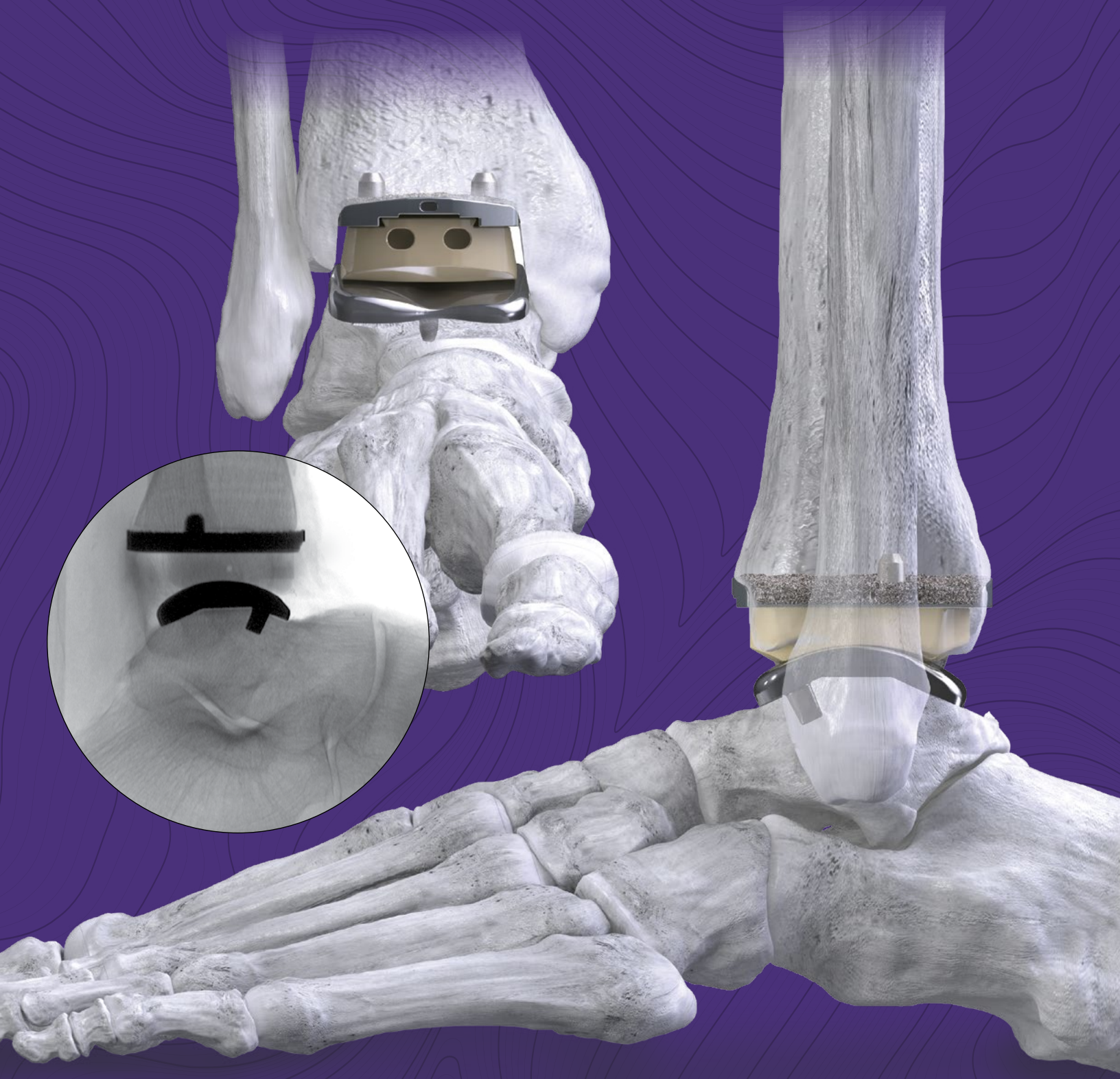
APEX 3D™
TOTAL ANKLE REPLACEMENT



SURGICAL TECHNIQUE GUIDE

Exclusively foot & ankle
Paragon 28®

PRODUCT INFORMATION

The Paragon 28® APEX 3D™ Total Ankle Replacement System is a fixed bearing device comprised of a tibial component, 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.

CONTENTS

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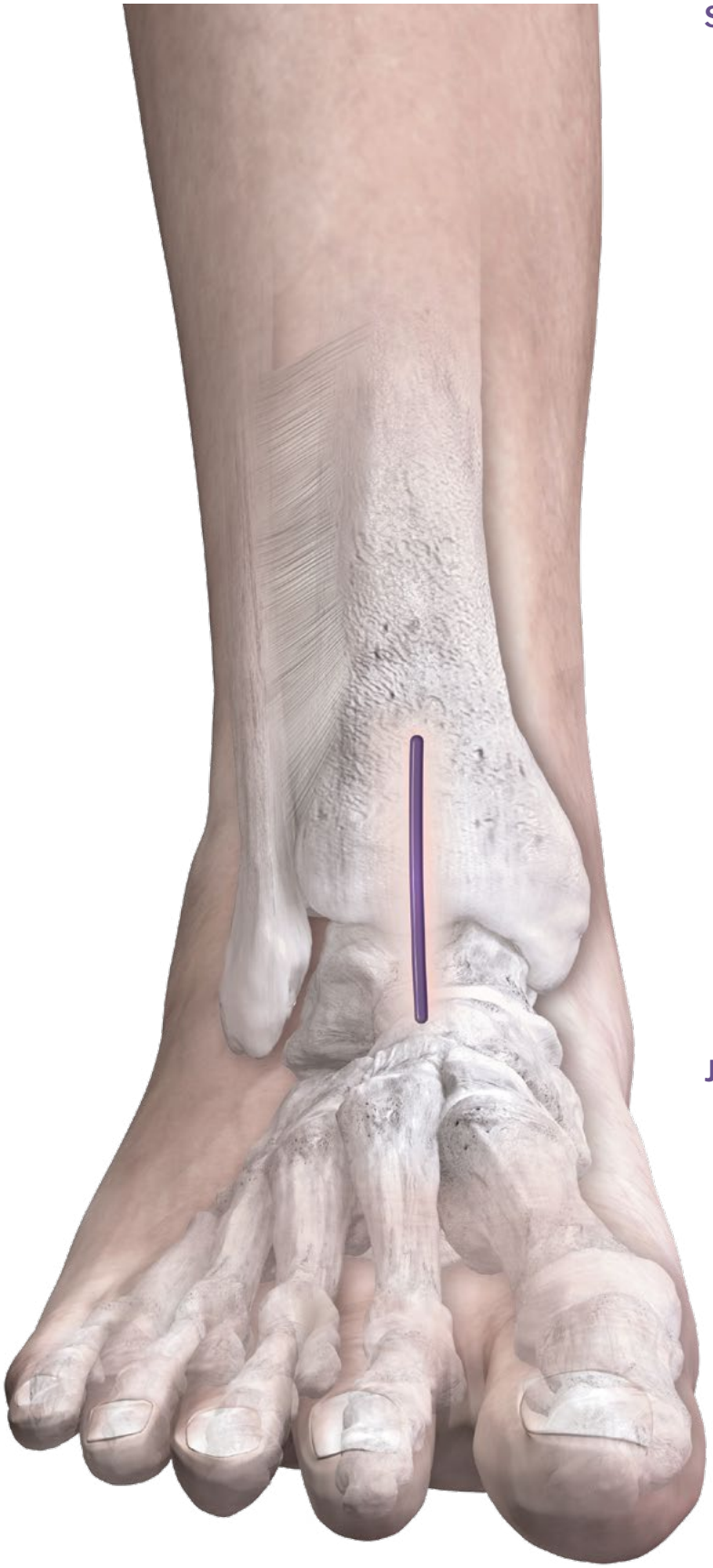
ACKNOWLEDGMENTS:

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

SURGICAL APPROACH



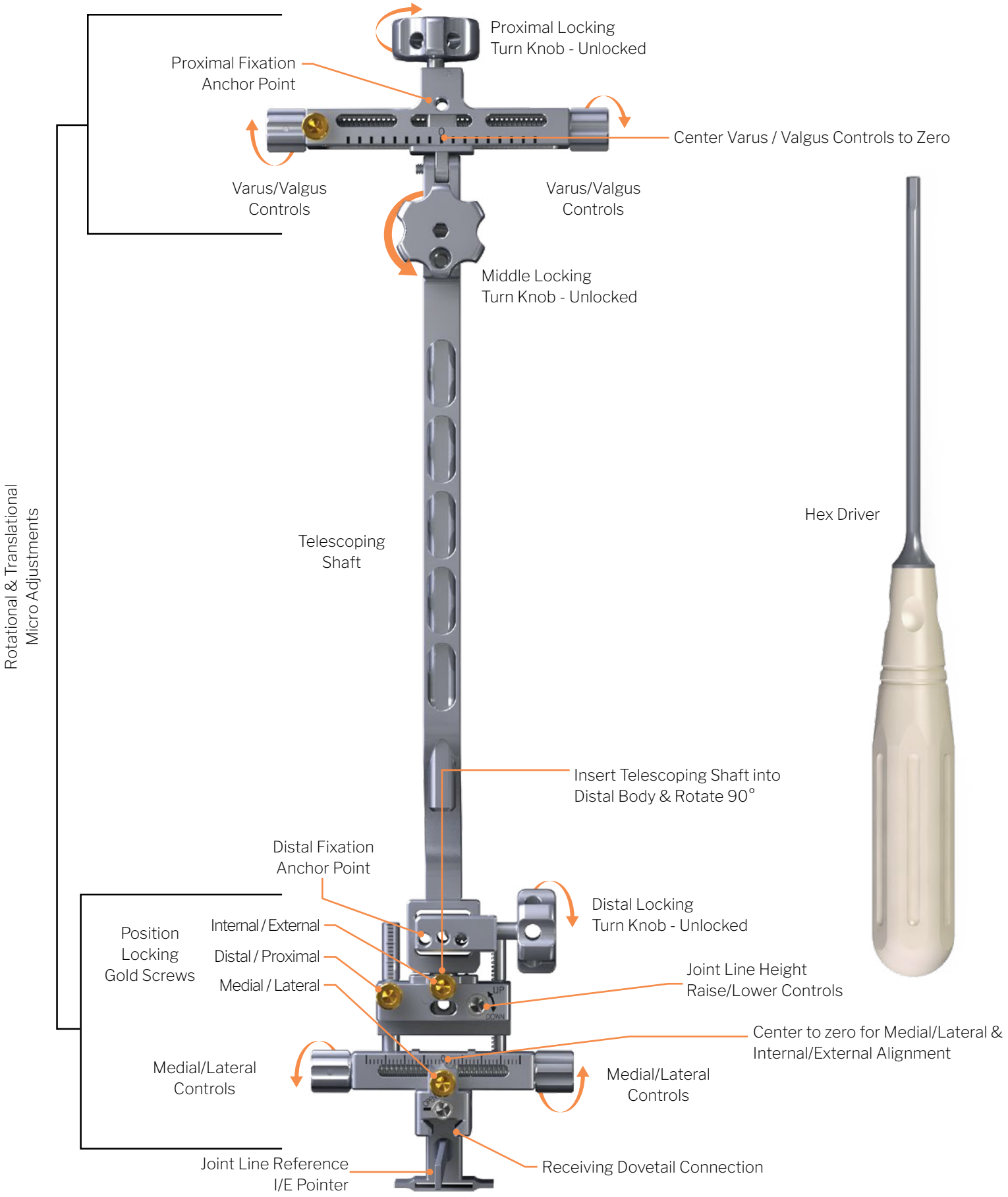
STANDARD ANTERIOR SURGICAL APPROACH

- 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 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 its respective sheath medially and the EHL and its 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.

JOINT EXPOSURE

- If necessary, remove marginal tibiotalar osteophytes from the anterior ankle which may impede instrumentation entry and placement.
- If excessive talar bossing or spurs are noted, it is recommended that the prominence is resected to normalize contour.

PREPARING THE TRADITIONAL ALIGNMENT GUIDE

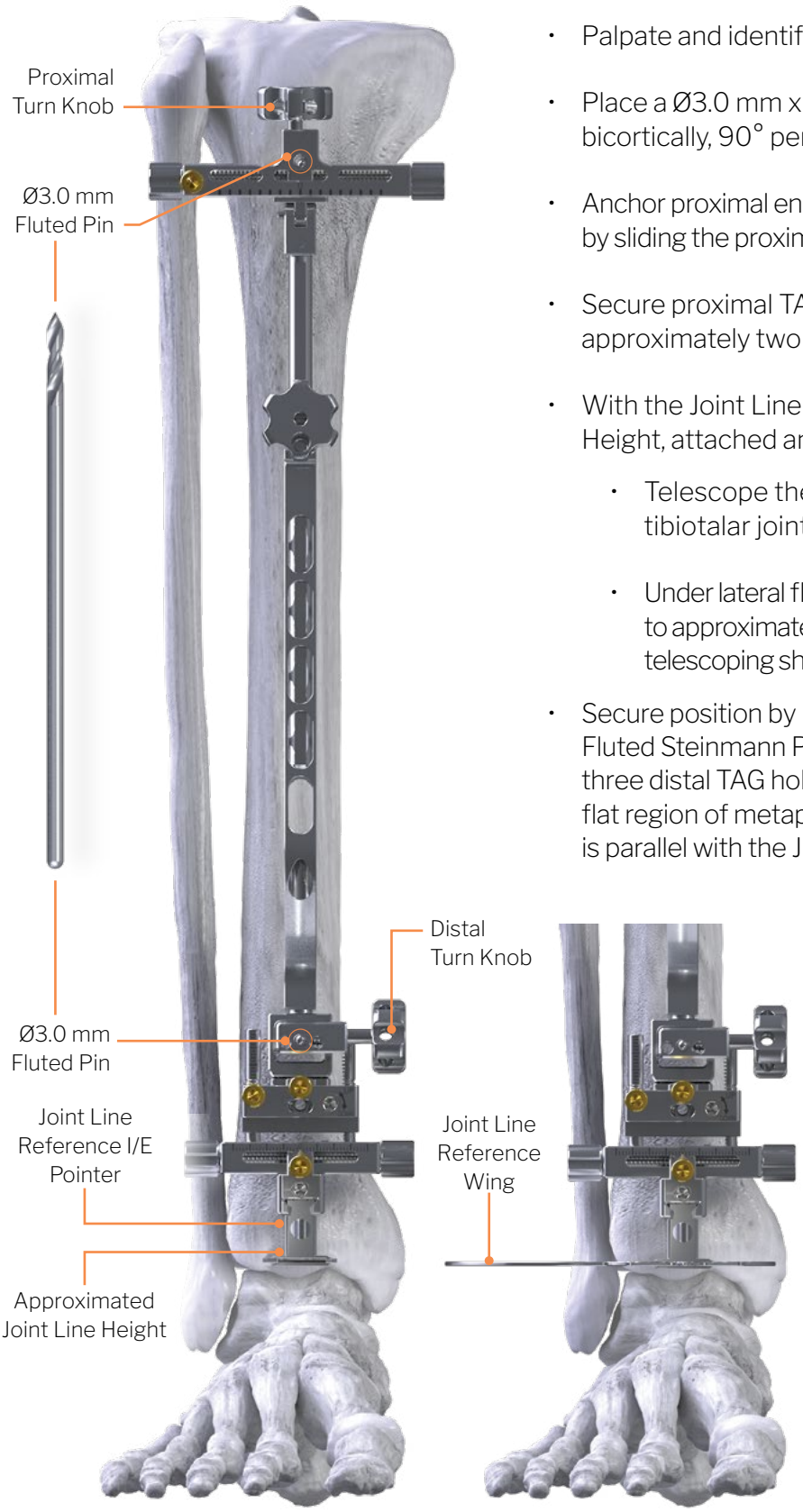


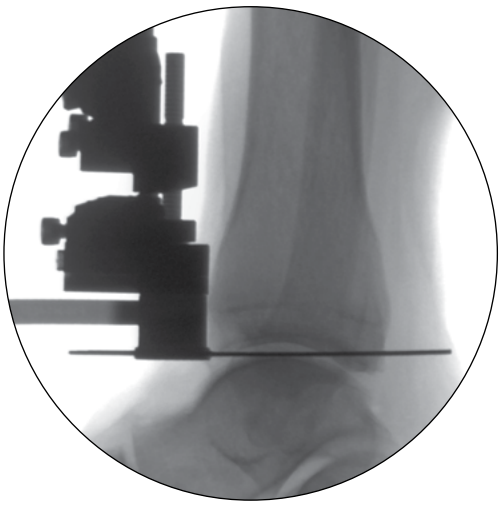
TRADITIONAL ALIGNMENT GUIDE (TAG)

SET UP:
Have large C-Arm in lateral position at the level of the ankle joint entering over the operative site from the contralateral side.

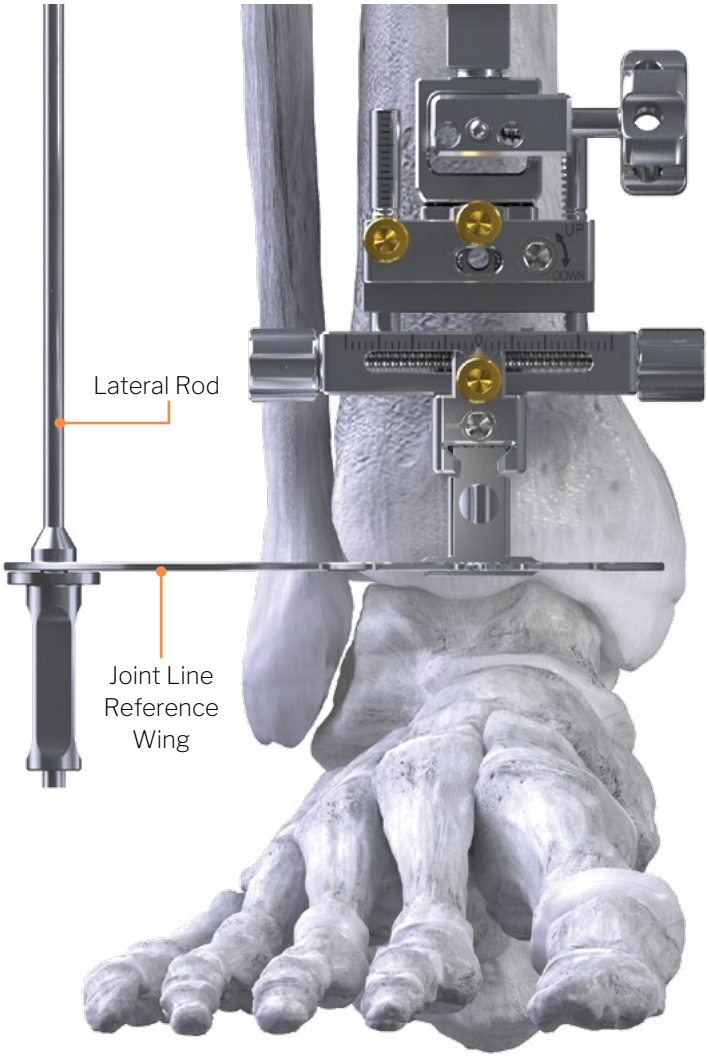
PROXIMAL TIBIAL FIXATION & GROSS JOINT POSITION

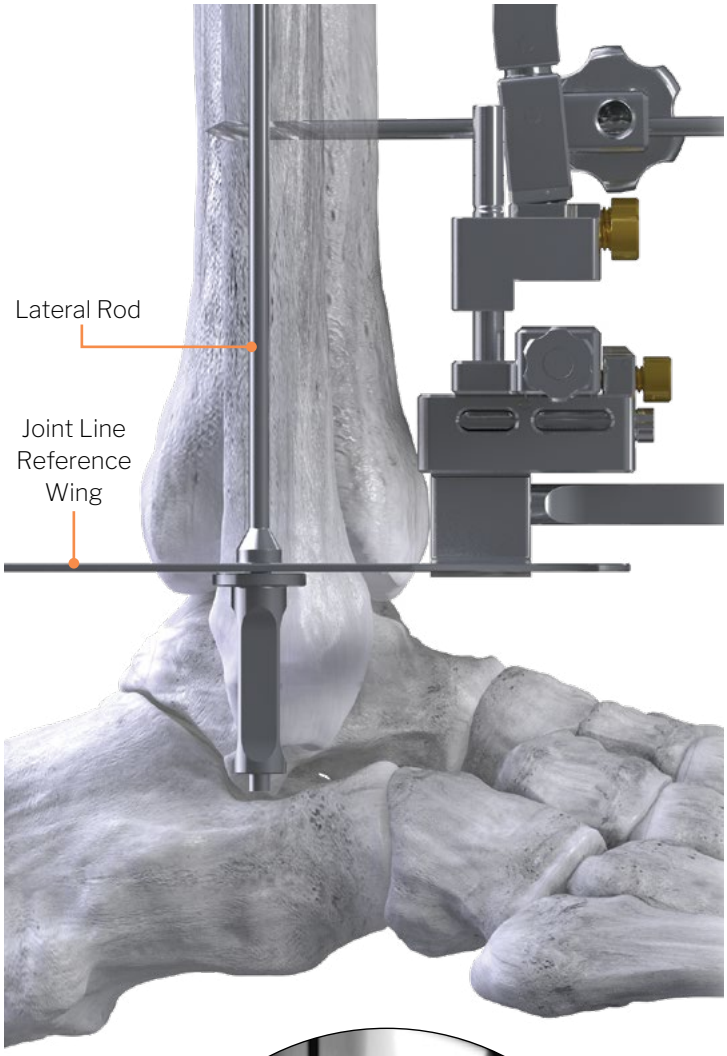
- Palpate and identify the tibial tuberosity (TT).
- Place a Ø3.0 mm x 160 mm [P10-902-3016] Fluted Steinmann Pin bicortically, 90° perpendicular to the tibial axis.
- Anchor proximal end of the Traditional Alignment Guide (TAG) assembly by sliding the proximal hole over the Ø3.0 mm Steinmann pin.
- Secure proximal TAG position by locking the Proximal Turn Knob, approximately two finger breadths from the tibial crest.
- With the Joint Line Reference I/E Pointer to approximate Joint Line Height, attached and locked into the TAG's dovetail connection:
  - Telescope the TAG assembly distally until approximated with tibiotalar joint line height.
  - Under lateral fluoroscopy, utilize the Joint Line Reference Wing to approximate Joint Line Height, then lock Middle Turn Knob on telescoping shaft.
- Secure position by placing a Ø3.0 mm x 100 mm [P10-902-3010] Fluted Steinmann Pin perpendicular and bicortically into one of the three distal TAG holes based on alignment requirements, targeting the flat region of metaphyseal bone, avoiding the tibial crest. Confirm Pin is parallel with the JLR I/E Pointer, then lock Distal Turn Knob.





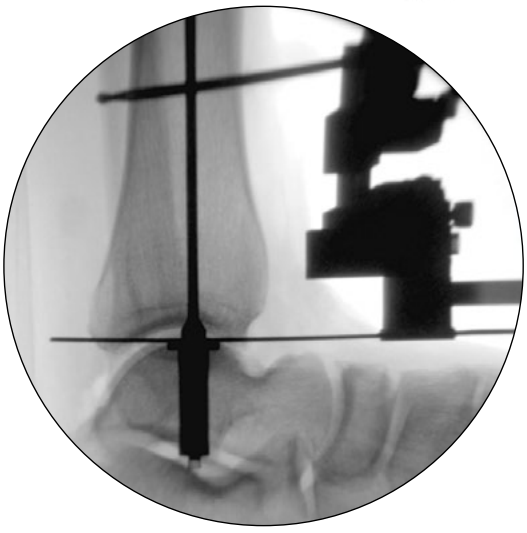
TRADITIONAL ALIGNMENT GUIDE (TAG)





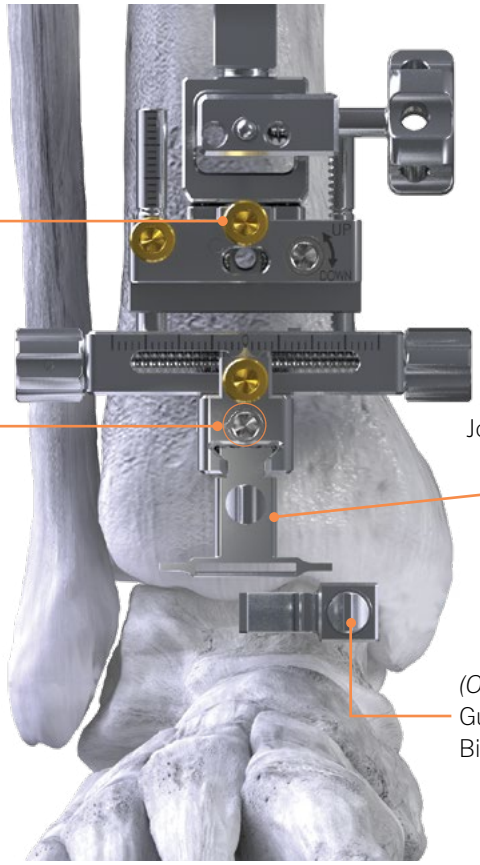
ESTABLISH SLOPE

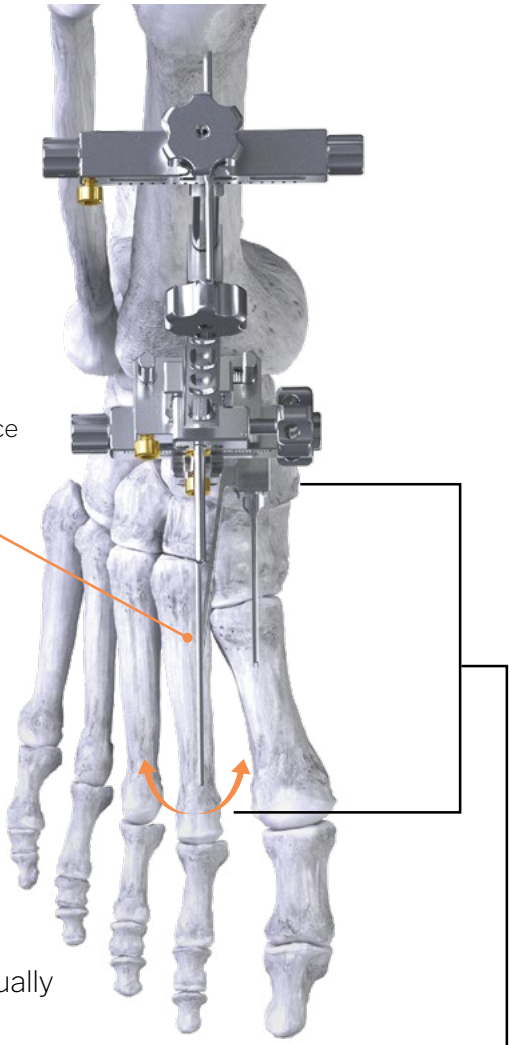
- Attach Lateral Rod [P10-941-AL04] to Joint Line Reference Wing and utilize assembly to approximate distal tibial slope under lateral fluoroscopy.
- Adjust for zero slope with Lateral Rod by aligning:
  - With tibial canal, or
  - Parallel to the posterior tibial cortex.
- Remove Wing/Rod assembly.

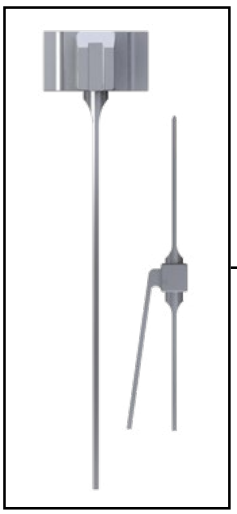


SURGICAL NOTE:
Zero distal tibial slope (90° to the tibial axis) is the default alignment with this system. It is recommended that the Wing also be used to evaluate slope. If adjustments are needed, raise and lower TAG on either the proximal or distal anterior tibial fixation pin locations, then re-tighten locking turn knobs to secure position.

TRADITIONAL ALIGNMENT GUIDE (TAG)







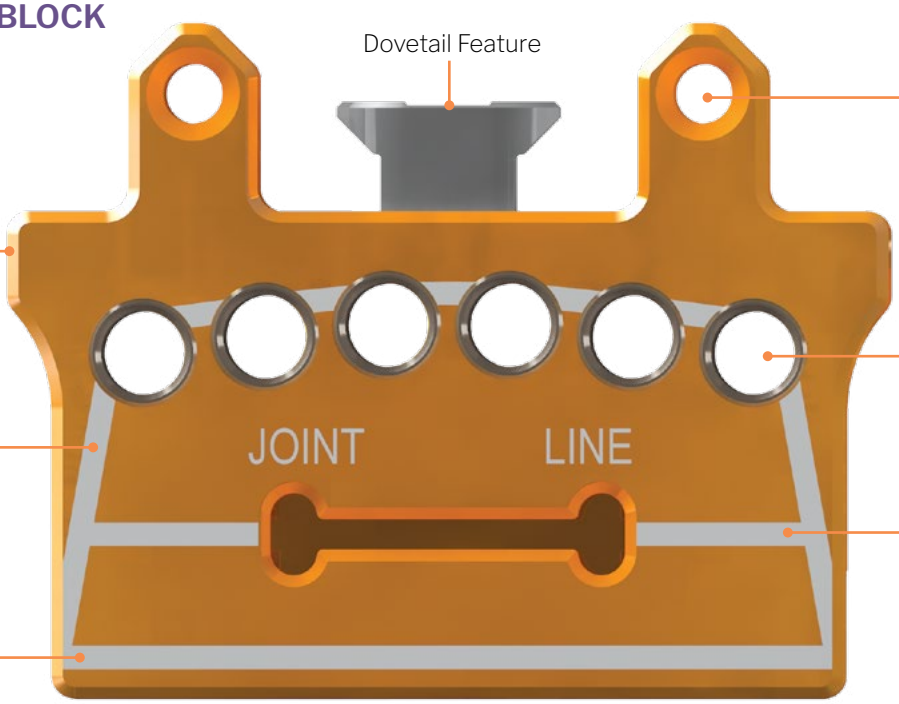
INTERNAL – EXTERNAL ROTATIONAL ADJUSTMENTS

- Based on preference, utilize the Joint Line Reference I/E Pointer to visually guide I/E rotation against:
  - *2nd – 3rd metatarsal, or*
  - *Medial Gutter, or*
  - *Gutter Bisection*
- Once final alignment has been established, lock in final position with corresponding gold screw.
- Unlock silver dovetail screw, then remove the I/E Pointer and Gutter Alignment Tool.

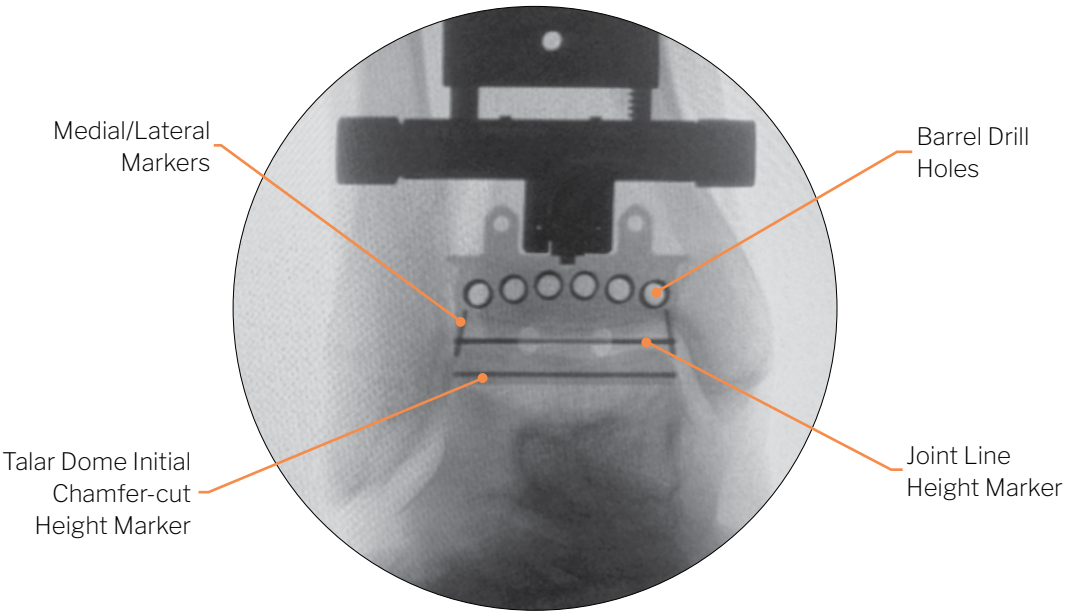
SURGICAL NOTE:
The Gutter Alignment Bisection Tool [P10-941-AL06], is designed to accommodate surgeon I/E rotational preference between 6-8°. The long axis of the tool indicates medial gutter orientation, while the angled projection indicates 8^0 of external rotation from the medial gutter, approximating gutter bisection. Select preferred I/E rotation given these landmarks. This device allows for both medial gutter alignment or gutter bisection based on preference or intra-operative requirements.

TRADITIONAL ALIGNMENT GUIDE (TAG)

SIZING RESECTION BLOCK



APEX 3D COLOR CODES					
Size 1 - Green	**Size 2** - Yellow	**Size 3** - Purple	**Size 4** - Orange	**Size 5** - Dark Blue	**Size 6** - Bronze



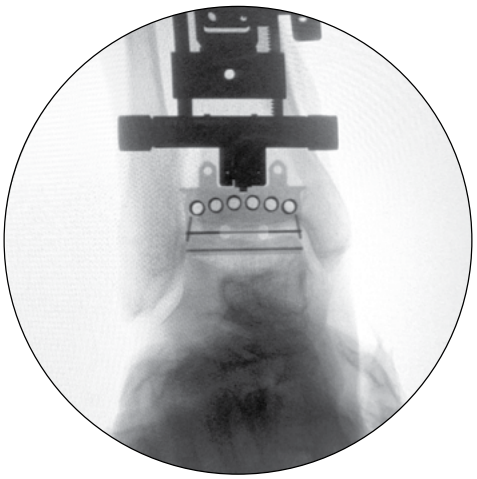
SURGICAL NOTE:
The Sizing Resection Block is utilized to evaluate and determine the appropriate Tibial Implant size and determine placement. Talar Chamfer-cut Height Marker serves as general talar resection level indicator for coupled cuts. Talar sizing will be determined during subsequent steps. See Section 7 for Chamfer-cut and Appendix A for Flat-cut sizing instructions.

TRADITIONAL ALIGNMENT GUIDE (TAG)

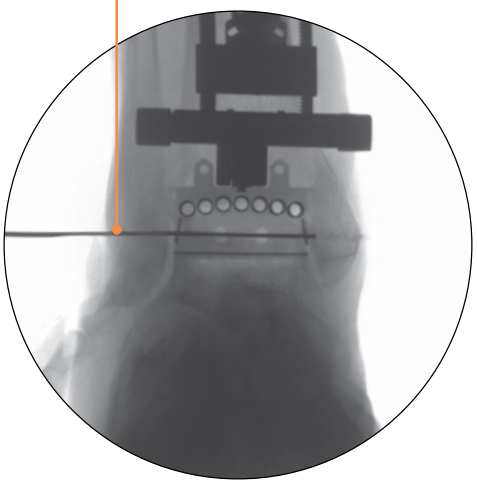
VARUS / VALGUS ADJUSTMENTS

- Select and attach the appropriate Sizing Resection Block [P10-942-SZxx] based on pre-op planning, and estimated tibial sizing requirements.
- With Sizing Block or optional JLR Angel Wing:
  - *Evaluate varus / valgus under an AP fluoroscopic view.*
  - *To adjust varus / valgus alignment, rotate the Proximal Control Knobs.*
- (Optional): Once confirmed, lock the gold screw adjacent to V/V proximal control knobs.

