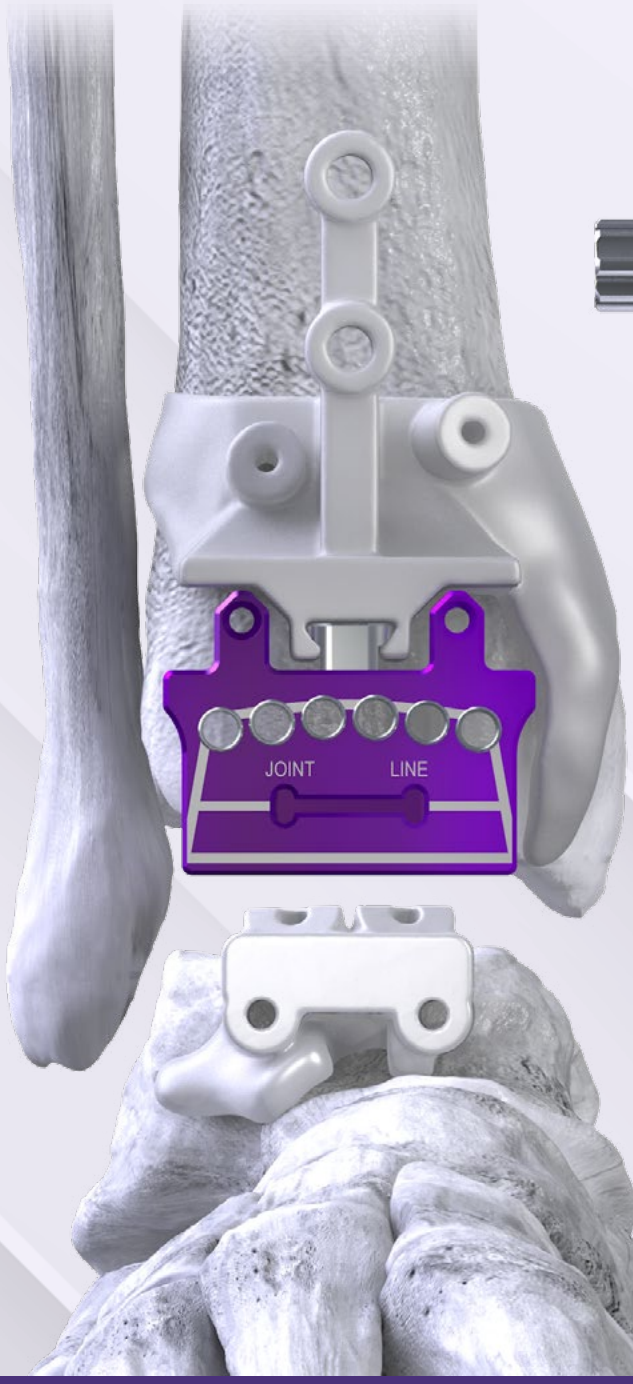
MAVEN™

PATIENT SPECIFIC SURGERY

FEATURING AP
POSITIONING TECHNOLOGY



Exclusively foot & ankle
Paragon 28®

PATIENT-SPECIFIC INSTRUMENTATION

Surgical Technique Guide

APEX 3D™
TOTAL ANKLE REPLACEMENT

Powered by MAVEN® Technology

The MAVEN® Patient-Specific Instrumentation System and Surgical Planning Case Reports are currently designed exclusively for the Paragon 28® APEX 3D™ Total Ankle Replacement System. The APEX 3D™ System consists of fixed-bearing anatomically contoured tibial and talar implant components, Vitamin E ultra-high molecular weight polyethylene insert, intuitive instrumentation and precision bone resection guides intended for use in primary or revision surgery for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis.

CONTENTS

DESIGN TEAM

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ACKNOWLEDGMENTS:

Contributing Surgeon Advisors, Paragon 28's Development Engineers, Clinical Researchers and Marketing Teams.

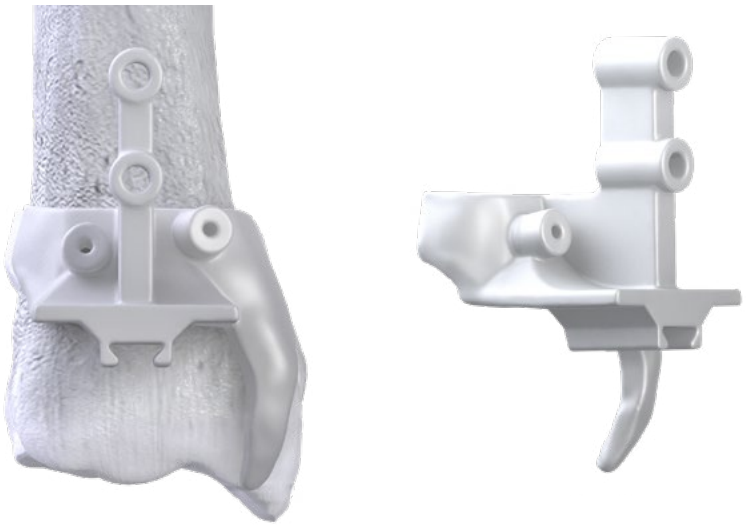
PRODUCT INFORMATION - PSI BONE MODELS & GUIDES

MAVEN® Patient-Specific Instrumentation (PSI) was developed to expedite positioning of the APEX 3D™ Total Ankle Replacement System. The MAVEN® PSI System provides an accurate and simple-to-use technology in the palm of your hand and utilizes an advanced CT-based coordinate system designed for reproducible alignment and accurate implant placement critical for long-term survivorship[1].

The MAVEN® PSI Guides are based on individual patient anatomic structures and aligned to the mechanical axis. Surgical Planning Case Reports (SPCR), PSI Guides, and Bone Models are generated using a segment of the patient's operative limb CT scans and intended to contour to the patient's anatomy. The technology and components are used to determine implant size selection, and properly position/orient cutting instrumentation within the APEX 3D™ Total Ankle Replacement System.

MAVEN® PSI Surgical Planning Case Reports and PSI Guides are based on surgeon approved inputs. MAVEN® PSI 3D Printed Nylon surgical instruments are designed for single use only. The MAVEN® PSI Surgical instruments are supplied clean, non-sterile, and must be sterilized before use.

Tibia PSI Guide & Bone Model



Tibial PSI AP Positioning Spacer

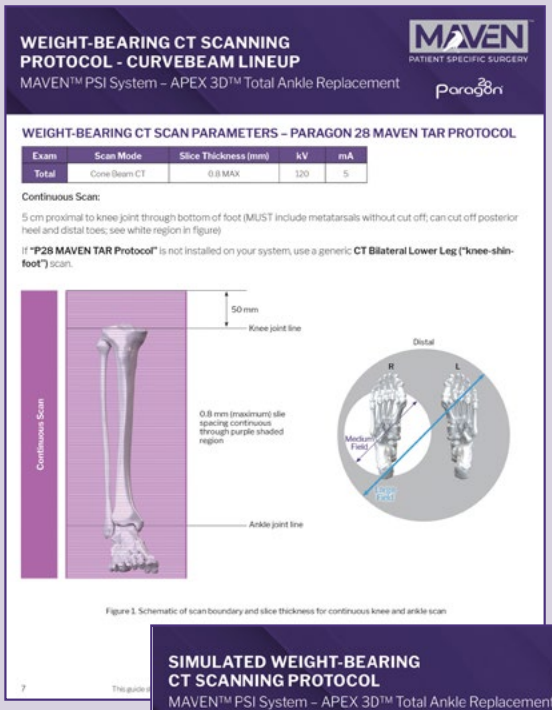
Talar PSI Guide & Bone Model

NOTE: Contoured Notch to Address Specific Anatomic Considerations

PRODUCT INFORMATION – CT SCANNING PROTOCOLS & SURGICAL PLANNING CASE REPORT

CT SCANNING PROTOCOLS

Successfully utilizing the MAVEN® PSI System requires adhering to the MAVEN® Weight-Bearing or Simulated Weight-Bearing CT Scan Protocols. Facilities conducting the CT scans are required to follow the specific instructions. The necessary scanning parameters are depicted within the documents and can be found on our website: www.apexankle.com.



WEIGHT-BEARING CT SCANNING PROTOCOL - CURVEBEAM LINEUP

MAVEN™ PSI System – APEX 3D™ Total Ankle Replacement

WEIGHT-BEARING CT SCAN PARAMETERS – PARAGON 28 MAVEN TAR PROTOCOL

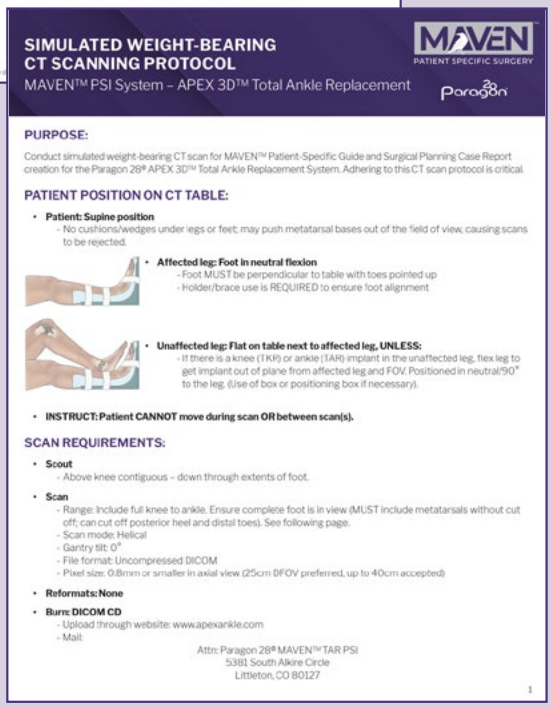
Exam	Scan Mode	Slice Thickness (mm)	kV	mA
Total	Cone Beam CT	0.8 MAX	120	5

Continuous Scan:

5 cm proximal to knee joint through bottom of foot (MUST include metatarsals without cut off; can cut off posterior heel and distal toes; see white region in figure)

If **"P28 MAVEN TAR Protocol"** is not installed on your system, use a generic **CT Bilateral Lower Leg ("knee-shin-foot")** scan.

Figure 1. Schematic of scan boundary and slice thickness for continuous knee and ankle scan



SIMULATED WEIGHT-BEARING CT SCANNING PROTOCOL

MAVEN™ PSI System – APEX 3D™ Total Ankle Replacement

PURPOSE:

Conduct simulated weight-bearing CT scan for MAVEN™ Patient-Specific Guide and Surgical Planning Case Report creation for the Paragon 28® APEX 3D™ Total Ankle Replacement System. Adhering to this CT scan protocol is critical.

PATIENT POSITION ON CT TABLE:

- **Patient: Supine position**
  - No cushions/wedges under legs or feet; may push metatarsal bases out of the field of view, causing scans to be rejected.
- **Affected leg: Foot in neutral flexion**
  - Foot MUST be perpendicular to table with toes pointed up
  - Holder/brace use is REQUIRED to ensure foot alignment
- **Unaffected leg: Flat on table next to affected leg, UNLESS:**
  - If there is a knee (TKR) or ankle (TAR) implant in the unaffected leg, flex leg to get implant out of plane from affected leg and FOV. Positioned in neutral/90° to the leg. (Use of box or positioning box if necessary).
- **INSTRUCT: Patient CANNOT move during scan OR between scan(s).**

SCAN REQUIREMENTS:

- **Scout**
  - Above knee contiguous – down through extents of foot.
- **Scan**
  - Range: Include full knee to ankle. Ensure complete foot is in view (MUST include metatarsals without cut off; can cut off posterior heel and distal toes). See following page.
  - Scan mode: Helical
  - Gantry tilt: 0°
  - File format: Uncompressed DICOM
  - Pixel size: 0.8mm or smaller in axial view (25cm DFOV preferred, up to 40cm accepted)
- **Reformats: None**
- **Burn: DICOM CD**
  - Upload through website: www.apexankle.com
  - Mail:

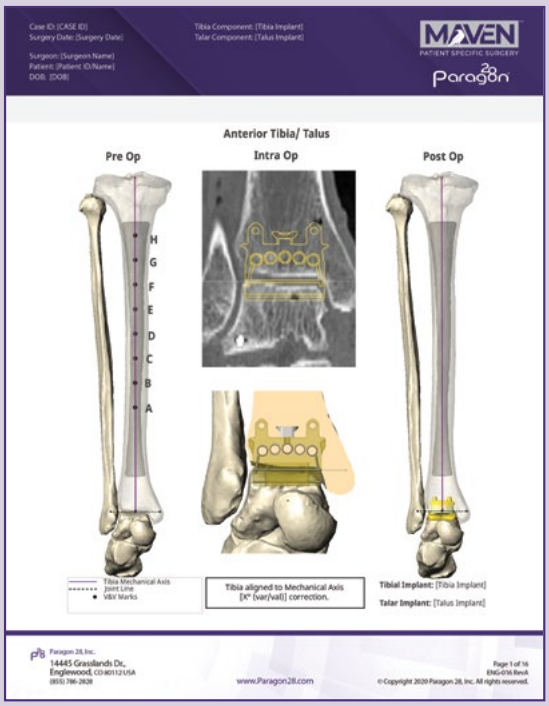
Attn: Paragon 28® MAVEN™ TAR PSI
5381 South Alkire Circle
Littleton, CO 80127

SURGICAL PLANNING CASE REPORTS

Pre-operative planning case reports are generated using surgeon inputs and the patient's native anatomic landmarks. Details from the case report allow for pre-operative visualization of anatomic structures, including AP images displaying the medial malleolus and mid-shaft to identify extra articular deformity anywhere in the tibia.

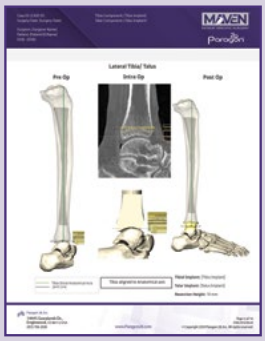
CT based segmentation and computer assisted modeling also help to plan implant size selection, as well as proper positioning and orientation of bone resection instrumentation.

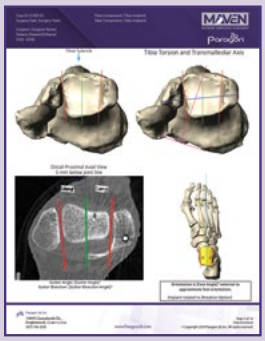
The patient's name is included on the Surgical Planning Case Report (SPCR) to verify that the Case ID printed on the PSI Guides and Bone Models match the SPCR and the SPCR matches the patient.



