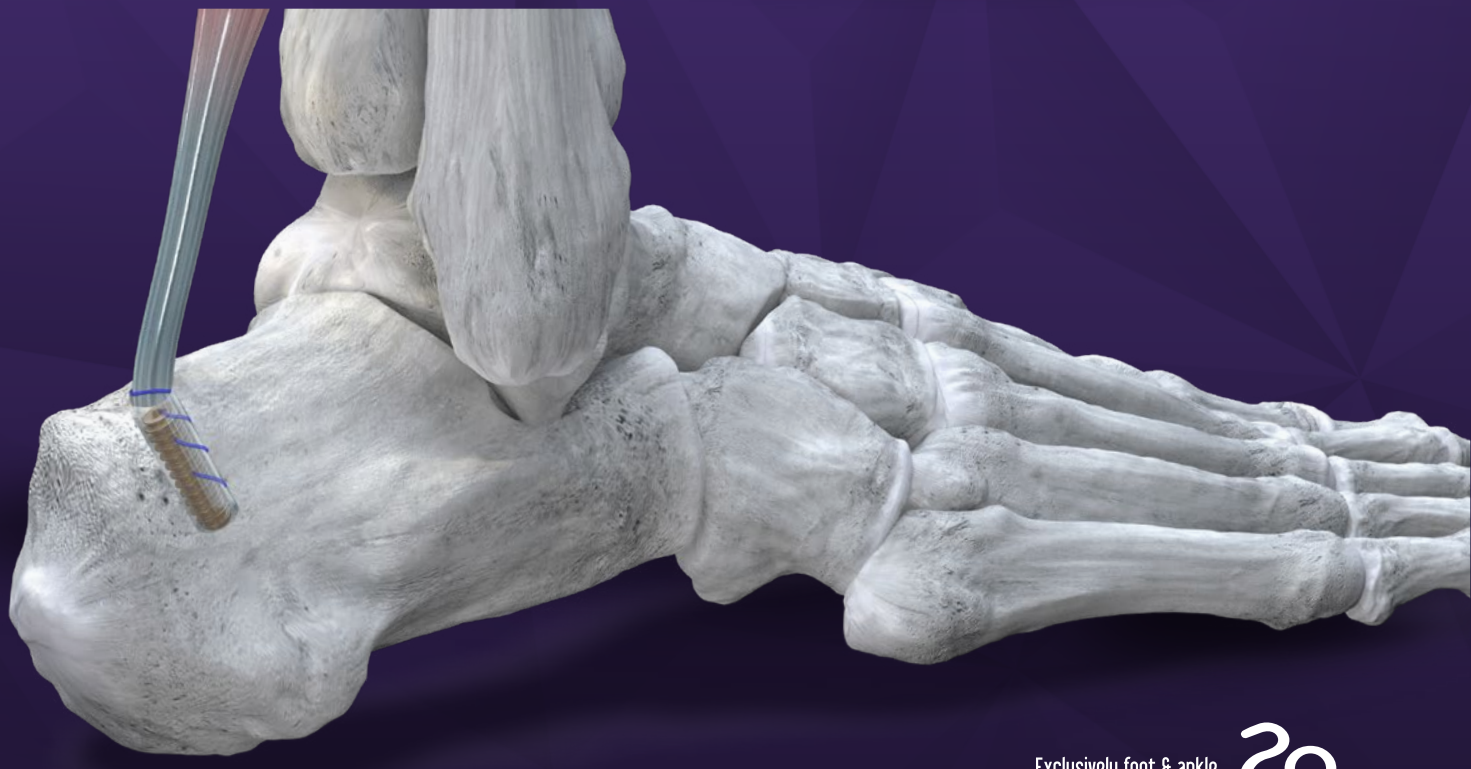
# GRAPPLER®
# INTERFERENCE SCREW SYSTEM

## 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.

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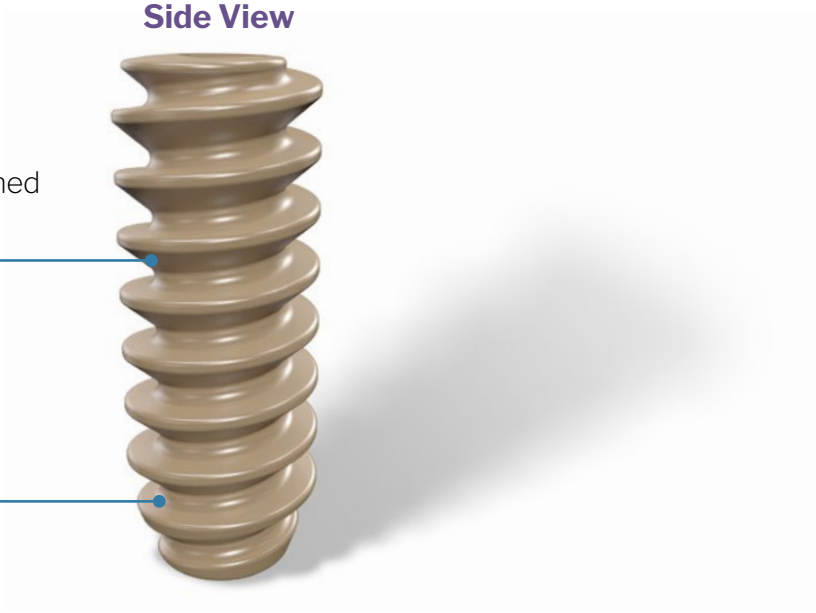
# INTERFERENCE SCREW OFFERING

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

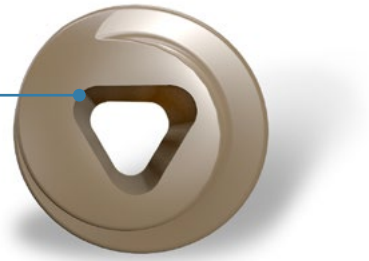
### Side View

- 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 |
|---|---|---|---|---|---|---|---|
| Ø10 mm | ● | ● | ● | | | | |
| Ø15 mm | ● | ● | ● | ● | ● | | |
| Ø20 mm | ● | ● | ● | ● | ● | ● | ● |
| Ø25 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

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

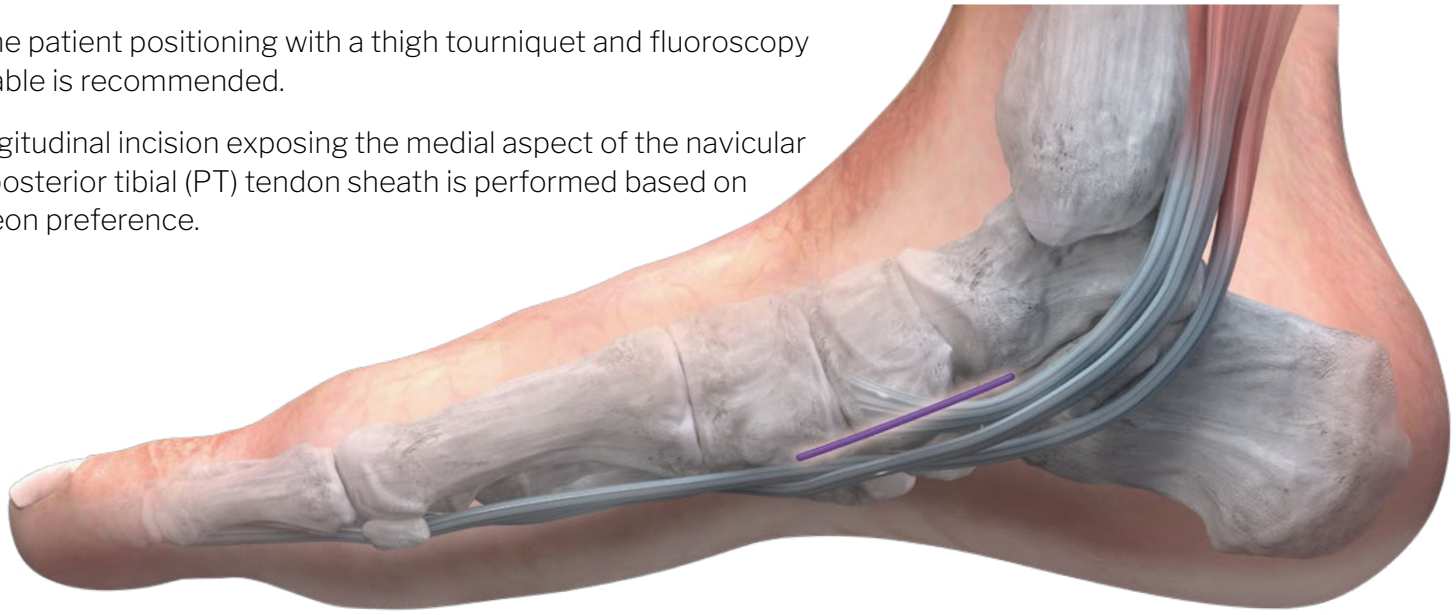
| Tissue Protector Insert Size | Drill Size* | Color Band |
|---|---|---|
| Ø6.5 mm | Ø6.5 mm |  |
| Ø7.5 mm | Ø7.5 mm |  |
| Ø8.5 mm | Ø8.5 mm |  |

