

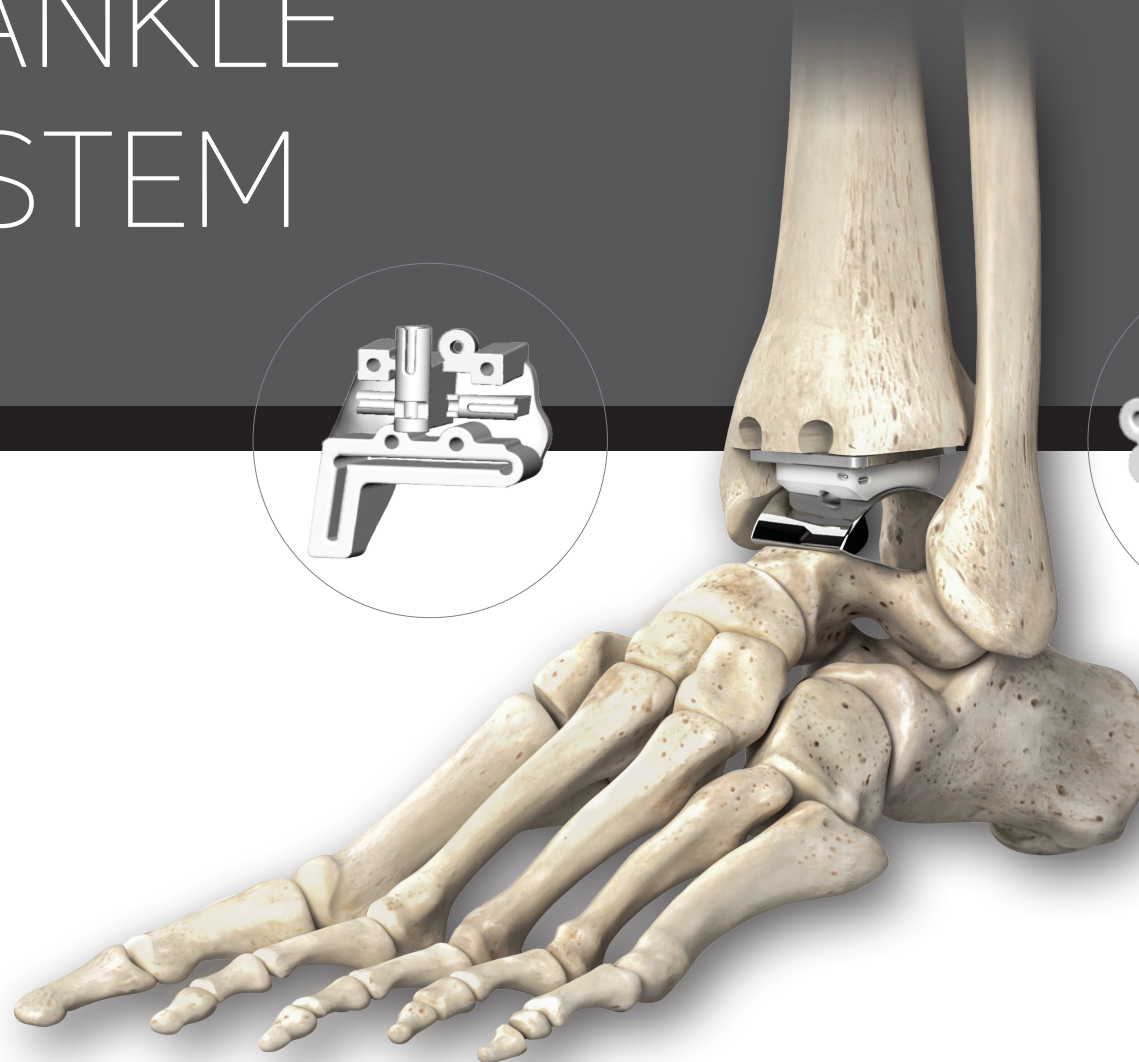


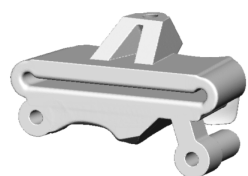
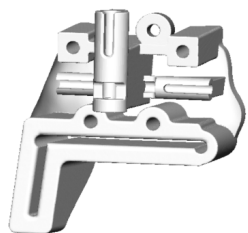
SURGICAL  
TECHNIQUE

enovis™

# STAR<sup>®</sup> ANKLE PSI SYSTEM

TOTAL ANKLE REPLACEMENT





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When indicated, stop and refer to the case report.

Enovis™ is a manufacturer of orthopedic implants and does not practice medicine. This surgical technique was prepared in conjunction with licensed health care professionals and details the principal tibial and talar cuts with the STAR® Ankle PSI System cut guides. Refer to the operative technique MKT0190301 for the full technique with original instrumentation. The treating surgeon is responsible for determining the appropriate treatment, technique(s), and product(s) for each individual patient.

See package insert (IFU 900-01-021) for complete list of potential adverse effects, contraindications, warnings and precautions.

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

Please remember that the compatibility of different product systems has not been tested unless specified otherwise in the product labeling.

The surgeon must discuss all relevant risks with the patient.

## INDICATIONS

### STAR® ANKLE PSI SYSTEM

The STAR® Ankle PSI System is intended to be used as patient specific surgical planning and instrumentation to assist in the positioning of total ankle replacement components intraoperatively, and in guiding bone cutting. The STAR Ankle PSI System is intended for use with Enovis' STAR Ankle System and its approved indications for use as approved in P050050.

The anatomical landmarks necessary for the design and creation of the STAR Ankle PSI System must be present and identifiable on computed tomography (CT) scan.

The STAR Ankle PSI System is indicated for single use only and is generated from CT imaging data.

## CONTRAINDICATIONS

### STAR™ PSI SYSTEM

The guides and models from the STAR Ankle PSI System and the associated case report should not be used if any of the following occur:

- Patient has an active infection.
- Significant changes to patient's anatomy have occurred since the medical scan used for product definition was obtained.
- The patient presents one of the contraindications for Enovis' STAR Ankle System (refer to Enovis' STAR Ankle System sterile implant instructions for use).

## WARNINGS & PRECAUTIONS

To avoid serious injury, patient identification on guides and models must be verified and confirmed against patient identification prior to use.

Guides and models are designed for a specific patient. To avoid the potential for serious injury, guides and models should not be modified in any way.

To avoid potentially serious allergic reactions, ensure that the patient is not allergic to the materials used in the guides and models prior to use.

Device(s) are single use only and designed for use with a specific patient only.

Prior to use of any STAR PSI guides and models, the user must thoroughly review the instructions for use (IFU 900-01-021) and all other labeling provided with the devices.

The presence of any moisture on the wrap should be visually monitored. If any moisture is observed after 60 minutes, then the cycle is not considered sterile.

Adequate training and familiarity with the STAR implant system surgical technique is required to avoid increased risk of device failure due to improper surgical technique.

Switch to standard STAR instrumentation if the device is dropped in the surgical suite.

Switch to standard STAR instrumentation if the device does not fit patient anatomy or pre-existing metal interferes with device use.

STAR PSI guides and models are shipped in a non-sterilized state. To avoid possibility of infection, open, clean, and sterilize per provided instructions before use.

To ensure that damage has not occurred during shipping and handling, inspect all guides and models for damage prior to use. Do not use if the guides or models are broken, cracked, or otherwise damaged.

To ensure successful surgery, have a tray of standard STAR instrumentation available at the time of surgery.

Guides and models may be sterilized up to two times for the prescribed patient, but may not be re-used for additional surgical procedures.

To avoid material toxicity reactions, contact time for each material should be limited to the time shown below:

<b>MATERIAL</b>	DURAFORM PROX PA®
<b>DEVICE</b>	GUIDES & MODELS
<b>CONTACT DURATION</b>	LIMITED (≤ 24 HOURS)
<b>BODY CONTACT</b>	TISSUE/BONE/ MUCOSAL MEMBRANE

## ADVERSE EFFECTS

Potential device related adverse effects include:

- Bone fracture
- Allergic reaction
- Loss of anatomic positioning with rotation or angulation
- Damage to ligamentous, tendinous, and surrounding soft tissues
- Pain and nerve injury
- Surgical complications including but not limited to: vascular disorders, thrombophlebitis, hematoma or damage to blood vessels resulting in blood loss, or death
- Superficial or deep infection at any point in time post-operatively

### CAUTION: MRI SAFETY INFORMATION


The STAR PSI System has not been evaluated for safety and compatibility in the Magnetic Resonance (MR) environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the STAR PSI System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

## TECHNIQUE OVERVIEW

Principal surgical technique steps include:

- Orienting the STAR PSI System Tibial Cut Guide in the axial and coronal planes on the tibia
- Tibial resection
- Orienting the STAR PSI System Talar Cut Guide on the talus
- Datum positioning
- Talar dome resection
- Talar component sizing
- Talar chamfer cuts
- Talar keel preparation
- Tibial barrel hole preparation
- Final implant placement

## REFERENCE CASE REPORT (PG. 10)

 **NOTE:** Prior to surgery date CT Scan shall be uploaded to develop a preoperative case report to be reviewed and approved by the surgeon.

## CT SCAN

To improve expected cut guide fit, a CT scan should be obtained per the Enovis STAR PSI CT scan protocol DF-PSI-0006. Failure to obtain a recent CT scan and utilization of the approved CT Scan Protocol may result in less than optimal cut guide fit. Increased intra-operative site preparation may be required and should be expected. The case report should be reviewed and approved by the case surgeon.

## USE BY DATE

Refer to the expiration date listed on the part package label for product shelf life. Note that it is required to perform the surgery within 6 months of the CT scan date to ensure anatomic changes are minimized. If the patient's anatomy has changed significantly since the time of the CT scan, the patient specific guides and models should not be used, even if the time period of 6 months has not expired.

The CT scan protocol can be accessed through the Enovis (<https://www.djoglobal.com/products/djo-global/star-ankle>) or eRequest (<https://enovis.enhatch.com>) website:

1. Log in (if you do not have an account, contact your local sales representative).
2. Select "Content Files" tab on left-hand side of screen.
3. Select STAR PSI 'CT Scan Protocol' to download.
4. Obtain CT scans and follow steps on the portal to initiate case planning.

### ORDER & DELIVERY

The surgeon must prescribe and order this device. Manufacturing will be initiated upon receipt of the surgeon's approval of the design. Requests for revision may extend the turnaround time pending surgeon approval.

