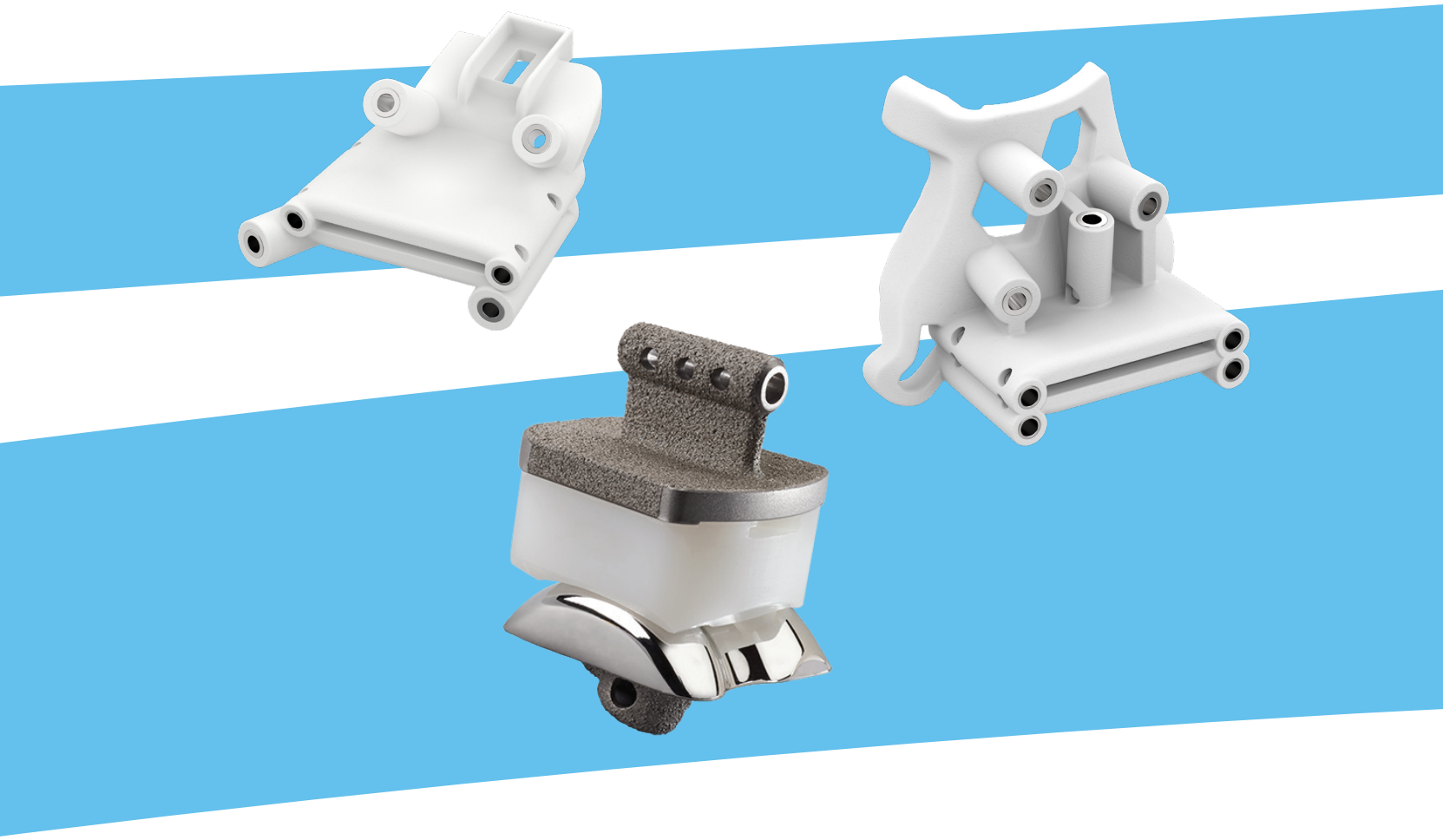
Smith+Nephew

SALTO TALARIS◊
Total Ankle Prosthesis

TOTAL ANKLE
Patient-Matched Guides

Flat Cut Talus Surgical Technique



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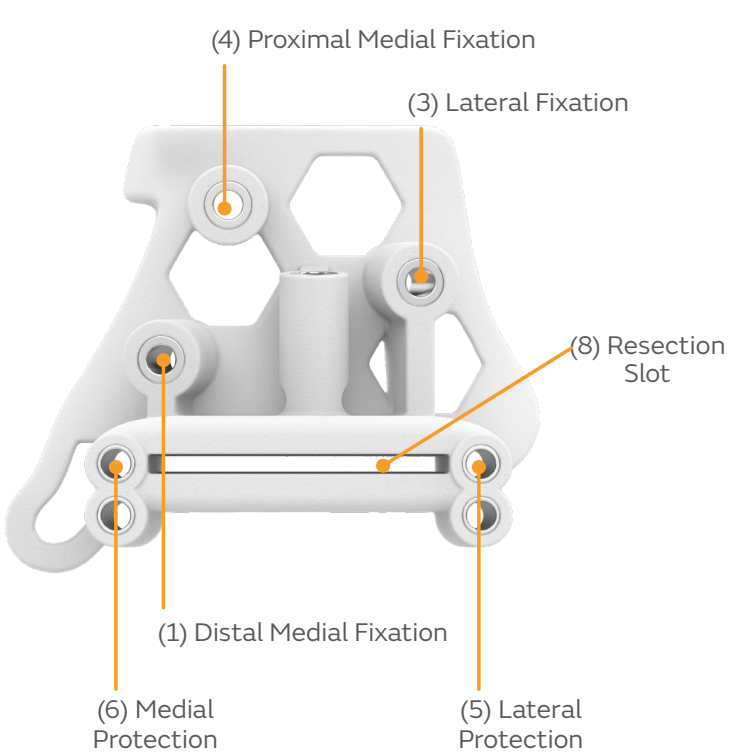
Consult the Preoperative Surgical Report for any specific information relative to the case.

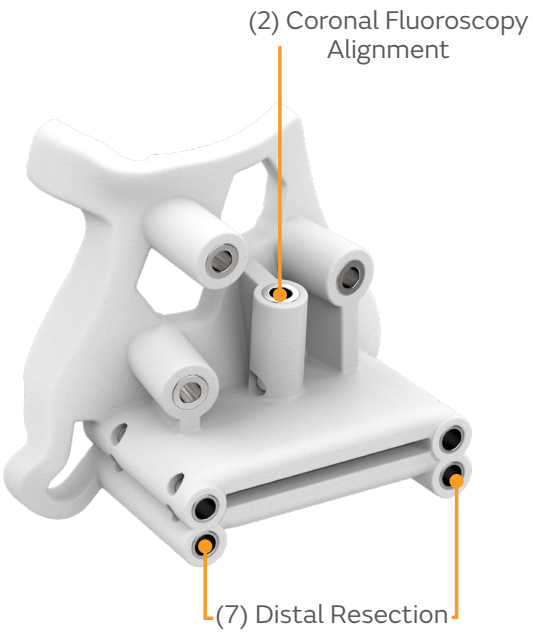
Note Bena

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.