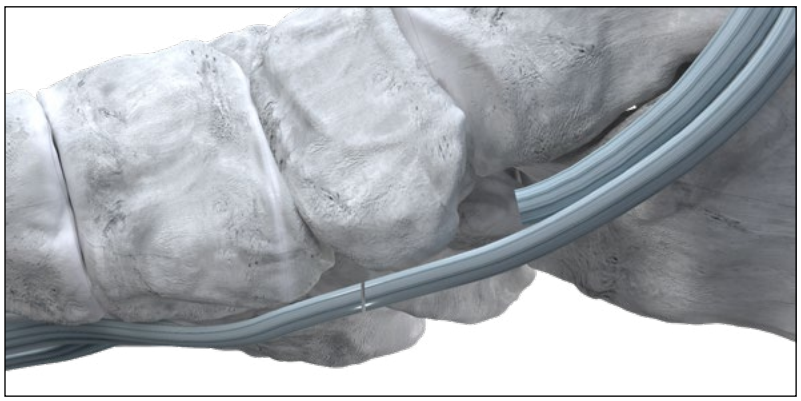
The technique demonstrated below is an FDL transfer to address stage II posterior tibial tendon dysfunction (PTTD) using a through and through technique.

## INCISION/EXPOSURE

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

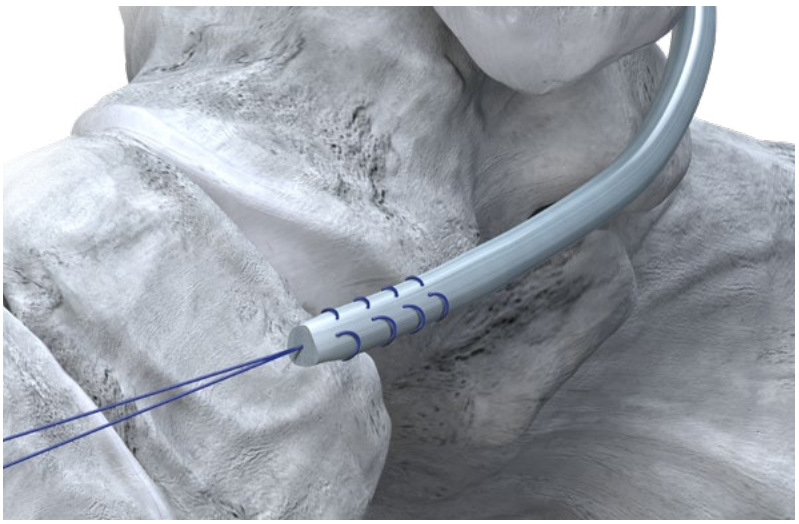
A longitudinal incision exposing the medial aspect of the navicular and posterior tibial (PT) tendon sheath is performed based on surgeon preference.





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



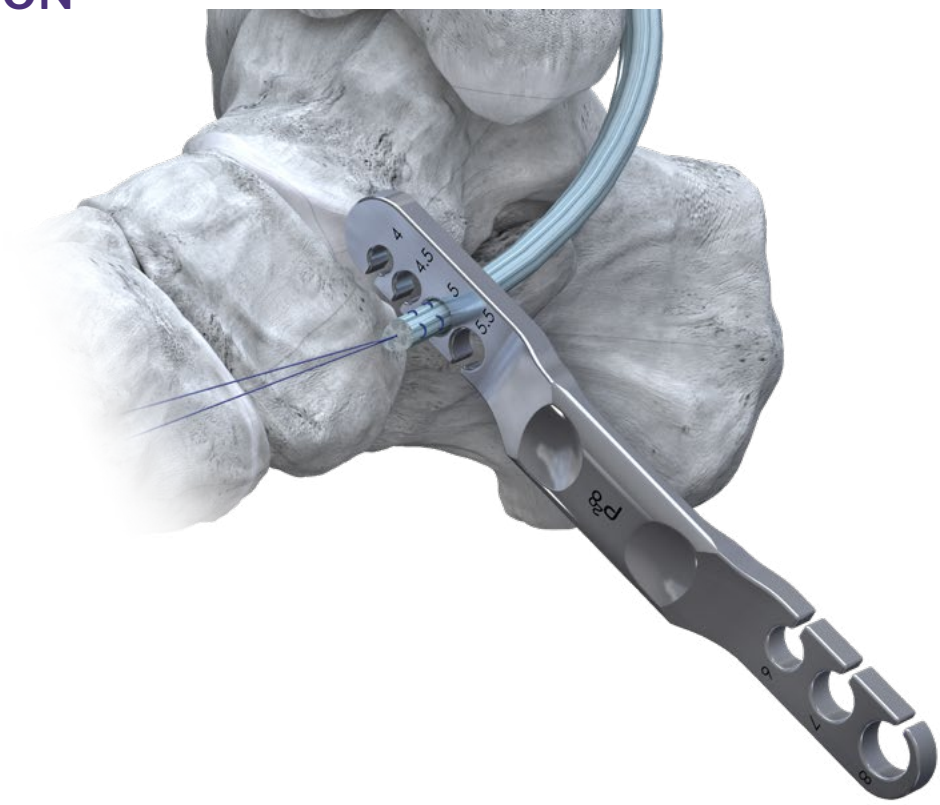
A resorbable size 0 suture is recommended for the through and through technique. Using this suture, place a whip stitch through the cut end of the FDL tendon. It is recommended to encompass approximately 10 mm of the cut tendon into the whip stitch.

Retrieve the Tendon Sizer.

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

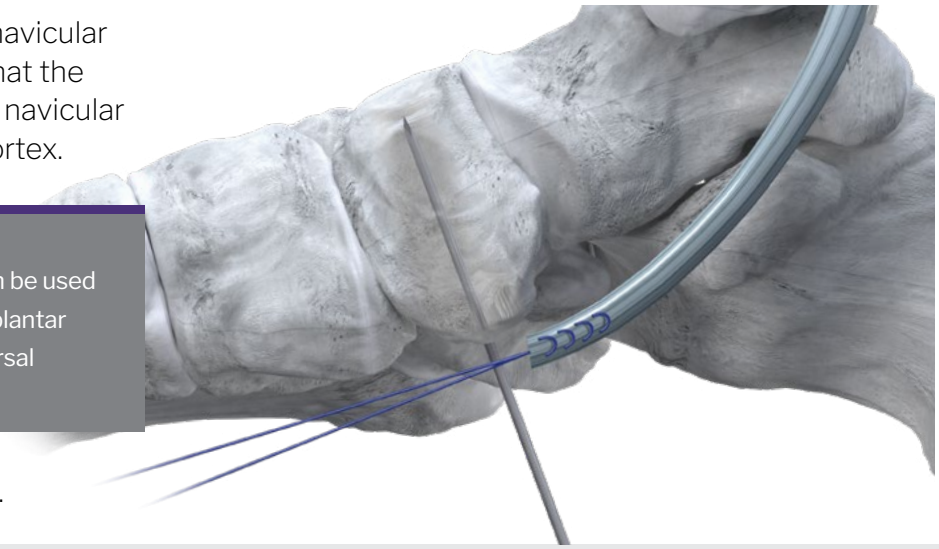
# FDL TENDON PREPARATION

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 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.



