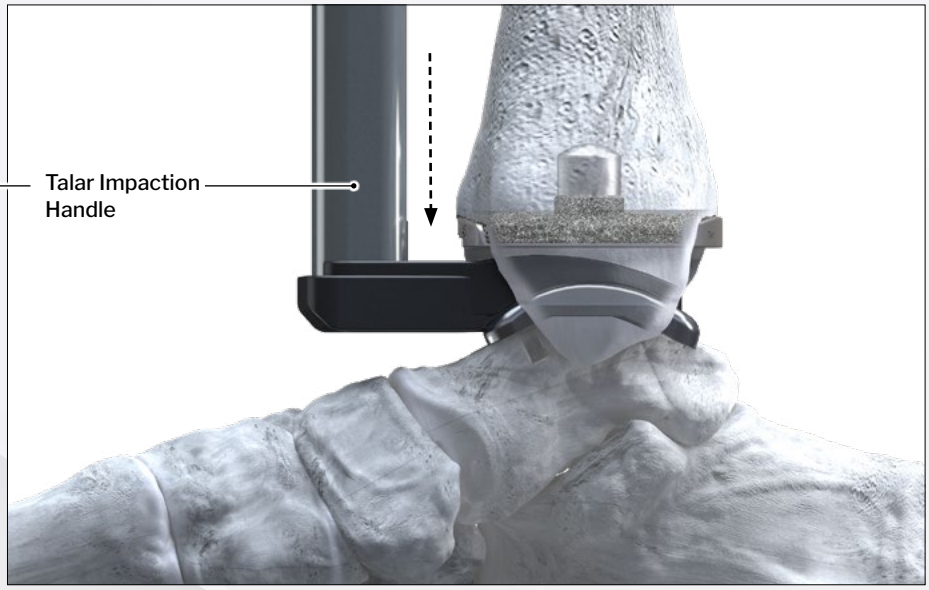
Confirm the Implant is fully seated under both lateral and AP fluoroscopy views. For cemented use, apply bone cement to the superior aspect of the tibial implant.

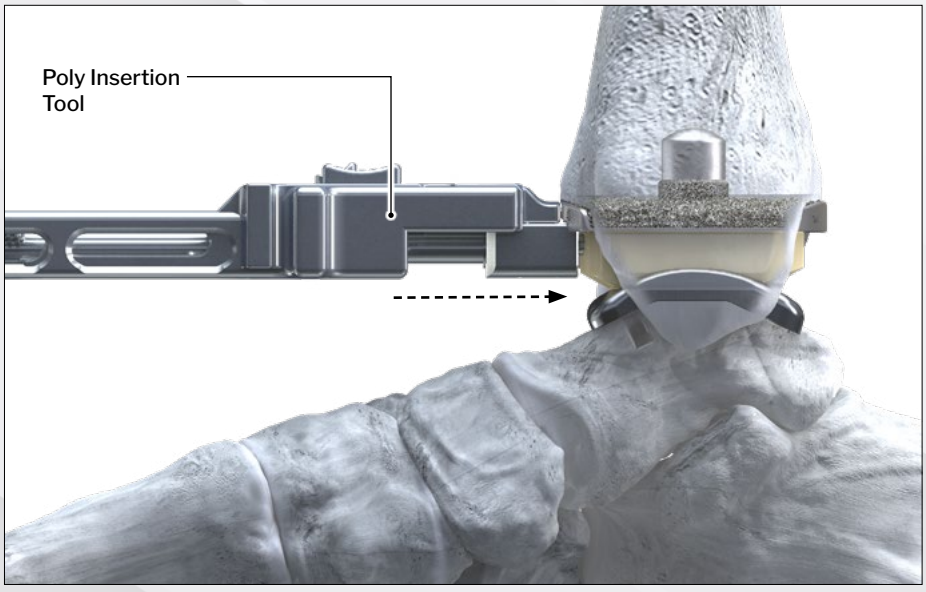




FINAL TALUS AND POLY IMPLANT PLACEMENT

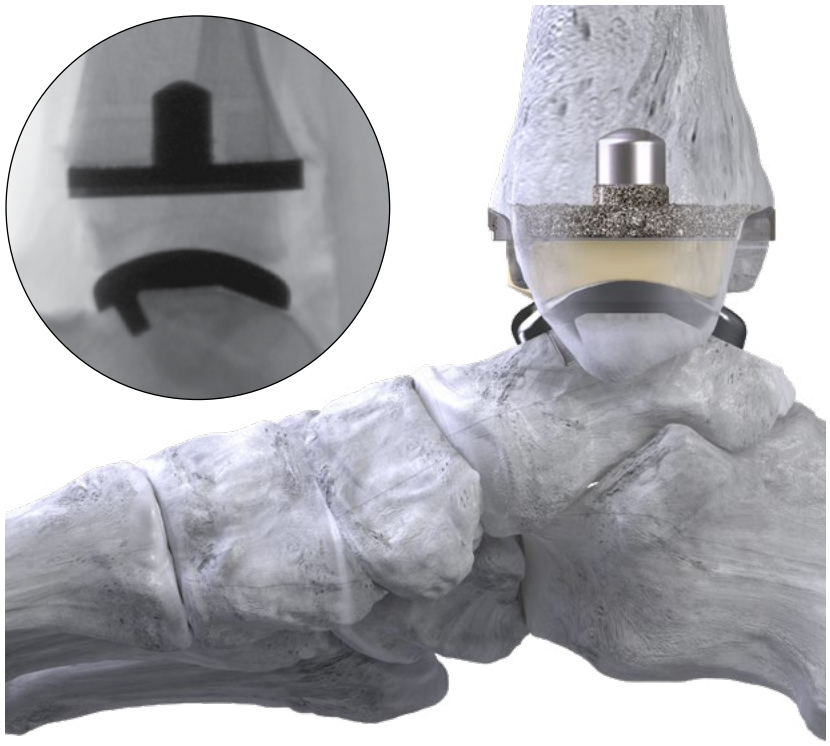
Reference APEX 3D™ Surgical Technique (P10-STG-0001) for the appropriate Final Implant Placement Section Poly Trialing Section.





FINAL IMPLANTATION:

Proceed to final fluoroscopic images and incision closure at this time.



IMPLANTATION REMOVAL:

- An anterior approach to the tibiotalar joint can be used, per surgeon preference and patient need.
- Retrieve the poly handling tool. Insert the poly handling tool into the recess at the anterior aspect of the poly insert. Clamp the poly handling tool onto the poly insert until tight.
- Pull the poly insert anteriorly (or posteriorly) while the foot is maintained in a plantar flexed position until released from the tibiotalar joint. Pass from operative field.

TIP: Use curve osteotome with poly handling tool to disengage poly implant with leverage by squeezing the handles of both instruments to release the poly implant barb from the tibial tray.

