GRAPPLER®
SUTURE ANCHOR SYSTEM

GRAPPLER™
KNOTLESS ANCHOR SYSTEM

LATERAL ANKLE INSTABILITY SURGICAL TECHNIQUE GUIDE

Exclusively foot & ankle
Paragon 28®

Acknowledgment:
Paragon 28® would like to thank Dr. Scott Ellis, MD; Dr. Mark Prissel, DPM; Dr. Emilio Wagner, MD; and Dr. Pablo Wagner, MD for their contributions as the surgeon design team.

PRODUCT DESCRIPTION

The Grappler® Suture Anchor System was designed to address the challenges that are present when performing soft tissue procedures in foot and ankle. A variety of all-suture anchors, PEEK anchors, titanium anchors, sutures, and suture tape provide foot and ankle surgeons the ability to select the appropriate implants for the surgery they are performing.

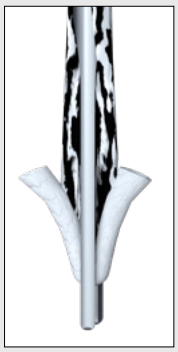
The Grappler® Knotless Anchors and Bridgeline™ suture tapes can be used to create tape augmentation constructs for lateral ankle instability, medial ankle instability, or other pathologies.

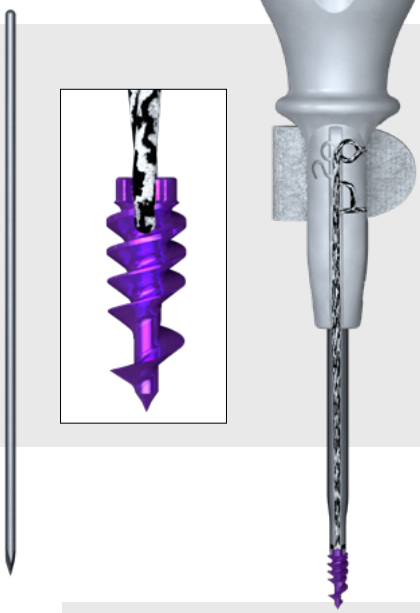
CONTENTS

SYSTEM OVERVIEW

ALL-SUTURE ANCHOR KITS

- **Ø1.4 mm Anchors:**
  - Single-Loaded #0 Suture
  - Ø1.4 mm Drill Tip K-wire
  - Drill/Insertion Guide
- **Ø2.8 mm Anchors:**
  - Double-loaded #2 Suture
  - Ø2.8 mm Drill Tip K-wire
  - Drill/Insertion Guide



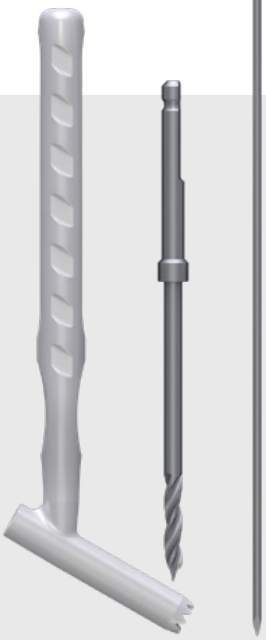


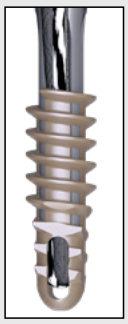
TITANIUM ANCHOR KITS

- Titanium Alloy, Ti-6AL-4V
- **Ø3.0 mm Anchors:**
  - Double-loaded with #0 Suture
  - Ø2.0 mm K-wire
- **Ø4.5 mm Anchors:**
  - Double-loaded with #2 Suture
  - Ø2.6 mm K-wire

PEEK ANCHOR KITS

- **Ø4.5 mm Anchors:**
  - Double-loaded with #2 Suture
  - or
  - Double-loaded with #2 Suture and 1.5 mm Tape
  - Ø3.5 mm Drill Bit
  - Drill Guide
  - Ø1.6 mm K-wire
- **Ø5.5 mm Anchors:**
  - Double-loaded with #2 Suture
  - or
  - Double-loaded with #2 Suture and 1.5 mm Tape
  - Ø4.3 mm Drill Bit
  - Drill Guide
  - Ø1.6 mm K-wire





NOTE: *Sterile-packed, cannulated Drills and Taps are available for the PEEK Anchors per surgeon preference*

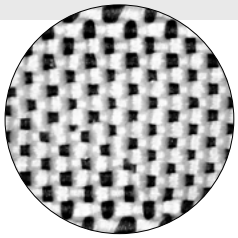
SYSTEM OVERVIEW

GRAPPLER KNOTLESS SYSTEM

- Cannulated Knotless Anchors (Ø4.5 mm or Ø5.5 mm)
- Tensioning Driver Handle , preloaded with Suture Passer
- Solid Drill Bit (Ø3.5 mm or Ø4.3 mm)
- Drill Guide
- Solid Tap (Ø4.5mm or Ø5.5mm)
- 4.0 mm Bridgeline™ Suture Tape (100% UHMWPE or Adaptive)

Tape Features:

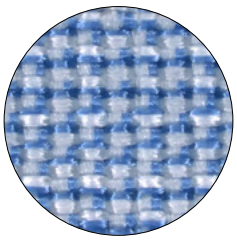
- *The central third of each Tape is demarcated by a black tracer strand. This allows the surgeon to plan for appropriate working length of the repair*



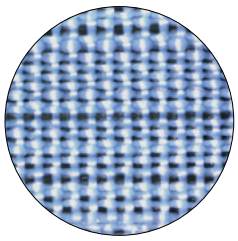
UHMWPE Weave

Adaptive Bridgeline™ Suture Tape:

- *The Adaptive version is comprised not only of UHMWPE but also PGLA so that it is partially absorbable.*
- *After absorption, the Tape has a longer working length which promotes load-sharing with soft tissue structures without losing strength.*
- *Over 12-24 weeks, the Tape will increase in length by 5-10% of its total length.*



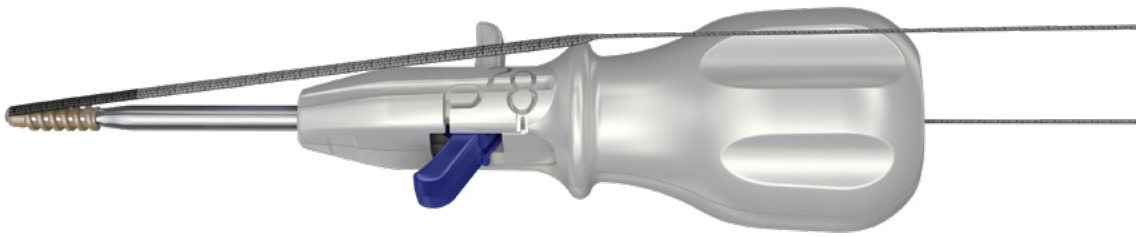
Pre-Absorption



Post-Absorption

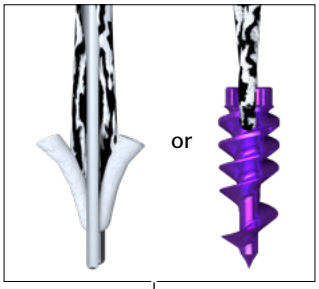
Tensioning Driver Features:

- *The cannulated Tensioning Driver is utilized with the Suture Passer and Knotless Anchors to pass and tension the Suture Tape through the Anchors.*



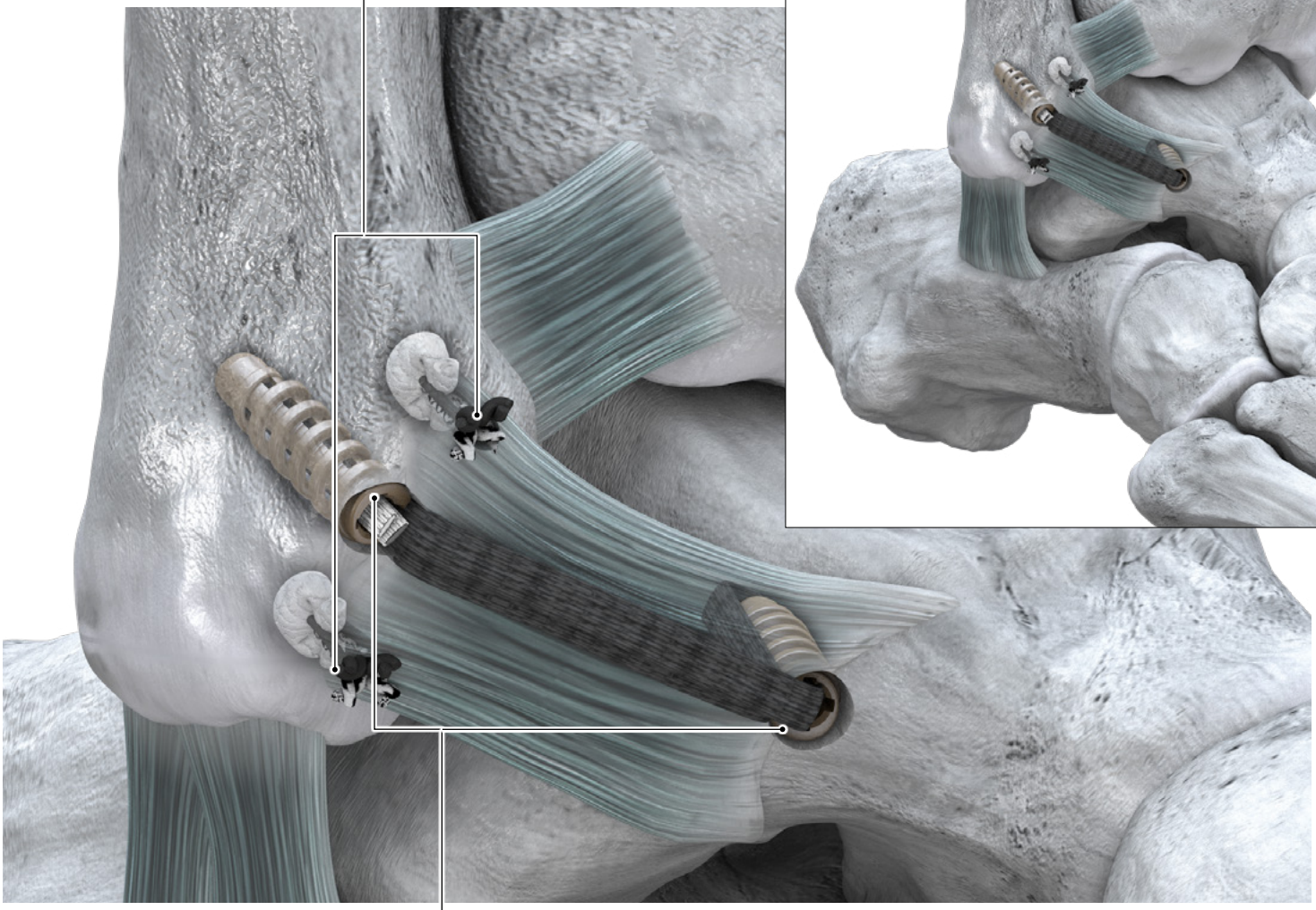
LATERAL ANKLE INSTABILITY: ATFL REPAIR (BROSTROM)

For patients with lateral ankle instability, a repair of the anterior talofibular ligament (ATFL) can be performed using the Grappler Suture Anchor System. If desired, the Grappler Knotless System can be used to augment the primary repair with a Tape brace construct.



