

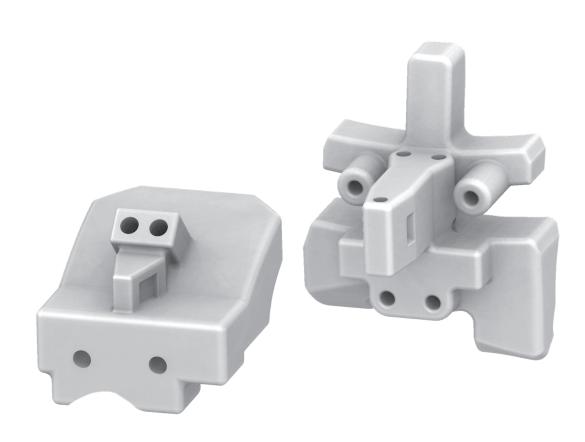
Infinity®

Total Ankle System with

Prophecy®

Surgical Planning Guides

Operative technique



Disclaimer

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

Important

The patient should be advised that the device cannot and does not replicate a normal healthy bone, that the device can break or become damaged as a result of strenuous activity or trauma and that the device has a finite expected service life.

- Removal or revision of the device may be required sometime in the future.
- Cleaning and sterilization information is provided in the applicable instructions for use.
- Non-sterile devices, including implants and instruments, must be cleaned and sterilized prior to use, in accordance with validated methods.
- Devices that are able to be disassembled should be disassembled prior to point-of-use processing.

- Additionally, devices with movable components that do not facilitate disassembly should be manually articulated during the point-of-use processing step in order to evacuate additional soils.
- Please remember that the compatibility of different product systems has not been tested unless specified otherwise in the product labeling.
- Consult Instructions for Use (www.ifu.stryker.com) for a complete list of potential adverse effects and adverse events, contraindications, warnings and precautions.
- The surgeon must advise patients of surgical risks, and make them aware of adverse effects and alternative treatments.
- An implant whose packaging is open or damaged or whose expiration date has passed must not be used.
 Every precaution must be taken to ensure sterility when opening the packaging of the implant and during implantation.

Surgeon design team

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Infinity Total Ankle System with

Prophecy Surgical Planning Guides

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Proper surgical procedures and techniques are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the procedures based on his or her personal medical training and experience. 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 operative technique and the package insert is available on the website listed. Please contact your local Stryker representative for product availability

Product information

Prophecy Surgical Planning 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 Instrument package insert for instructions on the proper steps for processing Stryker disposable surgical instruments.

Intended use

Prophecy Surgical Planning is intended to be used as patient specific surgical instrumentation to assist in the positioning of total ankle replacement components intraoperatively, in guiding the marking of bone before cutting, and in the presurgical planning of the ankle and surrounding anatomy to support the total ankle implant. The Prophecy Surgical Planning Guides and Reports are intended for use with the Infinity Total Ankle System and their cleared indications for use, provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

The Prophecy Surgical Planning Guides are intended for single use only.

Infinity total ankle 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 a polyethylene insert (UHMWPE). components are available in a variety of sizes and design configurations intended for primary applications.





Product information

Indications

The Infinity Total Ankle System is indicated for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis.

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);
- 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;
- 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).

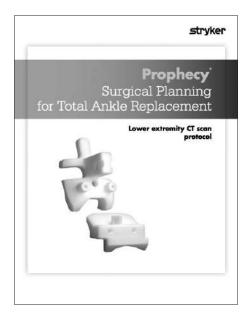
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Product information

CT scan protocol

Prophecy Surgical Planning
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 Lower extremity
CT scan protocol. Engineers at
Stryker have determined the
necessary scanning parameters
which are described in document
#AP-016564.

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



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

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

Tibial alignment guide fluoroscopic check assembly

To enhance fluoroscopic visualization of the Prophecy Tibia Alignment Guide (PROPINFE) it is recommended to place metallic markers in the guide prior to placement on thepatient. Begin by using a pair of pin cutters (200427) to remove the sharp end of a 2.4 steinmann pin (200072) (fig. 1). Note that it may be helpful to use a needle driver to retain the cut ends of the Pin (fig. 2).

Cut two ½" (or 12mm) segments of the Steinmann Pin and insert by hand into the two vertical holes in the Prophecy patient-specific tibia guide (fig. 3).







Fig. 2

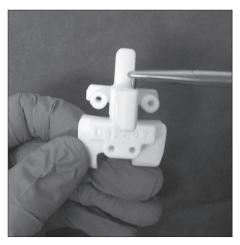


Fig. 3



Prophecy tibia alignment guide PROPINFE (EU only)



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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.

NOTICE

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



Anterior

Posterior

Tibial alignment guide

Prophecy Surgical Planning
Guides are designed to
incorporate fixed osteophytes on
or near the articulating surfaces,
and therefore osteophytes should
not be removed during the
surgical exposure of the ankle.
However any loose bodies,
specifically called out on the
Prophecy pre-operative plan,
should be removed as they will
not have been incorporated
into the proper seating of the
Prophecy 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 patient-specific tibia alignment guide in the best fit location (fig. 4). Please note that the guides are designed to fit in one and only one proper location.

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

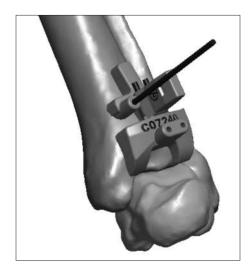


Fig. 4

Once the guide is in the proper location insert one 2.4 steinmann pin into one of the proximal holes of the tibia guide to temporarily hold it into position (fig. 5).

Next place a steinmann pin though the vertical hole in the center handle of the guide to serve as a coronal alignment cue (fig. 6).

With the tibia guide held in place, take an AP fluoro image to confirm that the tibial guide is in the correct orientation. To obtain a true AP view rotate the ankle (or conversely the c-arm) until the long pin lines up between the two short pins (fig. 7). This image should correspond to the "anterior view" tibial alignment guide image in the Prophecy pre-op plan (fig. 8).



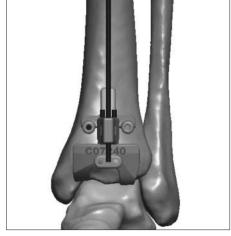


Fig. 5

Fig. 6



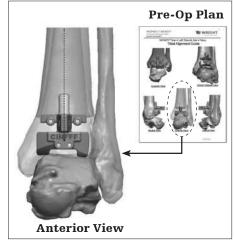


Fig. 8

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

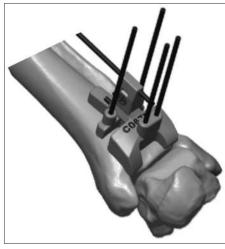
If the intra-op image is significantly different that the pre-op plan remove the tibia guide as well as any pins holding it in place. Ensure the periosteum has been cleaned from the tibia, and that skin retractors are effectively keeping all other soft-tissues from interfering with the guide. It may 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.

NOTICE

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 corticies of the tibia (fig. 9). Do not cut the pins at this time. Remove the Prophecy guide by sliding it up and over the pins, leaving the pins in place. It may be helpful to attach a kocher clamp in the notches built into the rectangular anterior handle to pull the tibia guide up.







Coronal sizing guide 33620032 - 33620035

Install coronal sizing guide

Select the appropriately sized coronal sizing guide (33620032 through 33620035) and slide over the two distal tibial pins. Let the coronal sizing guide slide down to the surface of the tibia. Next slide the Prophecy conversion instrument (33600200) over the two proximal tibial pins and onto the dovetail of the coronal sizing guide (fig. 10). Lock into position using the hex driver (E5001005) (fig. 11).



Fig. 10



Fig. 11



Prophecy conversion instrument 33600200



Hex driver E5001005

The surgeon has the option to fluoroscopically verify the size and orientation of the coronal sizing guide prior to making the tibial resection (fig. 12). To correct for parallax the coronal adjustment guide contains a "pin-in-circle" feature. The C-arm should be adjusted until that the pin appears in the center of the circle (fig. 13 and 14).

The dark outlines in the coronal guide represent the tibial resections as well as the coronal profile of the tibial component (fig. 14).

Refer to the Prophecy pre-op plan for verification of the resection.

NOTICE

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.

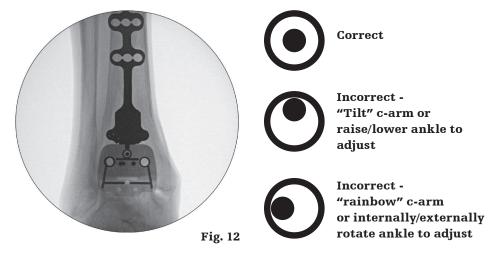
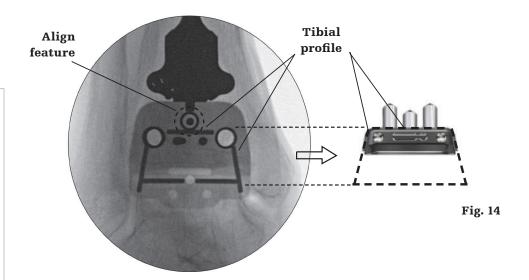


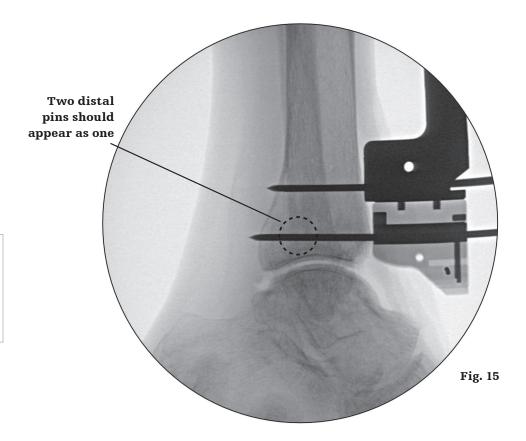
Fig. 13



The surgeon may also choose to obtain a fluoroscopic lateral view of the ankle perpendicular to the installed coronal 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 (fig. 15).

