

Kinos Total Ankle X-Stem, Tall

SURGICAL TECHNIQUE



restor3d

Personalized Orthopaedics
Enabling Surgeons to Repair and
Reconstruct the Human Body

Backed by Science
Driven by Outcomes

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Intended Use

Kinos 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 surgeon 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 Total Ankle System

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

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

CAUTION: The Kinos 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 Total Ankle system and its cleared indications for use.

Contraindications

Kinos Total Ankle System

- 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;

Contraindications Cont.

Kinos Total Ankle System Cont.

- 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.

Axiom PSR™

- 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 was obtained;
- Cases where there is inadequate neuromuscular status (e.g. prior paralysis, fusion and/or inadequate abductor strength);
- Suspected or documented metal allergy or intolerance.

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 refer to the Kinos Standard Instrumentation Surgical Technique 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.

Axiom® PSR

Surgical Plan
Kinos Axiom® Total Ankle System

Case ID:	XXXXX
Surgeon:	Surgeon Name
Patient ID:	Initials
Date of Surgery:	X/X/xxxx
Foot:	Left or Right
Suggested Tibial Implant:	size X
Suggested Talar Implant:	size X Chamfer/Flat Top

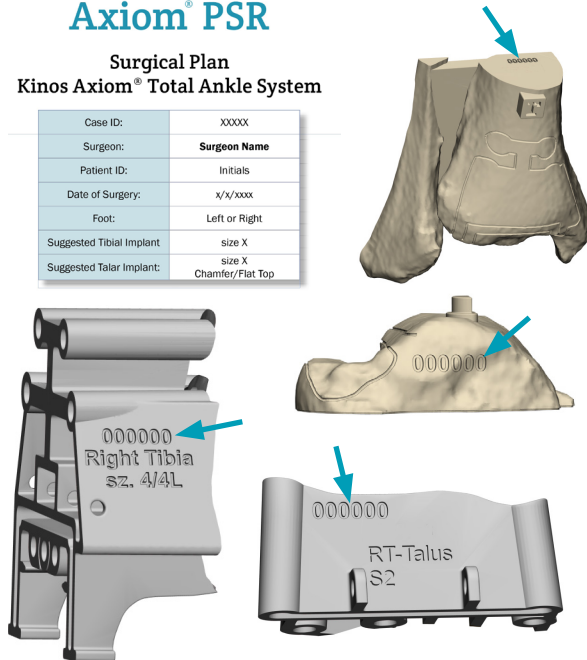


Fig. 1

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 patient specific information.