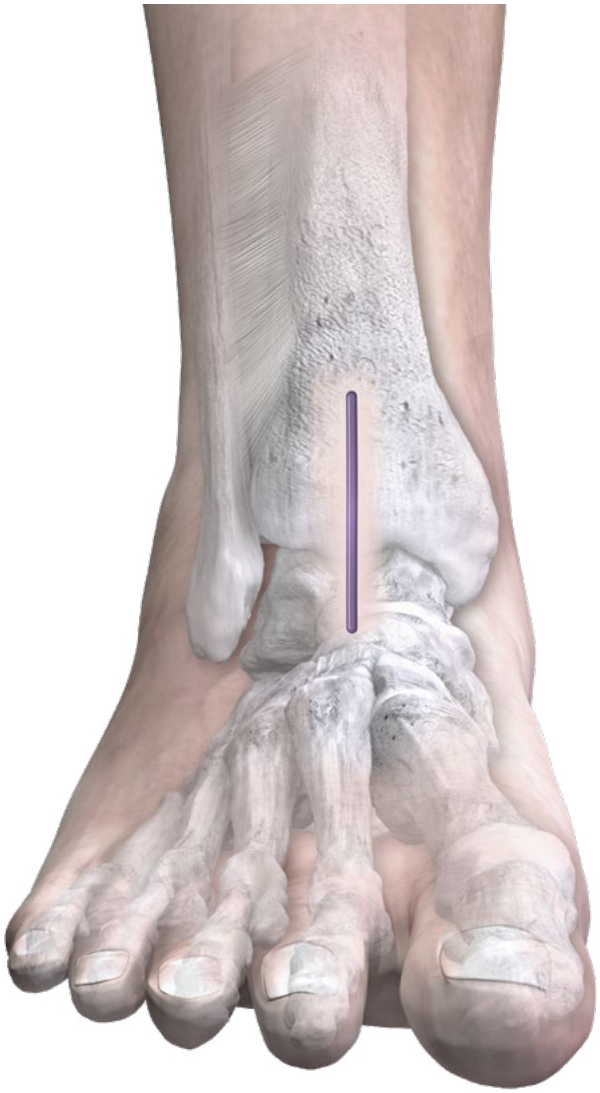
Anterior Tibia/ Talus

Pre Op | Intra Op | Post Op





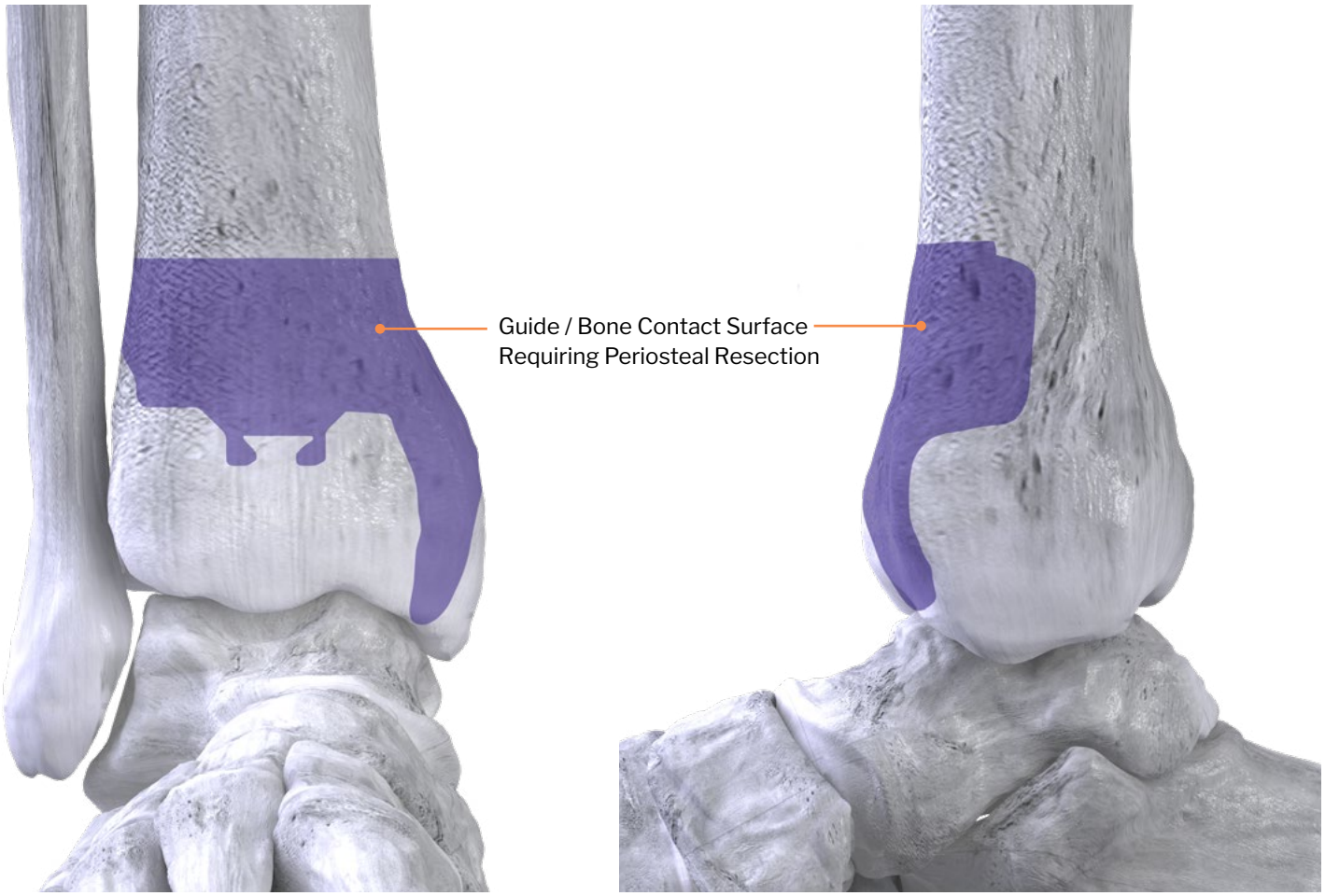
STANDARD ANTERIOR SURGICAL APPROACH



EXPOSURE

- A longitudinal midline incision is made over the anterior ankle, beginning approximately 7 cm proximal to the ankle joint and terminating at approximately or just distal to the talonavicular joint.
- Care should be taken to avoid excess retraction on the skin margins. Full thickness retraction is performed to protect the extensor tendons and neurovascular structures.
- After the initial skin incision, deepen through the subcutaneous tissue. The superficial peroneal nerve (SPN) is identified and protected in distal extension to avoid injury.
- Identify the extensor retinaculum and incise between the anterior tibia and EHL tendon, preserving as much of their respective sheaths as possible.
- Retract the anterior tibia tendon and it's respective sheath medially and the EHL and it's sheath laterally. Take care to avoid injury to the underlying neurovascular structures laterally.
- A longitudinal capsulotomy is performed creating medial and lateral capsular flaps, which are elevated and retracted. This exposes the anterior ankle joint, medial and lateral gutters, and dorsal talar neck.

DISTAL TIBIA PERIOSTEUM PREPARATION

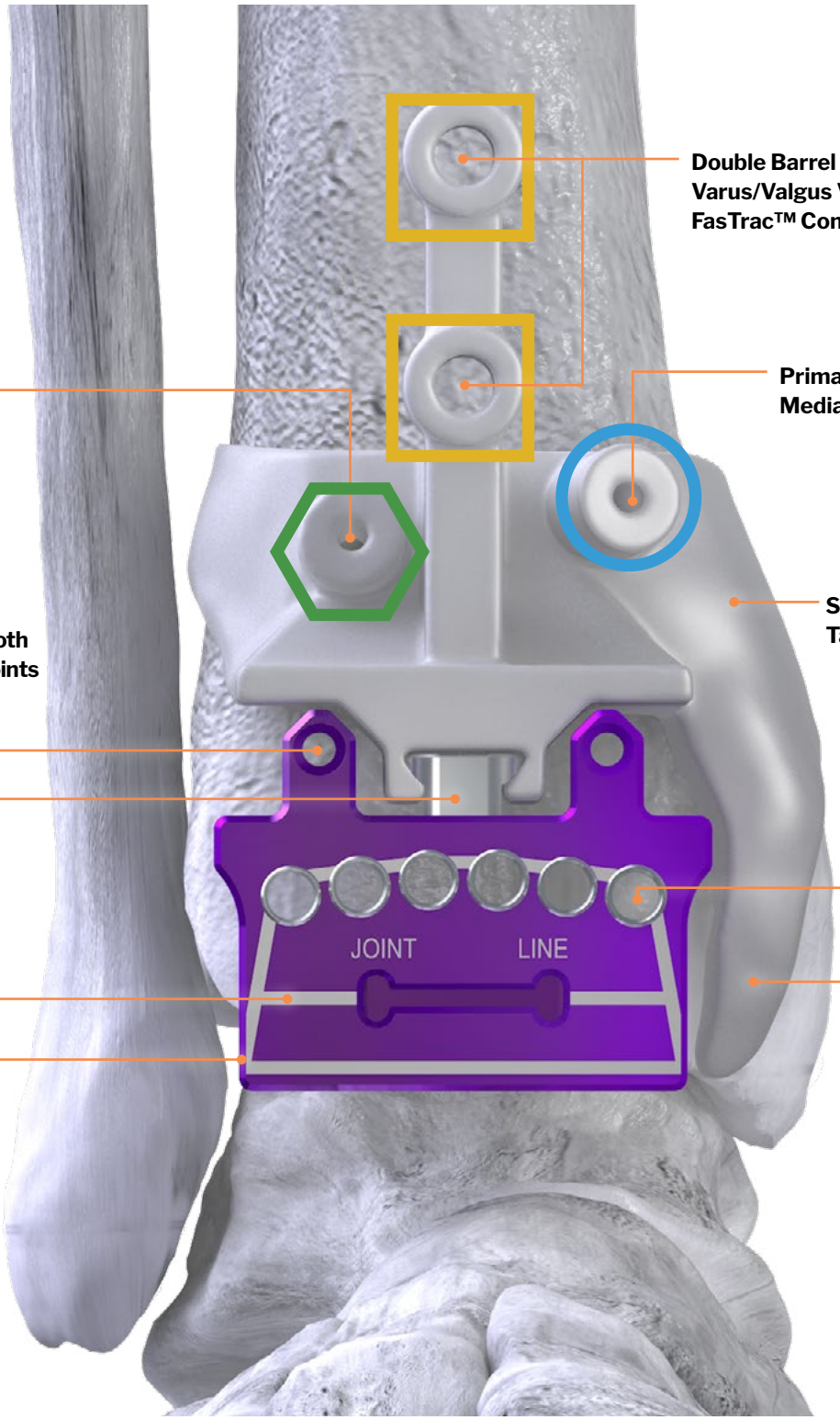


DISTAL TIBIA PREPARATION

- Periosteum will need to be elevated where the patient specific instruments make contact with the bone, making sure to expose cortical bone in the purple area indicated.
- Periosteal resection can be estimated by templating with the provided tibia bone model.
- Contact on the tibia is typically in the metaphyseal cone of the distal tibia, with an extension to the medial malleolus.

SURGICAL NOTE:
The PSI Guide's design contours the anatomy of tibial shaft, ensure uniform bone surface contact before securing the guide to the tibia is critical.

BACK-TABLE OVERVIEW: TIBIA PSI GUIDE



Double Barrel Varus/Valgus Verification Rod & FasTrac™ Conversion Points

Lateral Fixation Pin Sleeve

Primary Medial Fixation Pin Sleeve

Secure & Stable Tactile Feedback

Ø2.4 mm X 110 mm Smooth Steinmann Pin Fixation Points

Integrated Dovetail to preserve landmark positioning and establishes clearly defined bone resection plane

Ø3.5 mm Bicortical Resection Drill Holes

Medial Malleolus Wrap Utilizes Notch of Harty anatomic reference point

Joint Line Reference Radiopaque Markers

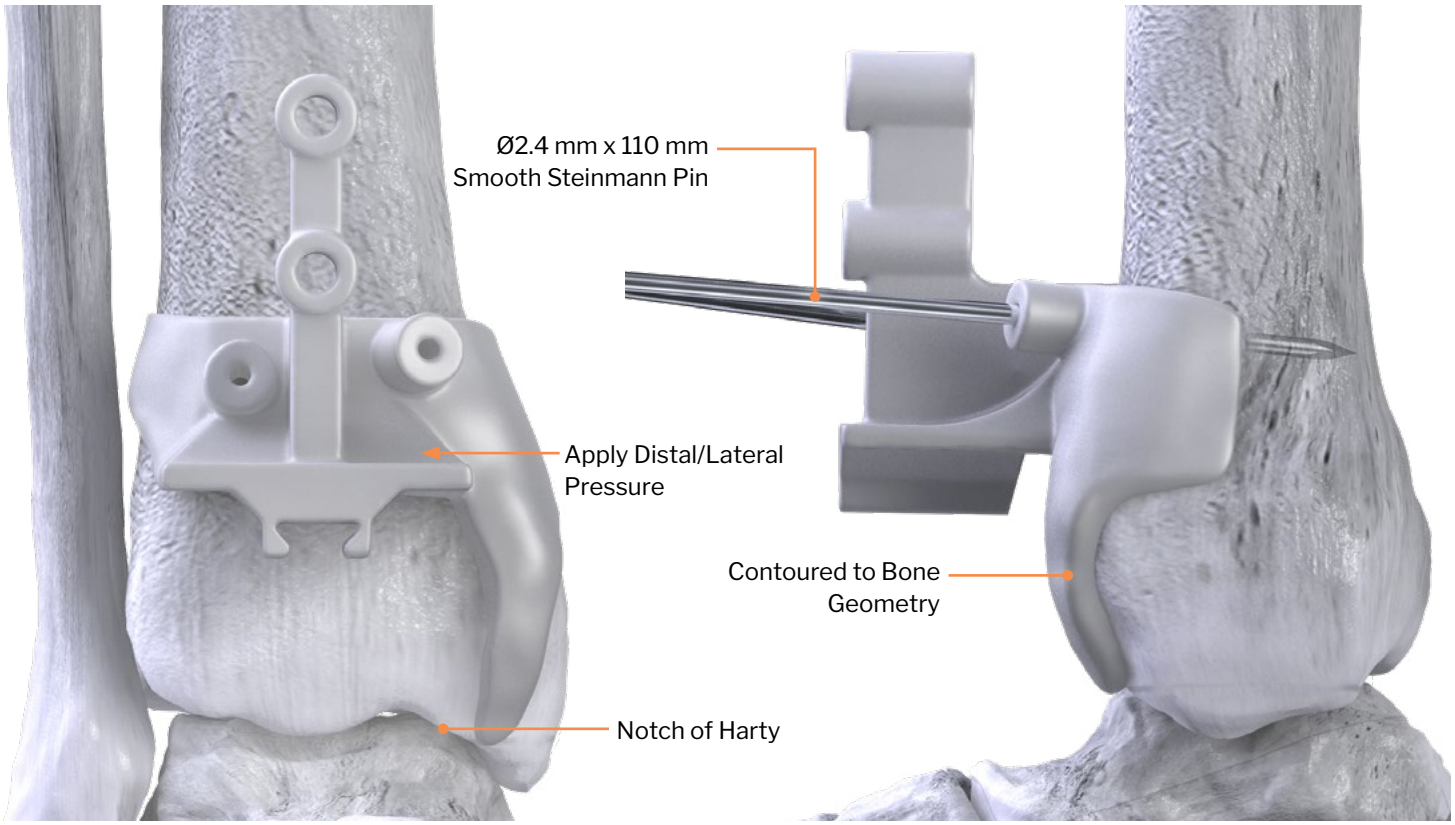
Medial / Lateral Radiopaque Markers

Lateral Fixation Pin Sleeve

Parallel Pin Holes (For use with Varus/Valgus Alignment Verification Rod and FasTrac™ Alignment Guide)