NOTICE

For instructions on how to couple the tibial and talar resections refer to page 53 – 55 in Appendix A.



Drill tibial corners

Using the Tibial corner drill (33600048), bi-cortically drill both proximal corners of the tibia (fig. 16).

Remove the coronal sizing guide and slide the appropriately sized resection guide (33620052 through 33620055) over the distal 2.4mm pins (fig. 17).

NOTICE

If the surgeon chooses to intraoperatively change the planned talar implant to a flat-cut Inbone talar dome instead of a chamfer-cut Infinity Talar Dome. Refer to Appendix C.

Optionally, install a 2.4mm steinmann pin through one of the divergent pin locations (fig. 18). 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 just behind the medial malleolus.

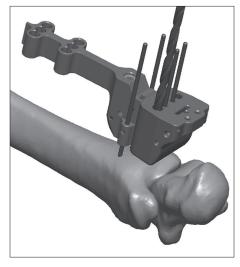


Fig. 16





Resection guide 33620052 - 33620055



Fig. 17

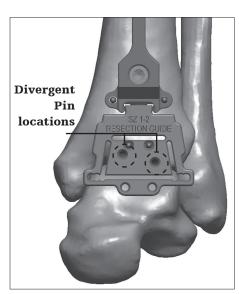


Fig. 18

Tibial bone resection

Using the pin cutter trim the pins flush to the surface of the resection guide. Leave enough length on the divergent pin to allow its removal with a pin driver or pin puller but short enough to allow saw blade clearance in the medial resection slot (approximately 15mm).

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

CAUTION

Do not make the talar cut at this time. If using tibia only spacer technique, see Appendix B.

Remove the divergent steinmann

pin, then remove the resection guide and distal tibial steinmann pins. Leave the two proximal tibial steinmann pins. At the top of the tibial cut, use an osteotome to cut down towards the talus at approximately 60° to remove the anterior section of the tibia (figs. 19 And 20). 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.





Fig. 19

Fig. 20

NOTICE

If the surgeon pre-operatively chose to utilize an Inbone Talar Dome instead of an Infinity talar dome refer to Appendix D.

Talar alignment guide

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 patient-specific alignment guide will surface match is free of all soft tissue. Place the Prophecy Patient-Specific Talus Alignment Guide (PROPINFE) on the talar surface in the best fit location (figs. 21, 22, and 23).

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).



Fig. 21



PROPINFE (EU only)

Prophecy talus alignment guide

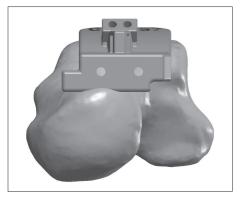


Anterior

Distal

NOTICE

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



Anterior view Fig. 22

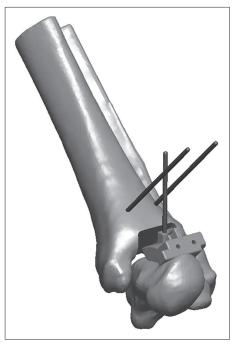


Medial-oblique view Fig. 23

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 (fig. 24). 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 (fig. 25). 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.



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.



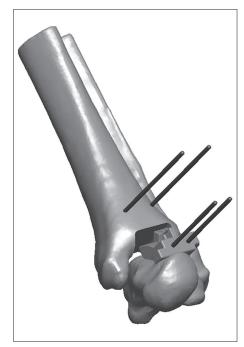
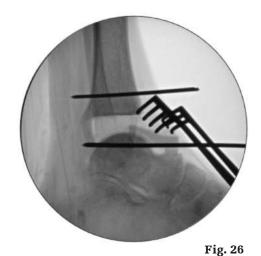


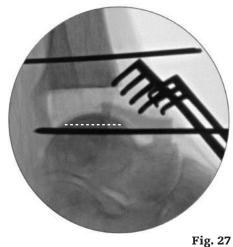
Fig. 24

Fig. 25

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 (fig. 26). The proximal talar resection (white dashed line) will be parallel to and approximately 2mm proximal to the top of the steinmann pin (fig. 27).

In addition the surgeon can compare to images in the Prophecy preoperative plan to verify accuracy of the talar guide (figs. 28 And 29).





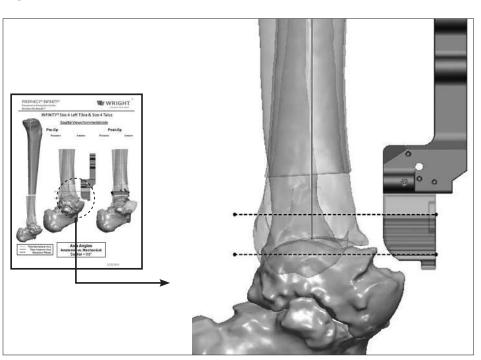




Fig. 28 Fig. 29

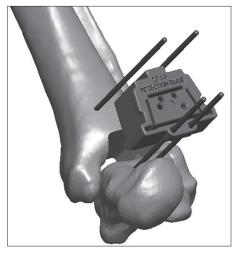
Talar bone resection

Choose the appropriately sized infinity resection guide, position the 2 talar pin holes over the 2 pins from the Prophecy talus alignment guide and slide down to the anterior surface of the talar dome (fig. 30). The resection guide will not necessarily be the same size used in the tibial resection. Consult the Prophecy pre-op plan for confirmation.



At this point the surgeon still has the option to intra-operatively change to an Inbone flat-cut talar resection. Refer to appendix c for details on using the inbone talar resection guide to translate the talar pin locations and make the desired resection.

Insert two additional 2.4mm Steinmann pins into the medial and lateral gutters for protection of the malleoli (fig. 31). Use the Pin Cutter to cut the Steinmann pins close to the surface of the Resection Guide.





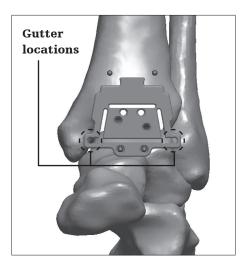


Fig. 31

Care must be taken to ensure that the placement of the gutter pins does not unintentionally cause a shift in the position of he resection guide. In addition, any unintentional pressure applied to the 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 (distal slot of the resection guide)

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.

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.

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 (fig. 32). 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.

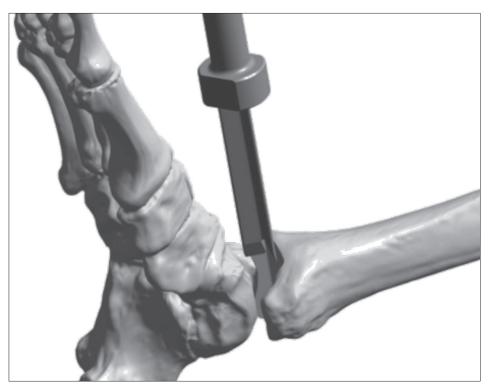


Fig. 32



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 (fig. 33).



Fig. 33



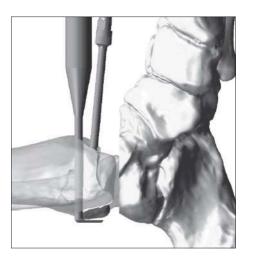


Fig. 34





Bone removal screw IB200051



Ratcheting handle 44180025



Posterior capsule release tool IB200050

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 (fig. 36).



Fig. 36

Tibial tray trialing and AP sizing

Place the appropriately sized tibial tray trial (33620061) through 33620065) over the two remaining tibial pins and into the resected joint space (fig. 37). 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 (fig. 38). 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.



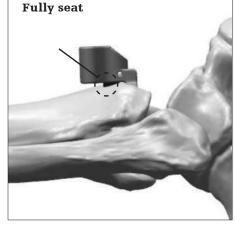


Fig. 37

Fig. 38



Tibial tray trial 33620062 - 33620065



Self-retaining laminar spreaders 33609012

The tibial trial allows the surgeon to determine both the optimal AP tibial coverage and positioning through fluoroscopic evaluation (fig. 39).

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 (fig. 40 and 41).

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&2 tibia trial the full length represents the size 2 and the notch indicates the length of the size 1 option.



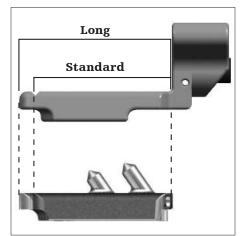
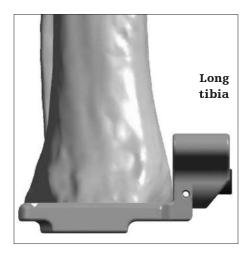


Fig. 39

Fig. 40



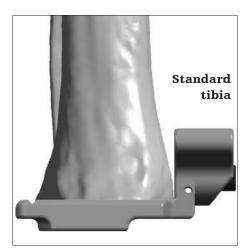


Fig. 41

The surgeon also has the option to anteriorly translate the tibial trial (maximum of 3mm) in order to minimize posterior overhang if desired (fig. 43). To adjust, insert the hex driver into the front of the tibial trial and turn clockwise (fig. 42 And 44).



