Paragon 28®

a ZIMMER BIOMET company

SURGICAL TECHNIQUE GUIDE

axIOLink™ PCFD Tether Implant System

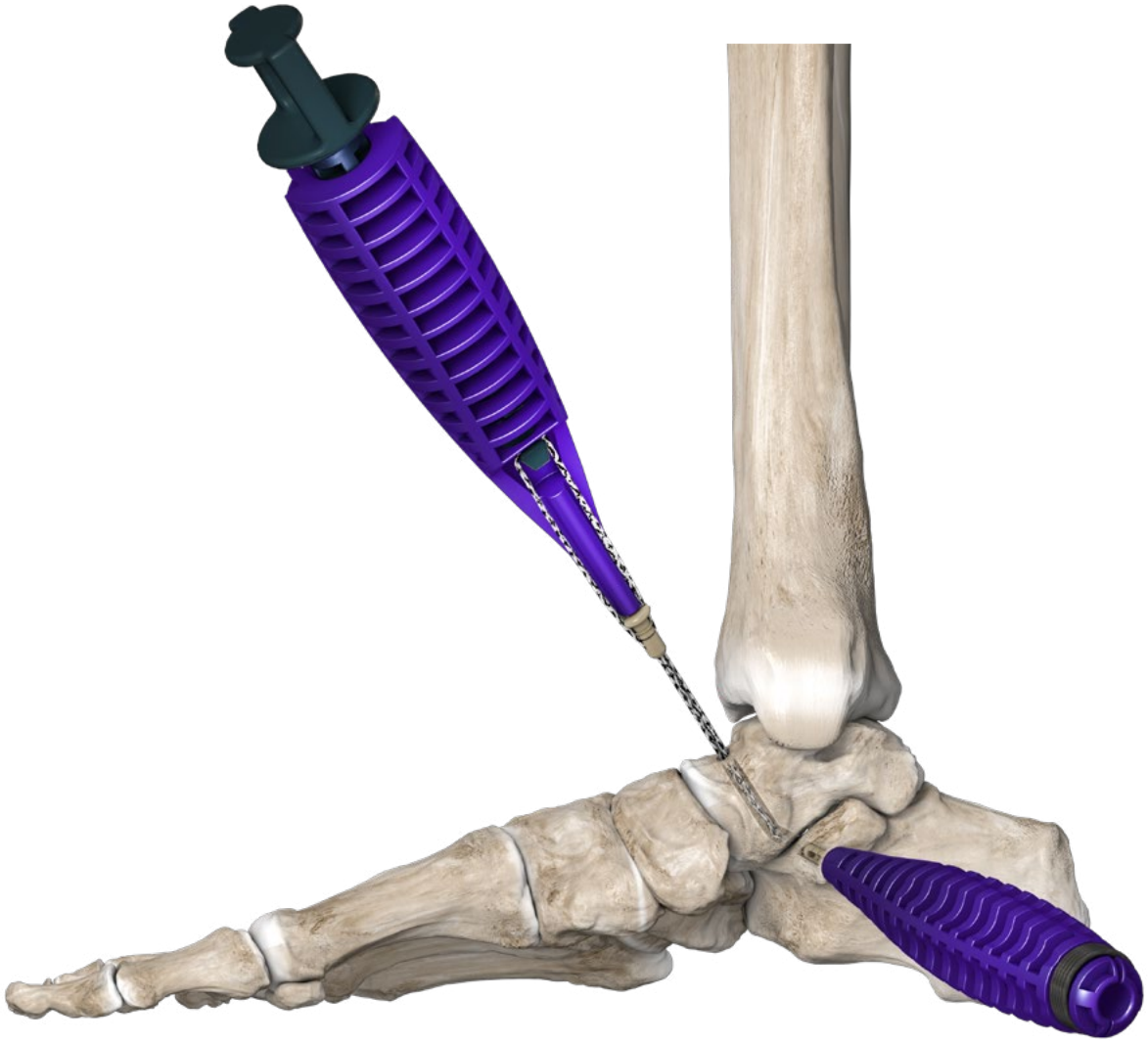


PRODUCT DESCRIPTION:

The Paragon 28® axIOLink™ PCFD Tether System is a soft tissue reconstruction system designed to address Progressive Collapsing Foot Deformity (PCFD) through anatomic restoration of the Interosseous Talocalcaneal Ligament (ITCL). Utilizing PEEK fixation anchors, UHMWPE surgical tape, and dedicated instrumentation, the system enables surgeons to restore subtalar joint stability, address peritalar subluxation, and support spring ligament and deltoid reconstruction as part of a comprehensive PCFD correction strategy. Designed to complement established bony reconstruction procedures, the axIOLink™ PCFD Tether System helps surgeons directly address the soft tissue drivers of deformity while minimizing surgical exposure and preserving future treatment options.

The axIOLink™ PCFD Tether System enables restoration of the talocalcaneal relationship through a targeted ligament reconstruction technique intended to reestablish the center of rotation of the subtalar joint while reducing peritalar subluxation. The system may also be utilized in conjunction with spring ligament and deltoid ligament repair procedures to address the multiplanar instability commonly encountered in flexible PCFD reconstruction.

The sterile implant offering consists of two PEEK fixation anchors preloaded with ultra-high molecular weight polyethylene (UHMWPE) surgical tape and associated disposable instrumentation. Included instrumentation consists of dedicated inserter handles, cannulated drills, eyelet K-wires, tissue protection components, and suture passing instruments designed to facilitate efficient implant placement while minimizing soft tissue disruption.

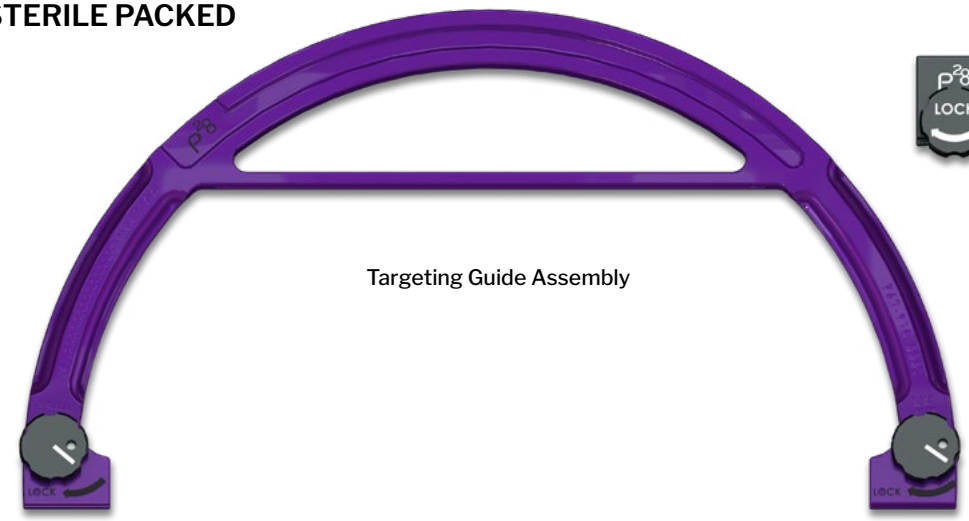


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FEATURED INSTRUMENTATION:

NON-STERILE PACKED



Talar Carriage Assembly

Targeting Guide Assembly



Sinus Tarsi Dilator



Talar K-Wire Sleeve



Calcaneal K-Wire Sleeve

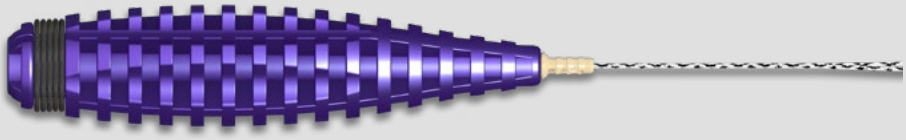


Suture Retriever

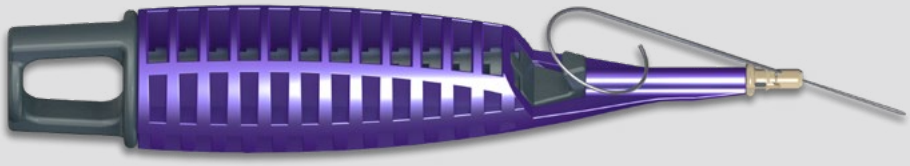


Ø1.60 X 200 mm Eyelet K-Wire
- **NOTE:** *included in both sterile and non-sterile kits*

STERILE PACKED

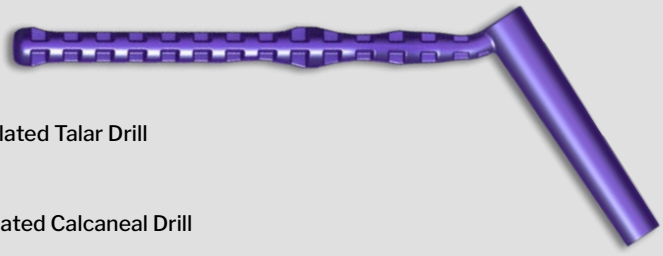


Calcaneal Inserter Handle
-Loaded with Ø3.5 mm PEEK Anchor Implant and 1.4 mm ApeTape with ZipLoop® Technology



Talar Inserter Handle
-Loaded with Suture Passer and Ø4.5 mm Talar PEEK Anchor Implant

Drill Guide





Ø4.7 mm Cannulated Talar Drill



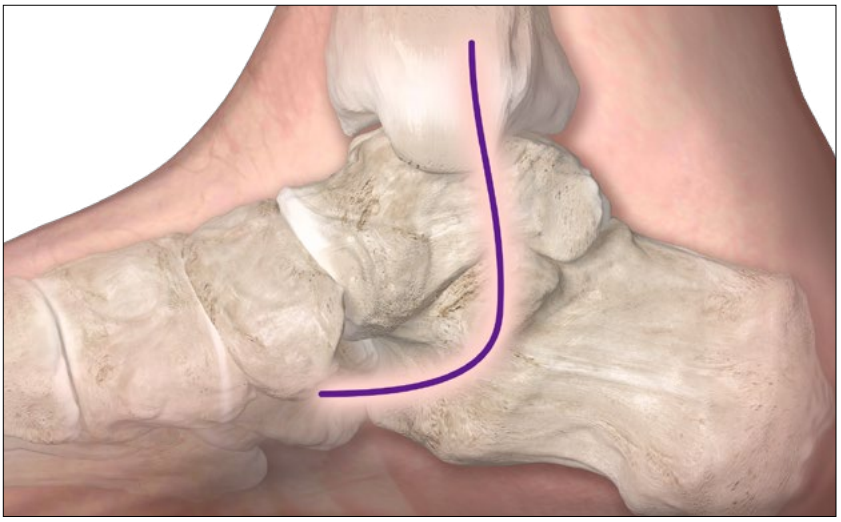
Ø3.5 mm Cannulated Calcaneal Drill



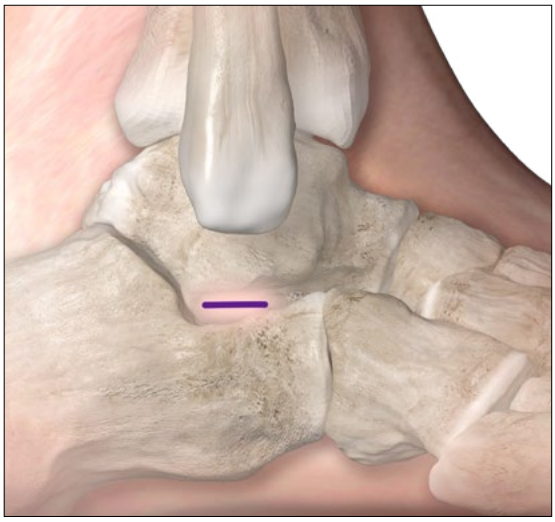
Ø1.60 X 200 mm Eyelet K-Wire
- **NOTE:** *included in both sterile and non-sterile kits*

INITIAL SURGICAL EXPOSURES:

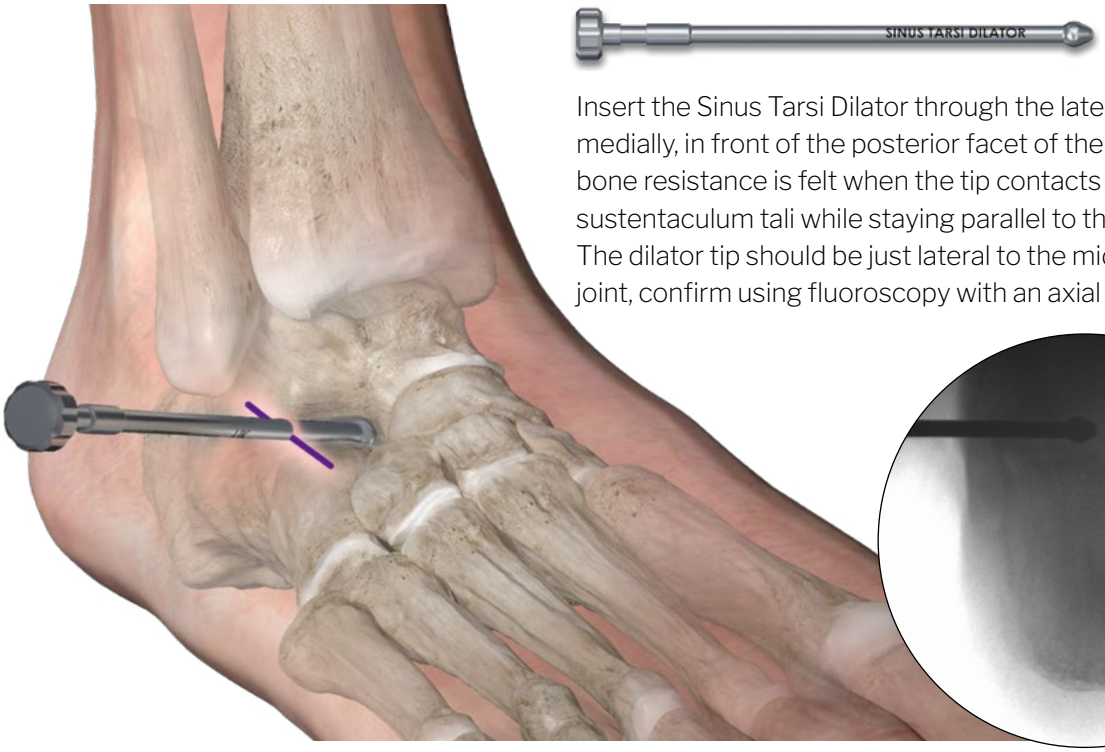
Patient should be positioned supine on the operating table, with the toes pointing up to allow easy access to the medial and lateral aspects of the foot and ankle.



Perform a "hockey-stick" like incision on the medial side of the foot along the course of the posterior tibial tendon (PTT) from the posterior aspect of the medial malleolus to the inferior aspect of the navicular tuberosity with the apex close to the palpable sustentaculum tali. Open the flexor retinaculum and the sheath of the PTT, reflect the PTT anteriorly exposing the spring ligament and the sustentaculum tali. Open the sheath of the FDL tendon and reflect it plantarly, avoiding damaging the neurovascular bundle.



On the lateral side of the foot, palpate the skin between the fibula tuberosity and the 4th metatarsal, approximately 2-3 mm proximal to the calcaneus Gissane angle, to locate the sinus tarsi. Perform a 4 mm stab incision at the soft spot of the sinus tarsi, then bluntly dissect until the sinus tarsi is accessible.



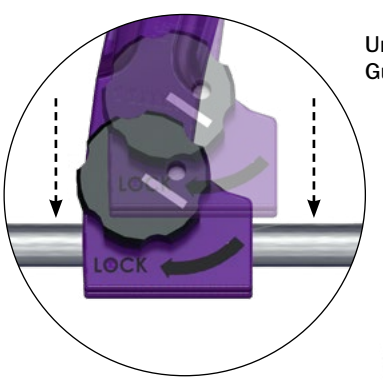
Sinus Tarsi Dilator

Insert the Sinus Tarsi Dilator through the lateral incision and push it medially, in front of the posterior facet of the subtalar joint. Push until bone resistance is felt when the tip contacts the lateral aspect of the sustentaculum tali while staying parallel to the plantar surface of the foot.. The dilator tip should be just lateral to the middle facet of the subtalar joint, confirm using fluoroscopy with an axial heel view.

Axial Heel View

TALAR TARGETING GUIDE PLACEMENT:

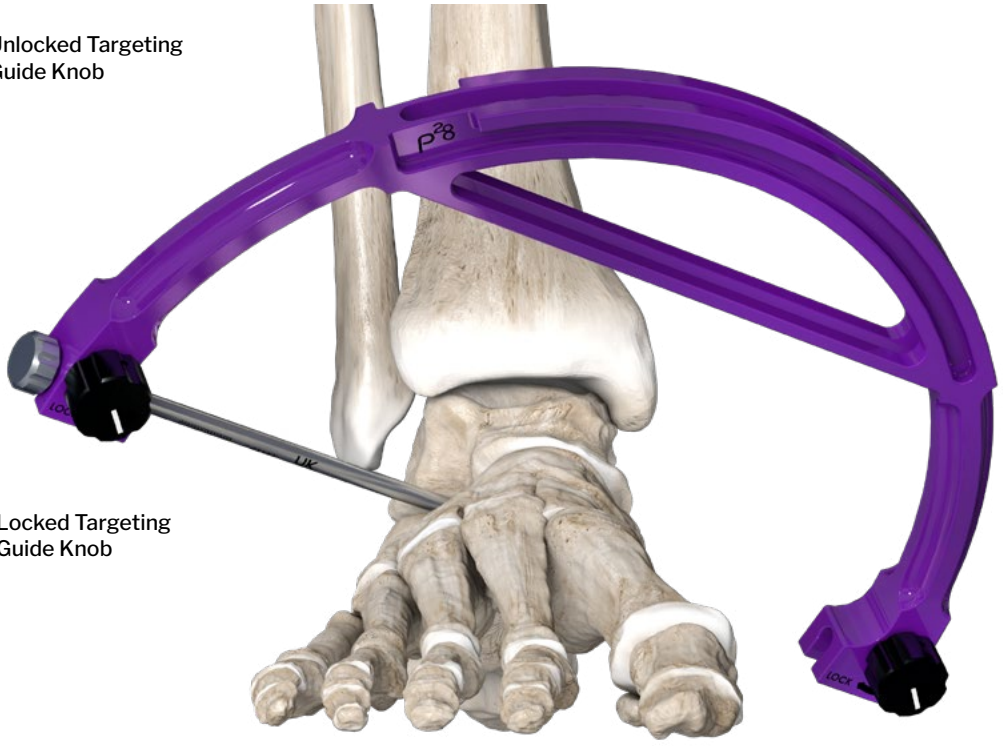
Place the one end of the Targeting Guide (ensuring all knobs are in the fully “unlocked” position) over the neck of the Sinus Tarsi Dilator while maintaining its positioning. Lock the attachment by sliding the Guide arm backward onto the grooved section of the Sleeve. Turn the knob on the Guide into the “locked’ position.