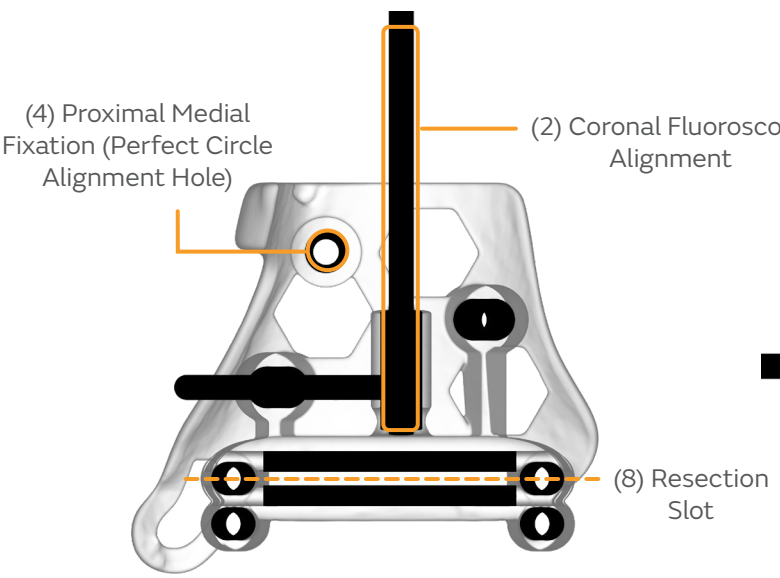
Patient-Matched Guide overview

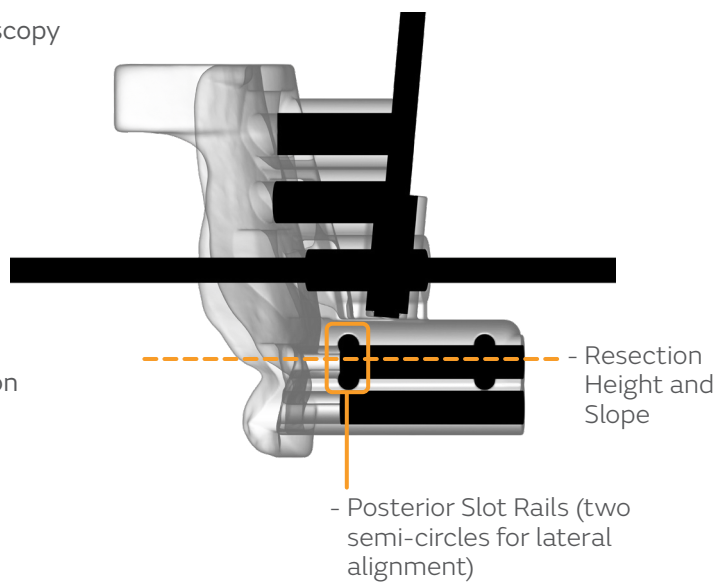
Tibial Guide:



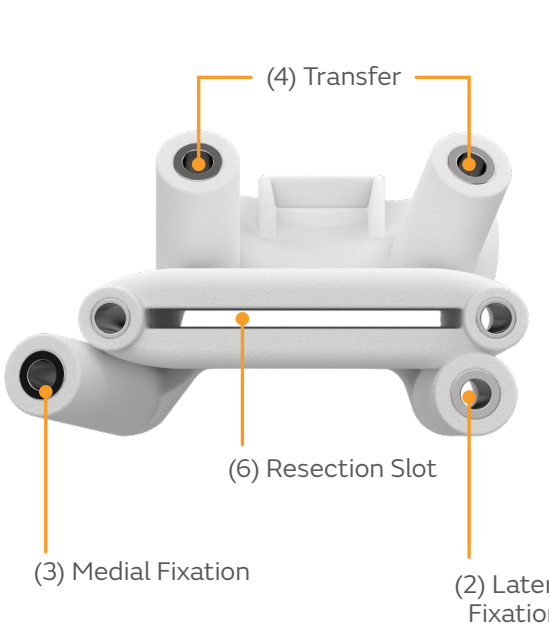


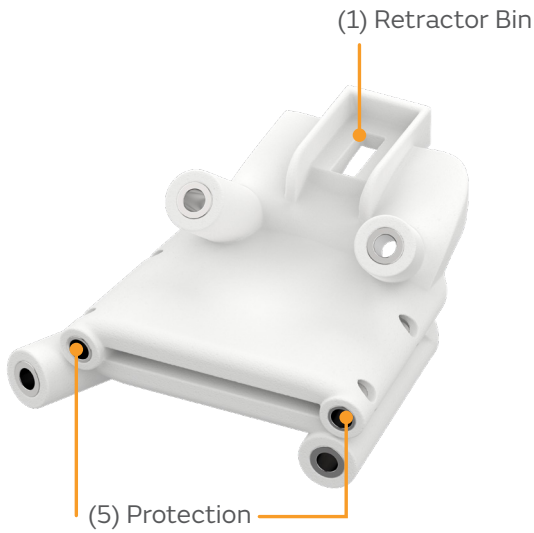
Fluoroscopic view:



