

Infinity[®]

with Adaptis[™] Technology

Total Ankle System

with

Prophecy[®]

Preoperative Navigation Alignment Guides

with Resect-Through Option

Operative technique



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Surgeon design team

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Prophecy Preoperative Navigation Alignment Guides with
Resect-Through Option
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Table of contents

| | |
|---|----------|
| Product information | 4 |
| • Prophecy Guide product information | 4 |
| • Intended use | 5 |
| • Infinity with Adaptis Technology Total Ankle product information | 5 |
| Intended use | 5 |
| • Indications | 5 |
| • Contraindications | 5 |
| • CT scan protocol | 6 |
| • Important information | 6 |
| Operative technique | 7 |
| • Surgical approach | 7 |
| • Tibial resect-through guide | 7 |
| • Drill tibial corners | 12 |
| • Tibial bone resection | 13 |
| • Talar alignment guide | 14 |
| • Talar bone resection | 17 |
| • Remove tibial bone resection | 19 |
| • Tibial tray trialing and ap sizing | 21 |
| • Tibial peg broaching | 24 |
| • Talar component sizing and positioning | 25 |
| • Talar chamfer resections | 27 |
| • Polyethylene thickness | 31 |
| • Talar peg drilling | 32 |
| • Tibial component implantation | 33 |
| • Talar component implantation | 36 |
| • Polyethylene bearing installation | 37 |
| • Explant information | 41 |
| • Postoperative management | 41 |
| • Appendix A: Conversion to standard instrumentation | 42 |
| • Install sizing and resection guide adjustment block | 43 |
| • Coronal plane sizing and positioning | 44 |
| • Sagittal plane sizing and resection height | 46 |
| • Drill tibial corners | 50 |
| • Bone resection | 51 |
| • Appendix B: Conversion between chamfered talus resection level and flat cut talus resection level | 52 |
| • Tibial bone removal and preparation | 54 |
| • Implanting tibial tray | 54 |
| • Verify talar dome size | 54 |
| • Appendix C: Prophecy Flat Cut Talar Dome technique | 55 |
| • Talar bone resection | 56 |
| • Tibial bone removal and preparation | 57 |
| • Implanting tibial tray | 57 |
| • Verify talar dome size | 58 |
| • Trial reduction | 59 |
| • Talar preparation | 60 |
| • Install talar dome | 61 |
| • Polyethylene bearing installation | 61 |
| • Appendix D: Infinity with Adaptis Technology Instrumentation | 62 |
| • Appendix E: Implant specifications | 71 |
| • Appendix F: Ordering information | 73 |

Product information

Prophecy Guide product information

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



Intended use

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

Infinity with Adaptis Technology Total Ankle System product information

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

Ankle joint replacement components consist of a talar dome, a tibial platform, and an UHMWPE component. Components are available in a variety of sizes and design configurations intended for both primary and revision applications.



Intended use

Indications

The Infinity with Adaptis Technology Total Ankle is indicated for patients with ankle joints damaged by severe rheumatoid, posttraumatic, or degenerative arthritis.

The Infinity with Adaptis Technology 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

Contraindications include:

1. Osteomyelitis
2. Insufficient bone stock or bone quality
3. Infection at the ankle site or infections at distant sites that could migrate to the ankle
4. Sepsis
5. Vascular deficiency in the ankle joint
6. Skeletally immature patients (patient is less than 21 years of age at the time of surgery)
7. 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
8. Neuropathic joints
9. Excessive loads as caused by activity or patient weight
10. Patient pregnancy
11. Severely compromised musculature or neuromuscular function
12. Uncooperative patient or patient with neurologic disorders, incapable of following instructions

Warning:

This device is not intended for subtalar joint fusion or subtalar joint 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 wound 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 using patient anatomy from a CT scan of the patient's extremity. One significant requirement for a successful case is adhering to the Prophecy Ankle CT Scan Protocol document. Engineers at Stryker have determined the necessary scanning parameters, Please contact your local sales rep for the Prophecy specific scanning parameters.

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

Important information

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.

Further:

- 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.wright.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.

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

Operative technique

Surgical approach

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.

Tibial resect-through guide

Prophecy Infinity Resect-Through Guides (PROPINF) 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 preoperative plan, should be removed as they will not have been incorporated into the proper seating of the Prophecy Infinity Guides.

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 Resect-Through Guide in the best fit location. Please note that the guides are designed to fit in one and only one proper location.

Insert appropriately sized tibia resection insert (33689002 through 33689005) into resect-through guide, and lightly press to seat. (Figure 1)

Note:

The resection guide will not sit flush to the alignment guide, but will be approximately 2mm to 3mm proud. (Figure 1)

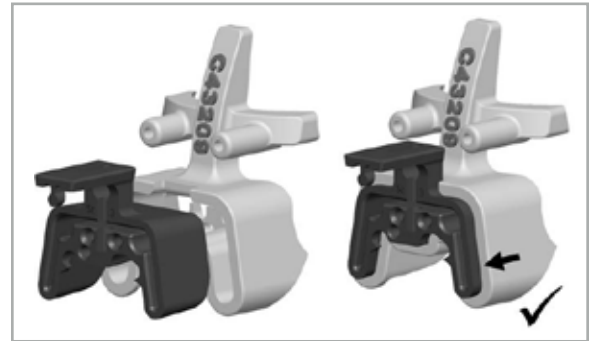


Figure 1



Prophecy Tibial Alignment Guide
Resect-Through version
PROPINF



Tibial resection guide insert
33689002 - 33689005

- 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.

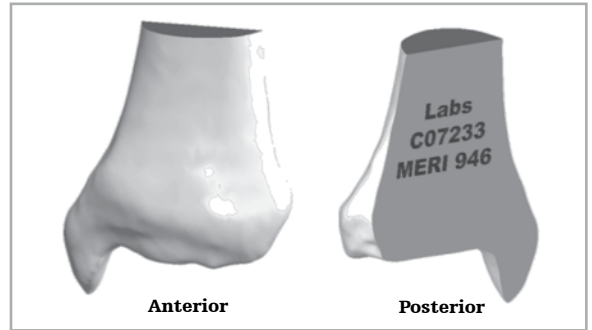
Note:

Use the provided bone models as an additional tactile and visual confirmation that the tibia guide is positioned correctly on the patient’s bone.

Once the guide is in the proper location, insert one 2.4 Steinmann pin (200072) into one of the straight holes in the metal tibial resection guide to temporarily hold it into position. (Figure 2)

Attach the Prophecy Conversion Instrument (33600200) to the tibia resection insert. Lock into position using the hex driver (E5001005). (Figure 3).

With the tibia guide held in place, take an A/P fluoro image to confirm that the tibial guide is in the correct orientation. To obtain a true A/P view rotate the ankle (or conversely the c-arm) until the fluoroscopic check feature is centered. (Figure 4) This image should correspond to the “anterior view” tibial resect-through guide image in the Prophecy preop plan. (Figure 5)



Prophecy Conversion Instrument 33600200



Hex driver E5001005



Figure 2

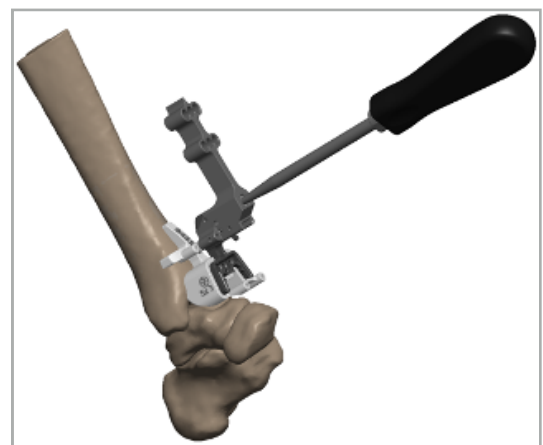
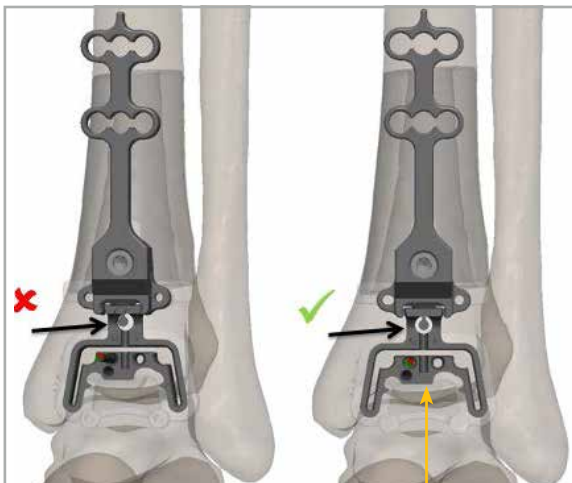
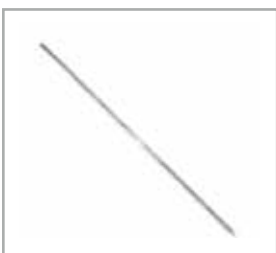


Figure 3



Anterior view Figure 4



Steinmann pin 200072



Figure 5

The x-ray of the Prophecy Conversion Instrument should correspond to the alignment reflected in the report (Figures 6 & 7).

Be sure to center the ankle on the fluoro projection screen to minimize the risk of parallax imaging error.

Note:

Proximal-distal and medial-lateral translation of the guide can be visualized at this time. The joint line indicators represent what will be the top of the implant articulating surface with the thinnest polyethylene (Figure 8).

If the intraop image is significantly different than the preop plan, remove the tibia guide as well as any pins holding it in place. Ensure the periosteum has been cleaned from the tibia, and that skin retractors are effectively keeping all other soft-tissues from interfering with the guide. It may also be beneficial to place the foot into slight plantarflexion and place a surgical bump under the tibia to elevate it. This allows the talus to drop away from the anterior tibia and prevent interference with the distal portion of the tibia guide.

Replace the tibia guide and repeat the procedure for AP fluoro check, using the opposite side pin hole to temporarily secure the guide in place.

Note:

By using only one pin to initially secure the guide, adjustments can be made to the guide location providing a second option to pin in place without finding the original pin hole.

Once the desired fit and alignment is confirmed, place a total of four 2.4mm Steinmann pins through the guide and through both cortices of the tibia. (Figure 9) Then trim the pins flush.



Figure 6

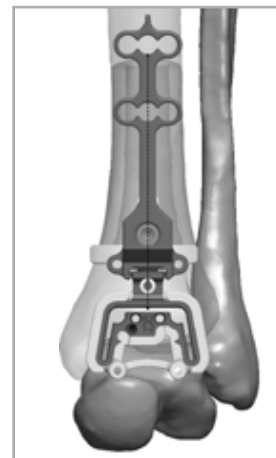


Figure 7



Pin cutters
200427



Figure 8
Joint line reference cues

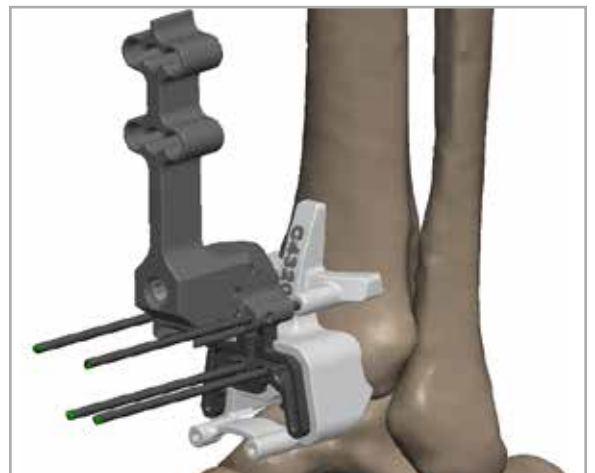


Figure 9

The surgeon may also choose to obtain a fluoroscopic lateral view of the ankle perpendicular to the installed tibial resect-through guide. This view is achieved when the medial and lateral pins in the tibia appear as one. In this view, the surgeon can verify the flexion/extension angle of the planned tibial resection. (Figure 10)

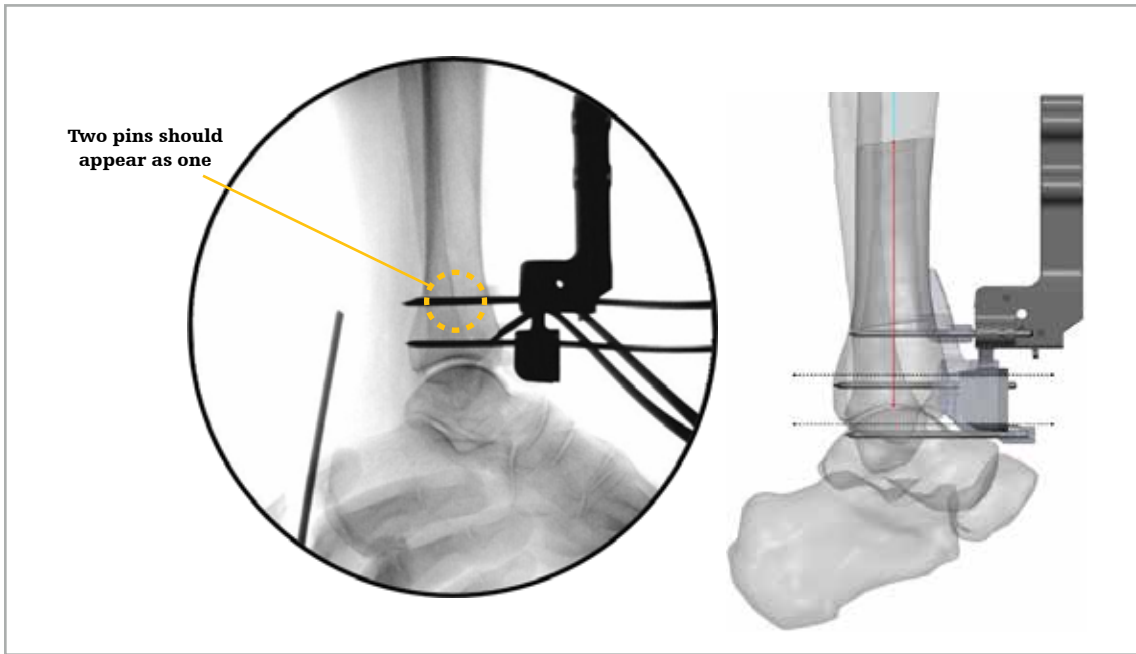


Figure 10

Note:

At this point, the surgeon can choose to revert back to the standard Infinity Instrumentation and operative technique if there are any concerns with the planned resection. Refer to Appendix A for detailed instructions.

Optionally, install a 2.4mm Steinmann pin through the divergent pin location to prevent the alignment guide from rising during sawing. To avoid damaging the posterior neurovascular bundle, ensure the pin does not advance past the posterior cortex. (Figure 11) Using the pin cutter (200427), trim the divergent pin; leave enough length to allow its removal with a pin driver or pin puller but short enough to allow saw blade clearance in the medial resection slot (approximately 15mm).



Figure 11

Option to couple the Talus Alignment

Note:

The talar holes for the option to couple alignment will only be included in the tibia guide as determined from the surgeon's preference preoperatively. Otherwise, with the exclusion of these pin holes, the following steps to couple tibia and talar alignment would not apply.

Note:

A separate talus resection guide can be used to complete the talus resection later as shown on page 14.

If talus pin holes exist in the tibia guide, the option to "couple" or manually position the talus underneath the tibia to achieve proper alignment and neutral dorsi-flexion position is available at this step. Using the joint line reference cues the surgeon may also choose to obtain a fluoroscopic coronal and sagittal views of the ankle prior to placing two Steinmann pins in the distal portion of the guide into the talus. (Figures 12a, 12b, & 12c)



Figure 12

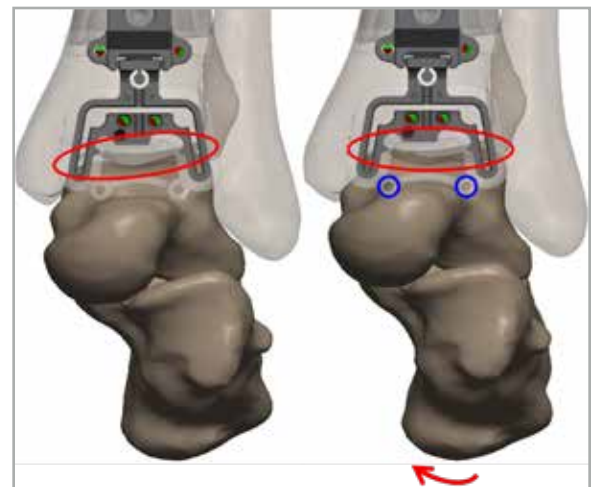


Figure 12a

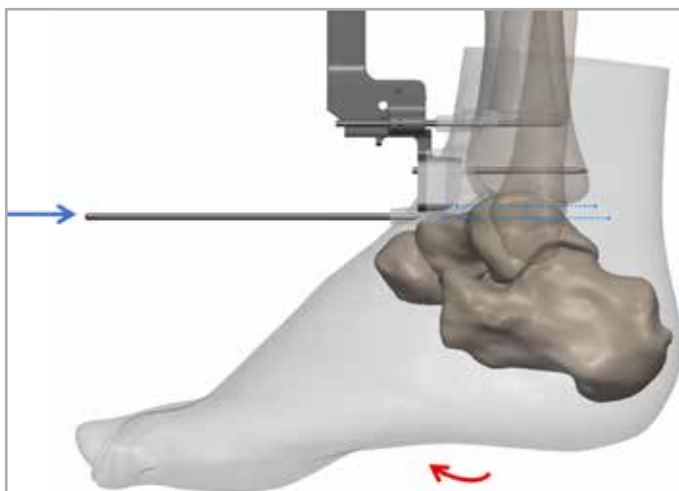


Figure 12b



Figure 12c

Drill tibial corners

Using the tibial corner drill (33600048), sequentially drill and then fill each of the proximal corners of the tibia with a corner protector peg (33689011). (Figures 13 & 13a) Ensure the drill goes bicortically without going into the posterior soft tissue.

The corner protector pegs prevent excursion of the saw blade past the saw slots, minimizing notches at the corners. The protector pegs are identical and can be used interchangeably in the medial and lateral corners of the tibia resection insert. Insertion can be done by hand or the head of the corner protector pegs can be loaded on to the hex driver (E5001005) to protect your fingers from the protruding Steinmann pins. (Figure 13a) With either insertion method, ensure the protector pegs are rotated with the outside shoulders hooking over the side of the resection insert. (Figure 14) A tactile click can verify that the corner pegs are fully seated.



Figure 13



Figure 13a

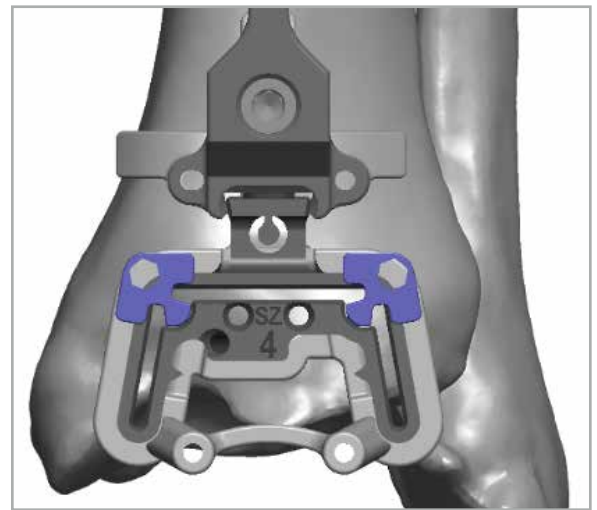


Figure 14



Tibial corner drill
33600048



Tibia corner protector peg
33689011

Tibial bone resection

Using the appropriate size saw blade and/or oscillating bone saw make the tibial resections only. The talar cut is not made at this time. (Figure 15)

Remove the divergent Steinmann pin, then remove the conversion instrument, corner protector pegs, and resection-through guide insert. Leave the two proximal tibial Steinmann pins and two talus Steinmann pins (if present). (Figure 16A)

At the top of the tibial cut, use an osteotome to cut down towards the talus at approximately 60° to remove the anterior section of the tibia. (Figure 16B) Remove as much of the tibia resection as possible; at a minimum, remove any anterior bone that may prevent proper seating of the Prophecy Talus Alignment Guide on the talar dome.



Figure 15

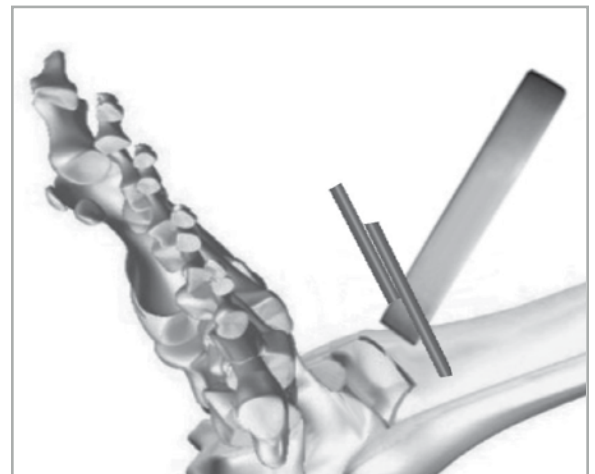


Figure 16A



Figure 16B

Talar alignment guide

If pins were not placed into the talus through the tibia alignment guide above, the talus alignment guide can be used next. Place the foot into plantar flexion for maximum exposure of the talar dome. Ensure the area around the neck and dome of the talus where the Prophecy Guide will surface match is free of all soft tissue. Place the Prophecy Talus Alignment Guide (PROPINF) on the talar surface in the best fit location.

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

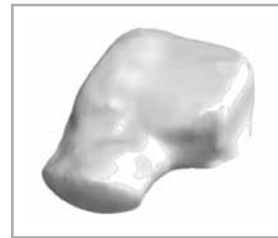
If any portion of the tibia bone prevents the talus guide from fitting properly on the talus, either remove more of the tibial resection or increase plantar flexion of the foot (or a combination of both).