A case must be approved through the eRequest site. To approve a case:

1. Go to <https://enovis.enhatch.com>.
2. Log in (if you do not have an account, contact your local sales representative).
3. Locate the pending approval and open PDF attachment. Review the preliminary report.
4. Either **approve** or **reject** the preliminary report. If the report is rejected, you will be prompted to enter notes pertaining to redesign or request a call with design engineers.
5. After accepting or rejecting the report, approval is a two step process. You must hit the submit button after accepting or rejecting the plan.

### WARRANTY & LIABILITY

Certain risks and harms are inherent with the use of all total ankle replacements. Please refer to the IFU 900-01-021 for indications, contraindications, adverse events and other similar information. It is your responsibility to review the IFU prior to proceeding.

Since the cut guides are patient-specific, it is your legal and ethical duty to ensure that these devices are not used in any patient other than the patient they were specifically designed for pursuant to the

original prescription. If you do not use these devices for the patient indicated in your prescription, it is your responsibility to dispose of the unused product.

### SURGICAL TECHNIQUE

This document is intended solely for the use of healthcare professionals. A surgeon must always rely on their own professional clinical judgment when deciding to use a product to treat their patient. Enovis does not dispense medical advice and recommends that surgeons be trained in the use of any product before using it in surgery.

The information presented is intended to demonstrate an Enovis product. A surgeon must always refer to the package insert, product label and/or instructions for use, including the instructions for cleaning and sterilization (if applicable), before using any Enovis product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Enovis representative if you have questions about the availability of Enovis products in your area.

Enovis or its divisions or other corporate affiliated entities own, use or have applied for the following trademarks or service marks: STAR® Ankle, Enovis™. All other trademarks are trademarks of their respective owners or holders.

## COMPONENTS

- Power equipment:
  - Oscillating saw handpiece and respective sawblade
  - Reciprocating saw handpiece and respective sawblade
  - Drill Handpiece with the following attachments:
    - Jacobs Chuck and Chuck Key
    - Pin driver (2.4mm to 3.2mm)
- Sterile Instruments (disposables):
  - 3.2mm drill tip pin (referred to as alignment rod in technique)
  - 2.4mm drill tip pins
  - Shoulder screws (15mm and 20mm)
  - Anterior mill
  - Barrel hole drill
  - Talar keel mill
- Other items needed:
  - Osteotomes (straight and curved)
  - Angled curette
  - Rongeurs
  - Army/navy retractors
  - 6mm pituitary rongeur
  - Pin (bolt) cutters

**⚠ CAUTION:** Before the patient is in the room or under anesthesia:

- Confirm the correct patient specific case report is present.
- Confirm the patient specific cut guides are in the room, have been sterilized and tibial/talar cut guide Case ID numbers match the patient case report.
- Confirm the correct power equipment and correlating sawblades are available.
- The three standard STAR instrument trays are complete.



**REFERENCE CASE REPORT** (PG. 15)

**Section:** Appendix: Kit Information

### APPROACH

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

After the foot and ankle have been correctly positioned, the leg is elevated for about 2 minutes, and a thigh high tourniquet is inflated with an appropriate amount of pressure for the size of the patient's leg and foot.

A longitudinal 20cm incision is centered over the ankle immediately lateral to the anterior tibial tendon. The incision is deepened to the ankle joint while retracting the extensor hallucis longus and the neurovascular bundle laterally. The superficial branch of the peroneal nerve in the foot is visible and must be retracted carefully to the lateral aspect of the ankle.

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

#### WARNING:

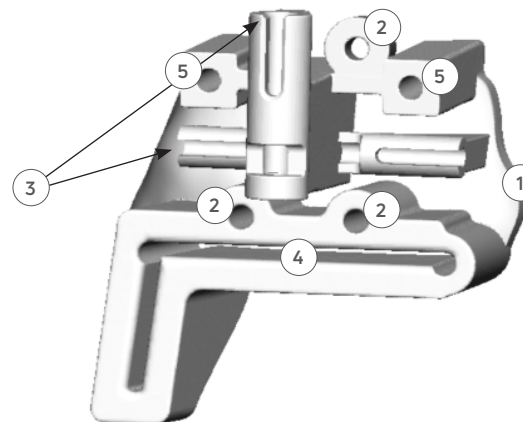
- Avoid opening the tendon sheath of the anterior tibial tendon, since this may cause difficulty in closure.
- After the tendon sheath of the extensor hallucis longus is opened, the deep peroneal nerve and artery are identified and are gently retracted. The ankle capsular tissues are incised in line with the skin incision and then are elevated and mobilized exposing the medial malleolus and lateral malleolus. If the capsule is of sufficient quality, it should be saved to close over the prosthesis.
- Avoid the release of the anterior talofibular ligament as this may lead to lateral instability.
- The ankle joint is distracted slightly, and hypertrophic synovium, intraarticular loose bodies or periarticular spurs are resected. Osteophytes on the anterior distal tibia are removed to visualize the tibial plafond.

#### CAUTION:

- Self-retaining retractors should be avoided when possible to eliminate excess pressure on the skin edges.
- Hand-held retractors should be frequently repositioned to minimize the risk of tissue trauma.

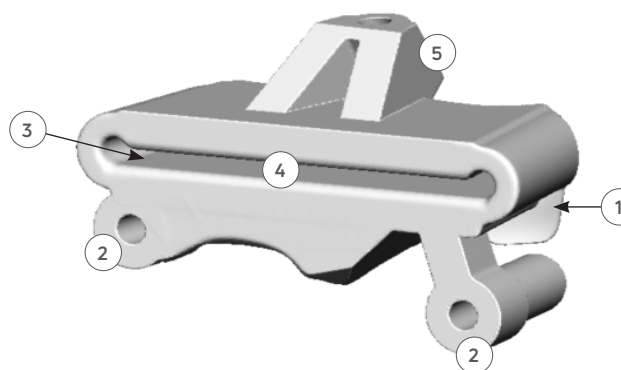
### TIBIAL CUT GUIDE

- 1. Patient specific feature** – bone contacting surface
- 2. Tibial attachment pins** – two tibial pin holes and one oblique hole for stability; tibial pin holes also identify the implant barrel holes
- 3. Alignment checks** – rotational alignment sight, tibial alignment rod, angel wing
- 4. Cut slot** – patient configured cut slot with malleolar protection pins
- 5. Recut holes** – quickly transition to original STAR instrumentation



### TALAR CUT GUIDE

- 1. Patient specific feature** – bone contacting surface on guides for proper cut guide placement
- 2. Talar attachment pins** – talar medial and lateral gutter pins that set the inferior margin of the M/L chamfer cuts.
- 3. Alignment checks** – coronal/rotational alignment, angel wing
- 4. Cut slot** – patient configured cut slot with malleolar protection pins
- 5. Datum pin hole** – places datum pin to complete A/P and M/L chamfer cuts with the original STAR instrumentation





## STEP 0: INITIAL PREPARATION

To improve alignment of the tibial cut guide under fluoroscopy, it is recommended to place marker pins in the guide. Using a Pin Cutter, remove the sharp tip of a 2.4mm K-Wire. Cut two 1/2" segments of the K-Wire and Insert them into the two Cross Pin Holes of the Tibia Guide (**FIGURE 1.1A**).

## STEP 1: TIBIAL CUT GUIDE SETUP


**1.1** Place the PSI tibial cut guide on the anterior distal portion of the tibia.

Ensure the PSI tibial cut guide is sitting flush against the bone. The cut guide should easily sit in the planned position on patient's tibia with minimal gapping, slope, or rocking.

Confirm the red highlighted areas are in contact with the guide, as shown in **FIGURES 1.1B, 1.1C** and **1.1D**.

### REFERENCE CASE REPORT

Patient Specific Footprint (Pg. 5)  
Appendix: Existing Hardware, Cysts (Pgs. 4-6)

 **NOTE:** Soft tissue needs to be stripped to ensure proper fit.

### CAUTION:

- Consult the case report for information on cysts or hardware that may be present on the patient.
- Cut guides that are dropped on the floor after removal from packaging may be damaged and must be discarded. Please revert to standard STAR™ instrumentation to continue the procedure.

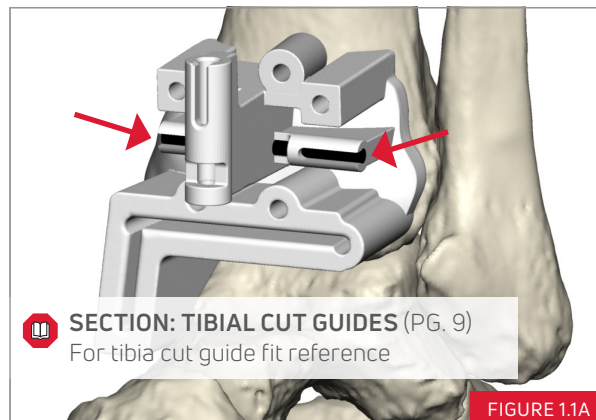


FIGURE 1.1A

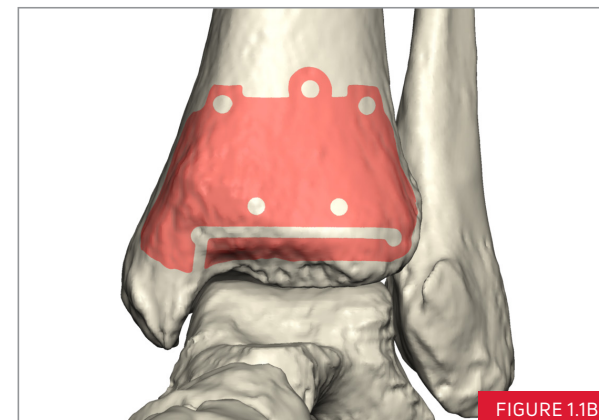


FIGURE 1.1B



FIGURE 1.1C

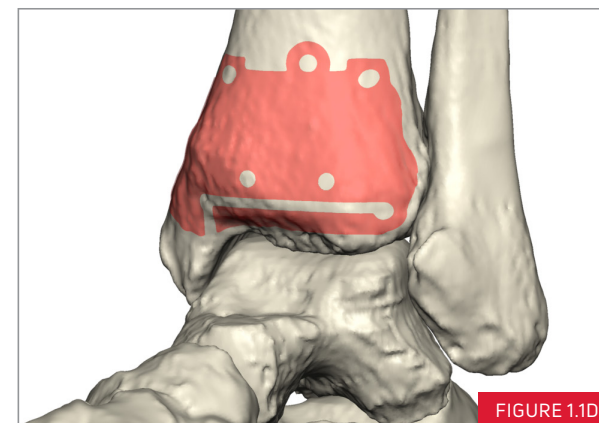




FIGURE 1.1D

**1.2** Once the proper position of the PSI tibial cut guide is confirmed, hold the guide firmly against the patient's bone and place a 2.4mm pin through one of the tibia barrel pin holes and through the first cortex and oblique hole.