Fig. 42

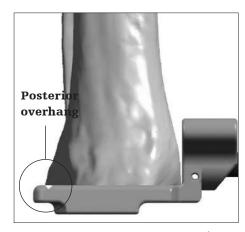


Fig. 43

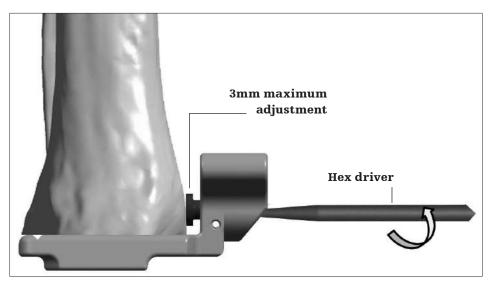


Fig. 44

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 (fig. 45). 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 (fig. 46).

After all three holes are prepared remove both broaches and leave the tibial tray trial in place (fig. 47).



Fig. 45

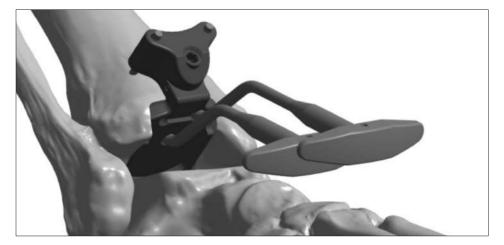


Fig. 46



Fig. 47



Anterior tibial peg broach 33600067



Posterior tibial peg broach 33600069

Talar component sizing and positioning

Place the appropriately sized talar dome trial (33600071 through 33600075) into the joint space. Using the poly insert trial holding tool (ib200110) install the appropriately sized poly insert trial (33621106 through 33625512) into the tibial tray trial.

The locking tab of the poly insert trial should engage the tibial tray trial (fig. 48).

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.

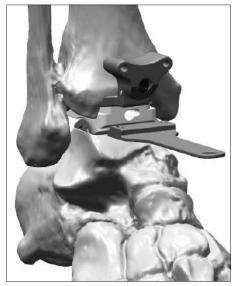


Fig. 48



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) (figs. 49 and 50).

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 (fig. 51).

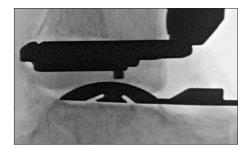


Fig. 49

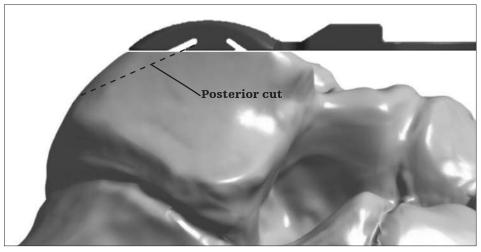


Fig. 50



Fig. 51

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 (fig. 52). The two 2.4mm tibial pins may now be removed as well.

Slide the talar resection guide base (33600091 through 33600095) onto the two 2.4mm pins in the talus and seat flush to the resected talar surface (fig. 53).

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 (fig. 54).

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.



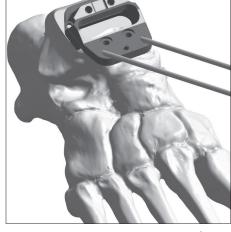


Fig. 52

Fig. 53

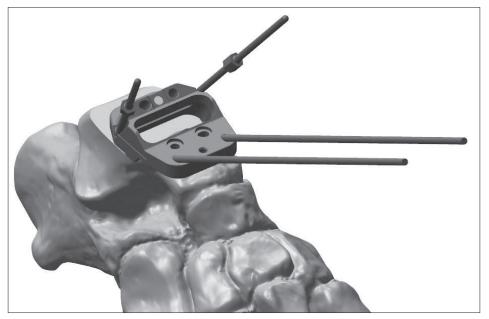


Fig. 54



Talar resection guide base 33600091 - 33600095



Temporary fixation screw Long - 33610002 Short - 33610003



T-handle pin driver 33600120

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 (fig. 55).

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 (fig. 56).



Fig. 55

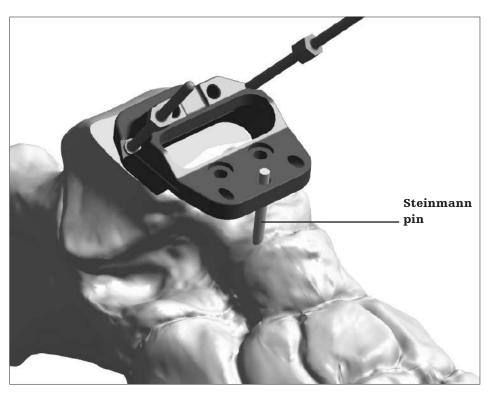


Fig. 56

Assemble the anterior talar pilot guide (33600101 through 33600105) with pegs facing down onto the anterior face of the talar resection guide base (fig. 57).

Use the appropriately sized talar reamer (33600123 or 33600126) to plunge cut through all four holes of the pilot guide (fig. 58). 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 through 33600115) (fig. 59).

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 (fig. 60). 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.







Fig. 58



Fig. 59



Fig. 60



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 (fig. 61).

Again use the talar reamer to plunge cut through all four holes of the pilot guide (fig. 62). 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 (fig. 63).

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 (fig. 64).







Fig. 62







Fig. 64

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 (fig. 65).

CAUTION

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

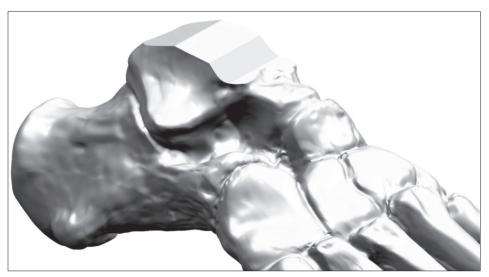


Fig. 65

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. Overtensioning 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 through 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 (fig. 66).

Slightly plantarflex the foot and install a 2.4mm steinmann pin through the talar peg drill guide to temporarily hold it in position (fig. 67).

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 (fig. 68).



Fig. 66

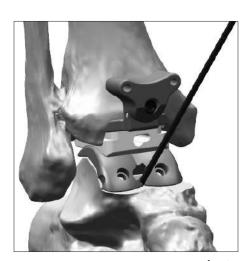






Fig. 68



Talar peg drill guide 33600161 - 33600165



Anterior peg drill IB200020

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 (fig. 69).

Choose the appropriately sized tibial tray impaction insert (33600132 through 33600135) and assemble the tibial tray component by sliding over the dovetail opening (fig. 70).

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.

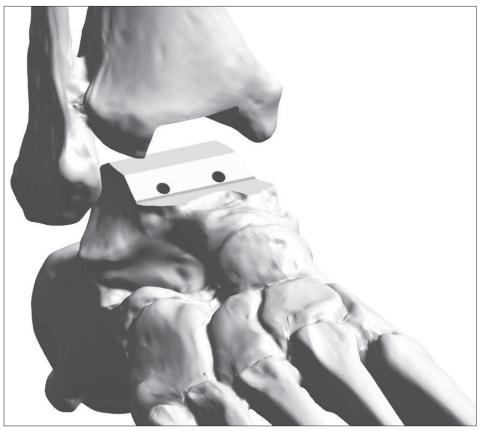


Fig. 69

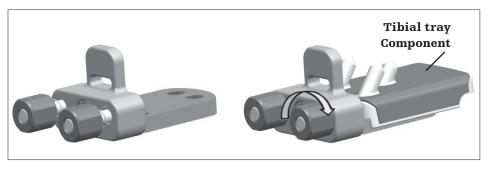


Fig. 70



Tibial tray impaction insert 33600132 - 33600135

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 (figs. 71 And 72).

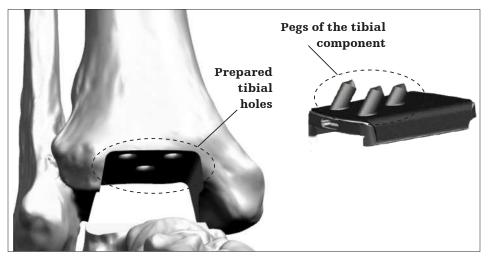


Fig. 71



Fig. 72



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 (fig. 73).

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.

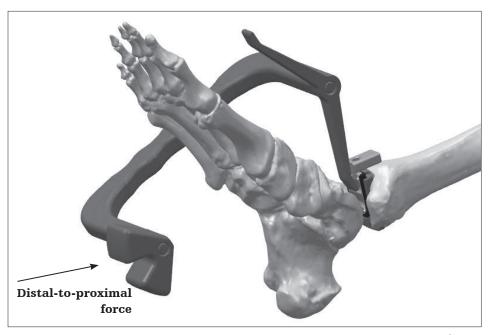


Fig. 73



Offset tibial tray impactor 33600140



Straight tibial tray impactor 33600141

Talar component implantation

Insert the appropriately sized tibial tray protector (33620152 through 33620155) into the tibial tray to protect the talar dome surface during installation (fig. 74).

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

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 (fig. 75). 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 (fig. 76).