Note:

Use the provided bone models as an additional tactile and visual confirmation that the talus guide is positioned correctly on the patient's bone.



Prophecy Talus Alignment Guide PROPINF



Anterior



Distal

While holding the Prophecy Guide in place install one 2.4mm Steinmann pin through either hole on the top surface of the guide and into the dome of the talus to temporarily hold the guide in place. Next, install two 2.4mm Steinmann pins through the anterior pin holes of the talus alignment guide and into the talar bone. Remove the Steinmann pin in the top of the guide. Do not cut the remaining pins at this time. Remove the Prophecy Guide by sliding it up and over the pins, leaving the pins in place. It may be helpful to attach a Kocher clamp to the notches built into the central triangular feature of the talar guide to pull the guide up. (Figure 17)

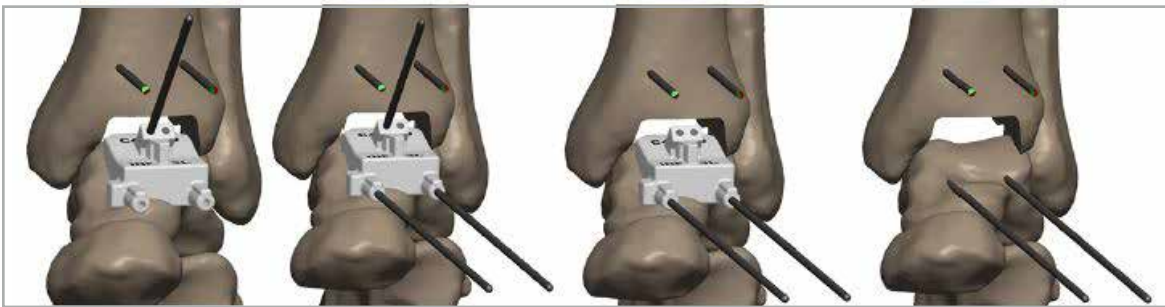


Figure 17

Note:

By using only one pin to initially secure the guide, adjustments can be made to the guide location providing a second option to pin in place without finding the original pin hole.

The surgeon has the option to fluoroscopically verify the proximal/distal location and flexion/extension angle of the talar component prior to talar resection. Obtain a true lateral view by aligning the c-arm so that both talar Steinmann pins appear as one. (Figure 18) The proximal talar resection for the Chamfered talus implant (white dashed line) will be parallel to and approximately 2mm proximal to the top of the Steinmann pin. (Figure 19)

Refer to the images in the report for visualization of the resection level relative to the pin. In addition the surgeon can compare to images in the Prophecy preop plan to verify accuracy of the talar guide. (Figure 20)



Figure 18



Figure 19

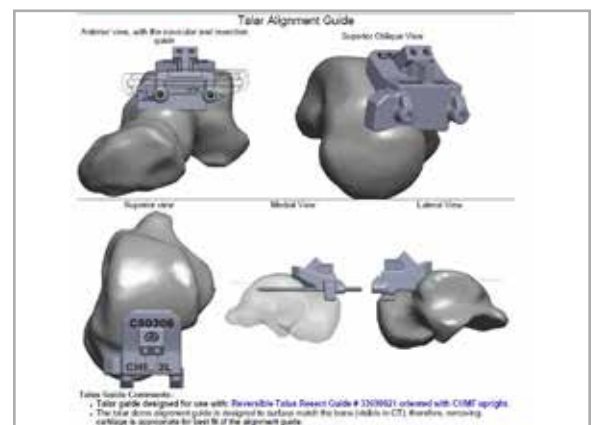


Figure 20

Note:

If the surgeon preoperatively chose to utilize an Infinity Flat Cut Talar Dome instead of an Infinity Chamfered Talar Dome, refer to Appendix C.

Talar bone resection

Refer to the patient’s Prophecy report for details regarding the appropriate talar resection guide type, paying special attention to the guide orientation, markings, and pin holes utilized. Typically, for a chamfered talar resection level, the reversible talar saw guide (33689021) should be positioned with the markings “CHMF” OR “CHF” upright. Position the reversible talar saw guide (33689021) over the talar pins and slide the guide down toward the talus. (Figure 21)

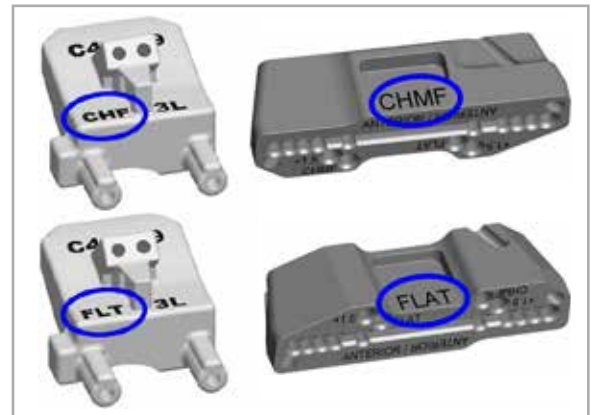


Figure 21

Note:

At this point, the surgeon still has the option to intra-operatively change to an Infinity Flat Cut talar resection. Refer to Appendix B for details on utilizing the reversible talar resection guide to translate the talar resection level and make the desired resection for a Flat Cut implant.

Insert two additional 2.4mm Steinmann pins into the medial and lateral gutters for protection of the malleoli. Optionally, install a 2.4mm Steinmann pin through one of the divergent pin locations. (Figure 22) Use the pin cutter to cut the Steinmann pins close 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.

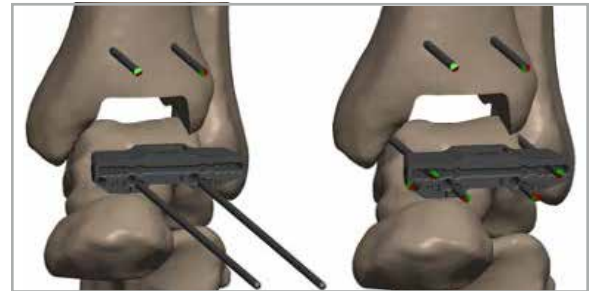


Figure 22

Care must be taken to ensure that the placement of the gutter pins does not unintentionally cause a shift in the position of the talar resection guide. In addition, any unintentional pressure applied to the talar resection guide by the soft tissue envelope or retractors may cause it to shift, leading to an inaccurate resection.

Using the appropriate saw blade and oscillating bone saw make the talar resection.



33689021

Located on the proximal plane of the talar resection guide is a notch that may be used to receive a generic instrument for manually holding the saw guide in position while making the talar resection. (Figure 22a)

Caution:

It may be necessary to manually hold the resection guide onto the bone as excessive vibration from the saw can cause the guide to move anteriorly and disengage from the pins.

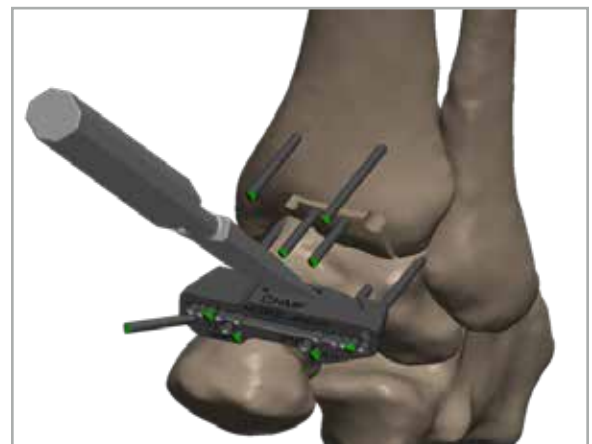


Figure 22a

The Prophecy Talar Resection Guide provides an option to adjust the resection level of the chamfer cut at an additional 1.5mm. To take an additional 1.5mm in the resection level, the resection guide can be placed in the proximal set of pin holes prior to the cut being made, or after the initial resection has been taken from the talus. (Figures 23 and 24)

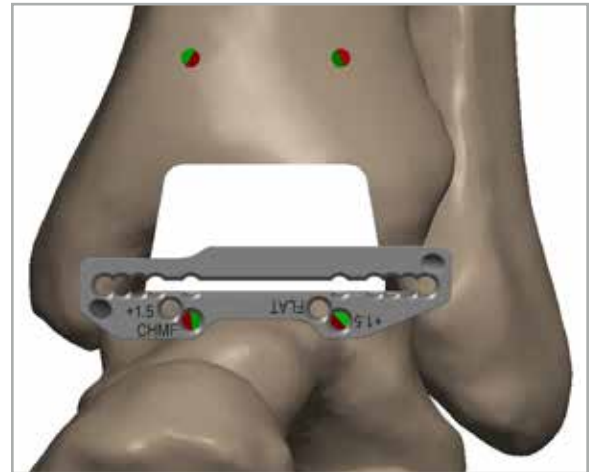


Figure 23

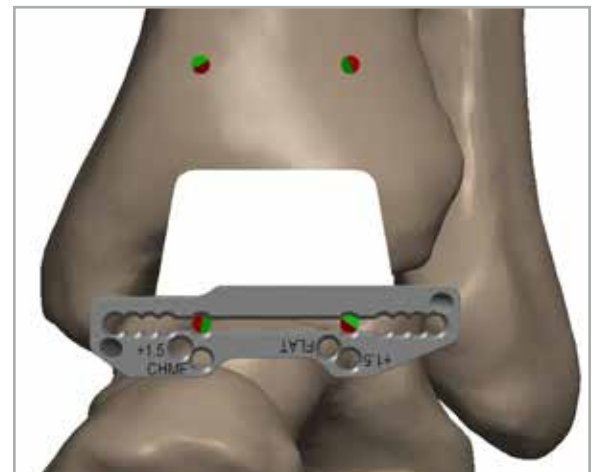


Figure 24

Remove the talar resection guide. Check that the talar resection is complete by using a 1/2 inch osteotome. Complete the cut if necessary and gently lever the resected dome out anteriorly.

Remove tibial bone resection

Optionally, to facilitate removal of the remaining posterior tibia, the corner chisel (33600058) and a mallet can be used to finish off bone cuts in the proximal corners of the resected tibia. (Figure 25) The corner chisel is laser marked to indicate the anterior to posterior depth of the various size tibial trays.

Caution:

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

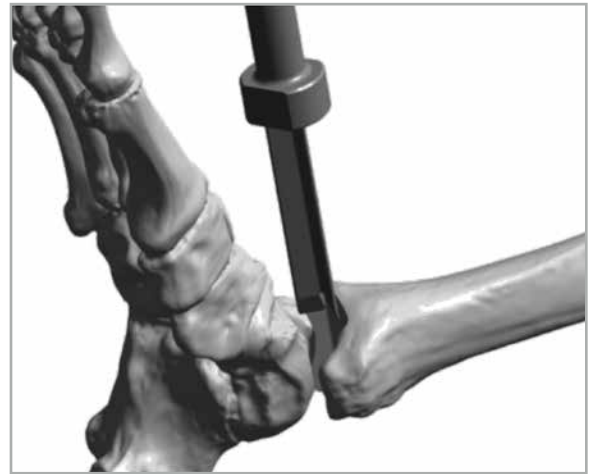


Figure 25



Corner chisel
33600058

Using a pin driver, insert the bone removal screw (IB200051) into the resected tibial bone. Attach the ratcheting handle (44180025) to the bone removal screw to aid in removing the remaining tibial section through traction. (Figure 26)

Insert the 90° posterior capsule release tool (IB200050) into the joint space and use to free up the posterior capsule soft tissues attachments to the resected tibia. (Figures 27 and 28)



Figure 26

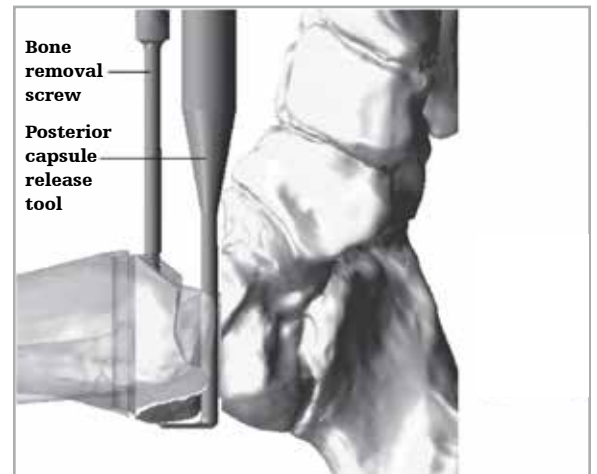


Figure 27



Bone removal screw
IB200051



Ratcheting handle
44180025



Posterior capsule
release tool
IB200050

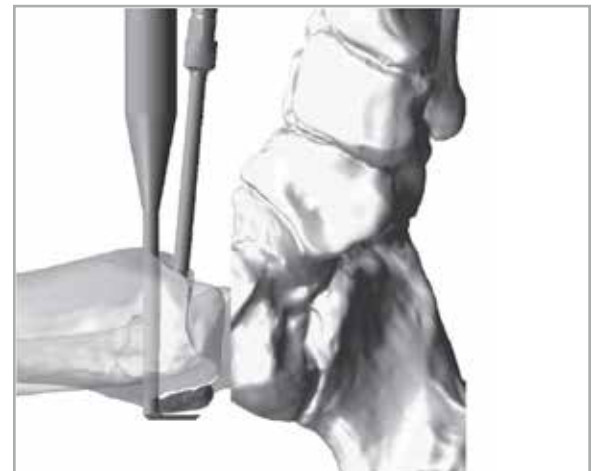


Figure 28

A reciprocating saw or bone rasp may be used to remove any excess bone, taking care to follow the previously made cut line. Remove loose bone pieces and irrigate the joint space. (Figure 29)

Tibial tray trialing and AP sizing

Place the appropriately sized tibial tray trial (33620061 – 33620065) over the two remaining tibial pins and into the resected joint space. (Figure 30) The padded self-retaining laminar spreaders (33609012) should be inserted between the trial and the talus to ensure the trial is seated flush. Ensure the tibial trial is fully seated against the anterior cortex of the tibia. (Figure 31) Pins may be trimmed flush to the tibial tray trial.

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



Figure 29



Figure 30



Tibial tray trial
33620061 - 33620065



Self-retaining laminar spreaders
33609012

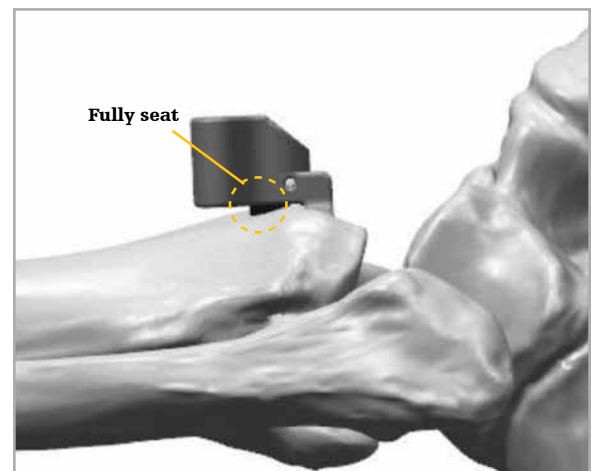


Figure 31

The tibial trial allows the surgeon to determine both the optimal AP tibial coverage and positioning through fluoroscopic evaluation. (Figure 32)

For sizes 3 through 5, the surgeon has the option to choose either a standard or long AP sized tibial tray. The notch in the tibial trial indicates the length of the “standard” option. (Figures 33 and 34)

Tibia component sizes 1 and 2 are each available in only one AP length. Because they share the same ML dimension, they utilize the same tibial trial. When using the size 1 and 2 tibia trial, the full length represents the size 2 and the notch indicates the length of the size 1 option.



Figure 32

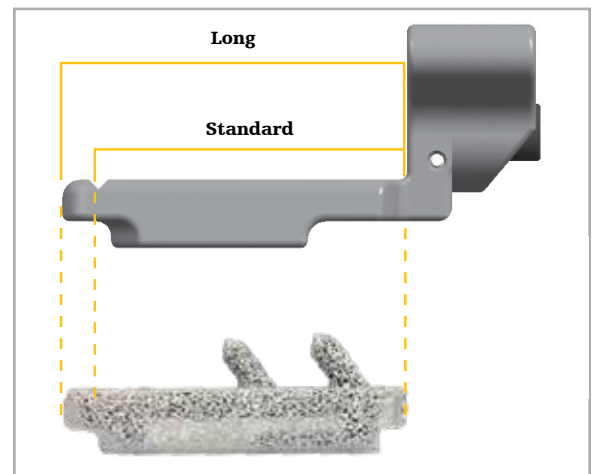


Figure 33

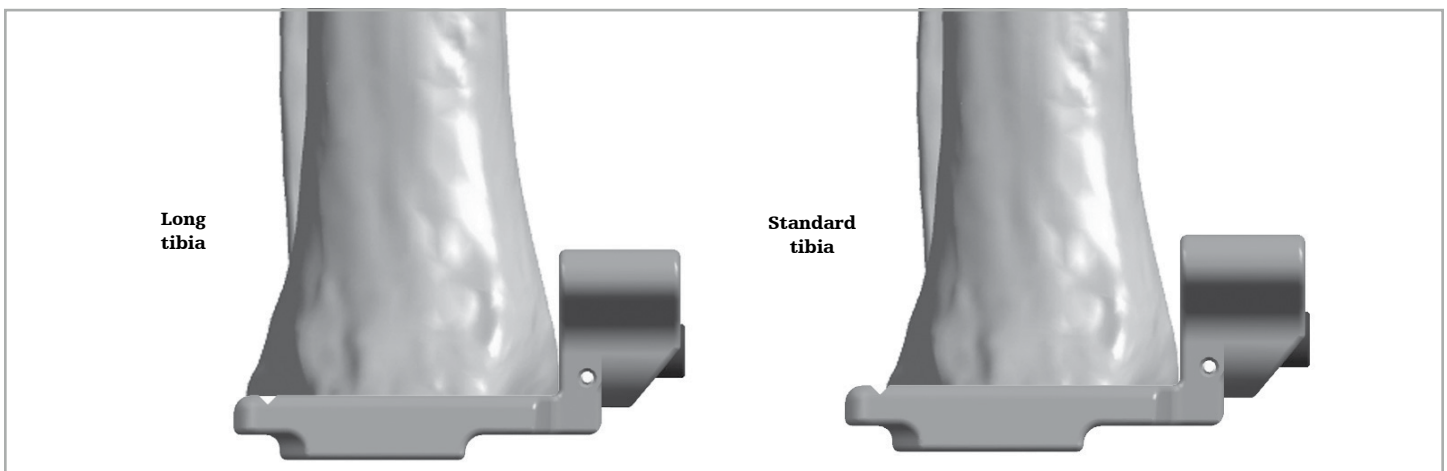


Figure 34

The surgeon also has the option to anteriorly translate the tibial trial (maximum of 3mm) in order to minimize posterior overhang if desired. (Figure 35) To adjust, insert the hex driver into the front of the tibial trial and turn clockwise. (Figures 36 and 37)

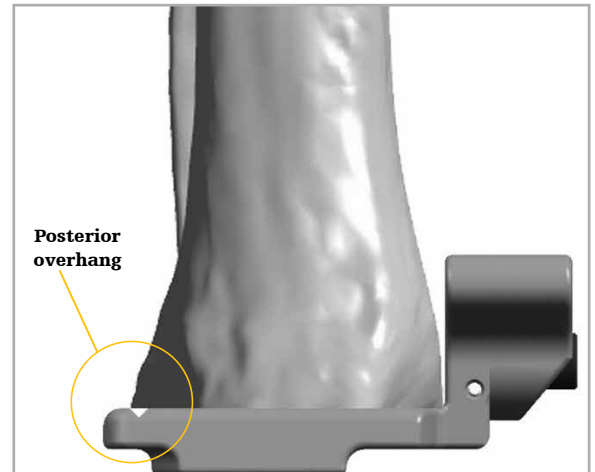


Figure 35

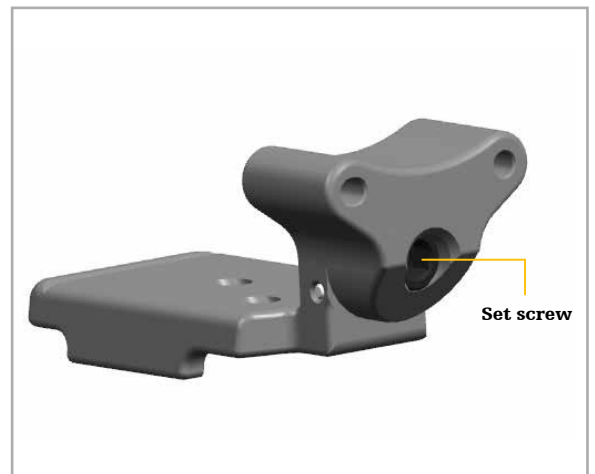


Figure 36

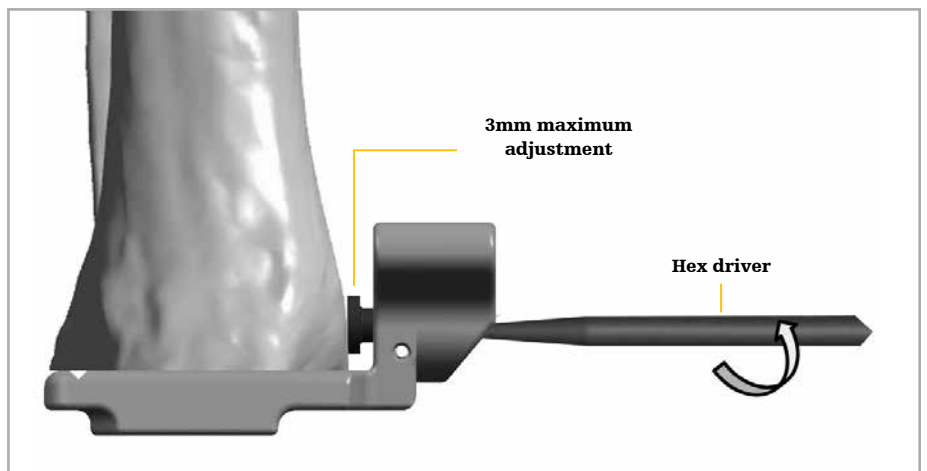


Figure 37

Tibial peg broaching

Cut the Steinmann pins to the surface of the tibial tray trial. Using the posterior tibial peg broach (33600069), prepare a hole in the resected tibia by malleting the broach through the posterior opening of the trial. (Figure 38) Temporarily leave the posterior broach in place while the two anterior holes are prepared.

