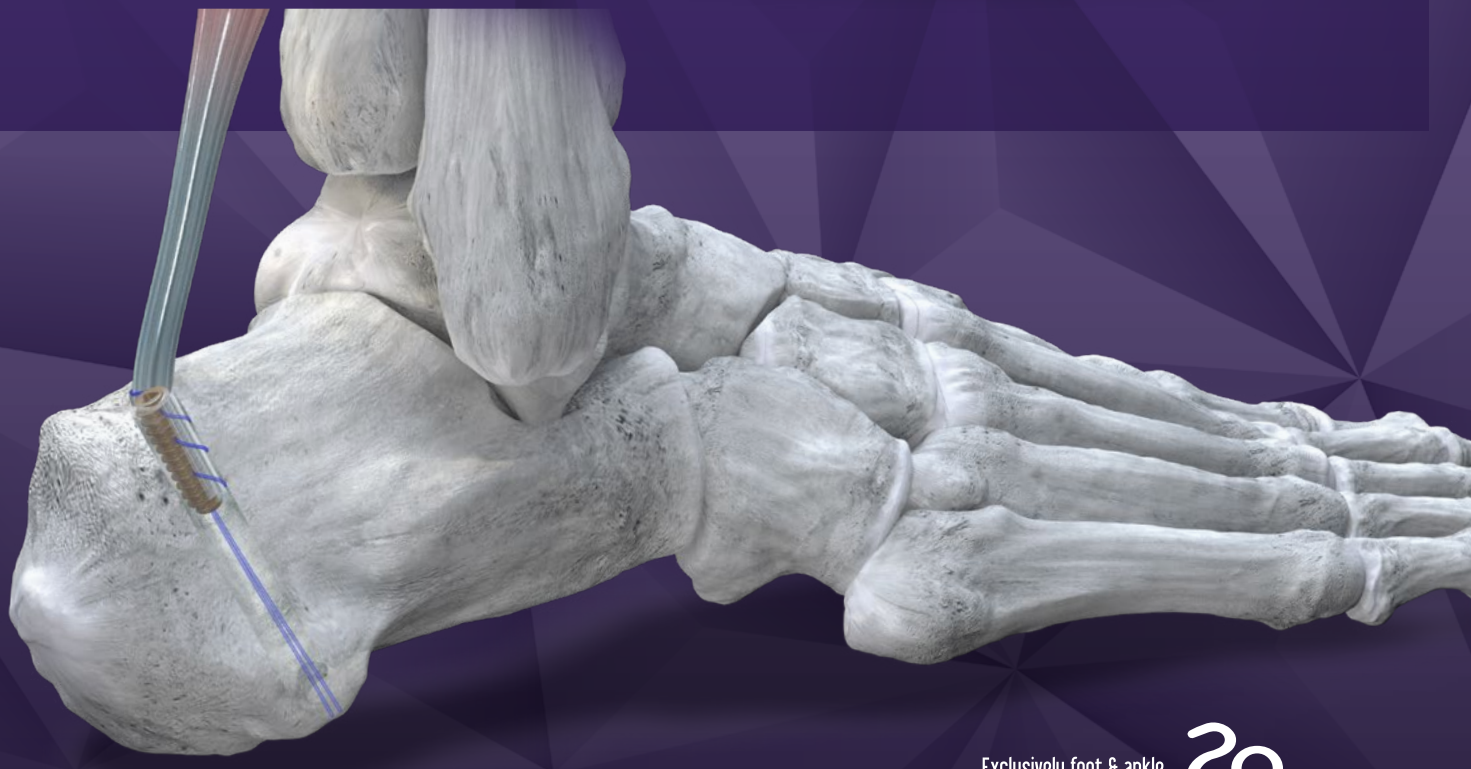
GRAPPLER® INTERFERENCE SCREW SYSTEM

SURGICAL TECHNIQUE GUIDE

Tendon Transfer using the Grappler® Interference Screw System



Exclusively foot & ankle

Paragon 28®

Acknowledgment:
Paragon 28® would like to thank Thomas San Giovanni, MD, for his contribution to the development of the surgical technique guide.

PRODUCT DESCRIPTION

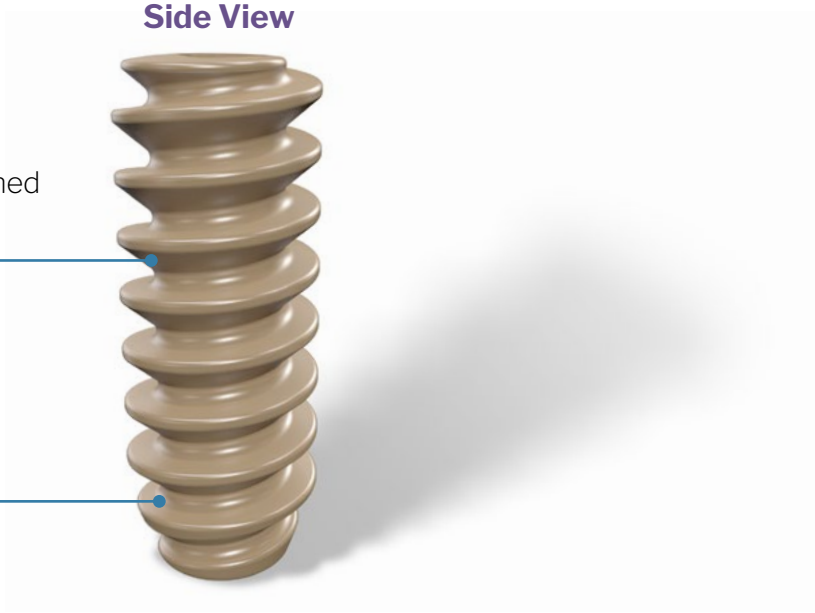
The Grappler® Interference Screw System was designed to address the challenges that are present when performing soft tissue tensioning in foot and ankle procedures. Twenty sizing options provide foot and ankle surgeons the ability to select the appropriate length and diameter Interference Screw for the specific surgery they are performing. The instrumentation is streamlined such that tendon size matches the Drill size and Interference Screw, and allows for a through and through or blind tunnel approach. Additionally, a novel Trilobe Driver helps to maximize torque while reducing the risk of stripping the Interference Screw during insertion.

CONTENTS

INTERFERENCE SCREW OFFERING

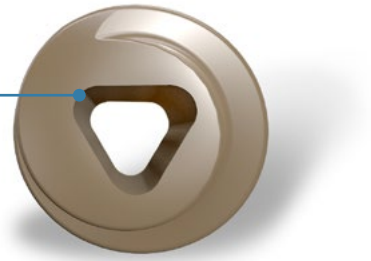
- All Interference Screws are provided sterile packaged
- Made of biocompatible PEEK material with inert properties and stiffness similar to bone[1]

Side View



- Interference Screw thread form designed to minimize Screw migration and loss of tension
- Tapered tip designed to ease insertion of Interference Screw

Top View



- Trilobe Driver feature extends through the length of the Interference Screw to help minimize the risk of stripping

Interference Screw Offerings

Length Options	Ø4.0 mm	Ø4.5 mm	Ø5.0 mm	Ø5.5 mm	Ø6.0 mm	Ø7.0 mm	Ø8.0 mm
10 mm	●	●	●				
15 mm	●	●	●	●	●		
20 mm	●	●	●	●	●	●	●
25 mm			●	●	●	●	●

FEATURED INSTRUMENTATION

Cannulated Drills
Available in Ø0.5 mm increments

Tissue Protector Inserts
Available in Ø0.5 mm increments

Tissue Protector/Driver Sleeve Handle

Tendon Sizer

Depth Gauge

Ø4.0 mm Solid Trilobe Driver

**Trilobe Drivers have an electropolish finish designed to help reduce friction between Driver surface and Interference Screw.*

Ø4.5/Ø5.0 mm Solid Trilobe Driver

Ø4.5/Ø5.0 mm Cannulated Trilobe Driver

Ø5.5/Ø6.0 mm Solid Trilobe Driver

Ø5.5/Ø6.0 mm Cannulated Trilobe Driver

Ø7.0/Ø8.0 mm Solid Trilobe Driver

Ø7.0/Ø8.0 mm Cannulated Trilobe Driver

Ø4.5/Ø5.0 mm Driver Sleeve

Ø5.5/Ø6.0 mm Driver Sleeve

Ø7.0/Ø8.0 mm Driver Sleeve

Jacobs Adapter

Palm Ratcheting Handle

Blind Tunnel Driver Handle

Ø1.6 mm K-wire with eyelet

Blind Tunnel Suture Passer

Through & Through Suture Passer

FEATURED INSTRUMENTATION

INSTRUMENTATION SIZING IS DESIGNED TO BE ONE TO ONE TO ONE

• Measured tendon size matches Drill and interference Screw size.

Tendon Size Measured	Tissue Protector Insert Size	Drill Size*	Color Band	Screw Size
Ø4.0 mm	Ø4.0 mm	Ø4.0 mm		Ø4.0 mm
Ø4.5 mm	Ø4.5 mm	Ø4.5 mm		Ø4.5 mm
Ø5.0 mm	Ø5.0 mm	Ø5.0 mm		Ø5.0 mm
Ø5.5 mm	Ø5.5 mm	Ø5.5 mm		Ø5.5 mm
Ø6.0 mm	Ø6.0 mm	Ø6.0 mm		Ø6.0 mm
Ø7.0 mm	Ø7.0 mm	Ø7.0 mm		Ø7.0 mm
Ø8.0 mm	Ø8.0 mm	Ø8.0 mm		Ø8.0 mm

**In the event of poor bone quality, under drilling 0.5 mm or over sizing the Screw by 0.5 mm may be considered. In the event of hard bone or use of synthetic material, over drilling 0.5 mm may be desired.*

ADDITIONAL DRILL SIZES AVAILABLE

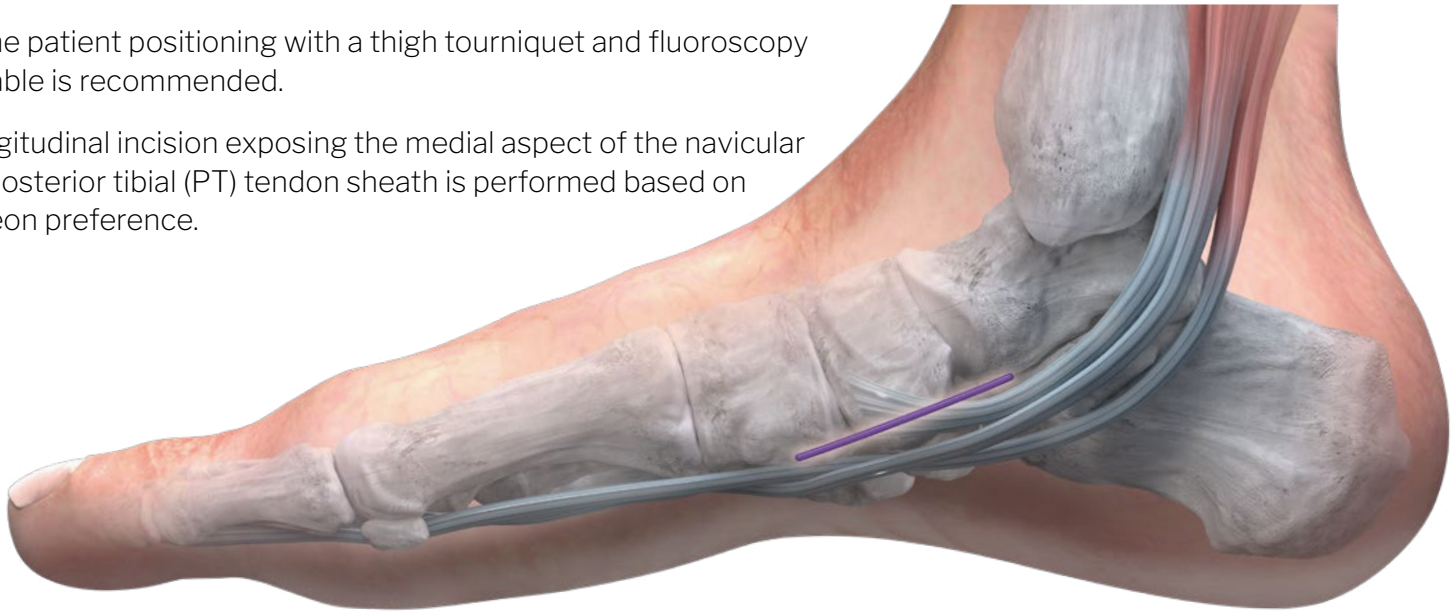
Tissue Protector Insert Size	Drill Size*	Color Band
Ø6.5 mm	Ø6.5 mm	
Ø7.5 mm	Ø7.5 mm	
Ø8.5 mm	Ø8.5 mm	