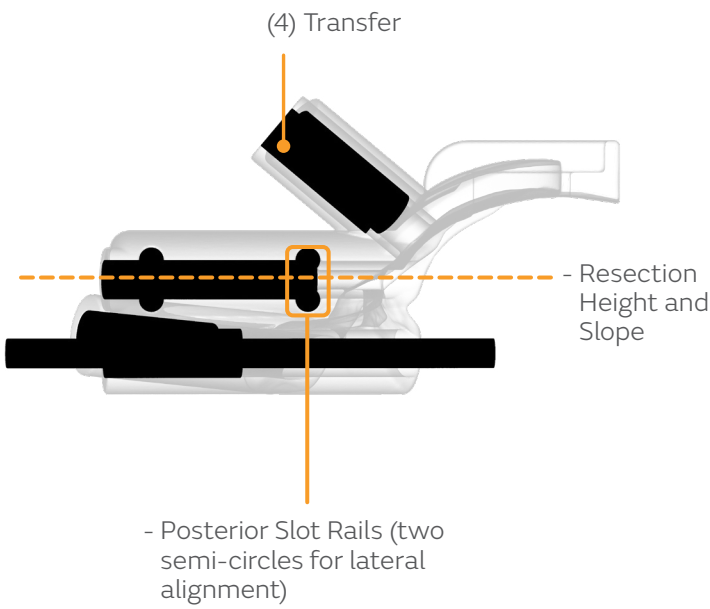


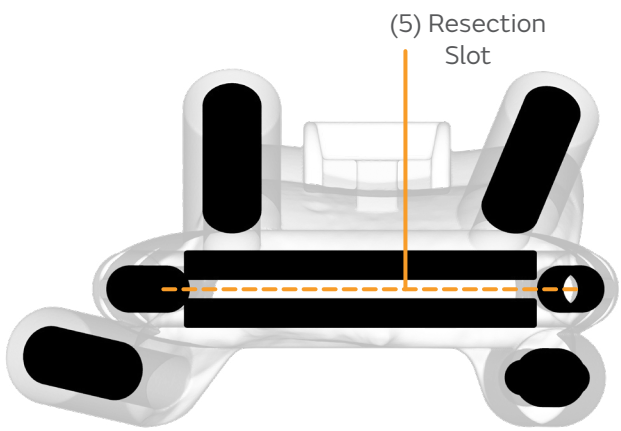
Flat Cut Talus Guide:

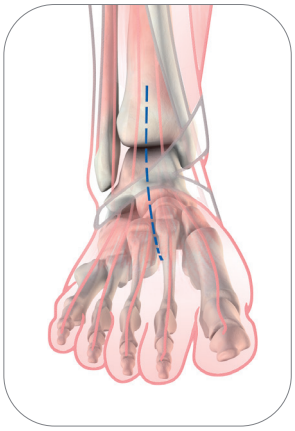




Fluoroscopic view:







Anterior approach

Surgical Technique

Consult Instructions for Use prior to using patient-matched resection guides.

1. Identification

a. The patient-matched tibial 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

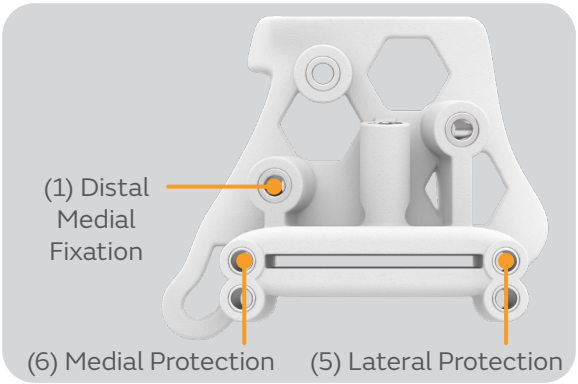
a. Place the tibial guide over the anterior aspect of the distal tibia.