 When indicated, stop and refer to the case report.

 **NOTE:** The two superior recut holes in the tibial cut guide are not required for fixation/stability during tibial resection. They are for standard STAR instrument alignment if additional bone resection is required after Joint Space Evaluator assessment (Step 5.6).

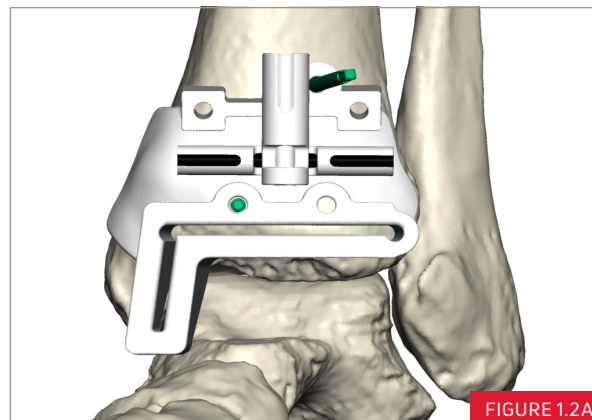


FIGURE 1.2A

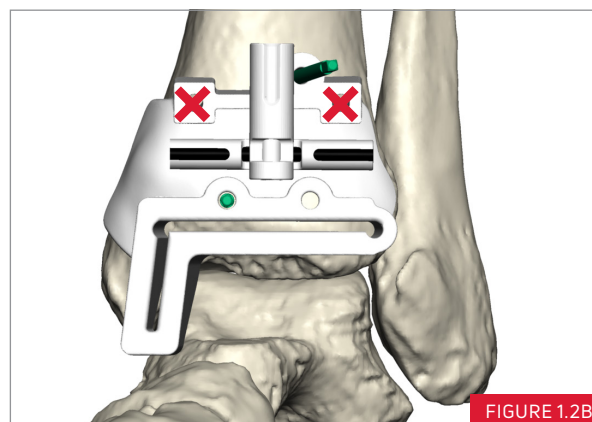


FIGURE 1.2B

## STEP 2: CORONAL PLANE ALIGNMENT

### 2.1 Confirm the PSI cut guide coronal plane alignment.

Place the 3.2mm drill tip pin into the tibial alignment hole on the tibial cut guide. Under fluoroscopy rotate the patient's tibia to achieve direct A/P perspective.

A direct A/P perspective is confirmed when the alignment rod is equidistant from the edge of the cross pins.

In the lateral view the alignment rod will not be 90 degrees to the cut plane. The alignment rod is angled by 3 degrees to the cut plane, regardless of the selected cut angle, in order to reduce the risk of alignment rod impingement on soft tissues.



*CORRECT ALIGNMENT: ALIGNMENT ROD IS CENTERED BETWEEN THE CROSS PINS*



*INCORRECT ALIGNMENT: ALIGNMENT ROD NOT CENTERED BETWEEN THE CROSS PINS*

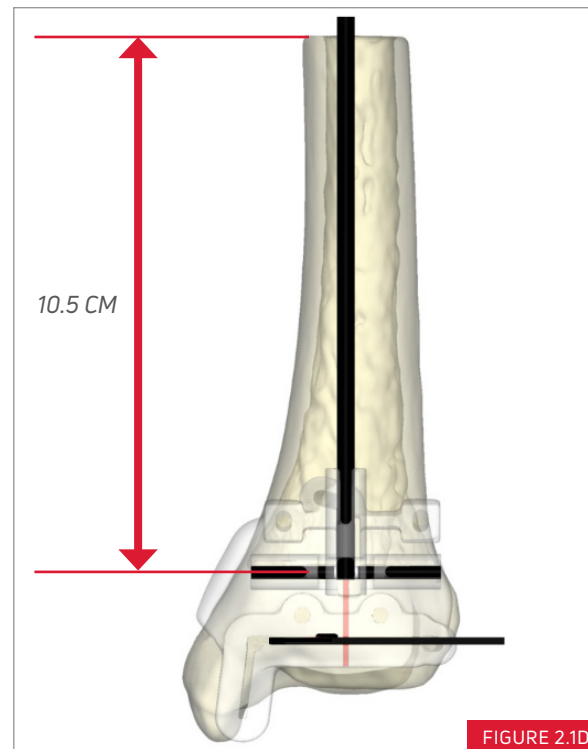
Refer to the Case Report for height location on the Alignment Rod, and mark corresponding height on the skin for reference

Compare the actual alignment against the case report alignment utilizing fluoroscopy.

**NOTE:** If coronal alignment is not correct, remove pins and reposition the guide.

**REFERENCE CASE REPORT**  
Tibial Cutting Guides (Pg. 10)

*ALIGNMENT ROD CORONAL PLANE ALIGNMENT*

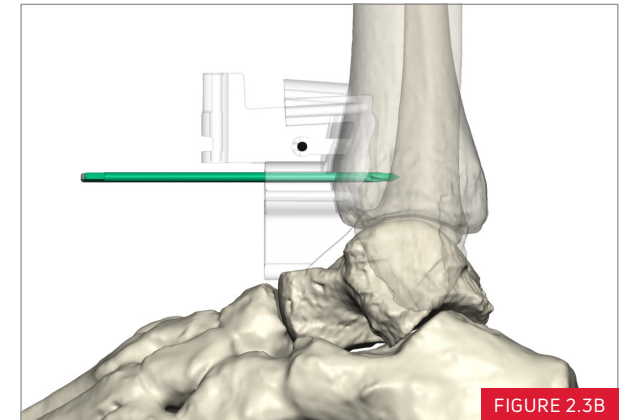
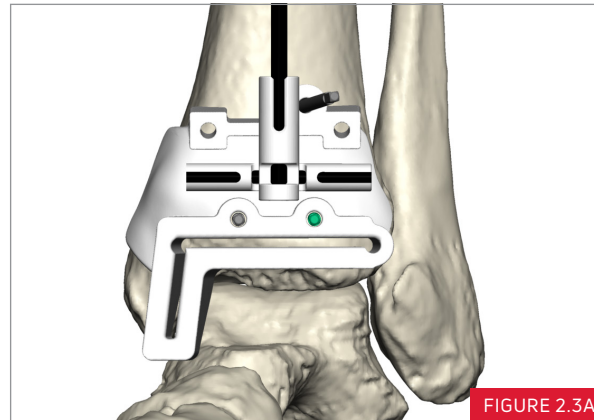
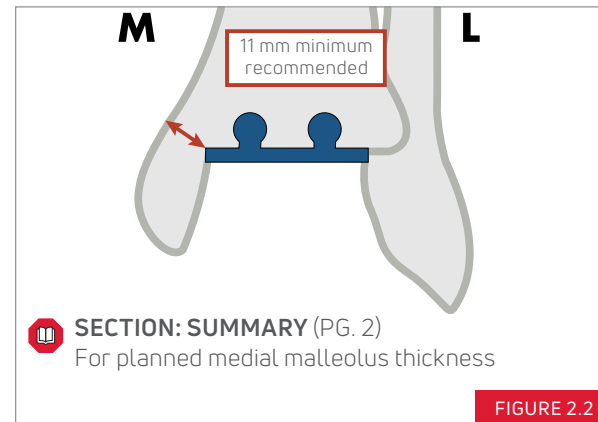


2.2 Compare fluoroscopic view of expected post-cut medial malleolus thickness against case report (pg. 2).

**⚠ WARNING:** Ensure the thickness is sufficient to avoid compromising the medial malleolus.

A minimum bridge of 11mm is recommended. If a narrower section is required due to patient anatomy, a reinforcing screw is recommended.

If alignment rod and PSI tibial cut guide position is acceptable, continue to Step 3.1.



### STEP 3: TIBIAL RESECTION

**3.1** Check the slope of the planned cut and the amount of bone resection. Insert the angel wing into the cut slot, then take a lateral fluoroscopic image. Adjust the foot positioning so the angel wing is parallel to the fluoro image and get a true picture of the amount of bone to be resected. Consult the case report for planned alignment.

The angel wing extends 5mm superior and inferior from the central blade. The pegs are spaced 10 mm apart and can be used to estimate tibial tray size.

Magnification will be affected by the distance of the angel wing from the bone and the orientation of the fluoro source relative to the foot.

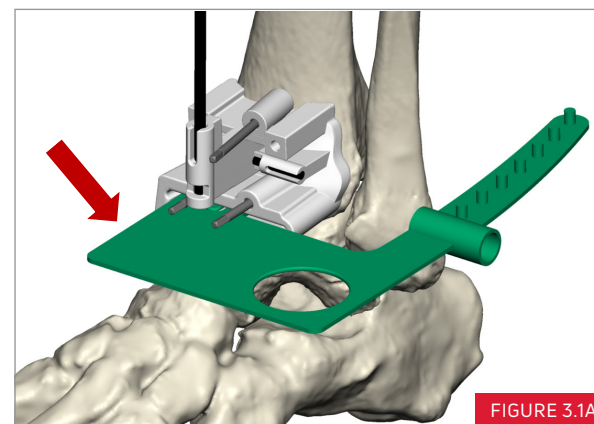


FIGURE 3.1A

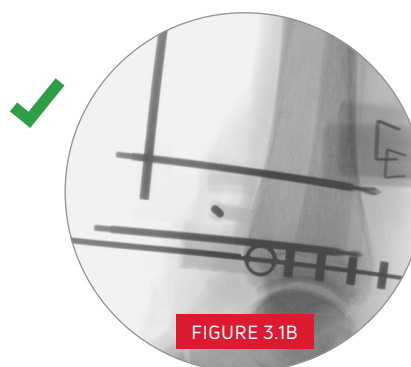


FIGURE 3.1B

CORRECT ANGEL WING ALIGNMENT

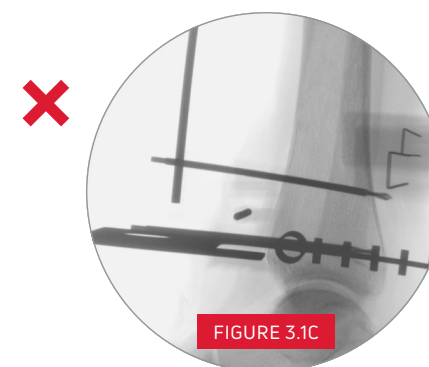


FIGURE 3.1C

INCORRECT ANGEL WING ALIGNMENT: ANGEL WING NOT PARALLEL TO FLUOROSCOPIC IMAGE

**NOTE:** The angel wing mimics the thickness of the saw blade.

**WARNING:** Proper slope and amount of bone resection must be confirmed using the angel wing and alignment rod prior to cutting. If proper alignment cannot be achieved, revert to general STAR™ instruments.