ATFL FIBULAR ATTACHMENT OPTIONS:

- Titanium Anchors (Ø3.0mm)
- All-Suture Anchors (Ø1.4mm or Ø2.8mm)

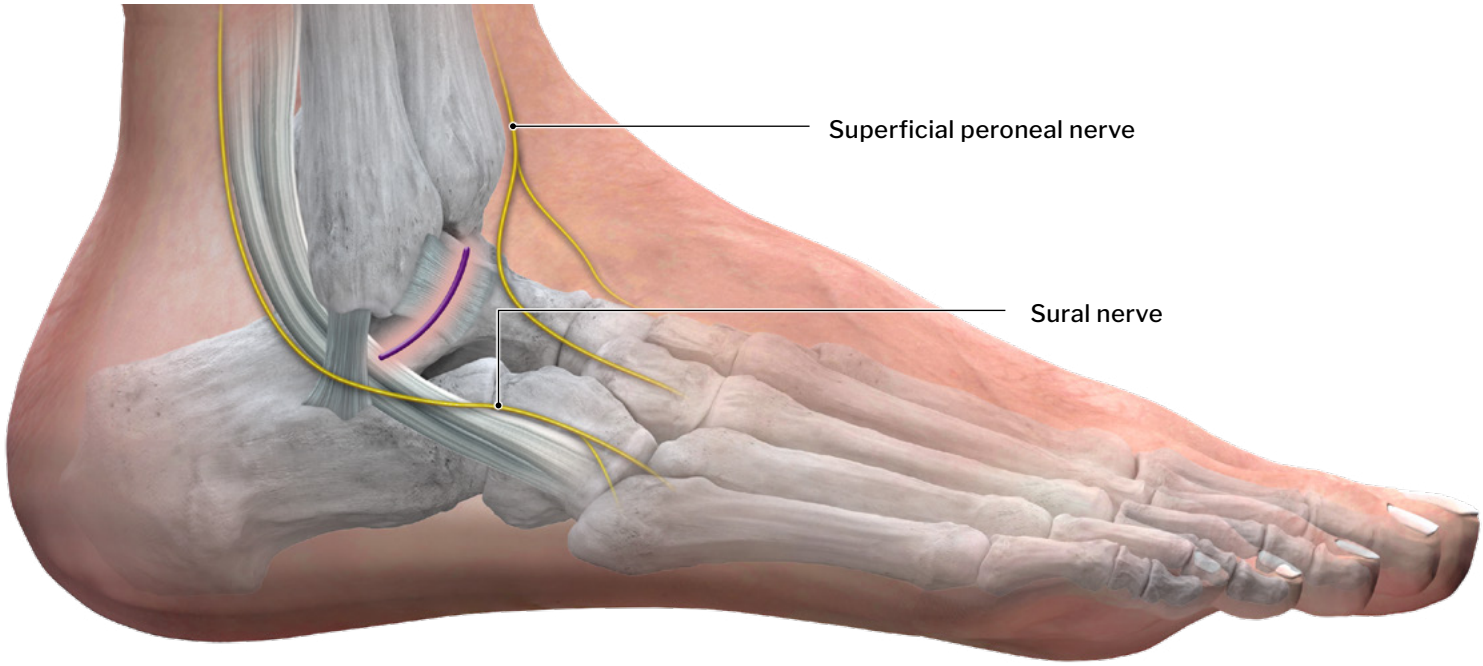


TAPE AUGMENTATION OPTIONS:

- Knotless Anchors with Standard Bridgeline™ Tape (Ø4.5mm)
- Knotless Anchors with Adaptive Bridgeline™ Tape (Ø4.5mm)

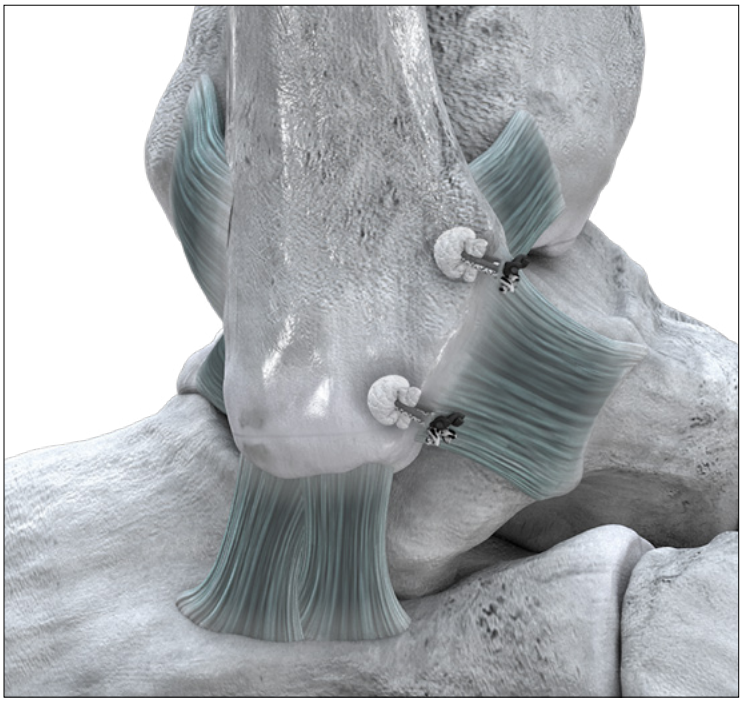
INCISION/EXPOSURE

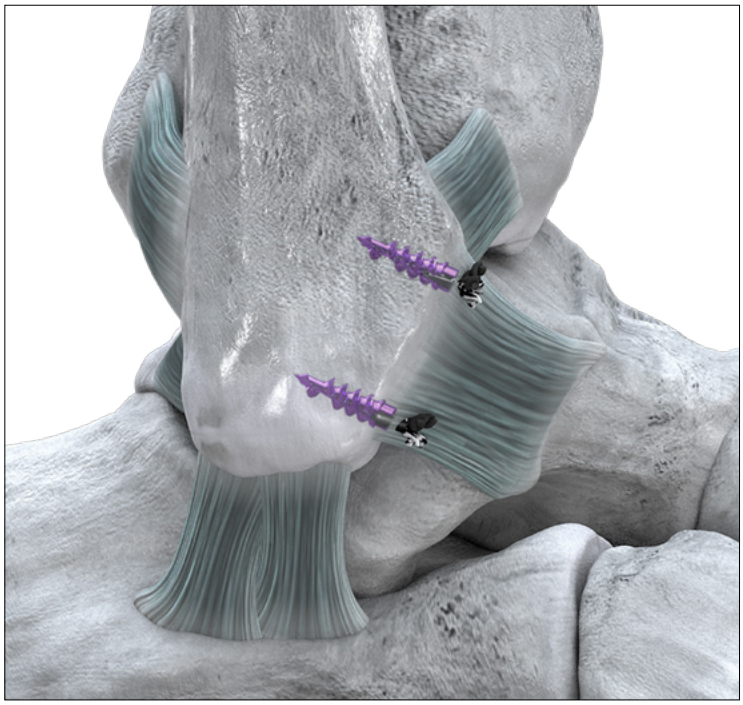
Position the patient supine such that the foot is near the end of the table, and place a pillow under the patient's hip to rotate the ankle internally. Perform a curved incision approximately 3-4cm long along the anterior border of the lateral malleolus between the superficial peroneal nerve and the sural nerve. Dissect subcutaneously until the capsule is reached.



Perform a capsular incision on the anterior side of the fibula and identify the ATFL. Mobilize and retract any soft tissue impeding access to the anatomic ATFL fibular and talar origins. Perform any necessary rupture repairs to the ATFL.

ATFL Fibula Reattachment Anchor Options

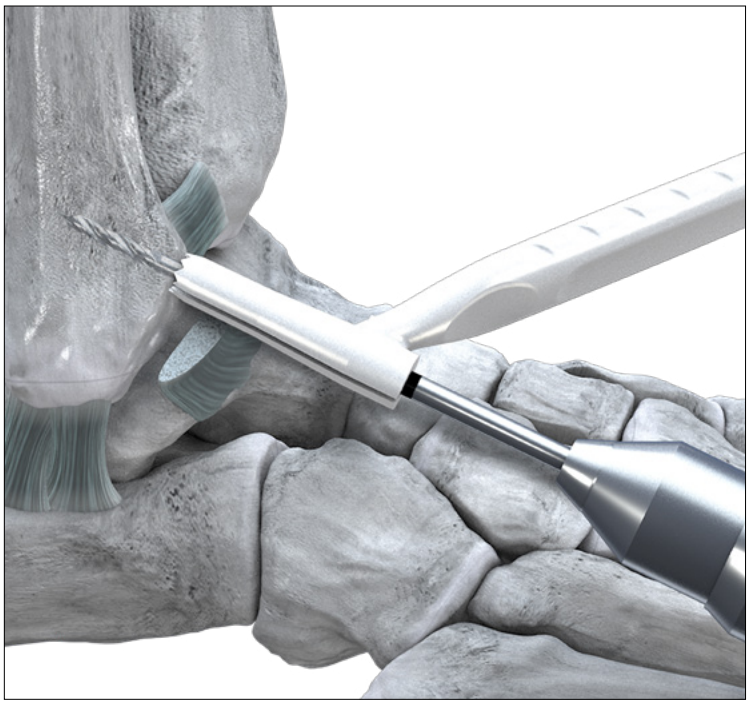




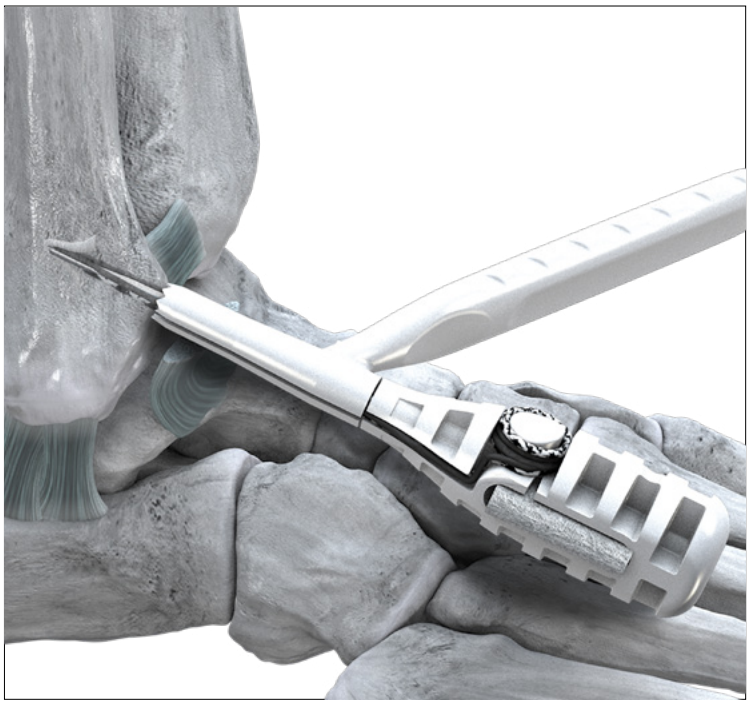
For All-Suture Anchors, follow pages 7-8

For Titanium Anchors, follow pages 9-10

ALL-SUTURE ANCHOR INSERTION

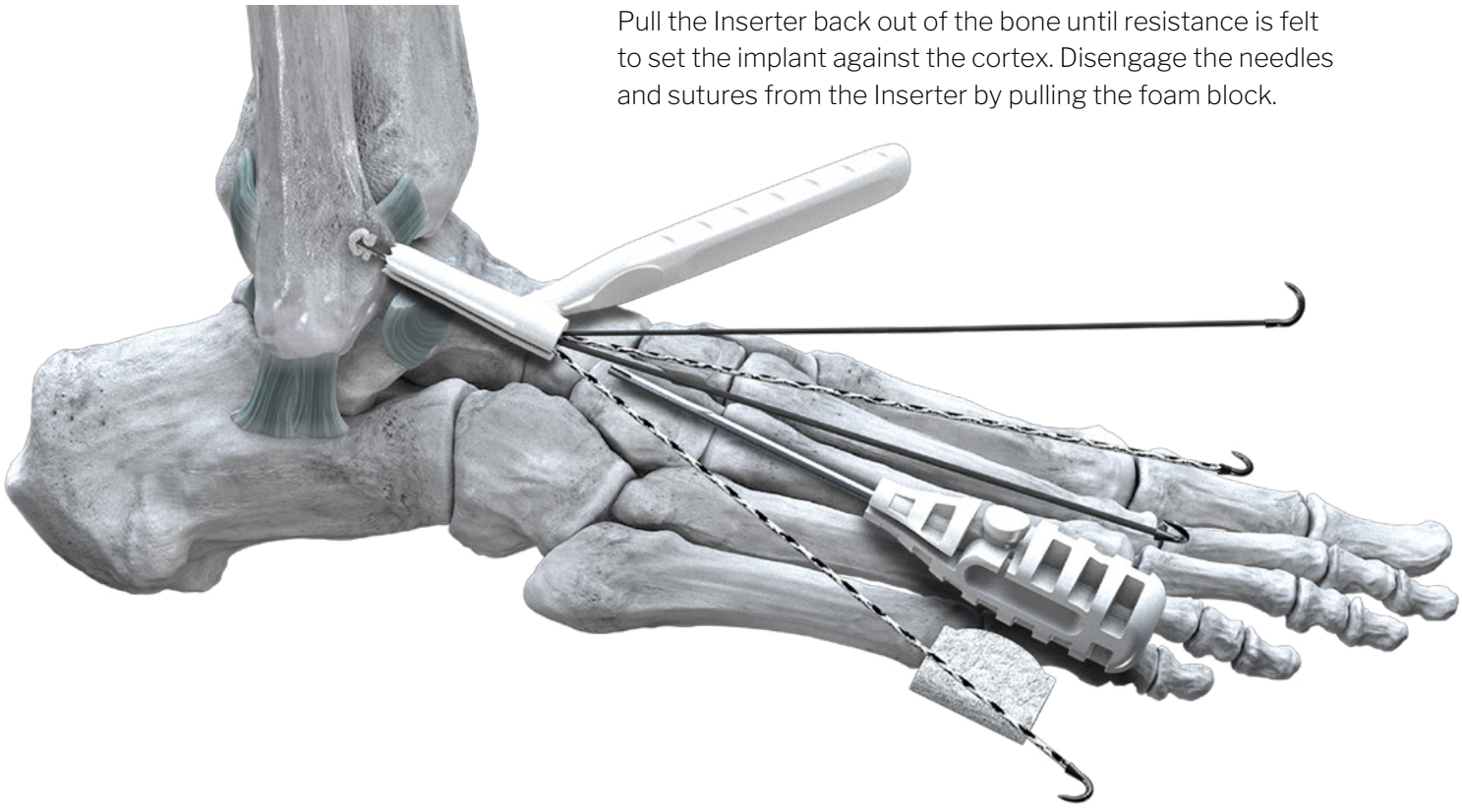


Place the Drill Guide against the distal anterior fibula at proximal edge of the anatomic ATFL fibular origin. Drill through the Drill Guide with the provided Ø1.4 mm or Ø2.8 mm Drill tip K-wire. Remove the K-wire without adjusting the position of the Drill Guide.

