

# PROPHECY<sup>®</sup> INBONE<sup>®</sup>

Preoperative Navigation Guides

SURGICAL TECHNIQUE



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# **PROPHECY® INBONE®**

Total Ankle System

SURGICAL TECHNIQUE

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*Wright recognizes that proper surgical procedures and techniques are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the procedures based on his or her personal medical training, experience, and patient condition. Prior to use of the system, the surgeon should refer to the product Instructions For Use package insert (146636) for additional warnings, precautions, indications, contraindications and adverse effects. Instructions For Use package inserts are also available by contacting the manufacturer. Contact information can be found on the back of this surgical technique and the Instructions For Use package inserts are available on [wmt.com](http://wmt.com) under the link for Prescribing Information.*

*Please contact your local Wright representative for product availability.*





## PROPHECY® INBONE® Alignment Guide Product Information

### General Product Information

These surgical instruments are designed for single use only. They are manufactured with certain patient-specific features, which render them unusable in cases other than that for which they were designed. These surgical instruments are supplied clean and non-sterile, and must be sterilized before use. After use, these instruments must be properly disposed of. Please refer to the PROPHECY® INBONE® Instrument package insert #146636 for instructions on the proper steps for processing Wright Medical disposable surgical instruments.

### Intended Use

Wright's PROPHECY® INBONE® Preoperative Navigation Alignment Guides are intended to be used as patient-specific surgical instrumentation to assist in the positioning of total ankle replacement components intraoperatively and in guiding the marking of bone before cutting. The PROPHECY® INBONE® Preoperative Navigation Alignment Guides are intended for use with Wright's INBONE® Total Ankle Systems and their cleared indications for use, provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans. The PROPHECY® INBONE® Preoperative Navigation Alignment Guides are intended for single use only.



## INBONE® Total Ankle Product Information

### General Product Information

Through the advancement of partial and total joint replacement, the surgeon has been provided with a means of restoring mobility, correcting deformity, and reducing pain for many patients. While the prostheses used are largely successful in attaining these goals, it must be recognized that they are manufactured from a variety of materials and that any joint replacement system, therefore, cannot be expected to withstand activity levels and loads as would normal healthy bone. In addition, the system, including the implant/bone interface, will not be as strong, reliable, or durable as a natural human joint.

Ankle joint replacement components consist of a talar dome, a talar stem that attaches to the talar dome with a Morse Taper, a tibial platform, a four-component tibial stem assembly that attaches to the tibial platform with a Morse Taper, and an UHMWPE component. Components are available in a variety of sizes and design configurations intended for both primary and revision applications.

In using joint prostheses, the surgeon should be aware of the following:

- The correct selection of the prosthesis is extremely important. The potential for success in joint replacement is increased by selection of the proper size, shape, and design of the prosthesis. Joint prostheses require careful seating and adequate bone support. Surgeons are encouraged to use their best medical judgment when choosing the proper implant size regardless of the endosteal area of the bone. Surgeons must be familiar with the applicable operative techniques and instructions for use for each implant system.
- In selecting patients for total joint replacements, the following factors can be critical to the eventual success of the procedure.
  1. Patient's weight. An overweight or obese patient can produce high loads on the prosthesis, which can lead to failure of the prosthesis. This becomes a major consideration when the patient is small boned and a small size prosthesis must be used.
  2. Patient's occupation or activity. If the patient is involved in an occupation or activity, which includes substantial walking, running, lifting, or muscle strain, the resultant forces can cause failure of the fixation or the device, or both. The prosthesis will not restore function to the level expected with normal healthy bone, and the patient should not have unrealistic functional expectations.
  3. Condition of senility, mental illness, or alcoholism. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the prosthesis, leading to failure or other complications.
  4. Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.

## Intended Use

The INBONE® Total Ankle is intended to give a patient limited mobility by reducing pain, restoring alignment and replacing the flexion and extension movement in the ankle joint.

## Indications

The INBONE® Total Ankle is indicated for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis. The INBONE® Total Ankle is additionally indicated for patients with a failed previous ankle surgery.

**CAUTION:** *The ankle prosthesis is intended for cement use only.*

## Contraindications

Absolute contraindications include:

1. osteomyelitis;
2. excessive bone loss at the ankle joint site;
3. steroid use;
4. infection at the ankle site or infections at distant sites that could migrate to the ankle;
5. sepsis;
6. muscular atrophy;
7. dementia;
8. vascular deficiency in the ankle joint;
9. skeletally immature patients (patient is less than 21 years of age at the time of surgery);
10. cases where there is inadequate neuromuscular status (e.g., prior paralysis, fusion and/or inadequate abductor strength), poor bone stock, poor skin coverage around the joint which would make the procedure unjustifiable;
11. neuropathic joints;
12. hepatitis or HIV infection;
13. excessive loads as caused by activity or patient weight;
14. female of childbearing age, for whom a negative pregnancy test is not obtained; and,
15. neurological or musculoskeletal disease that may adversely affect gait or weightbearing.

***Conditions presenting increased risk of failure include:***

1. uncooperative patient or patient with neurologic disorders, incapable of following instructions;
2. marked bone loss, severe osteoporosis, or revision procedures for which an adequate fit of the prosthesis cannot be achieved;
3. metabolic disorders that may impair bone formation;
4. osteomalacia; and,
5. poor prognosis for good wound healing (e.g., decubitus ulcer, end-stage diabetes, severe protein deficiency and/or malnutrition).

***WARNING: This device is not intended for subtalar joint fusion or subtalar joint impingement. Please carefully evaluate the anatomy of each patient before implantation.***

PROPHECY® INBONE® Preoperative Navigation Guides are patient-specific instruments designed for total ankle replacement surgery. One significant requirement for a successful case is adhering to the CT scan protocol. Engineers at Wright Medical Technology have determined the necessary scanning parameters, which are described in this document.

In every case, please follow these general instructions:

## Patient Position

- Patient must be in the supine position on the CT table
- The foot of interest should be positioned in dorsi-flexion (toes 90° to the table)
- If a contra-lateral implant is present, bend the contra-lateral limb out of the field of view of the ankle to be scanned
- Do not allow patient movement between or during scans

## Scanning Instructions

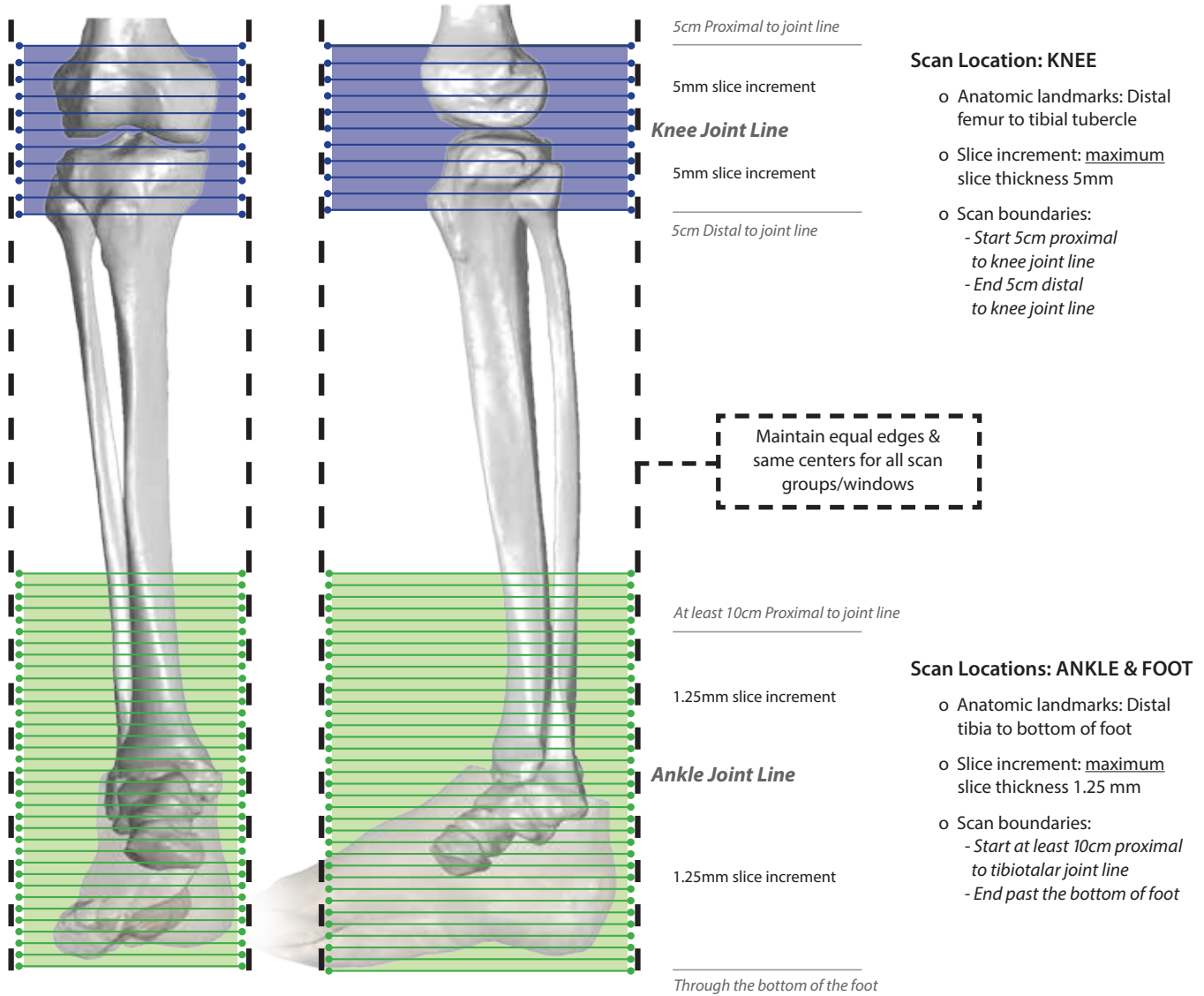
- Helical and Axial CT modes are acceptable
- Bone or Standard algorithms are acceptable
- Maintain a consistent field of view and pixel size for all scans
- Group edges should not be adjusted in the x or y directions (see dashed lines)
  - Adjusting the width of one group in order to match the borders of the largest group is appropriate
- Maintain a single coordinate system for all scans
- In-plane pixel size (resolution) must be less than 0.8mm
- Include coronal and sagittal scout images when submitting files to Wright
- Do not scan at higher slice spacing and reconstruct to smaller increments
- Only the raw axial images are needed, coronal and sagittal reconstructions are not necessary
- Images must be provided in uncompressed DICOM format

*Note: Inclusion of additional x-ray studies can be submitted to Wright as additional reference for PROPHECY® alignment.*

CONTACT FOR ASSISTANCE:  
Wright Medical Technology  
PROPHECY® Operations  
Phone: 901-290-5884  
Fax: 901-867-4791  
E-mail: [prophecy@wmt.com](mailto:prophecy@wmt.com)

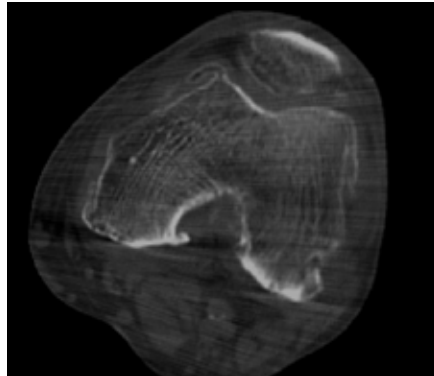


NOTE: All scan locations (knee, ankle and foot) are necessary.

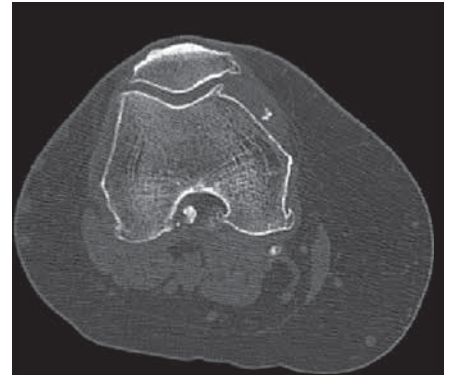


The Centers for Medicare & Medicaid Services (CMS) established a National Coverage Determination (NCD) for CT Scans. It states, in part, the following, "Diagnostic examinations of the head (head scans) and of other parts of the body (body scans) performed by computerized tomography (CT) scanners are covered if medical and scientific literature and opinion support the effective use of a scan for the condition, and the scan is: (1) reasonable and necessary for the individual patient." CTs performed prior to total joint replacement procedures for diagnostic purposes may be considered medically necessary. In which case, the procedure should be billed using the CPT codes that accurately describe the imaging procedure furnished to the patient. These same images from the diagnostic CT scan may, in turn, be further utilized for developing the personalized cutting or navigation guides that are used in orthopaedic procedures. However, if providers perform CT scans solely for the purpose of developing personalized cutting instruments or guides, providers should contact the payer for billing and coverage guidance and/or the American College of Radiology with billing questions.

## CT Imaging Examples



**Unacceptable CT imaging**  
Images are blurry and have poor contrast between the bone and the surrounding soft tissues. These images are difficult for the PROPHECY® guide engineers to segment out the three dimensional bone models.



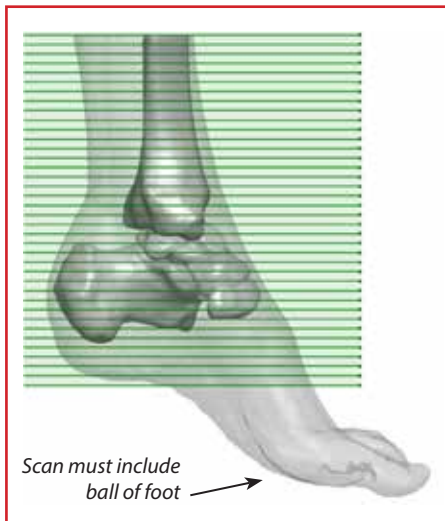
**Satisfactory CT Imaging**  
Quality images have clear, crisp bone definition. Distinct boundaries between the bone and the surrounding soft tissue are apparent in these images.

*NOTE: These images will not be accepted for processing by the PROPHECY® Guides.*

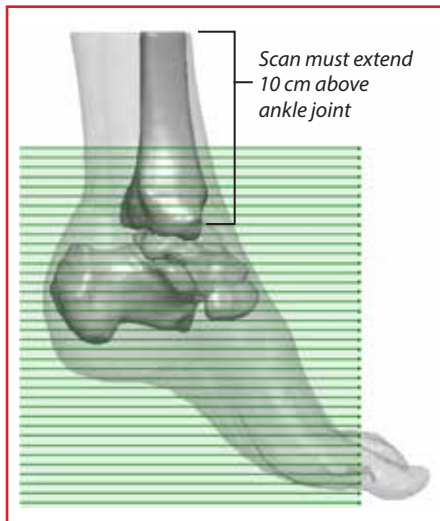
## Common Scan Protocol Errors

The two most common protocol errors resulting in failed scans are as follows:

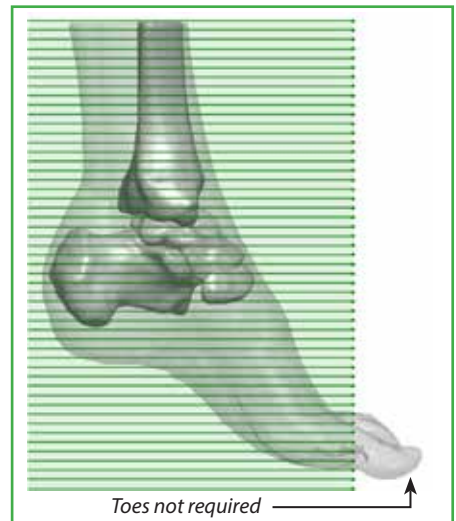
1. Failure to scan through the bottom of the foot including the ball of the foot. **FIGURE 1** shows a failed scan where the scan extends through the heel of the foot but does not include the ball of the foot.
2. Failure to scan at least 10cm above the ankle joint. **FIGURE 2** shows a scan without enough distal tibia included.



**FIGURE 1** | Bad Scan



**FIGURE 2** | Bad Scan



**FIGURE 3** | Good Scan

## Frequently Asked Questions

Q. "I can't put in a 1.25mm slice. I can only do a 1mm increment. Is that ok?"  
A. *Slices thinner than our specified slice thickness are acceptable; however, using larger slices will result in the scan being rejected for PROPHECY® processing.*

Q. "Do we use axial or helical reconstruction?"  
A. *Either is acceptable.*

Q. "Is it really necessary to scan 10cm above the ankle joint?"  
A. *Yes. Scanning less than 10cm above the ankle joint line prevents the PROPHECY® engineers from visualizing how the proximal end of the INBONE® tibial stems will be positioned in the diaphysis of the tibial shaft.*

Q. "Do I need to scan the knee for an ankle surgery?"  
A. *Yes. The knee scan is required to obtain the anatomical axis of the lower extremity. Information based on the entire tibia is used to plan the ankle procedure.*

## Submitting the Scan

*NOTE: There are two options to choose from when submitting preoperative scans to Wright; either electronic transfer or standard mail. Either is acceptable.*

### **Rapid Electronic Scan Transfer**

Preoperative CT may be sent to the PROPHECY® guides engineering team through our rapid electronic transfer system.

<https://prophecyscans.wmt.com>

Please follow these steps to request an account and transfer scans:

1. E-mail [prophecyscans@wmt.com](mailto:prophecyscans@wmt.com) with the e-mail address of the person who needs access to the system (No other information is needed).
2. Within a few hours, an invitation message will be sent to that address with instructions to complete registration on the scan transfer site.

*\*\* upload times may vary based on connection speed.*

### **Mail CD**

- Ensure the DICOM files are located on the CT Scan CD
- Mail the CD to:  
Wright Medical Technology:  
5677 Airline Road  
Arlington, TN 38002  
Attention: PROPHECY® Lab

## Tibia Alignment Guide Fluoroscopic Check Assembly

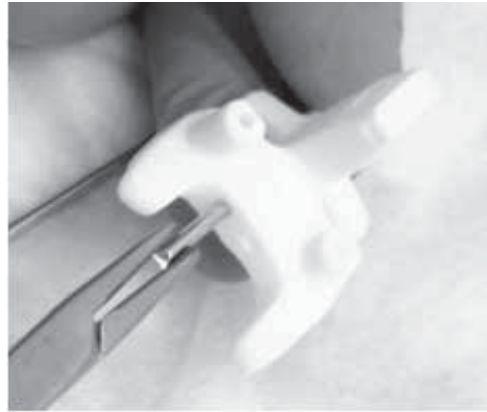
Prior to beginning the case, the surgical scrub tech should pre-assemble the fluoroscopic check guide wires into the PROPCECY® Tibia Alignment Guide (PROPINB or PROPINBE [EU only] ). Using the Pin Cutter (200427) and a needle driver, cut two ½" (~12mm) segments of a 2.4mm Steinmann Pin (200072).

| **FIGURE 4** Press-fit the two ½" segments into the holes in the base of the PROPCECY® Tibia Alignment Guide. | **FIGURE 5** Insert the remainder of the cut 2.4mm Steinmann Pin in the handle of the PROPCECY® Tibia Alignment Guide. | **FIGURE 6**

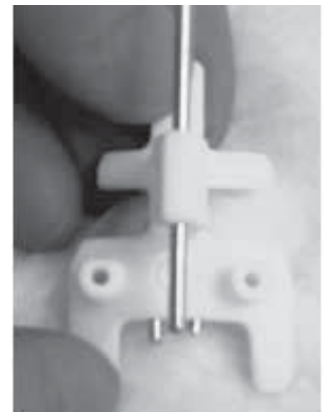
**CAUTION:** *To be assembled in the sterile field.*



| FIGURE 4



| FIGURE 5



| FIGURE 6



PROPCECY® Tibia Alignment Guide  
PROPINB  
PROPINBE (EU only)



2.4mm Steinmann Pin  
200072



Pin Cutter  
200427

## Alignment and Resections

Make the Anterior incision approximately 125mm long directly lateral of the tibialis, avoiding the anterior tendons and nerve bundle, exposing the tibia, talus and a portion of the midfoot.

***PROPHECY® INBONE® alignment guides are designed to incorporate fixed osteophytes on or near the articulating surfaces, and therefore should not be removed. Any loose bodies, however, may be removed if they interfere with the seating of the PROPHECY® INBONE® guides.***

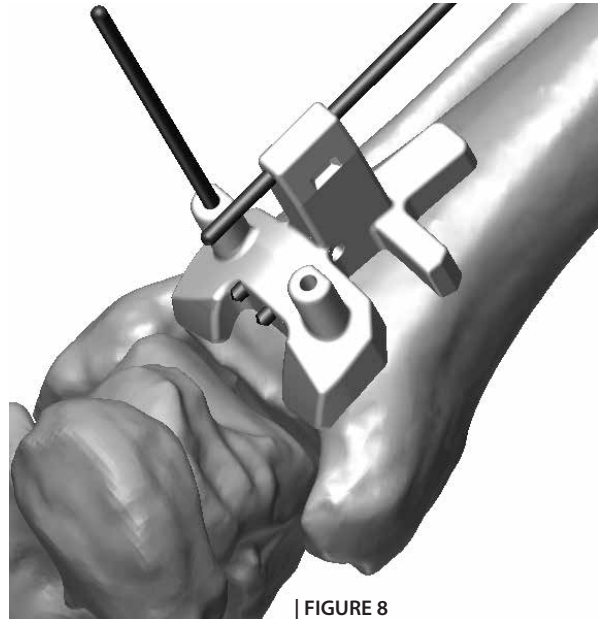
Ensure the area of the anterior tibia, where the PROPHECY® guide will surface match, is free of soft tissue and place the PROPHECY® Tibia Alignment Guide (PROPINB or PROPINBE [EU only] ) in the best fit location. | **FIGURE 7** Please note that the guides are designed to fit in one and only one proper location.

- If the tibia guide does not sit flush against the tibia - before driving any pins into the bone - remove the PROPHECY® guide and clean off any remaining soft tissue covering the bone.
- Re-evaluate the surface match fit between the guide and the bone. Repeat these steps until the guide sits flush against the bone in the best fit location.