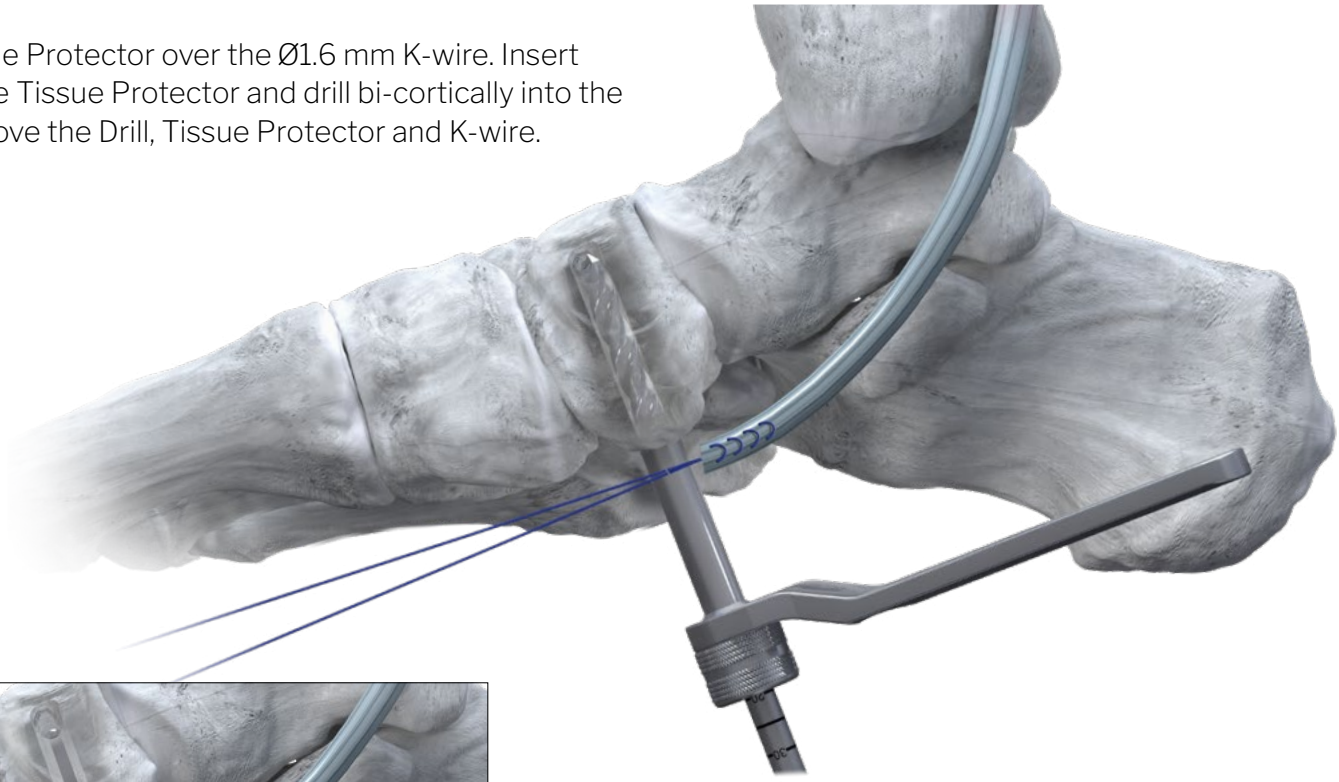
**NOTE:**
Alternatively, a slightly angled trajectory can be used where the wire is directed from the medial plantar junction dorsolaterally, exiting out of the dorsal lateral navicular.

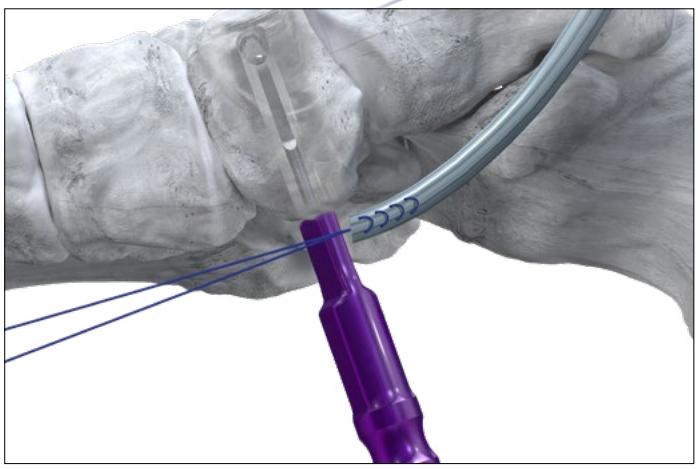
Confirm K-wire placement using fluoroscopy.


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.

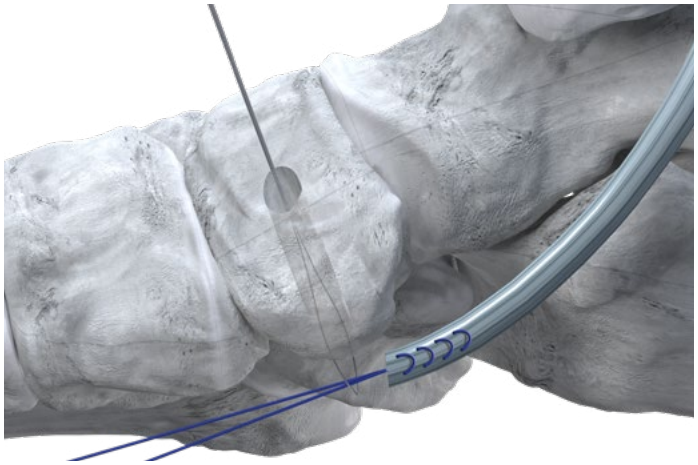
# INTERFERENCE SCREW SELECTION AND INSERTION

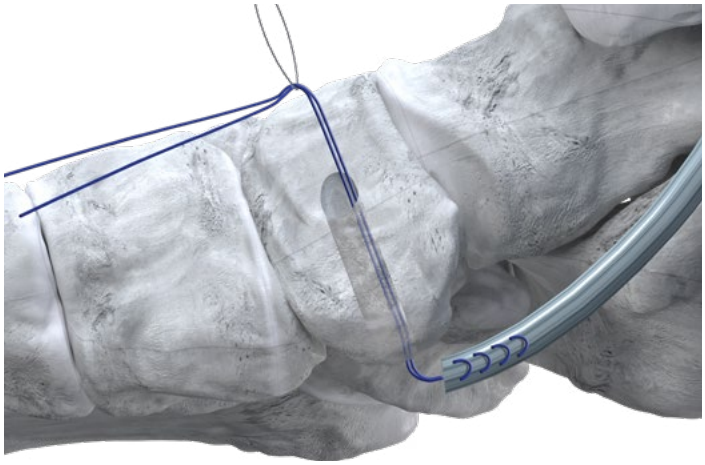
Place the Tissue Protector over the Ø1.6 mm K-wire. Insert the Drill into the Tissue Protector and drill bi-cortically into the navicular. Remove the Drill, Tissue Protector and K-wire.





Interference Screw length can be measured off the laser marked depth indications on the Drill. Alternatively, a Depth Gauge is provided to measure navicular length by hooking the far cortex and measuring bone length to give a reference for Interference Screw length required.