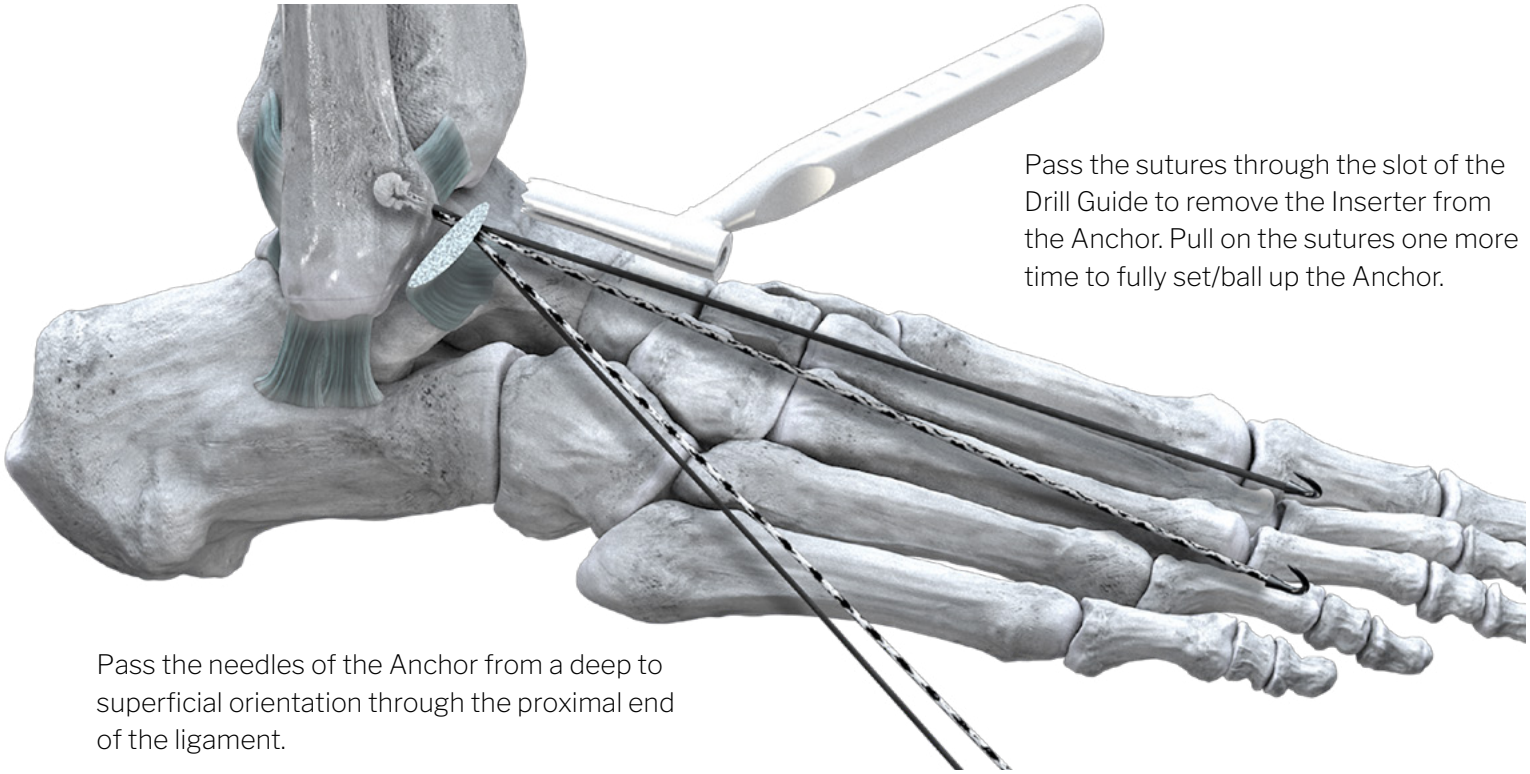


Pass the All-Suture Anchor on the Inserter through the Drill Guide into the bone. Impact with a mallet until the Inserter stops on the Drill Guide.

Pull the Inserter back out of the bone until resistance is felt to set the implant against the cortex. Disengage the needles and sutures from the Inserter by pulling the foam block.



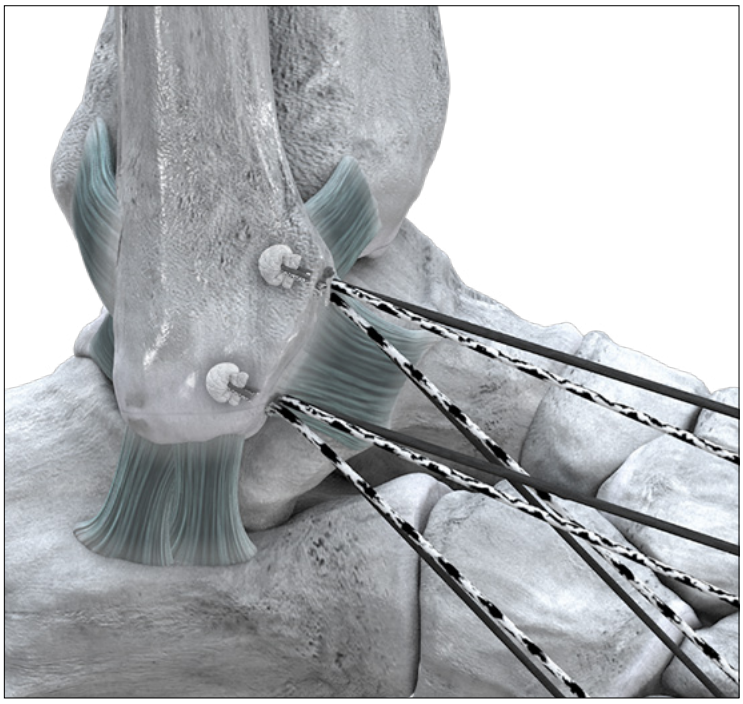
ALL-SUTURE ANCHOR INSERTION



Pass the sutures through the slot of the Drill Guide to remove the Inserter from the Anchor. Pull on the sutures one more time to fully set/ball up the Anchor.

Pass the needles of the Anchor from a deep to superficial orientation through the proximal end of the ligament.

NOTE: *The Ø2.8 mm All-Suture Anchors have four suture tails with four needles while the Ø1.4 mm All-Suture Anchors have two tails and two needles.*

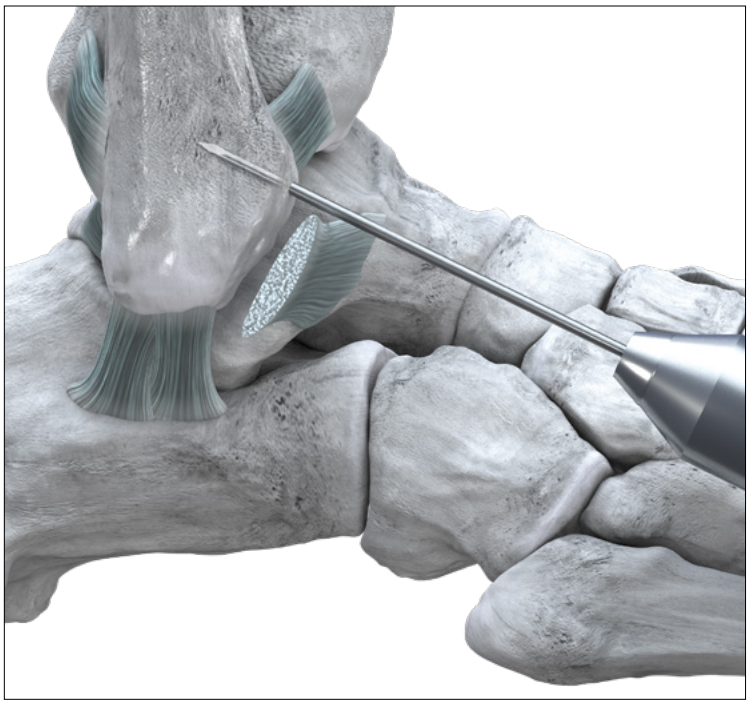


Repeat the previous steps to insert a second All-Suture Anchor into the distal anatomic ATFL origin on the fibula and similarly pass the sutures through the ATFL.

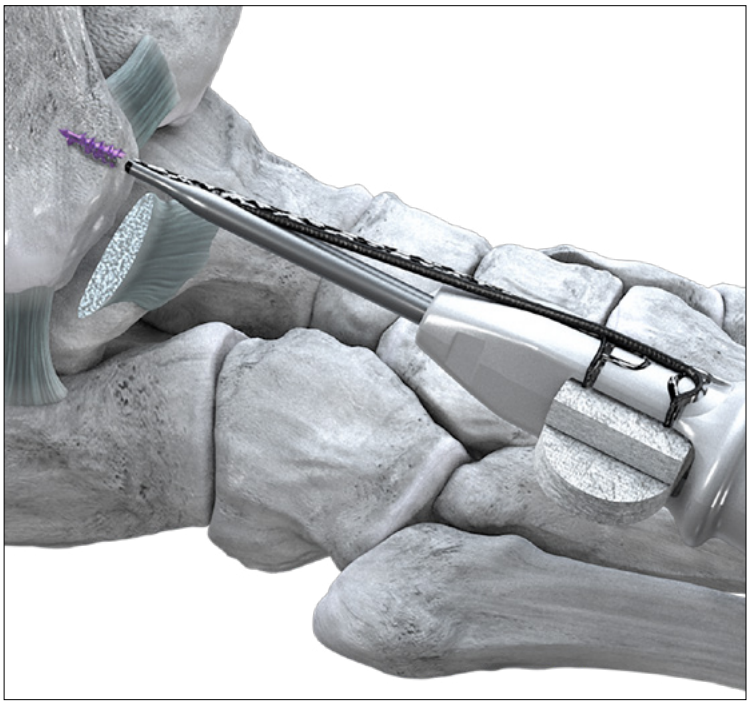
After tensioning the Anchor suture tails, tie knots to secure the ligament to the bone and cut the excess suture to complete the repair.

Continue on page 11 for Knotless Anchor Insertion

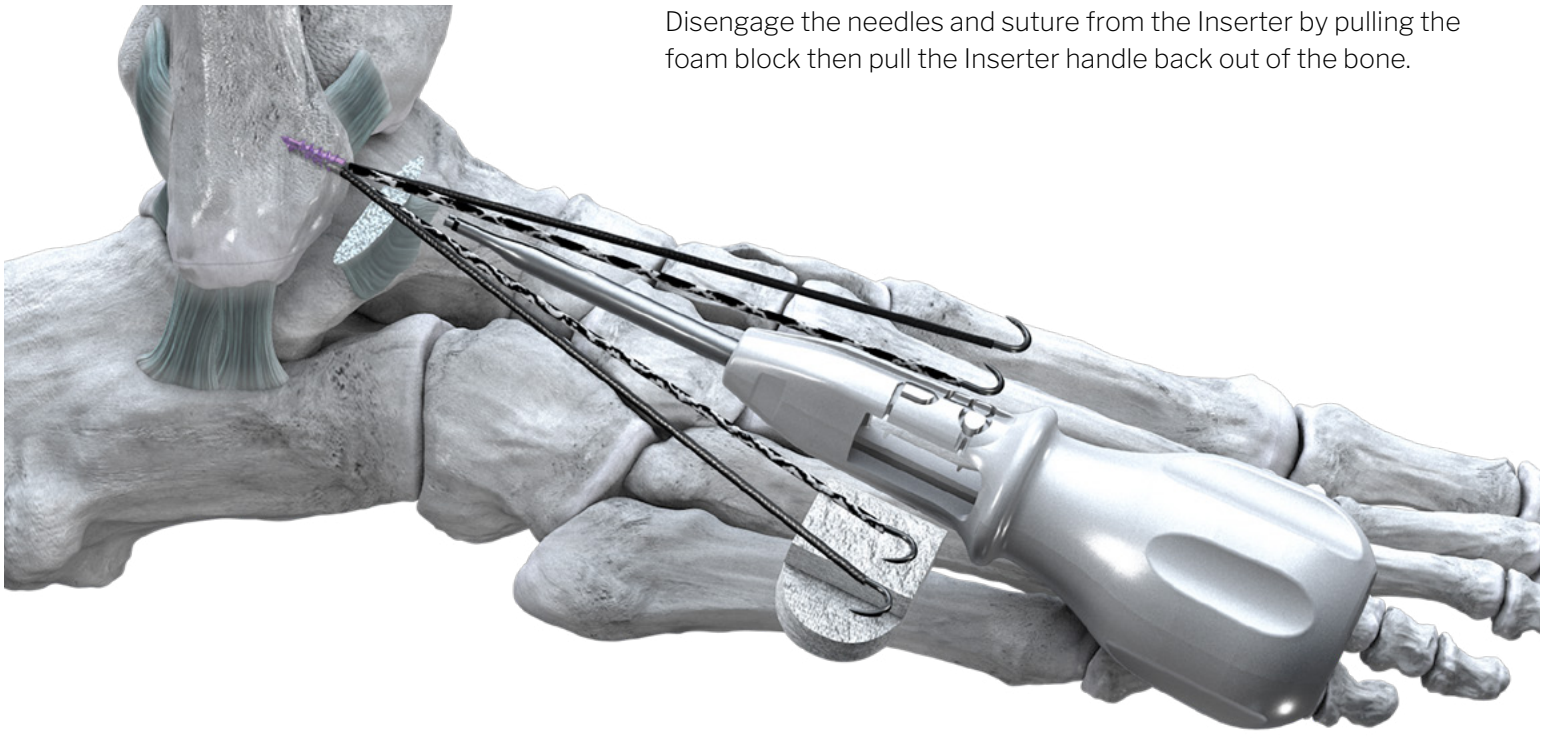
TITANIUM ANCHOR INSERTION



Drill with the provided Ø2.0 mm or Ø2.6 mm K-wire into the distal anterior fibula at the proximal edge of the anatomic ATFL fibular origin. For reference, the Ø3.0 mm Anchor is 12 mm long and the Ø4.5 mm Anchor is 15 mm long.