Primary Medial Fixation Pin Sleeve

TIBIAL PSI ALIGNMENT GUIDE POSITIONING



POSITIONING & FIT EVALUATION

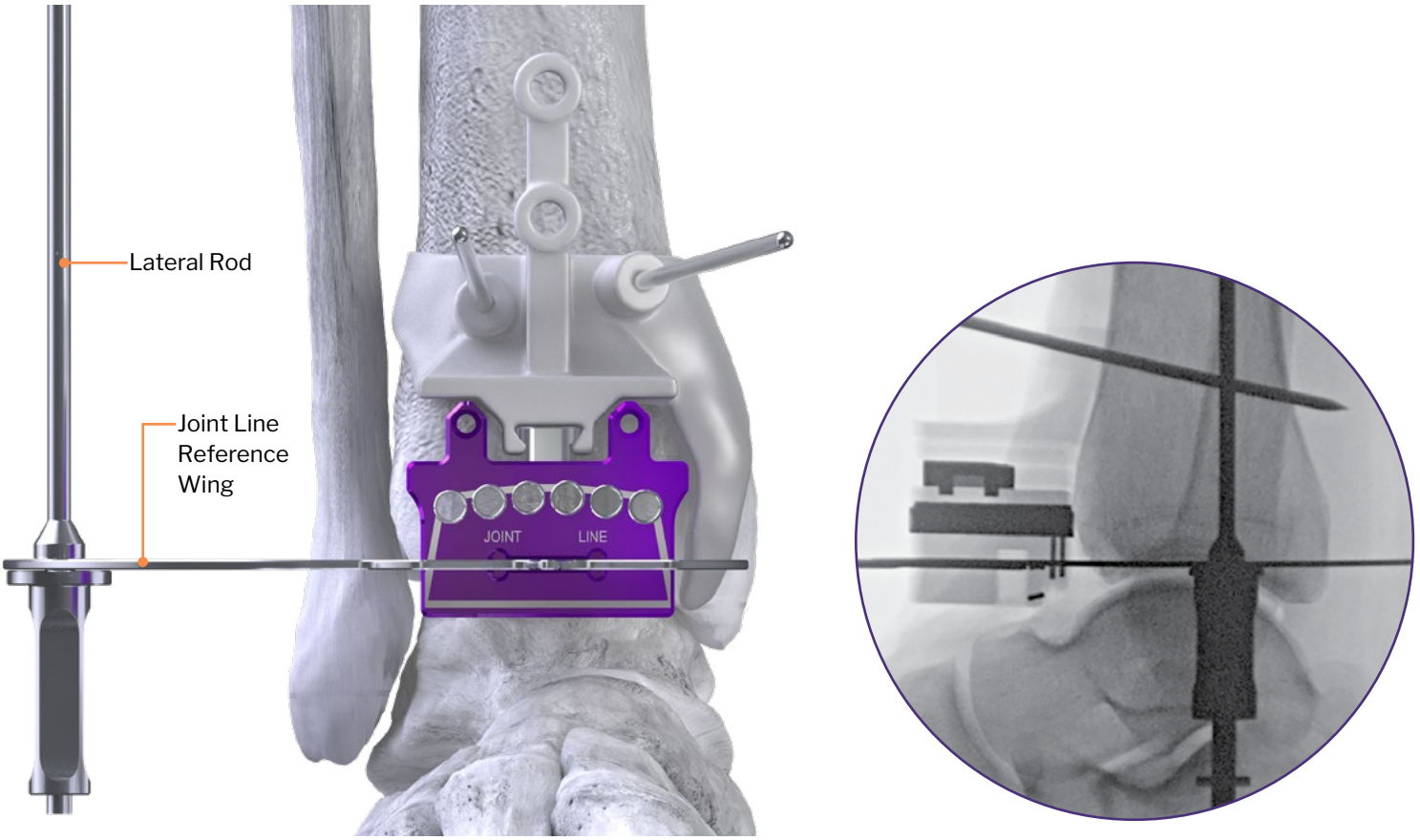
- Place the PSI Guide over the anterior aspect of the distal tibia.
- Apply slight pressure to the medial aspect of the guide in a lateral direction while sliding distally until a snug fit is achieved.
- The distal most portion of the PSI Guide's arm should wrap securely over the anterior aspect of the medial malleolus.
- A secure position has been achieved when no micromotion is present and when no gapping between the Guide and bone are visible.
- Utilize the provided bone model as an additional tactile and visual reference to confirm the PSI Guide is positioned correctly.
- Consult the surgeon-approved Surgical Planning Case Report (SPCR) to verify placement as an additional measure.

GUIDE FIXATION

- By hand, place a Ø2.4 mm x 110 mm Smooth Steinmann Pin through the primary medial converging fixation pin sleeve.
- Connect to power and advance the Pin until the posterior cortex is reached, taking care not to penetrate beyond.
- Place a second Ø2.4 mm x 110 mm Smooth Steinmann Pin into the lateral fixation pin sleeve and repeat the process outlined above to secure guide's position.

SURGICAL NOTE:
The guide's design provides an anatomically contoured fit. If the guide does not fully seat into a secure position, additional periosteum may need to be elevated.

SLOPE CONFIRMATION



SLOPE CONFIRMATION

- Attach the size-matched Sizing Resection Block, as depicted in the surgeon approved SPCR, to the Guide's integrated dovetail connection.
- Insert the Joint Line Reference Wing and Lateral Rod assembly into the anterior "Joint Line" slot of the Sizing Resection Block and utilize the construct to evaluate distal tibial slope under lateral fluoroscopy.
- Confirm zero slope with Lateral Rod by aligning:
  - With tibial canal, or
  - Parallel to the posterior tibial cortex
- Remove Wing/Rod Assembly

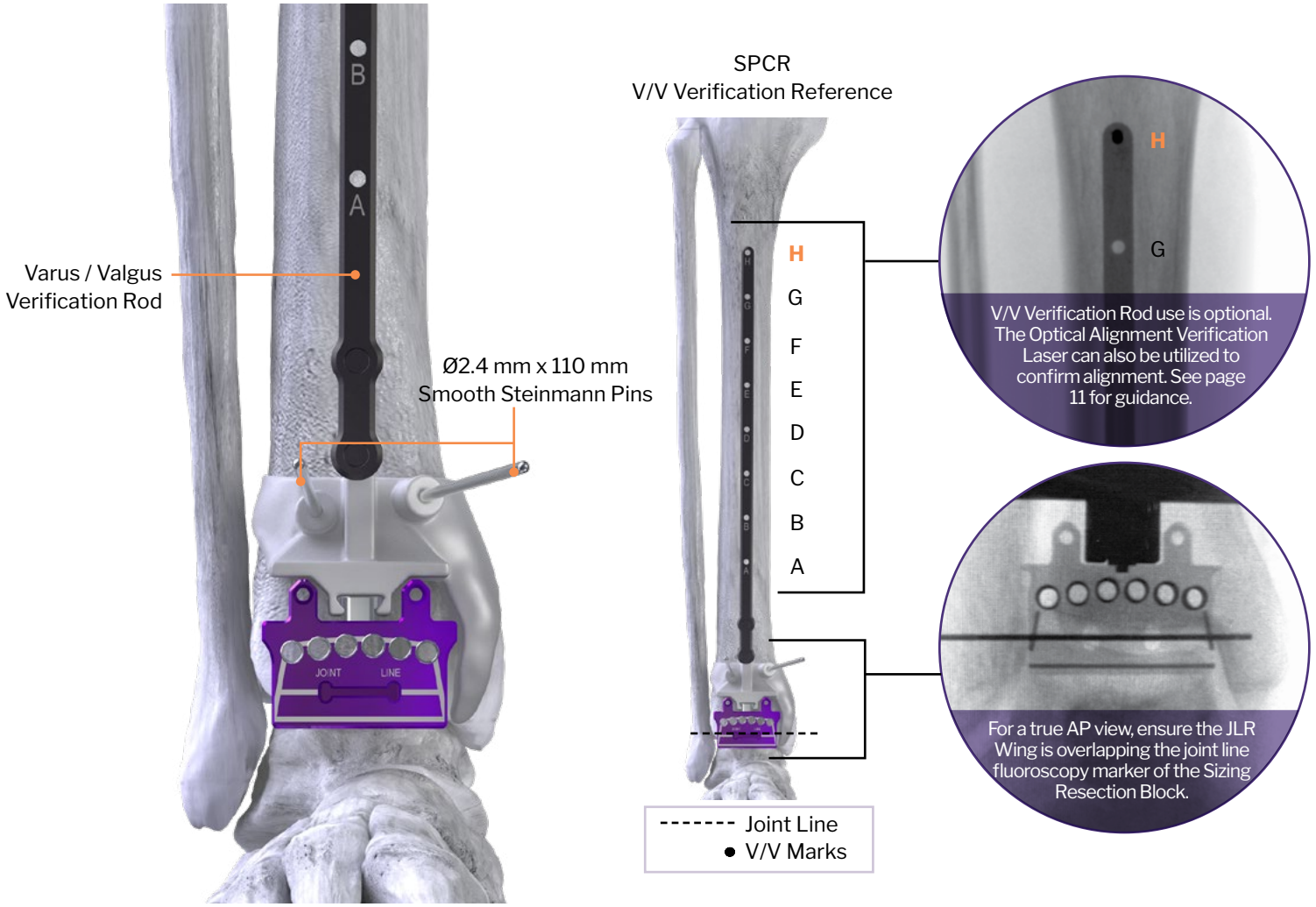
CRITICAL VERIFICATION : If Slope cannot be appropriately established or if the Guide cannot be fully seated into a secure position, additional periosteum may need to be elevated.

SURGICAL NOTE: Zero distal tibial slope (90° to the tibial axis) is the default alignment with this system. It is recommended that the Wing/Rod assembly noted above also be used to evaluate slope.

VARUS / VALGUS CONFIRMATION

OPTION TO CONFIRM "TRUE" ALIGNMENT:

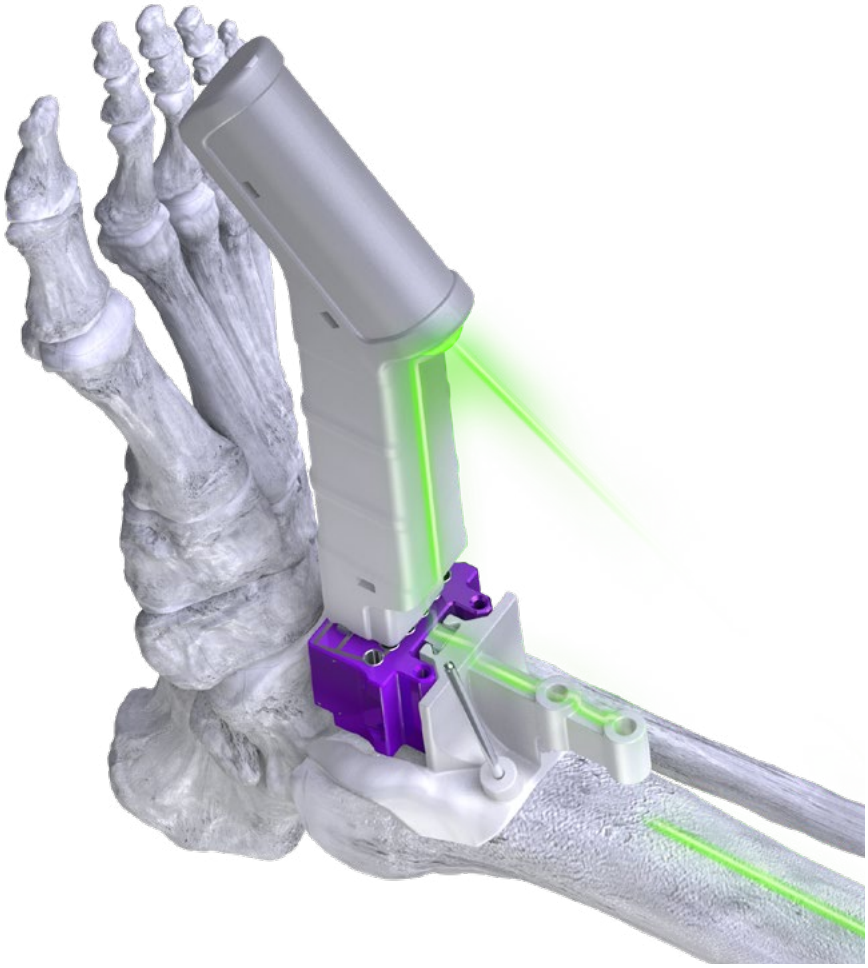
Place a Ø2.4 mm Smooth Pin (blunt end to patient) into the A-H slots based on level of interest. Center C-arm over the Ø2.4 mm Pin until a perfect circle is formed.



VARUS / VALGUS (V/V) CONFIRMATION

- Under an AP fluoroscopic view, utilize the V/V Verification Rod to compare the position of the radiopaque markers against the position referenced in the SPCR.
- Utilizing the Sizing Resection Block and Joint Line Reference Wing construct, confirm V/V position against the surgeon-approved SPCR or intraoperative anatomic landmarks under an AP view as an additional measure.

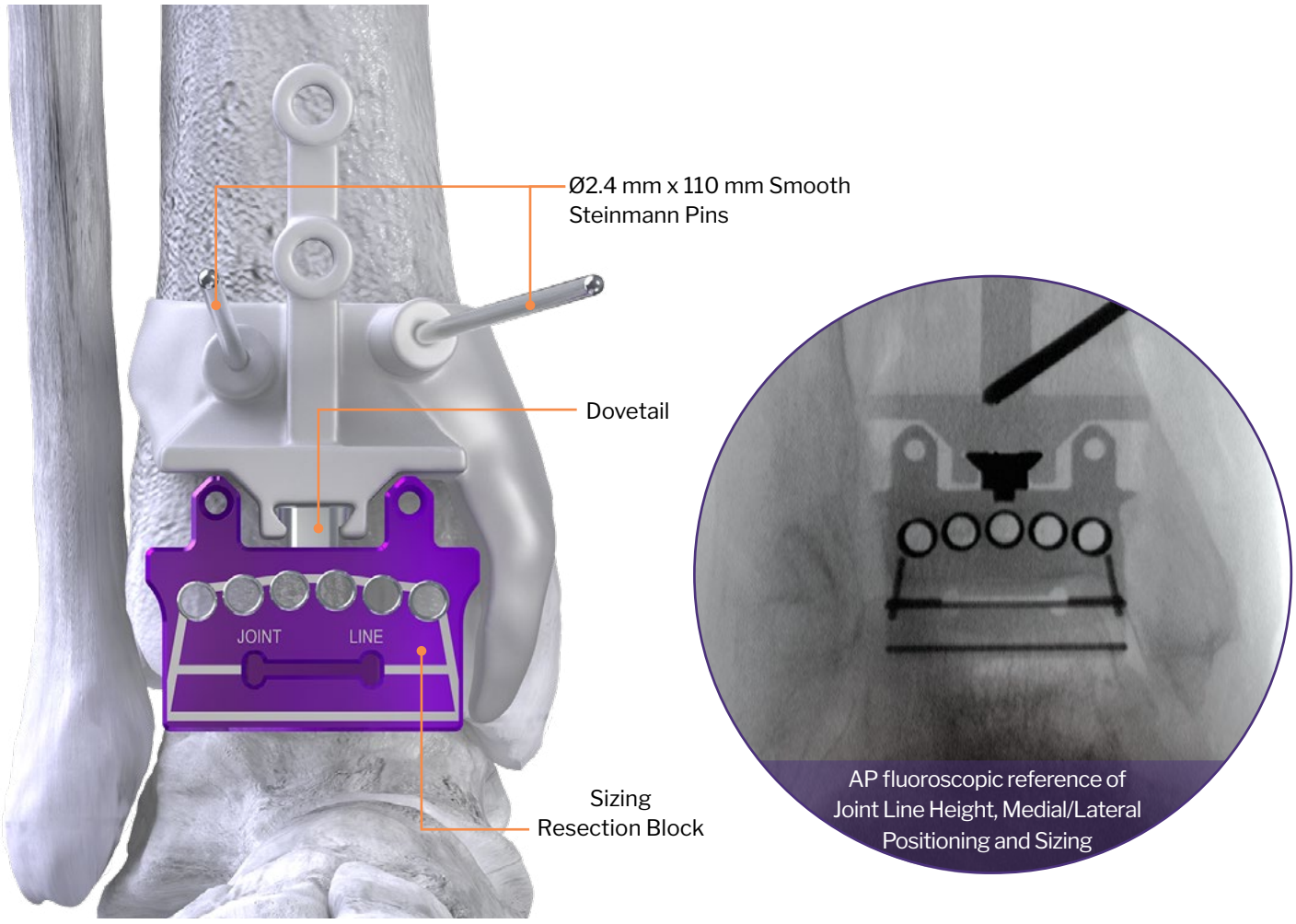
[OPTIONAL] VARUS/VALGUS OPTICAL ALIGNMENT VERIFICATION



VARUS / VALGUS LASER VERIFICATION

- The Optical Alignment Verification Laser can also be utilized to confirm varus/valgus position.
- Insert the Laser's shim into the "Joint Line" slot of the Sizing Resection Block, such that the Laser is facing towards the proximal portion of the operative limb. Confirm the varus/valgus position of the tibia to the MAVEN® surgeon-approved SPCR.
- The Laser features a self-activating switch. When fully inserted into the mating instrument feature, the Laser beam will activate.