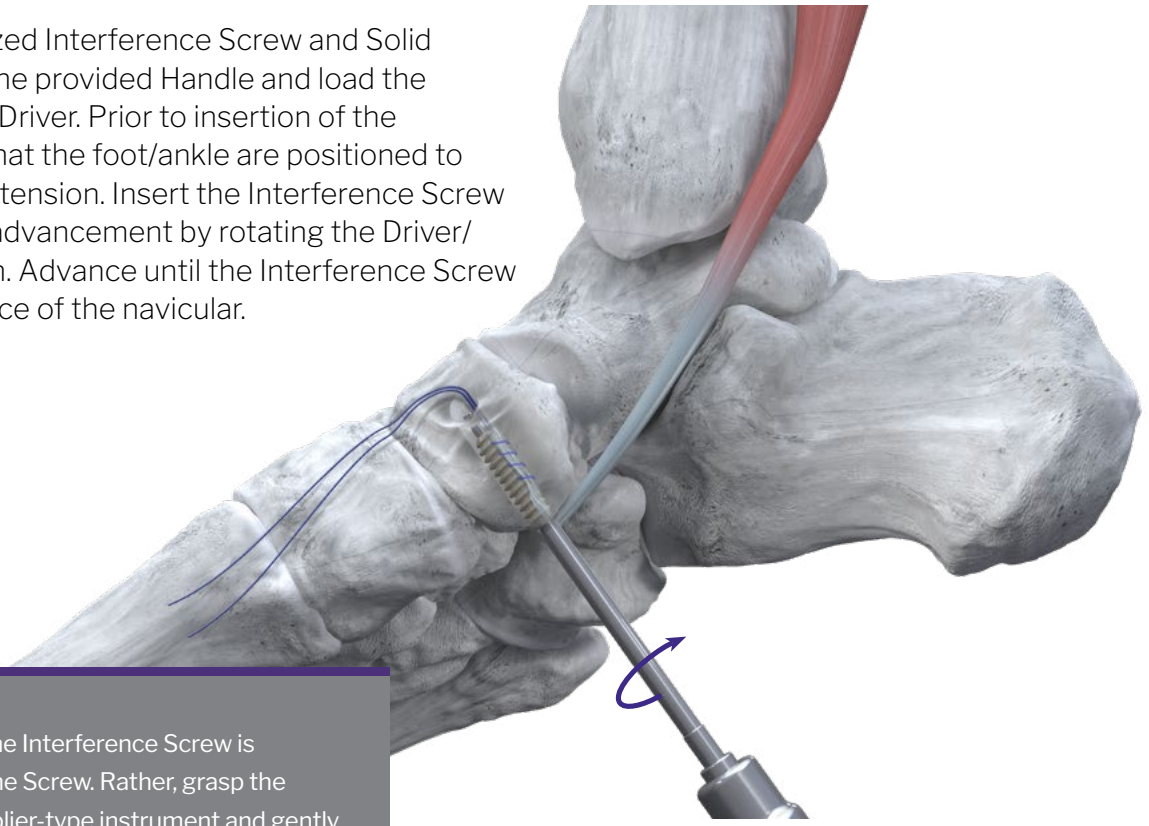




The ends of the whip stitched suture in the FDL tendon are inserted into the loop of the Through & Through Suture Passer. The Suture Passer is inserted plantar to dorsal into the drilled hole in the navicular. Pull the suture ends through the drilled hole and remove the Suture Passer. The sharp end of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

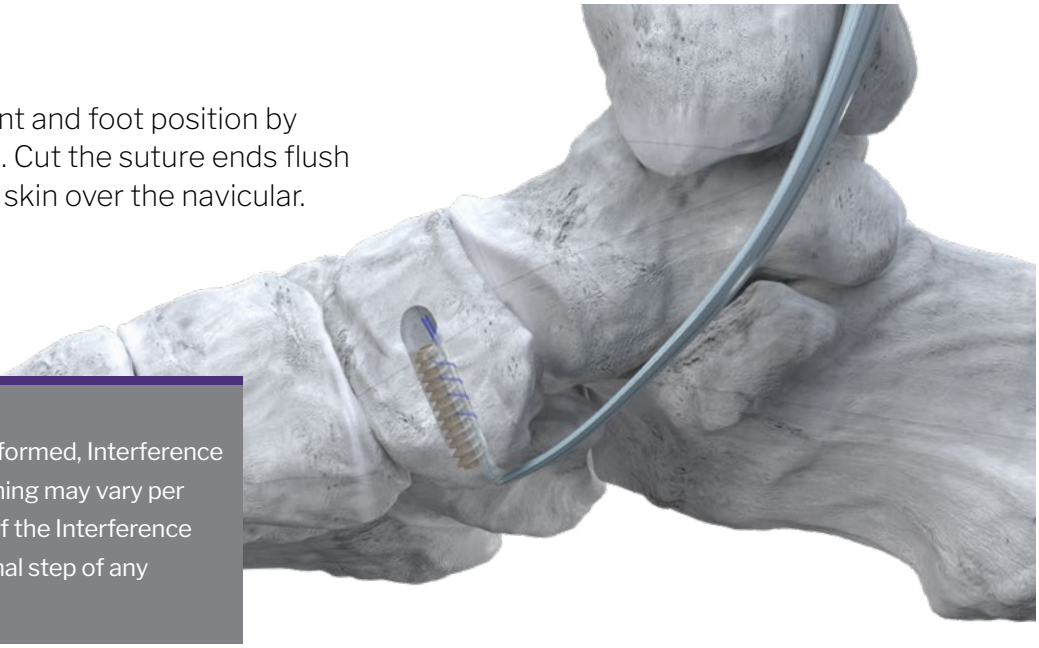
# INTERFERENCE SCREW SELECTION AND INSERTION

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 along the trajectory of 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 at this time.

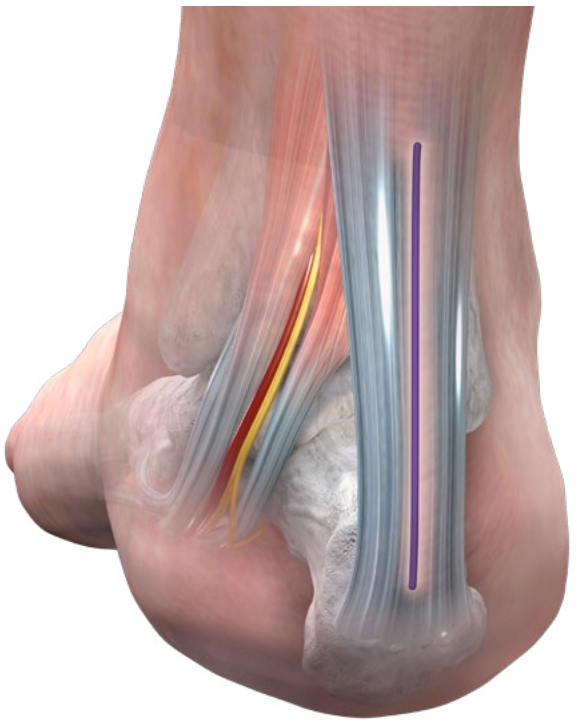
The technique demonstrated below is an FHL transfer for Achilles tendon augmentation to address chronic insertional Achilles tendonosis using a blind tunnel technique. Other applications of this technique can be performed for procedures such as chronic Achilles tendon rupture or tendon balancing with 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.

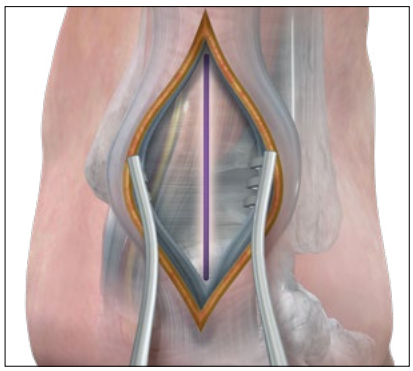
A longitudinal midline incision is made over the Achilles tendon, extending just distal to the insertion of the Achilles tendon over the posterior calcaneus.

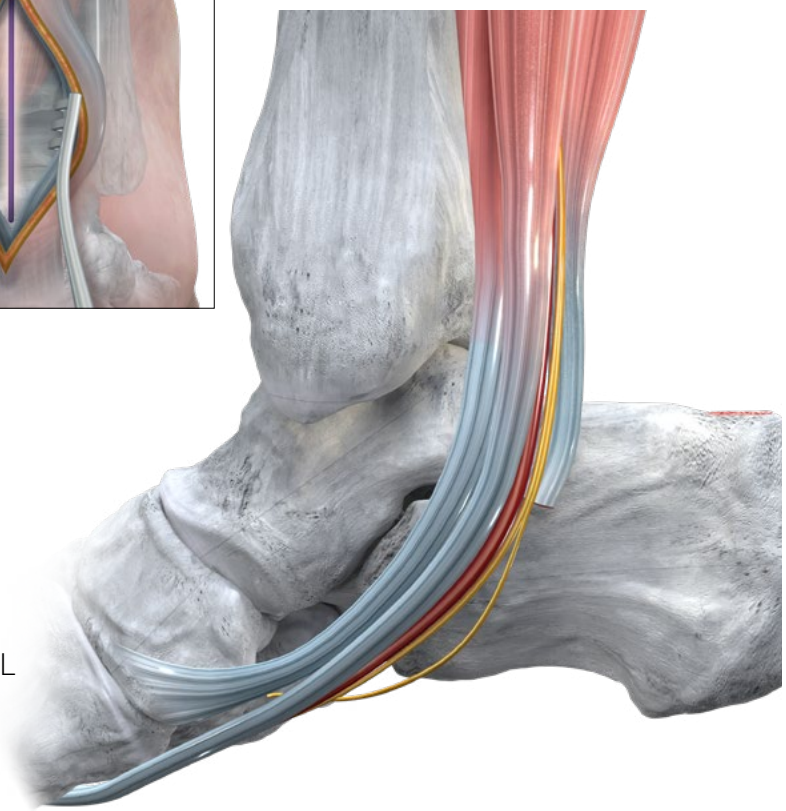
Dissect straight to the level of paratenon, keeping a deep flap to avoid undermining below skin. Incise the paratenon at the midline and reflect medial and lateral to expose the Achilles tendon. Use a deep knife to make a longitudinal incision along the central midline of the Achilles tendon, extending 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.