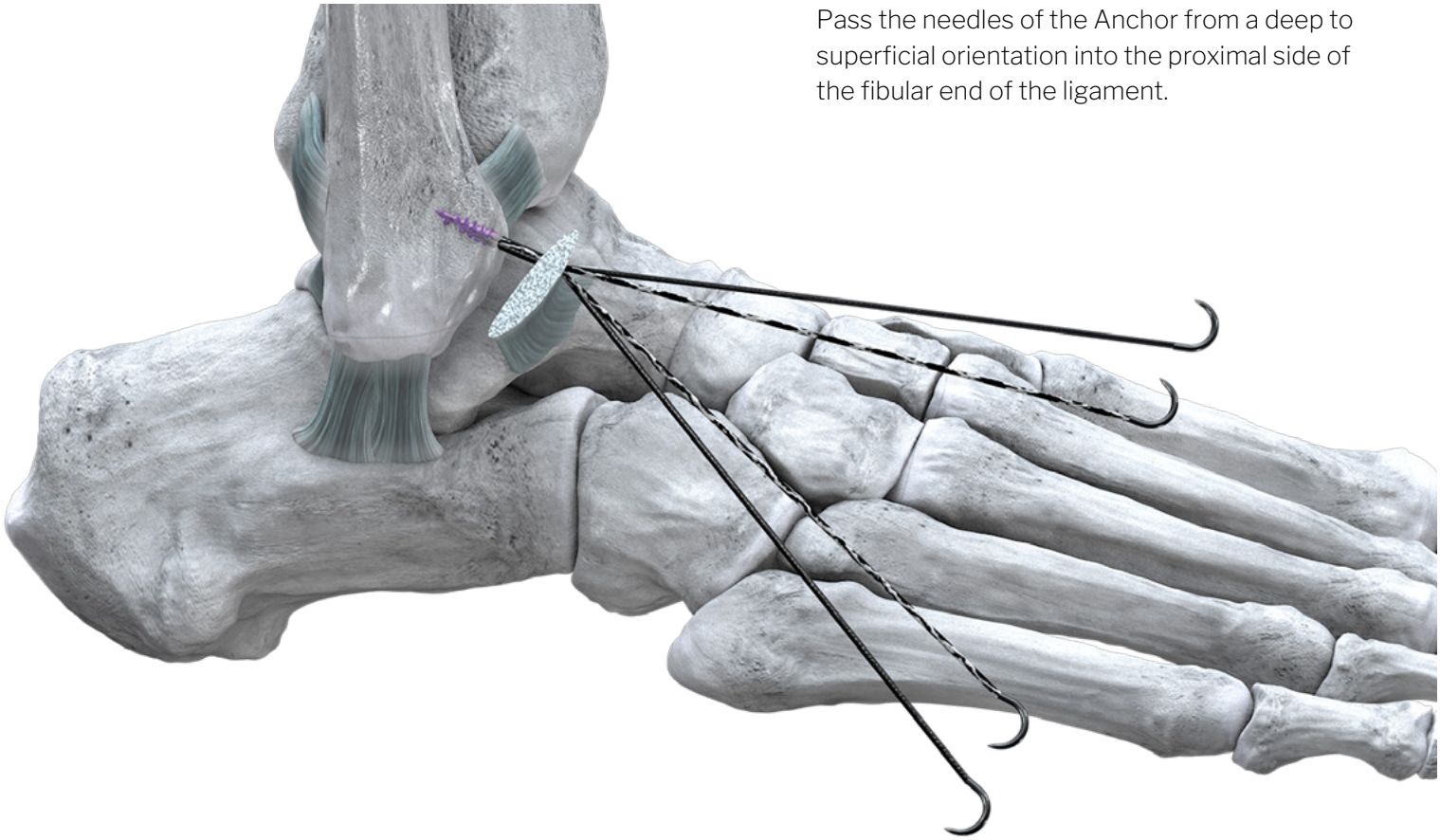


Insert the titanium Anchor by turning the Driver clockwise until visually confirming Anchor head is flush with bone. Laser mark indicates level of Anchor head.

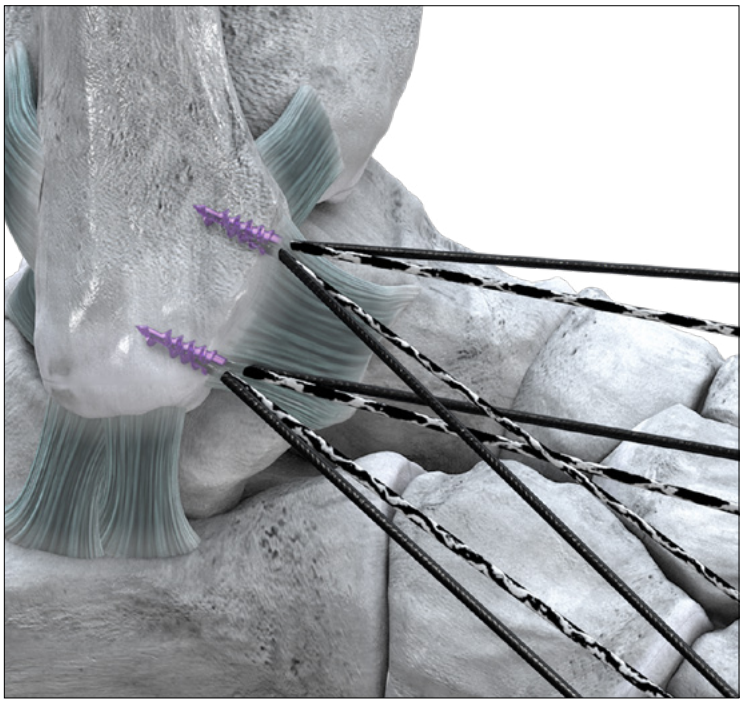


Disengage the needles and suture from the Inserter by pulling the foam block then pull the Inserter handle back out of the bone.

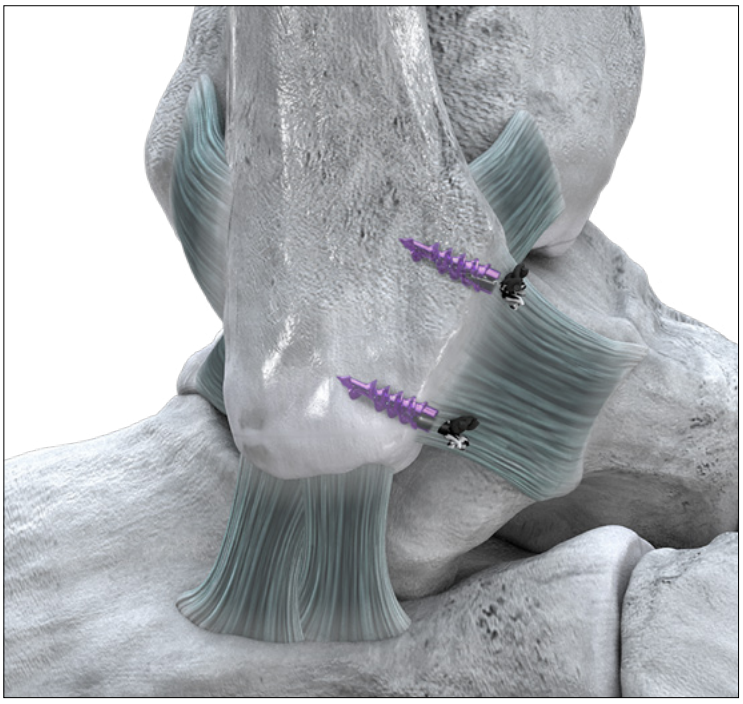
TITANIUM ANCHOR INSERTION



Pass the needles of the Anchor from a deep to superficial orientation into the proximal side of the fibular end of the ligament.



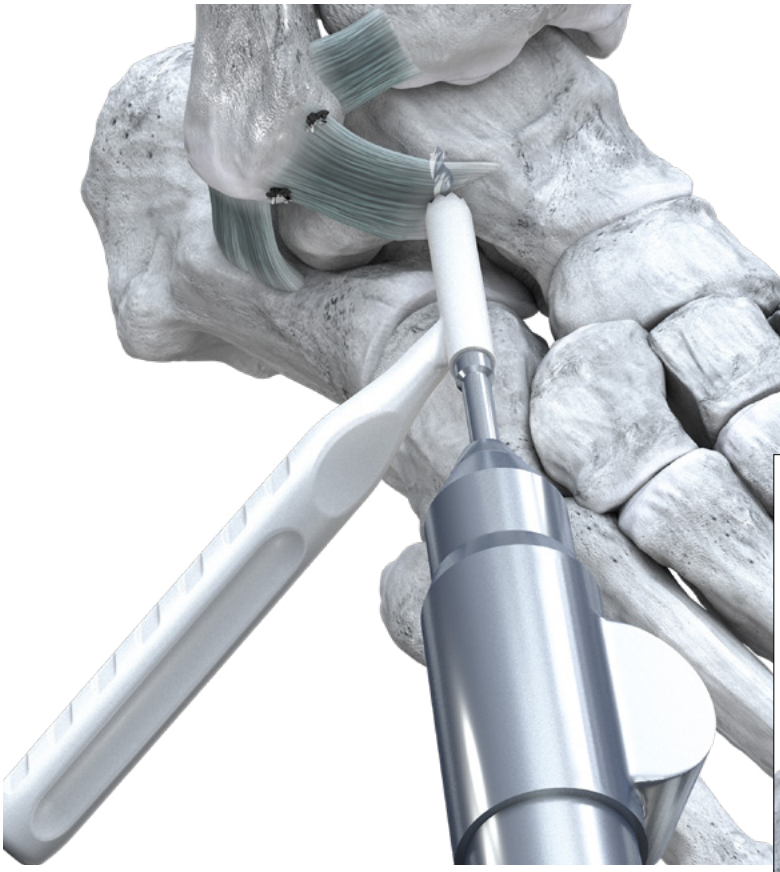
Repeat the previous steps to insert a second Titanium Anchor into the distal anatomic ATFL origin on the fibula and pass the suture into the distal side of the fibular end of the ATFL.



After tensioning the Anchor suture tails, tie knots to secure the ligament to the bone and cut the excess suture to complete the repair.

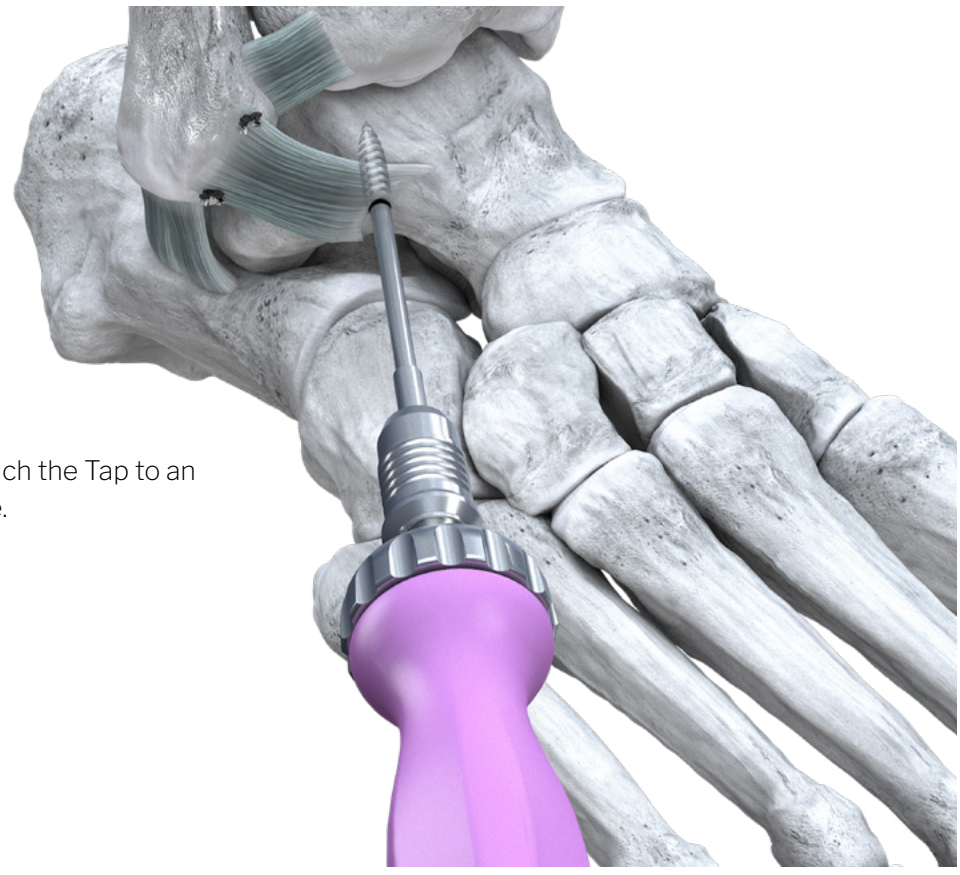
Continue on page 11 for Knotless Anchor Insertion