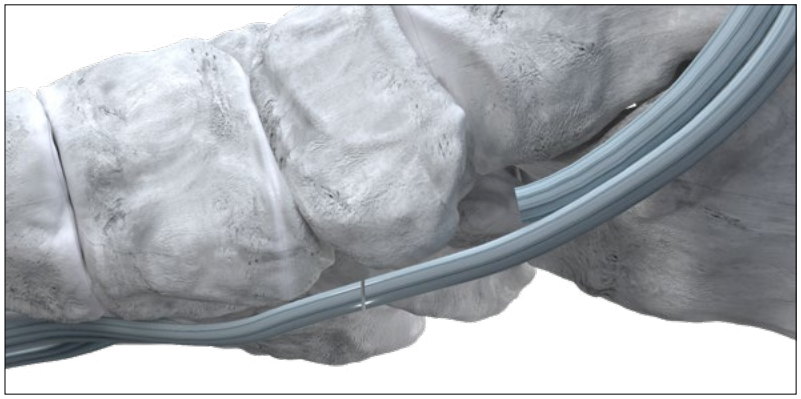
The technique demonstrated below is an FDL transfer to address stage II posterior tibial tendon dysfunction (PTTD) using a through and through technique.

INCISION/EXPOSURE

Supine patient positioning with a thigh tourniquet and fluoroscopy available is recommended.

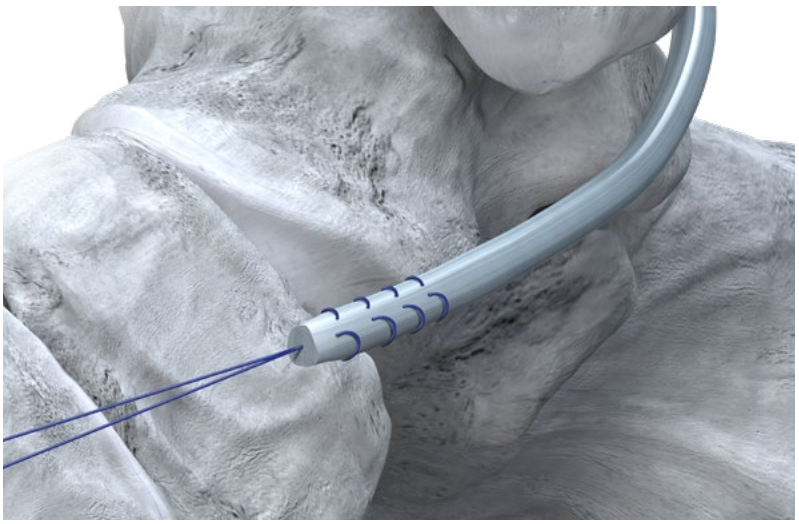
A longitudinal incision exposing the medial aspect of the navicular and posterior tibial (PT) tendon sheath is performed based on surgeon preference.





Identify the PT tendon and debride as necessary. Identify the FDL tendon and FHL tendon and perform an optional tenodesis distally. The FDL tendon is then transected proximal to the knot of Henry.

FDL TENDON PREPARATION



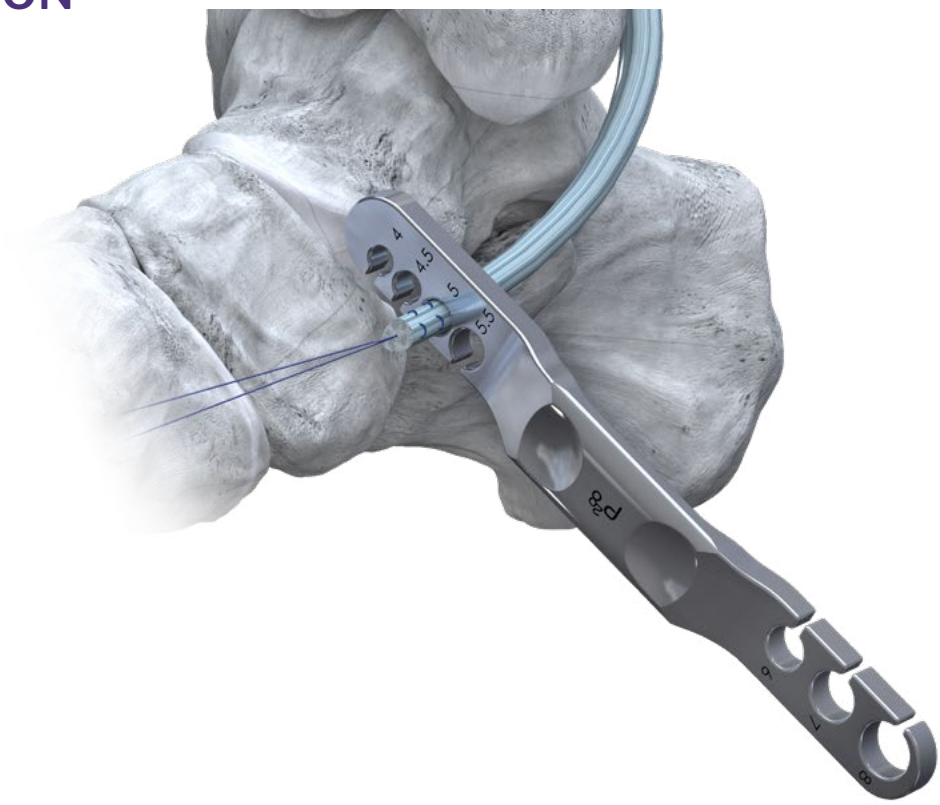
A resorbable size 0 suture is recommended for the through and through technique. Using this suture, place a whip stitch through the cut end of the FDL tendon. It is recommended to encompass approximately 10 mm of the cut tendon into the whip stitch.

Retrieve the Tendon Sizer.

NOTE: Trim the bulbous end of the whip stitched tendon if unable to slide the tendon through the Tendon Sizer.

FDL TENDON PREPARATION

Using the suture from the whip stitch, pull the tendon through the holes along the Tendon Sizer. The tendon size is measured as the last ring in which the tendon completely fills the inner diameter. For example, if the tendon fits within the Ø5.0 mm hole, but does not fit through the Ø4.5 mm hole, the tendon is sized as Ø5.0 mm.

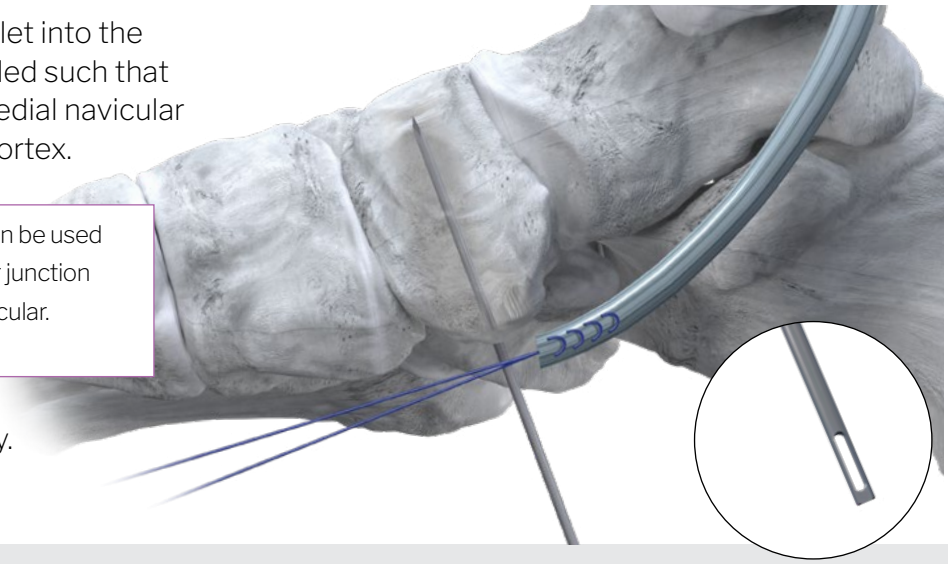


INTERFERENCE SCREW SELECTION AND INSERTION

Place the provided Ø1.6 mm K-wire with eyelet into the navicular in a plantar to dorsal direction, angled such that the wire trajectory begins inferiorly at the medial navicular tuberosity and extends through the dorsal cortex.

NOTE: Alternatively, a slightly angled trajectory can be used where the wire is directed from the medial plantar junction dorsolaterally, exiting out of the dorsal lateral navicular.