Using the anterior tibial peg broach (33600067), prepare the two anterior holes through the trial. (Figure 39)

After all three holes are prepared, remove both broaches and leave the tibial tray trial in place. (Figure 40)

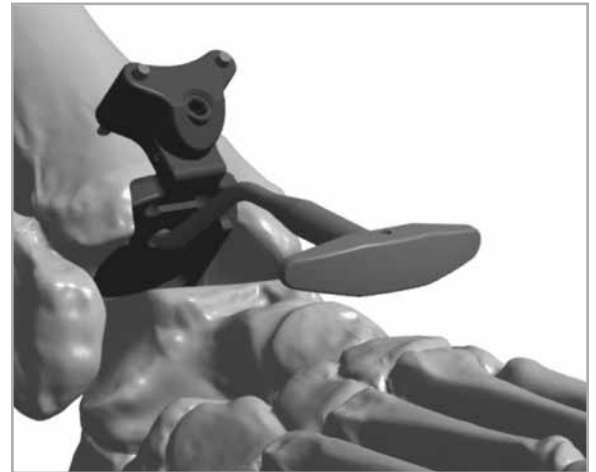


Figure 38



Figure 39



Anterior tibial peg broach
33600067



Posterior tibial peg broach
33600069



Figure 40

Talar component sizing and positioning

Place the appropriately sized talar dome trial (33600071 – 33600075) into the joint space. Using the poly insert trial holding tool (IB200110), install the appropriately sized poly insert trial (33621106 – 33625512) into the tibial tray trial. The locking tab of the poly insert trial should engage the tibial tray trial. (Figure 41)

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

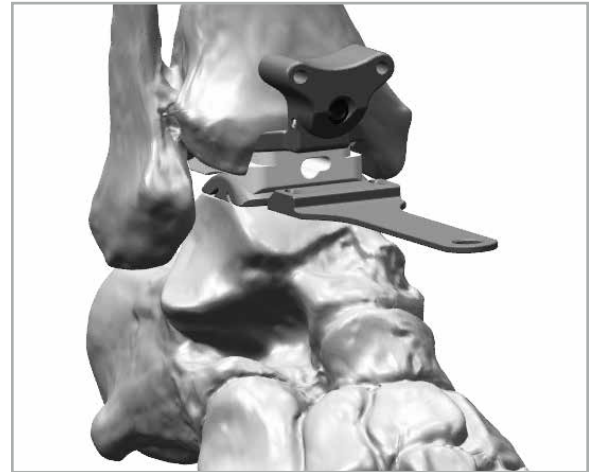


Figure 41



Poly trial holding tool
IB200110



Poly insert trial
33621106 - 33625512



Talar dome trial
33600071 - 33600075

Under sagittal plane fluoroscopy, ensure the posterior portion of the talar trial is resting on the posterior portion of the patient's residual talus (establish congruence). (Figures 42 and 43)

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, establishing the center of rotation for the ankle. Note that the surgeon must not only be cognizant of the talar position in the sagittal plane, but must simultaneously maintain medial/lateral coverage as evidenced by the previous A/P plane fluoroscopic views.

Once the talar dome trial has settled into optimum anatomical position, hold the foot in place and install two 2.4mm Steinmann pins through the talar dome trial to temporarily hold it in place. (Figure 44)

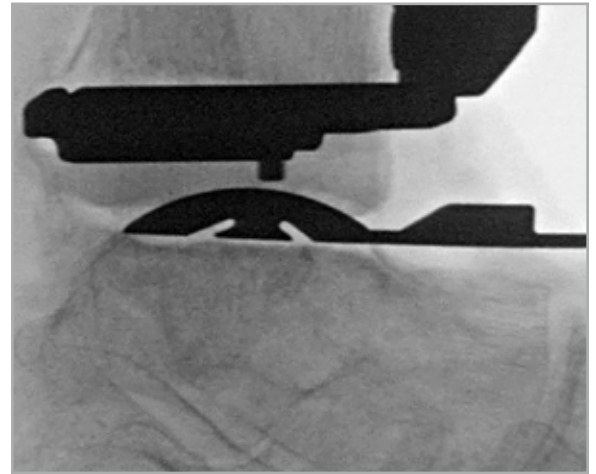


Figure 42

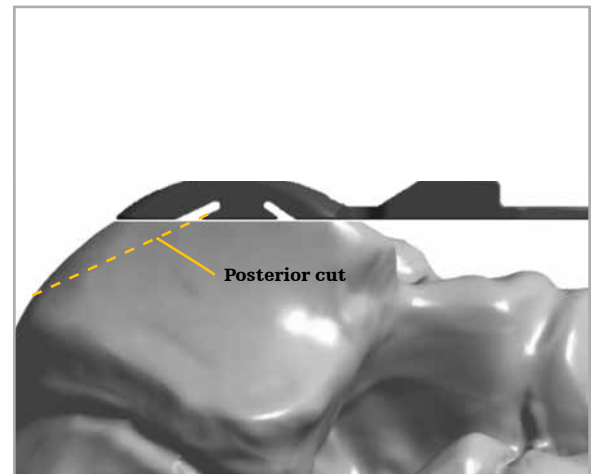


Figure 43

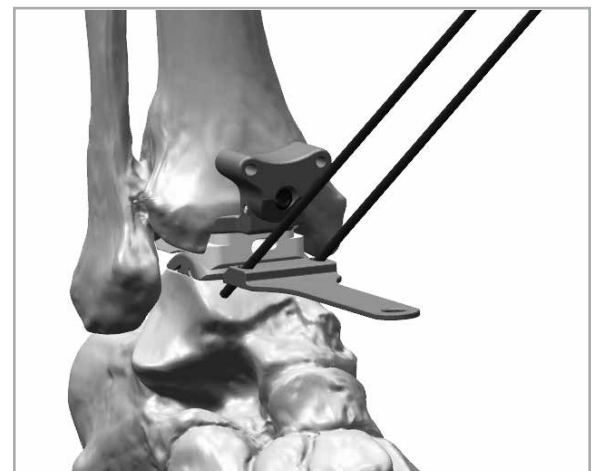


Figure 44

Talar chamfer resections

Using the poly insert trial holding tool, remove the poly insert trial. Slide the talar dome trial off the 2.4mm pins in the talus and slide the tibial tray trial off the 2.4mm pins in the tibia. (Figure 45) The two 2.4mm tibial pins may now be removed as well.

Slide the talar resection guide base (33600091 – 33600095) onto the two 2.4mm pins in the talus and seat flush to the resected talar surface. (Figure 46)

Using the T-handle pin driver (33600120) or under power, install two temporary fixation screws (33610002 or 33610003) through the talar resection guide base into the talus. (Figure 47)

Caution:

When installing the temporary fixations screws, care must be taken to avoid over torqueing. It is recommended to install the screws to 3/4 of their entire depth under power, finishing with the T-handle, to avoid inadvertent breakage.

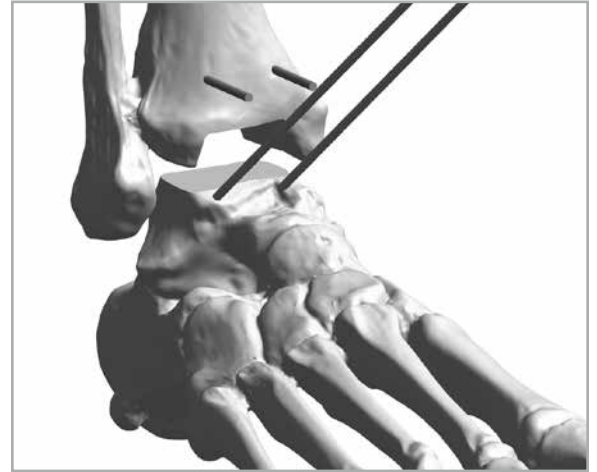


Figure 45



Figure 46



Talar resection guide base
33600091 - 33600095



Temporary fixation screw
Long - 33610002
Short - 33610003



T-handle pin driver
33600120



Figure 47

Using the appropriately sized saw blade and oscillating or reciprocating bone saw, make the posterior talar chamfer resection through the slot in the talar resection guide base. (Figure 48)

Remove the two anterior 2.4mm pins. One of these pins can then be installed through the anterior pin hole in the guide base to provide additional fixation during the talar preparation steps. Cut this pin flush to the surface of the guide base to prevent interference with the saw blades and reamers. (Figure 49)

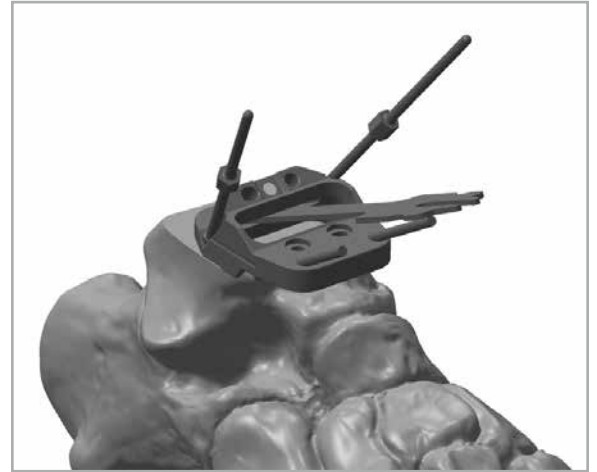


Figure 48

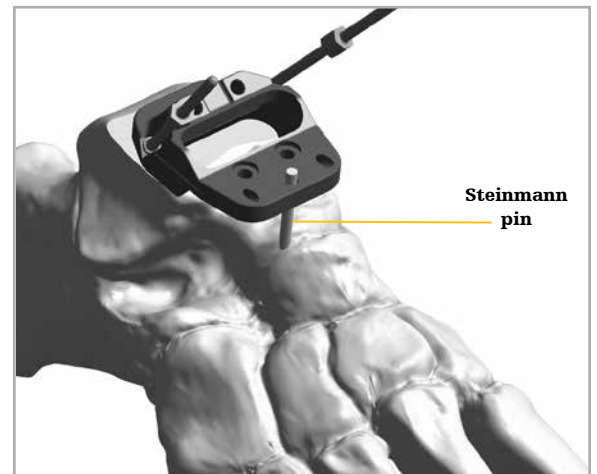


Figure 49

Assemble the anterior talar pilot guide (33600101 – 33600105) with pegs facing down onto the anterior face of the talar resection guide base. (Figure 50)

Use the appropriately sized talar reamer (33600123 or 33600126) to plunge cut through all four holes of the pilot guide. (Figure 51) This will prepare the talar surface for the anterior flat of the talar component.

Remove the pilot guide and replace with the anterior talar finish guide (33600111 – 33600115). (Figure 52)

Use the talar reamer to perform the finishing cuts for the anterior talar flat by sliding the reamer from side to side within the finish guide. (Figure 53) to ensure bone cuts are at the proper depth make sure the shoulder of the reamer is flush against the guide for each reaming step.

Caution:
Take care not to rock or dislodge the pilot/finishing guide and guide base during reaming.

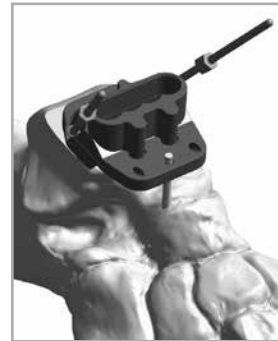


Figure 50

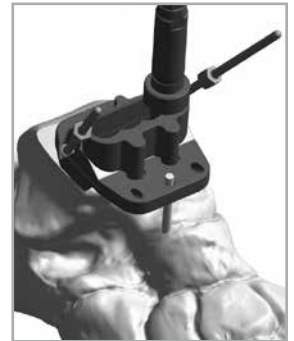


Figure 51



Figure 52



Figure 53



Anterior talar pilot guide
33600101 - 33600105



Talar reamer
Size 1-3 - 33600123
Size 4-5 - 33600126



Anterior talar finish guide
33600111 - 33600115

Remove the finish guide and reassemble the pilot guide onto the talar resection guide base. The pilot guide will now be rotated 180° from the previous steps. (Figure 54)

Again, use the talar reamer to plunge cut through all four holes of the pilot guide. (Figure 55) This will prepare the talar surface for the anterior chamfer of the talar component.

Remove the pilot guide and assemble the finish guide to complete the preparation of the anterior chamfer. (Figure 56)

Using the talar reamer, perform the finishing cuts for the anterior talar chamfer by sliding the reamer from side to side within the finish guide. (Figure 57)



Figure 54



Figure 55



Figure 56



Figure 57

Remove the fixation pins and resection guide base and remove any residual bone medial and lateral to the prepared chamfer cuts using either an osteotome or rongeur. (Figure 58)

Caution:

Failure to adequately remove residual bone from resected edges may lead to improper seating of the talar component.

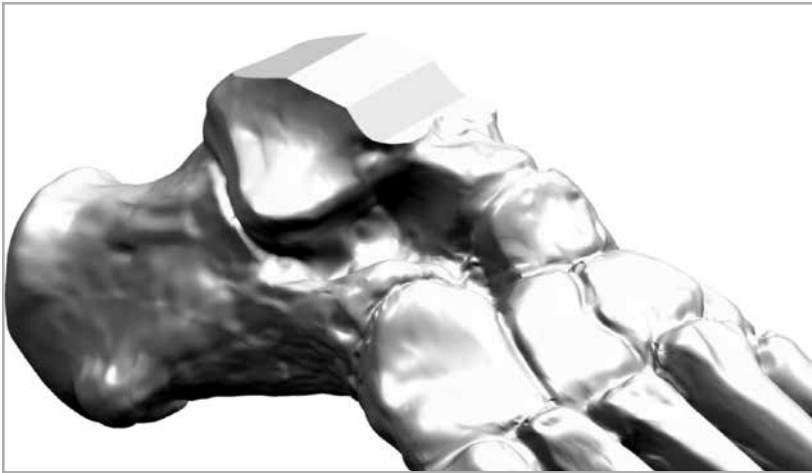


Figure 58

Polyethylene thickness

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

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

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

Talar peg drilling

Replace the tibial tray trial over the 2.4mm pins in the tibia. Insert the appropriately sized talar peg drill guide (33600161 – 33600165) into the joint space and over the resected talus. Reinstall the poly insert trial into the tibial tray trial and perform a trial reduction to establish optimal talar medial/lateral positioning. (Figure 59)

Slightly plantarflex the foot and install a 2.4mm Steinmann pin through the talar peg drill guide to temporarily hold it in position. (Figure 60)

Using the 4mm anterior peg drill (IB200020), drill a hole through the medial and lateral openings in the talar dome trial. The drill has a hard stop designed to set the appropriate drilling depth in the talus for the talar dome anterior pegs. (Figure 61)



Figure 59

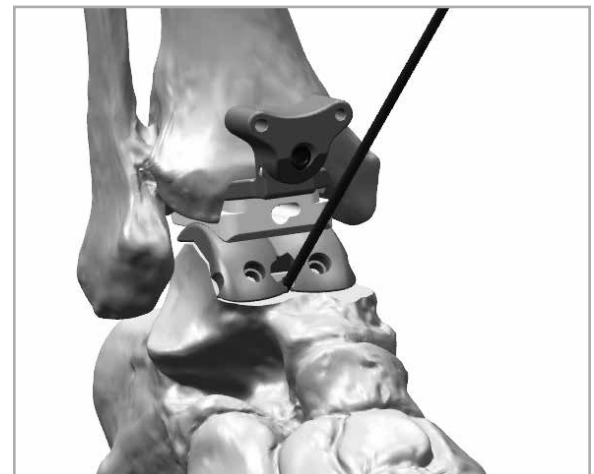


Figure 60



Talar peg drill guide
33600161 - 33600165



Anterior peg drill
IB200020



Figure 61

Tibial component implantation

Remove the 2.4mm pins in the talus and tibia and remove the talar peg drill guide, poly insert trial and tibial tray trial from the joint space. (Figure 62)

Choose the appropriately sized tibial tray impaction insert (33620132 – 33620135) and assemble the tibial tray component by sliding over the dovetail opening. (Figure 63)

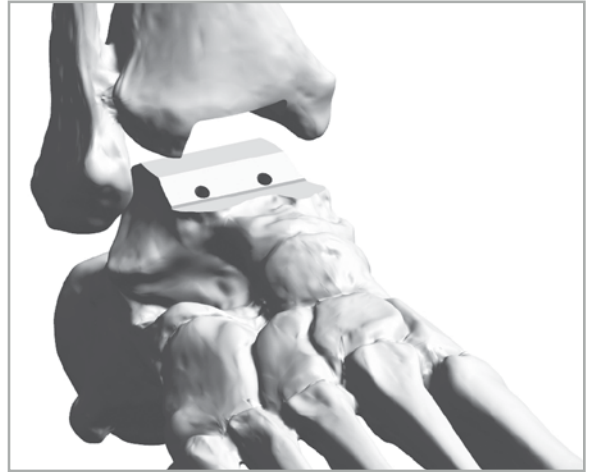


Figure 62

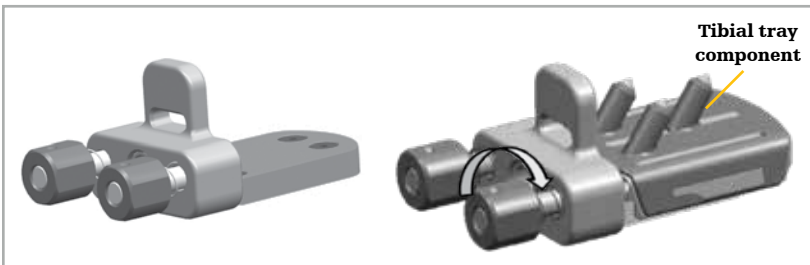
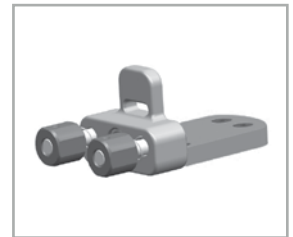


Figure 63

If choosing to cement, apply bone cement to the top and side walls of the tibial tray component, taking care not to get any cement on the anterior face or bottom of the tray.

Caution:

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



Tibial tray
impaction insert
33620132 - 33620135

Thread the insertion handle (33600130) into the front of the tibial tray impaction insert and begin insertion of the tibial tray component. Introduce the tibial tray into the joint space, ensuring all three pegs of the component are aligned with the prepared holes in the tibia. (Figures 64 and 65)

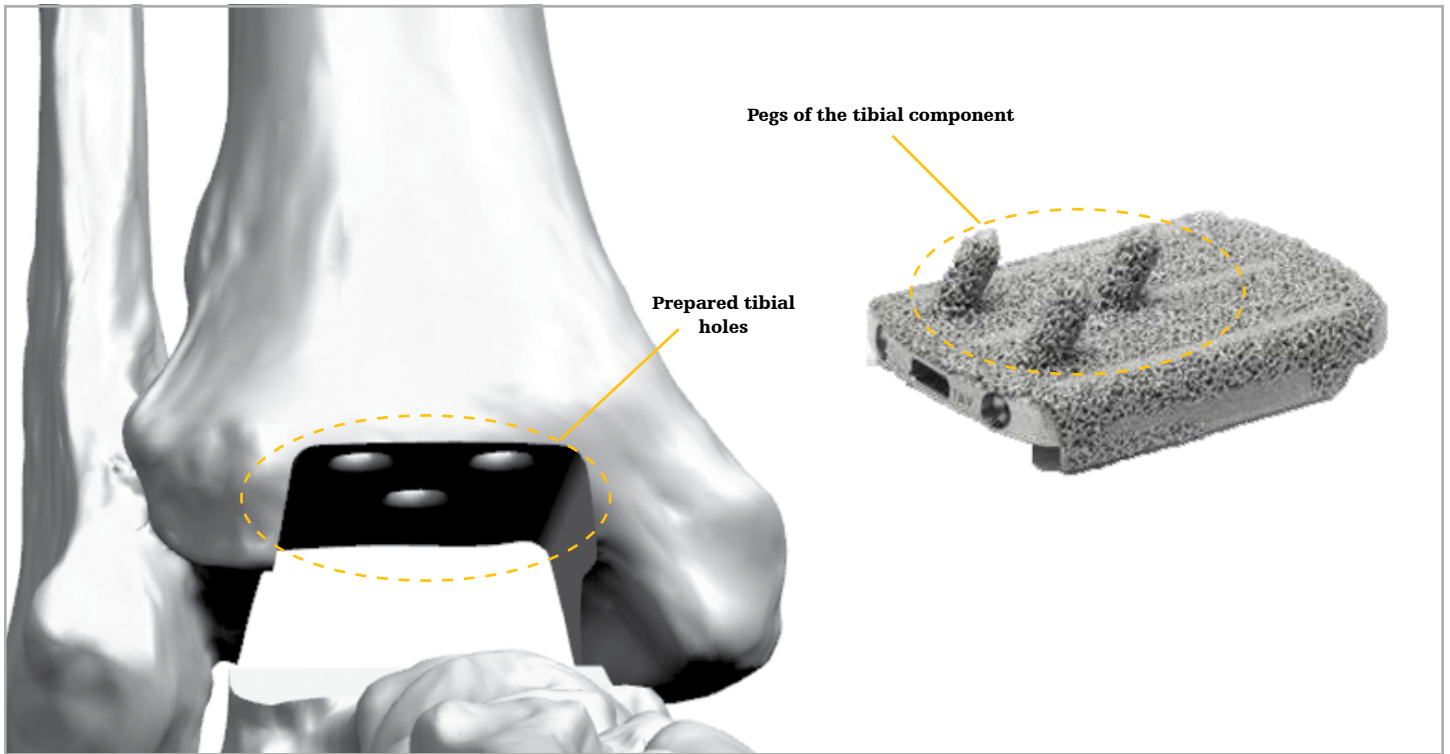


Figure 64



Insertion handle
33600130

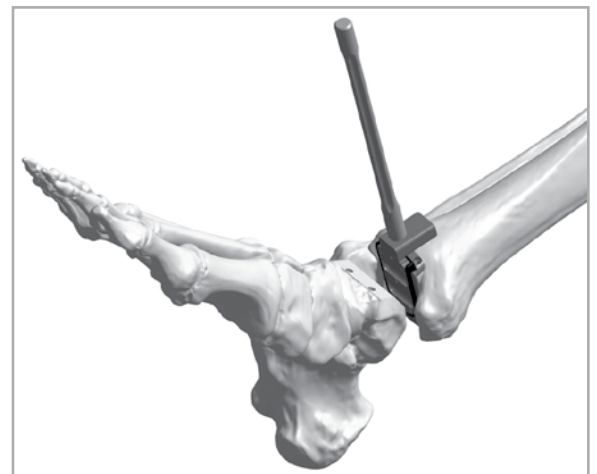


Figure 65

Use the offset tibial tray impactor (33600140) to complete the seating of the tibial tray. The impactor handle can be used on the lateral or medial side of the foot depending on surgeon preference. (Figure 66)

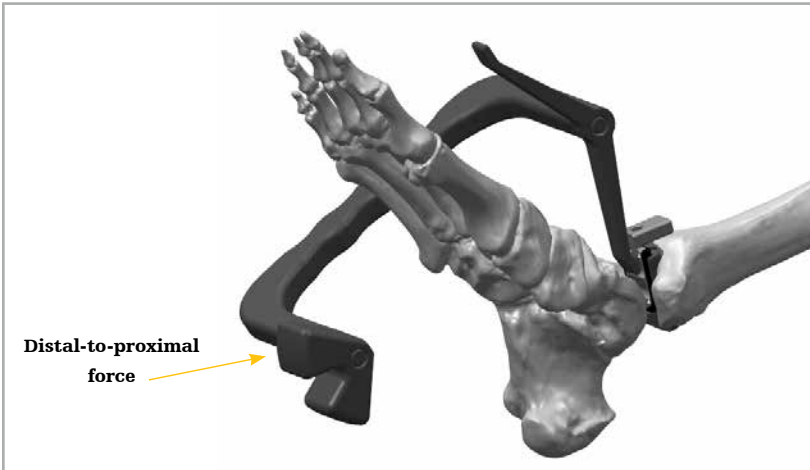


Figure 66



Offset tibial tray impactor
33600140



Straight tibial tray impactor
33600141

There are two impaction notch locations within the tibial tray impaction insert, one anterior and one posterior. For optimal results, proceed slowly beginning with the posterior notch and alternating between both impaction points. Verify progress via fluoroscopic imaging.

