stryker

Prophecy® Invision®
Preoperative Navigation Guides

Operative technique

Prophecy Invision
Preoperative Navigations Guides

This publication sets forth detailed recommended procedures for using Stryker devices and instruments. It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required.

Important

- The patient should be advised that the device cannot and does not replicate a normal healthy bone, that the device can break or become damaged as a result of strenuous activity or trauma and that the device has a finite expected service life.
- Removal or revision of the device may be required sometime in the future.
- Cleaning and sterilization information is provided in the applicable instructions for use.
- Non-sterile devices, including implants and instruments, must be cleaned and sterilized prior to use, in accordance with validated methods.
- Devices that are able to be disassembled should be disassembled prior to point-of-use processing. Additionally, devices with movable components that do not facilitate disassembly should be manually articulated during the point-of-use processing step in order to evacuate additional soils.
- Please remember that the compatibility of different product systems has not been tested unless specified otherwise in the product labeling.
- Consult Instructions for Use (https://ifu.stryker.com) for a complete list of potential adverse effects and adverse events, contraindications, warnings and precautions.
- The surgeon must advise patients of surgical risks, and make them aware of adverse effects and alternative treatments.

An implant whose packaging is open or damaged or whose expiration date has passed must not be used. Every precaution must be taken to ensure sterility when opening the packaging of the implant and during implantation.

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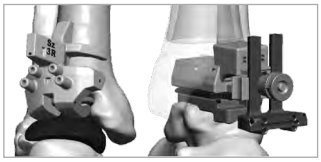
Acknowledgments:
Surgeon design team – Robert B. Anderson, MD (Green Bay, WI), Gregory C. Berlet, MD (Columbus, OH), W. Hodges Davis, MD (Charlotte, NC), Steven L. Haddad, MD (Chicago, IL), William McGarvey, MD FRCSC (Houston, TX), Murray J. Penner, MD FRCSC (Vancouver, BC)

Product information

Prophecy Invision alignment guide product information



The patient specific guides 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 patient specific guides are supplied clean and non-sterile, and must be sterilized before use. After use, these instruments must be disposed of properly. Please refer to the Prophecy Invision instrument package insert for instructions on the proper steps for processing disposable surgical instruments.

Intended use

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

Prophecy® Surgical Planning is intended to be used as patient specific surgical instrumentation to assist in the positioning of total ankle replacement components intraoperatively, in guiding the marking of bone before cutting, and in the pre-surgical planning of the ankle and surrounding anatomy to support the total ankle implant. The Prophecy Surgical Planning Guides and Reports are intended for use with the Inbone®, Infinity® and Invision® 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 (e.g. CT scans and X-rays). The Prophecy® Surgical Planning Guides are intended for single use only.

Invision and Inbone Total Ankle product information

The Invision Total Ankle Revision System is the next step in total ankle arthroplasty. This system retains the design principles of the Inbone Total Ankle System while introducing specific design enhancements utilized for previous failed total ankle replacement surgery.

The Invision Total Ankle Revision System utilizes Inbone tibial stems for proximal fixation. A minimum of two and a maximum of eight stems are cleared for use. These implants are provided sterile.

The Invision Total Ankle Revision System offers universal tibial trays; with four sizes (2-5), two lengths (standard and long), and two thicknesses (+4mm and +8mm). The tibial trays are manufactured from titanium (Ti) alloy and utilize a similar trapezoidal profile as the Inbone tibial trays. On the superior surface a morse taper identical to Inbone is utilized for compatibility with the Inbone tibial stems. The AP lengths of the Invision tibial trays have been optimized to match the resected anatomy. The lock detail of the Invision tibial trays is identical to Inbone and the proximal surface is coated. These implants are provided sterile.

The standard, revision and large revision Inbone tibial inserts are available for use with the Invision Total Ankle Revision System. The polyethylene inserts are manufactured from ultra height weight polyethylene (UHMWPE) and are provided sterile.

The Invision talar dome is available in five sizes (1-5), each with a standard and +3mm thickness option with a symmetric design that allows it to be used in both right and left ankles. It is manufactured from cobalt-chrome (CoCr) and possesses the same sulcus articulating geometry as the Inbone talar dome. On the inferior surface a central morse taper hole allows for coupling with the Invision talar plate implant. The same size talar dome or one size smaller can be used with the talar plate. The anterior-medial surface includes the morse taper release hole. The Invision talar domes are provided sterile.

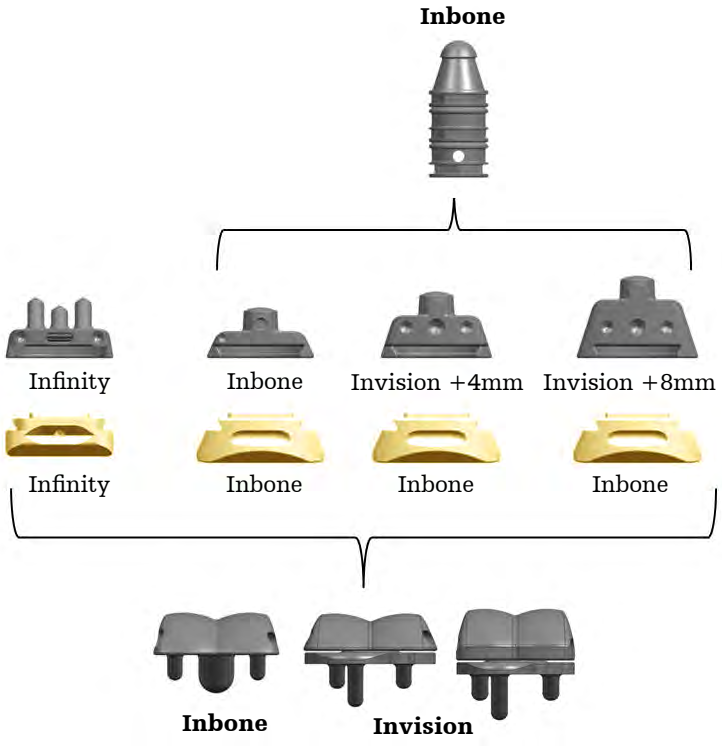
Five asymmetric talar plate implants, sizes 1-5, are included in the Invision Total Ankle Revision System. The implant profile was designed to maximize cortical coverage of the talus with fixation supported with three pegs on the distal surface. Manufactured from titanium alloy, the talar plates include a male morse taper which allow connection of Talar dome to plate. The inferior surface is coated on the distal surface. These implants are provided in standard and long lengths, and provided sterile.

Your final construct may utilize the same size talar dome as your tibial tray or one size smaller by switching to included "+" polys. Your talar plate may be the same size as your dome or one size larger to ensure the best coverage of talus.

Caution: Using a talar plate that is smaller than the chosen talar dome may result in torsional morse taper release.

Implant interchangeability

The Invision Total Ankle Revision System includes an array of options for each patient – modular tibial stems, six thicknesses of polyethylene inserts as well as multiple thicknesses and lengths for tibial trays. The Invision Total Ankle Revision System is interchangeable with the Inbone II talar dome and tibial components as well as Infinity tibial components.



Intended use

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

Caution: In the United States, the ankle prosthesis is intended for cement use only.

Contraindications

- Osteomyelitis
- Insufficient bone stock or bone quality
- Infection at the ankle site or infections at distant sites that could migrate to the ankle
- Sepsis
- Vascular deficiency in the ankle joint
- Skeletally immature patients (patient is less than 21 years of age at the time of surgery)
- Cases where there is inadequate neuromuscular status (e.g., prior paralysis, fusion and/or inadequate abductor strength), poor skin coverage around the joint which would make the procedure unjustifiable
- Neuropathic joints
- Excessive loads as caused by activity or patient weight
- Patient pregnancy
- Severely compromised musculature or neuromuscular function.
- Uncooperative patient or patient with neurologic disorders, incapable of following instructions

Warning: This device is not intended for subtalar or talonavicular joint fusion or impingement. Please carefully evaluate the anatomy of each patient before implantation. High levels of activity may increase the risk of adverse events. Surgeons should carefully consider the advisability of ankle replacement in patients with metabolic disorders or pharmacological treatments that impair bone formation or with conditions that may impede would healing (e.g., end stage diabetes or malnutrition).

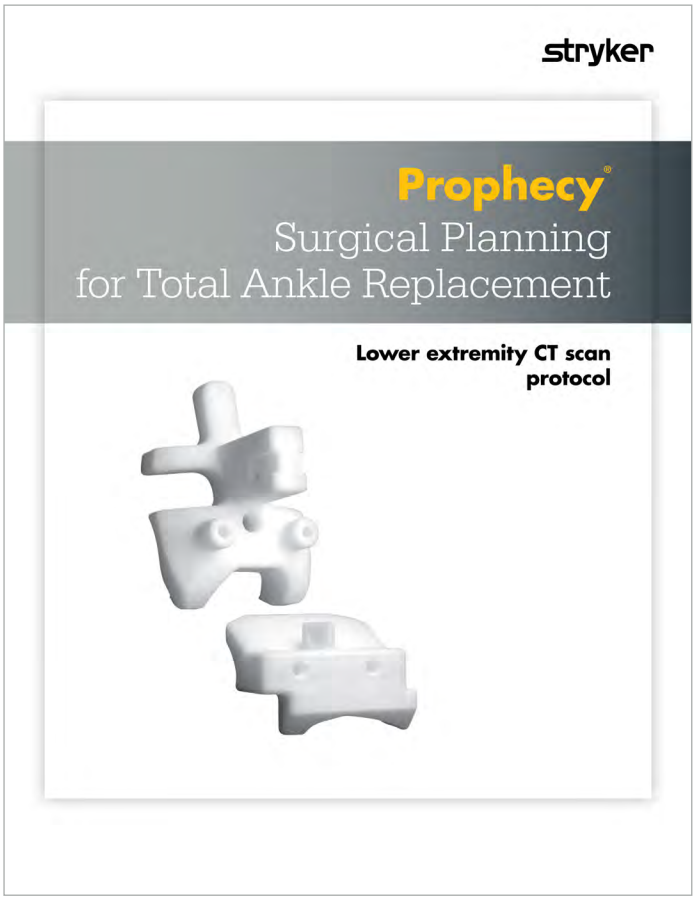
Prior to use of the system, the surgeon should refer to the product package insert for complete warnings, precautions, indications, contraindications and adverse effects. Package inserts are also available by contacting the manufacturer.

Contact information can be found on the back of this surgical technique and the package insert is available on the website listed.

CT scan protocol

Prophecy Preoperative Navigation Guides are patient-specific instruments designed for total ankle replacement surgery. Failure to adhere to Prophecy CT scan protocol may lead to denial of case. Engineers have determined the necessary scanning parameters, which are described in the Prophecy Surgical Planning for Total Ankle Replacement | Lower extremity CT scan protocol #AP-016564.

In every case, please have the scanning facility follow the specific instructions outlined in this document.



Prophecy
Surgical Planning for Total Ankle Replacement
Lower extremity CT scan protocol
#AP-016564

Operative technique

Note: If performing a talus-only or talus-first revision, please refer to the talus only revision section.

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 Prophecy tibia alignment guide and tibia spacer guide (PROPINV). Using the pin cutter (200427) and a needle driver, cut two ½" (~12mm) segments of a 2.4mm Steinmann pin (200072).

Press-fit the two ½" segments into the holes in the base of the Prophecy tibia alignment guide. Insert the remainder of the cut 2.4mm Steinmann pin in the handle of the Prophecy tibia alignment guide. **(Figure 1)**

Caution: To be assembled in the sterile field.

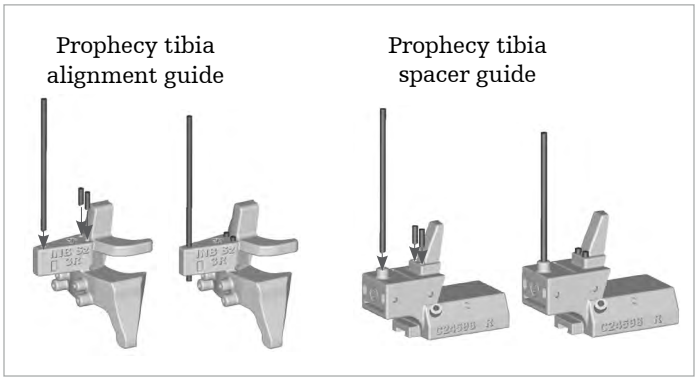


Figure 1

Alignment and resections

Make the anterior incision centered on the ankle, directly lateral to the palpable tibialis anterior tendon and medial to the extensor hallucis longus tendon. Define and avoid the deep peroneal nerve and anterior tibial artery. Once the nerve bundle is mobilized the anterior ankle (distal tibia and talus) is exposed with the dorsal talonavicular joint representing the distal extent of the incision. This incision can be modified according to the specific needs of the patient.

Tibia alignment guide

Prophecy Invision alignment guides are designed to incorporate fixed osteophytes on or near the articulating surfaces, and therefore osteophytes should not be removed during the surgical exposure of the ankle. However any loose bodies, specifically called out on the Prophecy pre-operative plan, should be removed as they will not have been incorporated into the proper seating of the Prophecy Invision guides.

Prophecy tibia alignment guide (PROPINV)

Pin cutter (200427)

2.4 Steinmann pin (200072)

Note: Use the provided anatomical models as an additional tactile and visual confirmation that the tibia guide is positioned correctly on the patient's anatomy.

Existing implants including prior TAR devices and cement spacers

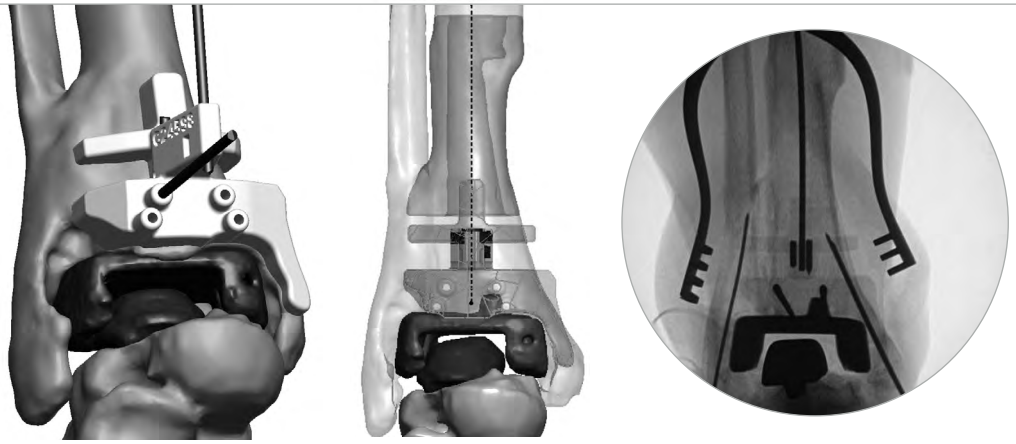
Unless otherwise stated on the report, it is best to leave existing implants or cement spacers intact when placing the tibia alignment guide.

Ensure the area of the anterior tibia where the Prophecy guide will surface match is completely free of soft tissue and place the Prophecy tibia alignment guide (PROPINV) in the best fit location. 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.

The Prophecy patient-specific tibial guide contains holes oriented vertically to hold 2.4mm K-wires to be used to check the alignment fluoroscopically. This K-wire is designed to match the dotted line contained in the provided preoperative report (labelled as "anterior view" in the Prophecy Invision preoperative plan). **(Figure 2)**

Once the guide is in the proper location insert one 2.4 Steinmann pin into one of the proximal holes of the tibia guide to temporarily hold it into position.



Tibia alignment guide

Figure 2

Once the desired fit and alignment is confirmed, place 2.4mm Steinmann pins through the guide and through both corticies of the tibia where possible. Some pin holes may be blocked by existing implants. Place the pins through those holes into the anterior cortex up to, but not contacting, any implants. If pins need to be removed it may be helpful to mark the holes in the bone so they can be found again.

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.

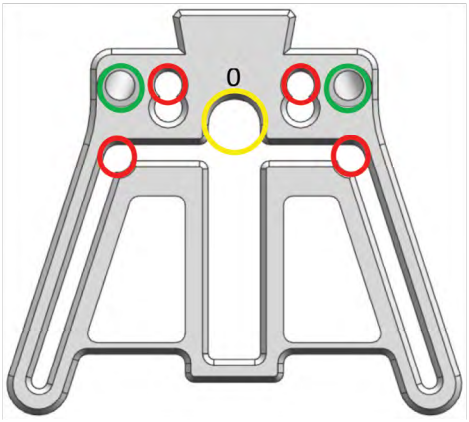
After any existing implants are removed, the tibia alignment guide can be placed over the K-wires again to advance all pins through the posterior cortex.

Once pins are placed in the tibia, the patient-specific guide is removed and the tibial resection guide is placed (PINV2000 - PINV5000 for Invision, PTA00092 - 96 for Inbone) over the pins in the corresponding holes. Typically this means the proximal corners of the tibia resection slots and the "0" proximal holes (circled in red). Refer to the pre-operative plan for any details related to K-wire placement. **(Figure 3)**

There are two holes directly distal, and intersecting with, to the "0" holes. The centers of the holes are 2 mm more distal than the "0" holes. They can be used to easily adjust the tibia resection 2mm more proximal over the pins placed through the Prophecy tibia alignment guide. These can be utilized if the tibia resection is found to be too distal intraoperatively, possibly due to bone that was removed when the prior implants were removed.

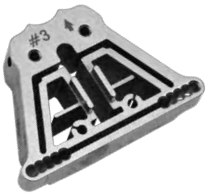
In rare cases, the Prophecy report will require the use of the Prophecy Infinity conversion instrument (33600200) for additional stability. Use of the conversion instrument also requires the 3.5mm hex driver (E5001005).

Note: Changing the tibia resection location or the type of guide to a different implant type is likely to prevent the tibia stem alignment guide from fitting on either the resected tibia, or the anterior tibial cortices.



Tibia resection guide

Figure 3



Tibial resection guide
(PTA00092 - 96)

PINV2000-5000

Prophecy Infinity
conversion instrument
(33600200)

The surgeon has the option to fluoroscopically verify the size and orientation of the tibial resection guide prior to making the tibial resection. To minimize parallax the C-arm should be adjusted until the surgeon can see through each cut slot. Refer to the Prophecy preoperative report for verification of the resection.

Note: At this point the surgeon can choose to revert back to the standard Invision instrumentation and surgical technique if there are any concerns with the planned resection. Refer to the Invision surgical technique for detailed instructions.

The surgeon may also choose to obtain a fluoroscopic lateral view of the ankle perpendicular to the installed resection guide.

Typically, a pin is placed in one of the off-axis holes of the tibia resection guide (highlighted in green in Figure 3 on the previous page) to provide additional stability for the resection guide. To avoid pinning into the posterior medial neurovascular bundle either utilize the medial converging pin or avoid pinning past the posterior cortex.

Using the pin cutter, trim the pins flush to the surface of the resection guide. Leave enough length on the divergent pin to allow its removal with a pin driver or pin puller but short enough to allow for ease of resection with the saw.

