Smith+Nephew

SALTO TALARIS◊
Total Ankle Prosthesis

TOTAL ANKLE
Patient-Matched Guides

Chamfer Cut Surgical Technique

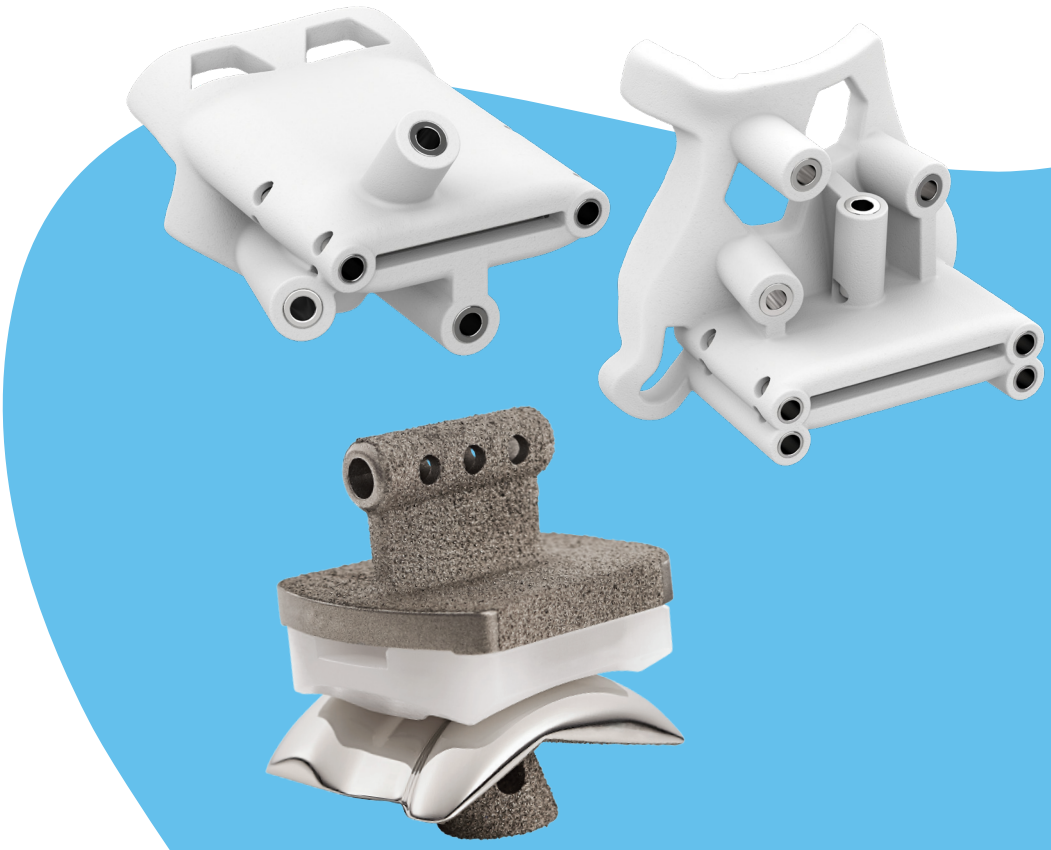


Table of Contents

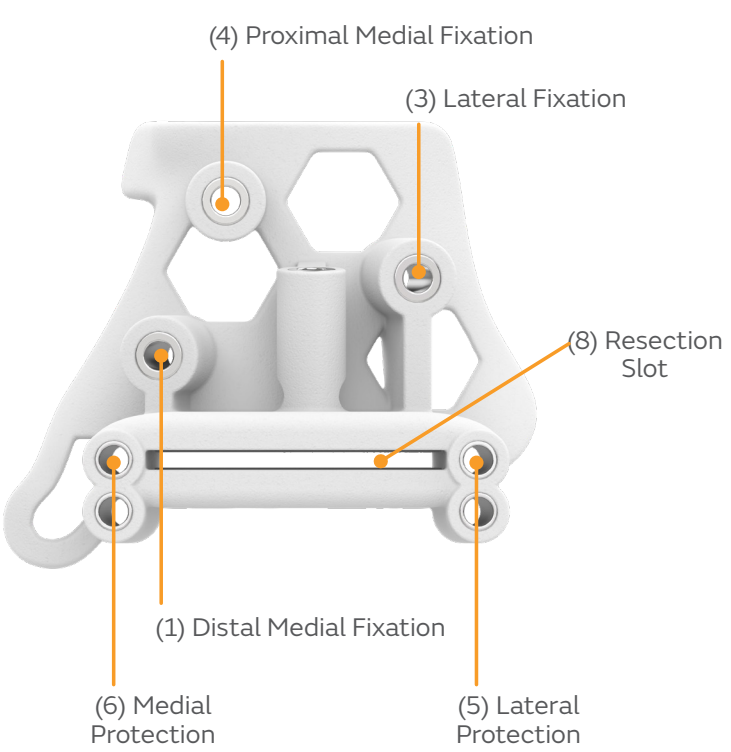
Consult the Preoperative Surgical Report for any specific information relative to the case.