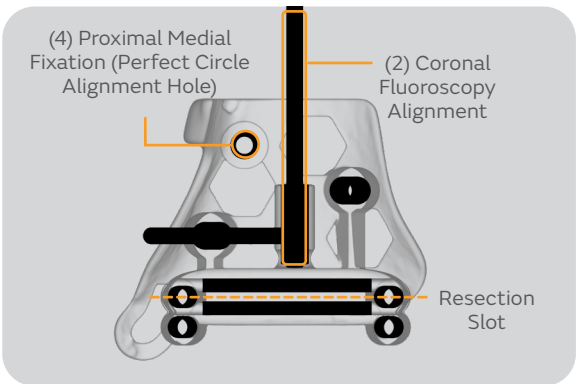
b. The guide should contour to the anatomy of the distal tibia. The tibial anatomic model provided can be used to check the intended fit with the guides.

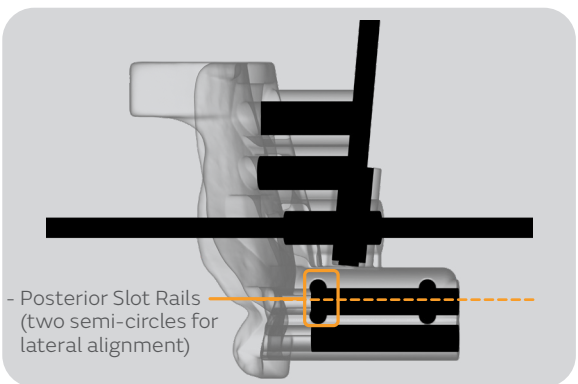
c. Soft tissue removal is required on all guide-contacting bony surfaces. See "heat map" image in the preoperative case report for guide coverage area. Reference the guide contact profile on the tibia anatomic model for guide contact area and visualization of bony anatomy after soft-tissue removal.

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.







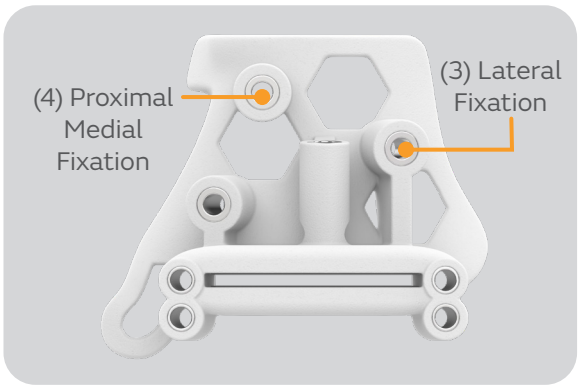
4. Tibial Guide – Alignment and Fixation

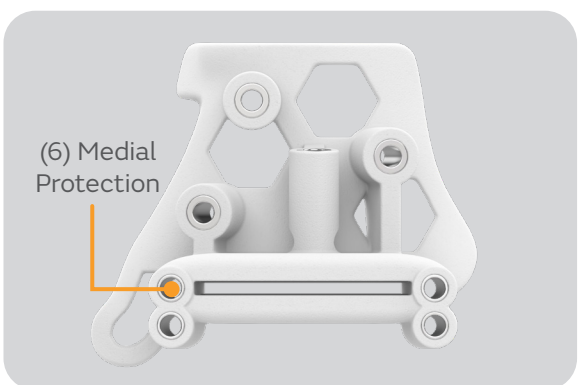
a. With firm pressure down on the guide to ensure it does not slip and maintains the alignment and contact with bony anatomy achieved in the previous step, place a **Self-drilling Pin (110mm, LJV527T or 75mm, LJV526T)** through one of three available fixation pin sleeves present on the tibial guide. 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 (Tibial Guide: Feature 2) to assess AP alignment. A perfect circle should be obtained through the Proximal Fixation Hole (Tibial Guide: Feature 4). Medial/lateral position of the tibial resection may be assessed by referencing the Lateral and Medial Protection Holes (Tibial 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 (Tibial 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 (Tibial Guide: Feature 3). If further adjustment is needed, the Proximal Fixation Hole (Tibial 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 (Tibial 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 (Tibial 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 (Tibial 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. Tibial Guide - Resection

a. Using the **3.0mm Drill (LJV528T),** drill bicortically through the Medial and Lateral Distal Resection Holes (Tibial 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 (Tibial 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.