FINAL POSITION CONFIRMATION

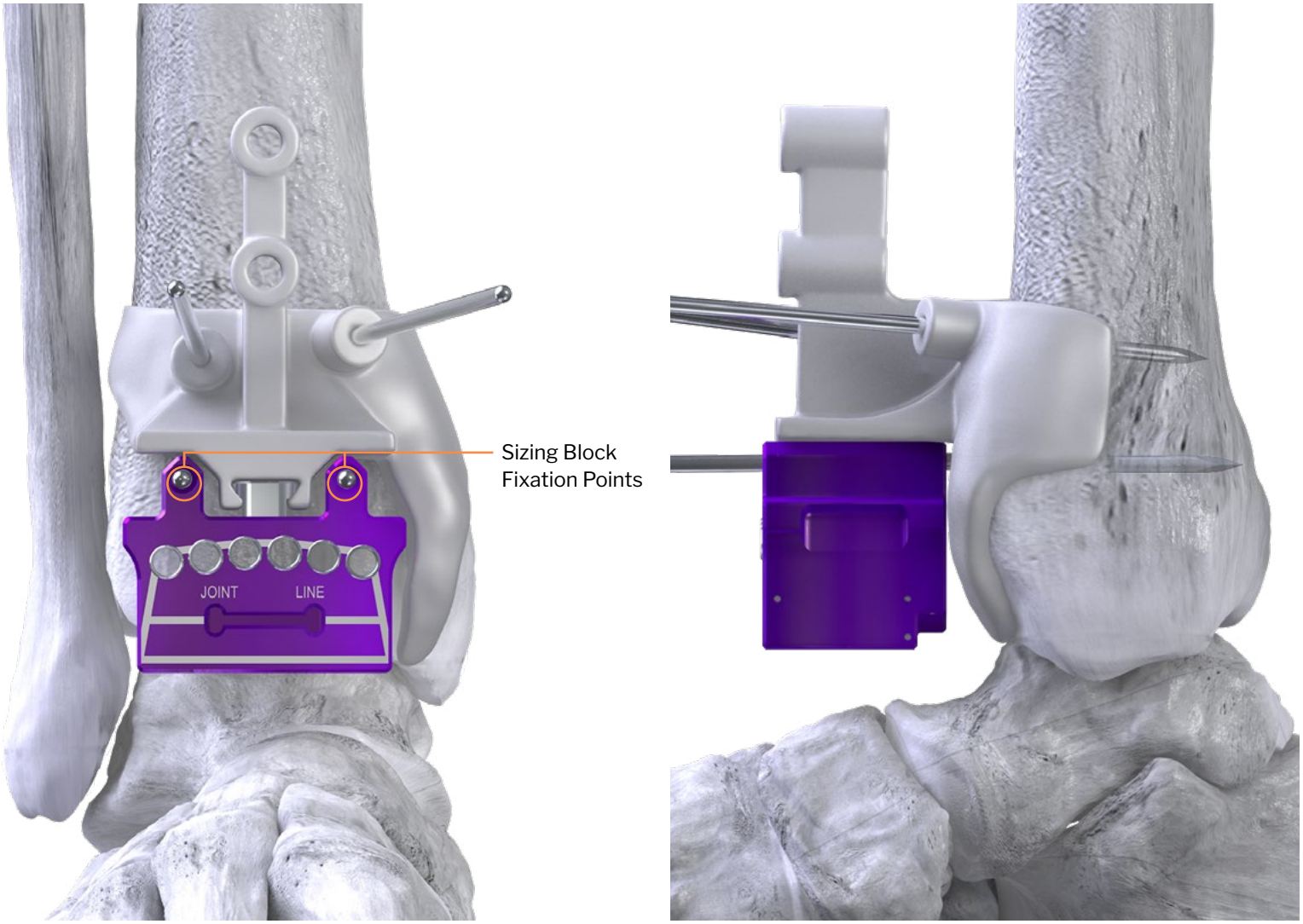


POSITIONING CONFIRMATION JOINT LINE HEIGHT, MEDIAL/LATERAL & SIZING

- With the size-matched Sizing Resection Block attached to the PSI Guide's dovetail connection, under an AP fluoroscopic view and against the surgeon-approved SPCR verify:
  - Joint Line Height
  - Medial / Lateral Positioning
  - Sizing, interchanging Sizing Resection Block options as necessary

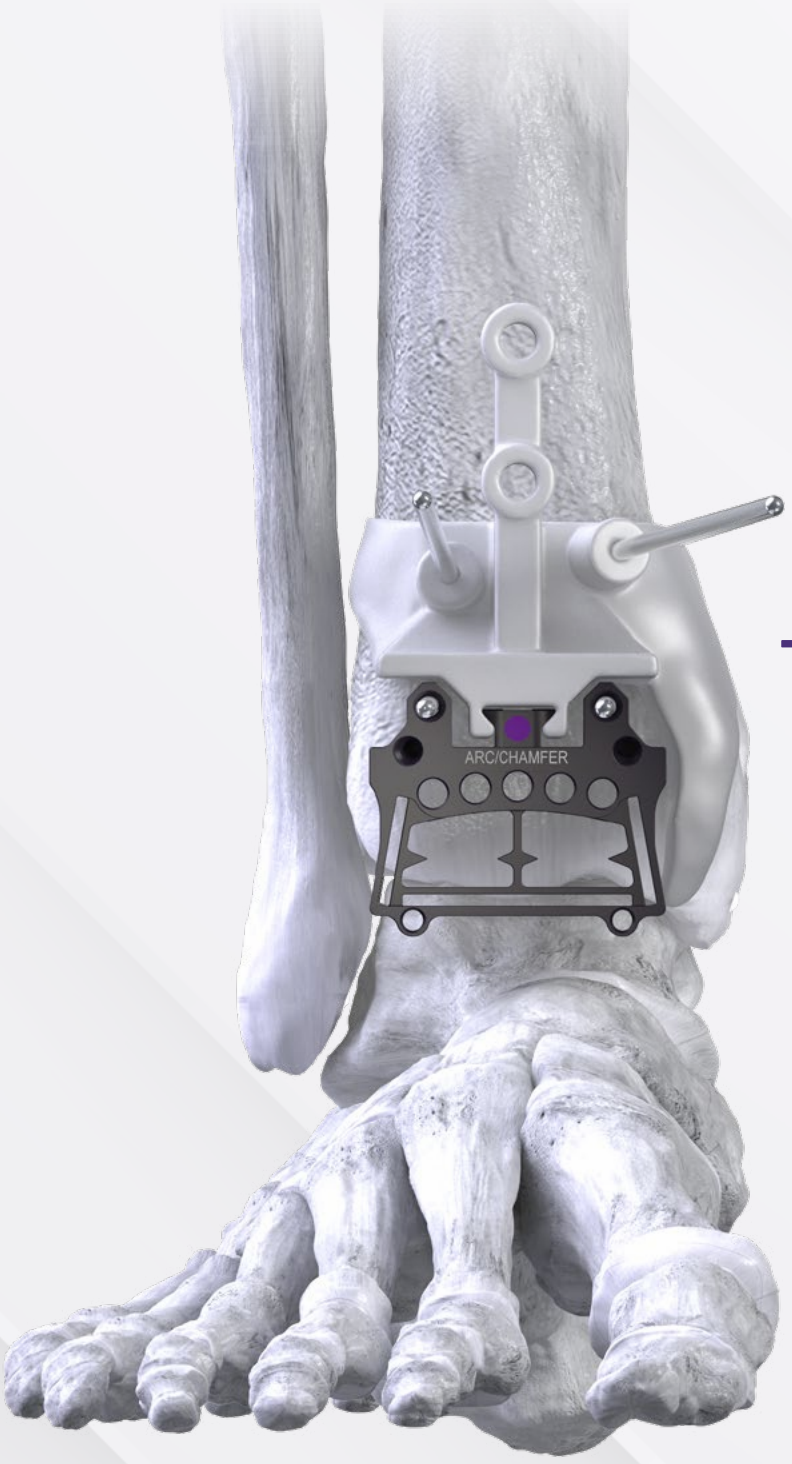
SURGICAL NOTE:
Additional sizing options are provided in the SPCR to ensure the most appropriate size is utilized.

LOCK FINAL POSITION



LOCK IN FINAL POSITION

- By hand, place a Ø2.4 mm x 110 mm Smooth Steinmann Pin into the proximal fixation hole of the Sizing Resection Block.
- Connect to power and advance the Pin until the posterior cortex is reached, taking care not to penetrate beyond.
- Repeat for second Pin to lock in final position.



TIBIAL BONE RESECTION

Reference APEX 3D™ Surgical Technique (P10-STG-0001): Pages 17-21 for ARC Tibia™

Page 52–55 for Flat-Cut Tibia

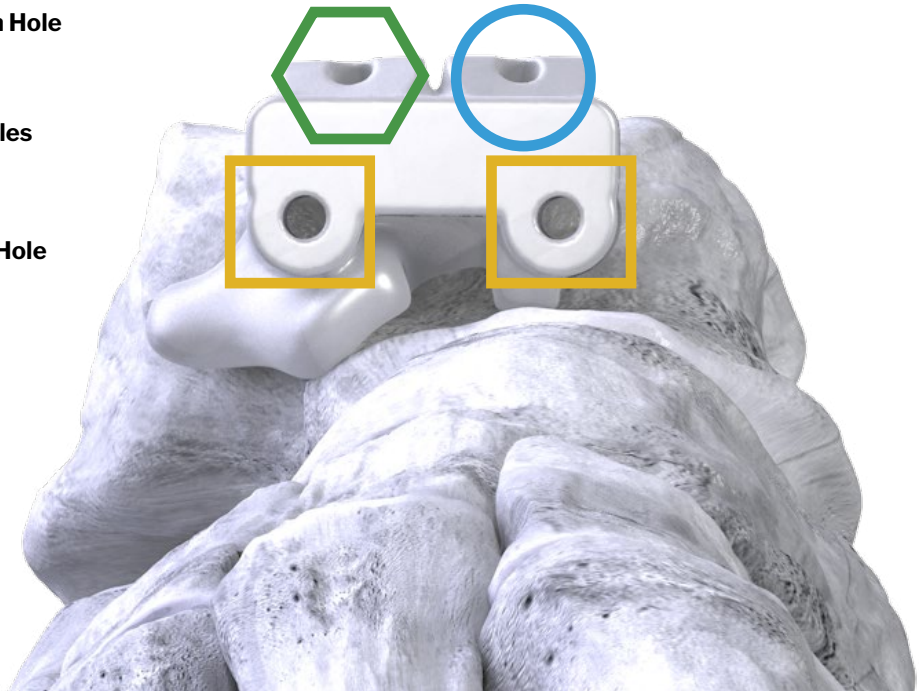
NOTE:
If a decoupled Talar PSI resection, as featured on page 15 of this surgical technique guide, is the selected option, DO NOT complete the initial talar dorsal cut with the coupled resection block featured in the APEX 3D Surgical Technique (P10-STG-0001): Pages 20-21 for Chamfer-Cut Talus Page 56 for Flat-Cut Talus