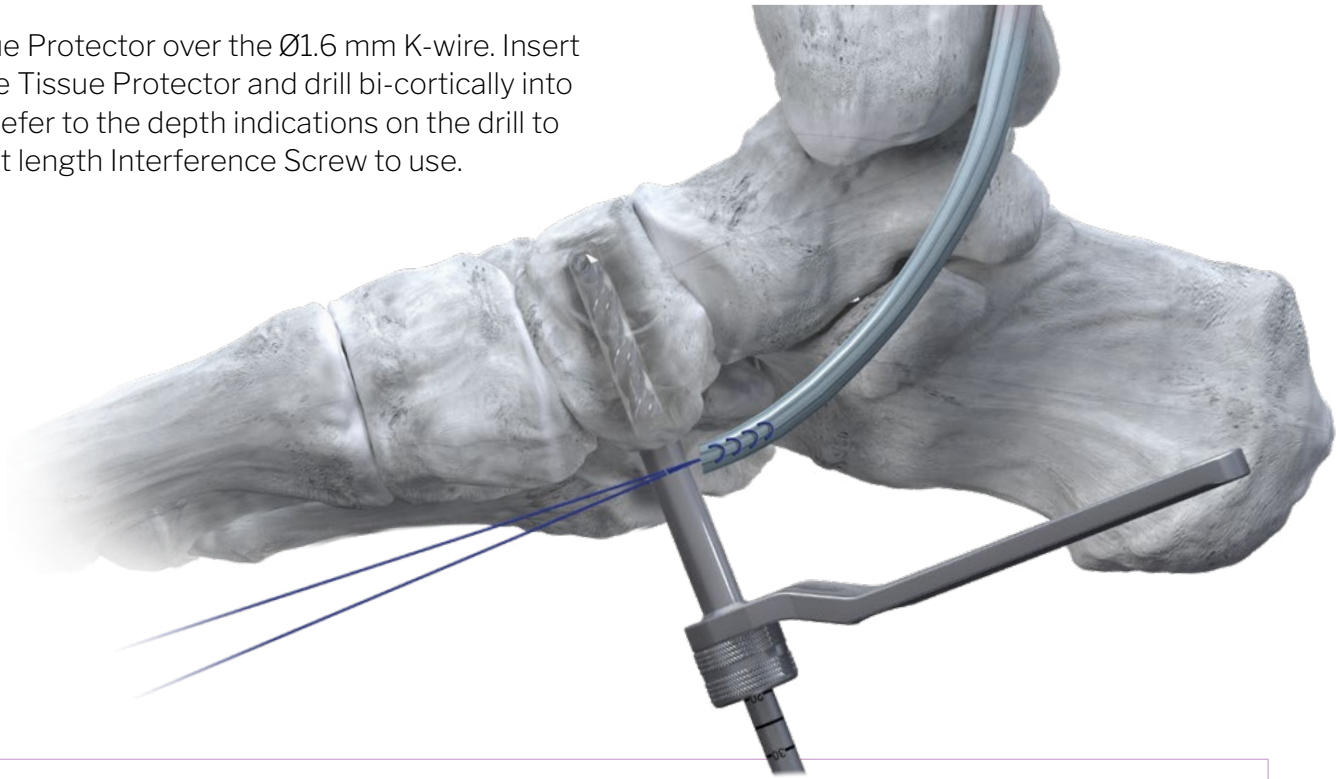
Confirm K-wire placement using fluoroscopy.



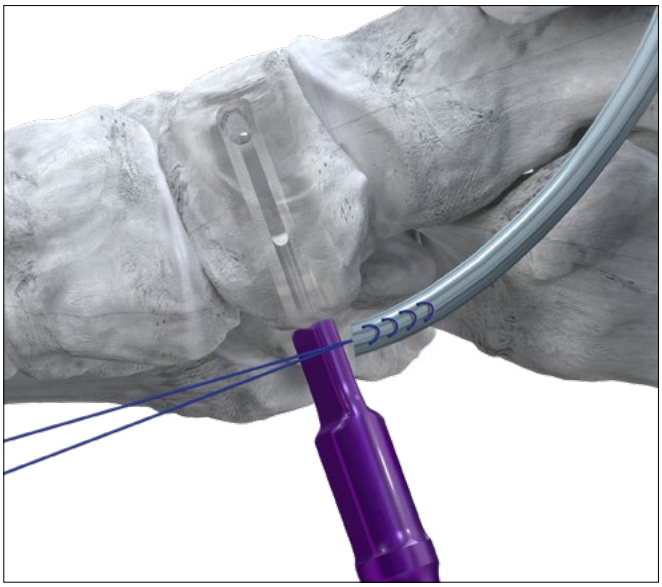
Refer to the Interference Screw sizing chart on page 5 for Drill and Interference Screw size. In this example, assuming normal bone quality, a Ø5.0 mm Drill and Ø5.0 mm Interference Screw will be used. Retrieve the Ø5.0 mm Tissue Protector Sleeve. Insert the Tissue Protector Sleeve into the Tissue Protector Handle by inserting the distal portion of the Tissue Protector Sleeve into the Handle and rotating it clockwise to tighten.

INTERFERENCE SCREW SELECTION AND INSERTION

Place the Tissue Protector over the Ø1.6 mm K-wire. Insert the Drill into the Tissue Protector and drill bi-cortically into the navicular. Refer to the depth indications on the drill to determine what length Interference Screw to use.

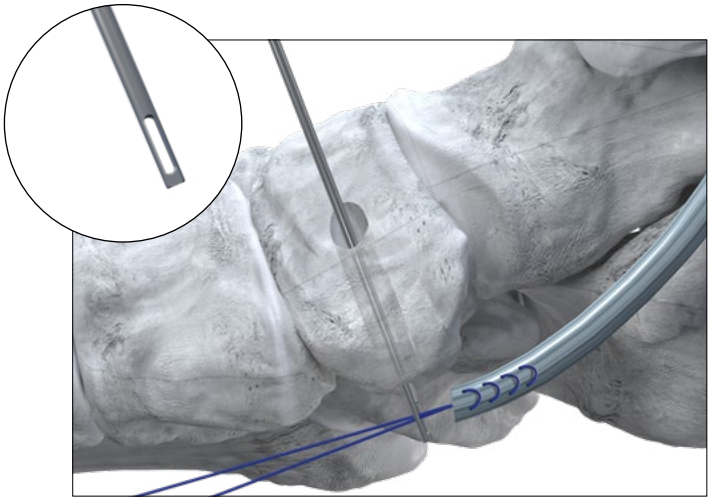


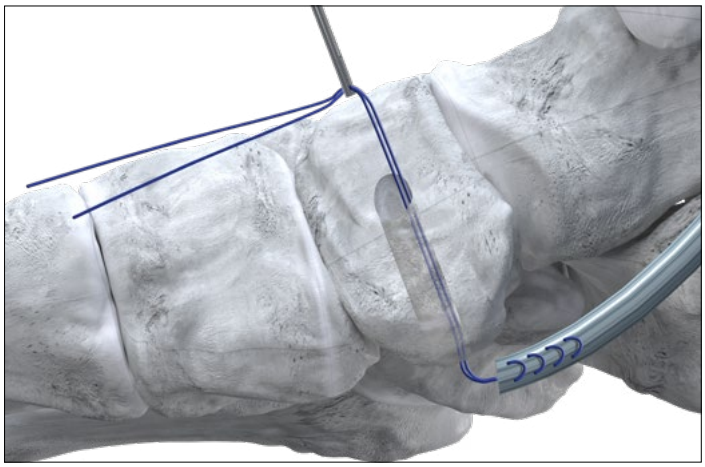
TIP: A Depth Gauge is provided as an alternative way to measure navicular length. Hook the far cortex and pull back to determine bone length, giving a reference for Interference Screw length required.



Remove the Drill and Tissue Protector.

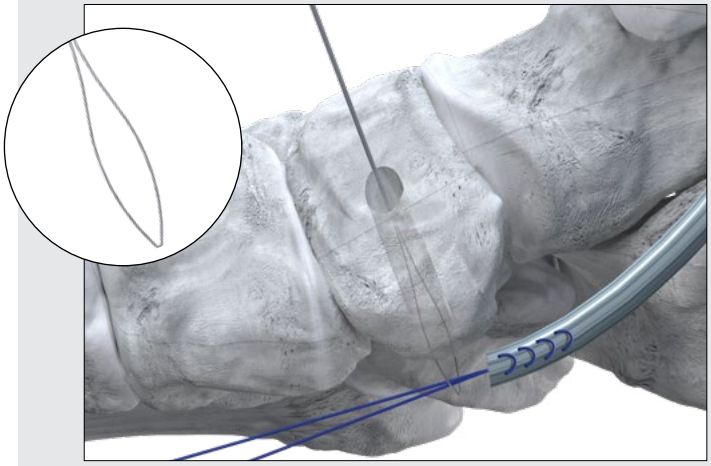
INTERFERENCE SCREW SELECTION AND INSERTION

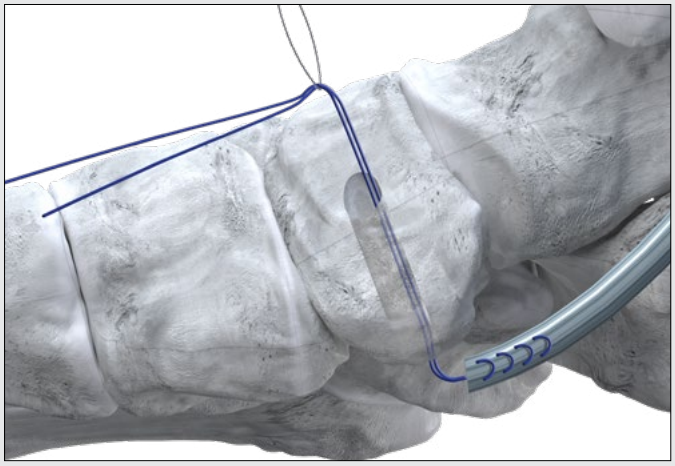




Pass the ends of the whip-stitched suture through the eyelet of the K-wire (using Suture Passer if necessary). Carefully pull the K-wire and captured suture dorsally through the tunnel. Pull the remainder of the suture ends through the tunnel and remove the K-wire.

ALTERNATIVE SUTURE PASSING METHOD:

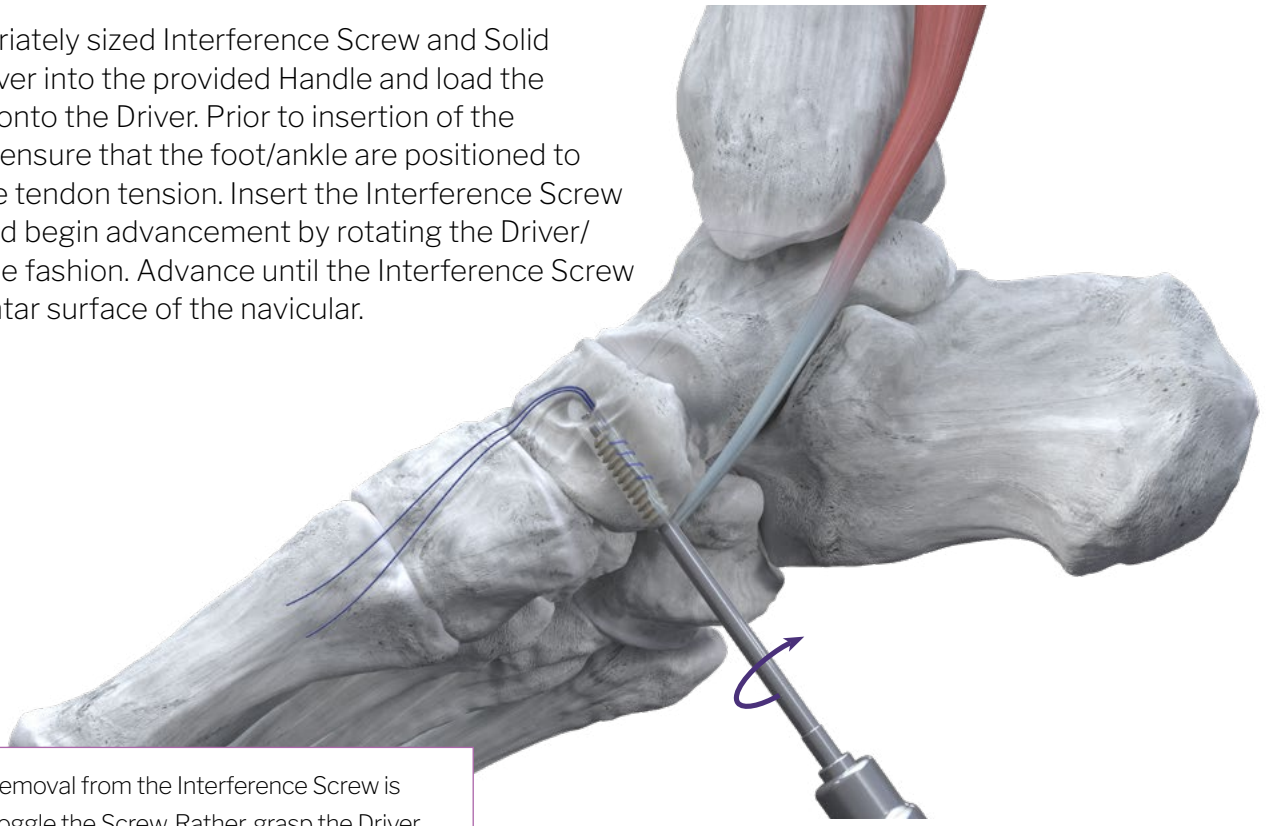




Remove the K-wire. Insert the ends of the whip-stitched suture in the FDL tendon into the loop of the Through & Through Suture Passer. Insert the Suture Passer plantar to dorsal through the drilled hole in the navicular. Pull the suture ends through the drilled hole and remove the Suture Passer. The sharp end of the Suture Passer can be pushed dorsally through the skin, if necessary.