Once surface match fit is flush against the tibia, place one 2.4mm Steinmann Pin (200072) through the guide and into both cortices of the tibia, then check it with fluoro. | **FIGURE 8** Then, if an adjustment is necessary, pull the pin from the first hole, and use the second hole which has fresh bone stock, to pin into.



| FIGURE 7



| FIGURE 8

## Intraoperative Tibia Alignment Guide Fluoroscopic Checks

Compare the intra-op fluoro image | **FIGURE 9**, to the sample case pre-op report image showing the planned tibia stem axis. | **FIGURE 10** The intra-op fluoro check shows the long central k-wire between the two short embedded k-wire segments in the tibia alignment guide like a “gun-sight,” which is similar to the case report image.

**IMPORTANT NOTE:** *If your fluoro check shows you are significantly different than the plan: remove the alignment guide and any pins in the bone, ensure the periosteum has been cleaned from the tibia and verify that the retractor(s) are preventing any soft tissue creepage. Also, make sure the foot is in slight plantar-flexion and that a bump has been placed under the tibia to elevate it.*

After correct alignment and positioning is achieved, place the second 2.4mm Steinmann Pin through the guide and into both cortices of the tibia. Do not cut the pins at this time. Remove the PROPHECY® guide by sliding it up and over the pins, leaving the pins in place. It may be helpful to attach a Kocher clamp in the notches built into the rectangular anterior handle to pull the tibia guide up.



| FIGURE 9

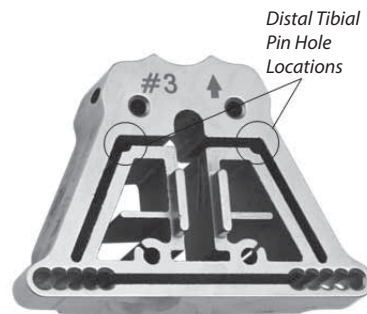


| FIGURE 10

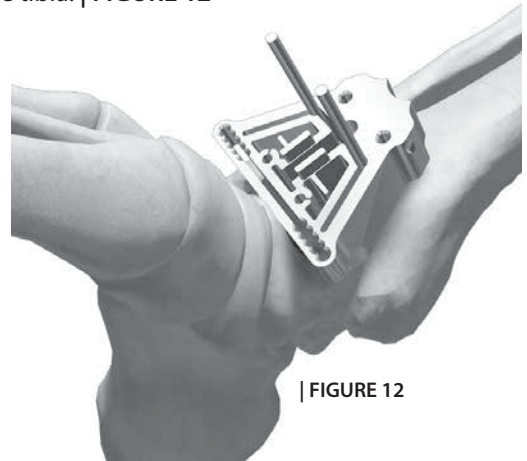


Resection Guide  
PTA00092 through PTA00096

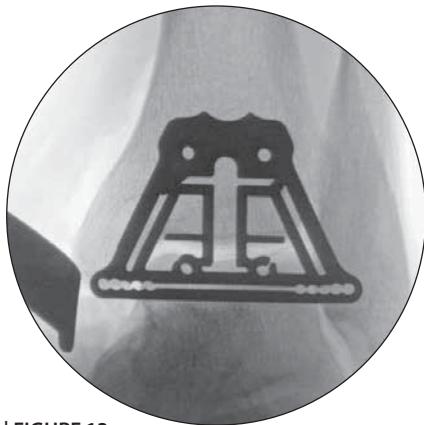
Select the appropriate sized metal Resection Guide (PTA00092 through PTA00096) and position the two distal tibial holes over the two Steinmann Pins in the tibia. | **FIGURE 11** The appropriate Resection Guide size can be found detailed in the PROPHECY® preoperative surgical plan. Slide the Resection Guide down to the anterior surface of the tibia. | **FIGURE 12**



| **FIGURE 11**



| **FIGURE 12**



| **FIGURE 13**

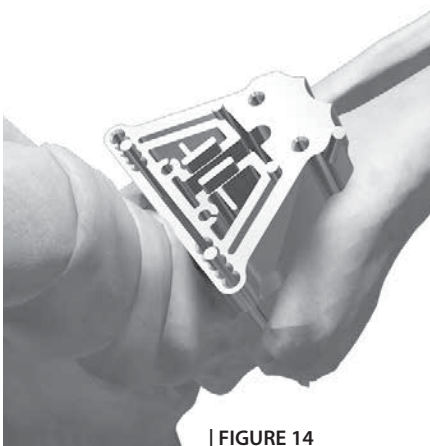
The surgeon has the option to fluoroscopically verify the saw guide size and positional orientation prior to tibial resection as follows:

- Obtain a fluoroscopic AP view of the ankle perpendicular to the installed resection block. This view is achieved when the holes in the resection block appear as perfect circles. In this view the surgeon can verify the medial/lateral translation, proximal/distal location and coronal rotation of the resection block. | **FIGURE 13**
- Obtain a fluoroscopic lateral view of the ankle and drop a saw blade into the proximal slot of the resection block. In this view the surgeon can verify the resection height and flexion/extension angle of the resection block.
- Refer to the PROPHECY® Pre-Op Plan for verification of the resection. At this point the surgeon can choose to revert back to the traditional INBONE® foot holder surgical technique if there are any concerns with the planned resection.

Insert additional 2.4mm Steinmann Pins into the cross-pin hole of the Resection Guide, as well as the medial and lateral gutter locations.

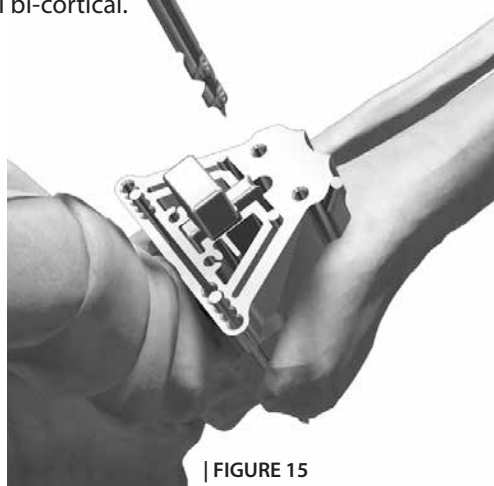
Optionally, two additional 2.4mm Steinmann Pins can be inserted in the two proximal tibial holes of the Resection Guide. This will allow removal of the two distal tibial pins prior to tibial resection. This may be done to allow the saw blade to reach the corners of the tibia resection.

Use the Pin Cutter to cut the Steinmann Pins close to the surface of the Resection Guide. For the cross-pin only, be sure to leave approximately 2 inches to facilitate removal with a pin puller. | **FIGURE 14**



| **FIGURE 14**

Install the Anti-Rotation Notch Insert (200290002 through 200290006) into the Resection Guide. Using the appropriate sized Anti-Rotation Drill (200178002 through 200178006) drill the tibia for the anti-rotational notch. | **FIGURE 15** Be sure to drill bi-cortical.

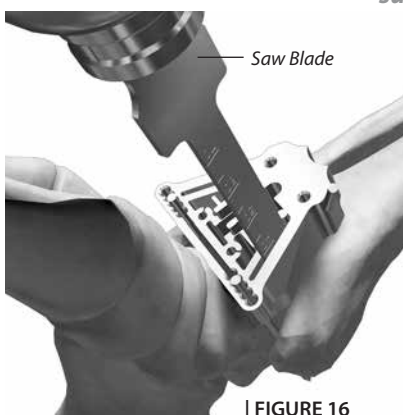


| FIGURE 15

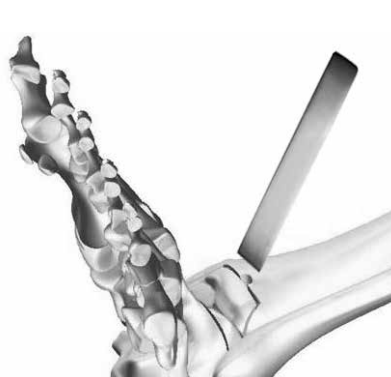
Using the appropriate Saw Blade and oscillating bone saw, make the tibial resection. This includes cutting through the proximal, medial and lateral slots of the Resection Guide. | **FIGURE 16** Do not make the talar cut at this time.

Remove the Resection Guide and Steinmann Pins. At the top of the tibial cut, use an osteotome to cut down towards the talus at approximately 60° to remove the anterior section of the tibia. | **FIGURE 17 and 18** Remove as much of the tibia resection as possible, at a minimum this includes any anterior bone that may prevent proper seating of the PROPHECY® Talus Alignment Guide on the talar dome.

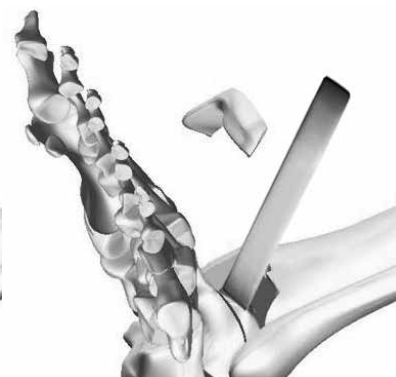
**CAUTION:** Be careful not to damage the anterior surface of the tibia proximal to the resection. This area of the tibia surface will later be referenced in the surface match features of the PROPHECY® Stem Alignment Guide.



| FIGURE 16



| FIGURE 17



| FIGURE 18



Anti-Rotation Notch Insert  
200290002 - 200290006



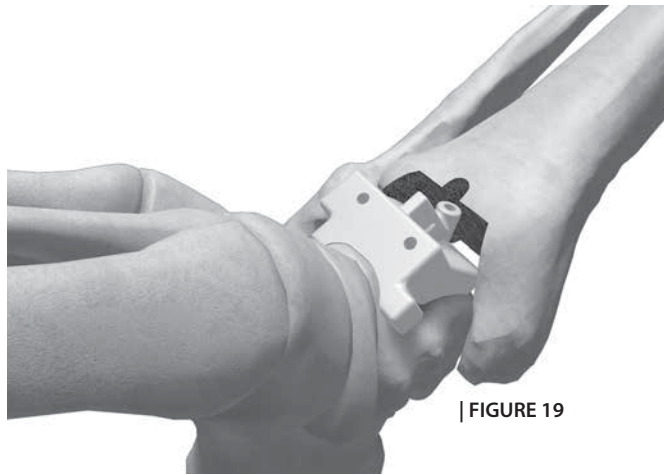
Anti-Rotation Notch Drill  
200178002 - 200178006



Place the foot into plantar flexion for maximum exposure of the talar dome, and place the PROPHECY® Talus Alignment Guide on the talar surface in the best fit location. | FIGURES 19, 20 and 21 Ensure the area around the neck and dome of the talus where the PROPHECY® guide will surface match is free of all soft tissue.

If any portion of the tibia bone prevents the talus guide from fitting properly on the talus, either remove more of the tibial resection or increase plantar flexion of the foot (or a combination of both).

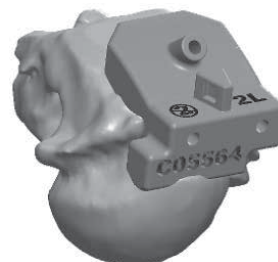
**HELPFUL HINT:** *In the case of uneven talar dome cartilage wear, improved talar alignment guide accuracy may be achieved by carefully removing the cartilage with a curette from the surface-match area of the talus prior to placing the talus alignment guide.*



| FIGURE 19



| FIGURE 20  
Anterior View

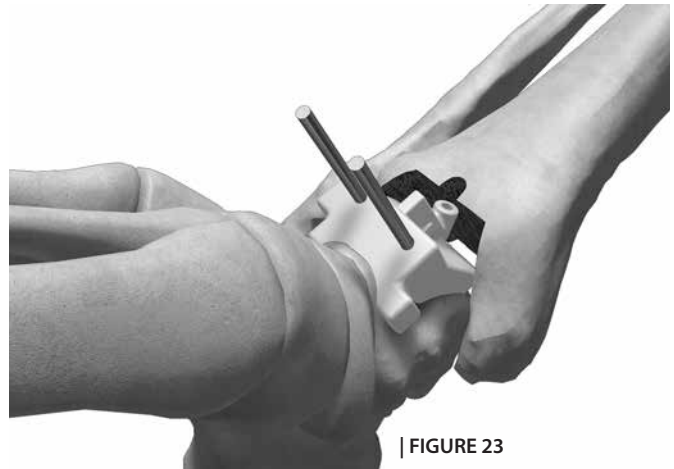
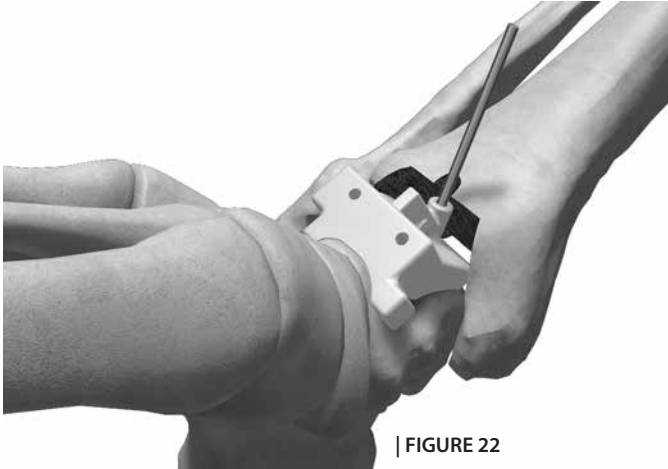


| FIGURE 21  
Lateral-Oblique View

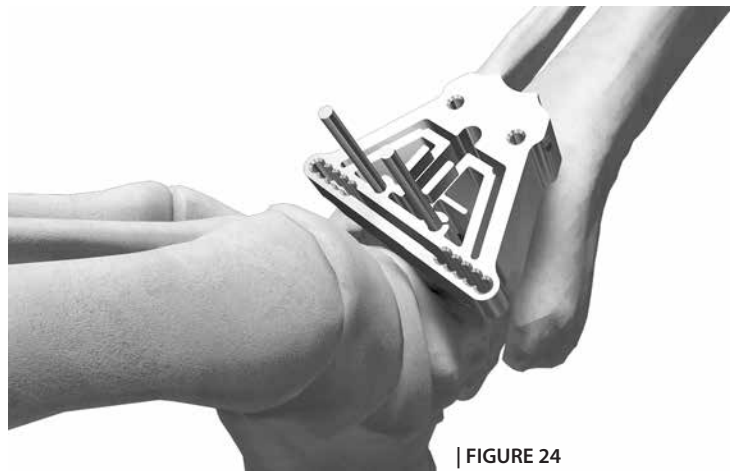


PROPHECY® Talus Alignment Guide  
PROPINB  
PROPINBE (EU only)

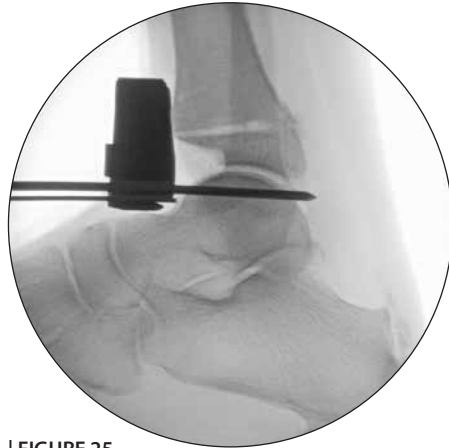
While holding the PROPHECY® guide in place install one 2.4mm Steinmann Pin through the top of the guide into the dome of the talus to temporarily hold the guide in place. | **FIGURE 22** Next, install two 2.4mm Steinmann Pins through the anterior pin holes of the Talus Alignment Guide and into the talar bone. Remove the Steinmann Pin in the top of the guide. | **FIGURE 23** Do not cut the remaining pins at this time. Remove the PROPHECY® guide by sliding it up and over the pins, leaving the pins in place. It may be helpful to attach a Kocher clamp to the notches built into the central triangular feature of the talar guide to pull the guide up.



Choose the appropriate sized metal Resection Guide, position the 2 talar pin holes over the 2 pins from the PROPHECY® Talus Alignment Guide and slide down to the anterior surface of the talar dome. | **FIGURE 24** The Resection Guide will not necessarily be the same size used in the tibial resection. Consult the PROPHECY® pre-op plan for confirmation.



The surgeon has the option to fluoroscopically verify the saw guide size and positional orientation prior to talar resection by following the steps previously described on page 11. In the lateral view, drop the saw blade in the distal resection slot to verify resection height and flexion/extension angle. | **FIGURE 25**



| **FIGURE 25**

Insert two additional 2.4mm Steinmann pins into the medial and lateral gutters for additional stability. | **FIGURE 26** Use the Pin Cutter to cut the Steinmann Pins close to the surface of the Resection Guide.

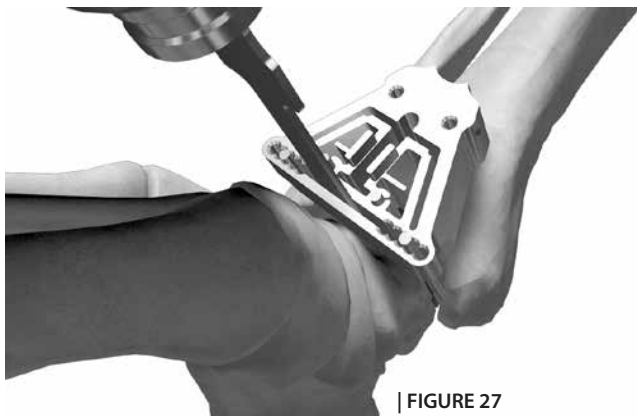


| **FIGURE 26**

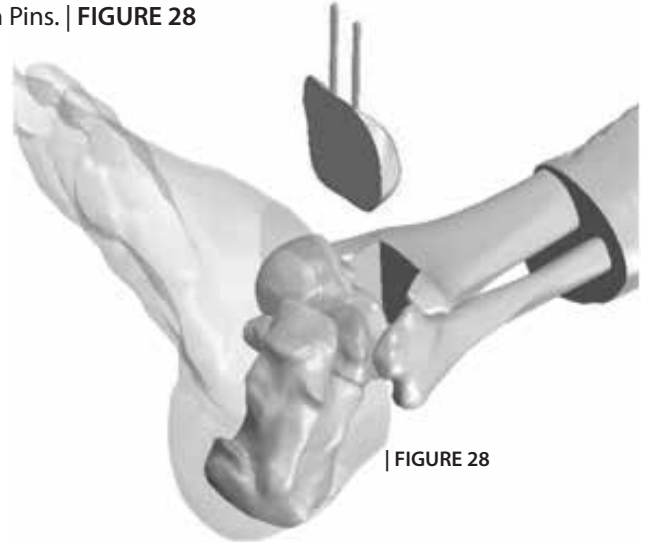
Using the appropriate Saw Blade and oscillating bone saw, make the talar resection (distal slot of the Saw Guide). | **FIGURE 27**

**CAUTION:** *It may be necessary to manually hold the resection guide in place as excessive vibration from the saw can cause the Saw Guide to work itself off the ends of the cut Steinmann Pins.*

Remove the Resecton Guide. Check that your talar resection is complete by using a ½" osteotome. Complete the cut if necessary and gently lever the resected dome out anteriorly. It can typically be removed in one piece by grabbing the Steinmann Pins. | **FIGURE 28**



| **FIGURE 27**



| **FIGURE 28**



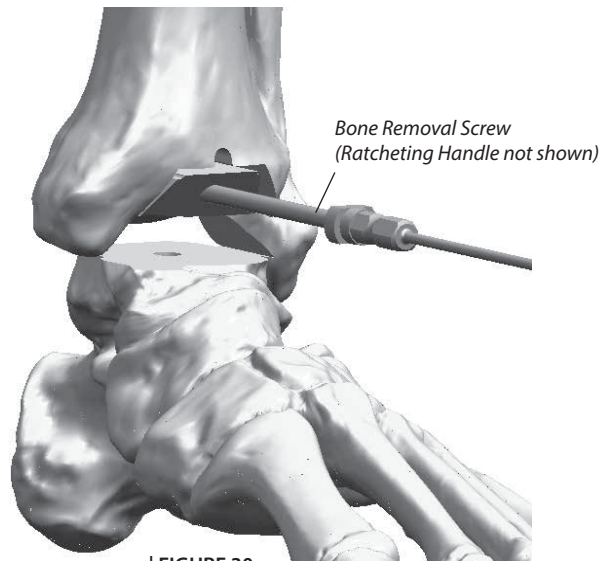
| **FIGURE 29**

To facilitate removal of the remaining posterior tibia, the Corner Chisel (IB200070) and a mallet can be used to finish off bone cuts in the proximal corners of the resected tibia. | **FIGURE 29** The Corner Chisel is laser marked to indicate the anterior to posterior depth of the various size tibial trays.