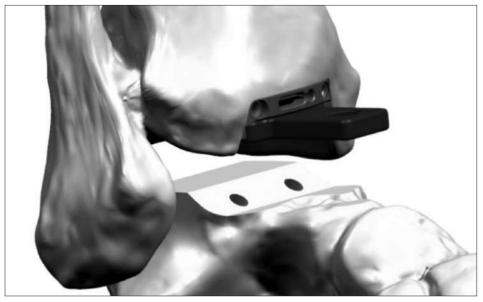


Fig. 74



Fig. 75



Fig. 76



Tibial tray protector 33620152 - 33620155



Talar dome impactor IB200030 impactor tip IB200031

Polyethylene bearing installation

Install two attachment screws (33600190) into the anterior face of the tibial tray (fig. 77).

Assemble the poly insert guide rail (33600172 through 33600175) onto the poly inserter (33600170) and ensure that the plunger handle is pulled back completely and locked in the start position (fig. 78).

Slide the dovetail feature of the poly insert implant into the poly insert guide rail ensuring correct A/P orientation of the component (fig. 79).



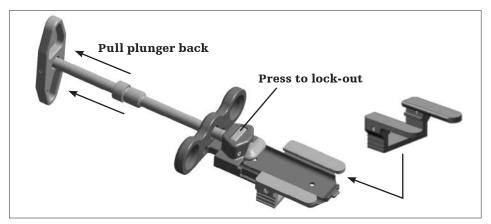


Fig. 77

Fig. 78



Fig. 79



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 (fig. 80).

/ 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.



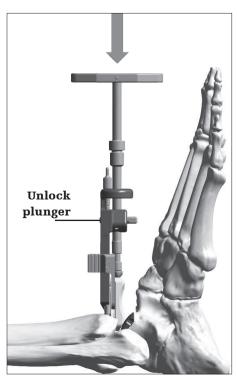
Fig. 80



Attachment nut 33600191

To begin Poly insertion, unlock the plunger and push it forward until it comes into contact with the poly inserter housing (figs. 81 and 82).

Once it contacts the housing, the plunger can be turned (clock-wise) to continue advancing the poly insert into the tibial tray (fig. 83).



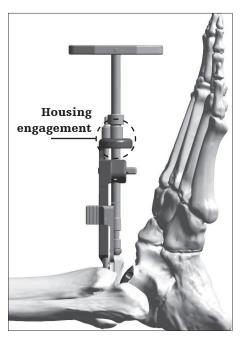


Fig. 82



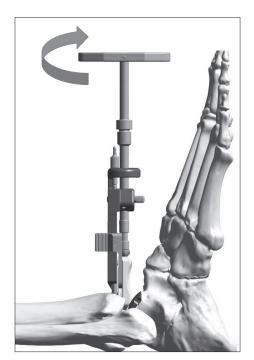


Fig. 83

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 (fig. 84).



Fig. 84

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 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 (figs. 85 and 86). Close the wound and cast foot in slight plantar flexion.





Fig. 86

Explant informationInsert 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 bonecement 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.

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

Postoperative management

Postoperative care is the responsibility of the medical professional.

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 010395.

First remove the coronal sizing guide from the Prophecy conversion instrument (fig. 87). 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 (fig. 88).

/ 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 (fig.89).

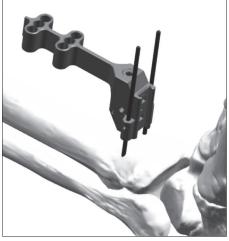


Fig. 87



Fig. 88



Fig. 89



Pin sleeve 33600025



33600026

Install sizing and resection guide adjustment block

Install a 3.2mm pin into each pin sleeve and through both cortices of the tibia (fig. 90). Remove both pin sleeves, the Prophecy conversion instrument and the two original distal pins (fig. 91).

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 (fig. 92). 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 (fig. 93).







Fig. 91





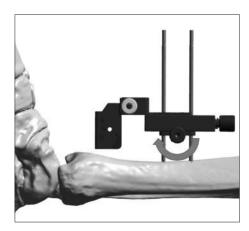


Fig. 93



Adjustment block 33600030

Coronal plane sizing and positioning

Connect the coronal sizing guide (33600032 through 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 (fig. 94).

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 (fig. 95 And 96).

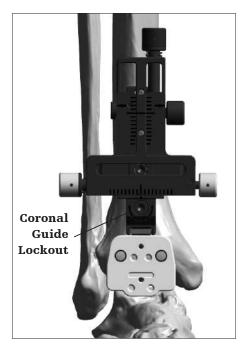


Fig. 96

Fig. 94



Correct



Incorrect -"Tilt" c-arm or raise/lower ankle to adjust



Incorrect -"Rainbow" c-armor internally/ externally rotate ankle to adjust

Fig. 95



Coronal sizing guide 33620032 - 33620035

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 (fig. 97).

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 (fig. 98).

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.

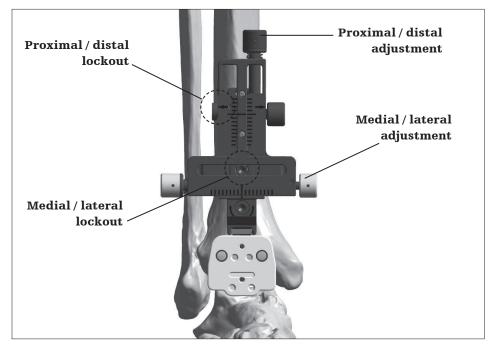
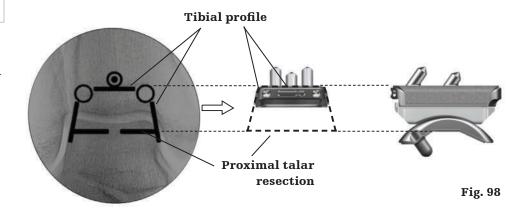
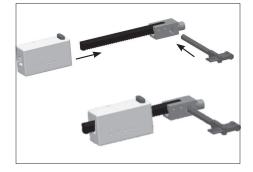


Fig. 97



NOTICE

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.



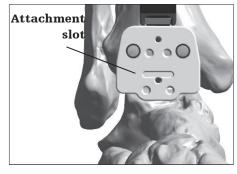


Fig. 99

Fig. 100

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 through 33620045) onto the ratcheting arm (fig. 99). 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 (fig. 100).

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 (fig. 101). 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.

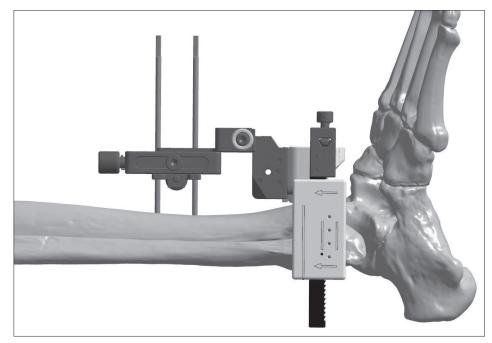


Fig. 101



Sagittal sizing guide arm 33600040



Sagittal sizing ratcheting arm 33600068



Sagittal sizing guide 33620042 - 33620045

To obtain a true lateral view fluoroscopically ensure that the center row of talar alignment pins appear as true solid circles (fig. 102). 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 (figs. 103 and 104).

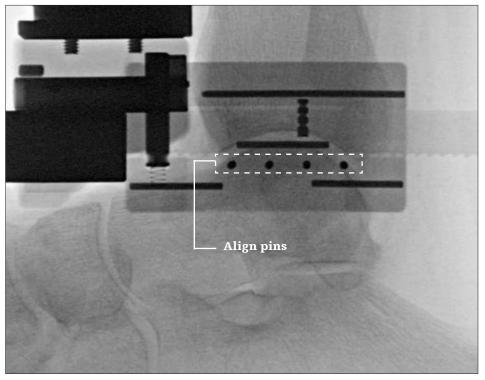


Fig. 102

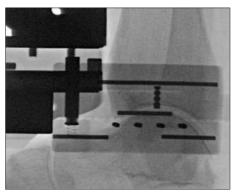


Fig. 103 Rotate or "Rainbow" c-arm to adjust

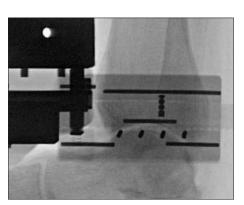


Fig. 104 Swing or "Wig-Wag" c-arm to adjust

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 (figs. 105 And 106).

CAUTION

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

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 (figs. 105 And 106).

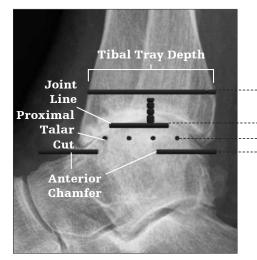




Fig. 105 Fig. 106

Note that the distal extent of the anterior chamfer also corresponds to the flat cut surface of an Inbone talar dome (figs. 107 and 108).

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 (fig. 109).