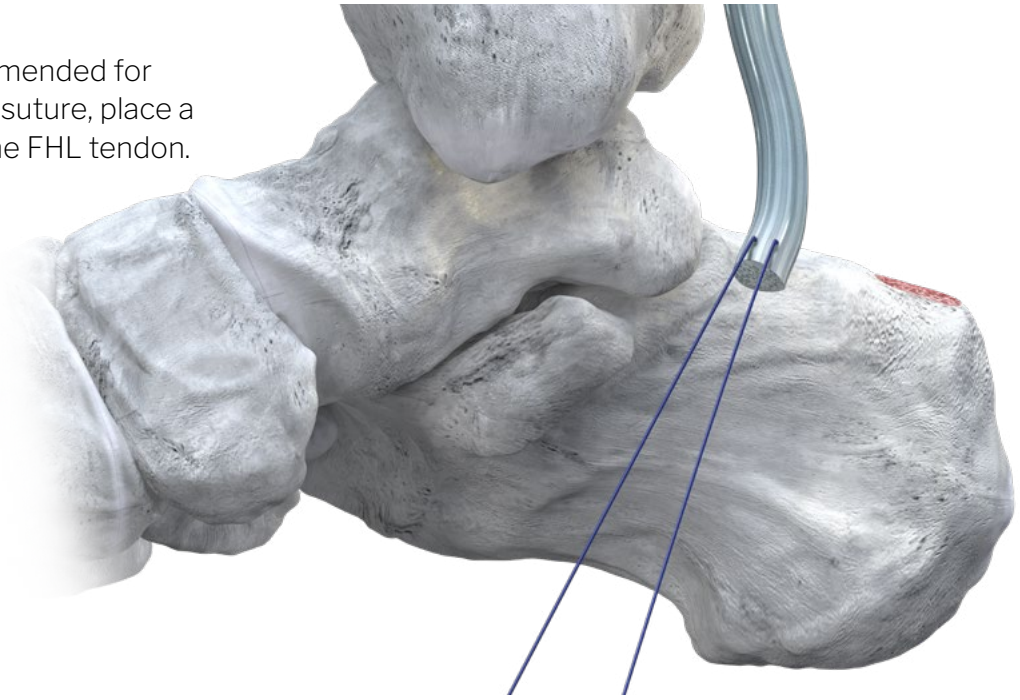


Continue following the FHL tendon distally until adequate tendon exposure is achieved. ***An assistant should maximally plantarflex the ankle and hallux interphalangeal joint to allow for maximal tendon harvest.***

While ensuring that the neurovascular bundle anterior to the tendon is protected, release the fibroosseous 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 size 2.0 suture is recommended for the blind tunnel technique. Using this suture, place a single stitch through the cut end of the FHL tendon.

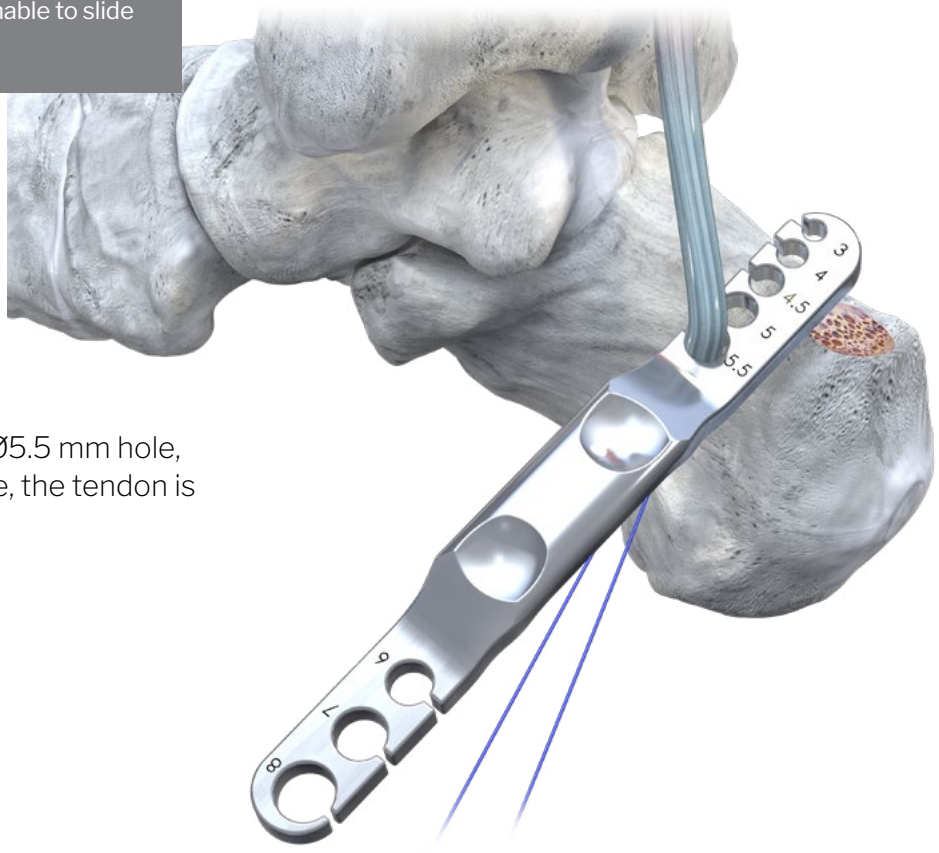


Retrieve the Tendon Sizer.

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

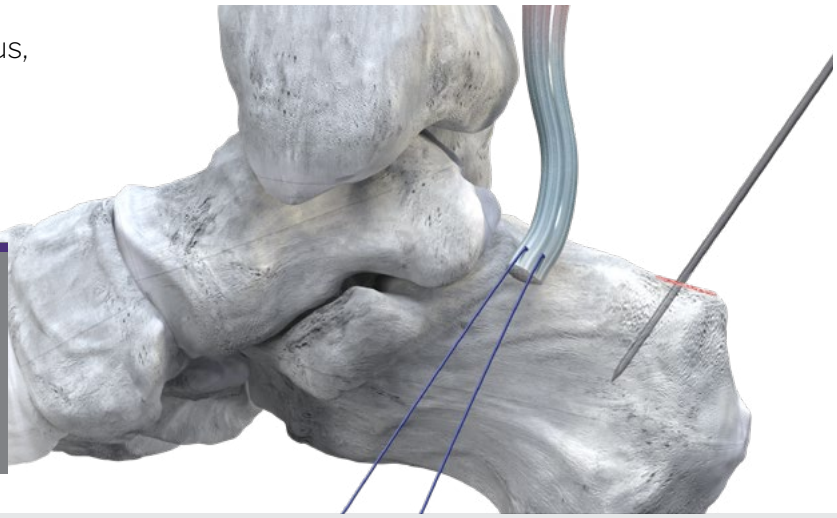
Using the suture from the single stitch, pull the tendon through the holes along the Tendon Sizer. The tendon size is measured as the last ring in which the tendon completely fills the inner diameter.

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.



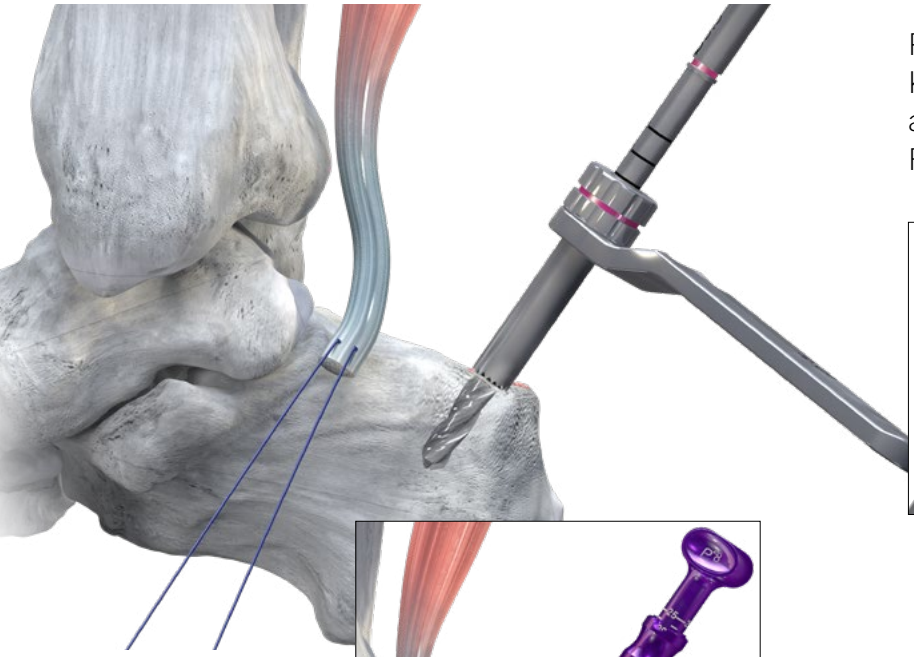
# INTERFERENCE SCREW SELECTION AND INSERTION

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.