**CAUTION:** *Care must be taken to ensure that the Corner Chisel does not penetrate too deeply, as neurovascular injury may occur. Do not rely solely on the depth indications on the Chisel to determine resection depth. If unsure, utilize a lateral fluoroscopic image to confirm proper depth of the chisel.*



Corner Chisel  
IB200070

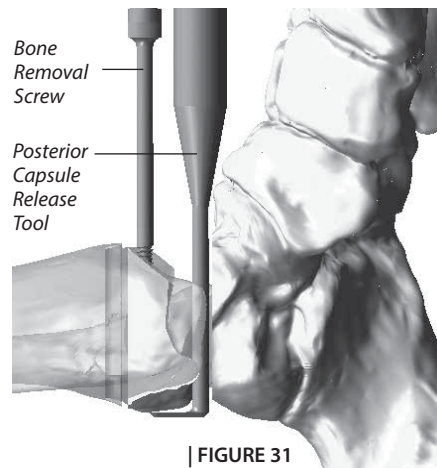


| FIGURE 30

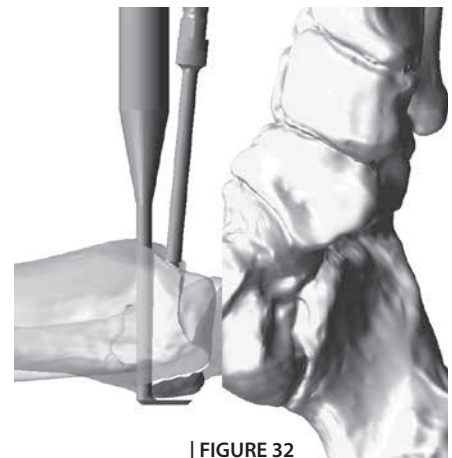
Using a pin driver, insert the Bone Removal Screw (IB200051) into the resected tibial bone. Attach the Ratcheting Handle (44180025) to the Bone Removal Screw to aid in removing the remaining tibial section through traction.

| FIGURE 30

Insert the 90° Posterior Capsule Release Tool (IB200050) into the joint space and use to free up the posterior capsule soft tissues attachments to the resected tibia. | FIGURES 31 and 32

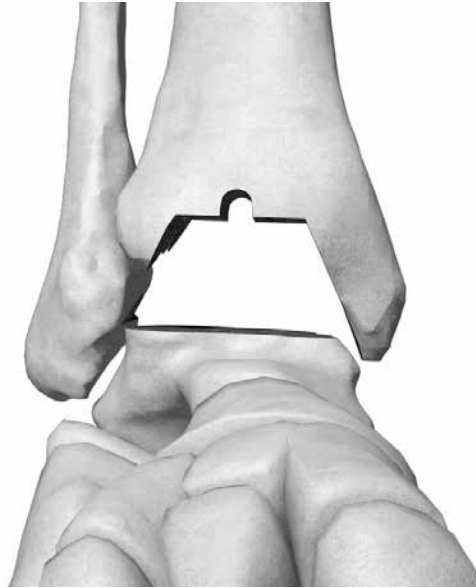


| FIGURE 31



| FIGURE 32

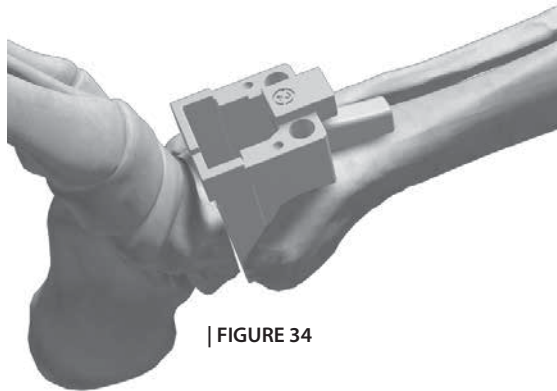
If necessary, use the drill and appropriate size drill bit to provide additional definition of anti-rotation notch. Take care not to widen the notch. A reciprocating saw or bone rasp may be used to remove excess bone, taking care to follow the previously made cut line. Remove loose bone pieces and irrigate the joint space. | **FIGURE 33**



| **FIGURE 33**

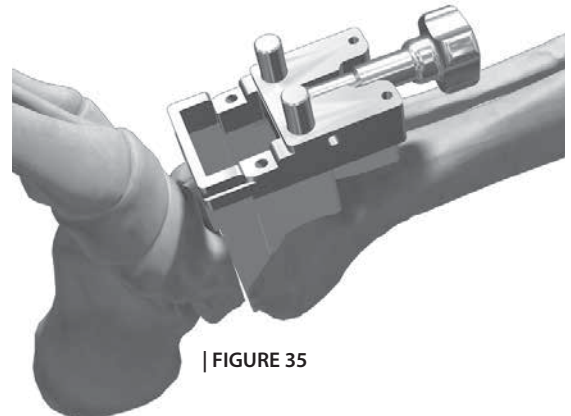
**CAUTION:** Failure to adequately clean the proximal corners of the tibial resection can lead to improper seating of the PROPHECY® INBONE® Tibial Stem Guide.

Slightly distract the ankle and place the PROPHECY® Tibial-Stem Alignment Guide (PROPINB or PROPINBE [EU only] ) into the resected joint space. The guide has surface matching features referencing the anterior surface of the tibia, and all four flat surfaces within the resection joint space. | **FIGURE 34**



| **FIGURE 34**

Place the metal Anterior Mounting Plate (PTA00040) onto the anterior surface of the PROPHECY® Tibial Stem Guide. The two metal dowel pins protruding from the back side of the Anterior Mounting Plate are designed to fit into round holes of the PROPHECY® Guide. The two flat mating surfaces must be fully seated. | **FIGURE 35**

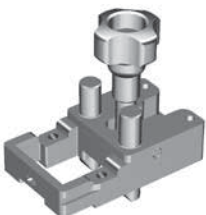


| **FIGURE 35**

Insert the Drill Guide Cartridge (PTA00070) into the PROPHECY® Tibial Stem Guide. The cartridge is fully seated when the ball detent is engaged and the anterior surfaces of the Drill Guide Cartridge and the Anterior Mounting Plate are flush. | **FIGURE 36**



PROPHECY® Tibia Stem Alignment Guide  
PROPINB  
PROPINBE (EU only)

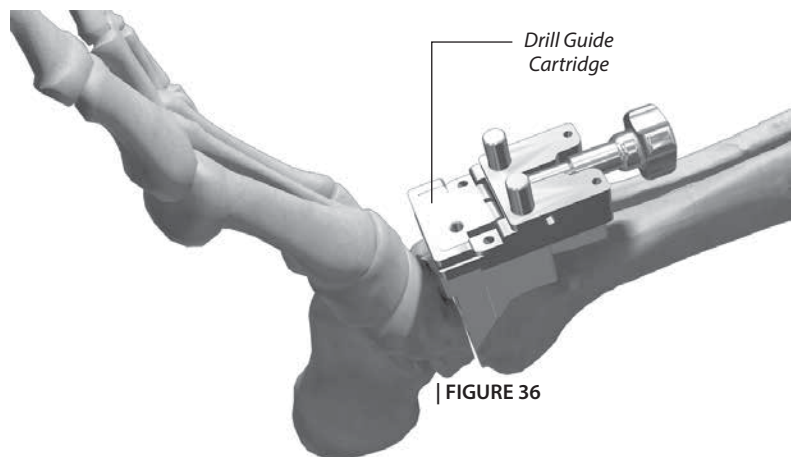


Anterior Mounting Plate  
PTA00040



Drill Guide Cartridge  
PTA00070

Alternatively the PROPHECY® Tibial-Stem Guide, Anterior Mounting Plate, and Drill Guide Cartridge may be assembled outside of the foot and then inserted into the joint space in one step.



| **FIGURE 36**

Check a lateral fluoroscopic image to ensure that the PROPHECY® Stem Alignment Guide is properly seated to the resected tibia. When the Stem Guide is properly seated, the metal Drill Guide Cartridge will appear flush to the surface of the resected tibia. | **FIGURE 37**

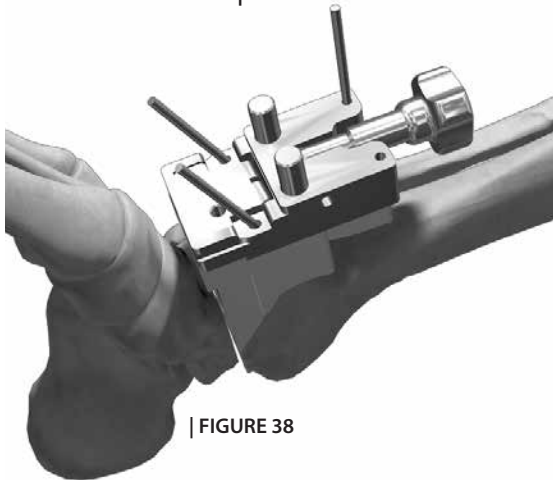
*Helpful Hint: See Appendix F for an optional AP fluoro check.*



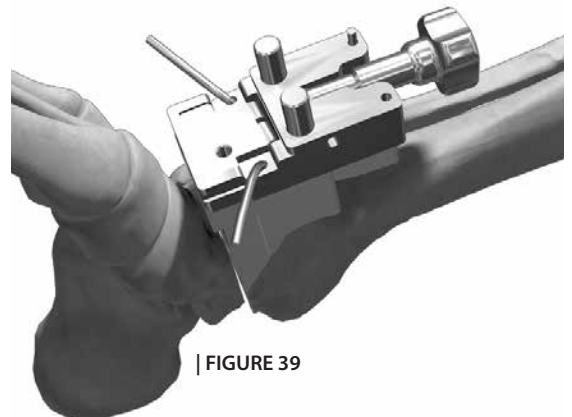
| **FIGURE 37**

Insert three 2.4mm Steinmann Pins through the Anterior Mounting Plate (one proximal, one medial and one lateral) and into the tibia. | **FIGURE 38**

Cut the proximal tibial pin flush to surface of the guide. Using the Wire Pliers (RR3034), bend the medial and lateral pins (medal and lateral respectively) in order to provide clearance for the Drill Guide Cartridge to be removed later. | **FIGURE 39**



| **FIGURE 38**



| **FIGURE 39**

At this step in the procedure, if the surgeon chooses to revert back to using the INBONE® foot holder, skip to Appendix E: PROPHECY® Tie-In to the INBONE® Foot Holder Surgical Procedure; otherwise proceed to the next page.



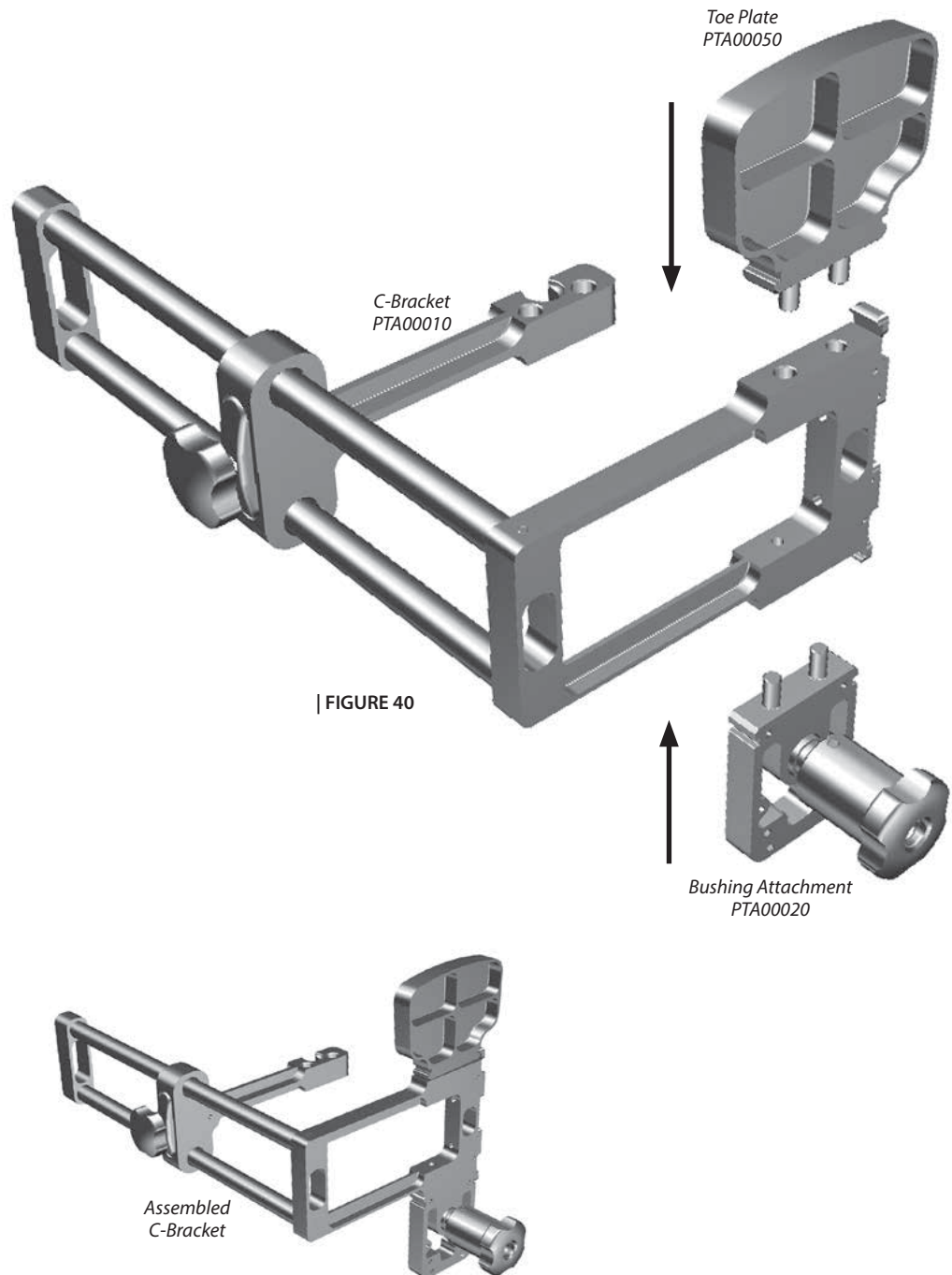
Wire Pliers  
RR3034



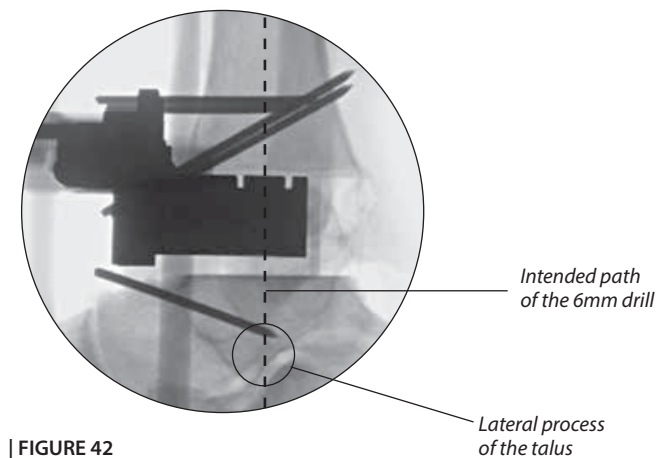
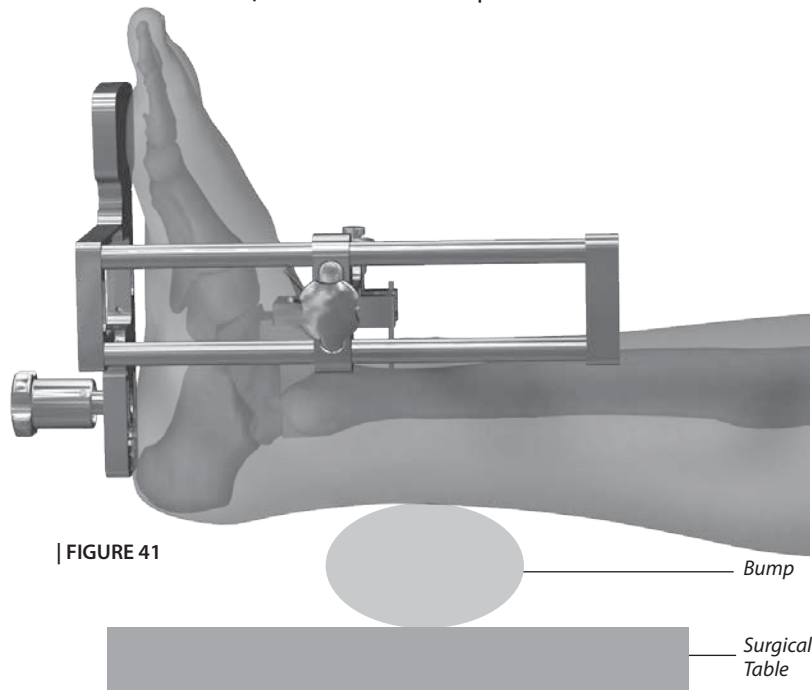
## Build the C-Bracket Assembly

Connect the Toe Plate (PTA00050) and the Bushing Attachment (PTA00020) to the C-Bracket (PTA00010). | **FIGURE 40**

The C-Bracket is symmetrically designed to be used on either the medial or lateral side of the foot based on surgeon preference.

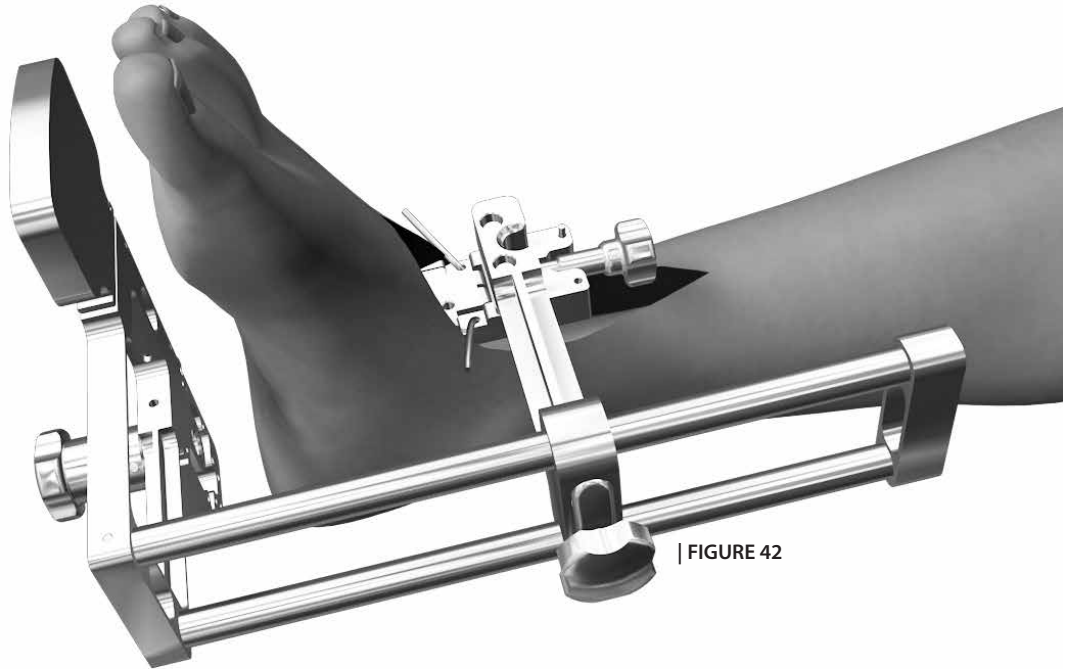


It is recommended to place a surgical bump under the Achilles prior to drilling through the C-Bracket. | **FIGURE 41** By placing a bump proximal to the talus, it will prevent the back of the heel from resting on the surgical table and potentially translating anterior in relation to the tibia. When properly aligned, the C-Bracket will place the 6mm drill anterior and medial to the posterior facet of the subtalar joint. Under a lateral fluoroscopic image, the drill should appear to be inline with the lateral process of the talus. | **FIGURE 42**



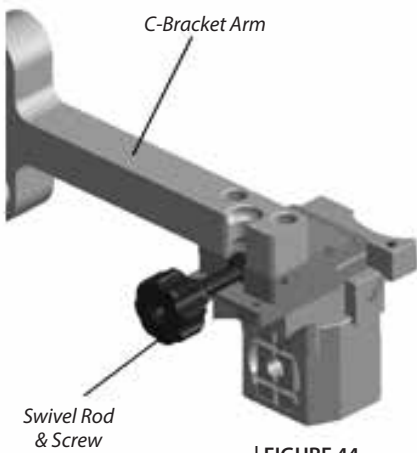
## Drill Primary Hole

Lower the C-Bracket assembly down over the Anterior Mounting Plate and attach through the two protruding dowel pins. | **FIGURE 43** The surface of the C-Bracket arm must sit flat against the Anterior Mounting Plate.

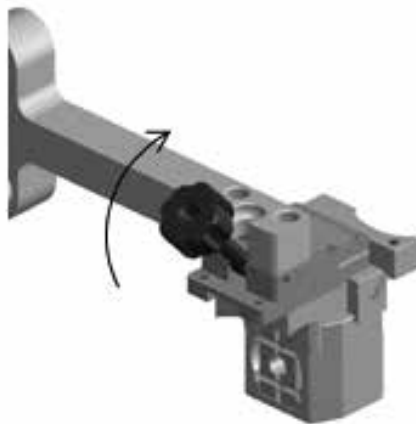


| **FIGURE 42**

Secure the C-Bracket to the Anterior Mounting Plate by rotating the swivel rod up and over the C-Bracket arm and tightening the screw on the end of the swivel rod. | **FIGURES 44, 45 and 46**



| **FIGURE 44**



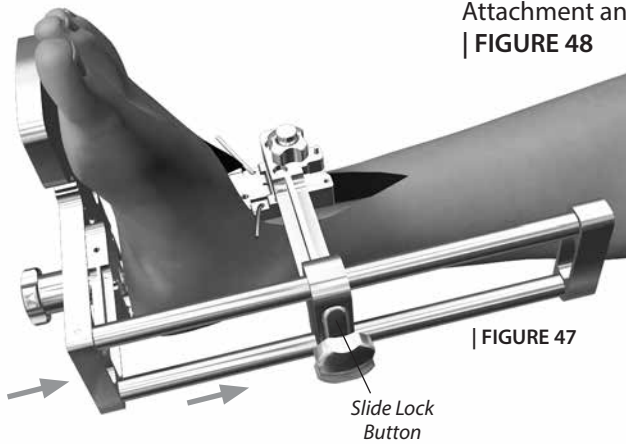
| **FIGURE 45**



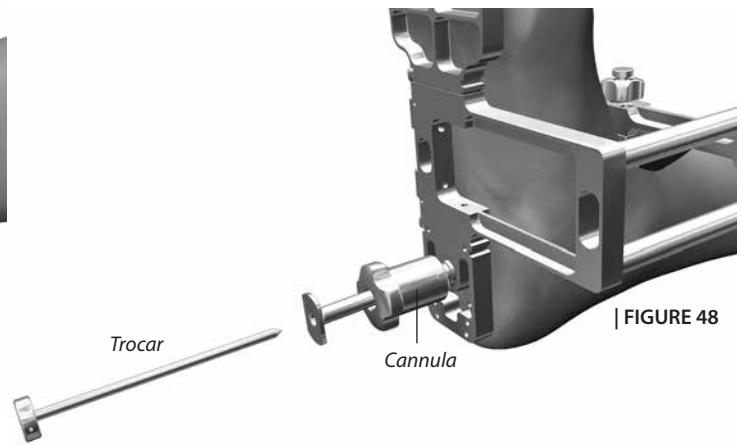
| **FIGURE 46**

Place the foot in slight dorsiflexion. Press and hold in the slide lock button on the outside arm of the C-Bracket and slide the distal end of the C-Bracket assembly close to the bottom of the foot. Leave a slight gap between the heel and the Bushing Attachment to facilitate its removal. | **FIGURE 47** To prevent the C-Bracket assembly from binding while adjusting the length, push the bottom of the assembly in-line with the side rods. Also, sterile mineral oil can be used to lubricate the side rods. Release the slide lock button and tighten the slide lock knob to lock the position of the C-Bracket.