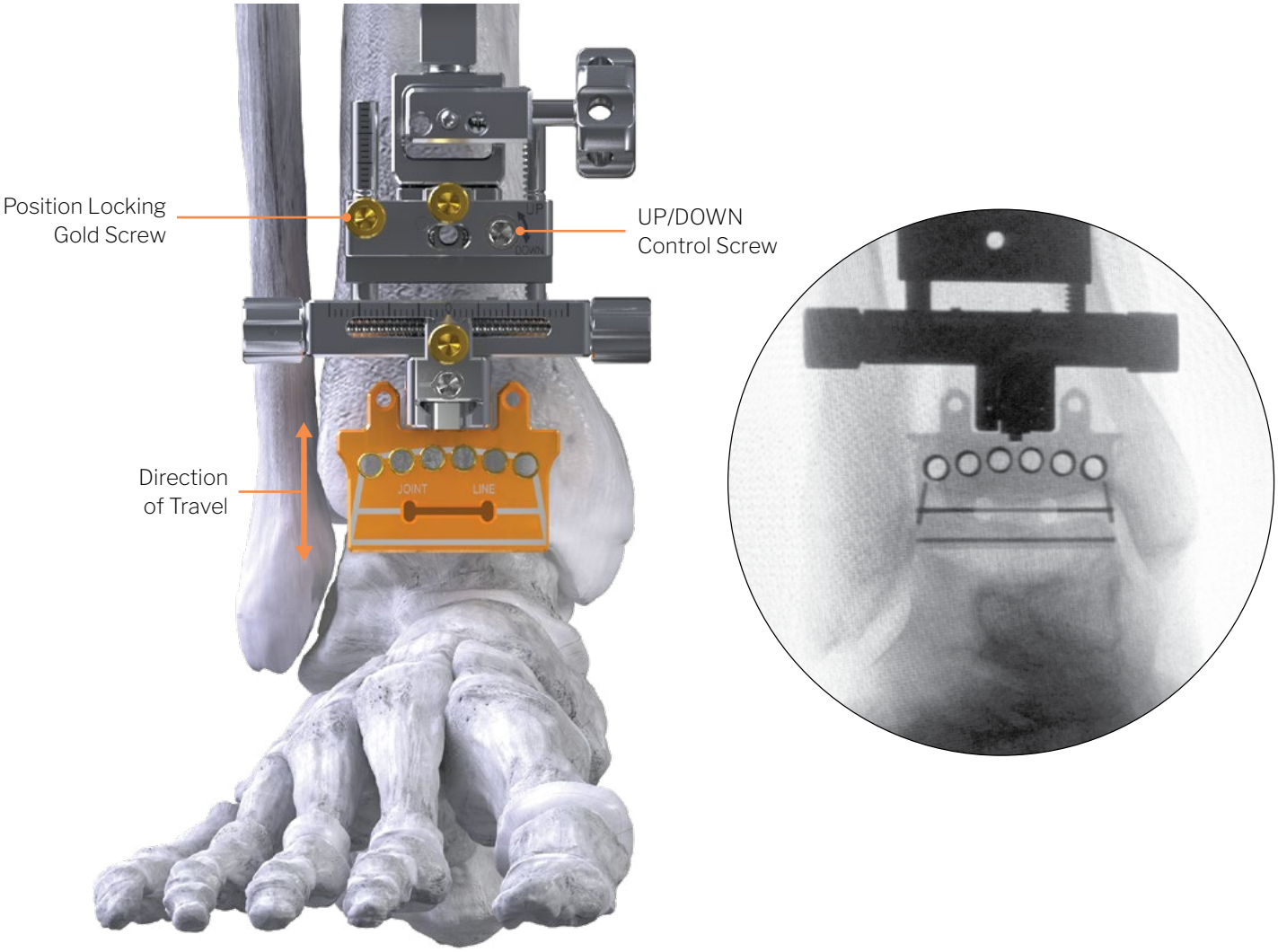
SURGICAL NOTE:
For a true AP view of the ankle, ensure Wing is overlapping the Joint line fluoroscopy marker of the Sizing Resection Block.



JLR Angel Wing



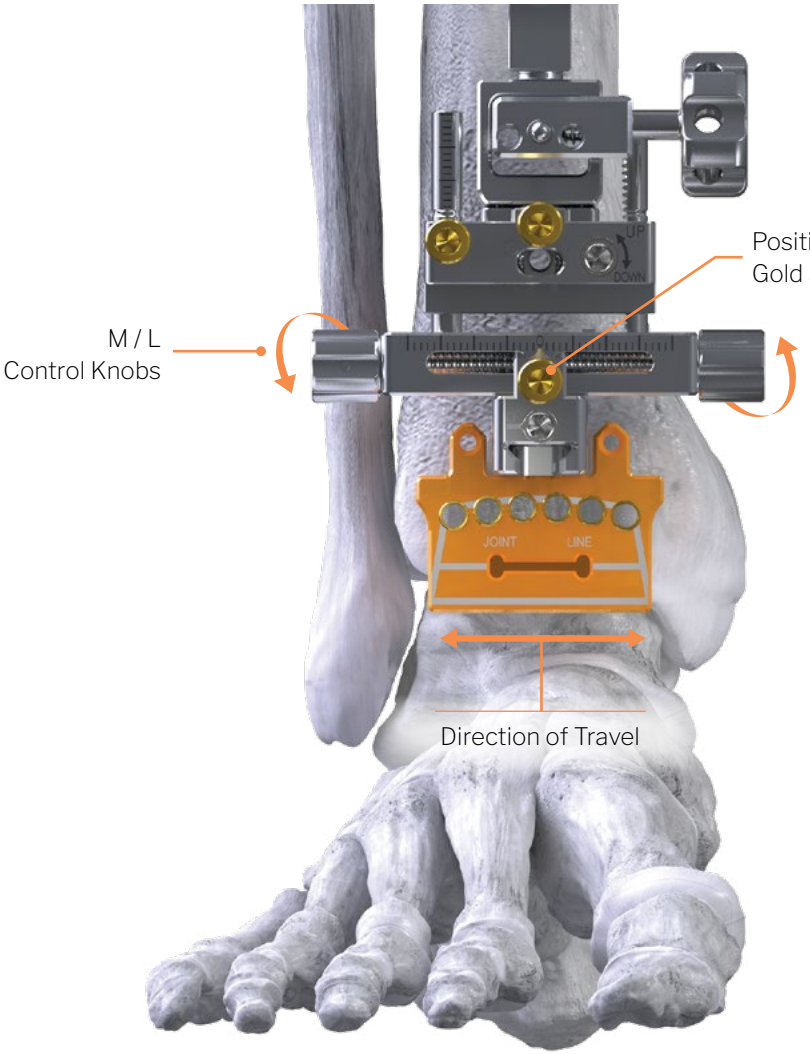
TRADITIONAL ALIGNMENT GUIDE (TAG)

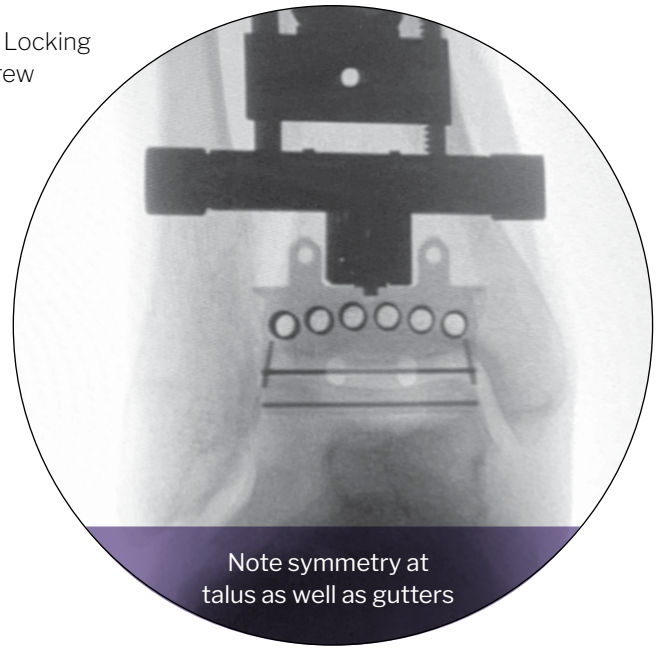


JOINT LINE HEIGHT: DISTAL - PROXIMAL MICRO ADJUSTMENTS

- Under an AP fluoroscopic view, evaluate and adjust joint line height by rotating the silver “UP/DOWN" control screw on the right side of the control block with hex driver.
- Once appropriate positioning has been achieved, secure the joint line height by rotating the position locking gold screw.

TRADITIONAL ALIGNMENT GUIDE (TAG)



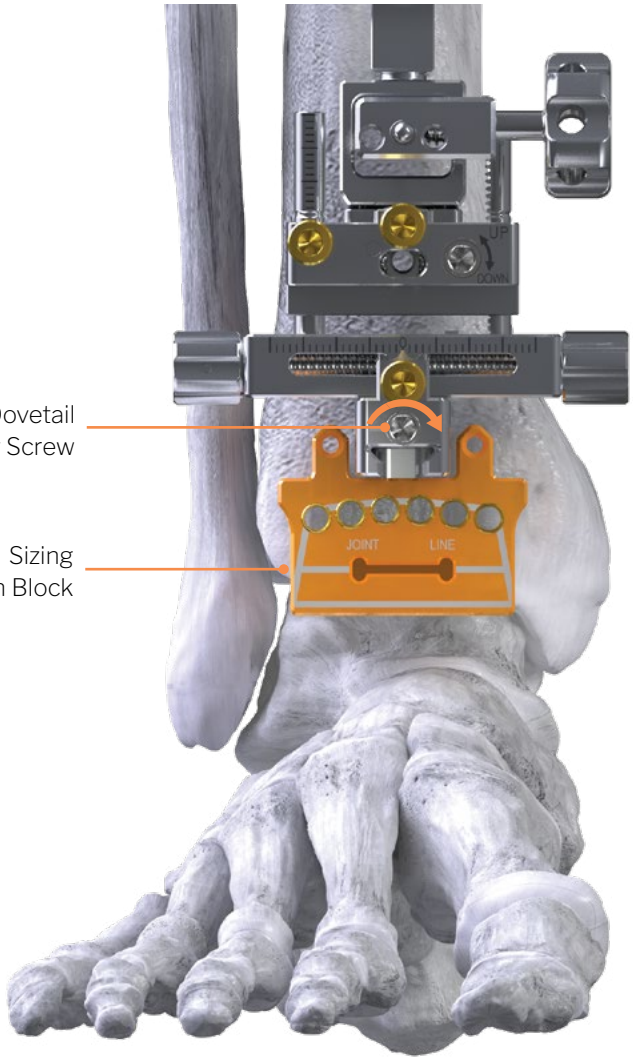


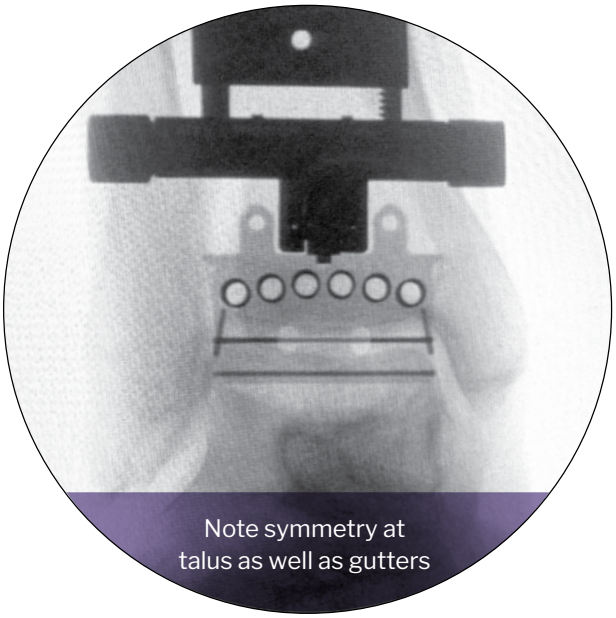
MEDIAL - LATERAL MICRO ADJUSTMENTS

- Adjust medial / lateral (M/L) alignment by rotating the Distal Control Knobs.
- Under an AP fluoroscopic view to verify the Sizing Resection Block is aligned with the medial and lateral gutters.
- Lock in M/L alignment by rotating the center most gold screw until threads are fully seated.

SURGICAL NOTE:
Use radiopaque alignment markers within the Sizing Resection Block to evaluate positioning.

TRADITIONAL ALIGNMENT GUIDE (TAG)



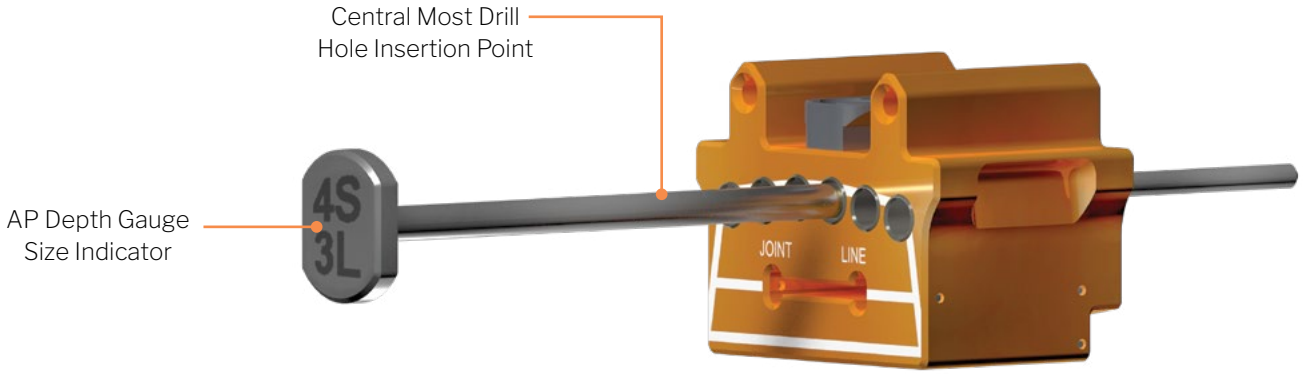


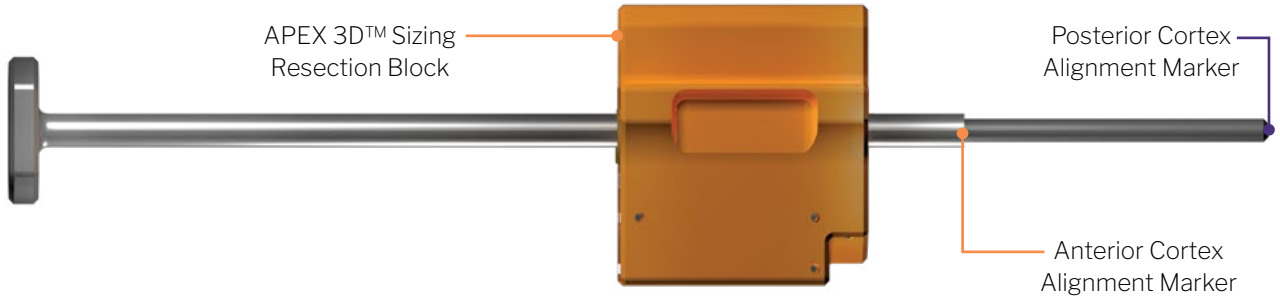
SIZING EVALUATION

- Under an AP Fluoroscopic view, evaluate position against M/L gutters, then swap blocks to adjust sizing as needed.

INSTRUMENT OVERVIEW*

APEX 3D COLOR CODES					
Size 1 - Green	Size 2 - Yellow	Size 3 - Purple	Size 4 - Orange	Size 5 - Dark Blue	Size 6 - Bronze

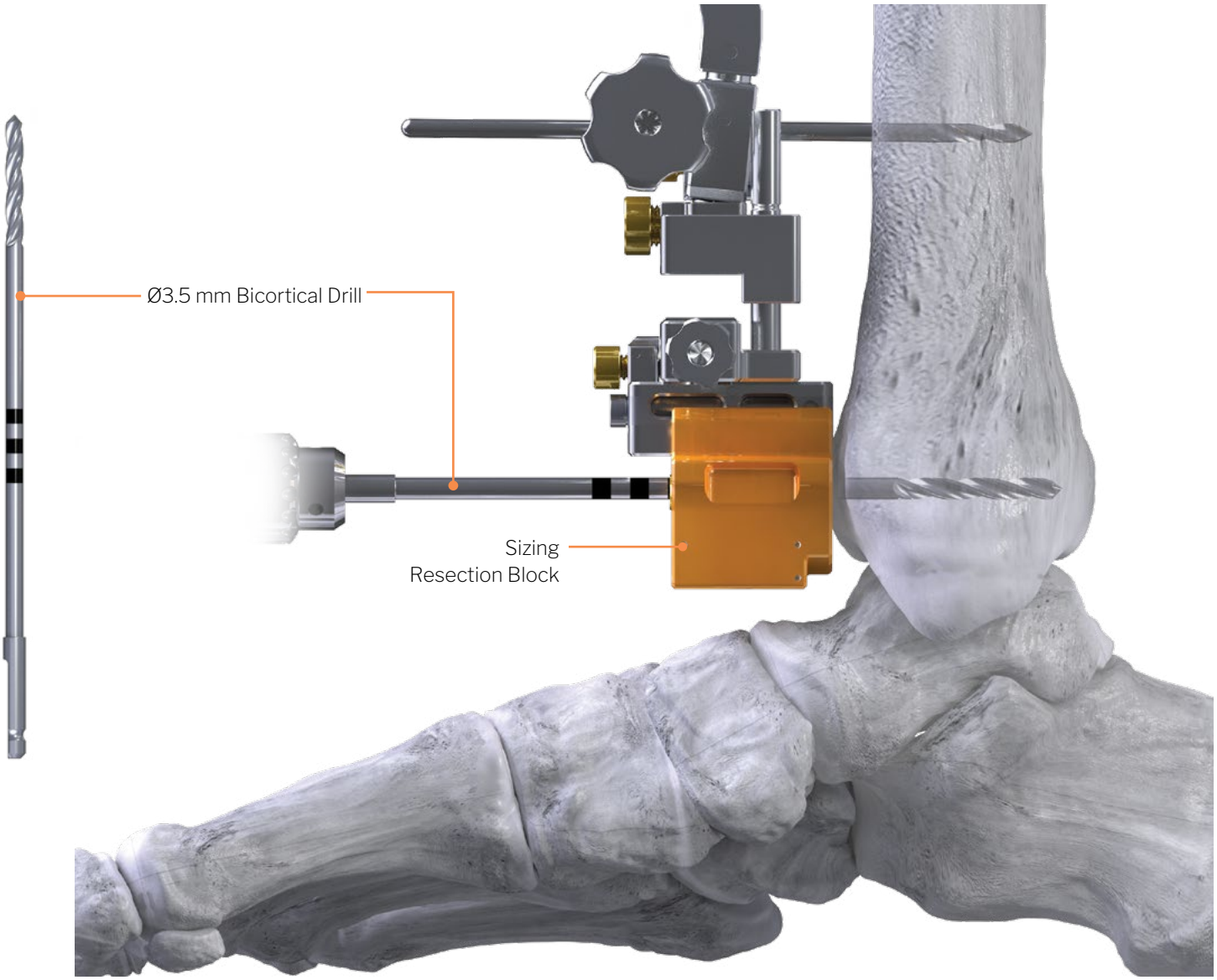




TIBIAL AP DEPTH GAUGES

Size -	1 Standard
Size -	2 Standard 1 Long
Size -	3 Standard 2 Long
Size -	4 Standard 3 Long
Size -	5 Standard 4 Long

TIBIAL AP SIZING CONFIRMATION



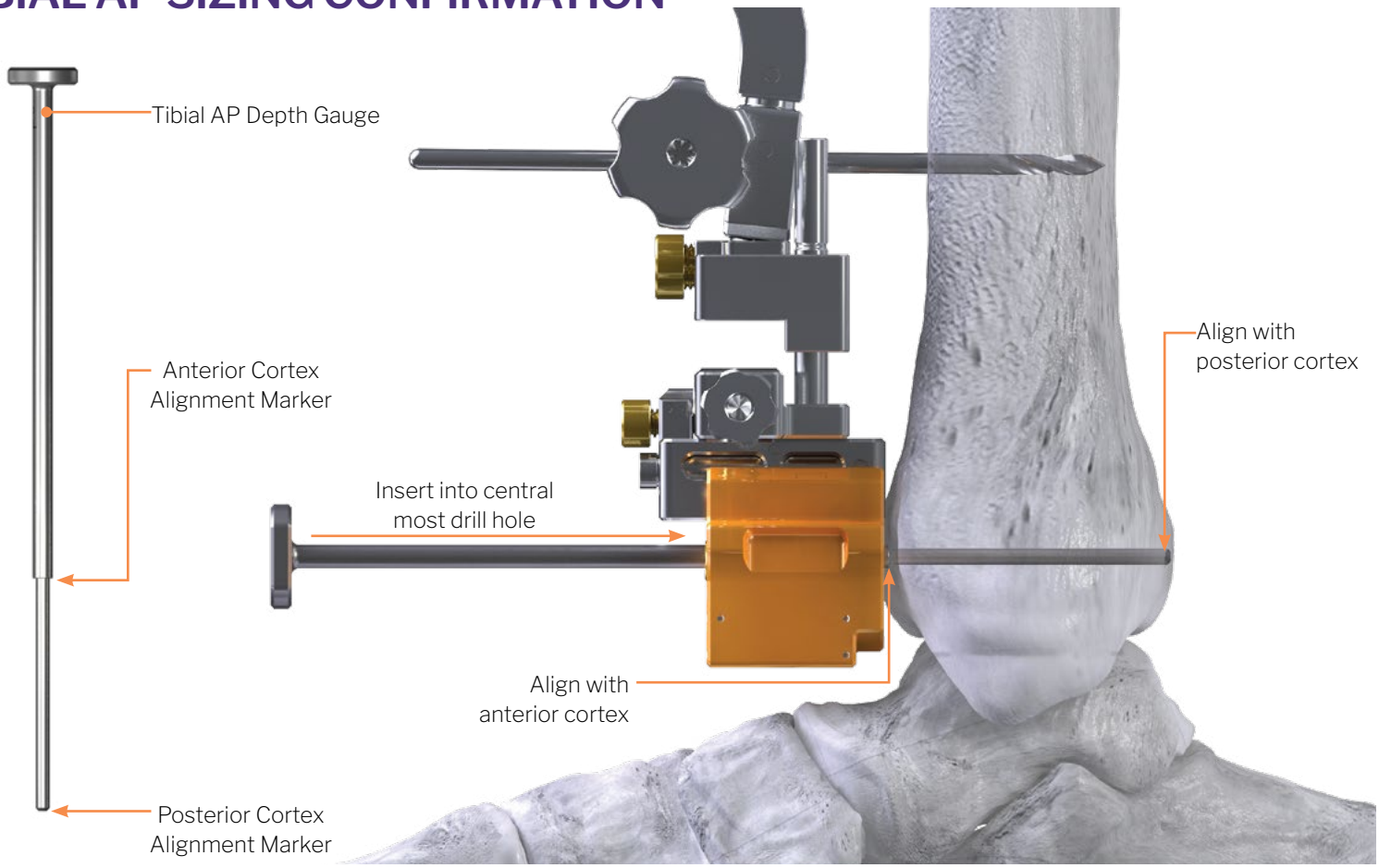
PILOT HOLE – Ø3.5 MM BICORTICAL RESECTION DRILL

- Create a pilot hole utilizing the Ø3.5 mm ARC Tibia Resection Drill [P10-942-3513] to insert the Tibial AP Sizing Depth Gauge [P10-942-APDx].
- Drill bicortically into the central most hole of the Sizing Resection Block, ensuring the Drill clears the posterior cortex, but does not penetrate beyond.
- Remove the Drill and prepare to insert the AP Sizing Depth Gauge.

SURGICAL NOTE: The medial or lateral drill holes should be avoided and not utilized during the initial AP sizing assessment. If a Flat-Cut tibia was the selected bone resection option, the Sizing Resection Block should still be utilized to assess AP depth and sizing prior to use of the Flat-Cut Resection Block.

SURGICAL NOTE: ARC Tibia Resection Drill laser markings should be noted and are for reference only. The markings will help to estimate at which point subsequent drilling will perforate the posterior cortex relative the critical drill depth.

TIBIAL AP SIZING CONFIRMATION



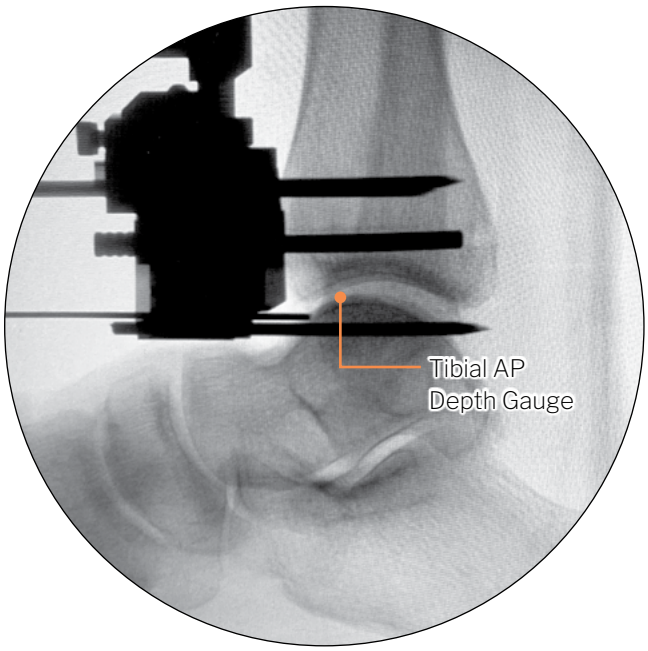
TIBIAL AP SIZING CONFIRMATION

- Insert the appropriately sized Tibial AP Depth Gauge into the previously drilled hole of the Sizing Resection Block.
- Based on the previously selected Sizing Resection Block, utilize the corresponding AP Depth Gauge to evaluate and confirm AP sizing by:

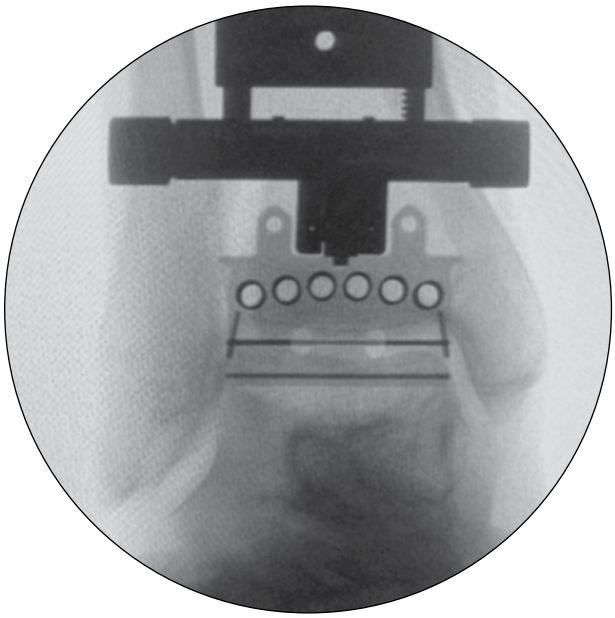
  - Aligning the anterior cortex marker with the anterior cortex of the tibia.

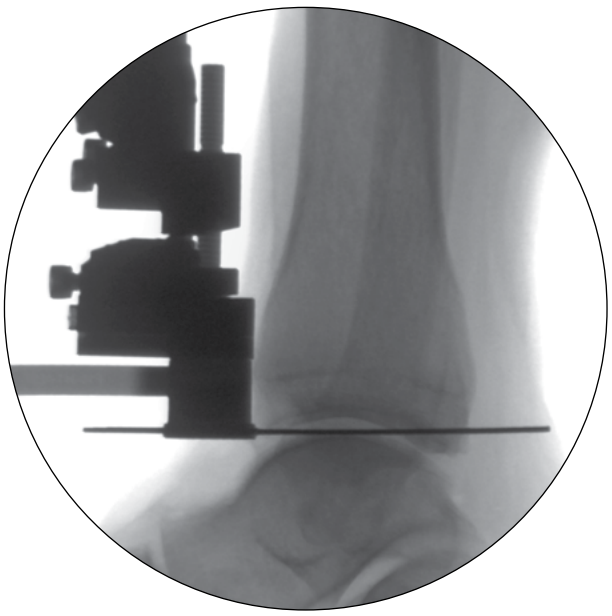
  - Then evaluating the position of the posterior cortex marker against the posterior cortex of the tibia.

  - If necessary, swap Depth Gauges to assess fit; appropriate sizing has been achieved when both the anterior and posterior aspects of the Depth Gauge sit flush with each respective cortices.



TRADITIONAL ALIGNMENT GUIDE (TAG)





FINALIZE ALIGNMENT

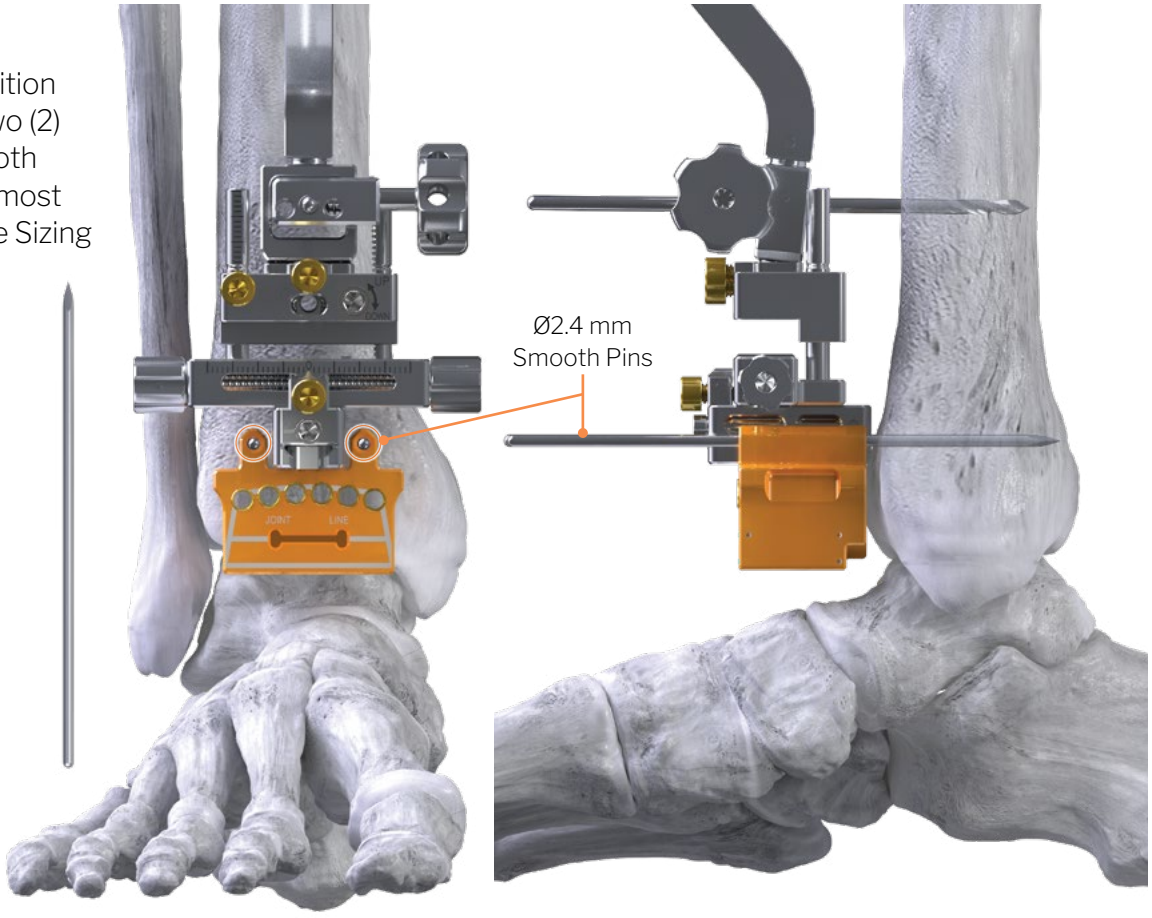
- Confirm all planes of alignment visually and under fluoroscopy.
- Make final adjustments as necessary

CHECK POINT

- ☐ SLOPE
- ☐ INTERNAL/EXTERNAL
- ☐ VARUS / VALGUS
- ☐ JOINT LINE HEIGHT
- ☐ MEDIAL / LATERAL
- ☐ SIZING

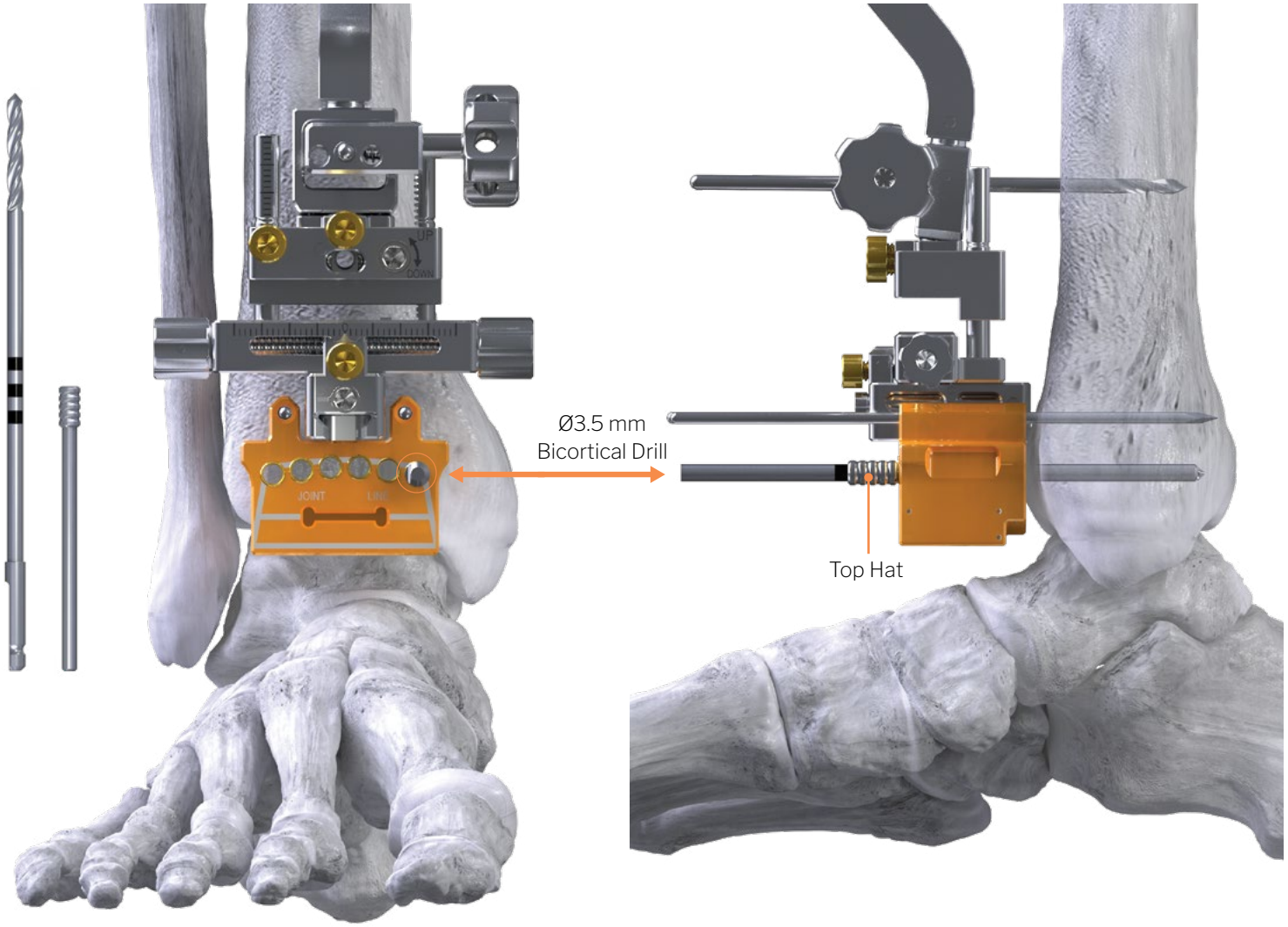
LOCK FINAL POSITION

- To establish the final position against the tibia, place two (2) Ø2.4 mm x 110 mm Smooth Steinmann Pins into the most proximal M/L holes of the Sizing Resection Block.



ALTERNATIVE BONE PREPARATION OPTION:
Flat Tibia | Flat Talus
Jump to page 48 ➔

ARC TIBIA - BONE PREPARATION



BICORTICAL ARC TIBIA RESECTION DRILL

- Utilizing the Ø3.5 mm ARC Tibia Resection Drill [P10-942-3513], drill bicortically into the medial most corner hole of the Sizing Resection Block, ensuring drill clears the posterior cortex, but does not penetrate beyond.
- Remove the drill and place the Ø3.5 mm Top Hat [P10-942-35TH] in the drilled hole to help secure the position of the block as the remaining holes are drilled.

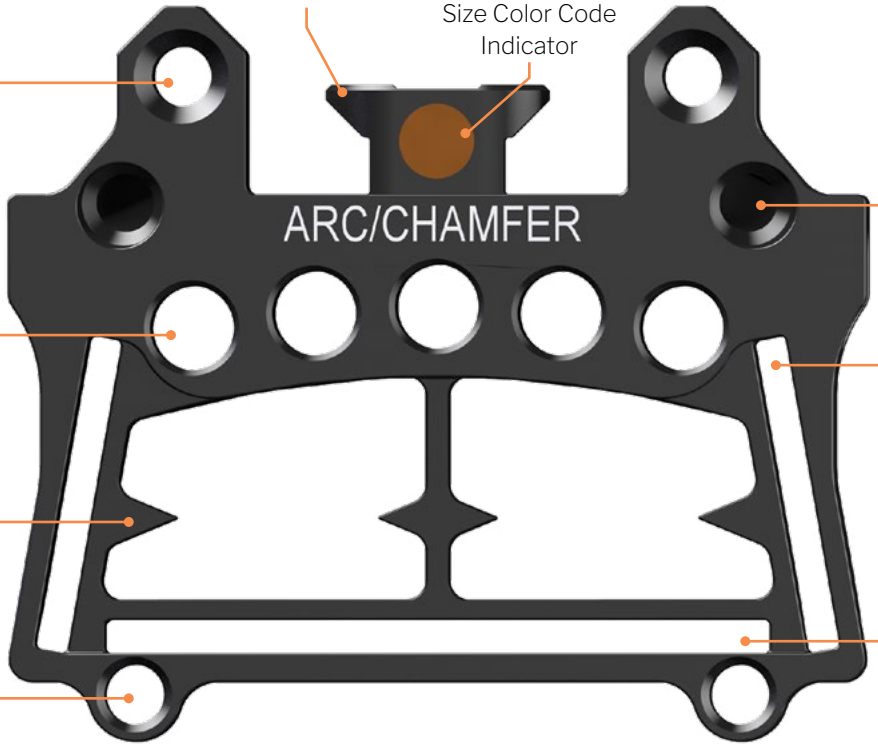
SURGICAL NOTE:
ARC Tibia Resection Drill laser markings should be noted and are for reference only. The markings will help to estimate at which point subsequent drilling will perforate the posterior cortex relative the critical drill depth.