The straight tibial tray impactor (33600141) can also be used to help seat the tibial tray, using an impaction force in line with the angled tibial tray pegs.

Caution:

it is important that the anterior surface of the tibial tray contacts and sustains load upon the anterior tibial cortex with weight bearing. Striking the impactor with excessive force or continuing to strike the impactor after the tibial tray is fully seated can result in the tibial tray pegs, plowing through cancellous bone leaving the tibial tray posteriorly translated from the anterior tibial cortex.

Talar component implantation

Insert the appropriately sized tibial tray protector (33620152 – 33620155) into the tibial tray to protect the talar dome surface during installation. (Figure 67)

If choosing to cement, apply bone cement to the bottom surface of the talar dome.

Caution:

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

Start insertion of the talar dome component into the joint space, introducing by hand to ensure the talar pegs align with the drilled holes in the talus. Remove the tibia tray protector and insert the assembled talar dome impactor (IB200030 and IB200031), aligning tip with the sulcus of the talar dome. (Figure 68) With the ankle in plantar flexion, strike the impactor to seat the talus posteriorly first followed by final seating with a direct vertical force being careful not the lever on the seated tibial base plate.

Utilize a lateral fluoroscopic image to verify that the component is fully seated. (Figure 69)

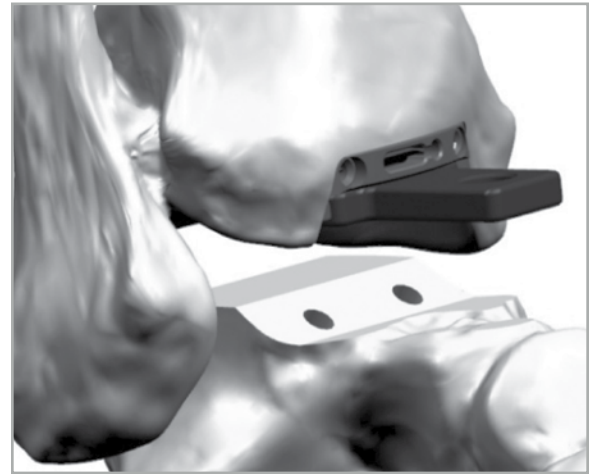


Figure 67

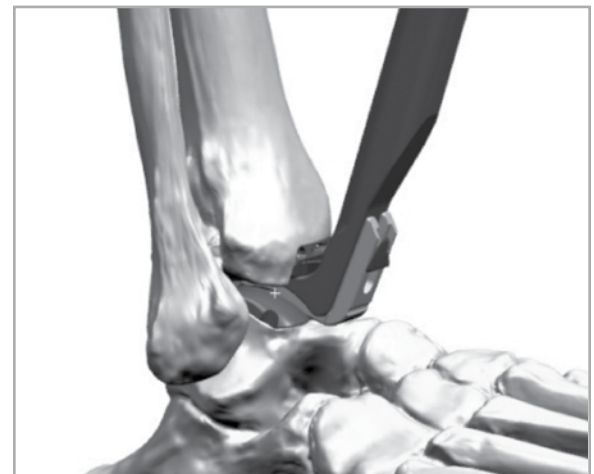


Figure 68



Tibial tray protector
33620152 - 33620155



Talar dome impactor
IB200030
Impactor tip
IB200031

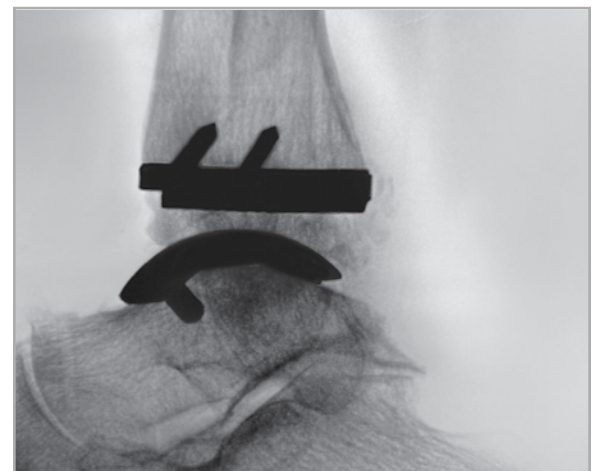


Figure 69

Polyethylene bearing installation

Install two attachment screws (33600190) into the anterior face of the tibial tray. (Figure 70)

Assemble the poly insert guide rail (33600172 – 33600175) onto the poly inserter (33600170) and ensure that the plunger handle is pulled back completely and locked in the start position. (Figure 71)



Figure 70

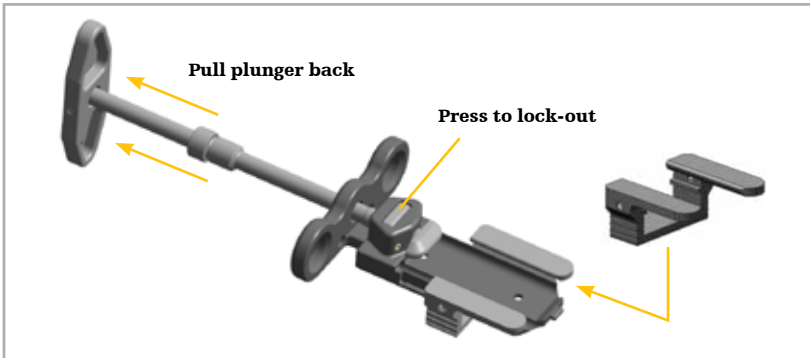


Figure 71

Slide the dovetail feature of the poly insert implant into the poly insert guide rail ensuring correct A/P orientation of the component. (Figure 72)

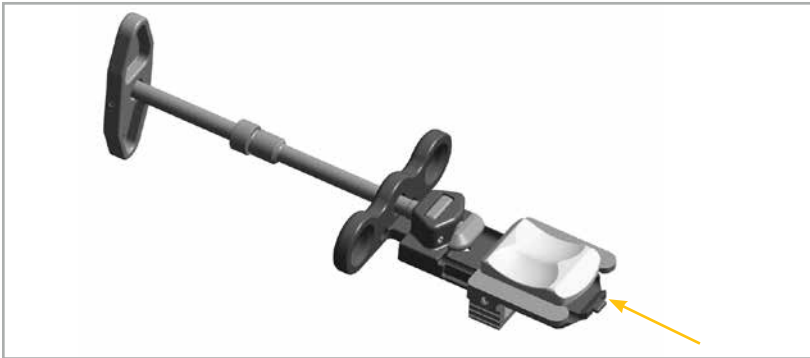


Figure 72



Attachment screw
33600190



Poly inserter
33600170



Poly insert guide rail
33600172 - 33600175

Slide the poly inserter assembly over the attachment screws and flush to the surface of the tibial tray. Thread an attachment nut (33600191) over the end of each attachment screw to tightly secure the poly inserter in place. (Figure 73)

Caution:

Properly irrigate prior to poly insertion. It is important to remove any fragments of bone or soft tissue from the lock detail on the tibial tray to insure that the polyethylene will seat completely within the tibial tray lock detail.



Figure 73



Attachment nut
33600191

To begin poly insertion, unlock the plunger and push it forward until it comes into contact with the poly inserter housing. (Figures 74 and 75)

Once it contacts the housing, the plunger can be turned (clockwise) to continue advancing the poly insert into the tibial tray. (Figure 76)

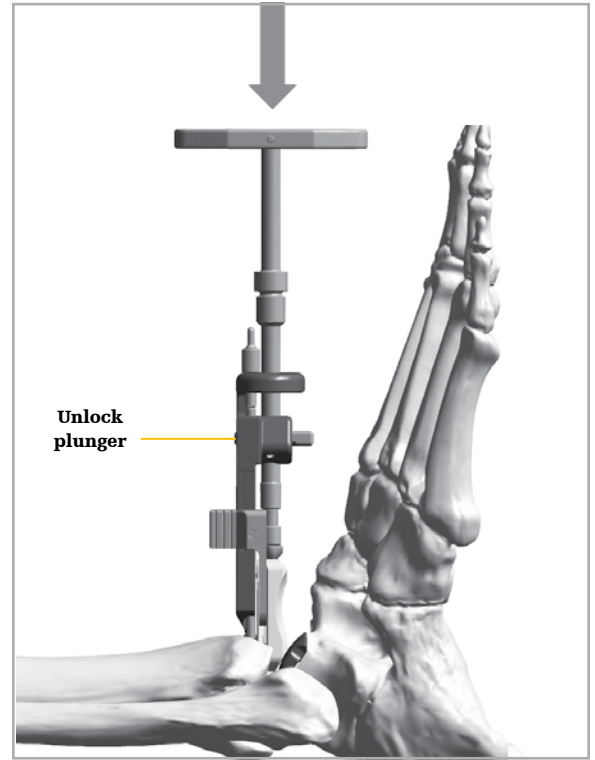


Figure 74

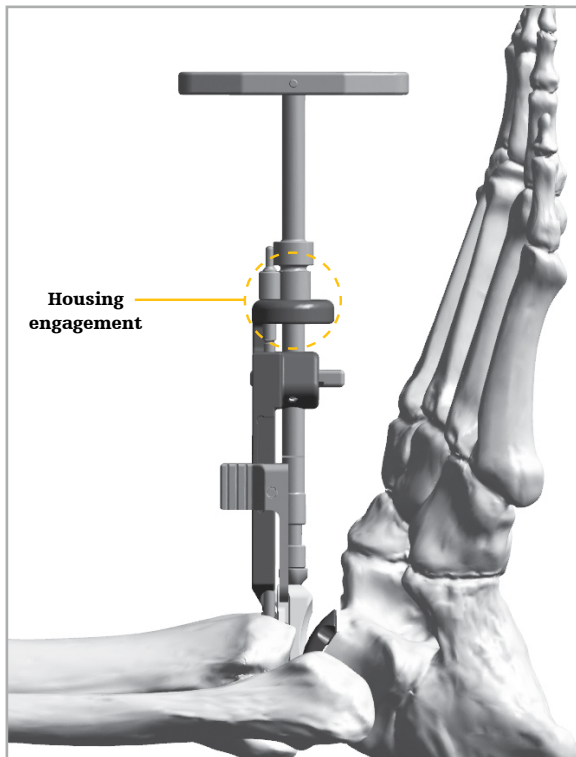


Figure 75

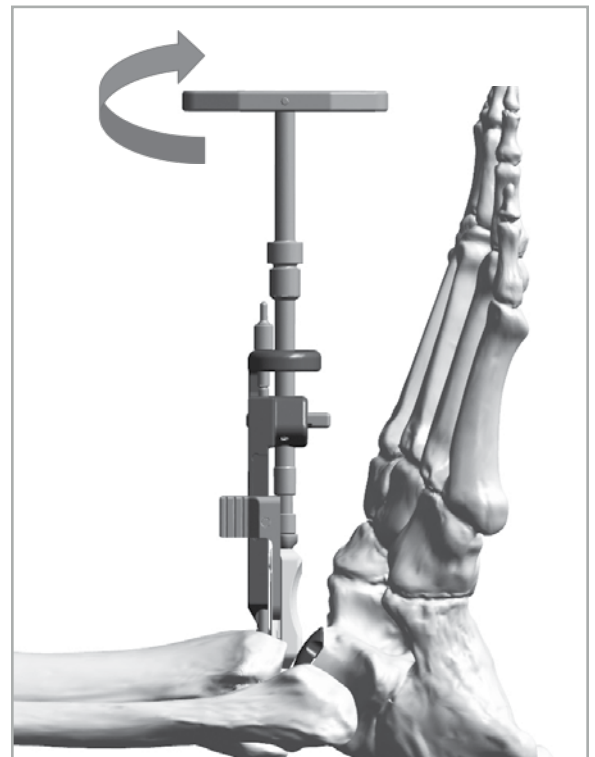


Figure 76

After the plunger has reached maximum depth, unthread the two attachment nuts, remove the poly inserter housing and unthread the two attachment screws from the tibial tray. (Figure 77)

In some cases, the poly may not fully seat using the insertion tool. In these rare cases only, line up the tip of the straight tibial tray impactor (33600141) with the groove in the anterior face of the poly insert. Angle the impactor slightly and use a gentle distal to proximal mallet strike to complete the seating.

Caution:

Striking the impactor with excessive force can result in the tibial tray pegs plowing through cancellous bone, leaving the tibial tray posteriorly translated from the anterior tibia cortex.

Check for proper articulation and observe the range of motion under fluoroscopy, ensuring appropriate gliding mechanics for the prosthesis. Also, perform one final check to be sure all components are appropriately seated. (Figures 78 and 79) close the wound and cast foot in slight plantar flexion.



Figure 77

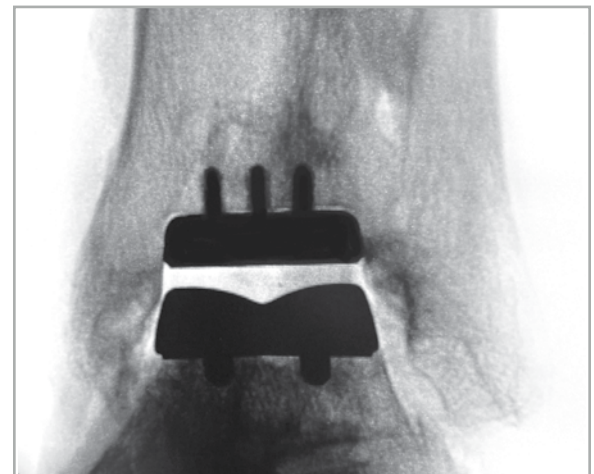


Figure 78

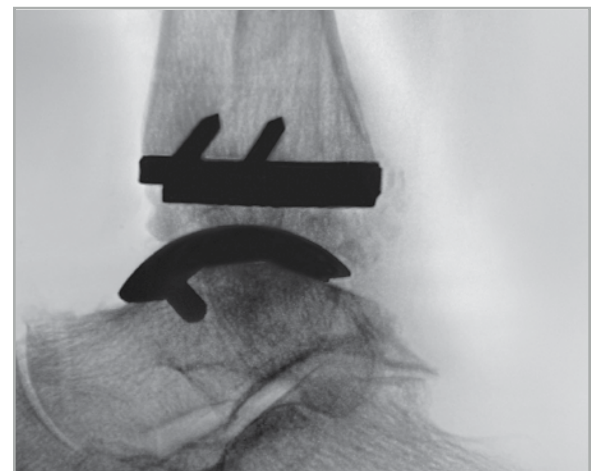


Figure 79

Explant information

Insert replacement

The poly insert has a pre-drilled hole feature on the anterior face. To remove the poly insert, first use a pin driver to install the bone removal screw through the pre-drilled hole. Attached the ratcheting handle and pull distally on the removal screw in an 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 tray. Care must be taken not to scratch or damage 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.

Appendix A: Conversion to standard instrumentation

Prior to making the tibial resection, the following modifications can be made:

- Medial-lateral position of tibial resection
- Proximal-distal level of tibial resection
- Tibial implant size

Caution:

In order to adjust the sagittal, coronal or axial rotation of the tibial resection, the surgeon must revert back to the standard Infinity operative technique. Refer to technique number 011938.

First remove the coronal sizing guide from the Prophecy Conversion Instrument. (Figure 80) Place two pin sleeves (33600025) into the two aligned holes that provide the optimal bone purchase. Typically (but not always), these will be the two center holes. (Figure 81)

Caution:

The two holes chosen must align with one another, e.g., both center holes, both medial holes or both lateral holes.

Insert the trocar (33600026) through each of the pin sleeves to create entrance portals for the percutaneous pins. (Figure 82)



Figure 80



Figure 81



Pin sleeve
33600025



Trocar
33600026



Figure 82

Install sizing and resection guide adjustment block

Install a 3.2mm pin into each pin sleeve and through both cortices of the tibia. (Figure 83) remove both pin sleeves, the Prophecy Conversion Instrument and the two original distal pins. (Figure 84)

Place the adjustment block (33600030) on the two parallel tibial pins, and lock it in place a few millimeters above the surface of the tibial crest. (Figure 85) It is important not to rest the block directly on the tibia as it may not freely translate into the desired position. Lock the adjustment block into this position by tightening the gray side knob with the hex driver. (Figure 86)



Figure 83



Figure 84



Figure 85

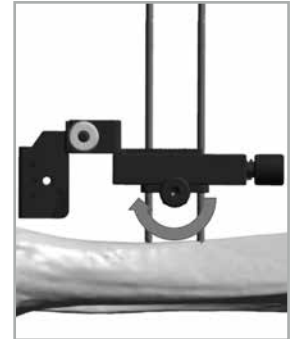


Figure 86



Adjustment block
33600030

Coronal plane sizing and positioning

Connect the coronal sizing guide (33600032 – 33600035) to the adjustment block by sliding it onto the dovetail opening. Allow the guide to slide into the dovetail until it rests against the surface of the tibia. Then, raise the guide to leave 1mm of clearance between the guide and the tibial plafond. Lock into place with the hex driver. (Figure 87)

To correct for parallax, the coronal adjustment guide contains a “pin-in-circle” feature. The c-arm should be adjusted so that the pin appears in the center of the circle. (Figures 88 and 89)

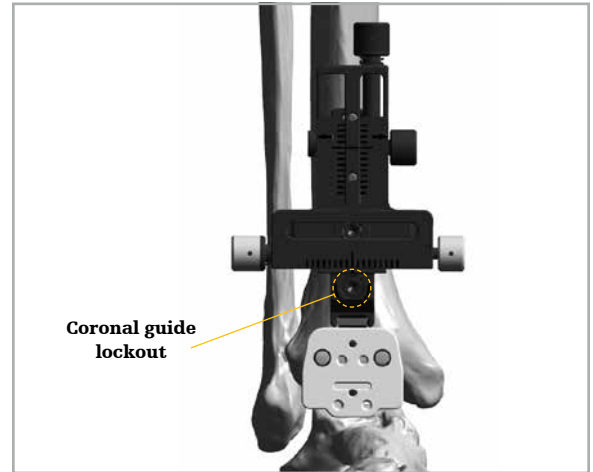


Figure 87

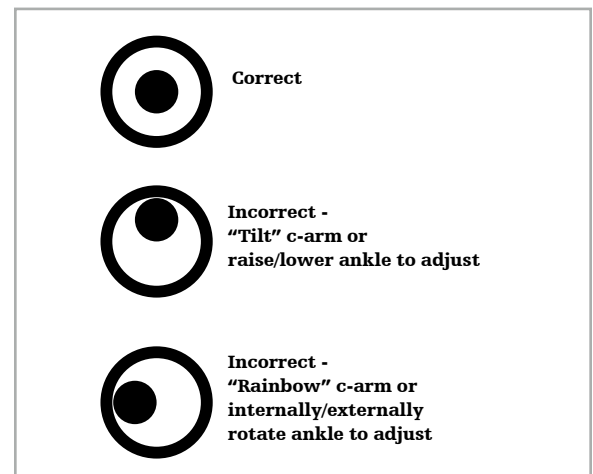


Figure 88



Coronal sizing guide
33620032 - 33620035



Figure 89

Once fluoroscopic alignment is established, use the adjustment block to translate the coronal sizing guide to the center of the joint. The purple knob will translate the guide proximal to distal and the green knobs will translate the guide medial to lateral. After adjustments are set, use the hex driver to lock out both positions. (Figure 90)

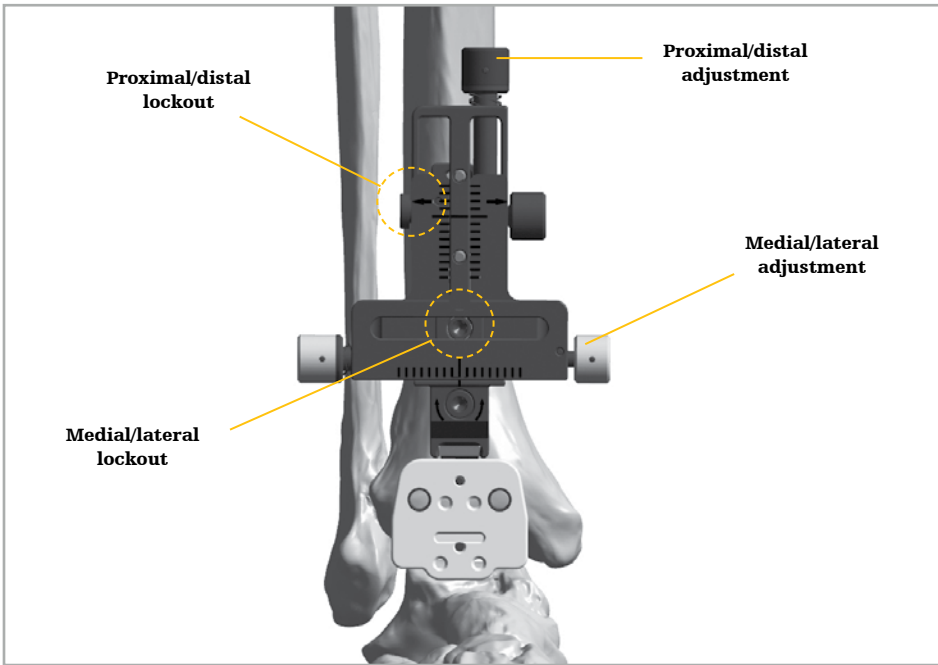


Figure 90

The dark outlines in the coronal sizing guide represent the tibial and talar bone resections as well as the coronal profile of the tibial component. (Figure 91)

Caution:

For proper evaluation, the ankle must be positioned at 90°.