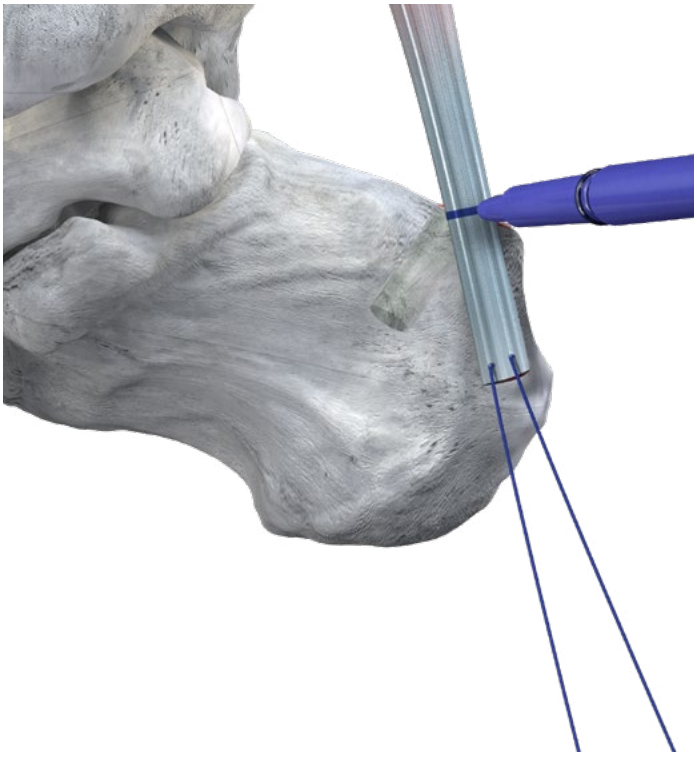


Place the Tissue Protector over the Ø1.6 mm K-wire. Insert the Drill into the Tissue Protector and drill into the calcaneus to a desired depth. Remove the Drill, Tissue Protector and K-wire.

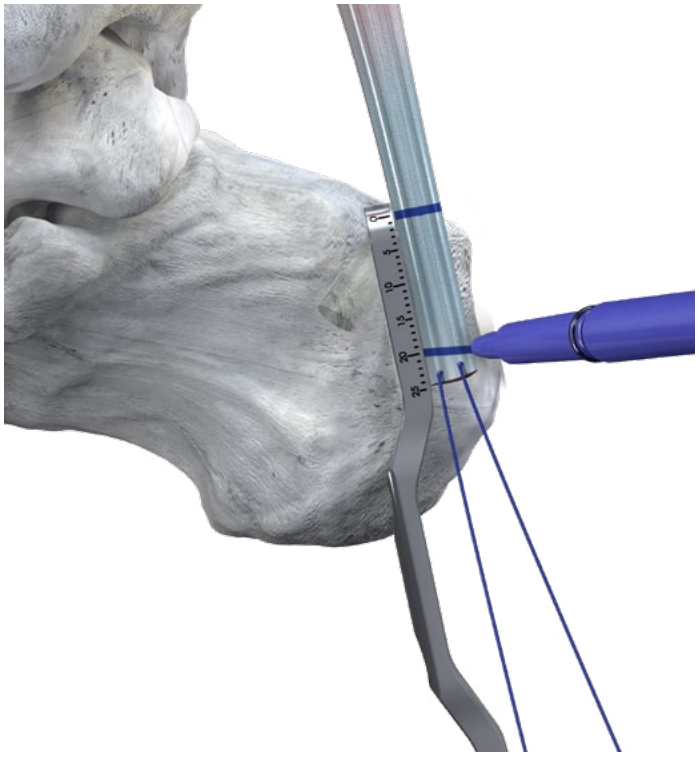

Interference Screw length can be measured off the laser marked depth indications on the Drill.

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.

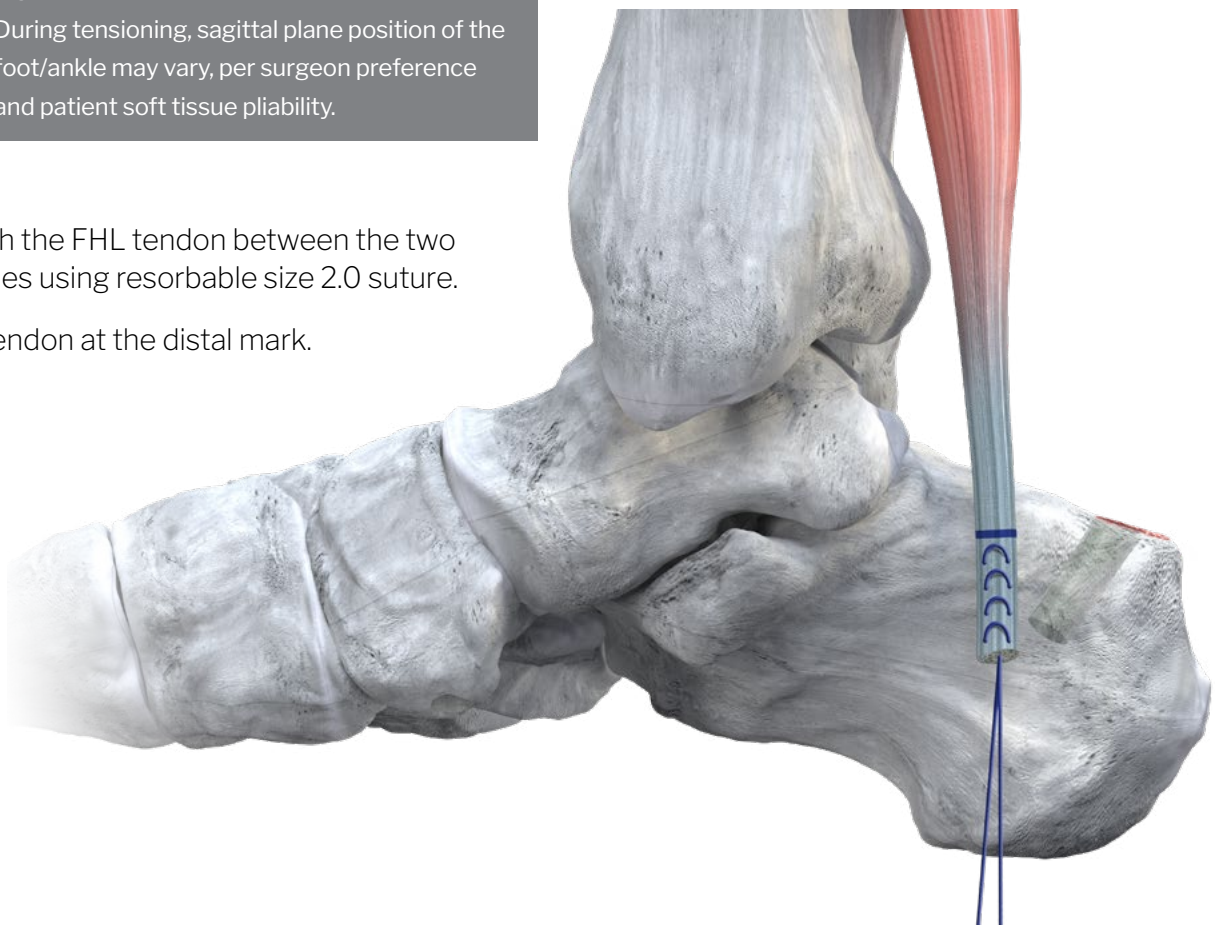


Make a second mark plantar to the first, equating to the intended Screw length.

**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 size 2.0 suture.

Trim the tendon at the distal mark.