KNOTLESS ANCHOR INSERTION



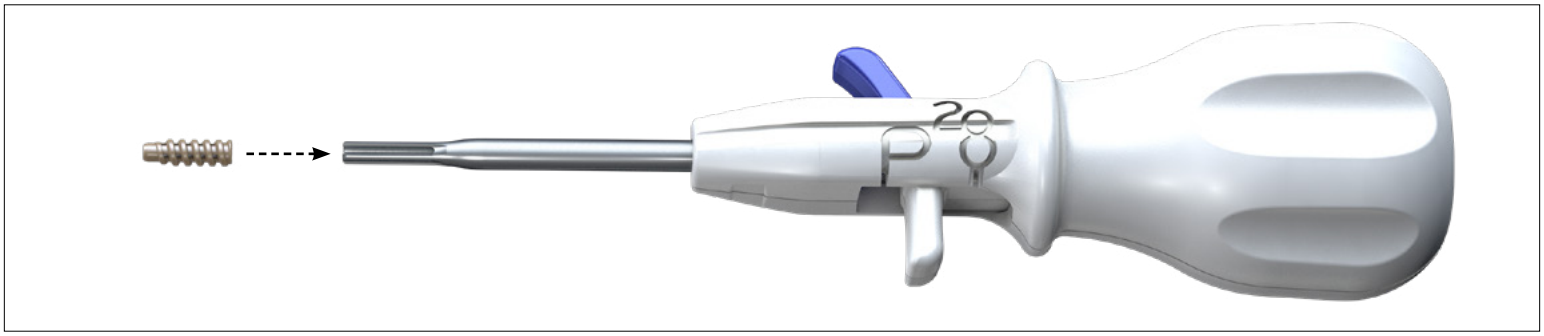
Tape Augmentation Technique

Use the provided Ø3.5 Drill to create the pilot hole for the Knotless Anchor at the talar ATFL insertion at a 45° posteromedial direction. If using the Drill Guide, drill until the hard stop is reached, otherwise drill until the flutes are buried.

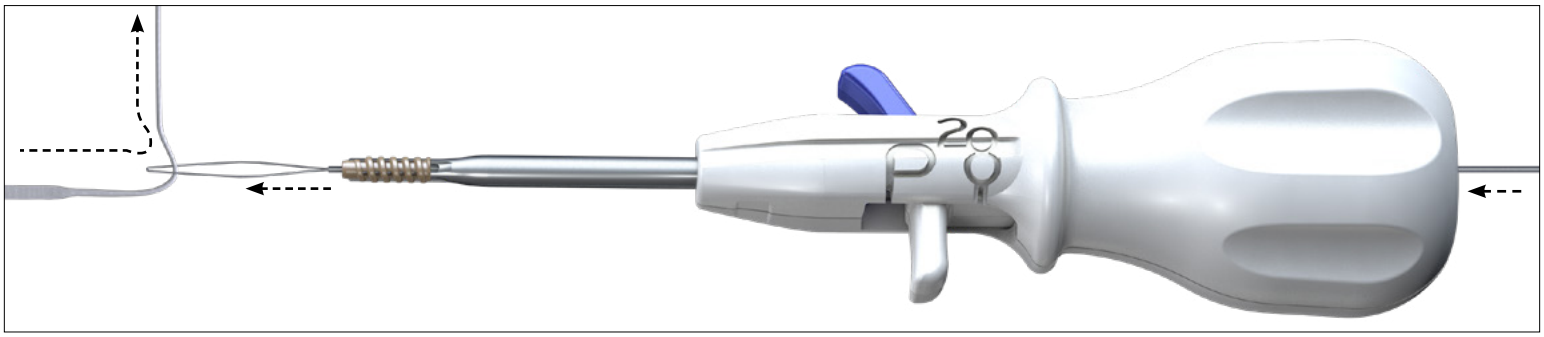


A Tap is provided to aid in insertion. Attach the Tap to an AO Handle and hand tap to the laser line.

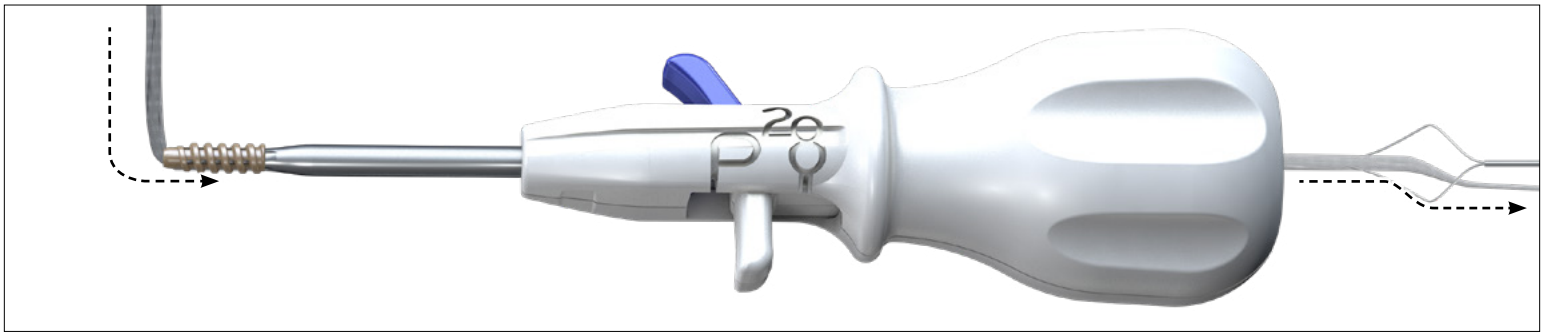
KNOTLESS ANCHOR INSERTION



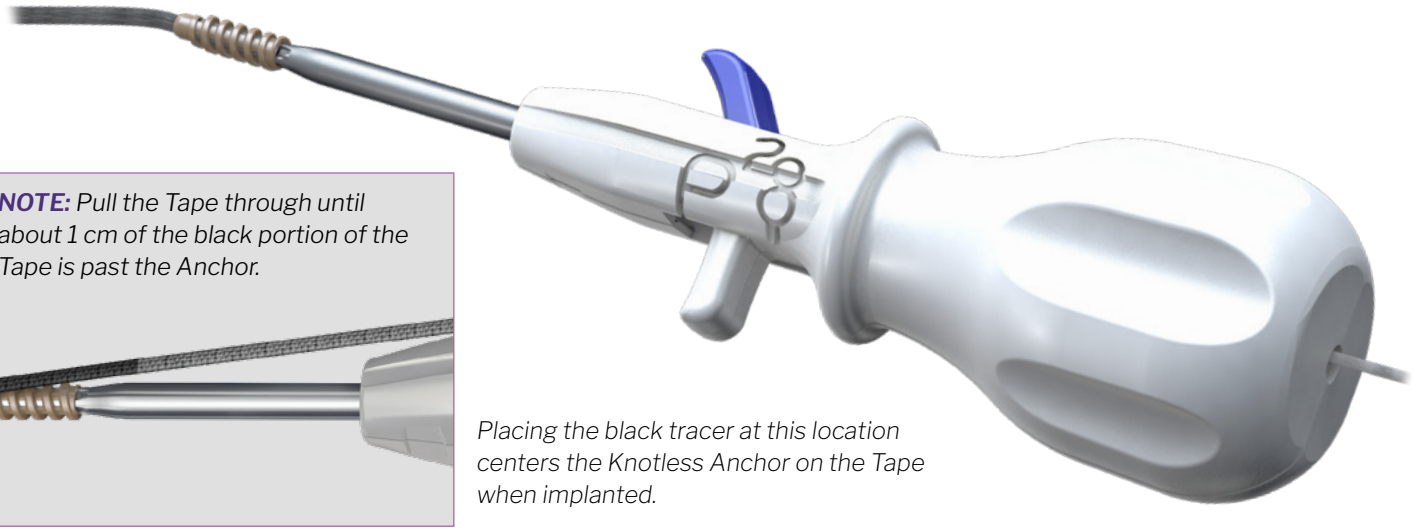
1. Insert the Knotless Anchor over the Tensioning Driver Handle tip.



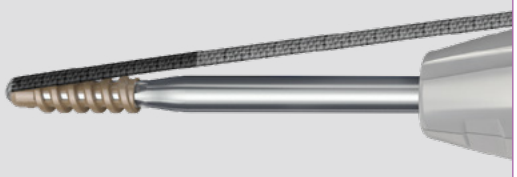
2. Pass the Suture Passer through the Tensioning Driver Handle. Feed 3-5 cm of the Suture Tape through the Suture Passer.



3. Pull the Suture Passer back through the center of the Tensioning Driver Handle to pass the Tape through the Knotless Anchor and Handle.

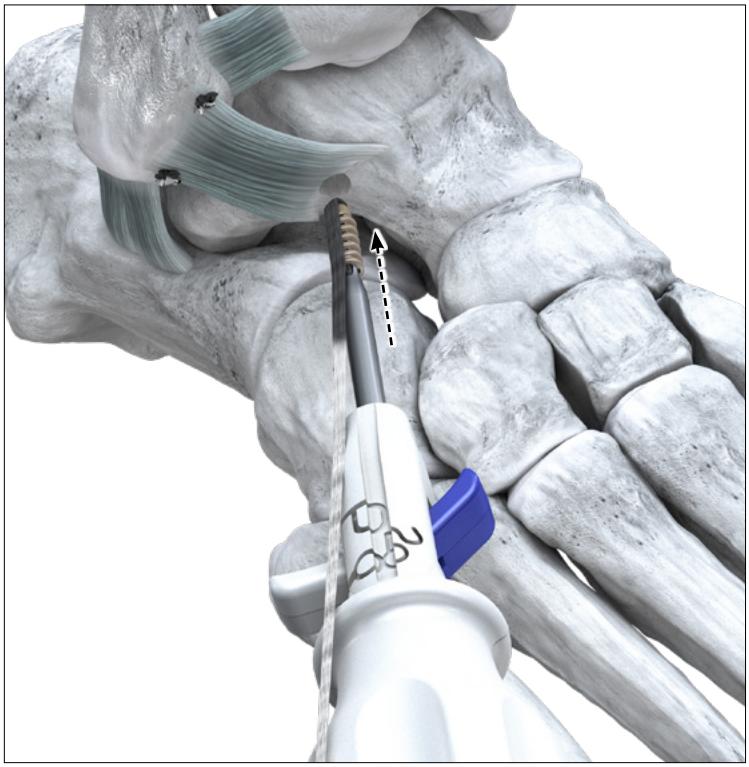


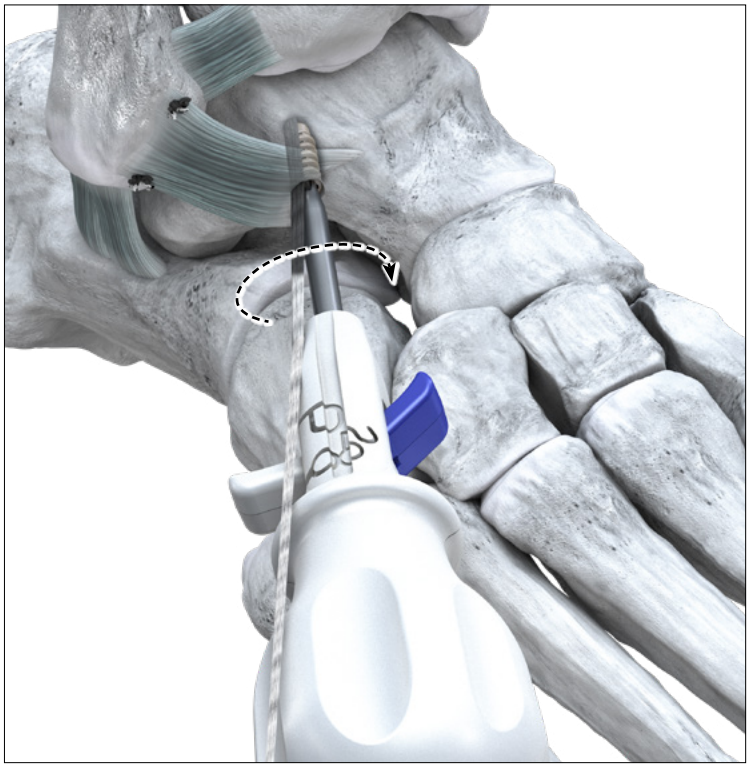
NOTE: *Pull the Tape through until about 1 cm of the black portion of the Tape is past the Anchor.*



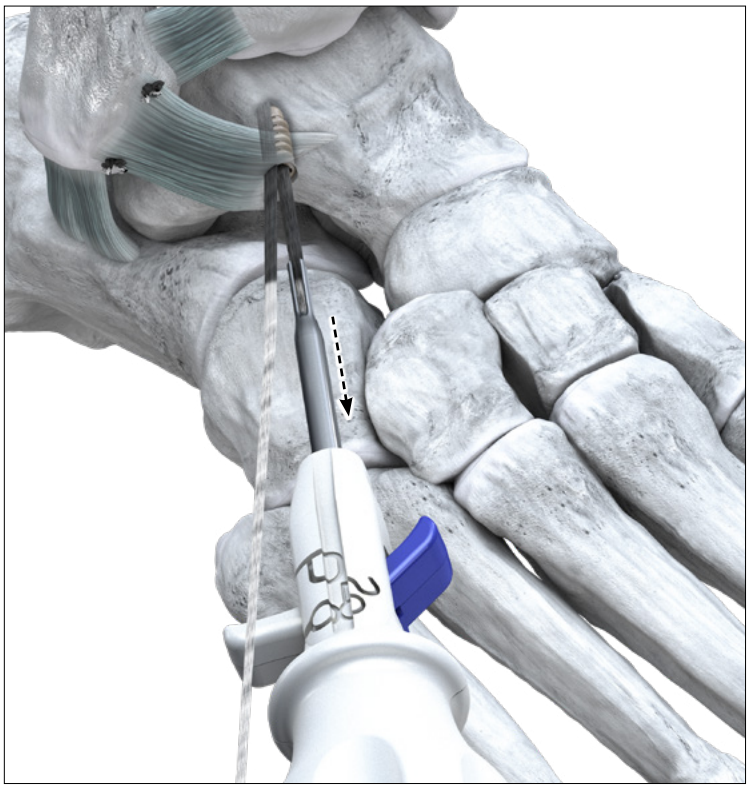
Placing the black tracer at this location centers the Knotless Anchor on the Tape when implanted.