Unlocked Targeting Guide Knob



Locked Targeting Guide Knob

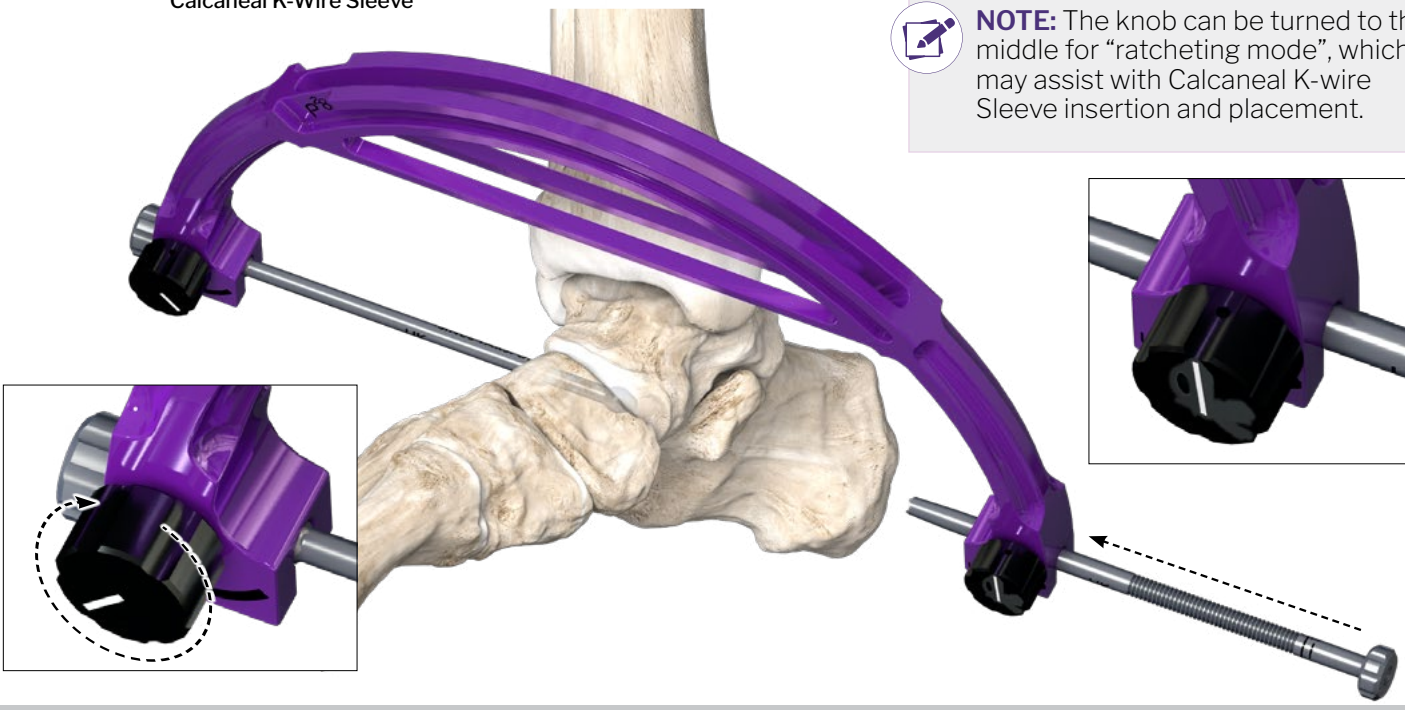




Calcaneal K-Wire Sleeve

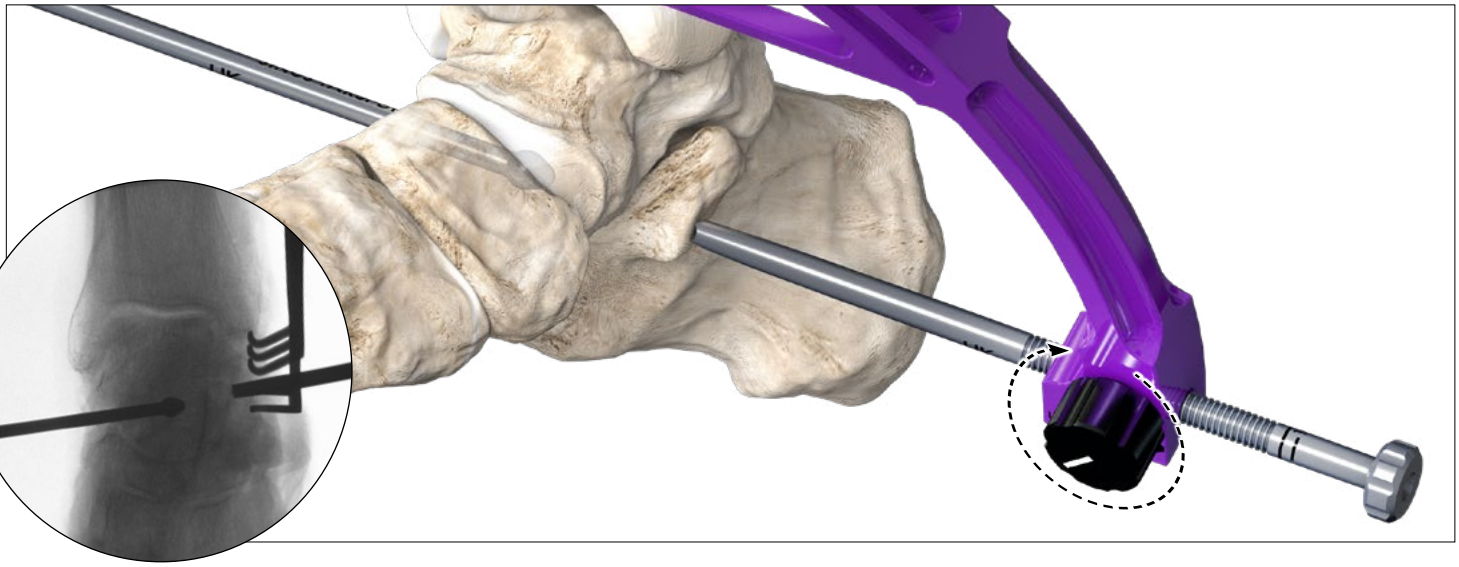
Insert the Calcaneal K-Wire Sleeve into the medial arm of the Targeting Guide.

NOTE: The knob can be turned to the middle for “ratcheting mode”, which may assist with Calcaneal K-wire Sleeve insertion and placement.



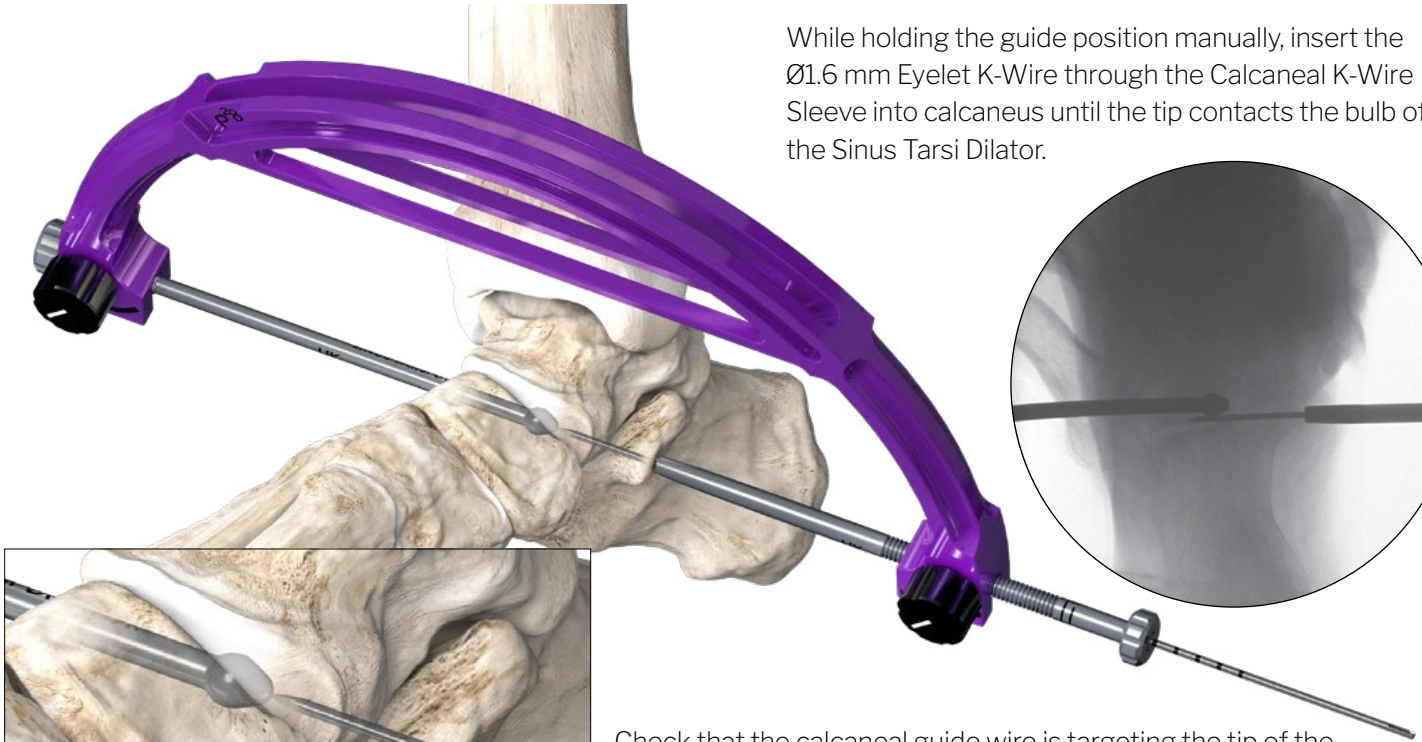
CALCANEAL K-WIRE PLACEMENT:

Slide the Calcaneal K-Wire Sleeve through the medial arm of the Targeting Guide and previously made incision up the plantar half of the sustentaculum tali, retracting PTT anteriorly and FDL posteriorly to assist positioning. Check positioning under fluoroscopy to ensure correct placement. Turn the knob on the guide arm to the "locked" position.



Ø1.60 X 200 mm Eyelet K-Wire

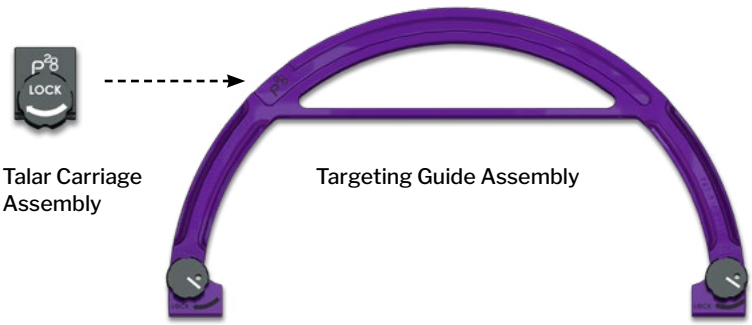
While holding the guide position manually, insert the Ø1.6 mm Eyelet K-Wire through the Calcaneal K-Wire Sleeve into calcaneus until the tip contacts the bulb of the Sinus Tarsi Dilator.



Check that the calcaneal guide wire is targeting the tip of the sinus tarsi dilator on fluoroscopy using AP and axial heel views. **It is acceptable if the wire has contacted and skived past the dilator bulb, so long as the trajectory is in-line with the dilator.** Ensure there is sufficient bone proximal and distal to the wire in the sustentaculum to accommodate a Ø3.5 mm drill.

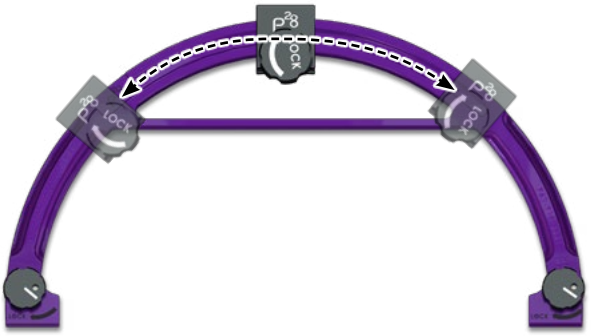
TALAR K-WIRE PLACEMENT:

Place the Talar Carriage Assembly onto the Targeting Guide Assembly using the notched section at either end.



Talar Carriage Assembly

Targeting Guide Assembly





With the Talar Carriage knob in the fully unlocked position, slide the Talar Carriage onto the Targeting Guide using the notched section at either end.

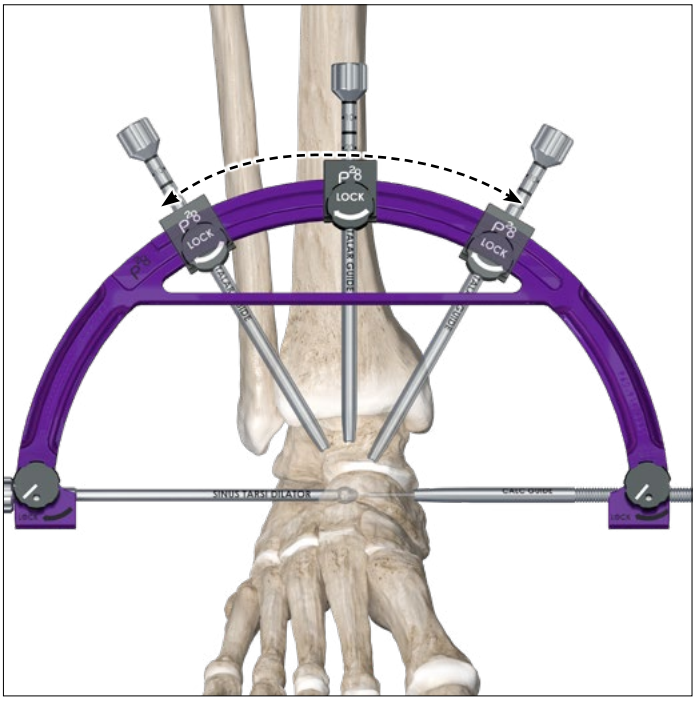


Talar K-Wire Sleeve

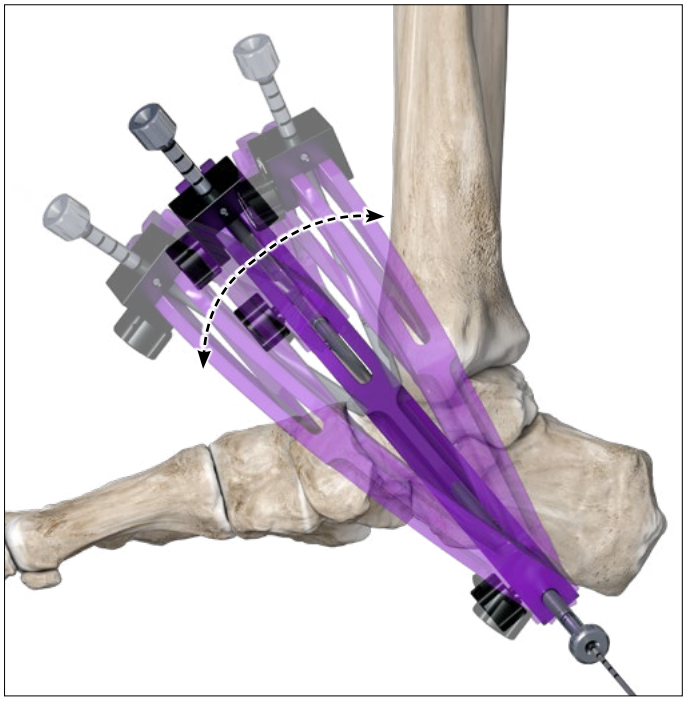
Place the Talar K-Wire Sleeve into the Talar Carriage of the Targeting Guide.



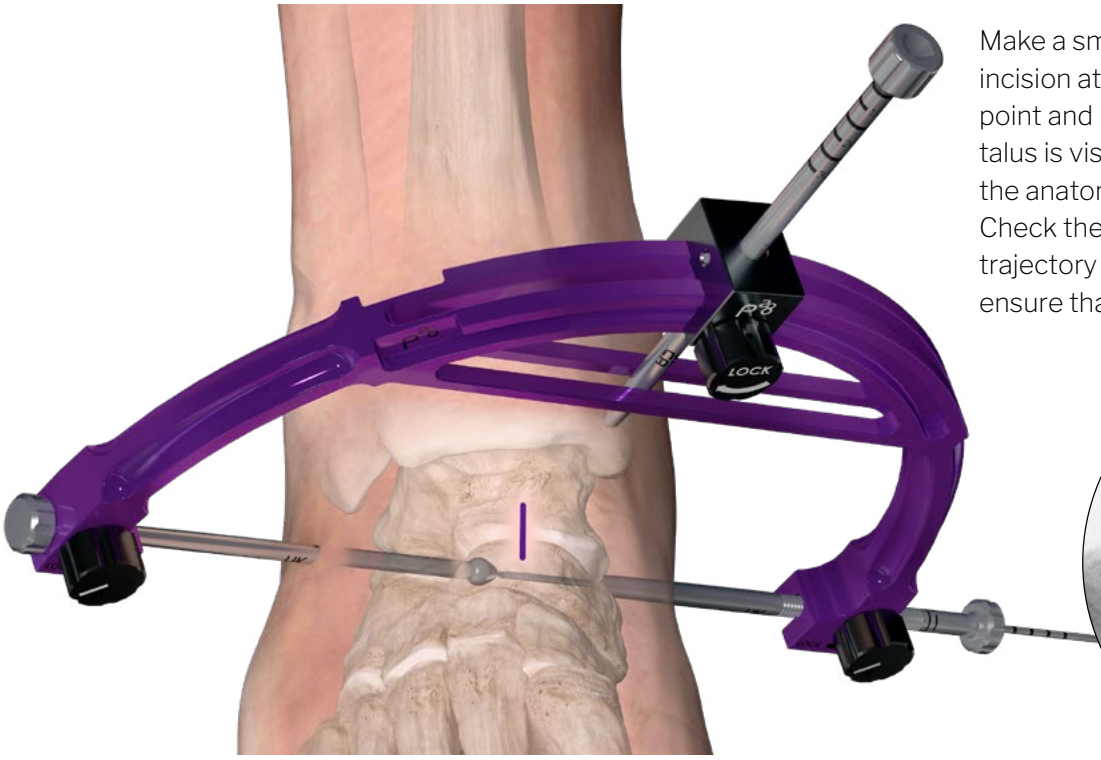
TALAR K-WIRE PLACEMENT:



Adjust the trajectory of the talar neck K-wire sleeve to be positioned in the central third of the talar neck in the sagittal plane, ensuring that k-wire will not violate the anterior aspect of the talar dome articular cartilage or the talonavicular joint.



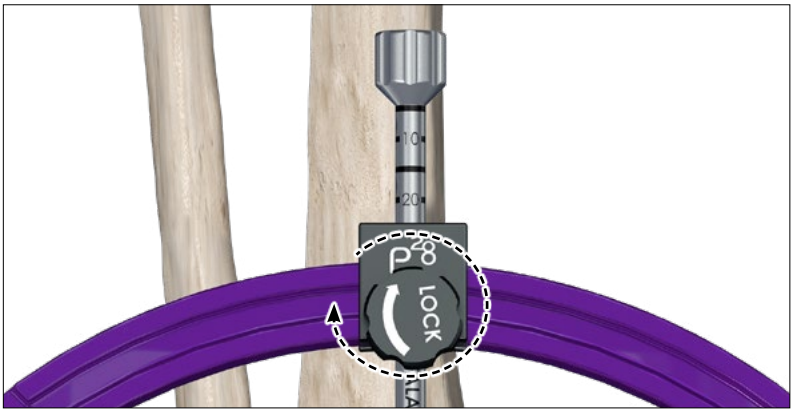
Pivot the guide in the coronal mediolateral plane so that the K-wire sleeve targets the mediolateral midpoint of the talar neck and sits just lateral of the anterior tibial tendon and medial to the EHL tendon.



Make a small 1.5 mm longitudinal incision at the K-Wire Sleeve contact point and bluntly dissect deep until the talus is visible. Insert the Sleeve into the anatomy until it contacts the talus. Check the positioning and insertion trajectory under lateral fluoroscopy to ensure that the joint space is avoided.



TALAR K-WIRE PLACEMENT:

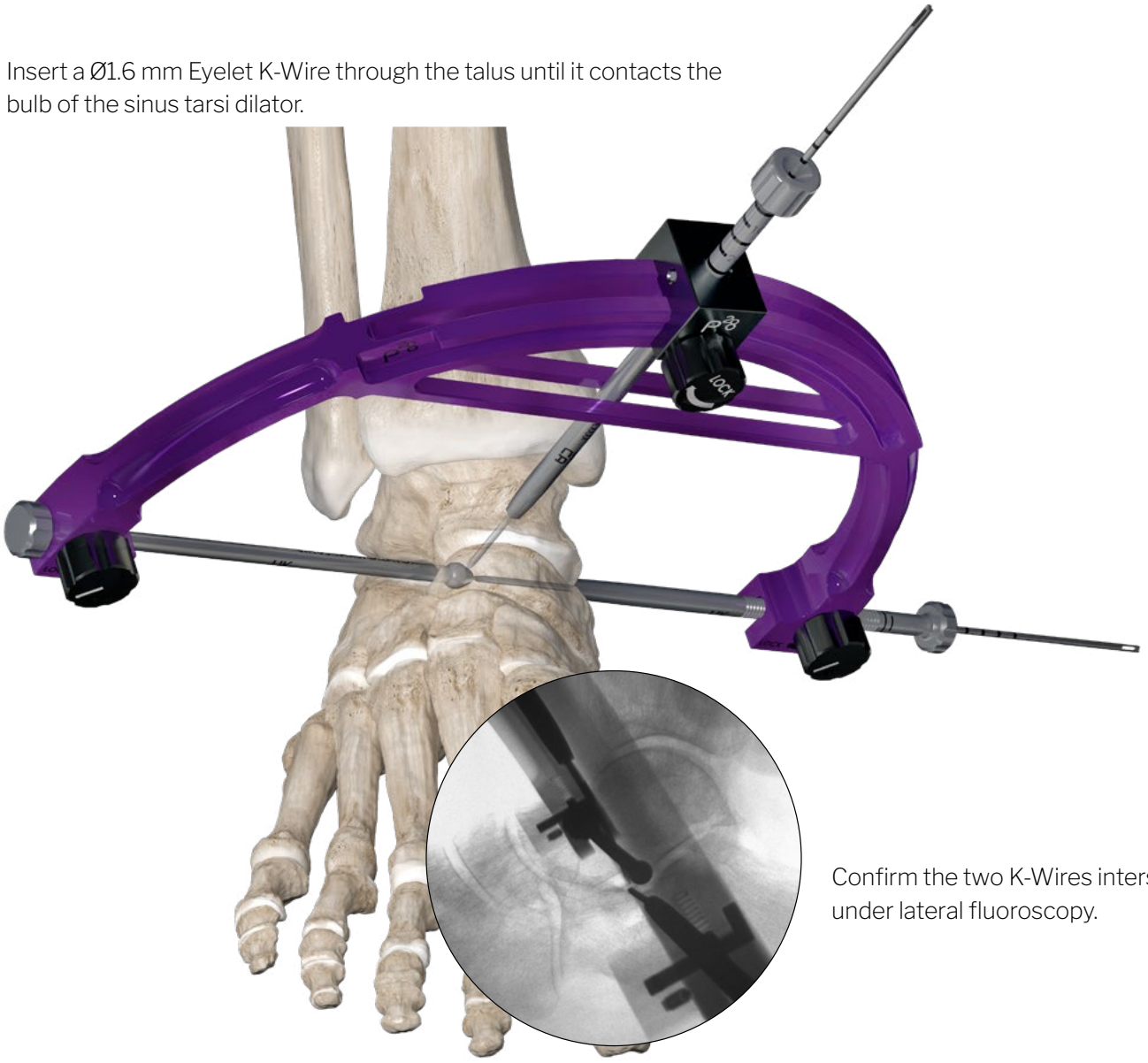


Once the trajectory is confirmed, turn the knob to the “locked” position.