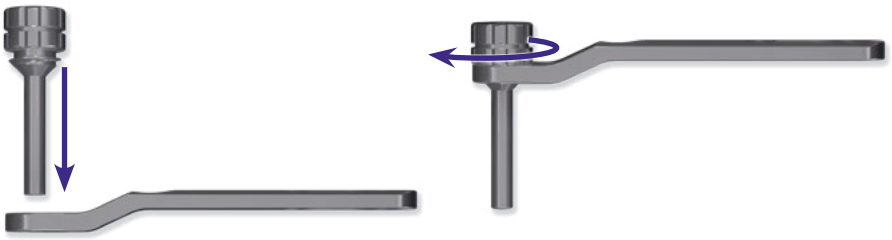


# INTERFERENCE SCREW SELECTION AND INSERTION

## ON THE BACK TABLE:

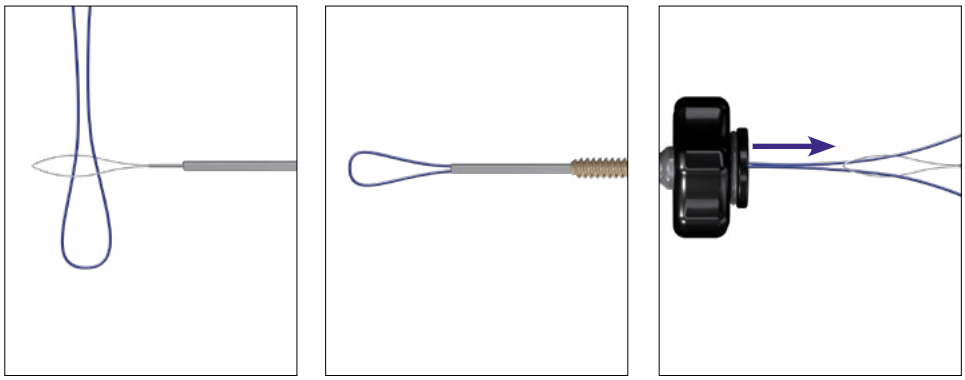
1. Refer to the Interference Screw sizing chart to retrieve the appropriately sized cannulated Driver and Driver Sleeve. Assemble the Driver to the Blind Tunnel Driver Handle.

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.

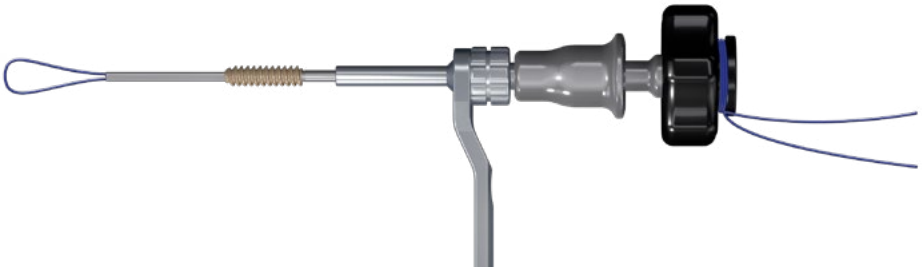


3. Slide the Driver Sleeve construct over the cannulated Driver, until the construct is retained by the Handle. Retrieve the appropriately sized Interference Screw and slide over the Driver. The Interference Screw will self-retain proximally on the Driver. Insert the Blind Tunnel Suture Passer through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

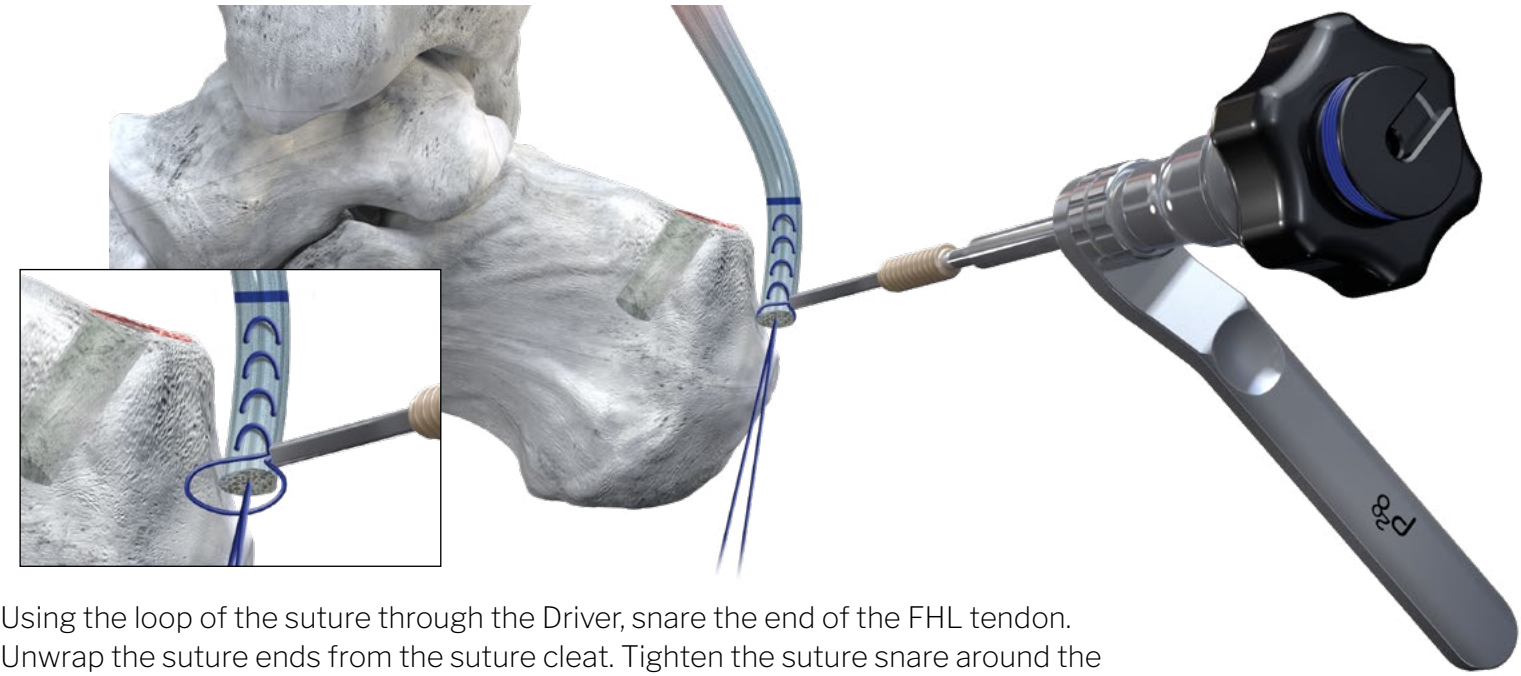
4. Using the Blind Tunnel Suture Passer, pass an additional size 2.0 suture through the Driver and Handle in a distal to proximal direction to create a loop at the distal end of the Driver. The suture loop should be held by the surgeon or assistant while the Suture Passer exits the proximal end of the Handle.



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



# INTERFERENCE SCREW SELECTION AND INSERTION



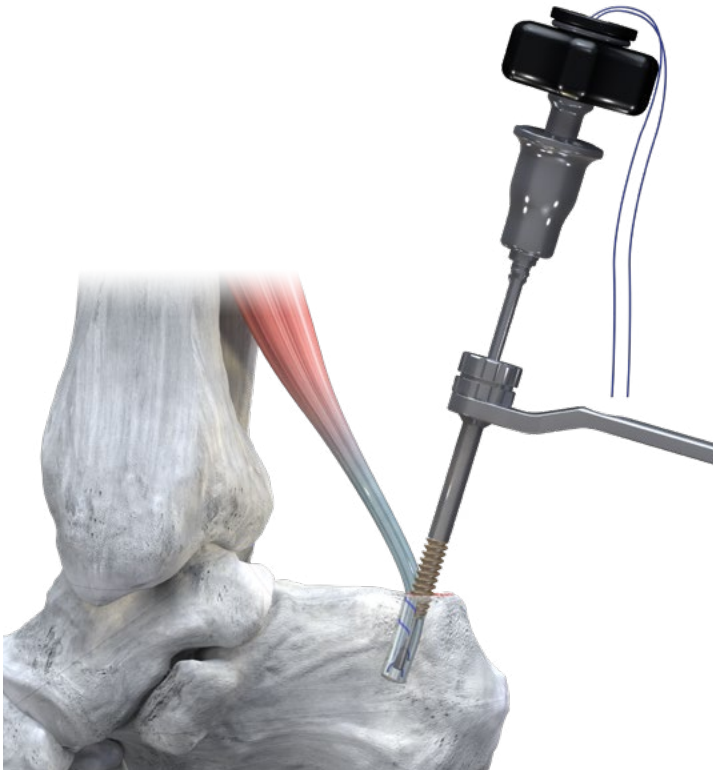
Using the loop of the suture through the Driver, snare the end of the FHL tendon. Unwrap the suture ends from the suture cleat. Tighten the suture snare around the tendon by pulling the suture ends away from the back of the Handle.