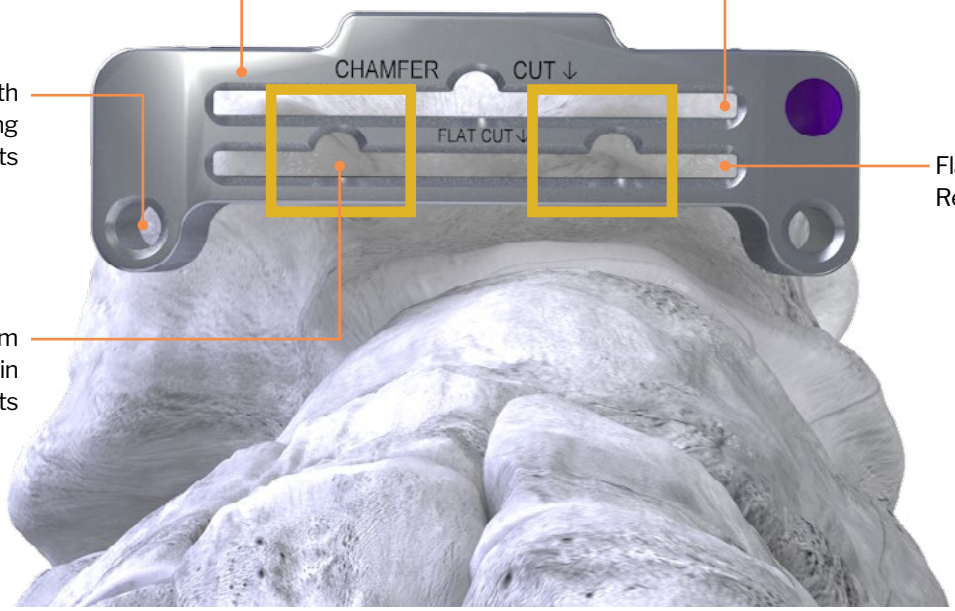
BACK-TABLE OVERVIEW: TALAR PSI GUIDE

Primary Medial Fixation Hole

Parallel Transfer Pin Holes

Repositioning Fixation Hole

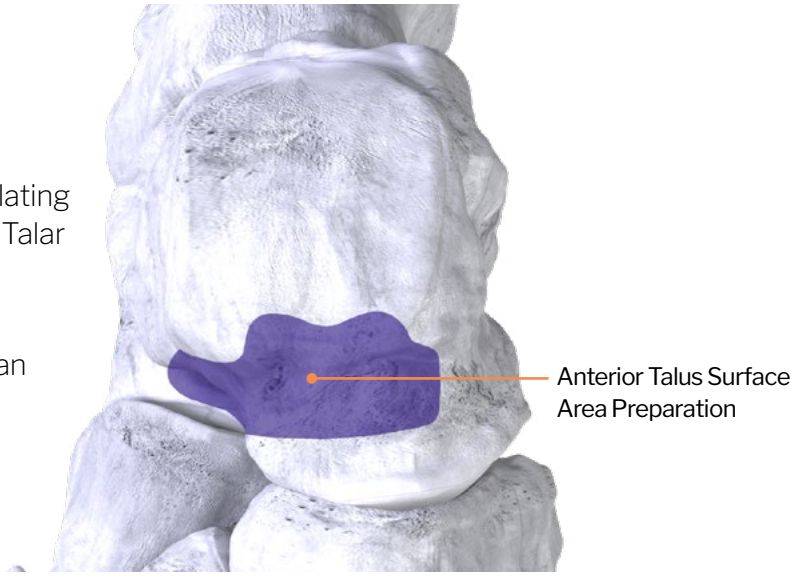




ANTERIOR TALUS PREPARATION

PREPARATION

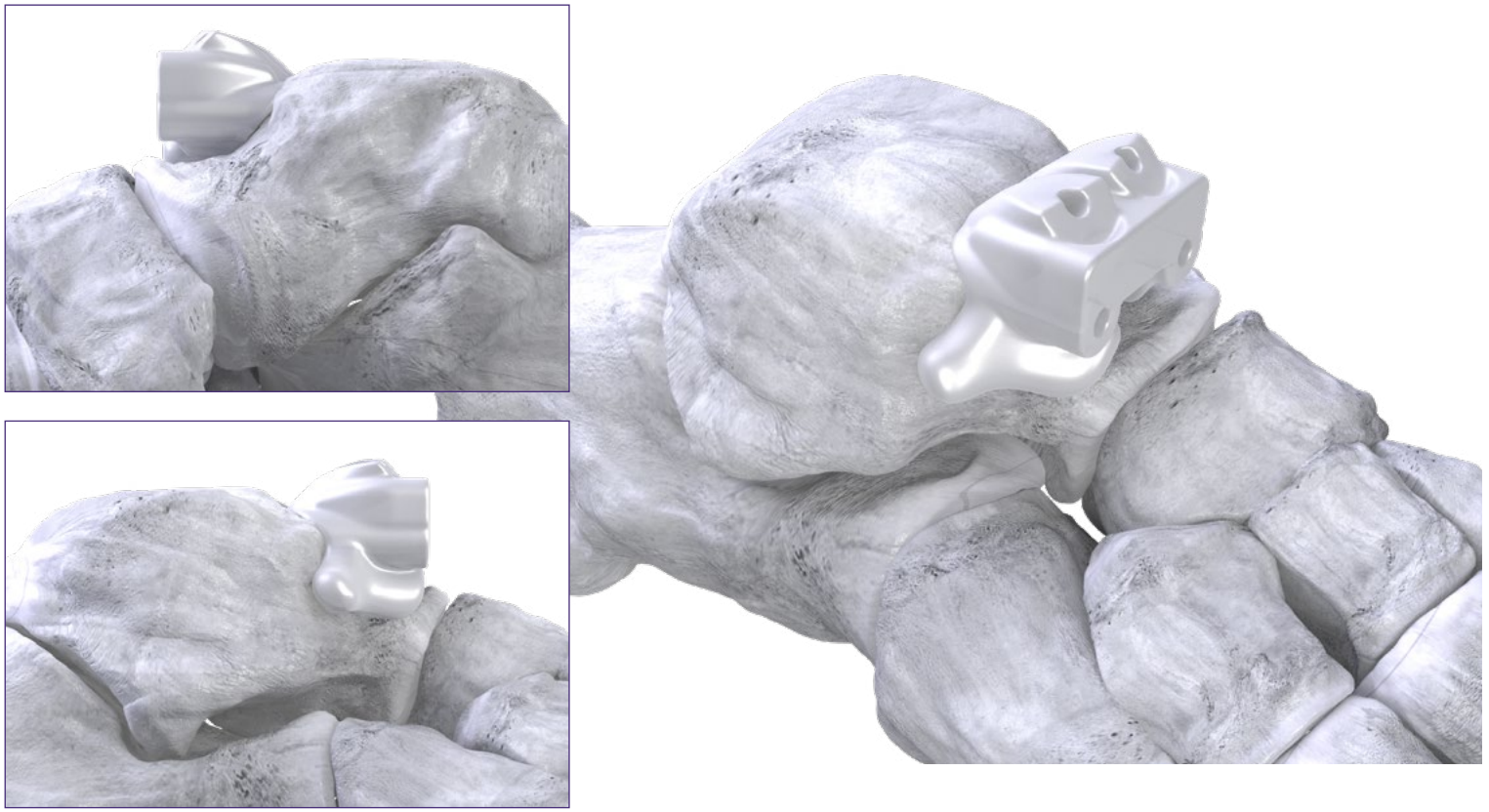
- Remove any residual anterior cartilage from the talar dome and elevate the periosteal capsule around the dorsal talar neck/lateral shoulder and adjacent articulating surface to establish a secure contact surface for the Talar PSI Alignment Guide.
- Additional preparation may be required to achieve a secure fit, such as anterior talar bone resection with an osteotome or saw blade.



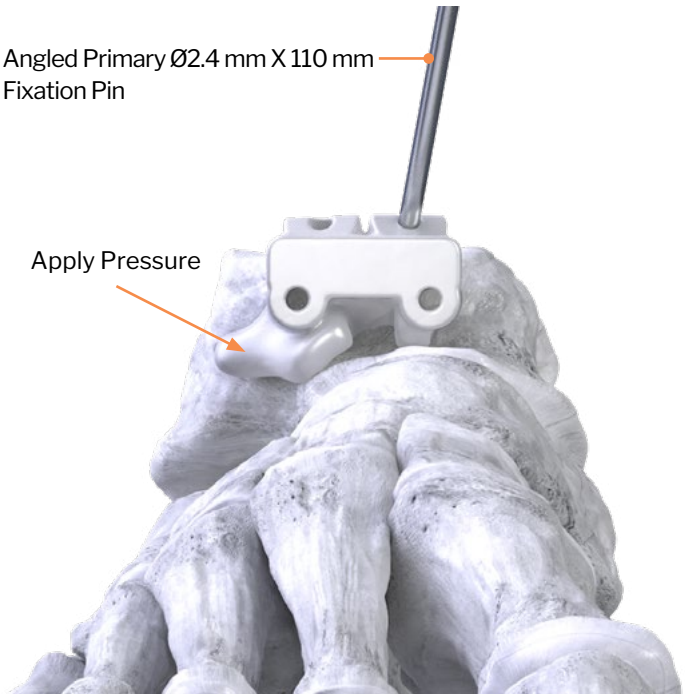
SURGICAL NOTE:
The Talar PSI Alignment Guide is designed to avoid contact with the talar head and the lateral wrap extends more laterally than medially. Residual anterior cartilage and periosteum can be estimated by templating with the provided talus bone model.

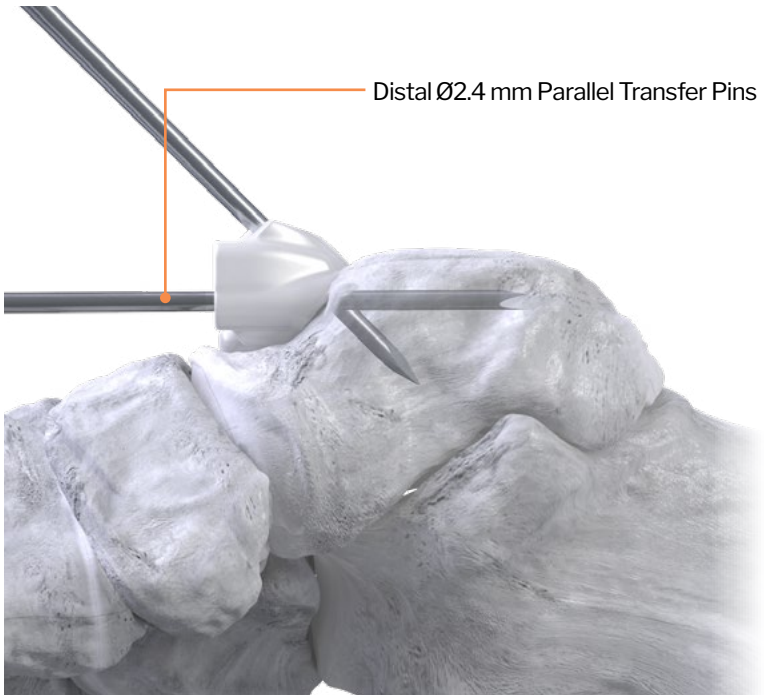
TALAR PSI GUIDE POSITION CONFIRMATION

- Utilize the provided bone model as an additional tactile and visual reference to confirm the PSI Alignment Guide is positioned correctly. Consult the surgeon-approved SPCR to verify placement as an additional measure.



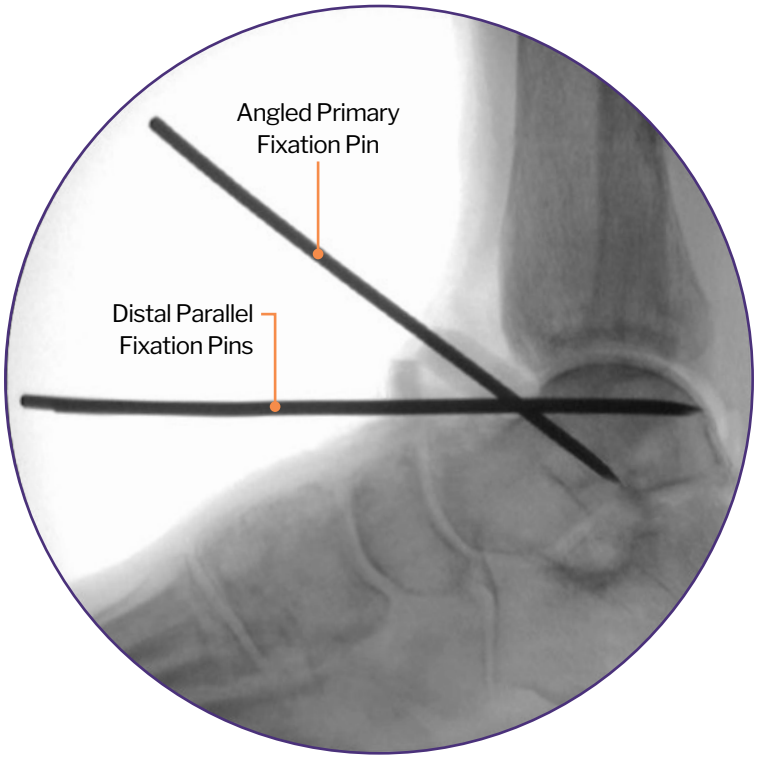
TALAR PSI ALIGNMENT GUIDE FIXATION





TALAR PSI ALIGNMENT GUIDE FIXATION

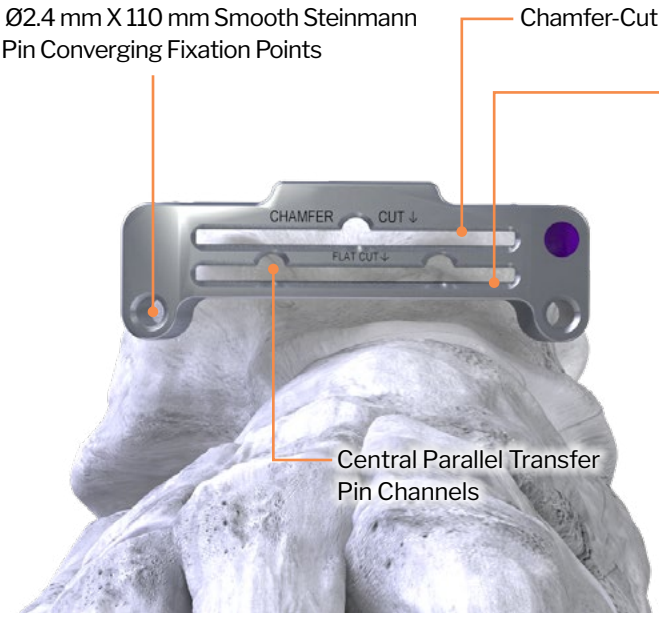
- By hand, place the PSI Alignment Guide on the previously prepared talar surface, aligning with the anatomic curvature of the talar neck.
- To establish proper placement, apply pressure to the lateral corner of the PSI Alignment Guide confirming congruent contact with the talar neck/lateral shoulder.
- By hand, place one (1) provisional Ø2.4 mm x 110 mm Smooth Steinmann Pin into the primary fixation hole, connect to power and advance, taking care to avoid crossing the sub-talar joint.
- By hand, place two (2) Ø2.4 x 110 mm Smooth Steinmann Pins into the two distal parallel pin holes, connect to power and advance, taking care to avoid drilling past the posterior cortex, then visually confirm the PSI Guide's position has not been disrupted.
- Remove the Angled Primary Fixation Pin, then slide the PSI Guide off the Distal Parallel Pins.

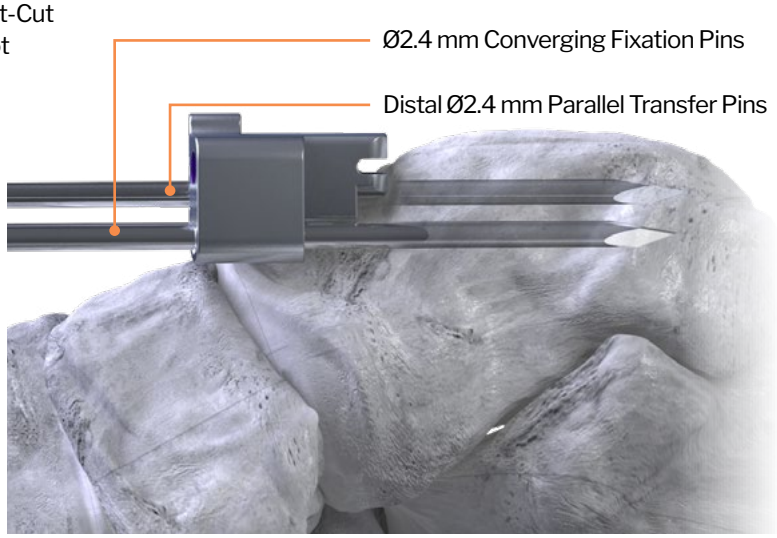


SURGICAL NOTE:
The proximal end of the PSI Guide will rest on the anterior talar articulating surface, while the distal end of the PSI Guide will contour to the talar neck.

SURGICAL NOTE:
The PSI Guide is equipped with a proximal converging primary fixation pin hole and a secondary fixation pin hole if initial repositioning is required.

TALAR BONE PREPARATION

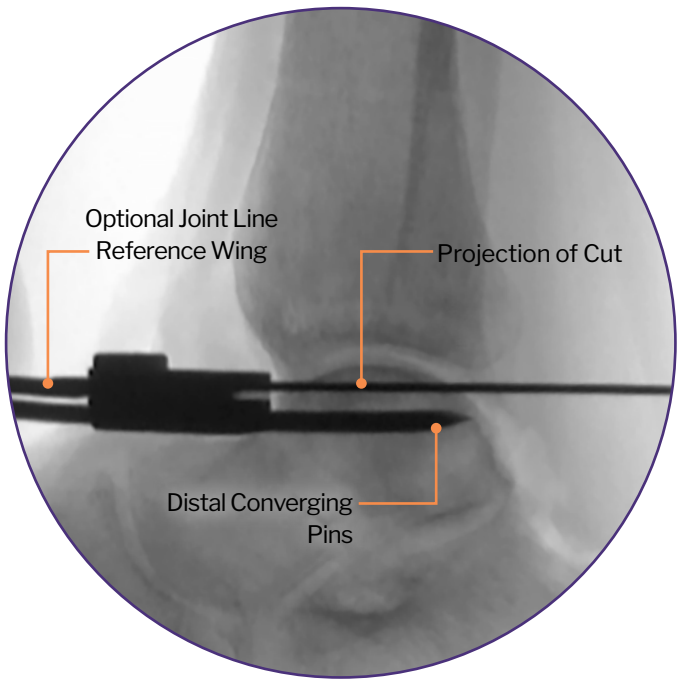




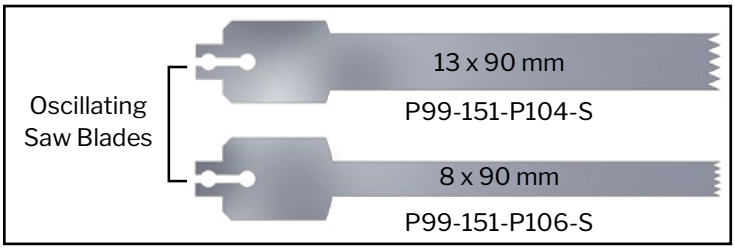
SURGICAL NOTE:
The Decoupled Size Specific Talar Resection Block allows for both initial dorsal Chamfer-Cut or primary Flat-Cut.