Ø1.60 X 200 mm Eyelet K-Wire

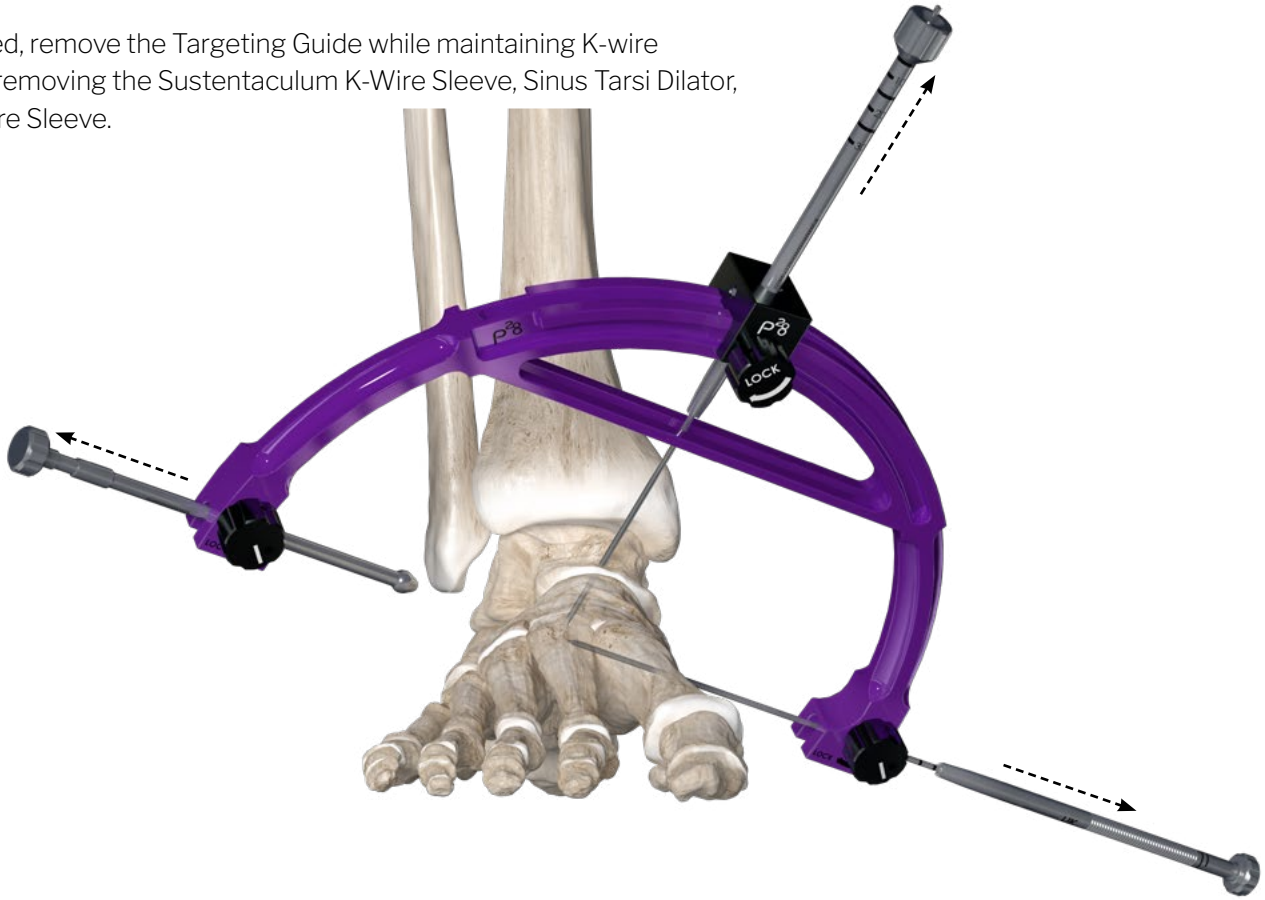
Insert a Ø1.6 mm Eyelet K-Wire through the talus until it contacts the bulb of the sinus tarsi dilator.



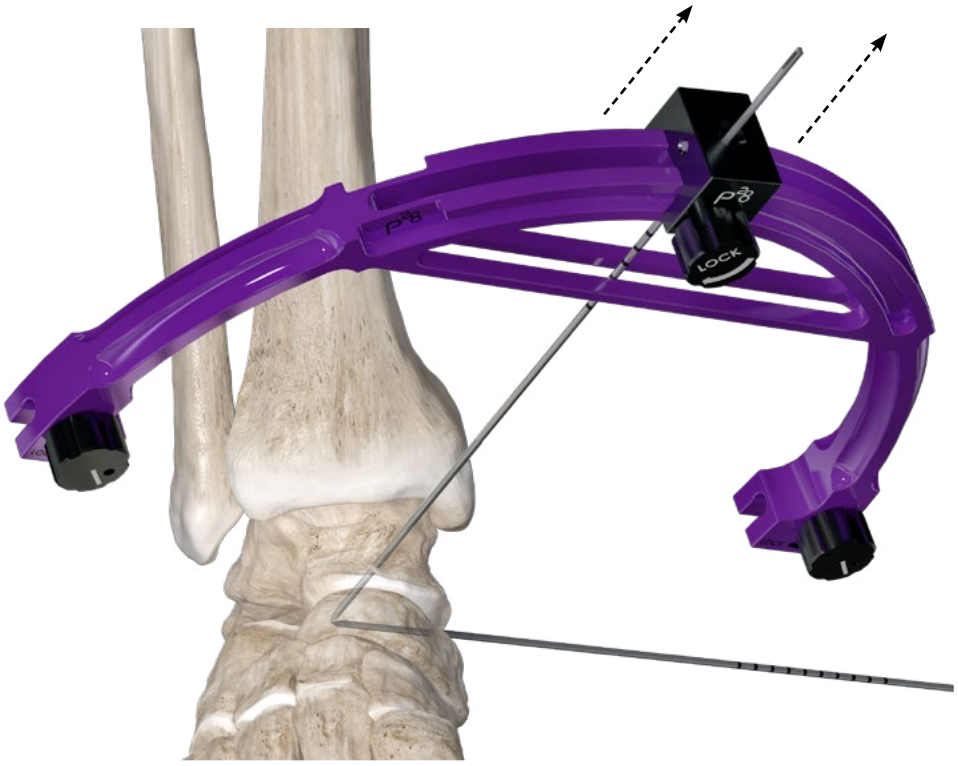
Confirm the two K-Wires intersect under lateral fluoroscopy.

TARGETING GUIDE REMOVAL:

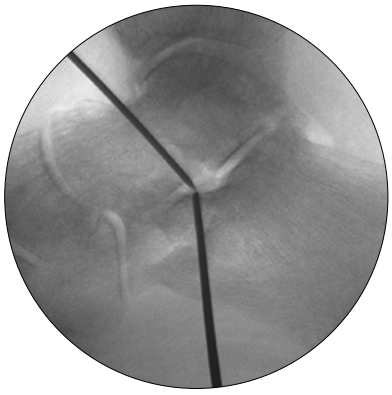
Once confirmed, remove the Targeting Guide while maintaining K-wire placement by removing the Sustentaculum K-Wire Sleeve, Sinus Tarsi Dilator, and Talar K-Wire Sleeve.



Remove the Targeting Guide leaving the K-Wires in place.







USING ALLOGRAFT AND GRAPPLER INTERFERENCE SCREW SYSTEM:

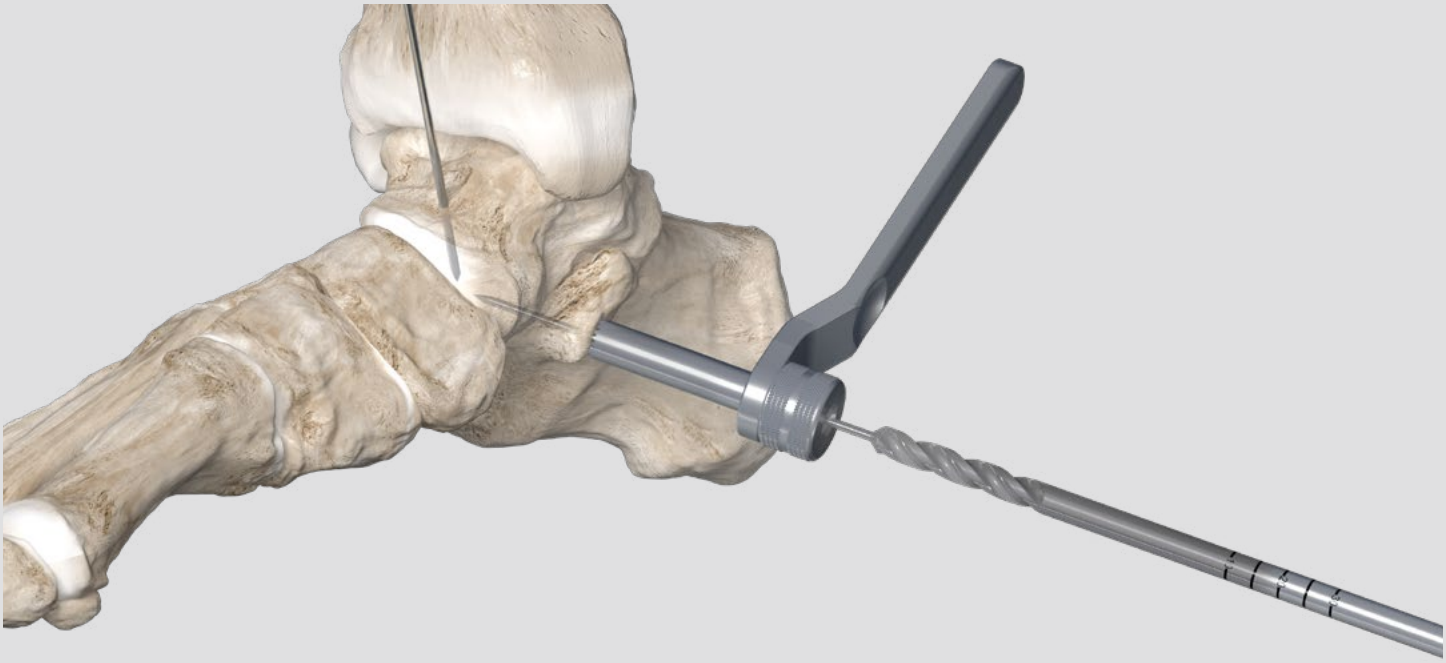


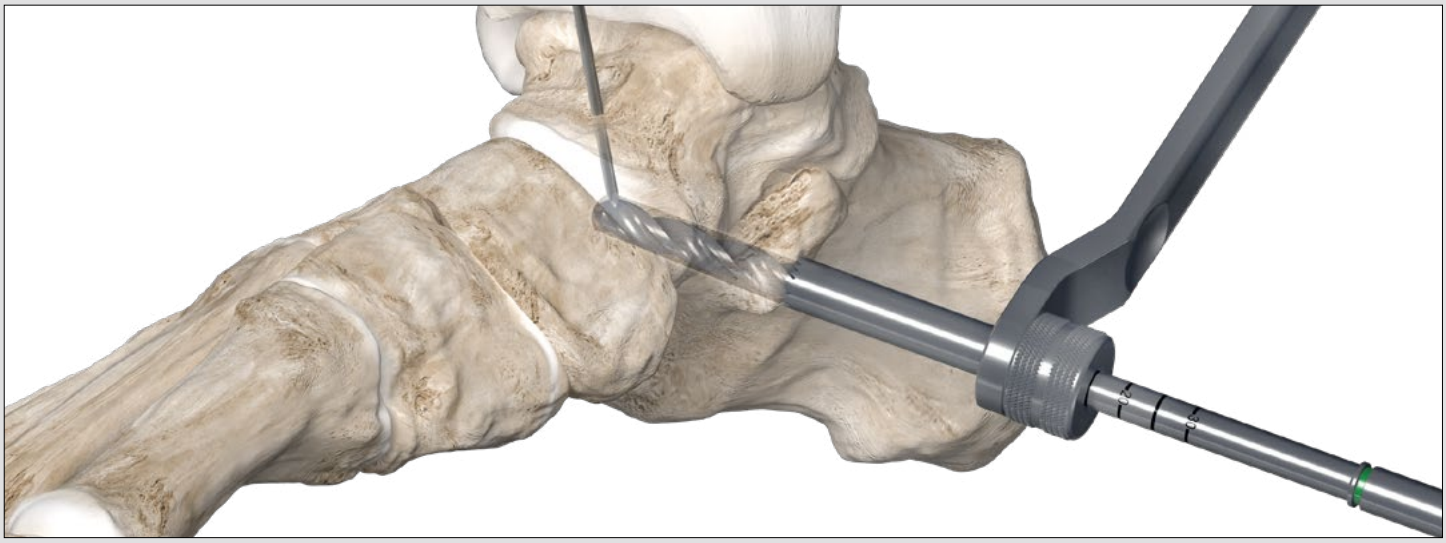
Ø5.0 Cannulated Drills
From Grappler® Interference Screw Caddy



Tissue Protector/Driver Sleeve Handle and Insert
From Grappler® Interference Screw Caddy

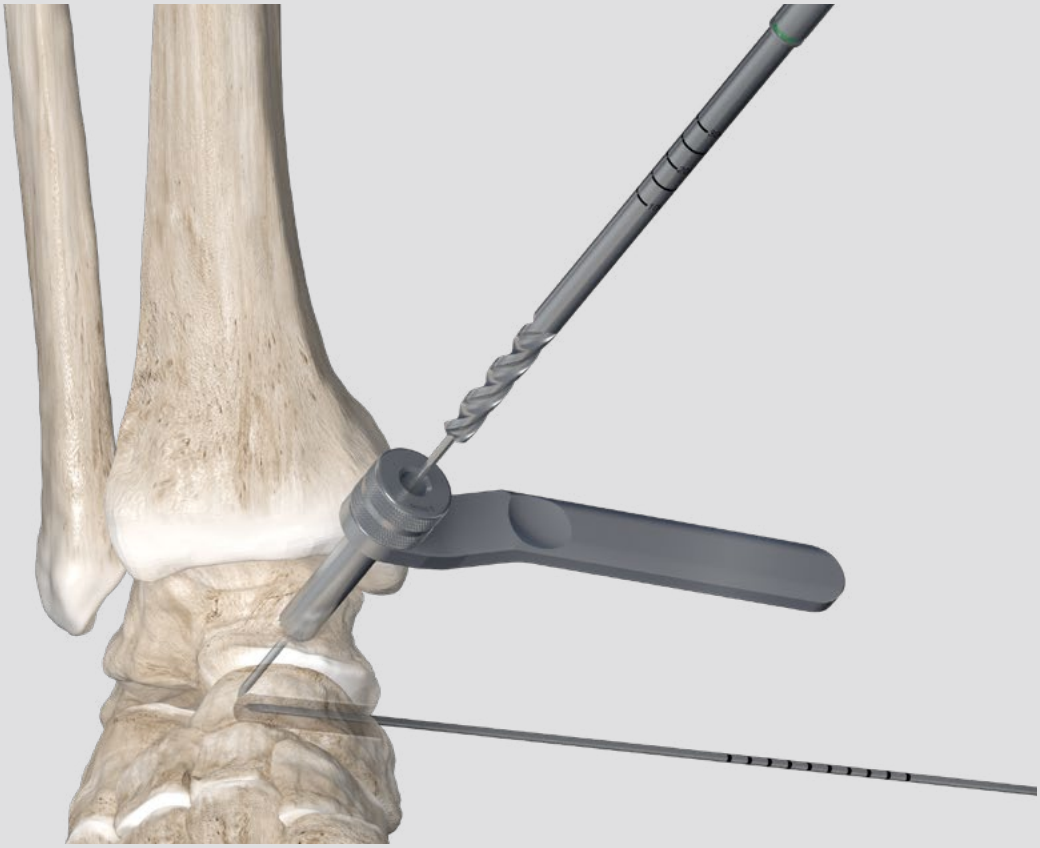
Measure the allograft to determine the drill size. Following the Grappler Interference Screw Surgical Technique Guide (P41-STG-0001), place an appropriately sized, assembled tissue protector over the calcaneal K-wire, then drill a tunnel into the sustentaculum using the matching sized drill until it contacts the talar K-wire. Remove the tissue protector and drill, leaving the calcaneal K-wire in place.

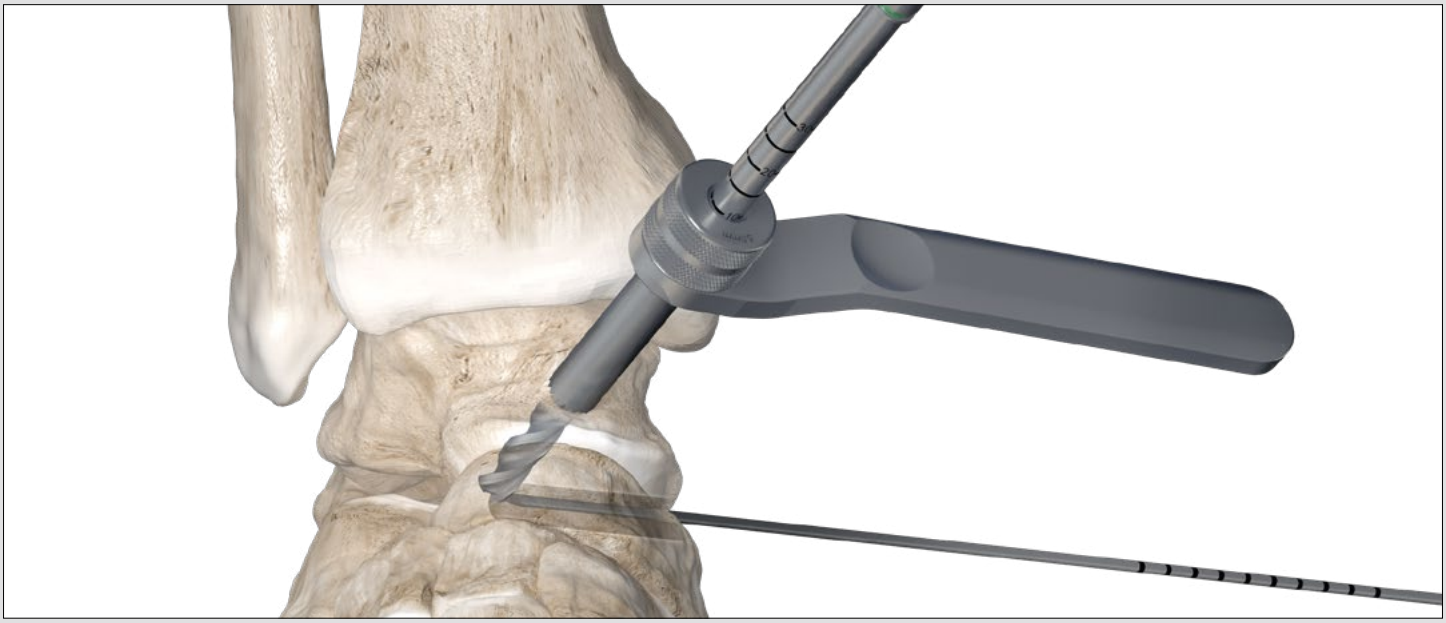




USING ALLOGRAFT AND GRAPPLER INTERFERENCE SCREW SYSTEM:

Utilize the same cannulated drill and matching assembled tissue protector for the talar K-wire, drill a tunnel in the talus through the tissue protector. If the trajectory is correct, the drill should intersect with the calcaneal K-Wire. Ensure the drill is fully through the Remove the Talar K-Wire and tissue protector.