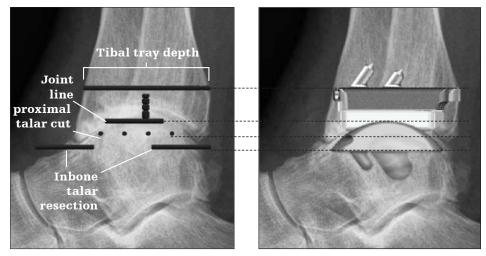
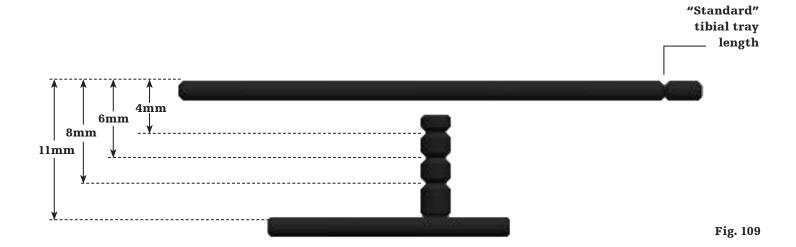


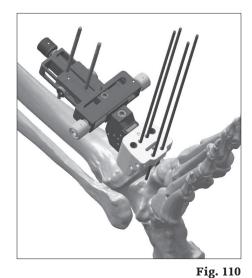
Fig. 107 Fig. 108



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 (fig. 110). Place the two tibial pins first then place the talar pins.



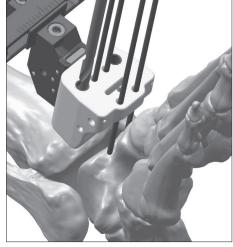


Fig. 111

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 (fig. 111).



Bone resection

Remove the coronal sizing guide and slide the appropriately sized resection guide (33620052 through 33620055) over the 2.4mm pins and into the adjustment block (fig. 112). Secure with hex driver.

NOTICE

For steps on how to utilize a flat-cut inbnone talar dome instead of the standard chamfer-cut infinity talar dome refer to Appendix C.

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 (fig. 113).

Optionally, for additional stability, install a 2.4mm pin through one of the two divergent pin locations (fig. 113). When using a divergent pin always use the medial option (in which the pin travels medial to lateral).

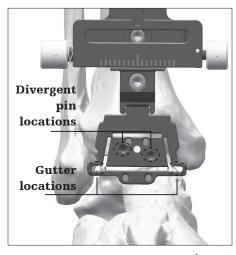


Fig. 112



Fig. 113

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).



Resection guide 33620052 - 33620055



200427

Using the appropriate size saw blade and oscillating bone saw make the tibial and talar bone resections. This includes cutting though 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.

NOTICE

Refer back to page 20 for the remaining steps to complete the procedure.

Remove the divergent steinmann pin, then remove the resection guide, adjustment block, and remaining steinmann pins.

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 (fig. 114). 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.

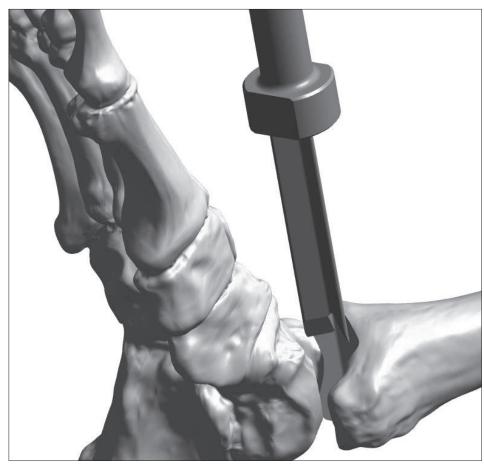


Fig. 114



Remove tibial bone resection

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 (fig. 115).

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 (fig. 116).



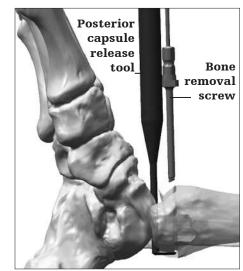


Fig. 115

Fig. 116





Ratcheting handle 44180025



Posterior capsule release tool IB200050

Tibial tray trialing and AP sizing

Remove tibial bone resection. 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 (fig. 117).

Place the appropriately sized tibial tray trial (33620062 through 33620065) into the resected joint space and seat flush against the resected tibia. Padded self-retaining laminar spreaders (33609012) can be inserted between the trial and the talus to ensure the trial is seated flush (fig. 118). Also ensure the tibial trial is fully seated against the anterior cortex of the tibia (fig. 119) And secure in place using two 2.4mm steinmann pins (fig. 120).

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.

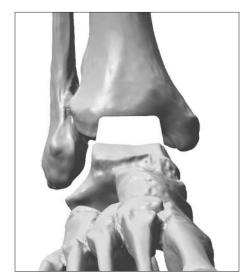
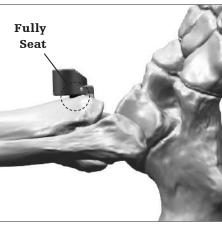


Fig. 118

Fig. 117

Fig. 118





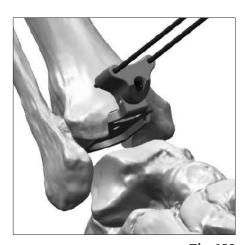


Fig. 120



Tibial tray trial 33620062 - 33620065



Self-retaining laminar spreaders 33609012

The tibial trial allows the surgeon to determine both the optimal AP tibial coverage and positioning through fluoroscopic evaluation (fig. 121).

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 (figs. 122 and 123).

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.



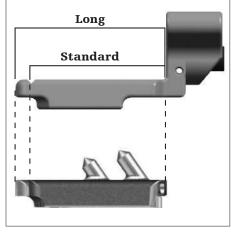


Fig. 121

Fig. 122

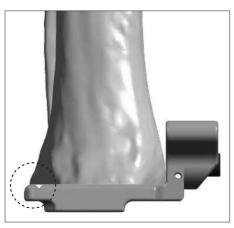


Fig 123 "Long" tibia

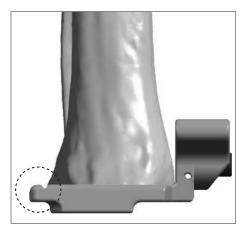


Fig 123 "Standard" tibia

The surgeon also has the option to anteriorly translate the tibial trial (maximum of 3mm) in order to minimize posterior overhang if desired (fig. 124). To adjust, insert the hex driver into the front of the tibial trial and turn clockwise (fig. 125a and 125b).

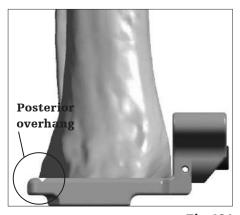
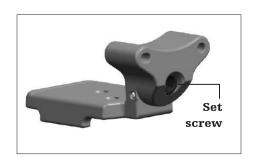


Fig. 124



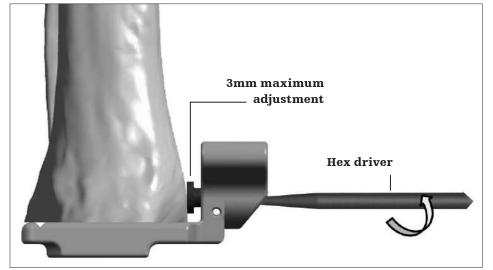


Fig. 125a Fig. 125b

Positioning proximal talar resection

Install the appropriately sized tibial spacer guide (33600424 through 33600456) into the tibial tray trial (figs. 126 and 127). Poly trial holding tool (ib200110) may be used to assist insertion and removed of spacer guides.

/ CAUTION

Prior to inserting the tibial spacer, the talus must be able to be positioned into neutral varus/valgus position and neutral flexion extension. If this cannot be achieved, appropriate soft tissue releases or other ligament balancing procedures will be required.







Fig. 127



Poly trial holding tool IB200110



Tibial spacer guide 33600424 - 33600456

There are two tibial spacer guide thickness options for each component size: standard (6mm) and minus (4mm) (fig. 128).

NOTICE

The spacer thickness does not represent the amount of talus to be resected. It represents the thickness required to properly tension the surrounding soft tissues for proper ankle assessment. Both tibial spacer options will result in the same amount of talar bone resection. Table 1.

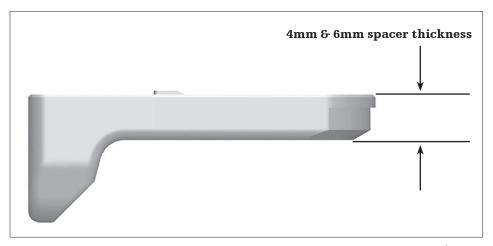
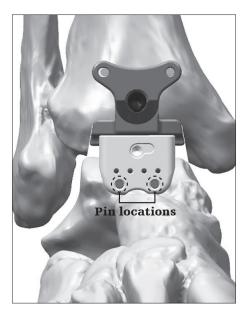


Fig. 128

Table 1

Talar resection	
Size 1 - 3	5mm
Size 4 - 5	6mm

After the proper thickness tibial spacer is chosen, the surgeon must position the foot so that the ankle joint is in a neutral alignment in both the coronal and sagittal plane (plantigrade). While holding the foot in this position, install two 2.4mm steinmann pins through the tibial spacer guide and into the talus (figs. 129 And 130).



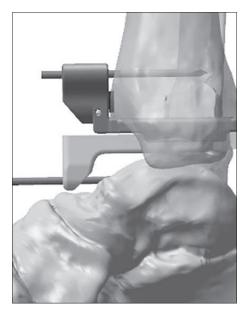


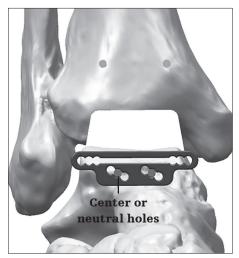
Fig. 129 Fig. 130

Proximal talar bone resection

NOTICE

For steps on how to utilize a flat-cut Inbone talar dome instead of the standard chamfer-cut Infinity talar dome, refer to Appendix C with reference to the talus.