TALAR PSI – BONE RESECTION

- Utilizing the Size Specific Talar Resection Block, slide the central parallel pin channels over the two (2) Ø2.4 mm x 110 mm Smooth Parallel Fixation Pins and confirm position under an AP fluoroscopic view.
- Under a lateral fluoroscopic view, a saw blade or provided Joint Line Reference Wing can be utilized to evaluate the bone resection level by inserting either into the "CHAMFER-CUT" or "FLAT-CUT" slots*, then compared against the bone resection level referenced in the surgeon-approved SPCR as an additional measure.
- By hand, place two (2) Ø2.4 mm X 110 mm Steinmann Pins into the medial and lateral converging pin holes of the Resection Block.
- Connect to power and advance into position.
- Remove the two Smooth Parallel Pins.
- Utilize the provided Oscillating Saw Blades to complete the bone resection cuts, then remove the PSI Guide and resected talar bone.

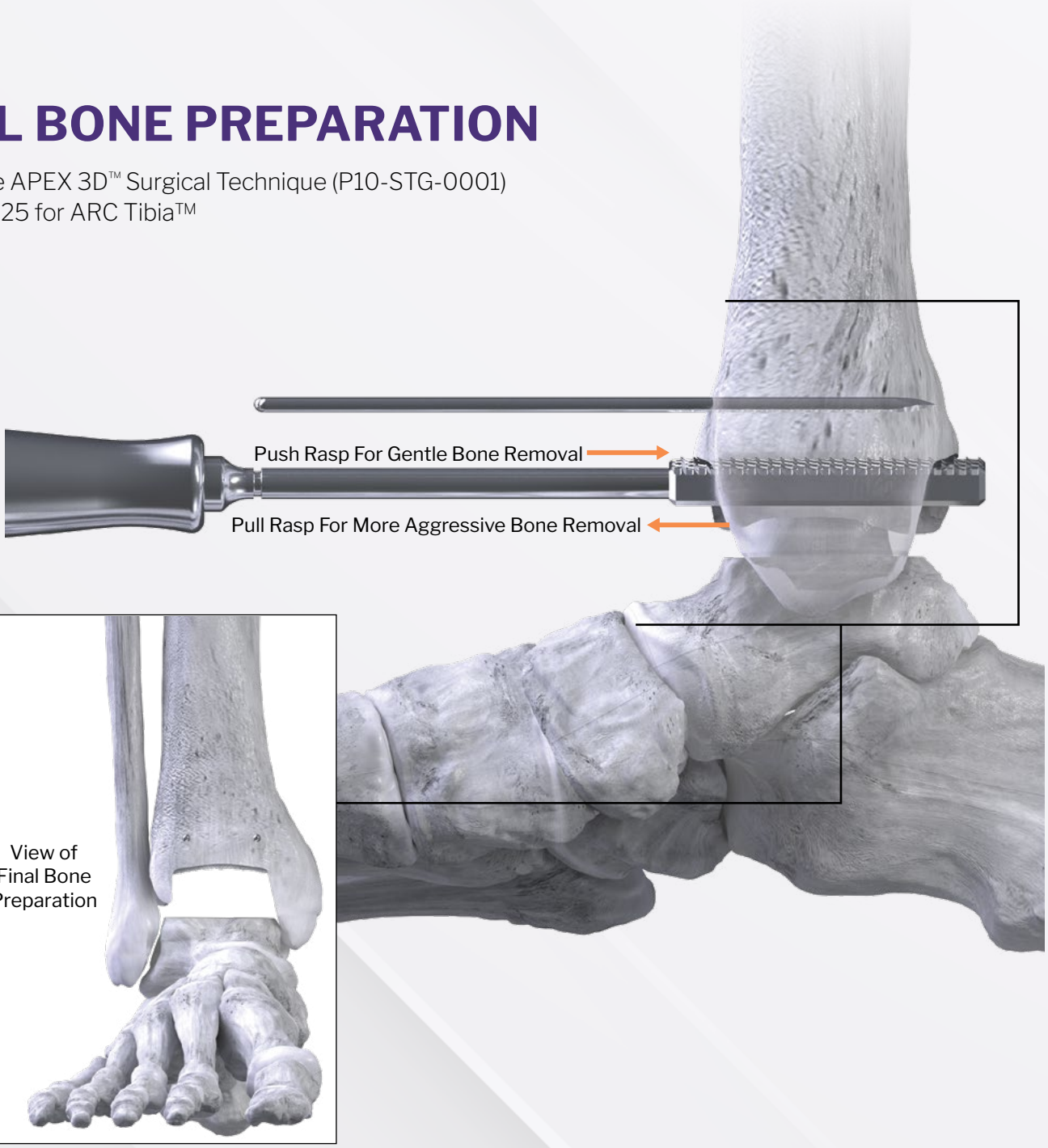


CRITICAL VERIFICATION :
* The two (2) Ø2.4 mm x 110 mm Smooth Parallel Transfer Pins must be removed in order to utilize the "FLAT-CUT" resection cut slot to evaluate the bone resection level.

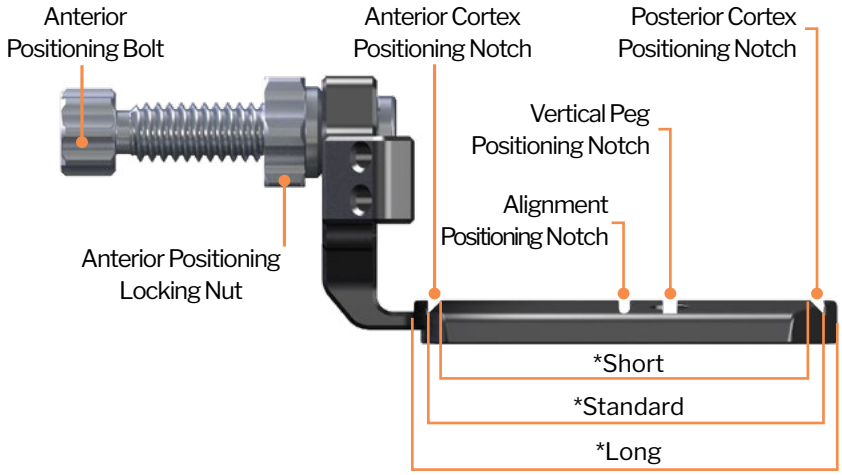


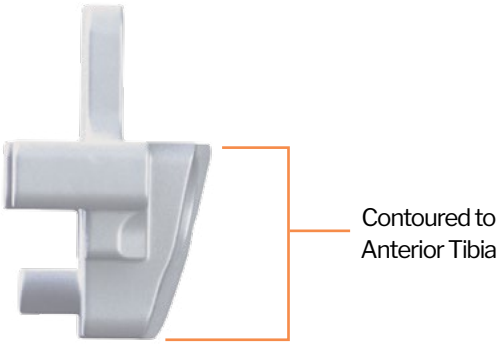
TIBIAL BONE PREPARATION

Reference APEX 3D™ Surgical Technique (P10-STG-0001)
Pages 22-25 for ARC Tibia™



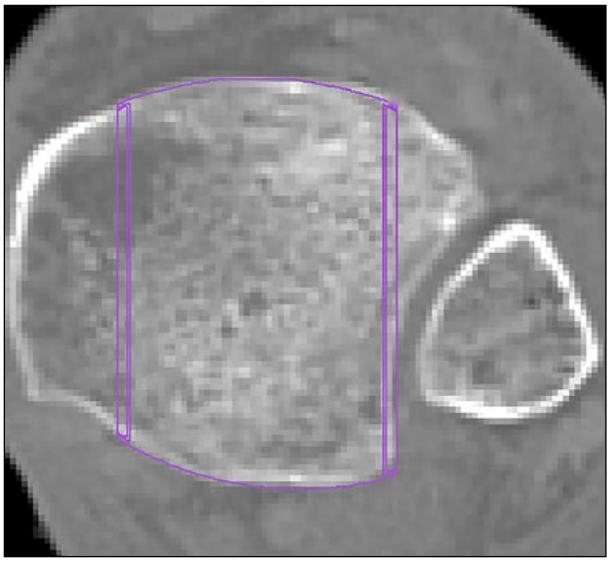
BACK-TABLE OVERVIEW: TIBIAL TRIALING - PSI AP POSITIONING SPACER





POSITIONING GUIDANCE

If the center of the posterior notch is located just beyond the posterior tibia cortex, a standard tibia size should be used. If the notch is located within the tibia, a long tibia size should be used.

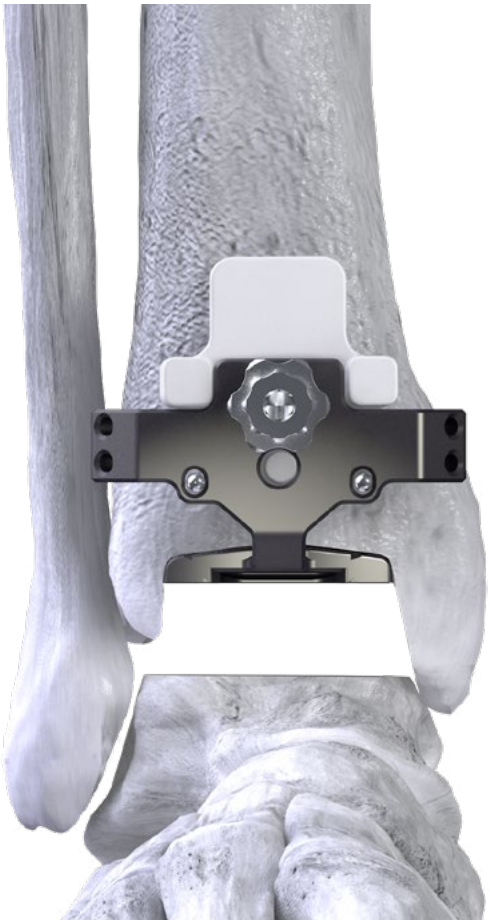


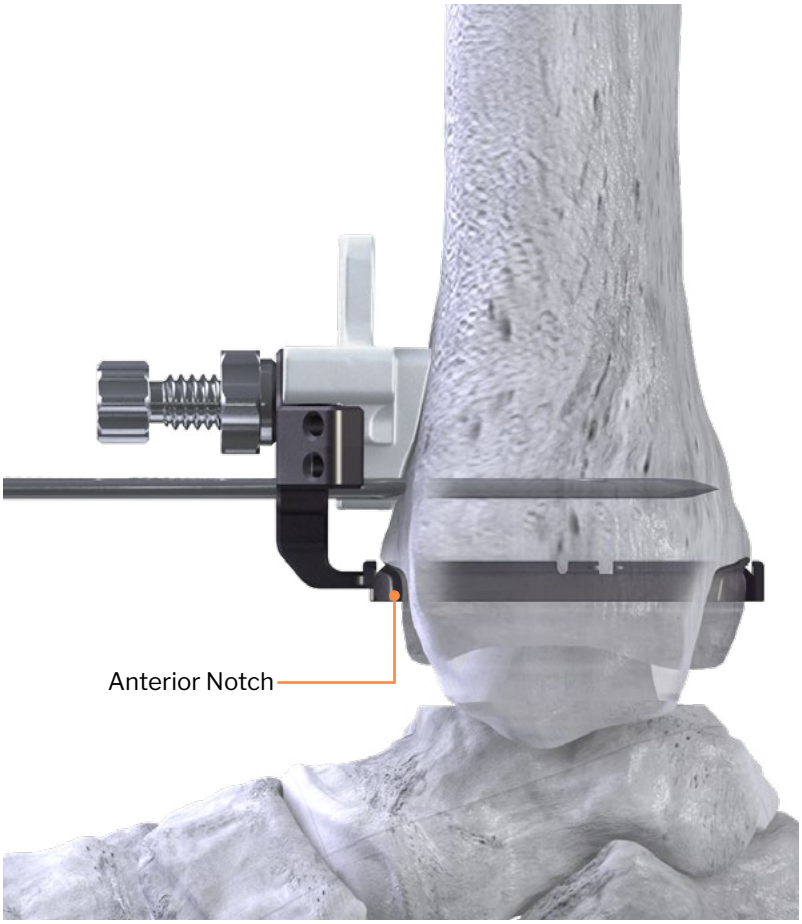
SURGICAL NOTE:

Depiction of APEX 3D™ Tibial Tray Implant placement featured in SPCR.

✓ BICORTICAL DRILLING ✓ ARC TIBIA™ OSTEOTOME ✓ SEQUENTIAL DRILLING ✓ ARC TIBIA™ RASP ✓ NEUTRAL PLANTIGRADE ✓ GAP CHECKER ☐ TRIAL SIZING ✓ BONE RESECTION CUTS ☐ VERTICAL PEG PREP

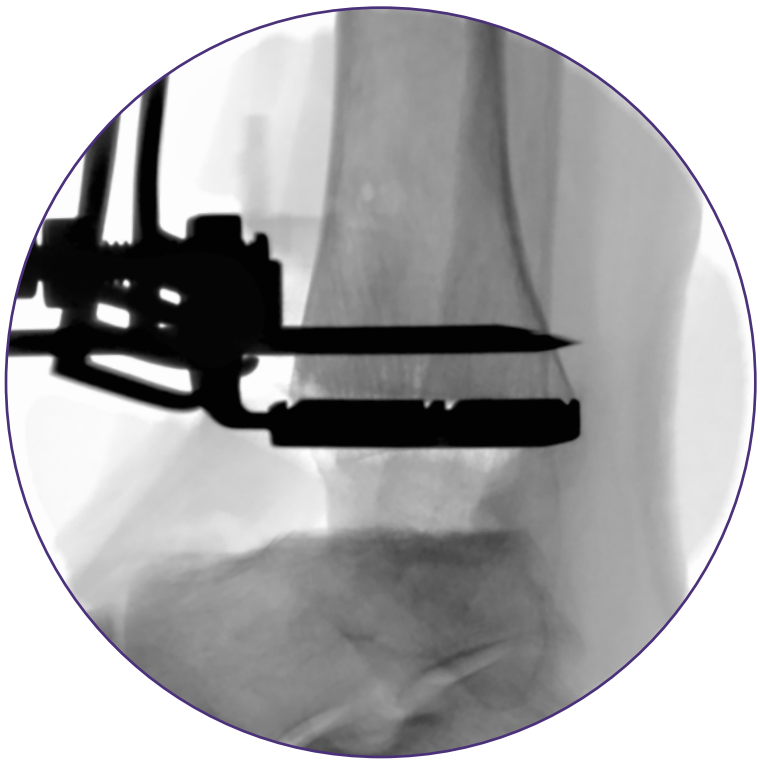
TIBIAL TRIALING - PSI AP POSITIONING SPACER