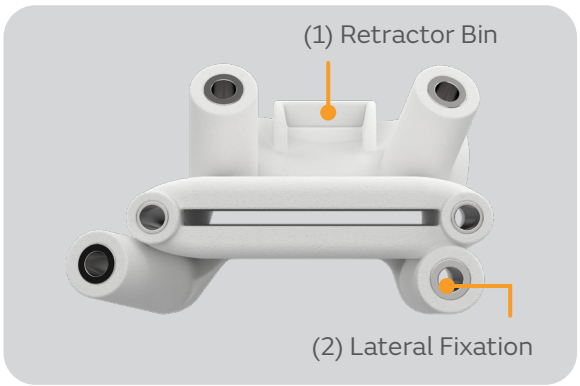
6. Flat Cut Talus Guide – Fit Check

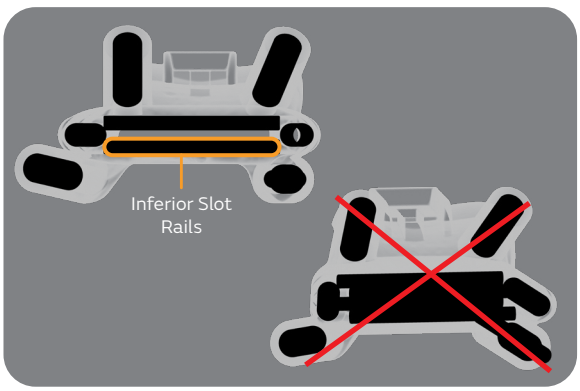
a. Place the talus guide over the anterior aspect of the anterior talus. Any cartilage remaining on the anterior or superior talus should be removed to ensure proper talus guide fit.

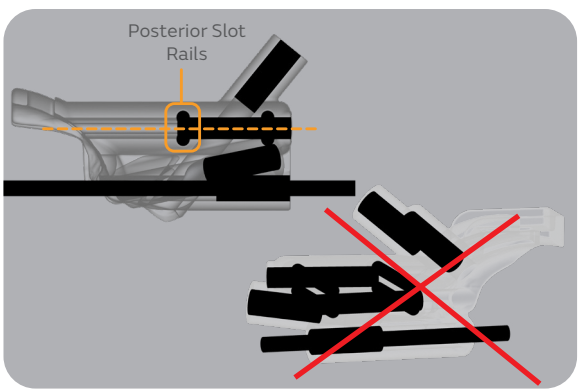
b. The guide should contour to the anatomy of the anterior talus. The talus anatomic model provided can be used to check the intended fit with the guide.

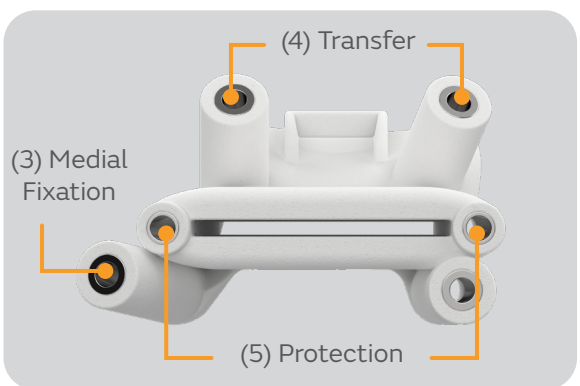
c. Soft tissue removal is required on guide-contacting bony surfaces. See “heat map” image in the preoperative case report for guide coverage area. Reference the guide contact profile on talus anatomic model for guide contact area and visualization of bony anatomy after soft-tissue removal.

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. Flat Cut 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 Lateral Fixation Hole (Talus Guide: Feature 2).

   i. Optional: Mate the **Joint Distractor (MJU245T/6T) or XT, Joint Distractor (MJU928T/9T**) into the Retractor Bin on the talus guide and retract against tibia resection plane to aide in retention of talus guide during fixation.