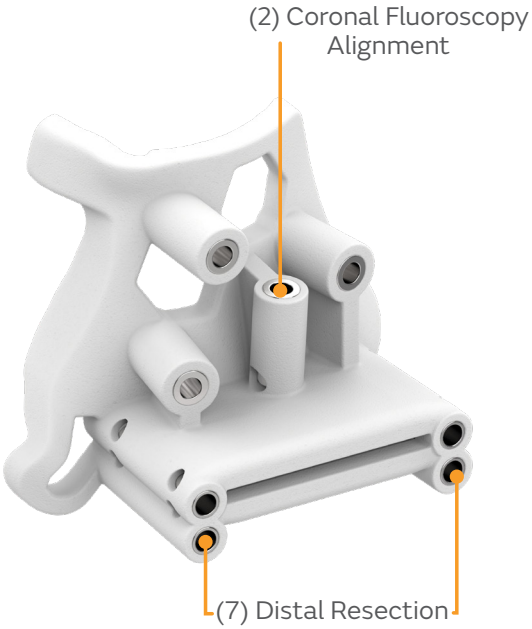
Note Bena

The following technique is for informational and educational purposes only. It is not intended to serve as medical advice. It is the responsibility of treating physicians to determine and utilize the appropriate products and techniques according to their own clinical judgment for each of their patients. For more information on the SALTO TALARIS◊ Total Ankle Prosthesis with TOTAL ANKLE Patient-Matched Guides, including its indications for use, contraindications, and product safety information, please refer to the product's label and the Instructions for Use packaged with the product.

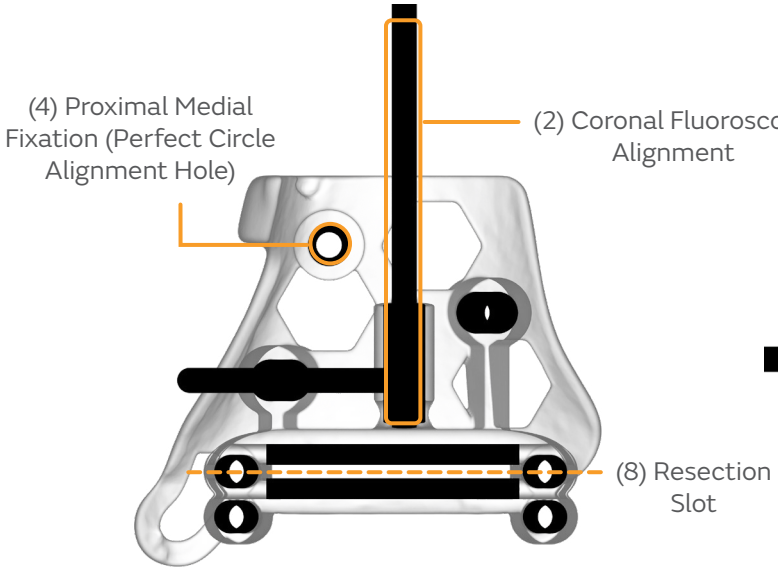
Patient-Matched Guide overview

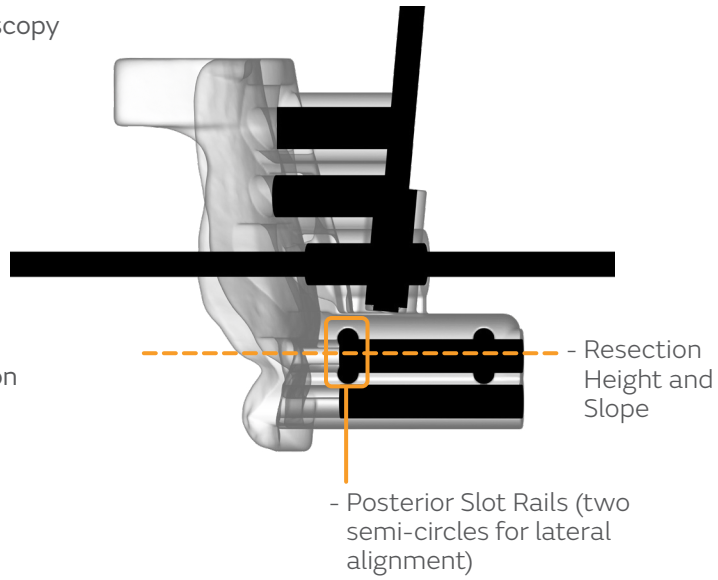
Tibial Guide:



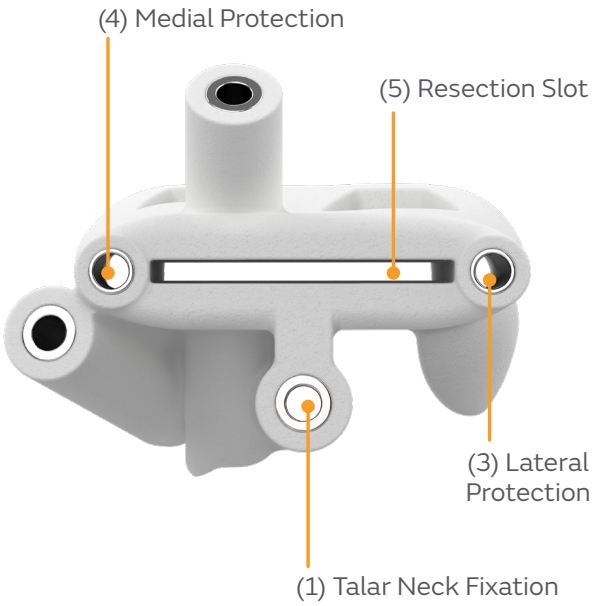


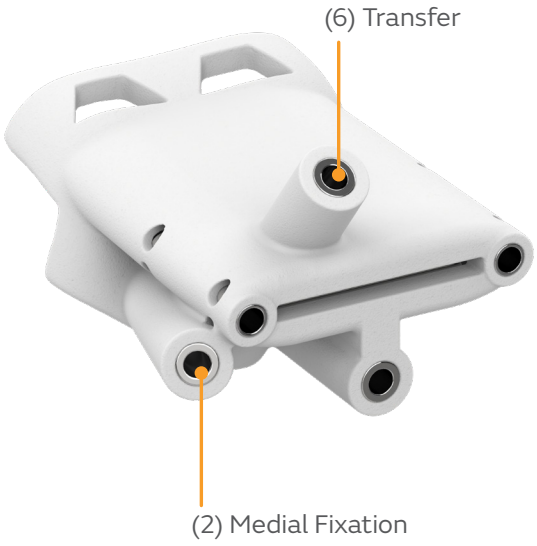
Fluoroscopic view:



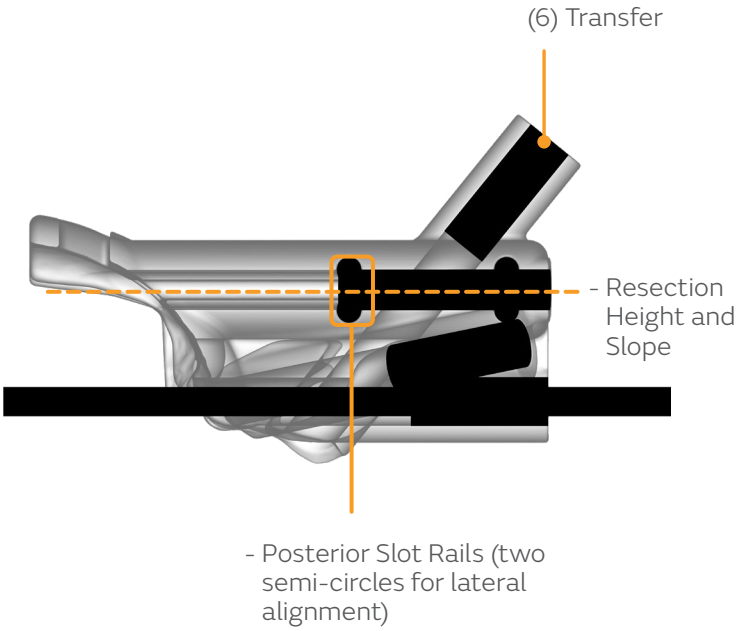


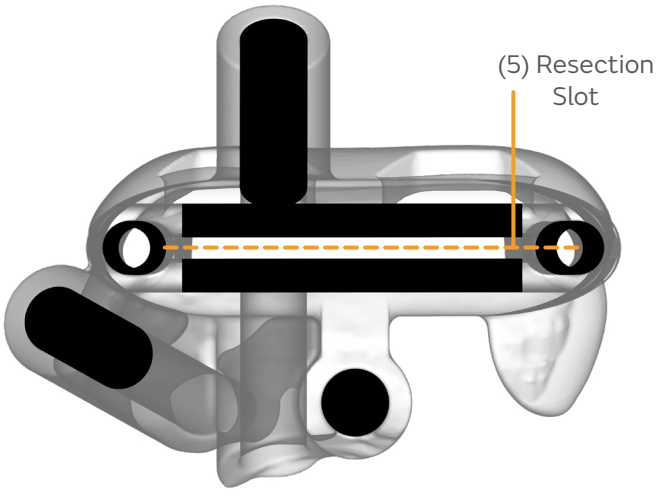
Talus Guide:

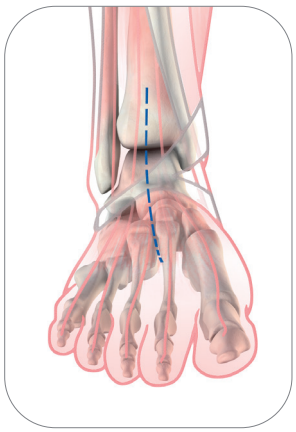




Fluoroscopic view:







Anterior approach

Surgical Technique

1. Identification

a. The patient-matched tibia guide, patient-matched talus guide, and anatomic models are labeled with patient information. This label includes "S+N SAL" to indicate compatibility with Smith+Nephew SALTO TALARIS Total Ankle Prothesis, Patient ID, and Work Order Number.

b. Check that the labels on the guides and anatomic models are legible and match the patient information found in the pre-operative case report.

c. Do not use the guides if the labels do not match.

2. Surgical approach

a. An anterior longitudinal incision is made extending across the midline of the ankle joint to the dorsal medial border of the midfoot.

b. Medial dissection is taken to the medial gutter so that the medial malleolus and the deltoid ligament are visible. Laterally, the dissection is taken so that the anterior inferior tibiofibular syndesmotic ligament and the tubercle of Chaput are visible. The lateral talofibular articulation and the medial aspect of the fibula should be visible by the end of this lateral exposure step.

3. Tibial Guide - Fit Check

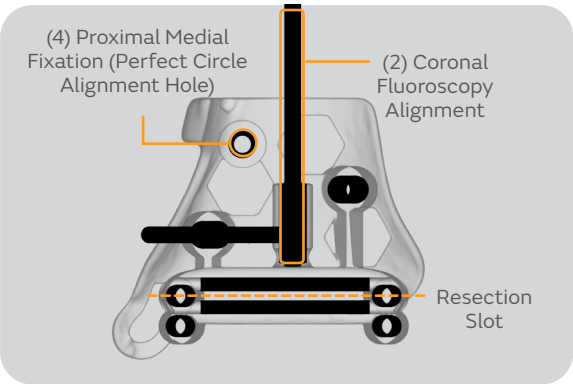
a. Place the tibia guide over the anterior aspect of the distal tibia.

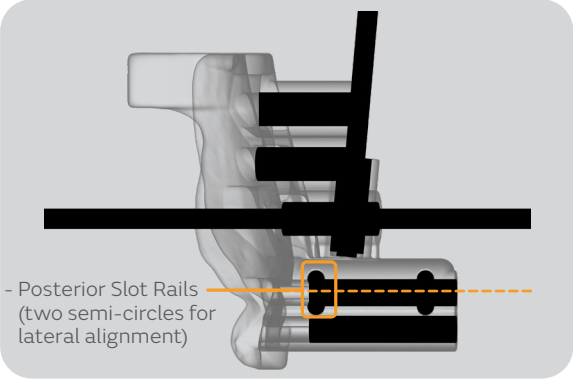
b. The guide should contour to the anatomy of the distal tibia. The tibial anatomic model provided can be used to check the intended fit with the guides.

c. Soft tissue removal is required on all guide-contacting bony surfaces. See "heat map" image in the preoperative case report for guide coverage area. Reference the guide contact profile on the tibia anatomic model for guide contact area and visualization of bony anatomy after soft-tissue removal.

d. Visually confirm the guide is flush against the tibia's surface with no gaps along its perimeter nor through the hexagonal windows of the guide before securing the guide to the tibia.

e. If the guide does not fully seat, periosteum may need to be removed from the surface of the bone. Guide placement that does not match the preoperative case report or that is not flush with the bony surface of the tibia will result in inaccurate cuts.