- Retrieve an osteotome. Place the osteotome between the talus and the bone contacting surface of the anterior aspect of the talar implant. While providing a superior force on the osteotome, lift the talar implant away from the talus. If necessary, retrieve a mallet and use the mallet to disengage the talar implant from the talus. Pull the talar implant anteriorly out of the tibiotalar joint, using forceps if necessary. Pass from the operative field.
- Using the same osteotome, place the osteotome between the tibia and the bone contacting surface of the anterior aspect of the tibial implant. While providing an inferior force on the osteotome, lift the tibial implant away from the tibia. If necessary, use the mallet to disengage the tibial implant away from the tibia. Pull the tibial implant anteriorly out of the tibiotalar joint, using forceps if necessary. Distraction may be required to remove the implant from the joint. Pass from the operative field.
- Continue to revision procedure as indicated.

Refer to www.paragon28.com/ifus for the complete and most current instructions for use document.

INDICATIONS FOR USE

All possible complications listed here are not typical of Paragon 28®. Inc. products but in principle, may be observed with any total joint replacement implant. Promptly inform Paragon 28®, Inc. as soon as complications occur in connection with the implants or surgical instruments used. In the event of premature failure of an implant in which a causal relationship with its geometry, surface quality or mechanical stability is suspected, please provide Paragon 28®, Inc. with the explant(s) in a cleaned, disinfected and sterile condition. Paragon 28®, Inc. cannot accept any other returns of used implants. The surgeon is held liable for complications associated with inadequate asepsis, inadequate preparation of the osseous implant bed in the case of implants, incorrect indication of surgical technique or incorrect patient information and consequent incorrect patient behavior

CONTRAINDICATIONS

Use of the APEX 3D™ Total Ankle Replacement System is contraindicated in cases of inflammation, cases of active or suspected sepsis/infection and osteomyelitis; or in patients with certain metabolic diseases.

All applications that are not defined by the indications are contraindicated. In addition, surgical success can be adversely affected by:

- Acute or chronic infections, local or systemic
- Any mental or neuromuscular disorder that could result in an unacceptable risk of failure at the time of fixations or complications in post-operative treatment (e.g. dementia, senility, alcoholism)
- Corpulence; an overweight or corpulent patient that can strain the prosthesis to such a degree that stabilization or prosthesis failure can occur
- Excessive loads as caused by activity or patient weight
- Female childbearing age, for whom a negative pregnancy test is not obtained
- Steroid use
- Inadequate neuromuscular status (e.g. prior paralysis, neuropathy, neuropathic joint, fusion and/or inadequate abductor strength)
- Muscular atrophy
- Osteomyelitis
- Poor bone stock, poor skin coverage, or excessive bone loss around the joint which would make the procedure unjustifiable
- Sepsis
- Skeletally immature patients (patient is less than 21 years of age at the time of surgery)
- Suspected or documented metal allergy or intolerance
- Musculoskeletal disease that may adversely affect gait or weightbearing
- Neurologic disorder/instability and non-compliance that may adversely affect gait or weight bearing
- Vascular deficiency in the ankle joint

Other medical or surgical pre-conditions that could compromise the potentially beneficial procedure, such as:

- Congenital abnormalities
- Immunosuppressive pathologies
- Increased sedimentation rates that cannot be explained by other pathologies
- Marked bone loss, severe osteoporosis, or revision procedures for which an adequate fit of the prosthesis cannot be achieved
- Metabolic disorders that may impair bone formation
- Osteomalacia
- Poor prognosis for good wound healing
- Presence of tumors
- Increased leukocyte (WBC) count
- Pronounced left shift in the differential leukocyte count
- Uncooperative patient or patient with neurological disorders, incapable of following instructions

POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS

In any surgical procedure, the potential for complications and adverse reactions exists. The risks and complications with these prosthetic components include:

- Asymptomatic, progressive bone resorption (osteolysis) due to foreign body reaction to particulate matter (See Important Physician Information section for more information)
- Sensitivity, allergy or other reactions to prosthetic component materials
- Peripheral neuropathies or nerve damage resulting in pain or numbness of the affected limb
- Loosening or migration of the prosthetic components
- Subluxation or dislocation of the prosthetic components with resulting reduction in range of movement
- Bending, disassembly and/or breakage of the prosthetic components
- Fractures resulting from unilateral joint loading
- Fatigue fracture of the prosthetic components as the result of trauma, strenuous activity, Improper alignment, incomplete implant seating, or duration of service
- Bone fracture by trauma or excessive loading, particularly in the presence of poor bone stock
- Drop in blood pressure intra-operatively due to the use of bone cement
- Thrombosis, embolism or myocardial infarction
- Wound hematoma and delayed wound healing
- Acute post-operative wound infections and late infections with possible sepsis

Refer to www.paragon28.com/ifus for the complete and most current instructions for use document.

- Pain, a feeling of malaise or abnormal sensations due to the prosthetic components
- Inadequate range of motion due to improper selection or positioning of components or periarticular calcification
- Temporary and protracted functional neurological perturbation
- Corrosion with localized tissue reaction and pain
- Bone loss due to stress shielding
- Secondary necrosis of the talus

All possible complications listed here are not typical of Paragon 28®. Inc. products but in principle, may be observed with any total joint replacement implant. Promptly inform Paragon 28®, Inc. as soon as complications occur in connection with the implants or surgical instruments used. In the event of premature failure of an implant in which a causal relationship with its geometry, surface quality or mechanical stability is suspected, please provide Paragon 28®, Inc. with the explant(s) in a cleaned, disinfected and sterile condition. Paragon 28®, Inc. cannot accept any other returns of used implants. The surgeon is held liable for complications associated with inadequate asepsis, inadequate preparation of the osseous implant bed in the case of implants, incorrect indication of surgical technique or incorrect patient information and consequent incorrect patient behavior

WARNINGS AND PRECAUTIONS

- This device is not intended for subtalar joint fusion or subtalar joint impingement. Please carefully evaluate the anatomy of each patient before implantation.
- The surgeon should discuss with the patient prior to surgery possible risks, precautions, warnings, consequences, complications, and adverse reactions associated with the surgical procedure and implantation of the device.
- Improper selection, placement, positioning, and fixation of the prosthetic components may result in unusual stress conditions and a subsequent reduction in service life of the prosthetic component.
- Periodic long-term follow-up is recommended to monitor the position and state of the prosthetic components, as well as the condition of the adjoining bone.
- Re-operation to remove or replace prosthetic components may be required at any time due to medical reasons or device failure if corrective action is not taken, complications may occur.
- Patients need to be informed regarding expectations pertaining to performance and limitations following surgery. The prosthesis does not replace normal bone, has a finite service life, and future revision surgeries may be necessary. Protection of the prosthesis from full weight bearing is needed until adequate fixation and healing is achieved. Certain activities and loading trauma should be limited to prevent unreasonable stresses that could lead to breaking or damage of the prosthetic components.
- Do not attempt a surgical procedure with faulty, damaged or suspect instruments or implants. Inspect all components preoperatively to assure utility.
- Never modify an implant.
- The implants and guide wires are intended for single use only.
- Instruments and implants are to be treated as sharps
- Do not implant the instruments
- **Do not use other manufacturer's instruments or implants in conjunction with the APEX 3D™ Total Ankle Replacement Device.**
- **Do not re-sterilize the APEX 3D™ Total Ankle Replacement Implants or Instruments.**