KNOTLESS ANCHOR INSERTION

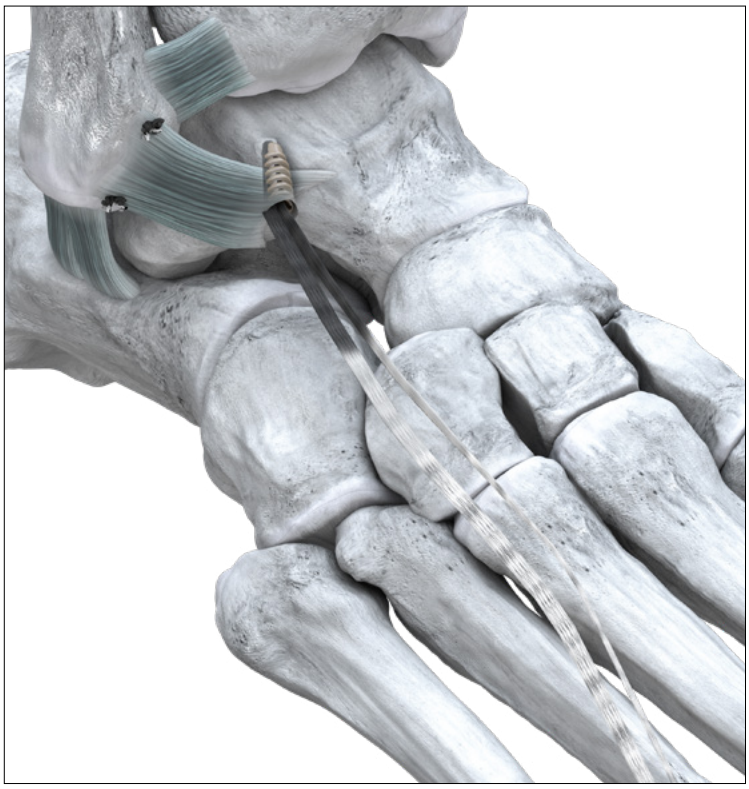




Insert the Anchor with the pre-loaded 4.0 mm Suture Tape and then turn the Driver in a clockwise direction. Ensure that the Tape is flat and not twisted when inserting the Anchor to prevent complications with insertion.

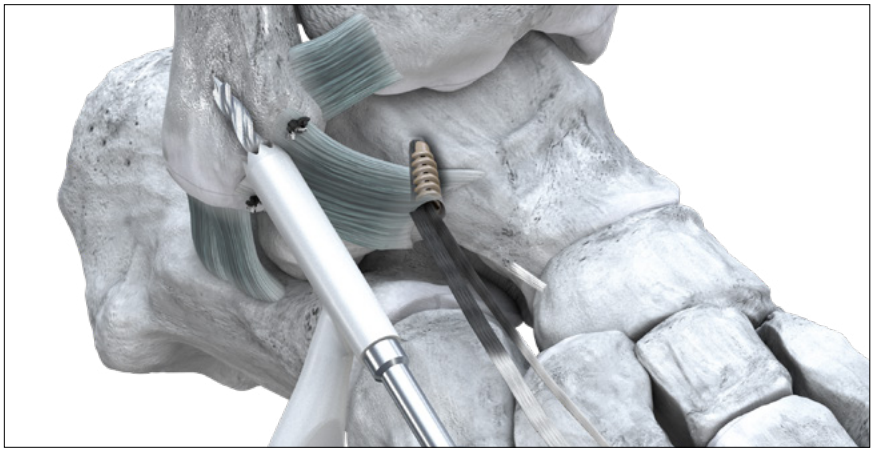


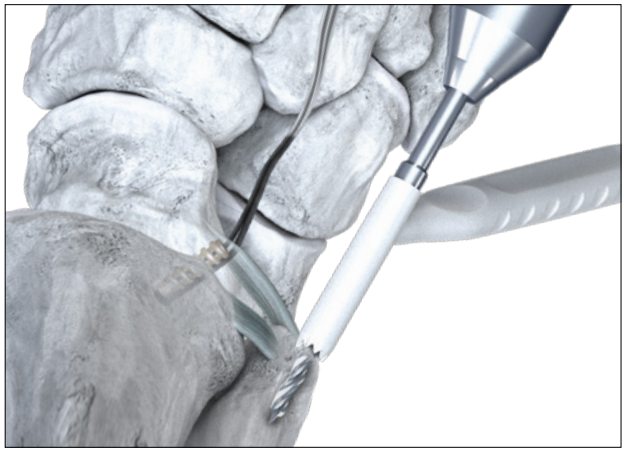
Slide the Tensioning Driver Handle off the Anchor along the Tape.



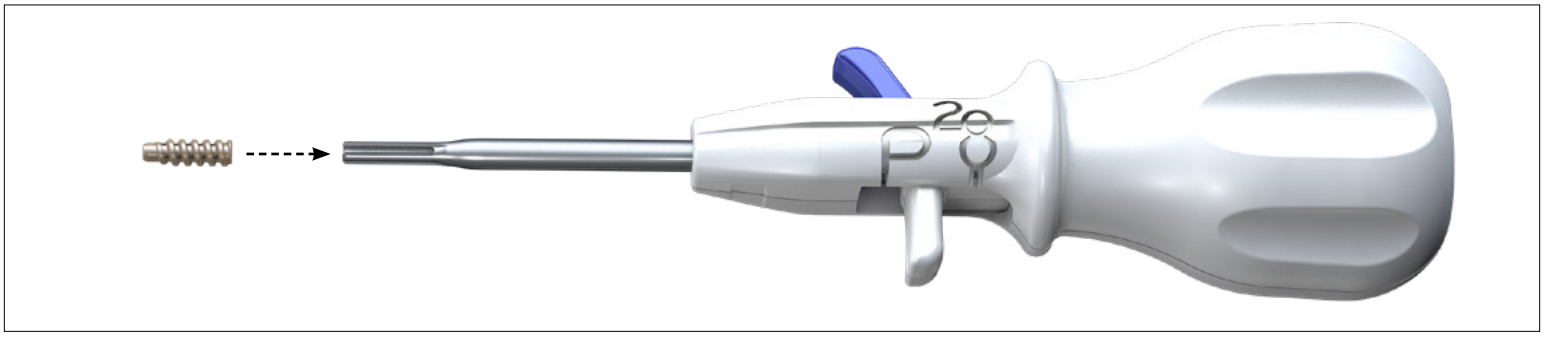
Examine the Tape to ensure it is not twisted so it can be smoothly passed through the second Knotless Anchor.

KNOTLESS ANCHOR INSERTION

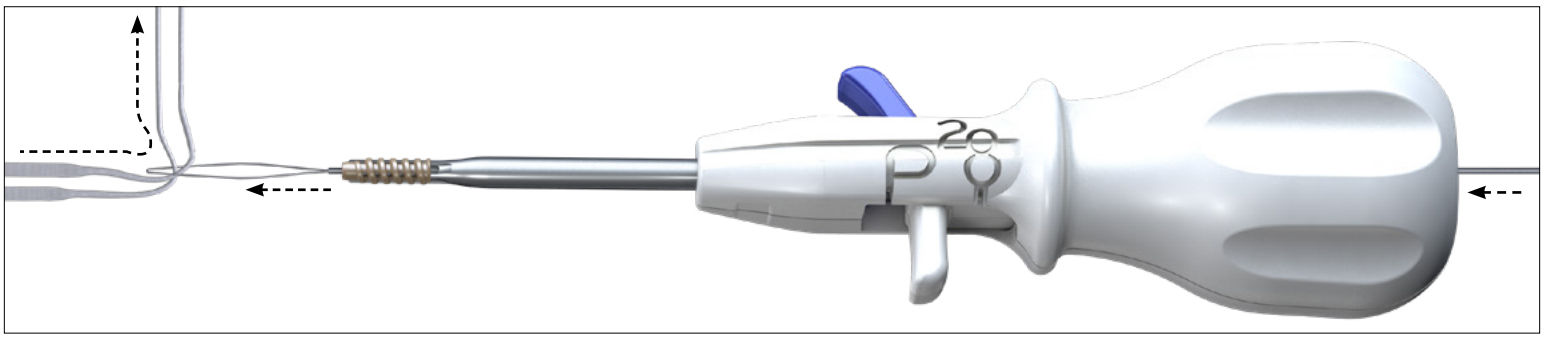




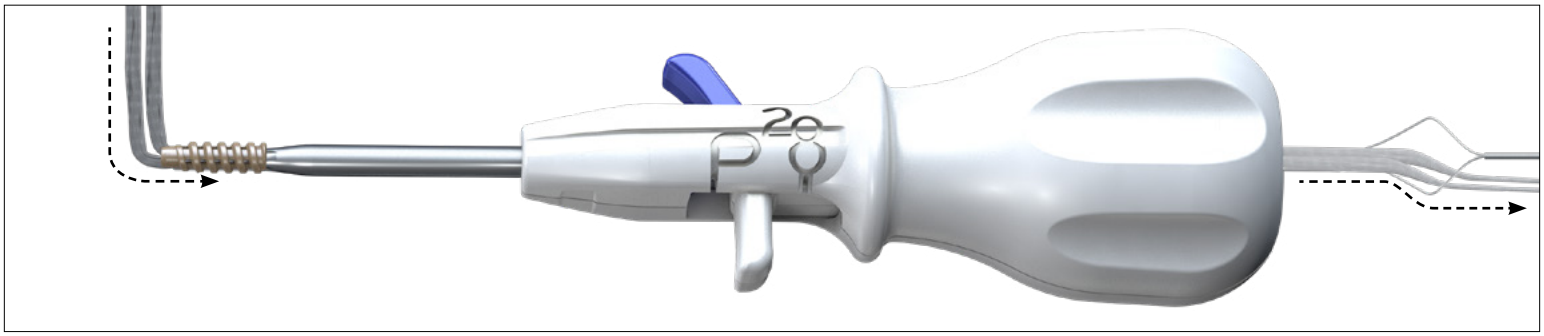
Once the first Knotless Anchor has been placed, use the provided Drill, Drill Guide, and Tap to create a second pilot hole for the second Anchor in the fibula at the origin of the ATFL.