Install the anti-rotation notch insert (200290002 – 200290006) into the resection guide. Using the appropriately sized anti-rotation notch drill (200178002 – 200178006) drill the tibia for the anti-rotation notch. **(Highlighted in yellow in Figure 3 on the previous page)** Be sure to drill bi-cortical.

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. Do not make the talar cut at this time.

The resection guide, off-axis pin(s), and corner pins are removed from the bone. The proximal parallel pins (for example, those occupying the "0" holes) can be left in place.

Ensure all bone is removed from the intended resections and the surfaces are clear.

Caution: In some instances, the resection of the distal medial malleolus must be completed outside the resection guide due to the dimensional restrictions of the guide. Failure to do so may increase the risk of medial malleolus fracture during the bone removal stage.

Joint space balancing

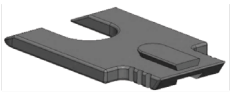
Refer to the patient specific report to determine what pre-existing hardware needs to be removed from the joint space. In order to re-create the preoperatively planned deformity correction, patient-specific spacers (PROPINV) are provided. One spacer interacts with the tibia and the second spacer is referenced to the talus. These spacers fill the joint space between the tibia and talus in order to allow the talus to be positioned relative to the tibia.

The talar spacer will be provided but is optional if the correction of the talus is minimal. In this instance you may utilize the spacer shims to provide necessary correction. If the joint space has laxity, you may use the talus spacer in conjunction with the spacer shims to stabilize the joint space and achieve correction of the talus.

3.5mm Hex driver
(E5001005)

Tibial spacer
PROPINV

Anti-rotation notch insert
(200290002 - 200290006)



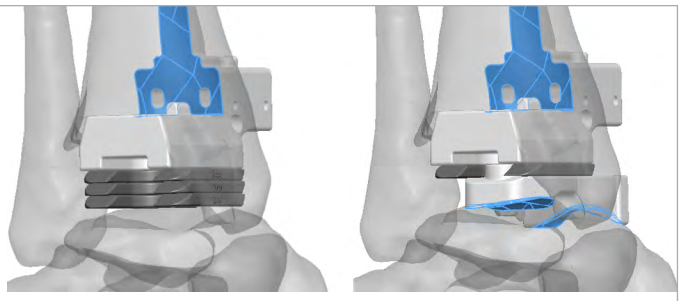
Spacer shim
PINV0064

Anti-rotation notch drill
(200178002 - 200178006)

Talus spacer
PROPINV

The guides help set the varus/valgus and flexion/extension relationship between the tibia and talus intraoperatively. The resection depth for the talus is set manually with the procedure. **(Figure 4)**

The patient-specific talus spacer is placed into the space. **(Figure 5)** A pin may be placed through the talus spacer into the talus for stability. The patient-specific tibia spacer is inserted into the joint. This can be inserted either over the remaining parallel proximal tibial pins, or interacting with the lock detail of the existing Infinity, Inbone, or Invision tibial tray in the case of a talus only revision. If gross laxity between the tibia and talus is observed, shims (PINV0064) may be added between the tibia and talus spacer to provide stability and drive the angular correction of the deformity as determined preoperatively. Each shim has a thickness of 3mm. The shims interact with other shims and with the tibia spacer dovetail connections. The talus spacer does not interact with the dovetail connection; instead, there is a cylindrical boss protruding from the talus spacer that interacts with the U-shaped feature of either the shims or the tibia spacer, depending upon what is inserted into the space. This cylindrical feature provides some medial-lateral constraint while allowing for internal/external rotational flexibility and some A-P translation.

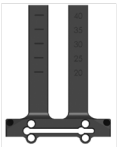


Joint spacing options on the talar side include using the plain reusable shims (PINV0064) or a semi-conforming patient talus spacer (PROPINV).

Figure 4

Talus guide capture
(PINV0074)

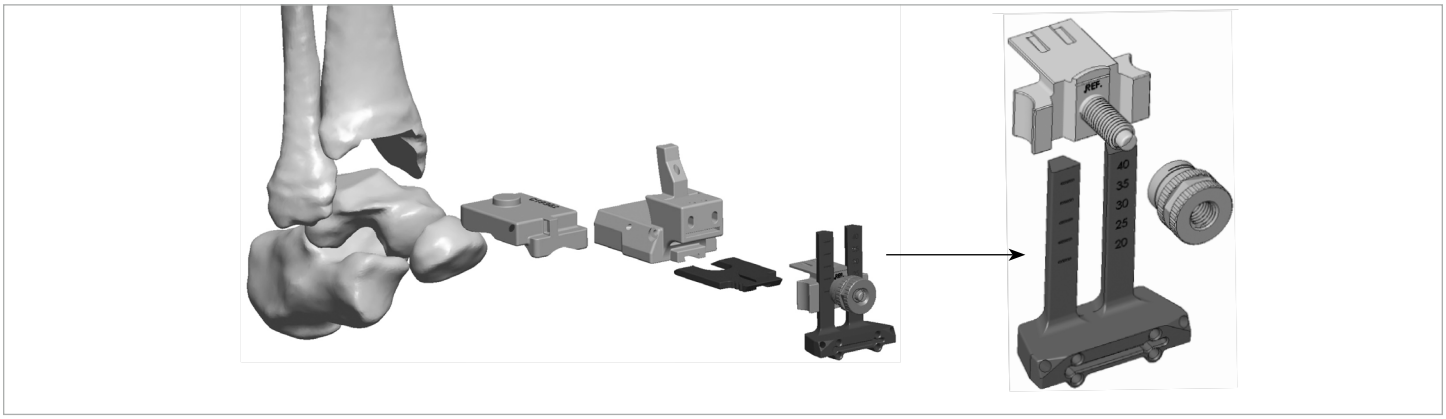
Guide capture knob
(PINV0075)



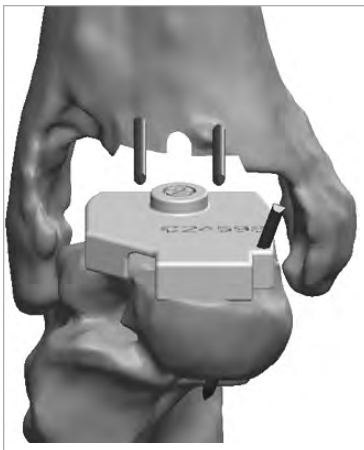
Talus resection guide
(PINV1000)

Talus resection

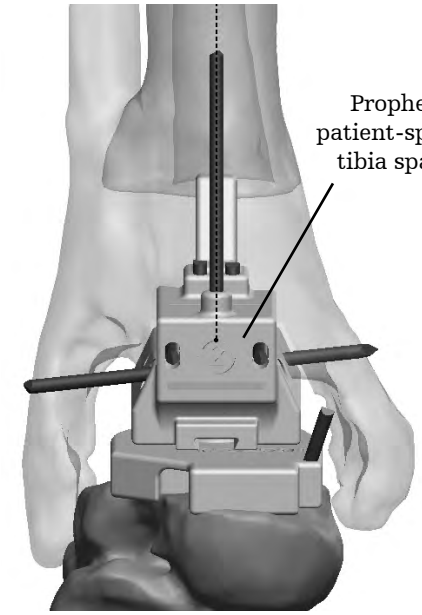
The adjustable talus guide capture (PINV0074) is assembled into the anterior slot of the patient-specific tibia spacer guide (PROPINV) with the guide capture knob (PINV0075) locking the adjustable talus resection guide (PINV1000). **(Figures 5-7)**



Exploded views of spacer guides and adjustable talus resection instruments. **Figure 5**

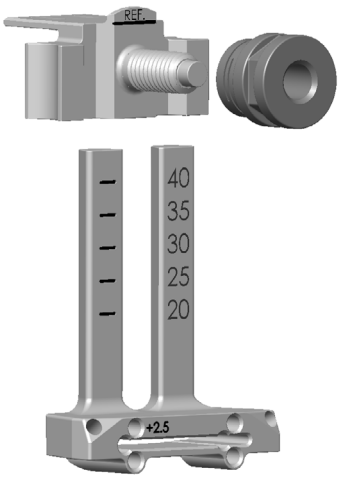


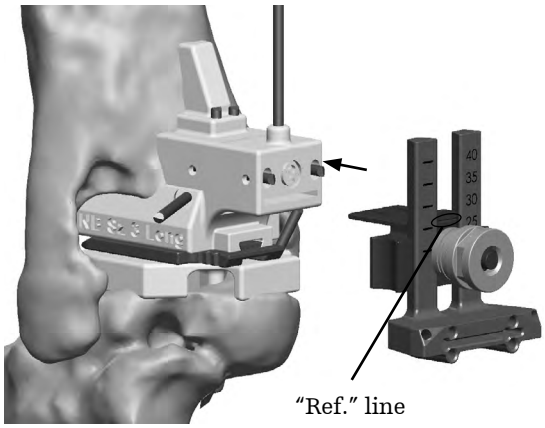
A temporary stabilization hole is provided on an anterior corner of both the tibia and talus spacers. They are angled obliquely posterior.



Insertion of the talus spacer guide and tibia spacer guide

Figure 6





Assembly of the adjustable talus resection guide into the tibia spacer guide. Combining of talus guide capture (PINV0074), guide capture knob (PINV0075), and talus resection guide (PINV1000).

Figure 7

Before pinning, the surgeon should hold the foot at neutral (90°) flexion and neutral hindfoot varus/valgus orientation. The talus resection slot position is adjusted proximal and distal. A lateral fluoro image can facilitate visualization of the resection depth. K-wires or the saw blade may be inserted at the level of the talus resection to visualize the resection and to determine the appropriate resection level intraoperatively. The resection depth and talus orientation is determined by the surgeon and is not set by the Prophecy system. **(Figure 8)**

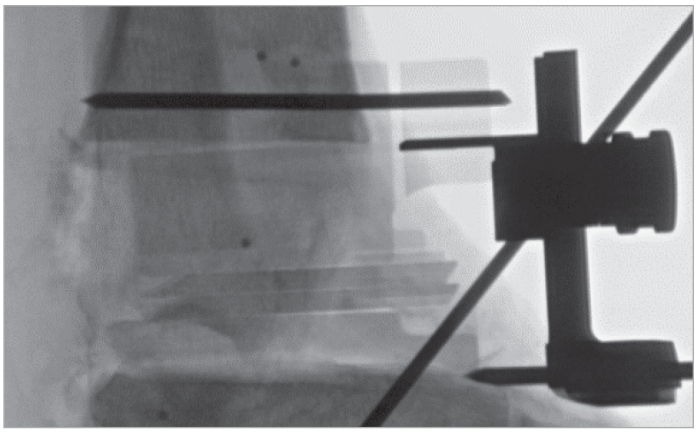


Figure 8

Coronal fluoro-check: a fluoro check of the tibia spacer's coronal alignment can be used. Refer to the report guide pages for the tibia guide and spacer guides; the vertical black dashed lines are identical.

Markings on the talus resection guide (PINV1000) indicate the distance of the talus resection from the tibia resection. There is a small "Ref." line on the talus guide capture (PINV0074) for referencing the resection depth. **(Figure 9)** The surgeon will need to refer to the implant thicknesses in order to consider which thickness of implant may be appropriate for the overall resection height.

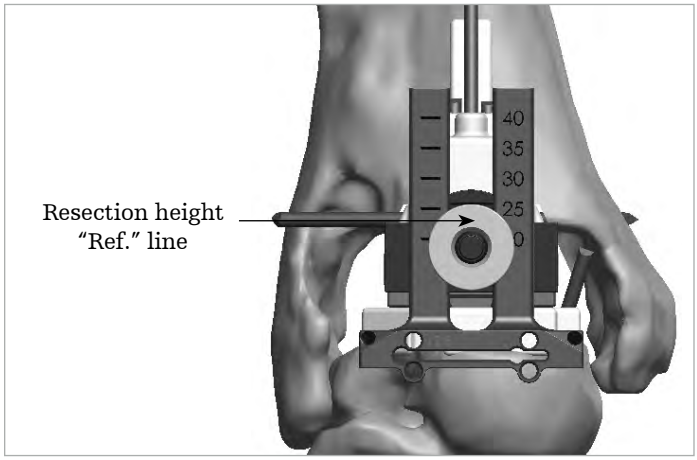


Figure 9

With the talus resection guide at the desired resection level pins are placed through the anterior holes. **(Figure 10)** A pin should be placed in a hole on both the medial and lateral side. Use caution when driving pins through the talus resection guide to avoid pinning into the spacer guides or shims as this could cause damage or make spacer guide removal difficult.

After placing at least two pins the entire construct is removed except the pins from the talus resection guide. The talus resection guide is slid back over the pins by itself. The reason for removing the entire construct is twofold:

1. To prevent resecting into the spacer instruments
2. To allow the talus resection guide to be positioned as close to the talus as possible.

If for any reason the talus resection depth needs to be adjusted there are additional holes in the resection guide that allow adjustment of the resection depth by 2.5mm both proximal and distal to the cut slot. **(Figure 10)**

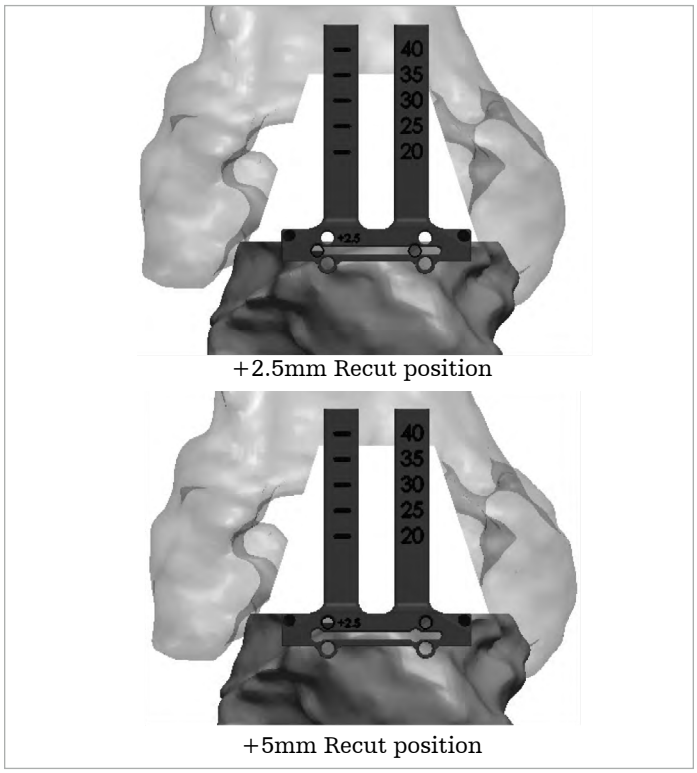


Figure 10

Pins may be placed in both the medial and lateral oblique holes of the talus resection guide. **(Figure 11)** The parallel talus K-wires may be trimmed, or removed, to prevent interference with the saw. The oblique K-wires may be left long enough that they can be removed after completing the talus resection.

The talus is resected, the pins are removed, and the space is cleared of all resected bone down to the level of the flat cut.

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 12)**

Talus resection guide with converging oblique K-wires placed into the talar body.

Figure 11

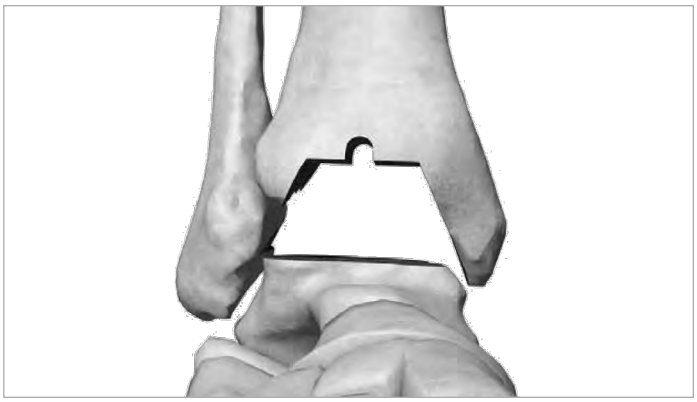
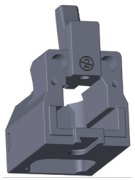


Figure 12

Preparing the tibia canal

Slightly distract the ankle and place the Prophecy tibial-stem alignment guide (PROPINV) into the resected joint space. The guide has surface matching features referencing the anterior surface of the tibia, the distal medial and lateral surfaces of the tibia resection and occasionally the inner surface of the medial malleolus and fibula for additional stability. Shims may be placed in the distal dovetail as necessary to provide stability for the tibia stem guide and talus. **(Figure 13)**

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 14)**



Prophecy tibial stem alignment guide (PROPINV)

Anterior mounting plate (PTA00040)

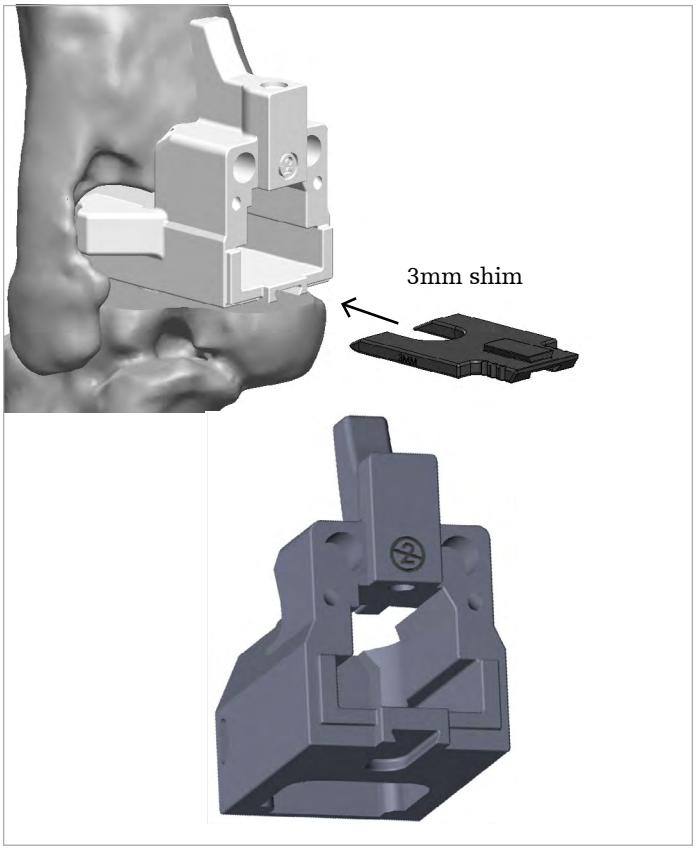


Figure 13

Figure 14

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 15)**

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.

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 16)**

Note: See intraoperative tibia stem guide fluoroscopic check assembly section for an optional AP flouro check.

Drill guide cartridge
(PTA00070)

2.4mm Steinmann pins may be used through the anterior mount plate and stem guide to stabilize the guide to the tibia. If Steinmann pins are used, bend the medial and lateral pins medially and laterally, respectively, in order to provide clearance for the drill guide cartridge to be removed later.