IMPORTANT PHYSICIAN INFORMATION

Bone resorption is a natural consequence of total joint arthroplasty due to changes in bone remodeling patterns. Bone remodeling is mediated by the changes in stress distribution caused by implantation. Extensive resorption around the prosthesis may lead to implant loosening and failure. It is generally agreed that osteolysis is the result of localized foreign-body reaction to particulate debris generated by the components of a prosthesis migrate into the synovial cavity and the bone-implant interface, where they recruit macrophages and stimulate phagocytic action. The degree of recruitment is determined by the size, distribution and amount of particulate debris (rate of debris generation) the phagocytic action results in the release of cytokines and intercellular mediators (IL-1, PE2) which encourage osteoclastic bone resorption. Clinical and basic research is continuing in order to provide scientific bases for the causes of this phenomenon and the potential ways to reduce its occurrence. Osteolysis can be asymptomatic and therefore routine periodic radiographic examination is vital to prevent any serious future complication. Presence of focal lesions that are progressive may necessitate replacement of the prosthetic components(s)

Refer to www.paragon28.com/ifus for the complete and most current instructions for use document.

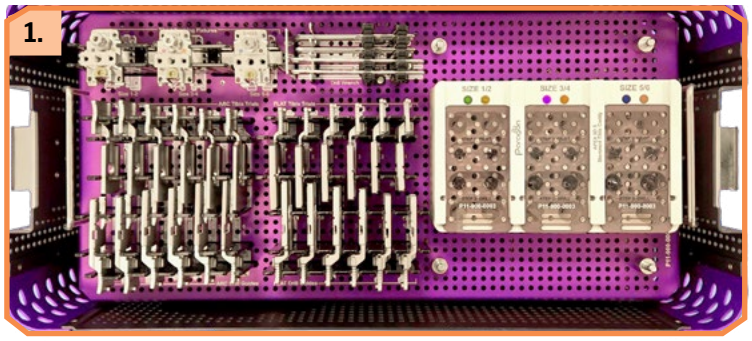
MRI SAFETY INFORMATION

A patient with the Paragon 28® APEX 3D™ Total Ankle Replacement System may be safely scanned under the following conditions. Failure to follow these conditions may results in injury to the patient.

Name/Identification of device	Paragon 28® APEX 3D™ Total Ankle Replacement System
Nominal value(s) of Static Magnetic Field [T]	1.5 T or 3 T
Maximum Spatial Field Gradient [T/m and gauss/cm]	30 T/m (3000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body transmit coil, Head RF transmit-receive coil
Operating Mode	Normal Operating Mode
Maximum Whole Body SAW [W/kg]	2.0 W/kg (Normal Operating Mode)
Limits on Scan Duration	2.0 W/kg whole body average SAR for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact.
If information about a specific parameter is not included, there are no conditions associated with that parameter.	

STEM TIBIA CASE & TRAY INSERTS

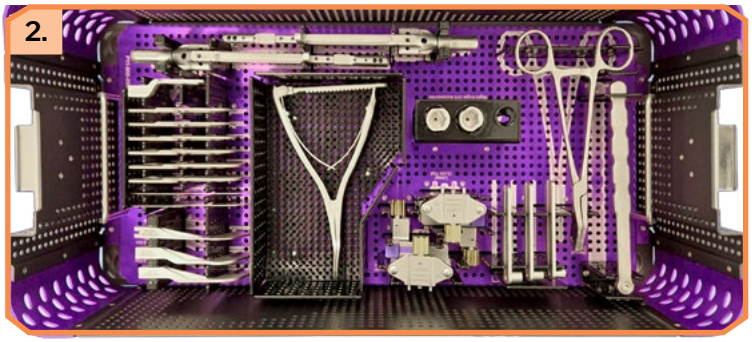
ALIGNMENT CASE – TOP



STEM TIBIA INSTRUMENTATION INCLUDING:

- Pilot and Final Drill Bits, Left & Right ARC Tibia™ / Flat Tibia, Tibia Trials, Left & Right ARC Tibia™ / Flat Tibia Drill Trials, Tibia Docking Fixtures, and Shoulder Pins

ALIGNMENT CASE – BOTTOM

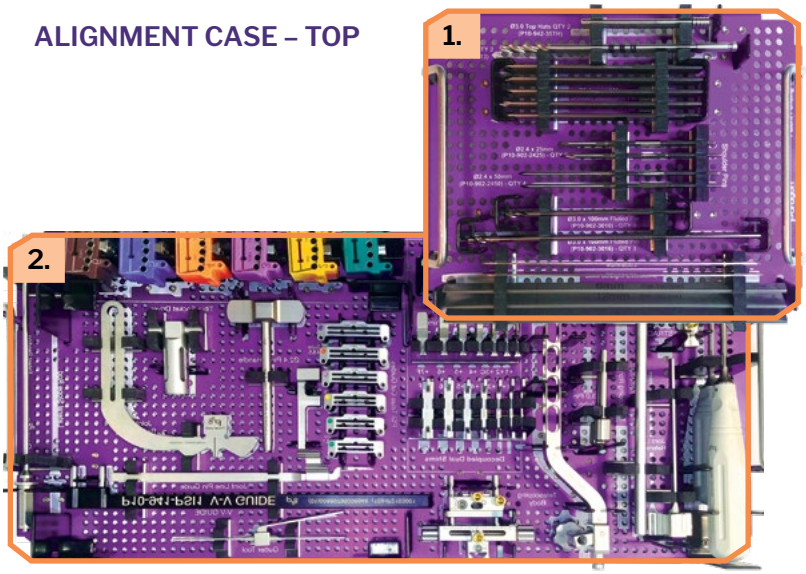


STEM TIBIA INSTRUMENTATION INCLUDING:

- Right Angle Drills, Linear Guides, ARC Tibia / Flat Tibia Distraction Paddles, Talar Shims, Impaction Protectors, Implantation Paddle, Lamina Spreader, Graft Impactors, Manual Drill, Trial Holder, and Hex Socket