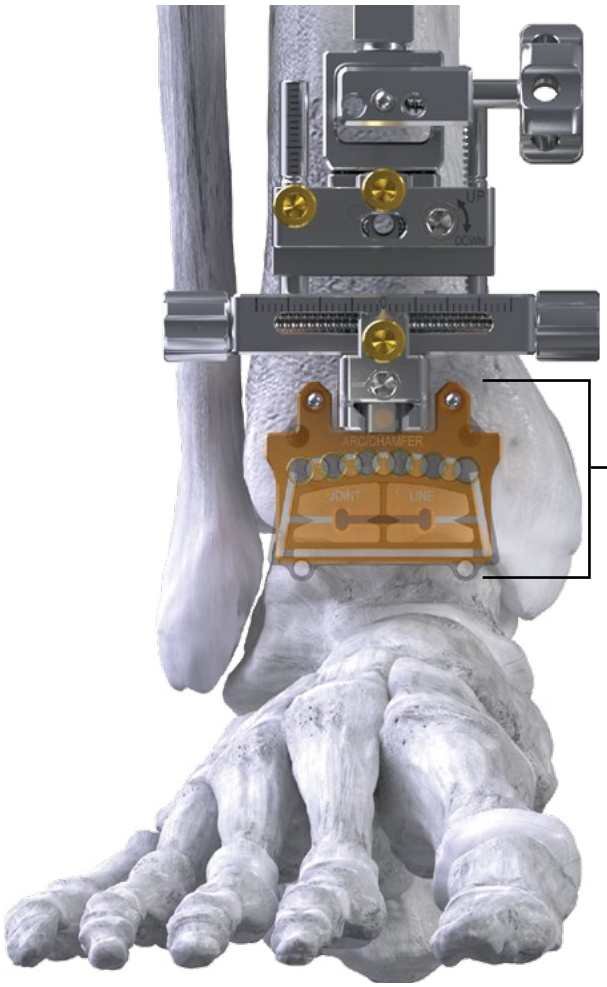
SEQUENTIAL DRILLING

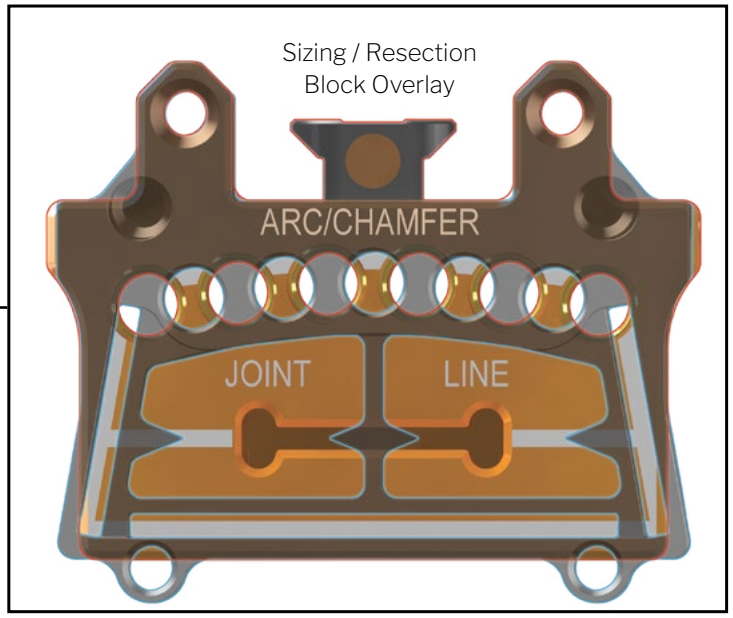
- Perform sequential drilling of the additional holes.
- Rotate the silver “OPEN” screw and remove the Sizing Block and Top Hat.

ARC TIBIA / CHAMFER-CUT TALUS - BONE PREPARATION

RESECTION BLOCK

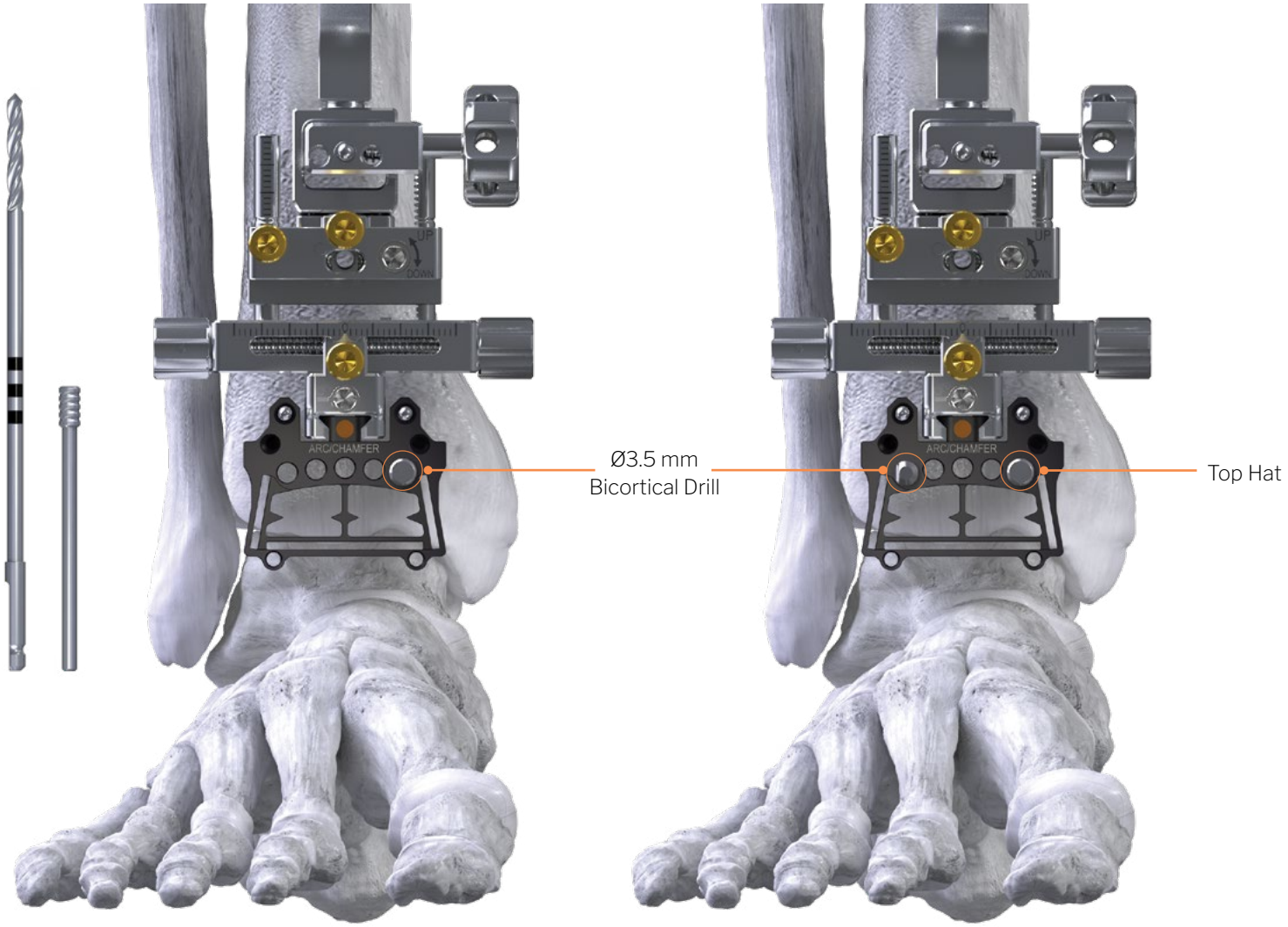






Note Overlapping Drill Holes

ARC TIBIA / CHAMFER-CUT TALUS - BONE PREPARATION



TIBIAL BONE PREPARATION – RESECTION BLOCK

- Slide the proximal portion of the Resection Block over the two (2) M/L Ø2.4 mm guide pins and into the dovetail connection of the Alignment Construct and lock in place.
- Perform sequential drilling with the Ø3.5 mm ARC Tibia Resection Drill to resect the remaining cortical bone, utilizing Top Hat to stabilize resection block after first hole has been drilled.

SURGICAL NOTE:

Prior to placing the ARC Tibia / Chamfer-Cut Resection Block [P10-942-RSxx], confirm the appropriate resection block type has been selected based on bone preparation preference, since four different options are offered.

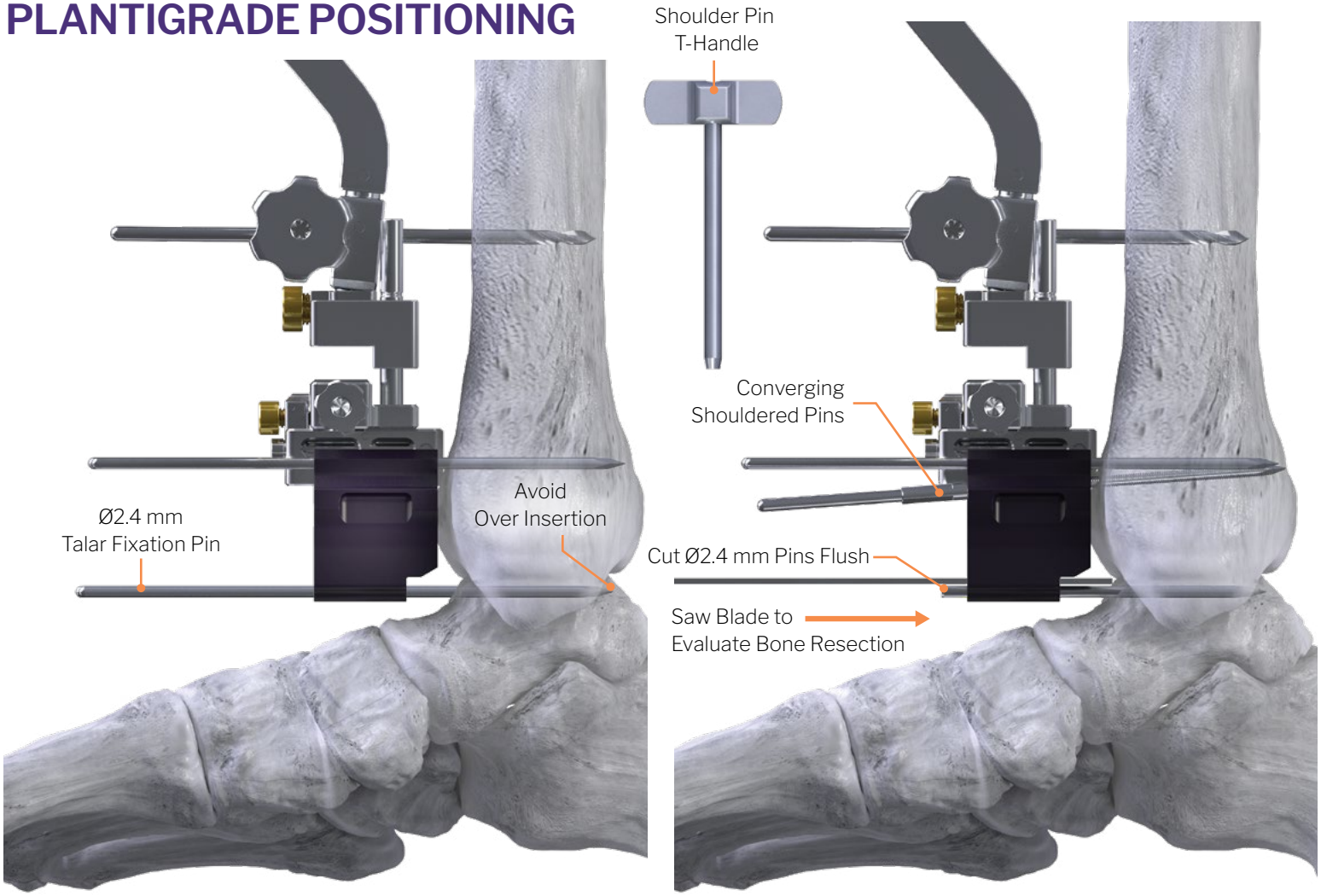
OPTIONAL PATHWAY:

The APEX 3D System offers both Coupled and Decoupled talar bone resection options.

If **Coupled** is the preferred method, follow instructions included in subsequent pages 20-21.

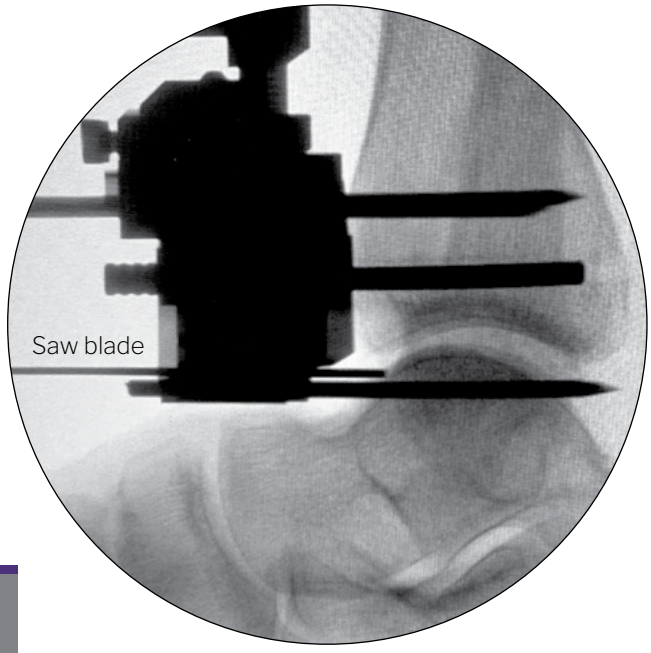
If **Decoupled** is the preferred method, please reference the APEX 3D Decoupled Talar Bone Preparation Auxiliary Surgical Technique Guide [P10-STG-0005].

ARC TIBIA / CHAMFER-CUT TALUS: TIBIOTALAR PLANTIGRADE POSITIONING



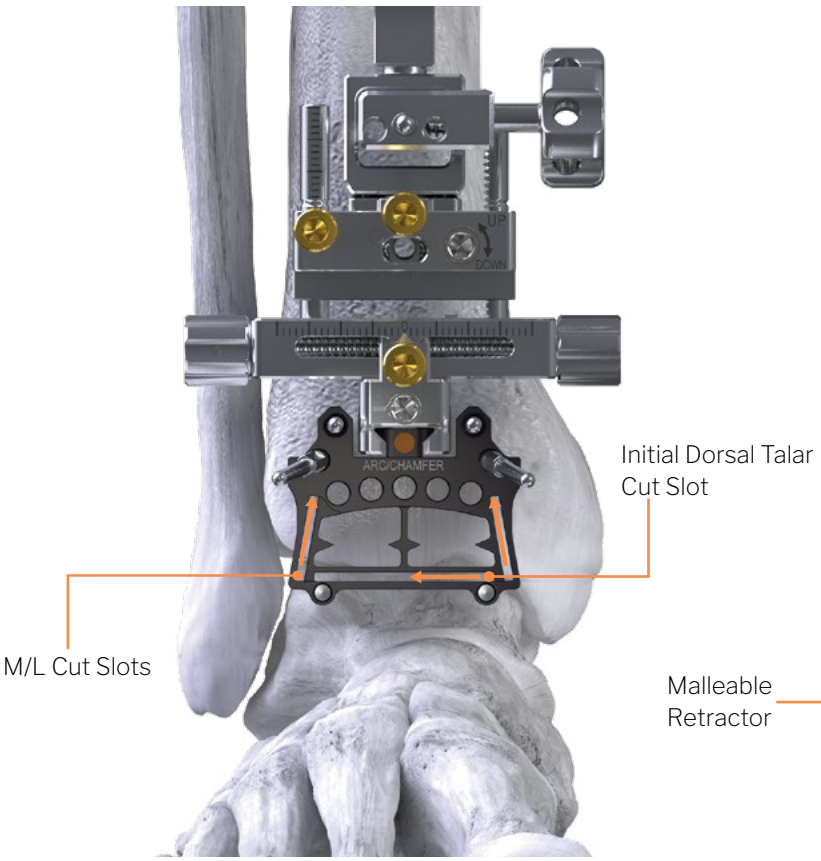
TIBIOTALAR NEUTRAL PLANTIGRADE POSITION

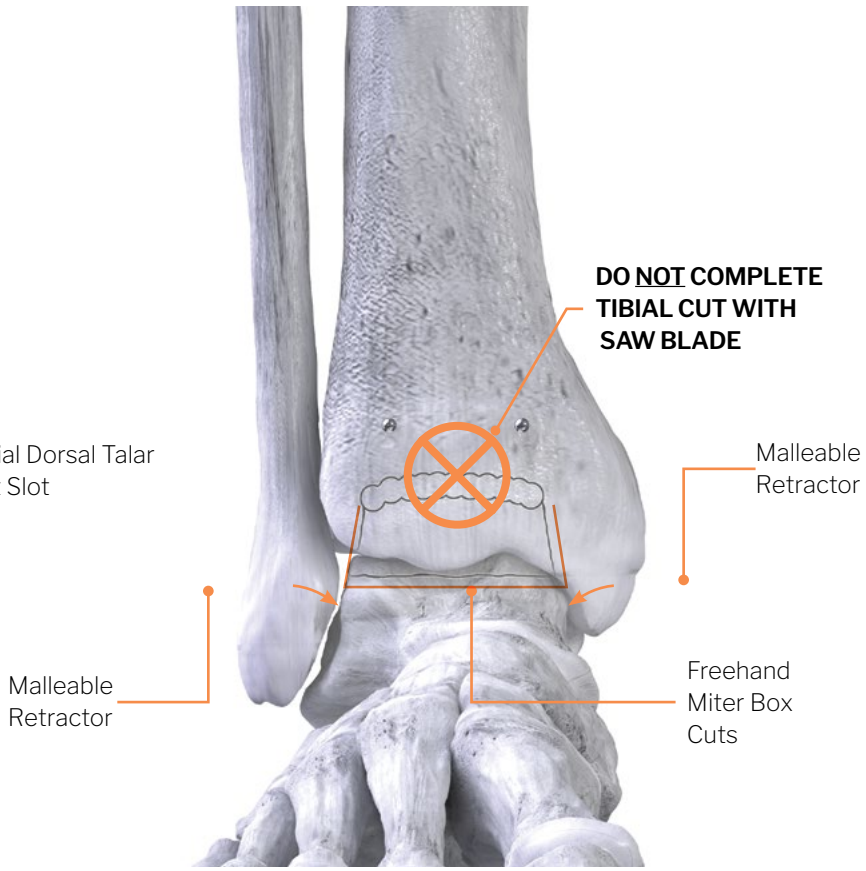
- With the foot held 90° to the tibial axis, reduce the tibiotalar joint, then secure position by placing two (2) Ø2.4 x 110 mm Smooth Steinmann Pins into the talus through the two distal most holes of the Resection Block , taking care not to penetrate beyond.
- Cut the Ø2.4 mm talar Pins flush with provided Pin Cutters to offset pin depth, allowing for easier access of the saw blade in subsequent steps.
- Insert two (2) Ø2.4 x 50 mm Threaded Shouldered Pins [P10-902-2450] for added block stability, utilizing the T-Handle to fully seat. (DO NOT SEAT UNDER POWER)



SURGICAL NOTE:
A saw blade may be used to evaluate initial talar bone resection level under a lateral fluoroscopic view.

ARC TIBIA / CHAMFER-CUT TALUS: – TIBIOTALAR BONE PREPARATION



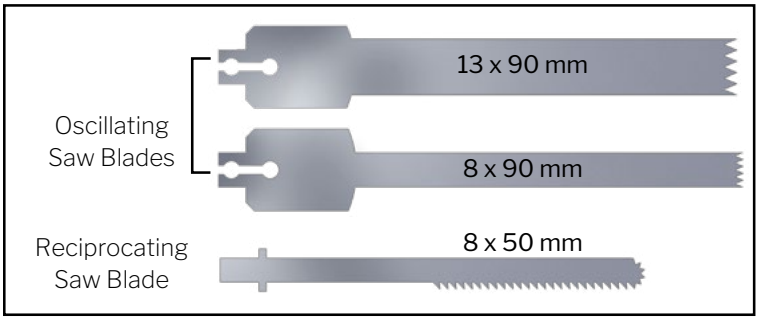


TALAR BONE PREPARATION: INITIAL CHAMFER-CUT

- Utilize the 13 x 90 mm Oscillating Saw Blade [P99-151-P104-S] to complete the initial dorsal talar cut, cutting the superior aspect of the talus through the cutting slot.
- Utilize the 8 x 50 mm Reciprocating Saw Blade or 8 x 90 mm Oscillating Blade to complete the M/L gutter bone resection cuts, starting distally, then walking the saw blade up proximally.

BONE RESECTION: FREEHAND MITER BOX

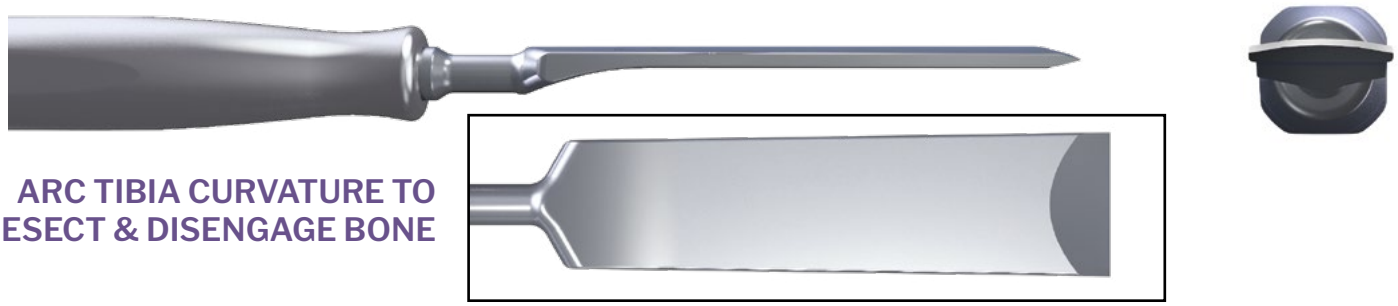
- Remove Threaded Shouldered Pins and Smooth Talar Pins, then the Resection Block by rotating the silver “OPEN” screw.
- Complete M/L talar bone resection with provided saw blade options, utilizing the provided Malleable Retractors [P99-158-06xx], to protect the M/L gutters. (Lateral Malleable Retractor: 152 mm x 9.5 mm, Medial Malleable Retractor: 152 mm x 12.7 mm (L x W))
- Remove the resected tibiotalar bone.



SURGICAL NOTE:
During freehand miter box cuts, take care to avoid contact of the saw with the medial malleolus, fibula and do not cut past existing cortical boundaries. Use of osteotomes or rongeurs is recommended to remove bone fragments.

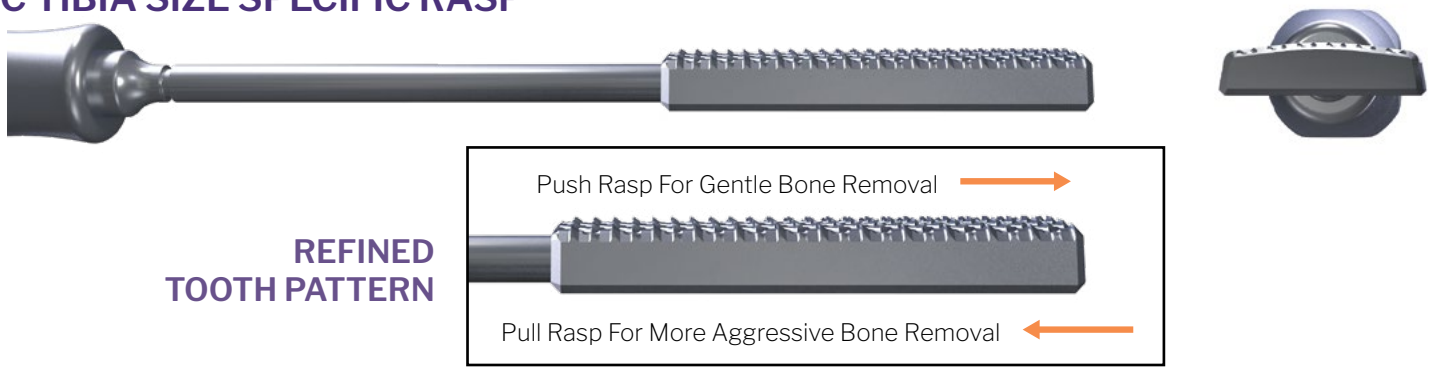
ARC TIBIA: BONE PREPARATION

ARC TIBIA OSTEOTOME



ARC TIBIA CURVATURE TO RESECT & DISENGAGE BONE

ARC TIBIA SIZE SPECIFIC RASP



REFINED TOOTH PATTERN

ARC TIBIA BONE PREPARATION

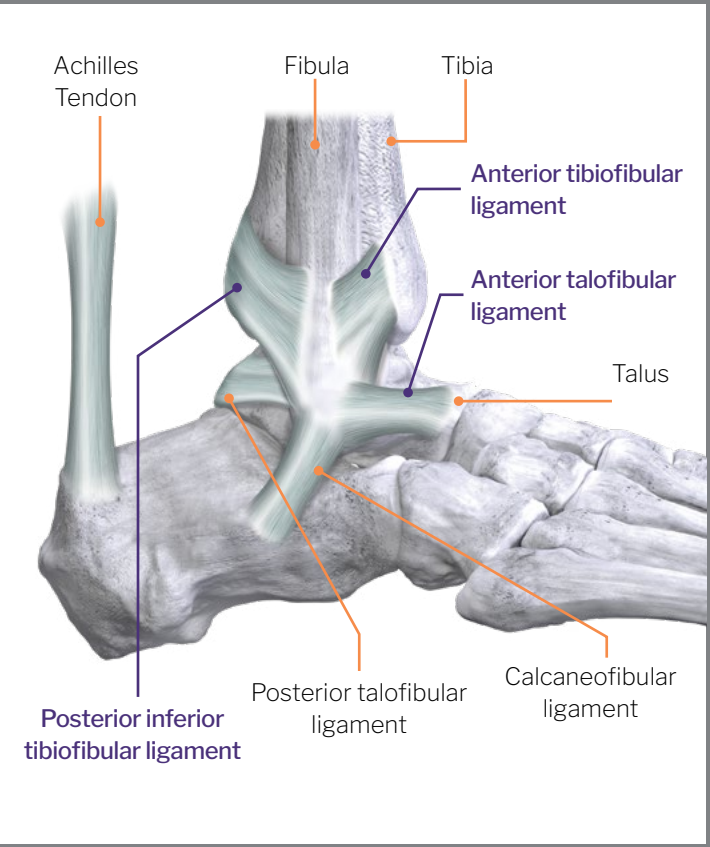
ARC TIBIA OSTEOTOME – TIBIAL PLANER

- Utilizing the custom ARC Tibia Osteotome [P10-901-OS01], align the leading edge against the ruffled cortical surface of the tibia ensuring the osteotome is parallel.
- Gently tap the anterior aspect of the osteotome to disengage the resected tibial bone, pulling distally using two hands while maintaining parallel alignment.
- Ensure bone is evenly disengaged from medial to lateral and anterior to posterior.

CAUTION:
DO NOT lever the osteotome proximally against the intact tibia to avoid causing any unwanted defects to the anterior cortex.

TIBIAL BONE FRAGMENT REMOVAL

SURGICAL NOTE: TIBIAL BONE FRAGMENT REMOVAL



Once the appropriate tibiofibular ligaments have been completely released, retrieve the curved curette and Kocher forcep. Insert the curved curette lengthwise between the tibia and talus such that the curved portion is parallel to the cut surface of the tibia and talus. Once the curved curette has passed beyond the bone, rotate the curved curette 90^0 pointing superiorly behind the tibia fragment.

Retrieve the Kocher forcep. Insert one side of the Kocher forcep between the tibia and talar cut surfaces and the second side into the tibia cut surface. Ensure that the posterior aspect of the bone is grasped by the Kocher forcep. Using the non-dominant hand, place counter pressure on the central aspect of the lower leg. Using the dominant hand, grip the Kocher forcep and curette. Pull the Kocher forcep and curette together directly anteriorly to retrieve the tibia bone fragment from the tibiotalar joint.

TIP: Utilize the Ø6 mm curved osteotome [P99-150-1340] to release the Anterior Inferior Tibiofibular Ligament (AITFL), the Interosseous Ligament (IOL) and Posterior Inferior Tibiofibular Ligament (PITFL).

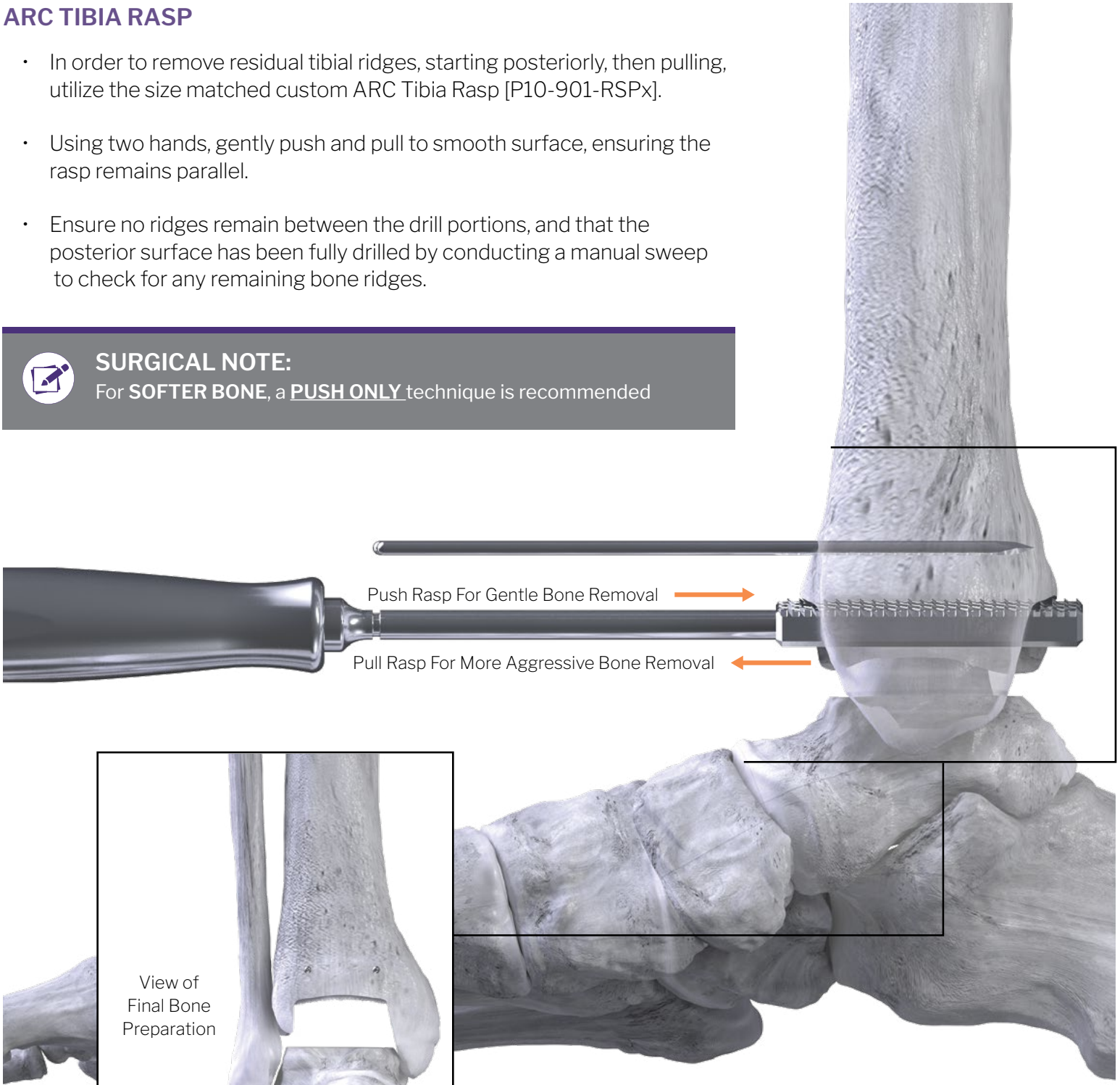
TIP: Curved osteotome should only be utilized laterally to release ligaments. Do not lever against bone to avoid damaging the shoulder of the tibial resection.

ARC TIBIA BONE PREPARATION

ARC TIBIA RASP

- In order to remove residual tibial ridges, starting posteriorly, then pulling, utilize the size matched custom ARC Tibia Rasp [P10-901-RSPx].
- Using two hands, gently push and pull to smooth surface, ensuring the rasp remains parallel.
- Ensure no ridges remain between the drill portions, and that the posterior surface has been fully drilled by conducting a manual sweep to check for any remaining bone ridges.

SURGICAL NOTE:
For **SOFTER BONE**, a **PUSH ONLY** technique is recommended



SURGICAL NOTE:
Medial-lateral surfaces may need to be refined by utilizing the Gold Rasp [P99-150-0105].

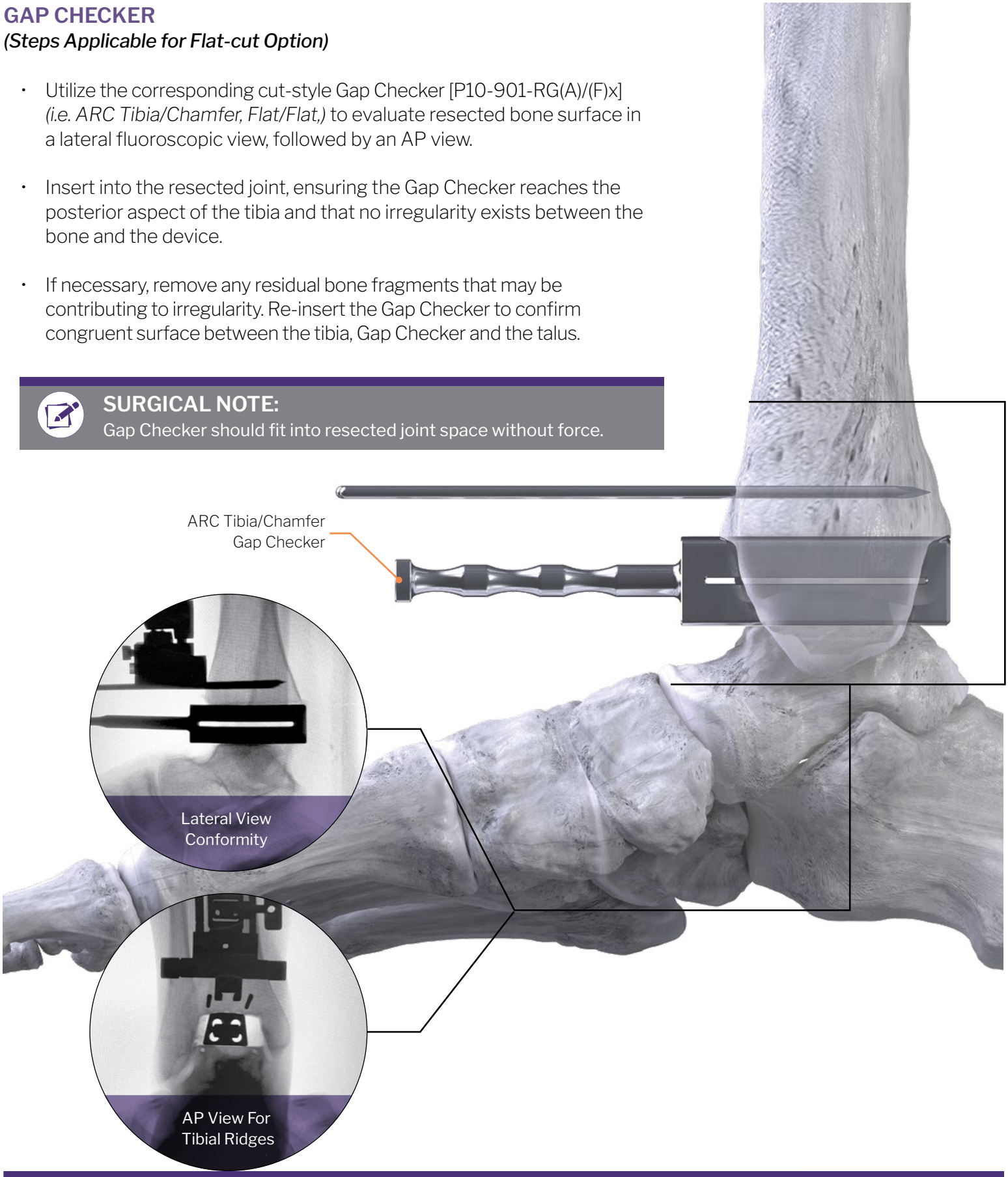
ARC TIBIA™- BONE PREPARATION - DIAGNOSTIC EVALUATION

GAP CHECKER

(Steps Applicable for Flat-cut Option)

- Utilize the corresponding cut-style Gap Checker [P10-901-RG(A)/(F)x] *(i.e. ARC Tibia/Chamfer, Flat/Flat,)* to evaluate resected bone surface in a lateral fluoroscopic view, followed by an AP view.
- Insert into the resected joint, ensuring the Gap Checker reaches the posterior aspect of the tibia and that no irregularity exists between the bone and the device.
- If necessary, remove any residual bone fragments that may be contributing to irregularity. Re-insert the Gap Checker to confirm congruent surface between the tibia, Gap Checker and the talus.

