Smith-Nephew

CADENCE

Total Ankle Replacement System

TOTAL ANKLE

Patient-Matched Guides

Chamfer Cut Surgical Technique



CADENCE[®] Total Ankle System with TOTAL ANKLE Patient-Matched Guides

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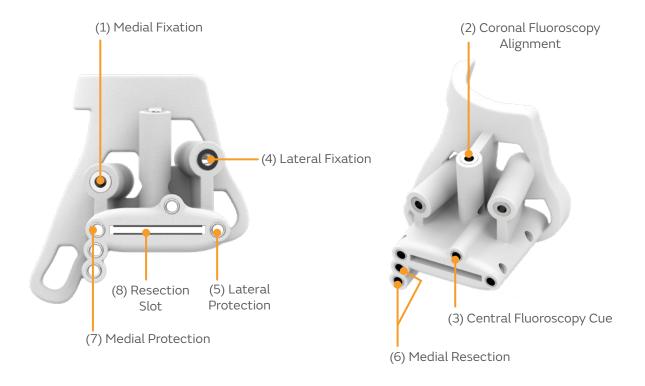
Consult the Preoperative Surgical Report for any specific information relative to the case.

Note Bena

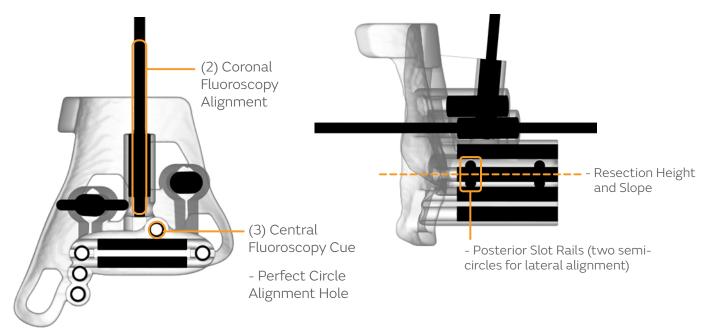
The following technique is for informational and educational purposes only. It is not intended to serve as medical advice. It is the responsibility of treating physicians to determine and utilize the appropriate products and techniques according to their own clinical judgment for each of their patients. For more information on the products, including indications for use, contraindications, and product safety information, please refer to the products' label and the Instructions for Use packaged with the products.

Patient-Matched Guide overview

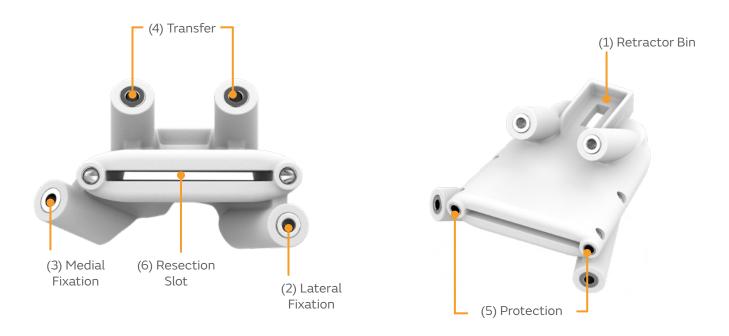
Tibial guide:



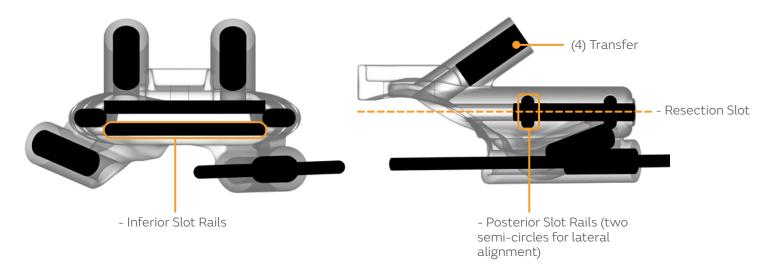
Fluoroscopic view:



Talar guide:



Fluoroscopic view:





Anterior approach

Surgical Technique

1. Identification

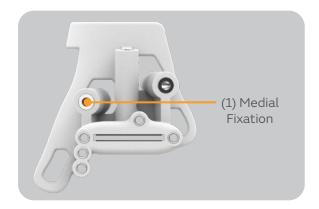
- a. The patient-matched tibial guide, patient-matched talar guide, and anatomic models are labeled with patient information. This label includes "S+N CAD" to indicate compatibility with Smith+Nephew CADENCE Total Ankle Replacement System, Patient ID, and Work Order Number.
- b. Check that the labels on the guides and anatomic models are legible and match the patient and information found in the preoperative case report.
- c. Do not use the guides if the labels do not match.