ALIGNMENT CASE & TRAY INSERTS

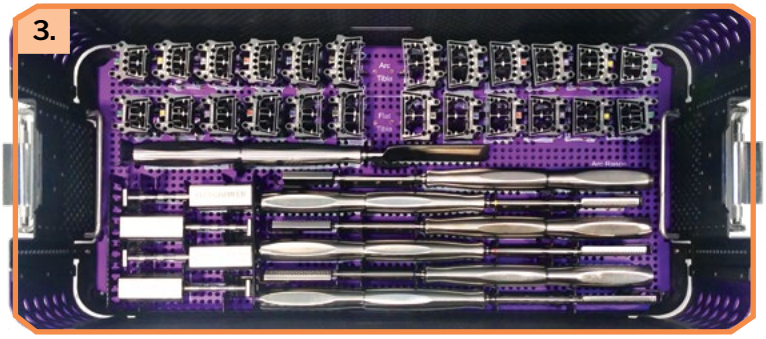
ALIGNMENT CASE – TOP



TRADITIONAL ALIGNMENT CONSTRUCT INCLUDING:

- Hex Driver, Telescoping Shaft & Distal Control Body, Joint Line Pointer, Reference Wing & Lateral Slope Rod, Sizing Resection Blocks and a Decoupled Resection Block with Shims are located within this top case insert, Smooth, Fluted & Threaded Shouldered Fixation Pins, Top Hat and three (3) Osteotome options also included.

ALIGNMENT CASE – BOTTOM

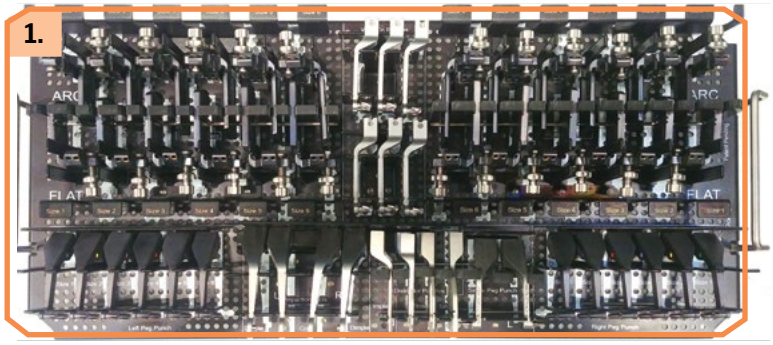


TIBIAL BONE PREPARATION INSTRUMENTS INCLUDING:

- ARC Tibia™ & Flat Tibia Coupled Resection Blocks, ARC Tibia Osteotome & Rasps, and Tibiotalar Gap Checkers are located within this bottom case insert.

RESECTION CASE & TRAY INSERTS

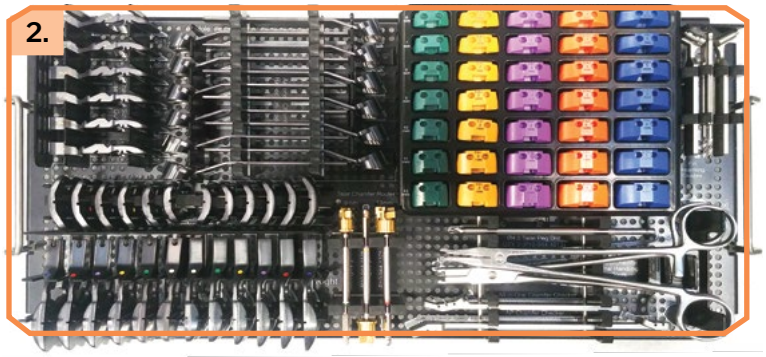
RESECTION CASE – TOP



TIBIAL SIZING GUIDES & VERTICAL PEG PREPARATION INSTRUMENTS INCLUDING:

- Left & Right ARC Tibia™ / Flat Tibia Sizing Trials, and Viper Tip, Distraction & Impaction Paddles are located within this top case insert.

RESECTION CASE – BOTTOM

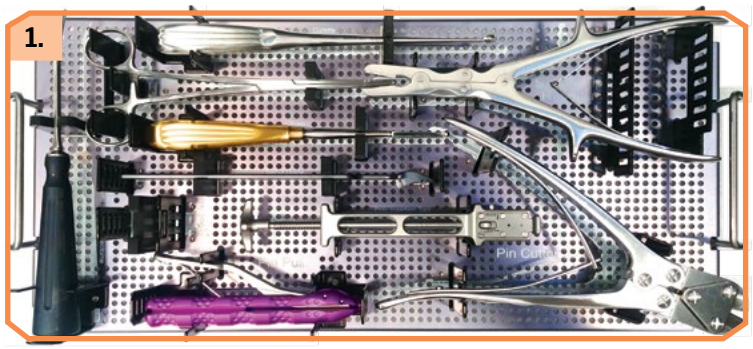


TALAR SIZING GUIDES & BONE PREPARATION INSTRUMENTS INCLUDING:

- Chamfer & Flat Sizing Guides, Reamers, Fin Towers, Peg Drills, Resection Checkers and implant Trials are located within this bottom case insert, as well as color coded Poly Trials & Handling Tools.

LARGE INSTRUMENT CASE & TRAY INSERTS

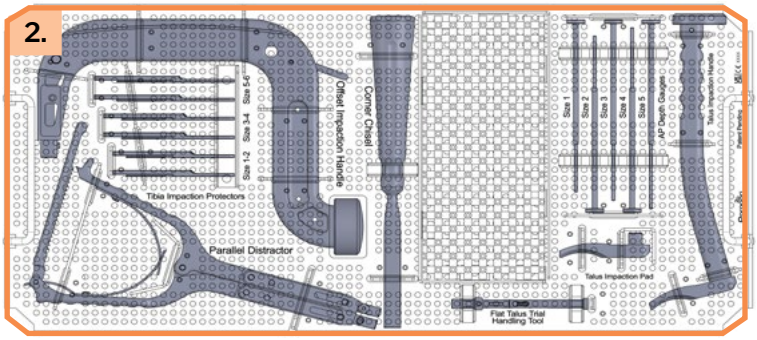
LARGE INSTRUMENT CASE – TOP



TIBIOTALAR BONE PREPARATION INCLUDING:

- Curved Tipped Osteotome, Gold Rasp, Square Tip Rongeur, Poly Implant Insertion Tool, Pin Cutter & Puller are located within this top case insert.

LARGE INSTRUMENT CASE – BOTTOM



IMPACTION TOOLS INCLUDING:

- Parallel Distractor, Offset Impaction Handle, Talar Implant Protectors, Talar Impaction Handle, ARC Polishing Blocks, 3.5 mm Square Tip Drill, and Depth Gauges are located within this bottom case insert.