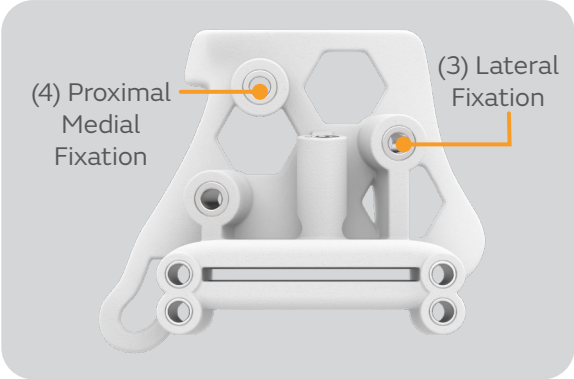
4. Tibia Guide – Alignment and Fixation

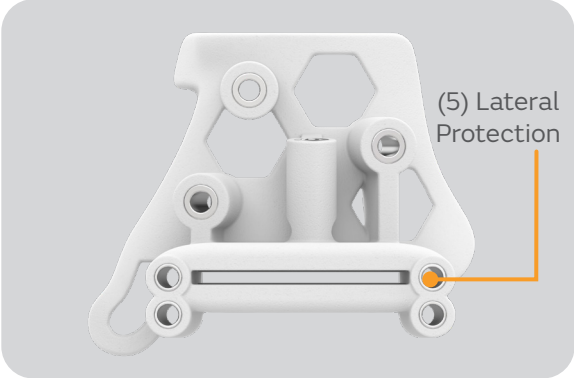
a. With firm pressure down on the guide to ensure it does not slip and maintains the alignment and contact with bony anatomy achieved in the previous step, place a Self-drilling Pin (110mm, LJV527T or 75mm, LJV526T) through one of three available fixation pin sleeves present on the tibial guide. The Distal Medial Fixation Pin (1) is recommended to be placed first.

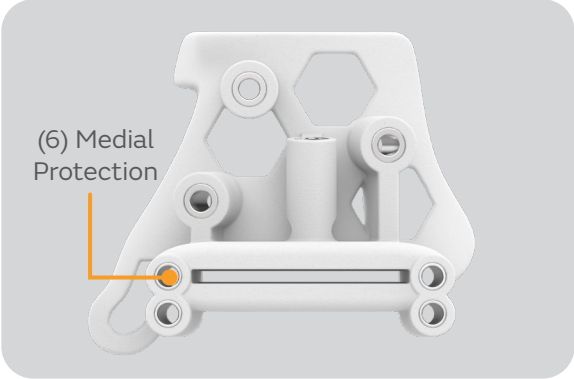
b. Perform visual and fluoroscopic assessment of the tibial guide to ensure proper placement has been maintained and no gapping is observed along perimeter. Confirm via fluoroscopy that the position of the guide matches the intended location described in the preoperative case report.

   i. **AP Alignment:** Place a 3.0mm Drill (LJV528T) in the Coronal Fluoroscopy Alignment Hole (Tibia Guide: Feature 2) to assess AP alignment. A perfect circle should be obtained through the Proximal Fixation Hole (Tibia Guide: Feature 4). Medial/lateral position of the tibial resection may be assessed by referencing the Lateral and Medial Protection Holes (Tibia Guide: Features 5 & 6) and comparing to the image in the preoperative case report.

   ii. **Lateral Alignment:** Use the posterior slot rails closest to the bony anatomy to acquire lateral alignment of fluoroscopy which will appear as semi-circles when aligned. The resection height and sagittal slope may be assessed by the Lateral and Medial Protection Holes (Tibia Guide: Features 5 & 6) in a lateral view. A free sagittal saw blade may be placed through the guide to better visualize resection height.







c. If the guide placement does not match the preoperative case report, additional soft tissue dissection may be required. Remove all fixation pins from the guide. Once the soft tissue has been dissected, repeat from Step 4a using the Lateral Fixation Hole (Tibia Guide: Feature 3). If further adjustment is needed, the Proximal Fixation Hole (Tibia Guide: Feature 4) can also be used for fixation.

d. Once proper guide position has been confirmed via visual inspection and fluoroscopy, place a Self-Drilling Pin (110mm, LJV527T or 75mm, LJV526T) through one or both remaining fixation holes (Tibia Guide: Features 3 & 4). Two of three of these fixation holes must be placed prior to moving forward with the procedure. Confirm placement via visual and fluoroscopic assessment before proceeding.

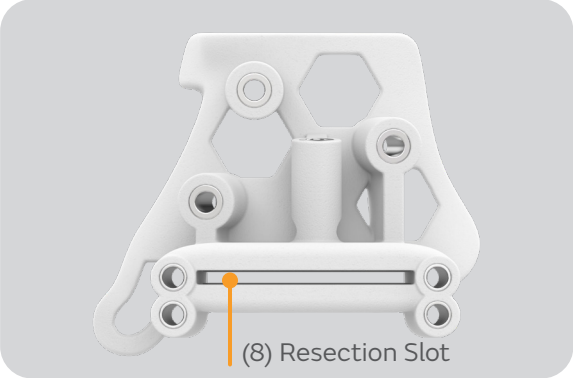
e. Place a Self-Drilling Pin (110mm, LJV527T or 75mm, LJV526T) as protection pins bicortically through the Lateral Protection Hole (Tibia Guide: Feature 5) on the lateral side in line with the resection slot.

f. Place a Self-Drilling Pin (110mm, LJV527T or 75mm, LJV526T) as protection pins bicortically through the Medial Protection Hole (Tibia Guide: Feature 6) on the medial side in line with the resection slot.