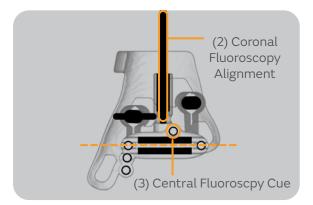
2. Surgical approach

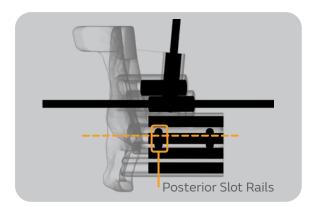
- a. An anterior longitudinal incision is made extending across the midline of the ankle joint to the dorsal medial border of the midfoot.
- b. Medial dissection is taken to the medial gutter so that the medial malleolus and the deltoid ligament can be visualized. Laterally, the dissection is taken so 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 tibial guide.
- c. Soft tissue removal is required on guide-contacting bony surfaces. See "heat map" image in the preoperative case report for guide contact area. Reference the guide contact profile on tibial 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.

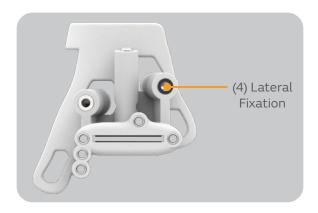


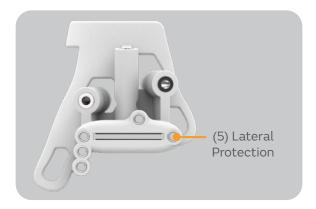


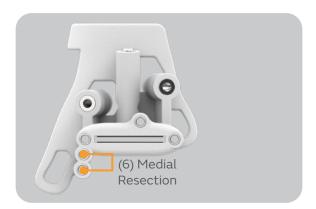


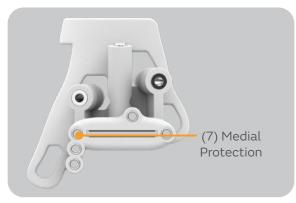
4. Tibial Guide - Alignment and Fixation

- a. With firm pressure down on the tibial guide to ensure it does not slip and maintains the alignment and contact with bony anatomy achieved in the previous step, place one Short Straight Bone Pin (10204026) through the Medial Fixation Hole (Tibial Guide: Feature 1).
- b. Perform visual and fluoroscopic assessment of the tibial guide to ensure proper placement has been maintained. Confirm via fluoroscopy that the position of the guide matches the intended location described in the preoperative case report.
 - i. **AP alignment:** Place a Straight Bone Pin Drill Tip (10204025) in the Coronal Fluoroscopy Alignment Hole (Tibial Guide: Feature 2) to assess AP alignment. A perfect circle should be obtained through the Central Fluoroscopy Cue (3). Medial/lateral position of the tibial resection may be assessed by referencing the Medial and Lateral Protection Holes (Tibial Guide: Features 5 & 7) 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. The resection height and sagittal slope may be assessed by the Medial and Lateral Protection Holes (Tibial Guide: Features 5 & 7) 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 surface has been further processed, repeat from Step 4a and 4b with the unused Lateral Fixation Hole (4). If further adjustment is needed, the Central Fluoroscopy Cue (3) can also be used for fixation.
- d. Once the proper guide position has been confirmed via fluoroscopy, place a Medium or Long Shouldered Bone Pin (10204027 or 10204023) through one of the remaining Fixation Holes. The Central Fluoroscopy Cue (Tibial Guide: Feature 3) can be used for fixation if needed. Minimum of two Fixation Pins must be placed prior to moving forward with the procedure. Confirm guide position before proceeding.
- e. Place one Short Straight Bone Pin (10204026) as a protection pin bicortically through the Lateral Protection Hole (Tibial Guide: Feature 5) on the lateral side of the resection slot.
- f. Optional: After placing the Lateral Protection Pin, perform visual and fluoroscopic assessment of the guide to ensure proper alignment.

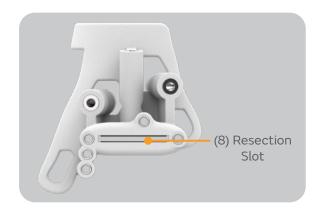
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Note: If alignment adjustments are needed, remove fixation and protection pins from the tibial guide and reassess the tibial guide fit beginning with Step 4a.