USING axIOLink™ PCFD TETHER SYSTEM IMPLANT:

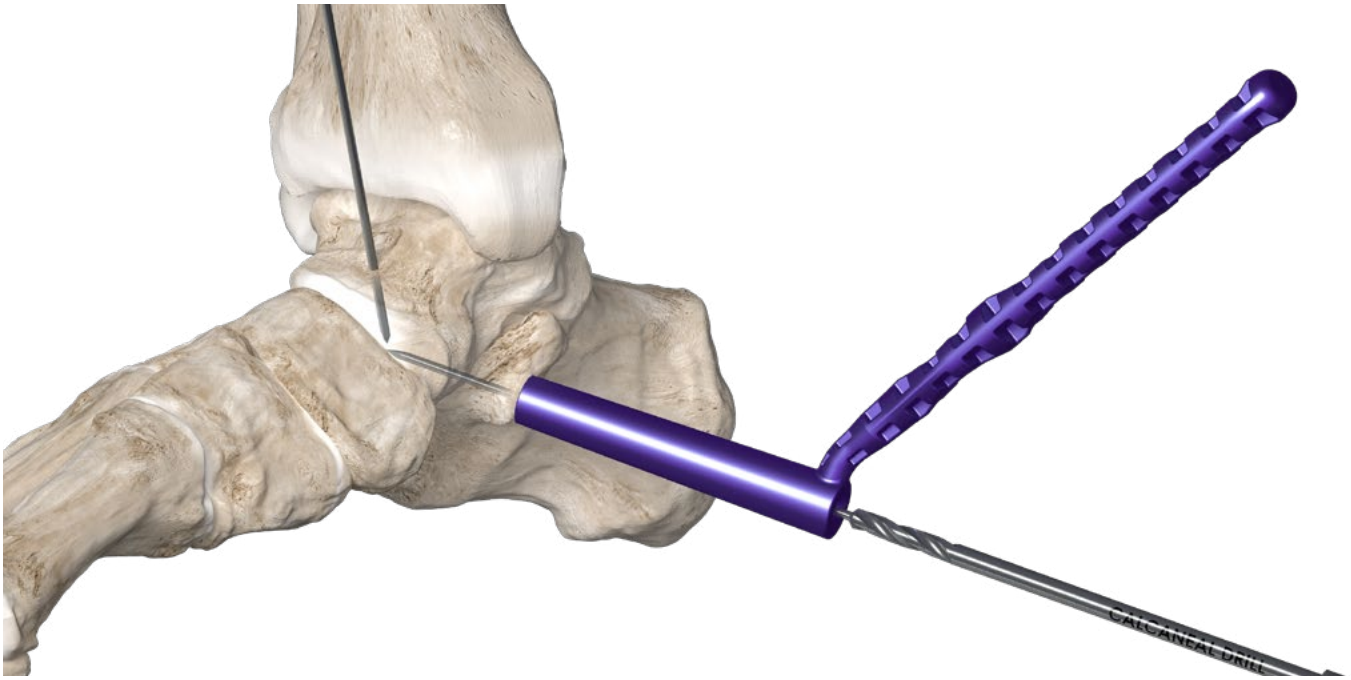


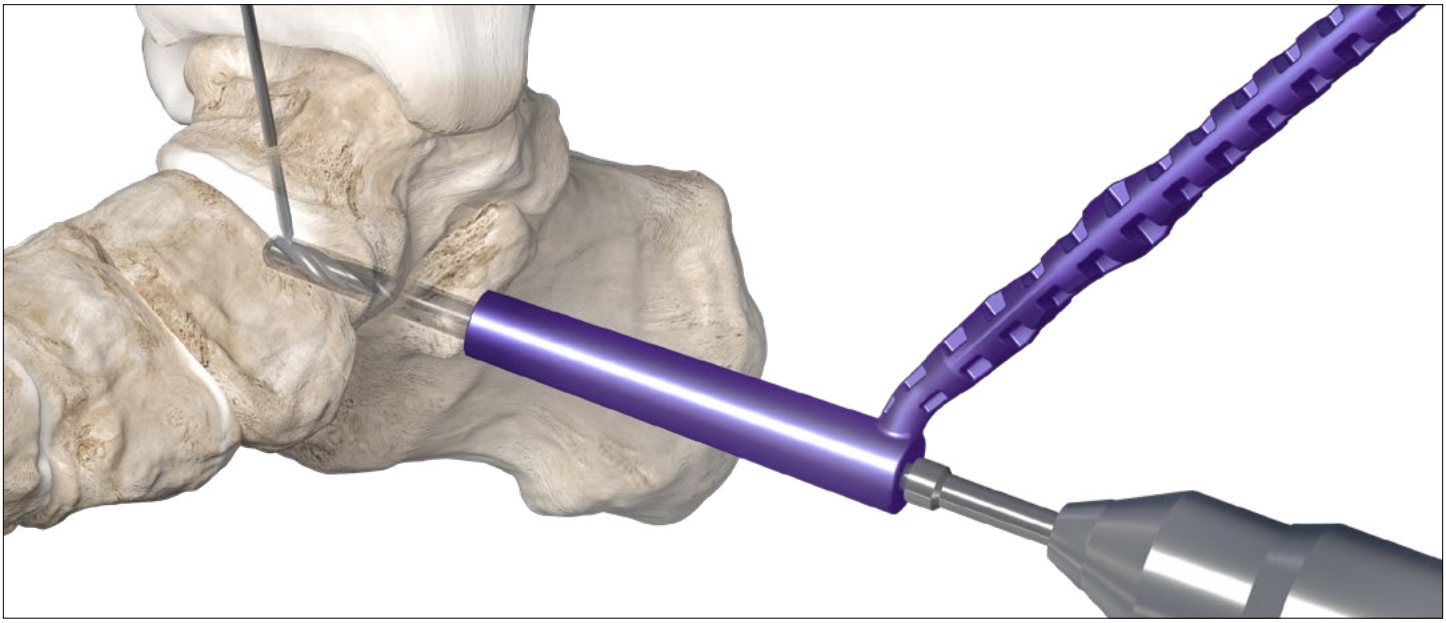
Ø5.0 mm Cannulated Drill



Drill Guide

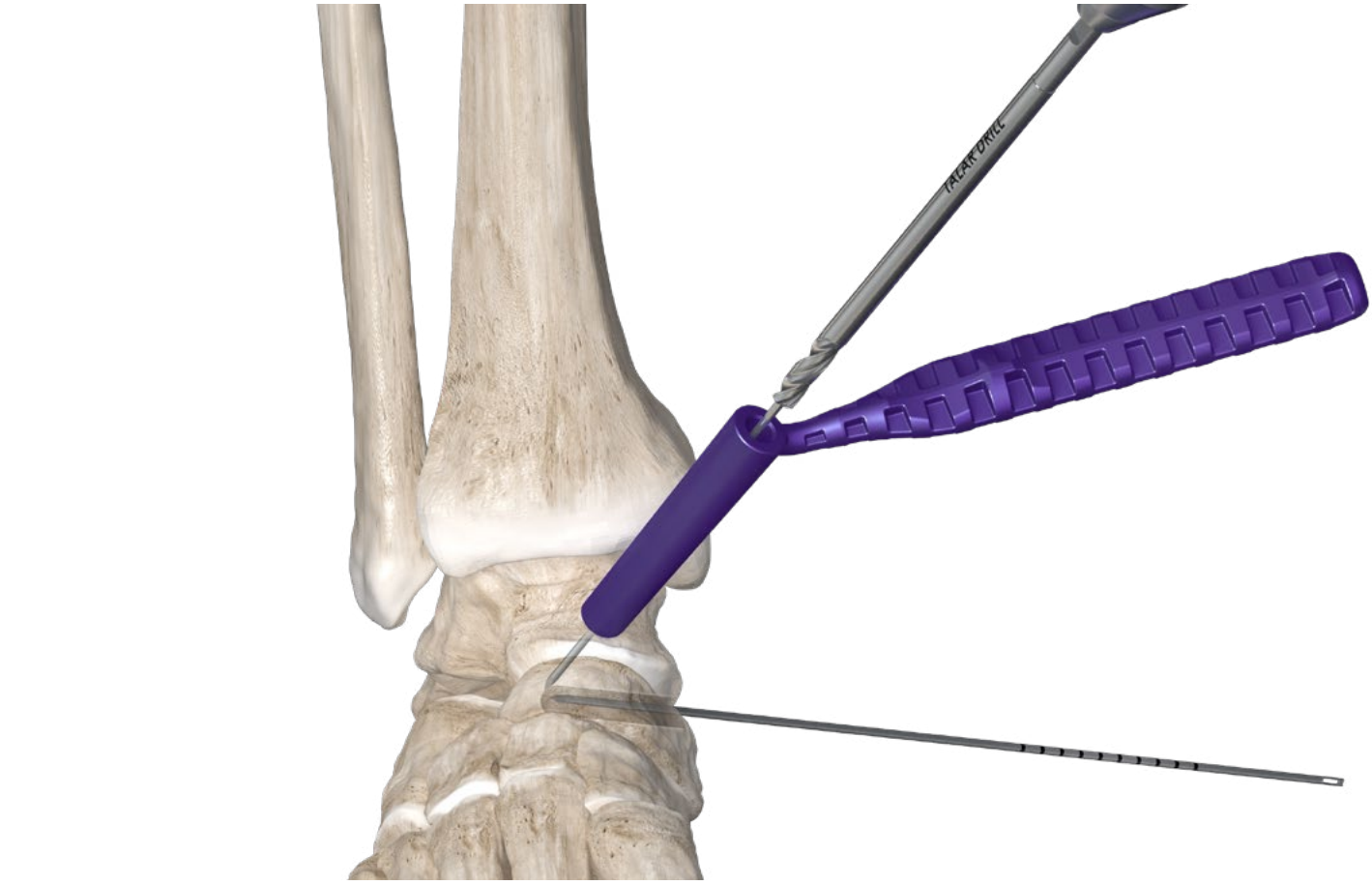
Slide the provided Drill Guide over the calcaneal K-wire, then drill over the wire using the Ø3.5 mm Calcaneal Drill until it contacts the talar K-wire. Remove the Drill Guide and drill, leaving the calcaneal K-wire in place.

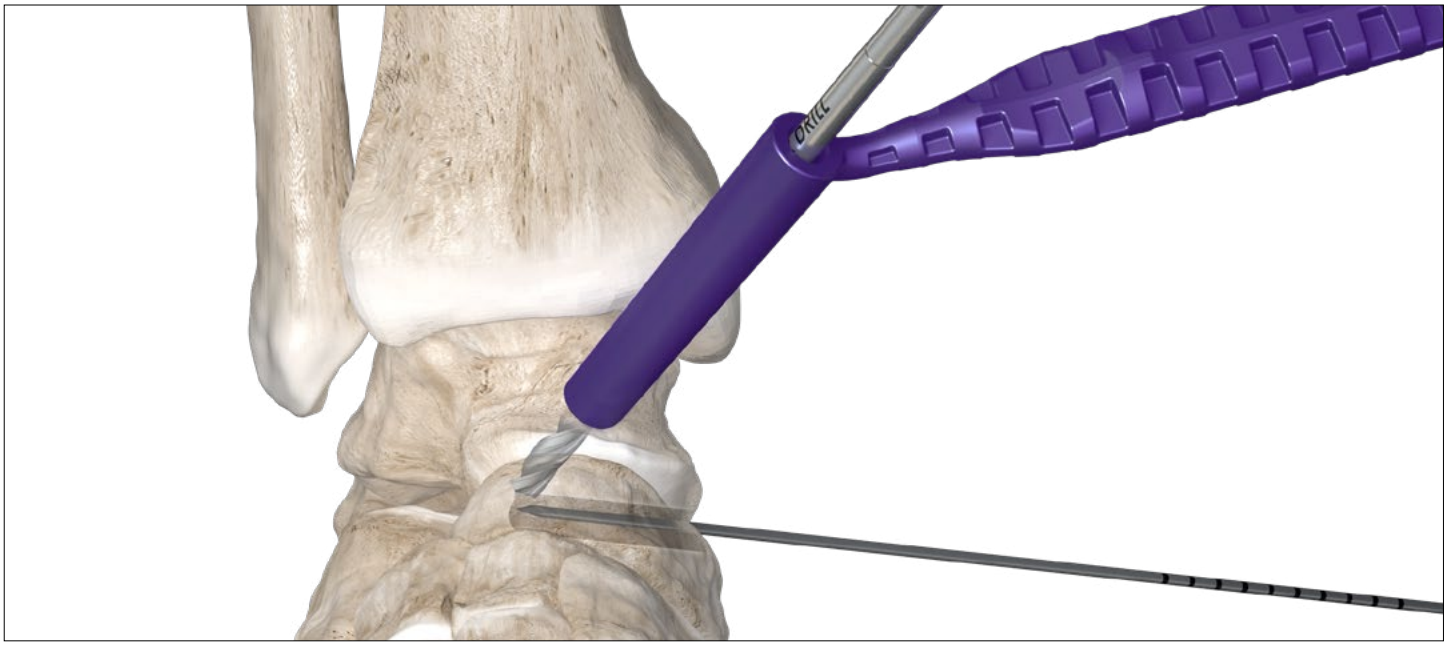




USING axIOLink™ PCFD TETHER SYSTEM IMPLANT:

Place Drill Guide over the talar K-Wire. Using the Ø4.7 mm Talus Drill, drill a tunnel in the talus. If the trajectory is correct, the drill should intersect with the calcaneal K-Wire. Remove the Talar K-Wire and Drill Guide.





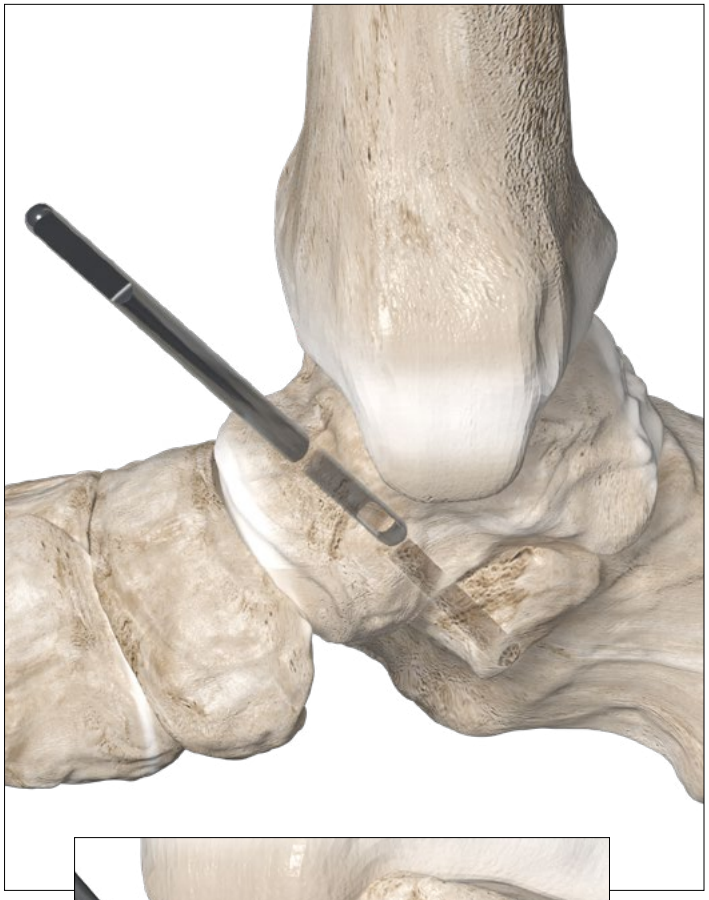
SUTURE RETRIEVER PLACEMENT:

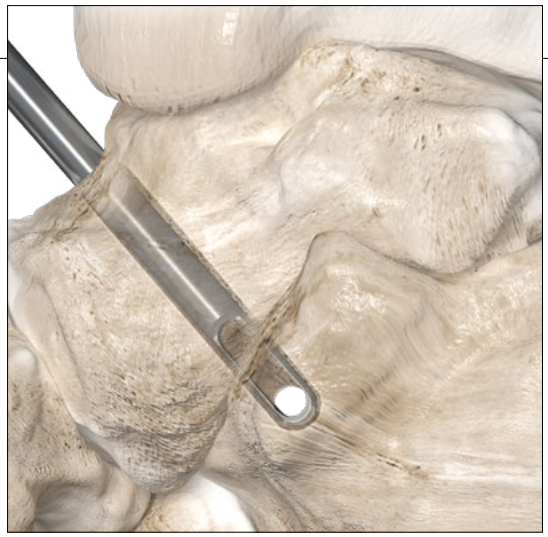


Suture Retriever

Partially or completely remove the calcaneal K-Wire, marking the medial insertion point for ease of reinsertion if needed. Place the eyelet end of the Suture Retriever into the talus, entering the subtalar joint space. The flat end of the retrieve indicates the direction of the eyelet.





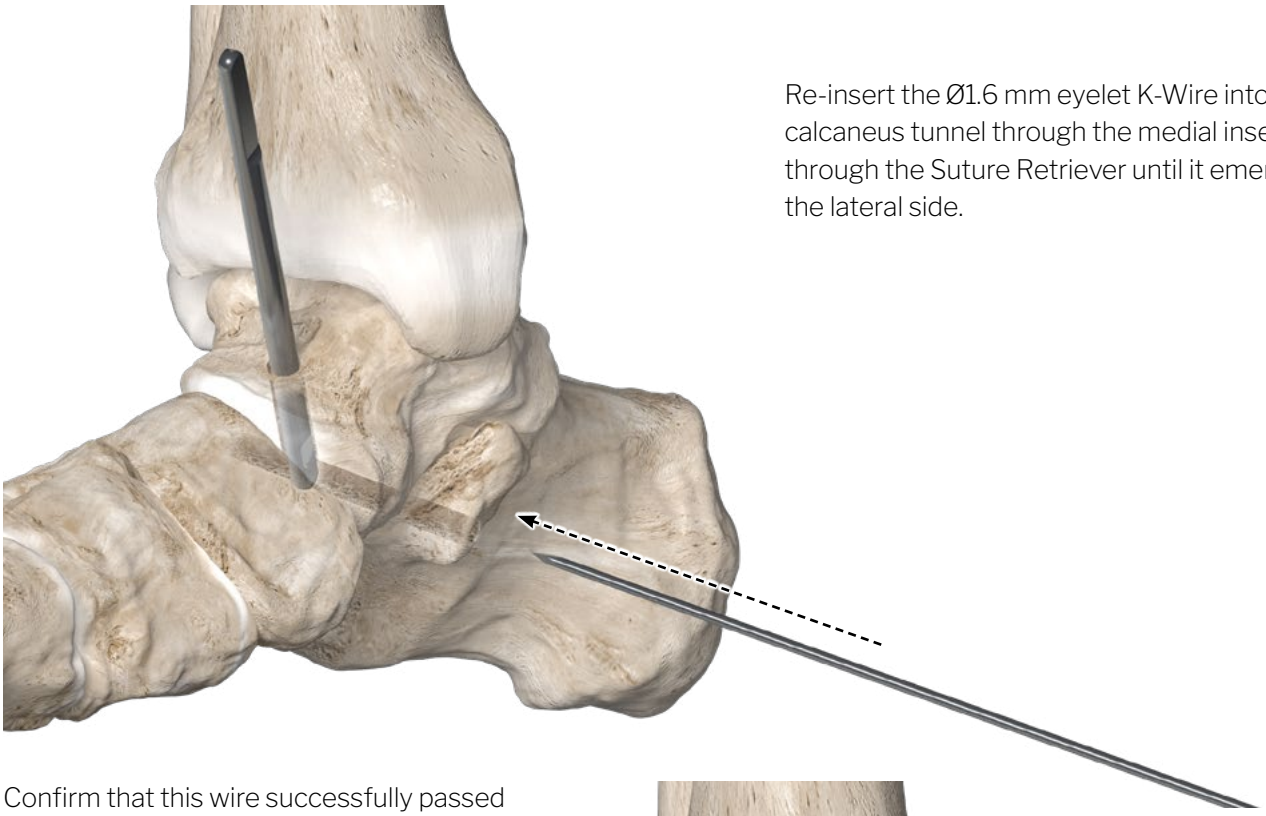


Eyelet hole within drilled bone

SUTURE RETRIEVAL:

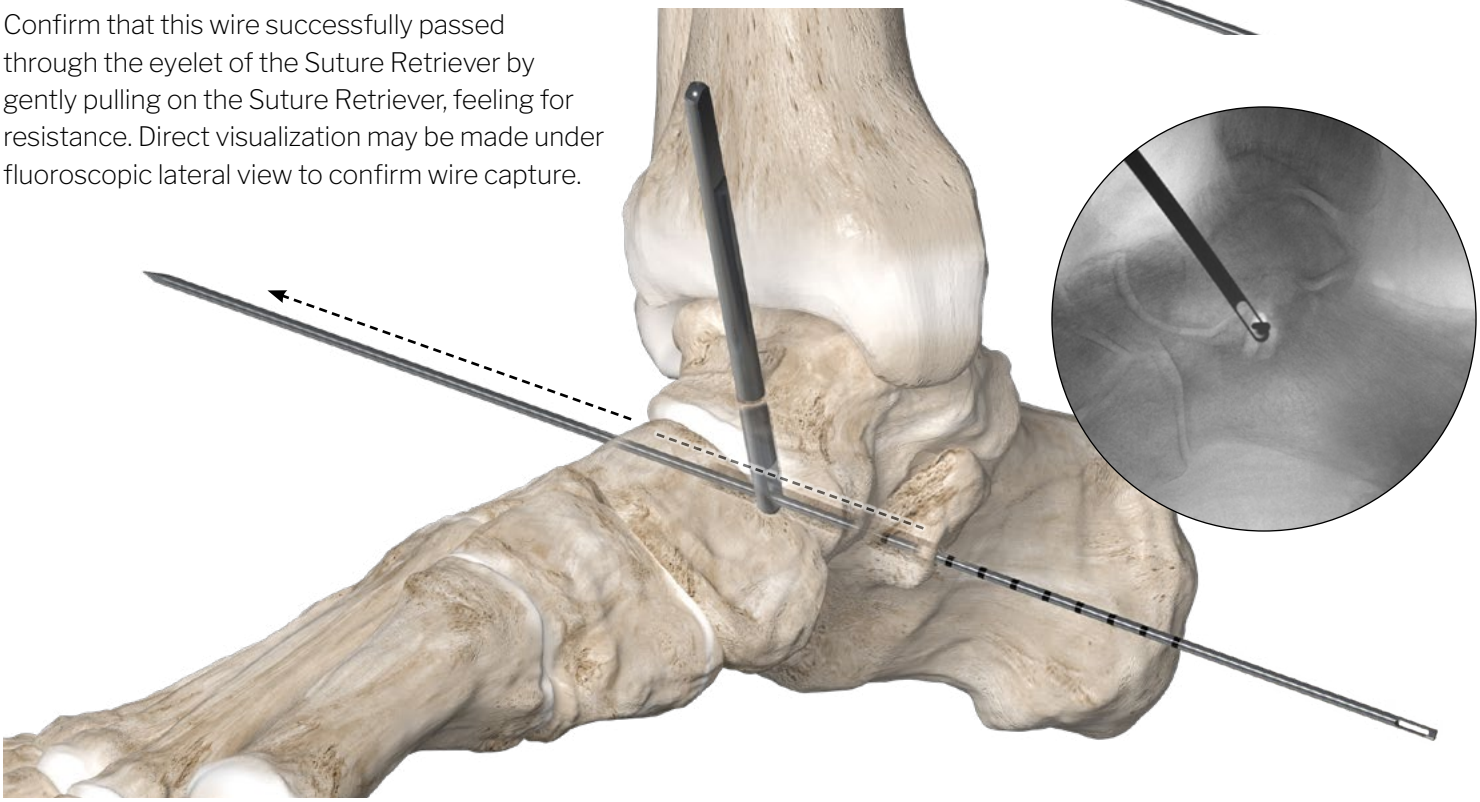


Ø1.60 X 200 mm Eyelet K-Wire



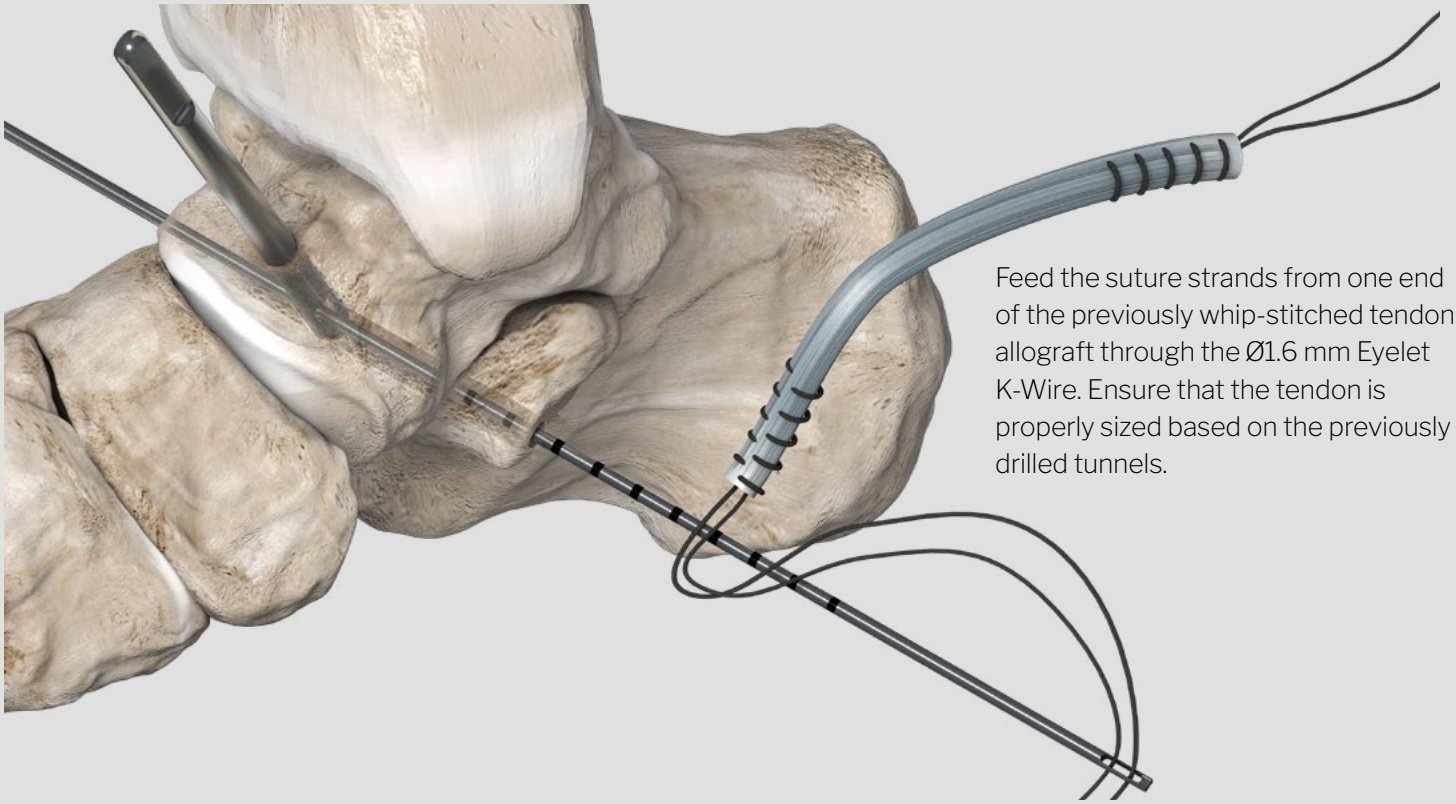
Re-insert the Ø1.6 mm eyelet K-Wire into the calcaneus tunnel through the medial insertion site through the Suture Retriever until it emerges from the lateral side.

Confirm that this wire successfully passed through the eyelet of the Suture Retriever by gently pulling on the Suture Retriever, feeling for resistance. Direct visualization may be made under fluoroscopic lateral view to confirm wire capture.

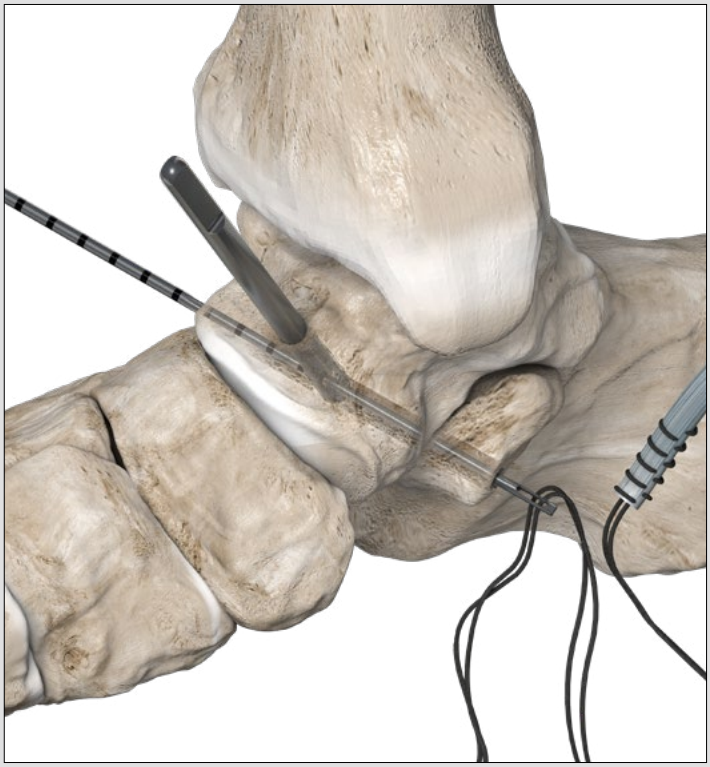


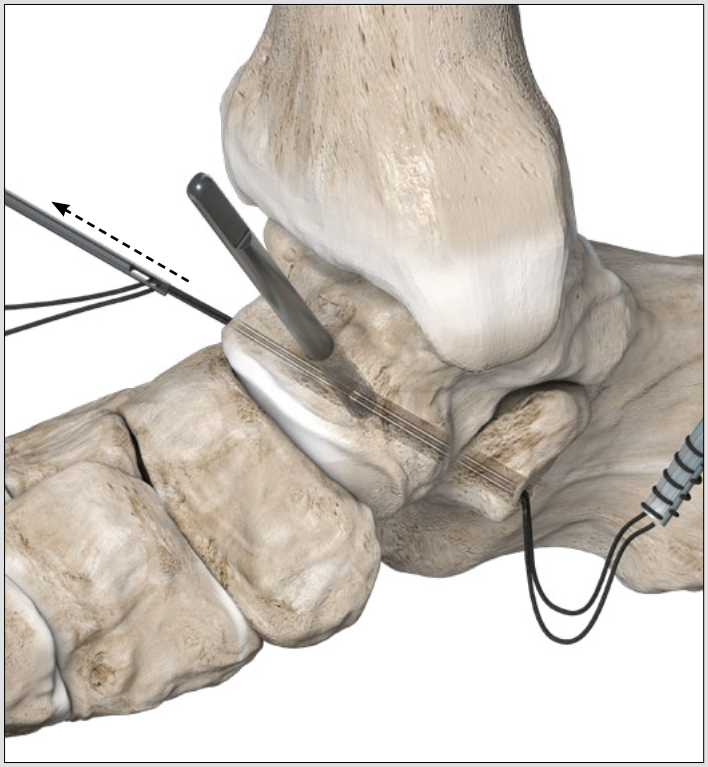
Proceed with either the allograft technique on page 18, or the PCFD Tether Implant technique on page 22.

USING ALLOGRAFT AND GRAPPLER INTERFERENCE SCREW SYSTEM:



Feed the suture strands from one end of the previously whip-stitched tendon allograft through the Ø1.6 mm Eyelet K-Wire. Ensure that the tendon is properly sized based on the previously drilled tunnels.

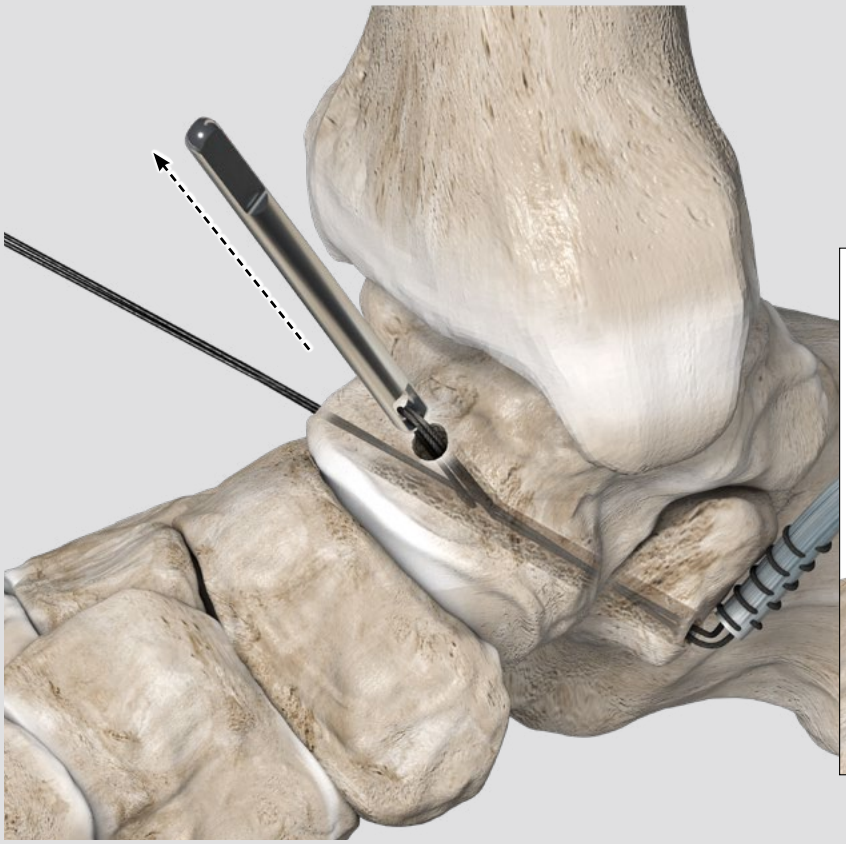


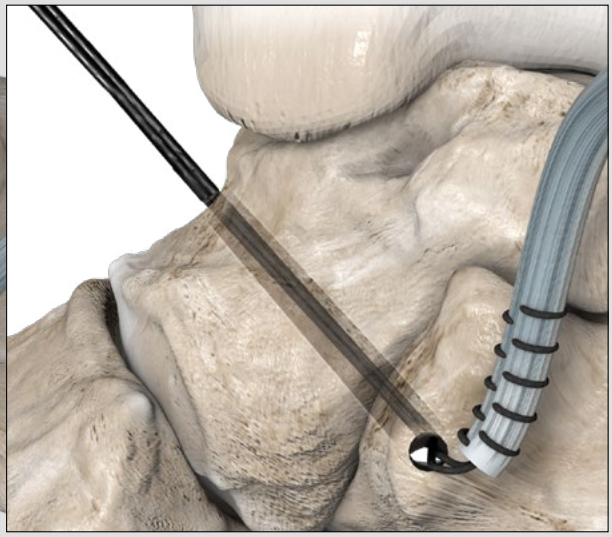


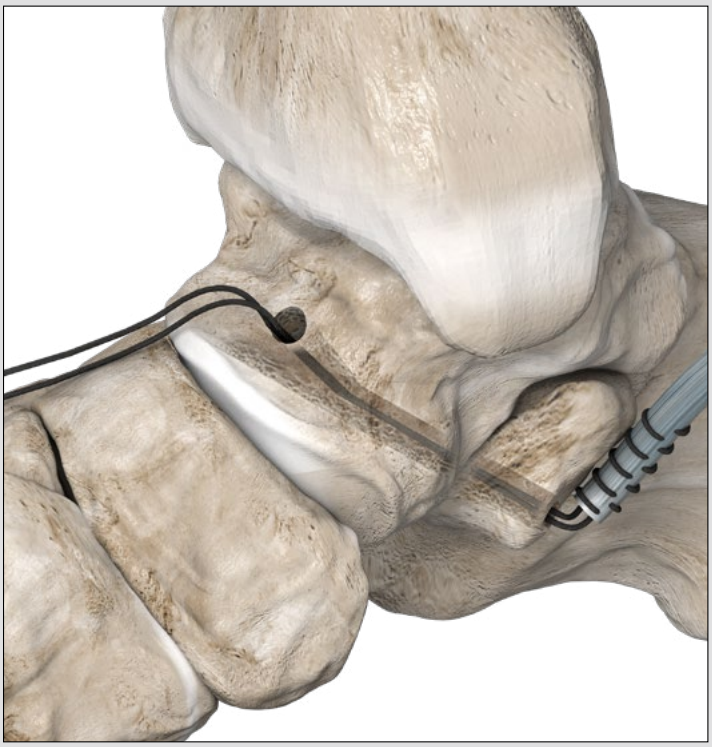
Pass the Ø1.6 mm Eyelet K-Wire with captured suture strands out the lateral side of the foot. Remove the strands from the eyelet K-Wire.

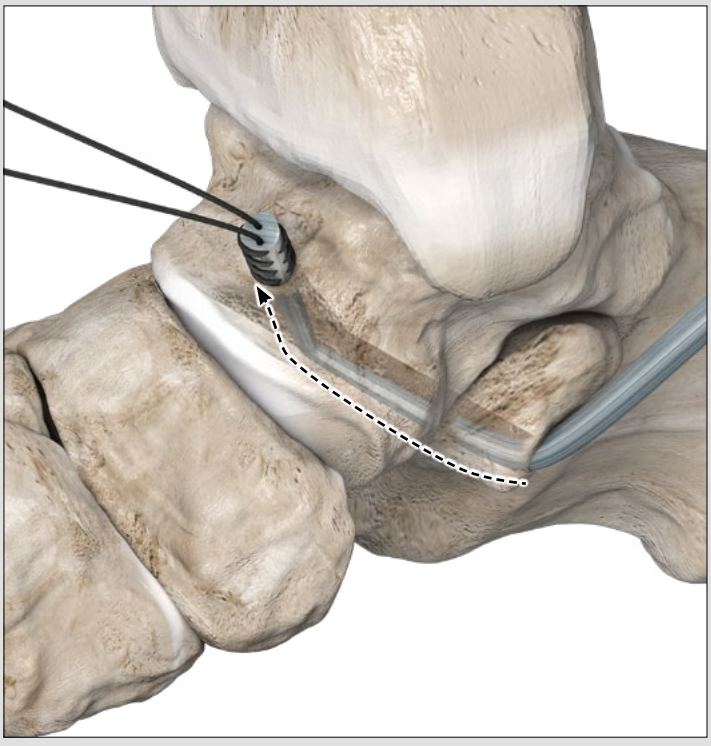
USING ALLOGRAFT AND GRAPPLER INTERFERENCE SCREW SYSTEM:

Pull the Suture Retriever out of the talus. The suture ends should follow and the tendon graft can be advanced into the sustentaculum tali tunnel, sinus tarsi and out through the talar neck tunnel.



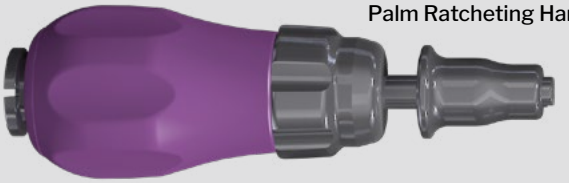






USING ALLOGRAFT AND GRAPPLER INTERFERENCE SCREW SYSTEM:

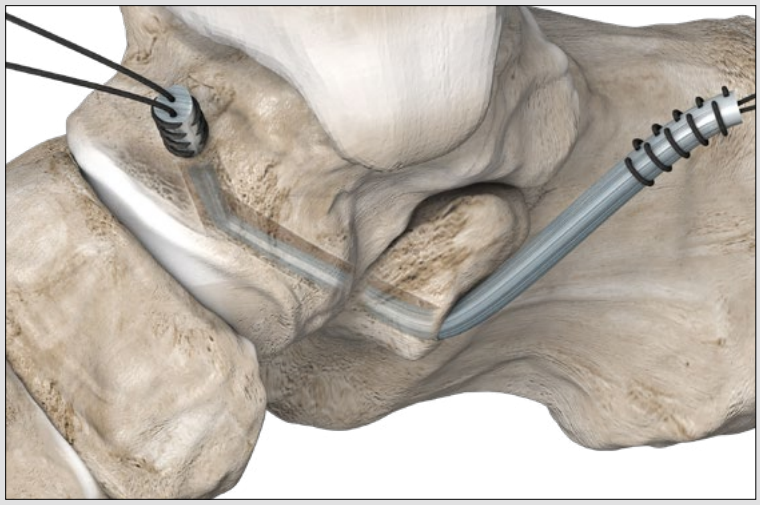
Palm Ratcheting Handle



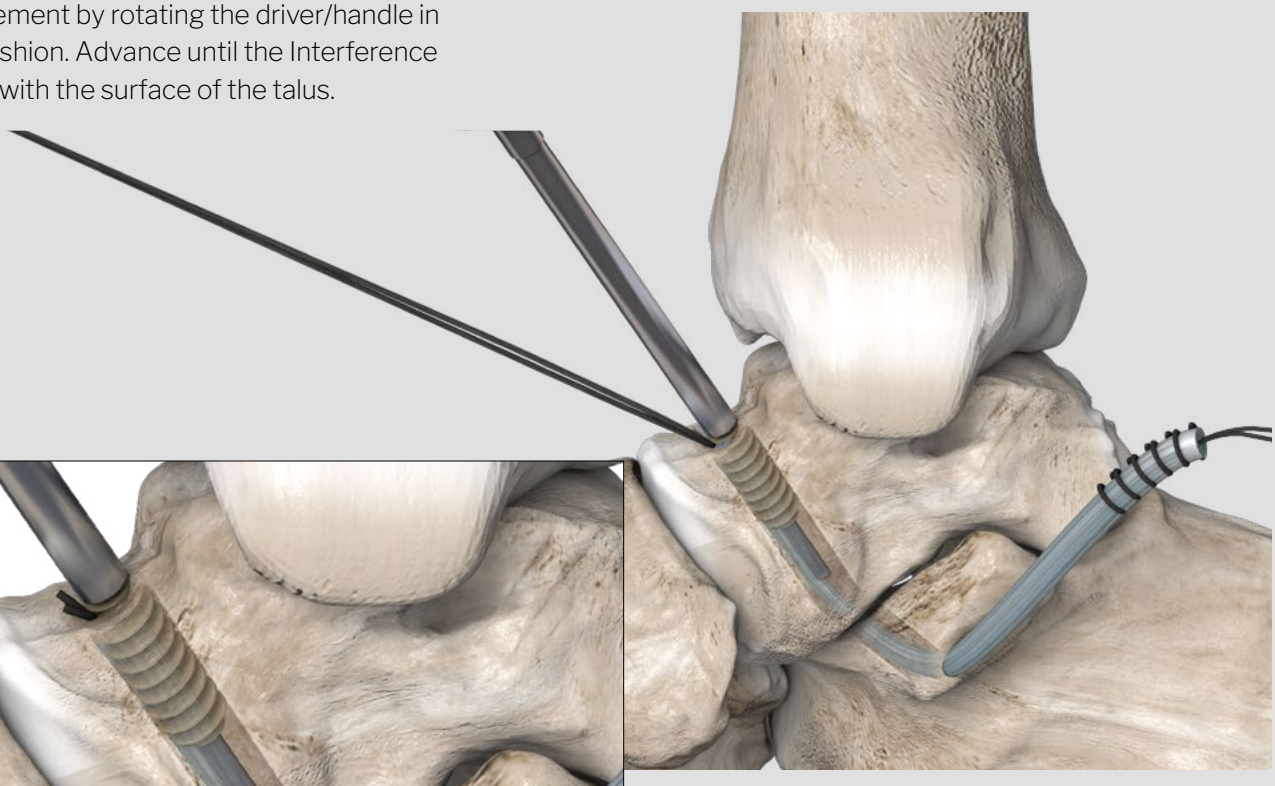
Ø4.5/Ø5.0 mm Solid Tri-lobe Driver

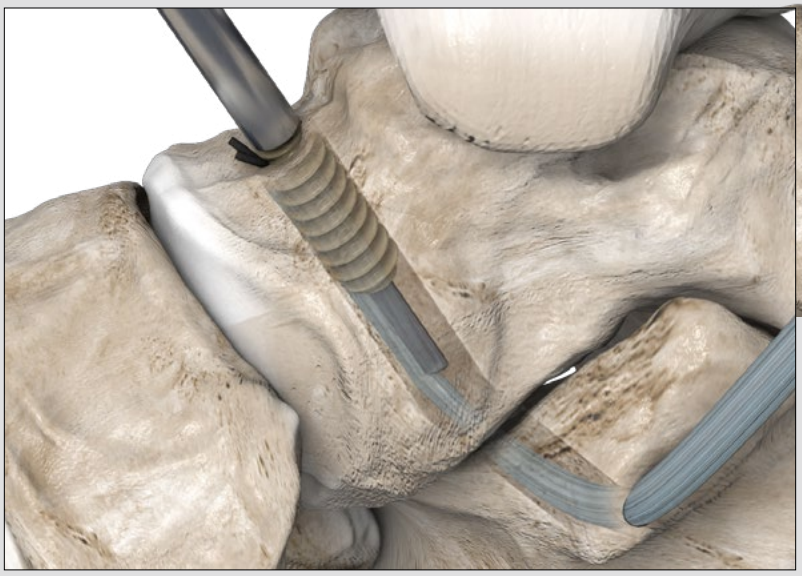


Reposition the allograft so that there is sufficient length emerging from the calcaneal hole for spring ligament (and superficial deltoid) reconstruction, if applicable.