With a skin marker, put ink on the tip of the Trocar (200099) and insert into the Cannula (200166). Insert the Trocar and Cannula through the Bushing Attachment and push the tip against the skin to mark the incision point. | **FIGURE 48**

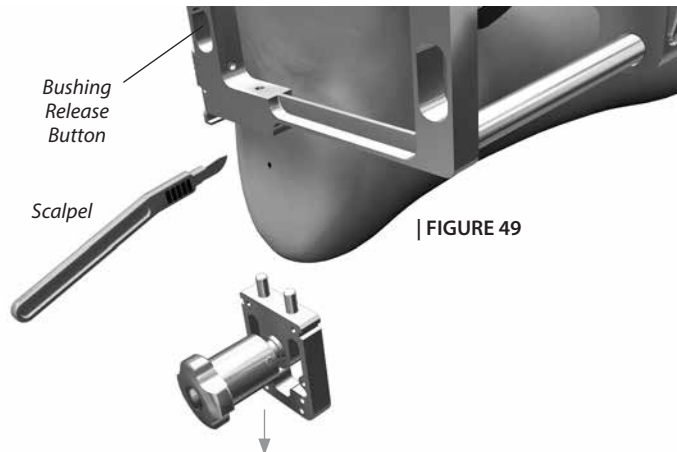


| **FIGURE 47**

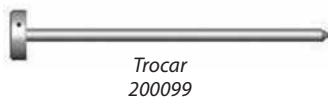


| **FIGURE 48**

Remove the Trocar and Cannula and push the Bushing Release Button on the C-Bracket to remove the Bushing Attachment. Centering on the previously marked spot, insert a #15 Scalpel and make a 1cm vertical incision in the bottom of the heel. | **FIGURE 49**



| **FIGURE 49**



Trocar  
200099

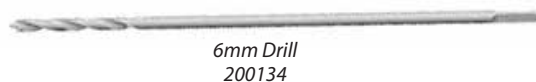
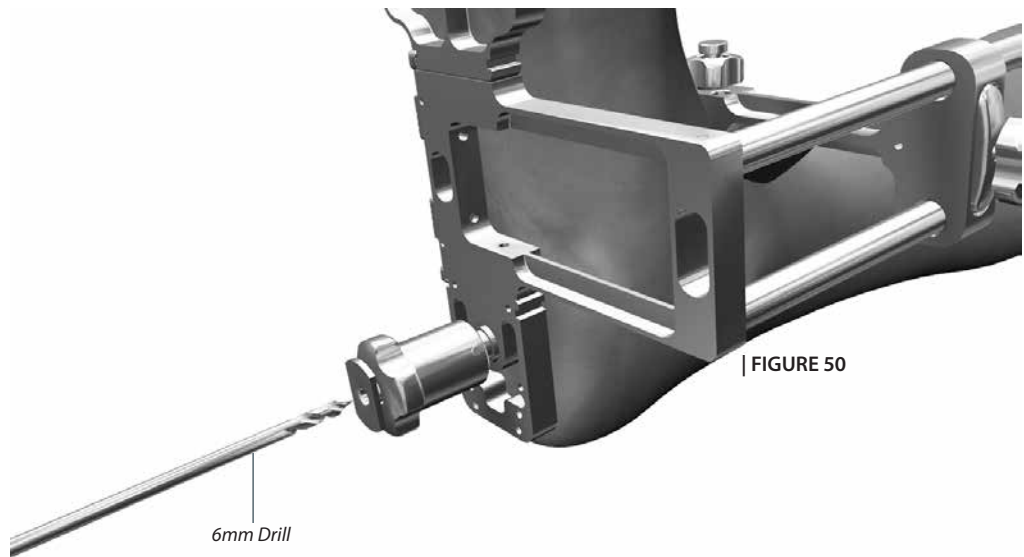


Cannula  
200166

Reattach the Bushing Attachment to the C-Bracket, and re-insert the Trocar and Cannula, pushing through soft tissue in the bottom of the foot, rotating the Cannula until it lightly contacts the calcaneus.

**CAUTION:** *Pushing too hard on the calcaneus will disturb alignment.*

Lock the Cannula in place by tightening the outer knob of the Drill Bushing. Remove the Trocar and place the 6mm Drill (200134) through the Cannula and slowly peck-drill through the calcaneus and talus. | **FIGURE 50** The tip of the 6mm Drill will be captured and guided by the conical anti-skiving feature of the Drill Guide Cartridge. Continue drilling into the tibial canal.





| FIGURE 51

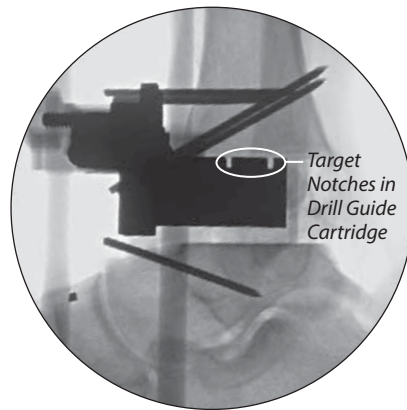


| FIGURE 52

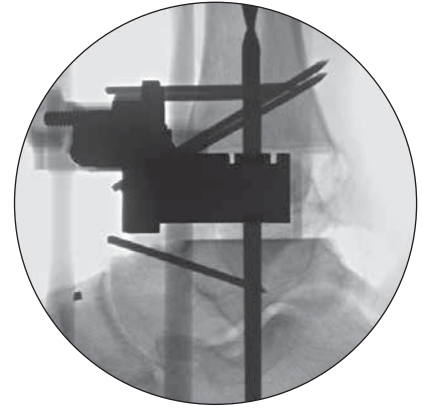
**CAUTION:** When drilling the IM canal it is important to take both an AP and Lateral fluoro image to ensure that the drill is going up the canal as planned.

An AP fluoro image will show the single notch in the Drill Guide Cartridge which is the desired/planned target for the 6mm Drill. | FIGURES 51 and 52

A Lateral fluoro image will show the two notches in the Drill Guide Cartridge that the 6mm Drill should go between. | FIGURES 53 and 54



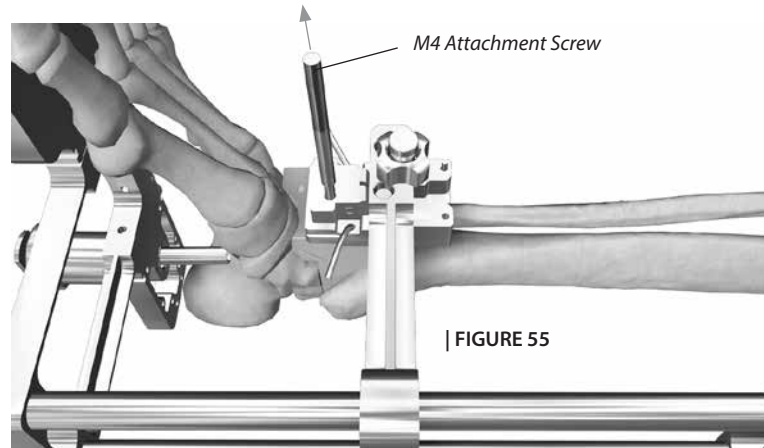
| FIGURE 53



| FIGURE 54

## Ream the Tibia

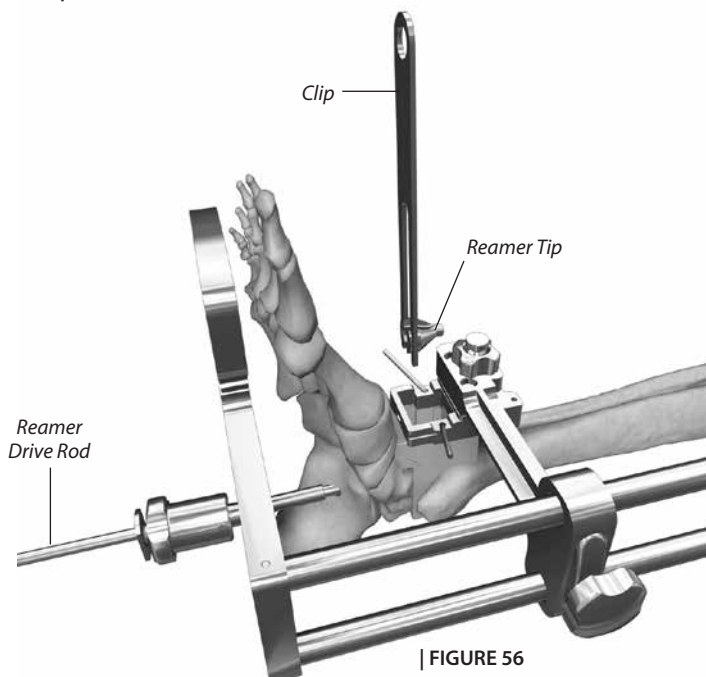
Remove the 6mm Drill from the foot and C-Bracket. Attach the M4 Attachment Screw (200329103) to the anterior threaded hole on the Drill Guide Cartridge and pull the Cartridge out anteriorly. | **FIGURE 55**



With the C-Bracket still secured, place the Reamer Drive Rod (with Jacobs chuck attached) through the distal bushing, calcaneus, and talus and into the resected joint space.

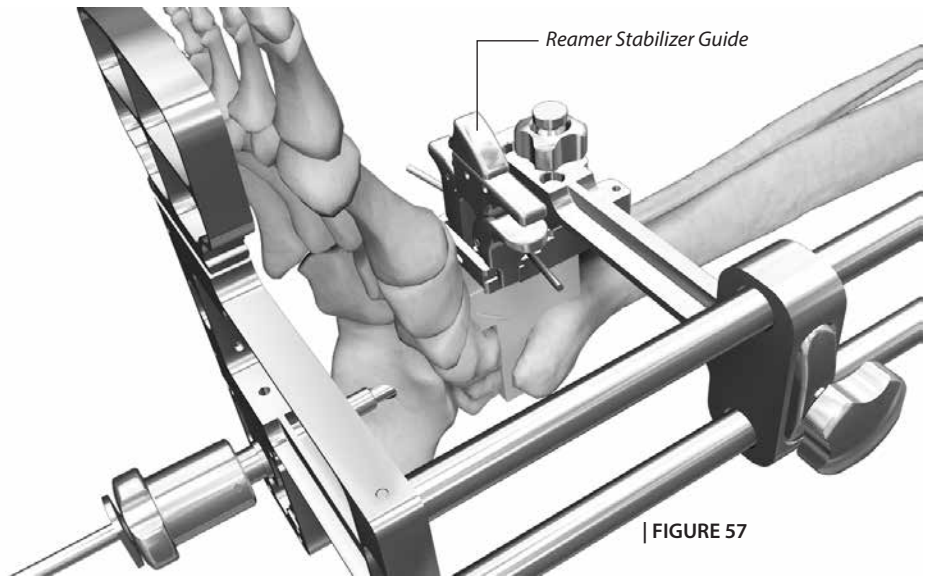
Using the appropriate size Tibial Stem Clip (200381001 through 200381004), attach and lower the appropriate size Reamer Tip (200046001 through 200046004) into the joint space through the anterior opening of the Anterior Mounting Plate. | **FIGURE 56**

Connect the Reamer Tip to the Reamer Drive Rod (200089 or 200395) and push the tip of the Reamer into the 6mm hole in the Tibia.

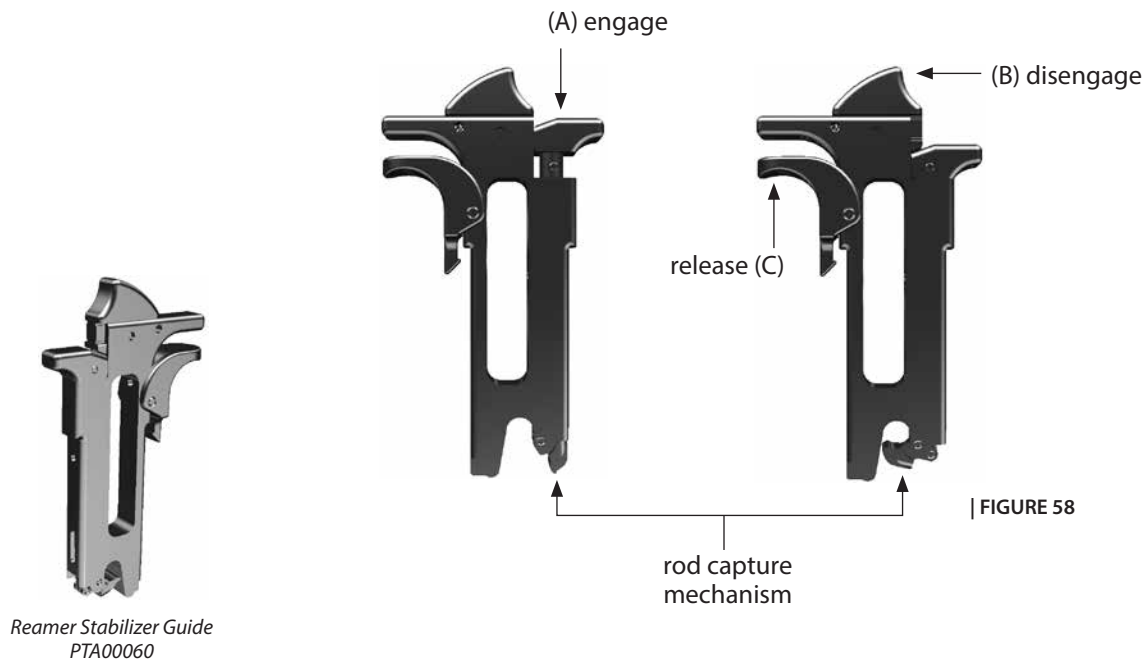


### Reamer Stabilizer Instructions

Insert the Reamer Stabilizer Guide (PTA00060) through the anterior opening of the Anterior Mounting Plate and push down until the side latch of the Guide connects to the Mounting Plate. | **FIGURE 57**



After inserting the Reamer Stabilizer, press the top button (A) to activate the rod capture mechanism. To disengage the rod capture mechanism, slide button (B) over as shown. To remove the Reamer Stabilizer from the Anterior Mounting Plate, pull up on lever (C) to release the side latch. | **FIGURE 58**





Ream the tibial IM canal to the depth of the tibial stem construct determined by the preoperative plan. Refer to Appendix B for tibial stem height details and recommended reaming depths. Note that the Reamer Drive Rod is marked with a depth indicator that can be viewed through the anterior window.

**CAUTION:** *It is highly recommended that AP fluoro images are made throughout the tibial reaming process to ensure the reamer is following the planned path.*

| FIGURE 59



| FIGURE 59

Pull the Reamer back into the joint space.

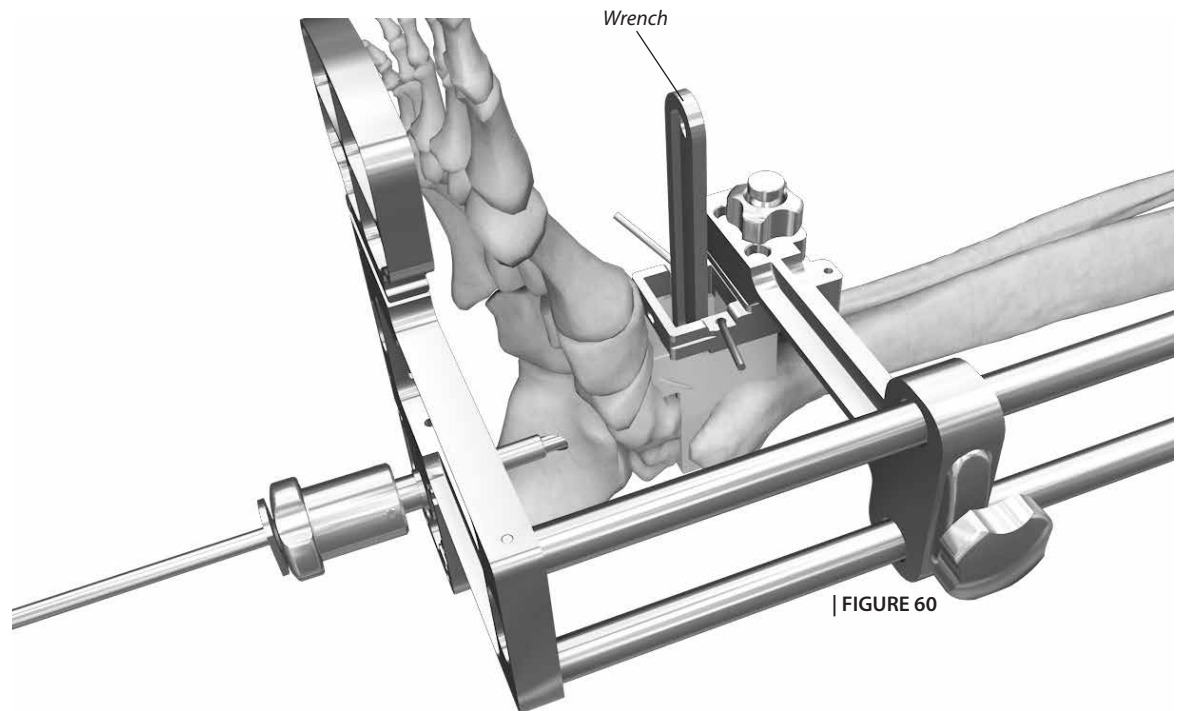
**CAUTION:** Do not reverse the drill rotation while the Reamer Tip is still in the tibia, as it will become unthreaded and remain in the tibia.

Disengage the Reamer Stabilizer Guide and remove it from the Anterior Mounting Plate.

Using the appropriate sized Tibial Stem Wrench (200380001 through 200380004), unthread the Reamer Tip from the Drive Rod and remove from the joint space. | **FIGURE 60** Repeat the reaming steps for all sizes of reamers required/desired.

**CAUTION:** It is strongly recommended that the surgeon use irrigation to clean the joint space between reamer sizes. The Reamer Stabilizer instrument will not be positioned properly if this step is not completed.

Leave the Reamer Drive Rod in the foot with the tip slightly distal to the surface of the talar resection.

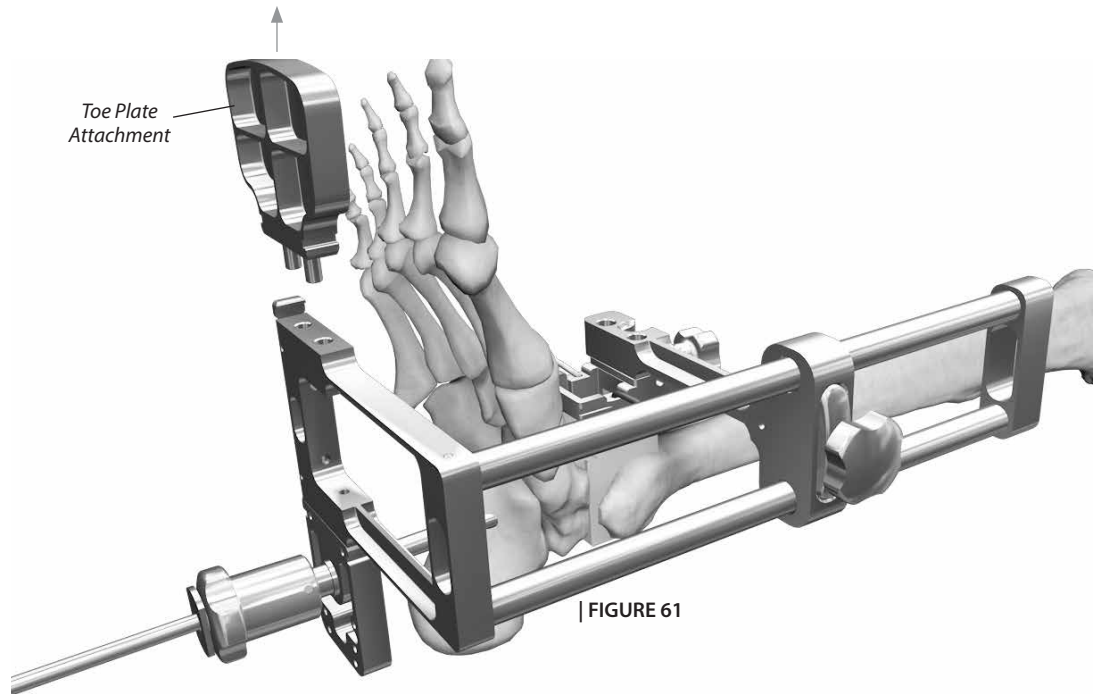


Tibial Stem Wrench  
200380001 - 200380004

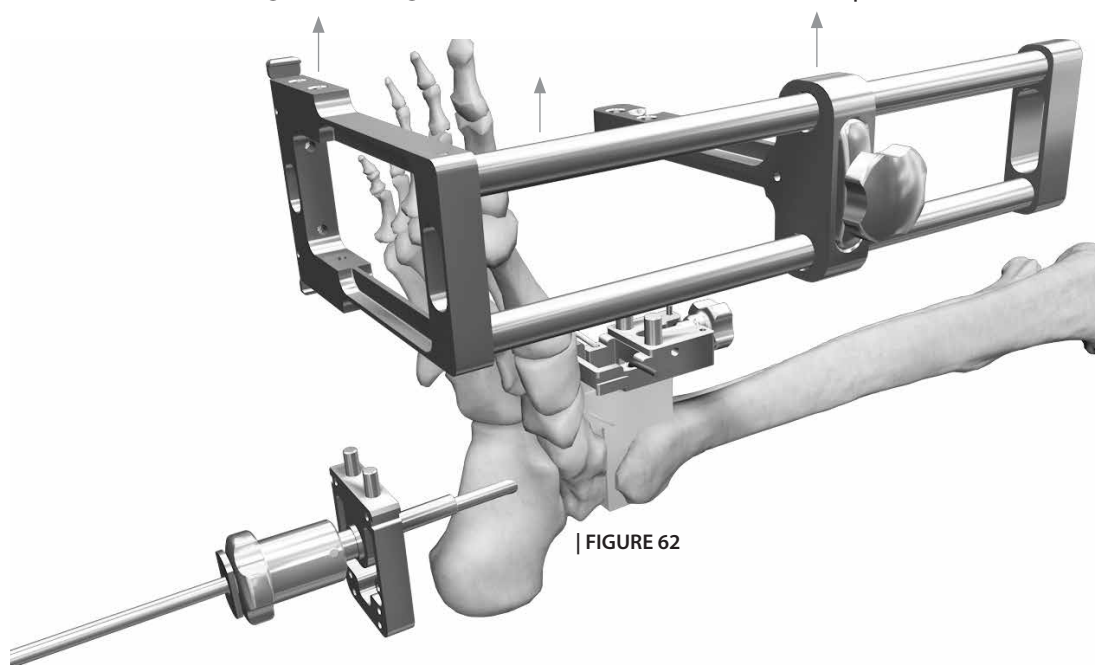
Release the screw and swivel rod attachment from the Anterior Mounting Plate.