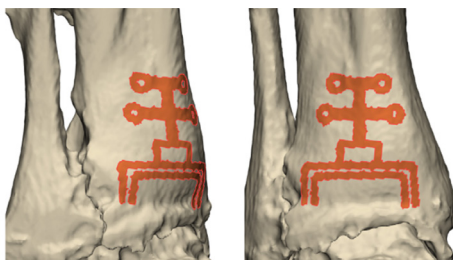


Fig. 2

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

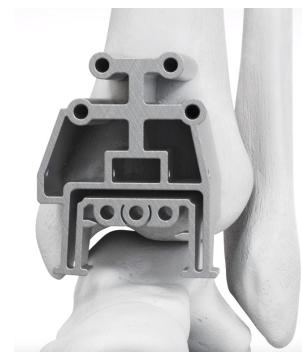


Fig. 3

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

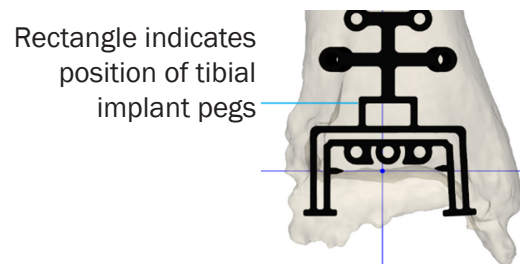


Fig. 4

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

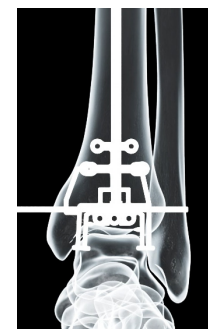


Fig. 5

1.6 Use a lateral radiograph to confirm cut height and slope angle positioning of the tibia PSR. (Fig. 6)

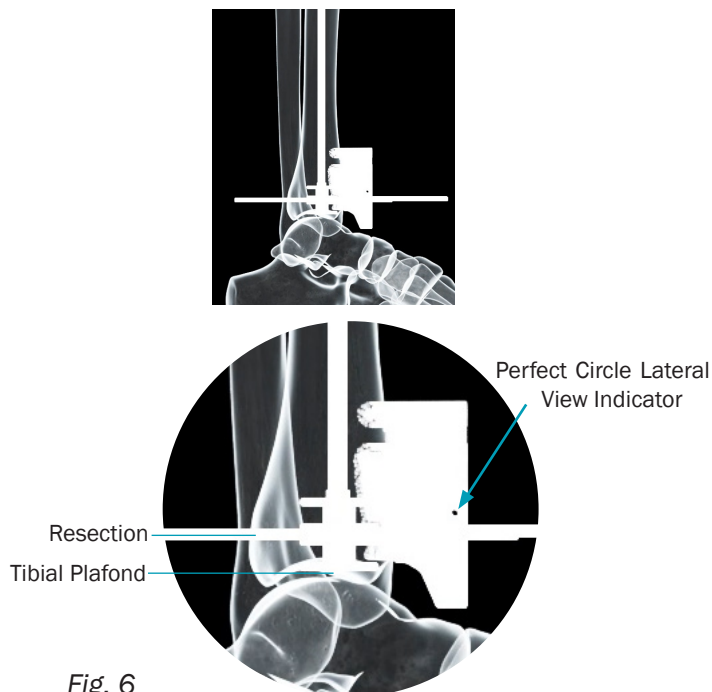


Fig. 6

NOTE: The Angel Wing knife edge indicates the resection plane. The bottom of the offset slider typically indicates the tibial plafond, though patient variability may exist. 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)

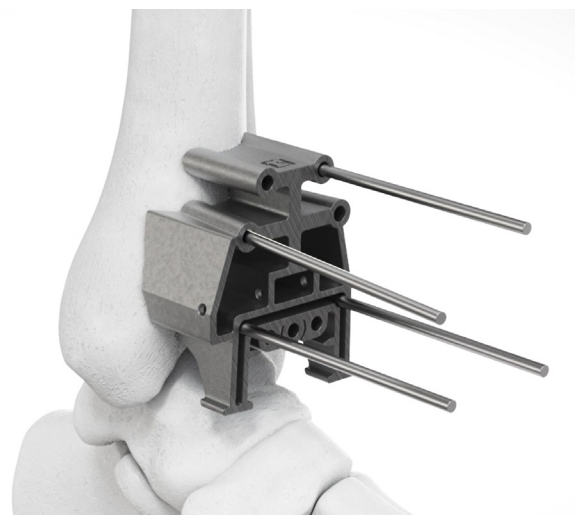


Fig. 7

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.

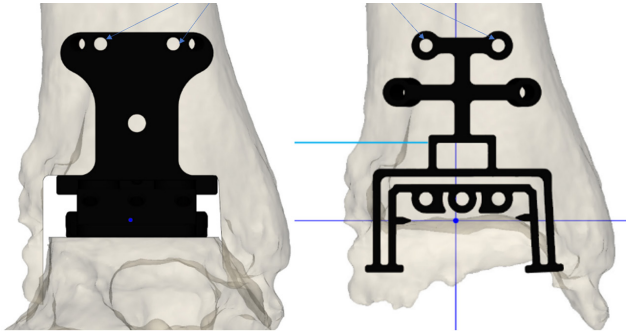


Fig. 8

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 patient specific information.