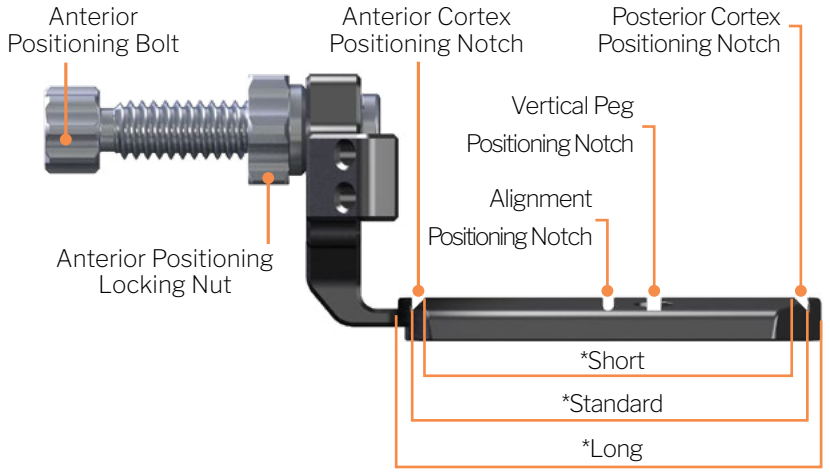
SURGICAL NOTE:
Gap Checker should fit into resected joint space without force.

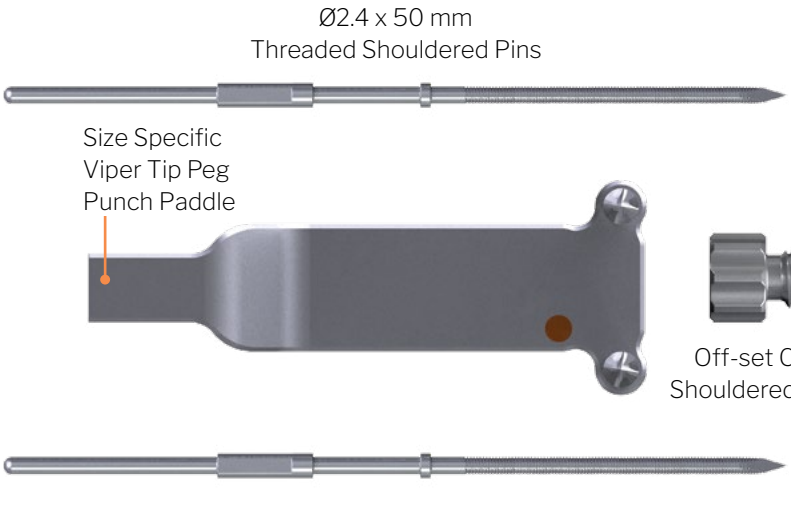


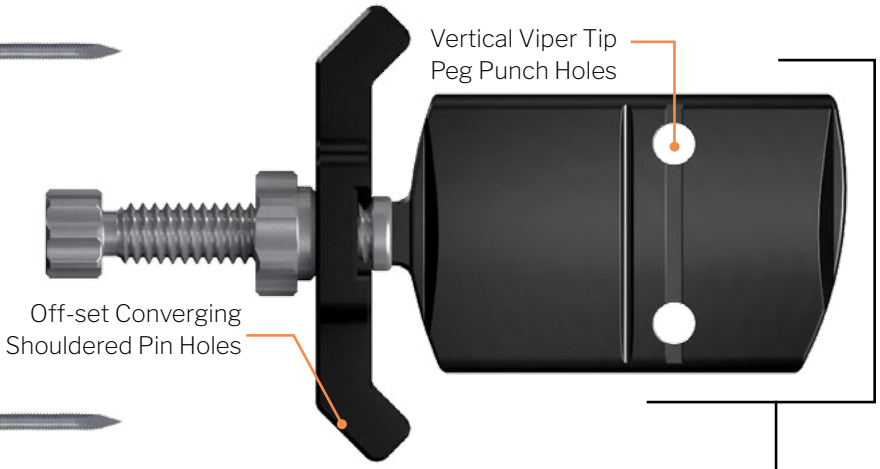
TIBIAL TRIALING: BACK-TABLE

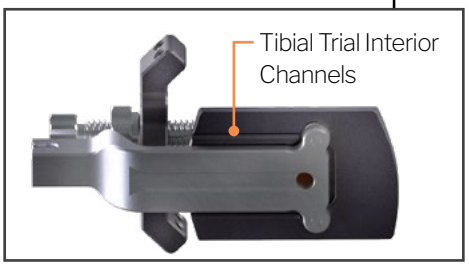
POSITIONING GUIDANCE

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.



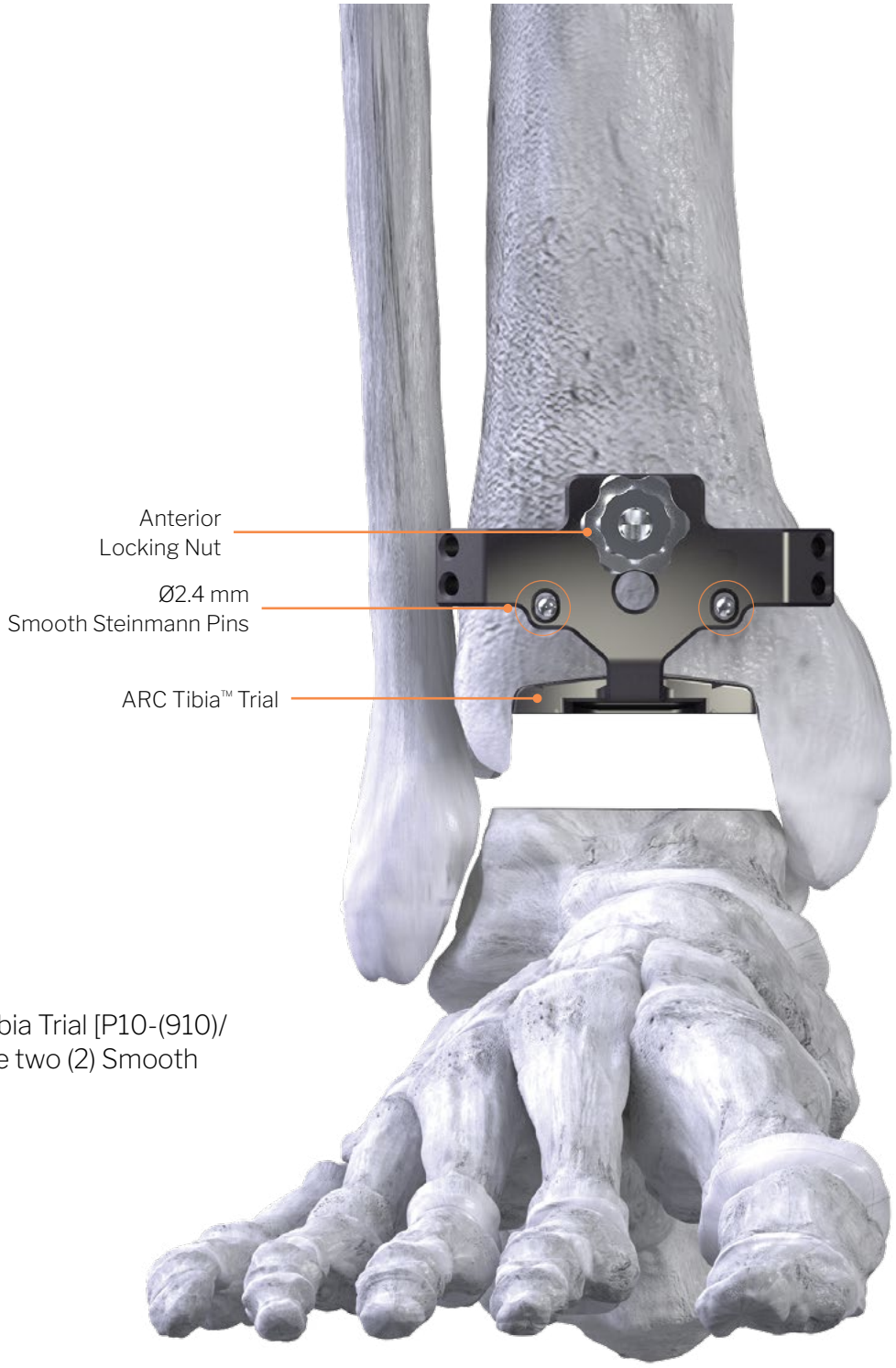






Instrumentation not to scale

TIBIAL TRIALING



TIBIAL TRIAL POSITIONING

(Steps Applicable for Flat-cut Option)

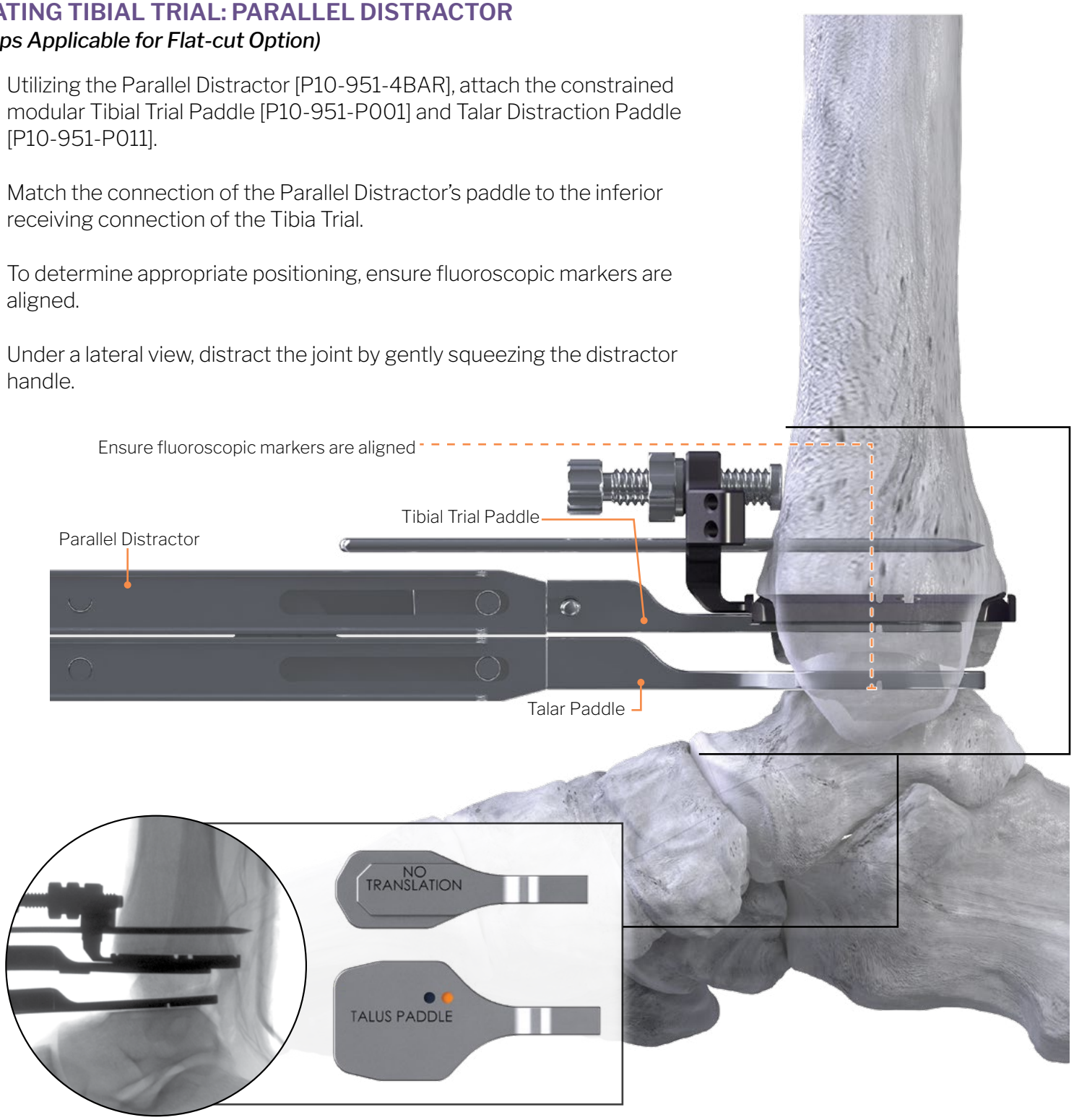
- Utilizing the size matched ARC Tibia Trial [P10-(910)/(911)-TBxx], by hand, slide over the two (2) Smooth Steinmann Pins already in place.

TIBIAL TRIALING

SEATING TIBIAL TRIAL: PARALLEL DISTRACTOR

(Steps Applicable for Flat-cut Option)

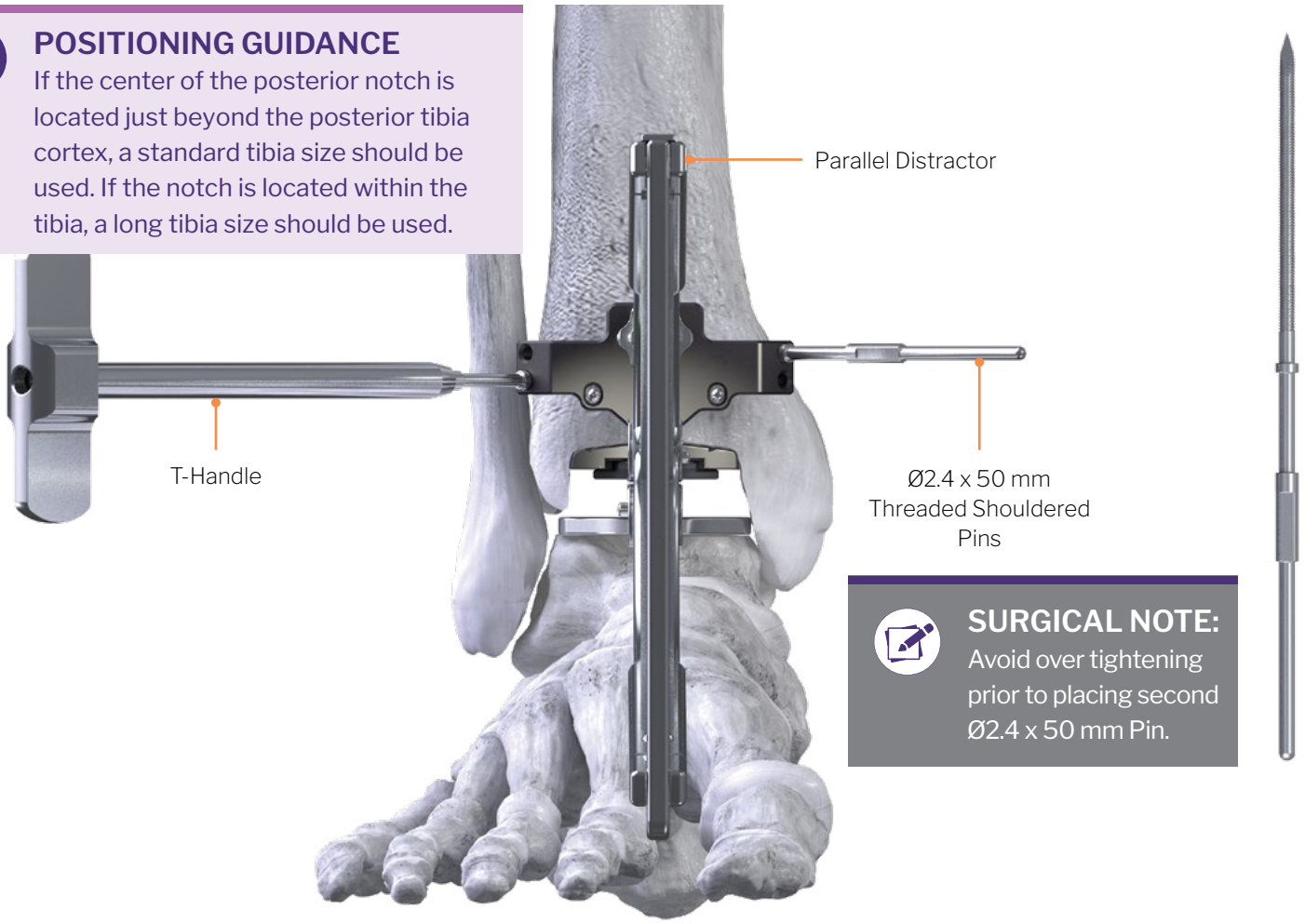
- Utilizing the Parallel Distractor [P10-951-4BAR], attach the constrained modular Tibial Trial Paddle [P10-951-P001] and Talar Distraction Paddle [P10-951-P011].
- Match the connection of the Parallel Distractor's paddle to the inferior receiving connection of the Tibia Trial.
- To determine appropriate positioning, ensure fluoroscopic markers are aligned.
- Under a lateral view, distract the joint by gently squeezing the distractor handle.



TIBIAL TRIALING

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:
Avoid over tightening prior to placing second Ø2.4 x 50 mm Pin.

TIBIAL TRIAL – SIZING EVALUATION

- Under a lateral fluoroscopic view determine tibia implant length.
- With the Parallel Distractor loosely retracted in position, fine tune the anterior position of the tibial trial by adjusting the AP positioning bolt.
- Once appropriate positioning has been achieved, secure the Tibial Trial's position by advancing the anterior friction locking nut until flush against trial.

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.

SECURE TIBIAL TRIAL

(Follow Similar Steps for Flat-cut Option)

- 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, utilizing caution to avoid over tightening.
- Remove the Distractor, re-check Tibial Trial position under lateral fluoroscopy to confirm position and fit.

TIBIAL VERTICAL PEG PREPARATION

[OPTIONAL] - TIBIAL VERTICAL PEG PREPARATION - PILOT PEG PUNCH

(Steps Applicable for Flat-Cut Option)

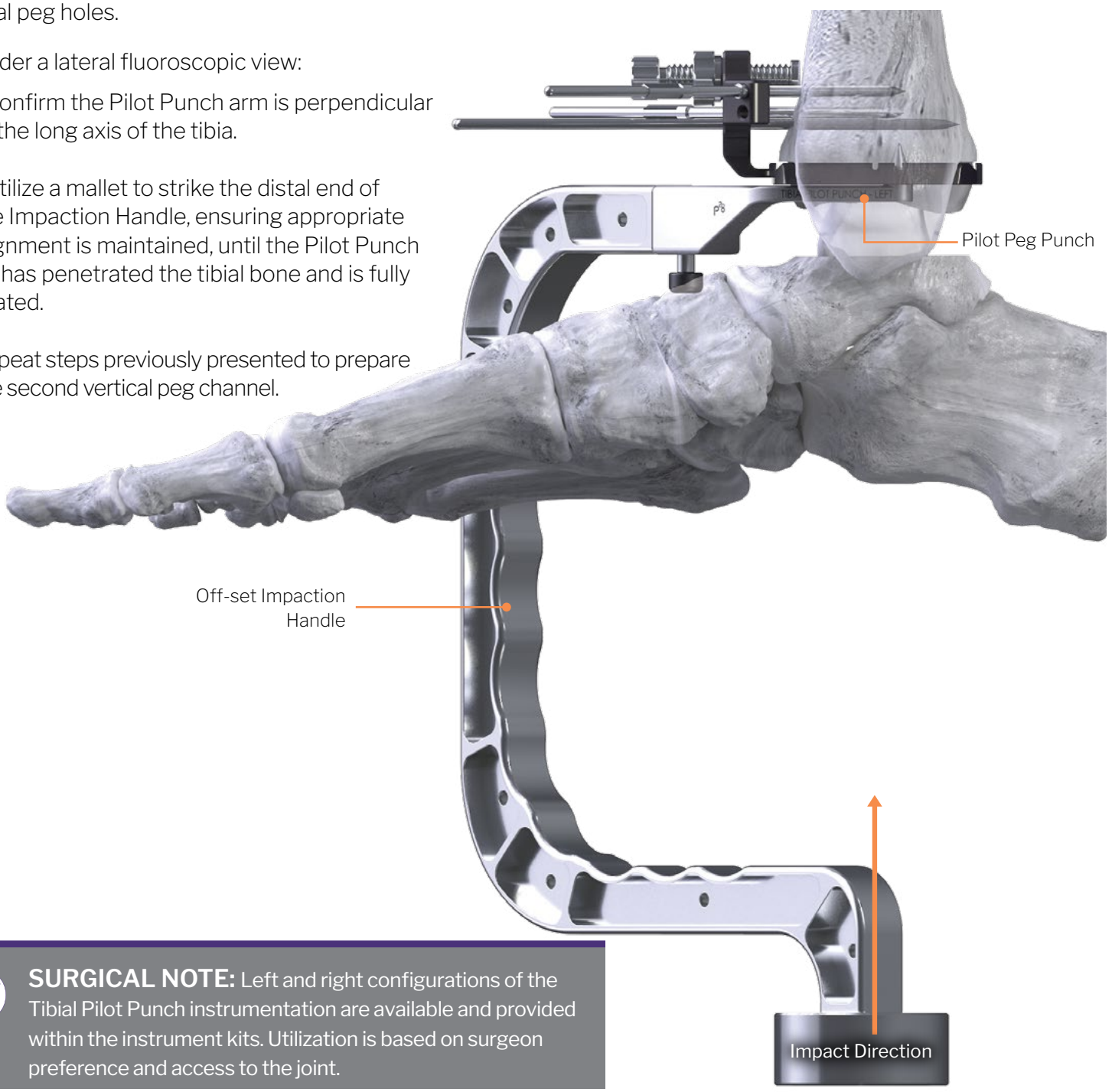
SURGICAL NOTE: The Tibial Pilot Peg Punch was designed to create pilot channels prior to final Vertical Peg Preparation. If the instrument is utilized, subsequent Vertical Peg Preparation steps, reflected on pages 31 - 33, are still required.

- Connect the Tibial Pilot Peg Punch [P10-951-PP(L)/(R)1] to the Off-set Impaction Handle.
- Insert the Pilot Punch by sliding the vertical tip posteriorly until it aligns with either the medial or lateral Tibial Trial peg holes.
- Under a lateral fluoroscopic view:

  - Confirm the Pilot Punch arm is perpendicular to the long axis of the tibia.

  - Utilize a mallet to strike the distal end of the Impaction Handle, ensuring appropriate alignment is maintained, until the Pilot Punch tip has penetrated the tibial bone and is fully seated.

- Repeat steps previously presented to prepare the second vertical peg channel.



SURGICAL NOTE: Left and right configurations of the Tibial Pilot Punch instrumentation are available and provided within the instrument kits. Utilization is based on surgeon preference and access to the joint.

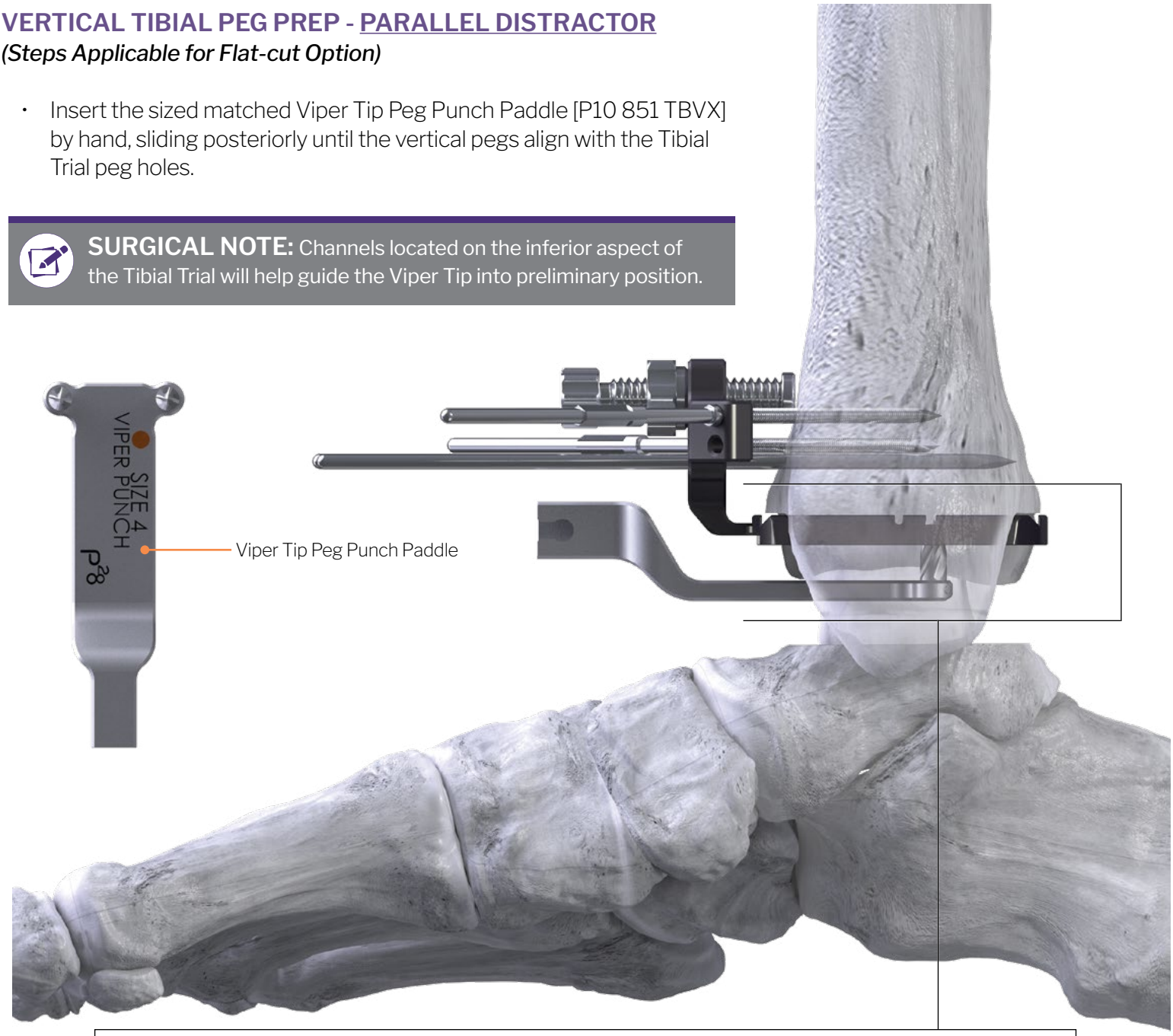
TIBIAL VERTICAL PEG PREPARATION

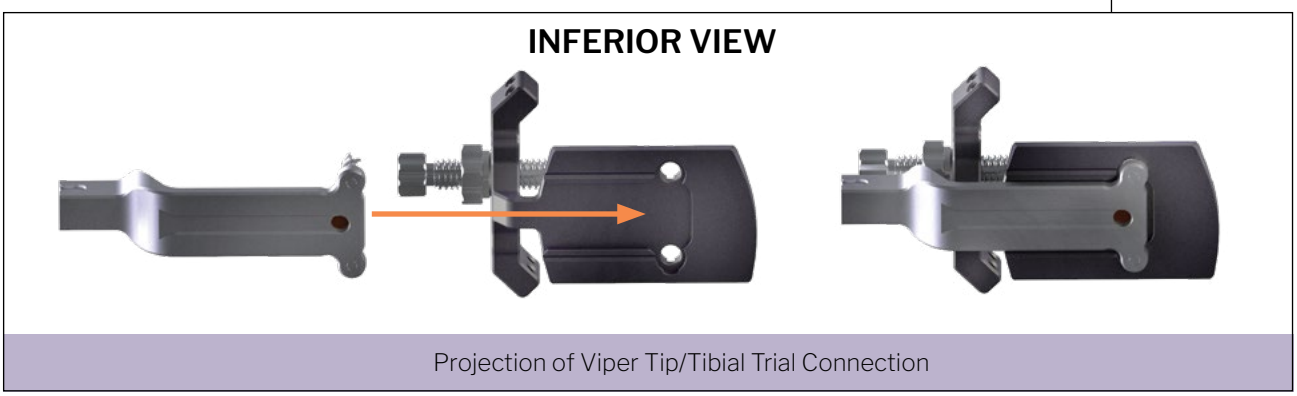
VERTICAL TIBIAL PEG PREP - PARALLEL DISTRACTOR

(Steps Applicable for Flat-cut Option)

- Insert the sized matched Viper Tip Peg Punch Paddle [P10 851 TBVX] by hand, sliding posteriorly until the vertical pegs align with the Tibial Trial peg holes.

SURGICAL NOTE: Channels located on the inferior aspect of the Tibial Trial will help guide the Viper Tip into preliminary position.





Projection of Viper Tip/Tibial Trial Connection

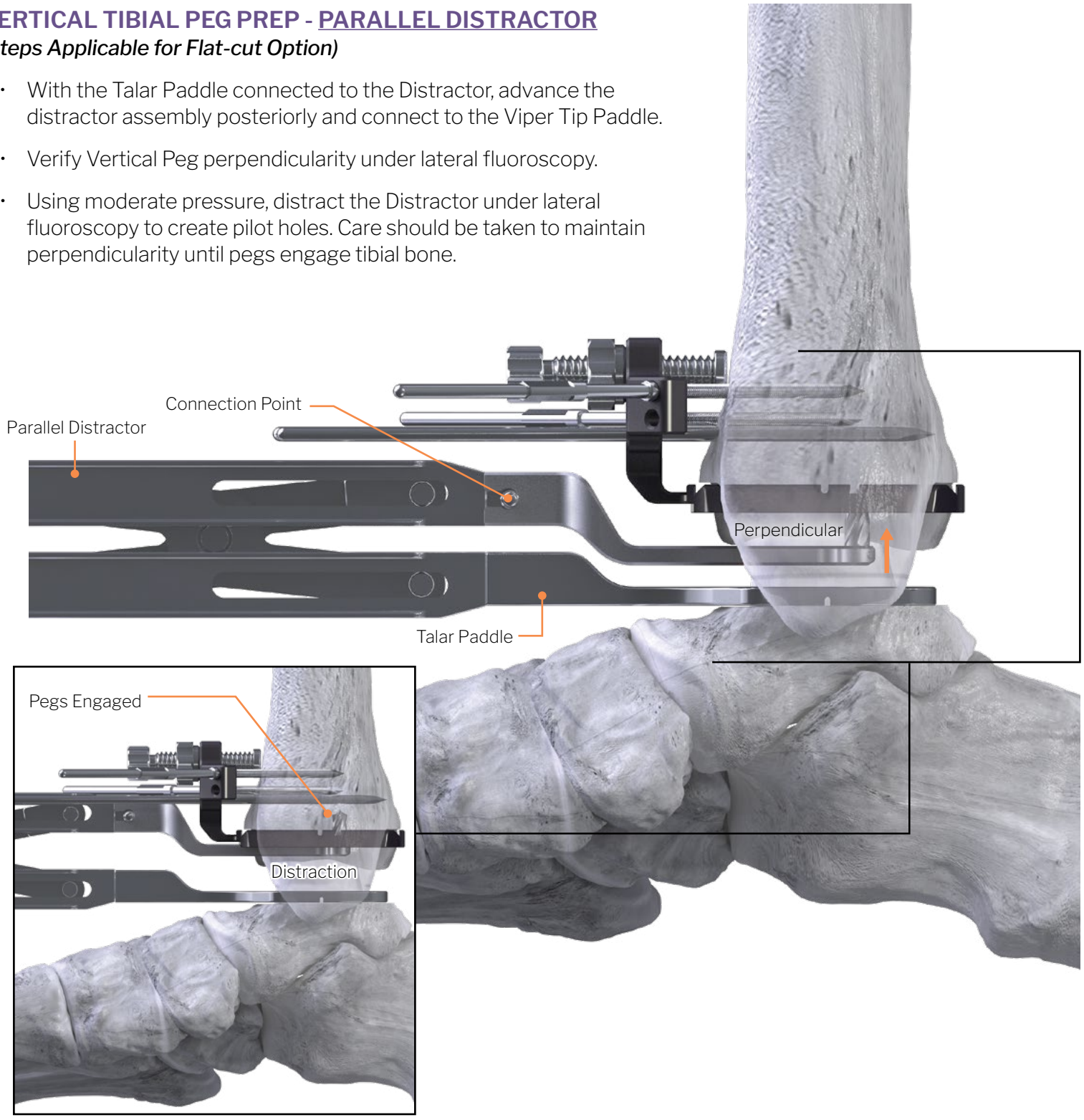
TIBIAL VERTICAL PEG PREPARATION

SURGICAL NOTE: Retrieve the Tibia Impaction Tool [P10-951-TB00] and attach the (right or left) Tibia Impaction Dimpled Tool [P10-951-TB(R)/(L)1] and have this modular construct available.

VERTICAL TIBIAL PEG PREP - PARALLEL DISTRACTOR

(Steps Applicable for Flat-cut Option)

- With the Talar Paddle connected to the Distractor, advance the distractor assembly posteriorly and connect to the Viper Tip Paddle.
- Verify Vertical Peg perpendicularity under lateral fluoroscopy.
- Using moderate pressure, distract the Distractor under lateral fluoroscopy to create pilot holes. Care should be taken to maintain perpendicularity until pegs engage tibial bone.

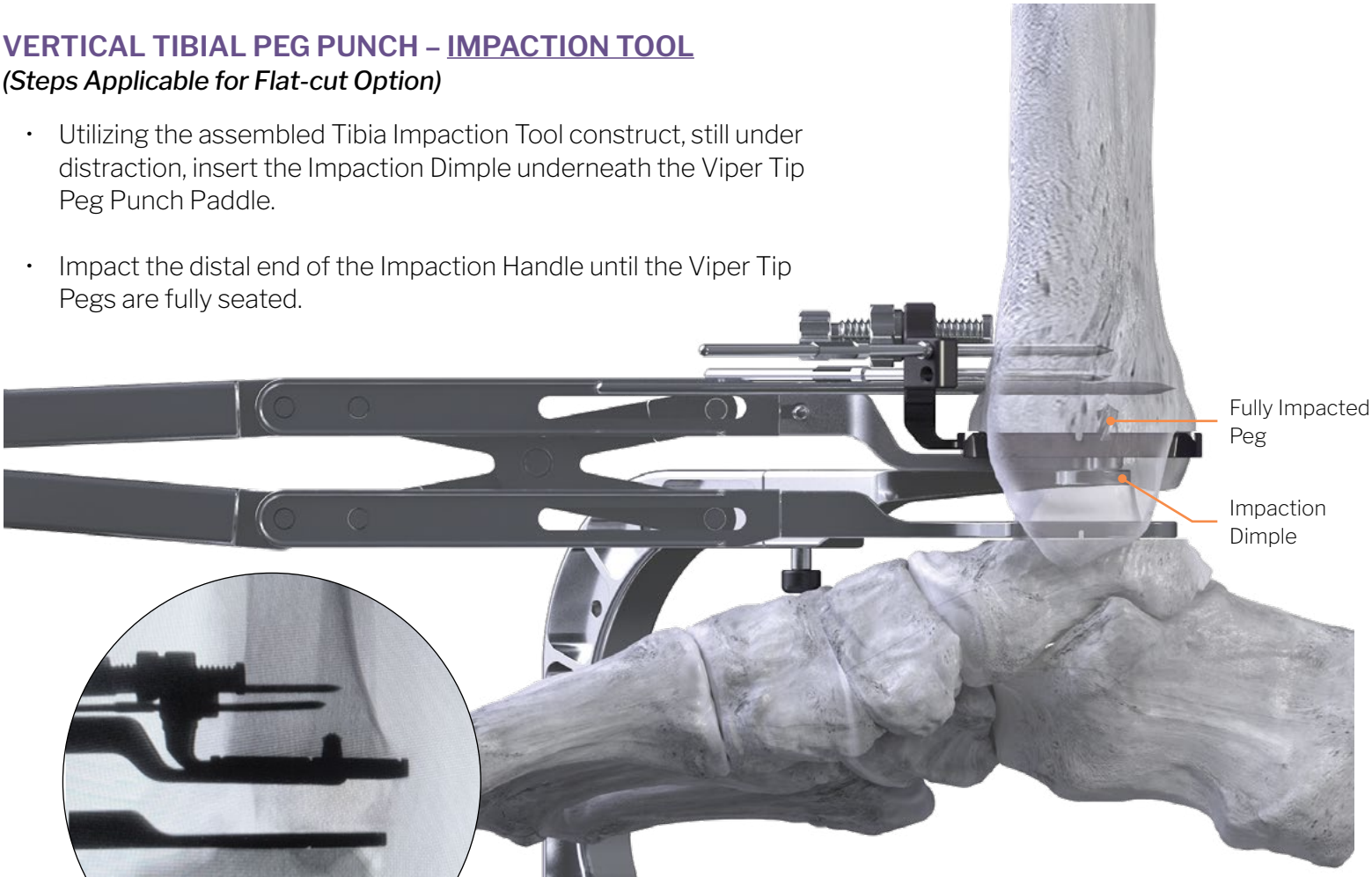


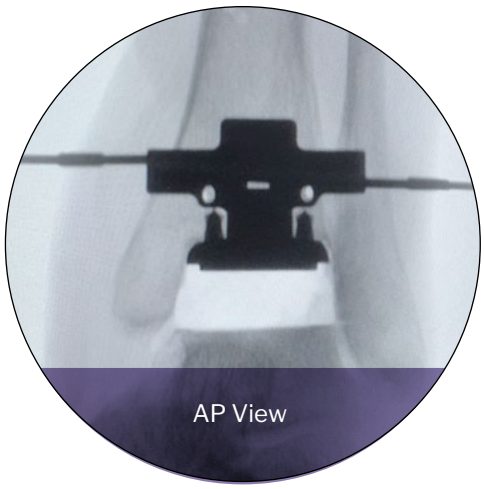
TIBIAL VERTICAL PEG PREPARATION

VERTICAL TIBIAL PEG PUNCH – IMPACTION TOOL

(Steps Applicable for Flat-cut Option)

- Utilizing the assembled Tibia Impaction Tool construct, still under distraction, insert the Impaction Dimple underneath the Viper Tip Peg Punch Paddle.
- Impact the distal end of the Impaction Handle until the Viper Tip Pegs are fully seated.





SURGICAL NOTE: Care should be taken, over impaction of the Pegs should be avoided if possible. 1-2 moderate strikes on the distal end of the impaction handle construct with counter pressure on the limb should be sufficient.

