Kinos Axiom® Total Ankle System

with Axiom **PSR™** Cut Guides

featuring TIDAL Technology™

SURGICAL TECHNIQUE

restor3d

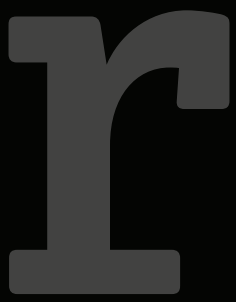
restor3d

Personalized Orthopaedics

Enabling Surgeons to Repair and Reconstruct the Human Body

Backed by Science

Driven by Outcomes



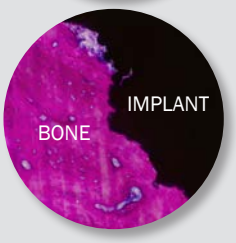
Contents

About TIDAL Technology™

Backed by years of scientific research and development

restor3d's TIDAL Technology is an optimized porous architecture designed for osseointegration. Derived from sinusoidal functions, TIDAL Technology™ guides bone growth through the fully interconnected structure with maximized surface area.

- 100% interconnectivity and up to 80% porosity[1]
- Mesoscale pores support graft retention and bony ingrowth[2]
- Direct bony apposition to implant surface guided by surface topography and curvature demonstrated in preclinical model[2,3]



IMPORTANT NOTE: restor3d, as the manufacturer of this device, does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any procedure is responsible for determining and utilizing the appropriate techniques for such procedure for each individual patient. restor3d is not responsible for selection of the appropriate surgical technique to be utilized for each individual patient. Always refer to the package insert, product label and/or product instructions prior to using any restor3d product.

For further product information or to arrange a product demonstration, please contact your local restor3d representative or call Customer Service toll-free in the U.S. at (984) 888-0593 or email customerservice@restor3d.com. You can also visit www.restor3d.com.

Product Overview

restor3d's Kinos Axiom® Total Ankle System was designed to treat ankle arthritis by replacing the ankle joint with a prosthesis, thus reducing pain, restoring alignment, and allowing for movement at the replaced joint.

Biomimetic Design Restores Natural Range of Motion

The Kinos Axiom® Total Ankle System increases patient satisfaction by improving implant function and life expectancy via biomimetic articulating surfaces, which mimic the biomechanics of the native ankle joint. The range of motion of the ankle joint occurs in the three anatomic planes.[4] The Kinos Axiom® implant construct recreates this natural motion. The talar implant internally rotates relative to the tibia with plantarflexion, and externally rotates with dorsiflexion. This "coupled motion" recreates that of a healthy ankle joint during normal gait.

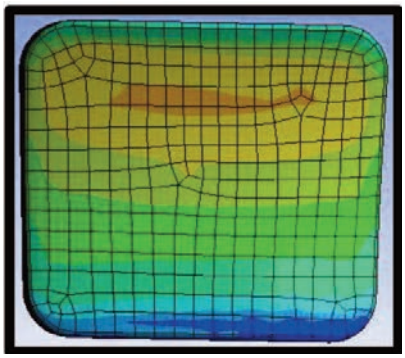
The biomimetic surface allows for independent inversion and eversion motion throughout the flexion profile. In mimicking the range of motion provided in a healthy joint, the Kinos Axiom® implant more evenly distributes the forces during gait. The polyethylene articular surface, as compared to the more constrained bi-condylar designs, provides the range of motion (ROM) and stability necessary to withstand the rigors of a patient's daily activities - including walking on uneven terrain.[5] Other devices do not provide for this anatomically accurate motion profile.[6]

KINOS AXIOM®	RANGE OF MOTION (ROM)	LEADING COMPETITOR[3]
±25°	Flexion/Extension	±25°
8°	Internal/External Rotation	0°
7°	Inversion/Eversion	0°

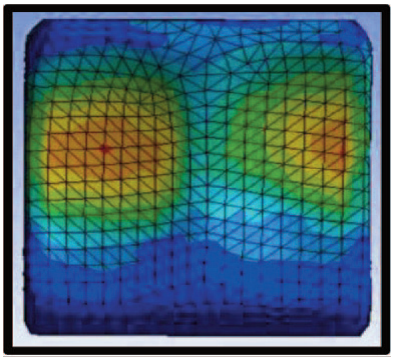
Kinos Axiom®'s semi-congruent design is better able to distribute loading across the ankle joint and greatly reduces the likelihood of point stress concentrations during a range of simulated use conditions, as shown in the images below.[7] Point loading creates areas of high stress along the surface of the polyethylene implant, leading to wear and asymmetric load transfer. Due to its articulating surfaces, Kinos Axiom® is less constrained within the prescribed ROM than competitors and provides uniform load transfer.

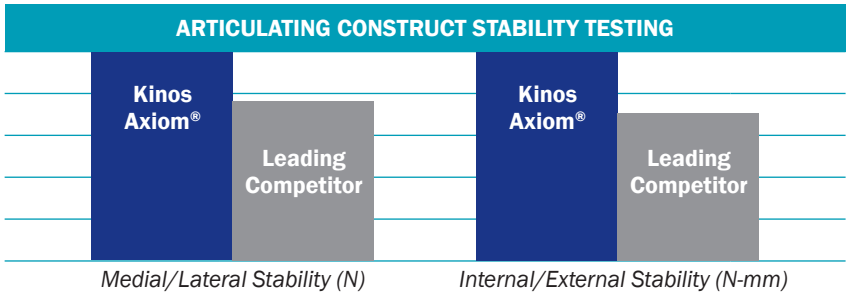
However, the medial and lateral aspects of the Kinos Axiom® design provide sufficient constraint to resist excessive loading directed during medial/lateral translations or internal/external rotations.[4]

Kinos Axiom®



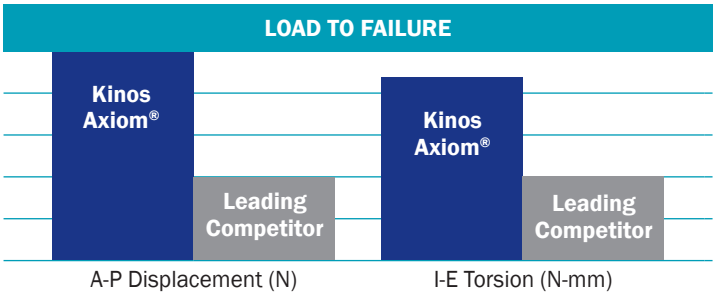
Leading Competitor





Maximizing Implant Stability

Tibial implant loosening is a major concern of total ankle systems. This concern was addressed through a novel design of the bone-implant interface. The Kinos Axiom® tibial implant employs vertically inserted fixation features that increase the implant-to-bone contact area without increasing the overall construct footprint. The vertical buttresses are oriented to maximally resist clinical loading.[7] Additionally, bone ingrowth holes are provided with an optimal size to promote stability.

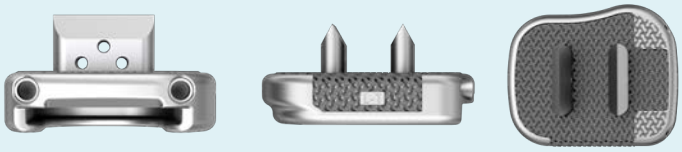


In vitro testing was conducted to evaluate the ability of various implant designs to resist clinically relevant loading. Testing confirms significantly improved implant-to-bone stability for the Kinos Axiom® implant compared to other systems on the market.[7]

Features

Tibial Implant

- Enhanced fixation and tibial stability
- Anatomically contoured Left & Right
- Available in Standard and long lengths
- Titanium Alloy (Ti-6Al-4V)



Talar Implant

- Biomechanically accurate articulating surface
- Left & Right specific ROM
- Enhanced fixation and cortical coverage
- Cobalt Chromium Alloy (Co-Cr-Mo)
- Available in 4 Sizes

Bearing Implant

- Biomechanically accurate articulating surface
- Left & Right specific ROM
- UHMWPE
- Available in 4 heights (6-12mm)

All components are available in left and right configurations in a variety of sizes, intended for primary surgery and revision surgery applications. Instrumentation is provided in a convenient single case.

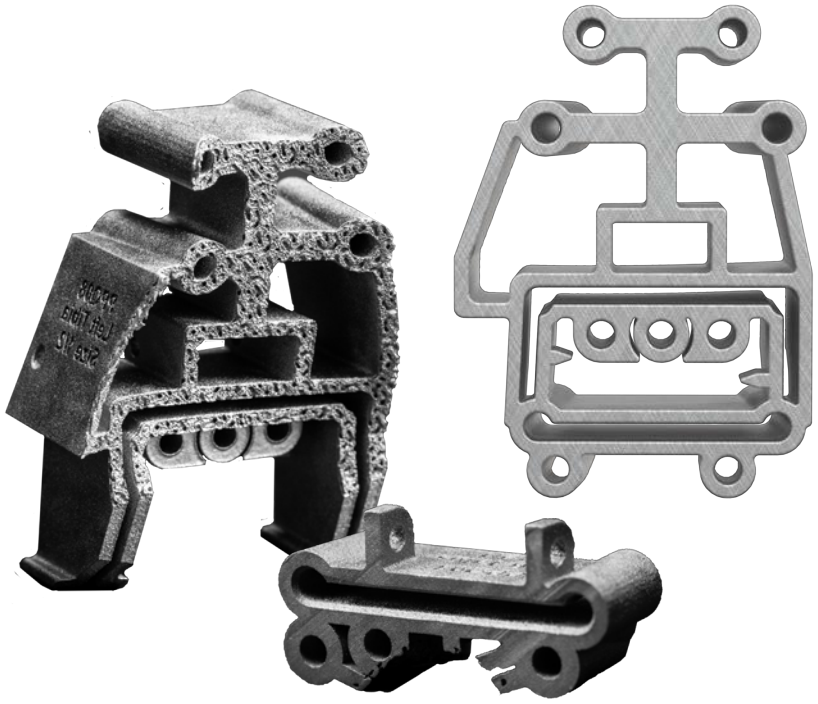
Foundational Research

Award winning research, contributing to the design of the Kinos Axiom® Total Ankle System, was conducted by Sorin Siegler, PhD, Director of the Biomechanics Lab at Drexel University. Dr. Siegler has been a leader in orthopedic biomechanics research for over 30 years. The new understanding of the natural articulating joint surfaces this research provided received the Clinical Biomechanics award in 2013 from *Clinical Biomechanics*. You can view this article at: https://www.sciencedirect.com/science/article/abs/pii/S0268003313002283

Axiom PSR™ Cut Guides

Standalone or Coupled

The Axiom PSR™ is the next generation of patient-specific instrumentation. Made from implant grade titanium alloy, the PSR guides deliver precision, accuracy, and efficiency. The Axiom PSR™ System offers coupled and standalone tibial and talar cut guides. PSR guides are provided with anatomic models to indicate the proper guide position on the tibia and talus for confidence before cut in the operating suite.



Proximal K-Wire holes align with tibial trials reducing pin holes and surgical steps

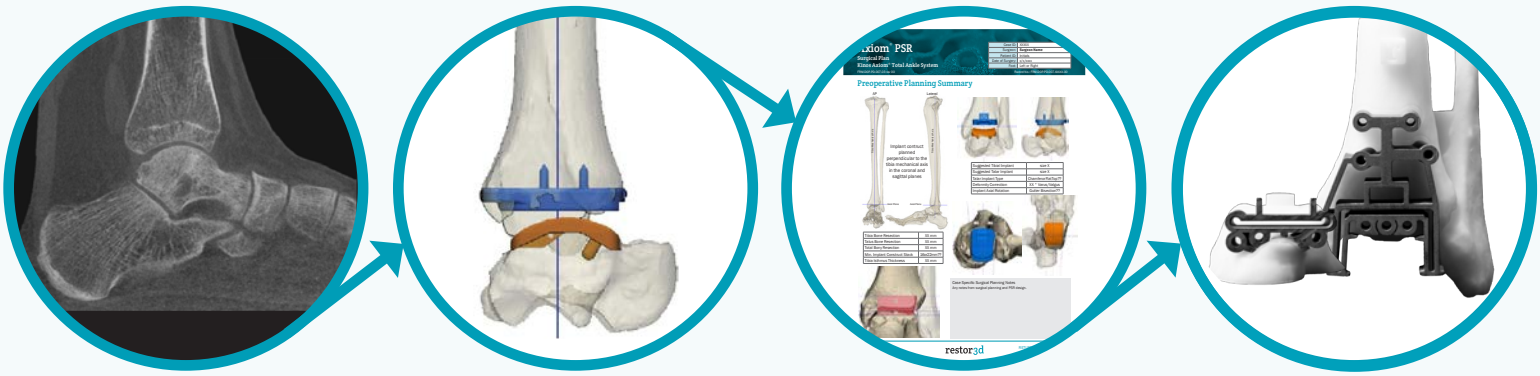
Rigid construction ensures accurate bone cuts

TIDAL Technology on bone contacting surface enhances stability

Radiographic indicators confirm intended position on bone

Space efficient design features limit soft tissue resection and periosteal disruption

Design and Manufacturing Process



Submit CT Scan in accordance to restor3d CT Protocol

Joint alignment is calculated and implants are positioned according to the surgeon's planned reconstruction

Approve surgical plan

Printed and delivered within 3 weeks

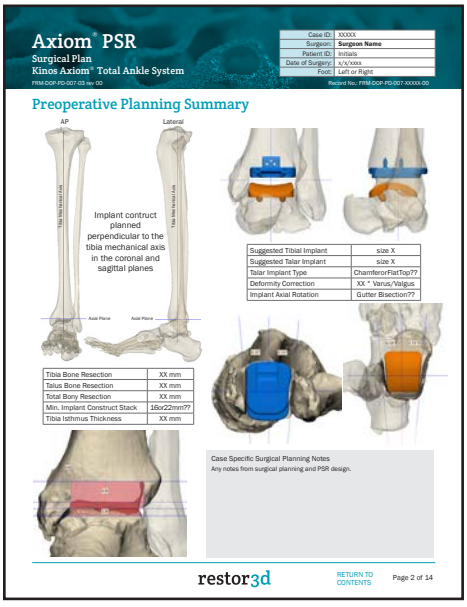
CT Scan Protocol

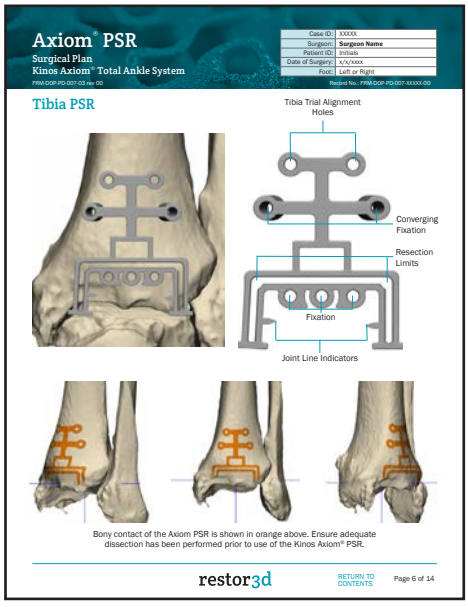
For information on how to submit a CT Scan, see the restor3d CT Scan Protocol.