If reverting to the general STAR instruments, please see Step 1 in the in the STAR (MKT0190301-001) operative technique.

### REFERENCE CASE REPORT

Tibial Cut Guides (Pg. 10) - for planned tibial cut angle and LM view

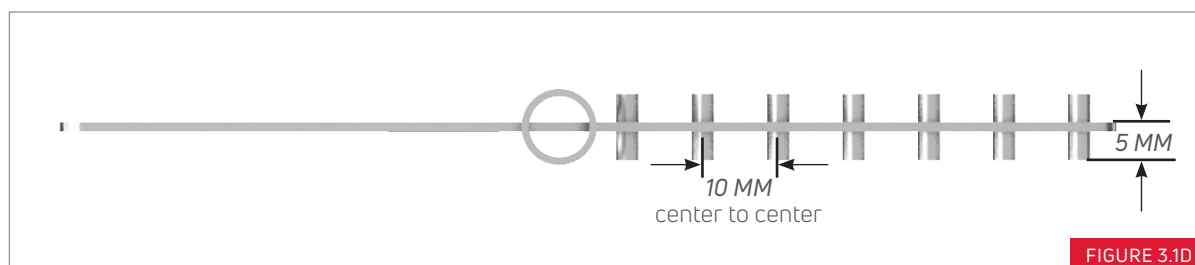


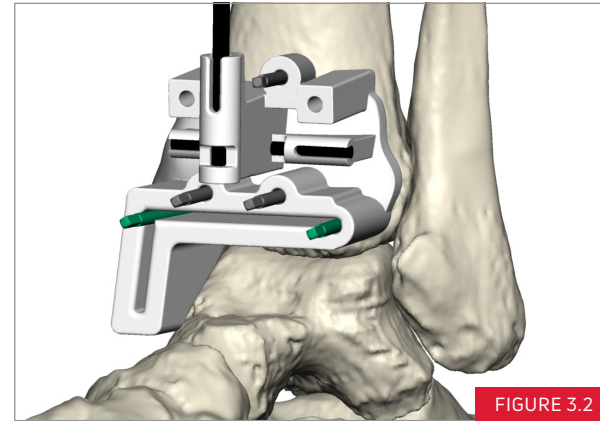
FIGURE 3.1D

**3.2** After the correct PSI tibial cut guide alignment is confirmed, insert a second 2.4mm drill tip pin in the tibial barrel hole. Remove the angel wing, and place two 2.4mm pins in the tibial cut capture on both the medial and lateral side. Medial/lateral pins are intended to protect the malleoli from fracture during the tibial cuts. Drive the pins bicortically to ensure the medial and lateral malleoli are protected during the transverse cuts.

**⚠ CAUTION:** Ensure pins are in the posterior cortex to provide stability to the guide and prevent interference of saw during cuts.

**3.3** Ensure the PSI cut guide did not shift while pinning and is still flush with the tibial surface.

**⚠ CAUTION:** Ensure guide is stable prior to cutting.



**3.4** Refer to the Case report (DF-PSI-0007 (Pg. 2)) for the sawblade cut depth, and mark the sawblade accordingly.

**3.5** Use the oscillating sawblade in a pecking motion to make the transverse distal tibial cut.

**⚠ CAUTION:** Care should be taken to not overcut the tibial bone. Avoid cutting beyond the posterior cortex to prevent soft tissue damage.

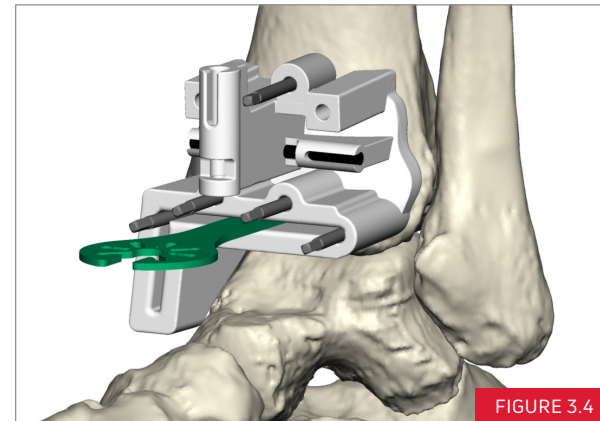


FIGURE 3.4

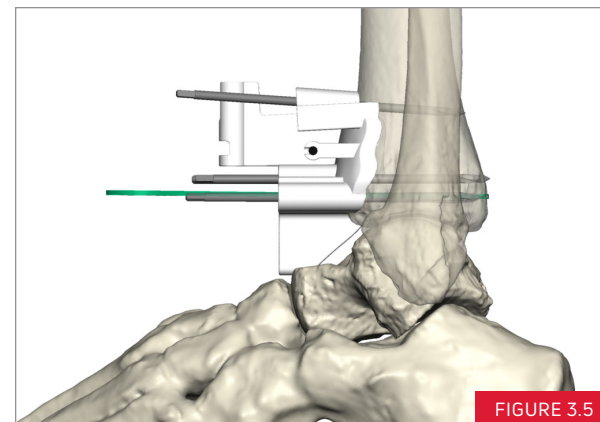


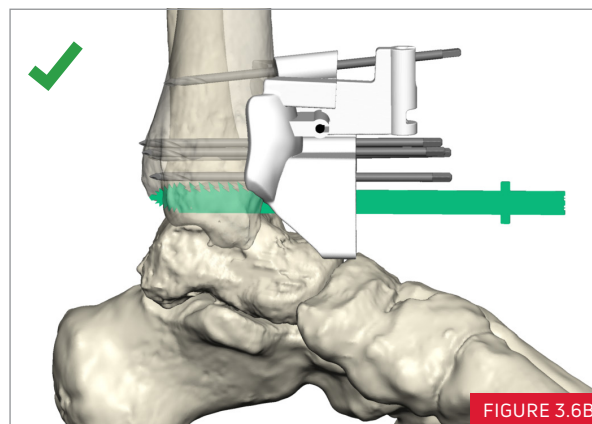
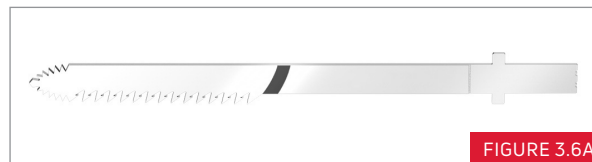
FIGURE 3.5



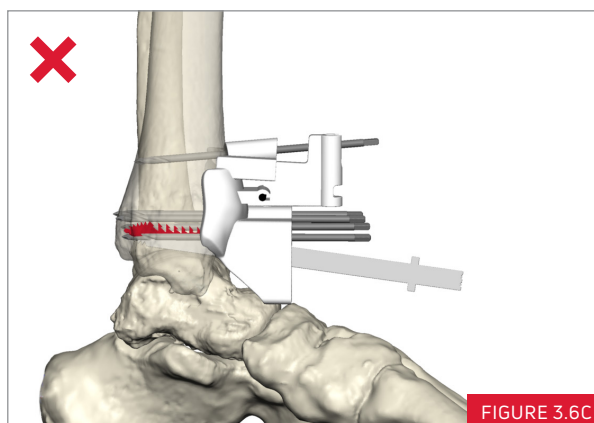
**3.6** Use STAR-approved reciprocating sawblade to connect the transverse cut and the medial gutter at the medial malleolus.

**NOTE:** Avoid notching the medial malleolus. By keeping the sawblade parallel to the pin. Do not angle the sawblade/handpiece inferiorly towards the foot, as the sawblade can bypass the protection pin.

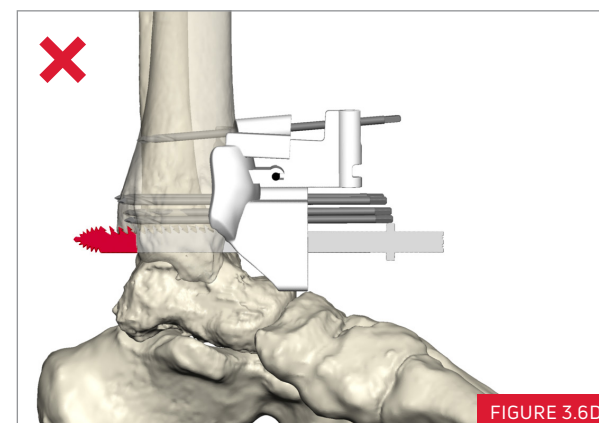
**CAUTION:** Care should be taken to not overcut the tibial bone. Avoid cutting beyond the posterior cortex to prevent soft tissue damage.



CORRECT



INCORRECT: SAWBLADE ANGLED TO THE PIN

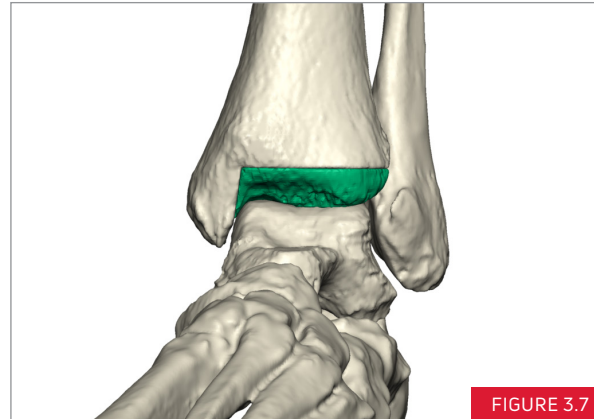


INCORRECT: SAWBLADE PAST THE POSTERIOR CORTEX

**3.7** Remove the oblique, tibial attachment, and cut capture protection pins. Then, remove the tibia PSI cut guide.

Save the PSI cut guide in case additional resection is required after Joint Space Evaluator assessment (Step 5.6). Remove resected bone.