ATTENTION: If Flat-cut was the selected bone preparation option, jump to page 56 to complete Talar Trial Placement and Bone Preparation.

[SUPPLEMENTAL RE-PUNCH:] TIBIAL VERTICAL PEG PREPARATION - OFFSET PEG PUNCH

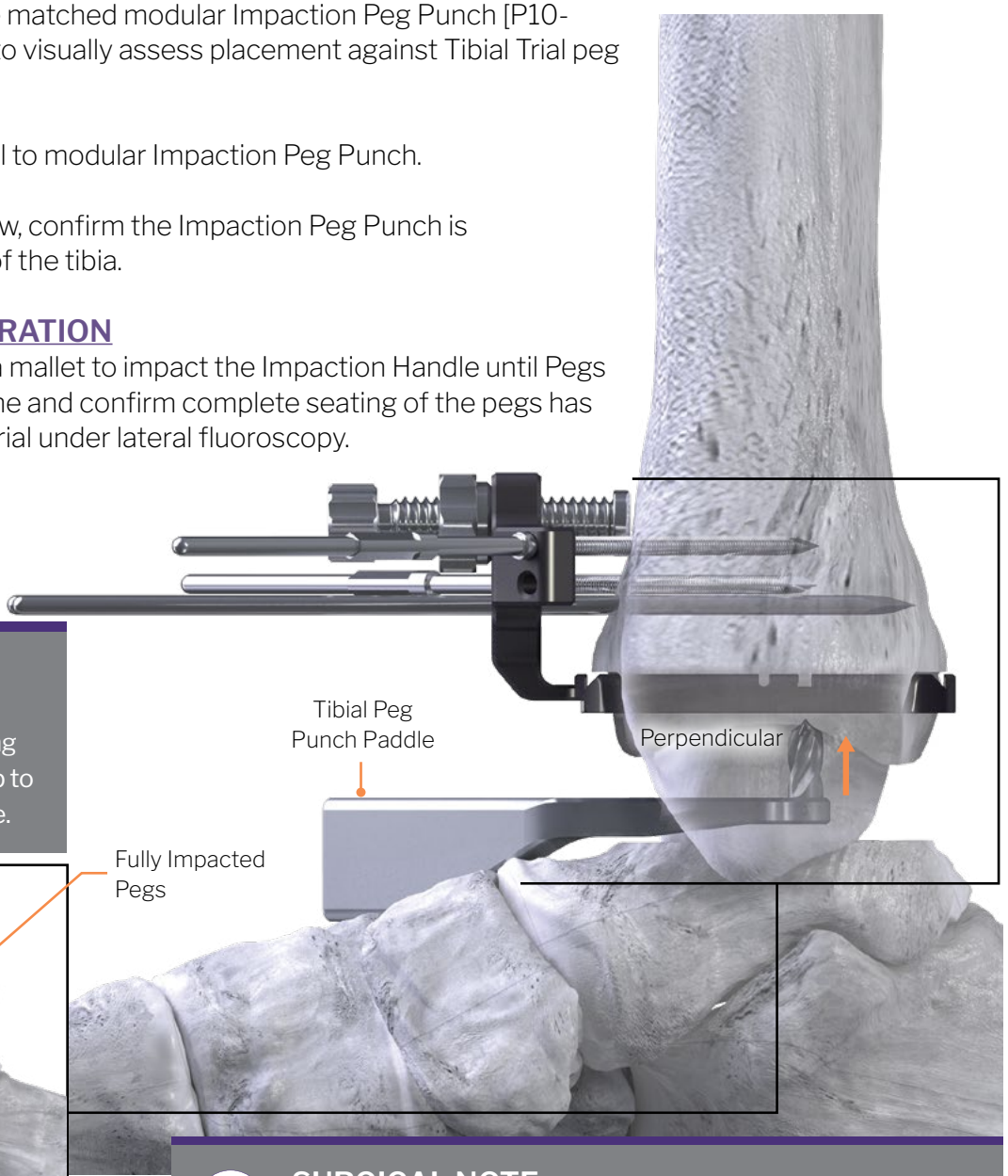
VERTICAL TIBIAL PEG PREPARATION

(Steps Applicable for Flat-cut Option)

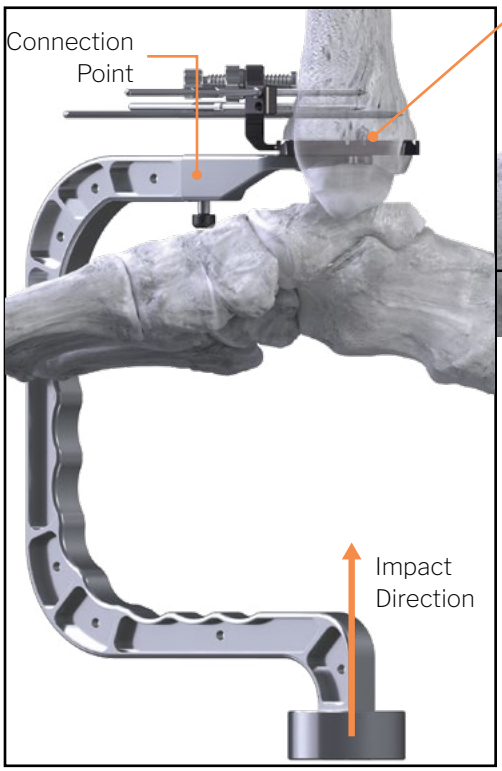
- Utilizing the corresponding size matched modular Impaction Peg Punch [P10-851-TP(R)/(L)x], insert by hand to visually assess placement against Tibial Trial peg holes.
- Connect Impaction Handle Tool to modular Impaction Peg Punch.
- Under a lateral fluoroscopic view, confirm the Impaction Peg Punch is perpendicular to the long axis of the tibia.

VERTICAL TIBIAL PEG PREPARATION

- Under lateral fluoroscopy, use a mallet to impact the Impaction Handle until Pegs are fully engaged with tibial bone and confirm complete seating of the pegs has occurred relative to the Tibial Trial under lateral fluoroscopy.



SURGICAL NOTE:
If hard sclerotic bone is encountered, re-punching the vertical pegs will help to clear any remaining bone.

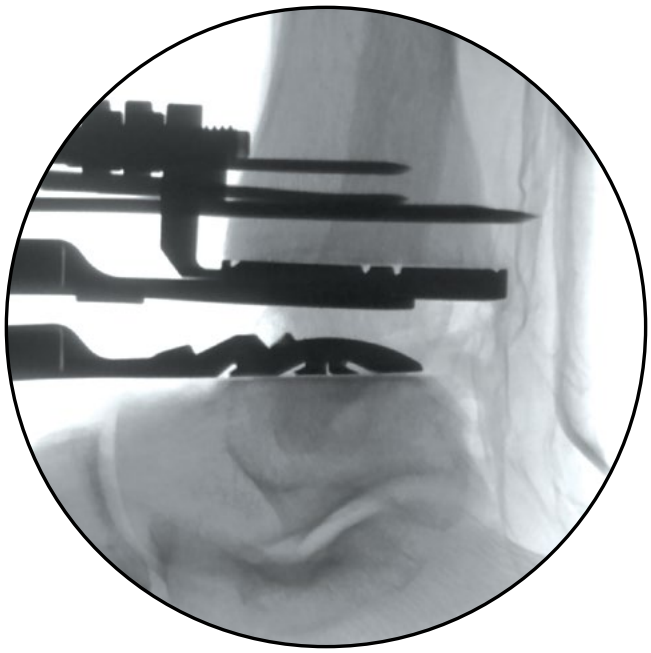


SURGICAL NOTE:
Care should be taken, such that over impaction of the Peg Punch is avoided. 1-2 moderate strikes on the distal end of the impaction handle construct with counter pressure on the limb should be sufficient.

SURGICAL NOTE:
Left and right configurations of the Tibial Peg Punch instrumentation are available and provided within the APEX™ System instrument kits.

CHAMFER-CUT: TALAR BONE PREPARATION

CHAMFER-CUT: TALAR RESECTION GUIDE POSITIONING



TALAR RESECTION GUIDE - SIZING ASSESSMENT

- By hand, initially place the appropriately sized Talar Trial Sizing Resection Guide [P10-944-LLxx] into the joint and evaluate M/L talar coverage visually.
- Ensure coverage of the medial and lateral aspect of the initial chamfer-cut, verifying that the Guide does not impinge on the M/L gutters.

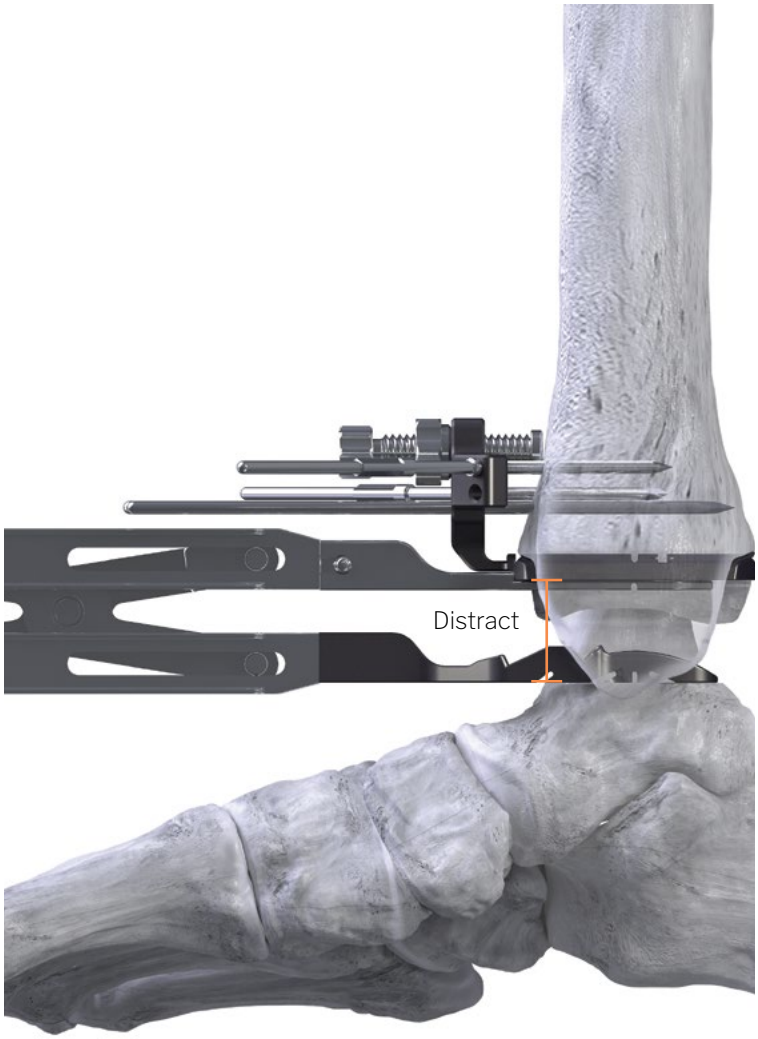
SURGICAL NOTE:
As it relates to the Tibial Trial size, the selected Talar Guide can be sized up by 1 or down without restriction to achieve appropriate coverage. If M/L coverage is appropriate, but too large in A/P, downsizing is recommended.

Plantarflexing the tibiotalar joint to achieve appropriate visualization before setting in place is acceptable.

FLUOROSCOPIC EVALUATION

- Under lateral fluoroscopy, confirm the Resection Guide size relative to the initial dorsal chamfer-cut.
- Ensure the Resection Guide:
  - Matches the fluoroscopic talar curvature adequately,
  - Vertical position marker on Talar Resection Guide can be used to align with the lateral process.

CHAMFER-CUT: TALAR RESECTION GUIDE POSITIONING



TALAR RESECTION GUIDE - POSITIONING

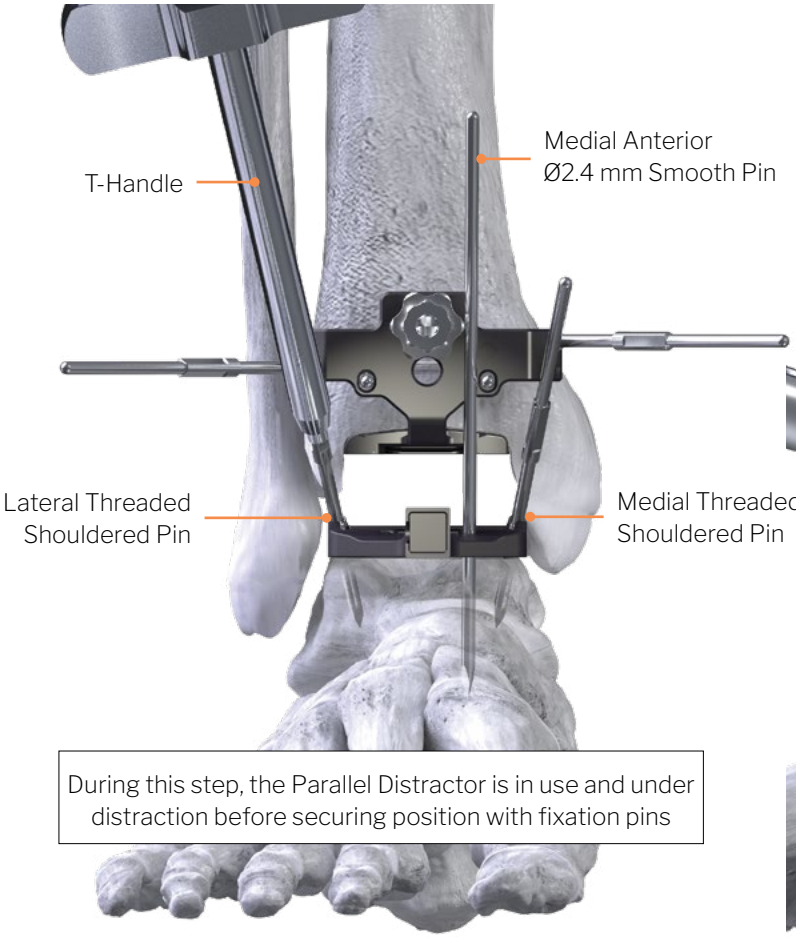
- Utilizing the Distractor, attach the appropriately sized Chamfer Talar Resection Guide and standard Tibial Trial Paddle*.
- Insert the Talar Resection Guide/Tibial Trial Paddle assembly into the resected space, matching the paddle's connection to the inferior aspect of the Tibial Trial and the Resection Guide to the resected talar bone surface.

SURGICAL NOTE:
*Two Tibial Trial Paddle Options Exist:
- One allows for secure fit and no A/P translation [P10-951-P001]
- Second allows for A/P translation [P10-951-P002]

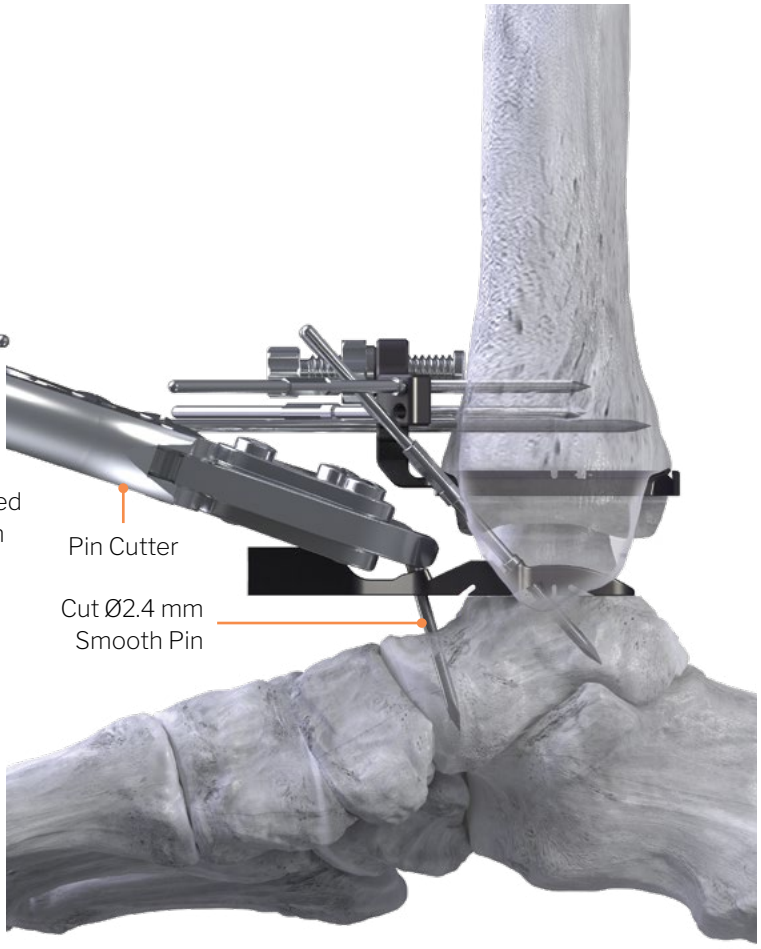
TALAR RESECTION GUIDE – PLACEMENT

- Under a lateral fluoroscopic view, evaluate and (adjust as necessary):
  - A/P translation
  - Sizing
  - Anticipated resected bone
- Distract the joint by gently squeezing down on the Distractor's Handle, applying even pressure to the tibiotalar cortical surface.
- With the Distractor in place, re-check the Talar Sizing Resection Guide position under a lateral fluoroscopy view to ensure position and fit before setting position with fixation pins.

CHAMFER-CUT: TALAR RESECTION GUIDE PLACEMENT



During this step, the Parallel Distractor is in use and under distraction before securing position with fixation pins



SURGICAL NOTE:
The subsequent pin fixation steps are critical. Care should be taken to establish an appropriate position.

TALAR RESECTION GUIDE - FIXATION

- With the Distractor connected to the Sizing Resection Guide, confirm that a flush contact interface and appropriate positioning have been achieved under a lateral fluoroscopic view.
  - By hand, insert a Ø2.4 mm x 110 mm Smooth Steinmann Pin [P99-160-2411] into the medial anterior pin hole, then secure position under power.
  - By hand, insert a Ø2.4 mm x 25 mm Threaded Shouldered Pin [P10-902-2425] into the medial converging pin hole, then secure position under power, advancing slowly using a ream setting, stopping pin insertion prior to fully seating against the guide.
  - Insert a second Shouldered Pin into the lateral hole of the guide following the method as outlined in the previous step.

TALAR RESECTION GUIDE

- Disconnect the Distractor by holding the release button located on the device and pulling anteriorly.
- Using the supplied Pin Cutters, trim the medial anterior Ø2.4 mm Smooth Steinmann Pins or remove to allow access to resection slots.

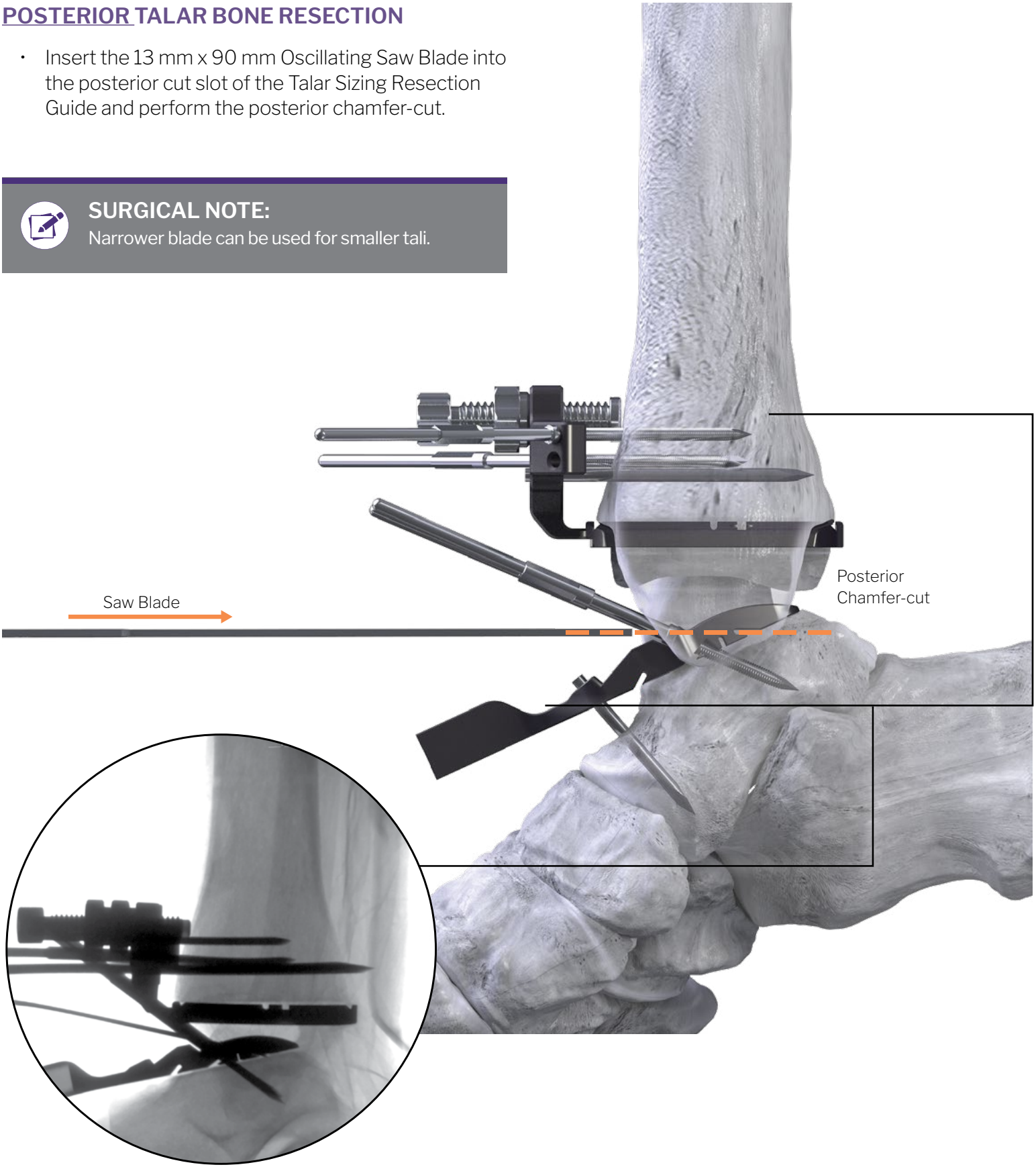
SURGICAL NOTE:
Shouldered pins will be fully seated by hand using the provided T-Handle after the second Ø2.4 mm x 25 mm shouldered pin has been set in place.

CHAMFER-CUT: TALAR BONE RESECTION

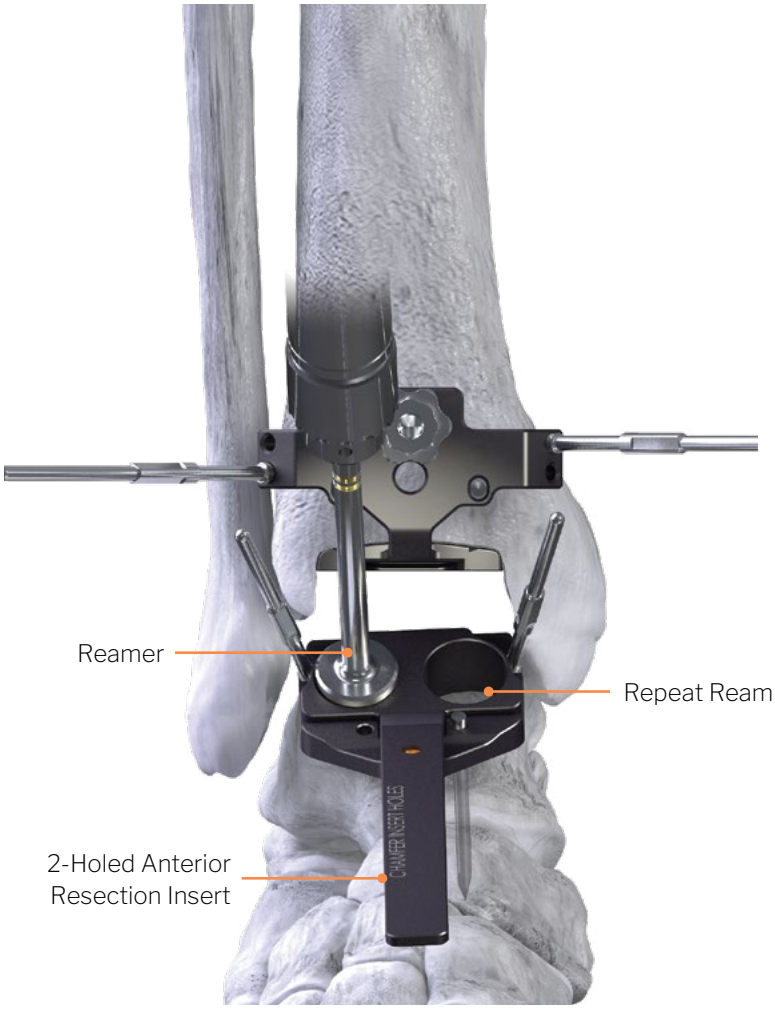
POSTERIOR TALAR BONE RESECTION

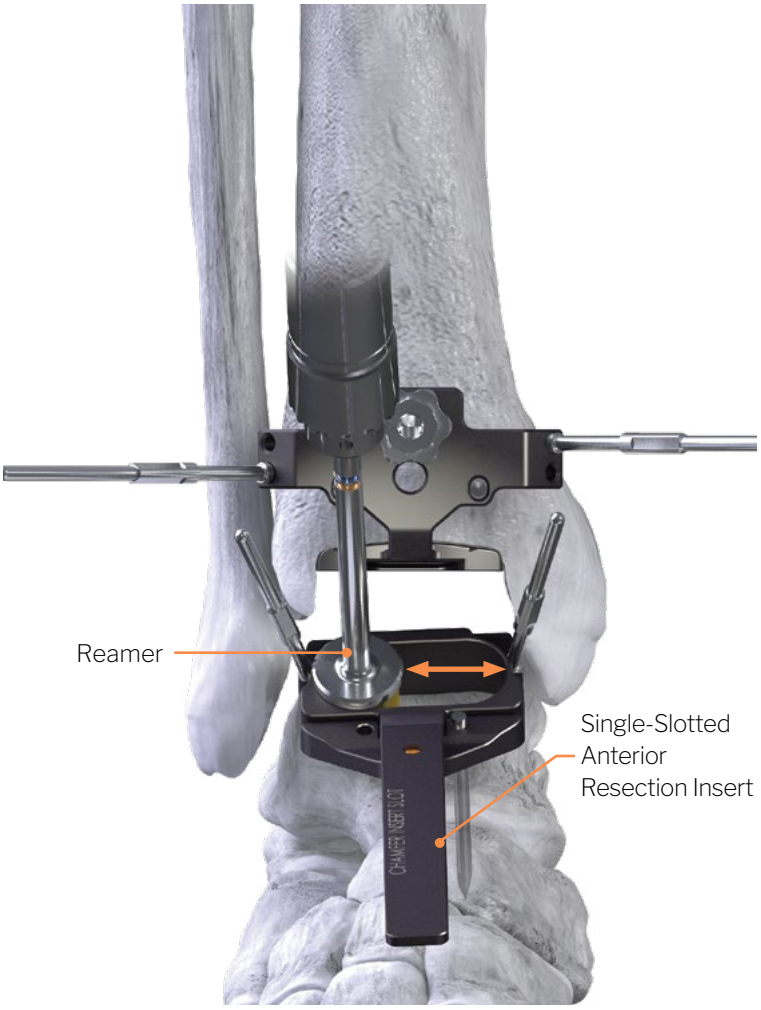
- Insert the 13 mm x 90 mm Oscillating Saw Blade into the posterior cut slot of the Talar Sizing Resection Guide and perform the posterior chamfer-cut.

SURGICAL NOTE:
Narrower blade can be used for smaller tali.



CHAMFER-CUT: TALAR BONE RESECTION





[OPTIONAL] ANTERIOR TALAR BONE RESECTION

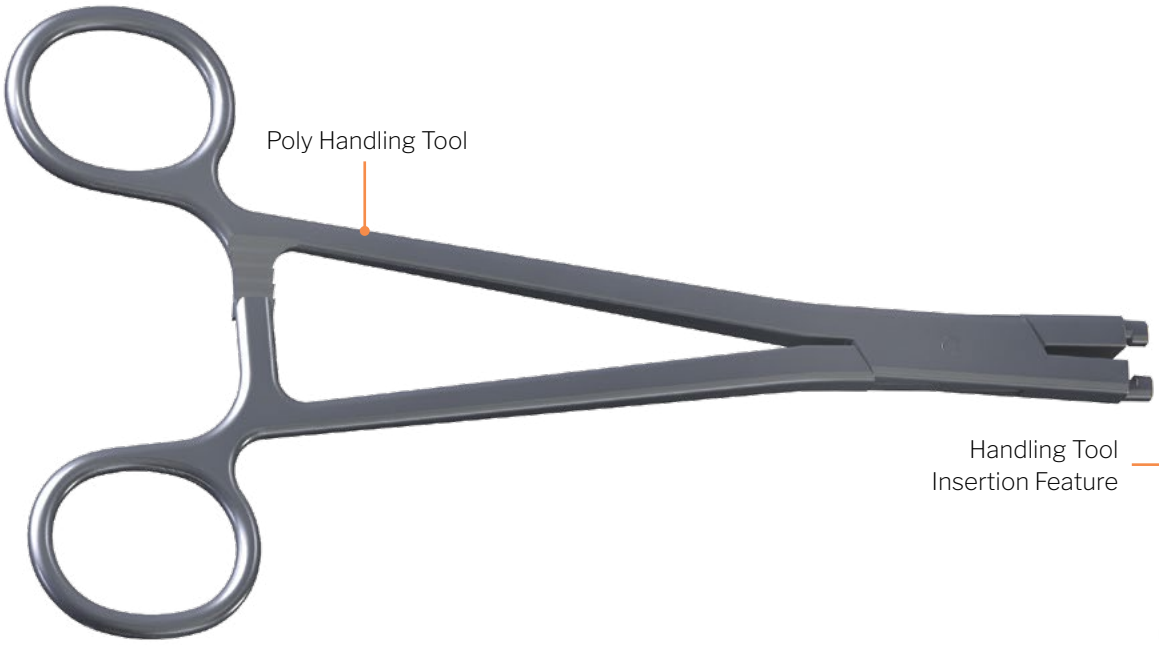
- Utilizing the appropriately sized anterior Chamfer 2-Holed Resection Insert [P10-944-LLxx], place into the anterior window of the Guide.
- Place the corresponding sized gold tipped Reamer [P10-944-xx75] into one of the two anterior holes, holding it perpendicular to the Resection Insert.
- Mill down to collared stop, repeat for second hole.

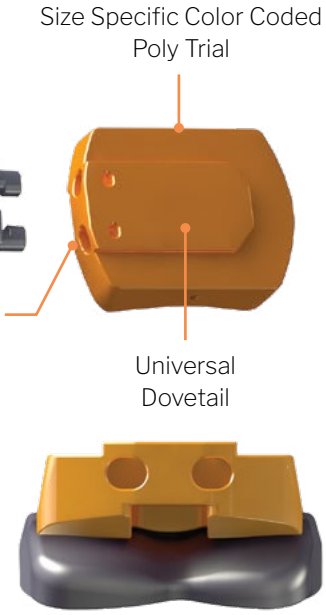
SURGICAL NOTE:
Wait to start the reamer until lightly pressed against the cortical bone.

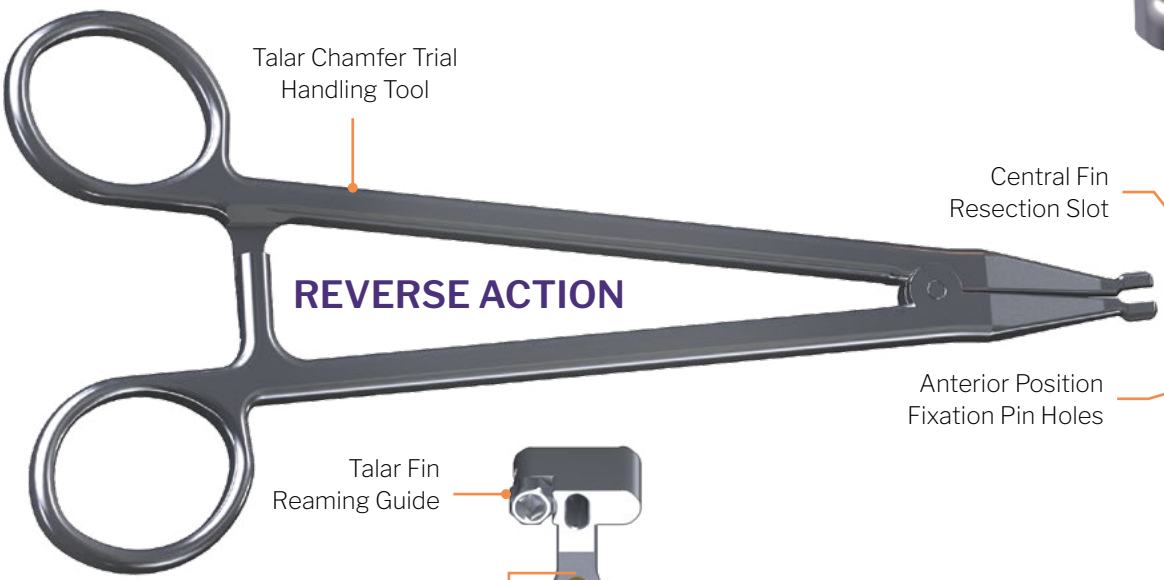
COMPLETE TALAR BONE RESECTION

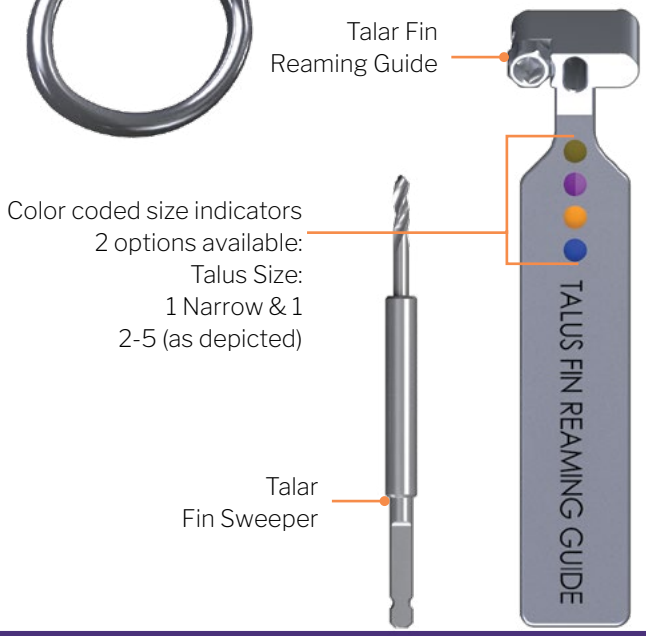
- Replace the 2-Holed Resection Insert with the Single-Slotted Resection Insert [P10-944-LLxx] to connect the anterior chamfer cut.
- Under power, sweep the Reamer from left to right until the bridge between the two reamed holes is resected, then remove the Single-Slotted Resection Insert.
- Remove the three (3) talar pins and complete posterior talar cuts as needed, then remove posterior talar resection.
- Complete anterior chamfer with the provided Square Tip Rongeur [P10-944-STR0].

CHAMFER TALUS & POLY TRIAL PLACEMENT





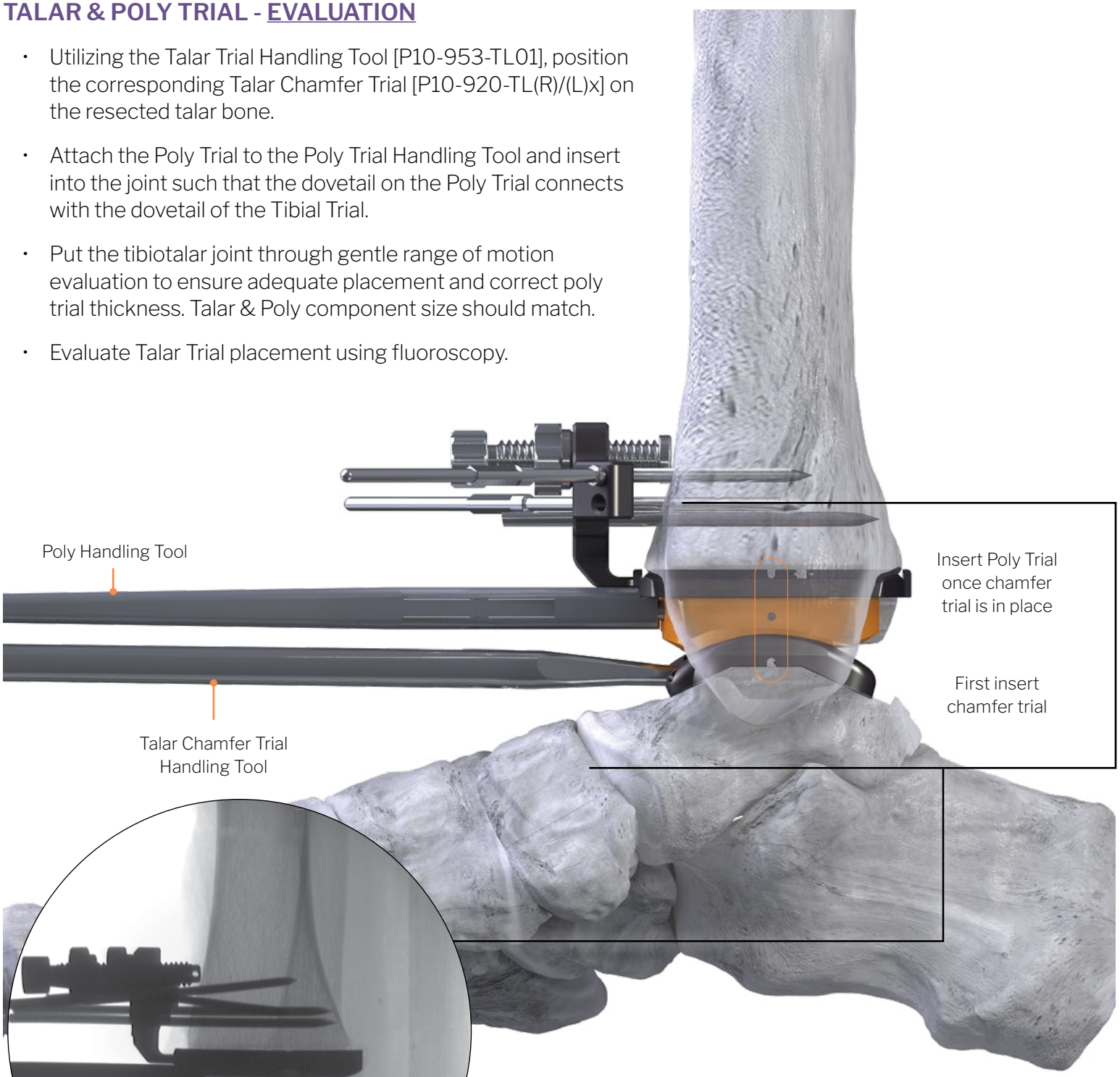




CHAMFER-CUT: TALAR & POLY TRIAL EVALUATION

TALAR & POLY TRIAL - EVALUATION

- Utilizing the Talar Trial Handling Tool [P10-953-TL01], position the corresponding Talar Chamfer Trial [P10-920-TL(R)/(L)x] on the resected talar bone.
- Attach the Poly Trial to the Poly Trial Handling Tool and insert into the joint such that the dovetail on the Poly Trial connects with the dovetail of the Tibial Trial.
- Put the tibiotalar joint through gentle range of motion evaluation to ensure adequate placement and correct poly trial thickness. Talar & Poly component size should match.
- Evaluate Talar Trial placement using fluoroscopy.