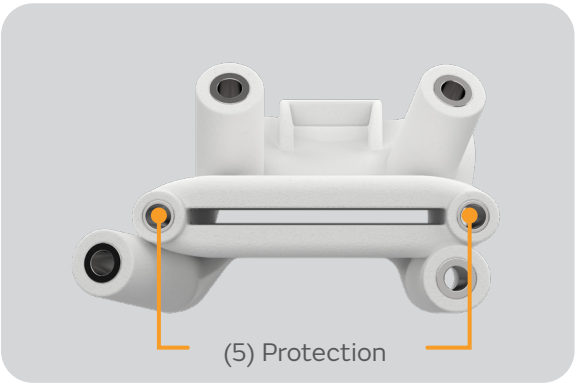
b. Perform visual and fluoroscopic assessment of the guide to ensure proper alignment.

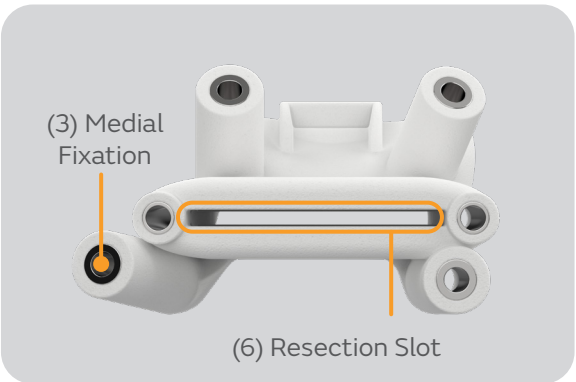
   i. **AP Alignment:** Align inferior slot rails for assessment of talus resection height in the AP view. Medial/lateral position of the talus resection may be assessed by referencing the Medial and Lateral Protection Holes (Talus Guide: Feature 5) and comparing to the image in the preoperative case report.

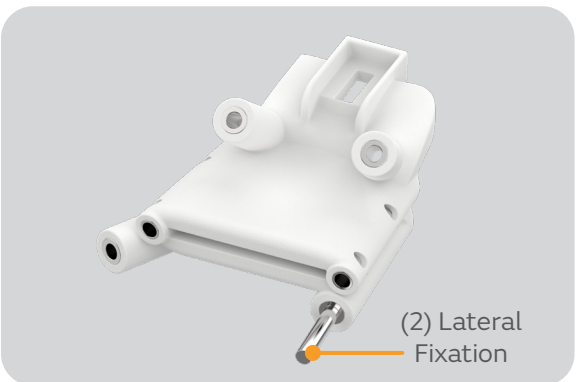
   ii. **Lateral Alignment:** Use the pair of slot rails closest to the bony anatomy to acquire lateral alignment of fluoroscopy. These slot rails will appear as semi-circles above and below the protection bushings when properly aligned. Resection height and sagittal slope may be assessed by the Medial and Lateral Protection Holes (Talus Guide: Feature 5) in a lateral view. A free sagittal saw blade may be placed through the guide to better visualize resection height.

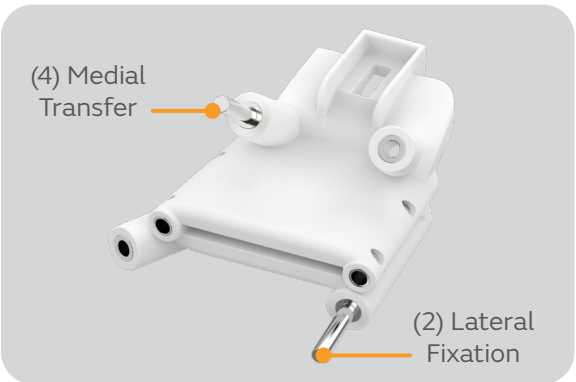
c. Place a **Self-Drilling Pin (110mm, LJV527T or 75mm, LJV526T)** through the Medial Fixation Hole (Talus Guide: Feature 3).

d. Use a 3.0mm Drill (LJV528T) to drill pilot holes through both Medial and Lateral Transfer Holes (Talus Guide: Feature 4) to be used in later Step 8e for Transfer Pin placement following resection.









e. Place a **Self-Drilling Pin (110mm, LJV527T or 75mm, LJV526T)** bicortically through the Medial and Lateral Protection Holes (Talus Guide: Feature 5).