Release the slide lock on the side arm of the C-Bracket Assembly and, with the Reamer Drive Rod still in the foot, slide the distal portion of the C-Bracket Assembly away from the bottom of the foot.

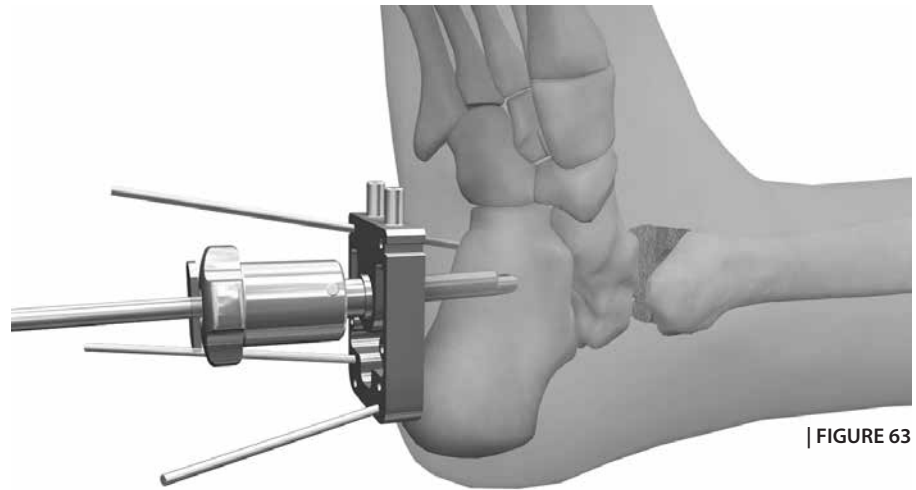
Release the Toe Plate Attachment from the C-Bracket Assembly by pressing the button on the side of the foot plate. | **FIGURE 61**



Release the Bushing Attachment from the C-Bracket Assembly by pressing the button on the side of the Foot Plate. Lift the C-Bracket off the foot anteriorly leaving the Bushing Attachment on the Reamer Drive Rod. | **FIGURE 62**



Remove the Anterior Mounting Plate and PROPHECY® Tibial Stem Guide from the joint space and slide the Bushing Attachment along the Drive Rod until it contacts the bottom of the foot and secure to the calcaneus with three 2.4mm Steinmann Pins. Two pins can be inserted through the bottom holes of the bushing attachment (one medial and one lateral) with the 3rd pin in one of the top hole locations (preferably on the lateral side). | **FIGURE 63** Remove the Drive Rod.

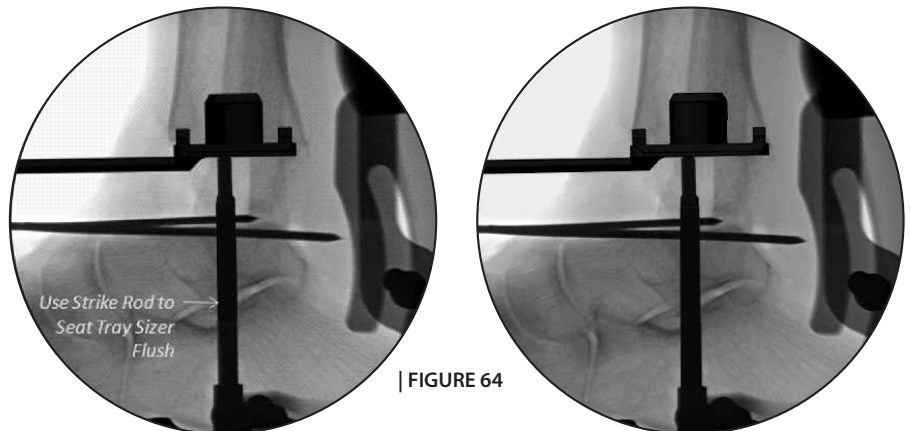


| **FIGURE 63**

Select the appropriate size Tibial Tray AP Sizer (IB282902 through IB282906) and insert into the resected joint space, using both ends of the sizing tool to determine the optimum AP size Tibial Tray (standard or long). The Strike Rod (200085) should be used to fully seat the Sizer into the tibial resection.

Utilize a lateral fluoroscopic image to evaluate the coverage (anterior and posterior) of the tibial cortex. | **FIGURE 64** It is critical to obtain sagittal plane coverage of the tibia, particularly anteriorly where more load is distributed. Thus, in choosing the correct size, overhang of the prosthesis is permitted if the standard size does not rest upon the tibial cortex.

The Tibial Tray AP Sizer is also used to check the tibial cut surfaces and ensure that no bone fragments will impede proper positioning of the Tibial Tray. Remove excess bone as necessary and irrigate.



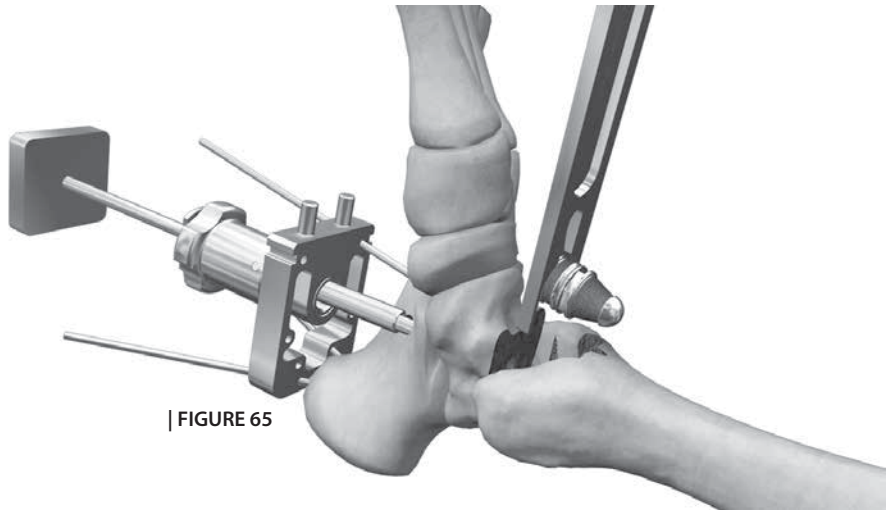
| **FIGURE 64**

AP Standard - illustrating undersized coverage.

AP Long - illustrating optimal coverage.

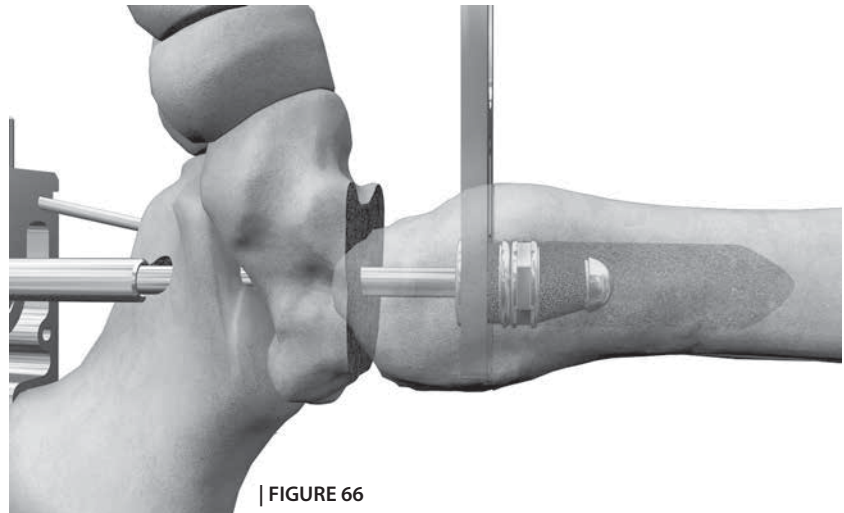
## Install Tibia Stems

In most cases the Top Tibial Stem and first Mid Stem piece can be pre-assembled and then placed into the joint space. Using the X-Drive and the appropriate sized Tibial Stem Wrench, firmly tighten these two components together on the back table. Orienting the Wrench in the distal direction as labeled, slide the Wrench onto the Mid Stem piece with a finger or thumb holding it in place. Introduce the components into the joint space, placing the Top Stem piece into the intramedullary canal of the tibia. | **FIGURE 65**

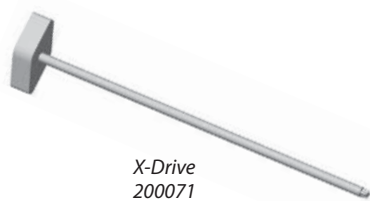


| FIGURE 65

Insert the X-Drive (200071) through the Bushing Attachment and up through the talus. | **FIGURE 66**

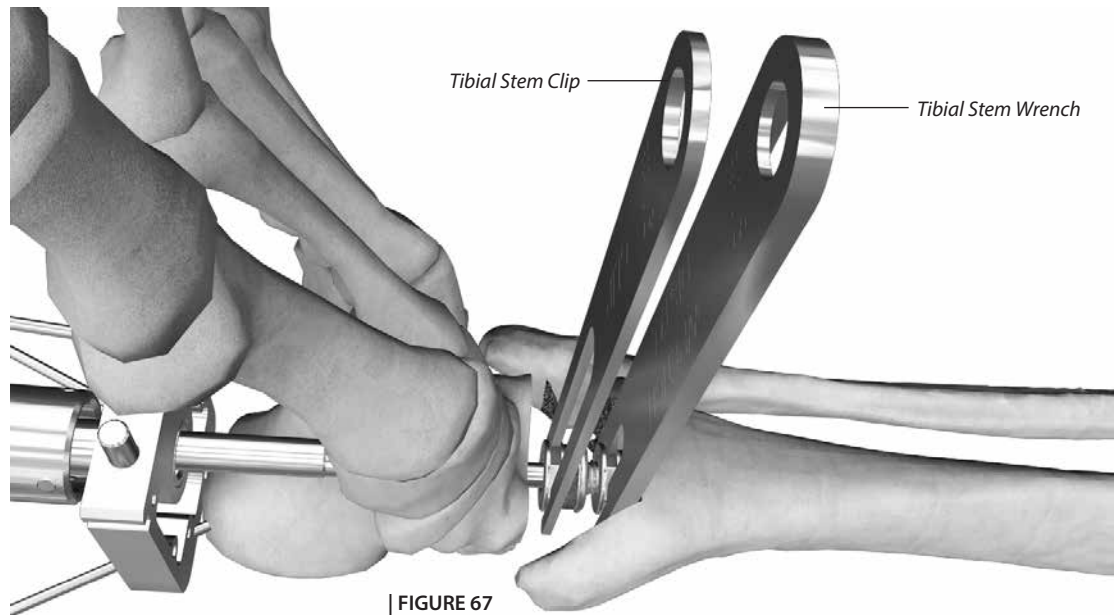


| FIGURE 66



X-Drive  
200071

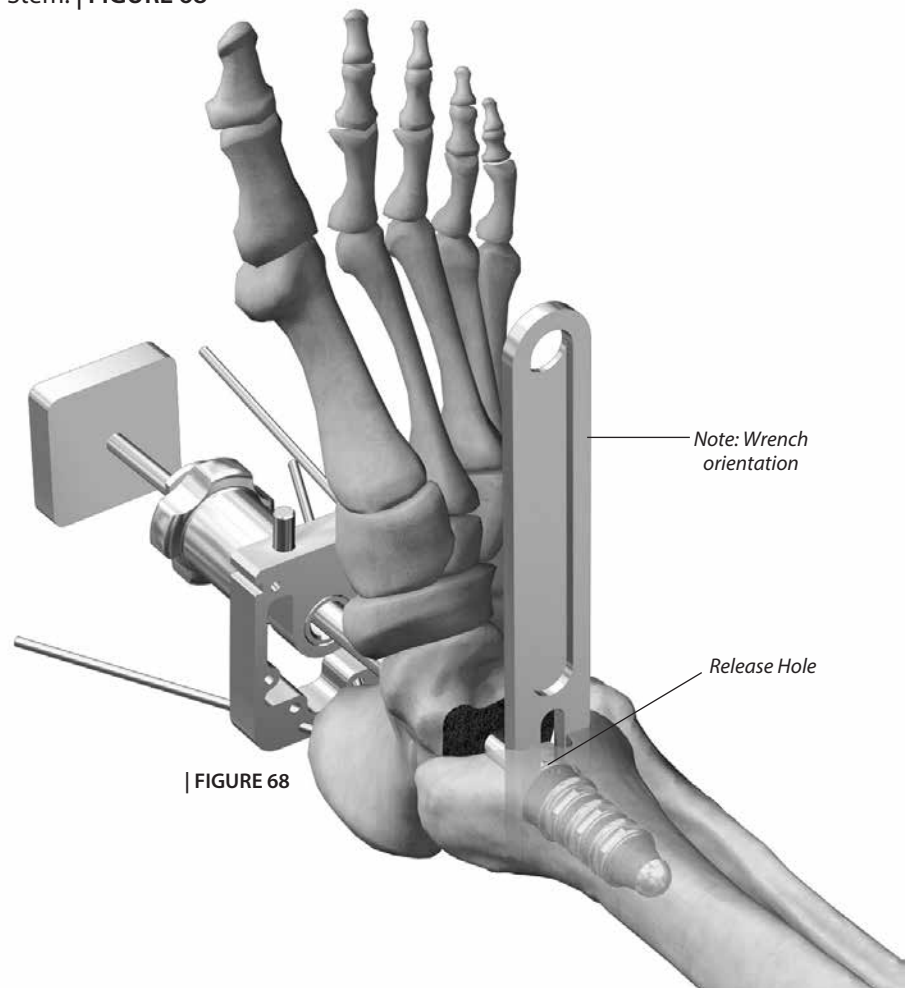
An assistant should hold the Wrench while the surgeon installs the next Mid Stem piece. Insert the next Mid Stem piece onto the appropriate sized Clip, introduce into the joint space and align with the Mid Stem piece. | **FIGURE 67**  
An assistant may hold on to the Wrench and distract the joint to aid insertion of the next piece.



Engage the X-Drive and thread the stems firmly together. Move the Wrench to the distal Stem piece before pushing the Stem up into the tibia.

**CAUTION:** Always leave the Wrench on the distal Stem piece or the stem construct may be inadvertently pushed up into the tibia.

Select the appropriate Base Stem piece and introduce with a Clip. Thread the Base Stem using the X-Drive. Remove the Clip and insert a Wrench on the Base Stem. | **FIGURE 68**



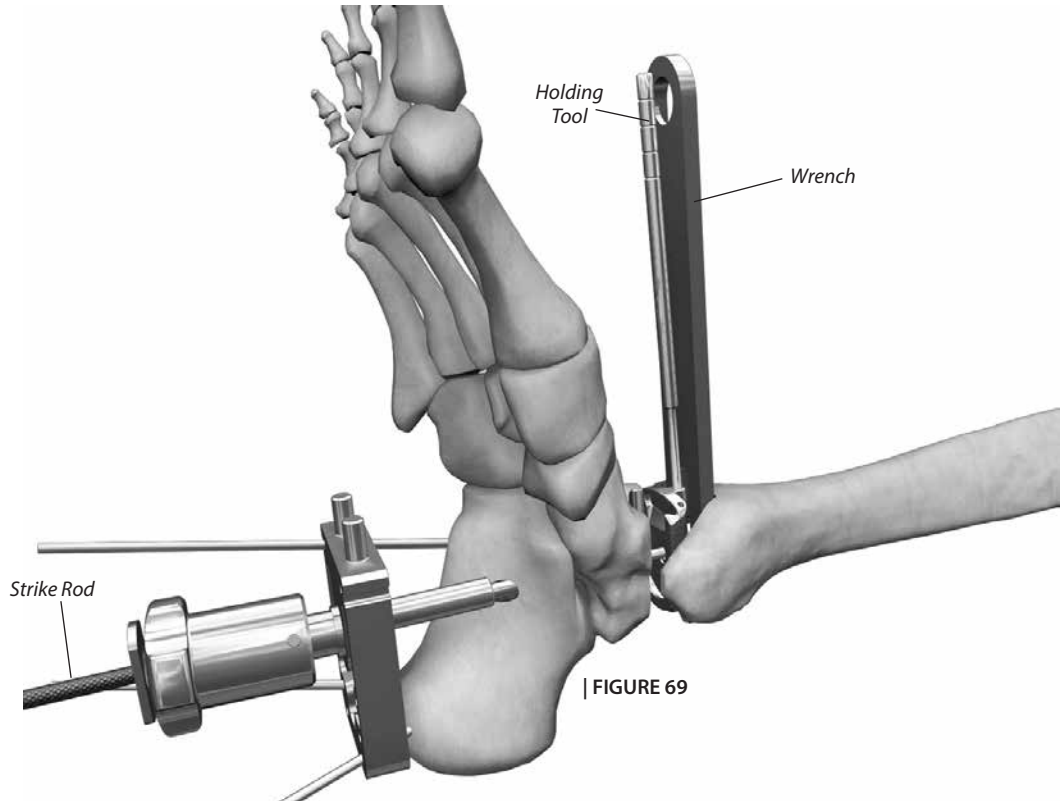
With the Base Stem tight, rotate it so the Morse taper release hole is pointing anteriorly and is in line with the anti-rotation notch. The Base Stem release hole is used to detach the Tibial Base Stem from the Tibial Tray in the event of revision. Leave the Wrench on the Base Stem.

## Install Tibia Tray

Irrigate the Morse Taper surface of the Base Stem to clean it.

**CAUTION:** Contamination on the Morse Taper surfaces can prevent proper seating.

Remove the X-Drive and replace with the Strike Rod. Hold the Tibial Stem Base with the Wrench and introduce the Tibial Tray using the Holding Tool (200364002 or 200364003). Insert the Morse Taper into the Stem Base. Push the Strike Rod into the small detent on the bottom surface of the Tibial Tray. | **FIGURE 69**



**CAUTION:** Remove the Holding Tool before striking the Strike Rod. Otherwise it can be locked in place.

Holding the Tibial Stem Base firmly, strike the end of the Strike Rod several times with a mallet to seat the Morse Taper.

**CAUTION:** The Tibial Tray will not seat if the wrench is in the wrong orientation. Wrench is marked "Distal" for correct orientation.

Remove the Wrench, rethread the Holding Tool to the Tibial Tray, and test the Morse Taper connection by trying to rotate the Tibial Tray against the Stem. If properly engaged, both the stem and Tibial Tray should move as one unit.



Holding Tool  
M4 - 200364003  
M3 - 200364002

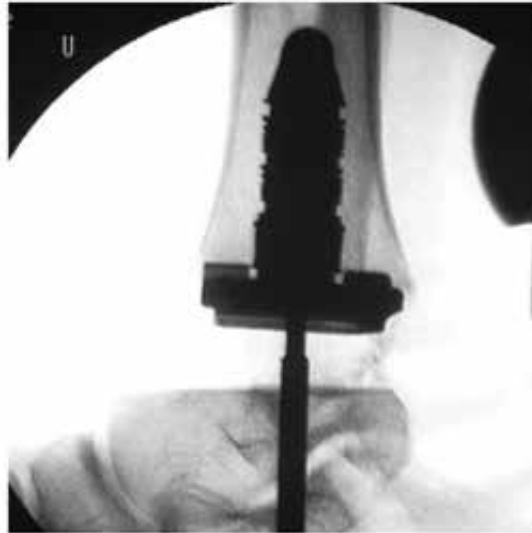


Apply bone cement to the top and sidewalls of the Tibial Tray component.

**CAUTION:** *The INBONE® Total Ankle is intended for cemented use only.*

**CAUTION:** *Be sure not to get any cement on the anterior face or bottom of the Tray.*

Seat the assembly firmly into the tibia using a mallet and the Strike Rod. Remove the Strike Rod and visually check the anterior alignment. Check the lateral fluoroscopic image for proper posterior seating. | **FIGURE 70**



| **FIGURE 70**

## Verify Talar Dome Size

The surgeon has two options for Talar Dome implant size at this juncture: either the matching size for the implanted Tibial Tray, or one size smaller. It is beneficial to assess both sizes under A/P and lateral fluoroscopic images. Please note that the A/P image is critical for sizing the talar component, as the surgeon's goal is to minimize overhang of the talar component, and thus minimize prosthetic impingement in the medial and lateral gutters of the ankle joint.



*Size-matched Talar Dome Trial showing medial and lateral talar overhang.*



*One size smaller Talar Dome Trial showing optimal coverage of the resected talus.*

Release the foot from the Foot Holder and remove the Foot Holder from the operating table.

Perform a thorough gutter debridement. The surgeon must be certain that there is no residual bone impinging between the talus and the medial fibula and lateral tibia. The talus must now be completely independent of the remaining ankle joint, free to rotate into its anatomic center of rotation, as well as translate to establish a position beneath the tibial tray. To achieve this, a generous debridement may be necessary.

Select the appropriate size Talar Dome Trial (IB220901-905) and Talar Dome Holding Tool (IB200010) and assemble.

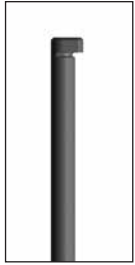
Assess overhang of the Talar Dome Trial in both the A/P and Lateral planes. Choose the Talar Dome that allows the most congruous coverage of the talar cut line.