Using Grappler Interference Screws for fixation, attach the appropriately sized Interference Screw Solid Driver onto the Palm Ratcheting Handle, then load the Grappler Interference Screw onto the driver. Insert the Interference Screw into the talar tunnel and begin advancement by rotating the driver/handle in a clockwise fashion. Advance until the Interference screw is flush with the surface of the talus.

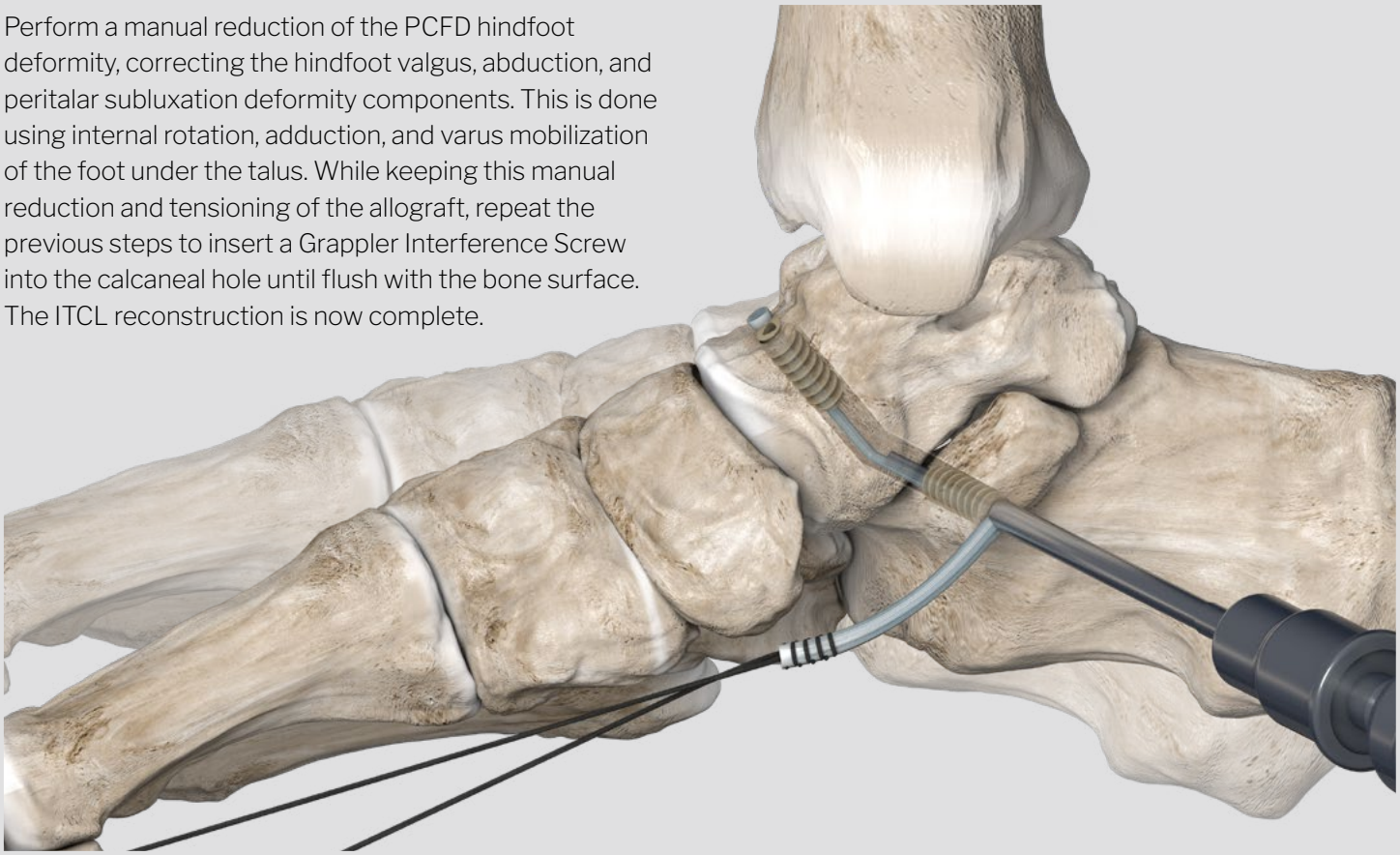




Ensure that the tendon is secured in the talar hole by pulling on the allograft end emerging from the calcaneus. Once the fixation is confirmed, trim away the excess allograft emerging from the talar hole.

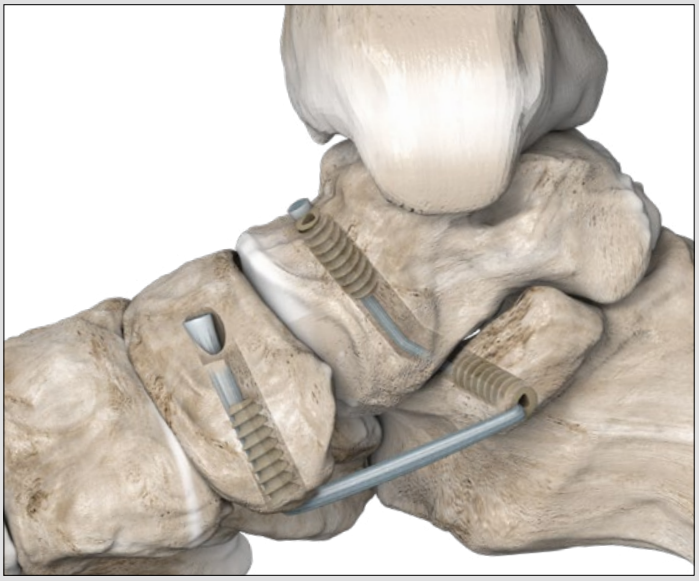
USING ALLOGRAFT AND GRAPPLER INTERFERENCE SCREW SYSTEM:

Perform a manual reduction of the PCFD hindfoot deformity, correcting the hindfoot valgus, abduction, and peritalar subluxation deformity components. This is done using internal rotation, adduction, and varus mobilization of the foot under the talus. While keeping this manual reduction and tensioning of the allograft, repeat the previous steps to insert a Grappler Interference Screw into the calcaneal hole until flush with the bone surface. The ITCL reconstruction is now complete.

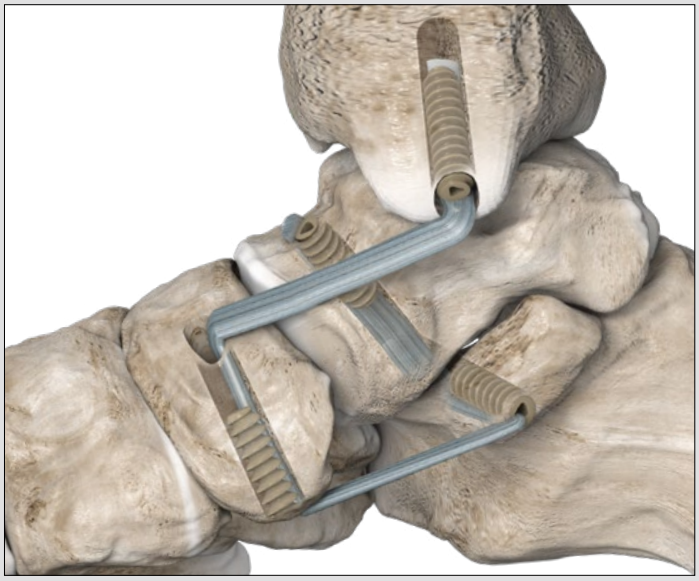


If Spring Ligament reconstruction is to be performed, follow a similar technique to drill, pass the allograft, and secure with an interference screw through the navicular. Details can be found in the Grappler Interference Screw System Surgical Technique Guide (P41-STG-0001).

The same allograft can be also be utilized to continue with a superficial deltoid tibionavicular reconstruction if needed, exiting out from the navicular and being inserted into the medial malleolus.

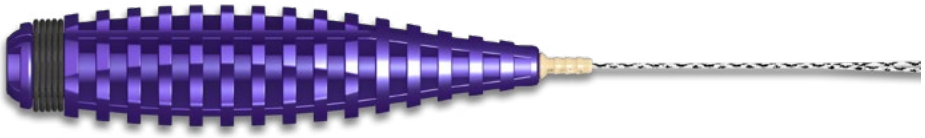


ITCL and spring ligament reconstruction

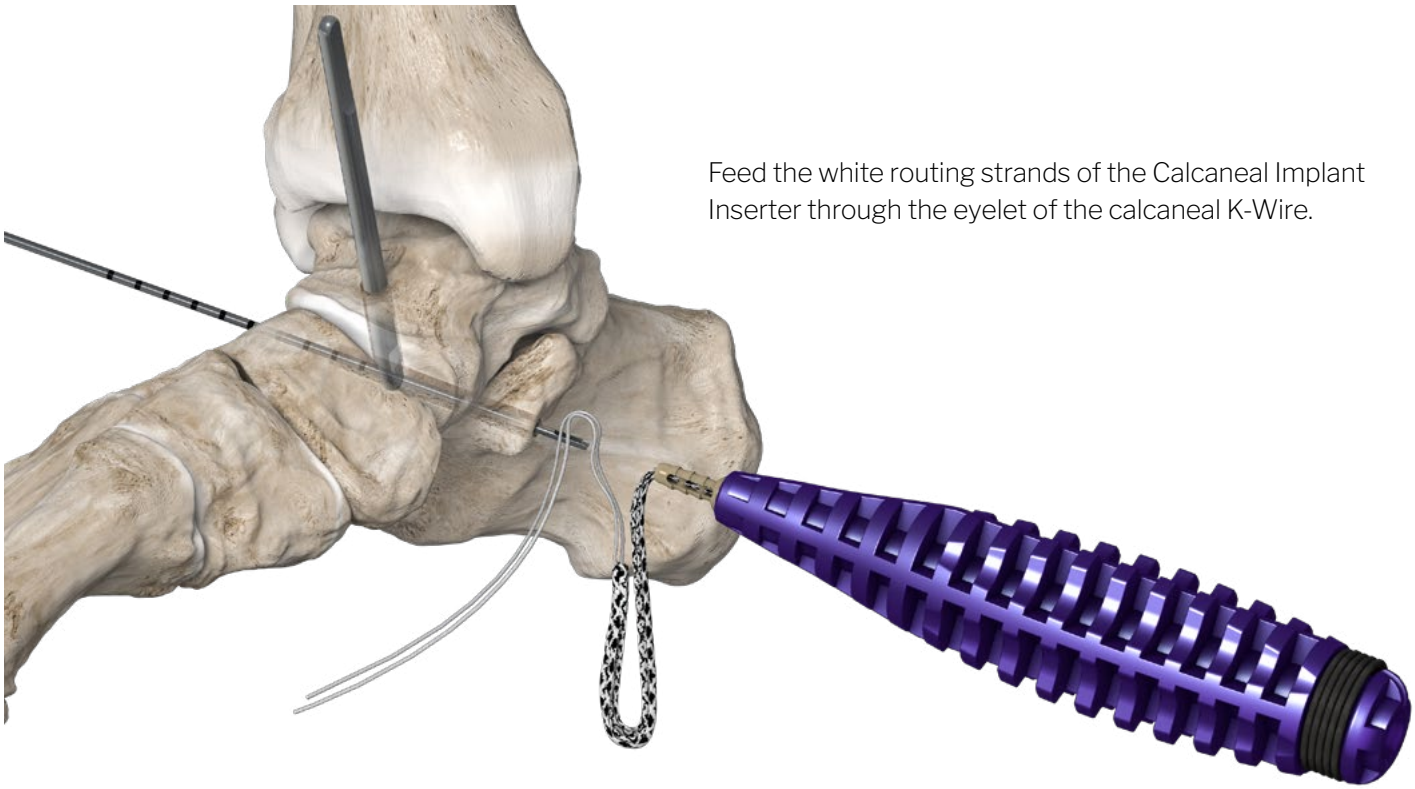


ITCL, spring ligament, and superficial deltoid reconstruction

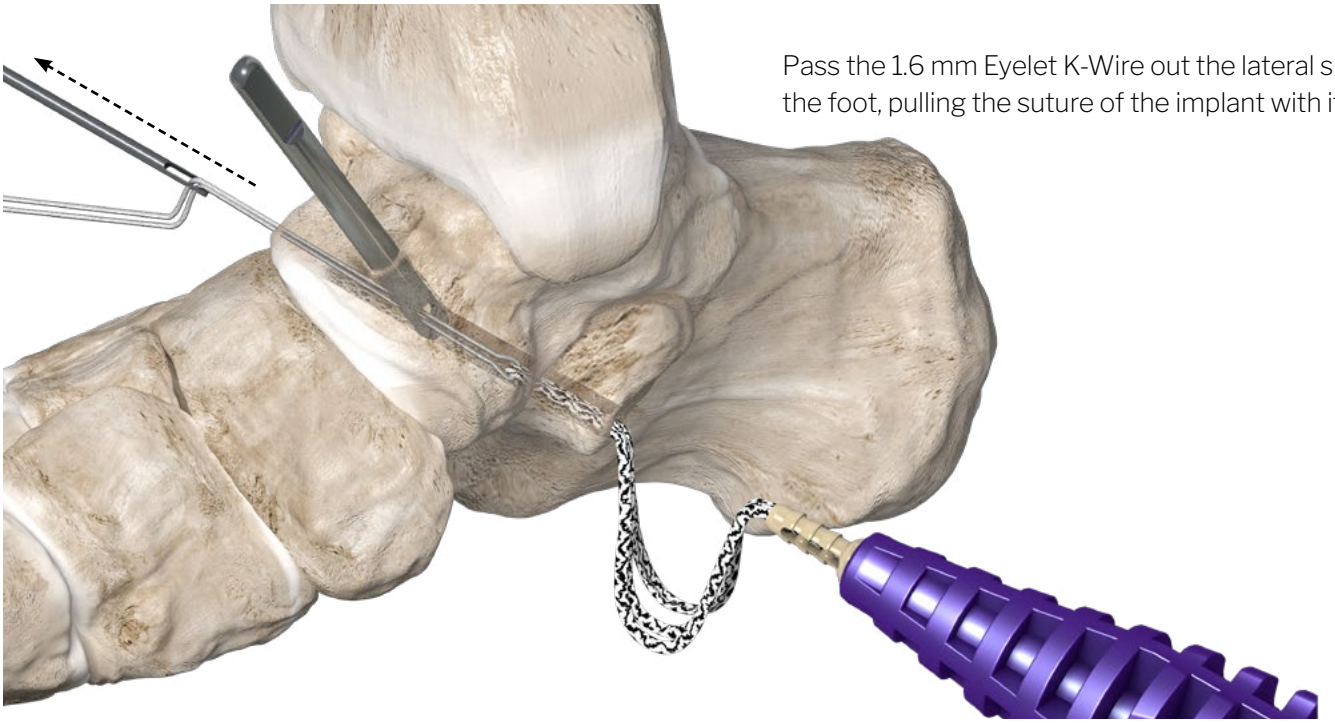
USING axIOLink™ PCFD TETHER SYSTEM IMPLANT:



Calcaneal Inserter Handle
-Loaded with Ø3.5 mm PEEK Anchor Implant and 1.4 mm ApeTape with ZipLoop® Technology



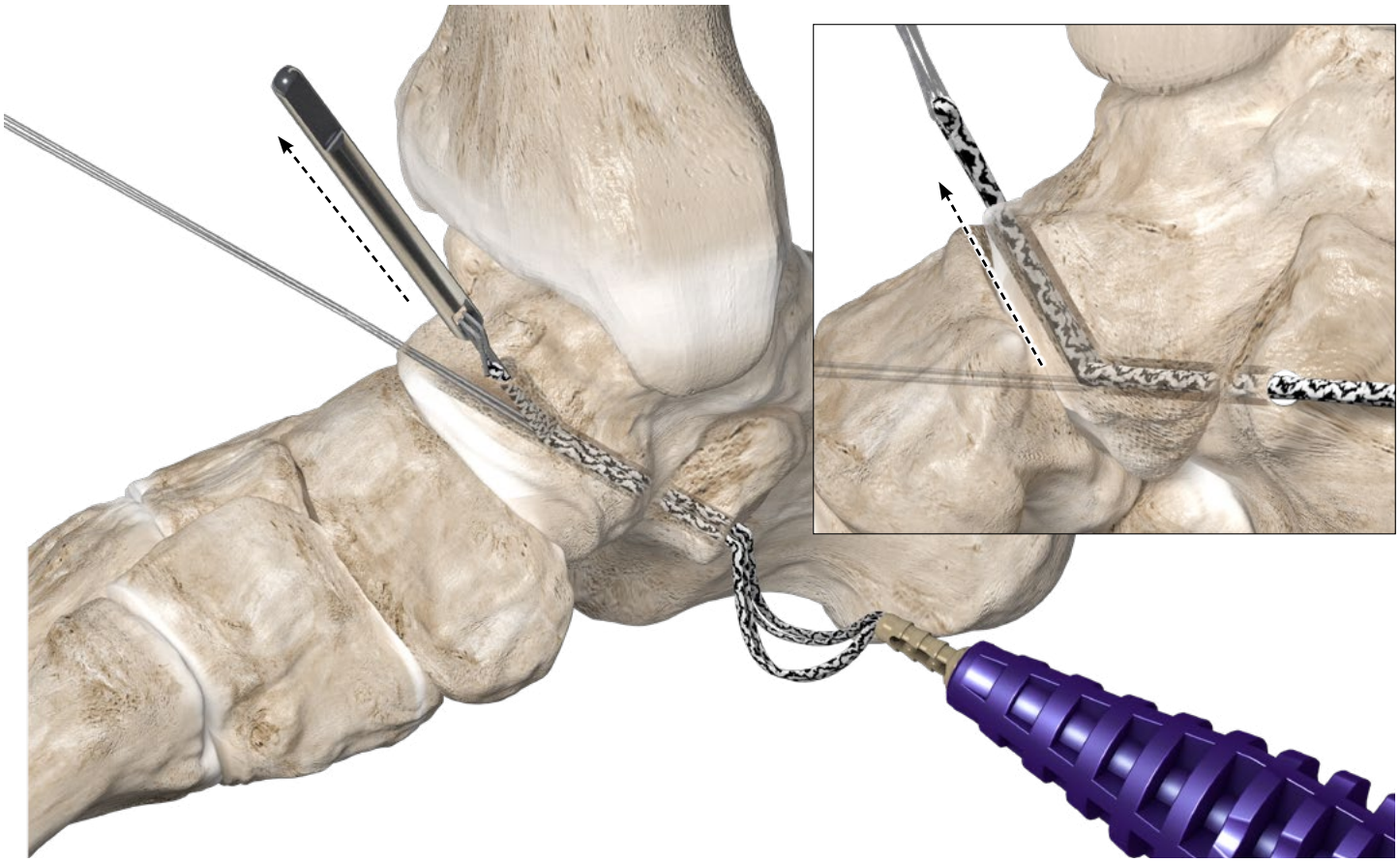
Feed the white routing strands of the Calcaneal Implant Inserter through the eyelet of the calcaneal K-Wire.