Using osteotomes, rongeurs, or other surgical instruments, remove all resected tibial bone and thoroughly irrigate the joint space to remove debris.



**⚠ CAUTION:**

- Avoid damage to the anterior cortex of the tibia while removing the resected tibia bone. The adjustable slider block can be slid over the pins for additional protection of the anterior cortex during bone removal.
- Pressure applied to either the medial or lateral malleolus may cause fracturing. The risk of fracture would increase if either of these surfaces are notched by aggressive cutting of the tibia.

**📄 NOTE:** Do not discard the STAR™ PSI cut guide as the recut holes may be used to switch to the standard instruments (see Appendix A).

## STEP 4: TALAR CUT GUIDE

### REFERENCE CASE REPORT

Existing Hardware, Cysts (Pgs. 4-6)  
Talar Cut Guides (Pg. 11)

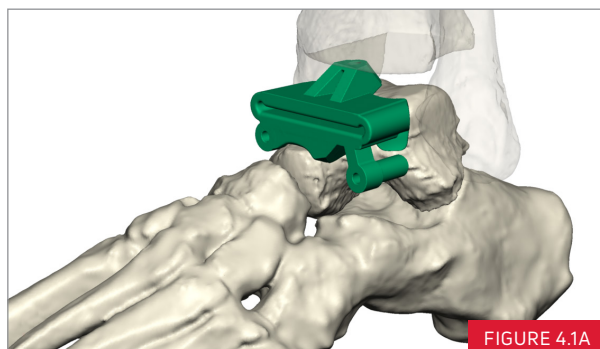
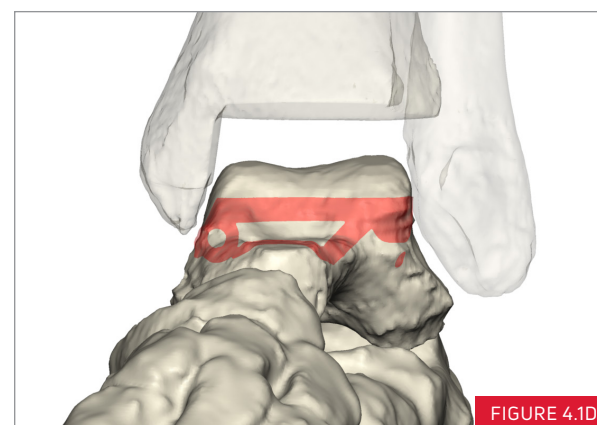
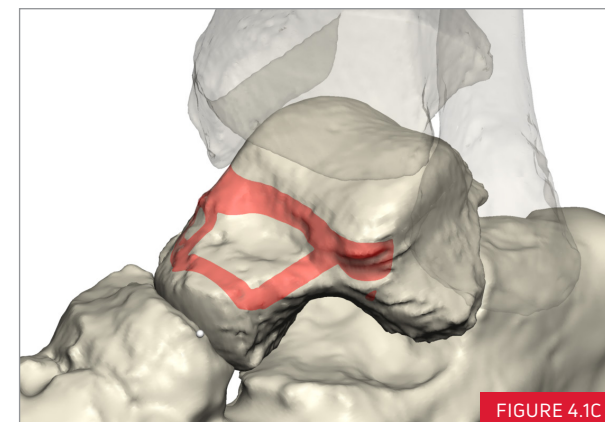
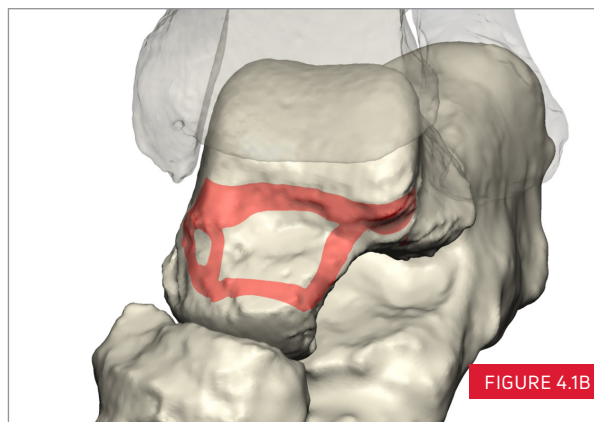
**4.1** Plantarflex the foot and place the PSI talar cut guide onto the talus until fully seated in the planned position. The talar PSI cut guide should fit into one position on the patient's talus. Slide the guide down on the talar neck and push back into the talar body to assist with placement of the talar cut guide.

Confirm the red highlighted areas are in contact with the guide, as shown in **FIGURES 4.1B, 4.1C** and **4.1D**.

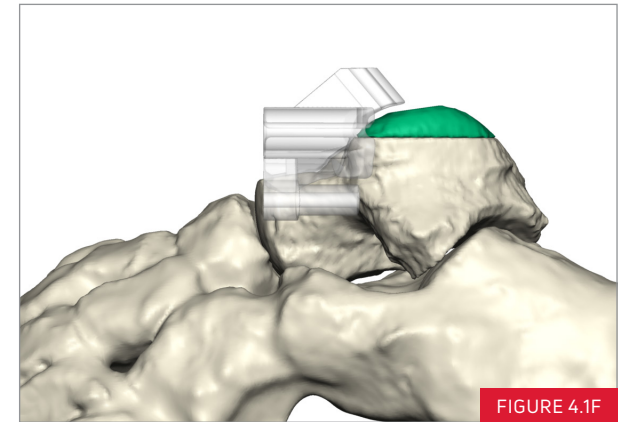
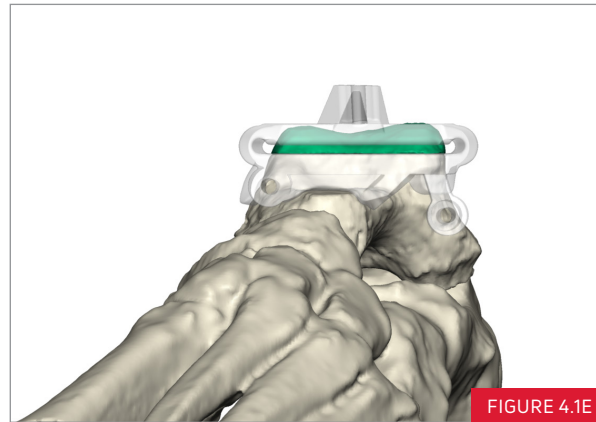
**⚠ CAUTION:** Consult the case report for information on osteophytes or hardware that may be present on the patient.

**📖 NOTE:** The talar cut guide design does not account for any cartilage present. Ensure soft tissue and/or remaining talar cartilage is removed from the PSI cut guide contact areas to allow proper seating of the guide.

### TALAR CUT GUIDE CONTACT AREAS



A/P and Lateral views confirm the amount of bone resection. Compare with the Case Report (pg. 12) to confirm placement of the Talar Cut Guide (FIGURES 4.1E and 4.1F).



**4.2** While holding the PSI talar cut guide in the correct position, plantarflex the foot and insert one 2.4mm pin into the datum pin hole on the top of the guide. Drive the 2.4mm pin past the talar cut plane to allow visualization of the datum hole location after the talar cut. This reduces the chance of the guide shifting when inserting the gutter pins.

If PSI cut guide fit is not acceptable, proceed to Appendix A (pg. 32).

**⚠ CAUTION:**

- Handfeed the pin into the datum hole to avoid changing the orientation of the PSI Cut Guide.
- Avoid driving the pin into the subtalar joint.

**📖 NOTE:** Place the datum pin prior to the gutter pins to ensure proper cut guide alignment.

**📖 REFERENCE CASE REPORT**

Section: Talar Cut Guides (Pgs. 11-12) - for talus cut guide fit reference

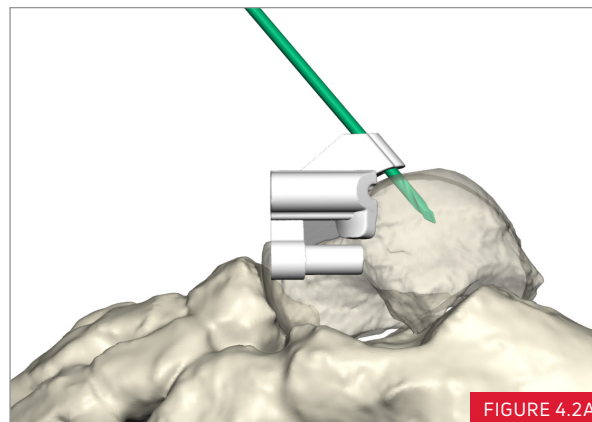


FIGURE 4.2A

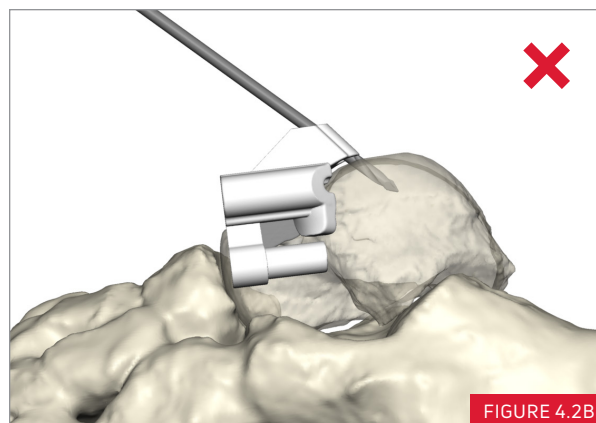


FIGURE 4.2B

*DORSIFLEXED: GAPPING ON TALAR DOME + DATUM PIN TRAJECTORY IS POSTERIOR IN TALAR BODY COMPARED TO PLAN*

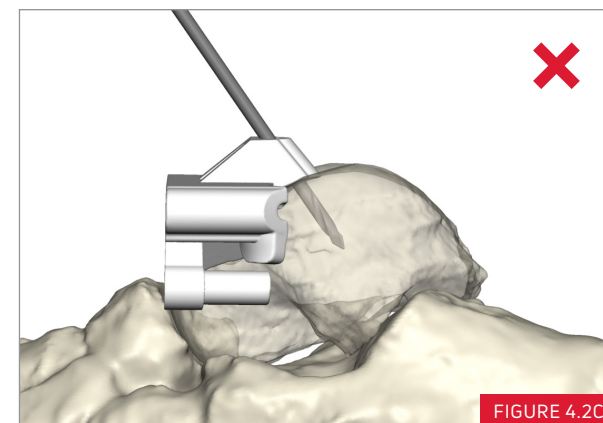


FIGURE 4.2C

*PLANTARFLEXED: GAPPING ON TALAR NECK + DATUM PIN TRAJECTORY IN TALAR BODY IS ANTERIOR COMPARED TO PLAN*

**4.3** While holding the talar PSI cut guide in the planned position, insert 2.4mm pins into the inferior medial and lateral gutter attachment pin holes. Drive both pins bicortically.