Caution: The surgeon is encouraged to avoid putting K-wires in holes of the anterior mount plate if they will result in weakening the tibia bone. If the Steinmann Pin holes will cause a stress-riser, the guide may be held in place by hand, without adding all K-wires, by a member of the surgical team during the 6mm drilling and tibia canal reaming steps.

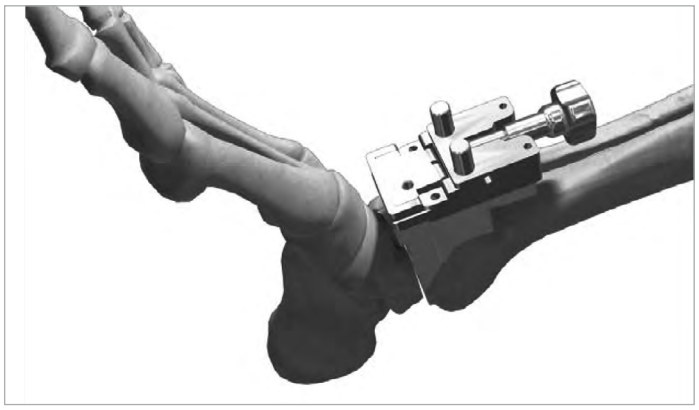


Figure 15

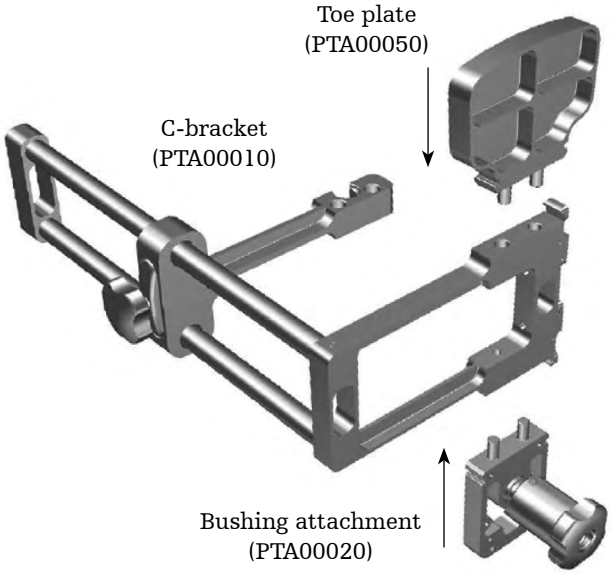
Figure 16

Build the C-bracket assembly

Connect the toe plate (PTA00050) and the bushing attachment (PTA00020) to the C-bracket (PTA00010). **(Figure 17)**

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 18)** 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 in line with the lateral process of the talus. **(Figure 19)**



Assembled C-bracket

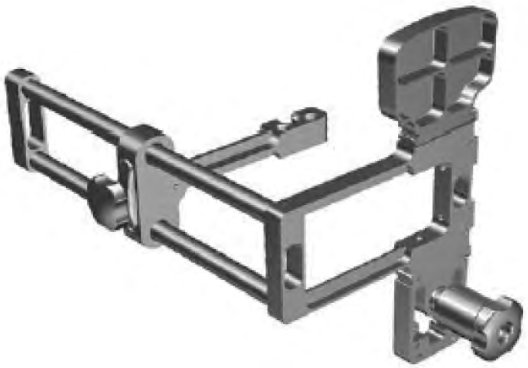


Figure 17

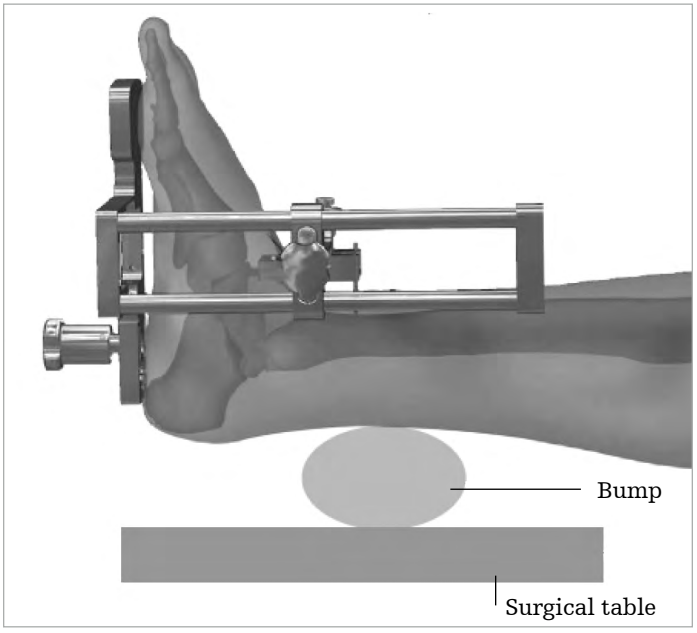


Figure 18

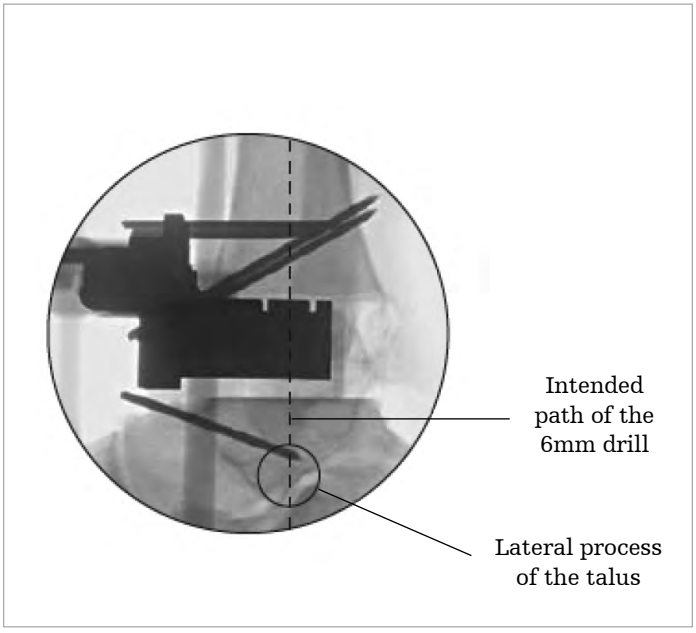


Figure 19

Drill primary hole

Lower the C-bracket assembly down over the anterior mounting plate and attach through the two protruding dowel pins. **(Figure 20)** The surface of the C-bracket arm must sit flat against the anterior mounting plate.

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. **(Figure 21)**

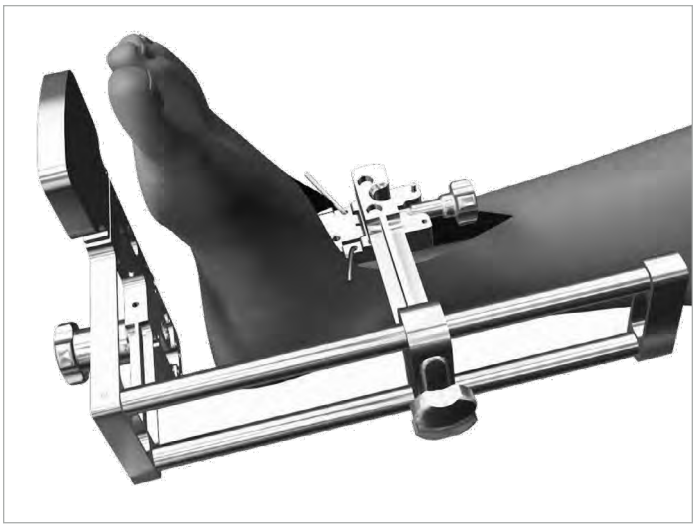


Figure 20

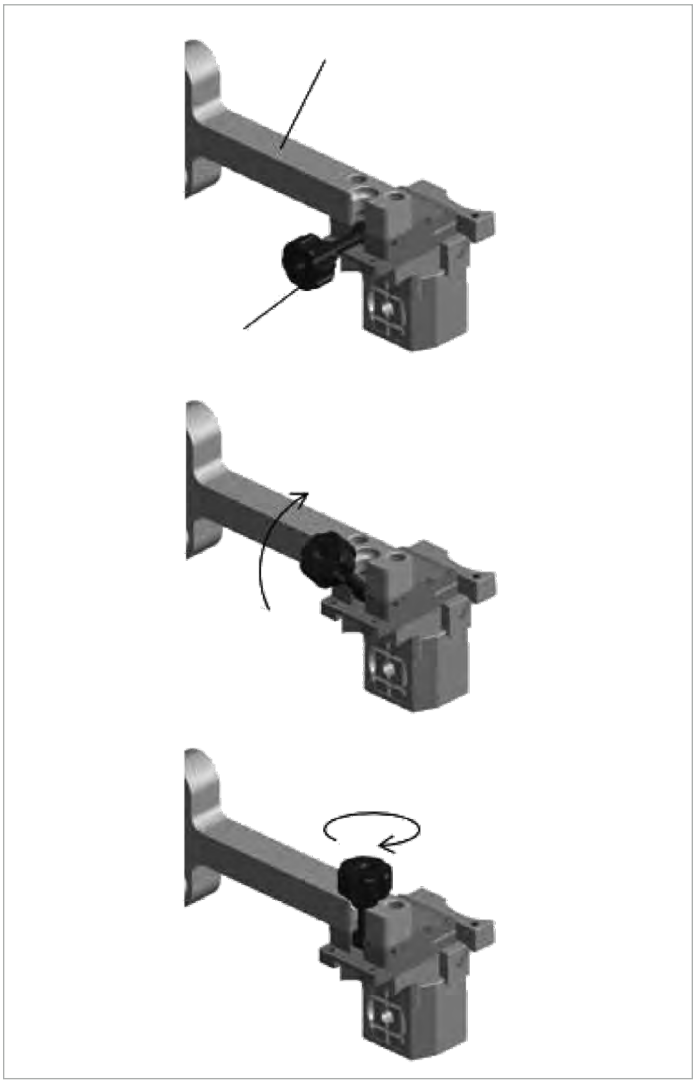


Figure 21

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 22)** To prevent the C-bracket assembly from binding while adjusting the length, push the bottom of the assembly in-line with 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 23)**

Figure 22

Trocar
(200099)

Cannula
(200166)

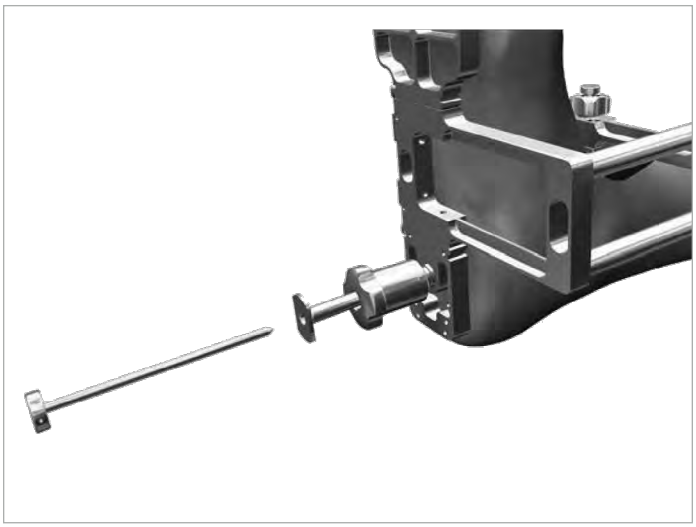


Figure 23

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 24)**

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.

C**aution:** 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 25)** 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.

6mm Drill
(200134)

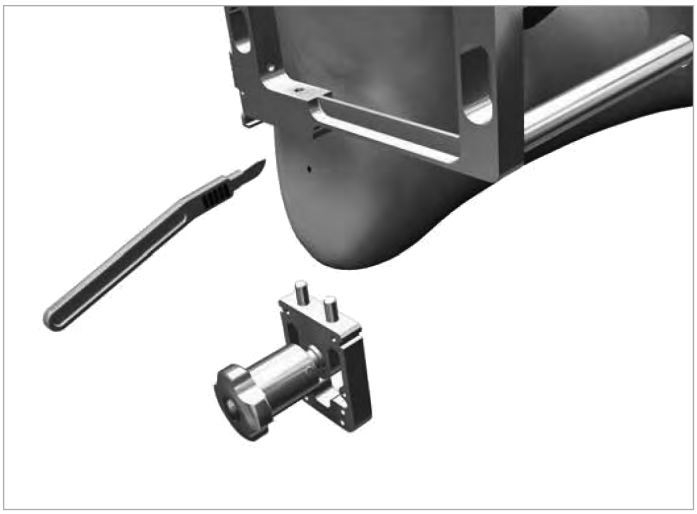


Figure 24

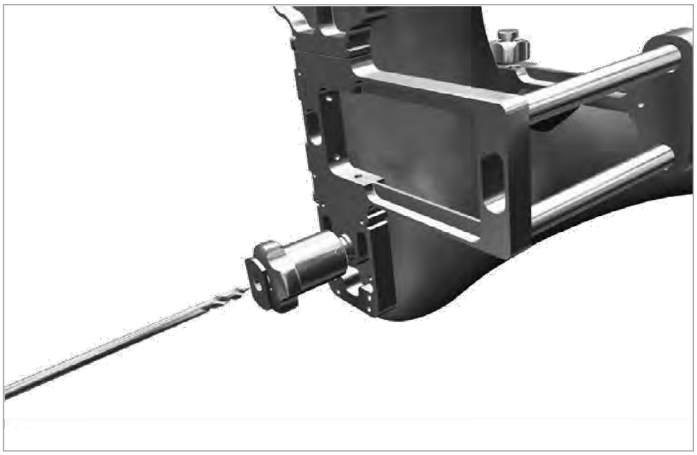


Figure 25

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 26 & 27)**

A lateral fluoro image will show the two notches in the drill guide cartridge that the 6mm drill should go between. **(Figures 28 & 29)**

Figure 26

Figure 27

Figure 28

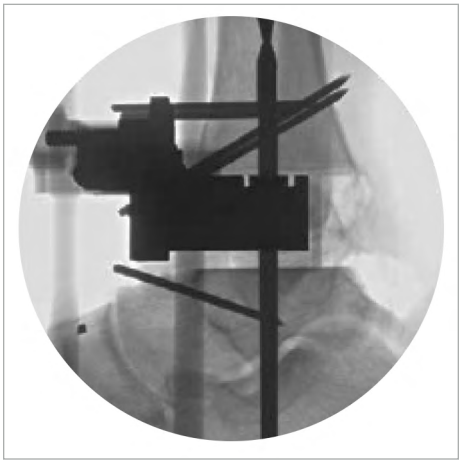


Figure 29

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 30)**

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.

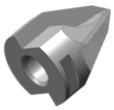
Using the appropriate size tibial stem clip (200381001 – 200381004), attach and lower the appropriate size reamer tip (Standard 200046001 – 200046004, sharp 22001200 – 22001800) into the joint space through the anterior opening of the anterior mounting plate. **(Figure 31)**

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.

M4 attachment screw
(200329103)

Tibial stem clip
(200381001 - 200381004)

Tibial reamer tip
(200046001 - 200046004)



Sharp reamer tip
(22001200 – 22001800)

Tibial reamer drive rods
(200089 or 200395 T-handle)

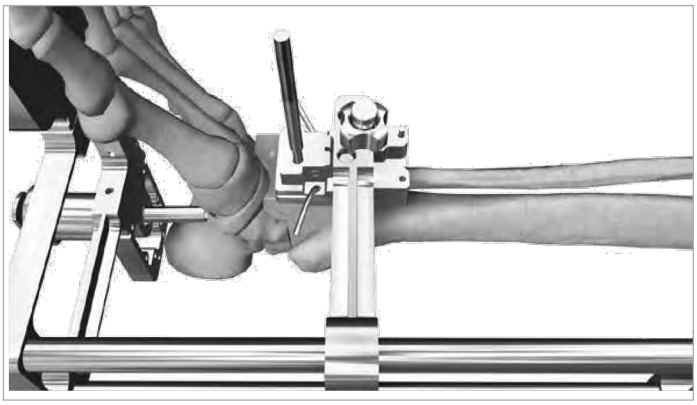


Figure 30

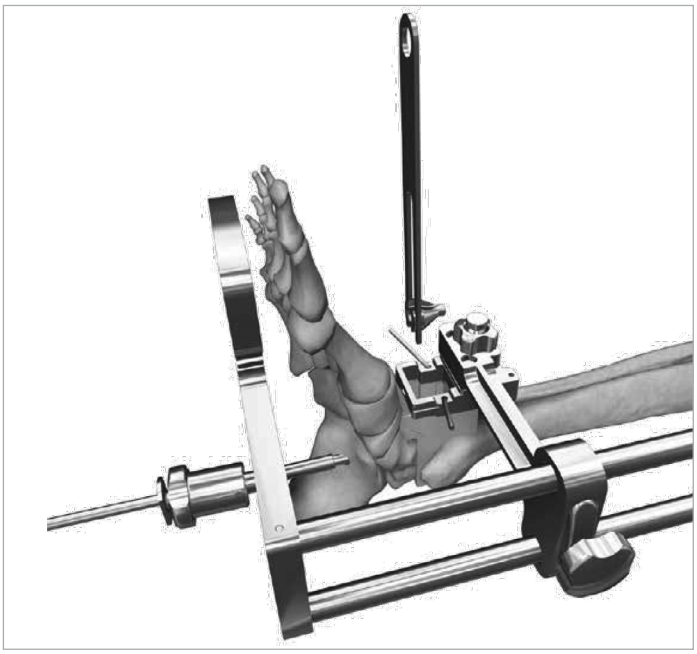


Figure 31

Ream the tibial IM canal to the depth of the tibial stem construct determined by the preoperative plan. Note that the Reamer Drive Rod is marked with a depth indicator that can be viewed through the anterior widow.

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.

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.

Using the appropriate sized tibial stem wrench (200380001 – 200380004), unthread the reamer tip from the drive rod and remove from the joint space. 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 to prevent debris from interfering with instrument attachments.

Leave the reamer drive rod in the foot with the tip slightly distal to the surface of the talar resection.

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 32)**

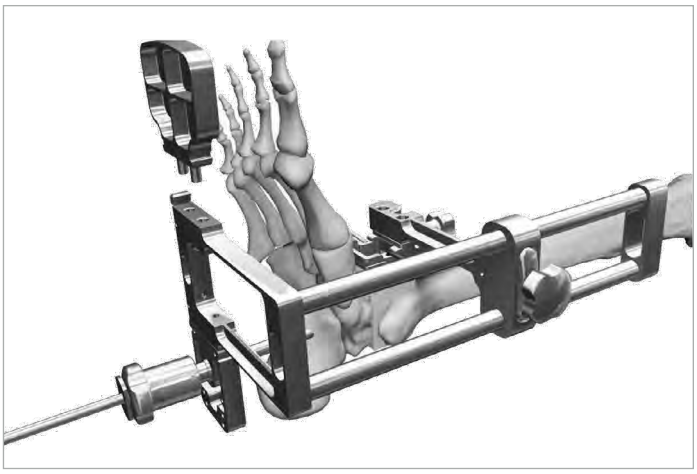


Figure 32

Tibial stem wrench
(200380001-0004)

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 33)**

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 third pin in one of the top hole locations (preferably on the lateral side). **(Figure 34)** Remove the drive rod.