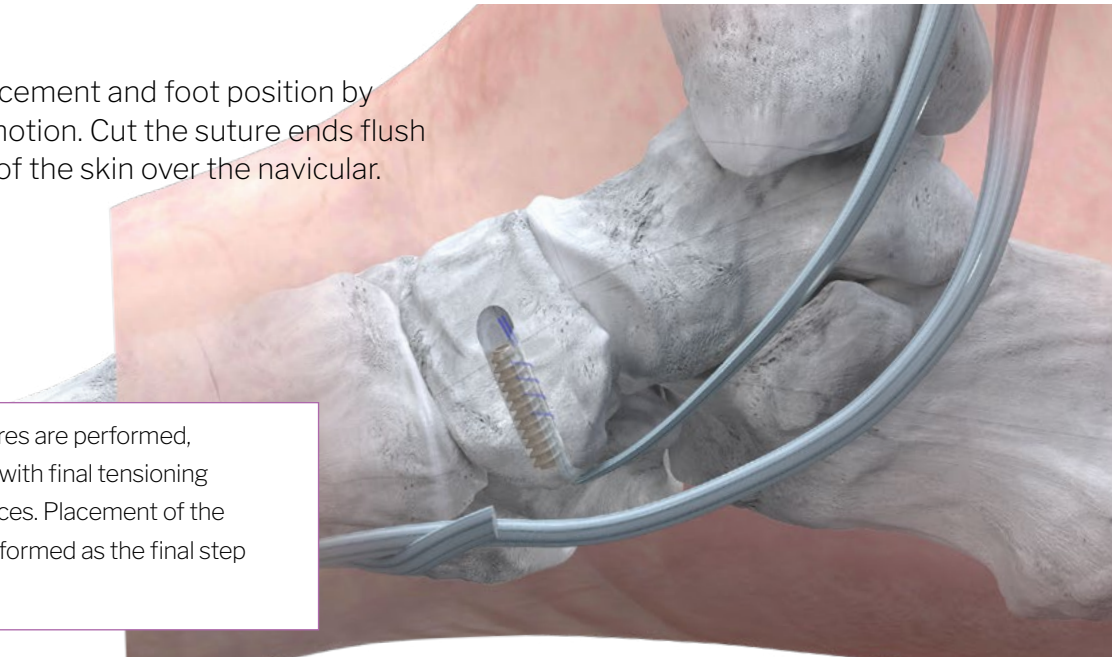
INTERFERENCE SCREW SELECTION AND INSERTION

Retrieve the appropriately sized Interference Screw and Solid Driver. Insert the Driver into the provided Handle and load the Interference Screw onto the Driver. Prior to insertion of the Interference Screw, ensure that the foot/ankle are positioned to allow for appropriate tendon tension. Insert the Interference Screw into the navicular and begin advancement by rotating the Driver/Handle in a clockwise fashion. Advance until the Interference Screw is flush with the plantar surface of the navicular.



NOTE: If Driver removal from the Interference Screw is difficult, do not toggle the Screw. Rather, grasp the Driver with a Kocher or plier-type instrument and gently tap the instrument inline with the Driver shaft to disengage the Driver from the Interference Screw.

Confirm Interference Screw placement and foot position by visual inspection and range of motion. Cut the suture ends flush to the skin at the dorsal aspect of the skin over the navicular.



NOTE: If concomitant procedures are performed, Interference Screw placement with final tensioning may vary per surgeon preferences. Placement of the Interference Screw may be performed as the final step of any combined procedure.

CLOSURE

Proceed to incision closure or other concomitant procedures at this time.

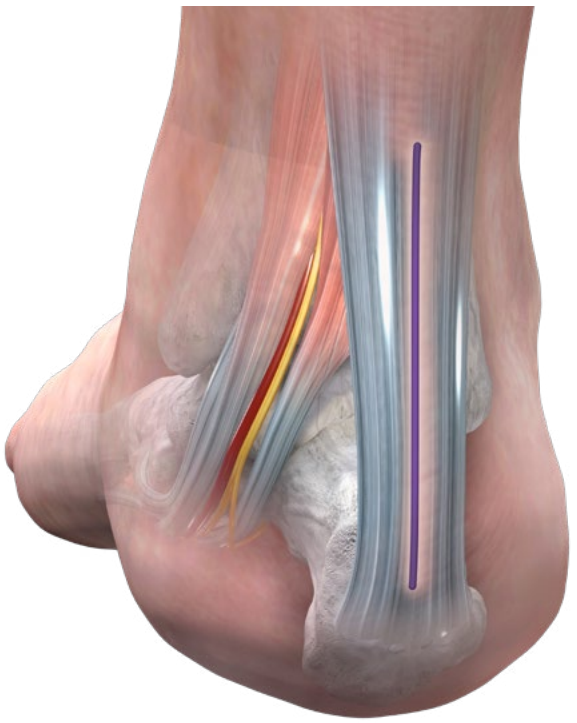
The technique demonstrated below is an FHL transfer for Achilles tendon augmentation to address chronic insertional Achilles tendonosis using a blind tunnel technique. Other applications of this technique can be performed for procedures such as chronic Achilles tendon rupture or tendon balancing with peroneal tendon deficiency, with modifications to the approach and exposure, per surgeon preference and experience.

INCISION/EXPOSURE

Prone patient positioning with a thigh tourniquet and fluoroscopy available is recommended.

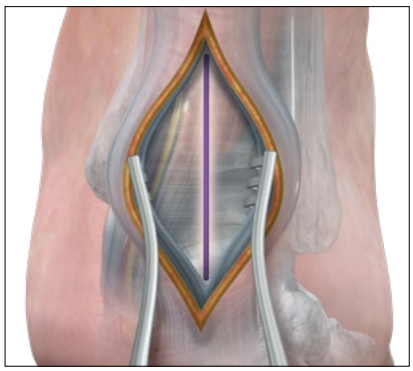
A longitudinal midline incision is made over the Achilles tendon, extending just distal to the insertion of the Achilles tendon over the posterior calcaneus.

Dissect straight to the level of paratenon, keeping a deep flap to avoid undermining below skin. Incise the paratenon at the midline and reflect medial and lateral to expose the Achilles tendon. Use a deep knife to make a longitudinal incision along the central midline of the Achilles tendon, extending proximally a few centimeters above the calcaneus and distally to the insertion of the Achilles tendon. Preservation or detachment of the most distal medial and distal lateral Achilles insertion may be performed, depending on the extent of pathology (not shown). Retraction of the Achilles tendon is performed and an exostectomy of the calcaneus is made (not shown).



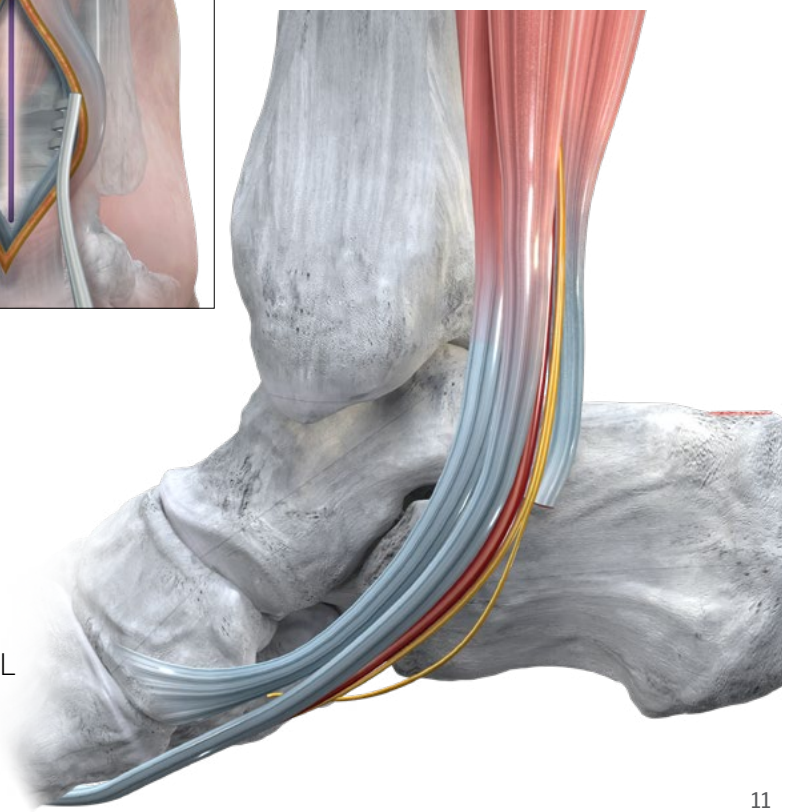
FHL TENDON HARVEST

With the Achilles tendon retracted medially and laterally, the deep posterior compartment fascia is visualized and incised longitudinally to expose the FHL muscle/tendon unit.