Note: If alignment adjustments are needed, remove fixation pins from the tibial guide and reassess the tibial guide fit beginning with Step 4a.

g. Optional: After placing the protection pins, visual and fluoroscopic assessment of the guide may be made to ensure proper alignment.

h. If at any point during the fixation of the tibial guide, the guide itself becomes unfit for resection with surgical instruments, revert to standard Smith+Nephew SALTO TALARIS Standard Instrumentation and refer to the standard Smith+Nephew SALTO TALARIS Total Ankle Prosthesis Operative Technique.



5. Tibia Guide - Resection

a. Using the 3.0mm Drill (LJV528T), drill bicortically through the Medial and Lateral Distal Resection Holes (Tibia Guide: Features 7) in preparation for the vertical resections.

b. Confirm guide placement via fluoroscopy, before making resection. If adjustments are needed, remove fixation and protection pins, and reset the tibial guide fit beginning with step 4a.

c. With a 1.27mm thick oscillating saw blade, cut through the Resection Slot (Tibia Guide: Feature 8) through posterior cortex of the tibia.

Note: A thinner saw blade is not acceptable because the accuracy of the cut will not be maintained.

d. After completing the resection, remove all pins and the tibial guide.

e. Complete the medial and lateral resections of the tibia by cutting the bone remaining between the previously drilled holes by using the provided osteotome or a reciprocating saw.

f. Use osteotomes, rongeurs, or other surgical instruments to remove the resected tibial bone.

g. Remove any generated debris using lavage.

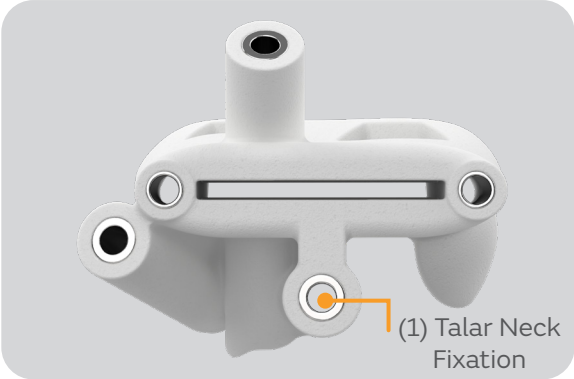
6. Talus Guide – Fit Check

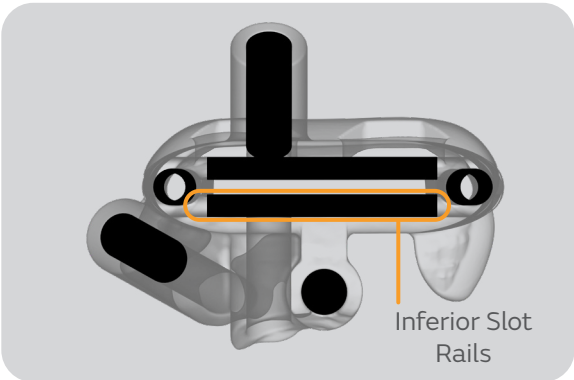
a. Place the talus guide over the anterior aspect of the anterior talus. Any cartilage remaining on the anterior or superior talus should be removed to ensure proper talus guide fit.

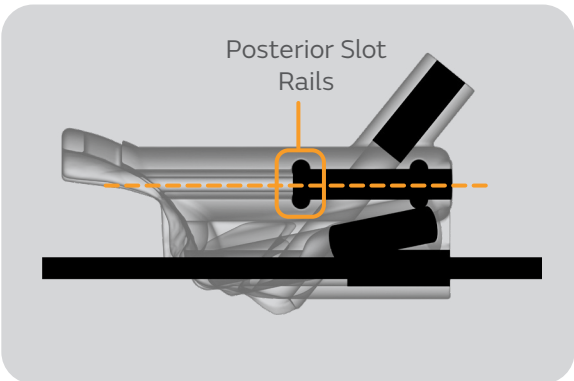
b. The guide should contour to the anatomy of the anterior talus. The talus anatomic model provided can be used to check the intended fit with the guide.

c. Soft tissue removal is required on guide-contacting bony surfaces. See “heat map” image in the preoperative case report for guide coverage area. Reference the guide contact profile on talus anatomic model for guide contact area and visualization of bony anatomy after soft-tissue removal.

d. Visually confirm the guide is flush against the talar surface with no gaps along its perimeter or within the hexagonal windows before securing the guide to the talus.







e. If the guide does not fully seat onto the talus it is possible that additional tissue may need to be removed from the surface of the bone. Guide placement that does not match the preoperative case report or that is not flush with the bony surface of the talus will result in inaccurate resection.