Remove both the tibial spacer guide and tibial trial and install the talar resection guide (33600400) by sliding the center (or neutral) holes over the talar pins (figs. 131 And 132). The neutral holes will be marked with a "0".



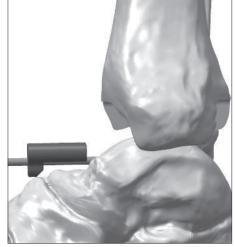


Fig. 131

Fig. 132



Talar resection guide 33600400

To assess the height of the talar resection, drop a saw blade through the resection slot and view in a lateral fluoroscopic image (fig. 133). The height of the talar resection can be adjusted either proximally (+1) or distally (-1) by 1mm by removing the resection guide and sliding it up or down to the next set of pin holes (fig. 134).

Make the talar bone resection through the slot of the resection guide (fig. 135). Remove the resection guide, steinmann pins, and resected talar bone.

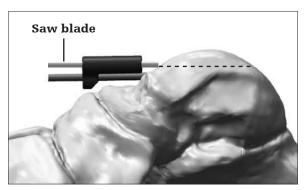


Fig. 133

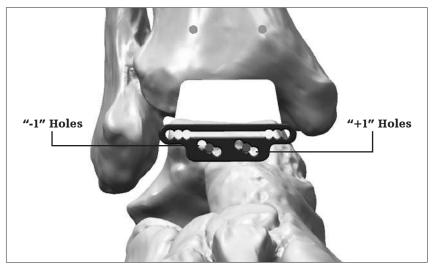


Fig. 134

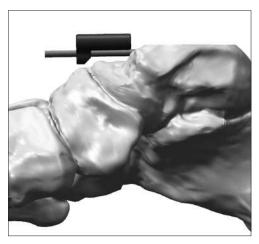


Fig. 135

Talar re-cut option

After the talar resection is made, the surgeon still has an option to make an additional 2mm talar re-cut. Thread the insertion handle (33600130) into the talar recut guide (33609056) and introduce the guide into the joint space. Make sure the paddle of the guide is seated flat on the resected talus and install two 2.4mm steinmann pins through the guide into the talus (fig. 136).

Make an additional 2mm talar bone resection through the slot of the resection guide (fig. 137).

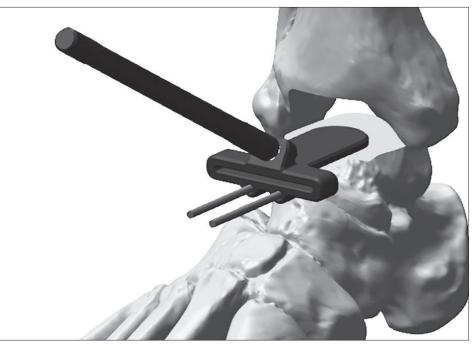


Fig. 136

NOTICE

Refer back to page 26 for the remaining steps to complete the procedure.

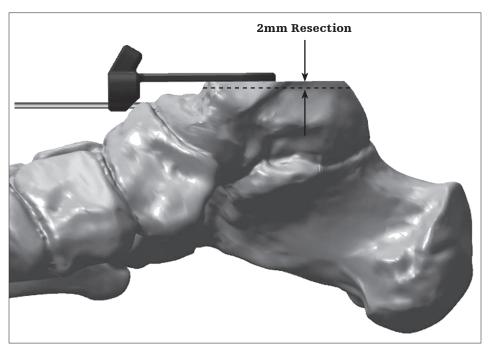


Fig. 137





Talar recut guide 33609056

Inbone talar dome resection technique

Slide the appropriately sized Infinity/Inbone resection guide (33620252 through 33620255) over the existing 2.4mm pins. If coupling the resections, secure the guide into either the adjustment block or the Prophecy conversion instrument (not shown) using the hex driver (fig. 138). If the resections have already been decoupled, the Infinity talar pin holes in the Infinity/Inbone resection guide must be used (fig. 139).

Next, install two 2.4mm pins through the Inbone talar hole locations (proximal to the slot) and into the talus (fig. 140). Alternately, the two pin holes distal to the slot can be used if they are accessible and provide better bone purchase.





Fig. 138

Fig. 139

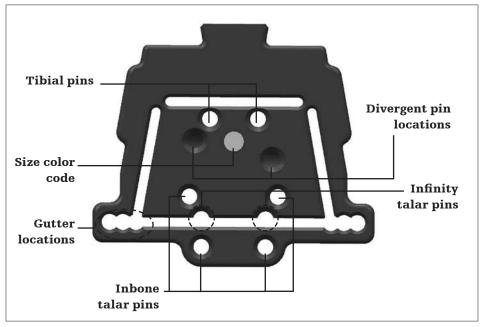


Fig. 140



Infinity/Inbone resection guide 33620252 - 33620255

Inbone talar dome resection technique

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 (fig. 141).

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 (fig. 142). 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 just behind the medial malleolus.



Fig. 141

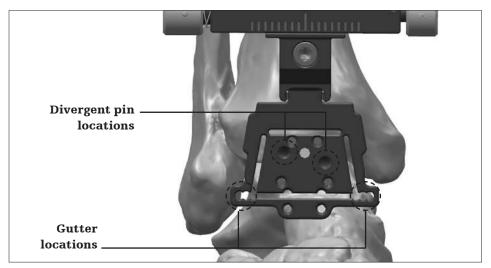


Fig. 142

Inbone talar dome resection technique

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 but short enough to allow saw blade clearance in the medial resection slot (approximately 15mm). Using the appropriate saw blade and oscillating bone saw make the tibia and talar resections.

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 & preparation

Refer to pages 20 - 26 for instructions on bone removal and tibia preparation for the Infinity tibial tray.

Implanting tibial tray

Refer to pages 35 - 37 for instructions on the implantation of the Infinity tibial tray.

Verify talar dome size

After completing the implantation of the Infinity tibial tray, proceed with the preparation of the talar dome on page 72.

During the Prophecy preoperative planning stage, if the surgeon chooses to use an Inbone talar dome instead of an Infinity talar dome this is possible due to the identical articulation geometry of the two systems (fig. 145). The Prophecy talus guide will then be designed to set talar resection depth to the level of the Inbone talar dome.

Talar alignment guide

Place the foot into plantar flexion for maximum exposure of the talar dome and ensure the area around the neck and dome of the talus where the Prophecy Patient-Specific Alignment Guide will surface match is free of all soft tissue. Place the Prophecy Patient-Specific Talus Alignment Guide (PROPINFE) on the talar surface in the best fit location (figs. 143, 144, and 145).

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).

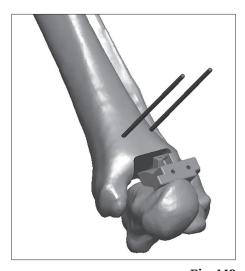


Fig. 143



Fig. 144a



Fig. 144b Anterior view



Fig. 145 Medial-oblique view



Anterior

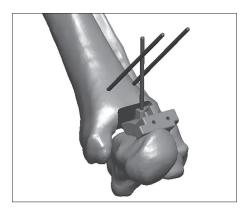
Distal



Prophecy talus alignment guide PROPINFE (EU only)

NOTICE

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





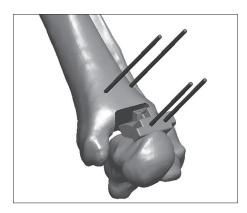


Fig. 147

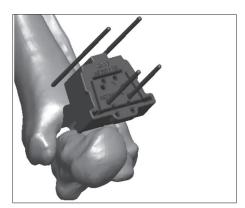


Fig. 148

While holding the Prophecy guide in place install one 2.4mm steinmann pin through the top of the guide into the dome of the talus to temporarily hold the guide in place (fig. 146). 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 (fig. 147). 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.

Talar bone resection

Choose the appropriately sized Infinity/Inbone resection guide (33600252 through 33600255), position the 2 proximal talar pin holes over the 2 pins from the Prophecy talus alignment guide and slide down to the anterior surface of the talar dome (fig. 148 and 149).

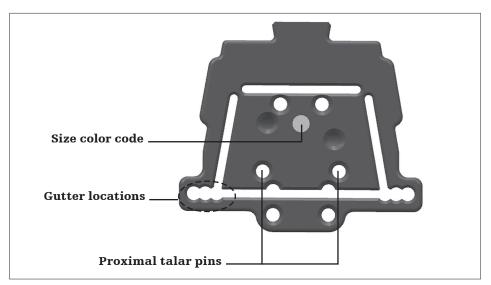


Fig. 149

The resection guide will not necessarily be the same size used in the tibial resection. Consult the Prophecy pre-op plan for confirmation.

NOTICE

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.



Infinity/Inbone resection guide 33620252 - 33620255

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 pre-operative 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.

Tibial bone removal & preparation

Refer to pages 20 - 26 for instructions on bone removal and tibia preparation for the Infinity tibial tray.

Implanting tibial tray

Refer to pages 35 - 37 for instructions on the implantation of the Infinity tibial tray.

Verify talar dome size

After completing the implantation of the Infinity tibial tray, proceed with the preparation of the talar dome on page 72.

Verify talar dome size

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 through 33625512) into the tibial trayn (fig. 150). The locking tab of the poly insert trial should engage the tibial tray.

Assemble the appropriately sized talar dome trial (IB220902 through IB220905) and talar dome holding tool (IB200010) and introduce the dome trial into the joint space (fig. 151).

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 (figs. 152 and 153).