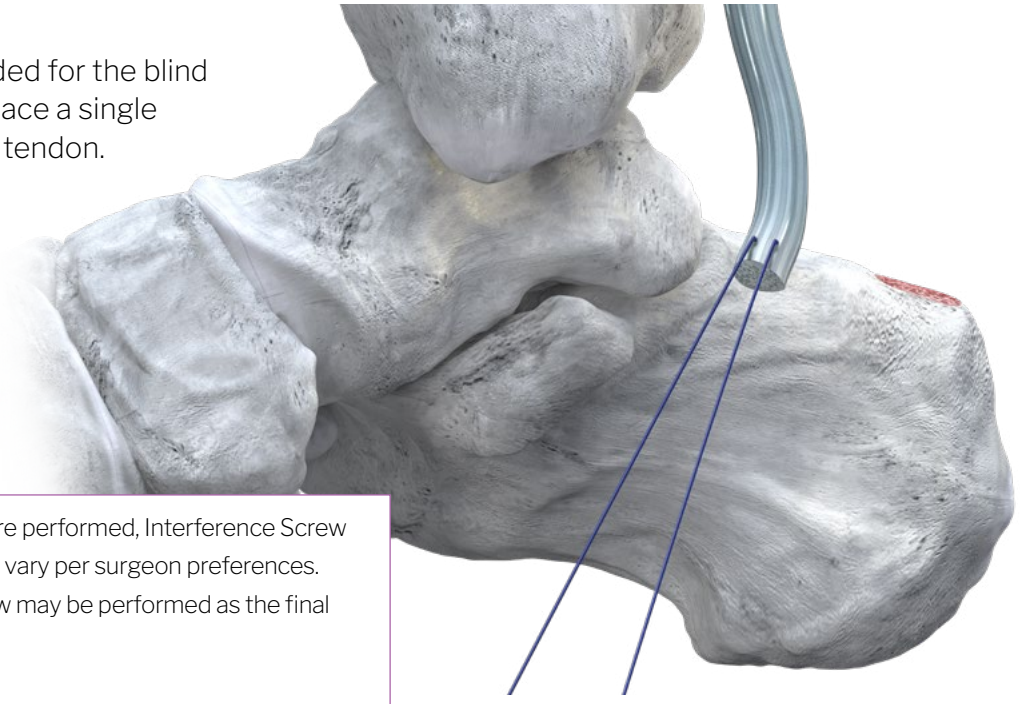
Continue following the FHL tendon distally until adequate tendon exposure is achieved. ***An assistant should maximally plantarflex the ankle and hallux interphalangeal joint to allow for maximal tendon harvest.***

While ensuring that the neurovascular bundle anterior to the tendon is protected, release the fibro-osseous tunnel posteriorly with scissors and then transect the FHL tendon using a deep knife directed in a medial to lateral and anterior to posterior direction.



FHL TENDON PREPARATION

A resorbable #2 suture is recommended for the blind tunnel technique. Using this suture, place a single stitch through the cut end of the FHL tendon.

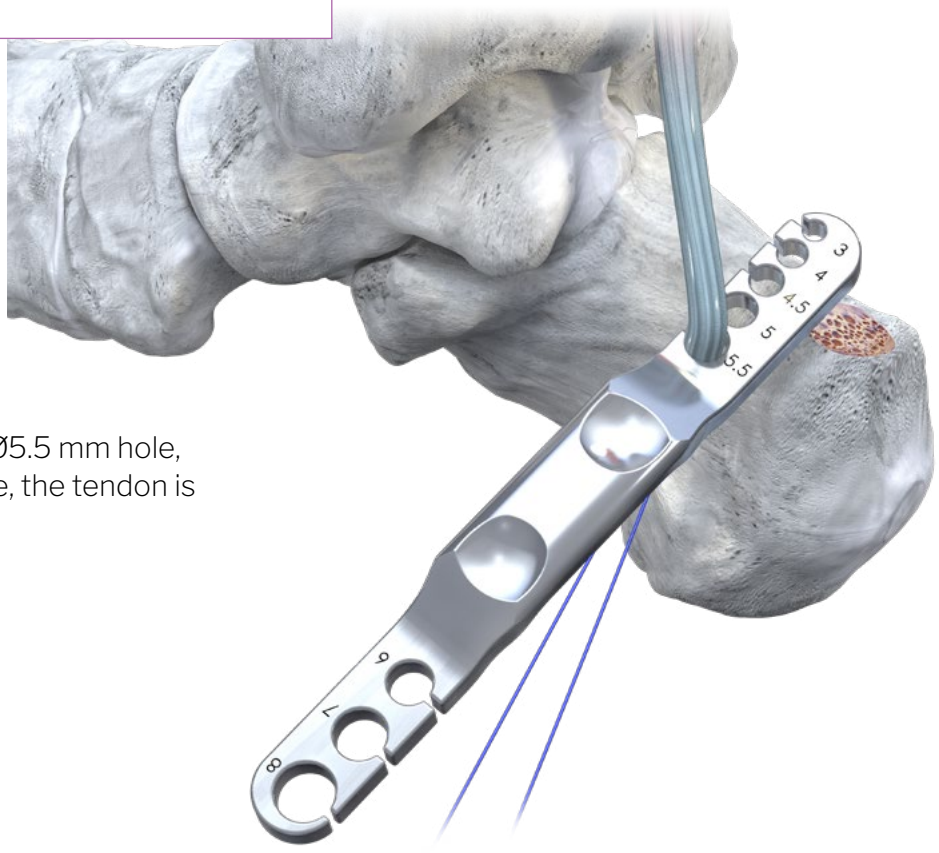


NOTE: If concomitant procedures are performed, Interference Screw placement with final tensioning may vary per surgeon preferences. Placement of the Interference Screw may be performed as the final step of any combined procedure.

Retrieve the Tendon Sizer.

NOTE: Trim the bulbous end of the tendon if unable to slide the tendon through the Tendon Sizer.

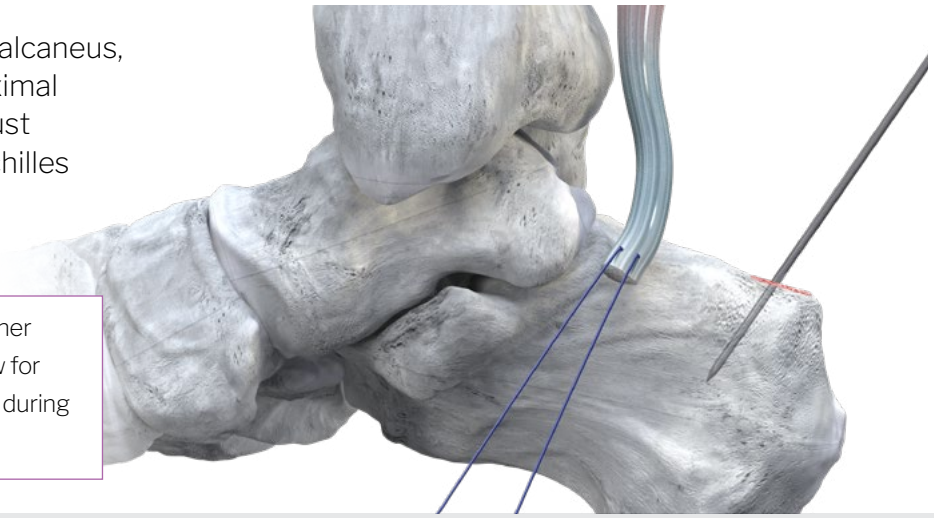
Using the suture from the single stitch, pull the tendon through the holes along the Tendon Sizer. The tendon size is measured as the last ring in which the tendon completely fills the inner diameter.



For example, if the tendon fits within the Ø5.5 mm hole, but does not fit through the Ø5.0 mm hole, the tendon is sized as Ø5.5 mm.

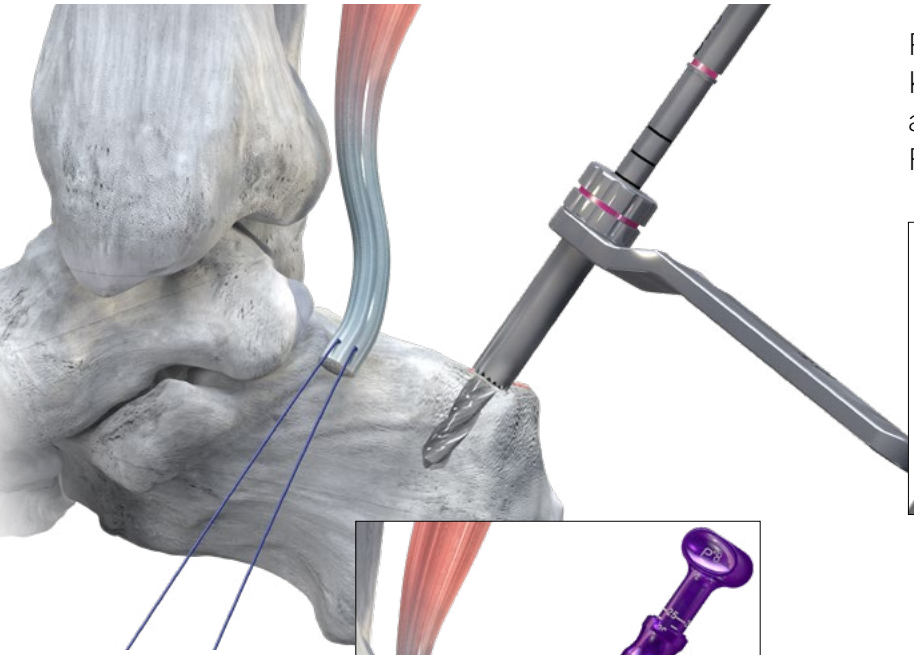
INTERFERENCE SCREW SELECTION AND INSERTION

Place the provided Ø1.6 mm K-wire into the calcaneus, angled such that the entry point is at the proximal dorsal aspect of the exostectomy centered just anterior to native proximal insertion of the Achilles tendon in the calcaneus.



NOTE: The K-wire may need to be inserted at a higher posterior to anterior angle in larger patients to allow for clearance between the calf muscle and the Handle during Interference Screw insertion.

Refer to the Interference Screw sizing chart on page 5 for Drill and Screw size. In this example, assuming normal bone quality, a Ø5.5 mm Drill and Ø5.5 mm Interference Screw will be used. Retrieve the Ø5.5 mm Tissue Protector Sleeve. Insert the Tissue Protector Sleeve into the Tissue Protector Handle by inserting the distal portion of the sleeve into the Handle and rotating it clockwise to tighten.

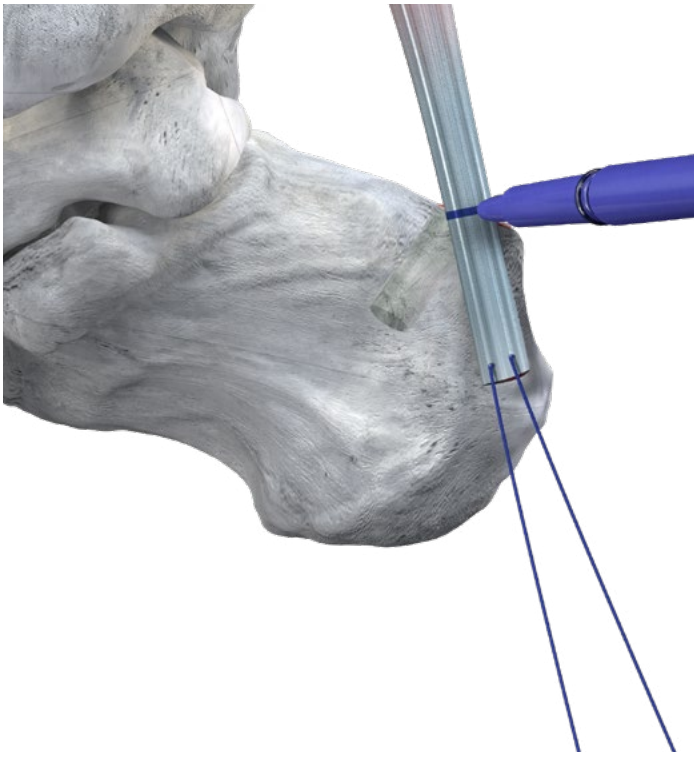


Place the Tissue Protector over the Ø1.6 mm K-wire. Insert the Drill into the Tissue Protector and drill into the calcaneus to a desired depth. Remove the Drill, Tissue Protector and K-wire.