Study the talus carefully, and if it is not in the 90 degree position due to posterior contracture, the surgeon should lengthen the achilles tendon and remove anterior impinging osteophytes.

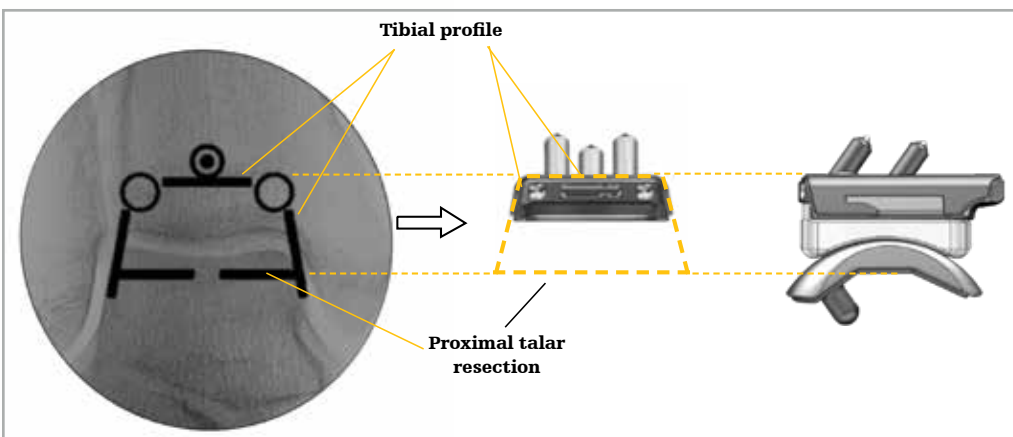


Figure 91

Note:

If the surgeon chooses to forego the Prophecy Talar Alignment Guide and make a coupled tibia/talar resection, continue with the following steps. Otherwise, return to page 14 to complete the technique.

Sagittal plane sizing and resection height

Slide the sagittal sizing ratcheting arm (33600068) onto the sagittal sizing guide arm (33600040) and install the guide arm into the coronal sizing guide. Next, slide the appropriately sized sagittal sizing guide (33620042 – 33620045) onto the ratcheting arm. (Figure 92) Attach the sagittal sizing guide assembly to the coronal guide by inserting the metal tab of the guide arm into the open slot of the coronal guide. (Figure 93)

To minimize parallax distortion and magnification error, the sizing guide should be oriented on the side of the ankle closest to the c-arm receiver and the sagittal sizing guide should be placed as close to the bone as possible. (Figure 94) Ideally, the c-arm should be situated on the same side of the bed as the ankle being replaced in order to allow the ankle to be placed as close to the receiver as possible.

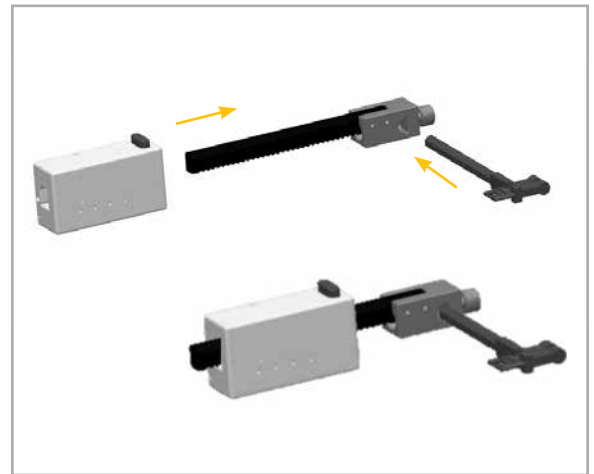


Figure 92

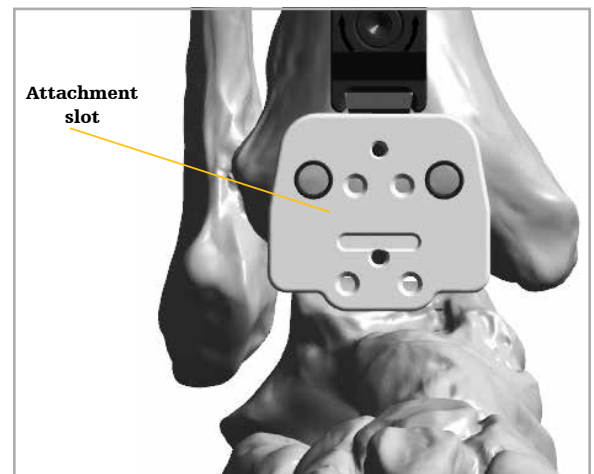


Figure 93



Sagittal sizing guide arm
33600040



Sagittal sizing ratcheting arm
33600068



Sagittal sizing guide
33620042 - 33620045

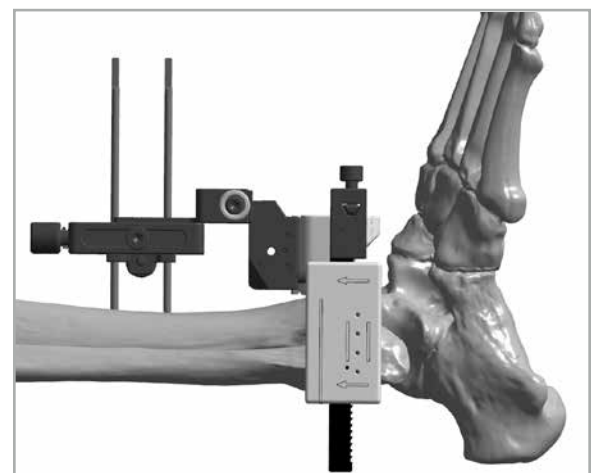


Figure 94

To obtain a true lateral view fluoroscopically, ensure that the center row of talar alignment pins appear as true solid circles. (Figure 95) These pins must be viewed “end on” to prevent misinterpretation of the fluoroscopic image.

Make c-arm adjustments as necessary in order to avoid parallax distortion. (Figures 96 and 97)

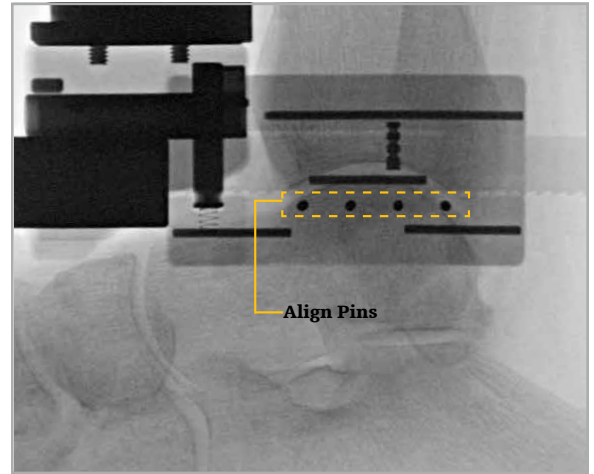
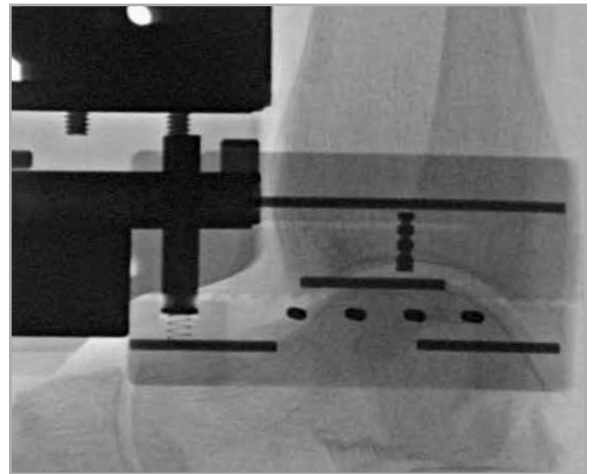
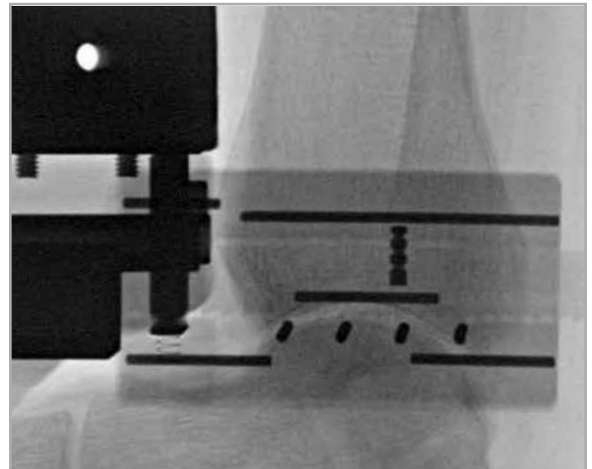


Figure 95



Rotate or “rainbow” c-arm to adjust
Figure 96



Swing or “wig-wag” c-arm to adjust
Figure 97

The sagittal sizing guide is used to fluoroscopically set the proximal extent of the tibial resection, and distal extent of the talar resection. The sizing guide also has an indicator for the anterior to posterior dimension of the tibial implant. (Figures 98 and 99)

Caution:

For proper evaluation, the ankle must be positioned at 90°.

Turn the purple knob of the adjustment block to achieve the desired resection height. Multiple component sizes can be evaluated by replacing both corresponding coronal and sagittal sizing guides.

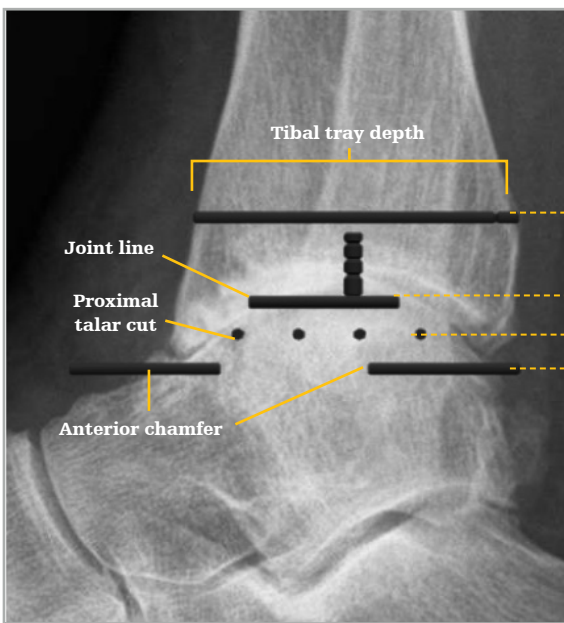


Figure 98

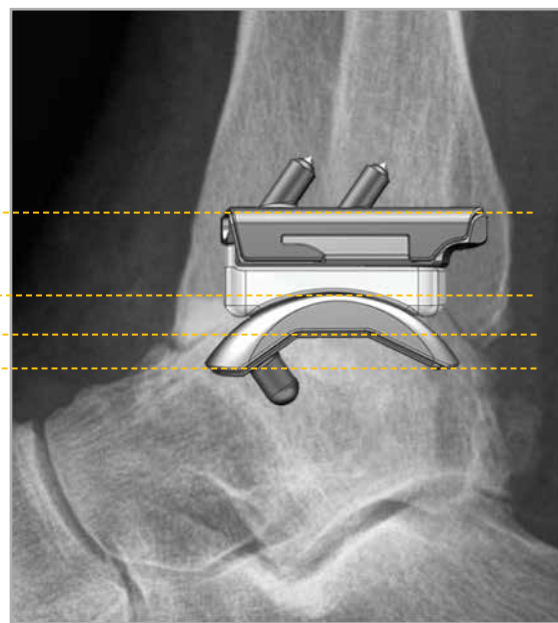


Figure 99

The sagittal sizing guide contains fluoroscopic indicators that correspond to the joint line (top of the talar dome), height of the proximal talar cut, and the distal extent of the anterior chamfer. (Figures 98 and 99)

Note that the distal extent of the anterior chamfer also corresponds to the flat cut surface of an Infinity with Adaptis Technology Flat Cut Talar Dome. (Figures 100 and 101)

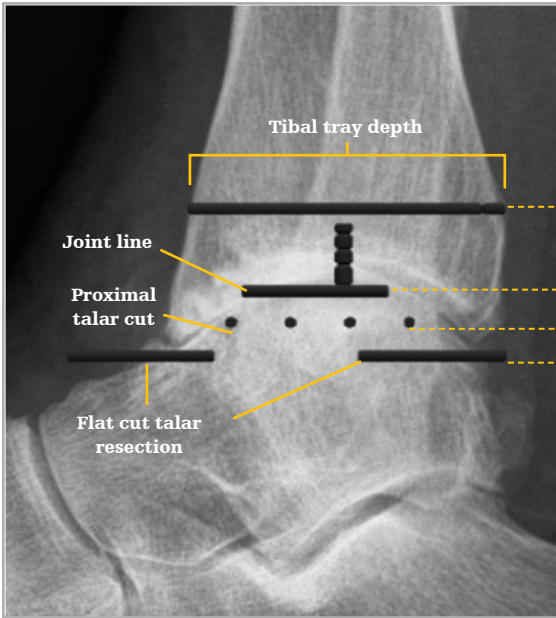


Figure 100

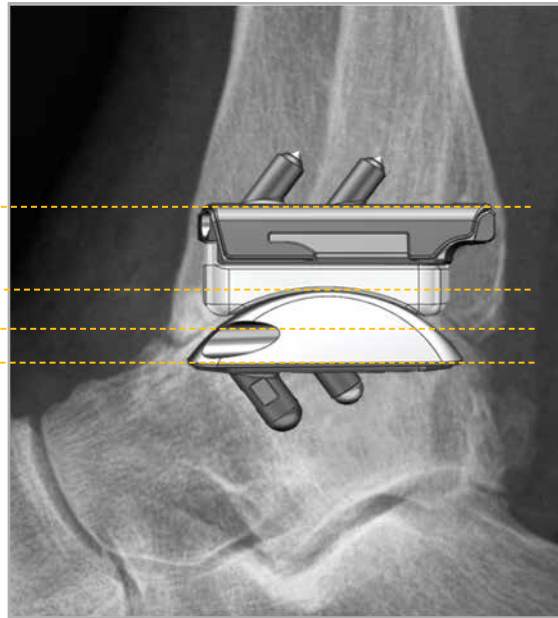


Figure 101

The sagittal sizing guide also has a proximal/distal tibial resection depth indicator for evaluating the amount of tibial resection. In addition, there is a notch in the tibia tray A/P length marker that allows the surgeon to evaluate whether a standard or long sized tibial tray may be required. (Figure 102)

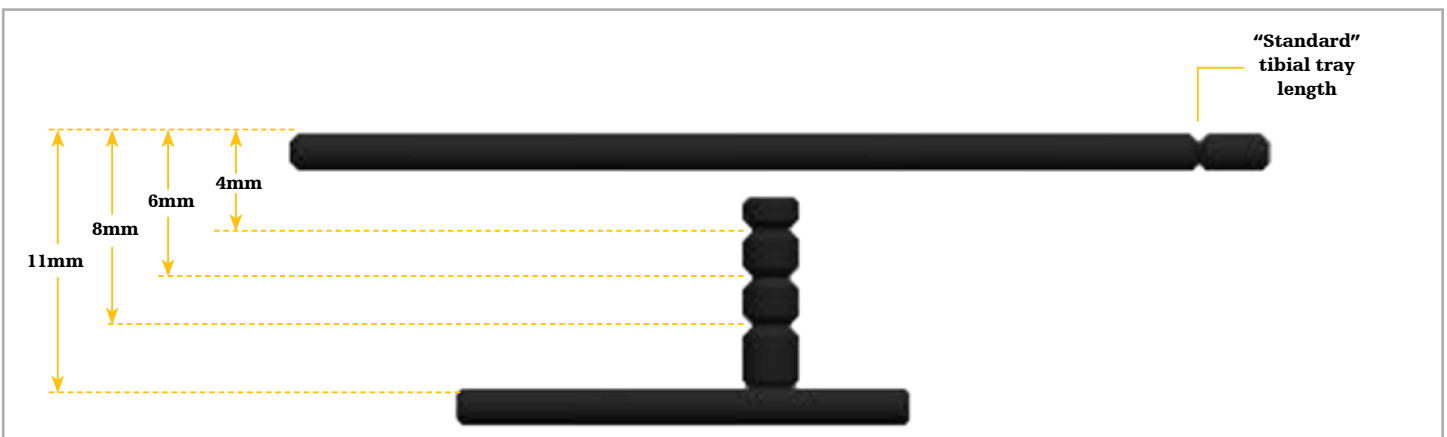


Figure 102

Drill tibial corners

If any translational adjustments were made it is recommended to take a final ap fluoroscopic image to confirm coronal positioning.

Ensure that all adjustment block positions are secured with the hex driver and place four 2.4mm Steinmann pins (200072) into the coronal sizing guide. (Figure 103) Place the two tibial pins first then place the talar pins.

Caution:

During installation of the distal talar pins, it is critical that the ankle be positioned at 90°.

Using the tibial corner drill (33600048), bi-cortically drill both proximal corners of the tibia. (Figure 104)

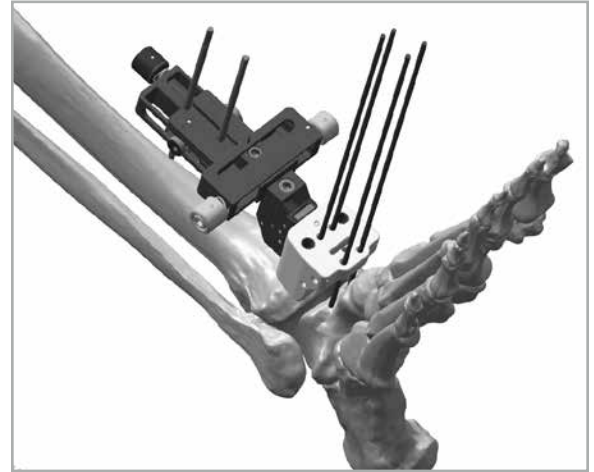


Figure 103

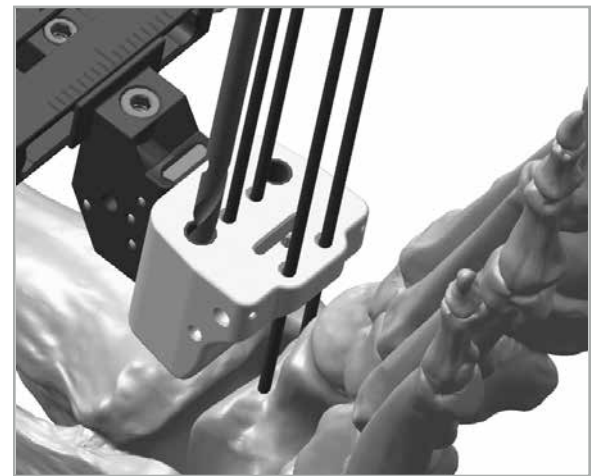


Figure 104



Tibial corner drill
33600048

Bone resection

Remove the coronal sizing guide and slide the appropriately sized resection guide (33620052 – 33620055) over the 2.4mm pins and into the adjustment block. (Figure 105) Secure with hex driver.

Note:

For steps on how to utilize an Infinity with Adaptis Technology Flat Cut Talar Dome instead of the standard chamfer-cut Infinity with Adaptis Technology Talar Dome, refer to Appendix B.

Install a 2.4mm Steinmann pin into each gutter location. Using the pin cutter, trim the pins flush to the surface of the resection guide. (Figure 106)

Optionally, for additional stability, install a 2.4mm pin through one of the two divergent pin locations. (Figure 105) When using a divergent pin, always use the medial option (in which the pin travels medial to lateral). This will help avoid the neurovascular bundle posterior to the medial malleolus. Cut the pin, leaving enough length to allow its later removal with a pin driver or pin puller but short enough to allow saw blade clearance in the medial resection slot (approximately 15mm).