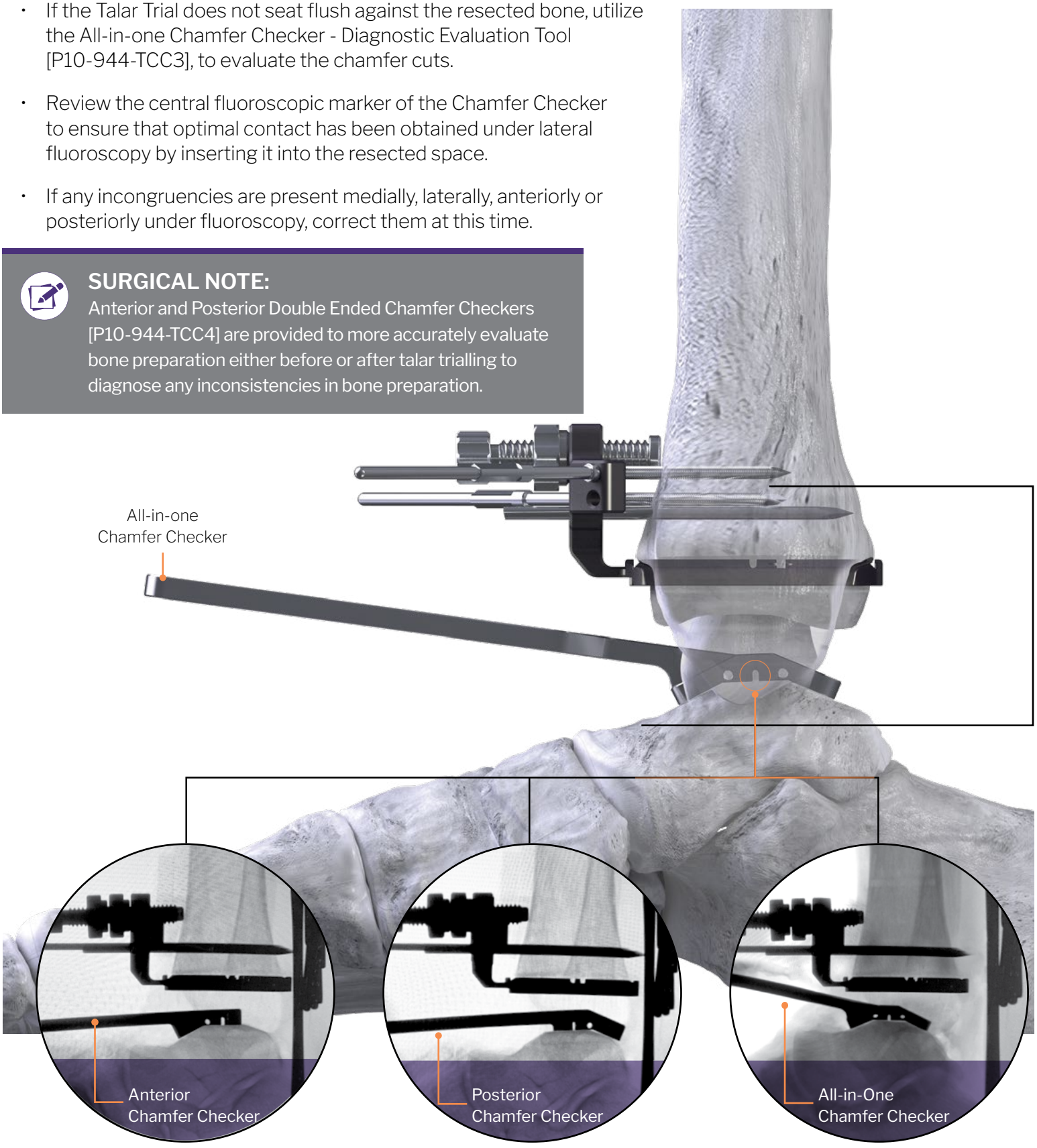
SURGICAL NOTE:
Ensure the fluoroscopic notch on the talar trial is visible on lateral fluoroscopy to ensure an optimal fit. Poly trial is equipped with M/L fluoroscopy markers to help determine fit and placement.

CHAMFER-CUT: TALAR BONE RESECTION - DIAGNOSTIC EVALUATION

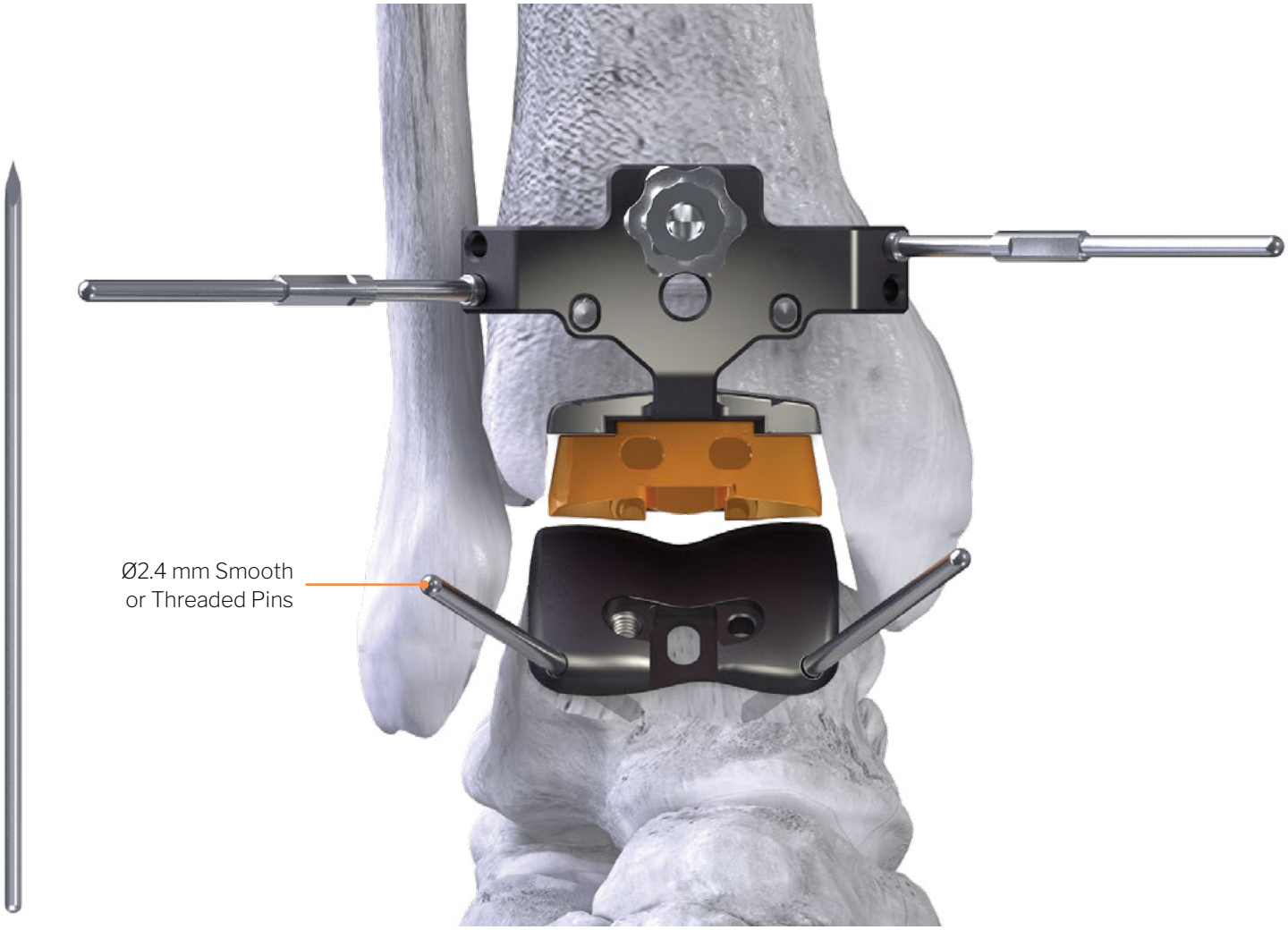
CHAMFER CHECKER

- If the Talar Trial does not seat flush against the resected bone, utilize the All-in-one Chamfer Checker - Diagnostic Evaluation Tool [P10-944-TCC3], to evaluate the chamfer cuts.
- Review the central fluoroscopic marker of the Chamfer Checker to ensure that optimal contact has been obtained under lateral fluoroscopy by inserting it into the resected space.
- If any incongruencies are present medially, laterally, anteriorly or posteriorly under fluoroscopy, correct them at this time.

SURGICAL NOTE:
Anterior and Posterior Double Ended Chamfer Checkers [P10-944-TCC4] are provided to more accurately evaluate bone preparation either before or after talar trialling to diagnose any inconsistencies in bone preparation.



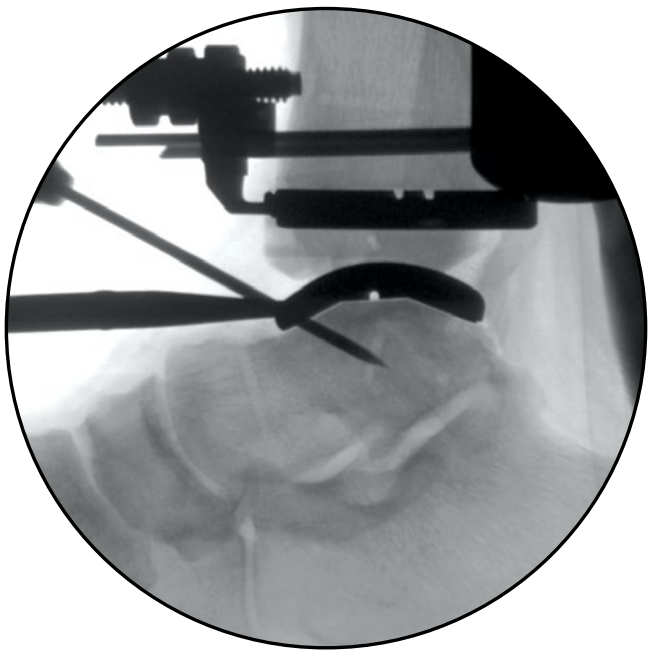
CHAMFER-CUT: TALAR TRIAL FIXATION



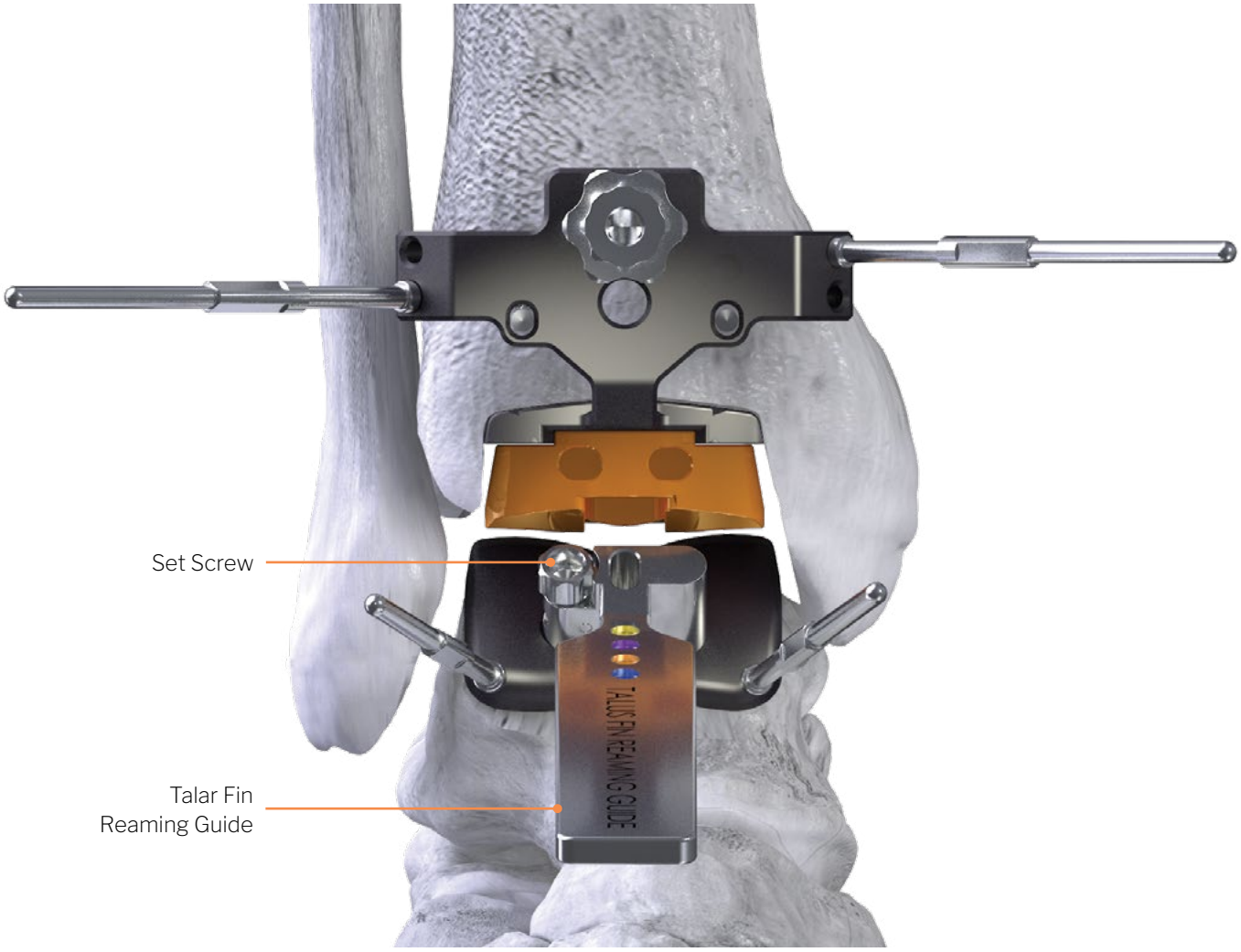
SECURE TRIAL - PIN PLACEMENT

- By hand, place a Ø2.4 mm x 110 mm Smooth Steinmann Pin or Ø2.4 mm x 25 mm Threaded Shouldered Pin into the medial anterior converging pin hole of the Talar Trial, then advance under power using a slight pecking technique, taking care not to penetrate the subtalar joint.

- By hand, place a second corresponding Shouldered or Smooth Pin into the lateral anterior pin hole of the Talar Trial, then advance under power to secure Trial in place.



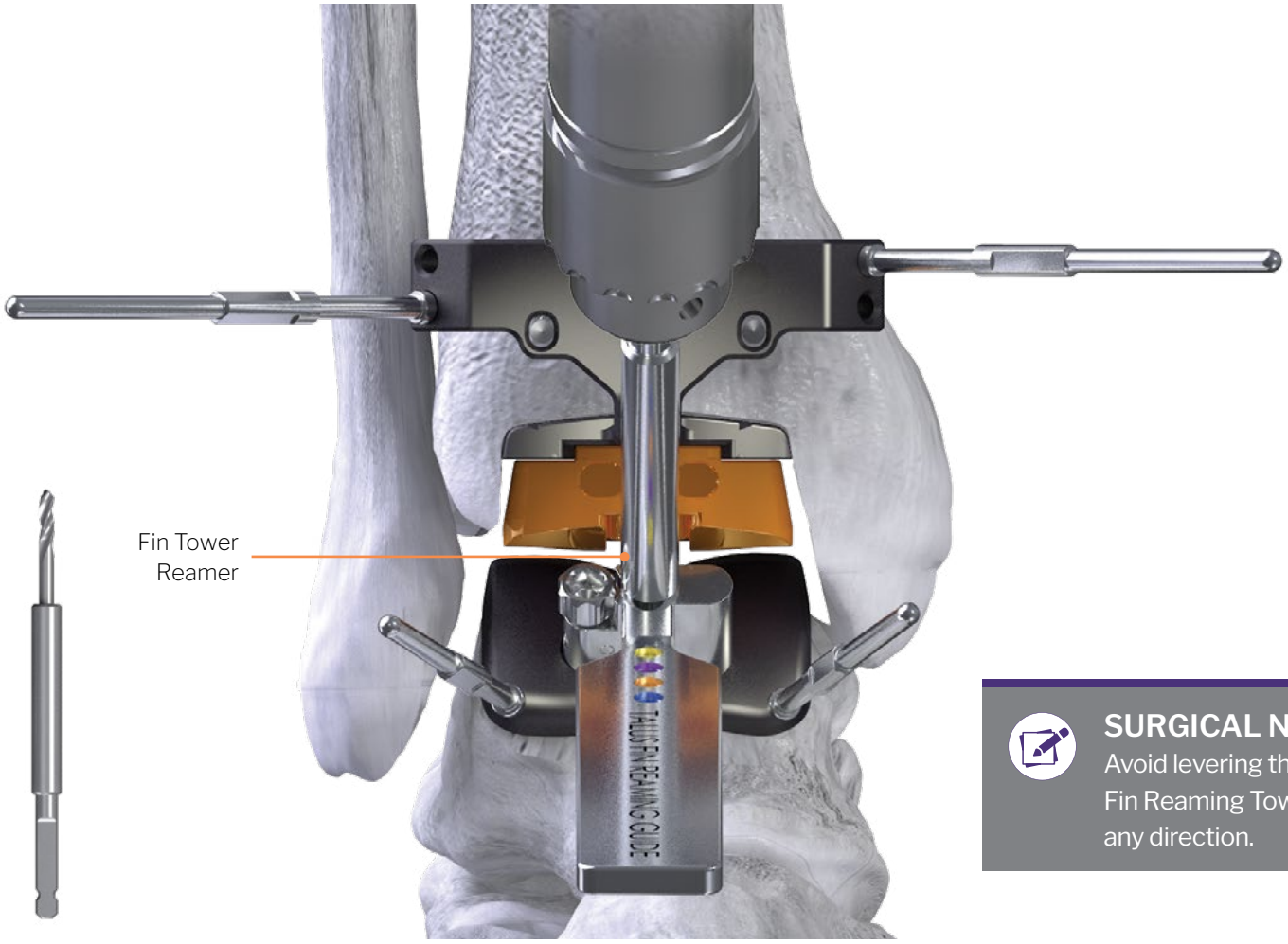
CHAMFER-CUT: TALAR TRIAL PREPARATION



SECURE TRIAL - PIN PLACEMENT

- In plantar flexion, attach the appropriately sized Talar Reaming Tower [P10-920-TFTx] to the anterior aspect of the Trial by locking set screw using the provided Hex Driver.

CHAMFER-CUT: TALAR TRIAL PREPARATION



SURGICAL NOTE:
Avoid levering the Talar Fin Reaming Tower in any direction.

TALAR FIN - PREPARATION

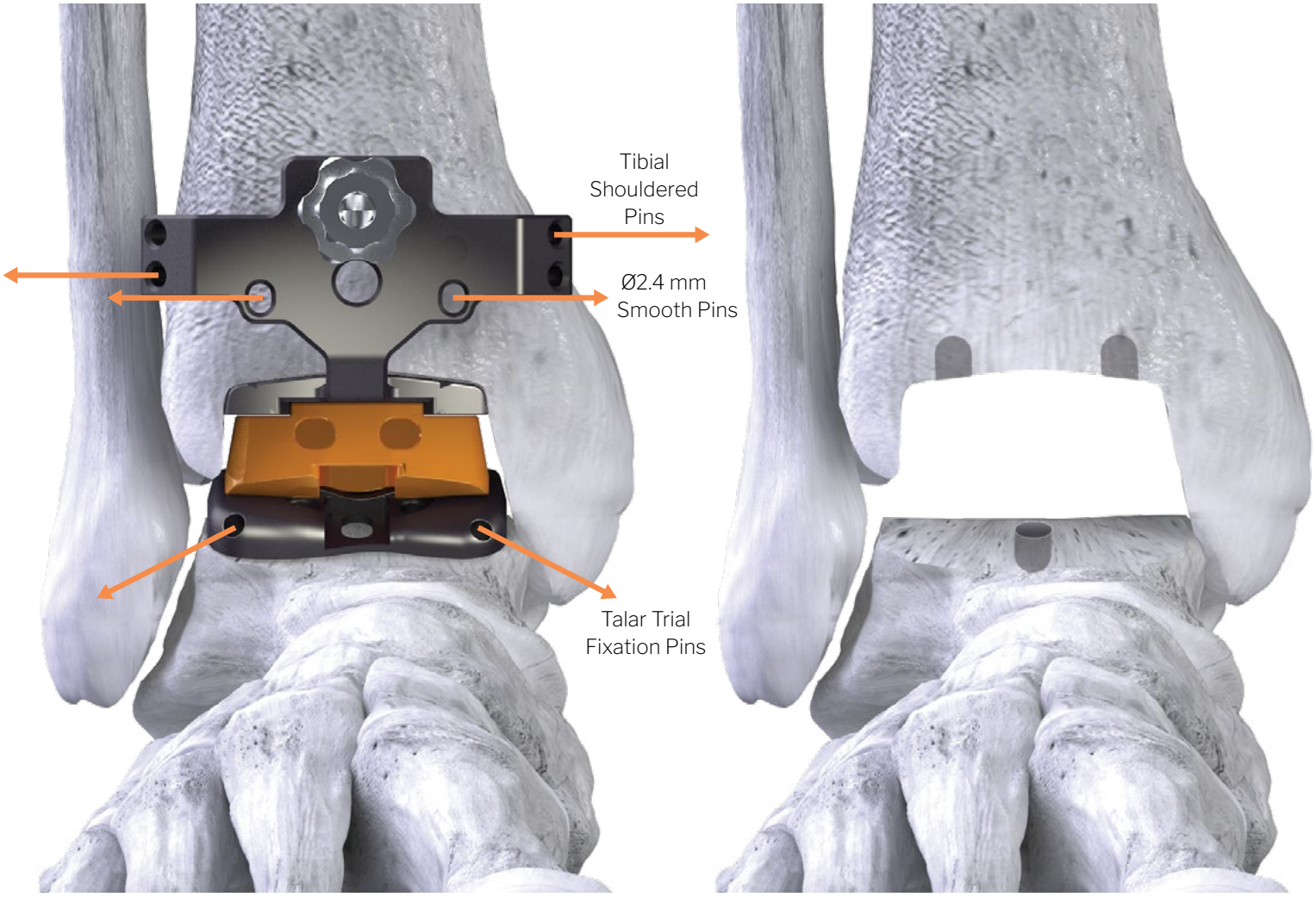
- In plantar flexion, under power, utilize the Talar Fin Reamer [P10-920-TLRM] to punch superiorly and inferiorly.
- Translate the Fin Reamer between the superior and inferior holes while maintaining flush surface contact with Reaming Tower.

TALAR FIN – COMPONENT REMOVAL

- Remove the Fin Reamer.
- Remove the Reaming Tower by unlocking set screw.

SURGICAL NOTE:
In some cases, the Tibial Trial might need to be removed to access the Talar Fin Tower with drill.

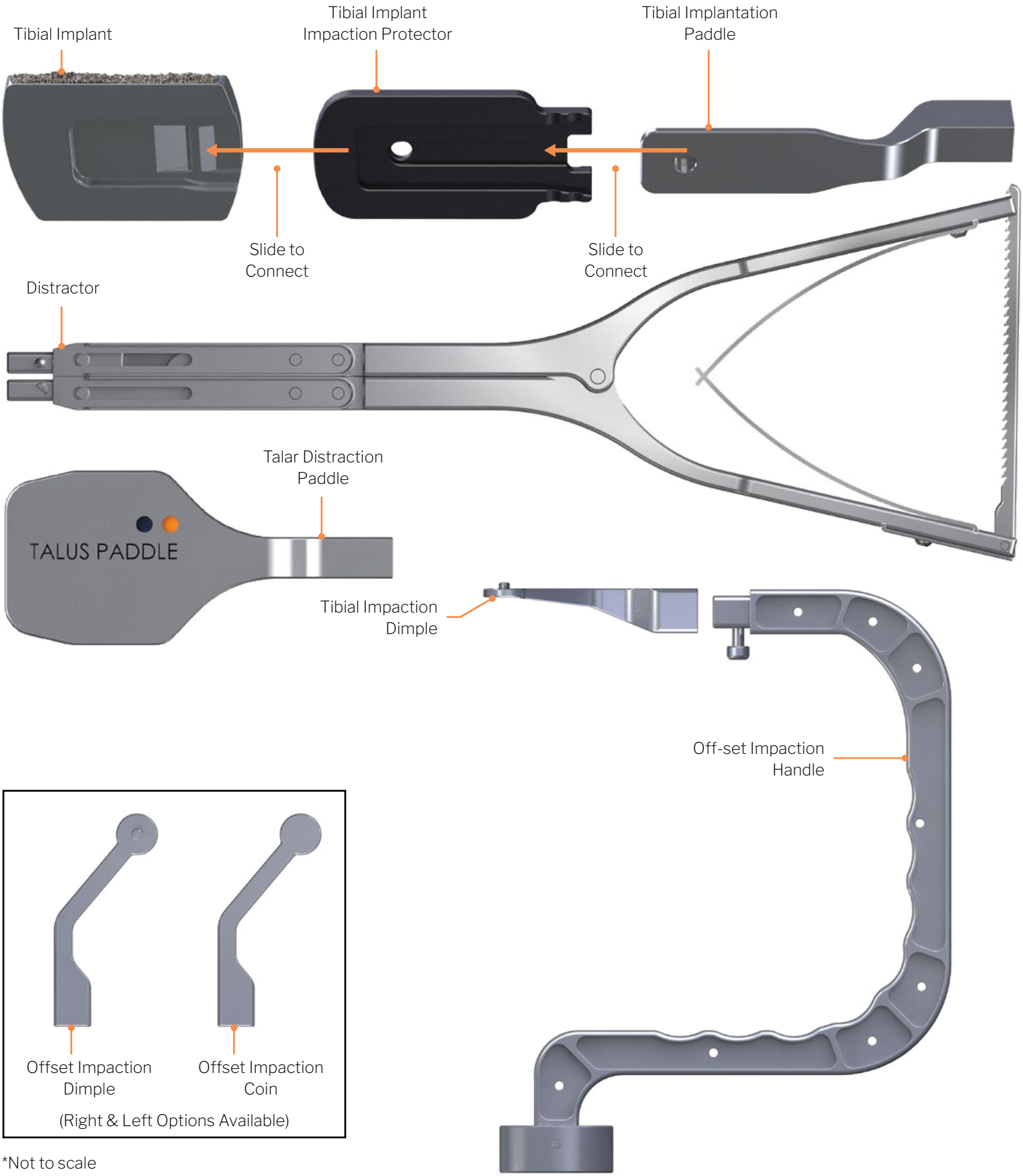
CHAMFER-CUT: TIBIAL & TALAR TRIAL REMOVAL



TIBIAL & TALAR TRIAL - CONSTRUCT REMOVAL

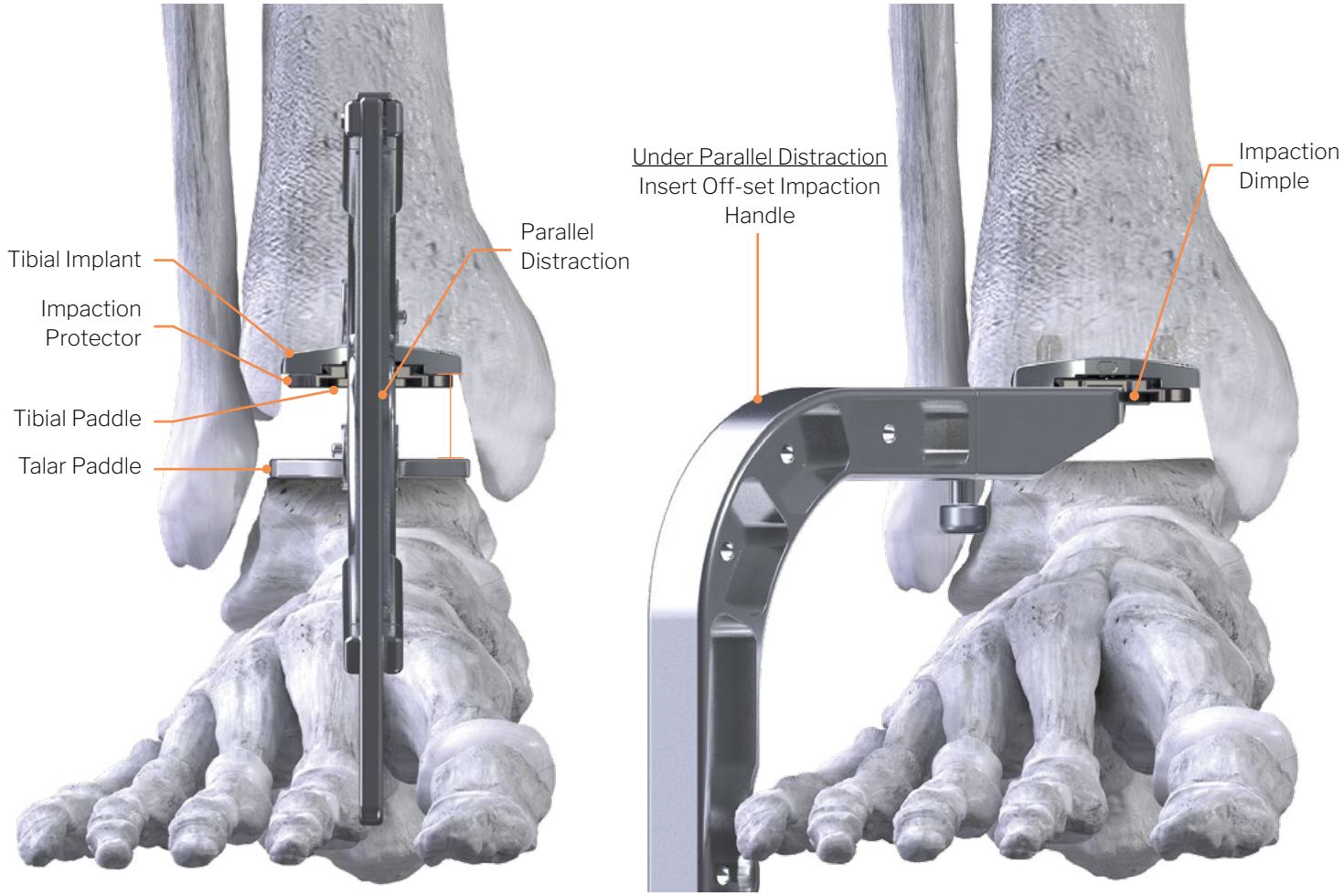
- Remove the Poly Trial using the Poly Handling Tool.
- Remove the Shouldered Pins from the Tibial Trial.
- Remove the Tibial Trial.
- Remove the Ø2.4 mm smooth Steinmann Pins from Tibial Trial.
- Remove the fixation Pins from Talar Trial.
- Remove the Talar Trial using the Talar Handling Tool

FINAL TIBIAL IMPLANT PLACEMENT INSTRUMENTATION*



*Not to scale

FINAL TIBIA IMPLANT PLACEMENT



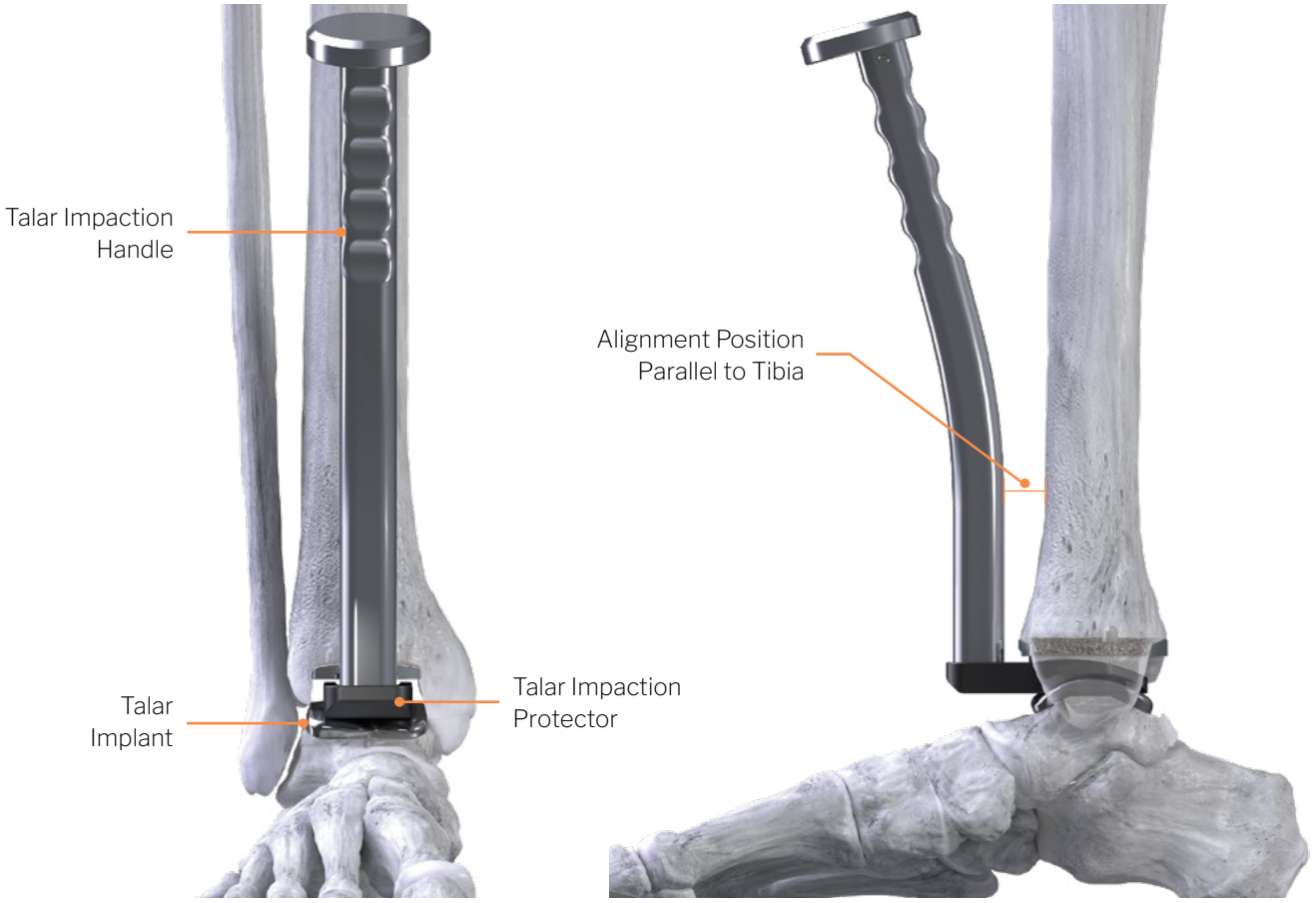
FINAL TIBIAL IMPLANT SET-UP & PLACEMENT

(Similar for ARC Tibia™ or Flat Tibia components styles)

- Connect the size matched Impaction Protector [P10-951-TP0x] to the tibial implant, the Tibial Insertion Paddle to Parallel Distractor, and the Paddle to the Impaction Protector.
- Attach the Centering Tibia Impaction Coin [P10-951-TB(R)/(L)2] or Dimple [P10-951-TB(R)/(L)X] to the Tibial Impaction Handle.
- For cemented use, apply bone cement to the superior aspect of the tibial implant. **Do not apply bone cement to the vertical pegs.**
- While connected to the Distractor and under lateral fluoroscopy, guide the Tibial Implant into position. Verify alignment, distract, insert impaction coin or dimple aligning with impaction paddle recess, then strike Impaction Handle with mallet to fully seat the Tibial Implant.
- Confirm the Implant is fully seated under both lateral and AP fluoroscopy views.

NOTE: In the United States, components are intended for cemented use only.