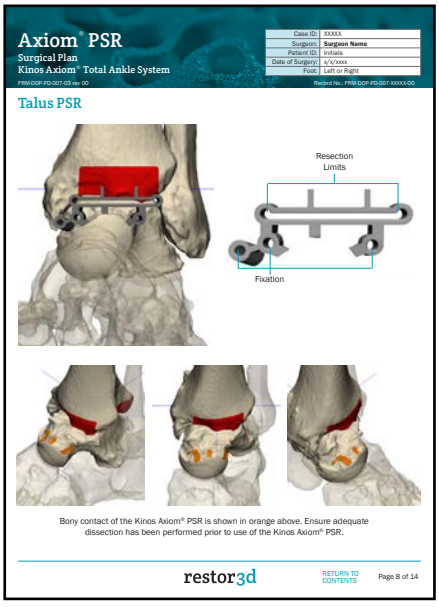
Knee Requirement	Include joint line, 2.5mm slice thickness
Ankle Requirement	10cm proximal to joint line through foot
Pixel Spacing	≤ 0.8mm
Slice Thickness	≤ 1.00mm

Surgical Planning

The Axiom PSR™ Surgical Plan provides detailed anatomic insights to aid in achieving the ideal surgical outcome. The plan includes simulated radiographic images that streamline confirmation of guide placement intraoperatively.







Intended Use

Kinos Axiom® Total Ankle System

The Kinos Axiom® Total Ankle System is intended to give a patient limited mobility by reducing pain, restoring alignment and allowing for movement at the replaced joint.

Axiom PSR™

The Axiom PSR™ System is intended to be used as patient specific surgical instrumentation to assist in the positioning of total ankle replacement components intraoperatively and in guiding bone cutting. Axiom PSR™ system is intended to be used with the Kinos Axiom® Total Ankle System and its cleared indications for use, provided that the anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans. While the Axiom PSR™ provide initial positioning of the instruments used in the total ankle replacement surgery, it is the responsibility of the operative suregon to confirm the final position of an implant construct for each individual patient and surgery. Axiom PSR™ are intended for single patient and one-time use only.

Indications

Kinos Axiom® Total Ankle System

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

The Kinos Axiom® Total Ankle System is additionally indicated for patients with failed previous ankle surgery.

CAUTION: The Kinos Axiom® Total Ankle System is intended for cement use only.

Axiom PSR™

The Axiom PSR™ System is intended to be used as a patient specific surgical instrumentation to assist in the positioning of total ankle replacement components intraoperatively and in guiding bone cutting. The Axiom PSR™ System is intended to be used with the Kinos Axiom® Total Ankle system and its cleared indications for use.

Contraindications

Kinos Axiom® Total Ankle System

Contraindications include:

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

WARNING: This device is not intended for subtalar joint fusion or subtalar joint impingement. Please carefully evaluate the anatomy of each patient before implantation. 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 at www.restor3d.com.

Contraindications

Axiom PSR™

Contraindications include:

- Insufficient bone quality to ensure close apposition of the cut bone surfaces to the prosthesis;
- Sepsis, infection, or osteomyelitis;
- Vascular deficiency in the ankle joint;
- Skeletally immature patients (patients less than 21 years old at the time of surgery);
- Neuropathic joints;
- Excessive loads caused by activity or patient weight;
- Pregnancy;
- Severely compromised musculature or neuromuscular function;
- Uncooperative patient or patient with neurologic disorders incapable of following instructions;
- Insufficient bone stock or bone quality or poor skin coverage around the ankle joint which would make the procedure unjustifiable;
- Significant changes to patient's anatomy have occurred since the medical scan used for product definition wasobtained;
- Cases where there is inadequate neuromuscular status (e.g. prior paralysis, fusion and/or inadequate abductor strength);
- Suspected or documented metal allergy or intolerance.

Materials

Implants

- Titanium Alloy (Ti-6Al-4V, per ASTM F136)
- Titanium Alloy (Ti-6Al-4V, per ASTM F2924)
- Ultra-High Molecular Weight Polyethylene (UHMWPE, per ASTM F648)
- Cobalt Chrome Alloy (Co-Cr-Mo, per ASTM F1537) with Titanium Plasma (CPTi, per ASTM F1580)
- Cobalt Chrome Alloy (Co-Cr-Mo, per ASTM F3213)

Instruments

- Stainless Steel per ASTM F899
- PPSU in the following colors: Red, Yellow, Blue, Green & Black
- Axiom PSR: Titanium Alloy (Ti-6Al-4V, per ASTM F2924)

Operative Technique

Patient Positioning

Place the patient supine on the operating table. A small bump may be used under the calf or thigh to maintain proper rotation of the leg. The patella should be facing directly anterior. General or regional anesthesia may be used. If using regional anesthesia, the sciatic or popliteal catheter must be positioned in a way that does not interfere with the surgery. Use a thigh tourniquet proximal to the popliteal catheter and IV antibiotics and sequential compression on the contralateral leg. Using proper sterile technique, prepare and drape the leg, leaving the knee to foot exposed. Perform exsanguination prior to tourniquet activation, if utilized.

Surgical Approach

Make a skin incision just lateral to the tibial crest, from approximately 5cm proximal of the tibial plafond and extending distal at least to the talonavicular joint. Identify the superficial peroneal nerve and mobilize laterally. When exposing the extensor retinaculum and EHL tendon sheath, the anterior tibial tendon sheath must not be exposed. Identify the deep peroneal nerve and artery and mobilize laterally. Care must be taken to protect these structures throughout the procedure. Finally, incise and expose the ankle joint capsule longitudinally from the medial malleolus to the syndesmosis. Remove any osteophytes on the neck of the talus and anterior tibia. Care must be taken to avoid weakening the underlying bone by removing too much substrate. If a varus deformity requires correction, perform a deltoid release. Care should be taken to release the talar deltoid attachment from anterior to posterior as a single structure.

When using the Axiom PSR™, Patient Specific Resection Guides, the bony anatomy of the tibia and talus must be free of any soft tissue in the region of contact between the Axiom PSR™ and bones. The guides are designed to fit in a unique position and flush against the anterior tibia and dorsal talus. If the guides do not sit properly, remove any remaining soft tissue and re-evaluate the mating surface areas until the fit is properly obtained.

Surgical Technique using Axiom PSR™ Cut Guides

Standalone Cut Guides

If at any time the PSR guides fall or become unsuitable for use in the operating theatre, proceed with the surgical technique using standard instruments. Please continue to page 25 of this technique guide for instruction using standard instrumentation.

1.1 Ensure the Case ID and patient's initials are matched for each surgery. Case IDs are located on the Surgical Plan Report for Tibia PSR, Talus PSR, and Bone Models.

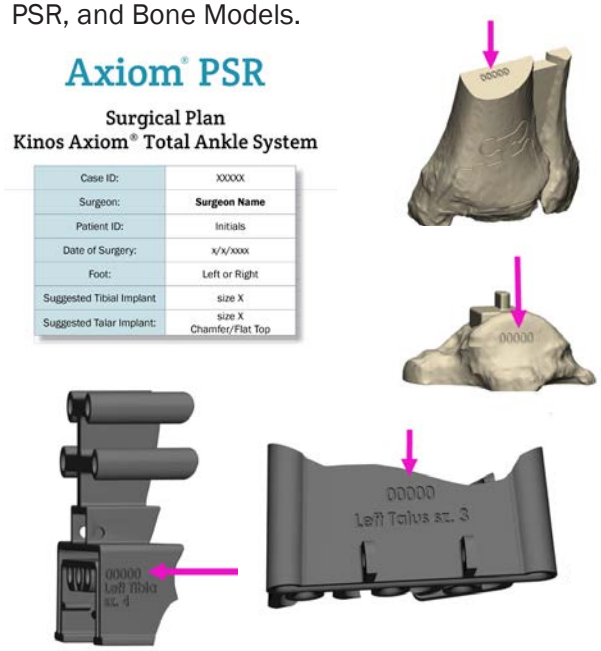


Fig. 1

1.2 Remove soft tissue in the region of interest on the distal tibia to allow fitment of the PSR. Refer to the Surgical Plan for detailed information regarding the surgical plan in relation to patient specific information.

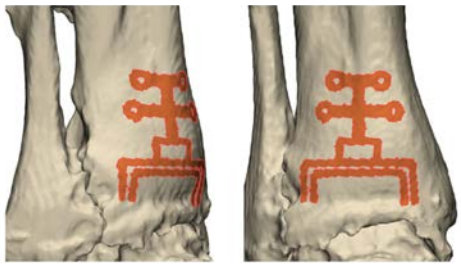


Fig. 2

1.3 Place the tibia PSR in the best fit location on the patient's distal tibia.

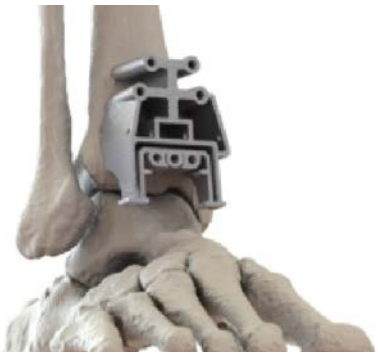


Fig. 3

1.4 An AP radiograph will confirm medial-lateral and coronal angle positioning of the tibia PSR.

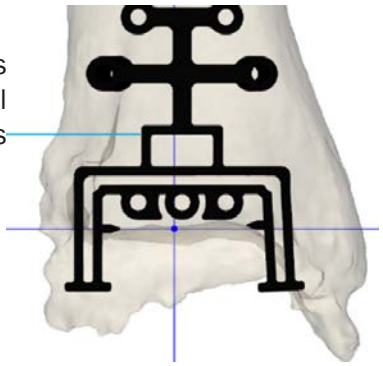


Fig. 4

1.5 Insert Angel Wing and thread Alignment Rod into anterior hole in Angel Wing to asses coronal angle.

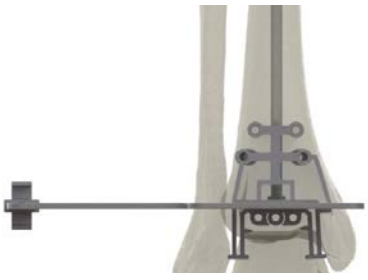


Fig. 5

1.6 Use a lateral radiograph to confirm cut height and slope angle positioning of the tibia PSR.

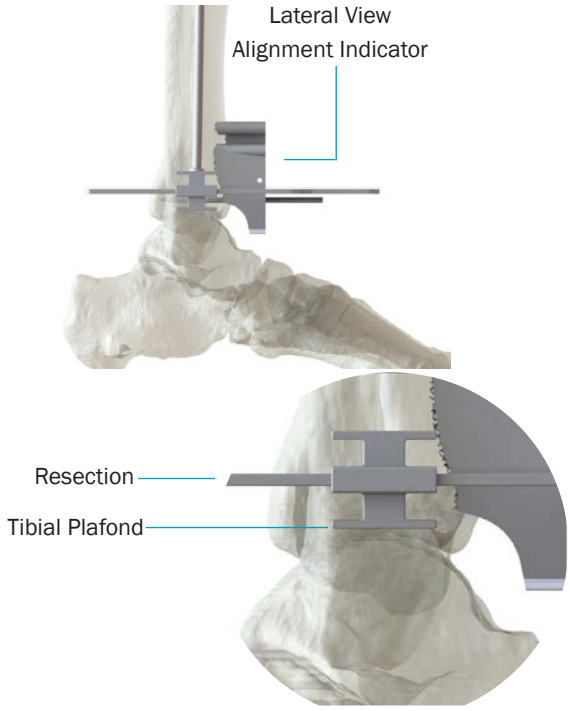


Fig. 6

NOTE: The Angel Wing knife edge indicates the resection plane. The bottom of the offset slider indicates the tibial plafond. Refer to the Surgical Plan for the indicated position of the Slider relative to the plafond for each individual case.

1.7 While holding the tibia PSR securely in place, insert two 2.4mm k-wires into the PSR and fixate the tibia PSR to the tibia.

TIP: The distal k-wire holes are distal to the resection plane and are best for provisional fixation. The proximal row of k-wire holes match to the tibial trial and should be used for definitive fixation.

1.8 Confirmatory AP & lateral radiographs may be taken and if adjustment is necessary, the previously placed pins may be removed, and steps 1.2-1.6 repeated with a different combination of k-wire holes.

1.9 Place two 2.4mm k-wires at the medial and lateral slot ends to prevent saw blade excursion.

Fig. 7

1.10 The tibia osteotomies are performed using an oscillating saw in the horizontal slot and a reciprocating saw in the vertical slots. The two proximal k-wire holes of the tibia PSR correspond to the planned position of the tibial trial, post bone resection.