*Talar Dome Trials  
IB220901-905*



*Talar Dome Trial  
Holding Tool  
IB200010*



Talar Dome Trial Holding Tool



Poly Insert Trial Holding Tool

### Training Note for Trial Holding Tools

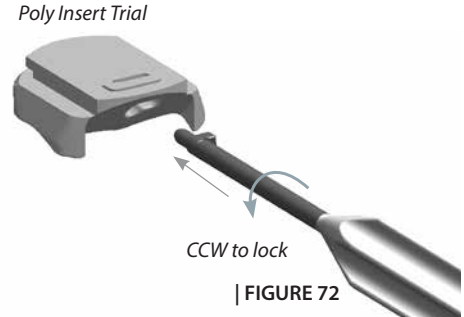
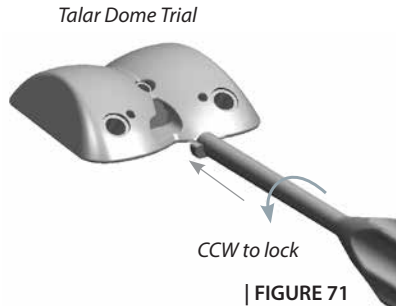
There are two different trial holding tools in the instrument set: one for the Talar Dome Trials (silver handle) and one for the Poly Insert Trials (gold handle). In addition to having different colored handles, the two instruments also have slightly different designed tips.

## Trial Reduction

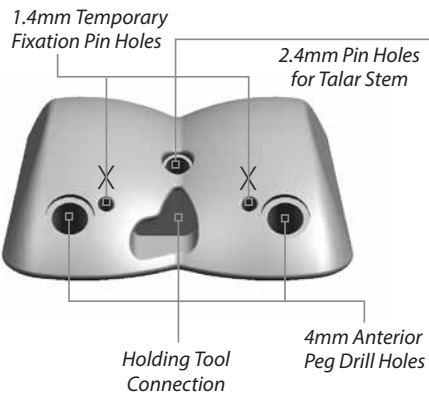
### Holding Tool to Trial Attachment

To attach the Holding Tool to the corresponding trial component, insert the tip of the tool into the keyed slot and turn 90° counter-clockwise to lock the connection. | FIGURES 71 and 72

To remove the holding tool turn the handle 90° Clockwise and remove.

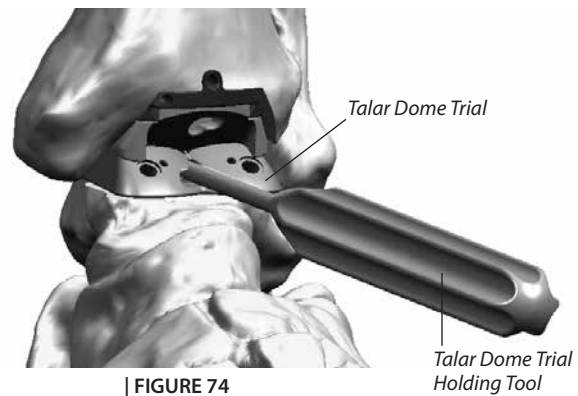
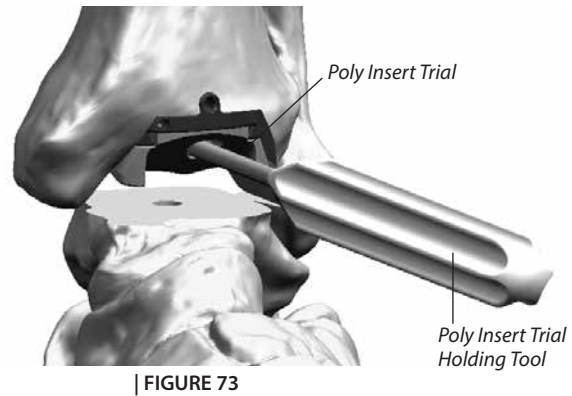


### Talar Dome Trial Detail



Using the Poly Insert Trial Holding Tool, install the appropriate size Poly Insert Trial (IB202106-6520) into the Tibial Tray. The locking tab of the Poly Insert Trial should engage the Tibial Tray. | FIGURE 73

Using the Talar Dome Trial Holding Tool, introduce the appropriate size Talar Dome trial into the joint space. | FIGURE 74



Poly Insert Trials  
IB202106-6520



Poly Insert Trial Holding Tool  
IB200110

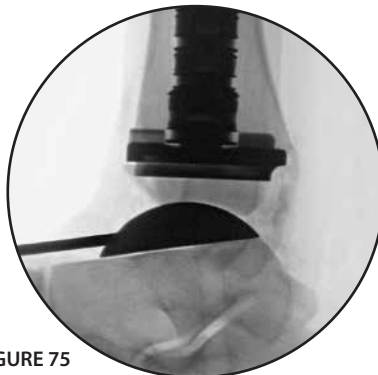
### **Polyethylene Thickness**

While the final polyethylene thickness does not have to be definitively chosen during the trial phase, it is important to have what is perceived to be the appropriate size trial poly to accurately determine the placement of the talar component. The trial poly used for the reduction should fit appropriately to determine the center of rotation of the talar component; therefore, trialing multiple size polys may be necessary. Note that after insertion of the final talar dome, the height of the poly can be reassessed.

In order to determine proper polyethylene height the following factors must be considered:

- Smooth range of motion of the ankle without anterior or posterior impingement.
- Ligaments are tensioned both medially and laterally **WITHOUT** over-tensioning. Over-tensioning is noted when the trial talar component tilts following trial poly insertion. Alternatively, with range of motion, the talar component becomes incongruent with the trial poly, which can identify too much tension on the ankle replacement. Over-tensioned joints may cause increased polyethylene wear, and should be avoided.
- Stress the ankle joint into varus and valgus. The trial components should not tilt.
- The trial poly should engage the sulcus in the talar dome trial without allowing medial/lateral translation.

Under lateral plane fluoroscopy, ensure the posterior portion of the talar component is resting on the posterior portion of the patient's residual talus (establish congruence). | **FIGURE 75**



| **FIGURE 75**

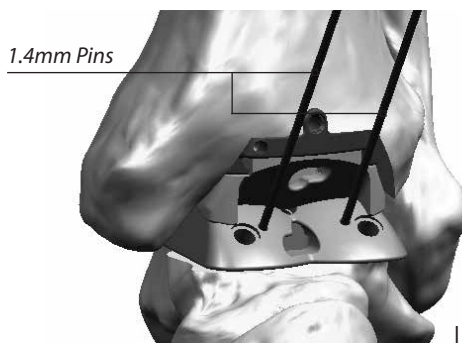
While holding the talus in this position, use a marking pen to mark the anterior portion of the talar component with reference to the patient's residual talus.

Be sure to observe the talar component with reference to the line on the residual talus previously drawn. This will ensure the talar component does not migrate anteriorly during the range of motion.

To accurately perform the range of motion, place some axial compression of the components to maintain position, and flex and extend the ankle. The surgeon will observe the talar component rotating into the anatomic position for this particular patient. Note that the surgeon must not only be cognizant of the talar position in the lateral plane, but must simultaneously maintain medial/lateral coverage as evidenced by the previous A/P plane fluoroscopic views.

Once Talar Dome Trial has settled into optimum anatomical position, install two 1.4mm pins through the Talar Dome Trial to temporarily hold it in place.

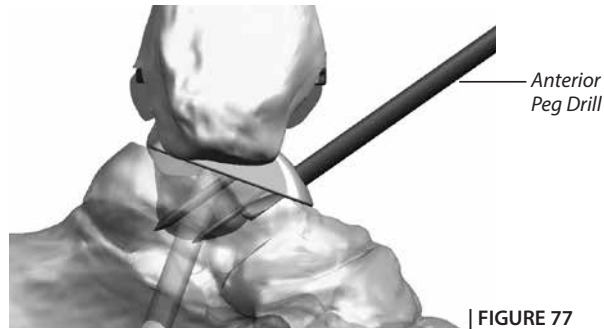
| **FIGURE 76**



| **FIGURE 76**

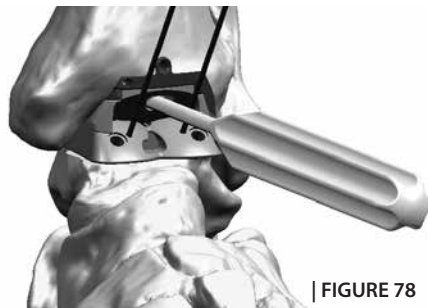
*Note that with the talar component pinned in position, the surgeon should once again place the ankle through a range of motion to ensure tibio-talar articular congruence. Also, confirm through lateral fluoroscopy that the prosthesis did not shift anteriorly.*

Using the 4mm Anterior Peg Drill (IB200020), drill a hole through the medial and lateral openings in the Talar Dome Trial. The drill has a hard stop designed to set the appropriate drilling depth in the talus for the Talar Dome anterior pegs.  
**| FIGURE 77**



Use the Poly Insert Trial Holding Tool to remove the Poly Insert Trial. Foot may be plantarflexed to aid in removal of Poly Insert Trial. **| FIGURES 78 and 79**

**CAUTION:** *The Poly Insert Trial has a small locking tab that engages the Tibial Tray. To remove Poly Insert Trial, be sure to first pull down on the holding tool to disengage tab before pulling out.*

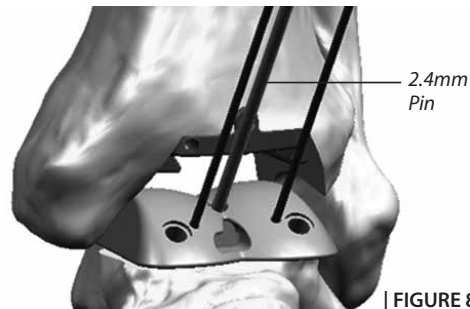


**| FIGURE 78**



**| FIGURE 79**

Install a 2.4mm Steinmann Pin through the center of the Talar Dome Trial to the depth of the selected Talar Stem using a lateral view to verify depth. Be certain that the Talar Dome Trial is sitting flush with the cut line of the talus before placing this pin. **| FIGURE 80**



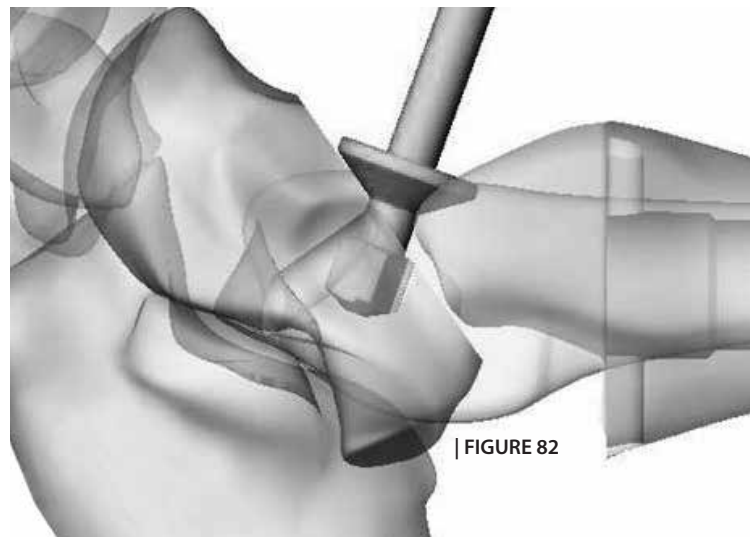
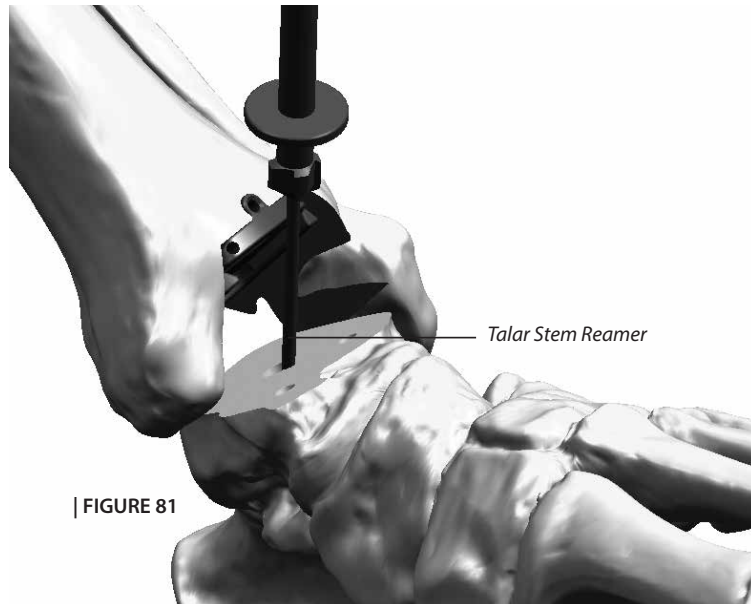
**| FIGURE 80**



Remove 1.4mm Pins and use the Talar Dome Trial Holding Tool to slide Talar Dome Trial off the remaining 2.4mm Steinmann Pin. The foot may be plantarflexed to aid in removal of Talar Dome Trial.

## Ream for Talar Stem

Install the appropriate length Talar Stem Reamer (10mm-200432010 or 14mm-200432014) over the pin and ream to the depth of the selected talar stem. | **FIGURE 81** The reamer has a hard stop designed to set the appropriate reaming depth. | **FIGURE 82** Optionally, use a lateral fluoroscopic view to verify depth.



Talar Stem Reamers  
(10mm-200432010)  
(14mm-200432014)

**CAUTION:** *The Talar Stem is not intended for subtalar fusion or subtalar joint impingement. Please carefully evaluate the anatomy of each patient before implantation.*

Remove the Reamer and Steinmann Pin.

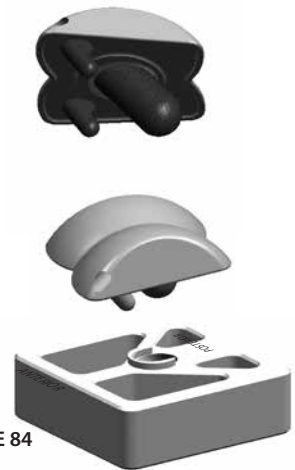
## Assemble Talar Stem

Insert the appropriate sized Talar Stem into the bottom of the Talar Dome | **FIGURE 83**, aligning the oblong post and matching the oblong hole in the Talar Stem. Talar Stem and anterior pegs should be parallel.

Insert the Talar Stem and Talar Dome assembly into the Strike Block (IB200060). | **FIGURE 84**



| **FIGURE 83**



| **FIGURE 84**

Align the Dome Strike Tool (IB200030 and IB200031) on the Talar Dome and with a mallet, hit the top of the strike tool 2-3 times to fully seat the Talar Stem.

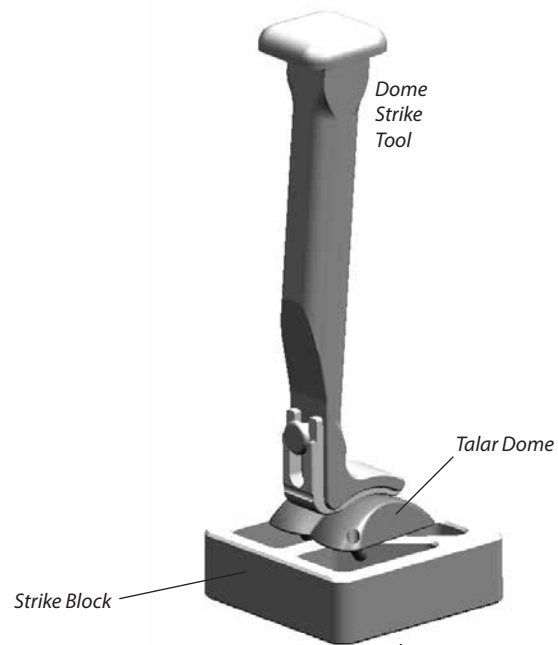
| **FIGURE 85**



Strike Block  
IB200060



Dome Strike  
(pre-assembled  
with Dome  
Strike Tip)  
IB200030  
IB200031

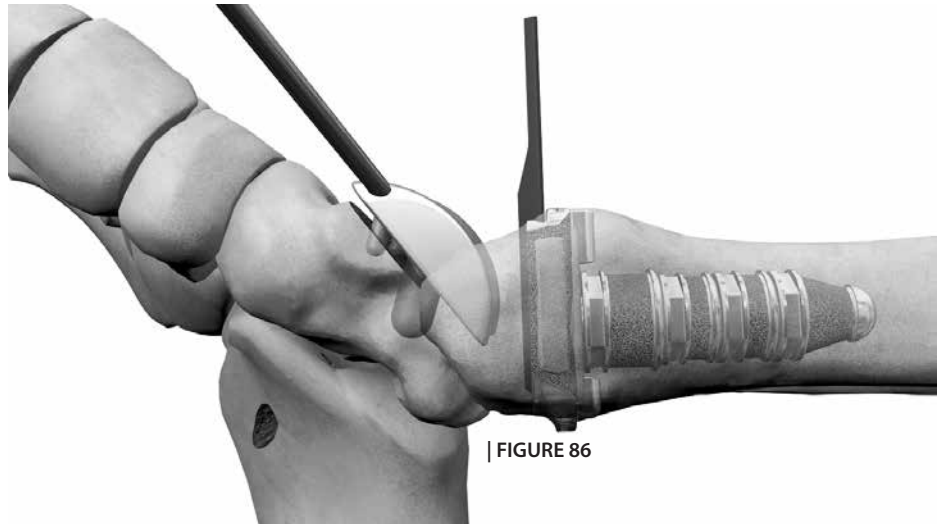


| **FIGURE 85**



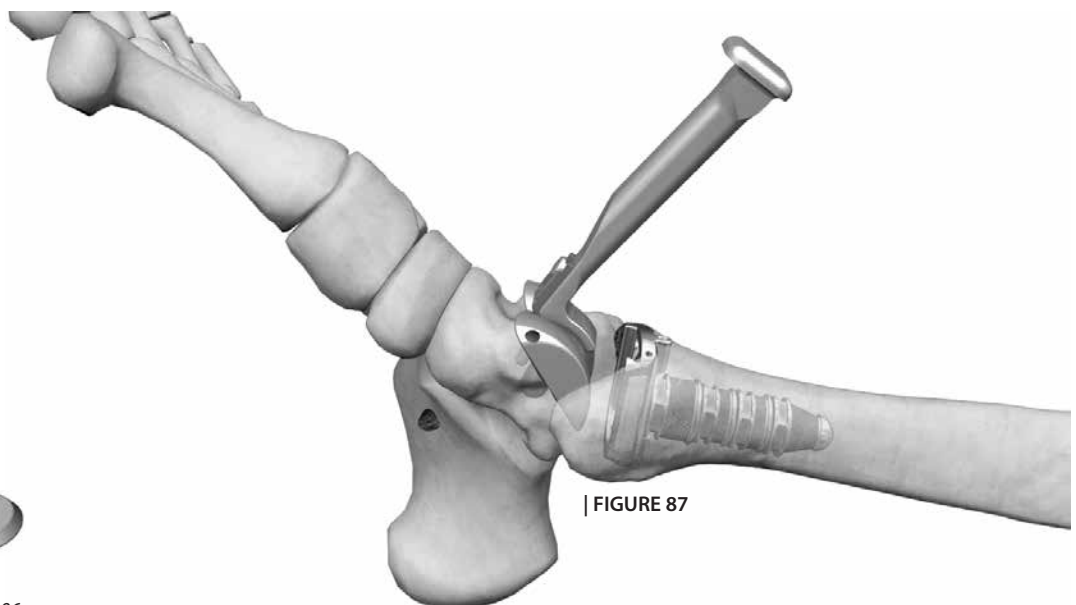
## Install Talar Dome

Place the foot in plantar flexion and insert the blue Tray Insert (200419002 through 200419006) into the Tibial Tray to protect the Talar Dome surface during installation. Apply bone cement to the bottom surface of the Talar Dome. Using the M4 Holding Tool, insert the Talar Dome, aligning the Talar Stem and pegs with the prepared holes in the talus. | **FIGURE 86** Once the Talar Dome is aligned, remove the Tray Insert.



**CAUTION:** *The INBONE® Total Ankle is intended for cemented use only.*

Align the Dome Strike Tool on the Talar Dome and with a mallet, hit the top of the strike tool to fully seat the Talar Dome. | **FIGURE 87** Utilize a lateral fluoroscopic image to ensure that the Talar Dome is fully seated. If the Talar Dome is difficult to fully seat in hard bone, it may be advisable to remove the Talar Dome and increase the diameter of the anterior peg holes slightly with the 4mm drill.



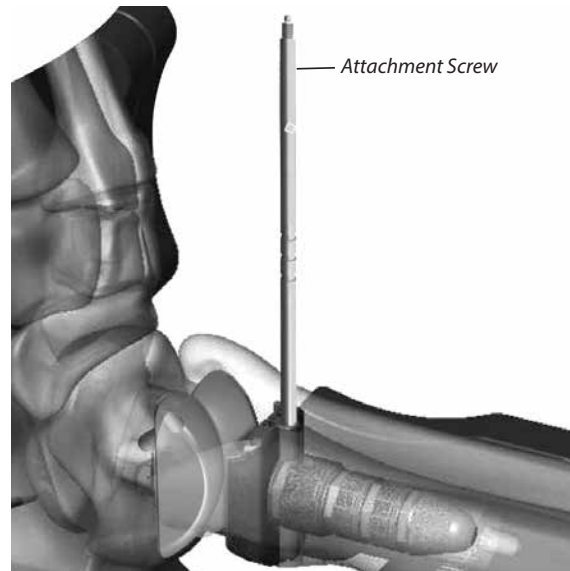
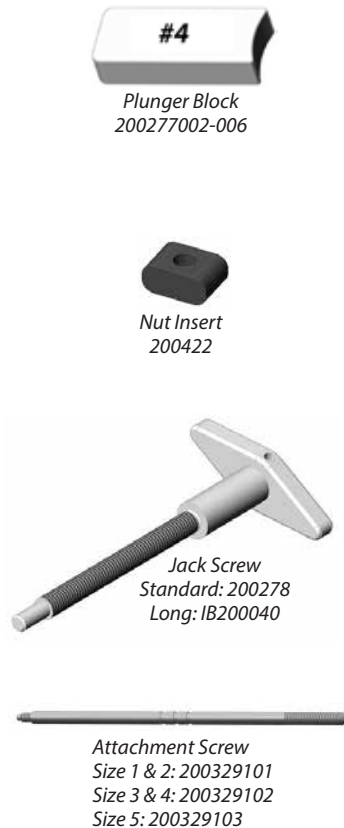
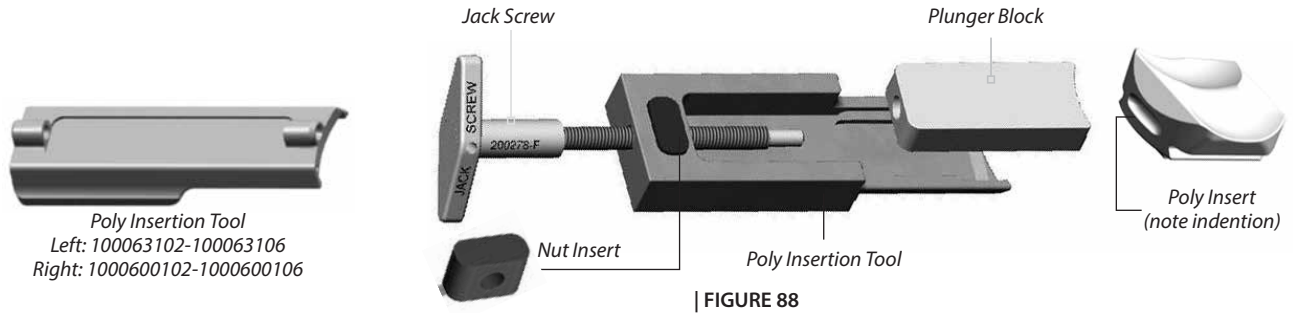
Tray Insert  
200419002-200419006

## Install Poly Insert

Select the appropriate size Poly Insertion Tool (1000600102 through 100063106) and Plunger Block (200277002-006). Place a Nut Insert (200422) into the pocket of the Poly Insertion Tool. Position the Plunger Block at the back of the tool and retain with the appropriate Jack Screw (200278 or IB200040). | **FIGURE 88** Jack Screw must match the Tibial Tray, e.g. size 3 Long Tibial Tray requires the use of the Long Jack Screw. Long Jack Screw is gold colored and standard Jack Screw is silver.