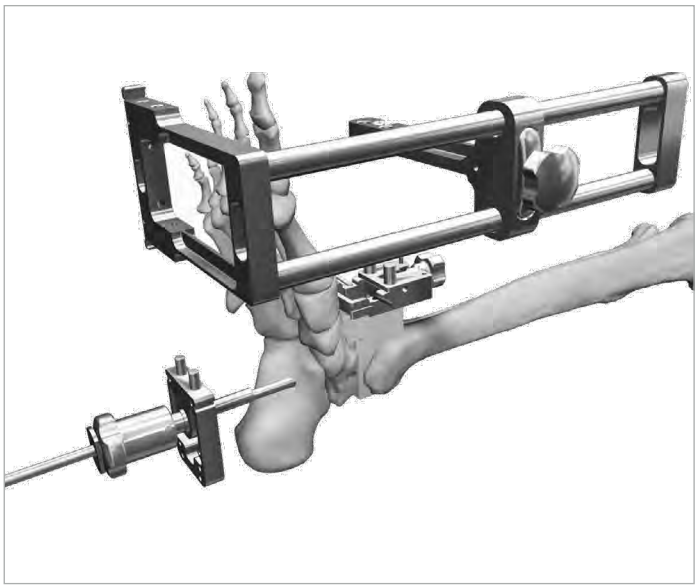


Figure 33

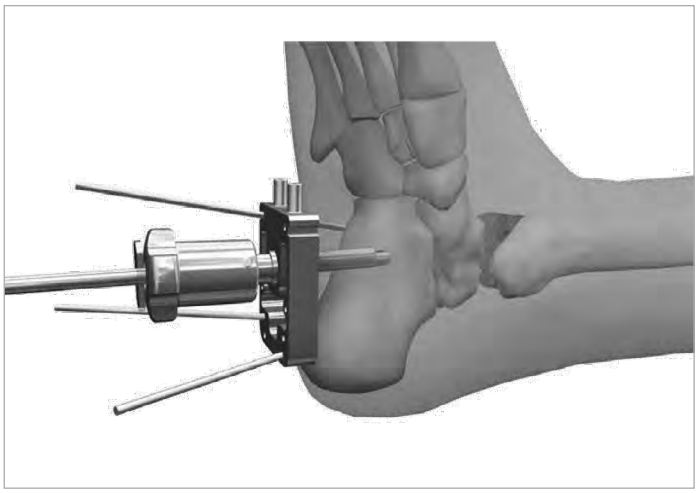
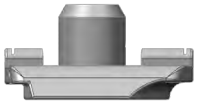


Figure 34

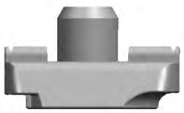
Tibial trialing

Select the appropriate size tibial tray trial (Invision 60022400 – 60025800 or Inbone IB600020 – IB600060). Insert trial into the resected joint space using the M4 holding tool (200364003). Use the strike rod (200085) to fully seat the tibial tray trial. Utilizing lateral fluoroscopic imaging, evaluate the anterior and posterior coverage of the tibial cortex. Determine if a standard or long tibial tray is appropriate and opt for overhang both anteriorly and posteriorly if the anatomy is between sizes. Note to check with both the +4mm and +8mm Invision tibial tray trials for a given size since the tibial lengths vary. **(Figures 35A & B)**

Note: It is critical to obtain sagittal plane coverage of the tibia, particularly anteriorly where more load is concentrated. Thus, in choosing the correct size, overhang with a longer prosthesis is preferred relative to shorter implants that do not reach the corticies.

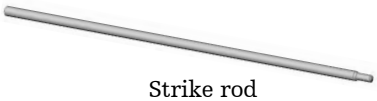


Inbone tibial tray trial
(IB600020 – 600060)



Invision tibial tray trial
(60022400 – 60025800)

M4 holding tool
(200364003)



Strike rod
(200085)

The tibial tray trial is also used to check the tibial cut surfaces and ensure that no bone fragment will impede proper positioning and seating of the tibial tray implant. Remove excess bone as necessary and irrigate. **(Figures 36 & 37)**

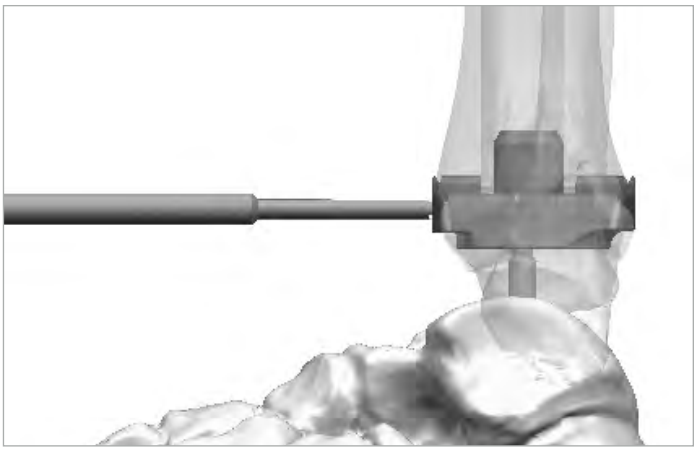


Figure 35A

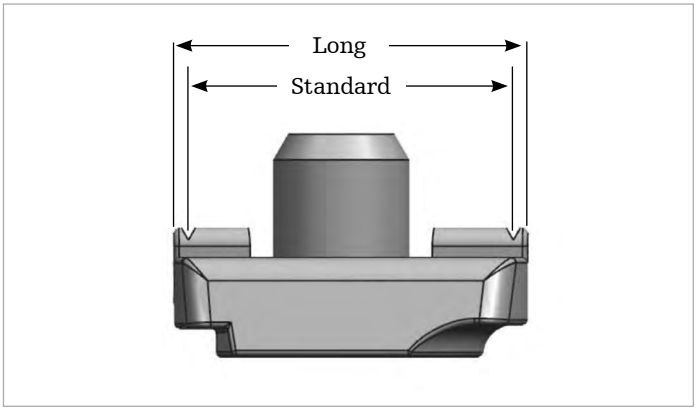


Figure 35B

Figure 36

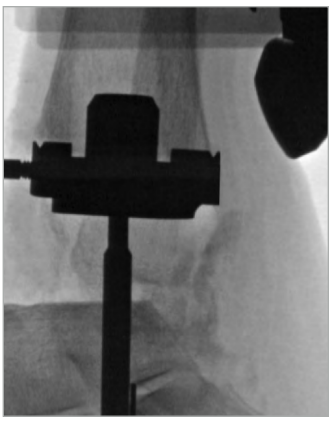


Figure 37

To assess if sufficient amount of bone has been removed for the implant construct, the resected bone must be trialed with the tibial tray trial, polyethylene insert trial (IB202206-6516), and talar dome trial (IB220801-805), talar plate trial (60001010-1150), and optional 3mm talar plate spacer (60003001). **(Figure 38)**

Do not be concerned with the positioning of the trial components at this time. Only the construct height is being assessed. Final position and component selection will be completed in subsequent steps.

Figure 38

Poly insert trials
(IB202206-6516)

Talar dome trials
(IB220801-805)

Talar plate trials
(60001010-1150)

3mm Talar plate spacer
(60003001)

Using the poly insert trial holding tool (IB200110) install the appropriate size poly insert trial into the tibial tray. The locking tab of the poly insert trial should engage the tibial tray.

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. **(Figure 39)**

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

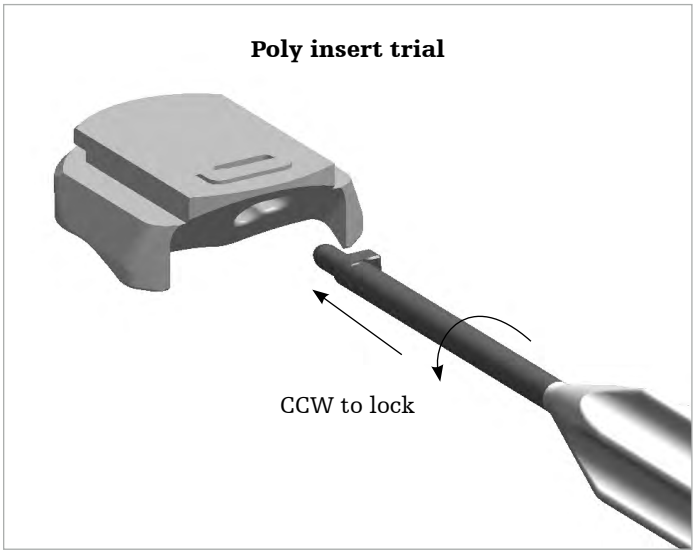


Figure 39

Poly insert trial holding tool
(IB200110)

Trial reduction

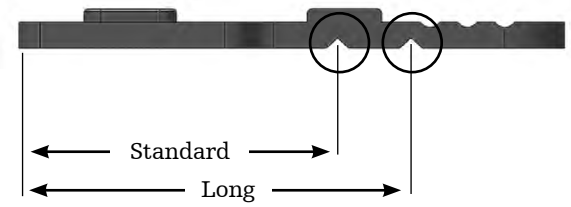
The talar plate implant size may be equivalent to the tibial tray implant size, one size larger than the tibial tray, or one size smaller. For example, a size 3 tibial tray may utilize a size 2, 3 or size 4 talar plate. The talar dome implant could be equivalent to the size of the tibial tray or one size smaller. If additional thickness is required to rebuild the anatomical joint line, utilize the 3mm trial talar plate spacer (60003001) to assess height of required talar plate.

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 poly insert trial to accurately determine the placement of the talar component. The poly insert trial used for the reduction should fit appropriately to determine the center of rotation of the talar component; therefore, trialing multiple sizes may be necessary. Note that after insertion of the talar plate and talar dome implants, the height of the poly can be reassessed.

In order to determine proper polyethylene height the following factors should 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.
- 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 plate and talar dome trial components are resting on the posterior portion of the patient's residual talus (establish congruence). Two length options are available for Invision talar plates (standard and long). These options are available to ensure best possible coverage of talar resection. **(Figure 40)**



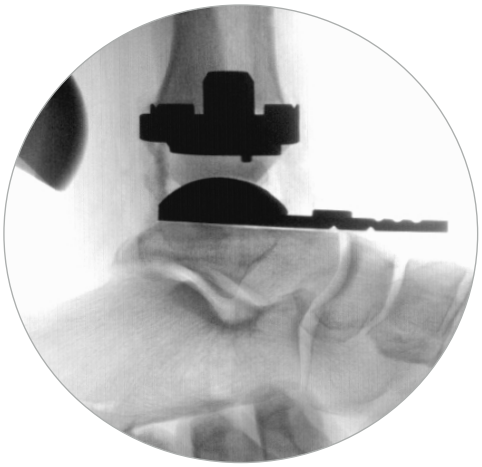


Figure 40

To accurately perform the range of motion, place some axial compression on 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: 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 the talar dome trial and talar plate trial have settled into optimum anatomical position, install two 2.4mm Steinmann pins through the talar plate trial into the calcaneus for additional stability and to temporarily hold it in place. **(Figure 41)**

Caution: Place pins by hand and ensure that pins do not cold weld while driving in via power.

Note: 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.

Cut the pins approximately 1.5" long and remove all trials except for the talar plate trial from the joint space.

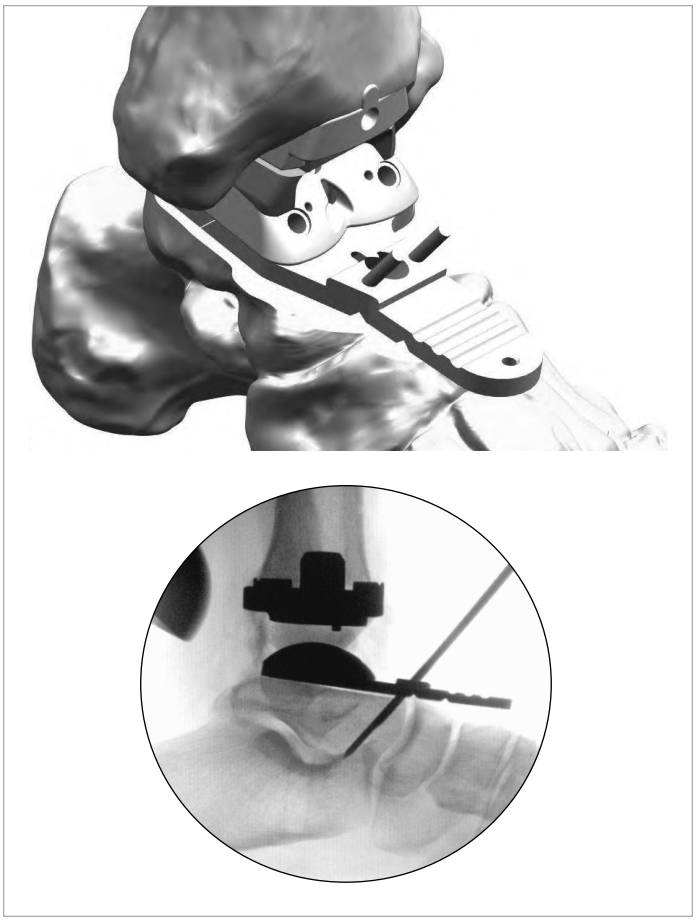


Figure 41

Talar preparation

Clip the anterior peg drill guide (60006011) and peg drill handle (60006012) together, ensure that the talar plate trial is flush to talus and slide peg drill guide into anterior peg hole. **(Figure 42A)** With the peg drill (60006022), drill for your anterior peg. Use the posterior peg drill guide (60006027) for the posterior holes. Follow same steps listed above to prep for medial and lateral posterior pegs. **(Figure 42B)** Once both posterior pegs are prepped, remove talar plate trial and 2.4 pins.

Anterior peg drill guide
(60006011)

Posterior peg drill guide
(60006027)

Peg drill handle
(60006012)

Peg drill
(60006022)

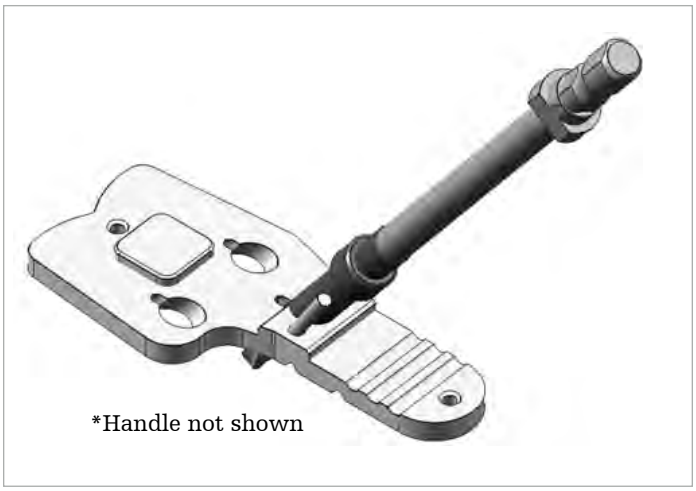


Figure 42A

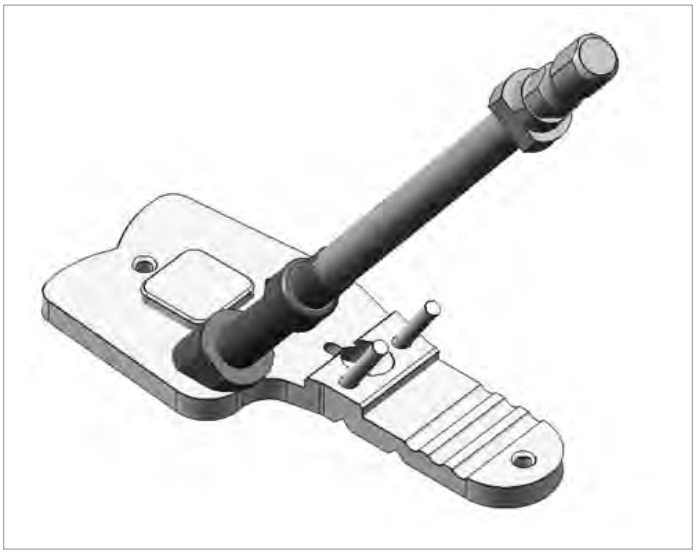


Figure 42B

Tibial trialing

Select the appropriate size tibial tray trial. Insert trial into the resected joint space using the M4 holding tool (200364003). Use the strike rod (200085) to fully seat the tibial tray trial. Utilizing lateral fluoroscopic imaging, evaluate the anterior and posterior coverage of the tibial cortex. Determine if a standard or long tibial tray is appropriate and opt for overhang both anteriorly and posteriorly if the anatomy is between sizes. Note to check with both the +4mm and +8mm Invision tibial tray trials for a given size since the tibial lengths vary.
(Figures 43 & 44)

The Inbone tibial trays may also be considered if they provide sufficient thickness and anterior-posterior coverage of the tibial cortex.

X-drive
(200071)

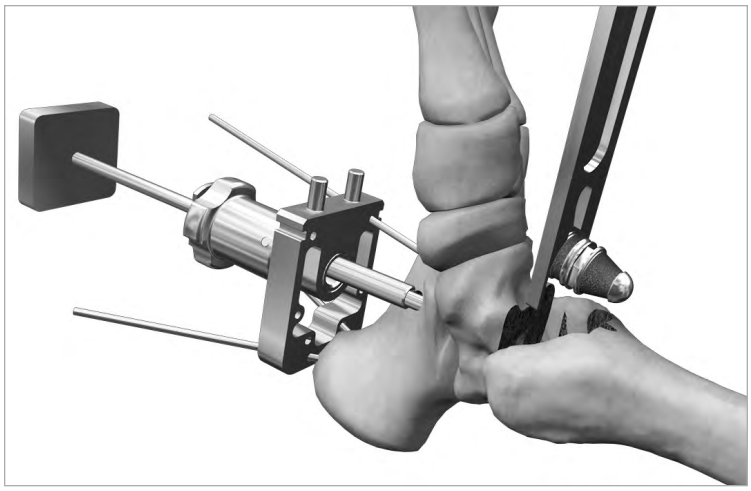


Figure 43

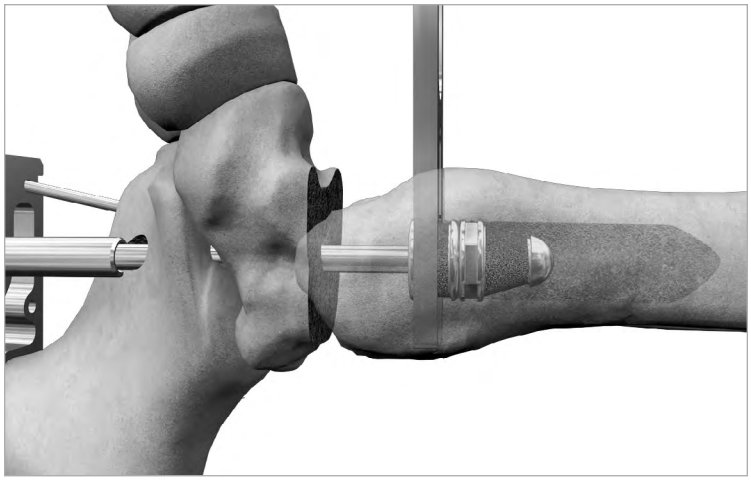


Figure 44

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. An assistant may hold on to the wrench and distract the joint to aid insertion of the next piece. **(Figure 45)**

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. If the stem pieces are inadvertently pushed into the tibia, please see stem retrieval instructions.