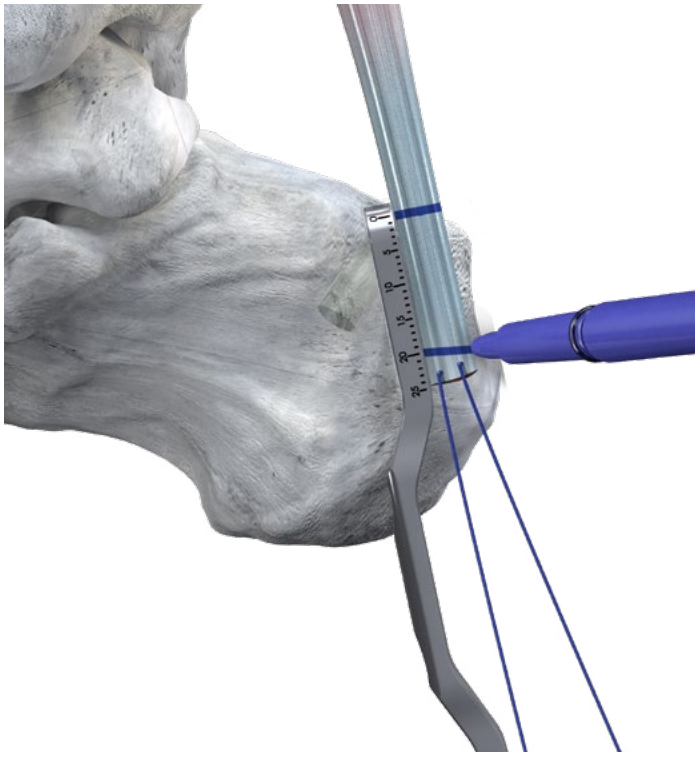
Interference Screw length can be measured off the laser marked depth indications on the Drill.

Alternatively, a Depth Gauge is provided to measure calcaneal length by measuring drilled depth to give a reference for Interference Screw length required. Typically, a 15 mm or 20 mm Screw length is appropriate for this indication.

INTERFERENCE SCREW SELECTION AND INSERTION



Tension the FHL tendon plantarly. Using a marking pen, mark the FHL tendon at the bone tunnel.

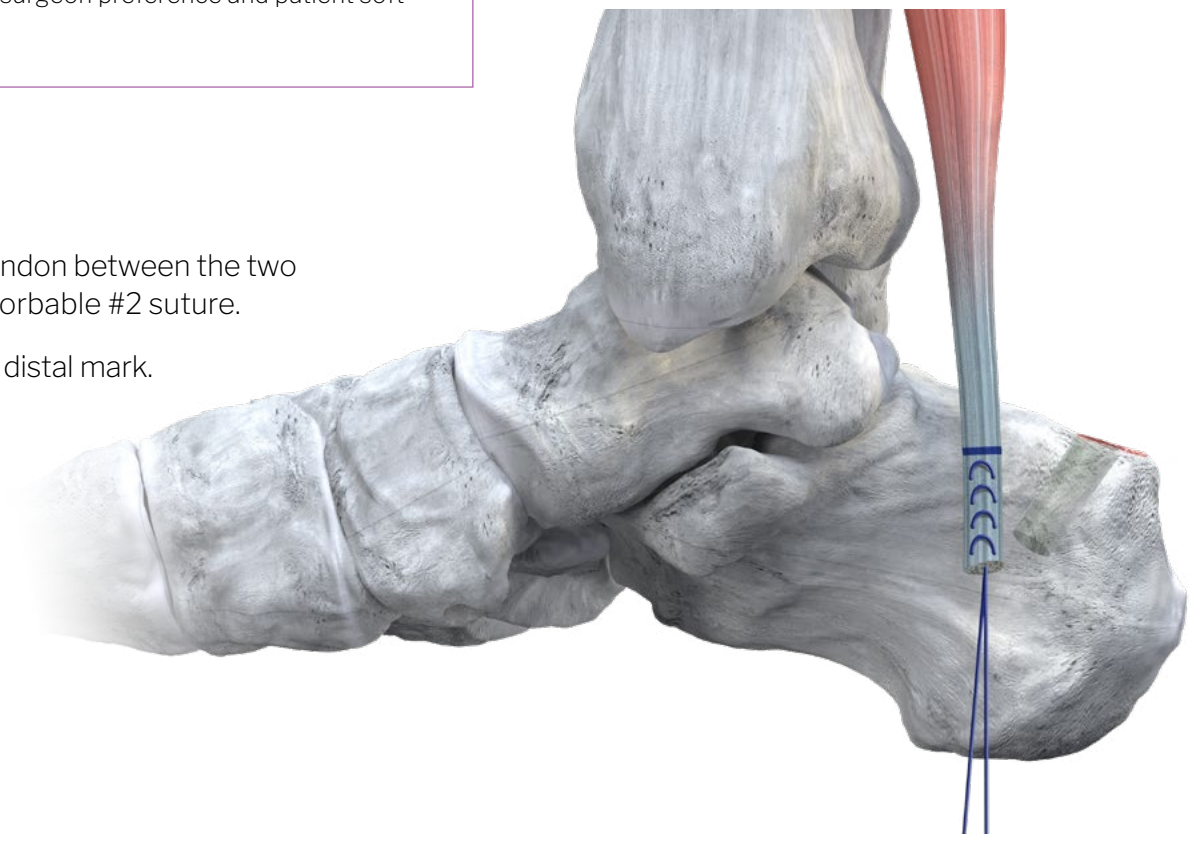


Make a second mark plantar to the first, equating to the intended Screw length.

NOTE: During tensioning, sagittal plane position of the foot/ankle may vary, per surgeon preference and patient soft tissue pliability.

Whip stitch the FHL tendon between the two marked lines using resorbable #2 suture.

Trim the tendon at the distal mark.

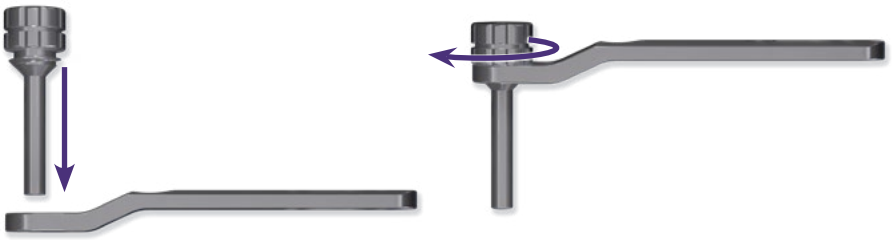


INTERFERENCE SCREW SELECTION AND INSERTION

ON THE BACK TABLE:

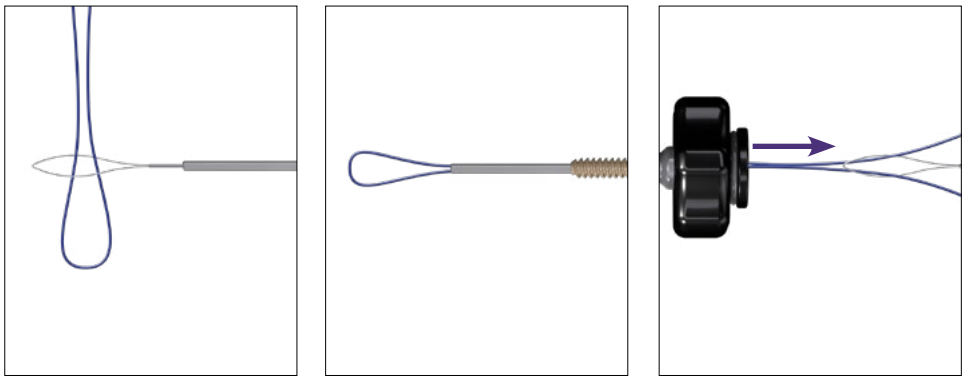
1. Refer to the Interference Screw sizing chart to retrieve the appropriately sized cannulated Driver and Driver Sleeve. Assemble the Driver to the Blind Tunnel Driver Handle.

2. Insert the Driver Sleeve into the Tissue Protector Handle by inserting the distal portion of the sleeve into the Handle and rotating it clockwise to tighten.

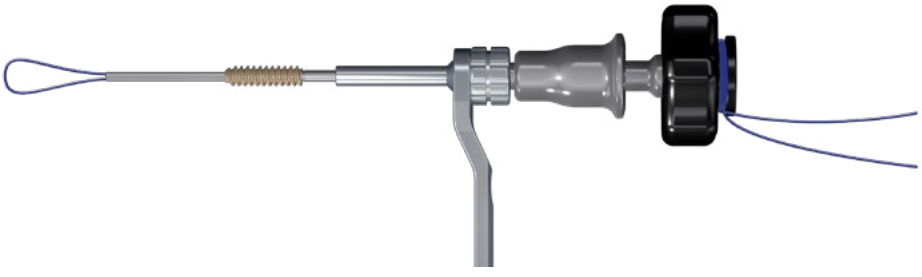


3. Slide the Driver Sleeve construct over the cannulated Driver, until the construct is retained by the Handle. Retrieve the appropriately sized Interference Screw and slide over the Driver. The Interference Screw will self-retain proximally on the Driver. Insert the Blind Tunnel Suture Passer through the construct, with the loop positioned distal to the Driver.

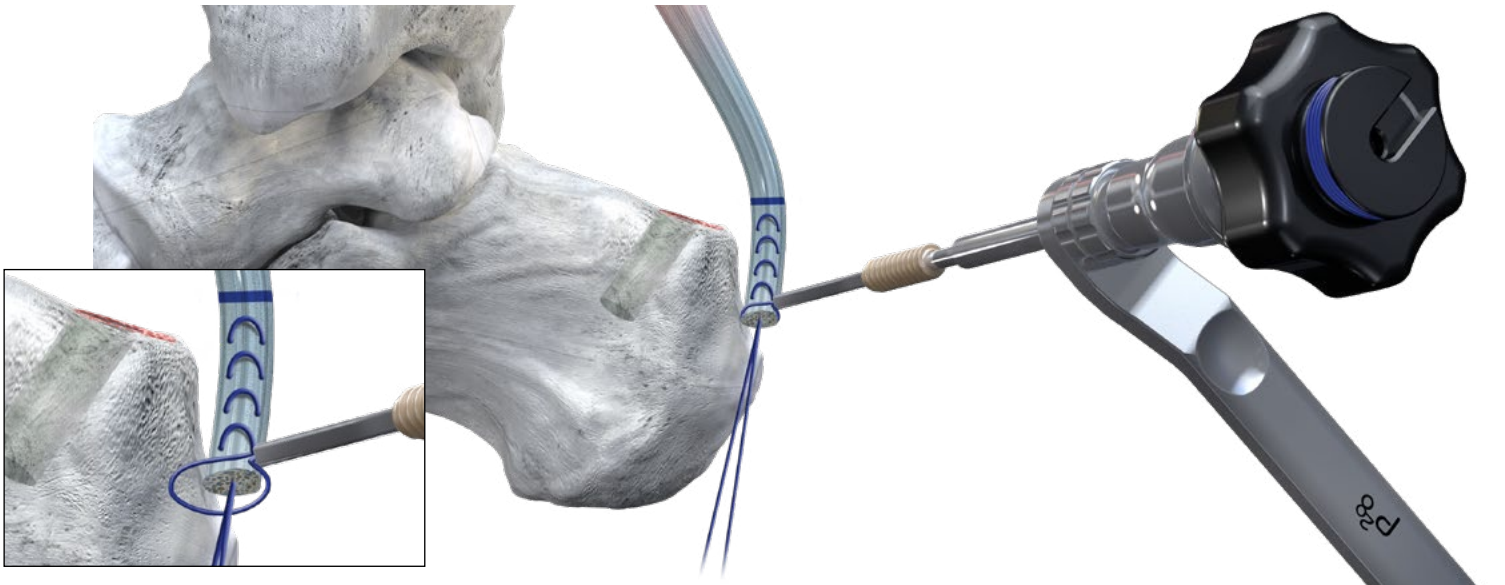
4. Using the Blind Tunnel Suture Passer, pass an additional size resorbable #2 suture through the Driver and Handle in a distal to proximal direction to create a loop at the distal end of the Driver. The suture loop should be held by the surgeon or assistant while the Suture Passer exits the proximal end of the Handle.