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

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

g. If at any point during the fixation of the talus 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 Operative Technique.

8. Flat Cut Talus Guide – Resection

a. Use a 1.27mm thick oscillating saw blade to carefully perform resection within the Resection Slot (Talus Guide: Feature 6) through the posterior cortex of the talus.

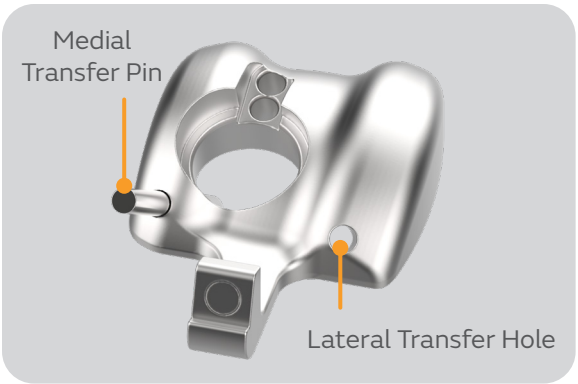
Note: A thinner saw blade is not acceptable because the accuracy of the resection will not be maintained.

b. After resection is complete, remove both Protection Pins (Talus Guide: Feature 5) and Medial Fixation Pin (Talus Guide: Feature 3). Slide the talus guide out of joint space **leaving the Lateral Fixation Pin in place.**

c. Use osteotomes, rongeurs, or other surgical instruments to remove all resected talar bone. Use caution around the malleoli.

Note: Ensure the talus resection is completed entirely. If any bone remnant remains proud of the resection plane especially around the outsides of the protection pin trajectories, the Talar Trial will not function as intended.

d. Place one **Self-Drilling Pin (75mm, LVJ526T)** in the medial pilot hole created in Step 7e. If the hole is challenging to locate, the talus guide can be replaced on the bony anatomy by sliding over the remaining Lateral Fixation Pin to aide in the placement of the Medial Transfer Pin though the Medial Transfer Holes.



e. Remove the Lateral Fixation Pin and guide, if used for Transfer Pin placement, from joint space, **leaving the Medial Transfer Pin in place.**

f. Remove any generated debris using lavage.

g. Slide the selected **Flat Cut Talar Trial (MJV940T/53T)** over the Medial Transfer Pin. Place a **Self-Drilling Pin (45mm, LJV525T)** through the Flat Cut Talar Trial and into the lateral pilot hole created in Step 7e. If there is impingement with the pin located in the medial hole, this may be changed to a **Self-Drilling Pin (45mm, LJV525T),** as well.

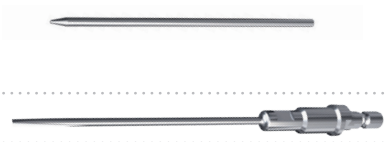
9. Continue to Standard Instrumentation

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.

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
MJU928T	Smith+Nephew XT, Joint Distractor, Right
MJU929T	Smith+Nephew XT, Joint Distractor, Left

Bone-Prep Instruments

Catalog Number	Description
MJU357T	SALTO TALARIS Osteotome Thin

Flat Cut Talar Trials

Catalog Number	Description
MJV940T	SALTO TALARIS, Talar Trial, Flat Cut, Size 0, Rt
MJU941T	SALTO TALARIS, Talar Trial, Flat Cut, Size 1, Rt
MJU942T	SALTO TALARIS, Talar Trial, Flat Cut, Size 2, Rt
MJU943T	SALTO TALARIS, Talar Trial, Flat Cut, Size 3, Rt
MJV950T	SALTO TALARIS, Talar Trial, Flat Cut, Size 0, Left
MJU951T	SALTO TALARIS, Talar Trial, Flat Cut, Size 1, Left
MJU952T	SALTO TALARIS, Talar Trial, Flat Cut, Size 2, Left
MJU953T	SALTO TALARIS, Talar Trial, Flat Cut, Size 3, Left

Patient Matched Guides

Catalog Number	Description
LJV531T	SALTO TALARIS Flat 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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