Select the appropriate base stem piece and introduce with a clip. Tightly thread the base stem using the X-drive. Remove the clip and insert a wrench on the base stem. **(Figure 46)**

With the base stem tight, remove the wrench and rotate the stem construct 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. Place the wrench back on the base stem.

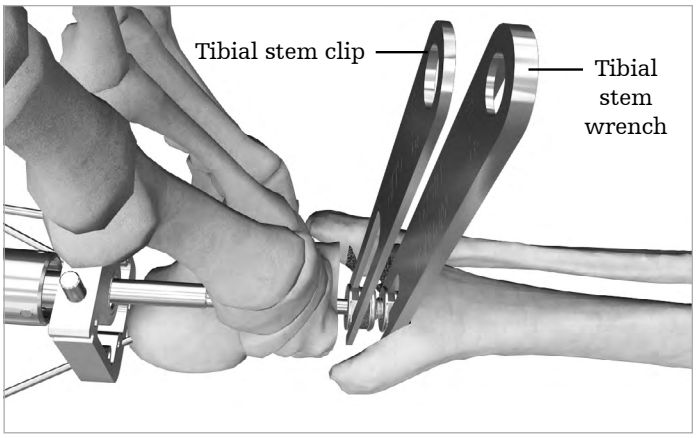


Figure 45

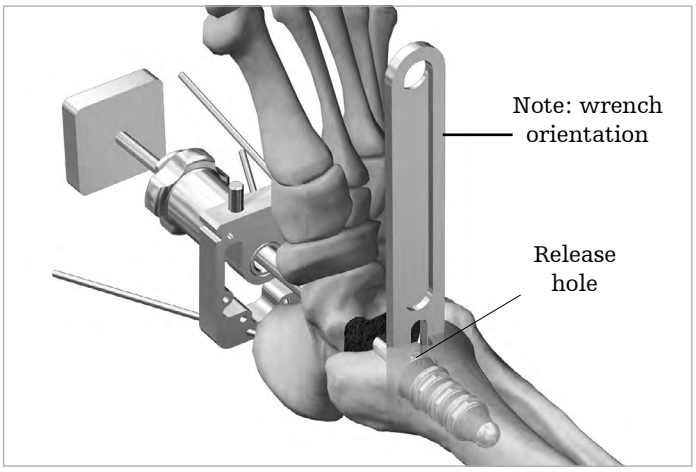


Figure 46

Install tibia tray

Irrigate the morse taper surface of the base stem to clean it.

Caution: The morse taper surfaces should be clean and dry for 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 (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. Apply cement to the top and sidewalls of the tibial tray component.

Caution: If using the Inbone tibial tray implant, remove the holding tool before striking the strike rod. Otherwise it can be locked in place. The holding tool does not need to be removed if using the Invision tibial tray.

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.

Caution: Be sure not to get any cement on the anterior face or bottom of tibial tray, as this may prevent poly from fully seating.

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 a lateral fluoroscopic image for proper posterior seating. **(Figure 47)**

Should the tibial tray need to be removed for any reason from the base stem, refer to the instructions for removal.

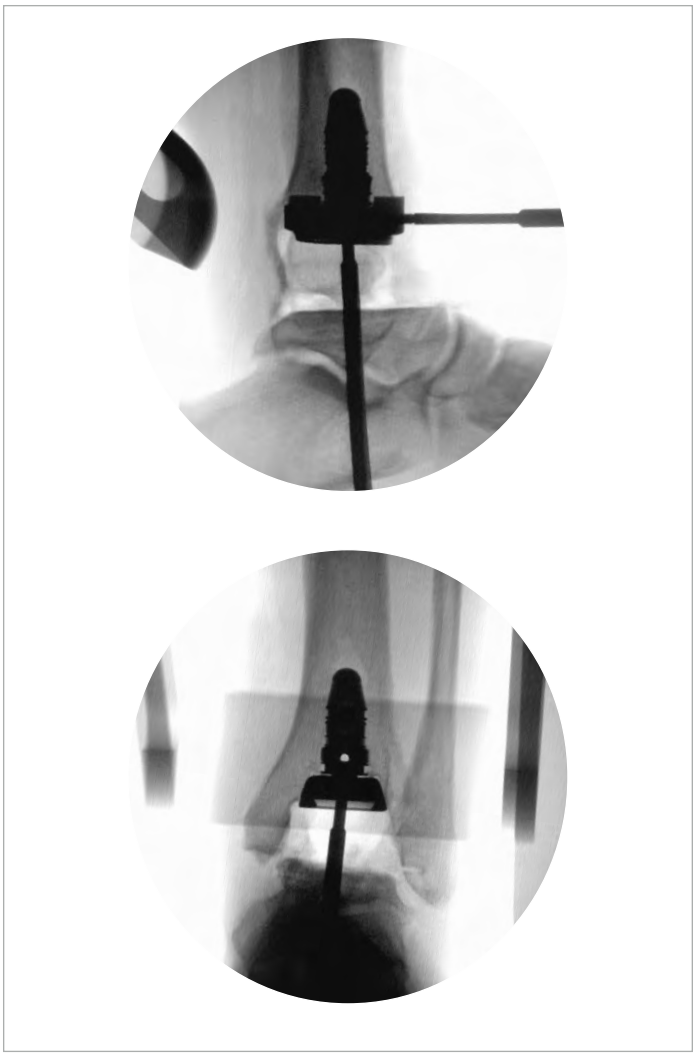


Figure 47

Implanting talar components

Assemble talar plate seating block (60006033) by inserting five of the Peek inserts (60006034) in the appropriate locations. Place the talar dome implant onto the morse taper of the talar plate implant and ensure that the talar dome is oriented correctly. There is an arrow and an "A" on the right side of implant indicating which direction should face anteriorly.

Next place the talar component assembly into the talar plate seating block. 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 dome to the talar plate. **(Figure 48)**

Place the blue tray insert (200419002 - 6) in the tibial tray to prevent scratching the articulating surface of talar dome.

Apply cement to the under surface of talar plate. Do not place cement on pegs as they are designed to be press fit into the prepared peg holes. Introduce talar dome/plate component by hand, aligning the pegs with the prepared holes. Remove the tray insert and with dome strike tool, impact the talar component in line with the oblique pegs until the plate is flush with the resected bone.

Take a lateral fluoroscopic image to ensure talar plate is fully seated.

Should the talar dome need to be removed from the talar plate for any reason, refer to the instructions for removal.

Caution: Due to morse taper connection, you will see a slight gap between talar dome and talar plate.

Talar plate seating block
(60006033)

Peek insert
(60006034)

Tray insert
(200419002 - 6)

Dome strike tool –
pre-assembled with dome strike tip
(IB200030 and IB200031)

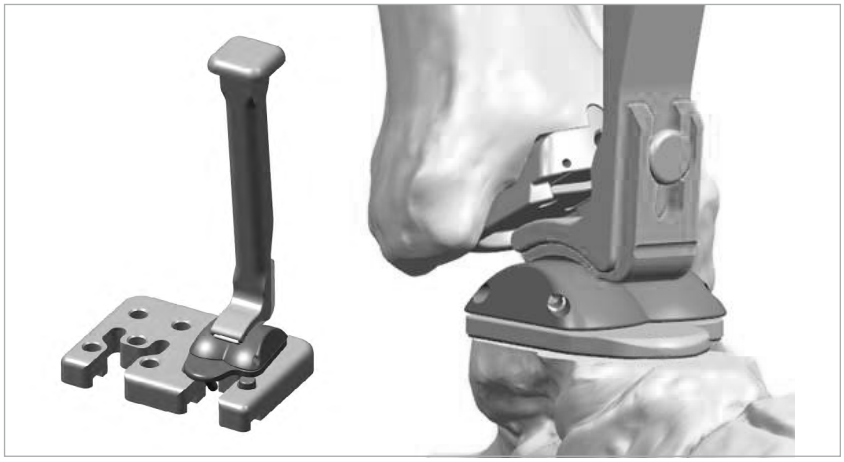


Figure 48

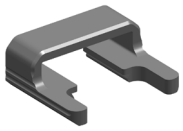
Poly insertion

Select the appropriate size poly inserter rail (60006002-5) and attach it to the poly insertion tool (60006018). The poly inserter rail should snap into position on the ball plungers of the poly insertion tool. Ensure that the numbers are aligned and the arrows are oriented in the same direction between the two components. **(Figure 49)**

Select the appropriate size polyethylene insert and slide it into the dovetail poly inserter rails. The anterior surface of the polyethylene insert should face the geared plunger.

Thread the attachment rod (60006021) into the anterior face of the tibial tray. **(Figure 50A)** Slide the poly insertion tool with poly insert assembled over the attachment rod and align flush with the anterior surface of the tibial tray. Thread the attachment nut (200329201) on the attachment rod to lock the poly insertion tool to the tibial tray. **(Figure 50B)**

Turn the geared handle of the poly inserter to drive the polyethylene insert into the tibial tray. **(Figure 50C)**



Poly inserter rail
(60006002-5)

Poly insertion tool
(60006018)

Attachment rod
(60006021)

Attachment nut
(200329201)

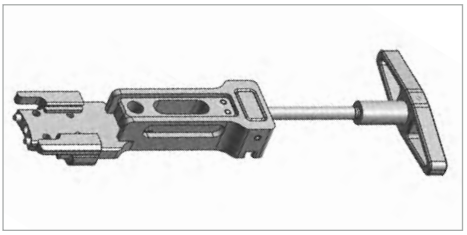


Figure 49

Figure 50A

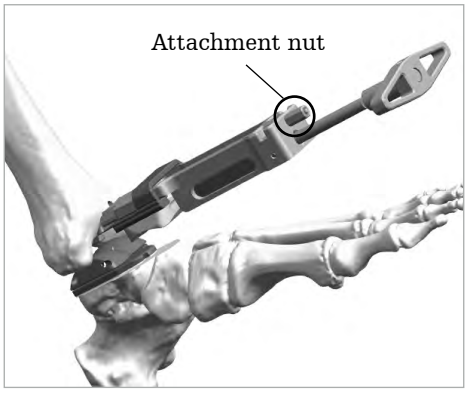


Figure 50B

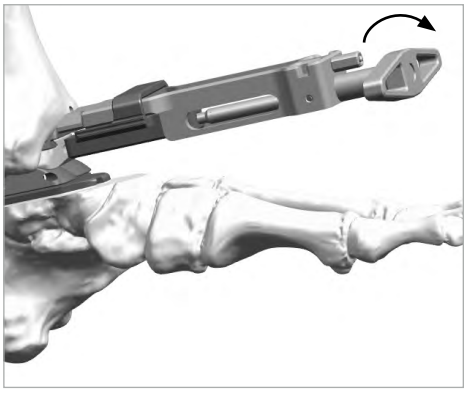


Figure 50C

Continue to advance the polyethylene implant until the locking tab engages the tibial tray, making certain not to lever on the previously implanted tibial tray. Visually check to ensure polyethylene seating. If required, select the poly impact tool (200286) and give the polyethylene a final tap to seat the insert. **(Figure 51)**

Poly impactor tool
(200286)

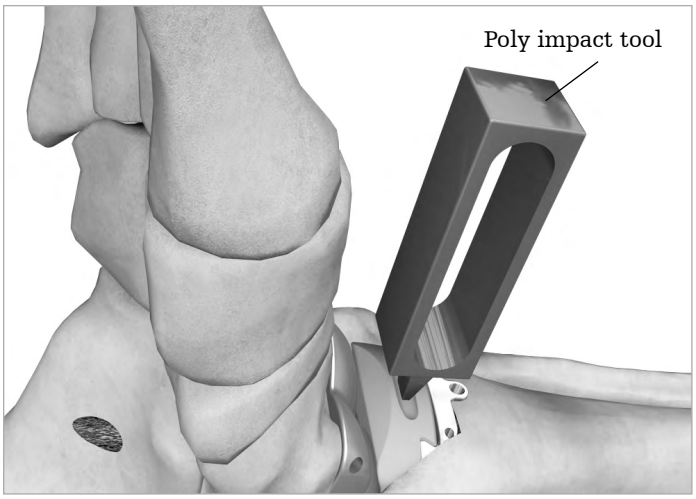


Figure 51

Take final AP and lateral fluoro images. **(Figure 52)**

Figure 52

Explant information

If the removal of the implant is required due to revision or failure of the device, the surgeon should contact the manufacturer using the contact information located on the back cover of this surgical technique to receive instructions for returning the explanted device to the manufacturer for investigation.

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.

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.

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.

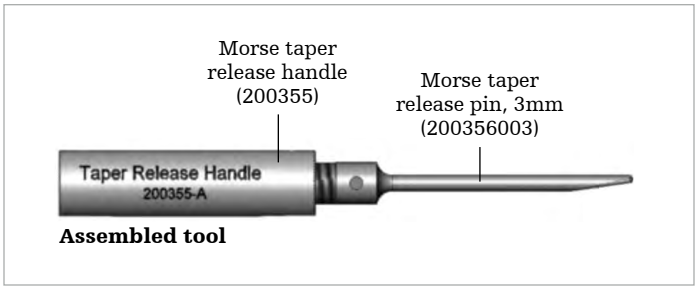
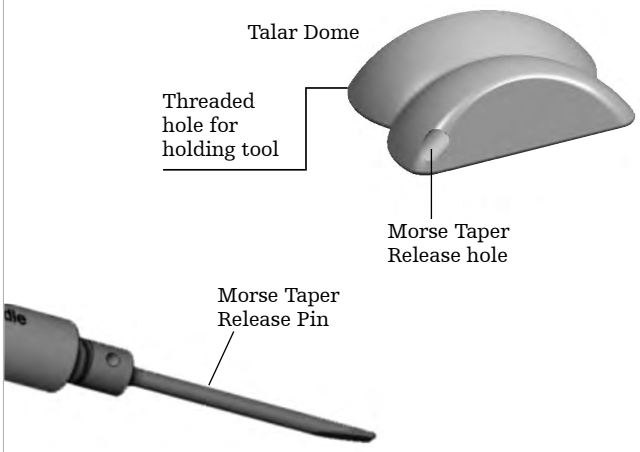
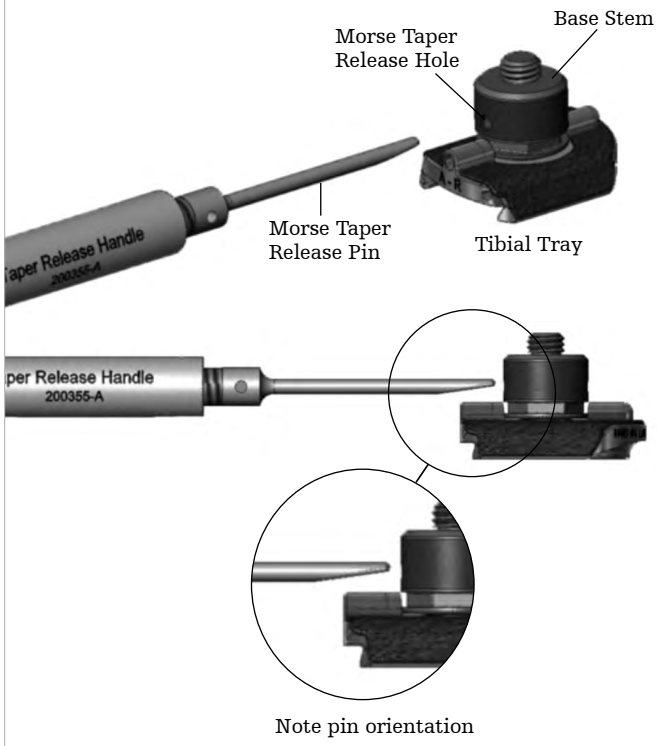


Figure 53

Talar Dome	Tibial Tray
	

Intraoperative tibia stem guide fluoroscopic check assembly

The M4 holding tool (purple) **(Figure 54)** or the strike rod **(Figure 55)** 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 intra-op fluoro image to the image of the tibia stem guide in the patient's preoperative alignment report.