1. Insert the second Knotless Anchor over the Tensioning Driver Handle tip.

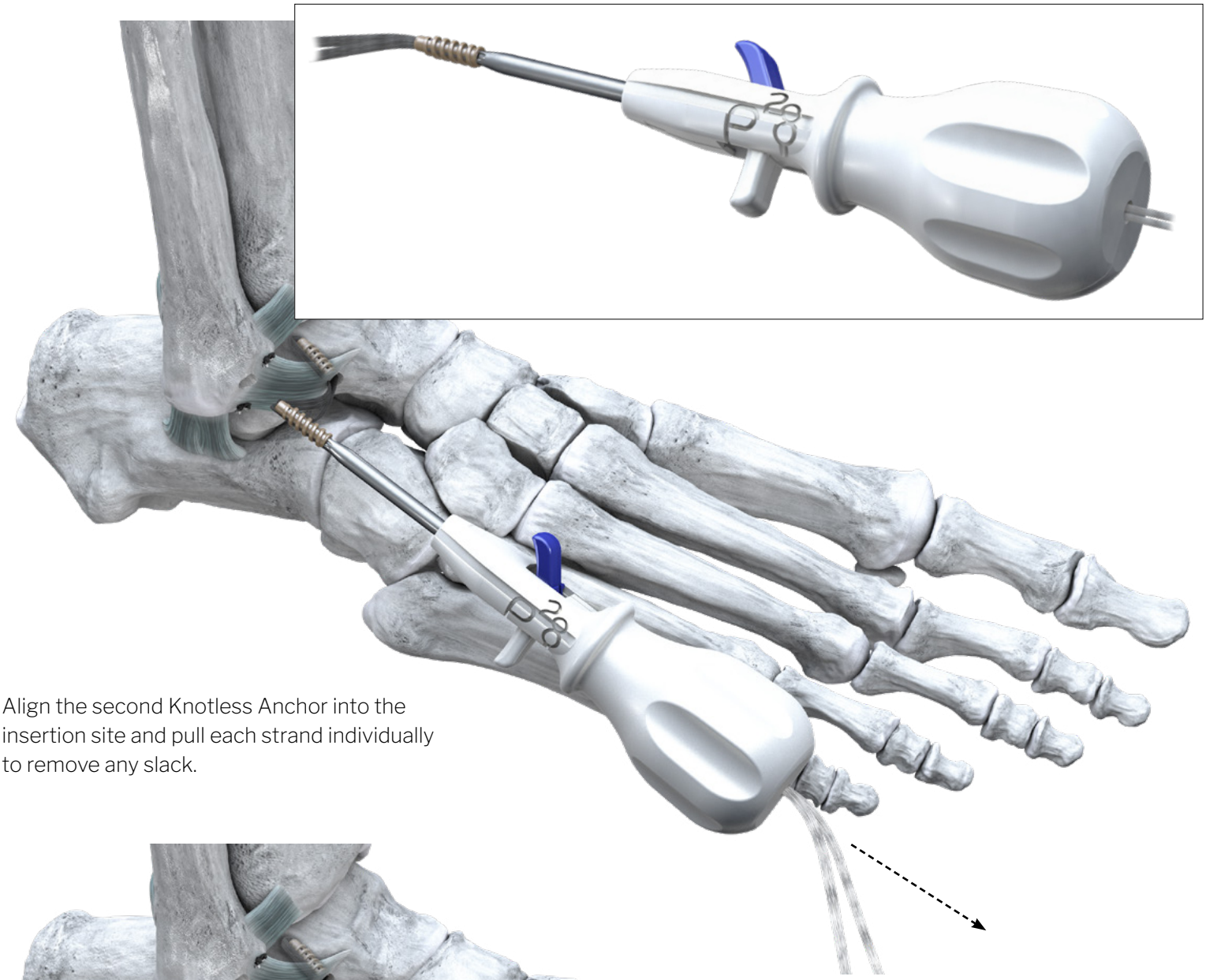


2. Pass the Suture Passer through the Tensioning Driver Handle. Feed 3-5 cm of the Suture Tape through the Suture Passer.

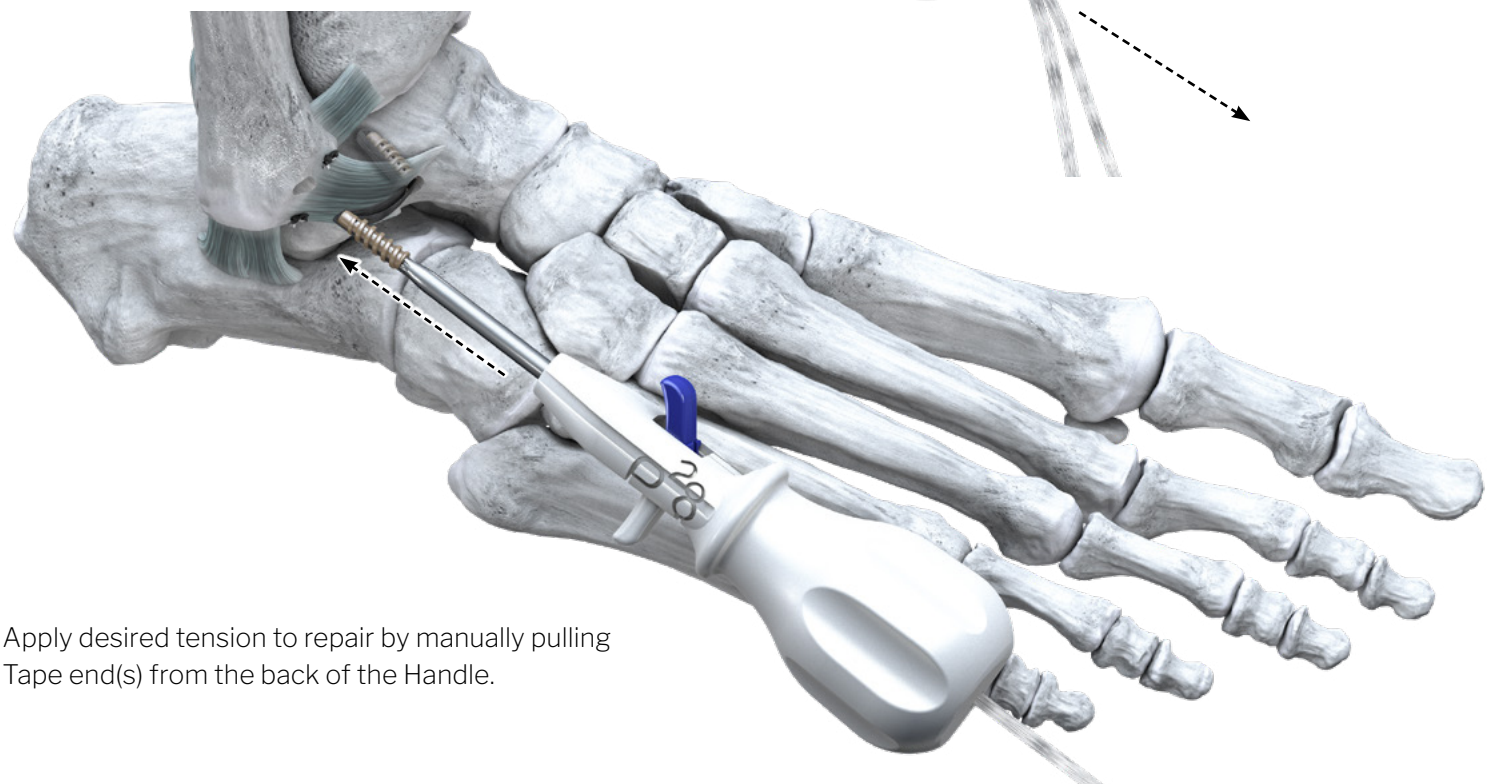


3. Pull the Suture Passer back through the center of the Tensioning Driver Handle to pass the Tape through the Knotless Anchor and Handle.

KNOTLESS ANCHOR INSERTION

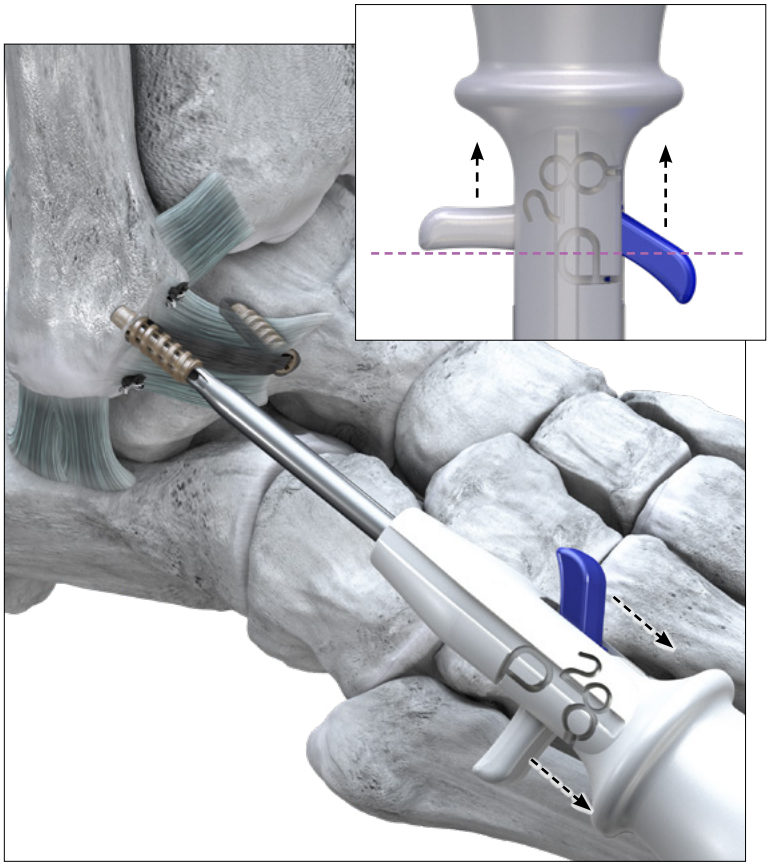


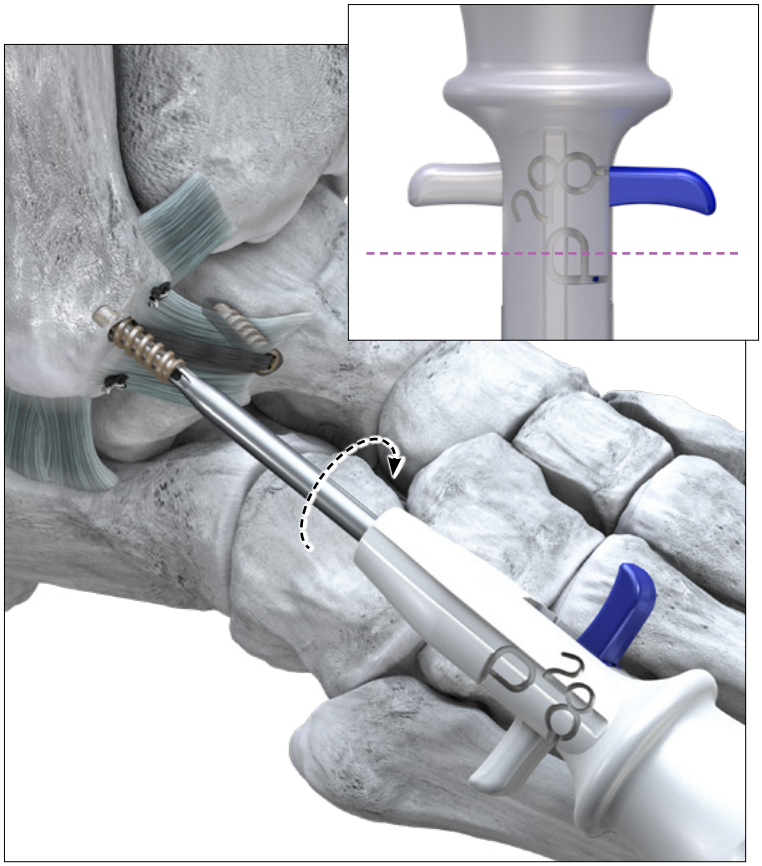
Align the second Knotless Anchor into the insertion site and pull each strand individually to remove any slack.



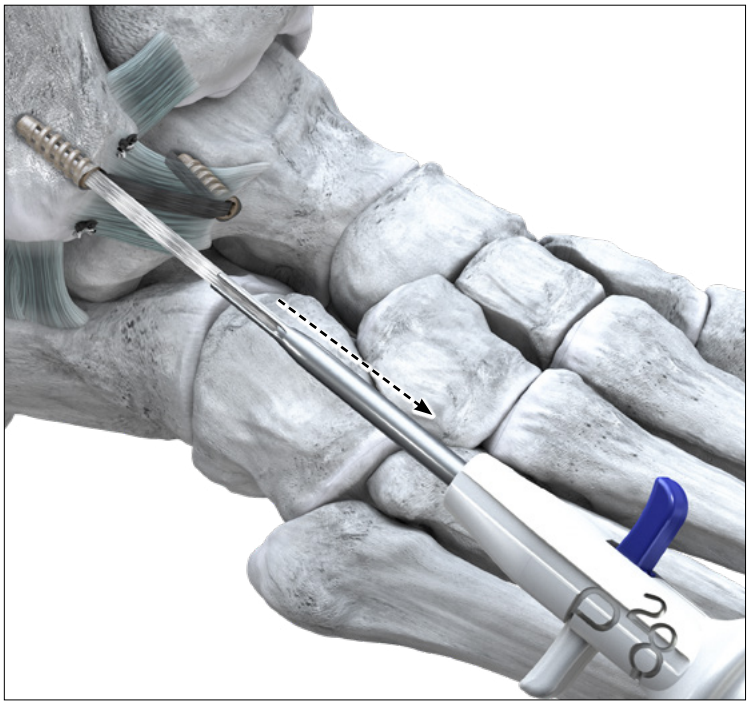
Apply desired tension to repair by manually pulling Tape end(s) from the back of the Handle.