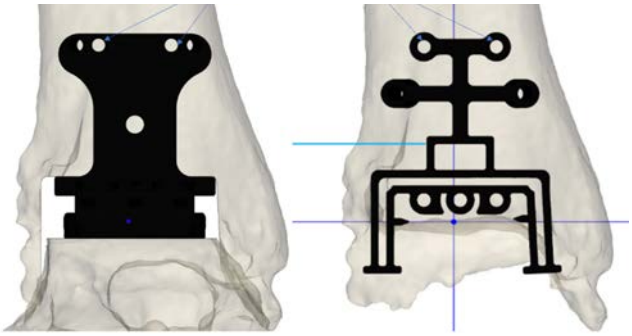


Fig. 8

TIP: Leave the proximal k-wires in place during bone resection. The tibial trial may be placed over the proximal k-wires after the tibial and talar bone resections are performed.

1.11 At the surgeon's discretion, the tibial bone may be removed before or after making the talar resection through the Talar PSR guide. (See Figure 11)

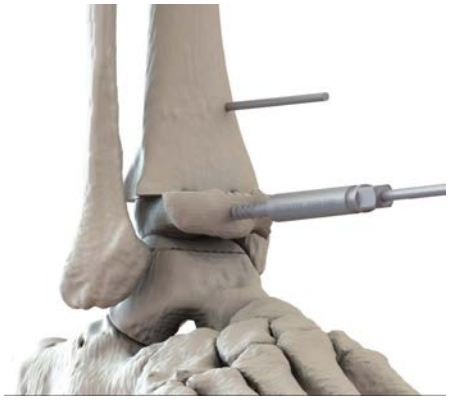


Fig. 9

1.12 Remove soft tissue in the region of interest on the talus to allow fitment of the PSR. Refer to the Surgical Plan for detailed information regarding the surgical plan in relation to patient specific information.

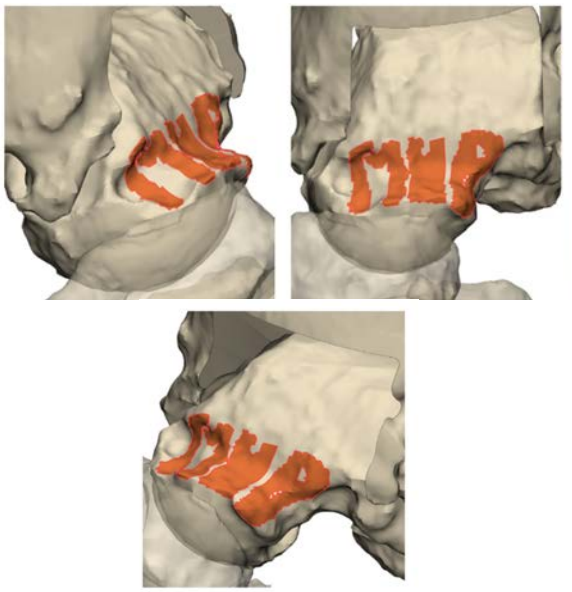


Fig. 10

1.13 Place the talus PSR in the best fit location.

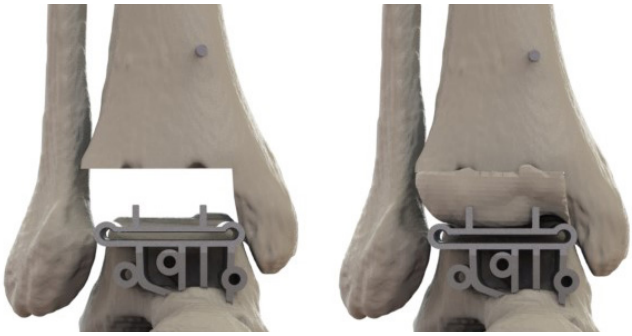


Fig. 11

1.14 An AP radiograph may be used to confirm medial-lateral and coronal angle positioning of the talus PSR.

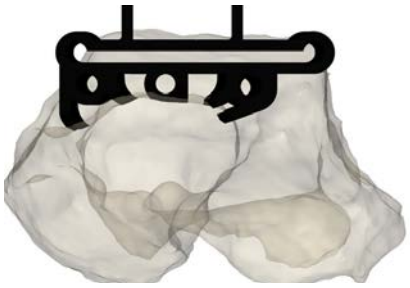


Fig 12.

1.15 Insert the angel wing, and use a lateral radiograph to confirm proximal-distal and slope angle positioning of the talus PSR.

1.16 Obtain an AP radiograph to confirm coronal angle positioning of the talus PSR.

Fig 13.

1.17 While holding the talus PSR in place, insert two 2.4mm k-wires into the designated fixation holes of the talus PSR.

1.18 Confirmatory AP and lateral radiographs may be taken and if adjustment is necessary, the previously placed k-wires may be removed, and steps 1.12-1.16 repeated.

1.19 Place two 2.4mm k-wires at the medial and lateral slot ends to prevent saw blade excursion.

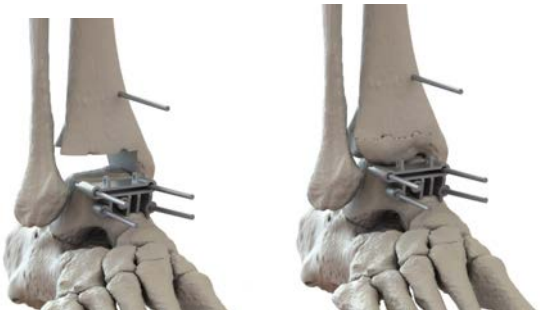


Fig. 14

1.20 The talus osteotomy is performed using an oscillating saw in the horizontal slot.

1.21 Remove all k-wires and the talus PSR.

1.22 Remove the resected talus bone.

1.23 Confirm adequate bone resection on the tibia and talus with the gap check tool (Fig 15). Use the re-cut guide if additional resection is required.

1.24 Refer to page 17 for all remaining surgical steps using Chamfer-Cut Talar Implants and page 21 for all steps using Flat-Cut Talar Implants.

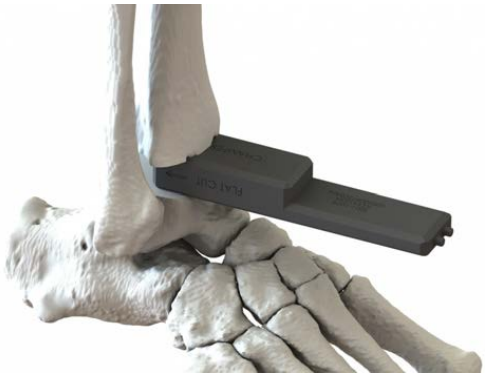


Fig. 15

Surgical Technique using Axiom PSR™ Cut Guides

Coupled Cut Guides

If at any time the PSR guides fall or become unsuitable for use in the operating theatre, proceed with the surgical technique using standard instruments. Please continue to page 25 of this technique guide for instruction using standard instrumentation.

1.25 Ensure the talus can be manipulated into the neutral position. Refer to the surgical plan for the as-planned talus position. Refer to the surgical plan if osteophytes must be removed to allow the talus to be oriented in the neutral position. Soft tissue balancing may be required to permit appropriate talus positioning.

1.26 Follow steps 1.1 through 1.18 to align and fixate the coupled PSR with the distal tibia.

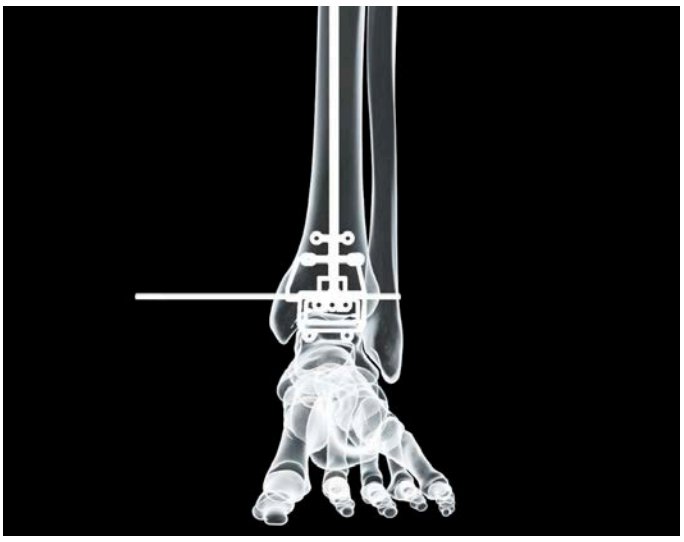


Image reference to steps 1.4 and 1.5 taking an AP radiograph to confirm medial-lateral and coronal angle positioning of the tibia PSR and inserting Angel Wing and thread Alignment Rod into anterior hole in Angel Wing to asses coronal angle.

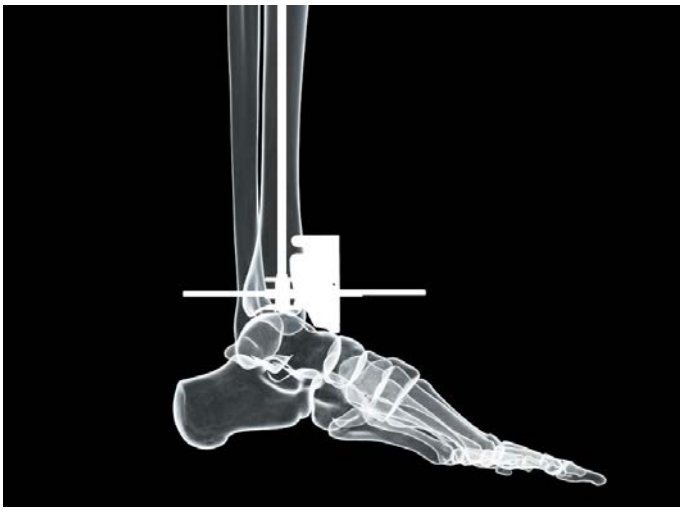


Image reference to step 1.6 using a lateral radiograph to confirm cut height and slope angle positioning of the PSR guide.

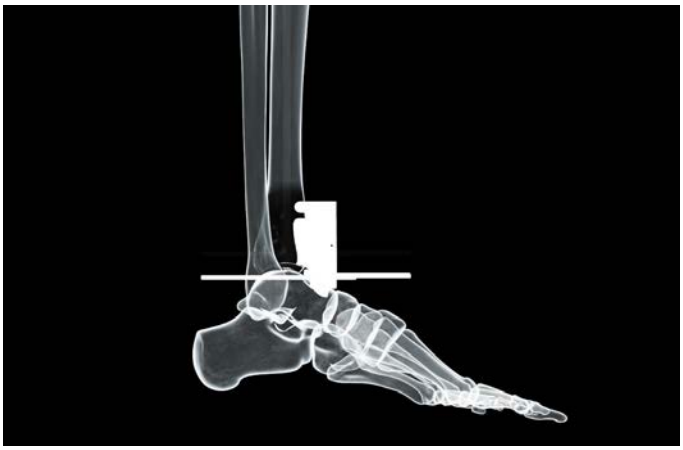


Image reference to step 1.14 to insert the angel wing, and use a lateral radiograph to confirm proximal-distal and slope angle positioning of the talus PSR.

1.27 Rotate the talus into neutral coronal and sagittal position and use 2.4mm k-wires to fixate the talus to the coupled PSR (Fig 16).

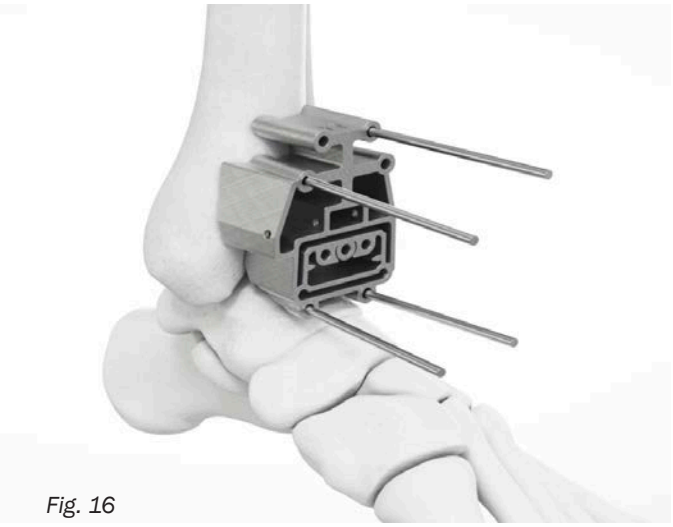


Fig. 16

1.28 Place resection limit pins in the cut slot.

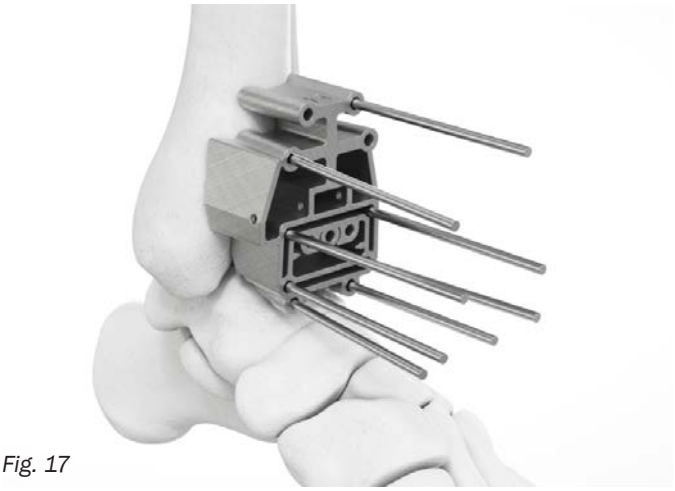


Fig. 17

1.29 Make the tibial (Fig 18) and talar (Fig 19) cuts through the coupled PSR cut guides.

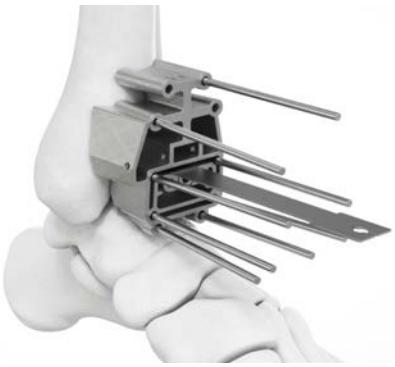


Fig. 18

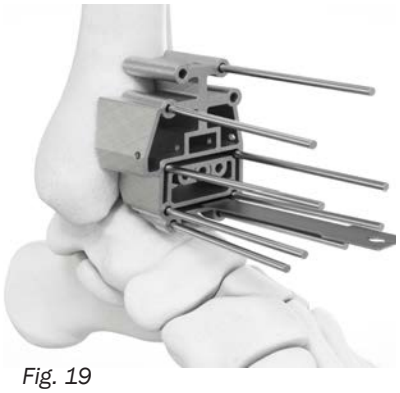


Fig. 19

1.30 Confirm adequate bone resection on the tibia and talus with the gap check tool (Fig. 20). Use the recut guide if additional resection is needed.