Select proper size Poly Insert and slide into the dovetail of the insertion tool. The anterior face of the Poly Insert (indentation) must face the Plunger.

Install the appropriate Attachment Screw (200329101 through 200329103) into the anti-rotation notch of the Tibial Tray. | **FIGURE 89**



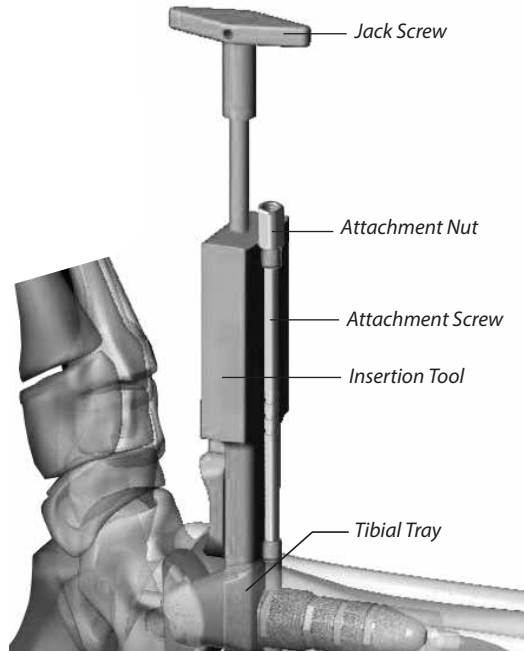
| **FIGURE 89**

Slide the Poly Insertion Tool assembly over the Attachment Screw and align flush with the anterior surface of the Tibial Tray. Thread the Attachment Nut (200329201) onto the Attachment Screw to lock the Poly Insertion Tool to the Tibial Tray. | **FIGURE 90**

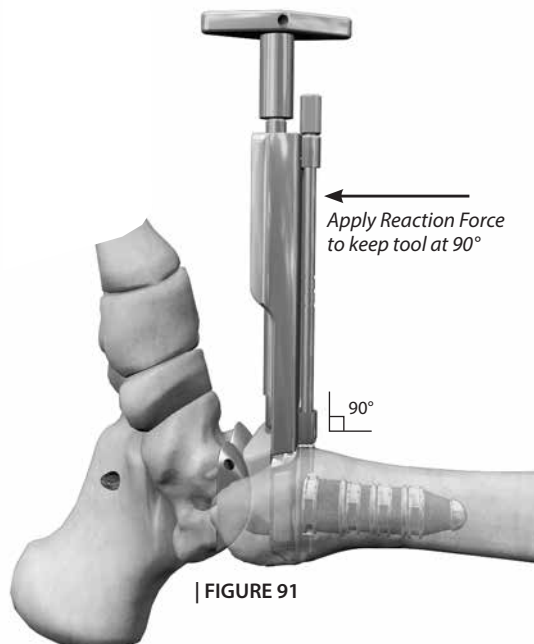
Turn the Jack Screw to advance the Poly Insert into the Tibial Tray.

**CAUTION:** To prevent incomplete seating of the poly insert, properly irrigate the tibial tray prior to poly insertion.

Apply slight "Reaction Force" as necessary to keep Insertion Tool at 90° to Tibia. | **FIGURE 91**



| **FIGURE 90**

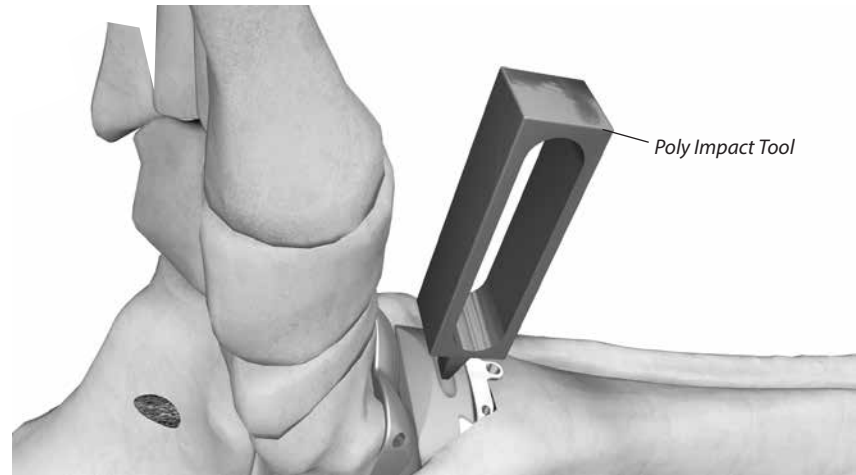


| **FIGURE 91**



Attachment Nut  
200329201

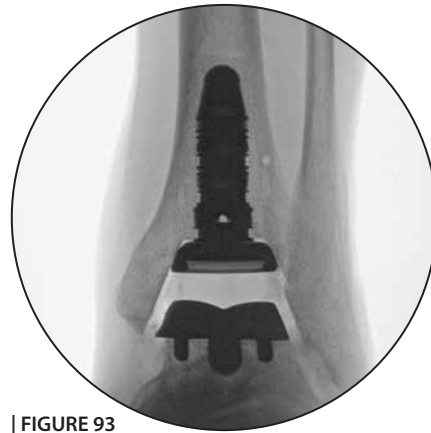
Continue turning the Jack Screw until it bottoms out, then remove the insertion tool. | **FIGURE 92**



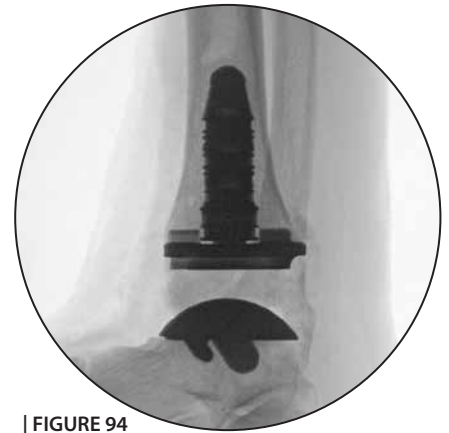
| **FIGURE 91**

Select the Poly Impact Tool (200286). At a 60° angle, give the Poly Impact Tool a final tap to fully seat the Poly Insert. Check that the Poly is fully seated.

Take final AP & Lateral fluoro images for record keeping. | **FIGURES 93 and 94**



| **FIGURE 93**



| **FIGURE 94**



*Poly Impact Tool  
200286*

### **Final Procedures**

Check for proper articulation.

Close the wound.

Cast the foot in a slight dorsiflexion position.

Keep the foot non-weight bearing for 6 weeks.

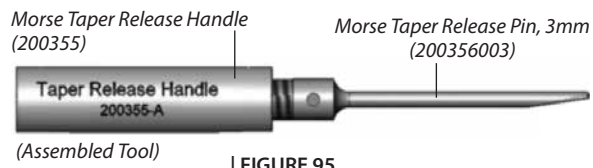
## Morse Taper Release

Thread Morse Taper Release Pin (200356003) into Morse Taper Release Handle (200355).

Insert tip of the Morse Taper Release Pin into the Morse Taper Release Hole of the Implant.

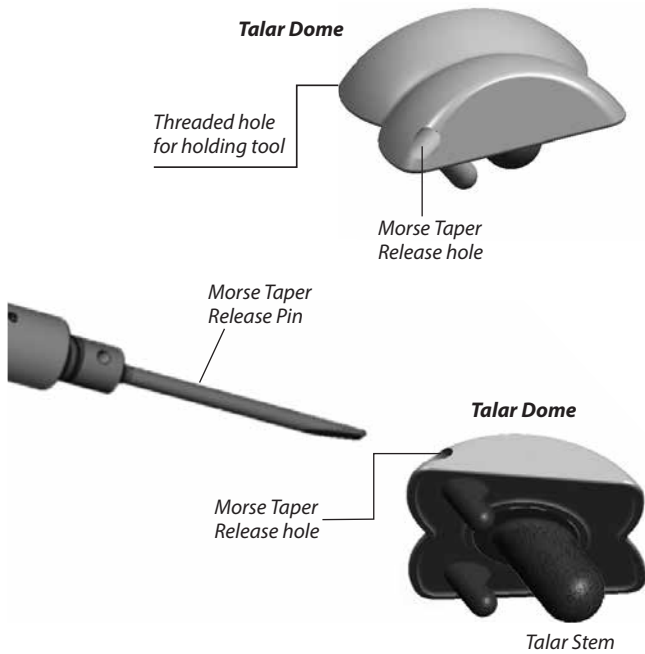
Angled surface of the Release Pin should face distally.

Holding the implant firmly, strike the end of the Morse Taper Release Handle with a mallet until the Morse Taper becomes unseated. | **FIGURE 95**

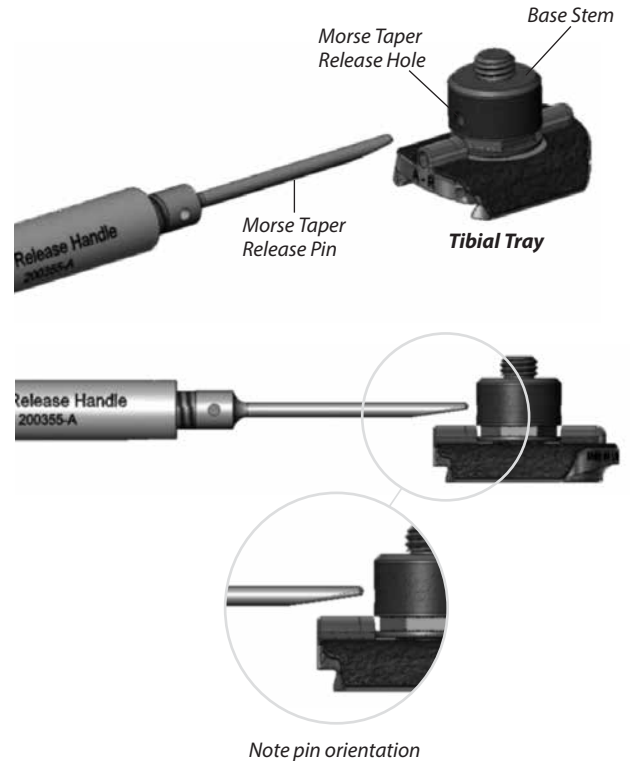


| **FIGURE 95**

### Talar Dome



### Tibial Tray



**CAUTION:** Release pin must be inserted into the Talar Dome from anterior to posterior to disengage taper. Failure to do so could result in pin becoming permanently jammed.

## Explant Information

### INSERT REPLACEMENT

To remove the Poly Insert, first install two large diameter threaded Steinmann Pins into the anterior face of the implant. With a pair of pliers, pull distally on the Steinmann Pins in attempt to unlock the Insert from the Tibial Tray. A narrow osteotome may be inserted into the anterior region of the insert to facilitate removal. A hemostat may be used to remove the insert once it is no longer locked to the tibial base. Care must be taken not to scratch or mar any component that is not intended to be removed.

### TIBIA AND TALAR COMPONENTS

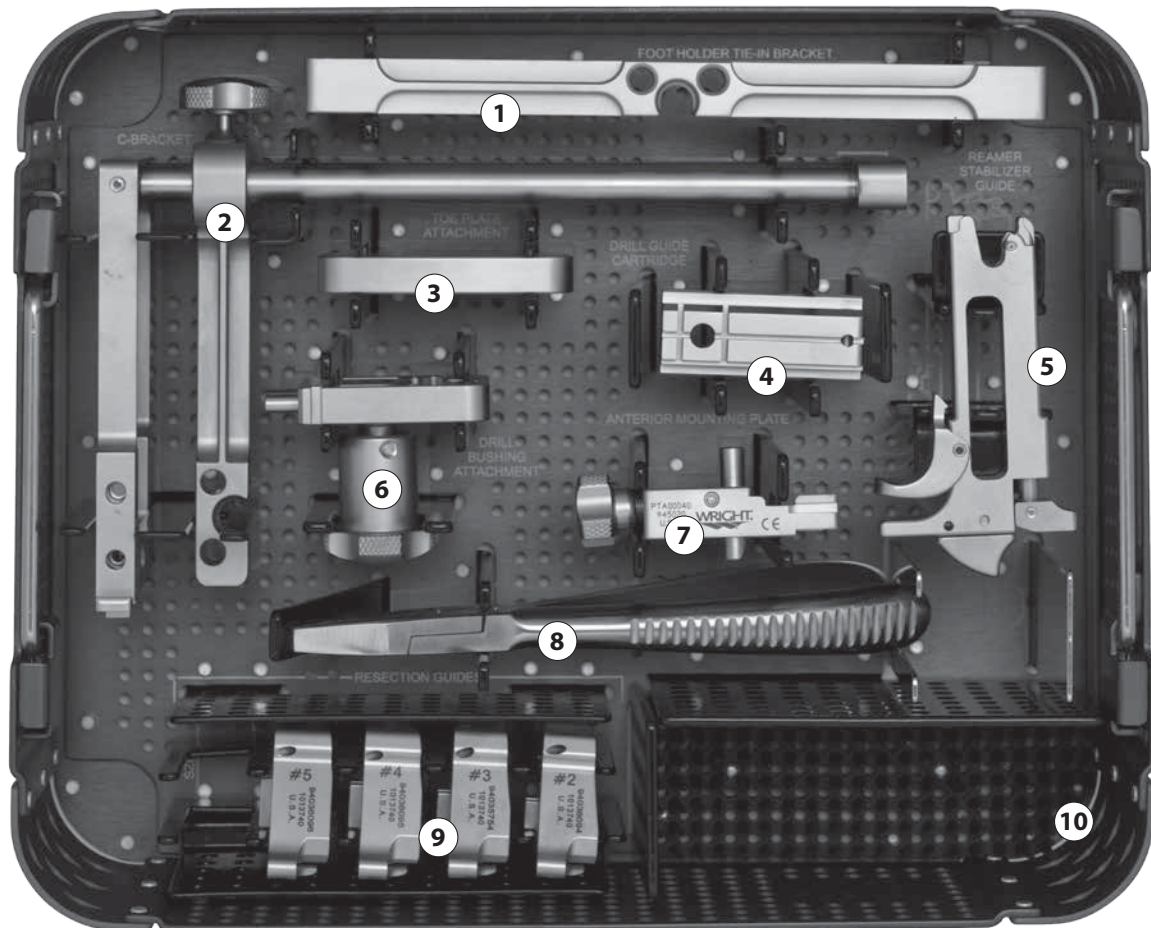
To remove the components, small osteotomes, power saws, or other surgical instruments may be used to disrupt the bone-cement interface. Care must be exhibited to save remaining bone stock as well as to prevent fracture. Once the components have been removed, rongeurs or small osteotomes, as well as other surgical instruments, may be used to remove the remaining cement.

## Postoperative Management

Postoperative care is the responsibility of the medical professional.

# PROPHECY® INBONE® Instrumentation

PTA-KIT1 PROPHECY® INBONE® Instrument Kit


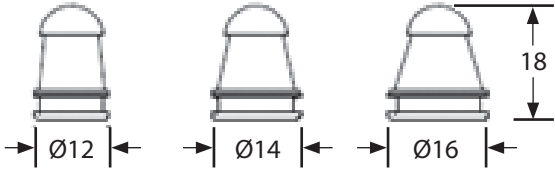

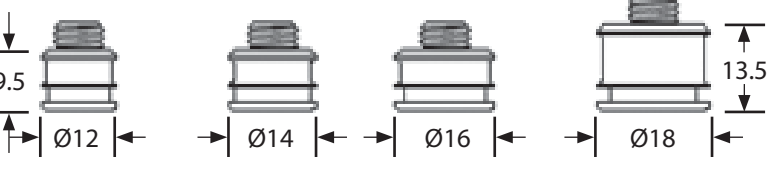

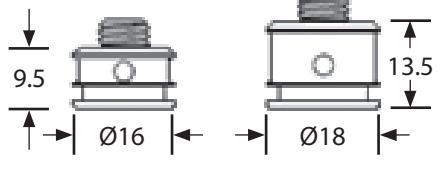




- |  |   |
|--|---|
| 1. Foot Holder Tie-In Bracket (PTA00080) | 6. Bushing Attachment (PTA00020)                |
| 2. C-Bracket (PTA00010)                  | 7. Anterior Mounting Plate (PTA00040)           |
| 3. Toe Plate Attachment (PTA00050)       | 8. Wire Pliers (RR3034)                         |
| 4. Drill Guide Cartridge (PTA00070)      | 9. Resection Guides (PTA00092 through PTA00096) |
| 5. Reamer Stabilizer Guide (PTA00060)    | 10. PROPHECY® INBONE® Instrument Case (PTA0100) |

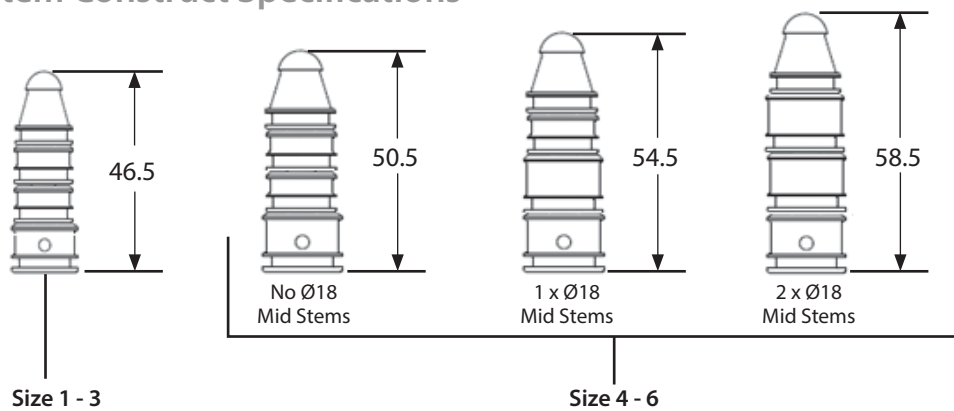
# Stem Specifications

## Stem Component Specifications

Units = mm

IMPLANT	OPTIONS	
 <p>Top Stem (Diameter)</p>		
 <p>Mid Stem (Diameter)</p>		
 <p>Base Stem (Diameter)</p>		<p>Exclusive Fit Size #2, #3 - 16mm only Size #4, #5, #6 - 18mm only</p>
 <p>Talar Stem (Diameter)</p>		

## Tibial Stem Construct Specifications

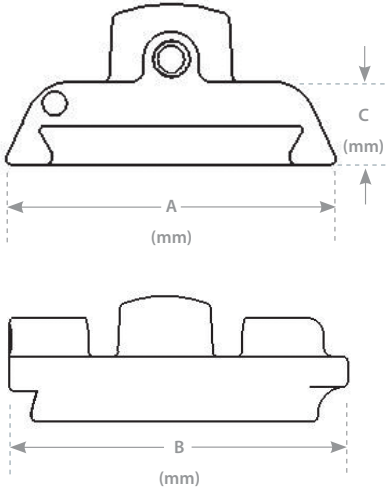




# Implant Specifications

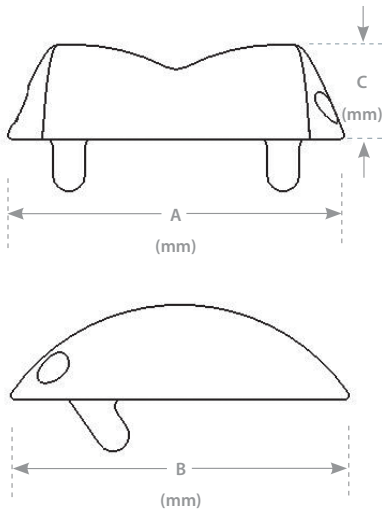
## INBONE® Tibial Component

Size	A	B	C
2	26	32	7
2 Long	26	36	7
3	28	36	7.5
3 Long	28	39	7.5
4	31	39	8
4 Long	31	42	8
5	34	42	9
5 Long	34	46	9
6	37	46	10



## INBONE® Sulcus Talar Component

Size	A	B	C
1	30	32	10
2	33	34	10
3	36	36	10
4	39	39	11
5	42	42	12



# Ordering Information



## Tibial Stems Plasma Coated

Catalog #	Description
200011901	Top Stem, 14mm, Plasma Coated
200011902	Top Stem, 16mm, Plasma Coated
200011904	Top Stem, 12mm, Plasma Coated
200010901	Mid Stem, 14mm, Plasma Coated
200010902	Mid Stem, 16mm, Plasma Coated
200010903	Mid Stem, 18mm, Plasma Coated
200010904	Mid Stem, 12mm, Plasma Coated
200009901	Base Stem, 16mm, Plasma Coated
200009902	Base Stem, 18mm, Plasma Coated