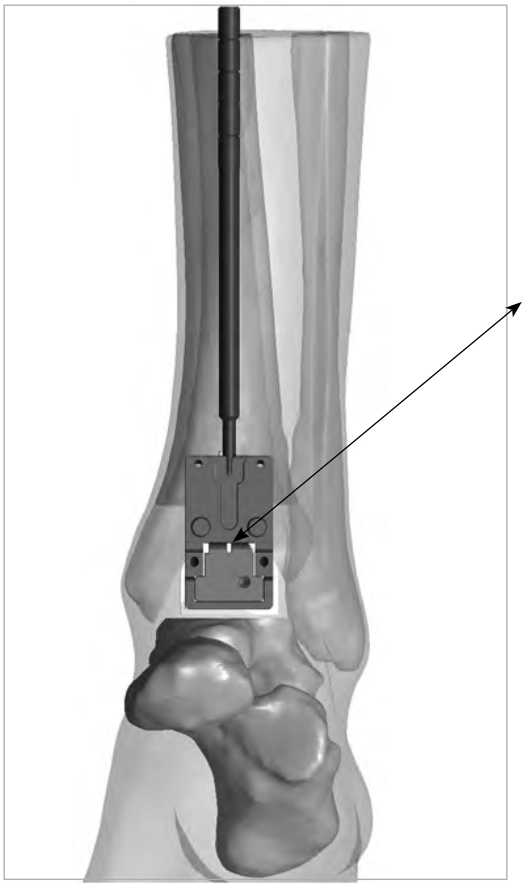


Figure 54

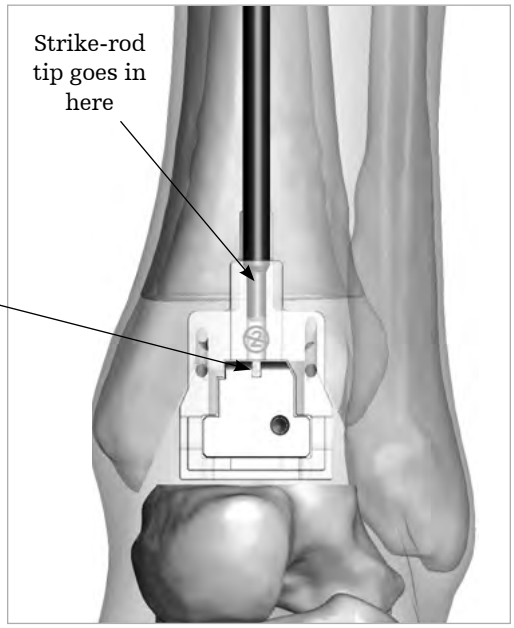


Figure 55

Stem retrieval

Retrieving a base stem piece from the tibia

Insert the T-handle reamer (200395) through the bottom of the foot and thread the base stem extraction Tool (200428) in the open joint space. **(Figure 56)** A size 14 clip (200381001-200381004) is used to introduce the base stem extraction tool. Once it is threaded onto the reamer replace the clip with a size 14 wrench (200380001-200380004) to tighten. **(Figure 57)**

Remove the wrench and push the extraction tool up in the tibia until contact is made with the base stem piece. Continue to turn the T-handle clockwise to engage the threads of the base stem piece. **(Figure 58)** Once threads are engaged, pull out the stem construct until the base stem is visible in the joint space. **(Figure 59)**

Place the appropriate size wrench on the base stem and turn the T-handle counter-clockwise to disengage the extraction tool from the base stem. Leaving the wrench on the base stem push the stem construct back into the tibia. **(Figure 60)** Use the size 14 wrench to remove the extraction tool from the T-handle reamer. **(Figure 61)**

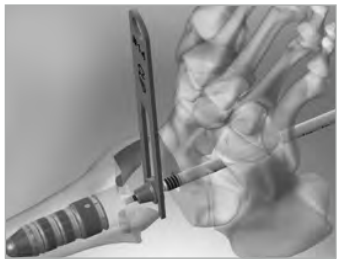


Figure 56

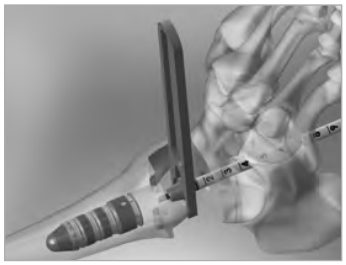


Figure 57

Figure 58

Figure 59

Figure 60

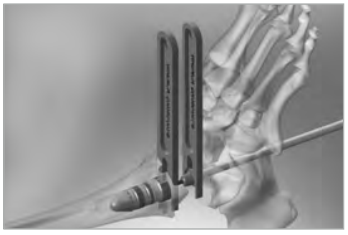


Figure 61

Select these tools:

Tibial T-handle reamer drive rod (200395)

Base stem extraction tool (200428)

Tibial stem clip #14 (200381001 - 200381004)

Tibial stem wrench #14 (200380001 - 200380004)

Retrieving a mid or top stem piece from the tibia

Follow the exact steps detailed on previous page for removing the base stem piece, substituting the mid/top stem extraction tool (200102) for the base stem extraction tool (200428). **(Figures 62-67)**

Mid/top stem extraction tool (200102)

Base stem extraction tool (200428)

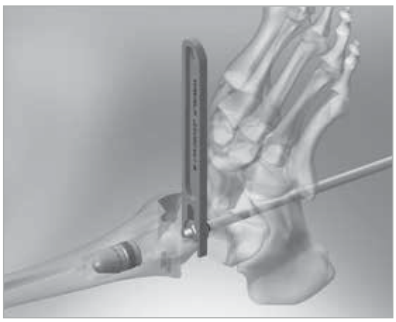


Figure 62

Figure 63

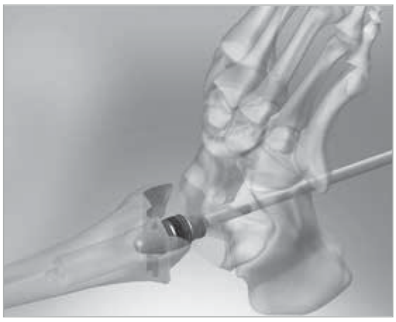


Figure 64

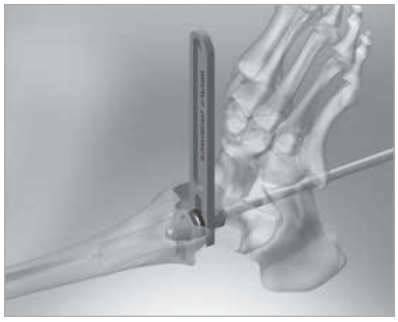


Figure 65

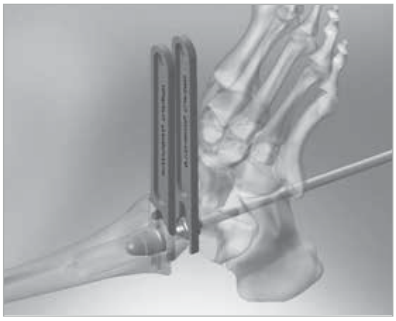


Figure 66

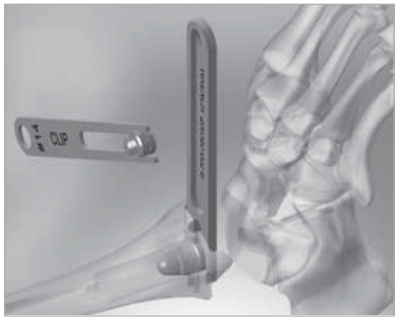
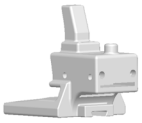


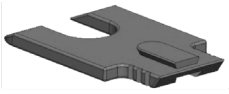
Figure 67

Talus-first or talus-only revision

Note: A talus-first or talus-only revision is preoperatively planned only if the existing tibia implant being revised is an Infinity, Inbone, or Invision implant in which the existing tibia may not be revised, or if the existing implant type and/or anatomy lends itself to resecting the talus bone first. Refer to the patient's preoperative alignment report for information related to the expected order of operations.



Tibia spacer
(PROPINV)



Spacer shim
(PINV0064)

Talus spacer
(PROPINV)

Setting the talus alignment and resection

If the case is preoperatively planned with the option of revising the tibia component after the talus resection, it is important that the tibia alignment guide is placed first. Perform the steps for the tibia alignment (detailed on pages above). Place the tibia guide, place one pin into bone, fluoro check the guide, finish drilling the other tibia guide holes. Remove tibia guide. Remove poly. Remove talus implant.

Make certain that the previous poly implant and previous talar implant are removed from the space prior to beginning the talus-first or talus-only revision. In order to re-create the preoperatively planned deformity correction, patient-specific spacers (PROPINV) are provided. One spacer references the tibia bone and existing tibia implant, and the talus spacer references the proximal talus. **(Figure 68)** These spacers fill the joint space between the tibia and talus in order to allow the talus to be positioned relative to the tibia.

The talar spacer will be provided but is optional if the correction of the talus is minimal. In this instance The spacers help set the varus/valgus and flexion/extension relationship between the tibia and talus intraoperatively. The resection depth for the talus is set manually with the procedure below.

Talus-first spacer guide configuration showing existing tibia implant, tibia spacer, spacer shim (PINV0064), and talus spacer (PROPINV). **(Figure 68)**

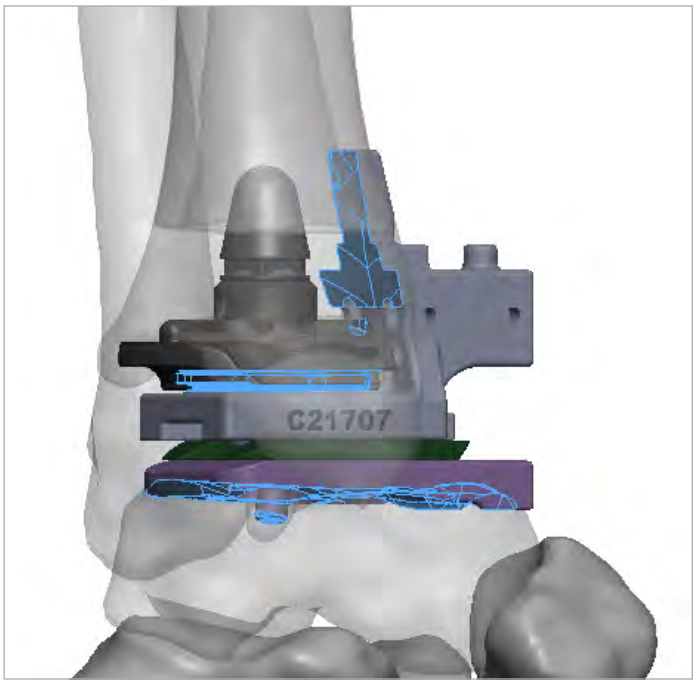


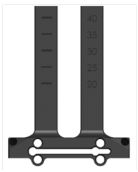
Figure 68

The patient-specific talus spacer is placed into the space. A pin may be placed through the talus spacer into the talus for stability. The patient-specific tibia spacer is inserted into the joint. This instrument interacts with the distal surface of the existing tibial tray. If gross laxity between the tibia and talus is observed, shims (PINV0064) may be added between the tibia and talus spacer to provide stability and drive the angular correction of the deformity as determined preoperatively. Each shim has a thickness of 3 mm. The shims interact with other shims and with the tibia spacer dovetail connections. The talus spacer does not interact with the dovetail connection; instead, there is a cylindrical boss protruding from the talus spacer that interacts with the U-shaped feature of either the shims or the tibia spacer, depending upon what is inserted into the space. This cylindrical feature provides some medial-lateral constraint while allowing for internal/external rotational flexibility and some A-P translation.

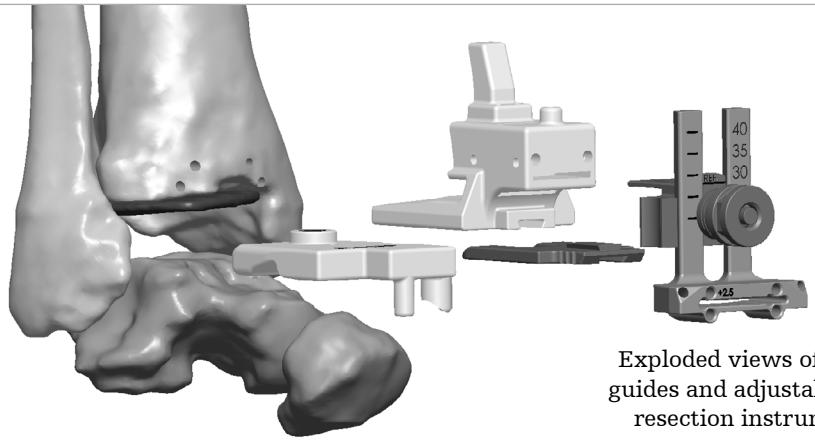
The adjustable talus guide capture (PINV0074) is assembled into the anterior slot of the patient-specific tibia spacer guide (PROPINV) with the guide capture knob (PINV0075) locking the adjustable talus resection guide (PINV1000). **(Figures 69-71)**

Talus guide capture (PINV0074)

Guide capture knob (PINV0075)

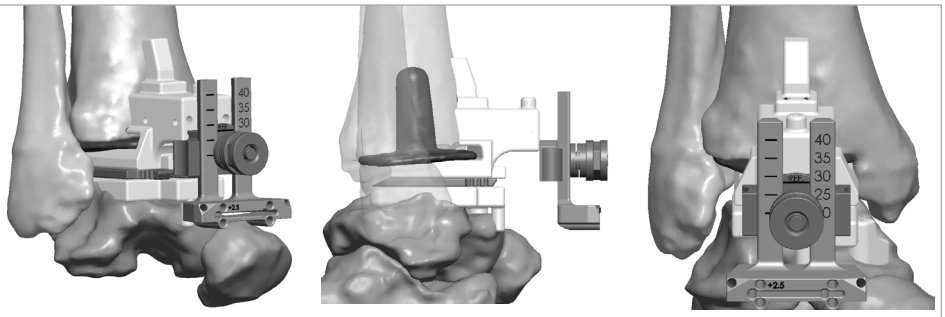


Talus resection guide (PINV1000)



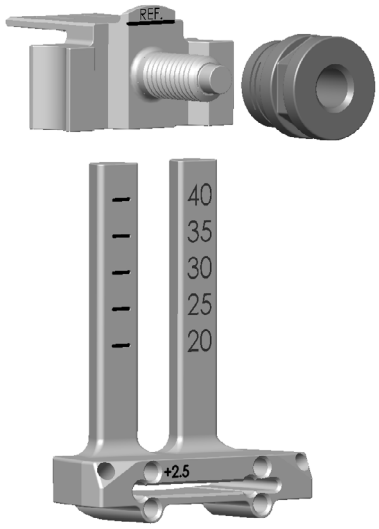
Exploded views of spacer guides and adjustable talus resection instruments.

Figure 69



Combined views of spacer guides and adjustable talus resection guide.

Figure 70



Talus guide capture (PINV0074)
Guide capture knob (PINV0075)

Figure 71

Before pinning, the surgeon should hold the foot at neutral (90°) flexion and neutral hindfoot varus/valgus orientation. The talus resection slot position is adjusted proximal and distal. A lateral fluoro image can facilitate visualization of the resection depth. K-wires or the saw blade may be inserted at the level of the talus resection to visualize the resection and to determine the appropriate resection level intraoperatively. The resection depth and talus orientation is determined by the surgeon and is not set by the Prophecy system. **(Figure 72)**

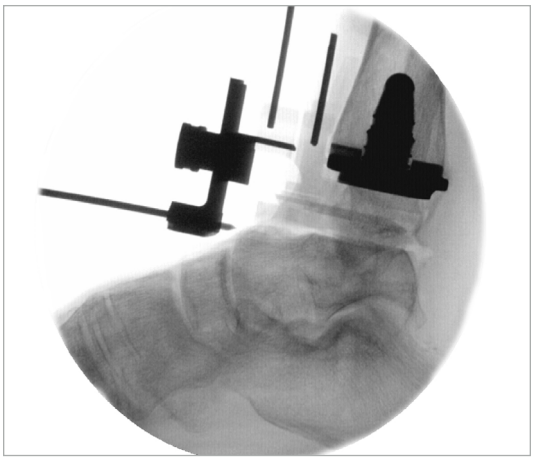


Figure 72

Markings on the talus resection guide (PINV1000) indicate the distance of the talus resection from the tibia resection. There is a small "Ref." line on the talus guide capture (PINV0074) for referencing the resection depth.

The surgeon will need to refer to the implant thicknesses in order to consider which thickness of implant may be appropriate for the overall resection height.

With the talus resection guide at the desired resection level pins are placed through the anterior holes. A pin should be placed in a hole on both the medial and lateral side. Use caution when driving pins through the talus resection guide to avoid pinning into the spacer guides or shims as this could cause damage or make spacer guide removal difficult. After placing at least two pins the entire construct is removed except the pins from the talus resection guide. The talus resection guide is slid back over the pins by itself. The reason for removing the entire construct is two-fold:

1. To prevent resecting into the spacer instruments.
2. To allow the talus resection guide to be positioned as close to the talus as possible.

If, for any reason, the talus resection depth needs to be adjusted there are additional holes in the resection guide that allow adjustment of the resection depth by 2.5 mm both proximal and distal to the cut slot.

Pins may be placed in both the medial and lateral oblique holes of the talus resection guide. **(Figure 73)** The parallel talus K-wires may be trimmed, or removed, to prevent interference with the saw. The oblique K-wires may be left long enough that they can be removed after completing the talus resection.

The talus is resected, the pins are removed, and the space is cleared of all resected bone down to the level of the flat cut.

Note: If the tibia implant also needs to be revised after completing the talus resection, return to the steps above of removing the existing tibia implant, re-inserting pins into the tibia, and setting the tibia resection guide.

Talus resection guide with converging oblique K-wires placed into the talar body.

Figure 73

Trial reduction

Using the poly insert trial holding tool (IB200110) install the appropriate size poly insert trial into the tibial tray. The locking tab of the poly insert trial should engage the tibial tray.

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. **(Figure 74)**

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

Introduce the appropriate size talar dome (IB220901-905) and talar plate trial (60001010 - 1150). The talar plate implant size may be equivalent to the tibial tray implant size, one size larger than the tibial tray, or one size smaller. For example, a size 3 tibial tray may utilize a size 2, 3, or size 4 talar plate. The talar dome implant could be equivalent to the size of the tibial tray or one size smaller. If additional thickness is required to rebuild the anatomical joint line, utilize the 3mm trial talar plate spacer (60003001) to assess height of required talar plate.

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 poly insert trial to accurately determine the placement of the talar component. The poly insert trial used for the reduction should fit appropriately to determine the center of rotation of the talar component; therefore, trialing multiple sizes may be necessary. Note that after insertion of the talar plate and talar dome implants, the height of the poly can be reassessed.

Poly insert trial holding tool
(IB200110)

Poly insert trials
(IB202206-6516)

Talar dome trials
(IB220901-905)

Talar plate trials
(60001010-1150)

3mm Talar plate spacer
(60003001)

Poly insert trial

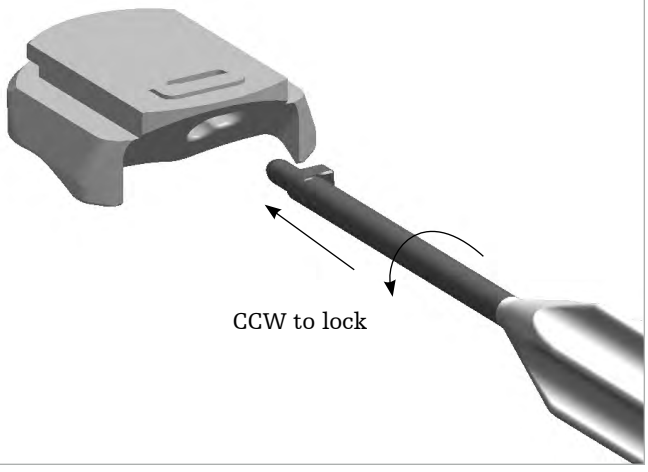


Figure 74

In order to determine proper polyethylene height the following factors should 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.
- 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 plate and talar dome trial components are resting on the posterior portion of the patient's residual talus (establish congruence). Two length options are available for Invision talar plates (standard and long). These options are available to ensure best possible coverage of talar resection. **(Figure 75)**

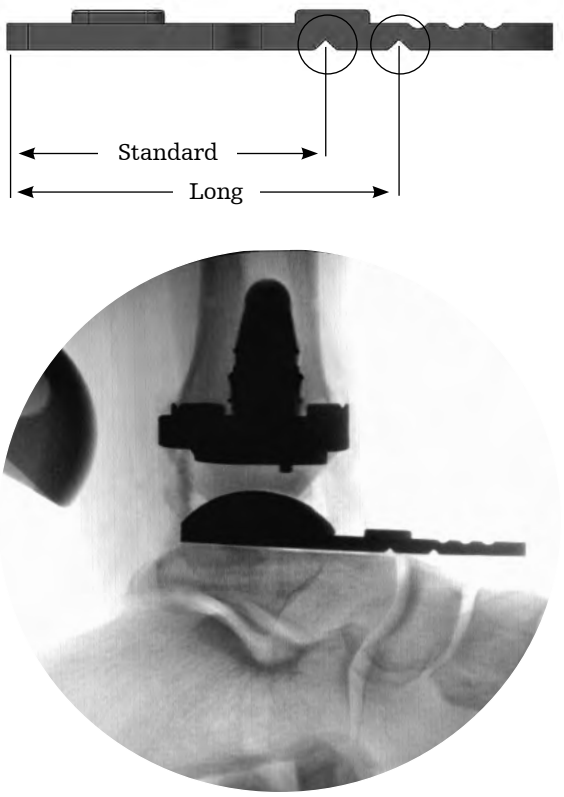


Figure 75

To accurately perform the range of motion, place some axial compression on 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 the talar dome trial and talar plate trial have settled into optimum anatomical position, install two 2.4mm Steinmann pins through the talar plate trial into the calcaneus for additional stability and to temporarily hold it in place. **(Figure 76)**

Caution: Place pins by hand and ensure that pins do not cold weld while driving in via power.