FINAL TALAR IMPLANT PLACEMENT



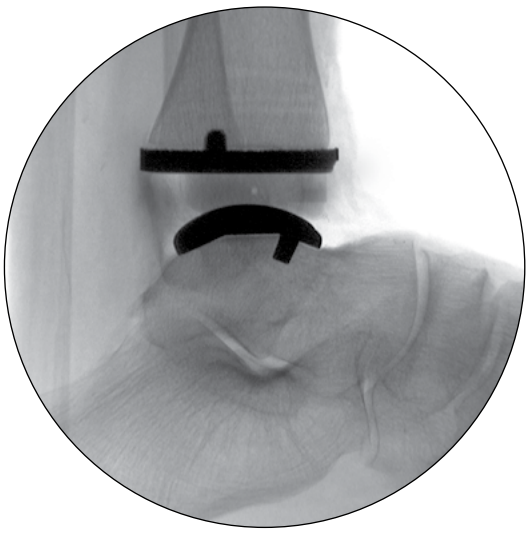
FINAL TALAR IMPLANT PLACEMENT

(Similar for Chamfer or Flat Talar components)

- For cemented use, apply bone cement to the Titanium Plasma Spray coated surface of the talar implant. **Do not apply bone cement to the central fin.**
- By hand, insert the talar implant such that the central fin aligns with the reamed slot.
- Confirm placement on lateral fluoroscopy to ensure the fin is provisionally seated within the talar bone.
- Remove Tibial Impaction Protector.
- Align the Talar Impactor [P10-952-TL00] over the implant and press down, then use mallet to impact Handle until the implant is fully seated against talus.
- Flex and extend to adjust AP / Dorsal implantation.
- Confirm implant seating using fluoroscopy.

NOTE: In the United States, components are intended for cemented use only.

SURGICAL NOTE:
Tibial Impaction Protector should remain in place during Talar Implant placement. Removal prior to final Talar Implant impaction required.



FINAL POLY IMPLANT PLACEMENT

CHECK POINT - POLY TRIAL CONFIRMATION

TO CONFIRM APPROPRIATE POLY INSERT THICKNESS, ATTACH THE PREVIOUSLY SELECTED POLY TRIAL TO THE POLY TRIAL HANDLING TOOL AND INSERT INTO THE JOINT SUCH THAT THE DOVETAIL OF THE POLY TRIAL CONNECTS WITH THE DOVETAIL OF THE TIBIAL IMPLANT. PREFORM GENTLE RANGE OF MOTION OF THE TIBIOTALAR JOINT TO EVALUATE PLACEMENT AND THICKNESS. IF THE THICKNESS IS NOT APPROPRIATE, SWAP TRIALS AS NEEDED TO FURTHER EVALUATE, THEN REPEAT TRIAL INSERTION AND RANGE OF MOTION EVALUATION.

FINAL POLY IMPLANT PLACEMENT

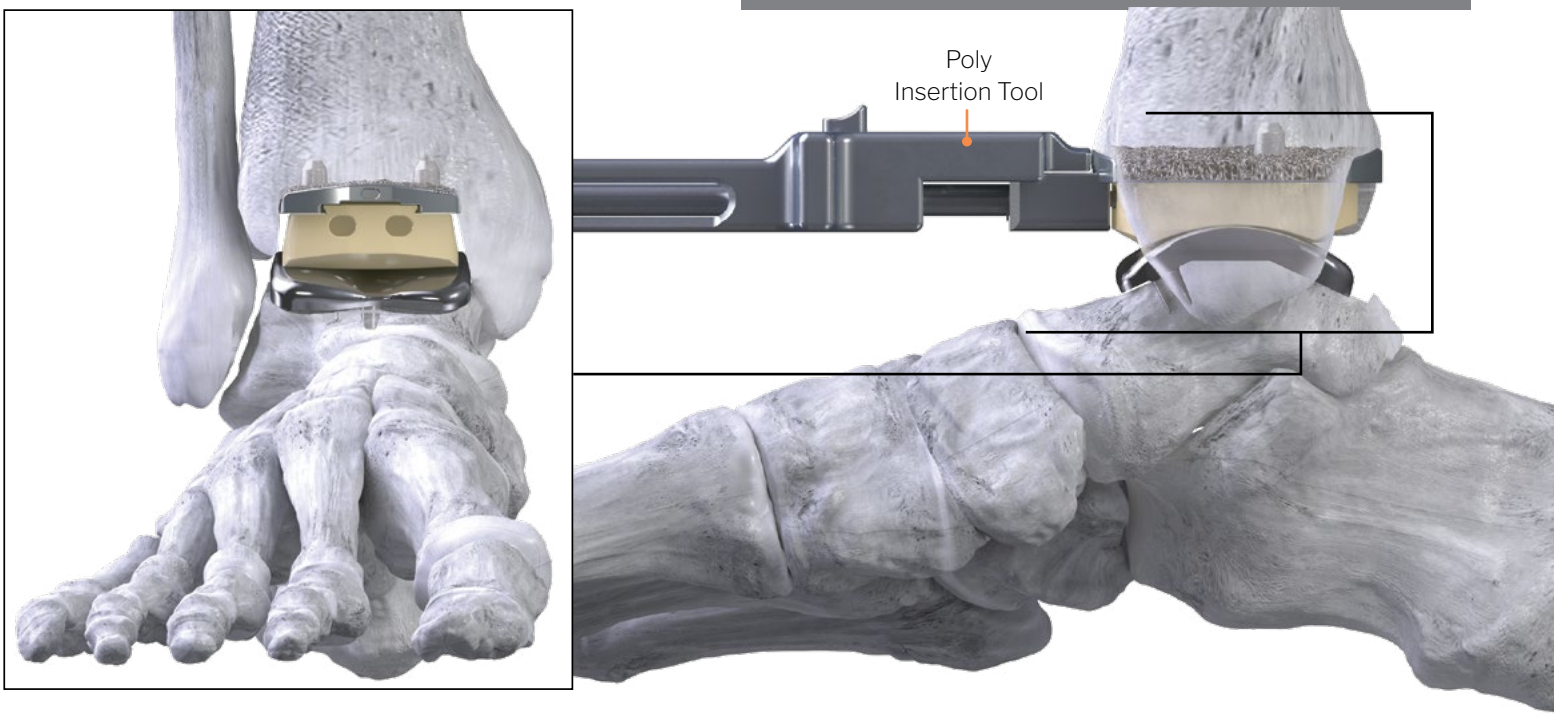
- The Poly Implant should be inserted as far as possible by hand before introducing the Insertion Tool.
- Attach the Poly Insertion Tool [P10-951-IN02] to the Tibial Implant by inserting the hooked tip catch feature, located on the leading edge of the device, into the anterior recess of the implant making sure to keep alignment of the instrument parallel with the Tibia Base Implant.
- Slide the “LOCK” button to the locked position to create a secure connection. Note: The Insertion Tool's Shim acts as a wedge to hold placement and is spring loaded to always be in the unlocked position
- Rotate the turn knob on the end of the Insertion Tool to engage the Poly Insert. Advance the Poly Insert until a click is heard or felt.
- Press the release button to disengage the shim and device construct from the Tibial Implant, then remove the Poly Insertion Tool.
- Conduct a range of motion evaluation.

CONFIRM FINAL PLACEMENT & CLOSURE

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

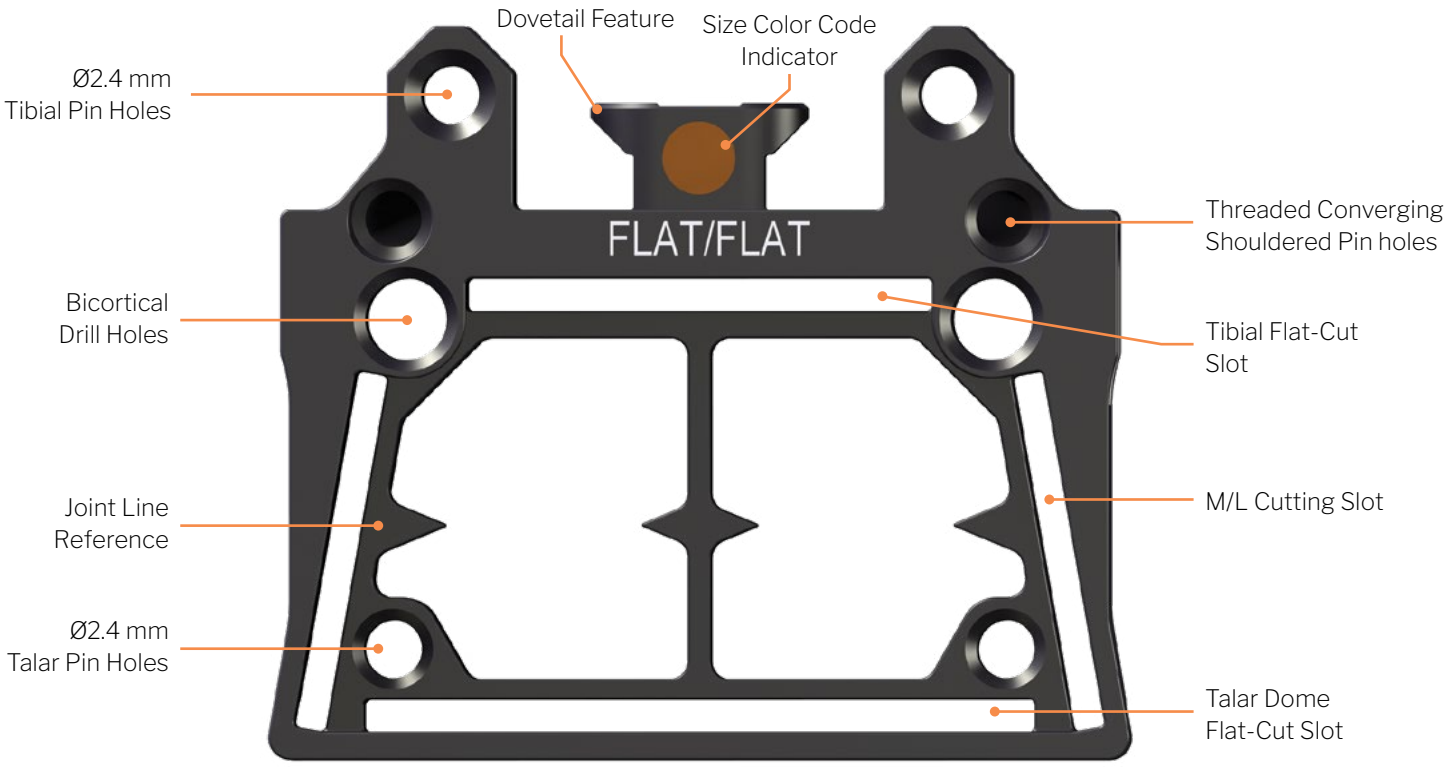
SURGICAL NOTE:

If size matched or downsized, the anterior aspect of the Poly Implant and anterior aspect to the Tibial Implant will not sit flush, Poly is designed to be recessed.

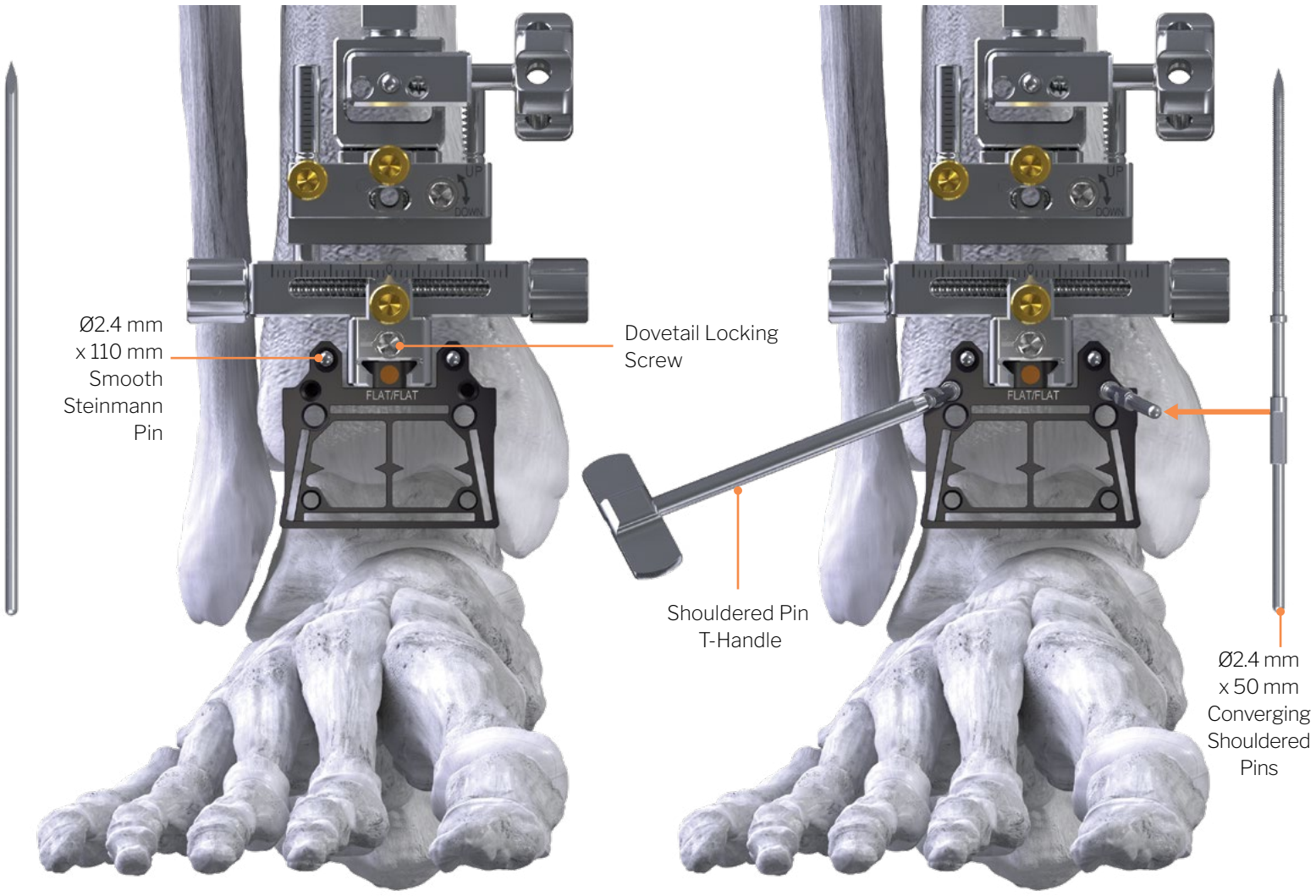


FLAT-CUT: COUPLED TIBIOTALAR RESECTION BLOCK

RESECTION BLOCK

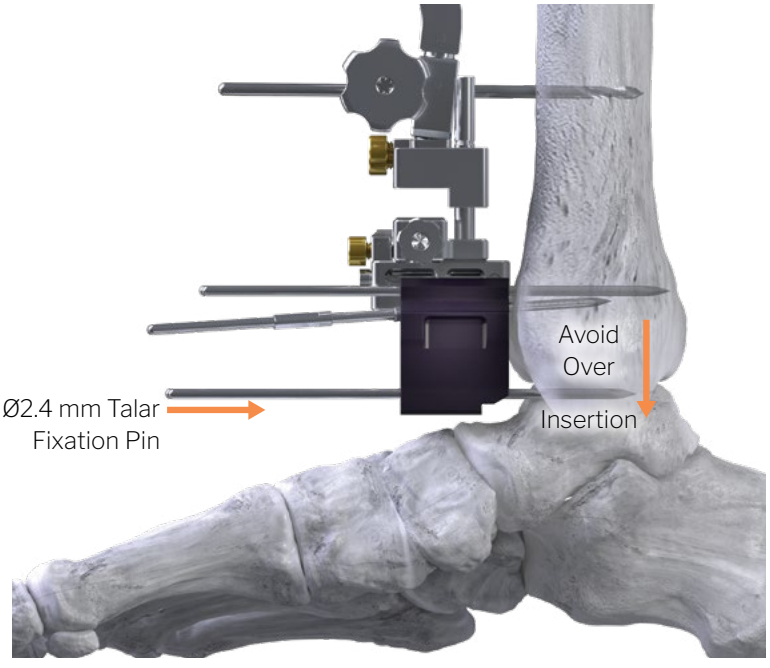


FLAT-CUT: TIBIAL BONE PREPARATION

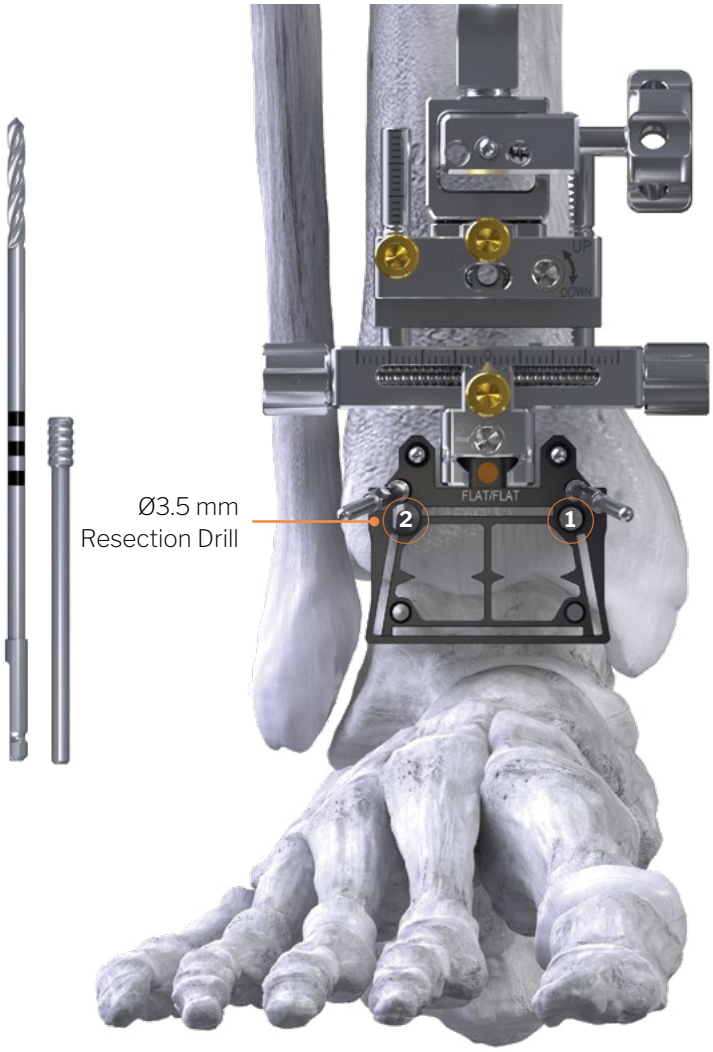


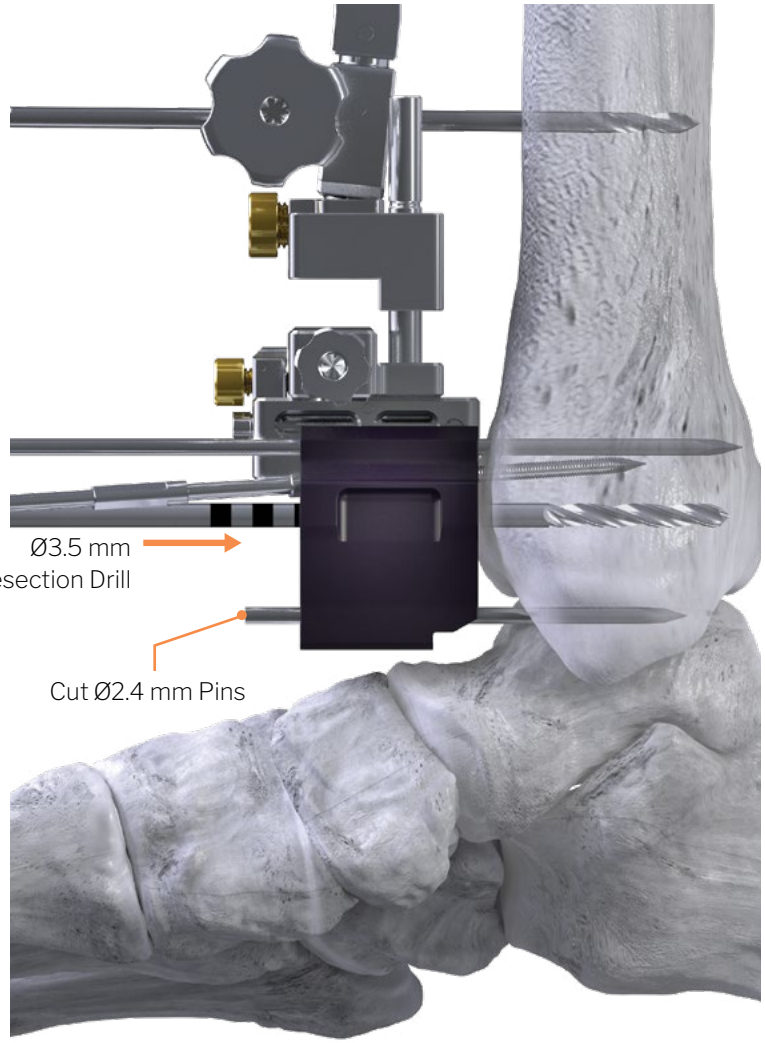
FLAT-CUT TIBIAL BONE PREPARATION

- Slide the proximal portion of the Tibial FLAT-Cut Resection Block [P10-942-FL1x] over the two (2) Ø2.4 mm M/L guide pins and into the dovetail connection of the Alignment Construct and lock in place.
- By hand, place two (2) Ø2.4 mm x 50 mm Threaded Shouldered Pins [P10-902-2450] into the proximal converging pin holes of the Resection Block for added block stability, then begin to advance under power, utilizing the T-Handle to fully seat. (DO NOT SEAT UNDER POWER)
- With the foot held 90° to the tibial axis, reduce the tibiotalar joint, then secure position by placing two (2) Ø2.4 mm x 110 mm Smooth Steinmann Pins into the talus, targeting the two distal most holes of the Resection Block, then cut with Pin Cutters.



FLAT-CUT: TIBIAL BONE PREPARATION

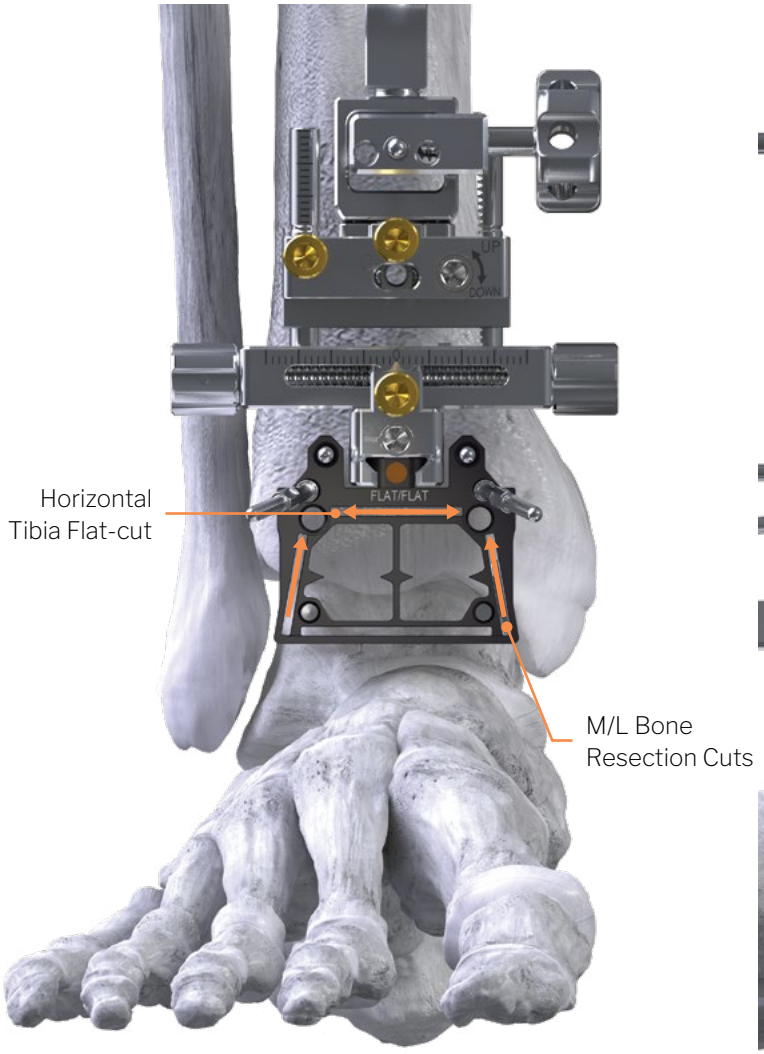




FLAT-CUT TIBIAL BONE PREPARATION

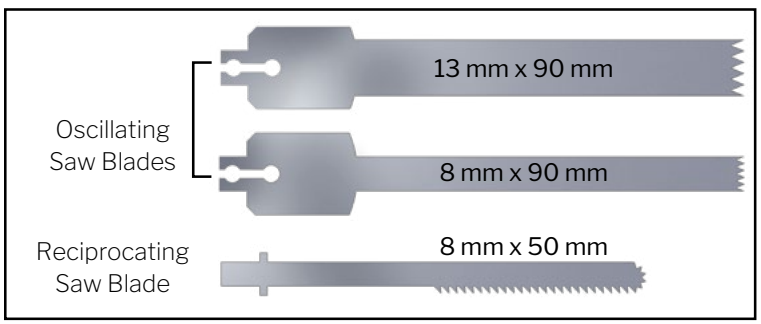
- Utilizing the Ø3.5 mm Tibial Bone Resection Drill [P10-942-3513]:
  - Drill the medial hole bicortically, taking care not to penetrate beyond, utilizing the depth drill markers as a general reference.
  - Insert Ø3.5 mm Top Hat to secure position, then drill lateral hole.

FLAT-CUT: TIBIAL BONE PREPARATION



FLAT-CUT TIBIAL BONE RESECTION: PROXIMAL CUT

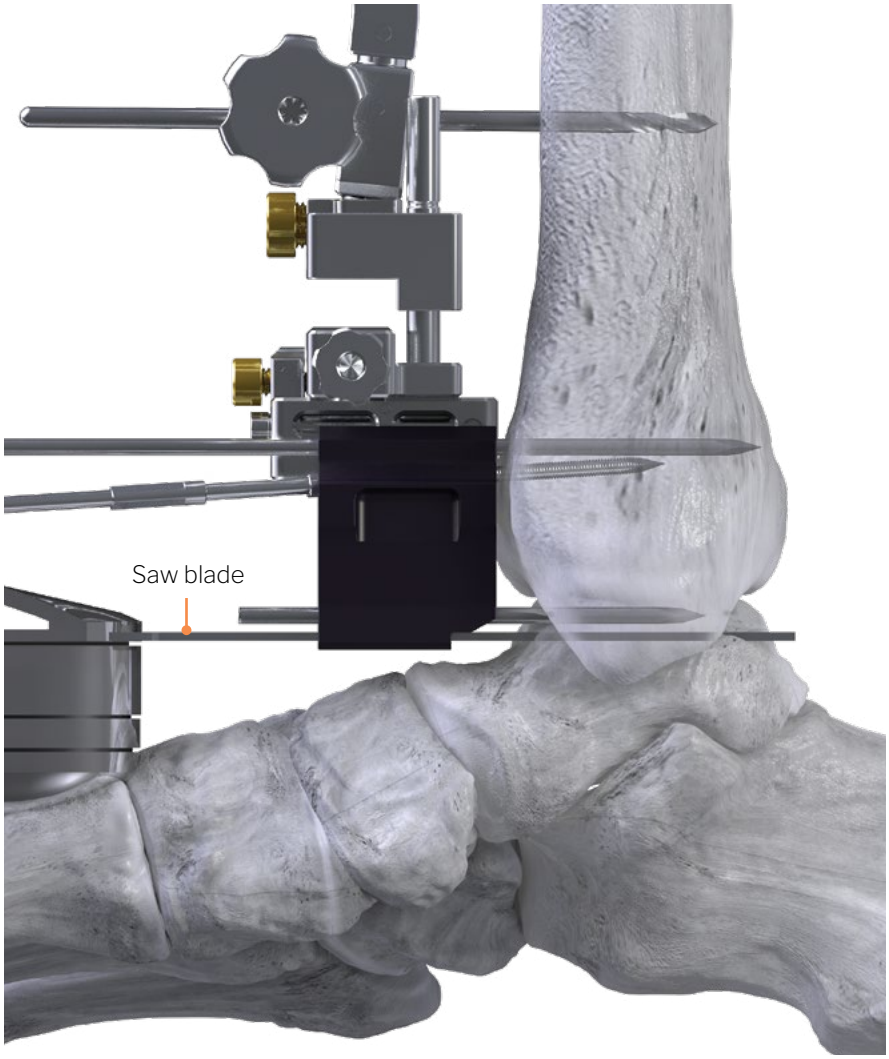
- Utilize the 13 mm x 90 mm Oscillating Saw Blade [P99-151-P104-S] to complete the horizontal tibial flat cut across the top of the Resection Block cut slot.

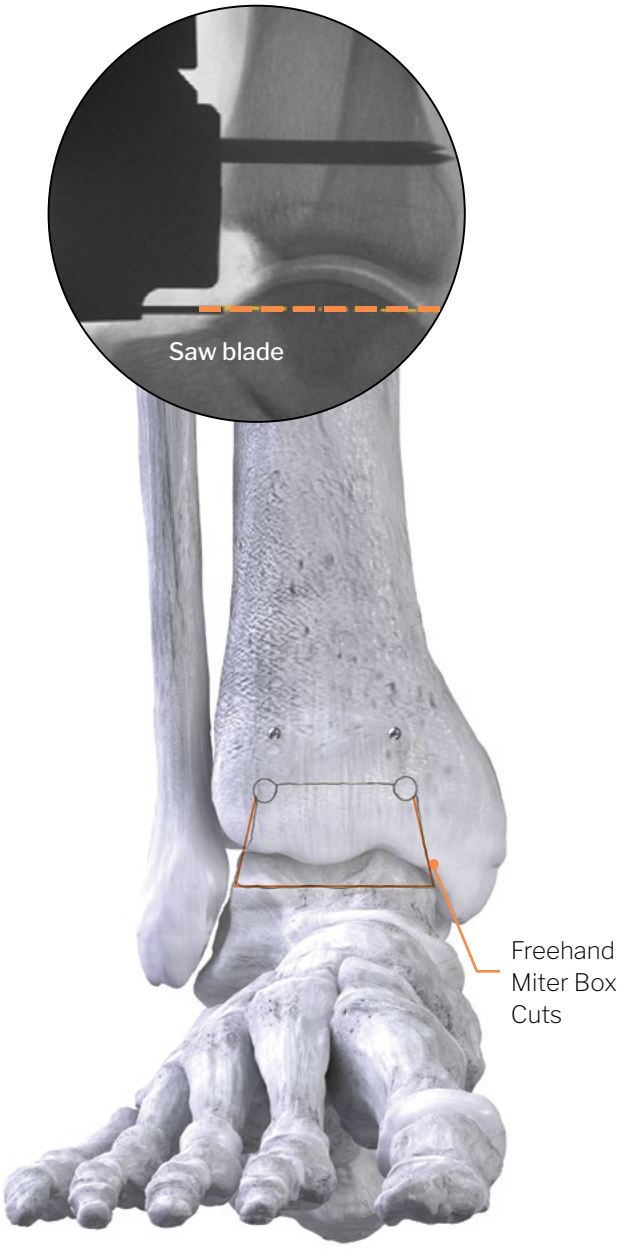


FLAT-CUT TIBIAL BONE RESECTION: M/L CUTS

- Utilize the optional 8 mm x 50 mm Reciprocating Saw Blade [P99-151-P105-S] to complete the M/L gutter bone resection cuts, starting distally and walking the saw blade up proximally.

FLAT-CUT: TALAR BONE PREPARATION





FLAT-CUT: TALAR BONE RESECTION – DORSAL CUT

- Before initiating the dorsal talar flat-cut, a saw blade may be used to evaluate bone resection level under a lateral fluoroscopic view.
- Utilize the 13 x 90 mm Oscillating Saw Blade [P99-151-P104-S] to complete the dorsal talar flat-cut through the distal cutting slot.

FLAT-CUT: RESECTION BLOCK REMOVAL

- Remove the Threaded Shouldered Pins and Smooth Talar Pins, then the Resection Block by rotating the silver “OPEN” screw.
- Finish the tibiotalar bone preparation freehand with saw blade.
- Remove the resected talar bone.

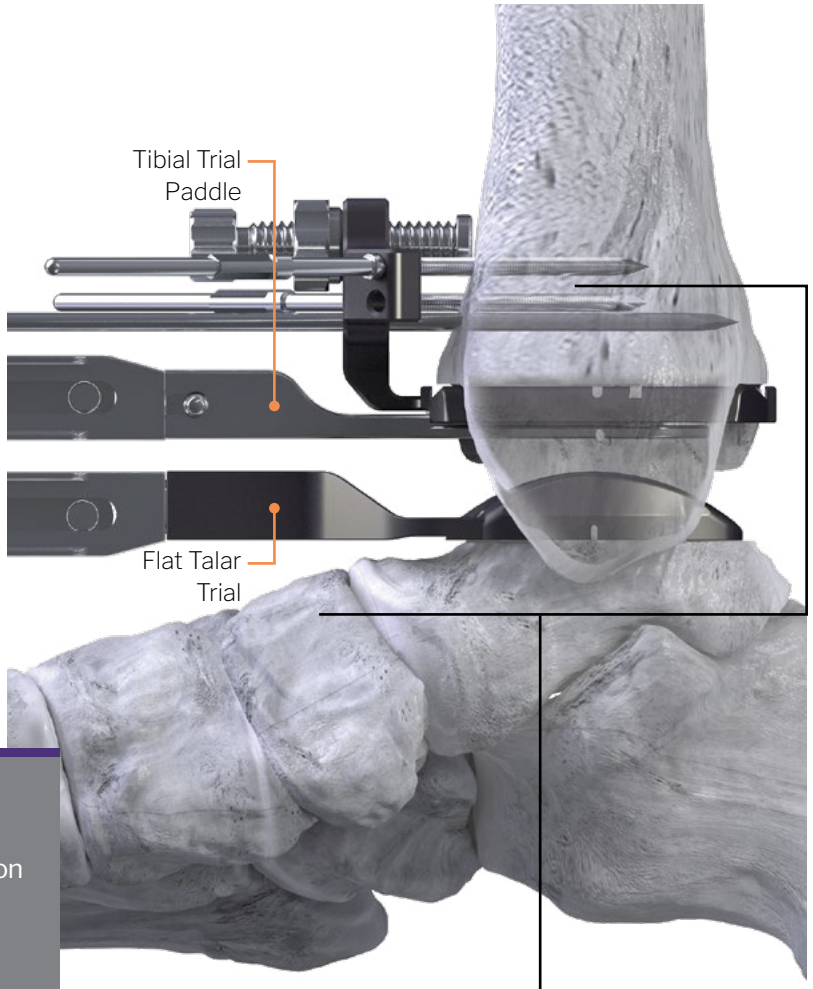
SURGICAL NOTE:
Refer to Surgical Note page 23 for information on Tibial Bone Fragment Removal

ATTENTION:
Once this step has been completed, return to pages 25-34 to complete Tibial Trail placement and Vertical Peg Bone Preparation, then return to page 57 to complete Talar Trialing Bone Preparation.

FLAT-CUT: TALAR TRIAL PLACEMENT

FLAT-CUT: TALAR TRIAL PLACEMENT

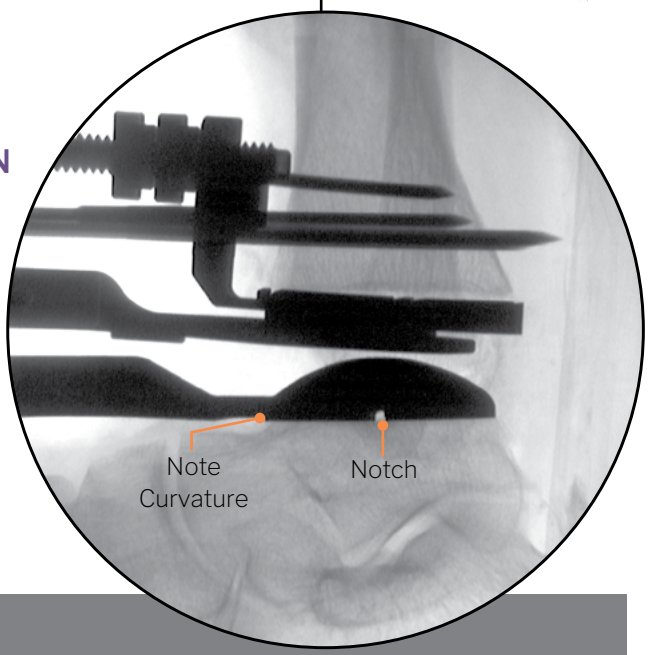
- Insert the Flat Talar Trial by hand to evaluate M/L coverage.
- Ensure coverage of the medial and lateral aspect of the talus by verifying that the Trial does not impinge on the M/L gutters.
- Utilizing the Parallel Distractor [P10-951-4BAR], attach the appropriately sized Flat Talar Trial and standard Tibial Trial Paddle*.
- Insert the Flat Talar Trial/Tibial Trial Paddle assembly into the resected space, matching the Tibial Paddle's connection to the inferior aspect of the Tibial Trial and the Flat Talar Trial to the resected talar bone surface.