**⚠ CAUTION:** Use a pecking motion as each pin first contacts the talus to help reduce pin skiving and guide shifting. If needed, the Shoulder Pin Drivers can be used to insert 2.4mm pins.

**📄 NOTE:** If expected alignment of the talus cannot be achieved, other procedures may be necessary to properly balance the foot.

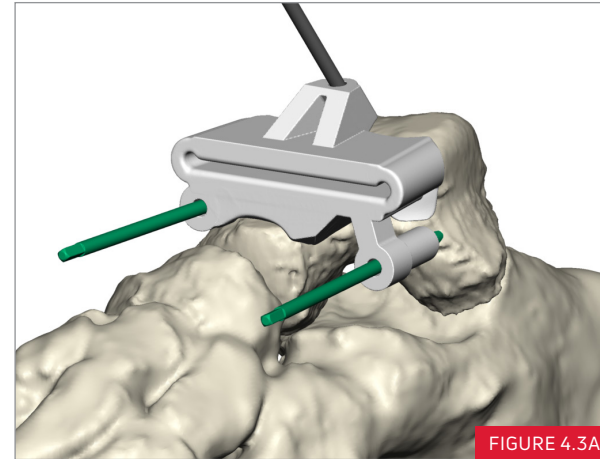


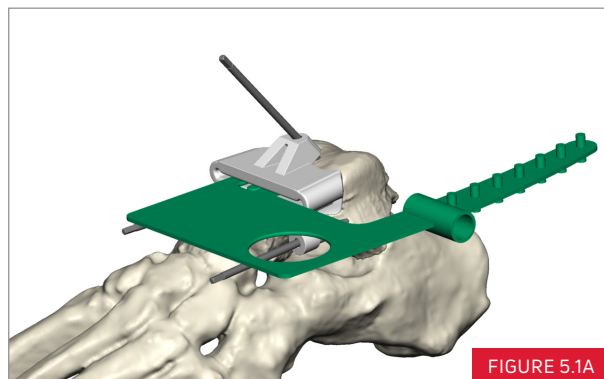
FIGURE 4.3A

## STEP 5: TALAR RESECTION

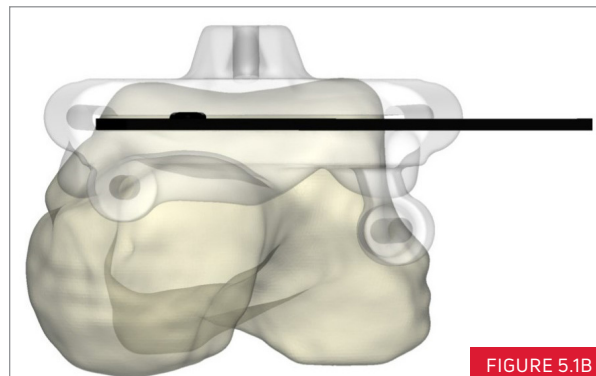
**5.1** Confirm the amount of bone resection and orientation on the talus by inserting the angel wing into the PSI talar cut guide slot. Take an A-P and lateral fluoro shot to confirm the coronal plane orientation and bone resection. Compare this to the design plan.

 **REFERENCE CASE REPORT** (PG. 12)  
Section: Talar Cut Guides

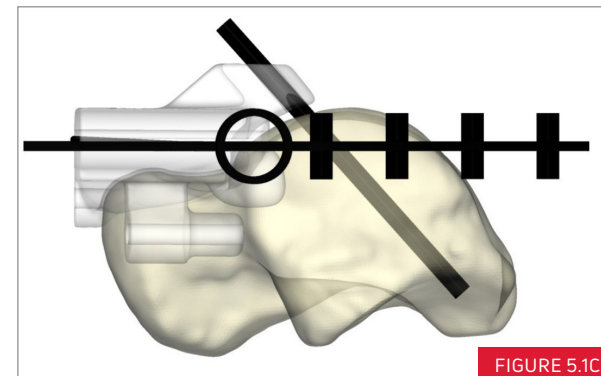
The resection plane should be evaluated and compared to the information in the Talar Cut Guide section of the case report.



### PLANNED TALAR CUT PER DESIGN PROPOSAL



A-P VIEW

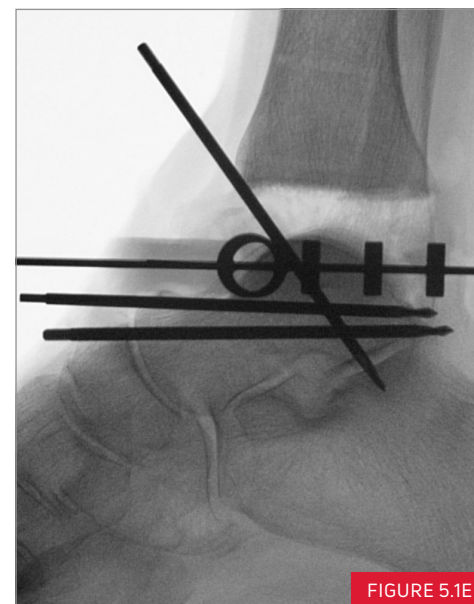


LATERAL VIEW

### FLUOROSCOPIC VIEWS



A-P VIEW



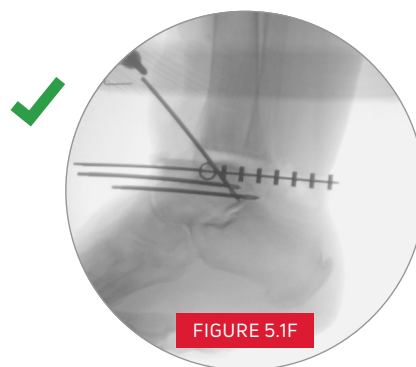
LATERAL VIEW

Be sure the fluoroscopy view is parallel to the angel wing to show an accurate representation of the bone resection. Compare the actual amount of bone resection and orientation with the expected cut on the case report.

If the talar cut guide does not fit appropriately, see Appendix A (Pg. 32) to continue with the tibial alignment guide setup for a standard talar cut.

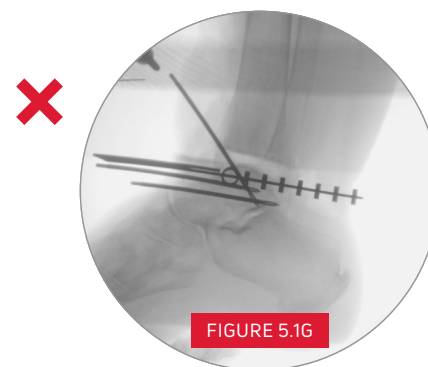
**NOTE:** The angel wing mimics the thickness of the saw blade.

**WARNING:** Proper slope and amount of bone resection must be confirmed using the angel wing prior to cutting. If proper alignment cannot be achieved, revert to general STAR™ instruments.



*CORRECT ANGEL WING ALIGNMENT*

**SECTION: TALAR CUT GUIDES** (PGS. 2-3)  
For planned LM view and resection depth



*INCORRECT ANGEL WING ALIGNMENT:  
ANGEL WING NOT PARALLEL TO  
FLUOROSCOPIC VIEW*

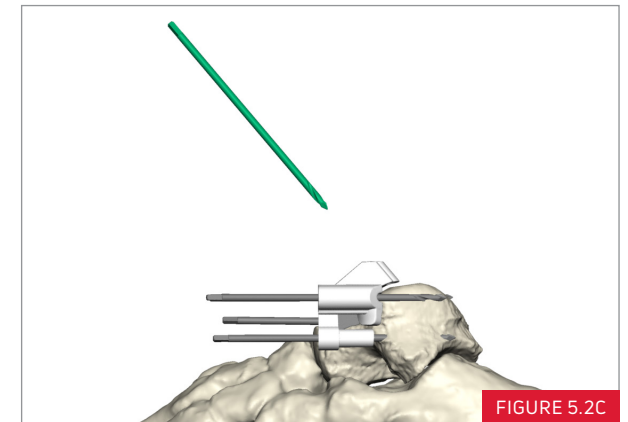
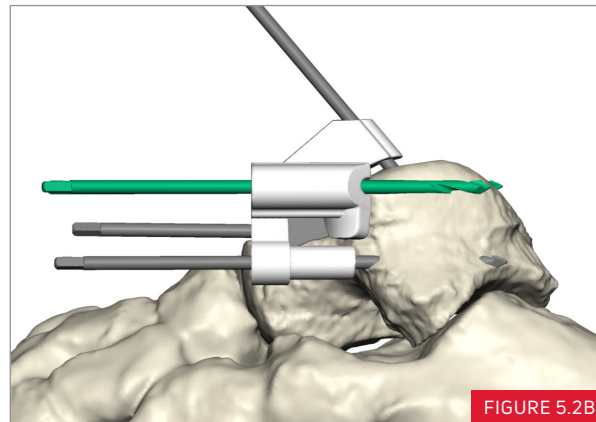
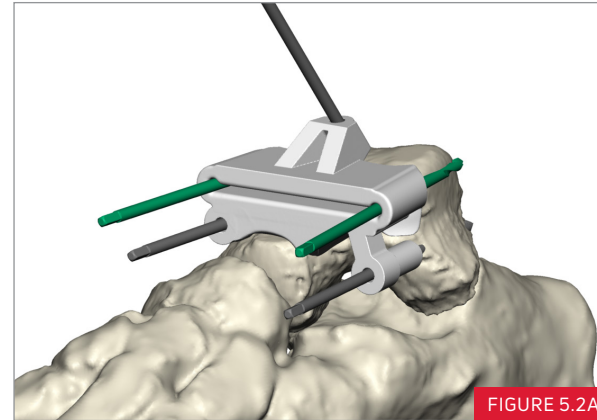


**5.2** Once correct position of the talar PSI cut guide is confirmed, remove angel wing, and insert two 2.4mm pins into the medial and lateral sides of the cut slot. Doing so protects the malleoli while making the dorsal transverse cut to the talus.