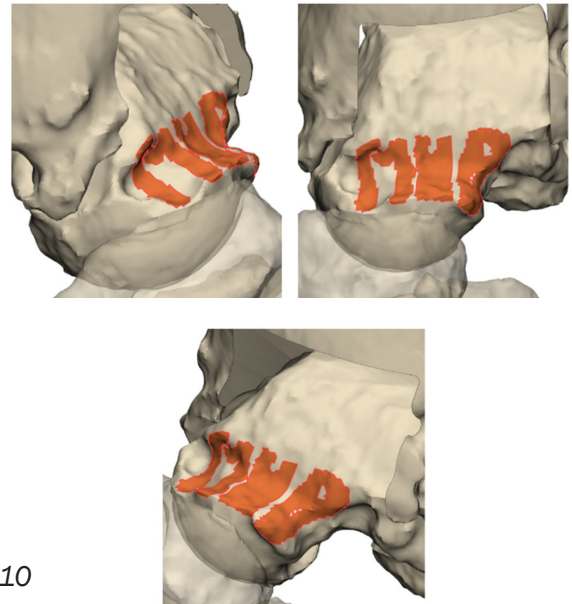


Fig. 10

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. Refer to the Surgical Plan for detailed patient specific information. (Fig. 12)

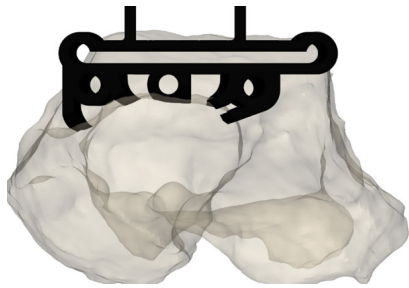


Fig. 12

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.

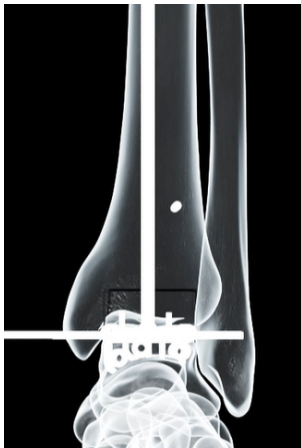


Fig 13.

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.

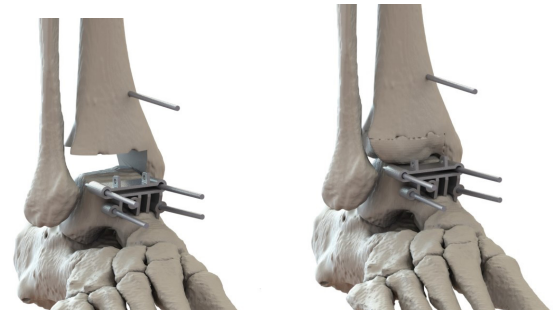


Fig. 14

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 13 for all remaining surgical 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 refer to the Kinoss Standard Instrumentation Surgical Technique 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 assess coronal angle.