ALIGNMENT CASE CONTENTS:

PART #	DESCRIPTION	USE
P10-901-24TH	T-Handle	Reusable
P10-901-OS01	Tibial Osteotome, ARC	Reusable
P10-901-RGA1	Resection Gap Checker, ARC/Chamfer-Cut	Reusable
P10-901-RGA2	Resection Gap Checker, ARC/Flat-Cut	Reusable
P10-901-RGF1	Resection Gap Checker, FLAT/Chamfer-Cut	Reusable
P10-901-RGF2	Resection Gap Checker, FLAT/Flat-Cut	Reusable
P10-901-RSP[1-6]	Tibial Rasp, ARC, Size 1-6	Reusable
P10-902-3010	Ø3.0 Pin, 316LVM, Fluted, 100 mm	Single-Use
P10-902-3016	Ø3.0 Pin, 316LVM, Fluted, 160 mm	Single-Use
P10-902-2425	Shoulder Threaded Pin 2.4 x 25 mm	Single-Use
P10-912-2450	Shoulder Threaded Pin 2.4 x 50 mm	Single-Use
P10-940-JL01	Joint-Line, Pin-Guide	Reusable
P10-940-JL10	Joint-Line, Pin Tube	Reusable
P10-941-AL01	Tibial Alignment Guide, Telescoping Rod	Reusable
P10-941-AL02	Tibial Alignment Guide, Telescoping Base	Reusable
P10-941-AL03	Tibial Alignment Guide, Distal Body	Reusable
P10-941-AL04	Tibial Alignment Guide, Lateral Rod	Reusable
P10-941-AL05	Tibial Alignment Guide, Fast-Track	Reusable
P10-841-AL07	Tibial Alignment Guide, Joint Line Pointer ("JLP"), GEN II	Reusable
P10-841-AW01	Alignment Wing, Gen II	Reusable
P10-941-PSI1	V-V Alignment Guide	Reusable
P10-942-3513	Arc Resection Drill, SS, Ø3.5 mm	Single-use
P10-942-35TH	Top Hat, SS, Ø3.5 mm	Reusable
P10-942-DT0[1-3, 7]	Decoupled Talar Resection, Shim, 1, 2, 3, 7 mm	Reusable
P10-942-DT1[1-3]	Decoupled Talar Resection, Split Shim, 1-3 mm	Reusable
P10-942-DTSM	Decoupled Talar Resection, Body, Small	Reusable
P10-942-FL0[1-6]	Coupled Resection Block, FLAT/Chamfer-Cut, Size 1-6	Reusable
P10-942-FL1[1-6]	Coupled Resection Block, FLAT/Flat-Cut, Size 1-6	Reusable
P10-942-RS0[1-6]	Coupled Resection Block, ARC/Chamfer-Cut, Size 1-6	Reusable
P10-942-RS1[1-6]	Coupled Resection Block, ARC/Flat-Cut, Size 1-6	Reusable
P10-942-SZ0[1-6]	Sizing Resection Block, Size 1-6	Reusable
P10-944-PSI0	Talar PSI Resection Block, Size 1N	Reusable
P10-944-PSI[1-6]	Talar PSI Resection Block, Size 1-5	Reusable
P99-150-0040	Osteotome, Straight, 6 mm	Reusable
P99-150-0041	Osteotome, Straight, 12 mm	Reusable
P99-150-0042	Osteotome, Straight, 19 mm	Reusable
P99-150-HB35	3.5 mm Ball Nose Hex Screw Driver, 225 mm Length	Reusable
P99-150-HB35-SHORT	3.5 mm Ball Nose Hex Screw Driver, Short	Reusable
P99-158-0638	Malleable Ribbon Retractor, 6" x 3/8"	Reusable
P99-158-0650	Malleable Ribbon Retractor, 6" x 1/2"	Reusable
P99-160-2411	Steinmann Pin, 316LVM, Smooth, Ø2.4x110 mm	Single-use
P10-842-35SQ	Ø3.5 mm Square Tip, 13CM, Total Ankle Drill	Single-use

RESECTION CASE CONTENTS:

PART #	DESCRIPTION	USE
P10-920-TFT0	Talar Fin Tower, Size 1N & 1	Reusable
P10-920-TFT2	Talar Fin Tower, Size 2-5	Reusable
P10-920-TLL0	Trial Talus, Chamfer, Size 1N, Left	Reusable
P10-920-TLL[1-5]	Trial Talus, Chamfer, Size 1-5, Left	Reusable
P10-920-TLR0	Trial Talus, Chamfer, Size 1N, Right	Reusable
P10-920-TLR[1-5]	Trial Talus, Chamfer, Size 1-5, Right	Reusable
P10-920-TLRM	Talar Fin Sweeper	Single-use
P10-921-TLL0	Trial Talus, Flat, Size 1N, Left	Reusable
P10-921-TLL[1-5]	Trial Talus, Flat, Size 1-5, Left	Reusable
P10-921-TLR0	Trial Talus, Flat, Size 1N, Left	Reusable
P10-921-TLR[1-5	Trial Talus, Flat, Size 1-5, Right	Reusable
P10-930-I1[06-12]	Poly Trial Insert, Size 1, 6-12 mm	Reusable
P10-930-I2[06-12]	Poly Trial Insert, Size 2, 6-12 mm	Reusable
P10-930-I3[06-12]	Poly Trial Insert, Size 3, 6-12 mm	Reusable
P10-930-I4[06-12]	Poly Trial Insert, Size 4, 6-12 mm	Reusable
P10-930-I5[06-12]	Poly Trial Insert, Size 5, 6-12 mm	Reusable
P10-944-0975	Talar Chamfer Resection Router, Ø9 mm	Single-use
P10-944-1175	Talar Chamfer Resection Router, Ø11 mm	Single-use
P10-944-1375	Talar Chamfer Resection Router, Ø13 mm	Single-use
P10-944-4013	Talar Peg Router	Single-use
P10-944-LL00	Talar Sizing Resection Guide, Chamfer, Size 1N	Reusable
P10-944-LL0[1-5]	Talar Sizing Resection Guide, Chamfer, Size 1-5	Reusable
P10-944-LL10	Anterior Chamfer Resection Insert, Single-Slotted, Size 1N	Reusable
P10-944-LL1[1-5]	Anterior Chamfer Resection Insert, Single-Slotted, Size 1-5	Reusable
P10-944-TCC3	Chamfer Checker, All-in-one, V2.0	Reusable
P10-944-TCC4	Chamfer Checker, AP Double-Ended, V2.0	Reusable
P10-951-P001	4-Bar Distractor, Tibia Paddle, Constrained	Reusable
P10-951-P002	4-Bar Distractor, Tibia Paddle, A-P Translation	Reusable
P10-951-P011	4-Bar Distractor, Talus Paddle, Size 1N & 1	Reusable
P10-851-P021	4-Bar Distractor, Tibia Implantation Paddle, Gen II	Reusable
P10-951-TBL1	Tibia Impaction Dimple, Left	Reusable
P10-951-TBL2	Tibia Impaction Coin, Left	Reusable
P10-951-TBR1	Tibia Impaction Dimple, Right	Reusable
P10-951-TBR2	Tibia Impaction Coin, Right	Reusable
P10-953-IN01	Poly Trial Handling Tool	Reusable
P10-953-TL01	Talus Trial Handling Tool	Reusable
P10-851-L001	Fluted Single Peg Punch, Left	Reusable
P10-851-TBV[1-6]	4-Bar Distractor, Viper Tip, Sizes 1-6, SS	Reusable
P10-851-TPL[1-6]	Tibia Peg Punch, Left, Sizes 1-6,SS	Reusable
P10-910-TB[1-6]L	Trial Tibia, ARC, Sizes 1-6, Left, SS	Reusable
P10-910-TB[1-6]R	Trial Tibia, ARC, Sizes 1-6, Right, SS	Reusable