Remove the datum pin and ensure the guide did not shift during pinning.

**⚠ CAUTION:**

- Ensure the pins are seated deeply enough to avoid interfering with the saw to properly conduct the talar cuts.
- Ensure guide is stable prior to cutting.



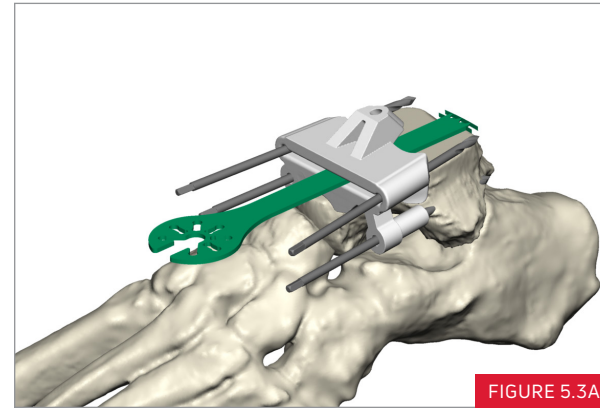
**5.3** Use the oscillating sawblade in a pecking motion to resect the top of the talus. On smaller sizes, space between pins may get too narrow for the sawblade to complete the full depth/width of the cut. If the saw binds on the gutter protection pins, remove the lateral pin, protect the malleoli, and complete the cut.

**⚠ WARNING:** It may be necessary to remove excess bone to ensure the surface of the talus is flat to properly position the post talar cut template (PTCT).



### REFERENCE CASE REPORT

Section: Summary (Pg. 2) - see table for planned talus sawblade cut depth



**5.5** Leaving the inferior lateral attachment pin in place, remove all other pins from the STAR PSI talar cut guide. Slide the guide off the lateral pin.

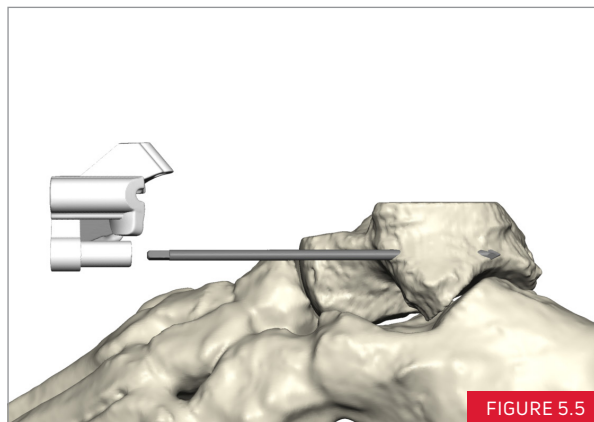
**NOTE:** Leave the medial gutter pin out during reaming of the anterior chamfer. It may interfere with the milling tool, limiting completion of the anterior chamfer cut.

### **REFERENCE CASE REPORT** Appendix: Treatment Details

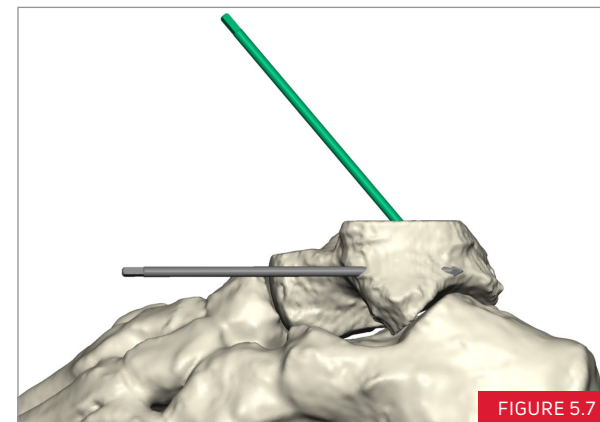
**5.6** Remove resected bone from the top of the talus and thoroughly irrigate the joint space to remove debris. Make sure there are no ridges of bone that may affect the fit of the PTCT. Insert the 12mm end of the joint space evaluator between the cut surfaces of the tibia and talus.

**NOTE:** A minimum of 12mm of space is required for placement of the STAR tibial and talar components with a 6mm polyethylene bearing.

If the joint space evaluator does not fit, additional bone may need to be resected. See Appendix A (pgs. 31-32) to continue with the tibial alignment guide setup for a tibial or talar recut.



*INFERIOR LATERAL PIN SHOULD REMAIN IN TALUS*



**5.7** Plantarflex the foot, locate the previously created datum pin hole, and manually insert the datum pin.

**CAUTION:** Avoid driving the pin into the subtalar joint.



**FIGURE 5.6**

## STEP 6: TALAR COMPONENT SIZING

### REFERENCE CASE REPORT

Section: Selected Talar Trial (Pg. 2)

**6.1** Reference the case report to review the selected size. Select the planned PTCT size from the case report and attach the drill guide with the appropriate orientation (left/right). Slide the assembly over the datum pin and check the placement, rotation, and size compared to the case report. If the surface of the bone does not match the case report, check that the desired cut depth was achieved. Check to ensure the cut is complete and the cut surface matches the case report. If not enough bone was removed, reseat the talar cut guide and repeat the previous steps. Refer to Appendix A (Pgs. 31-32) to revert to the existing STAR instrumentation to complete the cut.

The template confirms proper cut depth (A/P) and aids in determination of the correct talar component size (M/L).

#### WARNING:

- One side of the PTCT is labeled for the left ankle, and the other is labeled for the right ankle.
- For optimal sizing, the outer surface of the PTCT should match the outer edge of the talar bone (**FIGURE 6.1B**).
- If template selected is too large it will cause overlap in the gutters (**FIGURE 6.1C**).
- If template selected is too small it will cause too much bone to be removed (**FIGURE 6.1D**).

Refer to the case report for planned rotational alignment. The PTCT shaft is typically aligned with the second metatarsal when the foot is in a neutral position.

**NOTE:** Fully seat the PTCT using the joint space evaluator. Use the lamina spreader to hold the PTCT to the top of the talus.

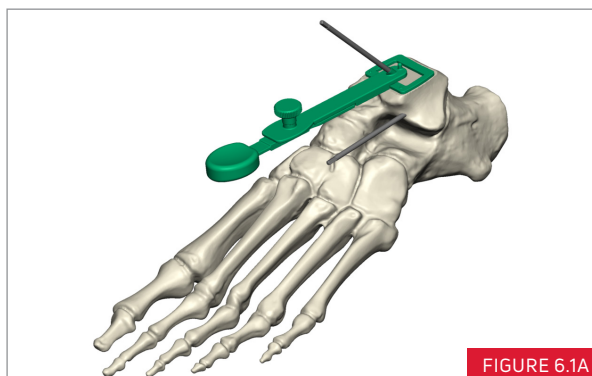


FIGURE 6.1A

### TALAR SIZING

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

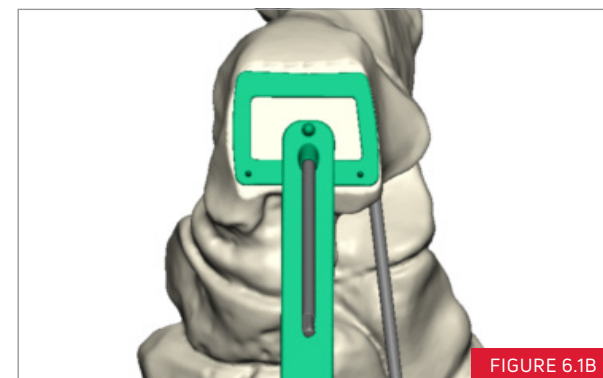


FIGURE 6.1B



FIGURE 6.1C

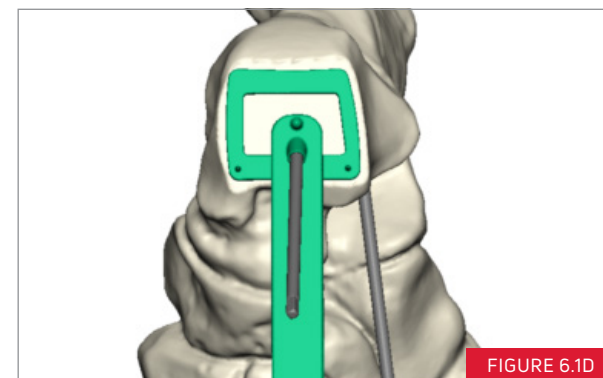


FIGURE 6.1D

**6.2** Refer to the case report for planned lateral process alignment. Confirm the alignment of the PTCT drill guide with a lateral fluoroscopic view. Typically the post of the PTCT drill guide is centered over the lateral process.

**⚠ CAUTION:** Pay particular attention that there is no gap between the PTCT and the top of the talus, especially posteriorly.

Loosen the thumbscrew on the PTCT drill guide and remove, leaving the 2.4mm datum pin in the talus.



### REFERENCE CASE REPORT

Section: Summary (Pg. 13) - for planned PTCT to lateral process alignment and for implant alignment and sizing

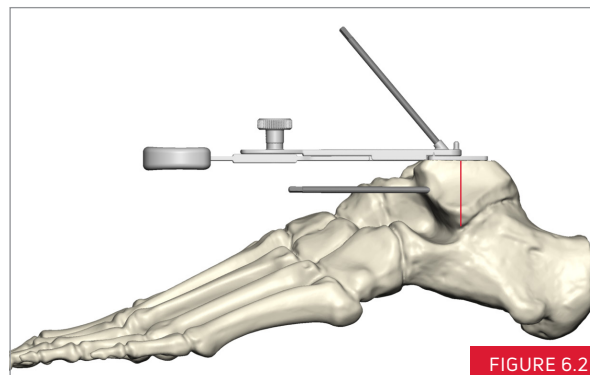


FIGURE 6.2

### STEP 7: TALAR CHAMFER CUTS

**7.1** The procedure continues from Step 7 of the STAR™ (MKT0190301-001) surgical technique, with the talar chamfer cuts.

Ensure the following A/P and M/L instructions are applied.

#### ANTERIOR & POSTERIOR CHAMFER CUTS

Leave the medial gutter pin out during reaming of the anterior chamfer, as it may interfere with the milling tool, limiting completion of the anterior chamfer cut.