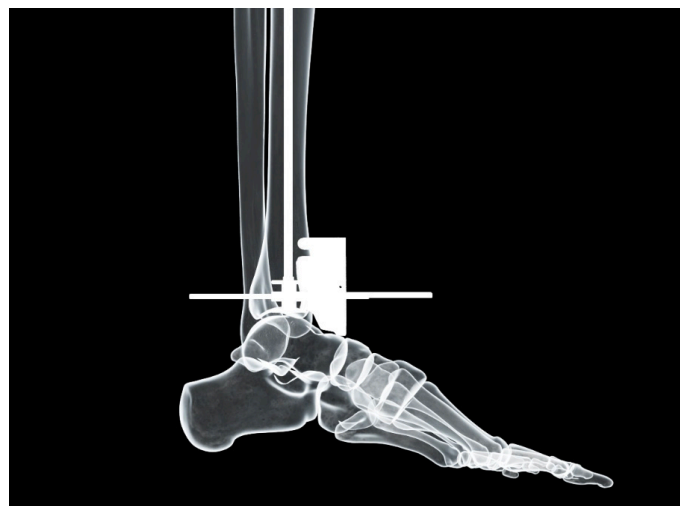
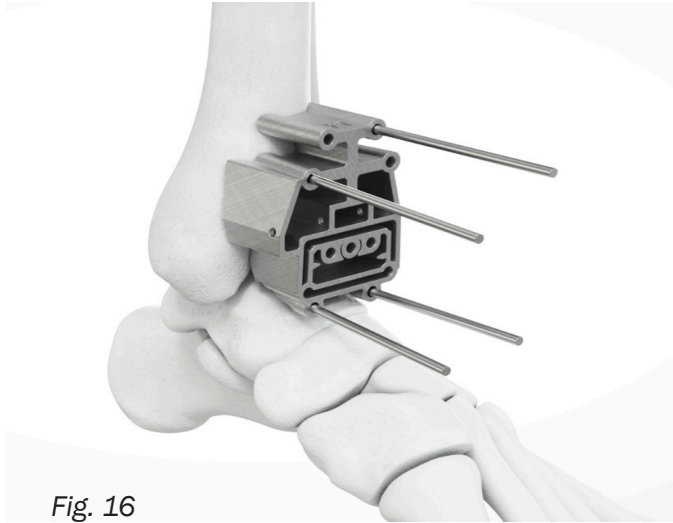


Image reference to step 1.6 using a lateral radiograph to confirm cut height and slope angle positioning of the PSR guide.

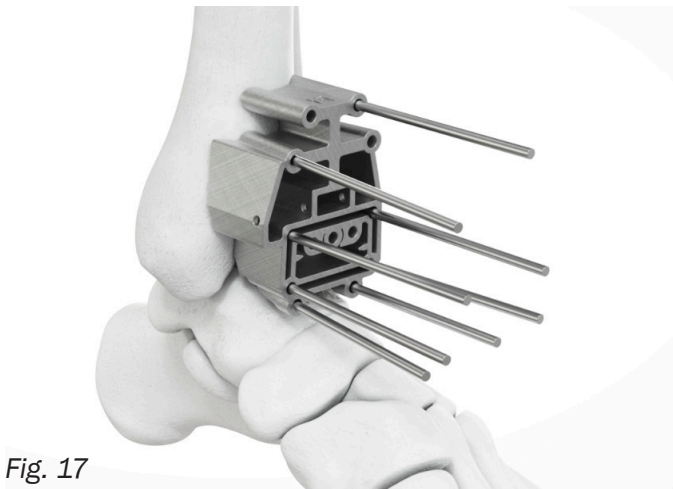


Image reference to step 1.14 to insert the angel wing, and use a lateral radiograph to confirm proximal-distal and slope angle positioning of the talus PSR.

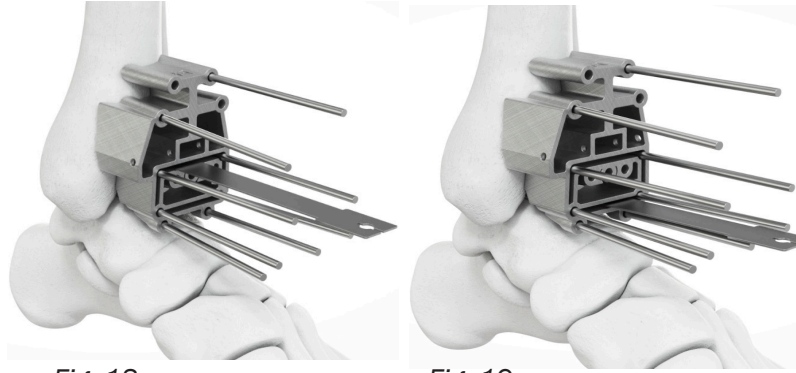
1.27 Rotate the talus into neutral coronal and sagittal position and use 2.4mm k-wires to fixate the talus to the coupled PSR (Fig 16).