Fig. 20

1.31 Refer to page 17 for all remaining surgical steps using Chamfer-Cut Talar Implants and page 21 for all steps using Flat-Cut Talar Implants.

Surgical Technique:

Chamfer-Cut Talar Implant - Tibial & Talar Bone Prep

For Flat-Cut Talar Implant, proceed to Page 21.

2.1 Select the appropriate Talar Trial and ensure adequate ML & AP coverage (Fig. 21).

TIP: If between two sizes for the talar implant, choose the smaller size to prevent gutter impingement.

2.2 Insert the appropriate Tibial Trial aligned with the medial vertical cut. The AP Sizer can be used to measure the AP length of the tibial bone.

2.3 Insert 6 or 8mm Thickness Trial, size matched to the Talus Trial (i.e. Size 2 talar trial => Size 2 thickness trial).

TIP: Use the tallest Thickness Trial possible to keep adequate tension on the trial components and the joint.

2.4 The Trial Assembly sets relative alignment between the tibial and talar components. Use range of motion to ensure the assembly tracks to the patient's kinematics. Ensure proper axial rotation noting the direction of the talar handle (Fig. 22).

2.5 In a lateral view, align the talar trial with the lateral process. The chamfer locations are indicated by the slots (Fig. 23).

TIP: In cases of anterior or posterior subluxation of the talus, center the talar trial under the long axis of the tibia.

2.6 Ensure adequate AP coverage of the tibial trial and use the anterior screw to adjust AP position as necessary. The standard length tibial implant is indicated by the posterior slot on the trial. The "Long" implant is the posterior edge of the trial (Fig. 23).

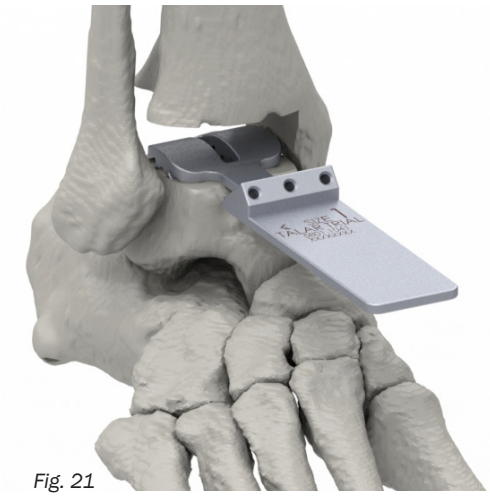


Fig. 21

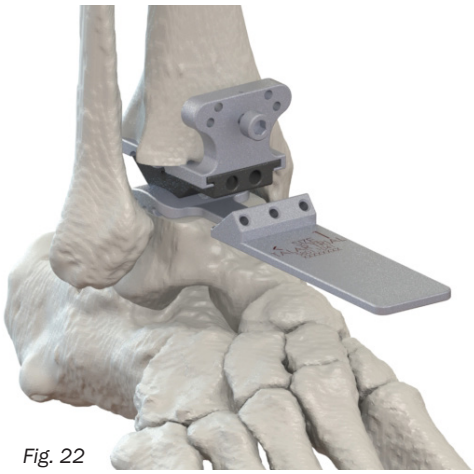


Fig. 22

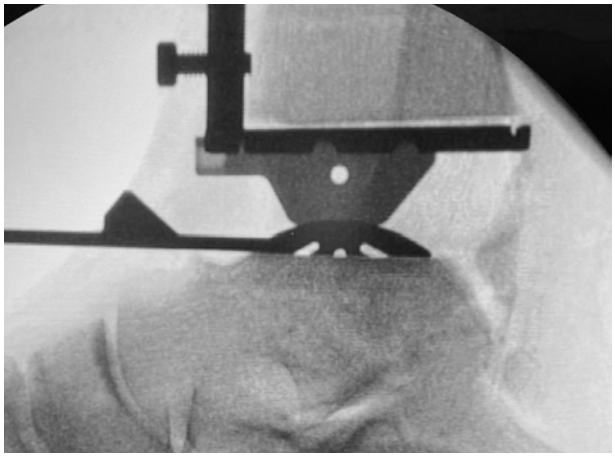


Fig. 23

2.7 With the Trial Assembly in the desired position, place the break-off wires into the talar trial. Do not insert the break off section into the talar trial. The medial and lateral holes are preferred. Though the middle hole can be used as an alternate (Fig. 24).

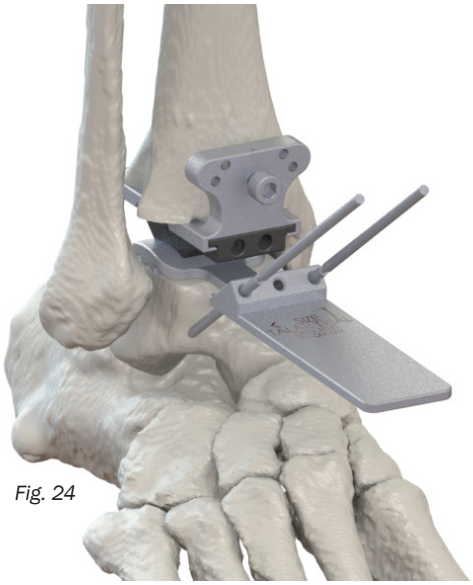


Fig. 24

2.8 Insert two K-Wires into the tibial trial. First into the straight hole on the medial side, then into the converging hole on the lateral side (Fig. 25).

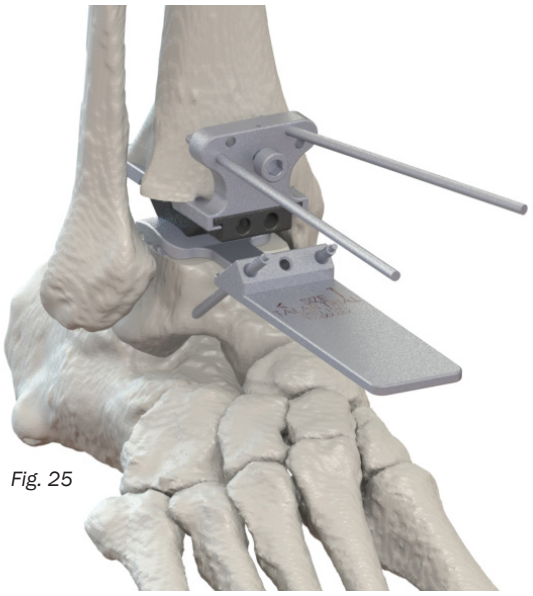


Fig. 25

2.9 Using a Wire Cutter, cut the break-off wires at the notch (Fig. 26).

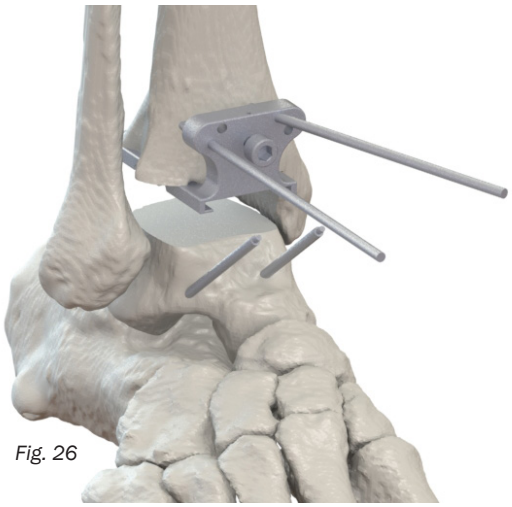


Fig. 26

2.10 Remove the Thickness Trial and Talar Trials.

2.11 Broach through both slots in the Tibial Trial using the Starter Broach and the Offset Impactor (Fig. 27).

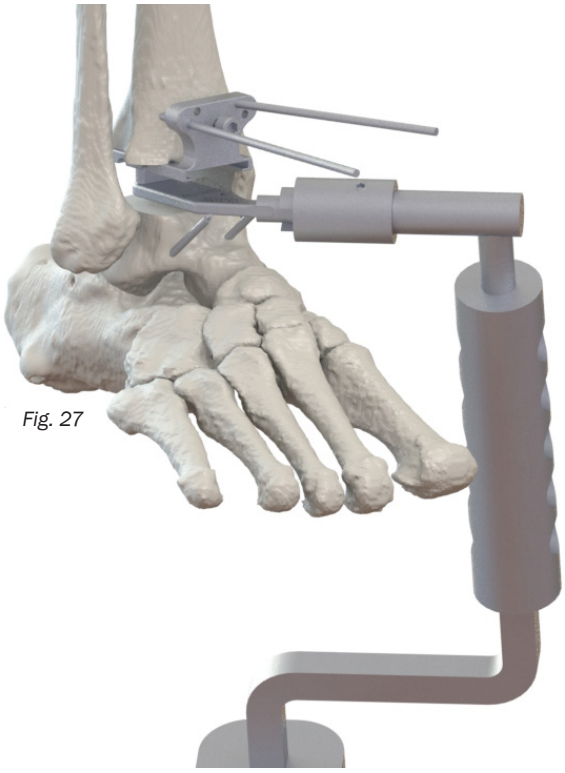


Fig. 27

2.12 Broach through both slots using the Finish Broach and the Offset Impactor. Confirm the broach is fully seated in the tibial trial with a lateral x-ray.

TIP: Use the Straight Impactor to impact vertically on the undersurface of both broaches to fully seat the broaches in the bone.

2.13 Remove the Tibial Trial (Fig. 28).

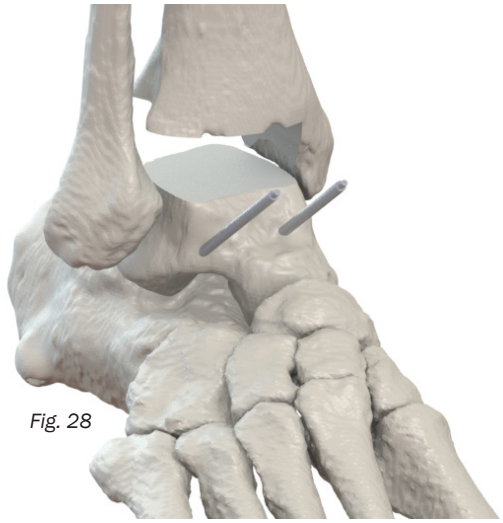


Fig. 28

2.14 Place the Chamfer Guide over the Break Off wires. Ensure the flat undersurface is fully seated on the flat cut of the talus. Use a lateral x-ray to confirm placement.

TIP: Use the Parallel Distractor without the plastic tip to ensure the chamfer guide flat on bone posteriorly (Fig. 29).

2.15 Place the K-wires with Stops (5801-0003) into the Chamfer Guide.

2.16 Make the posterior cut with an oscillating saw.

2.17 Using the Talar Bone Mill sized for the trial, drill and connect plunge cuts to shape the anterior chamfer (Fig. 30).

TIP: Make a sweeping motion around the perimeter of and in between the slots to ensure adequate bone removal between slots and at all four margins.

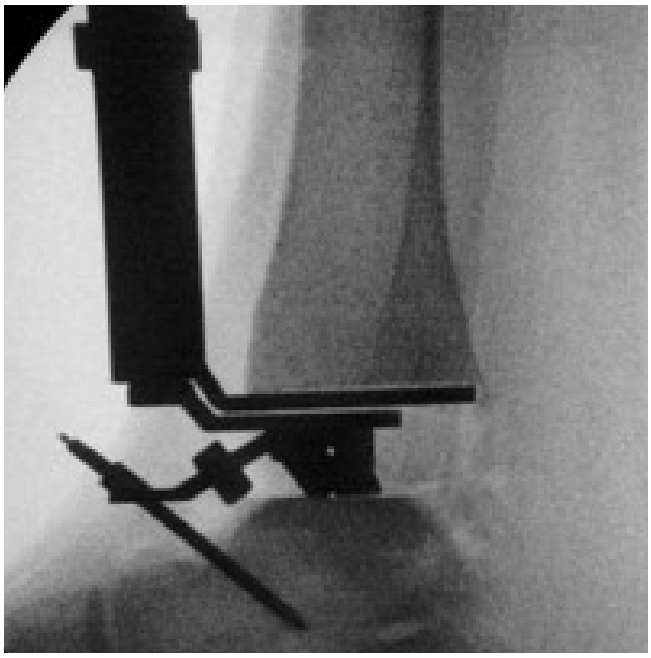


Fig. 29

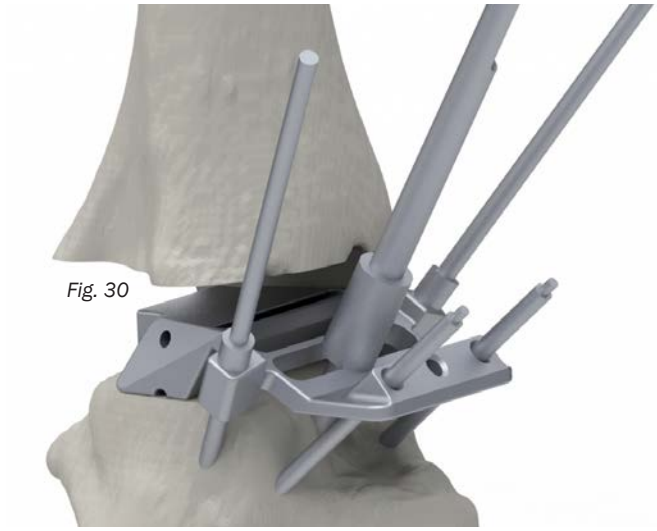


Fig. 30

2.18 Remove the Chamfer Guide and ensure both chamfer cuts are smooth from Medial to Lateral.

2.19 Place the Rail & Peg Guide (RPG) over the Break-Off Wires. Use the Parallel Distractor to fully seat the Rail & Peg Guide. Bone should contact the guide on all 3 facets.