#### MEDIAL AND LATERAL CHAMFER CUTS

Replace medial pin before proceeding with medial-lateral talar chamfer cuts.

The medial and lateral attachment pins mark the inferior edge of the talar implant selected during the planning process. These pins can be used as a reference during the medial and lateral chamfer cuts. An osteotome can be used on top of the pins as a guide to ensure the appropriate depth of bone is removed from the medial-lateral chamfer cuts.



FIGURE 7.1A

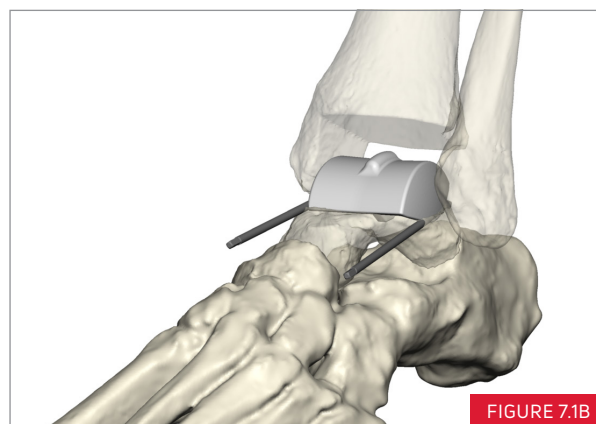


FIGURE 7.1B

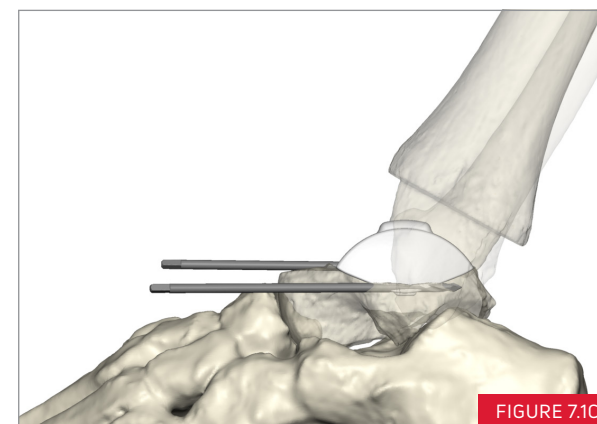


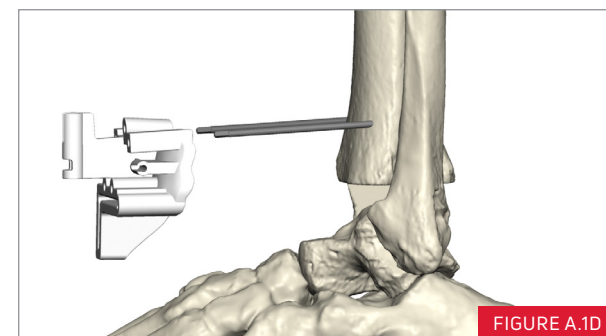
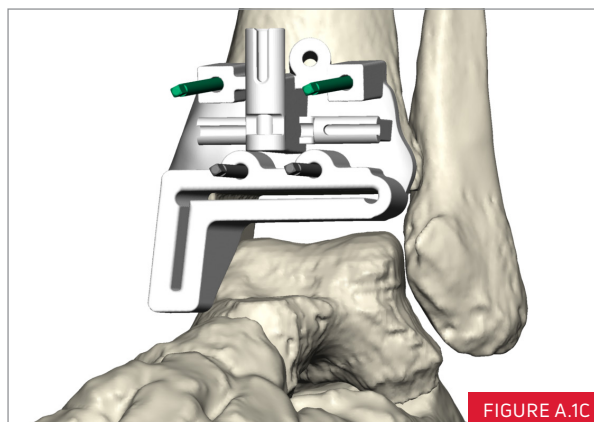
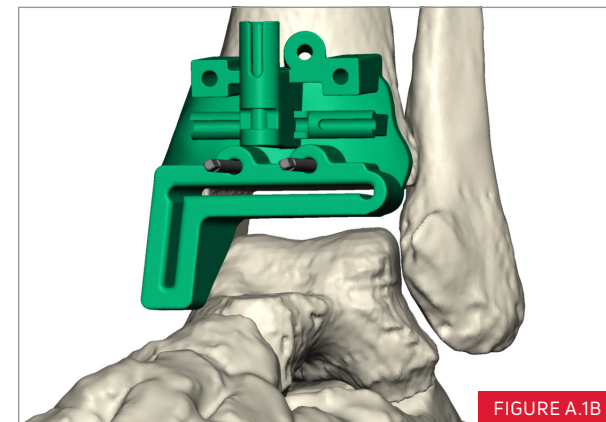
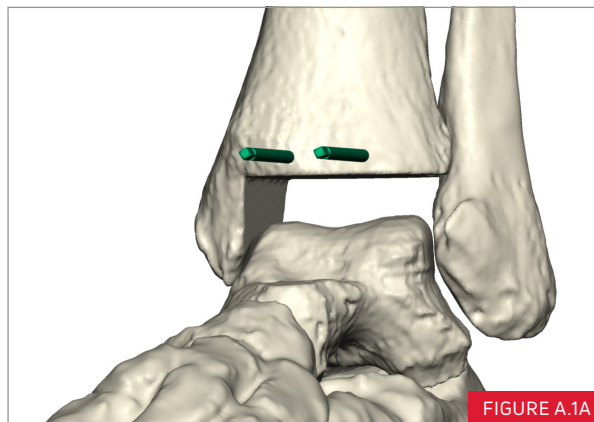
FIGURE 7.1C

### REVERT TO ORIGINAL STAR INSTRUMENTS

**A.1** If the tibia has been previously cut, find the original holes and gently tap the pins back into place with a mallet.

Slide the tibial PSI cut guide over the barrel pins and insert two 2.4mm pins into the recut pin holes. Remove the barrel pins and the PSI tibial cut guide.

If the STAR tibial alignment guide was used for the tibial resection, the PSI talar cut guide may still be used as an uncoupled guide for talar resection (Step 4).



*SUPERIOR PINS SHOULD REMAIN IN TIBIA*

### TIBIAL RECUT

**A.2** Slide the STAR tibial alignment guide over the recut pins and adjust for required amount of bone resection. For example, sliding the adjustable slider block over the pins via the “2” hole will result in a 2mm recut.

Continue from Step 4 of the STAR® Ankle (MKT0190301-001) surgical technique with the tibial resection. To complete the tibial recut, adjust the guide for the amount of bone resection, medial/lateral position, and slope.

### TALAR RESECTION/RECUT

**A.3** If PSI talar cut guide fit is not acceptable or talar recut is needed, revert to existing instrumentation. Select the proper talar cut guide for the amount of bone necessary. The procedure continues from Step 5 of the STAR Ankle (MKT0190301-001) surgical technique, with the talar prep and resection.

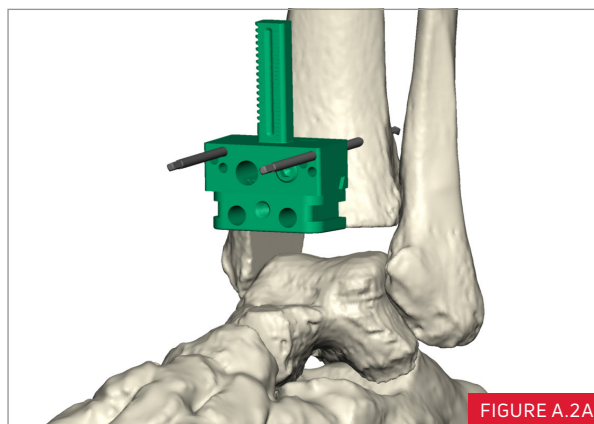


FIGURE A.2A

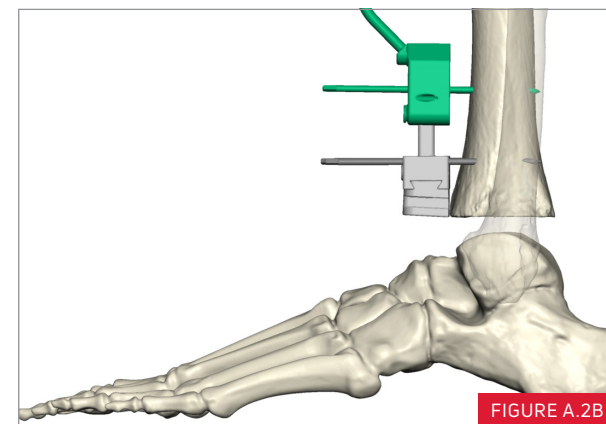


FIGURE A.2B

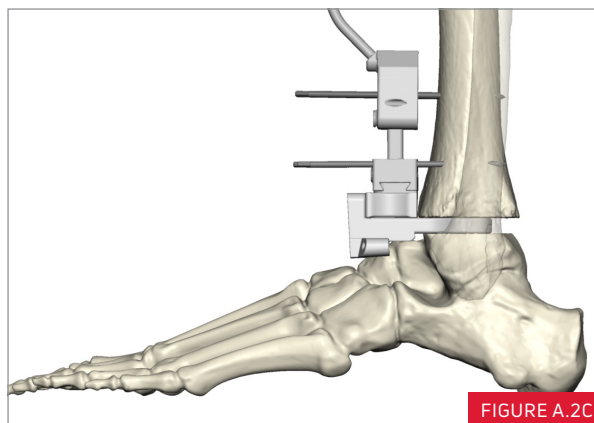


FIGURE A.2C

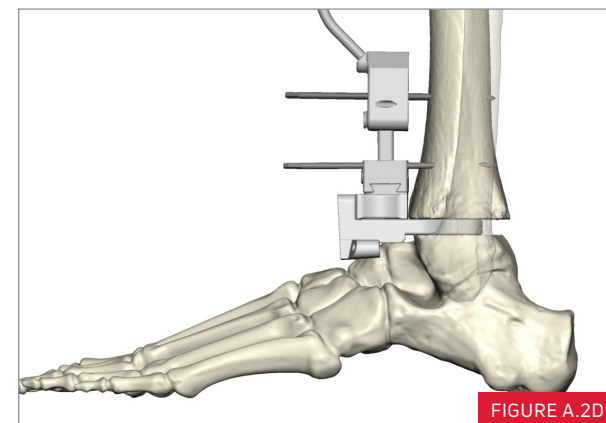


FIGURE A.2D









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