1.28 Place resection limit pins in the cut slot.



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



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.



1.31 Refer to page 13 for all remaining surgical steps using Flat-Cut Talar Implants.

Surgical Technique:

Flat-Cut Talar Implant – Tibial & Talar Bone Prep

2.1 Select the appropriate Flat-Cut Talar Trial, assemble the joystick and place on the talus to 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 X-Stem Tibial Trial aligned with the medial vertical cut.

2.3 Insert Thickness Trial of appropriate height, size matched to the Talus Trial (i.e. Size 2 talar trial => Size 2 thickness trial) (Fig. 22).

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.

2.5 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. 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

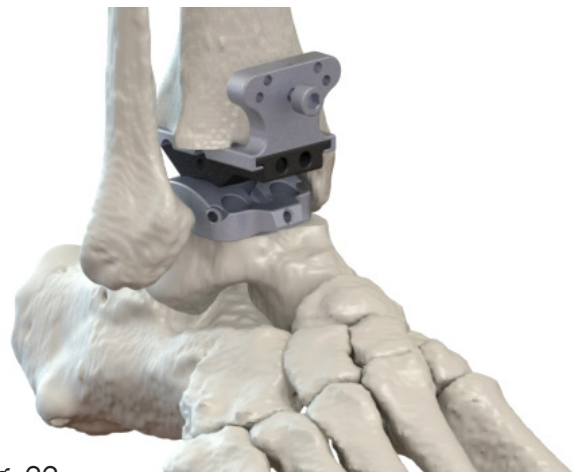


Fig. 22



Fig. 23

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

2.8 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. 24)

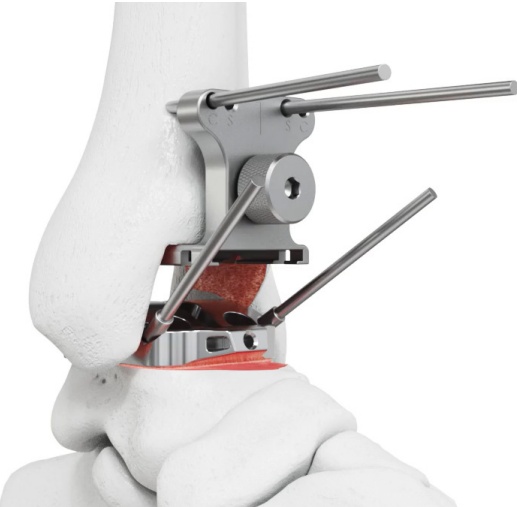


Fig. 24

2.9 Drill the central and anterior peg holes using the Peg Drill. Plantarflexion may help obtain the correct drill angle while avoiding the tibial trial. (Fig. 25)