5. Wrap the proximal end of the suture around the cleat to temporarily secure the suture loop.



INTERFERENCE SCREW SELECTION AND INSERTION



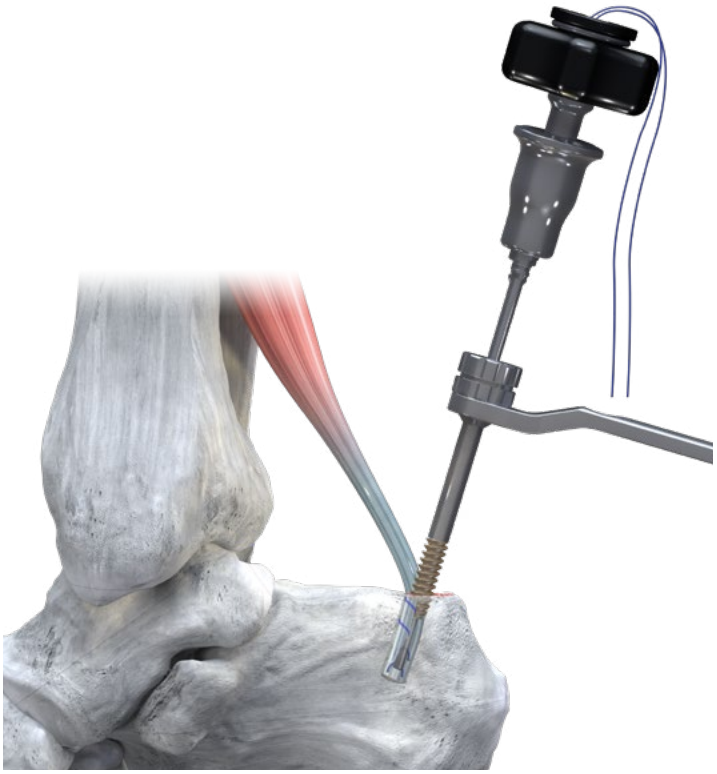
Using the loop of the suture through the Driver, snare the end of the FHL tendon. Unwrap the suture ends from the suture cleat. Tighten the suture snare around the tendon by pulling the suture ends away from the back of the Handle.

Secure the suture to the Handle by wrapping the suture ends around the suture cleat at the end of the Handle.

Prior to insertion of the Interference Screw, ensure that the foot/ankle are positioned to allow for appropriate tendon tension.

Place the snared FHL tendon and Driver tip within the drilled hole.

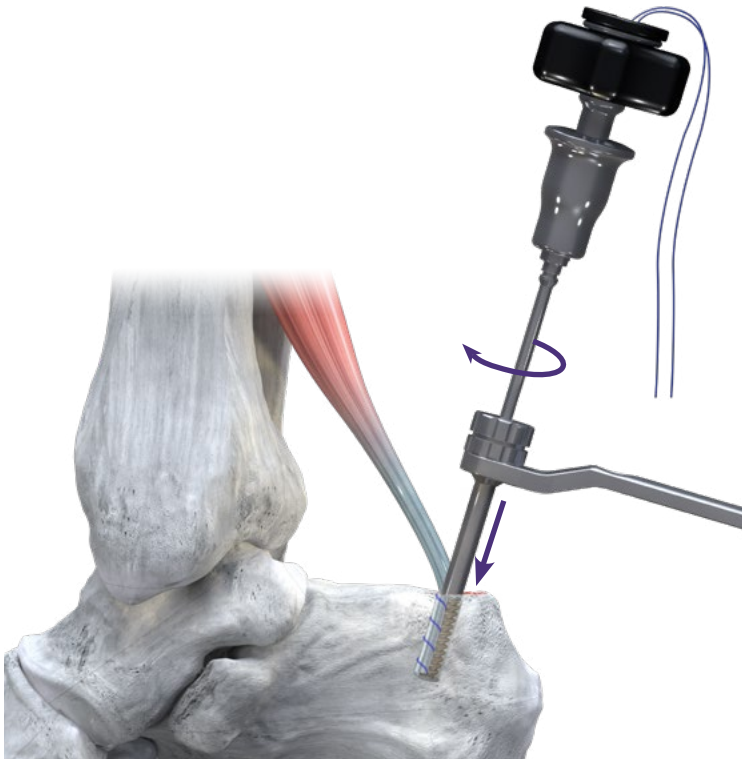
INTERFERENCE SCREW SELECTION AND INSERTION



TIP: Do not apply pressure through the Blind Tunnel Handle upon insertion.

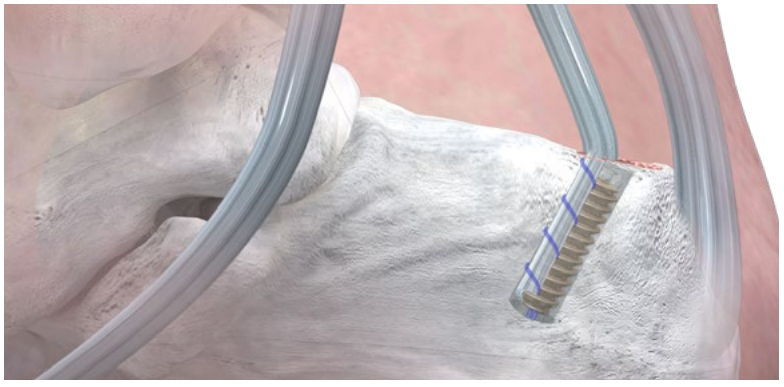
Using the Driver Sleeve, apply downward pressure on the Interference Screw until it abuts the tendon/bone tunnel using the surgeon's non-dominant hand. Unwrap the suture from the suture cleat of the Blind Tunnel Handle. With the surgeon's dominant hand, rotate the Driver/Handle in a clockwise fashion.

Confirm Interference Screw placement and foot position by visual inspection and range of motion.



Advance the Interference Screw until it is flush or slightly countersunk relative to the dorsal surface of the calcaneus. Remove the Driver from the Interference Screw.

NOTE: If Driver removal from the Interference Screw is difficult, do not toggle the Screw. Rather, grasp the Driver with a Kocher or plier-type instrument and gently tap the instrument to remove the Driver from the Interference Screw inline with the Driver shaft to disengage the Driver from the Screw.



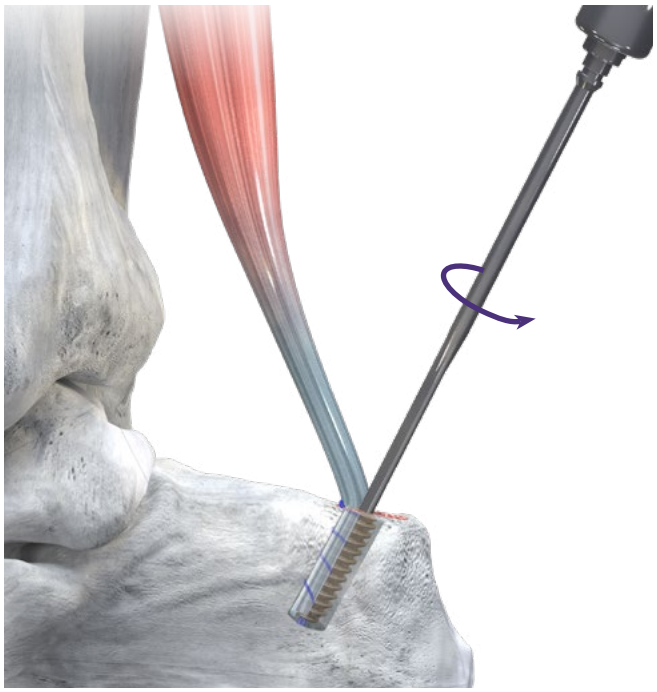
CLOSURE

Proceed to Achilles tendon repair and incision closure or concomitant procedures at this time.

INTERFERENCE SCREW REMOVAL

Perform incision and soft tissue dissection to expose the proximal end of the Interference Screw. Retrieve the Driver size that matches the Interference Screw size. Insert the Driver into the Interference Screw until completely inserted.

Rotate the Driver in a counterclockwise fashion to back out the Interference Screw until completely out of the bone, and pass from operative field. Perform revision procedure per surgeon preference.



THE GRAPPLER® INTERFERENCE SCREW SYSTEM CADDY

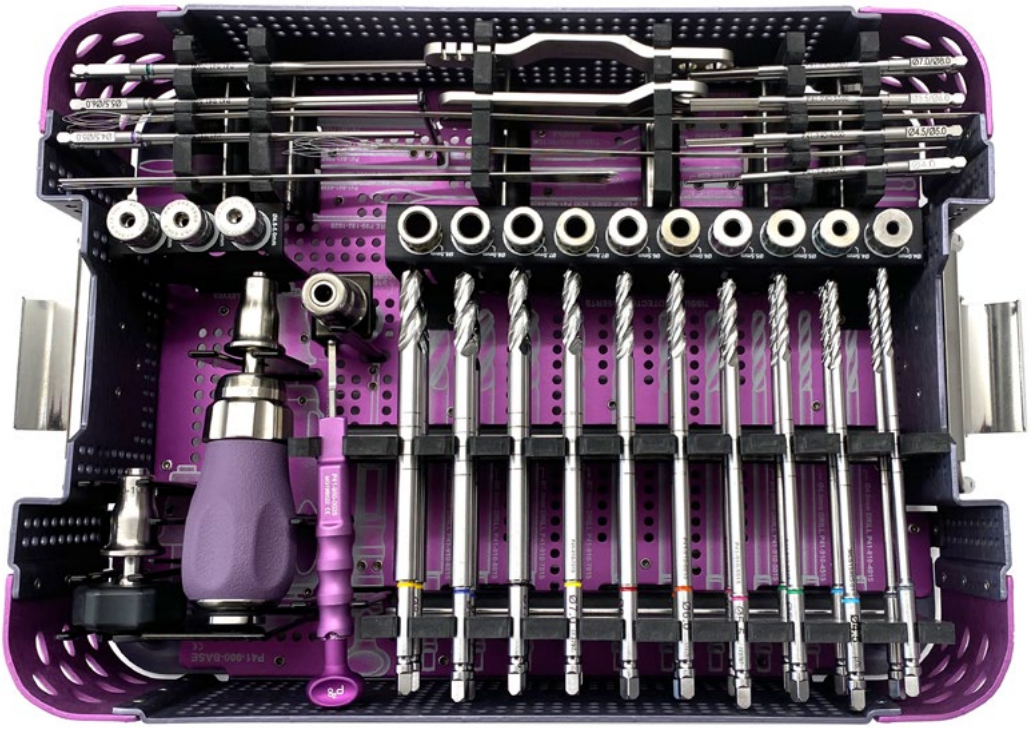
Grappler® Interference Screw System Non-Sterile Case