Fig. 150

Fig. 151



Fig. 152

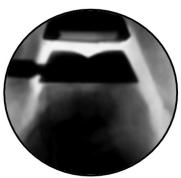


Fig. 153



Poly trial holding tool IB200110



Dome trial holding tool IB200010



Poly insert trial 33621106 - 33625512



Talar dome trial IB220902 – IB220905

Trial reduction

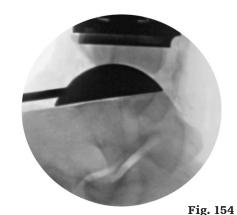
Under lateral plane fluoroscopy ensure the posterior portion of the talar component is resting on the posterior portion of the patient's residual talus (establish congruence) (fig. 154).

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 (fig. 155).



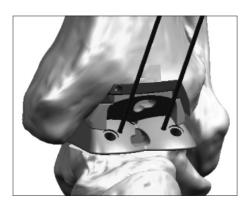


Fig. 155

NOTICE

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 41 for further details on choosing the appropriate polyethylene thickness.

Talar preparation

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 (fig. 156).

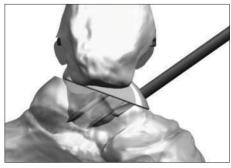
Use the poly insert trial holding tool to remove the poly insert trial. Foot may be plantarflexed to aid in removal of poly insert trial (figs. 157 And 158).



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.

Install a 2.4mm steinmann pin through the center of the talar dome trial to the depth of the selected talar stem using a lateral view to verify depth. Be certain that the talar dome trial is sitting flush with the cut line of the talus before placing this pin (fig. 159).

Remove 1.4mm pins and use the talar dome trial holding tool to slide the talar dome trial off the remaining 2.4mm pin. The foot may be plantarflexed to aid in removal of the talar dome trial.





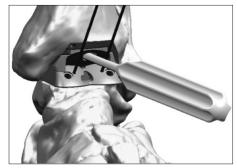


Fig. 157

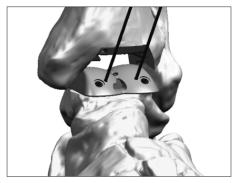


Fig. 158

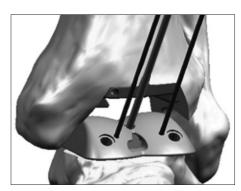


Fig. 159



4mm Anterior peg drill IB200020

Ream for talar stem

Install the appropriate length talar stem reamer (10mm-200432010 or 14mm-200432014) over the pin and ream to the depth of the selected talar stem (fig. 160). The reamer has a hard stop designed to set the appropriate reaming depth (fig. 161). Optionally, use a lateral fluoroscopic view to verify depth.

CAUTION

The talar stem is not intended for subtalar fusion or subtalar joint impingement. Please carefully evaluate the anatomy of each patient before implantation.

Remove the reamer and steinmann pin.



Fig. 160

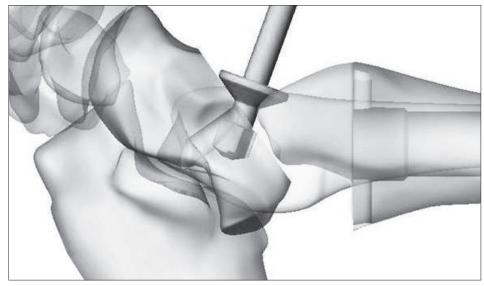


Fig. 161



Talar stem reamers (10mm-200432010) (14mm-200432014)

Assemble talar stem

Insert the appropriate sized talar stem into the bottom of the talar dome (fig. 162), aligning the oblong post and matching the oblong hole in the talar stem. Talar stem and anterior pegs should be parallel.

Insert the talar stem and talar dome assembly into the strike block (IB200060) (fig. 163).

Align the dome strike tool (IB200030 and IB200031) on the talar dome and with a mallet, hit the top of the strike tool 2-3 times to fully seat the talar stem (fig. 164).







Fig. 163



Fig. 164



Strike block IB200060



Talar dome impactor IB200030 Impactor tip IB200031

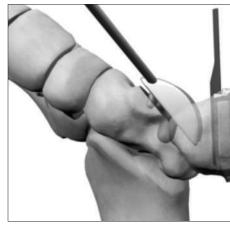
Install talar dome

Place the foot in plantar flexion and insert the tibial tray protector (33620152 through 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.

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 (fig. 166). 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 39 for instructions on the polyethylene bearing installation.





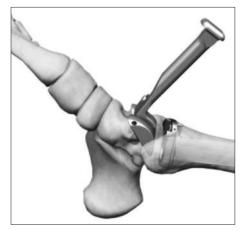


Fig. 166

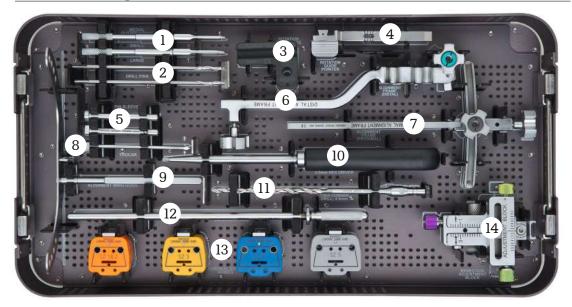


Tibial tray protector 33620152 - 33620155

Holding tool M4 - 200364003

3365KIT1

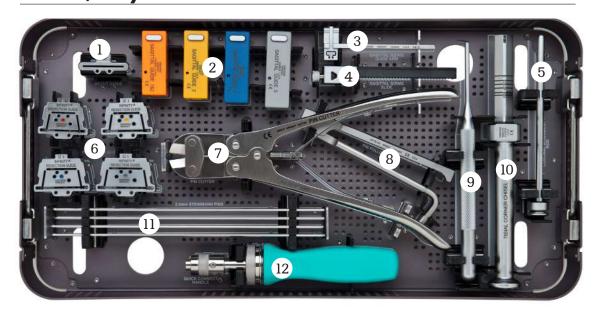
Case 1, Tray 1



- 1. Medial gutter forks (33600009 & 33600010)
- 2. Pins 3.2mm x 102mm (33610001)
- 3. Rotation guide slide (33600012)
- 4. Rotation guide pointer (33600011)
- 5. Pin sleeves (33600025)
- 6. Alignment frame distal assembly (33600020)
- 7. Alignment frame proximal assembly (33600021)

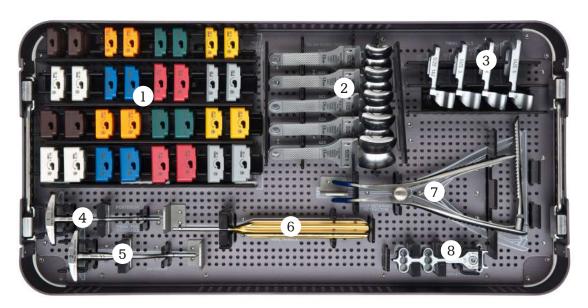
- 8. Trocar (33600026)
- 9. Alignment wing guide (33600023)
- 10. 3.5mm hex driver (e5001005)
- 11.4.8mm tibial corner drill (33600048)
- 12. Alignment rod (33600024)
- 13. Coronal sizing guides (33620032 33620035)
- 14. Resection guide adjustment block (33600030)

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 laminar spreader (33609012)
- 8. Prophecy conversion guide (33600200)

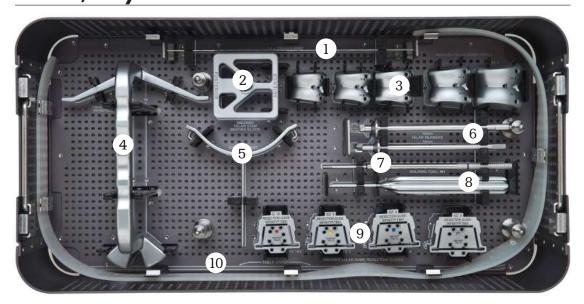
3365KIT1 Case 2, Tray 2



- 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 & 33600126)
- 5. T-handle pin driver (33600120)

- 6. Threaded talar pins (3361002 & 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 (33600132 33620135)

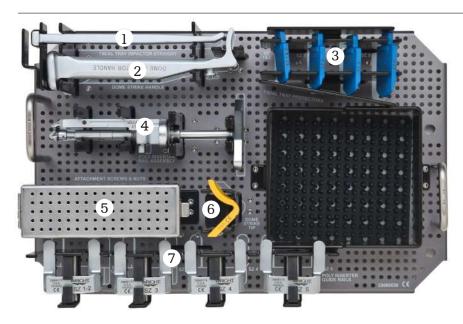
3365KIT1 Case 3, Tray 1



- 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 & 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



- 1. Straight impactor (33600141)
- 2. Dome strike handle (IB200030)
- 3. Tibial tray protectors (33620152 33620155)
- 4. Poly inserter assembly (33600170)
- 5. Attachment screws (33600190) & nuts (33600191)
- 6. Dome strike tip (IB200031)
- 7. Poly inserter guide rails (33600172 33600175)