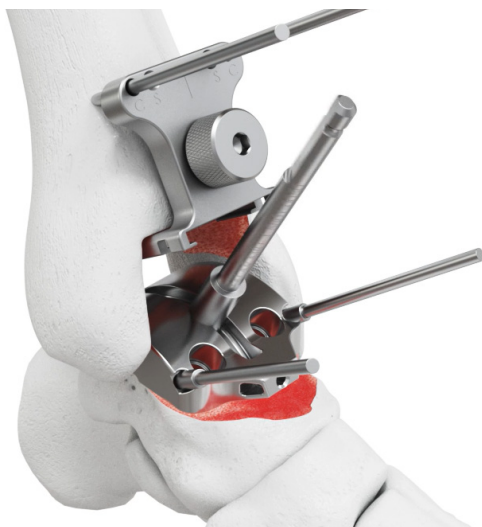


Fig. 25

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

2.11 Insert the X-Stem Drill Plate into the pinned Tibial Trial until it snap locks into place (Fig. 26).

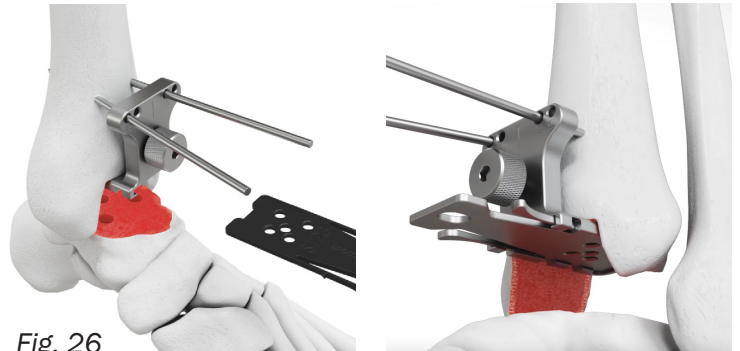


Fig. 26

2.12 Using the Right Angle Drill, drill through all four corners and the center hole of the Drill Plate. (Fig. 27)

NOTE: Use the handle to ensure the superior face of the Right Angle Drill housing sits flush on the Drill Plate.

TIP: Position the handle at 45° to the drill axis to aid in axial alignment with the tibia. (Fig. 27)



Fig. 27

2.13 Using the Spike Broach attached to the offset impactor, chase all four corners and the center hole of the Drill Plate. (Fig. 28)

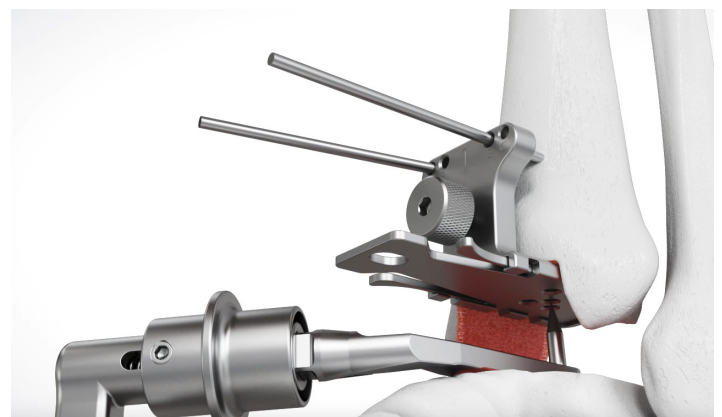


Fig. 28

2.14 Remove the Drill Plate. Flip the plate 180 degrees about the long axis and reinsert into the Tibial Trial. Push the Drill Plate until it locks into place.

2.15 Using the Spike Broach attached to the offset impactor, broach all four corners of the Drill Plate. The central hole does not need to be re-broached. (Fig. 30)

2.16 Using the Right Angle Drill, drill through all four corners of the Drill Plate.

2.17 Remove the Drill Plate.

2.18 Using the X-Stem Starter Broach attached to the offset impactor, broach serially through the Tibial Trial. If necessary, use the straight impactor to impact the broaches up into the tibia (Fig 29).

NOTE: Ensure superior faces of the broaches sit flush on the Tibial Trial once broaching is complete.