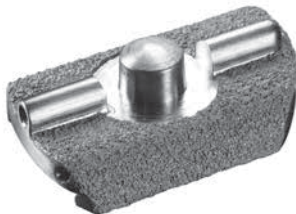
## Tibial Stems Smooth Coated

Catalog #	Description
200012904	Top Stem, 12mm, Smooth
200012901	Top Stem, 14mm, Smooth
200012902	Top Stem, 16mm, Smooth
200014904	Mid Stem, 12mm, Smooth
200014901	Mid Stem, 14mm, Smooth
200014902	Mid Stem, 16mm, Smooth
200014903	Mid Stem, 18mm, Smooth



## Standard Tibial Trays

Catalog #	Description
200252902	Size #2, Left
200252903	Size #3, Left
200252904	Size #4, Left
200252905	Size #5, Left
200252906	Size #6, Left
200222902	Size #2, Right
200222903	Size #3, Right
200222904	Size #4, Right
200222905	Size #5, Right
200222906	Size #6, Right



## Long Tibial Trays

Catalog #	Description
220252902	Size #2 Long, Left
220252903	Size #3 Long, Left
220252904	Size #4 Long, Left
220252905	Size #5 Long, Left
220222902	Size #2 Long, Right
220222903	Size #3 Long, Right
220222904	Size #4 Long, Right
220222905	Size #5 Long, Right



### Sulcus Talar Dome

Catalog #	Description
220220902	Size #2, Right & Left
220220903	Size #3, Right & Left
220220904	Size #4, Right & Left
220220905	Size #5, Right & Left

### Talar Stem

Catalog #	Description
200347901	10mm Long
200347902	14mm Long

### Sulcus Poly Insert

Catalog #	Description
220222106E	Size #1+, 6mm Thick, Right & Left
220222108E	Size #1+, 8mm Thick, Right & Left
220222206E	Size #2, 6mm Thick, Right & Left
220222208E	Size #2, 8mm Thick, Right & Left
220222210E	Size #2, 10mm Thick, Right & Left
220222212E	Size #2, 12mm Thick, Right & Left
220223308E	Size #3, 8mm Thick, Right & Left
220223310E	Size #3, 10mm Thick, Right & Left
220223312E	Size #3, 12mm Thick, Right & Left
220223314E	Size #3, 14mm Thick, Right & Left
220224409E	Size #4, 9mm Thick, Right & Left
220224411E	Size #4, 11mm Thick, Right & Left
220224413E	Size #4, 13mm Thick, Right & Left
220224415E	Size #4, 15mm Thick, Right & Left
220225509E	Size #5, 9mm Thick, Right & Left
220225511E	Size #5, 11mm Thick, Right & Left
220225513E	Size #5, 13mm Thick, Right & Left
220225515E	Size #5, 15mm Thick, Right & Left



### Sulcus Plus-Size Poly Insert

Catalog #	Description
220223208E	Size #2 Plus, 8mm Thick, Right & Left
220223210E	Size #2 Plus, 10mm Thick, Right & Left
220223212E	Size #2 Plus, 12mm Thick, Right & Left
220223214E	Size #2 Plus, 14mm Thick, Right & Left
220224310E	Size #3 Plus, 10mm Thick, Right & Left
220224312E	Size #3 Plus, 12mm Thick, Right & Left
220224314E	Size #3 Plus, 14mm Thick, Right & Left
220224316E	Size #3 Plus, 16mm Thick, Right & Left
220225410E	Size #4 Plus, 10mm Thick, Right & Left
220225412E	Size #4 Plus, 12mm Thick, Right & Left
220225414E	Size #4 Plus, 14mm Thick, Right & Left
220225416E	Size #4 Plus, 16mm Thick, Right & Left
220226510E	Size #5 Plus, 10mm Thick, Right & Left
220226512E	Size #5 Plus, 12mm Thick, Right & Left
220226514E	Size #5 Plus, 14mm Thick, Right & Left
220226516E	Size #5 Plus, 16mm Thick, Right & Left



### Accessories

Catalog #	Description
200178002	Drill, Size 2 Anti-Rotation Notch
200178003	Drill, Size 3 Anti-Rotation Notch
200178004	Drill, Size 4 Anti-Rotation Notch
200178005	Drill, Size 5 Anti-Rotation Notch
200178006	Drill, Size 6 Anti-Rotation Notch
200134	Drill, 6mm
200072	2.4mm Steinmann Pin
500036	1.4mm K-Wire
200138001	Saw Blade Stryker Narrow
200138002	Saw Blade Stryker Wide
200138003	Saw Blade Hall/Linvatec Narrow
200138004	Saw Blade Hall/Linvatec Wide
200138105S	Saw Blade Stryker System 6 Narrow
200138106S	Saw Blade Stryker System 6 Wide
IB200051	Bone Removal Screw



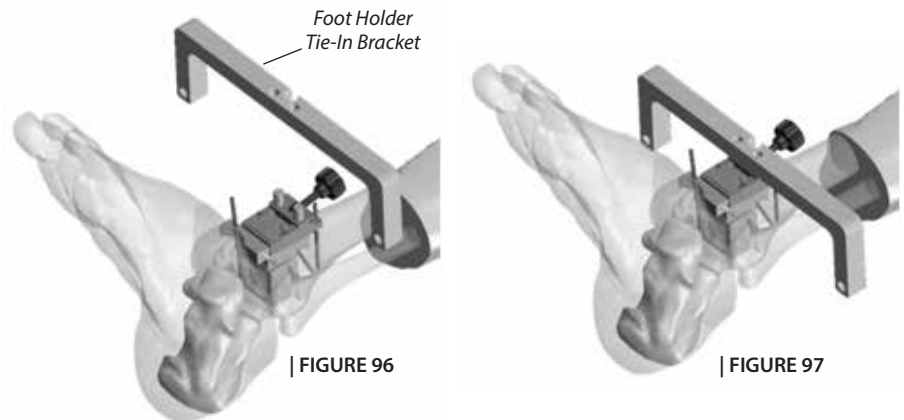
### Large Revision Polys

Catalog #	Description
220222114E	INBONE® Poly SZ 1+ 14mm Sulcus Total Ankle
220222116E	INBONE® Poly SZ 1+ 16mm Sulcus Total Ankle
220222214E	INBONE® Poly SZ 2 14mm Sulcus Total Ankle
220222216E	INBONE® Poly SZ 2 16mm Sulcus Total Ankle
220223216E	INBONE® Poly SZ 2+ 16mm Sulcus Total Ankle
220223218E	INBONE® Poly SZ 2+ 18mm Sulcus Total Ankle
220223316E	INBONE® Poly SZ 3 16mm Sulcus Total Ankle
220223318E	INBONE® Poly SZ 3 18mm Sulcus Total Ankle
220224318E	INBONE® Poly SZ 3+ 18mm Sulcus Total Ankle
220224320E	INBONE® Poly SZ 3+ 20mm Sulcus Total Ankle
220224417E	INBONE® Poly SZ 4 17mm Sulcus Total Ankle
220224419E	INBONE® Poly SZ 4 19mm Sulcus Total Ankle
220225418E	INBONE® Poly SZ 4+ 18mm Sulcus Total Ankle
220225420E	INBONE® Poly SZ 4+ 20mm Sulcus Total Ankle
220225517E	INBONE® Poly SZ 5 17mm Sulcus Total Ankle
220225519E	INBONE® Poly SZ 5 19mm Sulcus Total Ankle
220226518E	INBONE® Poly SZ 5+ 18mm Sulcus Total Ankle
220226520E	INBONE® Poly SZ 5+ 20mm Sulcus Total Ankle

# PROPHECY® Tie-In to the INBONE® Foot Holder Surgical Procedure

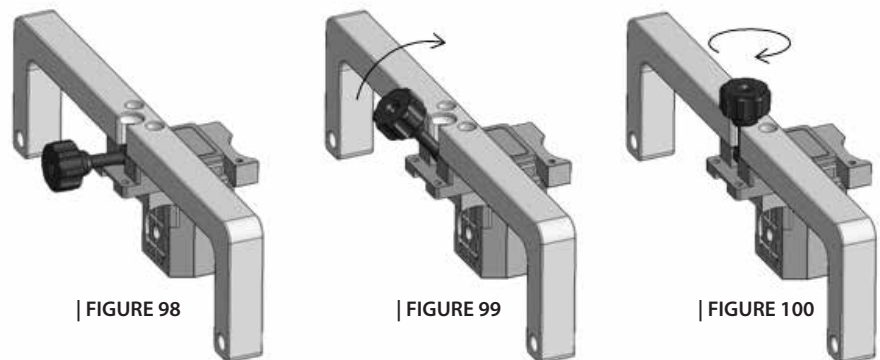
The following steps must occur after the Tibia Stem Guide assembly is secured in the resected joint space.

Attach the Foot Holder Tie-In Bracket (PTA00080) to the Anterior Mounting Plate.  
| FIGURES 96 and 97



Lower the Foot Holder Tie-In Bracket assembly down over the Anterior Mounting Plate and attach through the two protruding dowel pins. The surface of the Foot Holder Tie-In Bracket arm must sit flat against the Anterior Mounting Plate. | FIGURE 98

Secure the Foot Holder Tie-In Bracket to the Anterior Mounting Plate by rotating the swivel rod up and over the Foot Holder Tie-In Bracket arm and tightening the screw on the end of the swivel rod. | FIGURES 99 and 100



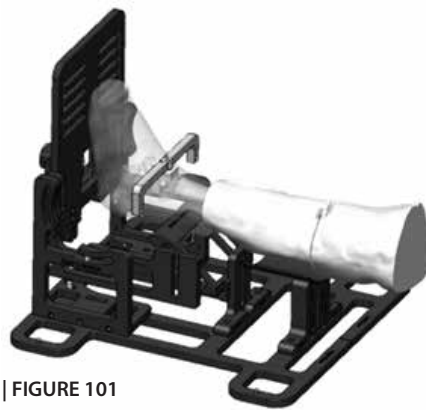
Place the foot in the INBONE® Foot Holder. (The foot holder must be set to zero/neutral location for all adjustment directions.) | **FIGURE 101**

Place the M/L Guide Rods through the INBONE® foot holder and through the matching holes in the Tie-In Bracket. (Adjust the location of the entire foot holder and the foot until the holes are aligned. Adjust the Achilles and Calf supports to align the foot to the ML alignment rods in the AP direction.) | **FIGURE 102**

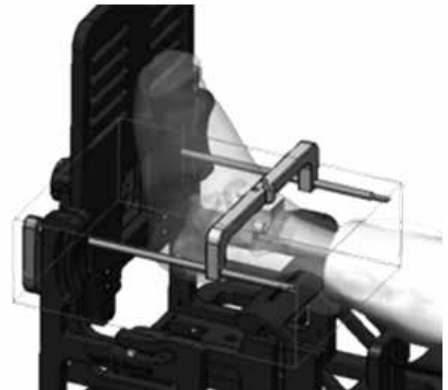
Slide the foot down until it hits the foot plate. Do not secure the foot/leg to the foot holder at this time. Follow the standard procedure for marking and starting the distal incision.

Use the AP and ML alignment rods with fluoroscopy to confirm the alignment in the foot holder. Secure the foot/leg to the foot holder with coban and k-wires into the calcaneus. Remove the M/L Guide Rods, the Tie-In Bracket, and the Tibia Stem Guide assembly.

Complete the procedure following the standard INBONE® surgical technique (FA553-712) for alignment (if necessary), drilling, reaming, and implantation.



| FIGURE 101



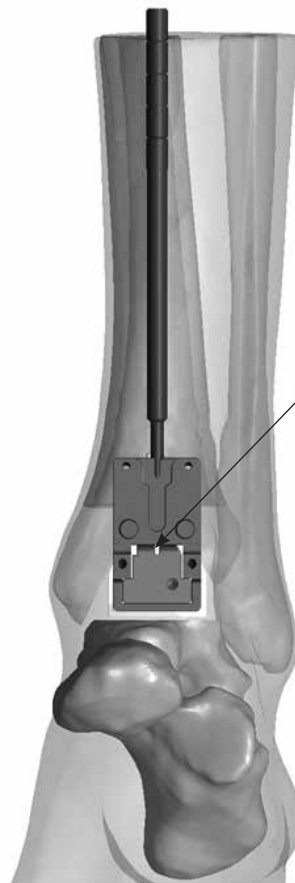
| FIGURE 102



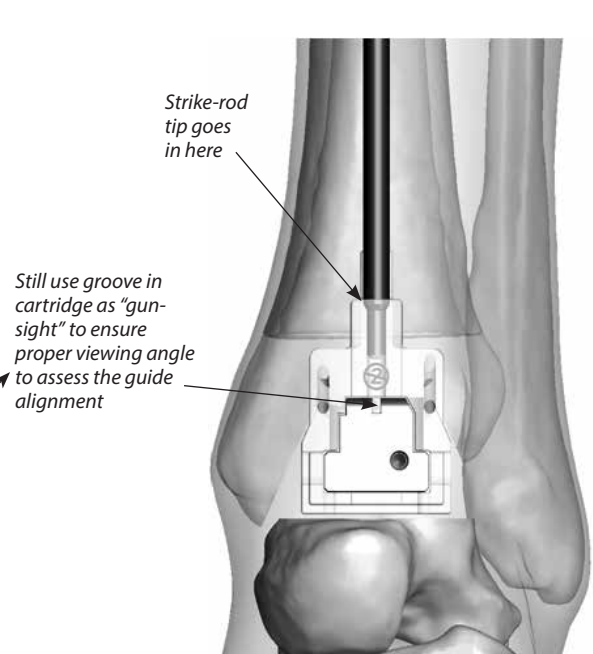
INBONE® Foot Holder

# Intraoperative Tibia Stem Guide Fluoroscopic Check Assembly

The M4 Holding Tool (purple) | **FIGURE 103** or the Strike Rod | **FIGURE 104** can be used in the proximal hole of the tibia stem alignment guide as an extramedullary alignment rod, or as a fluoro check indicator. The M4 tool is shorter, whereas the Strike Rod may interfere with the proximal tibia tubercle. Compare the intraop fluoro image to the image of the tibia stem guide in the patient's pre-op alignment report."



| **FIGURE 103**

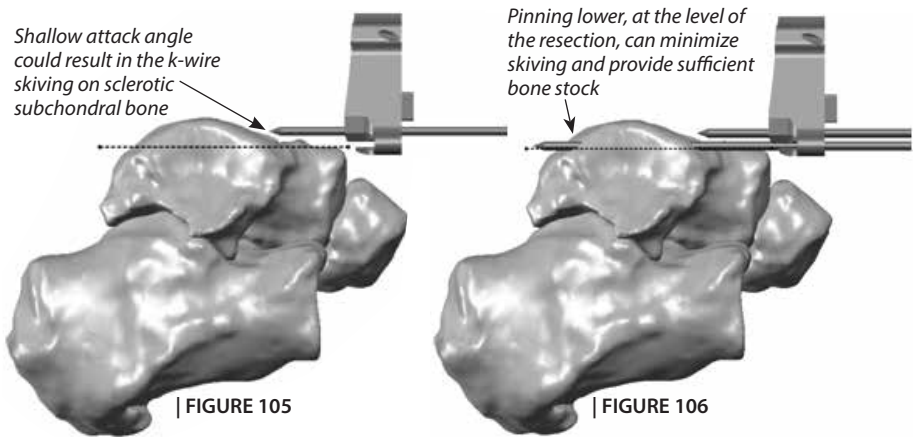


| **FIGURE 104**

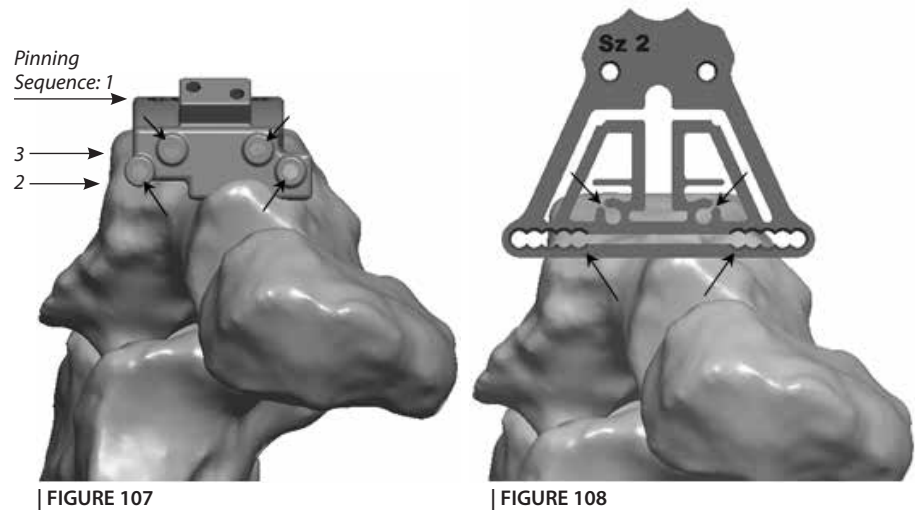


# Additional Holes in Talus Alignment Guide

In some cases, the PROPHECY® engineering team may provide additional holes in the talus alignment guide that correspond to the narrowest “gutter” pin holes of the resection block. These may be used in some cases to provide additional stability and reduce the risk of skiving. | FIGURES 105 and 106 In this situation, it will not be possible to complete the talus resection all the way to the medial and lateral gutters. A clean-up resection will likely be necessary to complete the resection.



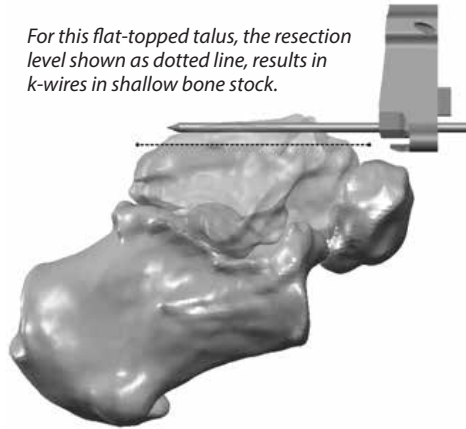
Order of pinning the talus guide: It is recommended that after pinning through one of the top, angled anti-skiving holes, place the lowest pins next which are less likely to skive, before placing k-wires through the mid-level holes. | FIGURES 107 and 108



For severely flat-topped taluses or other conditions in which insufficient bone stock for pinning exists, holes may be provided in the talus alignment guide for the size 6 cut block in an upside-down orientation. This allows us to place pins below the level of the resection in order to get sufficient bone fixation.

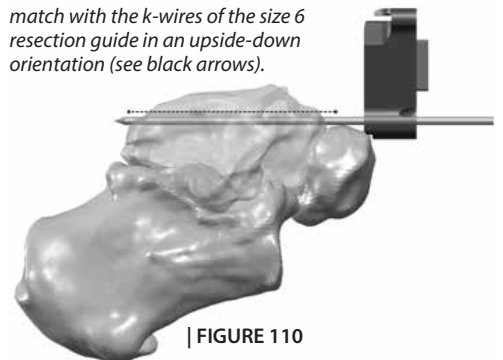
When pinning above the resection could result in k-wire skiving or insufficient fixation in thin bone stock as shown in **FIGURE 109**, the alternative talus alignment guide design may be implemented by the case processing engineers, as depicted in **FIGURES 110, 111 and 112**.

*For this flat-topped talus, the resection level shown as dotted line, results in k-wires in shallow bone stock.*



| **FIGURE 109**

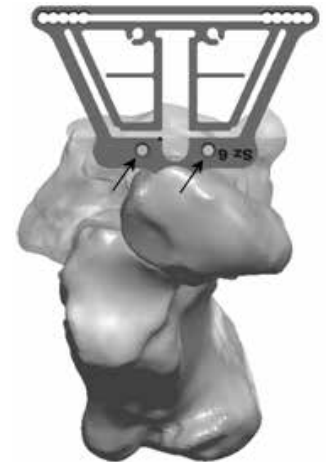
*As an alternative, the talus alignment guide may be designed to place k-wires below the resection level which match with the k-wires of the size 6 resection guide in an upside-down orientation (see black arrows).*



| **FIGURE 110**



| **FIGURE 111**

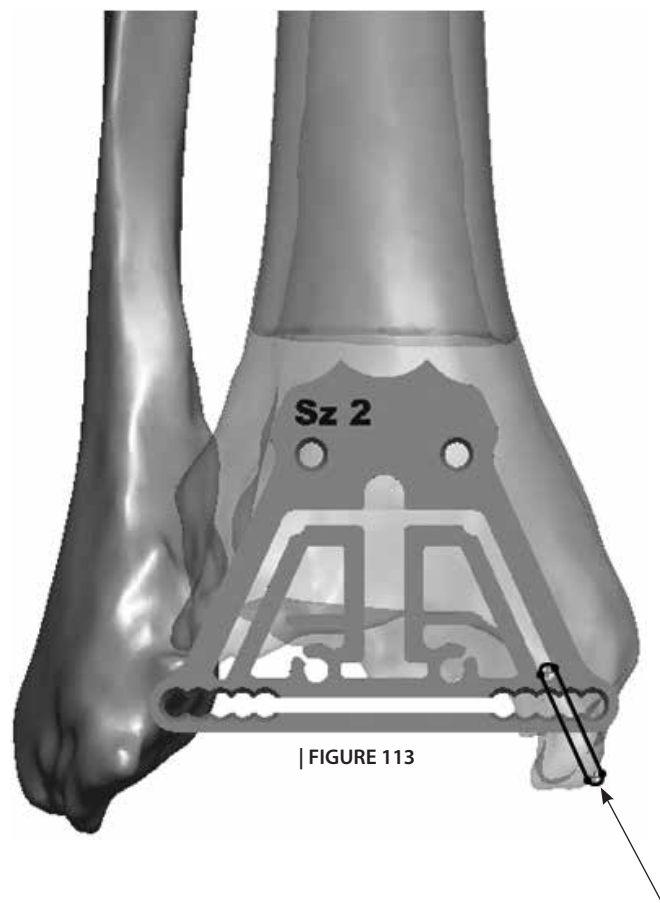


| **FIGURE 112**

## Tips & Tricks

### Complete the Medial Mal Resection

Complete the resection of the medial malleolus distal to the extent of the resection slot using a reciprocating saw to separate the resected tibia bone from the remaining tibia. Failure to do so may increase the risk of medial mal fracture during the resected bone removal stage. | **FIGURE 113**





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