Using the appropriate size saw blade and oscillating bone saw, make the tibial and talar bone resections. This includes cutting through the proximal, distal, medial and lateral slots of the resection guide.

Remove the divergent Steinmann pin, then remove the resection guide and remaining Steinmann pins. Check that the talar resection is complete by using a 1/2 inch osteotome. Complete the cut if necessary and gently lever the resected bone out anteriorly.

Refer back to page 19 for the remaining steps to complete the procedure.

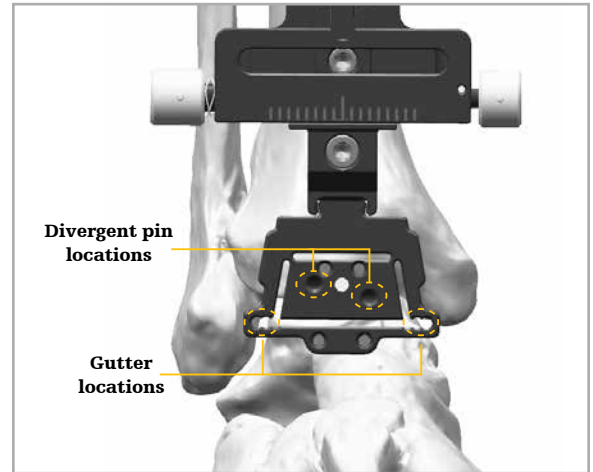


Figure 105

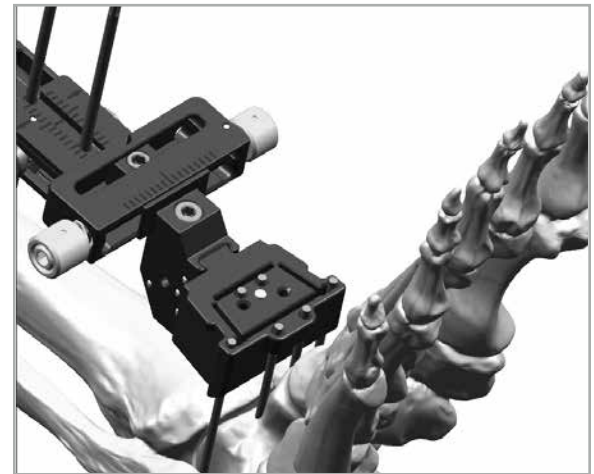
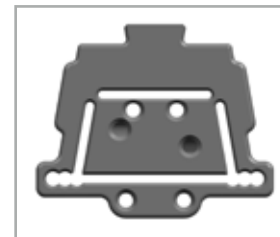


Figure 106



Resection guide
33620052 – 33620055



Pin cutters
200427

Appendix B: Conversion between chamfered talus resection level and flat cut talus resection level

The following steps are provided to indicate how to lower the talus resection from the chamfered talus resection level to the flat cut talus resection level. With the talus pins still in place for a chamfered talus plan, orient the talar resection guide to show the markings “flat” and slide over existing 2.4mm pins in the talus so that the pins go through the resection slot. (Figure 107) Next, install two additional 2.4mm pins in pin holes proximal to the resection slot into the talus. (Figure 108)

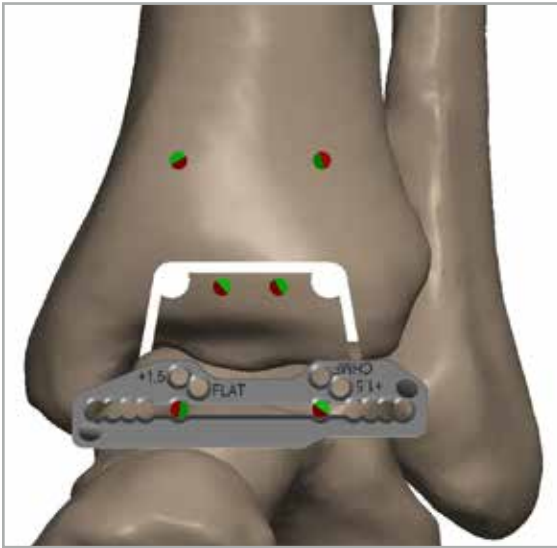


Figure 107

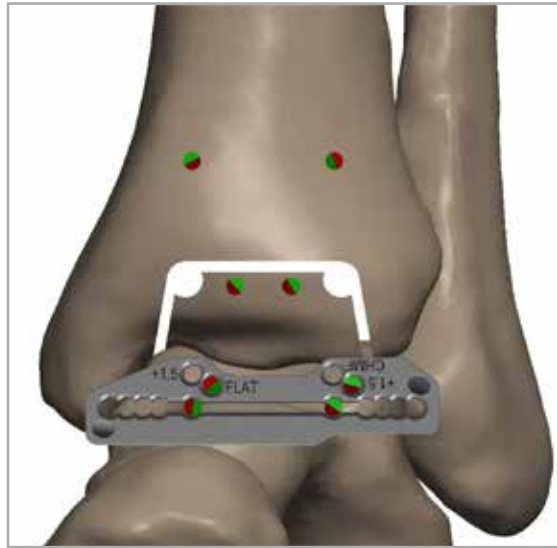


Figure 108

Remove the two 2.4mm pins from the talar resection slot. Using the pin cutter trim the pins flush to the surface of the resection guide. (Figure 109)

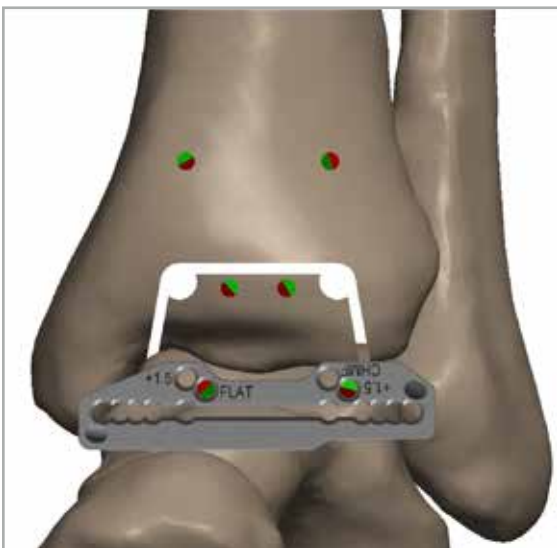


Figure 109

Optionally, the surgeon can install a 2.4mm Steinmann pin into each gutter location and an additional 2.4mm pin through one of the divergent pin locations.

Using the pin cutter, trim the gutter pins flush to the surface of the resection guide. Leave enough length on the divergent pin to allow its later removal with a pin driver or pin puller. Using the appropriate saw blade and oscillating bone saw make the talar resection.

Remove the resection guide. Check that the talar resection is complete by using a 1/2 inch osteotome. Complete the cut if necessary and gently lever the resected dome out anteriorly.

Tibial bone removal and preparation

Refer to pages 19-22 for instructions on bone removal and tibia preparation for the Infinity with Adaptis Technology Tibial Tray.

Implanting tibial tray

Refer to pages 33-35 for instructions on the implantation of the Infinity with Adaptis Technology Tibial Tray.

Verify talar dome size

After completing the implantation of the Infinity with Adaptis Technology Tibial Tray, proceed with the preparation of the talar dome on page 55.

Appendix C: Prophecy Flat Cut Talar Dome technique

During the preoperative planning stages of the Prophecy process, if the surgeon chooses to use a flat cut talar dome instead of an Infinity with Adaptis Technology Talar Dome, this is possible due to the identical articulation geometry of the two systems. (Figure 110) The Prophecy Talus Guide will then be designed to set talar resection depth to the level of the flat cut talar dome.

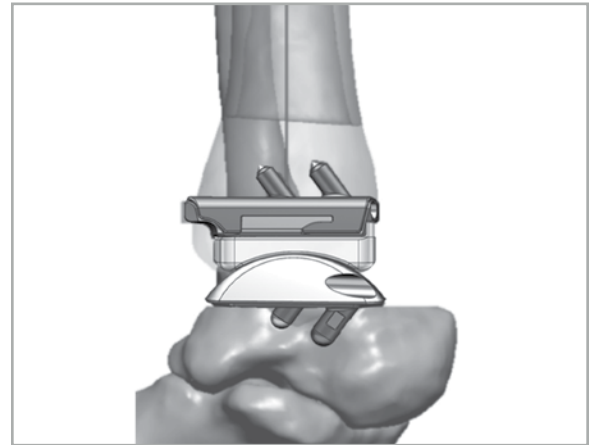


Figure 110

Talar bone resection

Refer to the patient's Prophecy report for details regarding the appropriate talar resection guide type, paying special attention to the guide orientation, markings, and pin holes utilized. Typically, for a flat cut talar resection level the reversible talar saw guide (33689021) should be positioned with the markings "FLAT" OR "FLT" upright. (Figure 111) Position the two talar pin holes over the two pins from the Prophecy Talus Alignment Guide and slide down to the anterior surface of the talar dome. Consult the Prophecy preop plan for confirmation.

Note:

In some cases, the Prophecy Talus Guide may be designed to place pins that utilize alternative holes in the resection guide for optimal fixation. Refer to the patient-specific, Prophecy case report to confirm which holes to use in the resection guide.

The surgeon has the option to fluoroscopically verify the proximal/distal location and flexion/extension angle of the talar component prior to talar resection. Obtain a true lateral view by aligning the c-arm so that both talar Steinmann pins appear as one.

In addition, the surgeon can compare to images in the Prophecy preoperative plan to verify accuracy of the talar guide.

Insert two additional 2.4mm Steinmann pins into the medial and lateral gutters for protection of the malleoli. Use the pin cutter to cut the Steinmann pins close to the surface of the resection guide.

Using the appropriate saw blade and oscillating bone saw, make the talar resection (distal slot of the saw guide).

Caution:

It may be necessary to manually hold the resection guide in place as excessive vibration from the saw can cause the saw guide to work itself off the ends of the cut Steinmann pins.

Remove the resection guide. Check that the talar resection is complete by using a 1/2 inch osteotome. Complete the cut if necessary and gently lever the resected dome out anteriorly.

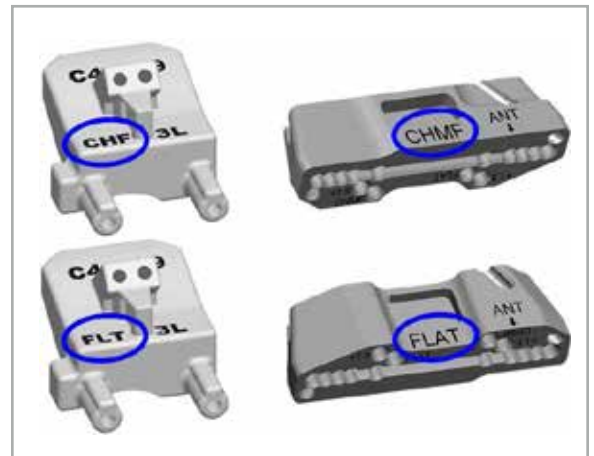


Figure 111

Tibial bone removal and preparation

Refer to pages 19-22 for instructions on bone removal and tibia preparation for the Infinity with Adaptis Technology Tibial Tray.

Implanting tibial tray

Refer to pages 33 - 35 for instructions on the implantation of the Infinity with Adaptis Technology Tibial Tray.

Verify talar dome size

After completing the implantation of the Infinity with Adaptis Technology Tibial Tray, proceed with the preparation of the talar dome.

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

Using the poly insert trial holding tool (IB200110), install the appropriately sized poly insert trial (33621106 – 33625512) into the tibial tray. (Figure 112) The locking tab of the poly insert trial should engage the tibial tray.

Assemble the appropriately sized talar dome trial (33680071 – 33680075) and talar dome holding tool (IB200010) and introduce the dome trial into the joint space. (Figure 113)

The surgeon has two options for talar dome implant size at this juncture: either the matching size for the implanted tibial tray, or one size smaller. It is beneficial to assess both sizes under A/P and lateral fluoroscopic images. Please note that the A/P image is critical for sizing the talar component, as the surgeon's goal is to minimize overhang of the talar component, and thus minimize prosthetic impingement in the medial and lateral gutters of the ankle joint. (Figures 114 and 115)



Figure 112



Figure 113

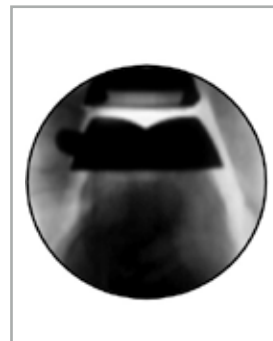


Figure 114



Figure 115



Poly trial holding tool
IB200110



Poly insert trial
33621106 - 33625512



Dome trial holding tool
IB200010



Talar dome trial
33680071 - 33680075

Trial reduction

Under lateral plane fluoroscopy, ensure the posterior portion of the talar component is resting on the posterior portion of the patient's residual talus (establish congruence). (Figure 116)

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

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

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

Once the talar dome trial has settled into optimum anatomical position, install two 1.4mm pins (500036) through the talar dome trial to temporarily hold it in place. (Figure 117)

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.

Refer back to page 31 for further details on choosing the appropriate polyethylene thickness.

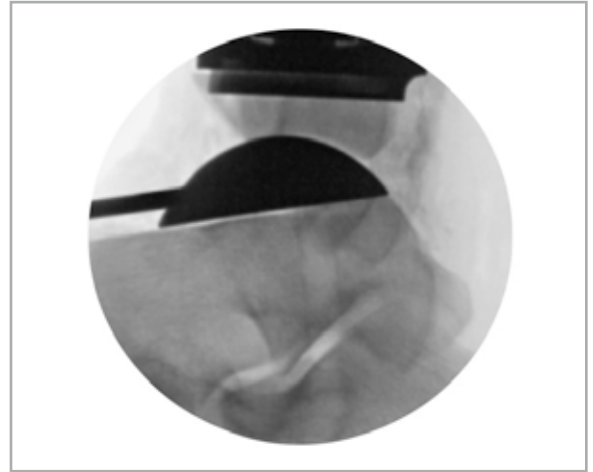


Figure 116

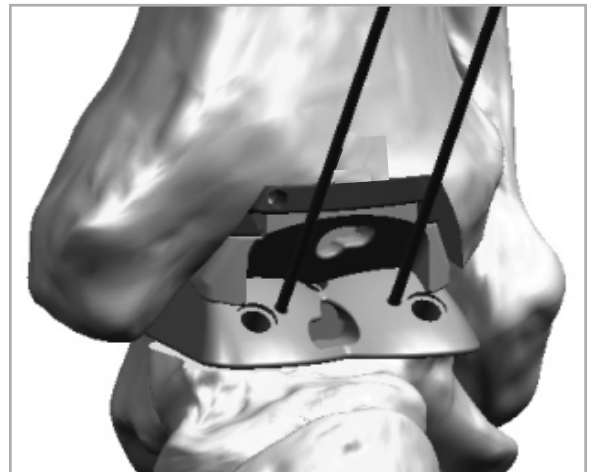


Figure 117

Talar preparation

Use the poly insert trial holding tool to remove the poly insert trial. Foot may be plantarflexed to aid in removal of poly insert trial. (Figures 118 and 119)

Caution:

The poly insert trial has a small locking tab that engages the tibial tray. To remove poly insert trial, be sure to first pull down on the holding tool to disengage tab before pulling out.

Using the 4mm anterior peg drill (IB200020), drill a hole through the medial and lateral openings and central posterior opening in the flat cut talar dome trial. The drill has a hard stop designed to set the appropriate drilling depth in the talus for the talar dome anterior pegs and central stem. (Figure 120)

Remove 1.4mm pins and use flat cut talar dome trial.

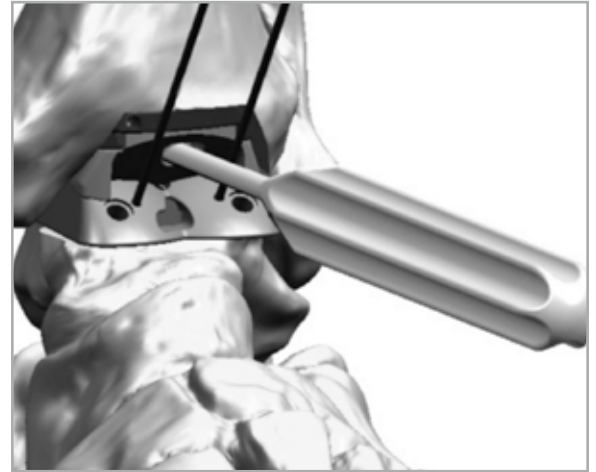


Figure 118

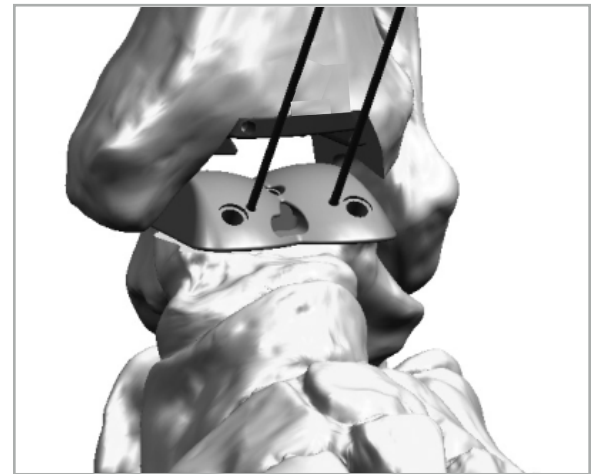


Figure 119



4mm anterior peg drill
IB200020

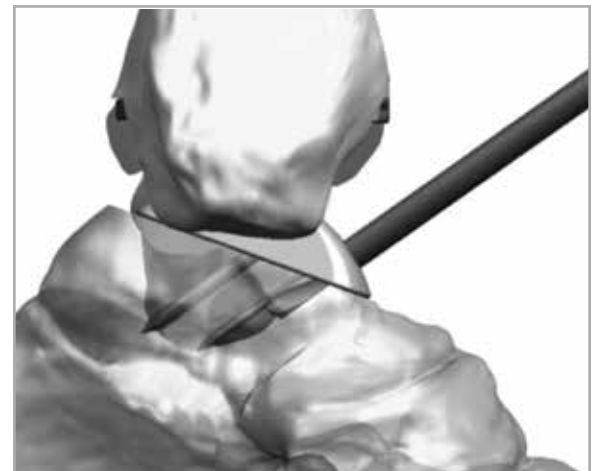


Figure 120

Install talar dome

Place the foot in plantar flexion and insert the tibial tray protector (33620152 – 33620155) into the tibial tray to protect the talar dome surface during installation. If choosing to cement, apply bone cement to the bottom surface of the talar dome.

Caution:

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

Thread the M4 holding tool (200364003) into the corner of the talar dome and introduce the talar dome into the joint space, aligning the talar stem and pegs with the prepared holes in the talus. (Figure 121) Once the talar dome is aligned, remove the tray protector.

Align the talar dome impactor on the talar dome and with a mallet, hit the top of the impactor to fully seat the talar dome. (Figure 122) Utilize a lateral fluoroscopic image to ensure that the talar dome is fully seated. If the talar dome is difficult to fully seat in hard bone, it may be advisable to remove the talar dome and increase the diameter of the anterior peg holes slightly with the 4mm drill.

Polyethylene bearing installation

Following final impaction of the talar dome, refer to page 37 for instructions on the polyethylene bearing installation.