- g. If at any point during the fixation of the tibial guide, the guide itself becomes unfit for resection, revert to standard instrumentation Distal Tibial Alignment Block (10203001) and standard technique.
- h. To prepare the medial resection, drill bicortically through the Medial Resection Holes (6) using the Straight Bone Pin Drill Tip (10204025).

Note: It is recommended to drill through the Medial Resection Holes (Tibial Guide: Feature 6) from most distal to most proximal.

i. Place one Short Straight Bone Pin (10204026) as protection pin bicortically through the Medial Protection Hole (Tibial Guide: Feature 7) on the medial side of the resection slot.



5. Tibial Guide - Resection

- a. 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.
- b. Use a 1.27mm thick oscillating saw blade to carefully perform resection within the Resection Slot (Tibial Guide: Feature 8) through the posterior cortex of the tibia.

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

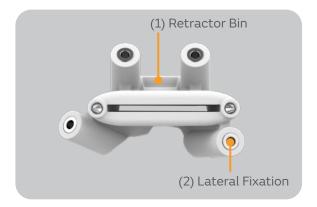
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Note: If the optional Central Fluoroscopy Cue (3) pin hole was used, it may be necessary to replace this pin with a Short Straight Bone Pin (10204026) or remove it entirely to avoid potential interference between this pin and the power system being used to drive the sawblade. Removal of this pin can only be done if both remaining fixation pins are placed.

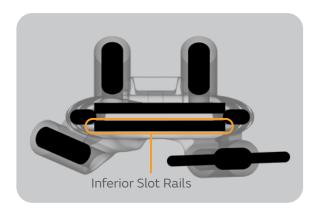
- c. After completing the resection, remove all pins and the tibial guide.
- d. Using general instruments, ensure the resection is extended laterally through the tubercle of Chaput. Ensure the lateral depth of resection reaches but does not violate the fibula.
- e. Complete the medial resection of the tibia by cutting the bone remaining between the previously drilled holes with either the Corner Osteotome (10204079) or a reciprocating saw.
 - i. Do not lever medial-lateral with the corner osteotome, as levering medial-lateral increases risk of fracturing medial malleolus.
 - ii. Tip: Check etchings on the Corner Osteotome (10204079), which correspond to AP depth of implants, to ensure sufficient bone is resected and avoid over-insertion.
 - iii. The Slap Hammer (10203194) may be used to assist in extracting the Corner Osteotome (10204079), from bone.
- f. Use osteotomes, rongeurs, or other instrumentation to remove the resected tibial bone.
- g. Remove any generated debris with lavage.

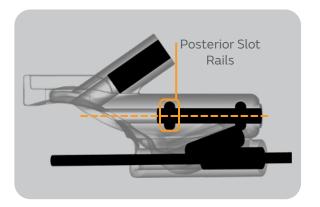
6. Talus Guide – Fit Check

- a. Place the talar guide over the anterior aspect of the anterior talus. Any cartilage remaining on the anterior or superior talus should be removed to ensure proper talar guide fit.
- b. The guide should contour to the anatomy of the anterior talus. The talar anatomic model provided can be used to check the intended fit with the talar guide.
- c. Soft tissue removal is required on guide-contacting bony surfaces. See "heat map" image in the preoperative case report for guide contact area. Reference the guide contact profile on talar 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 anatomy with no gaps along its perimeter nor through the rectangular window 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.



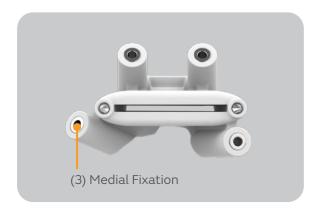


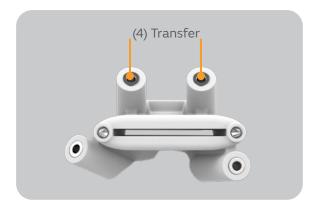


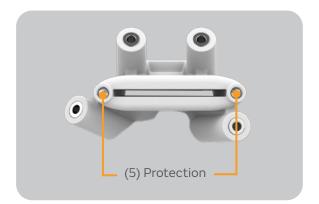


7. Talus Guide – Alignment and Fixation

- 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 Short Straight Bone Pin (10204026) through the Lateral Fixation Hole (Talar Guide: Feature 2).
 - i. Optional: Mate the narrow end of the Talar Sizer Holder (10203008) or Lamina Spreader (10203035) into the Retractor Bin (Talar Guide: Feature 1) on the talar guide and retract against tibial resection plane to aide in retention of talar 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 talar resection height in the AP view. Medial/lateral position of the talar resection may be assessed by referencing the Medial and Lateral Protection Holes (Talar 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 semicircles above and below the protection bushings when properly aligned. Resection height and sagittal slope may be assessed by the Medial and Lateral Protection Holes (Talar Guide: Feature 5) in a lateral view. A free sagittal saw blade may be placed through the guide to better visualize resection height.