SURGICAL NOTE:
*Two Tibial Trial Paddle Options Exist:
- One allows for secure fit and no A/P translation [P10-951-P001]
- Second allows for A/P translation [P10-951-P002]

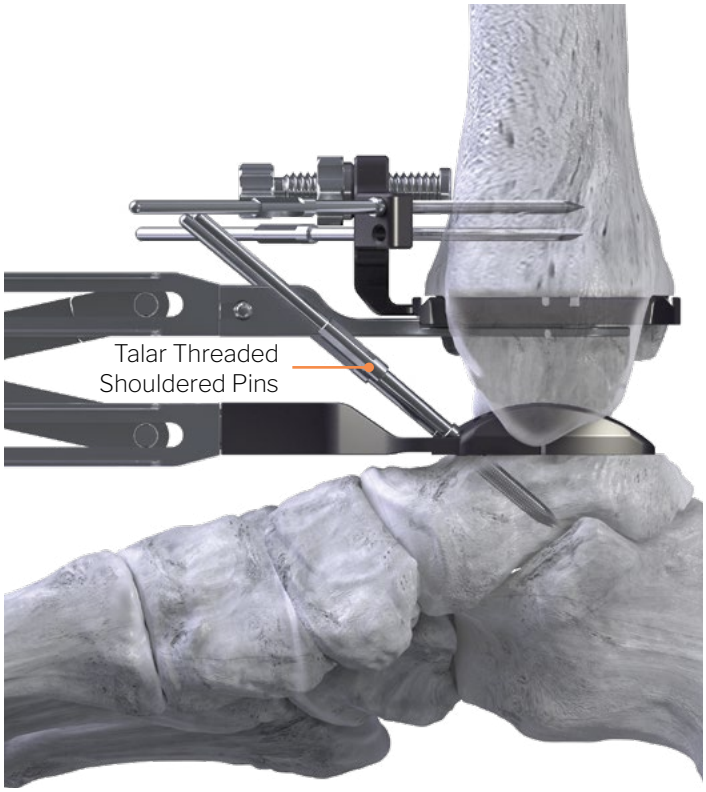
TALAR TRIAL PLACEMENT - FLUOROSCOPIC EVALUATION

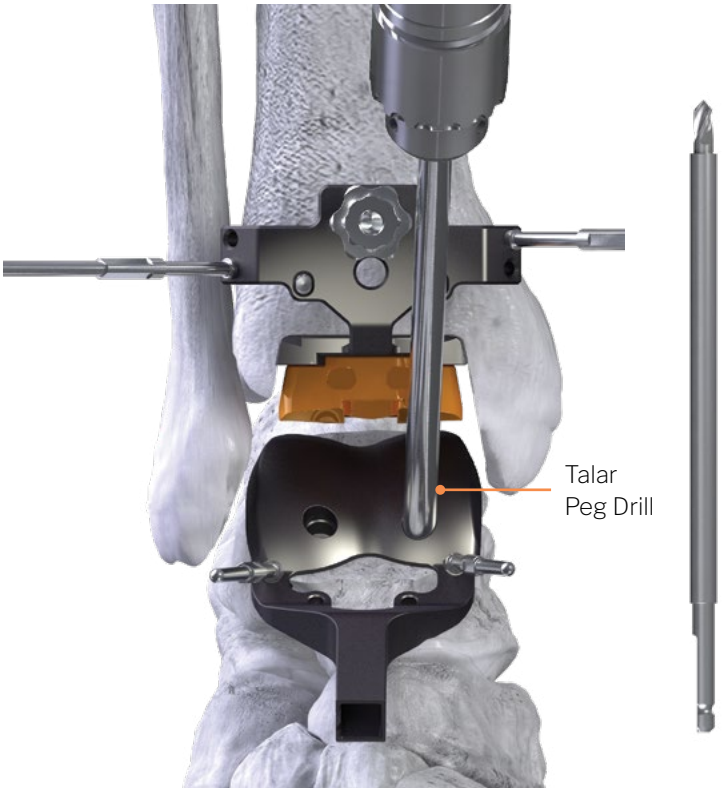
- Both visually and under a lateral fluoroscopic view, evaluate (and adjust as necessary):
  - A/P and M/L fit
  - Confirm the Trial size relative to the talar dorsal cut.
  - Ensure the Trial aligns with the vertical positioning marker on Tibial Trial or the lateral process.
  - Distract the joint by gently squeezing down on the Handle.



SURGICAL NOTE:
With the Parallel Distractor in place, re-check the Talar Trial under a lateral fluoroscopy view, verify position and fit before securing position with shouldered pins. Ensure fluoroscopic notch, located on the distal aspect of the Talar Trial, is visible to verify a perfect lateral is taken. As it relates to the Tibial Trial size, the selected Talar Trial can be sized up by 1 or down without restriction to achieve appropriate coverage. If M/L coverage is appropriate, but too large in A/P, downsizing is recommended.

FLAT-CUT: TALAR TRIAL BONE PREPARATION





FLAT-CUT: SECURE TALAR TRIAL PLACEMENT

- Under distraction, secure the Flat Talar Trial position by placing two (2) Ø2.4 mm x 25 mm Threaded Shouldered Pins [P10-902-2425] by hand into the medial/lateral holes of the Talar Trial as depicted above, then begin to advance under power, utilizing the T-Handle to fully seat. [DO NOT SEAT UNDER POWER] utilizing the T-Handle to fully seat.
- Disconnect the Distractor by holding the release button located on the device and pulling anteriorly.
- Under lateral fluoroscopic view, confirm Talar Trial is fully seated and appropriately aligned.

FLAT-CUT: TALAR PEG DRILL HOLES

- Place the tibiotalar joint in slight plantarflexion to gain access to the drill holes on the anterior face of the Flat Talar Trial.
- Utilize the Talar Peg Drill [P10-944-4013], drilling the medial and lateral Talar Trial peg holes until the drill shouldered bottoms out on the proximal surface of the Talar Trial. (DO NOT INSERT PEG DRILL UNDER POWER.)

POLY TRIALING

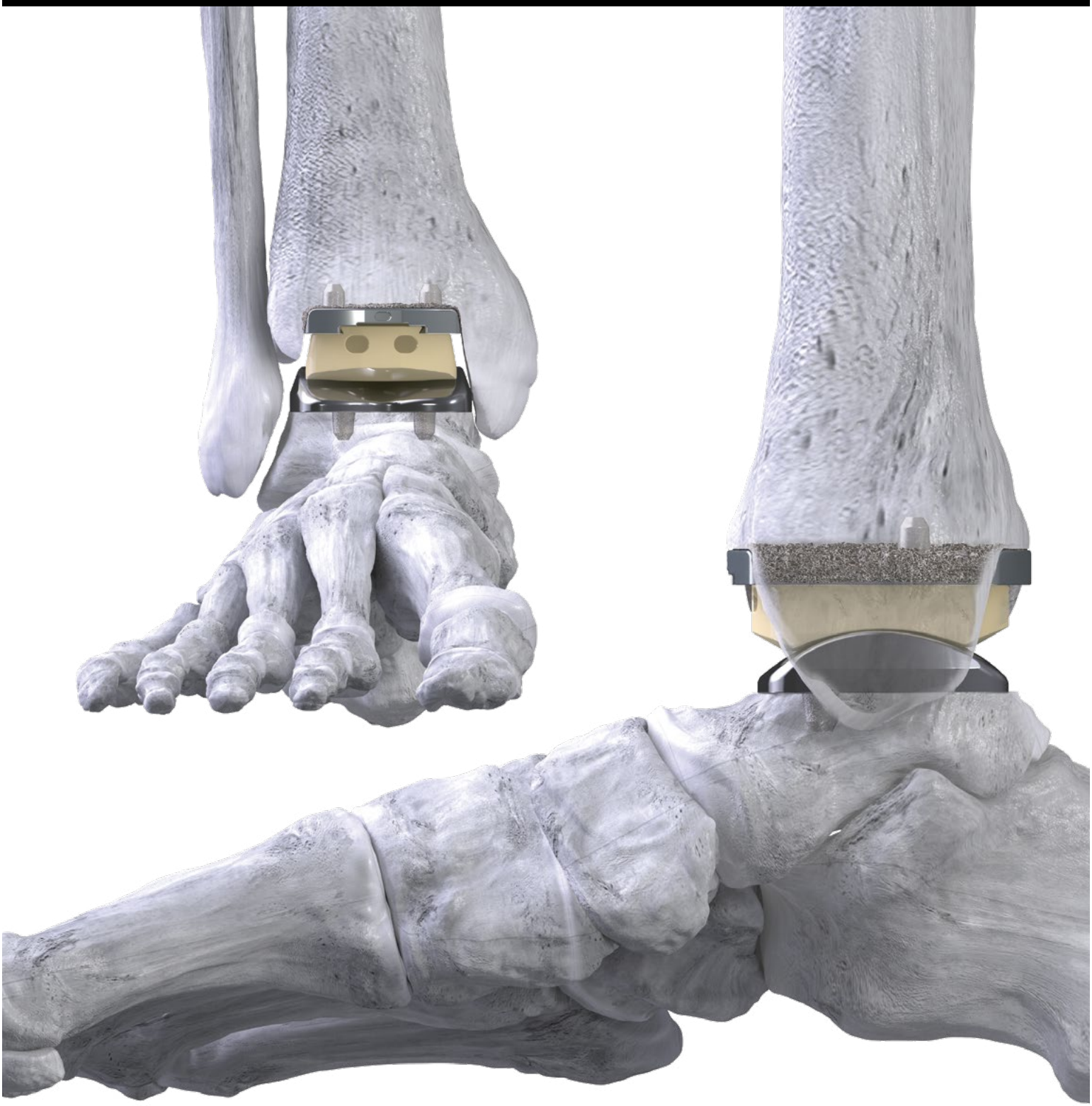
- Insert the Talar size matched Poly Trial, utilizing the Poly Handling Tool [P10-953-IN01] such that the dovetail on the Poly Trial connects with the dovetail of the Tibial Trial.
- Put the tibiotalar joint through gentle range of motion evaluation to ensure adequate placement and correct Poly Trial thickness.
- Evaluate Poly Trial placement using fluoroscopy ensuring the radiopaque markers are vertically aligned.

TRIAL REMOVAL

- Remove the Poly Trial using the Poly Handling Tool [P10-953-IN01].
- Remove the four (4) Threaded Shouldered Pins from the anterior Tibial/Talar Trials. Then remove both Trials.

FLAT-CUT: FINAL IMPLANTATION

ATTENTION:
For final implantation instructions, return to pages 48-51.



IMPLANT REMOVAL INSTRUCTIONS

- 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 oseteotome 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 a forcep 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 a forcep if necessary. 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

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

POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS (CONTINUED)

- 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 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.

TIBIAL IMPLANT OPTIONS

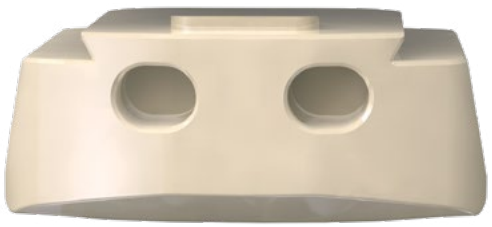
ARC Tibia™ Implant

FLAT Tibia Implant

PART #	DESCRIPTION
P10-100-BL10-S	APEX 3D™ ARC Tibia, Left, Size 1, Short, 3DP
P10-100-BL1L-S	APEX 3D™ ARC Tibia, Left, Size 1, Long, 3DP
P10-100-BL1S-S	APEX 3D™ ARC Tibia, Left, Size 1, Standard, 3DP
P10-100-BL2L-S	APEX 3D™ ARC Tibia, Left, Size 2, Long, 3DP
P10-100-BL2S-S	APEX 3D™ ARC Tibia, Left, Size 2, Standard, 3DP
P10-100-BL3L-S	APEX 3D™ ARC Tibia, Left, Size 3, Long, 3DP
P10-100-BL3S-S	APEX 3D™ ARC Tibia, Left, Size 3, Standard, 3DP
P10-100-BL4L-S	APEX 3D™ ARC Tibia, Left, Size 4, Long, 3DP
P10-100-BL4S-S	APEX 3D™ ARC Tibia, Left, Size 4, Standard, 3DP
P10-100-BL5L-S	APEX 3D™ ARC Tibia, Left, Size 5, Long, 3DP
P10-100-BL5S-S	APEX 3D™ ARC Tibia, Left, Size 5, Standard, 3DP
P10-100-BL6L-S	APEX 3D™ ARC Tibia, Left, Size 6, Long, 3DP
P10-100-BL6S-S	APEX 3D™ ARC Tibia, Left, Size 6, Standard, 3DP
P10-100-BR10-S	APEX 3D™ ARC Tibia, Right, Size 1, Short, 3DP
P10-100-BR1L-S	APEX 3D™ ARC Tibia, Right, Size 1, Long, 3DP
P10-100-BR1S-S	APEX 3D™ ARC Tibia, Right, Size 1, Standard, 3DP
P10-100-BR2L-S	APEX 3D™ ARC Tibia, Right, Size 2, Long, 3DP
P10-100-BR2S-S	APEX 3D™ ARC Tibia, Right, Size 2, Standard, 3DP
P10-100-BR3L-S	APEX 3D™ ARC Tibia, Right, Size 3, Long, 3DP
P10-100-BR3S-S	APEX 3D™ ARC Tibia, Right, Size 3, Standard, 3DP
P10-100-BR4L-S	APEX 3D™ ARC Tibia, Right, Size 4, Long, 3DP
P10-100-BR4S-S	APEX 3D™ ARC Tibia, Right, Size 4, Standard, 3DP
P10-100-BR5L-S	APEX 3D™ ARC Tibia, Right, Size 5, Long, 3DP
P10-100-BR5S-S	APEX 3D™ ARC Tibia, Right, Size 5, Standard, 3DP
P10-100-BR6L-S	APEX 3D™ ARC Tibia, Right, Size 6, Long, 3DP
P10-100-BR6S-S	APEX 3D™ ARC Tibia, Right, Size 6, Standard, 3DP

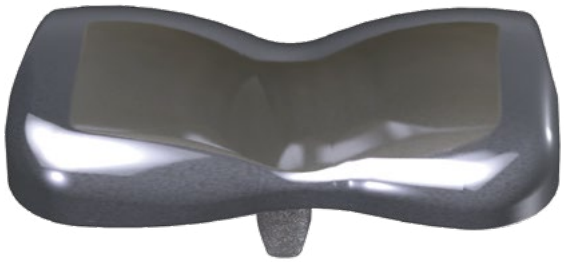
PART #	DESCRIPTION
P10-101-BL10-S	APEX 3D™ Tibia, Flat, Left, Size 1, Short, 3DP
P10-101-BL1L-S	APEX 3D™ Tibia, Flat, Left, Size 1, Long, 3DP
P10-101-BL1S-S	APEX 3D™ Tibia, Flat, Left, Size 1, Standard, 3DP
P10-101-BL2L-S	APEX 3D™ Tibia, Flat, Left, Size 2, Long, 3DP
P10-101-BL2S-S	APEX 3D™ Tibia, Flat, Left, Size 2, Standard, 3DP
P10-101-BL3L-S	APEX 3D™ Tibia, Flat, Left, Size 3, Long, 3DP
P10-101-BL3S-S	APEX 3D™ Tibia, Flat, Left, Size 3, Standard, 3DP
P10-101-BL4L-S	APEX 3D™ Tibia, Flat, Left, Size 4, Long, 3DP
P10-101-BL4S-S	APEX 3D™ Tibia, Flat, Left, Size 4, Standard, 3DP
P10-101-BL5L-S	APEX 3D™ Tibia, Flat, Left, Size 5, Long, 3DP
P10-101-BL5S-S	APEX 3D™ Tibia, Flat, Left, Size 5, Standard, 3DP
P10-101-BL6L-S	APEX 3D™ Tibia, Flat, Left, Size 6, Long, 3DP
P10-101-BL6S-S	APEX 3D™ Tibia, Flat, Left, Size 6, Standard, 3DP
P10-101-BR10-S	APEX 3D™ Tibia, Flat, Right, Size 1, Short, 3DP
P10-101-BR1L-S	APEX 3D™ Tibia, Flat, Right, Size 1, Long, 3DP
P10-101-BR1S-S	APEX 3D™ Tibia, Flat, Right, Size 1, Standard, 3DP
P10-101-BR2L-S	APEX 3D™ Tibia, Flat, Right, Size 2, Long, 3DP
P10-101-BR2S-S	APEX 3D™ Tibia, Flat, Right, Size 2, Standard, 3DP
P10-101-BR3L-S	APEX 3D™ Tibia, Flat, Right, Size 3, Long, 3DP
P10-101-BR3S-S	APEX 3D™ Tibia, Flat, Right, Size 3, Standard, 3DP
P10-101-BR4L-S	APEX 3D™ Tibia, Flat, Right, Size 4, Long, 3DP
P10-101-BR4S-S	APEX 3D™ Tibia, Flat, Right, Size 4, Standard, 3DP
P10-101-BR5L-S	APEX 3D™ Tibia, Flat, Right, Size 5, Long, 3DP
P10-101-BR5S-S	APEX 3D™ Tibia, Flat, Right, Size 5, Standard, 3DP
P10-101-BR6L-S	APEX 3D™ Tibia, Flat, Right, Size 6, Long, 3DP
P10-101-BR6S-S	APEX 3D™ Tibia, Flat, Right, Size 6, Standard, 3DP

VITAMIN E POLY INSERT OPTIONS



PART #	DESCRIPTION
P10-310-I106-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 1 x 6MM, NEUTRAL
P10-310-I107-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 1 x 7MM, NEUTRAL
P10-310-I108-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 1 x 8MM, NEUTRAL
P10-310-I109-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 1 x 9MM, NEUTRAL
P10-310-I110-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 1 x 10MM, NEUTRAL
P10-310-I111-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 1 x 11MM, NEUTRAL
P10-310-I112-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 1 x 12MM, NEUTRAL
P10-310-I206-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 2 x 6MM, NEUTRAL
P10-310-I207-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 2 x 7MM, NEUTRAL
P10-310-I208-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 2 x 8MM, NEUTRAL
P10-310-I209-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 2 x 9MM, NEUTRAL
P10-310-I210-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 2 x 10MM, NEUTRAL
P10-310-I211-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 2 x 11MM, NEUTRAL
P10-310-I212-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 2 x 12MM, NEUTRAL
P10-310-I306-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 3 x 6MM, NEUTRAL
P10-310-I307-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 3 x 7MM, NEUTRAL
P10-310-I308-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 3 x 8MM, NEUTRAL
P10-310-I309-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 3 x 9MM, NEUTRAL
P10-310-I310-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 3 x 10MM, NEUTRAL
P10-310-I311-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 3 x 11MM, NEUTRAL
P10-310-I312-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 3 x 12MM, NEUTRAL
P10-310-I406-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 4 x 6MM, NEUTRAL
P10-310-I407-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 4 x 7MM, NEUTRAL
P10-310-I408-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 4 x 8MM, NEUTRAL
P10-310-I409-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 4 x 9MM, NEUTRAL
P10-310-I410-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 4 x 10MM, NEUTRAL
P10-310-I411-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 4 x 11MM, NEUTRAL
P10-310-I412-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 4 x 12MM, NEUTRAL
P10-310-I506-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 5 x 6MM, NEUTRAL
P10-310-I507-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 5 x 7MM, NEUTRAL
P10-310-I508-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 5 x 8MM, NEUTRAL
P10-310-I509-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 5 x 9MM, NEUTRAL
P10-310-I510-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 5 x 10MM, NEUTRAL
P10-310-I511-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 5 x 11MM, NEUTRAL
P10-310-I512-S	APEX 3D™ Cross-linked Vitamin E POLY, SIZE 5 x 12MM, 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, Flat, Left, Size 1 Narrow, TPS
P10-251-TLL1-S	APEX 3D™ Talus, Flat, Left, Size 1, TPS
P10-251-TLL2-S	APEX 3D™ Talus, Flat, Left, Size 2, TPS
P10-251-TLL3-S	APEX 3D™ Talus, Flat, Left, Size 3, TPS
P10-251-TLL4-S	APEX 3D™ Talus, Flat, Left, Size 4, TPS
P10-251-TLL5-S	APEX 3D™ Talus, Flat, Left, Size 5, TPS
P10-251-TLR0-S	APEX 3D™ Talus, Flat, Right, Size 1 Narrow, TPS
P10-251-TLR1-S	APEX 3D™ Talus, Flat, Right, Size 1, TPS
P10-251-TLR2-S	APEX 3D™ Talus, Flat, Right, Size 2, TPS
P10-251-TLR3-S	APEX 3D™ Talus, Flat, Right, Size 3, TPS
P10-251-TLR4-S	APEX 3D™ Talus, Flat, Right, Size 4, TPS
P10-251-TLR5-S	APEX 3D™ Talus, Flat, Right, Size 5, TPS

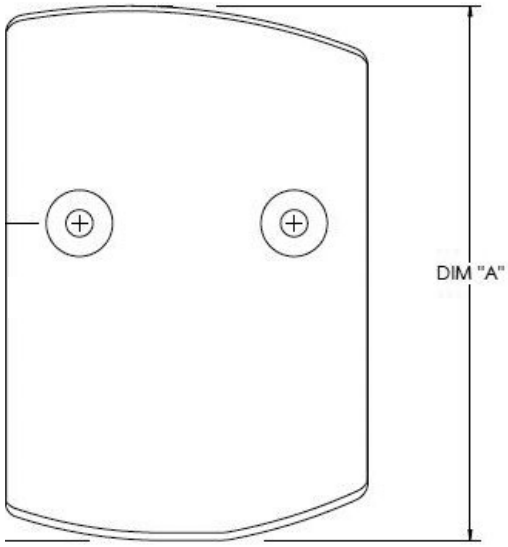
IMPLANT CONFIGURATIONS

IMPLANT SIZE OFFERING & INTERCHANGEABILITY

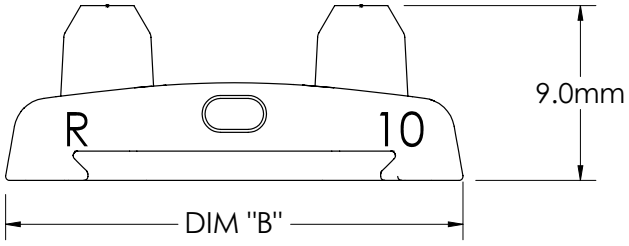
		TALUS (CHAMFER AND FLAT)					
		1N (Narrow)	1	2	3	4	5
TIBIA (ARC TIBIA™ & FLAT)	1 Short	1	1	2			
	1 Standard	1	1	2			
	1 Long	1	1	2			
	2 Standard	1	1	2	3		
	2 Long	1	1	2	3		
	3 Standard	1	1	2	3	4	
	3 Long	1	1	2	3	4	
	4 Standard	1	1	2	3	4	5
	4 Long	1	1	2	3	4	5
	5 Standard	1	1	2	3	4	5
	5 Long	1	1	2	3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

IMPLANT SPECS – TIBIAL TRAY



PART #	CONFIGURATION	DIM "A" [mm]	DIM "B" [mm]
P10-100-BR10	Size 1 - Short	31.0	23.5
P10-100-BR1S	Size 1 - Standard	34.0	23.5
P10-100-BR1L	Size 1 - Long	37.0	23.5
P10-100-BR2S	Size 2 - Standard	37.0	25.9
P10-100-BR2L	Size 2 - Long	40.0	25.9
P10-100-BR3S	Size 3 - Standard	40.0	28.3
P10-100-BR3L	Size 3 - Long	43.0	28.3
P10-100-BR4S	Size 4 - Standard	43.0	30.7
P10-100-BR4L	Size 4 - Long	46.0	30.7
P10-100-BR5S	Size 5 - Standard	46.0	33.1
P10-100-BR5L	Size 5 - Long	49.0	33.1
P10-100-BR6S	Size 6 - Standard	49.0	35.5
P10-100-BR6L	Size 6 - Long	52.0	35.5



IMPLANT SPECS – VITAMIN E INSERT

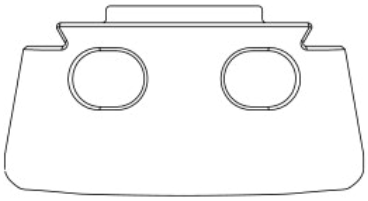
PART #	CONFIGURATION	DIM "A" [mm]
P10-310-I106	Size 1, 6mm	6.0
P10-310-I107	Size 1, 7mm	7.0
P10-310-I108	Size 1, 8mm	8.0
P10-310-I109	Size 1, 9mm	9.0
P10-310-I110	Size 1, 10mm	10.0
P10-310-I111	Size 1, 11mm	11.0
P10-310-I112	Size 1, 12mm	12.0

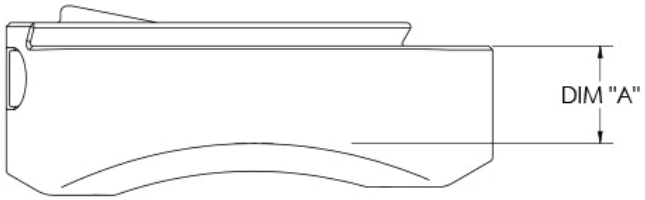
PART #	CONFIGURATION	DIM "A" [mm]
P10-310-I206	Size 2, 6mm	6.0
P10-310-I207	Size 2, 7mm	7.0
P10-310-I208	Size 2, 8mm	8.0
P10-310-I209	Size 2, 9mm	9.0
P10-310-I210	Size 2, 10mm	10.0
P10-310-I211	Size 2, 11mm	11.0
P10-310-I212	Size 2, 12mm	12.0

PART #	CONFIGURATION	DIM "A" [mm]
P10-310-I306	Size 3, 6mm	6.0
P10-310-I307	Size 3, 7mm	7.0
P10-310-I308	Size 3, 8mm	8.0
P10-310-I309	Size 3, 9mm	9.0
P10-310-I310	Size 3, 10mm	10.0
P10-310-I311	Size 3, 11mm	11.0
P10-310-I312	Size 3, 12mm	12.0

PART #	CONFIGURATION	DIM "A" [mm]
P10-310-I406	Size 4, 6mm	6.0
P10-310-I407	Size 4, 7mm	7.0
P10-310-I408	Size 4, 8mm	8.0
P10-310-I409	Size 4, 9mm	9.0
P10-310-I410	Size 4, 10mm	10.0
P10-310-I411	Size 4, 11mm	11.0
P10-310-I412	Size 4, 12mm	12.0

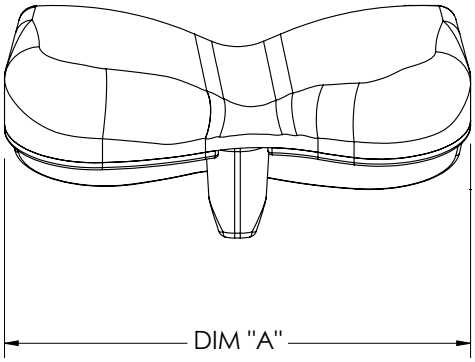
PART #	CONFIGURATION	DIM "A" [mm]
P10-310-I506	Size 5, 6mm	6.0
P10-310-I507	Size 5, 7mm	7.0
P10-310-I508	Size 5, 8mm	8.0
P10-310-I509	Size 5, 9mm	9.0
P10-310-I510	Size 5, 10mm	10.0
P10-310-I511	Size 5, 11mm	11.0
P10-310-I512	Size 5, 12mm	12.0

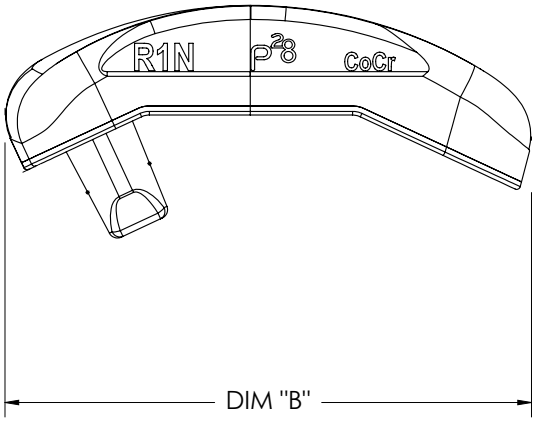




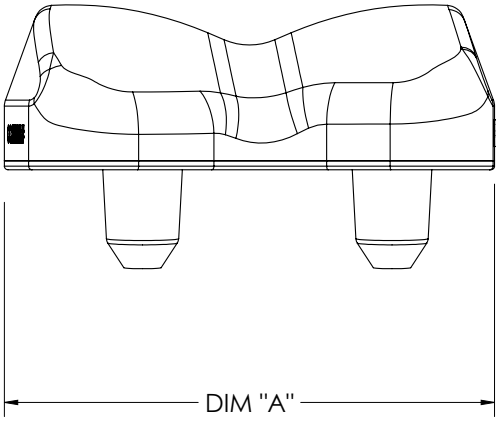
IMPLANT SPECS – TALAR DOME

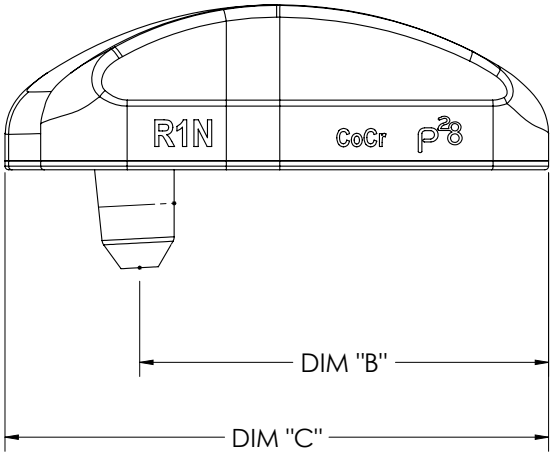
PART #	CONFIGURATION	DIM "A" [mm]	DIM "B" [mm]
P10-250-TLR0	Size 1 N	25.5	28.8
P10-250-TLR1	Size 1	27.0	29.8
P10-250-TLR2	Size 2	29.3	31.7
P10-250-TLR3	Size 3	31.5	33.6
P10-250-TLR4	Size 4	33.8	36.4
P10-250-TLR5	Size 5	36.0	37.2





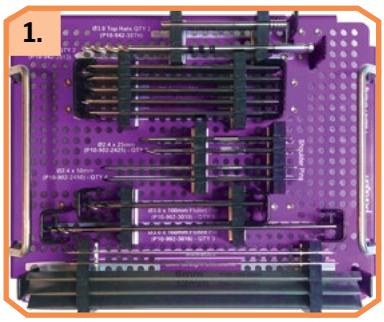
PART #	CONFIGURATION	DIM "A" [mm]	DIM "B" [mm]	DIM "C" [mm]
P10-251-TLR0	Size 1N	27.5	22.9	30.5
P10-251-TLR1	Size 1	29.0	23.5	31.5
P10-251-TLR2	Size 2	31.3	25.2	33.3
P10-251-TLR3	Size 3	33.6	26.0	35.0
P10-251-TLR4	Size 4	35.8	27.0	36.9
P10-251-TLR5	Size 5	38.0	27.8	38.6

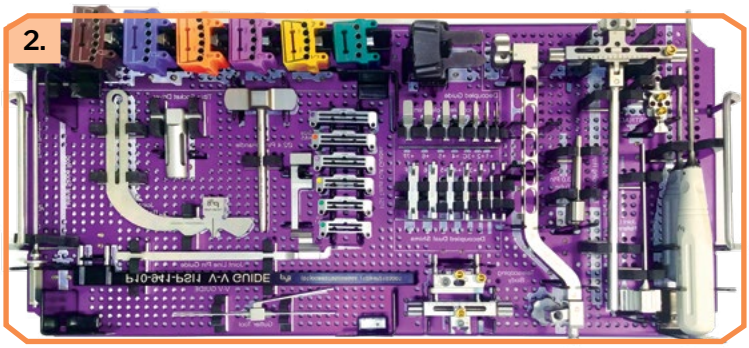




ALIGNMENT CASE & TRAY INSERTS

ALIGNMENT CASE – TOP

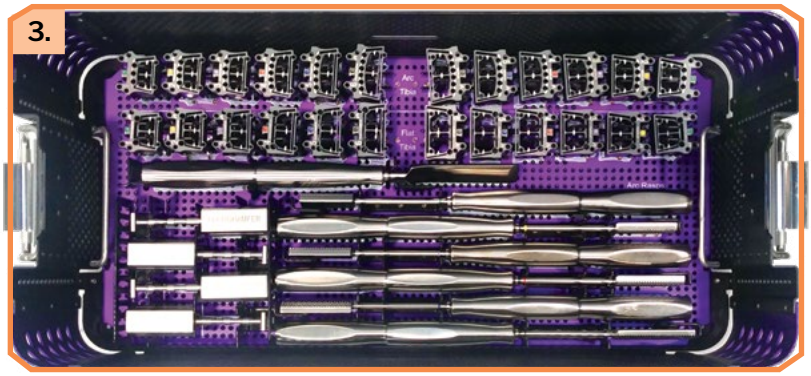




TRADITIONAL ALIGNMENT CONSTRUCT INCLUDING:

- Hex Driver, Telescoping Shaft & Distal Control Body, Joint Line Pointer, Reference Wing & Lateral Slope Rod, Sizing Resection Blocks and a Decoupled Resection Block with both Split & Dual 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

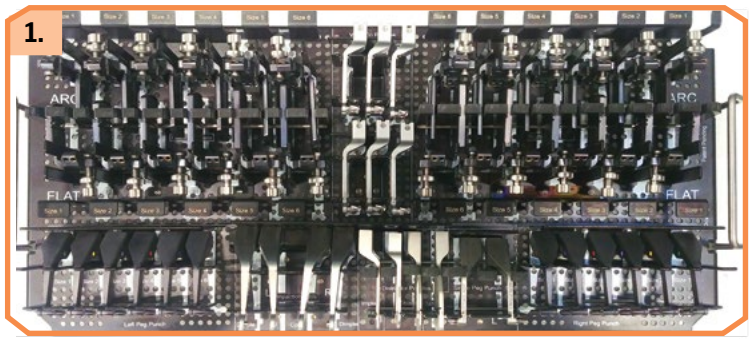


TIBIAL BONE PREPARATION INSTRUMENTS INCLUDING:

- 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

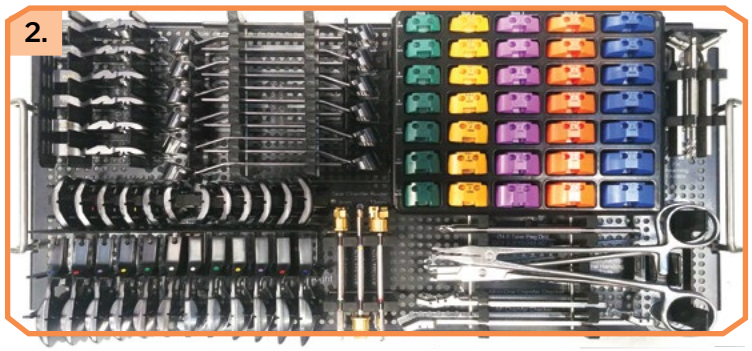
RESECTION CASE – TOP



TIBIAL SIZING GUIDES & VERTICAL PEG PREPARATION INSTRUMENTS INCLUDING:

- Left & Right ARC Tibia™ / Flat Tibia Sizing Trials, and 4-Bar Viper Tip, Distraction & Impaction Paddles are located within this top case insert.

RESECTION CASE – BOTTOM

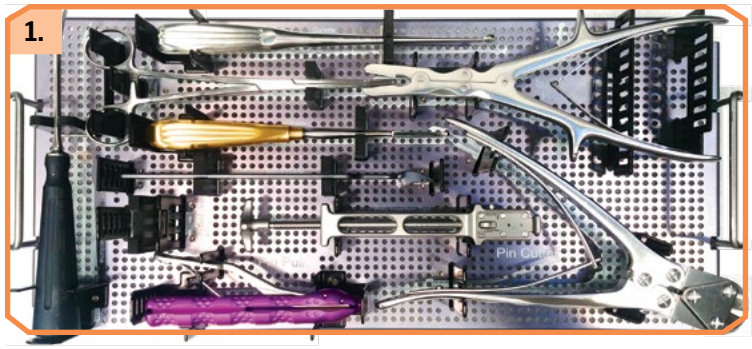


TALAR SIZING GUIDES & BONE PREPARATION INSTRUMENTS INCLUDING:

- 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

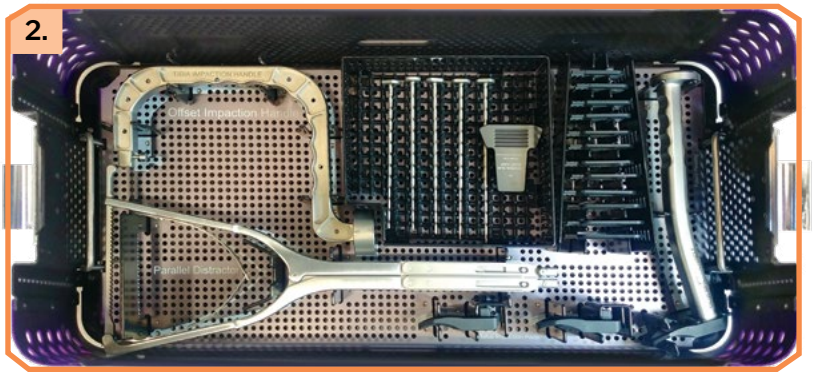
LARGE INSTRUMENT CASE – TOP



TIBIOTALAR BONE PREPARATION INCLUDING:

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

LARGE INSTRUMENT CASE – BOTTOM



IMPACTION TOOLS INCLUDING:

- 4-Bar Distractor, Offset Handle, Talar Implant Protectors & Handle are located within this bottom case insert.

APEX 3D™
TOTAL ANKLE REPLACEMENT

P10-STG-0001 Rev F [2023-01-20]

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