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.

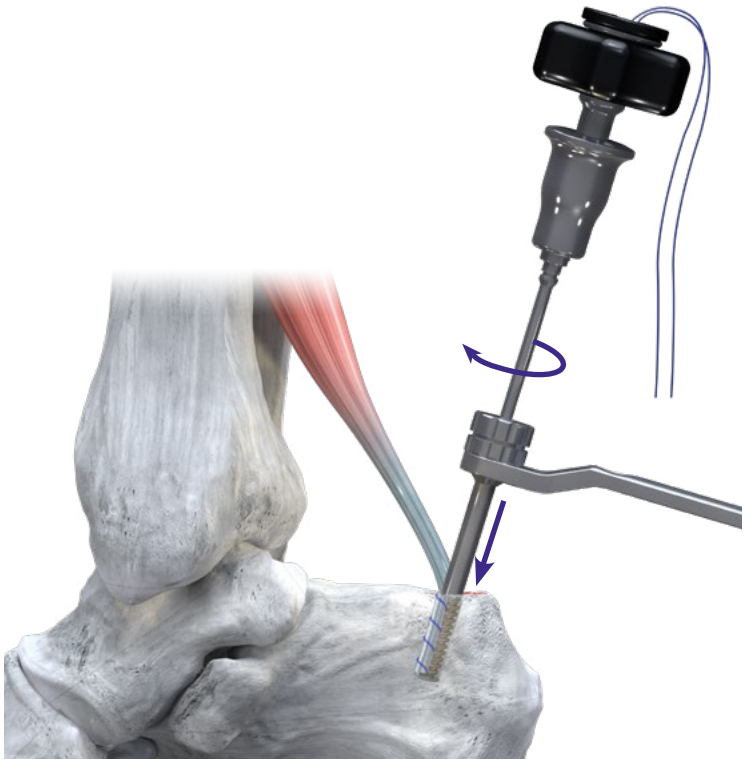
# INTERFERENCE SCREW SELECTION AND INSERTION



**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 along the trajectory of the Driver shaft to disengage the Driver from the Screw.

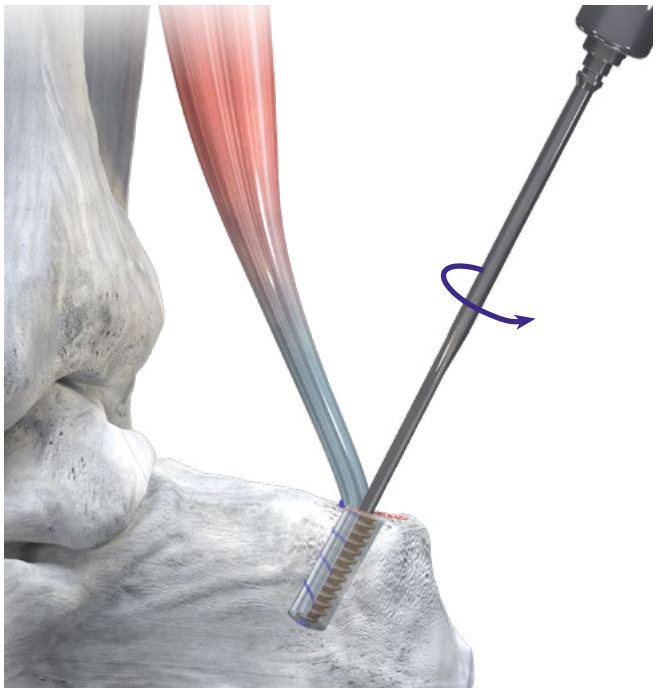
# CLOSURE

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

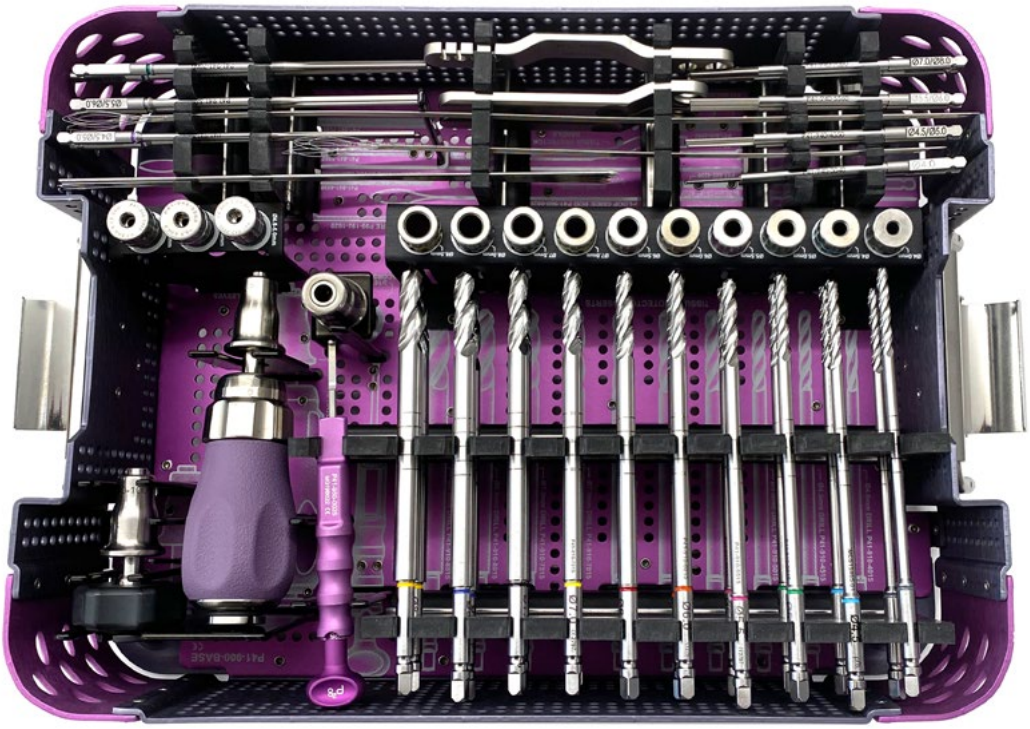
**Grappler® Interference Screw System Non-Sterile Case**

**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



**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 reattachment, i.e. fixation of ligament and tendon graft tissue and tendon transfers in surgeries of the shoulder, elbow, knee, foot/ankle, and hand/wrist. Specifically:

Shoulder:
- Rotator Cuff Repairs
- Bankart Repair
- SLAP Lesion Repair
- Biceps Tenodesis
- Acromio-Clavicular Separation Repair
- Deltoid Repair
- Capsular Shift or Capsulolabral Reconstruction.

Foot/Ankle:
- Lateral Stabilization
- Medial Stabilization
- Achilles Tendon Repair
- Hallux Valgus Reconstruction
- Midfoot Reconstruction
- Metatarsal Ligament Repair
- Flexor Hallucis Longus Transfer for Achilles Tendon Reconstruction, and
- Flexor Digitorum Longus Transfer for Posterior Tibial Tendon Reconstruction.

Knee:
- Anterior Cruciate Ligament Repair
- Medial Collateral Ligament Repair
- Lateral Collateral Ligament Repair
- Patellar Tendon Repair
- Posterior Oblique Ligament Repair
- Illiotibial Band Tenodesis

Elbow:
- Biceps Tendon Reattachment
- Ulnar or Radial Collateral Ligament Reconstruction

Hand/Wrist:
- Scapholunate Ligament Reconstruction
- Ulnar Collateral Ligament Reconstruction
- Radial Collateral Ligament Reconstruction
- Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty)
- Carpal Ligament Reconstructions and repairs
- Ligament Reconstruction and Tendon Interposition.

## 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 previously sensitized to titanium
- 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**

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

## 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-0001 RevG [2023-03-08]



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

Australian Sponsor
Emergo Australia
Level 20, Tower II, Darling Park
201 Sussex St., Sydney, NSW 2000
Australia

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.