2.20 The fixation screw can be placed in the central slot to ensure the RPG is fully seated with the screw head recessed (Fig. 31).

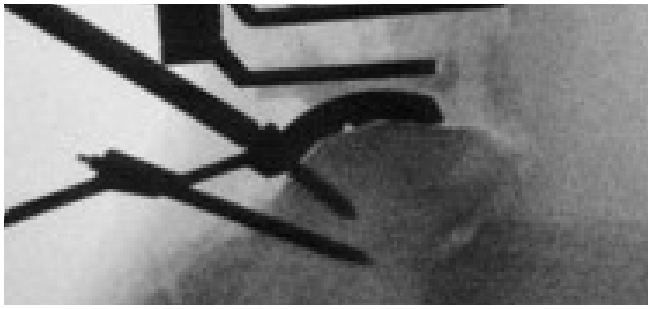


Fig. 31

2.21 Insert the Talar Rail Drill into the RPG. Initially set the Talar Rail Drill Guide to orientation 1st drill with the Talar Rail Drill (5801-0008). Then flip the Talar Rail Drill Guide to 2nd and drill again (Fig. 32).

NOTE: 2nd orientation shown below.

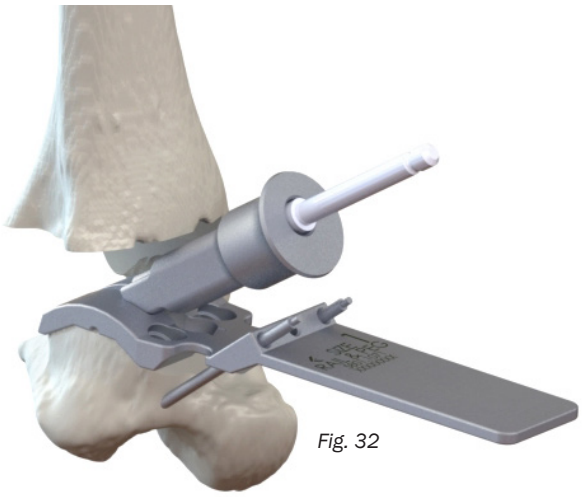


Fig. 32

2.22 Drill the Peg Holes with the Peg Drill (5801-0007).

2.23 Remove the Fixation Screw and RPG.

2.24 Perform a final check of the Rail Drill Hole. Using the rail chisel, ensure no posterior bone ridge will prevent fully seating the talar implant (Fig. 33).

Fig. 33

Surgical Technique:

Flat-Cut Talar Implant – Tibial & Talar Bone Prep

3.1 Select the appropriate Flat-Cut Talar Trial, assemble the joystick and place on the talus to ensure adequate ML & AP coverage. (Fig. 34)

TIP: If between two sizes for the talar implant, choose the smaller size to prevent gutter impingement.

3.2 Insert the appropriate Tibial Trial aligned with the medial vertical cut. The AP Sizer can be used to measure the AP length of the tibial bone.

3.3 Insert a 6 or 8mm Thickness Trial, size matched to the Talus Trial (i.e. Size 2 talar trial => Size 2 thickness trial) (Fig. 35).

TIP: Use the tallest Thickness Trial possible to keep adequate tension on the trial components and the joint.

3.4 The Trial Assembly sets relative alignment between the tibial and talar components. Use range of motion to ensure the assembly tracks to the patient's kinematics. Ensure proper axial rotation noting the direction of the talar handle.

3.5 In a lateral view, align the Flat-Cut Talar Trial with the lateral process. The anterior and posterior margins are indicated by the slots (Fig. 36).

TIP: In cases of anterior or posterior subluxation of the talus, center the talar trial under the long axis of the tibia.

3.6 Ensure adequate AP coverage of the tibial trial and use the anterior screw to adjust AP position as necessary. The standard length tibial implant is indicated by the posterior slot on the trial. The "Long" implant is the posterior edge of the trial (Fig. 36).

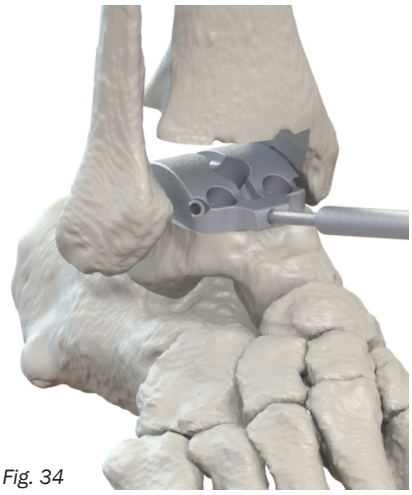


Fig. 34

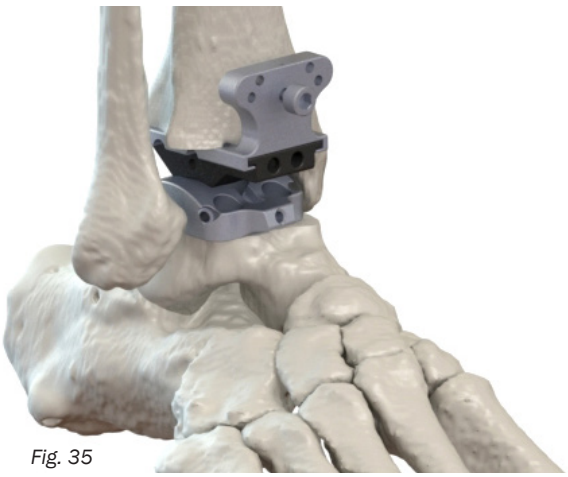


Fig. 35

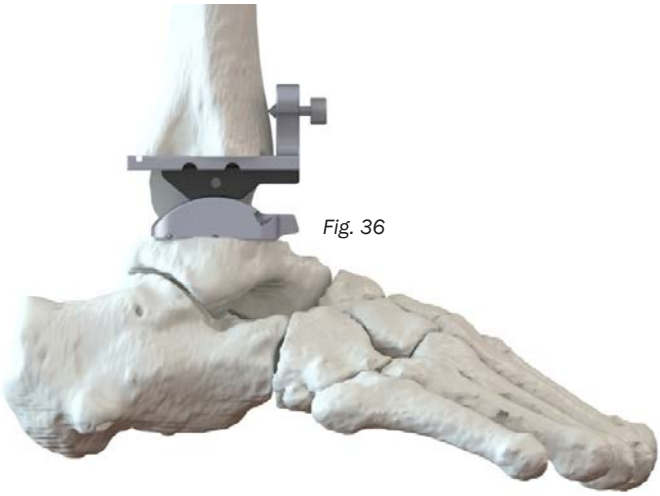


Fig. 36

3.7 With the Trial Assembly in the desired position, place the K-wires with stops (5801-0003, “shoulder pins”) into the Flat-Cut Talar Trial.

3.8 Insert two K-Wires into the tibial trial. Use the converging hole (top row) on the lateral side and the straight hole (bottom row) medially. Remove the Thickness Trial (Fig. 37)

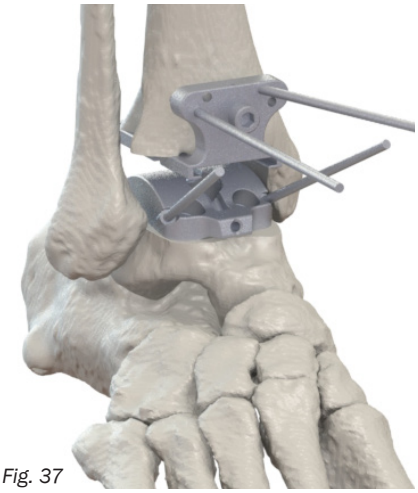


Fig. 37

3.9 Using the Center Drill (5801-0012), drill the central posterior talar peg hole. Plantarflexion may help obtain the correct drill angle while avoiding the tibial trial. (Fig. 38)

3.10 Using the Peg Drill (5801-0007), drill the anterior medial and lateral talar peg holes.

3.11 Remove the shoulder pins and the Flat-Cut Talar Trial.

3.12 Broach through both slots in the Tibial Trial using the Starter Broach and the Offset Impactor. (Fig. 39)

3.13 Broach through both slots using the Finish Broach and the Offset Impactor. Confirm the broach is fully seated in the tibial trial with a lateral x-ray. **TIP: Use the Straight Impactor to impact vertically on the undersurface of both broaches to fully seat the broaches in the bone.**

3.14 Remove the Tibial Trial.

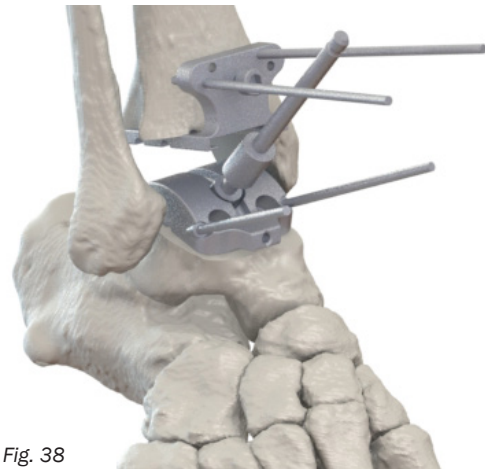


Fig. 38

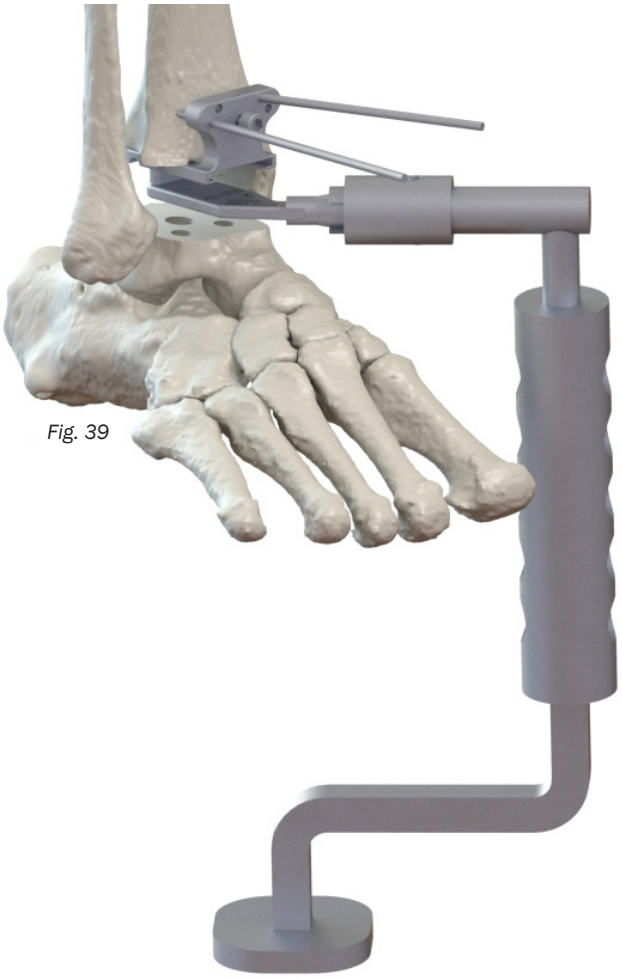


Fig. 39

Surgical Technique: Implant Insertion

4.1 Place the Tibial Implant first. Apply cement to the superior flat surface of the Tibial Implant (Fig. 40).

4.2 Thread the Joystick into the Tibial Implant and insert into the broached holes (Fig. 41).

TIP: Use a toothless lamina spreader to start the tibial implant into the broached holes taking care not to damage the talus.

4.3 Insert the Tibial protector into the bearing slot on the Tibial Implant and unthread the Joystick.

4.4 Fully seat the Tibial Implant using the Tibial Impactor and the Offset Impactor. Leave the Tibial Protector in place (Fig. 42).

TIP: The straight impactor can be used directly on the tibial protector to ensure the implant is fully seated.

4.5 Apply cement to the inferior flat surface of the Talar Implant.

4.6 Fully seat the Talar Implant using the Talar Impactor. (Fig. 43).

TIP: Engage the pegs into the peg holes first and rotate the Talar Implant into place.

4.7 Use a Bearing Trial to determine final Bearing Implant height. Insert the Bearing Trial and range the joint. The articulating surfaces should remain in contact through the range of motion.

TIP: The Gap Check Tool can be used to gently impact the Bearing Trial or Bearing Implant into the Tibial Implant.

4.8 Hand feed the Bearing Implant into the Tibial Implant.

4.9 Thread both posts of the Bearing Inserter into the Tibial Implant.

Fig. 40

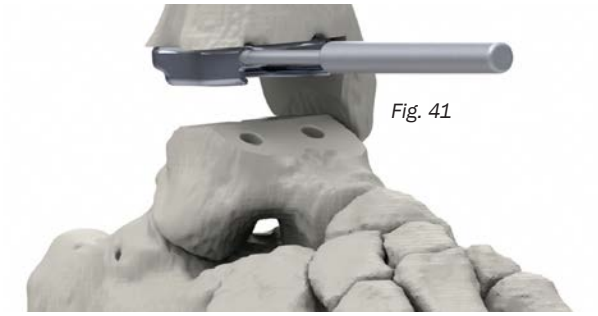


Fig. 41

Fig. 42

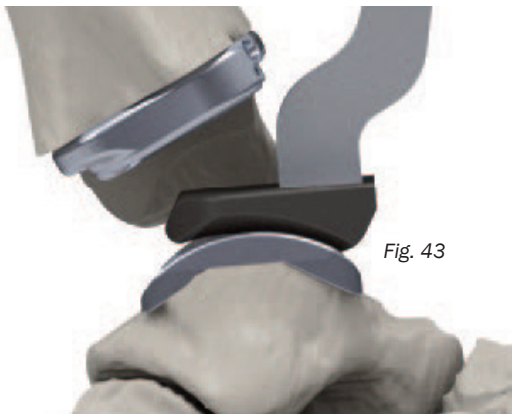


Fig. 43

4.10 While holding counter torque on the outer sleeve, actuate the Insertion Knob until it pushes the Bearing Implant fully into position into the Tibial Implant (Figs. 44-46).