Reusable Items Include:

- Solid and Cannulated Drivers
- Driver Sleeves
- Tissue Protector Inserts
- Tissue Protector Handle
- Tendon Sizer
- Depth Gauge
- Jacobs Adapter
- AO Handles

Single-Use Items Include:

- Size-Specific Cannulated Drills
- Through & Through and Blind Tunnel Suture Passers
- Eyelet K-wires



The Grappler® Interference Screw Caddy

Part #	Description	Use
P41-040-1000-S	Grappler™ PEEK Interference Screw 4 x 10mm	Single use
P41-040-1500-S	Grappler™ PEEK Interference Screw 4 x 15mm	Single use
P41-040-2000-S	Grappler™ PEEK Interference Screw 4 x 20mm	Single use
P41-045-1000-S	Grappler™ PEEK Interference Screw 4.5 x 10 mm	Single use
P41-045-1500-S	Grappler™ PEEK Interference Screw 4.5 x 15mm	Single use
P41-045-2000-S	Grappler™ PEEK Interference Screw 4.5 x 20mm	Single use
P41-050-1000-S	Grappler™ PEEK Interference Screw 5 x 10mm	Single use
P41-050-1500-S	Grappler™ PEEK Interference Screw 5 x 15mm	Single use
P41-050-2000-S	Grappler™ PEEK Interference Screw 5 x 20mm	Single use
P41-050-2500-S	Grappler™ PEEK Interference Screw 5 x 25mm	Single use
P41-055-1500-S	Grappler™ PEEK Interference Screw 5.5 x 15mm	Single use
P41-055-2000-S	Grappler™ PEEK Interference Screw 5.5 x 20mm	Single use
P41-055-2500-S	Grappler™ PEEK Interference Screw 5.5 x 25mm	Single use
P41-060-1500-S	Grappler™ PEEK Interference Screw 6 x 15mm	Single use
P41-060-2000-S	Grappler™ PEEK Interference Screw 6 x 20mm	Single use
P41-060-2500-S	Grappler™ PEEK Interference Screw 6 x 25mm	Single use
P41-070-2000-S	Grappler™ PEEK Interference Screw 7 x 20mm	Single use
P41-070-2500-S	Grappler™ PEEK Interference Screw 7 x 25mm	Single use
P41-080-2000-S	Grappler™ PEEK Interference Screw 8 x 20mm	Single use
P41-080-2500-S	Grappler™ PEEK Interference Screw 8 x 25mm	Single use
P68-101-0000-SK	Mister Tendon Harvester System, Sterile Kit	Single use

GRAPPLER® Interference Screw System Instruments

Part #	Description	Use
P41-910-4015	Ø4.0 x 15cm Length, Cannulated Drill w/ Depth Markings	Single use
P41-910-4515	Ø4.5 x 15cm Length, Cannulated Drill w/ Depth Markings	Single use
P41-910-5015	Ø5.0 x 15cm Length, Cannulated Drill w/ Depth Markings	Single use
P41-910-5515	Ø5.5 x 15cm Length, Cannulated Drill w/ Depth Markings	Single use
P41-910-6015	Ø6.0 x 15cm Length, Cannulated Drill w/ Depth Markings	Single use
P41-910-6515	Ø7.0 x 15cm Length, Cannulated Drill w/ Depth Markings	Single use
P41-910-7515	Ø7.5 x 15cm Length, Cannulated Drill w/ Depth Markings	Single use

GRAPPLER® Interference Screw System Instruments

Part #	Description	Use
P41-910-8015	Ø8.0 x 15cm Length, Cannulated drill w/ Depth Markings	Single use
P41-910-8515	Ø8.5 x 15cm Length, Cannulated Drill w/ Depth Markings	Single use
P41-910-8515	Tendon Sizer	Reusable
P41-920-0001	Tissue Protector Handle	Reusable
P41-930-4000	Tissue Protector Insert Ø4.0	Reusable
P41-930-4500	Tissue Protector Insert Ø4.5	Reusable
P41-930-5000	Tissue Protector Insert Ø5.0	Reusable
P41-930-5500	Tissue Protector Insert Ø5.5	Reusable
P41-930-6000	Tissue Protector Insert Ø6.0	Reusable
P41-930-6500	Tissue Protector Insert Ø6.5	Reusable
P41-930-7000	Tissue Protector Insert Ø7.0	Reusable
P41-930-7500	Tissue Protector Insert Ø7.5	Reusable
P41-930-8000	Tissue Protector Insert Ø8.0	Reusable
P41-930-8500	Tissue Protector Insert Ø8.5	Reusable
P41-940-3040	Ø4.0 Driver, Solid	Reusable
P41-940-4550	Ø4.5/5.0 Driver, Solid	Reusable
P41-940-5560	Ø5.5/6.0 Driver, Solid	Reusable
P41-940-7080	Ø7.0/8.0 Driver, Solid	Reusable
P41-941-4550	Ø4.5/5.0 Driver, Cannulated	Reusable
P41-941-5560	Ø5.5/6.0 Driver, Cannulated	Reusable
P41-941-7080	Ø7.0/8.0 Driver, Cannulated	Reusable
P41-942-4550	Ø4.5/5.0 Driver Sleeve	Reusable
P41-942-5560	Ø5.5/6.0 Driver Sleeve	Reusable
P41-942-7080	Ø7.0/8.0 Driver Sleeve	Reusable
P41-950-0025	GRAPPLER™ Depth Gauge, 25mm	Reusable
P41-960-0020	Through-Hole Suture Loop Guide Rod w/ Nitinol Loop	Single-Use
P41-960-0030	Blind-Tunnel Suture Loop Guide Rod w/ Nitinol Loop	Single-Use
P41-980-1000	Blind Tunnel Driver Handle w/ AO Connect w/ Suture Cleat	Reusable
P99-000-AORP	PALM Ratcheting Driver Handle w/ AO Connect w/ Suture Cleat	Reusable
P99-000-316A	3/16” Square/Jacobs Adapter	Reusable
P99-197-1620	Ø1.6 x 200mm K-Wire with Eyelet	Single-Use

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

INDICATIONS FOR USE

The Grappler Interference Screw System is intended for soft tissue to bone repair including ligament and tendon reconstruction in foot and ankle surgery. The Grappler Interference Screw System instruments are used to facilitate the implantation of the Grappler Interference Screw.

The drill is an orthopedic drill surgical instrument consisting in a shaft of metal with a cutting edge designed to be rotated to bore into bone to create a hole. Wires are intended for the temporary fixation of bone fractures, positioning of implants, and guiding of instruments.

The Grappler Interference Screw System is indicated for:

- Lateral Ankle Instability
  - Lateral Ankle Stabilization Procedure
  - Brostrum Procedure
  - Brostrum Gould Procedure
  - Syndesmosis Repair Procedure

- Achilles Tendon Repair/Reconstruction
  - Flexor Hallucis Longus Transfer Procedure

- Flatfoot Deformity ("Adult Acquired Flatfoot Deformity" or "Progressive Collapsing Flatfoot Deformity") with one or more of the following clinical findings - deformity, synovitis, tendinosis, posterior tibial tendon dysfunction, deltoid insufficiency, and valgus deformity
  - Deltoid Ligament Reconstruction Procedure
  - Flexor Digitorum Longus Transfer Procedure
  - Spring Ligament Repair Procedure
  - Flexor Hallucis Longus Transfer Procedure

- Neurogenic Dropfoot
  - Posterior Tibial Tendon Transfer Procedure

- Pes Cavus Deformity
  - Lateral Ankle Stabilization Procedure

- Tarsal Coalition
  - Flexor Digitorum Longus Transfer Procedure

CONTRAINDICATIONS

The Paragon 28® Grappler® Interference Screw System implants are not designed or sold for any use except as indicated. Use of the Grappler® Interference Screw System is contraindicated in the following situations:

- Active, suspected or latent infection in the affected area
- Patients who are physiologically or psychologically inadequate
- Patients who are hypersensitive or allergic to device materials
- Insufficient quantity or quality of bone to permit stabilization, conditions that retard healing (not including pathological fractures) and conditions causing poor blood supply
- In patients where there is a possibility for conservative treatment
- Indications not included in the **INDICATIONS FOR USE**

POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS

In any surgical procedure, the potential for complications and adverse reactions exist. The risks and complications with these implants include:

- Loosening, deformation or fracture of the implant
- Acute post-operative infections and late infections with possible sepsis
- Migration, subluxation of the implant
- Thrombosis and embolism
- Wound hematoma and delayed wound healing
- Temporary and protracted functional neurological perturbation
- Tissue reactions as a result of allergy or foreign body reaction to dislodged particles or implant material
- Pain, a feeling of malaise or abnormal sensations due to the implant used
- Bone resorption or over-production
- Nonunion or delayed union

All possible complications listed here are not typical of Paragon 28®, Inc. products but are in principle observed with any implant. Promptly inform Paragon 28®, Inc. as soon as complications occur in connection with the implants or surgical instruments used. In the event of premature failure of an implant in which a causal relationship with its geometry, surface quality or mechanical stability is suspected, please provide Paragon 28®, Inc. with the explant(s) in a cleaned, disinfected and sterile condition. Paragon 28®, Inc. cannot accept any other returns of used implants. The surgeon is held liable for complications associated with inadequate asepsis, inadequate preparation of the osseous implant bed in the case of implants, incorrect indication or surgical technique or incorrect patient information and consequent incorrect patient behavior.

WARNINGS AND PRECAUTIONS

- Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
- Use of an undersized implant in areas of high functional stresses may lead to implant fracture and failure.
- Implants, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
- The implants are intended for single use only.
- Instruments and implants are to be treated as sharps.
- **Do not use other manufacturer's instruments or implants in conjunction with the Grappler® Interference Screw System.**
- **Do not resterilize the Grappler® Interference Screw System Implants.**

MR SAFETY INFORMATION

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.

MR

GRAPPLER®
INTERFERENCE SCREW SYSTEM

PATENTED, DESIGNED & EXCLUSIVELY DISTRIBUTED BY

Exclusively foot & ankle Paragon 28®

P41-STG-2001 Rev A [2024-09-04]

Paragon 28, Inc.
14445 Grasslands Dr.
Englewood, CO 80112 US
(855) 786-2828

1. Kurtz S, Devine J, PEEK Biomaterials in Trauma, Orthopedic, and Spinal Implants. Biomaterials. 2007. Nov 28 (32); 4845-4869.

DISCLAIMER

The purpose of the Grappler® Interference Screw System Surgical Technique Guide is to demonstrate the optionality and functionality of the Grappler® Interference Screw implants and instrumentation. Although variations in placement and use of the Grappler® Interference Screw implants can be performed, the fixation options demonstrated in this technique were chosen to demonstrate the functionality of the system and for simplicity of explanation. Other uses for the Grappler® Interference Screw Screws can be employed, appropriate for the size of the device.