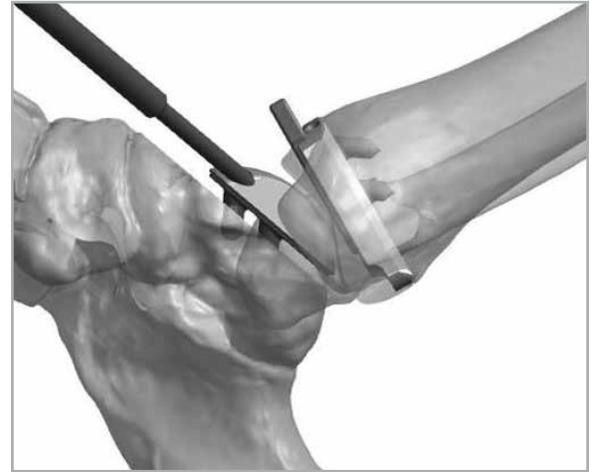


Figure 121

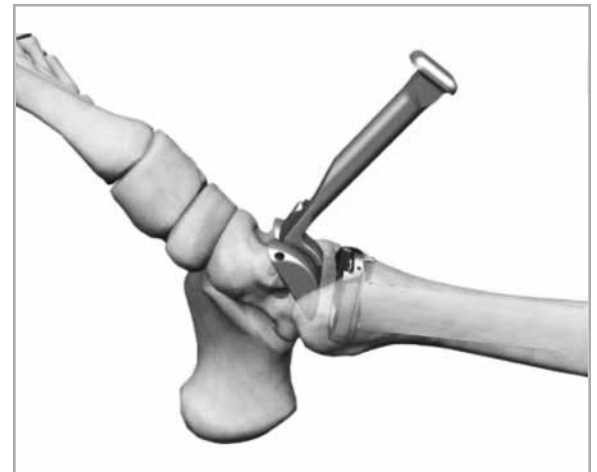


Figure 122



Tibial tray protector
33620152 - 33620155

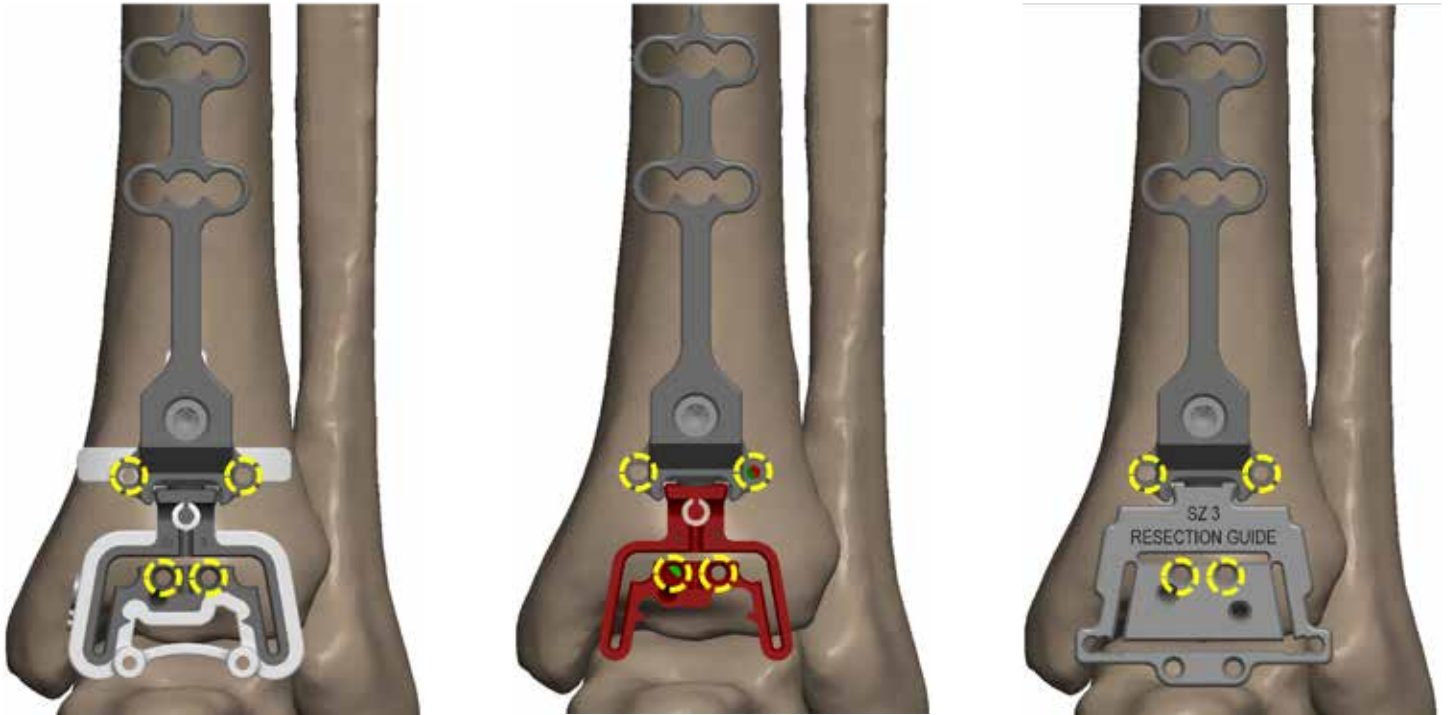


Holding tool
M4 - 200364003

Appendix D: Alternative Instrumentation Compatibility

Common holes of the tibia saw guides

The circled holes are common to all sizes of Infinity tibia saw guides, therefore, after placing at least 2 of these pins, an alternative tibia saw guide size can be evaluated and utilized.

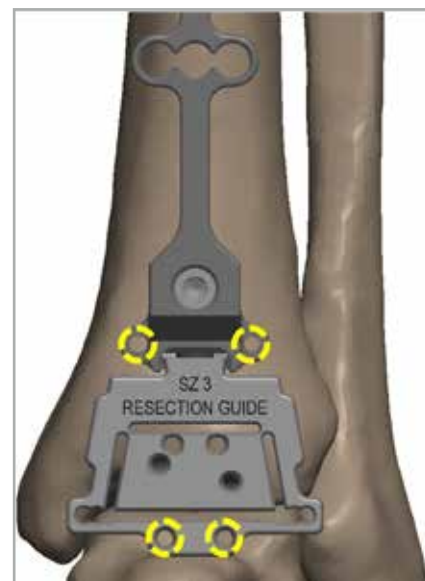


Backup solutions for talus resection

The new reversible talus resection guide holes are spaced wider than the legacy saw guide for enhanced stability. The holes, therefore, do not match legacy saw guides. Backup solutions for the talus resection remain:

Backup talus solution 1:

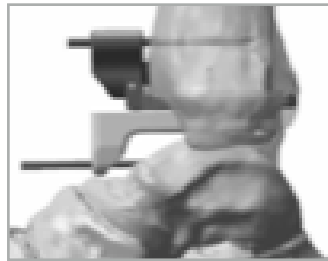
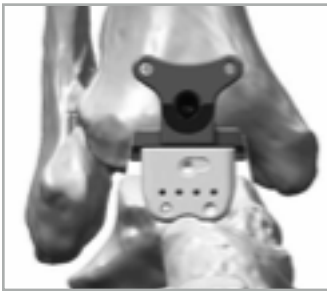
- Use the legacy saw guide and couple the talus cut:
- Use legacy saw guide and conversion instrument on the proximal pins.
- Manually correct the talus, add pins and couple the talus resection.



Backup talus solution 2:

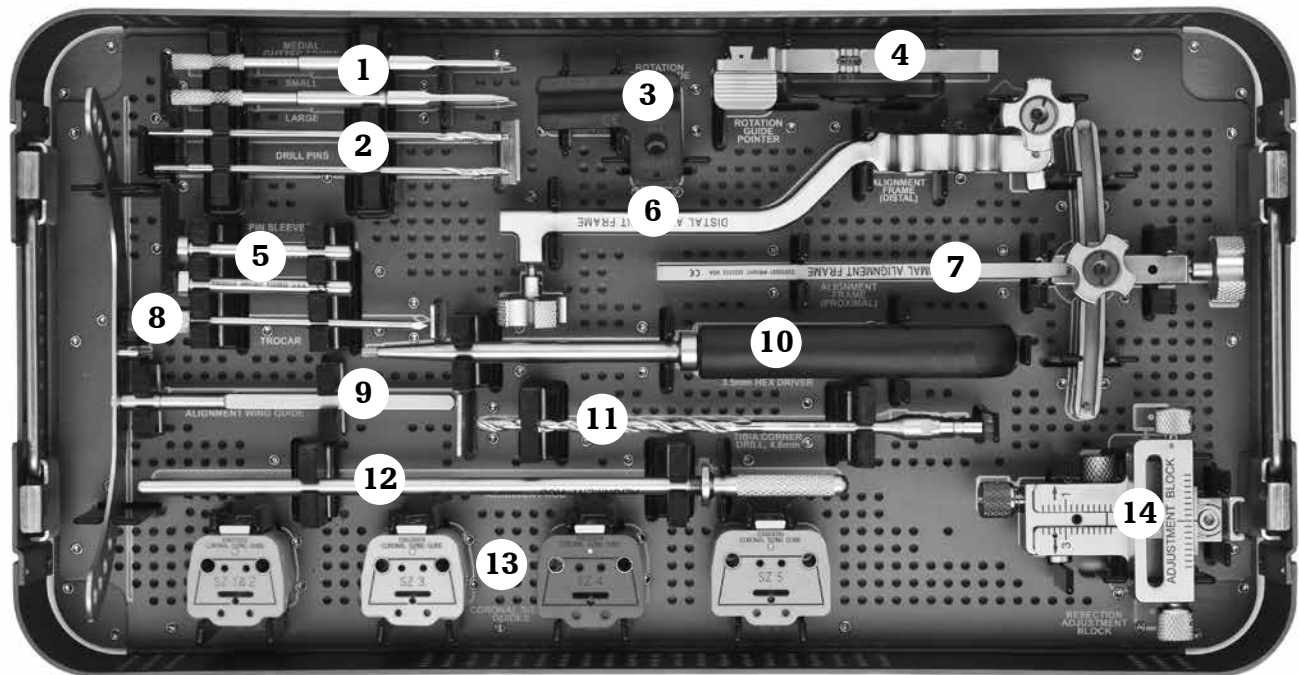
- Use the legacy Infinity Spacer Guide technique.
- Remove resected tibia bone and add tibia trial.
- Insert talus spacer shims to facilitate manual talar correction.
- Pin into talus.
- Use legacy talus-spacer resection guide 33600400

See AP-011469 or AP-012815



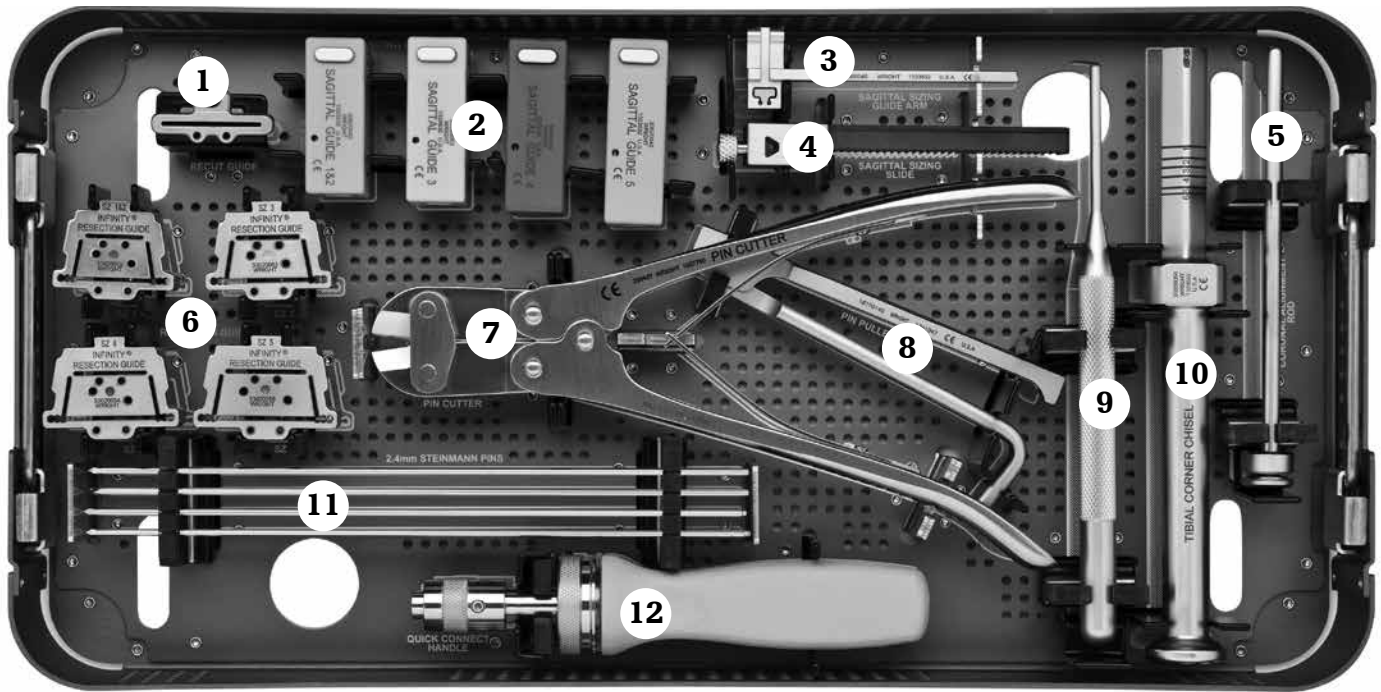
Appendix E: Infinity with Adaptis Technology Instrumentation

3365KIT1 Case 1, Tray 1



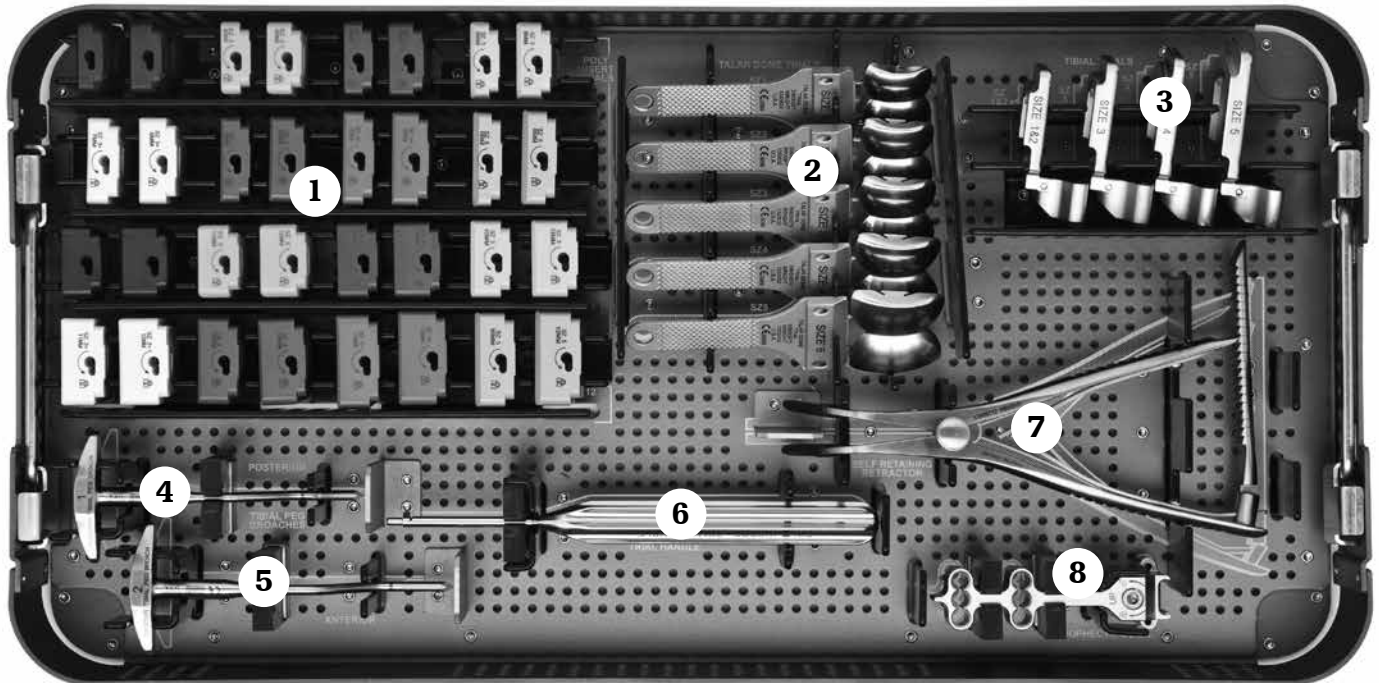
- | | |
|---|---|
| 1. Medial gutter forks (33600009 and 33600010) | 8. Trocar (33600026) |
| 2. Pins 3.2mm x 102mm (33610001) | 9. Alignment wing guide (33600023) |
| 3. Rotation guide slide (33600012) | 10. 3.5mm hex driver (E5001005) |
| 4. Rotation guide pointer (33600011) | 11. 4.8mm tibial corner drill (33600048) |
| 5. Pin sleeves (33600025) | 12. Alignment rod (33600024) |
| 6. Alignment frame distal assembly (33600020) | 13. Coronal sizing guides (33620032 - 33620035) |
| 7. Alignment frame proximal assembly (33600021) | 14. Resection guide adjustment block (33600030) |

3365KIT1 Case 1, Tray 2



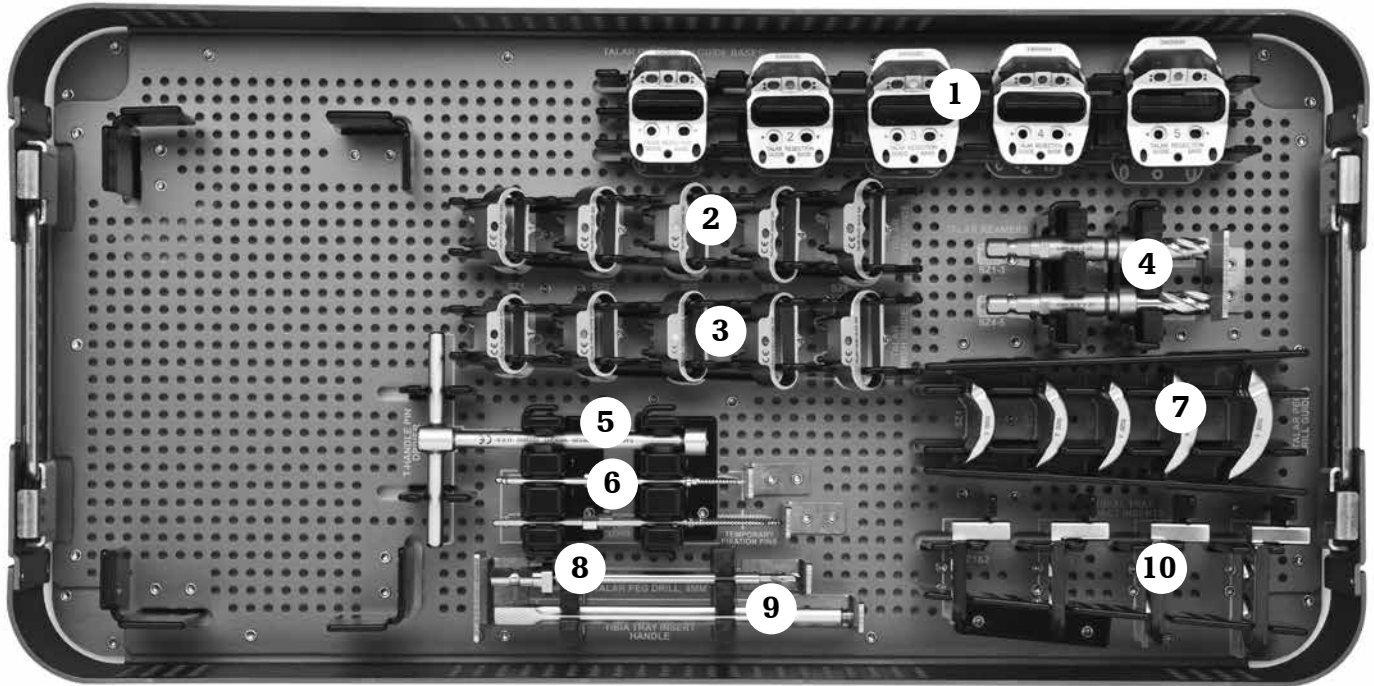
1. Talar 2mm recut guide (33609056)
2. Sagittal sizing guides (33620042-33620045)
3. Sagittal sizing guide arm (33600040)
4. Sagittal sizing guide ratchet arm (33600068)
5. Coronal alignment rod (33600027)
6. Resection guides (33620052-33620055)
7. Pin cutter (200427)
8. Pin puller (18770140)
9. Bone release tool (IB200050)
10. Tibia corner chisel (33600058)
11. Steinmann pins 2.4mm (200072)
12. Quick connect handle (44180025)

3365KIT1 Case 2, Tray 1



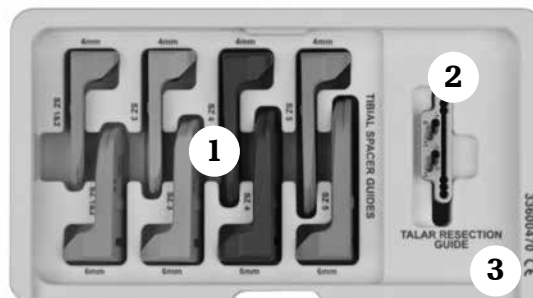
1. Poly insert trials (33621106-33625512)
2. Talar dome trials (33600071-33600075)
3. Tibial tray trials (33620062-33620065)
4. Posterior tibial peg broach (33600069)
5. Anterior tibial peg broach (33600067)
6. Poly trial handle (IB200110)
7. Self retaining retractor (33609012)
8. Prophecy Conversion Guide (33600200)

3365KIT1 Case 2, Tray 2



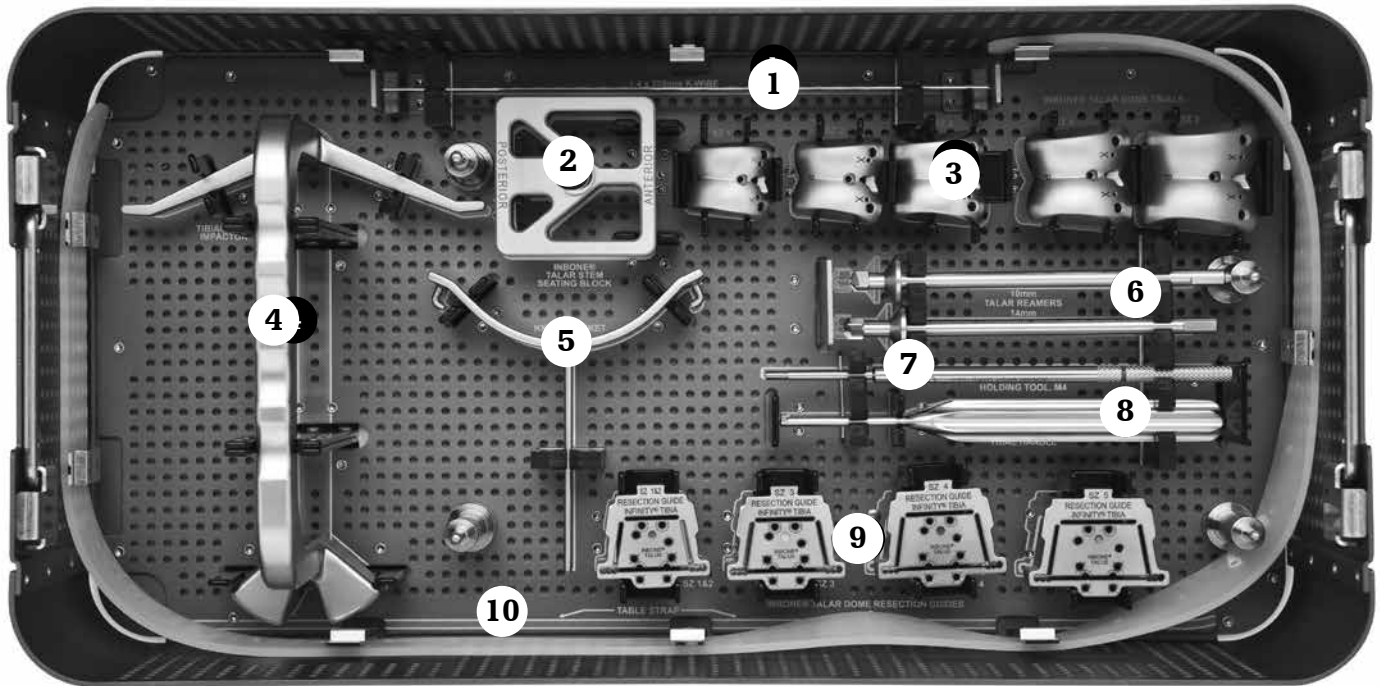
1. Talar resection guide bases (33600091-33600095)
2. Talar chamfer pilot guides (33600101-33600105)
3. Talar chamfer finish guides (33600111-33600115)
4. Talar reamers (33600123 and 33600126)
5. T-handle pin driver (33600120)
6. Threaded talar pins (33610002 and 33610003)
7. Talar peg drill guides (33600161-33600165)
8. Talar peg drill, 4mm (IB200020)
9. Tibial tray insertion handle (33600130)
10. Tibial tray impaction inserts (33620132-33620135)