TIBIAL SIZING & TRIALING – PSI AP POSITIONING SPACER

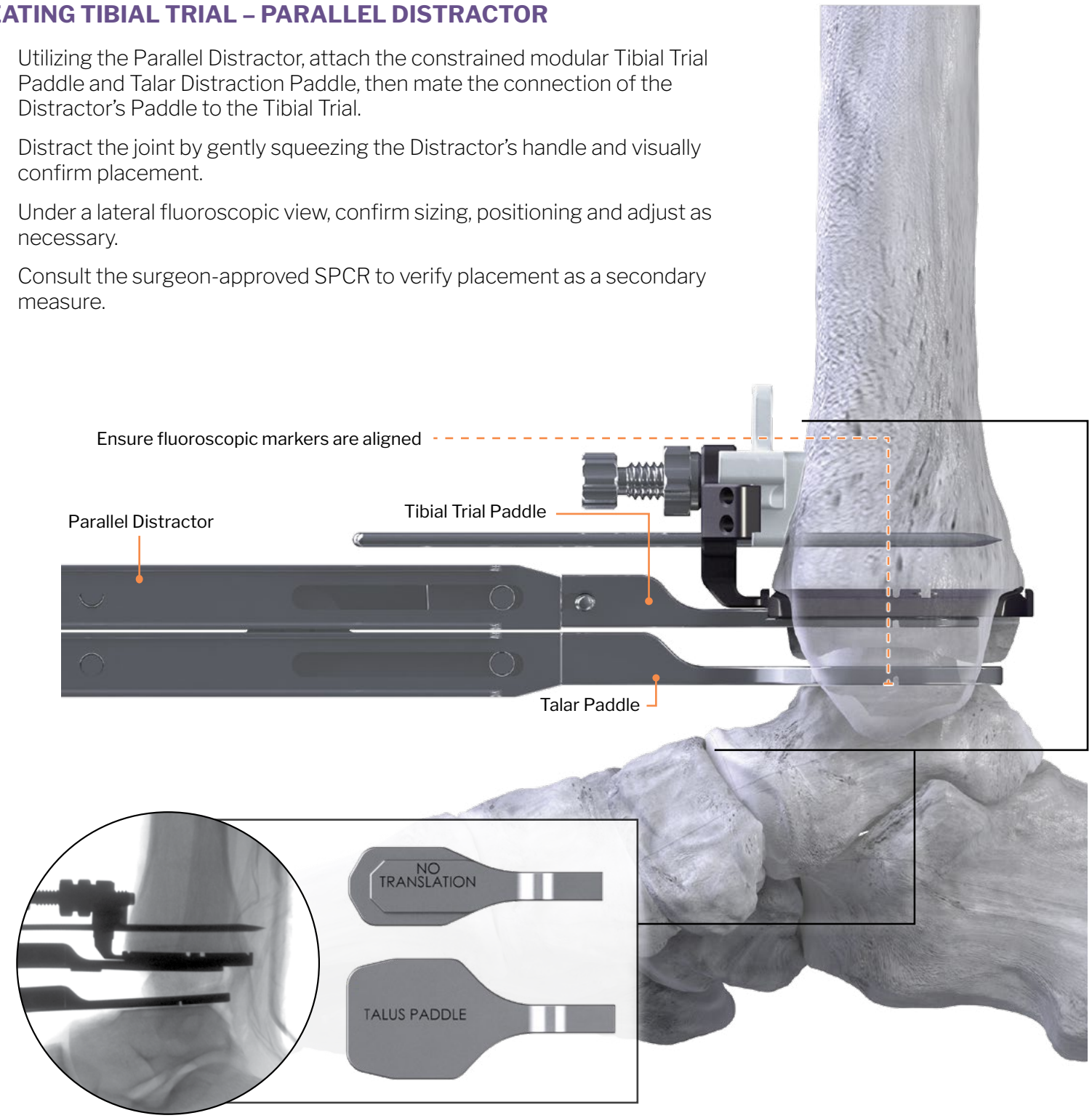
- Attach the PSI AP Positioning Spacer to the size-matched Tibial Trial ensuring the anterior positioning bolt is fully retracted.
- By hand, slide the Tibial Trial & PSI AP Positioning Spacer construct over the two (2) Ø2.4 mm x 110 mm Smooth Steinmann Pins already in place, aligning the posterior aspect of the anatomically contoured AP Spacer against the anterior cortex of the tibia.



TIBIAL TRIALING - PSI AP POSITIONING SPACER

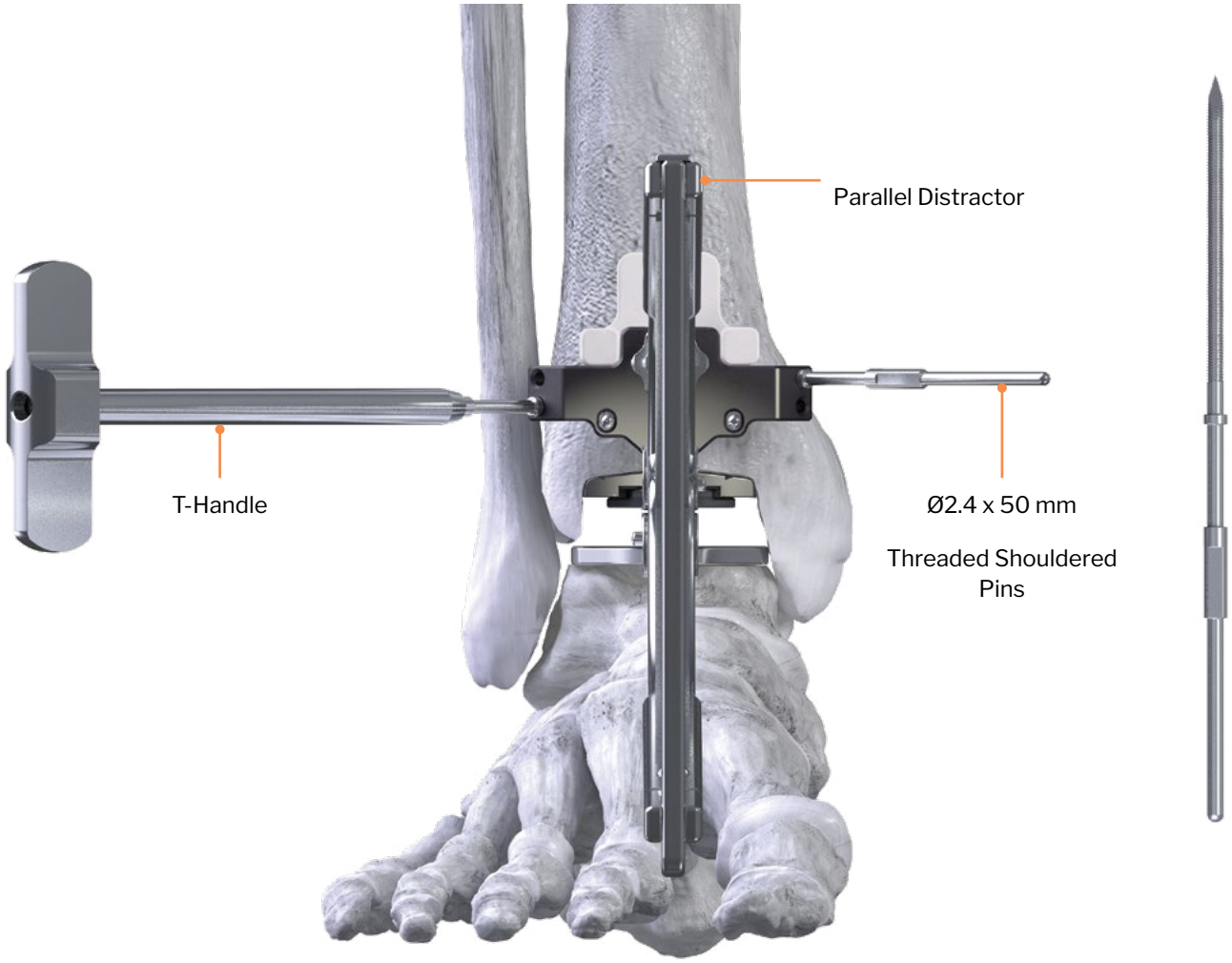
SEATING TIBIAL TRIAL – PARALLEL DISTRACTOR

- Utilizing the Parallel Distractor, attach the constrained modular Tibial Trial Paddle and Talar Distraction Paddle, then mate the connection of the Distractor's Paddle to the Tibial Trial.
- Distract the joint by gently squeezing the Distractor's handle and visually confirm placement.
- Under a lateral fluoroscopic view, confirm sizing, positioning and adjust as necessary.
- Consult the surgeon-approved SPCR to verify placement as a secondary measure.



SURGICAL NOTE:
The PSI Tibial AP Spacer was designed to streamline placement of the Tibial Trial for alignment with the mechanical axis center point. Proper anterior to posterior trial placement is critical during vertical peg preparation.

TIBIAL TRIALING - PSI AP POSITIONING SPACER



SECURE TIBIAL TRIAL

- By hand, place two (2) Ø2.4 mm x 50 mm Threaded Shouldered Pins into a set of the offset converging pin holes located on the medial and lateral aspect of the Tibial Trial.
- Ensure that either both laser marked pin holes are used together, or non-laser marked pin holes are used together.
- Connect to power and advance stopping before the shoulder engages the trial. (DO NOT FULLY SEAT UNDER POWER)
- By hand, secure the pin against trial using the provided T-Handle.
- Remove the Distractor, re-check Tibial Trial position under lateral fluoroscopy to confirm position and fit.

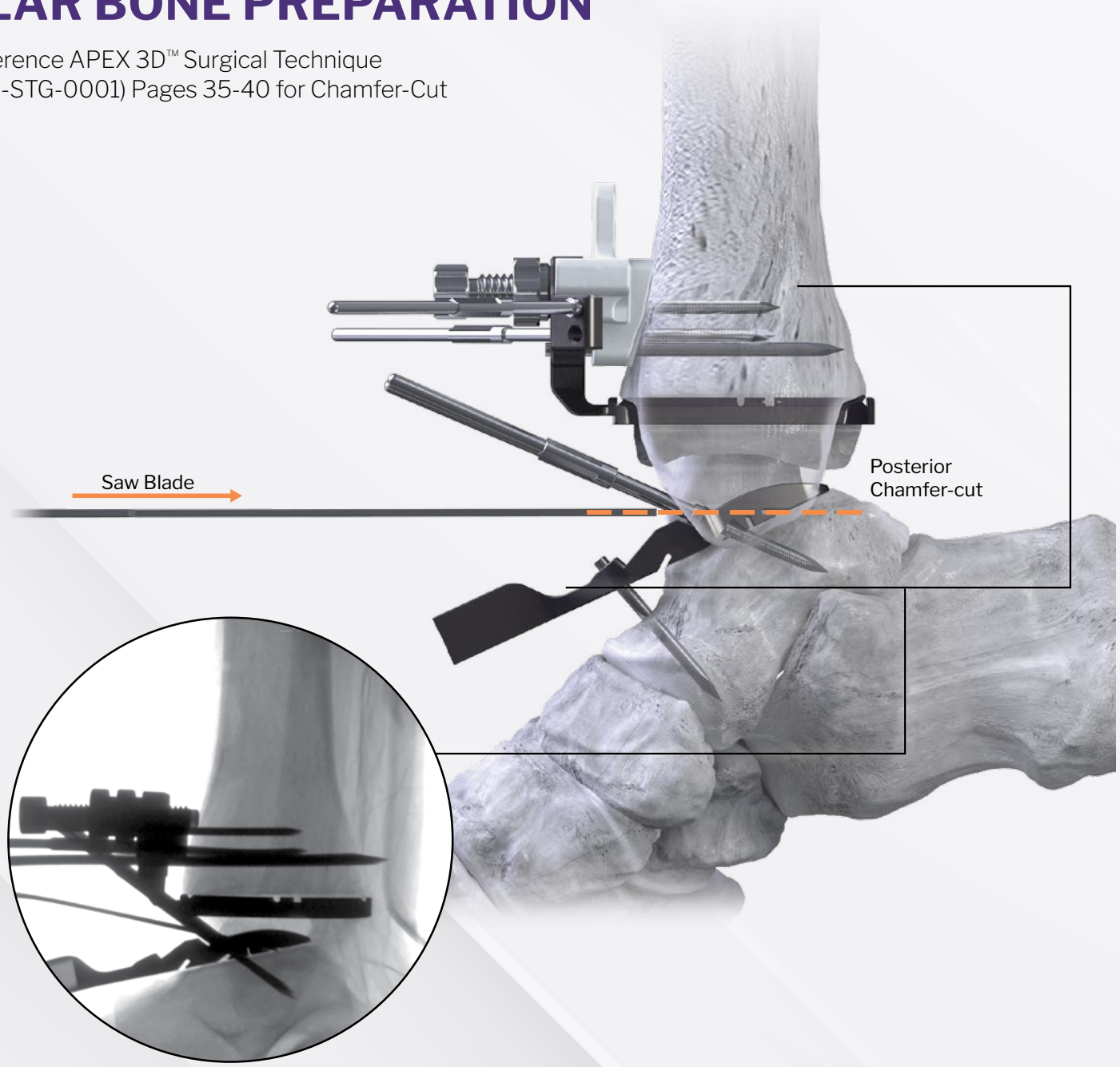
SURGICAL NOTE:
It is recommended to use a long tibial size if uncertain whether the posterior tibial cortex is located within the notch of the trial or not. Full anterior/posterior coverage with minimal overhang is preferred.

TIBIAL VERTICAL PEG PREPARATION

Reference APEX 3D™ Surgical Technique (P10-STG-0001) Pages 30-34 for remaining Tibial Bone Preparation

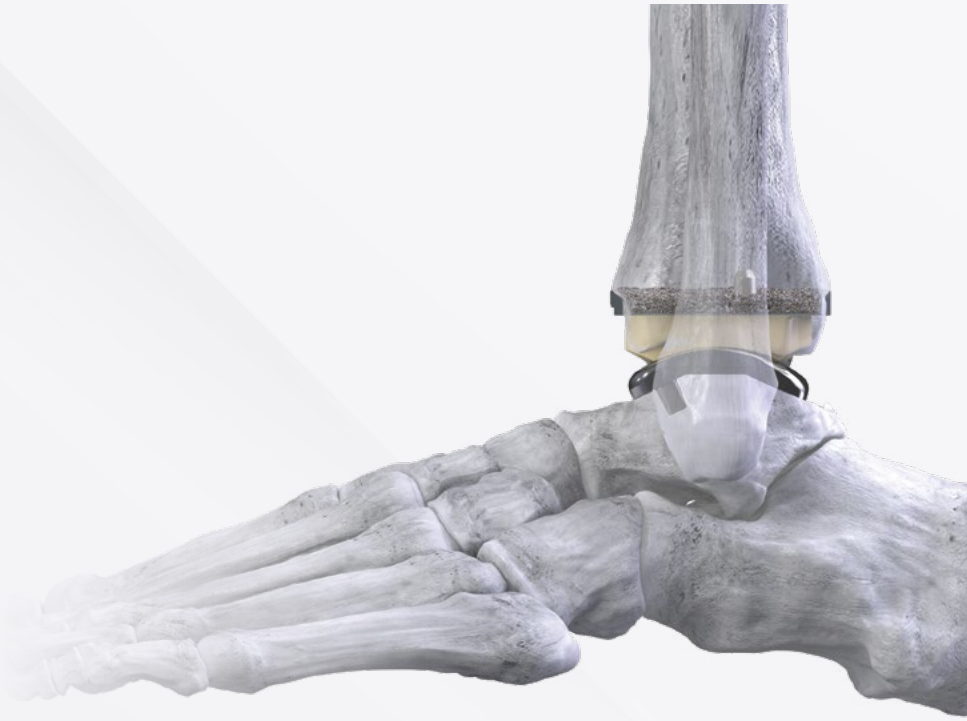
TALAR BONE PREPARATION

Reference APEX 3D™ Surgical Technique
(P10-STG-0001) Pages 35-40 for Chamfer-Cut



TALAR & POLY TRIALING

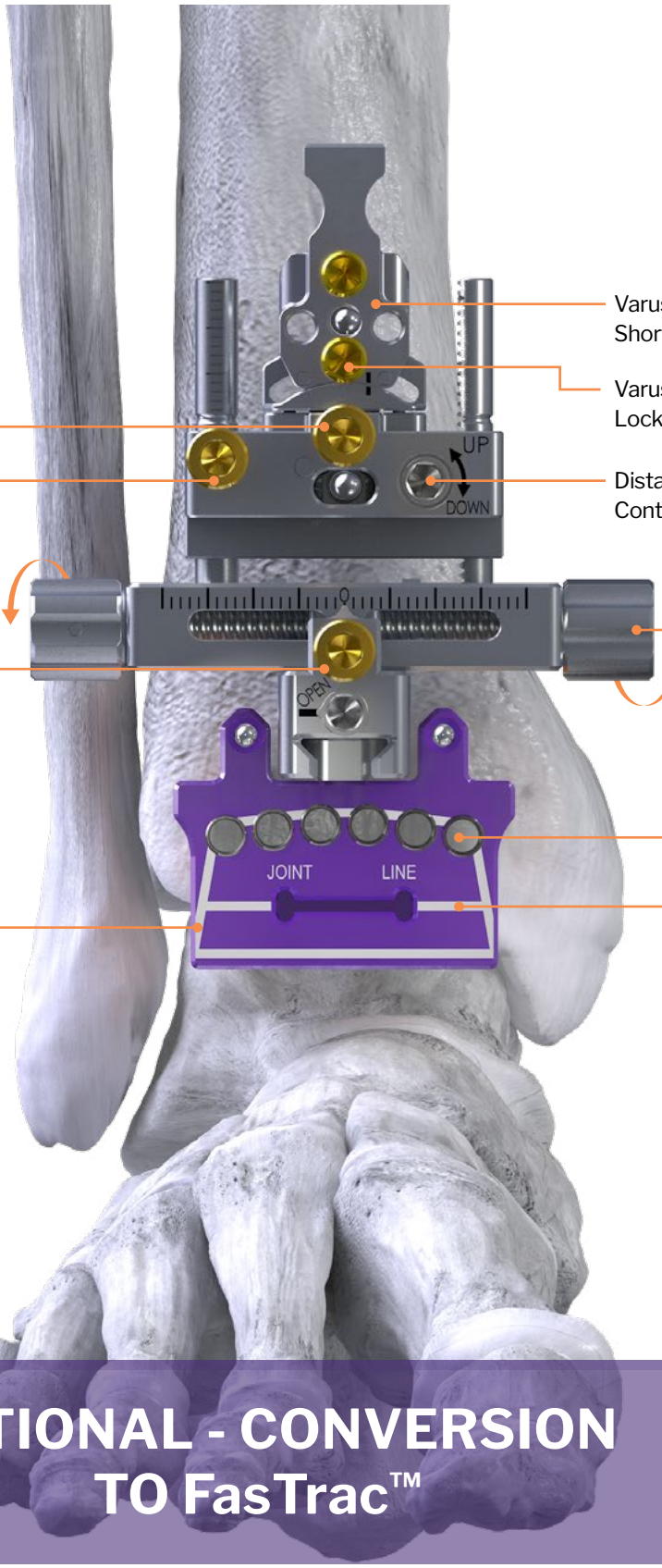
Reference APEX 3D™ Surgical Technique
(P10-STG-0001) Pages 41-47 for Chamfer-Cut
Pages 57-58 for Flat-Cut