4.11 Back the Insertion Knob off by 1 turn and unthread the Bearing Inserter from the Tibial implant.

4.12 Irrigate the wound with antibiotics and place a drain. Using an interrupted stitch, close the deep tissue, extensor retinaculum, subcutaneous tissue and skin. Apply a sterile compression dressing and short leg cast with the ankle in a neutral position.

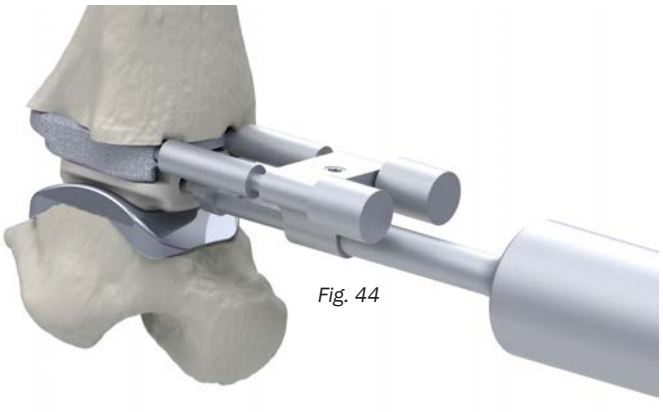


Fig. 44

Fig. 45

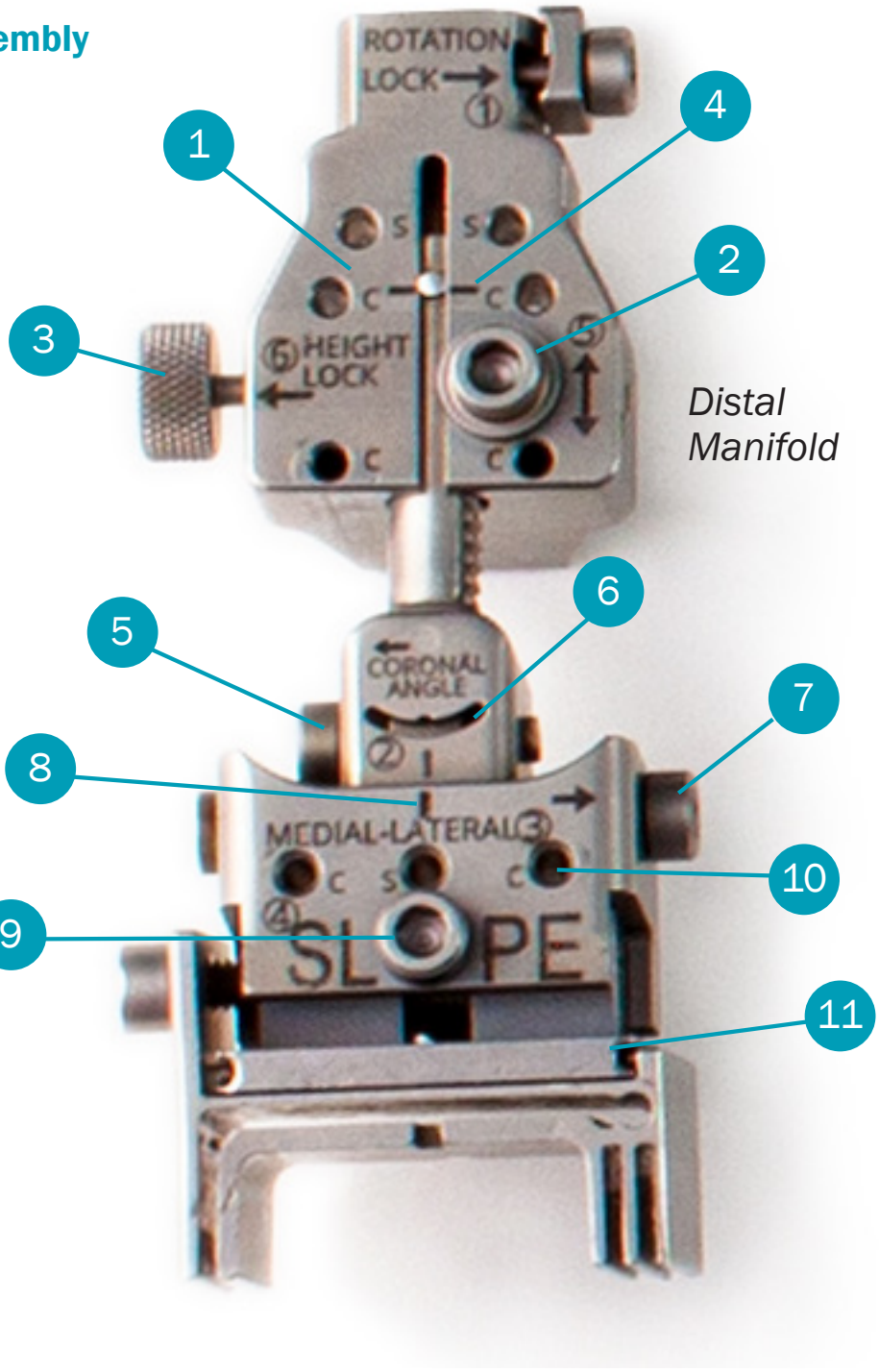
Fig. 46

Surgical Technique using the Standard Instruments

Instrument Set-up and Assembly

Distal Manifold

1. Proximal Fixation Holes. Used after setting axial rotation. “S”= Straight hole; “C”= Converging hole. One bone fixation hole required in this block.
2. Proximal-Distal adjustment gear
3. Lock for proximal-distal height adjustment
4. Line indicating mid-point of proximal distal adjustment is the suggested starting point
5. MICRO coronal alignment Dial-In™ Screw
6. Window to visualize coronal angle adjustment
7. MICRO medial-lateral Dial-In™ Screw
8. Lines indicating medial-lateral adjustment. Shown in neutral position
9. MICRO Slope Dial-In™ Screw
10. Distal Fixation Holes. Middle hole is straight, outer holes convergent. One bone fixation hole required in this block
11. Cut guide attachment



Distal Manifold

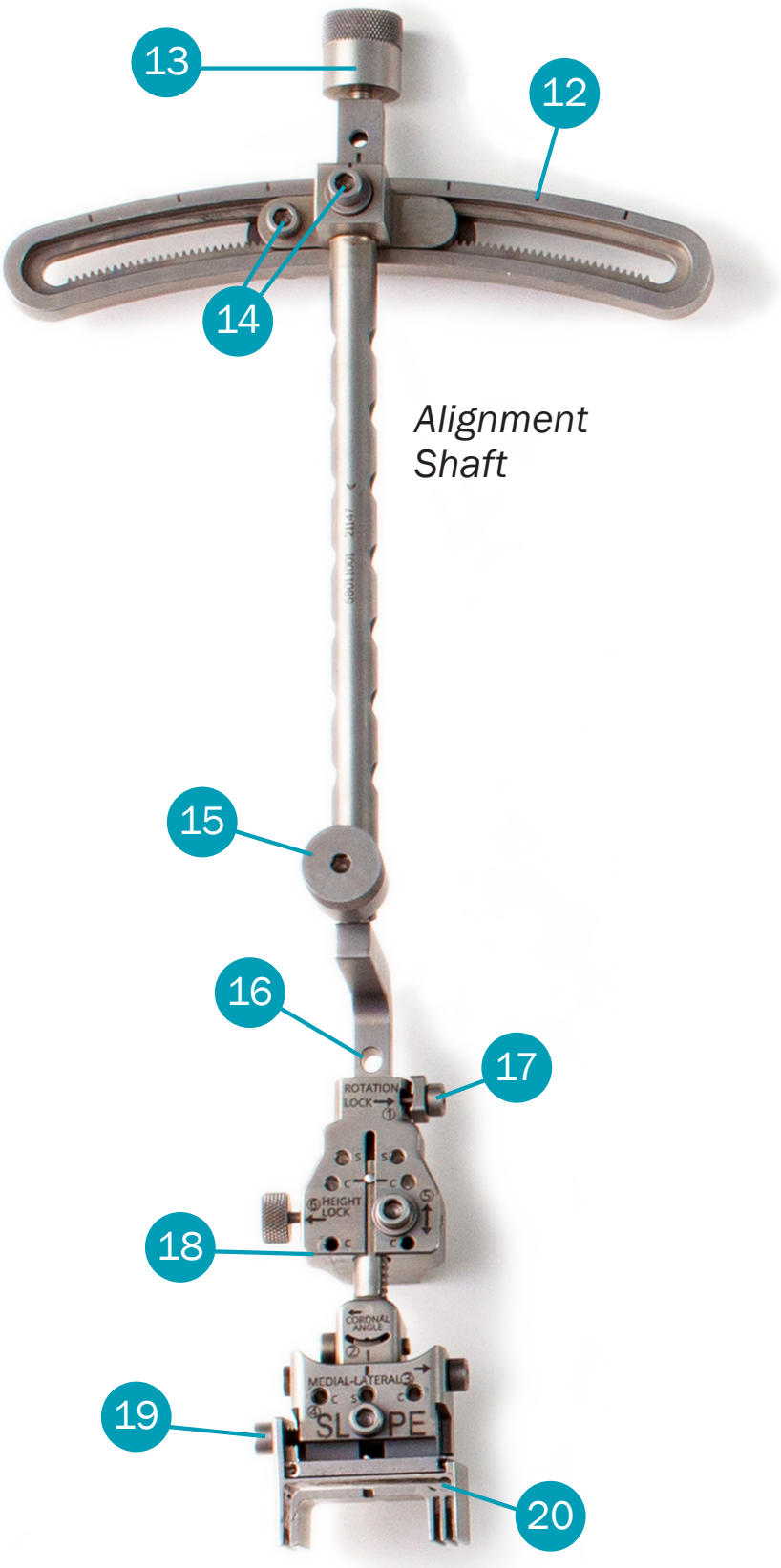
Instrument Set-up and Assembly

Alignment Shaft

12. Proximal adjustment for coronal plane angle
13. Hole and lock for tibial tubercle pin
14. Adjustment gear and lock for MACRO coronal alignment
15. Telescoping shaft lock
16. “Freedom Hole” - Provisional fixation prior to setting rotation (usage optional). This is usually percutaneous if used.
17. Axial rotation lock
18. Distal manifold, assembled
19. Tibial cut guide lock screw
20. Tibial cut guide, assembled

Starting Position

1. Assemble the Manifold to the alignment shaft and lightly tighten rotation lock (17).
2. Rotate Proximal gear to the neutral position and lightly lock distal height lock.
3. Ensure Coronal Plane, Medial-Lateral and Slope Screws are in neutral position.
4. Select appropriate Tibial Cut Guide (Size 1/2/3 or Size 4/5) and assemble with single vertical slot MEDIAL.



Surgical Technique: Alignment Guide Attachment

5.1 Locate the proximal tibial tubercle and insert the Tubercle Pin (5801-0006) into the anterior tibial cortex, approximately parallel to the 2nd Webspace.

5.2 Ensure tibial cut guide is assembled for Left/ Right foot. The single vertical slot is medial.

5.3 Slide assembly over the Tubercle Pin. Provisionally align the shaft approximately parallel with the long axis of the tibia in the sagittal and coronal planes. Ensure the Manifold is on bone distal to the rotation lock.

5.4 Place the horizontal slot of the tibial cut guide one finger breadth proximal to the distal tibial plafond. Lock the macro height adjustment along the shaft. The freedom hole can be used for provisional fixation (Fig. 47).

5.5 Insert the Rotation Shim into the tibial cut guide and align to the 2nd Webspace. Gutter Shims are available for alternative alignment. Lock the Rotation Screw and then insert a K-Wire (5801-0002) into the proximal manifold block (Fig. 48).

5.6. Obtain a true A/P x-ray by looking through the horizontal slot in the Tibial Cut Guide (Fig. 48).

5.7 Coronal Angle (Varus Valgus) – adjust the Coronal Screw so the distal cutting guide is perpendicular to the mechanical axis of the tibia (Fig. 49).

5.8 Medial Lateral Position – adjust the Medial-Lateral Screw until the medial vertical cut exits into the medial gutter at the proximal-medial talar margin. The lateral vertical cut should not extend into the incisura.

5.9 Insert the Angel Wing into the Tibial Cut Guide.

Fig. 47

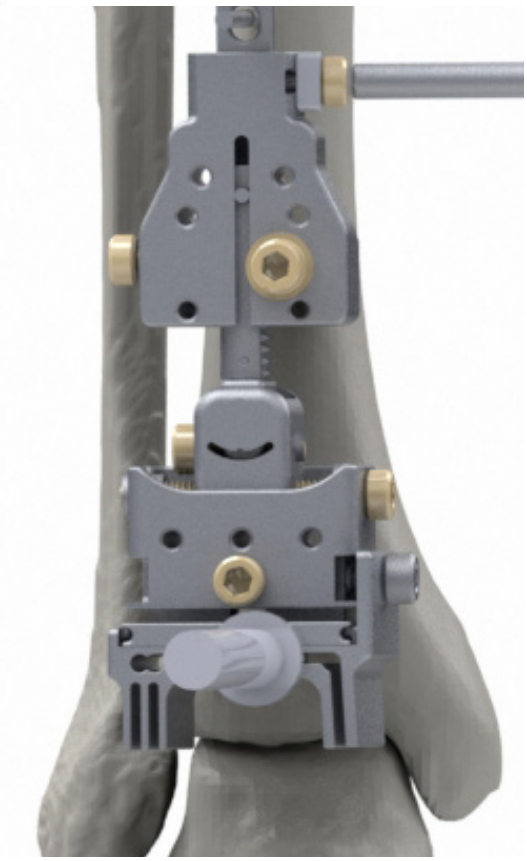


Fig. 48

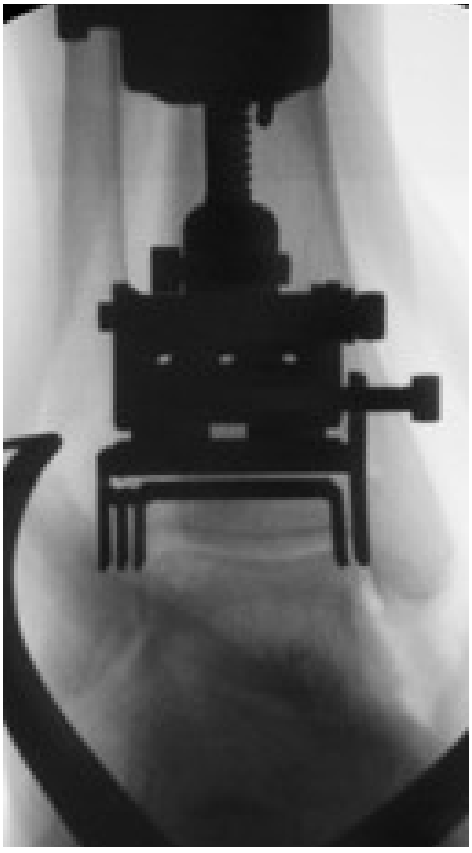


Fig. 49

Obtain a True Lateral view with a knife edge anteriorly. The posts indicate the tibial and talar resection planes. The AP Bar approximates the joint line (Fig. 50).