LARGE INSTRUMENT CASE CONTENTS:

PART #	DESCRIPTION	USE
P10-901-PP24	Pin Puller	Reusable
P10-942-APD[1-5]	AP Depth Gauge, Size 1-5	Reusable
P10-944-STR0	Square Tip Ronguer	Reusable
P10-844-02SM	2 mm Dorsal, Re-cut Guide, Narrow	Reusable
P10-844-02LG	2 mm Dorsal, Re-cut Guide, Wide	Reusable
P10-944-TCR2	Posterior, Re-cut Guide	Reusable
P10-851-4BAR	4-Bar Distractor, Gen II	Reusable
P10-851-PT02	Poly Insertion Tool	Reusable
P10-851-TB00	Tibia Impaction Handle	Reusable
P10-952-TL00	Talus Impaction Handle	Reusable
P10-952-TL00-04	Talus Impaction Handle, Pad	Reusable
P99-150-0016	Pin Cutter	Reusable
P99-150-0105	Rasp, General	Reusable
P99-150-1341	Osteotome, Large Handled, Curved, 6 mm	Reusable
P99-150-KC01	Kocher Clamp, 8"	Reusable
P99-150-0098	Curette, 9 mm, 45 Degrees	Reusable
P10-842-AC0[1-6]	Arc Cleanup Block, Size 1-6	Reusable
P10-851-TP12	Impaction Protector, Size 1-2	Single-use
P10-851-TP34	Impaction Protector, Size 3-4	Single-use
P10-851-TP56	Impaction Protector, Size 5-6	Single-use
P10-951-TP0{1-6]	APEX 3D Tibia Impaction Protector, Sizes 1-6	Single-use

STEM TIBIA INSTRUMENTATION CASE CONTENTS:

PART #	DESCRIPTION	USE
P10-912-2450	Shoulder Threaded Pin 2.4 x 50 mm	Single-use
P11-854-LG10	Linear Guide Rail	Reusable
P11-854-RAD1	Right Angle Drill	Reusable
P11-854-D09[S/T]	Size 1-2 Drill Bits	Single-Use
P11-854-D10[S/T]	Size 3-4 Drill Bits	Single-Use
P11-854-D12[S/T]	Size 5-6 Drill Bits	Single-Use
P11-854-C09[S/T]	Size 1-2 Drill Bit Caps	Single-Use
P11-854-C10[S/T]	Size 3-4 Drill Bit Caps	Single-Use
P11-854-C12[S/T]	Size 5-6 Drill Bit Caps	Single-Use
P11-810-TUA[1-6]	Tibia Drill Guide, ARC	Reusable
P11-810-PLA[1-6]	Tibia Poly Trial, ARC	Reusable
P11-810-TUF[1-6]	Tibia Drill Guide, FLAT	Reusable
P11-810-PLF[1-6]	Tibia Poly Trial, FLAT	Reusable
P11-810-TB[1,3,5][2,4,6]	Tibial Docking Fixture	Reusable
P11-851-P032	Flat Paddle	Reusable
P11-851-P0[4/5]1	Forked Paddles (Arc/Flat)	Reusable

STEM TIBIA INSTRUMENTATION CASE CONTENTS:

PART #	DESCRIPTION	USE
P11-851-GR0[1-3]	Graft Impactor	Reusable
P11-851-P021	Implantation Paddle	Reusable
P11-810-TH01	Trial Holder	Reusable
P11-854-MD01	Manual Drill	Reusable
P11-854-WR01	Drill Wrench	Reusable
P99-150-0030	Lamina Spreader	Reusable
P11-854-RAD1-17	Hex Socket	Reusable

STEM TIBIA IMPLANT CASE CONTENTS:

PART #	DESCRIPTION	USE
P11-180-BL[1-6][0/S/L]-S	ARC, Left, Stem Tibia Implants	Single-Use
P11-180-BR[1-6][0/S/L]-S	ARC, Right, Stem Tibia Implants	Single-Use
P11-181-BL[1-6][0/S/L]-S	FLAT, Left, Stem Tibia Implants	Single-Use
P11-181-BR[1-6][0/S/L]-S	Flat, Right, Stem Tibia Implants	Single-Use

VITAMIN E POLY IMPLANTS:

PART #	DESCRIPTION	USE
P10-310-I1[0/1][0,1,2,6,7,8,9]	APEX 3D Vitamin E Poly, Size 1 X 6-12 mm Neutral	Single-Use
P10-310-I2[0/1][0,1,2,6,7,8,9]	APEX 3D Vitamin E Poly, Size 2 X 6-12 mm Neutral	Single-Use
P10-310-I3[0/1][0,1,2,6,7,8,9]	APEX 3D Vitamin E Poly, Size 3 X 6-12 mm Neutral	Single-Use
P10-310-I4[0/1][0,1,2,6,7,8,9]	APEX 3D Vitamin E Poly, Size 4 X 6-12 mm Neutral	Single-Use
P10-310-I5[0/1][0,1,2,6,7,8,9]	APEX 3D Vitamin E Poly, Size 5 X 6-12 mm Neutral	Single-Use

TALUS IMPLANTS:

PART #	DESCRIPTION	USE
P10-250-TLL[0-5]-S	APEX 3D Talus, Chamfer, Left	Single-Use
P10-250-TLR[0-5]-S	APEX 3D Talus, Chamfer, Right	Single-Use
P10-251-TLL[0-5]-S	APEX 3D Talus, Flat, Left	Single-Use
P10-251-TLR[0-5]-S	APEX 3D Talus, Flat, Right	Single-Use