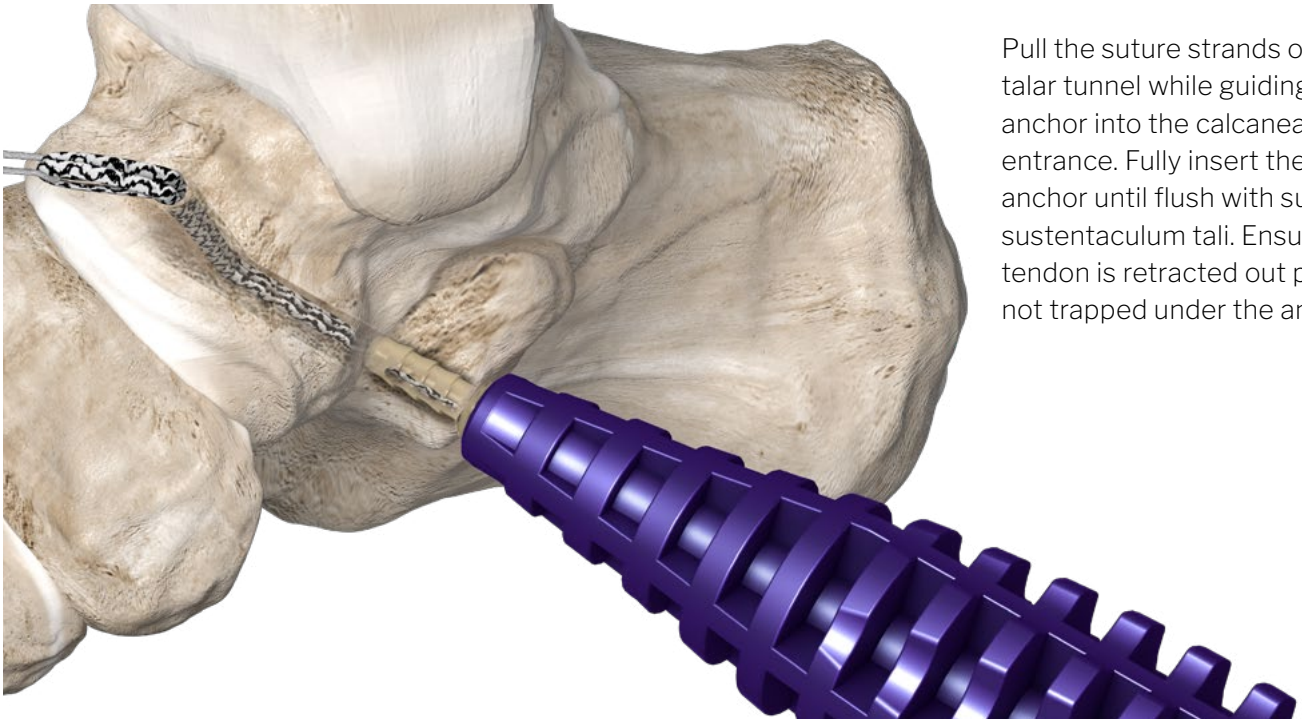


Pass the 1.6 mm Eyelet K-Wire out the lateral side of the foot, pulling the suture of the implant with it.

USING axIOLink™ PCFD TETHER SYSTEM IMPLANT:

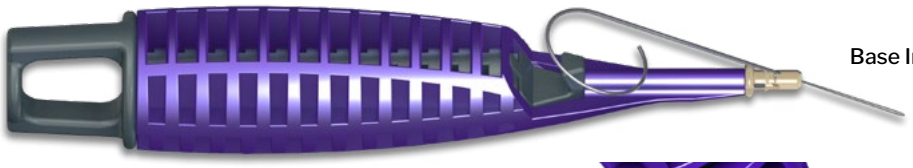
Pull the Suture Retriever out of the talus, redirecting the suture out of the talar tunnel.



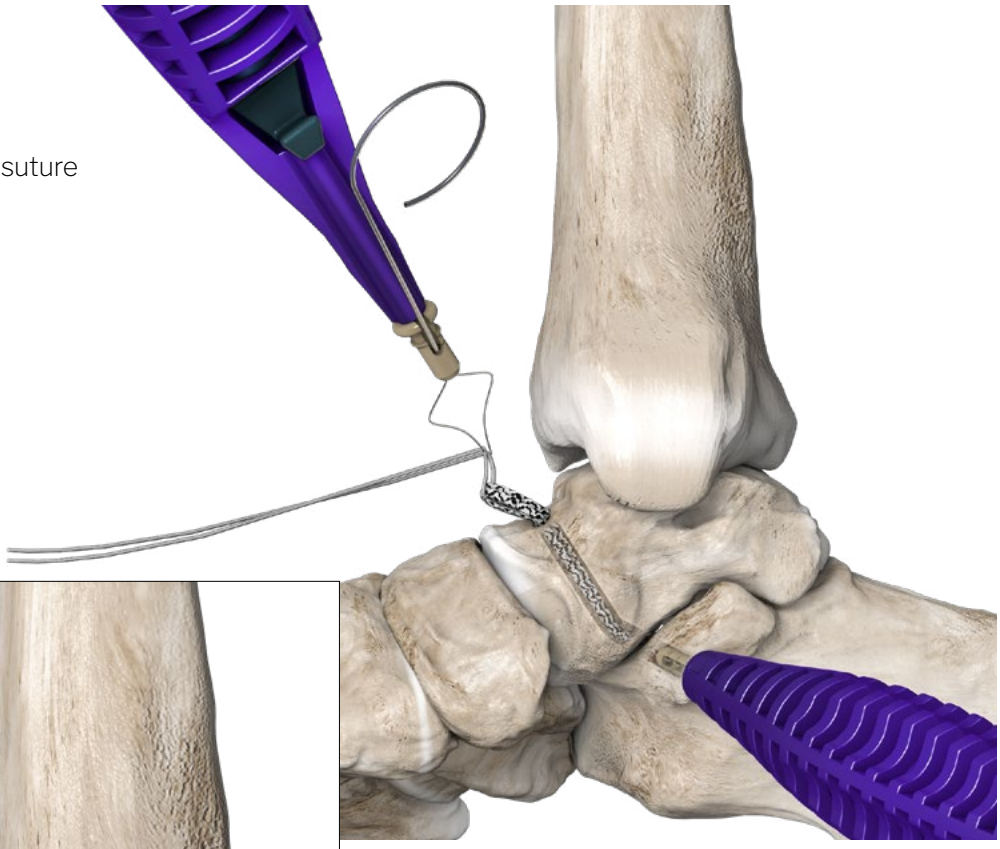


Pull the suture strands out of the talar tunnel while guiding the medial anchor into the calcaneal tunnel entrance. Fully insert the calcaneal anchor until flush with surface of the sustentaculum tali. Ensure the FDL tendon is retracted out plantarly and not trapped under the anchor.

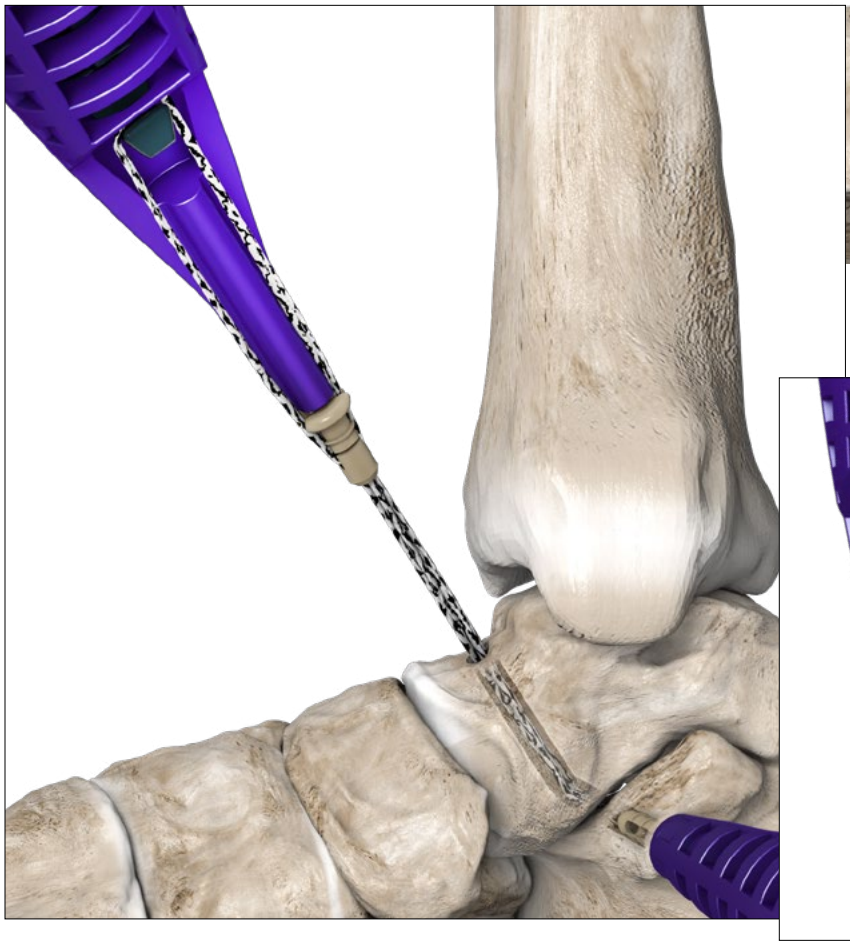
USING axIOLink™ PCFD TETHER SYSTEM IMPLANT:



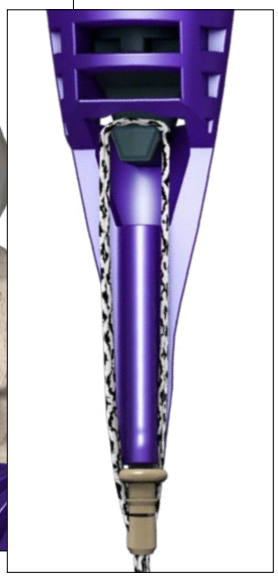
Base Inserter Handle



Reroute the white strand through the suture passer on the Talar Implant Inserter.



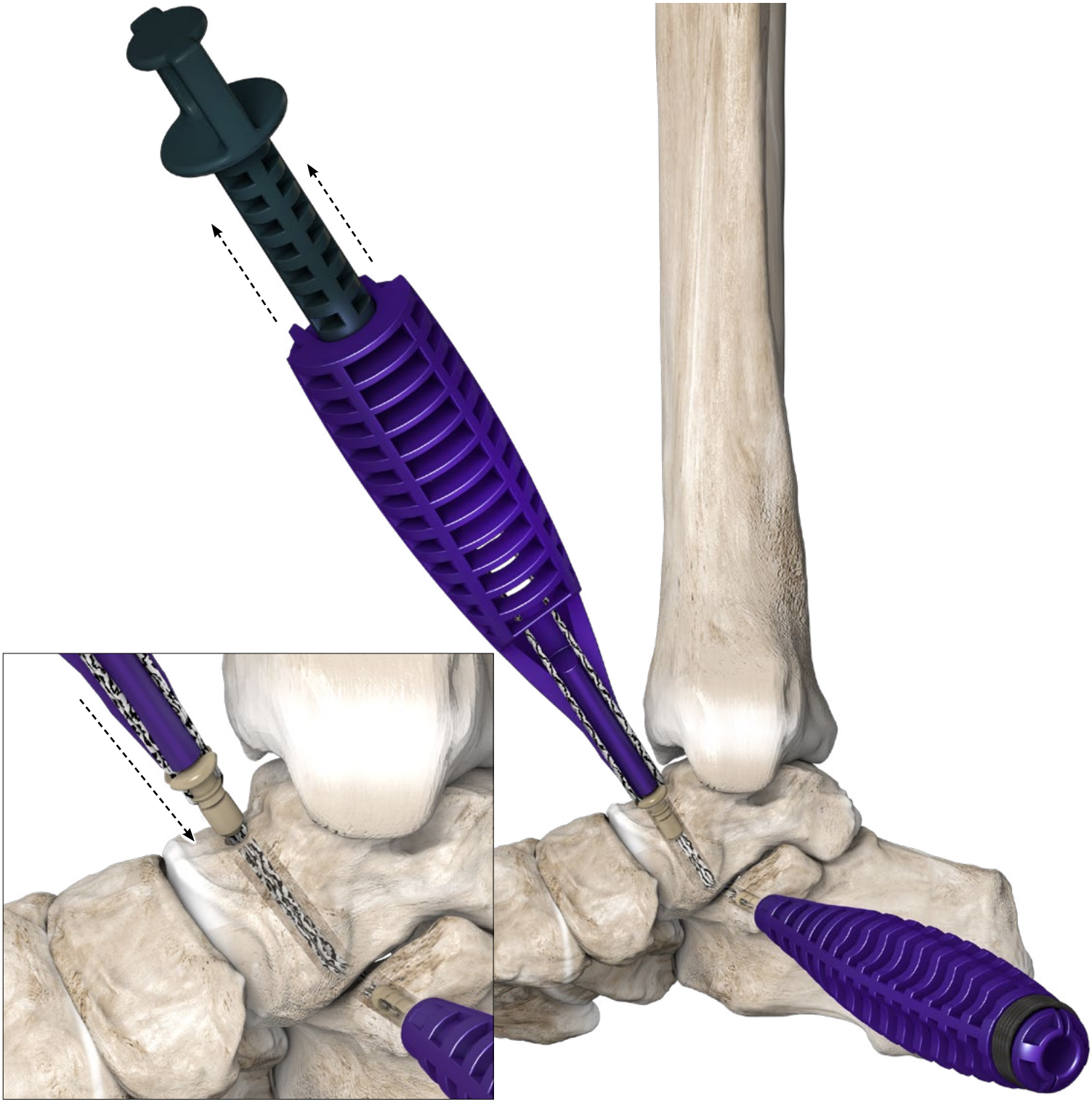
Pull the suture passer to route both striped suture tape loops through the talar anchor,



Set the loops into the hooked portion. Cut and discard the white passing suture strands, ensure that the striped suture loops are not twisted, and that loops are aligned with the grooves on talar anchor head.

USING axIOLink™ PCFD TETHER SYSTEM IMPLANT:

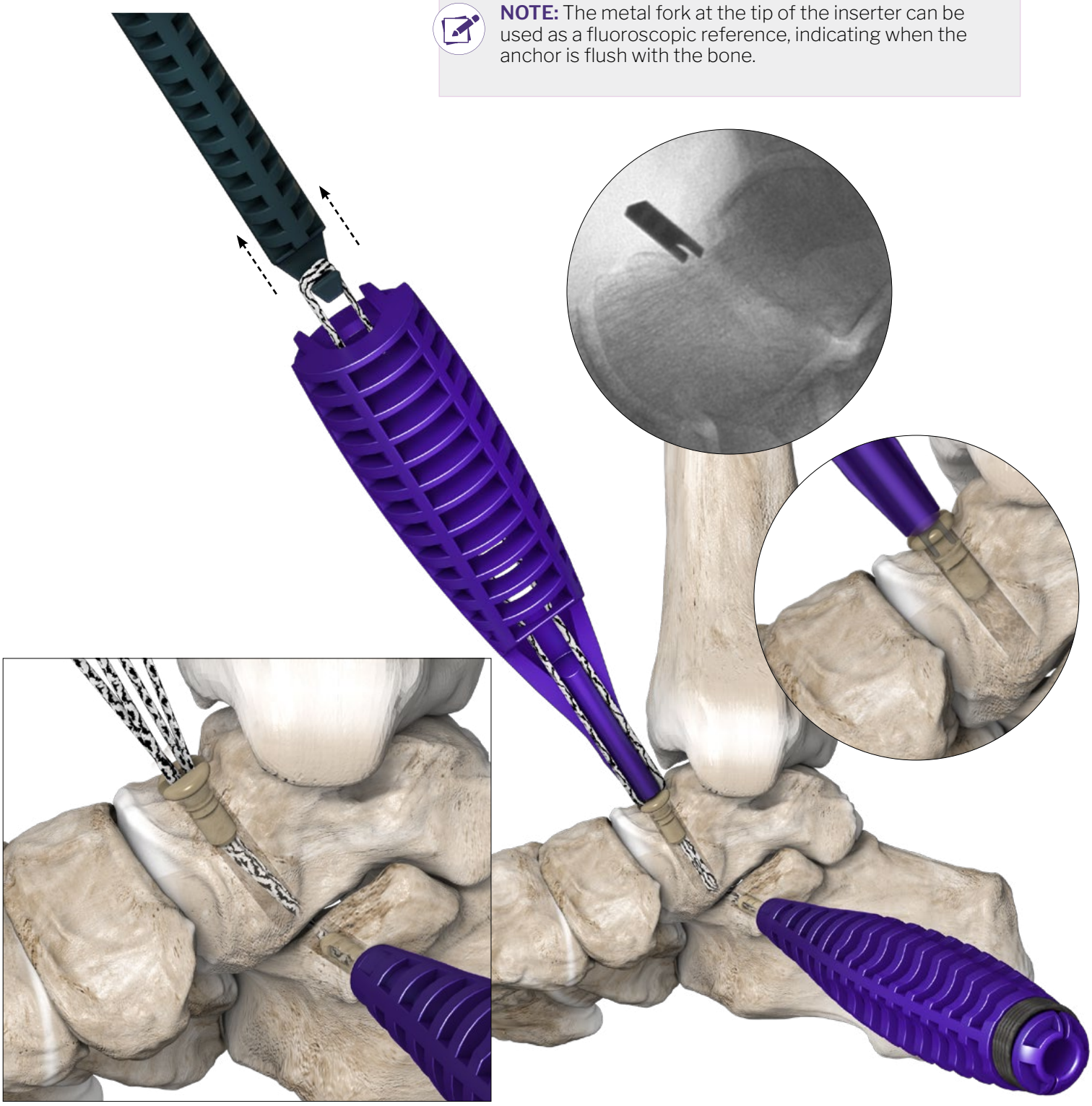
While retracting the soft tissue and under direct visualization of the talar neck tunnel, guide the talar anchor into the talar tunnel entrance by pushing the body of the inserter toward the hole while pulling the back handle of the inserter to maintain tension on the suture tape loops, preventing tangles.



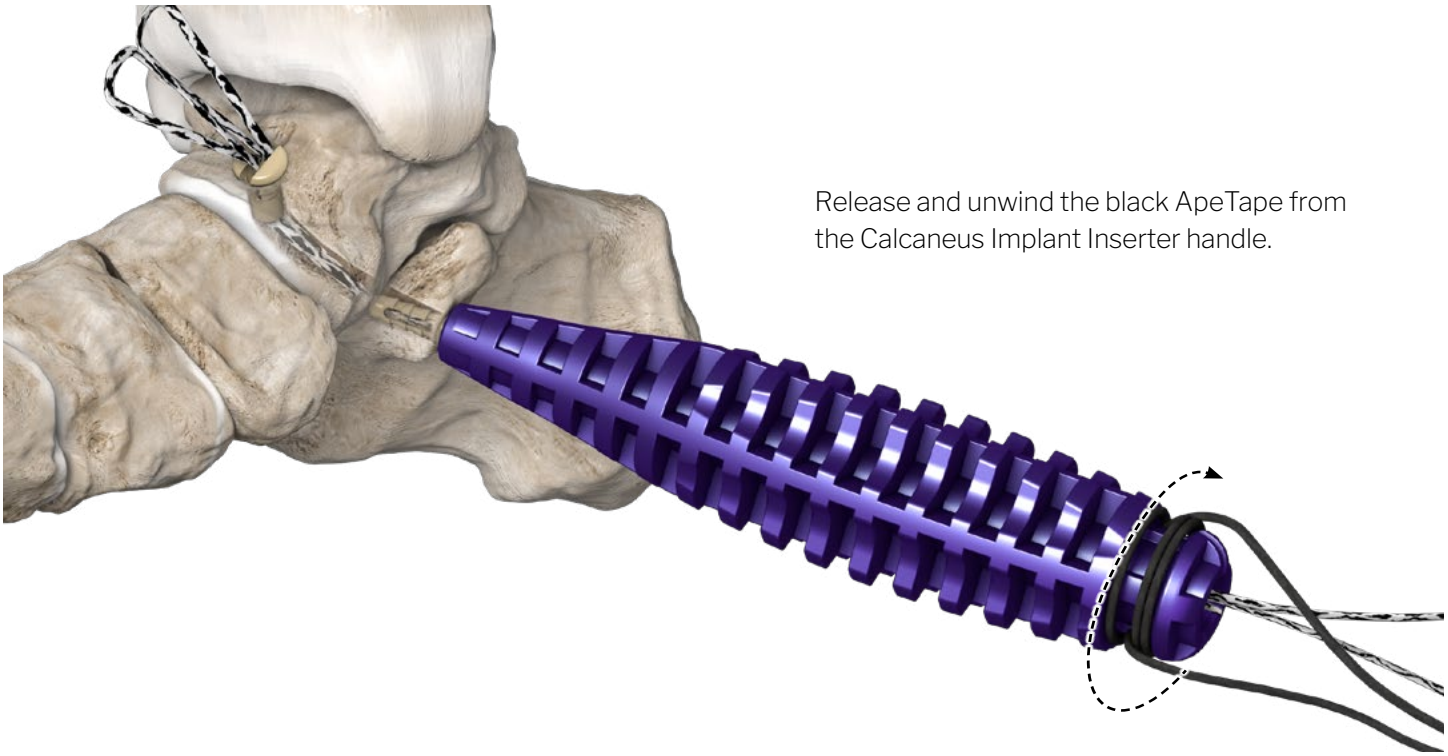
USING axIOLink™ PCFD TETHER SYSTEM IMPLANT:

Once the talar anchor is securely inserted into the talar hole, disengage the suture loops on the inserter. After suture disengagement, the inserter can be tamped in order to seat the anchor flush with the talar neck. Pull the inserter off the anchor and out of the anatomy.