5.10 Slope Angle – adjust the Slope Screw so the tibial resection plane is perpendicular or neutral to the long axis of the tibia, or slightly open, depending on patient anatomy. Place the Lateral Shaft on the posts of the Angel Wing to assess parallel alignment with the intramedullary canal (Figs. 51 and 52).

5.11 Height Adjustment – unlock the Height Lock Screw and adjust the Proximal Distal Gear until the distal end of the AP bar is just above the proximal most point of the tibial plafond. The posts indicate nominal tibial and talar bone resection planes. Lock Height Lock Screw.

5.12 Go back to the AP view and double check medial lateral cut guide position.

5.13 Place at least one K-Wire (5801-0002) adjacent to the Slope Screw in the distal manifold block.

TIP: Confirm coronal & M/L position prior to K-Wire insertion with an AP x-ray.

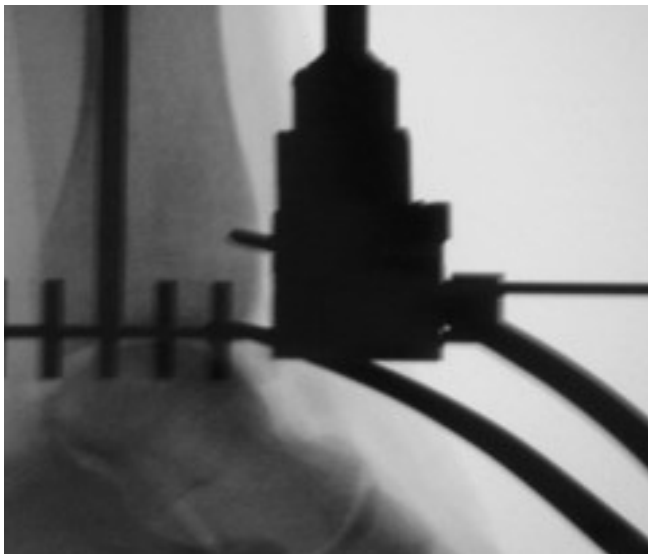


Fig. 50

Too Far Distal

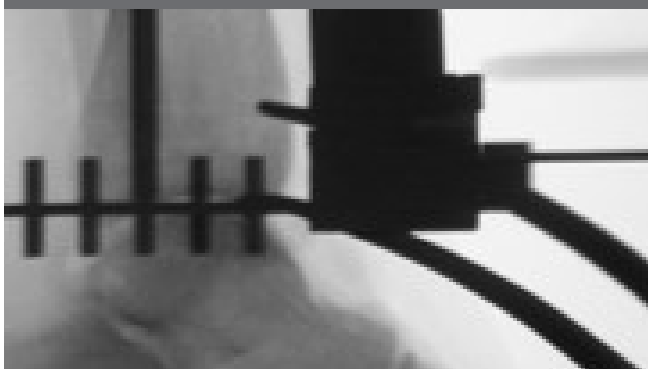


Fig. 51

Closed Slope

Fig. 52

Surgical Technique:
Tibial & Talar Flat Cuts

6.1 Place malleolar protector pins (5801-0002). The lateral K-wire should not violate the fibula. In size 1/2/3 Tibial Cut Guides, use the medial hole for a Size 1 & 2 Tibial implant. In sizes 4/5 Tibial Cut Guides, use the medial hole for a Size 4 Tibial Implant (Fig. 53).

6.2 Make the horizontal tibial cut using an oscillating saw.

6.3. Make the vertical cuts medial and lateral using a reciprocating saw and remove the Tibial Cut Guide.

6.4 Insert the Corner Chisel into the medial and lateral cuts. The laser marked lines indicate the AP length of the tibial implants. Take care not to over insert posteriorly. Use the T-Handle for traction. Take care not to rotate or rock the chisel medially as this may break the medial malleolus. Use a mallet to back tap on the undersurface of the T-Handle to remove the chisel.

TIP: Use the corner chisel as a rasp on its outer edge if needed.

6.7 Under power, insert the Removal Screw (5801-0092) into the tibial fragment. Take care not to exit posteriorly into the soft tissues or skive proximally into the uncut tibia. Use the T-Handle for traction. Use the Posterior Release tool to aid in bone removal if needed (Fig. 54).

6.8 With the tibial fragment removed, remove any cartilage central on the talus, as cartilage thickness on the talar dome is not included in the cut guide offset.

6.9 Select the standard or Flat-Cut Talar Cut Guide and assemble the guide onto the Manifold and lock with the screw. Place the talus in neutral flexion and neutral varus-valgus. Extend the gear until the tongue contacts the talar dome. Overextending the gear will force the talus into plantarflexion (Fig. 55).

NOTE: The Standard Talar Guide removes 3.5mm of talar bone. The Flat-Cut Guide removes 8.5mm of bone.

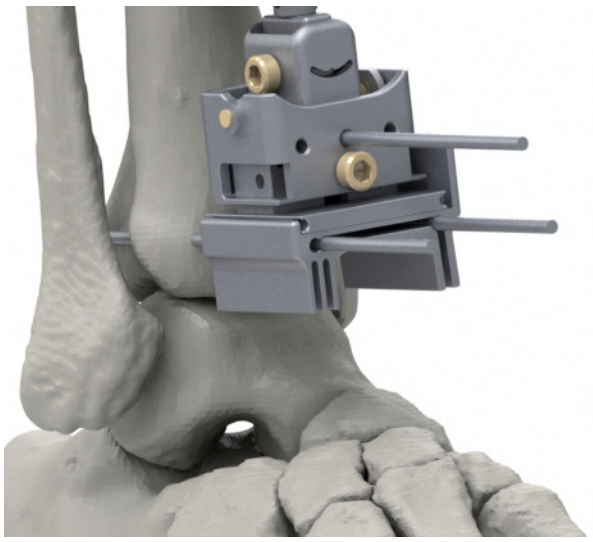


Fig. 53

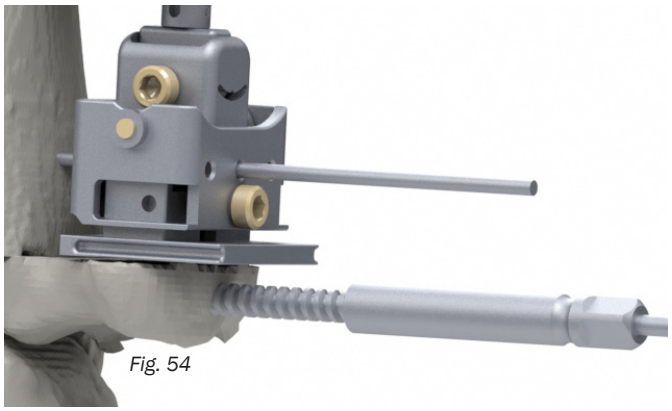


Fig. 54

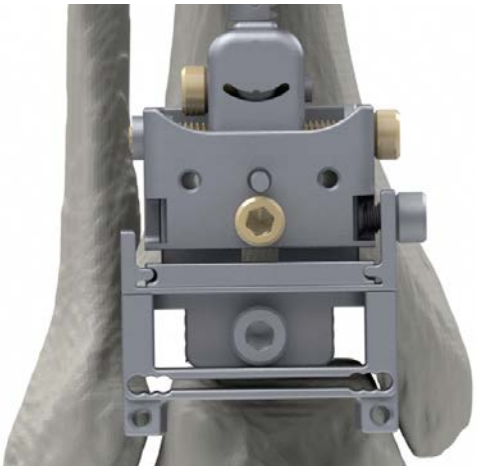


Fig. 55

6.10 Use the Talar Angel Wing to ensure the talar cut is parallel to the previously made tibial cut when the ankle is in a neutral position (Fig. 56).

6.11 Holding the talus in a neutral sagittal and coronal position, place two K-Wires (5801-0002) to stabilize the cut guide.

6.12 Place Protector Pins in the gutter holes if needed. Make the flat talar cut using an oscillating saw and remove the Talar Cut Guide.

6.13 Confirm adequate bone resection with the Gap Sizer. The short side of the Gap Sizer corresponds to a Standard chamfer talar implant resection. The long side of the Gap Sizer corresponds to a Flat-Cut talar implant resection.

TIP: Take AP and lateral x-rays to confirm the horizontal tibial and talar flat cuts are parallel. (Fig. 57).

6.14 The Gap Sizer should fit in the joint space. If it is tight to insert, a second talar cut is recommended. Reattach the Chamfer Talar Cut Guide to the Manifold and distract to resect 3.5mm more bone from the talus. (Fig. 58)

6.15 Once the appropriate resection is made, remove the alignment shaft and distal manifold.

For the remaining surgical steps, proceed to page 17 for chamfer-cut implant use or to page 21 for flat-cut implant use.

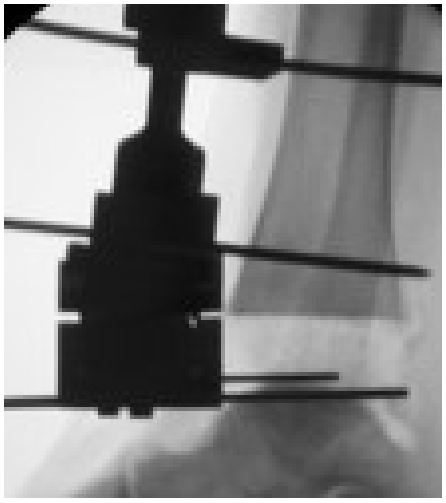


Fig. 56

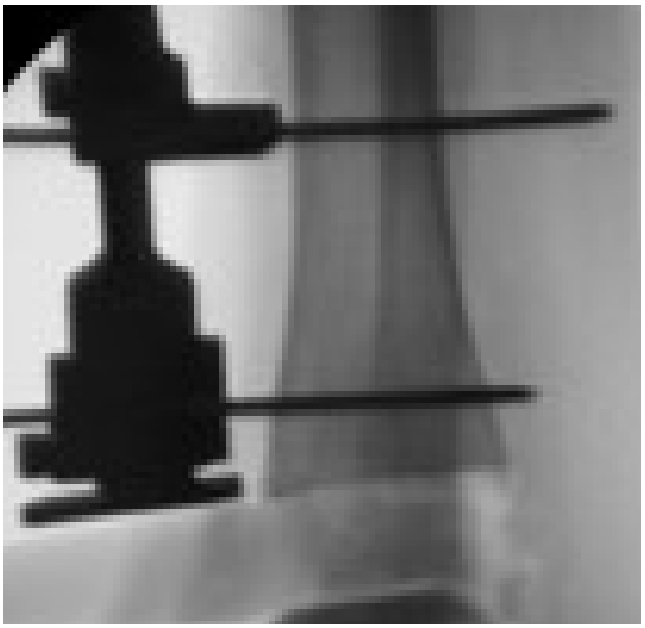


Fig.57

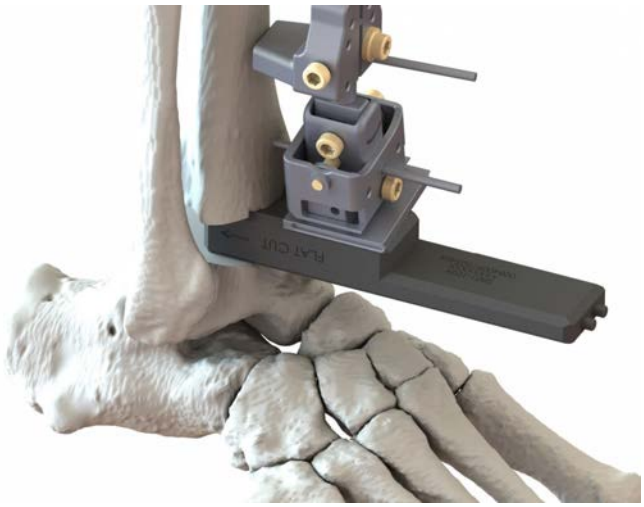
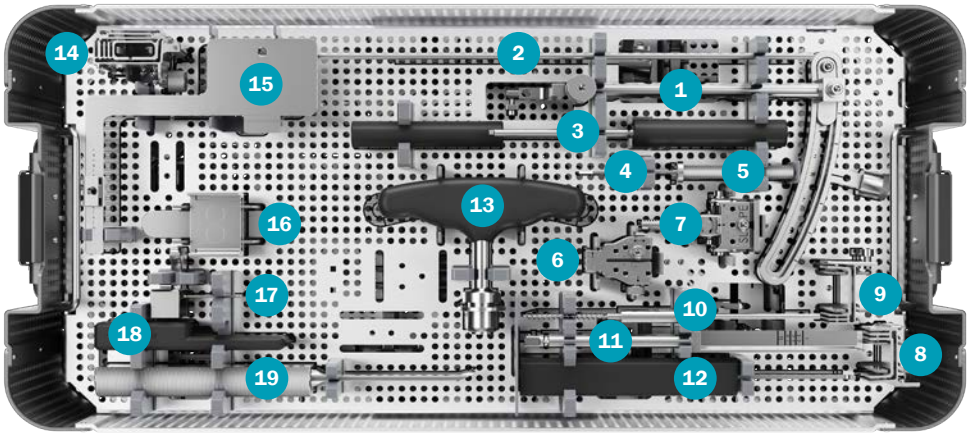