FINAL IMPLANTATION

Reference APEX 3D™ Surgical Technique
(P10-STG-0001) Pages 48-51 for:
ARC Tibia™ / Chamfer-Cut Talus & Flat-Cut Tibia / Flat-Cut Talus

BACK-TABLE OVERVIEW: FasTrac™ INSTRUMENTATION OVERVIEW



Varus / Valgus FasTrac™ ShortStack Alignment Jig

Varus / Valgus Position Locking Screw

Internal / External Position Locking Gold Screw

Distal / Proximal Control Screw

Distal / Proximal Position Locking Gold Screw

Medial / Lateral Control Knobs

Medial / Lateral Position Locking Gold Screw

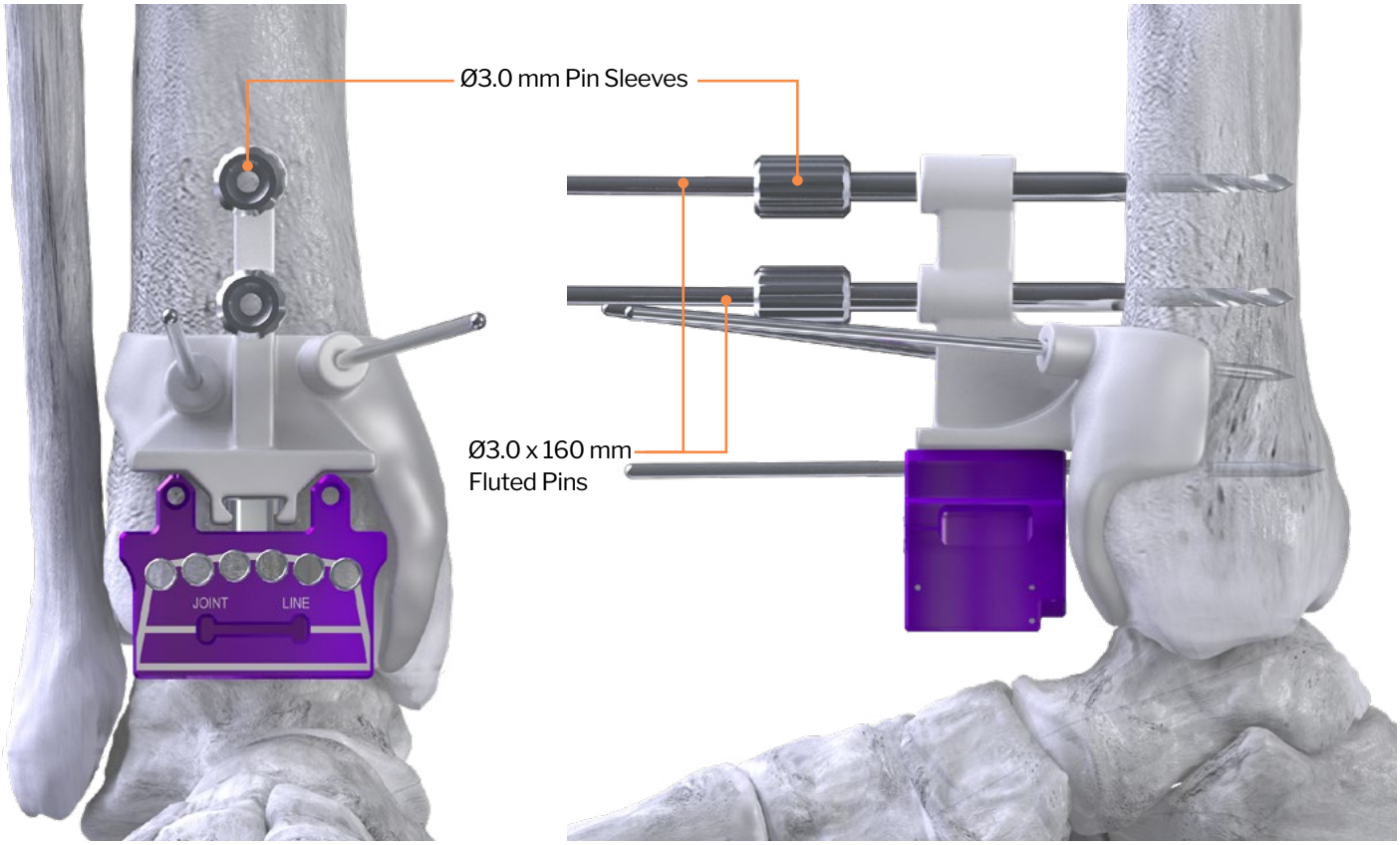
Ø3.5 mm Bicortical Drill Holes

Medial/Lateral Radiopaque Markers

Joint Line Radiopaque Marker

OPTIONAL - CONVERSION TO FasTrac™

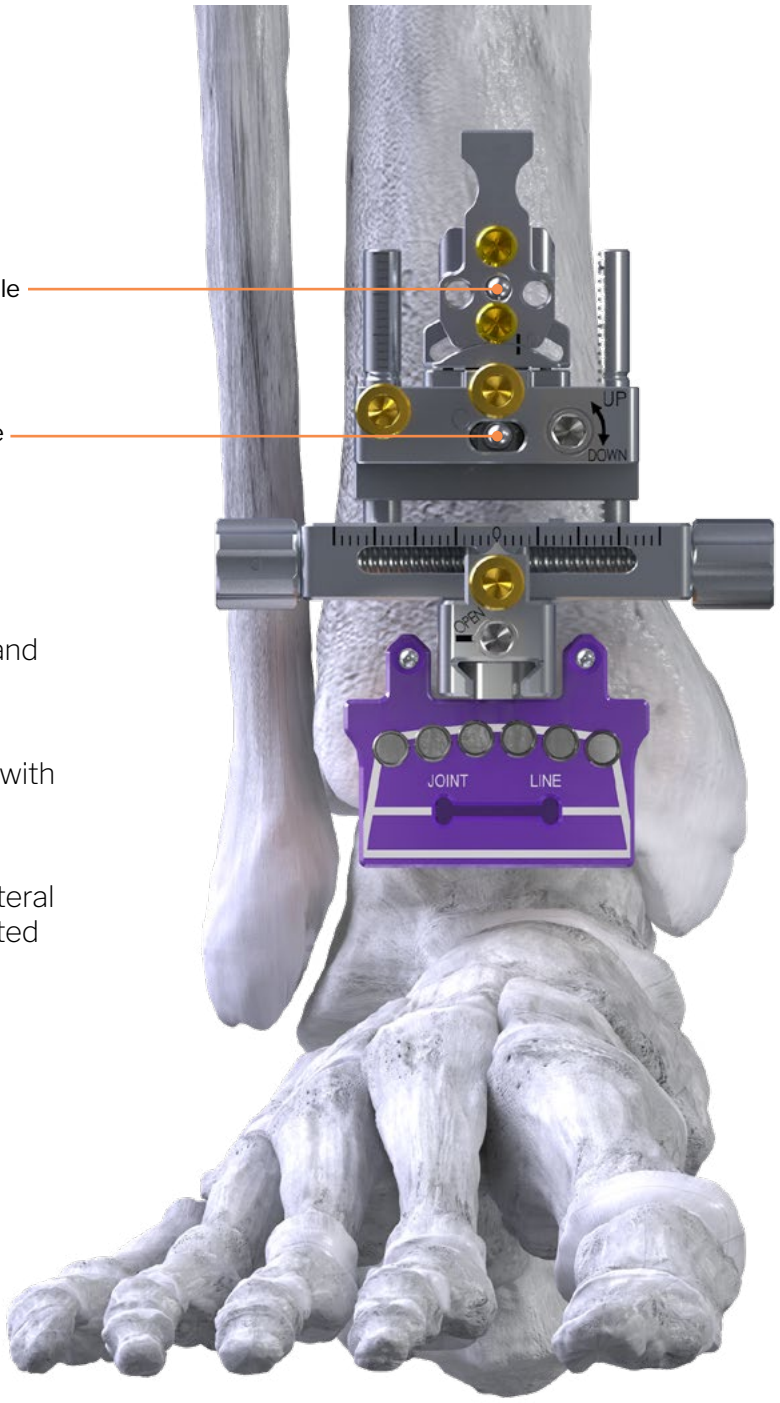
OPTIONAL - CONVERSION TO FasTrac™



CONVERSION TO READJUST

- If alignment is not satisfactory based on intraoperative anatomic considerations, the FasTrac alignment construct will allow for refined positioning and micro adjustments.
- Place two (2) Ø3.0 mm Pin Sleeves into the proximal end of the Tibia PSI Guide.
- Utilizing two (2) Ø3.0 x 160 mm Fluted Pins, by hand, place them into the Pin Sleeves, connect to power and advance until it clears the posterior cortex, but does not penetrate beyond, then repeat the process for the second pin.
- Remove the primary converging fixation pins from Tibial PSI Guide, then remove the Guide and Pin Sleeves.

REFINE ALIGNMENT



REFINE ALIGNMENT

- Align the proximal end of the FasTrac™ construct and central pin hole located on the Distal Control Block with the Fixation Pins.
- Slide the construct into place, ensuring it sits flush with the anterior cortex of the tibia.
- Conduct Internal/External and Varus/Valgus micro adjustments, evaluate Joint Line Height, Medial/Lateral position and confirm Sizing is appropriate as depicted in the FasTrac Surgical Technique Guide.

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

MAVEN® PATIENT-SPECIFIC INSTRUMENTATION INSTRUCTIONS FOR USE

INDICATIONS FOR USE

The MAVEN® Patient-Specific Instrumentation System is intended to be used as patient specific surgical instrumentation to assist in the positioning of total ankle replacement components intraoperatively and in guiding the marking of bone before cutting. The MAVEN® Patient-Specific Instrumentation System is intended for use with the Paragon 28® APEX 3D™ Total Ankle Replacement System and its cleared indications for use, provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging CT scans. The MAVEN® Patient-Specific Instrumentation System is intended for single use only. The MAVEN® Surgical Planning Case Reports are intended for use with the Paragon 28® APEX 3D™ Total Ankle Replacement System and its cleared indications for use, provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging CT scans.

CONTRAINDICATIONS

All applications of the MAVEN® PSI System that are not defined by the indications are contraindicated. In addition, surgical success can be adversely affected by

- Patients with significant changes to anatomy occurring after the medical scan used for product definition was obtained. Surgery should occur no later than one year after the patient scans

WARNING AND PRECAUTIONS

- To avoid potentially serious allergic reactions, ensure that the patient is not allergic to the materials used in the guides prior to use.
- To avoid serious injury, patient identification on guides and reports must be verified and confirmed against patient identification prior to use.
- Device(s) are single use only and designed for use with a specific patient only. All unused devices must be destroyed upon the conclusion of the case for which the devices were designed.
- Guides are designed for a specific patient. To avoid the potential for serious injury, guides should not be modified in any way.
- Do not attempt a surgical procedure with faulty, damaged or suspect instruments or case reports. Inspect all components preoperatively to assure utility. Inspect holes to ensure no debris is present.
- MAVEN® PSI guides are shipped in a non-sterilized state. To avoid possibility of infection, open, clean and sterilize per provided instructions before use.
- These instruments are created based on patient-specific data which may be subject to change at varying rates depending on the patient condition. It is up to the medical provider to determine if the patient's condition or anatomy may have changed sufficiently to require redesign of the device.
- The surgeon is held liable for complications associated with incorrect indication or surgical technique or incorrect patient information and consequent incorrect patient behavior.
- Do not to drop or contaminate the device during surgery.
- Improper placement, positioning, and fixation of the instruments may result in unusual stress conditions and a subsequent reduction in service life of the total ankle replacement components.
- **Do not use other manufacturer's instruments or implants in conjunction with the MAVEN® PSI System**

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

APEX 3D™ TOTAL ANKLE REPLACEMENT SYSTEM INSTRUCTIONS FOR USE

INDICATIONS FOR USE

The APEX 3D™ Total Ankle Replacement System is indicated as a total ankle replacement in primary surgery for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis. Revision surgery for these patients is also indicated for patients with sufficient bone stock present. In the United States, components are intended for cemented use only.

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 fixation or complications in post-operative treatment (e.g. dementia, senility, alcoholism)
- Corpulence; an overweight or corpulent patient 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 of 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 exist. 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
- 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

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

APEX 3D™ TOTAL ANKLE REPLACEMENT SYSTEM INSTRUCTIONS 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 or 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 cement, metal, UHMWPE, and ceramic. Regarding the etiology, it has been hypothesized that 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, 2, PE2) which encourage osteoclastic bone resorption. Clinical and basic research is continuing in order to provide scientific basis 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 component(s).

MR SAFETY INFORMATION

The APEX 3D™ Total Ankle Replacement System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the APEX 3D™ Total Ankle Replacement System in the MR environment is unknown. MR scanning of a patient who has this device may result in patient injury.

NOTES:

MAVEN

PATIENT SPECIFIC SURGERY

APEX 3D™

TOTAL ANKLE REPLACEMENT

Powered by MAVEN® Technology

P10-STG-0002 RevE [2023-06-15]

Paragon 28, Inc.
14445 Grasslands Dr.
Englewood, CO 80112
(855) 786-2828

References:
1. Insall JN, Binazzi R, Soudry M, Mestriner LA. Total knee arthroplasty. Clin Orthop Relat Res. 1985;(192):13 22

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www.Paragon28.com

DISCLAIMER

The purpose of the MAVEN® Patient-Specific Instrumentation (PSI) Surgical Technique Guide is to demonstrate the use of the MAVEN® Patient Specific Instrument Guides designed for the APEX 3D™ 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.