Note: 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.

Cut the pins approximately 1.5" long and remove all trials except for the talar plate trial from the joint space.

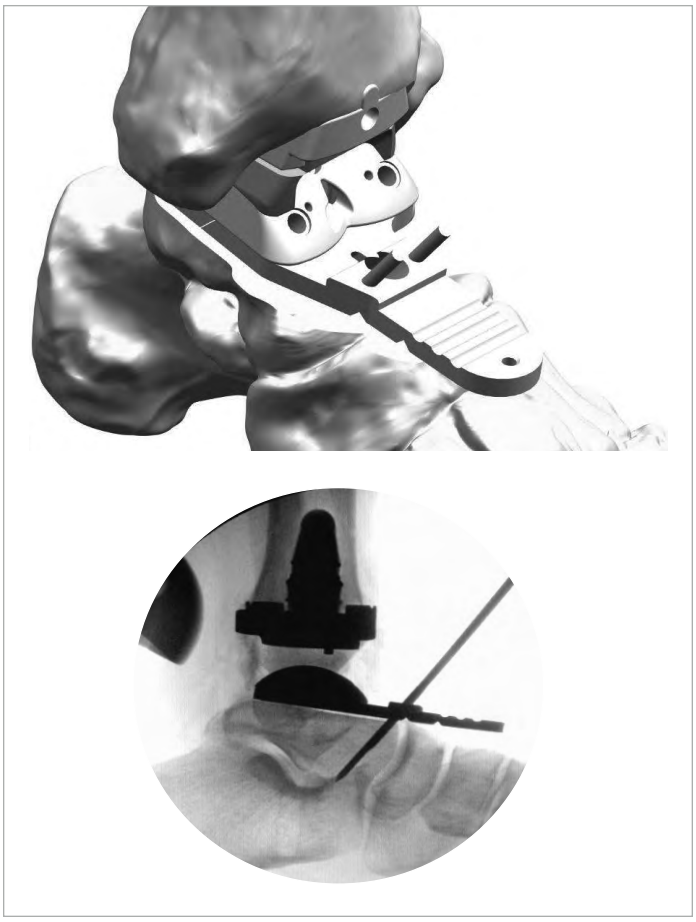


Figure 76

Talar preparation

Clip the anterior peg drill guide (60006011) and peg drill handle (60006012) together, ensure that the talar plate trial is flush to talus and slide peg drill guide into anterior peg hole. **(Figure 77A)** With the peg drill (60006022), drill for your anterior peg. Use the posterior peg drill guide (60006027) for the posterior holes. Follow same steps listed above to prep for medial and lateral posterior pegs. **(Figure 77B)** Once both posterior pegs are prepped, remove talar plate trial and 2.4 pins.

Anterior peg drill guide
(60006011)

Posterior peg drill guide
(60006027)

Peg drill handle
(60006012)

Peg drill
(60006022)

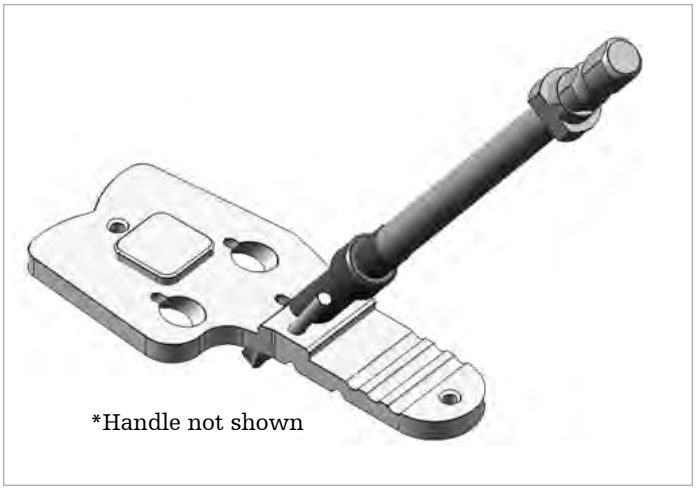


Figure 77A

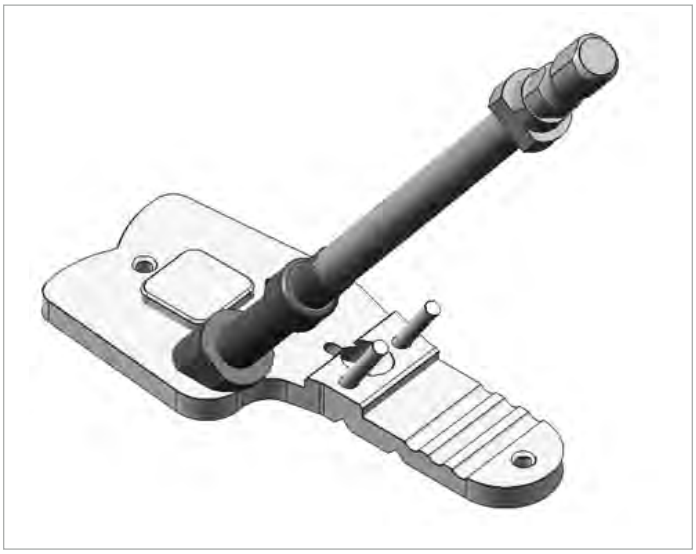


Figure 77B

Implanting talar components

Assemble talar plate seating block (60006033) by inserting five of the Peek inserts (60006034) in the appropriate locations. Place the talar dome implant onto the morse taper of the talar plate implant and ensure that the talar dome is oriented correctly. There is an arrow and an "A" on the right side of implant indicating which direction should face anteriorly.

Next place the talar component assembly into the talar plate seating block. 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 dome to the talar plate. **(Figure 78)**

Place the blue tray insert (200419002 - 6) in the tibial tray to prevent scratching the articulating surface of talar dome.

Apply cement to the under surface of talar plate. Do not place cement on pegs as they are designed to be press fit into the prepared peg holes. Introduce talar dome/ plate component by hand, aligning the pegs with the prepared holes. Remove the tray insert and with dome strike tool, impact the talar component in line with the oblique pegs until the plate is flush with the resected bone. **(Figure 78)**

Take a lateral fluoroscopic image to ensure talar plate is fully seated.

Should the talar dome need to be removed from the Talar plate for any reason, refer to instructions for removal.

Caution: Due to morse taper connection, you will see a slight gap between talar dome and talar plate.

Talar plate seating block
(60006033)

Peek insert
(60006034)

Tray insert
(200419002 - 6)

Dome strike tool –
pre-assembled with dome strike tip
(IB200030 and IB200031)

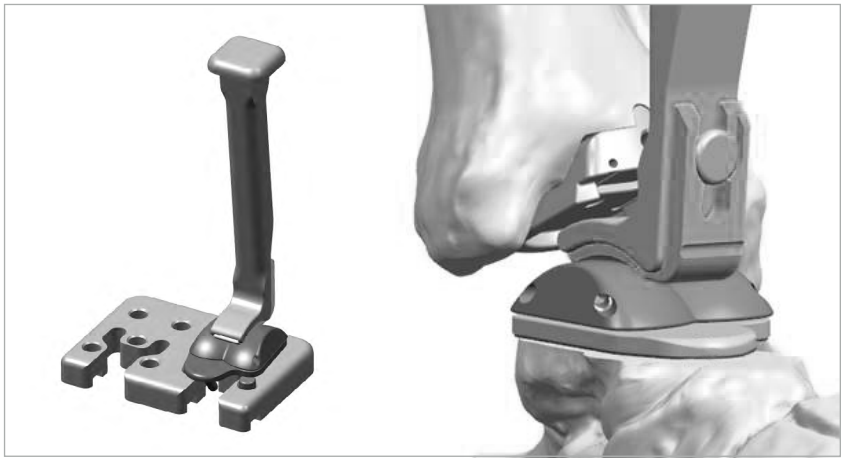


Figure 78

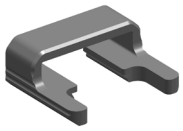
Poly insertion

Select the appropriate size poly inserter rail (60006002-5) and attach it to the poly insertion tool (60006018). The poly inserter rail should snap into position on the ball plungers of the poly insertion tool. Ensure that the numbers are aligned and the arrows are oriented in the same direction between the two components. **(Figure 79)**

Select the appropriate size polyethylene insert and slide it into the dovetail poly inserter rails. The anterior surface of the polyethylene insert should face the geared plunger.

Thread the attachment rod (60006021) into the anterior face of the tibial tray. **(Figure 80A)** Slide the poly insertion tool with poly insert assembled over the attachment rod and align flush with the anterior surface of the tibial tray. Thread the attachment nut (200329201) on the attachment rod to lock the poly insertion tool to the tibial tray. **(Figure 80B)**

Turn the geared handle of the poly inserter to drive the polyethylene insert into the tibial tray. **(Figure 80C)**



Poly inserter rail
(60006002-5)

Poly insertion tool
(60006018)

Attachment rod
(60006021)

Attachment nut
(200329201)

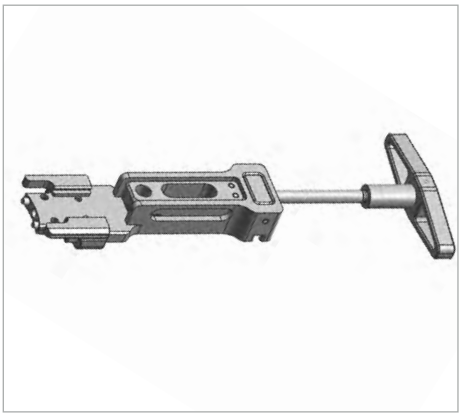


Figure 79

Figure 80A

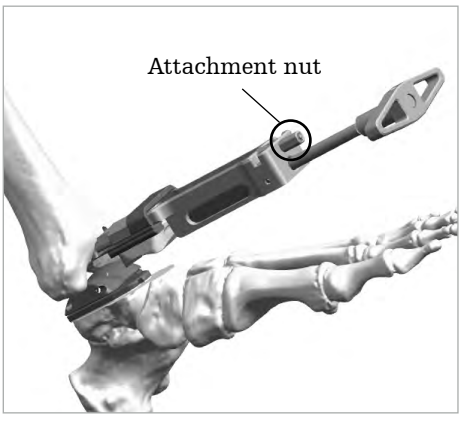


Figure 80B

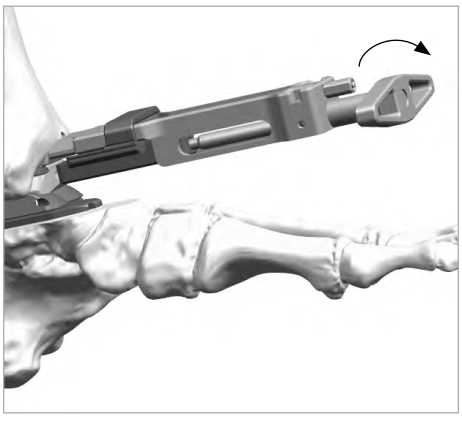


Figure 80C

Continue to advance the polyethylene implant until the locking tab engages the tibial tray, making certain not to lever on the previously implanted tibial tray. Visually check to ensure polyethylene seating. If required, select the poly impact tool (200286) and give the polyethylene a final tap to seat the insert. **(Figure 81)**

Poly impactor tool
(200286)

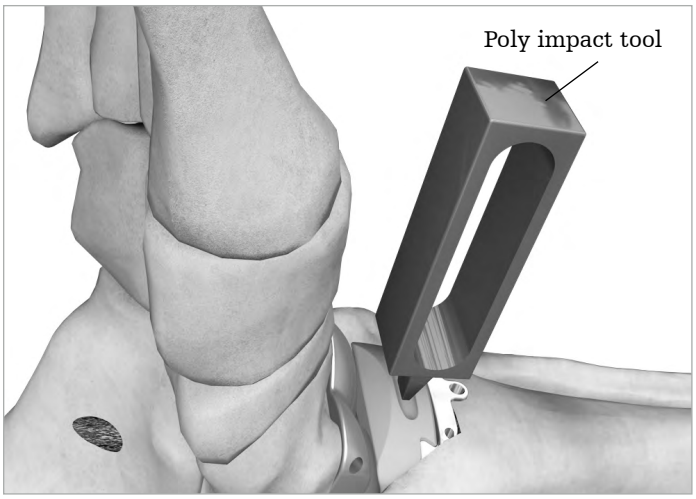
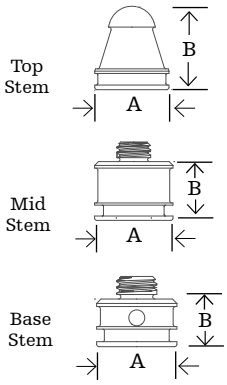


Figure 81

Implant specifications

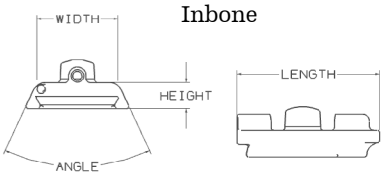
Note: All dimensions are shown in millimeters and have been approximated to the nearest half millimeter.

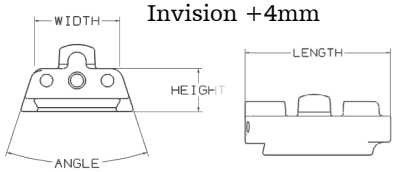


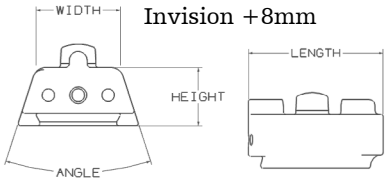
Stems

	Size 12mm		Size 14mm		Size 16mm		Size 18mm	
Implant	A	B	A	B	A	B	A	B
Top stem	12	18	14	18	16	18	N/A	N/A
Mid stem	12	9.5	14	9.5	16	9.5	18	13.5
Base stem	N/A	N/A	N/A	N/A	16	9.5	18	13.5

Tibial trays





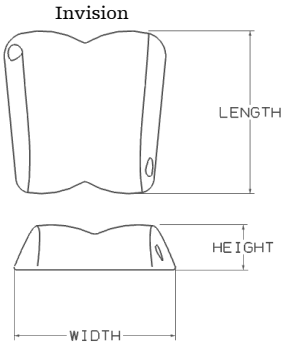


Size	Implant	Type	Height	Width	Angle	Length
2	Inbone	Standard	7	21	50	32
		Long				36
	Invision +4mm	Standard	10		33	33
		Long				36
	Invision +8mm	Standard	14			30
		Long				33

Size	Implant	Type	Height	Width	Angle	Length
4	Inbone	Standard	8	24.5	50	39
		Long				42
	Invision +4mm	Standard	11.5		39	40
		Long				43
	Invision +8mm	Standard	15.5			37
		Long				40

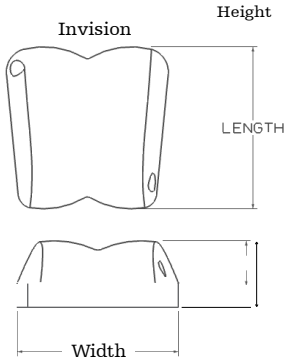
Size	Implant	Type	Height	Width	Angle	Length
3	Inbone	Standard	7.5	23	50	36
		Long				39
	Invision +4mm	Standard	11		36	37
		Long				40
	Invision +8mm	Standard	15			34
		Long				37

Size	Implant	Type	Height	Width	Angle	Length
5	Inbone	Standard	9	26	50	42
		Long				46
	Invision +4mm	Standard	12		41	43.5
		Long				46.5
	Invision +8mm	Standard	16			40.5
		Long				43.5



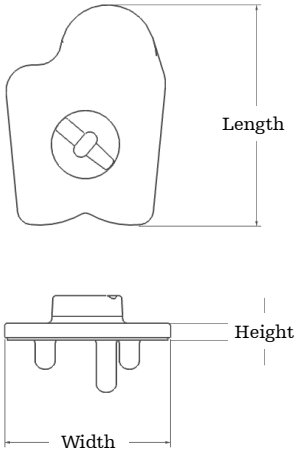
Standard talar domes

Implant	Width	Length	Height
Size 1	30	31.5	10
Size 2	33	34	10
Size 3	36	36	10
Size 4	39	39	11
Size 5	42	42	12



+3mm Talar domes

Implant	Width	Length	Height
Size 1	30	31.5	13
Size 2	33	34	13
Size 3	36	36	13
Size 4	39	39	14
Size 5	42	42	15



Talar plates

Size	Thickness	Type	Width	Length	Height
1	Standard	Standard	30	43.5	3mm
		Long		53.5	

Size	Thickness	Type	Width	Length	Height
3	Standard	Standard	35	48.5	3mm
		Long		58.5	

Size	Thickness	Type	Width	Length	Height
2	Standard	Standard	32	46.5	3mm
		Long		56.5	

Size	Thickness	Type	Width	Length	Height
4	Standard	Standard	38.5	52	3mm
		Long		62	

Size	Thickness	Type	Width	Length	Height
5	Standard	Standard	41.5	55	3mm
		Long		65	

Implant compatibility

Invision or Inbone tibia with Invision talus

Top stem	Mid stem	Base stem	Tibial tray	Poly insert	Dome	Talar plate
12mm 14mm 16mm	12mm 14mm 16mm	16mm	2	1+	1	1
				2	2	2
						3
12mm 14mm 16mm	12mm 14mm 16mm	16mm	3	2+	2	2
				3	3	3
						4
12mm 14mm 16mm	12mm 14mm 16mm 18mm	18mm	4	3+	3	3
				4	4	4
						5
12mm 14mm 16mm	12mm 14mm 16mm 18mm	18mm	5	4+	4	4
				5	5	5