TIBIAL IMPLANT OPTIONS

ARC Stem Tibia Implant

Flat Stem Tibia Implant

PART #	DESCRIPTION
P11-180-BL10-S	APEX 3D S™ ARC Stem Tibia, Left, Size 1, Short, 3DP
P11-180-BL1L-S	APEX 3D S™ ARC Stem Tibia, Left, Size 1, Long, 3DP
P11-180-BL1S-S	APEX 3D S™ ARC Stem Tibia, Left, Size 1, Standard, 3DP
P11-180-BL2L-S	APEX 3D S™ ARC Stem Tibia, Left, Size 2, Long, 3DP
P11-180-BL2S-S	APEX 3D S™ ARC Stem Tibia, Left, Size 2, Standard, 3DP
P11-180-BL3L-S	APEX 3D S™ ARC Stem Tibia, Left, Size 3, Long, 3DP
P11-180-BL3S-S	APEX 3D S™ ARC Stem Tibia, Left, Size 3, Standard, 3DP
P11-180-BL4L-S	APEX 3D S™ ARC Stem Tibia, Left, Size 4, Long, 3DP
P11-180-BL4S-S	APEX 3D S™ ARC Stem Tibia, Left, Size 4, Standard, 3DP
P11-180-BL5L-S	APEX 3D S™ ARC Stem Tibia, Left, Size 5, Long, 3DP
P11-180-BL5S-S	APEX 3D S™ ARC Stem Tibia, Left, Size 5, Standard, 3DP
P11-180-BL6L-S	APEX 3D S™ ARC Stem Tibia, Left, Size 6, Long, 3DP
P11-180-BL6S-S	APEX 3D S™ ARC Stem Tibia, Left, Size 6, Standard, 3DP
P11-180-BR10-S	APEX 3D S™ ARC Stem Tibia, Right, Size 1, Short, 3DP
P11-180-BR1L-S	APEX 3D S™ ARC Stem Tibia, Right, Size 1, Long, 3DP
P11-180-BR1S-S	APEX 3D S™ ARC Stem Tibia, Right, Size 1, Standard, 3DP
P11-180-BR2L-S	APEX 3D S™ ARC Stem Tibia, Right, Size 2, Long, 3DP
P11-180-BR2S-S	APEX 3D S™ ARC Stem Tibia, Right, Size 2, Standard, 3DP
P11-180-BR3L-S	APEX 3D S™ ARC Stem Tibia, Right, Size 3, Long, 3DP
P11-180-BR3S-S	APEX 3D S™ ARC Stem Tibia, Right, Size 3, Standard, 3DP
P11-180-BR4L-S	APEX 3D S™ ARC Stem Tibia, Right, Size 4, Long, 3DP
P11-180-BR4S-S	APEX 3D S™ ARC Stem Tibia, Right, Size 4, Standard, 3DP
P11-180-BR5L-S	APEX 3D S™ ARC Stem Tibia, Right, Size 5, Long, 3DP
P11-180-BR5S-S	APEX 3D S™ ARC Stem Tibia, Right, Size 5, Standard, 3DP
P11-180-BR6L-S	APEX 3D S™ ARC Stem Tibia, Right, Size 6, Long, 3DP
P11-180-BR6S-S	APEX 3D S™ ARC Stem Tibia, Right, Size 6, Standard, 3DP

PART #	DESCRIPTION
P11-181-BL10-S	APEX 3D S™ Stem Tibia, Flat, Left, Size 1, Short, 3DP
P11-181-BL1L-S	APEX 3D S™ Stem Tibia, Flat, Left, Size 1, Long, 3DP
P11-181-BL1S-S	APEX 3D S™ Stem Tibia, Flat, Left, Size 1, Standard, 3DP
P11-181-BL2L-S	APEX 3D S™ Stem Tibia, Flat, Left, Size 2, Long, 3DP
P11-181-BL2S-S	APEX 3D S™ Stem Tibia, Flat, Left, Size 2, Standard, 3DP
P11-181-BL3L-S	APEX 3D S™ Stem Tibia, Flat, Left, Size 3, Long, 3DP
P11-181-BL3S-S	APEX 3D S™ Stem Tibia, Flat, Left, Size 3, Standard, 3DP
P11-181-BL4L-S	APEX 3D S™ Stem Tibia, Flat, Left, Size 4, Long, 3DP
P11-181-BL4S-S	APEX 3D S™ Stem Tibia, Flat, Left, Size 4, Standard, 3DP
P11-181-BL5L-S	APEX 3D S™ Stem Tibia, Flat, Left, Size 5, Long, 3DP
P11-181-BL5S-S	APEX 3D S™ Stem Tibia, Flat, Left, Size 5, Standard, 3DP
P11-181-BL6L-S	APEX 3D S™ Stem Tibia, Flat, Left, Size 6, Long, 3DP
P11-181-BL6S-S	APEX 3D S™ Stem Tibia, Flat, Left, Size 6, Standard, 3DP
P11-181-BR10-S	APEX 3D S™ Stem Tibia, Flat, Right, Size 1, Short, 3DP
P11-181-BR1L-S	APEX 3D S™ Stem Tibia, Flat, Right, Size 1, Long, 3DP
P11-181-BR1S-S	APEX 3D S™ Stem Tibia, Flat, Right, Size 1, Standard, 3DP
P11-181-BR2L-S	APEX 3D S™ Stem Tibia, Flat, Right, Size 2, Long, 3DP
P11-181-BR2S-S	APEX 3D S™ Stem Tibia, Flat, Right, Size 2, Standard, 3DP
P11-181-BR3L-S	APEX 3D S™ Stem Tibia, Flat, Right, Size 3, Long, 3DP
P11-181-BR3S-S	APEX 3D S™ Stem Tibia, Flat, Right, Size 3, Standard, 3DP
P11-181-BR4L-S	APEX 3D S™ Stem Tibia, Flat, Right, Size 4, Long, 3DP
P11-181-BR4S-S	APEX 3D S™ Stem Tibia, Flat, Right, Size 4, Standard, 3DP
P11-181-BR5L-S	APEX 3D S™ Stem Tibia, Flat, Right, Size 5, Long, 3DP
P11-181-BR5S-S	APEX 3D S™ Stem Tibia, Right, Size 5, Standard, 3DP
P11-181-BR6L-S	APEX 3D S™ Stem Tibia, Flat, Right, Size 6, Long, 3DP
P11-181-BR6S-S	APEX 3D S™ Stem Tibia, Flat, Right, Size 6, Standard, 3DP