7. Talus Guide – Alignment and Fixation

a. With firm pressure down on the guide to ensure it does not slip and maintains the alignment and contact with bony anatomy achieved in the previous step, place a Self-Drilling Pin (110mm, LJV527T or 75mm, LJV526T) through the Talar Neck Fixation Hole (Talus Guide: Feature 1).

b. Perform visual and fluoroscopic assessment of the guide to ensure proper alignment.

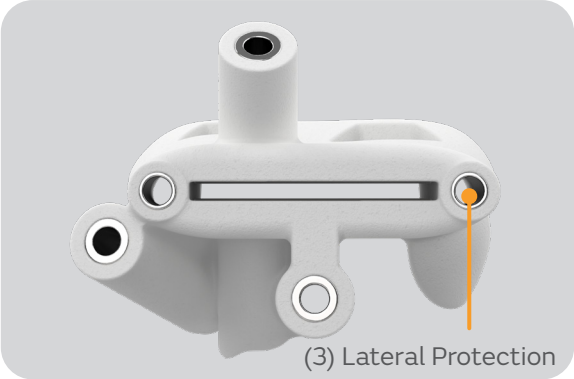
   i. **AP Alignment:** Align the inferior slot rails for assessment of the talus resection height in the AP view. Medial/lateral position of the talus resection may be assessed by referencing the Lateral and Medial Protection Holes (Talus Guide: Feature 3 & 4) and comparing to the image in the preoperative case report.

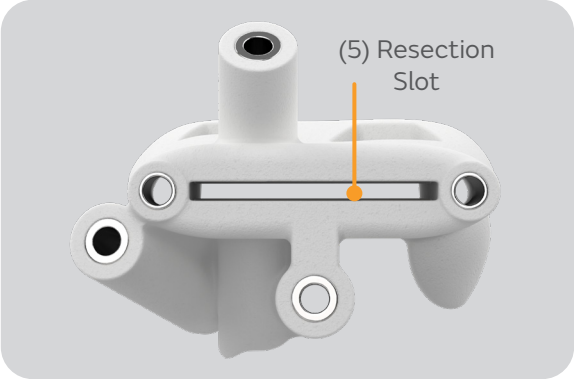
   ii. **Lateral Alignment:** Use the pair of slot rails closest to the bony anatomy to acquire lateral alignment of fluoroscopy which appear as semi-circles when properly aligned. Resection height and sagittal slope may be assessed by the Lateral and Medial Protection Holes (Talus Guide: Feature 3 & 4) in the lateral view. A free sagittal saw blade may be placed through the guide to better visualize talar resection height.

c. Place a Self-Drilling Pin (110mm, LJV527T or 75mm, LJV526T) through the Medial Fixation Hole (Talus Guide: Feature 2).

d. Perform visual and fluoroscopic assessment of the guide.

   i. Note: If alignment adjustments are needed, remove fixation pins from the talar guide and reassess the talar guide fit beginning with step 7a.





e. Place a Self-Drilling Pin (110mm, LJV527T or 75mm, LJV526T) through the Lateral Protection Hole (Talus Guide: Feature 3). Visual and fluoroscopic assessment of the guide may be made at this time to ensure proper alignment of the talus guide.

f. Place Self-Drilling Pin (110mm, LJV527T or 75mm, LJV526T) through the Medial Protection Hole (Talus Guide: Feature 4). Visual and fluoroscopic assessment of the guide may be made at this time to ensure proper alignment of the talus guide.

Note: Place Protection Pins slowly to prevent skiving off talar dome cortical bone.

g. Confirm guide placement with fluoroscopy before making resection. If adjustments are needed, remove fixation and protection pins reset the talar guide fit beginning with Step 7a.

Note: If at any point during the fixation of the talar guide, or if the guide itself becomes unfit for resection, revert to standard instrumentation.

8. Talus Guide – Resection

a. A 1.27mm thick oscillating saw blade should be used to carefully cut through Talar Guide Cut Slot (Talus Guide: Feature 5) through the posterior cortex of the talus.

Note: a thinner saw blade is not acceptable because the accuracy of the resection will not be maintained.

b. After the resection has been completed, place up to two (2) Self-Drilling Pin (110mm, LJV527T or 75mm, LJV526T) through the Transfer Holes (Talus Guide: Features 6). In cases where the joint space would be violated by a transfer pin, only one transfer pin will be present. A minimum of one transfer pin must be placed.

c. Remove all pins except for the transfer pin(s) placed in Step 8b and remove the talus guide over the transfer pin(s).

d. Use osteotomes, rongeurs, or other surgical instruments to remove all resected talar bone. Take care to protect both the medial and lateral malleoli during this process.