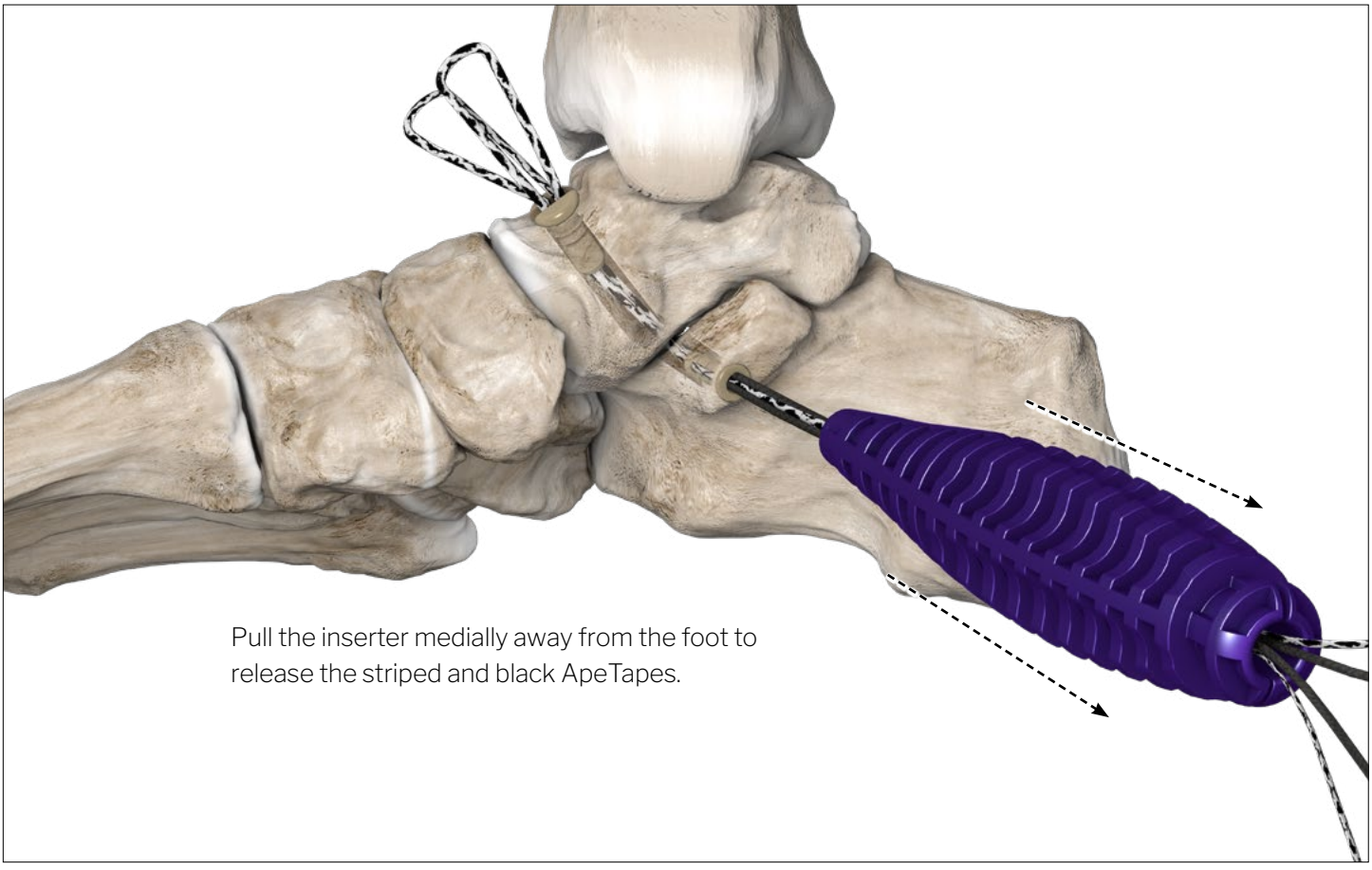
NOTE: The metal fork at the tip of the inserter can be used as a fluoroscopic reference, indicating when the anchor is flush with the bone.



USING axIOLink™ PCFD TETHER SYSTEM IMPLANT:



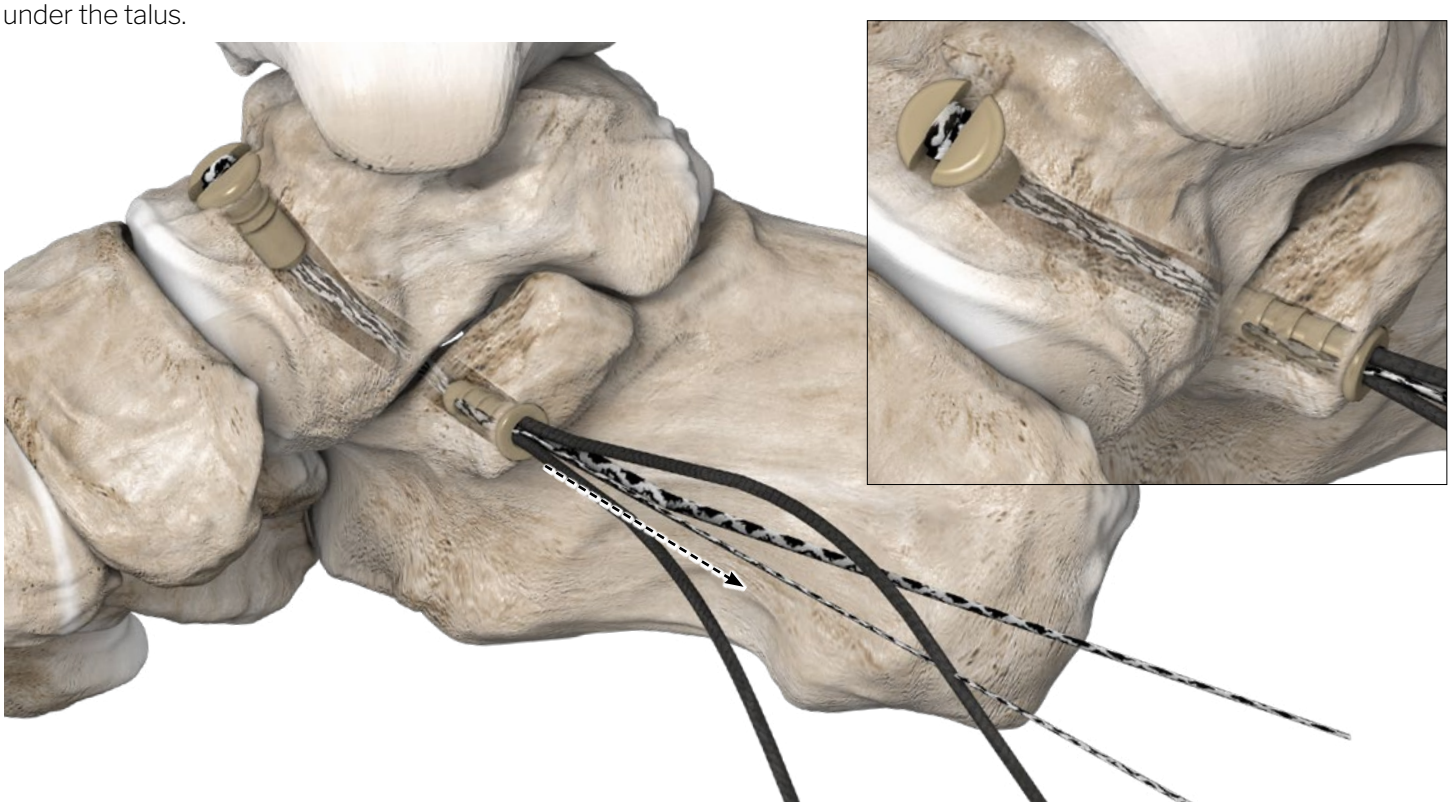
Release and unwind the black ApeTape from the Calcaneus Implant Inserter handle.



Pull the inserter medially away from the foot to release the striped and black ApeTapes.

USING axIOLink™ PCFD TETHER SYSTEM IMPLANT:

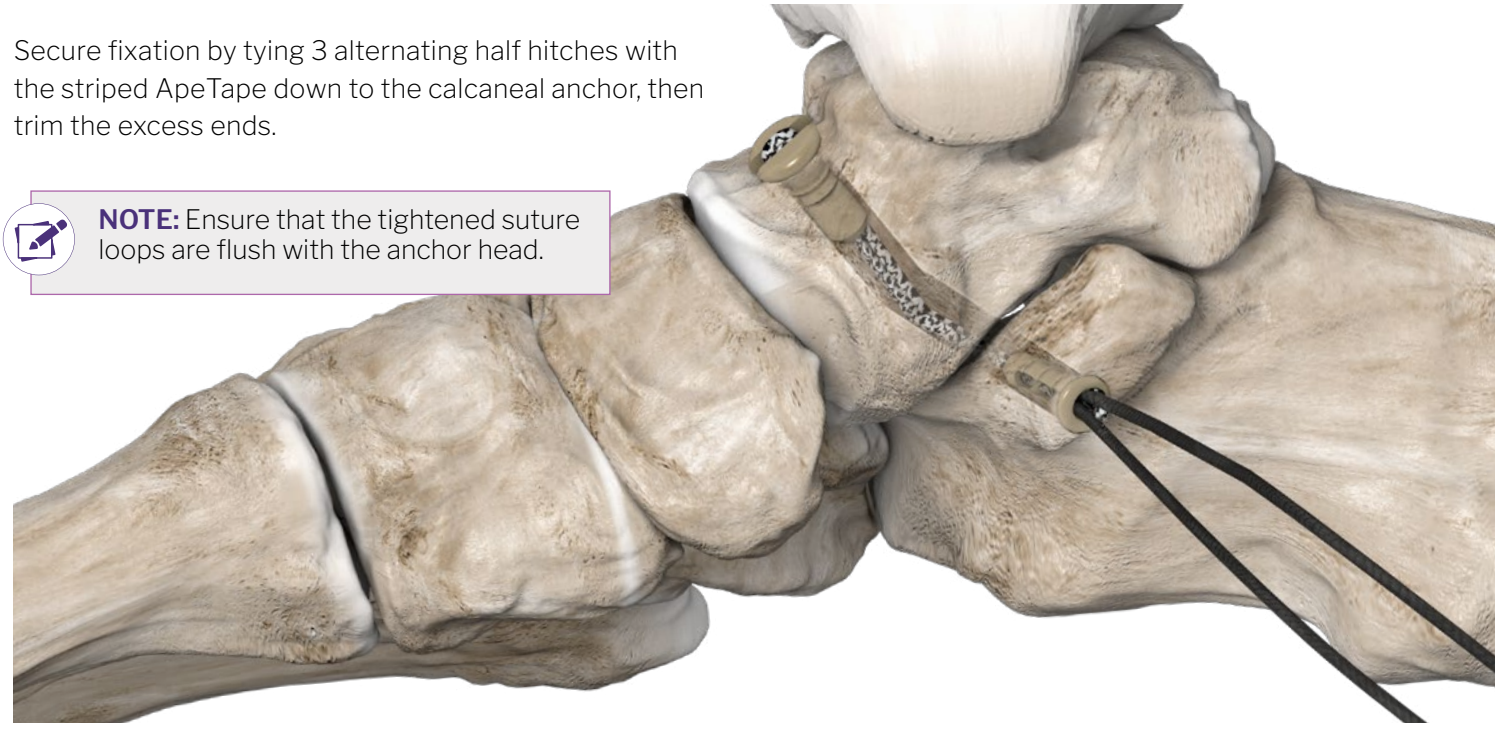
Perform a manual reduction of the PCFD hindfoot deformity, correcting the hindfoot valgus, abduction, and peritalar subluxation deformity components. This is done using internal rotation, adduction, and varus mobilization of the foot under the talus.



While holding the aforementioned reduction, pull the striped ApeTape emerging from the Calcaneal Anchor until the suture loops emerging from the talar anchor are flush with anchor and no additional tensioning can be applied.

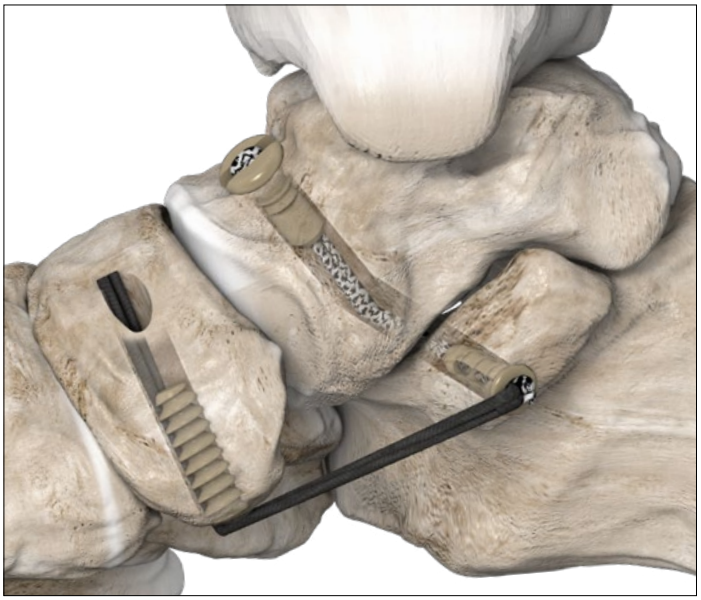
Secure fixation by tying 3 alternating half hitches with the striped ApeTape down to the calcaneal anchor, then trim the excess ends.

NOTE: Ensure that the tightened suture loops are flush with the anchor head.

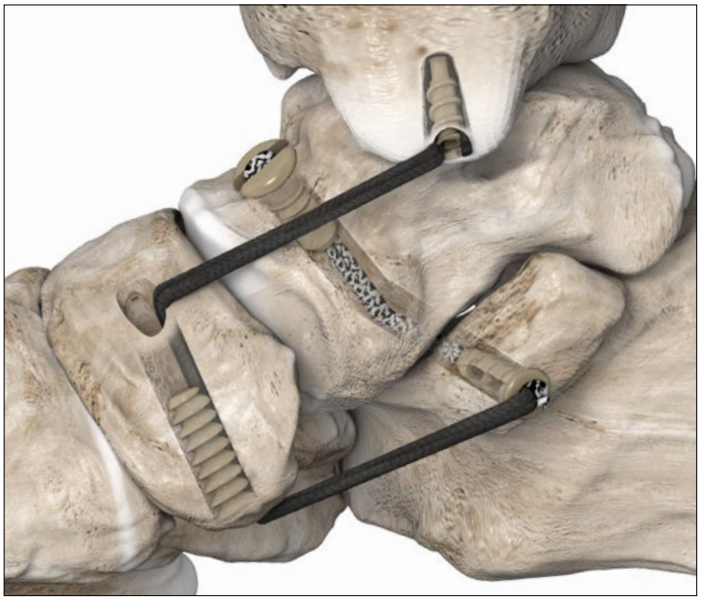


USING axIOLink™ PCFD TETHER SYSTEM IMPLANT:

The black ApeTape can be used to complete a spring ligament repair and/or deltoid repair, per surgeon's preference. The ApeTape can be secured with Grappler Interference Screws, Genie Knotless Anchors, or Mpire™ Knotless Anchors (see P63-STG-0001 for suture compatibility).



ITCL and spring ligament reconstruction



ITCL, spring ligament, and superficial deltoid reconstruction

SYSTEM REMOVAL:

USING axIOLink™ SYSTEM IMPLANT:

Cut the suture tape loops at the talar anchor, then use forceps or similar grasping instruments to pull out both the talar and calcaneal anchors.

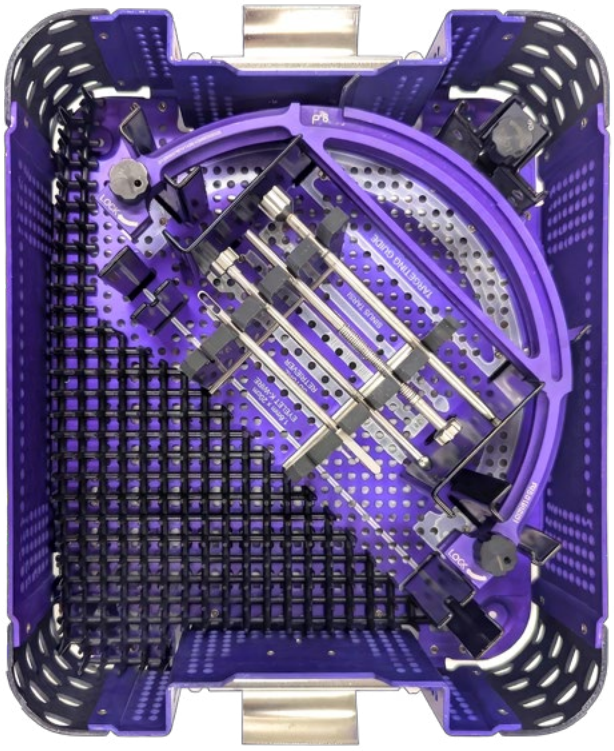
USING ALLOGRAFT AND GRAPPLER INTERFERENCE SCREW SYSTEM:

Follow the removal instructions associated with the fixation implants used (e.g. Grappler Interference Screws) to remove the implants from the talar and calcaneal holes. Remove the Allograft. Perform revision procedure per surgeon preference.

DISASSEMBLY PRIOR TO CLEANING:

Remove the sustentaculum wire guide, talar carriage, talar wire guide and sinus tarsi dilator from the targeting guide assembly prior to cleaning.

INSTRUMENT CASE:



The axIOLink™ Instrument Case contains:

- Targeting Guide
- Talar Carriage
- Calcaneal Wire Guide
- Talar Wire Guide
- Sinus Tarsi Dilator
- Suture Retriever
- Ø1.6 x 200 mm Eyelet K-wires



Part #	Description	Use
P62-910-0001	PCFD Tether, Targeting Guide Assembly	Reusable
P62-910-0002	PCFD Tether, Talar Carriage Assembly	Reusable
P62-910-0006	PCFD Tether, Calcaneal Wire Guide	Reusable
P62-910-0007	PCFD Tether, Talar Wire Guide	Reusable
P62-910-0009	PCFD Tether, Sinus Tarsi Dilator	Reusable
P62-910-0010	PCFD Tether, Suture Retriever	Reusable
P62-910-1620	1.6 X 200 mm, Eyelet K-Wire w/ Markings	Single-use

IMPLANT KIT:

axIOLink™ PCFD Tether Implant System (P62-001-3512-SK) is sterile-packed and single-use only.



The axIOLink™ Implant Kit contains:

- Drill Guide
- Ø4.7 mm Cannulated Talar Drill
- Ø3.5 mm Cannulated Calcaneal Drill
- Talar Inserter Handle
- Calcaneal Inserter Handle
- PEEK Implants w/ Knotless 1.4 mm ApeTape
- Ø1.6 x 200 mm Eyelet K-wires

Refer to www.paragon28.com/ifus for the complete and most current instructions for use document.

axIOLink™ PCFD TETHER SYSTEM – ALLOGRAFT TECHNIQUE

Instructions for Use: Grappler® Interference Screw System

Indications, Contraindications, Warnings and Precautions relevant to the use of the axIOLink™ PCFD Tether System with allograft are contained in the Instructions for Use document of the Grappler® Interference Screw System, P41-IFU-0001.

MR Safety Information

MR

The implants of the Grappler® Interference Screw System have been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. Since the Grappler® devices are composed of nonconductive, nonmetallic, and nonmagnetic materials, there are no known hazards resulting from exposure of these devices to any magnetic resonance (MR) environment. The Grappler® Interference Screw implant is MR safe.

axIOLink™ PCFD TETHER SYSTEM – IMPLANT TECHNIQUE

Instructions for Use: axIOLink™ PCFD Tether System

Indications, Contraindications, Warnings and Precautions relevant to the use of the axIOLink™ PCFD Tether System implant are contained in the Instructions for Use document of the axIOLink™ PCFD Tether System, P62-IFU-0001.

MR Safety Information

The axIOLink™ PCFD Tether System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the axIOLink™ PCFD Tether System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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SURGICAL TECHNIQUE GUIDE

axIOLink™ PCFD Tether Implant System

axIOLink™

PCFD TETHER SYSTEM

P62-STG-0001 RevD [2026-11-05]

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