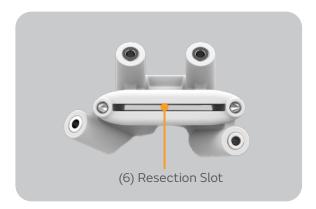


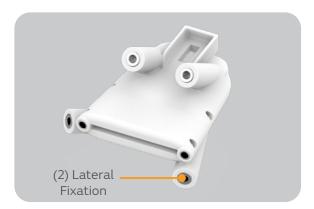
- c. Place a Medium or Long Shouldered Bone Pin (10204027 or 10204023) through the Medial Fixation Hole (Talar Guide: Feature 3).
- d. Use a Straight Bone Pin Drill Tip (10204025) to drill pilot holes through both Medial and Lateral Transfer Holes (Talar Guide: Feature 4) to be used in later Step 8e for Transfer Pin placement following resection.
- e. Place a Short Straight Bone Pin (10204026) or a Straight Bone Pin Drill Tip (10204025) bicortically through the Medial and Lateral Protection Holes (Talar 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 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 Distal Tibial Alignment Block (10203001), Talar Cut Guide (10203031-10203032), and standard technique for talar resection.





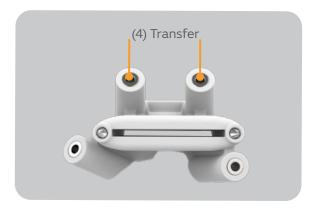
8. Talar Guide - Resection

a. Use a 1.27mm thick oscillating saw blade to carefully perform resection within the Resection Slot (Talar 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 (Talar Guide: Feature 5) and Medial Fixation Pin (Talar Guide: Feature 3). Slide the talar guide out of joint space leaving the Lateral Fixation Pin (Talar Guide: Feature 2) in place.
- c. Use osteotomes, rongeurs, or other surgical instruments to remove all resected talar bone. Use caution around the malleoli.

Note: Ensure the talar 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 Sizer will not function as intended.





- d. Place one Short Straight Bone Pin (10204026) and one Straight Bone Pin Drill Tip (1020425) in the pilot holes created in Step 7e. If the holes are challenging to locate, the talar guide can be replaced on the bony anatomy by sliding over the remaining Lateral Fixation Pin to aide in the placement of Transfer Pins through the Transfer Holes (Talar Guide: Feature 4).
- e. Remove the Lateral Fixation Pin and guide, if used for Transfer Pin placement, from joint space, leaving Transfer Pins in place.
- f. Remove any generated debris using lavage.
- g. Slide the selected Talar Sizer (10204085-10204088) over the Transfer Pins and onto the resected surface of the talus. Engage the Talar Sizer Holder (10203008) into the selected Talar Sizer. Replace one Short Straight Bone Pin (10204026) with a one Short Shouldered Bone Pin (10204022) for additional fixation.

9. Continue to Standard Instrumentation

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

Catalog

Pins

Catalog Number	Description
10204025	Straight Bone Pin – Drill Tip
10204026	Short Straight Bone Pin
10204022	Shouldered Bone Pin – Short
10204027	Shouldered Bone Pin – Medium
10204023	Shouldered Bone Pin – Long

Retractors

Catalog Number	Description
10203008	Talar Sizer Holder
10203035	Lamina Spreader

Saw Blade

Catalog Number	Description
SAW6944T	Sagittal Blade 70 X 13mm, Stryker System 7
SAW6945T	Sagittal Blade 85 x 21mm, Stryker System 7
SAW6950T	Reciprocating Blade 70 x 12.5mm, Brasseler

Alignment Block

Catalog Number	Description
10203001	Distal Tibial Alignment Block

Talar Sizers

Catalog Number	Description
10204085 – 10204088	Talar Sizers

Bone-Prep Instruments

Catalog Number	Description
10204079	Corner Osteotome
10203194	Slap Hammer

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

Patient-Matched Guides

Catalog Number	Description
10204090	CADENCE [®] Chamfer Cut PSI
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Manufactured by:



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.