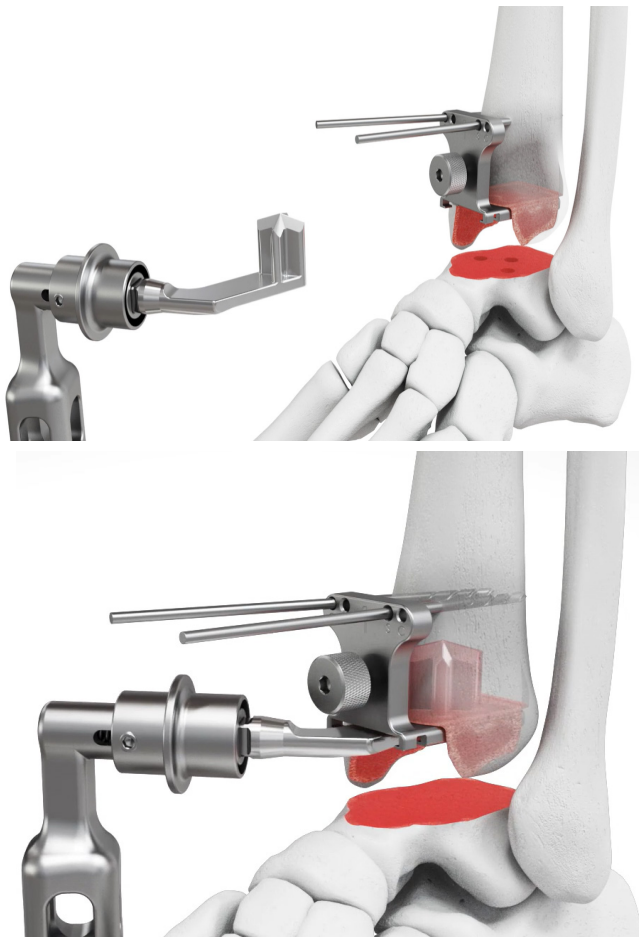


Fig. 29

2.19 Using the X-Stem Finish Broach attached to the offset impactor, repeat the steps described in 2.18. Steps 2.12-2.19 are summarized below. (Fig. 30)

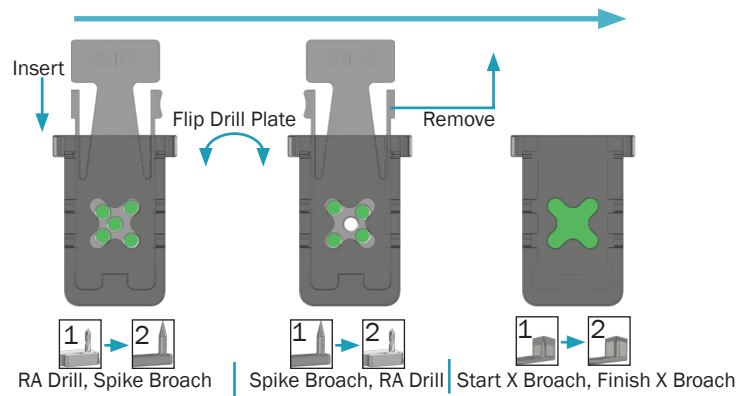


Fig. 30

2.20 Remove the Tibial Trial.

Surgical Technique: Implant Insertion

3.1 Place the Tibial Implant first (Fig. 31). Apply cement to the superior flat surface of the implant.

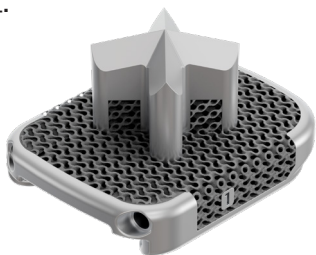


Fig. 31

3.2 Thread the Joystick into the Tibial Implant and guide the proximal buttress of the implant into the pre-broached cavity (Fig. 32).



Fig. 32

3.3 Insert the Tibial Protector into the bearing slot on the Tibial Implant and unthread the Joystick

3.4 Fully seat the Tibial Implant using the Tibial Impactor, Offset Impactor and/or Straight Impactor to seat the implant into the tibial canal (Fig. 33). Remove the Tibial Protector.

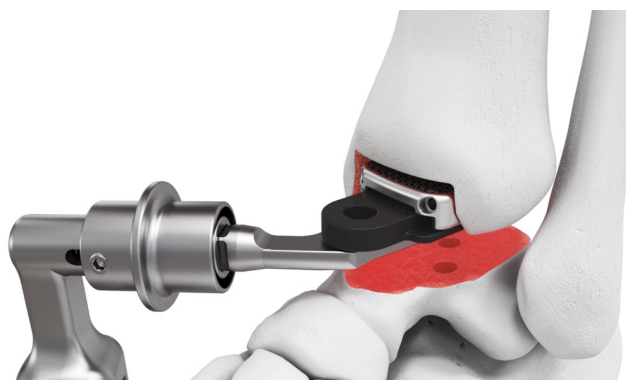


Fig. 33

3.5 Apply cement to the inferior flat surface of the talar implant.

3.6 Fully seat the Talar Implant using the Talar Impactor (Fig. 34).



Fig. 34

3.7 Using a Bearing Trial to determine final Bearing Implant height, Insert the Bearing Trial and range the joint (Fig. 35). The articulating surfaces should remain in contact through the range of motion.