Fig. 58

Surgical Technique: Implant Removal

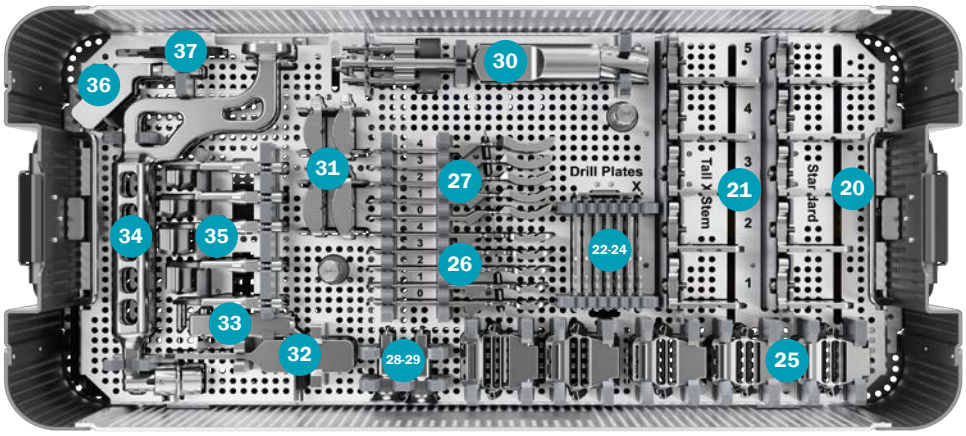
1. Insert a 1/4” osteotome into the anterior slot of the Tibial Implant.
2. Rotate the osteotome clockwise or counterclockwise to separate the Bearing Implant from the Tibial Implant.
3. Remove the Bearing Implant using forceps.
4. Using an osteotome, wedge the tapered end between the anterior chamfer surface of the Talar Implant and the talus.
5. Pry the implant anterior and superior with the osteotome.
6. Using an osteotome, wedge the tapered end between the superior surface of the Tibial Implant and the tibia.
7. Pry the implant distal with the osteotome.
8. Alternatively, power (i.e. sagittal saw, reciprocating saw) and general instruments (i.e. rongeurs, osteotomes) may be used as necessary to loosen the bone-to-cement interface or facilitate Tibial or Talar implant removal.

Tray Overview



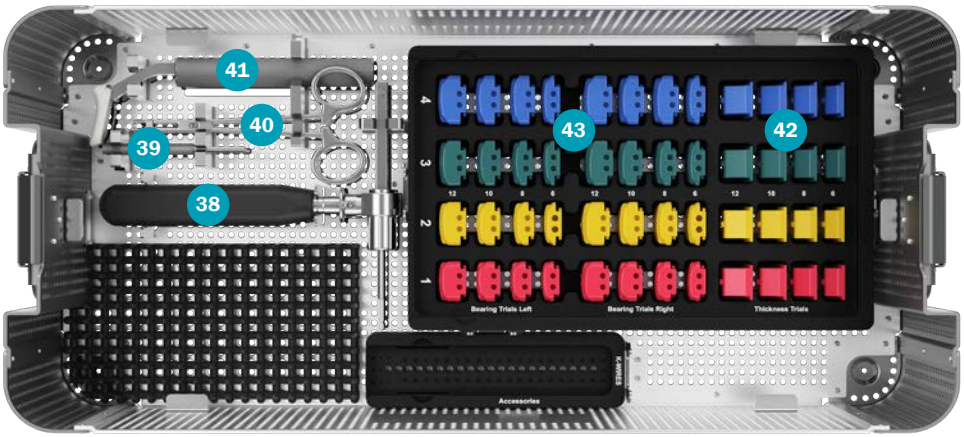
LEVEL 1

1. Alignment Shaft
2. Lateral Alignment Shaft
3. Hex Driver (QTY 2)
4. Gutter Shim (QTY 2)
5. Rotation Shim
6. Proximal Alignment Manifold
7. Distal Alignment Manifold
8. Tibial Cut Guide, Size 1/2/3
9. Tibial Cut Guide, Size 4/5
10. Bone Removal Screw (QTY 2)
11. Corner Chisel
12. Capsule Release Tool
13. T-Handle
14. Coupled Cut Guide
15. Angel Wing
16. Talar Cut Guide
17. Recut Guide
18. Gap Sizer
19. Straight Impactor



LEVEL 2

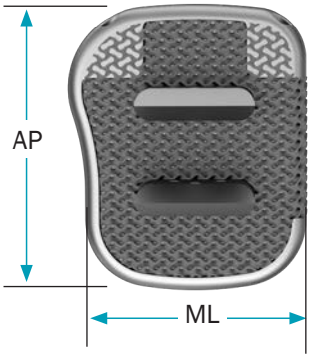
20. Tibial Trials, Size 1-5
21. X-Stem Tibial Trials, Size 1-5
22. Buttress Drill Plates, Size 1-5
23. X-Stem Drill Plate, Size 1/2/3
24. X-Stem Drill Plate, Size 4/5
25. Chamfer Guides, Size 1-4
26. Talar Trials, Size 1-4
27. Rail & Peg Guides, Size 1-4
28. Rail Drill Guide, Size 1/2/3
29. Rail Drill Guide, 4/5
30. Bearing Implant Inserter
31. Flat Top Trials, Size 1-4
32. Rail Rasp
33. Parallel Distractor
34. Offset Impactor
35. Broaches
36. Tibial Impactor
37. TIbial Protector



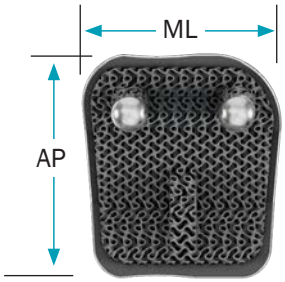
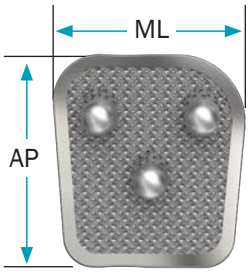
LEVEL 3

38. Right Angle Drill
39. Tibial Joystick
40. Trial Inserter
41. Talar Impactor
42. Bearing Thickness Trials, Sizes 1-4, 6-12mm Heights
43. Bearing Trials, Sizes 1-4, 6-12mm Heights

Ordering Information – Tibial Implants

IMPLANT	PART NUMBER	DESCRIPTION	AP LENGTH	ML LENGTH
3D Printed Tibial Implants				
	1831.1110	Tibial Implant, Size 1, Left, w/TIDAL Technology	34	26
	1831.1120	Tibial Implant, Size 2 Left, w/TIDAL Technology	38	26
	1831.1130	Tibial Implant, Size 3, Left, w/TIDAL Technology	38	28
	1831.1131	Tibial Implant, Size 3, Long, Left, w/TIDAL Technology	41	28
	1831.1140	Tibial Implant, Size 4, Left, w/TIDAL Technology	41	31
	1831.1141	Tibial Implant, Size 4, Long, Left, w/TIDAL Technology	44	31
	1831.1150	Tibial Implant, Size 5, Left, w/TIDAL Technology	44	34
	1831.1151	Tibial Implant, Size 5, Long, Left, w/TIDAL Technology	48	34
	1831.2110	Tibial Implant, Size 1, Right, w/TIDAL Technology	34	26
	1831.2120	Tibial Implant, Size 2 Right, w/TIDAL Technology	38	26
	1831.2130	Tibial Implant, Size 3, Right, w/TIDAL Technology	38	28
	1831.2131	Tibial Implant, Size 3, Long, Right, w/TIDAL Technology	41	28
	1831.2140	Tibial Implant, Size 4, Right, w/TIDAL Technology	41	31
	1831.2141	Tibial Implant, Size 4, Long, Right, w/TIDAL Technology	44	31
	1831.2150	Tibial Implant, Size 5, Right, w/TIDAL Technology, w/TIDAL Technology	44	34
	1831.2151	Tibial Implant, Size 5, Long, Right	48	34

Ordering Information – Talar Implants

IMPLANT	PART NUMBER	DESCRIPTION	AP LENGTH	ML LENGTH
Chamfer-Cut Talar Implants				
	2832-1001	Chamfer Talar Implant with Tidal Technology, Size 1, Lt	31	28
	2832-1002	Chamfer Talar Implant with Tidal Technology, Size 2, Lt	34	30
	2832-1003	Chamfer Talar Implant with Tidal Technology, Size 3, Lt	36	32
	2832-1004	Chamfer Talar Implant with Tidal Technology, Size 4, Lt	39	34
	2832-2001	Chamfer Talar Implant with Tidal Technology, Size 1, Rt	31	28
	2832-2002	Chamfer Talar Implant with Tidal Technology, Size 2, Rt	34	30
	2832-2003	Chamfer Talar Implant with Tidal Technology, Size 3, Rt	36	32
	2832-2004	Chamfer Talar Implant with Tidal Technology, Size 4, Rt	39	34
Flat-Cut Talar Implants				
	2831.3001	Flat-Cut Talar Implant with Tidal Technology, Size 1, Lt	31	28
	2831.3002	Flat-Cut Talar Implant with Tidal Technology, Size 2, Lt	34	30
	2831.3003	Flat-Cut Talar Implant with Tidal Technology, Size 3, Lt	36	32
	2831.3004	Flat-Cut Talar Implant with Tidal Technology, Size 4, Lt	39	34
	2831.4001	Flat-Cut Talar Implant with Tidal Technology, Size 1, Rt	31	28
	2831.4002	Flat-Cut Talar Implant with Tidal Technology, Size 2, Rt	34	30
	2831.4003	Flat-Cut Talar Implant with Tidal Technology, Size 3, Rt	36	32
	2831.4004	Flat-Cut Talar Implant with Tidal Technology, Size 4, Rt	39	34

Ordering Information – Bearing Implants

PART NUMBER	DESCRIPTION
3801.1106	Bearing Implant Size 1, Left, 6mm
3801.1108	Bearing Implant Size 1, Left, 8mm
3801.1110	Bearing Implant Size 1, Left, 10mm
3801.1112	Bearing Implant Size 1, Left, 12mm
3801.1206	Bearing Implant Size 2, Left, 6mm
3801.1208	Bearing Implant Size 2, Left, 8mm
3801.1210	Bearing Implant Size 2, Left, 10mm
3801.1212	Bearing Implant Size 2, Left, 12mm
3801.1306	Bearing Implant Size 3, Left, 6mm
3801.1308	Bearing Implant Size 3, Left, 8mm
3801.1310	Bearing Implant Size 3, Left, 10mm
3801.1312	Bearing Implant Size 3, Left, 12mm
3801.1406	Bearing Implant Size 4, Left, 6mm
3801.1408	Bearing Implant Size 4, Left, 8mm
3801.1410	Bearing Implant Size 4, Left, 10mm
3801.1412	Bearing Implant Size 4, Left, 12mm
3801.2106	Bearing Implant Size 1, Right, 6mm
3801.2108	Bearing Implant Size 1, Right, 8mm
3801.2110	Bearing Implant Size 1, Right, 10mm
3801.2112	Bearing Implant Size 1, Right, 12mm
3801.2206	Bearing Implant Size 2, Right, 6mm
3801.2208	Bearing Implant Size 2, Right, 8mm
3801.2210	Bearing Implant Size 2, Right, 10mm
3801.2212	Bearing Implant Size 2, Right, 12mm
3801.2306	Bearing Implant Size 3, Right, 6mm
3801.2308	Bearing Implant Size 3, Right, 8mm
3801.2310	Bearing Implant Size 3, Right, 10mm
3801.2312	Bearing Implant Size 3, Right, 12mm
3801.2406	Bearing Implant Size 4, Right, 6mm
3801.2408	Bearing Implant Size 4, Right, 8mm
3801.2410	Bearing Implant Size 4, Right, 10mm
3801.2412	Bearing Implant Size 4, Right, 12mm

Ordering Information – Instrumentation

Kinos Axiom® Ankle Replacement Instrumentation

PART NUMBER	DESCRIPTION
5801-0001	Axiom® Procedure Kit, Sterile
5801-0002	Axiom® K-Wire Kit, QTY 4, Sterile
5801-0003	K-Wires w/ Stop, QTY 2, Sterile
5801-0005	Break-Off Wires, QTY 2, Sterile
5801-0006	Tibial Tubercle Pin, Sterile
5801-0007	Talar Peg Drill, Sterile
5801-0008	Talar Rail Drill, Sterile
5801-0009	Talar Bone Mill Size 1, Sterile
5801-0010	Talar Bone Mill Size 2/3, Sterile
5801-0011	Talar Bone Mill Size 4/5, Sterile
5801-0012	Center Drill, Sterile
5801-0045	Talar Peg Drill, Non-Sterile
5801-0047	Talar Rail Drill, Non-Sterile
5801-0092	Bone Removal Screw, Non-Sterile
5801-1069	Tibial Protector, Non-Sterile
5801-1076	Talar Fixation Screw, Non-Sterile
5801-4105	90.0mm X 12.7mm X 1.26mm Sagittal Blade
5801-4109	50.5mm X 1.21mm Reciprocating Blade

Ordering Information – Axiom PSR

PART NUMBER	DESCRIPTION
5831-9001	Axiom Tibial PSR
5831-9003	Axiom Talar PSR, Chamfer-Cut
5831-9004	Axiom Talar PSR, Flat-Cut
5831-9005	Axiom Coupled PSR, Chamfer-Cut
5831-9006	Axiom Coupled PSR, Flat-Cut
5831-910	Axiom PSR Bone Model

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6. *Per manufacturer's documentation.*
7. *Data on File.*