TIBIAL IMPLANT OPTIONS

9 mm Stem Diameter
12 mm Stem Height

Size 1

Size 2

10.5 mm Stem Diameter
12 mm Stem Height

Size 3

Size 4

12 mm Stem Diameter
12 mm Stem Height

Size 5

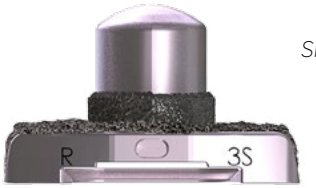
Size 6

9 mm Stem Diameter
12 mm Stem Height

Size 1

Size 2

10.5 mm Stem Diameter
12 mm Stem Height



Size 3

Size 4

12 mm Stem Diameter
12 mm Stem Height

Size 5

Size 6

VITAMIN E POLY INSERT OPTIONS

Poly Insert

PART #	DESCRIPTION
P10-310-I106-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 1 x 6 mm, Neutral
P10-310-I107-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 1 x 7 mm, Neutral
P10-310-I108-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 1 x 8 mm, Neutral
P10-310-I109-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 1 x 9 mm, Neutral
P10-310-I110-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 1 x 10 mm, Neutral
P10-310-I111-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 1 x 11 mm, Neutral
P10-310-I112-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 1 x 12 mm, Neutral
P10-310-I206-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 2 x 6 mm, Neutral
P10-310-I207-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 2 x 7 mm, Neutral
P10-310-I208-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 2 x 8 mm, Neutral
P10-310-I209-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 2 x 9 mm, Neutral
P10-310-I210-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 2 x 10 mm, Neutral
P10-310-I211-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 2 x 11 mm, Neutral
P10-310-I212-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 2 x 12 mm, Neutral
P10-310-I306-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 3 x 6 mm, Neutral
P10-310-I307-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 3 x 7 mm, Neutral
P10-310-I308-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 3 x 8 mm, Neutral
P10-310-I309-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 3 x 9 mm, Neutral
P10-310-I310-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 3 x 10 mm, Neutral
P10-310-I311-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 3 x 11 mm, Neutral
P10-310-I312-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 3 x 12 mm, Neutral
P10-310-I406-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 4 x 6 mm, Neutral
P10-310-I407-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 4 x 7 mm, Neutral
P10-310-I408-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 4 x 8 mm, Neutral
P10-310-I409-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 4 x 9 mm, Neutral
P10-310-I410-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 4 x 10 mm, Neutral
P10-310-I411-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 4 x 11 mm, Neutral
P10-310-I412-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 4 x 12 mm, Neutral
P10-310-I506-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 5 x 6 mm, Neutral
P10-310-I507-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 5 x 7 mm, Neutral
P10-310-I508-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 5 x 8 mm, Neutral
P10-310-I509-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 5 x 9 mm, Neutral
P10-310-I510-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 5 x 10 mm, Neutral
P10-310-I511-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 5 x 11 mm, Neutral
P10-310-I512-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 5 x 12 mm , Neutral

TALAR DOME OPTIONS

Chamfer Talar Implant

Flat Talar Implant

PART #	DESCRIPTION
P10-250-TLL0-S	APEX 3D™ Talus, Chamfer, Left, Size 1 Narrow, TPS
P10-250-TLL1-S	APEX 3D™ Talus, Chamfer, Left, Size 1, TPS
P10-250-TLL2-S	APEX 3D™ Talus, Chamfer, Left, Size 2, TPS
P10-250-TLL3-S	APEX 3D™ Talus, Chamfer, Left, Size 3, TPS
P10-250-TLL4-S	APEX 3D™ Talus, Chamfer, Left, Size 4, TPS
P10-250-TLL5-S	APEX 3D™ Talus, Chamfer, Left, Size 5, TPS
P10-250-TLR0-S	APEX 3D™ Talus, Chamfer, Right, Size 1 Narrow, TPS
P10-250-TLR1-S	APEX 3D™ Talus, Chamfer, Right, Size 1, TPS
P10-250-TLR2-S	APEX 3D™ Talus, Chamfer, Right, Size 2, TPS
P10-250-TLR3-S	APEX 3D™ Talus, Chamfer, Right, Size 3, TPS
P10-250-TLR4-S	APEX 3D™ Talus, Chamfer, Right, Size 4, TPS
P10-250-TLR5-S	APEX 3D™ Talus, Chamfer, Right, Size 5, TPS

PART #	DESCRIPTION
P10-251-TLL0-S	APEX 3D™ Talus, Chamfer, Left, Size 1 Narrow, TPS
P10-251-TLL1-S	APEX 3D™ Talus, Chamfer, Left, Size 1, TPS
P10-251-TLL2-S	APEX 3D™ Talus, Chamfer, Left, Size 2, TPS
P10-251-TLL3-S	APEX 3D™ Talus, Chamfer, Left, Size 3, TPS
P10-251-TLL4-S	APEX 3D™ Talus, Chamfer, Left, Size 4, TPS
P10-251-TLL5-S	APEX 3D™ Talus, Chamfer, Left, Size 5, TPS
P10-251-TLR0-S	APEX 3D™ Talus, Chamfer, Right, Size 1 Narrow, TPS
P10-251-TLR1-S	APEX 3D™ Talus, Chamfer, Right, Size 1, TPS
P10-251-TLR2-S	APEX 3D™ Talus, Chamfer, Right, Size 2, TPS
P10-251-TLR3-S	APEX 3D™ Talus, Chamfer, Right, Size 3, TPS
P10-251-TLR4-S	APEX 3D™ Talus, Chamfer, Right, Size 4, TPS
P10-251-TLR5-S	APEX 3D™ Talus, Chamfer, Right, Size 5, TPS

IMPLANT SIZE OFFERING & INTERCHANGEABILITY

		TALUS (CHAMFER AND FLAT)					
		1N (Narrow)	1	2	3	4	5
TIBIA (ARC TIBIA™ & FLAT)	1 Short	1	1	2			
	1 Standard	1	1	2			
	1 Long	1	1	2			
	2 Standard	1	1	2	3		
	2 Long	1	1	2	3		
	3 Standard	1	1	2	3	4	
	3 Long	1	1	2	3	4	
	4 Standard	1	1	2	3	4	5
	4 Long	1	1	2	3	4	5
	5 Standard	1	1	2	3	4	5
	5 Long	1	1	2	3	4	5
	6 Standard	1	1	2	3	4	5
	6 Long	1	1	2	3	4	5

*All numbers listed in Plum are the compatible polyethylene sizes.

NOTES:

NOTES:

NOTES:

APEX 3D S™
STEMMED TIBIA

Exclusively foot & ankle Paragon 28®

www.Paragon28.com

P11-STG-0001 Rev B [2024-11-15]

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(855) 786-2828

DISCLAIMER

The purpose of the APEX 3D S™ Stemmed Tibia Total Ankle Replacement System Surgical Technique Guide is to demonstrate the use of the APEX 3D S™ Stemmed Tibia Total Ankle Replacement System. Although various methods can be employed for this procedure, the fixation options demonstrated were chosen for simplicity of explanation and demonstration of the unique features of our device. Federal law (U.S.A.) restricts this device to sale and use by, or on order of, a physician.