Case 2, Caddy 1



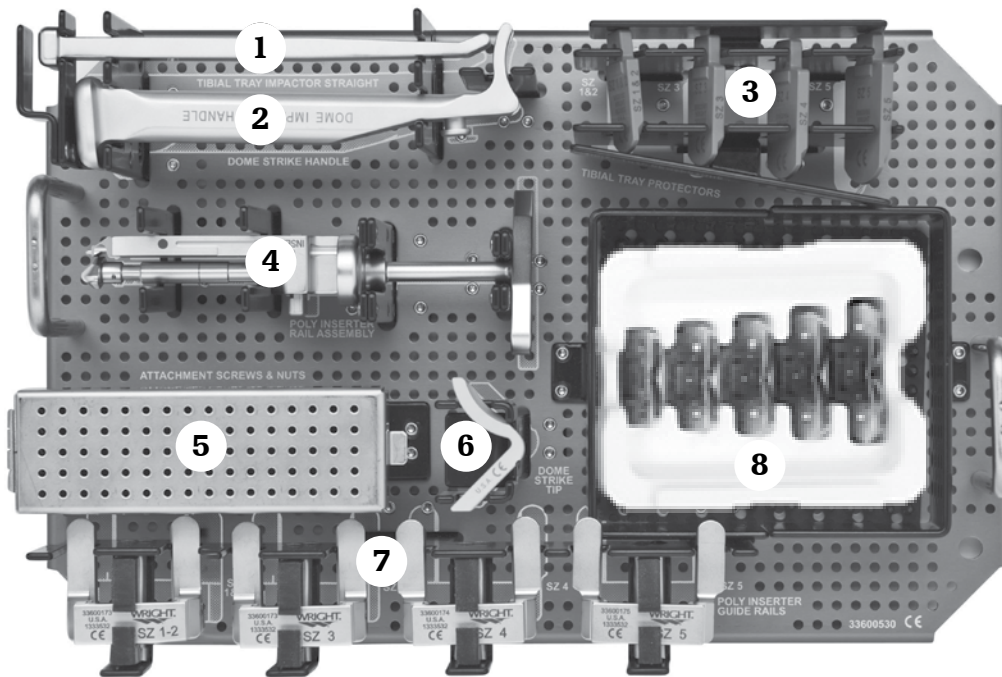
1. Tibial spacer guides (33600424-33600456)
2. Talar resection guide (33600400)
3. Caddy (33600470)

3365KIT1 Case 3, Tray 1



1. K-wires 1.4mm x 228mm (500036)
2. Inbone Talar Stem Seating Block (IB200060)
3. Inbone Talar Dome Trials (IB220901-IB220905)
4. Tibial tray offset impactor (33600140)
5. Knee bracket (33600022)
6. Inbone Talar Stem Reamers (200432010 and 200432014)
7. Inbone Talar Dome M4 Holding Tool (200364003)
8. Inbone Talar Dome Trial Handle (IB200010)
9. Inbone Talar Dome Resection Guides (33620252-33620255)
10. Table strap (200430)

3365KIT1 Case 3, Tray 2



1. Straight impactor (33600141)
2. Dome strike handle (IB200030)
3. Tibial tray protectors (33620152-33620155)
4. Poly inserter assembly (33600170)
5. Attachment screws (33600190) and nuts (33600191)
6. Dome strike tip (IB200031)
7. Poly inserter guide rails (33600172-33600175)
8. Infinity with Adaptis Technology Flat Cut Trials (33680071-33680075)

PRTTKIT1



1. Tibial resection guide insert (33689002-33689005)
2. Reversible talar resection guide (33689021)
3. Corner protector pegs (33689011)

3365KIT1 - Infinity with Adaptis Technology Instrument Kit

| Part # | Description |
|----------|-------------------------------|
| 33600009 | Medial gutter fork, small |
| 33600010 | Medial gutter fork, large |
| 33600011 | Rotation guide pointer |
| 33600012 | Rotation guide slide |
| 33600020 | Alignment frame dist sub assy |
| 33600021 | Alignment frame prox sub assy |
| 33600022 | Knee bracket |
| 33600023 | Alignment wing guide |
| 33600024 | Alignment rod |
| 33600025 | Pin sleeve |
| 33600026 | Trocar |
| 33600030 | Resection adjustment block |
| 33620032 | Coronal sizing guide, sz1-2 |
| 33620033 | Coronal sizing guide, sz3 |
| 33620034 | Coronal sizing guide, sz4 |
| 33620035 | Coronal sizing guide, sz5 |
| 33620040 | Sagittal sizing guide arm |
| 33620042 | Sagittal sizing guide, sz1-2 |
| 33620043 | Sagittal sizing guide, sz3 |
| 33620044 | Sagittal sizing guide, sz4 |
| 33620045 | Sagittal sizing guide, sz5 |
| 33600048 | Tibial corner drill, 4.8mm |
| 33620052 | Resection guide, sz1-2 |
| 33620053 | Resection guide, sz3 |
| 33620054 | Resection guide, sz4 |
| 33620055 | Resection guide, sz5 |
| 33600058 | Tibial corner chisel |

| Part # | Description |
|----------|-------------------------------|
| 33620062 | Trial tibial tray, sz1-2 |
| 33620063 | Trial tibial tray, sz3 |
| 33620064 | Trial tibial tray, sz4 |
| 33620065 | Trial tibial tray, sz5 |
| 33600069 | Tibial peg drill, 3.7mm |
| 33600071 | Trial talar dome, sz1 |
| 33600072 | Trial talar dome, sz2 |
| 33600073 | Trial talar dome, sz3 |
| 33600074 | Trial talar dome, sz4 |
| 33600075 | Trial talar dome, sz5 |
| 33600091 | Talar resect guide base, sz1 |
| 33600092 | Talar resect guide base, sz2 |
| 33600093 | Talar resect guide base, sz3 |
| 33600094 | Talar resect guide base, sz4 |
| 33600095 | Talar resect guide base, sz5 |
| 33600101 | Anter talar pilot guide, sz1 |
| 33600102 | Anter talar pilot guide, sz2 |
| 33600103 | Anter talar pilot guide, sz3 |
| 33600104 | Anter talar pilot guide, sz4 |
| 33600105 | Anter talar pilot guide, sz5 |
| 33600111 | Anter talar finish guide, sz1 |
| 33600112 | Anter talar finish guide, sz2 |
| 33600113 | Anter talar finish guide, sz3 |
| 33600114 | Anter talar finish guide, sz4 |
| 33600115 | Anter talar finish guide, sz5 |
| 33600120 | T-handle pin driver |
| 33600123 | Talar reamer, sz1-3 |
| 33600126 | Talar reamer, sz4-6 |

3365KIT1 - Infinity with Adaptis Technology Instrument Kit

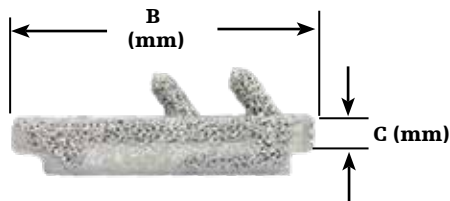
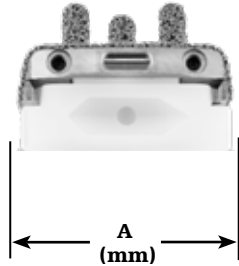
| Part # | Description |
|----------|-------------------------------------|
| 33600130 | Tibial tray insert handle |
| 33620132 | Tib tray impact insert, sz1-2 |
| 33620133 | Tib tray impact insert, sz3 |
| 33620134 | Tib tray impact insert, sz4 |
| 33620135 | Tib tray impact insert, sz5 |
| 33600140 | Tibial tray impactor, offset |
| 33600141 | Tibial tray impactor, straight |
| 33620152 | Tibial tray protector, sz1-2 |
| 33620153 | Tibial tray protector, sz3 |
| 33620154 | Tibial tray protector, sz4 |
| 33620155 | Tibial tray protector, sz5 |
| 33600161 | Talar peg drill guide, sz1 |
| 33600162 | Talar peg drill guide, sz2 |
| 33600163 | Talar peg drill guide, sz3 |
| 33600164 | Talar peg drill guide, sz4 |
| 33600165 | Talar peg drill guide, sz5 |
| 33600170 | Poly inserter rail assy |
| 33600172 | Poly insert guide rail, sz1-2 |
| 33600173 | Poly insert guide rail, sz3 |
| 33600174 | Poly insert guide rail, sz4 |
| 33600175 | Poly insert guide rail, sz5 |
| 33600190 | Poly insert attachment screw |
| 33600191 | Poly insert attachment nut |
| 33620252 | Resection guide Inbone talus, sz1-2 |
| 33620253 | Resection guide Inbone talus, sz3 |
| 33620254 | Resection guide Inbone talus, sz4 |
| 33620255 | Resection guide Inbone talus, sz5 |

| Part # | Description |
|----------|--------------------------------|
| 33621106 | Trial poly insert, sz1/1+ 6mm |
| 33621108 | Trial poly insert, sz1/1+ 8mm |
| 33621110 | Trial poly insert, sz1/1+ 10mm |
| 33621112 | Trial poly insert, sz1/1+ 12mm |
| 33622206 | Trial poly insert, sz2 6mm |
| 33622208 | Trial poly insert, sz2 8mm |
| 33602210 | Trial poly insert, sz2 10mm |
| 33602212 | Trial poly insert, sz2 12mm |
| 33623206 | Trial poly insert, sz2+ 6mm |
| 33623208 | Trial poly insert, sz2+ 8mm |
| 33603210 | Trial poly insert, sz2+ 10mm |
| 33603212 | Trial poly insert, sz2+ 12mm |
| 33623306 | Trial poly insert, sz3 6mm |
| 33623308 | Trial poly insert, sz3 8mm |
| 33603310 | Trial poly insert, sz3 10mm |
| 33603312 | Trial poly insert, sz3 12mm |
| 33624307 | Trial poly insert, sz3+ 7mm |
| 33624309 | Trial poly insert, sz3+ 9mm |
| 33604311 | Trial poly insert, sz3+ 11mm |
| 33604313 | Trial poly insert, sz3+ 13mm |
| 33624406 | Trial poly insert, sz4 6mm |
| 33624408 | Trial poly insert, sz4 8mm |
| 33604410 | Trial poly insert, sz4 10mm |
| 33604412 | Trial poly insert, sz4 12mm |
| 33625407 | Trial poly insert, sz4+ 7mm |
| 33625409 | Trial poly insert, sz4+ 9mm |
| 33605411 | Trial poly insert, sz4+ 11mm |
| 33605413 | Trial poly insert, sz4+ 13mm |
| 33625506 | Trial poly insert, sz5 6mm |
| 33625508 | Trial poly insert, sz5 8mm |
| 33605510 | Trial poly insert, sz5 10mm |
| 33605512 | Trial poly insert, sz5 12mm |

3365KIT1 - Infinity with Adaptis Technology Instrument Kit

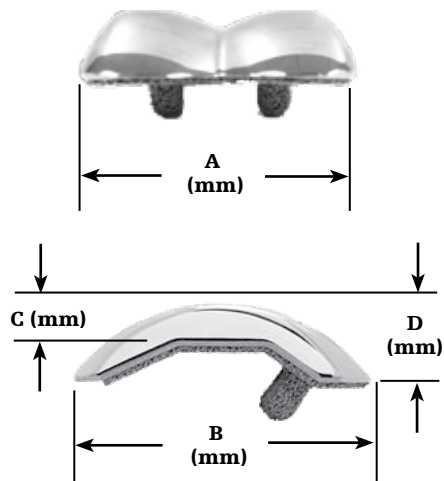
| Part # | Description |
|-----------|----------------------------------|
| 33609012 | Self retaining laminar spreaders |
| 33610001 | Pin 3.2mm x 102mm |
| 33610002 | Temp fix pin, talar guide long |
| 33610003 | Temp fix pin, talar guide short |
| E5001005 | Evolution 3.5mm Hex Driver |
| 200430 | Inbone Table Strap |
| 200072 | Inbone Steinmann pin, 2.4mm |
| IB200050 | Inbone Bone Release Tool |
| IB200110 | Inbone Handle Trial Implants |
| IIB200020 | Inbone Drill Talar Peg, 4mm |
| IB200030 | Inbone Handle Dome Striker |
| IB200031 | Inbone Dome Strike Tip Sulcus |
| 500036 | 1.4mm k-wire |
| 18770140 | Ortholoc Pin Puller |
| 200427 | Inbone Pin Cutter 3.2 |
| 44180025 | 7.0 Muc handle quick connect |
| IB220901 | Inbone Trial Tal Dome #1 Sulc |
| IB220902 | Inbone Trial Tal Dome #2 Sulc |
| IB220903 | Inbone Trial Tal Dome #3 Sulc |
| IB220904 | Inbone Trial Tal Dome #4 Sulc |
| IB220905 | Inbone Trial Tal Dome #5 Sulc |
| 200432010 | Inbone Talar Reamer, 10mm |
| 200432014 | Inbone Talar Reamer, 14mm |
| IB200060 | Inbone Seat Block Talar Stem |
| IB200010 | Inbone Talar Dome Trial Handle |
| 200364003 | Inbone Holding, Tool, M4 |
| 33600200 | Prophecy Conversion Instrument |
| 33680071 | Flat cut talar dome trial, sz1 |
| 33680072 | Flat cut talar dome trial, sz2 |
| 33680073 | Flat cut talar dome trial, sz3 |
| 33680074 | Flat cut talar dome trial, sz4 |
| 33680075 | Flat cut talar dome trial, sz5 |
| 33680000 | Flat cut talar dome trial caddy |

Appendix F: Implant specifications



Infinity with Adaptis Technology Tibial Component

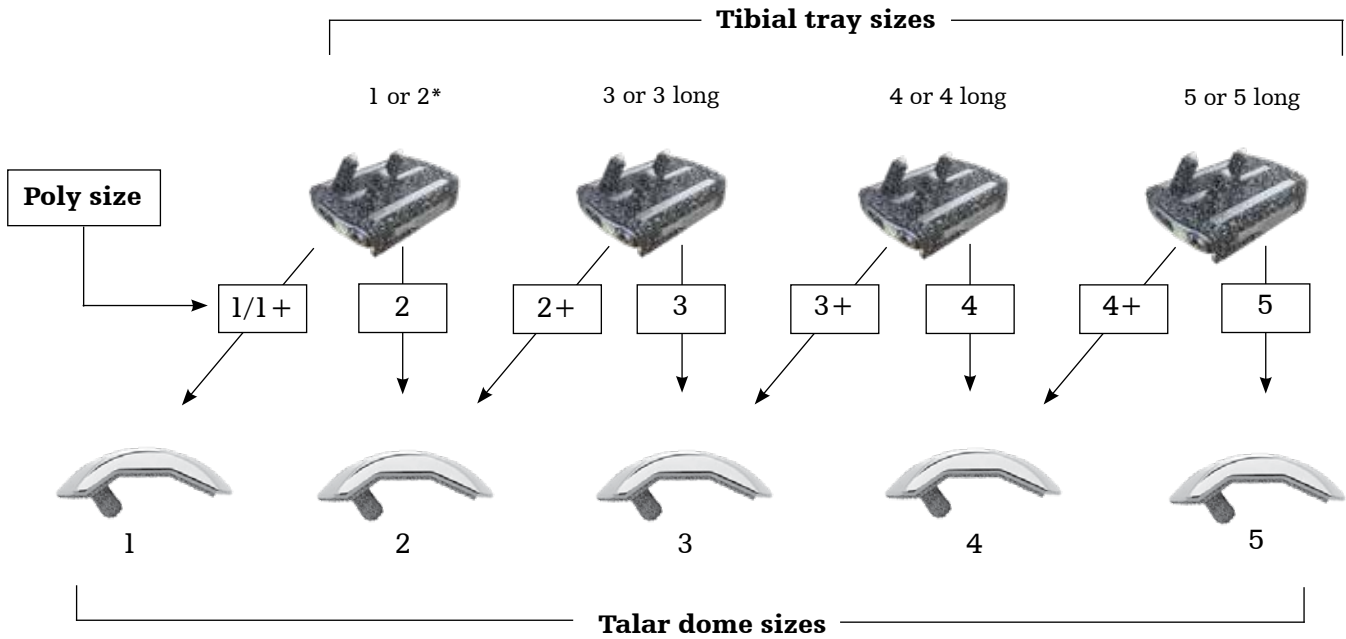
| Size | A | B | C |
|--------|----|----|---|
| 1 | 26 | 34 | 5 |
| 2 | 26 | 38 | 5 |
| 3 | 28 | 38 | 5 |
| 3 long | 28 | 41 | 5 |
| 4 | 31 | 41 | 5 |
| 4 long | 31 | 44 | 5 |
| 5 | 34 | 44 | 5 |
| 5 long | 34 | 48 | 5 |



Infinity with Adaptis Technology Talar Component

| Size | A | B | C | D |
|------|----|----|---|----|
| 1 | 30 | 31 | 5 | 10 |
| 2 | 32 | 34 | 5 | 10 |
| 3 | 34 | 36 | 5 | 10 |
| 4 | 36 | 39 | 6 | 11 |
| 5 | 38 | 42 | 7 | 12 |

Infinity with Adaptis Technology Total Ankle System Poly Insert size usage diagram



***Tibial sizes 1 and 2 share the same ML width and therefore share the same poly insert lock detail.**

Appendix G: Ordering information



Infinity with Adaptis Technology Tibial Component

| Part # | Description |
|----------|----------------------|
| 33680001 | Tibial tray sz1 std |
| 33680002 | Tibial tray sz2 std |
| 33680003 | Tibial tray sz3 std |
| 33680004 | Tibial tray sz4 std |
| 33680005 | Tibial tray sz5 std |
| 33680013 | Tibial tray sz3 long |
| 33680014 | Tibial tray sz4 long |
| 33680015 | Tibial tray sz5 long |



Infinity with Adaptis Technology Talar Component

| Part # | Description |
|----------|----------------|
| 33680021 | Talar dome sz1 |
| 33680022 | Talar dome sz2 |
| 33680023 | Talar dome sz3 |
| 33680024 | Talar dome sz4 |
| 33680025 | Talar dome sz5 |



Infinity with Adaptis Technology Flat Cut Talar Component

| Part # | Description |
|----------|--------------------------|
| 33680031 | Flat cut talat dome, sz1 |
| 33680032 | Flat cut talat dome, sz2 |
| 33680033 | Flat cut talat dome, sz3 |
| 33680034 | Flat cut talat dome, sz4 |
| 33680035 | Flat cut talat dome, sz5 |

Accessories

| Part # | Description |
|------------|-----------------------------------|
| Ib200051 | Bone removal screw |
| 200138101s | Saw blade Stryker system 5 narrow |
| 200138102s | Saw blade Stryker system 5 wide |
| 200138103s | Saw blade Hall/Linvatec narrow |
| 200138104s | Saw blade Hall/Linvatec wide |
| 200138105S | Saw blade Stryker System 6 narrow |
| 200138106S | Saw blade Stryker system 6 wide |
| 200138107S | Saw blade Stryker system 7 narrow |
| 200138108S | Saw blade Stryker system 7 wide |



Infinity Everlast Poly Insert

| Part # | Description |
|----------|-------------------------------|
| 33681106 | Infinity Everlast sz1/1+ 6mm |
| 33681108 | Infinity Everlast sz1/1+ 8mm |
| 33681110 | Infinity Everlast sz1/1+ 10mm |
| 33681112 | Infinity Everlast sz1/1+ 12mm |
| 33682206 | Infinity Everlast sz2 6mm |
| 33682208 | Infinity Everlast sz2 8mm |
| 33682210 | Infinity Everlast sz2 10mm |
| 33682212 | Infinity Everlast sz2 12mm |
| 33683206 | Infinity Everlast sz2+ 6mm |
| 33683208 | Infinity Everlast sz2+ 8mm |
| 33683210 | Infinity Everlast sz2+ 10mm |
| 33683212 | Infinity Everlast sz2+ 12mm |
| 33683306 | Infinity Everlast sz3 6mm |
| 33683308 | Infinity Everlast sz3 8mm |
| 33683310 | Infinity Everlast sz3 10mm |
| 33683312 | Infinity Everlast sz3 12mm |
| 33684307 | Infinity Everlast sz3+ 7mm |
| 33684309 | Infinity Everlast sz3+ 9mm |
| 33684311 | Infinity Everlast sz3+ 11mm |
| 33684313 | Infinity Everlast sz3+ 13mm |
| 33684406 | Infinity Everlast sz4 6mm |
| 33684408 | Infinity Everlast sz4 8mm |
| 33684410 | Infinity Everlast sz4 10mm |
| 33684412 | Infinity Everlast sz4 12mm |
| 33685407 | Infinity Everlast sz4+ 7mm |
| 33685409 | Infinity Everlast sz4+ 9mm |
| 33685411 | Infinity Everlast sz4+ 11mm |
| 33685413 | Infinity Everlast sz4+ 13mm |
| 33685506 | Infinity Everlast sz5 6mm |
| 33685508 | Infinity Everlast sz5 8mm |
| 33685510 | Infinity Everlast sz5 10mm |
| 33685512 | Infinity Everlast sz5 12mm |

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