Invision tibia with Inbone talus

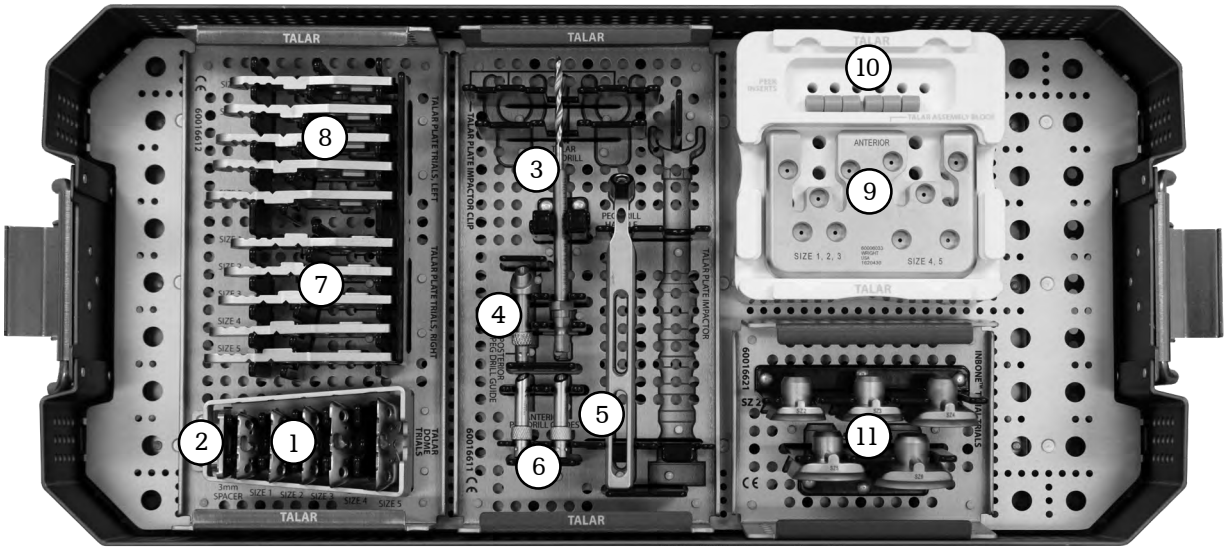
Top stem	Mid stem	Base stem	Tibial tray	Poly insert	Dome	Talar plate
12mm 14mm 16mm	12mm 14mm 16mm	16mm	2	1+	1	10mm 14mm
				2	2	
12mm 14mm 16mm	12mm 14mm 16mm	16mm	3	2+	2	10mm 14mm
				3	3	
12mm 14mm 16mm	12mm 14mm 16mm 18mm	18mm	4	3+	3	10mm 14mm
				4	4	
12mm 14mm 16mm	12mm 14mm 16mm 18mm	18mm	5	4+	4	10mm 14mm
				5	5	

Infinity tibia with Invision talus

Tibial tray	Poly insert	Dome	Talar plate
1 2	1+	1	1
	2	2	2
			3
3	2+	2	2
	3	3	3
			4
4	3+	3	3
	4	4	4
			5
5	4+	4	4
	5	5	5

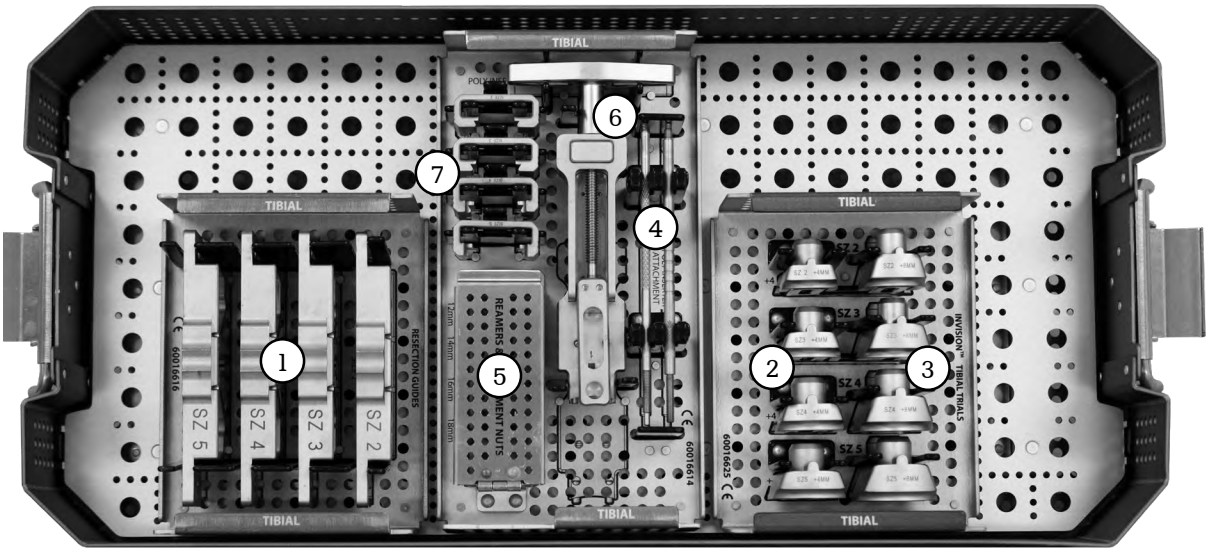
Ordering information

IVTPKIT1 — Invision



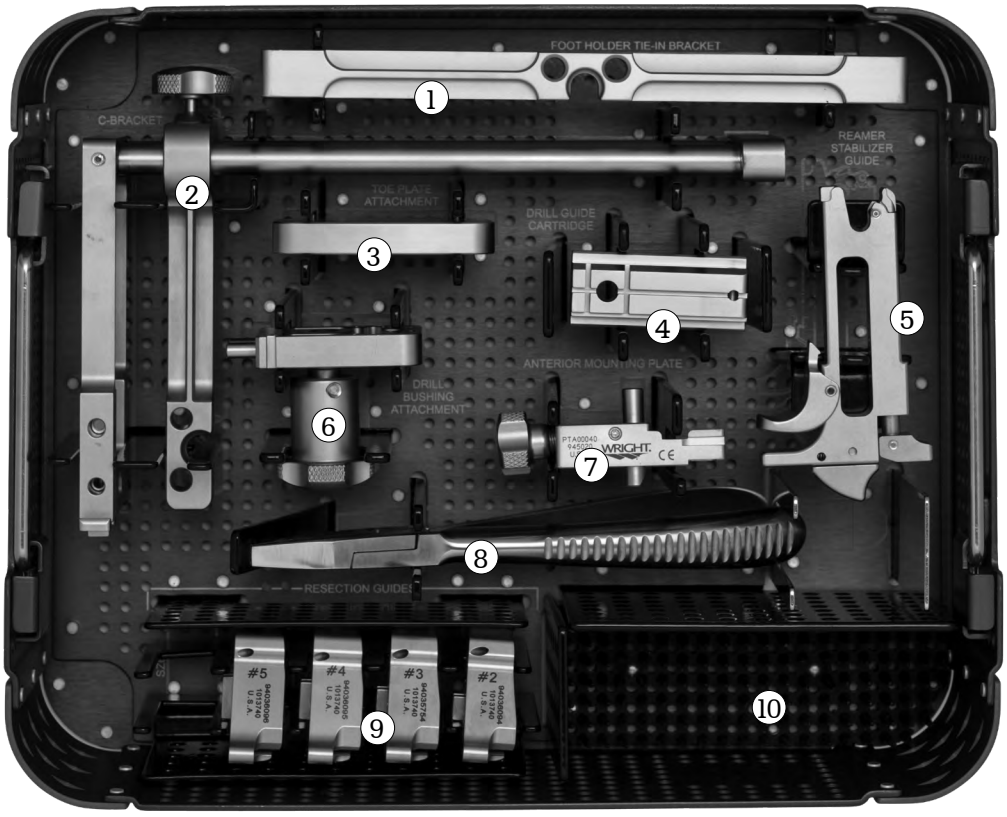
1. Inbone dome trial sizes 1-5 (IB220801-IB220805)
2. Talar trial plate spacer 3mm (60003001)
3. Invision peg drill (60006022)
4. Invision posterior peg drill guide (60006027)
5. Invision peg drill handle (60006012)
6. Invision anterior peg drill guide (60006011)
7. Invision talar plate trial sizes 1-5 right (60001110 - 60001150)
8. Invision talar plate trial sizes 1-5 left (60001010 - 60001050)
9. Invision talar assembly block (60006033)
10. Invision talar assembly Peek insert (60006034)
11. Inbone tibial trial sizes 2-6 (IB600020 - IB600060)

IVTTKIT1 — Invision



1. Invision resection guide sizes 2-5 (60002000-60005000)
2. Invision tibial tray trial sizes 2-5 +4mm (60002400 - 60005400)
3. Invision tibial tray trial sizes 2-5 +8mm (60002800 - 60005800)
4. Attachment screw (60006021)
5. Attachment screw nut (200329201) sharp tibial reamers (22001200 - 22001800)
6. Invision threaded poly inserter (60006018)
7. Invision poly inserter rail sizes 2-5 (60006002 - 60006005)

PTAKIT1 — Prophecy Inbone instrument kit



1. Foot holder tie-in bracket (PTA00080)
2. C-bracket (PTA00010)
3. Toe plate attachment (PTA00050)
4. Drill guide cartridge (PTA00070)
5. Reamer stabilizer guide (PTA00060)
6. Bushing attachment (PTA00020)
7. Anterior mounting plate (PTA00040)
8. Wire pliers (RR3034)
9. Resection guides (PTA00092 – PTA00096)
10. Prophecy Inbone instrument case (PTA0100)

PINVKIT1 — Prophecy Invision instrument kit

Part number	Description
PINV1000	Prophecy Invision TAL RSCTN guide
PINV2000	Prophecy Invision TIB RSCTN guide, size 2
PINV3000	Prophecy Invision TIB RSCTN guide, size 3
PINV4000	Prophecy Invision TIB RSCTN guide, size 4
PINV5000	Prophecy Invision TIB RSCTN guide, size 5
PINV0064	Prophecy Invision guide shim
PINV0074	Prophecy Invision TAL guide capture
PINV0075	Prophecy Invision TAL guide capture knob
60016618	Prophecy Invision spacer instrument caddy
60016619	Prophecy Invision resection instrument caddy

PINVKIT1 — Prophecy Invision instrument kit

1. Invision tibial resection guides sizes 2-5 (PINV2000 - PINV5000)
2. Guide shims (PINV0064)
3. Talar guide capture (PINV0074)
4. Talar guide capture knob (PINV0075)
5. Talar resection guide (PINV1000)

Note: Contact Stryker if material content information is required.

Inbone tibial stems plasma coated

Part number	Description
200011901	Top stem, 14mm
200011902	Top stem, 16mm
200011904	Top stem, 12mm

Part number	Description
200010901	Mid stem, 14mm
200010902	Mid stem, 16mm
200010903	Mid stem, 18mm
200010904	Mid stem, 12mm

Part number	Description
200009901	Base stem, 16mm
200009902	Base stem, 18mm

Inbone standard tibial tray

Part #	Description
200252902	Size 2, left, standard
200222902	Size 2, right, standard
200252903	Size 3, left, standard
200222903	Size 3, right, standard
200252904	Size 4, left, standard
200222904	Size 4, right, standard
200252905	Size 5, left, standard
200222905	Size 5, right, standard

Inbone long tibial tray

Part #	Description
220252902	Size 2, left, long
220222902	Size 2, right, long
220252903	Size 3, left, long
220222903	Size 3, right, long
220252904	Size 4, left, long
200222904	Size 4, right, long
220252905	Size 5, left, long
220222905	Size 5, right, long

Invision standard tibial tray

Part #	Description
60002401	Size 2, +4mm, standard
60002801	Size 2, +8mm, standard
60003401	Size 3, +4mm, standard
60003801	Size 3, +8mm, standard
60004401	Size 4, +4mm, standard
60004801	Size 4, +8mm, standard
60005401	Size 5, +4mm, standard
60005801	Size 5, +8mm, standard

Invision long tibial tray

Part #	Description
60002402	Size 2, +4mm, long
60002802	Size 2, +8mm, long
60003402	Size 3, +4mm, long
60003802	Size 3, +8mm, long
60004402	Size 4, +4mm, long
60004802	Size 4, +8mm, long
60005402	Size 5, +4mm, long
60005802	Size 5, +8mm, long

Everlast poly inserts

Part #	Description
22022106	Size 1+, 6mm thick, right & left
22022108	Size 1+, 8mm thick, right & left
22022110	Size 1+, 10mm thick, right & left
22022112	Size 1+, 12mm thick, right & left
22022206	Size 2, 6mm thick, right & left
22022208	Size 2, 8mm thick, right & left
22022210	Size 2, 10mm thick, right & left
22022212	Size 2, 12mm thick, right & left
22023208	Size 2+, 8mm thick, right & left
22023210	Size 2+, 10mm thick, right & left
22023212	Size 2+, 12mm thick, right & left
22023214	Size 2+, 14mm thick, right & left
22023308	Size 3, 8mm thick, right & left
22023310	Size 3, 10mm thick, right & left
22023312	Size 3, 12mm thick, right & left
22023314	Size 3, 14mm thick, right & left
22024310	Size 3+, 10mm thick, right & left
22024312	Size 3+, 12mm thick, right & left
22024314	Size 3+, 14mm thick, right & left
22024316	Size 3+, 16mm thick, right & left
22024409	Size 4, 9mm thick, right & left
22024411	Size 4, 11mm thick, right & left
22024413	Size 4, 13mm thick, right & left
22024415	Size 4, 15mm thick, right & left
22025410	Size 4+, 10mm thick, right & left
22025412	Size 4+, 12mm thick, right & left
22025414	Size 4+, 14mm thick, right & left
22025416	Size 4+, 16mm thick, right & left
22025509	Size 5, 9mm thick, right & left
22025511	Size 5, 11mm thick, right & left
22025513	Size 5, 13mm thick, right & left
22025515	Size 5, 15mm thick, right & left

Everlast large revision poly inserts

Part #	Description
22022114	Size 1+, 14mm thick, right & left
22022116	Size 1+, 16mm thick, right & left
22022214	Size 2, 14mm thick, right & left
22022216	Size 2, 16mm thick, right & left
22023216	Size 2+, 16mm thick, right & left
22023218	Size 2+, 18mm thick, right & left
22023316	Size 3, 16mm thick, right & left
22023318	Size 3, 18mm thick, right & left
22024318	Size 3+, 18mm thick, right & left
22024320	Size 3+, 20mm thick, right & left
22024417	Size 4, 17mm thick, right & left
22024419	Size 4, 19mm thick, right & left
22025418	Size 4+, 18mm thick, right & left
22025420	Size 4+, 20mm thick, right & left
22025517	Size 5, 17mm thick, right & left
22025519	Size 5, 19mm thick, right & left

Legacy poly inserts

Part #	Description
22022106	Size 1+, 6mm thick, right & left
22022108	Size 1+, 8mm thick, right & left
22022110	Size 1+, 10mm thick, right & left
22022112	Size 1+, 12mm thick, right & left
22022206	Size 2, 6mm thick, right & left
22022208	Size 2, 8mm thick, right & left
22022210	Size 2, 10mm thick, right & left
22022212	Size 2, 12mm thick, right & left
22023208	Size 2+, 8mm thick, right & left
22023210	Size 2+, 10mm thick, right & left
22023212	Size 2+, 12mm thick, right & left
22023214	Size 2+, 14mm thick, right & left
22023308	Size 3, 8mm thick, right & left
22023310	Size 3, 10mm thick, right & left
22023312	Size 3, 12mm thick, right & left
22023314	Size 3, 14mm thick, right & left
22024310	Size 3+, 10mm thick, right & left
22024312	Size 3+, 12mm thick, right & left
22024314	Size 3+, 14mm thick, right & left
22024316	Size 3+, 16mm thick, right & left
22024409	Size 4, 9mm thick, right & left
22024411	Size 4, 11mm thick, right & left
22024413	Size 4, 13mm thick, right & left
22024415	Size 4, 15mm thick, right & left
22025410	Size 4+, 10mm thick, right & left
22025412	Size 4+, 12mm thick, right & left
22025414	Size 4+, 14mm thick, right & left
22025416	Size 4+, 16mm thick, right & left
22025509	Size 5, 9mm thick, right & left
22025511	Size 5, 11mm thick, right & left
22025513	Size 5, 13mm thick, right & left
22025515	Size 5, 15mm thick, right & left

Legacy large revision poly inserts

Part #	Description
22022114	Size 1+, 14mm thick, right & left
22022116	Size 1+, 16mm thick, right & left
22022214	Size 2, 14mm thick, right & left
22022216	Size 2, 16mm thick, right & left
22023216	Size 2+, 16mm thick, right & left
22023218	Size 2+, 18mm thick, right & left
22023316	Size 3, 16mm thick, right & left
22023318	Size 3, 18mm thick, right & left
22024318	Size 3+, 18mm thick, right & left
22024320	Size 3+, 20mm thick, right & left
22024417	Size 4, 17mm thick, right & left
22024419	Size 4, 19mm thick, right & left
22025418	Size 4+, 18mm thick, right & left
22025420	Size 4+, 20mm thick, right & left
22025517	Size 5, 17mm thick, right & left
22025519	Size 5, 19mm thick, right & left

Inbone talar domes

Part #	Description
220220901	Size 1, right & left
220220902	Size 2, right & left
220220903	Size 3, right & left
220220904	Size 4, right & left
220220905	Size 5, right & left

Inbone talar stems

Part #	Description
200347901	10mm, long
200347902	14mm, long

Invision talar domes

Part #	Description
60002001	Size 1, standard
60002002	Size 2, standard
60002003	Size 3, standard
60002004	Size 4, standard
60002005	Size 5, standard
60022001	Size 1, +3mm
60022002	Size 2, +3mm
60022003	Size 3, +3mm
60022004	Size 4, +3mm
60022005	Size 5, +3mm

Infinity talar domes

Part #	Description
33630021	Flat Cut Talar Dome, Size 1
33630022	Flat Cut Talar Dome, Size 2
33630023	Flat Cut Talar Dome, Size 3
33630024	Flat Cut Talar Dome, Size 4
33630025	Flat Cut Talar Dome, Size 5

Invision standard talar plates

Part #	Description
6000501L	Size 1, left, 3mm, standard
6000501R	Size 1, right, 3mm, standard
6000502L	Size 2, left, 3mm, standard
6000502R	Size 2, right, 3mm, standard
6000503L	Size 3, left, 3mm, standard
6000503R	Size 3, right, 3mm, standard
6000504L	Size 4, left, 3mm, standard
6000504R	Size 4, right, 3mm, standard
6000505L	Size 5, left, 3mm, standard
6000505R	Size 5, right, 3mm, standard

Invision long talar plates

Part #	Description
6000511L	Size 1, left, 3mm, long
6000511R	Size 1, right, 3mm, long
6000512L	Size 2, left, 3mm, long
6000512R	Size 2, right, 3mm, long
6000513L	Size 3, left, 3mm, long
6000513R	Size 3, right, 3mm, long
6000514L	Size 4, left, 3mm, long
6000514R	Size 4, right, 3mm, long
6000515L	Size 5, left, 3mm, long
6000515R	Size 5, right, 3mm, long

Notes

Foot & Ankle

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Manufacturer:

Stryker Corporation
1023 Cherry Road
Memphis, TN 38117
800 238 7117
901 867 9971

stryker.com