Note: It may be necessary to remove any additional bone from around the transfer pins, if this is the case remove one pin at a time and replace back into the existing hole.

e. Remove any generated debris using lavage.

f. Select the correctly sized Anterior Chamfer Guide (MJU643T or MJU665T) and slide it over the remaining transfer pin(s).

h. Replace the distal talar neck pin through the Anterior Chamfer Guide in the existing pin hole in the talus. A minimum of one transfer pin and one talar neck pin through the anterior chamfer guide are required before proceeding.

i. Complete remaining steps to finalize talus bone prep and place the implants per Smith+Nephew SALTO TALARIS Operative Technique.

9. Continue to Standard Instrumentation

a. Complete remaining steps to finalize bone preparation and place the implants per standard Smith+Nephew SALTO TALARIS Operative Technique. Reference preoperative case report for planned implant sizing.

Required Pin + Saw Blade part number reference:

- Pin Pack: LJV529T includes:
  - 110mm Self-drilling Pin: LJV527T
  - 75mm Self-drilling Pin: LJV526T
  - 45mm Self-drilling Pin: LJV525T
- 3.0mm diameter Drill: LJV528T
- Saw Blade:
  - Sagittal Blade 70 X 13mm, Stryker System 7: SAW6944T
  - Sagittal Blade 85 x 21mm, Stryker System 7: SAW6945T
  - Reciprocating Blade 70 x 12.5mm, Brasseler: SAW6950T
  - Required thickness to ensure accuracy: 1.27mm

Anterior Chamfer Guide

- SALTO TALARIS, Anterior Chamfer Guide, Size 0,1: MJU643T
- SALTO TALARIS, Anterior Chamfer Guide, Size 2,3: MJU665T

Reference Preoperative Case Report for planned implant sizing.

Catalog

Pin Pack: LJV529T Includes:

Description	Reference
3 x 110 mm Self-drilling Pins	LJV527T
5 x 75 mm Self-drilling Pins	LJV526T
3 x 45 mm Self-drilling Pins	LJV525T
Reamer	LJU097T

Saw Blades

S+N Number	SAW5944T/ SAW6944T	SAW5945T/ SAW6945T	SAW5946T/ SAW6946T	SAW5947T/ SAW6947T	SAW5948T/ SAW6948T	SAW5949T/ SAW6949T	SAW5950T/ SAW6950T	SAW6951T
Depth	70.0 mm	85.0 mm	80.0 mm	90.0 mm	75.0 mm	90.0 mm	70.0 mm	70.0 mm
Width	13.0 mm	21.0 mm	13.0 mm	21.0 mm	13.0 mm	21.0 mm	12.5 mm	12.5 mm
Mtl Thk	1.24 mm	1.24 mm	1.24 mm	1.24 mm	1.24 mm	1.24 mm		
Cut Thk	1.27 mm	1.27 mm	1.27 mm	1.27 mm	1.27 mm	1.27 mm	0.94 mm	0.94 mm
Hub	Stryker System 7	Stryker System 7	Hall Versipower	Hall Versipower	Hall Power Pro	Hall Power Pro	Brasseler	Brasseler

Retractors

Catalog Number	Description
MJU345T	SALTO TALARIS◊, Joint distractor, Model A
MJU346T	SALTO TALARIS, Joint distractor, Model B

Bone-Prep Instruments

Catalog Number	Description
MJU357T	SALTO TALARIS Osteotome Thin

Anterior Chamfer Guide

Catalog Number	Description
MJU643T	SALTO TALARIS, Anterior Chamfer Guide, Size 0,1
MJU665T	SALTO TALARIS, Anterior Chamfer Guide, Size 2,3

Patient Matched Guides

Catalog Number	Description
LJV530T	SALTO TALARIS Chamfer Cut PSI

To ensure successful surgery in the event of device malfunction, have a tray of standard Smith+Nephew SALTO TALARIS Total Ankle Prosthesis instrumentation available at the time of surgery. Switch to standard Smith+Nephew SALTO TALARIS Total Ankle Prosthesis instrumentation if the patient-matched guides are dropped or damaged in the surgical suite.

Notes

Notes

Ascension Orthopedics, Inc.
11101 Metric Blvd.
Austin, TX 78758 USA

Manufactured by:

3D SYSTEMS

Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Smith+Nephew representative or distributor if you have questions about the availability of Smith+Nephew products in your area. For detailed product information, including indications for use, contraindications, precautions and warnings, please consult the product's applicable Instructions for Use (IFU) prior to use.

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