3365KIT1 Infinity instrument kit

3365KIT1 Infinity instrument kit

Ref #	Description	Ref #	Description
33600009	Medial gutter fork, small	33620062	Trial tibial tray sz 1-2
33600010	Medial gutter fork, large	33620063	Trial tibial tray sz 3
33600011	Rotation guide pointer	33620064	Trial tibial tray sz 4
33600012	Rotation guide slide	33620065	Trial tibial tray sz 5
33600020	Alignment frame dist sub assy	33600069	Tibial peg drill, 3.7mm
33600021	Alignment frame prox sub assy	33600071	Trial talar dome, sz 1
33600022	Knee bracket	33600072	Trial talar dome, sz 2
33600023	Alignment wing guide	33600073	Trial talar dome, sz 3
33600024	Alignment rod	33600074	Trial talar dome, sz 4
33600025	Pin sleeve	33600075	Trial talar dome, sz 5
33600026	Trocar	33600091	Talar resect guide base, sz 1
33600030	Resection adjustment block	33600092	Talar resect guide base, sz 2
33620032	Coronal sizing guide, sz 1-2	33600093	Talar resect guide base, sz 3
33620033	Coronal sizing guide, sz 3	33600094	Talar resect guide base, sz 4
33620034	Coronal sizing guide, sz 4	33600095	Talar resect guide base, sz 5
33620035	Coronal sizing guide, sz 5	33600101	Anter talar pilot guide, sz 1
33620040	Sagittal sizing guide arm	33600102	Anter talar pilot guide, sz 2
33620042	Sagittal sizing guide, sz 1-2	33600103	Anter talar pilot guide, sz 3
33620043	Sagittal sizing guide, sz 3	33600104	Anter talar pilot guide, sz 4
33620044	Sagittal sizing guide, sz 4	33600105	Anter talar pilot guide, sz 5
33620045	Sagittal sizing guide, sz 5	33600111	Anter talar finish guide, sz 1
33600048	Tibial corner drill, 4.8mm	33600112	Anter talar finish guide, sz 2
33620052	Resection guide, sz 1-2	33600113	Anter talar finish guide, sz 3
33620053	Resection guide, sz 3	33600114	Anter talar finish guide, sz 4
33620054	Resection guide, sz 4	33600115	Anter talar finish guide, sz 5
33620055	Resection guide, sz 5	33600120	T-handle pin driver
33600058	Tibial corner chisel	33600123	Talar reamer, sz 1-3
		33600126	Talar reamer, sz 4-6

3365KIT1 Infinity instrument kit

Ref# Description 33600130 Tibial tray insert handle 3360132 Tib tray impact insert, sz 1-2 33600133 Tib tray impact insert, sz 3 Tib tray impact insert, sz 4 33600134 33600135 Tib tray impact insert, sz 5 33600140 Tibial tray impactor, offset Tibial tray impactor, straight 33600141 33620152 Tibial tray protector, sz 1-2 33620153 Tibial tray protector, sz 3 33620154 Tibial tray protector, sz 4 33620155 Tibial tray protector, sz 5 Talar peg drill guide, sz 1 33600161 Talar peg drill guide, sz 2 33600162 Talar peg drill guide, sz 3 33600163 33600164 Talar peg drill guide, sz 4 Talar peg drill guide, sz 5 33600165 33600170 Poly inserter rail assy 33600172 Poly insert guide rail, sz 1-2 Poly insert guide rail, sz 3 33600173 33600174 Poly insert guide rail, sz 4 33600175 Poly insert guide rail, sz 5 33600190 Poly insert attachment screw 33600191 Poly insert attachment nut Resection guide inbone talus, sz 1-2 33620252 Resection guide inbone talus, sz 3 33620253 33620254 Resection guide inbone talus, sz 4 33620255 Resection guide inbone talus, sz 5

3365KIT1 Infinity instrument kit

Description
Trial poly insert, sz 1/1+ 6mm
Trial poly insert, sz 1/1+8mm
Trial poly insert, sz 1/1+ 10mm
Trial poly insert, sz 1/1+ 12mm
Trial poly insert, sz 2 6mm
Trial poly insert, sz 2 8mm
Trial poly insert, sz 2 10mm
Trial poly insert, sz 2 12mm
Trial poly insert, sz 2+ 6mm
Trial poly insert, sz 2+ 8mm
Trial poly insert, sz 2+ 10mm
Trial poly insert, sz 2+ 12mm
Trial poly insert, sz 3 6mm
Trial poly insert, sz 3 8mm
Trial poly insert, sz 3 10mm
Trial poly insert, sz 3 12mm
Trial poly insert, sz 3+ 7mm
Trial poly insert, sz 3+ 9mm
Trial poly insert, sz 3+ 11mm
Trial poly insert, sz 3+ 13mm
Trial poly insert, sz 4 6mm
Trial poly insert, sz 4 8mm
Trial poly insert, sz 4 10mm
Trial poly insert, sz 4 12mm
Trial poly insert, sz 4+ 7mm
Trial poly insert, sz 4+ 9mm
Trial poly insert, sz 4+ 11mm
Trial poly insert, sz 4+ 13mm
Trial poly insert, sz 5 6mm
Trial poly insert, sz 5 8mm
Trial poly insert, sz 5 10mm
Trial poly insert, sz 5 12mm

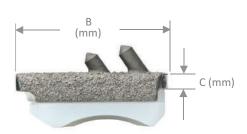
3365KIT1

Infinity instrument kit

Ref#	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
IB200020	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

Implant specifications

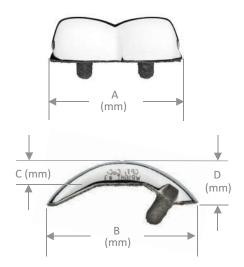




Infinity tibial component

Size	A	В	С
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

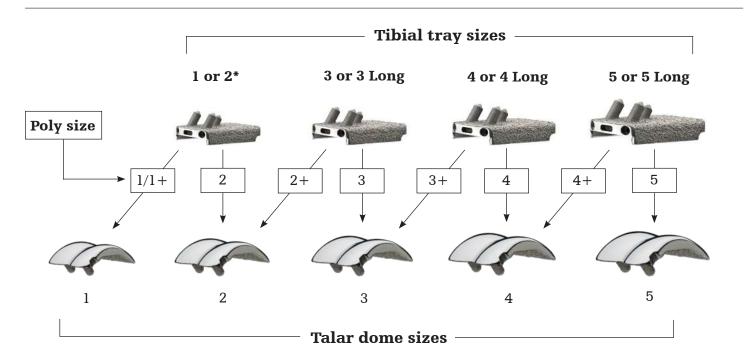




Size	A	В	С	D
1	30	31	5	10
2	32	34	5	10
3	34	36	5	10
4	36	39	6	11
5	38	42	7	12

Implant specifications

Infinity total ankle system poly insert size usage diagram



^{*}Tibial Sizes 1 & 2 share the same ML width and therefore share the same poly insert lock detail.

Ordering information



Infinity tibial component

_		
	Ref #	Description
	33650001	Tibial tray sz 1 std
	33650002	Tibial tray sz 2 std
	33650003	Tibial tray sz 3 std
	33650004	Tibial tray sz 4 std
	33650005	Tibial tray sz 5 std
	33650013	Tibial tray sz 3 long
	33650014	Tibial tray sz 4 long
	33650015	Tibial tray sz 5 long



Inbone II talar component

Ref #	Description
220220901	Talar dome sz 1 sulcus
220220902	Talar dome sz 2 sulcus
220220903	Talar dome sz 3 sulcus
220220904	Talar dome sz 4 sulcus
220220905	Talar dome sz 5 sulcus



Infinity talar component

Ref #	Description
33630021	Talar dome sz 1
33630022	Talar dome sz 2
33630023	Talar dome sz 3
33630024	Talar dome sz 4
33630025	Talar dome sz 5



Inbone II talar stem

Ref #	Description
200347901	Talar stem 10mm
200347902	Talar stem 14mm

Accessories

Ref #	Description
IB200051	Bone removal screw
200138107S	Saw blade Stryker system 7 narrow
200138108S	Saw blade Stryker system 7 wide

Ordering information



Infinity poly insert

Ref #	Description
33651106	Poly insert, sz l/l+6mm
33651108	Poly insert, sz l/l+8mm
33651110	Poly insert, sz l/l+ 10mm
33651112	Poly insert, sz l/l+ 12mm
33652206	Poly insert, sz 2 6mm
33652208	Poly insert, sz 2 8mm
33652210	Poly insert, sz 2 10mm
33652212	Poly insert, sz 2 12mm
33653206	Poly insert, sz 2+ 6mm
33653208	Poly insert, sz 2+ 8mm
33653210	Poly insert, sz 2+ 10mm
33653212	Poly insert, sz 2+ 12mm
33653306	Poly insert, sz 3 6mm
33653308	Poly insert, sz 3 8mm
33653310	Poly insert, sz 3 10mm
33653312	Poly insert, sz 3 12mm
33654307	Poly insert, sz 3+ 7mm
33654309	Poly insert, sz 3+ 9mm
33654311	Poly insert, sz 3+ 11mm
33654313	Poly insert, sz 3+ 13mm
33654406	Poly insert, sz 4 6mm
33654408	Poly insert, sz 4 8mm
33654410	Poly insert, sz 4 10mm
33654412	Poly insert, sz 4 12mm
33655407	Poly insert, sz 4+ 7mm
33655409	Poly insert, sz 4+ 9mm
33655411	Poly insert, sz 4+ 11mm
33655413	Poly insert, sz 4+ 13mm
33655506	Poly insert, sz 5 6mm
33655508	Poly insert, sz 5 8mm
33655510	Poly insert, sz 5 10mm
33655512	Poly insert, sz 5 12mm

Notes



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