Fig. 35

3.8 Hand feed the Bearing Implant into the Tibial Implant.

3.9 Thread both posts of the Bearing Inserter into the Tibial Implant (Fig. 36).

3.10 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 (Fig. 37).

3.11 Back the Insertion Knob off by 1 turn and unthread the Bearing Inserter from the Tibial Implant.

3.12 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. 36

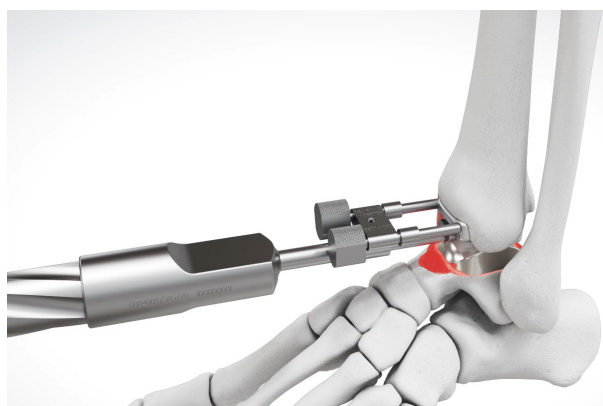


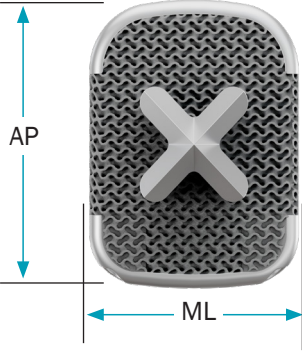
Fig. 37



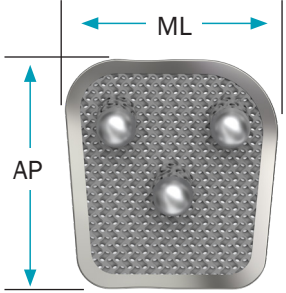
Surgical Technique: Implant Removal

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 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.

Ordering Information: Tibial Implants

IMPLANT	PART NUMBER	DESCRIPTION	AP LENGTH	ML LENGTH
3D Printed Tibial Implants				
	1834-0110	X-Stem Implant, Tall, Size 1, with Tidal Technology	34	26
	1834-0120	X-Stem Implant, Tall, Size 2, with Tidal Technology	38	26
	1834-0130	X-Stem Implant, Tall, Size 3, with Tidal Technology	38	28
	1834-0131	X-Stem Implant, Tall, Size 3 Long, with Tidal Technology	41	28
	1834-0140	X-Stem Implant, Tall, Size 4, with Tidal Technology	41	31
	1834-0141	X-Stem Implant, Tall, Size 4 Long, with Tidal Technology	44	31
	1834-0150	X-Stem Implant, Tall, Size 5, with Tidal Technology	44	34
	1834-0151	X-Stem Implant, Tall, Size 5 Long, with Tidal Technology	48	34
	1834-0152	X-Stem Implant, Tall, Size 5 Extra Long, with Tidal Technology	52	34

Ordering Information: Talar Implants

IMPLANT	PART NUMBER	DESCRIPTION	AP LENGTH	ML LENGTH
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
5801-0101	Right Angle Drill Driving Shaft
5801-0113	13mm Drill Tip, Right Angle Drill
5801-3101	Right Angle Drill Driving Shaft, Non-Sterile
5801-3113	13mm Drill Tip, Right Angle Drill, Non-Sterile

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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