KNOTLESS ANCHOR INSERTION

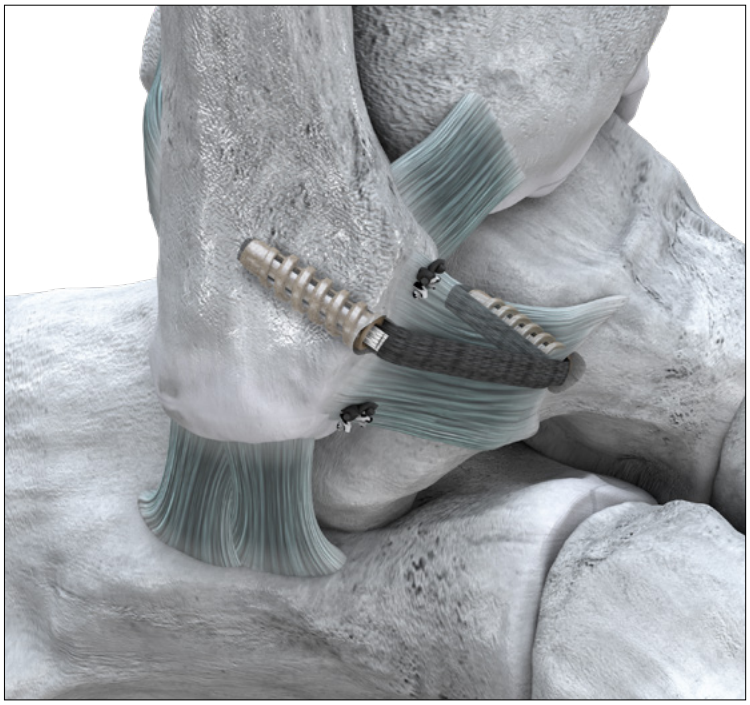




The Tensioning Trigger if desired can be used to hold the Tape when setting the tension. When proper tension is achieved, fully insert the Knotless Anchor into the insertion site by driving in clockwise. If using the Tensioning Trigger, it must be released right after beginning Anchor insertion. A freer or hemostat can be placed underneath the Tape prior to tensioning to prevent overconstraining the joint.



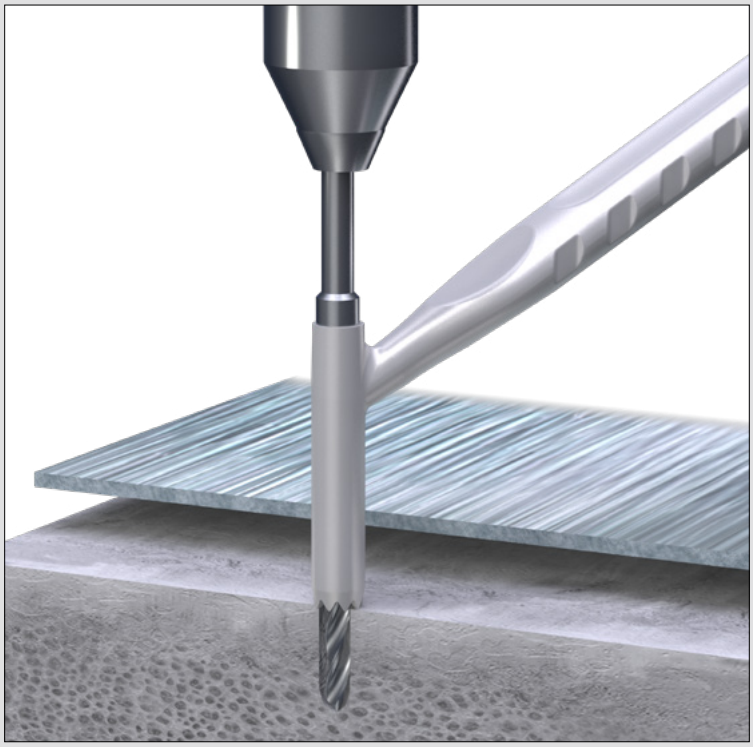
Slide the handle straight back off the Anchor.



Cut off the excess Tape to complete the repair.

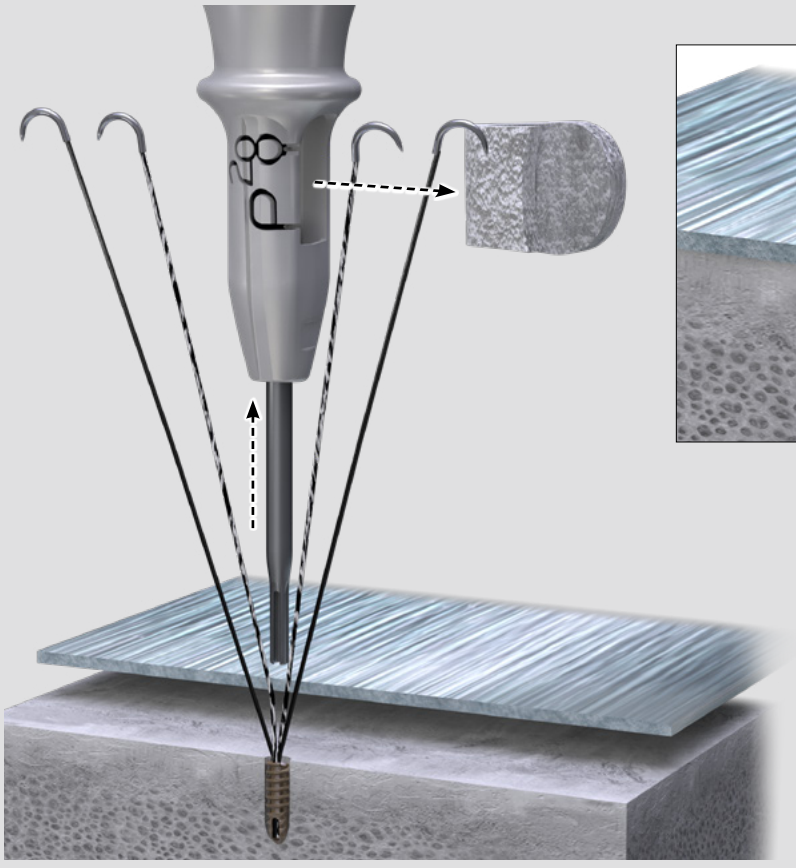
PEEK ANCHOR INSERTION

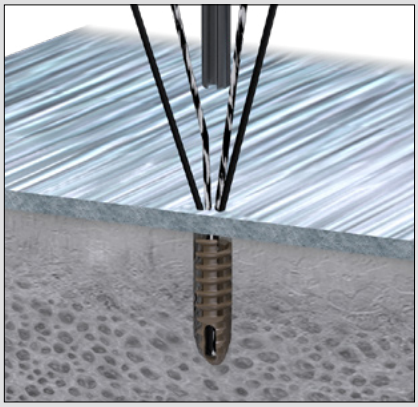
NOTE: *PEEK Anchors due to their size offerings are not recommended for use in the Brostrom technique, therefore instructions for their general use is provided here.*

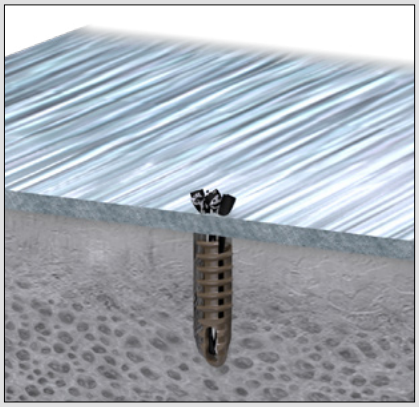


Drill with the provided Solid Drill Bit through the Drill Guide to the hard stop at the desired bone insertion site.

Turn the driver in a clockwise direction to insert the Anchor until flush or slightly countersunk.







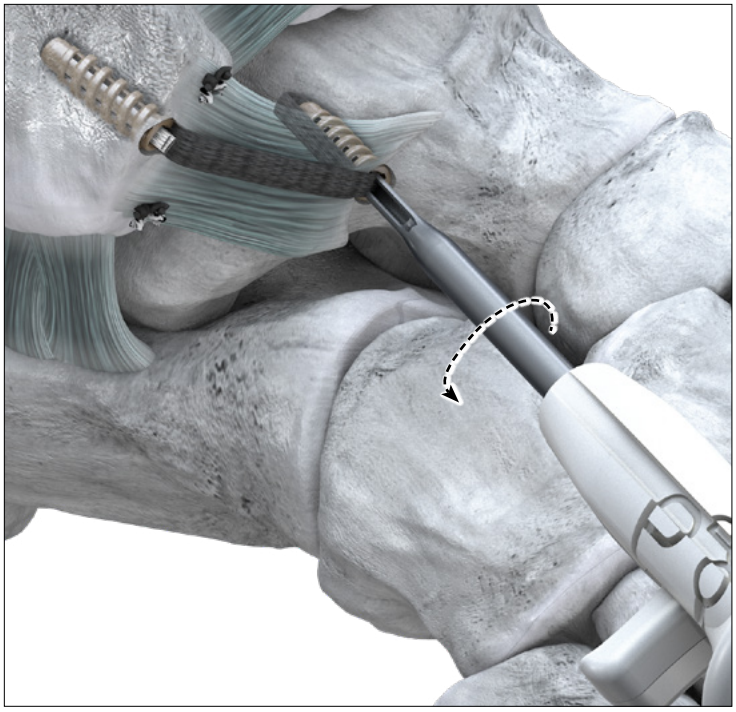
Disengage the needles and suture from the driver by pulling the foam block. Proceed to pass the needles from a deep to superficial orientation in the desired location of the ligament.

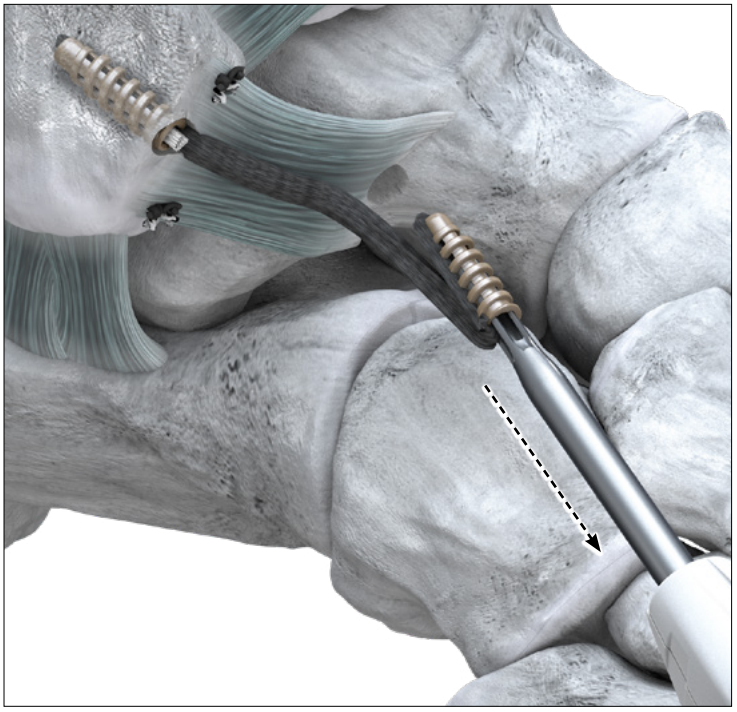
After tensioning the Anchor suture tails, tie a knot to secure the ligament to the bone and cut the excess suture to complete the repair.

REMOVAL

The Titanium, PEEK, and Knotless Anchors may be removed using their respective drivers. To remove, engage the drive feature of the Anchor and turn counterclockwise. Removal instrumentation can be supplied upon request.

TIP: *If experiencing difficulty engaging the Knotless Anchor for removal, slide the Tape through the slot of the Driver tip to guide the tip to the Knotless Anchor.*





GRAPPLER® SUTURE ANCHOR SYSTEM STERILE KITS

Grappler® Suture Anchor, All-Suture, Ø1.4mm:

[P44-210-0014-SK]

- #0 Suture w/Needles (qty 2)
- Ø1.4mm x 15cm K-wire (qty 1)
- Drill Guide

Grappler® Suture Anchor, All-Suture, Ø2.8mm:

[P44-210-0028-SK]

- Two #2 Suture w/Needles (qty 4)
- Ø2.8mm x 15cm K-wire (qty 1)
- Drill Guide

Grappler® Suture Anchor, Titanium, Ø3.0 x 12 mm:

[P44-111-3012-SK]

- Two #0 Suture w/Needles (qty 4)
- Ø2.0mm x 15cm K-wire (qty 1)

Grappler® Suture Anchor, Titanium, Ø4.5 x 15 mm:

[P44-110-4515-SK]

- Two #2 Suture w/Needles (qty 4)
- Ø2.6mm x 15cm K-wire (qty 1)

Grappler® Suture Anchor, PEEK, Ø4.5 x 15 mm:

[P44-120-4515-SK]

- Two #2 Suture w/Needles (qty 4)
- Ø1.6mm x 15cm K-wire (qty 1)
- Ø3.5mm Drill (qty 1)
- Drill Guide

Grappler® Suture Anchor, PEEK, Ø4.5 x 15 mm, w/ Tape:

[P44-121-4515-SK]

- #2 Suture and 1.5mm Tape w/Needles (qty 4)
- Ø1.6mm x 15cm K-wire (qty 1)
- Ø3.5mm Drill (qty 1)
- Drill Guide

Grappler Suture Anchor System, Cannulated Drill, Ø4.5mm:

[P44-941-3510-S]

Grappler Suture Anchor System, Tap for PEEK Anchor, Ø4.5mm

[P44-960-0045-S]

Grappler® Suture Anchor, PEEK, Ø5.5 x 15 mm:

[P44-120-5515-SK]

- Two #2 Suture w/Needles (qty 4)
- Ø1.6mm x 15cm K-wire (qty 1)
- Ø4.3 mm Drill (qty 1)
- Drill Guide

Grappler® Suture Anchor, PEEK, Ø5.5 x 15 mm, w/ Tape:

[P44-121-5515-SK]

- #2 Suture and 1.5mm Tape w/Needles (qty 4)
- Ø1.6mm x 15cm K-wire (qty 1)
- Ø4.3 mm Drill (qty 1)
- Drill Guide

Grappler Suture Anchor System, Cannulated Drill, Ø5.5mm

[P44-941-4310-S]

Grappler Suture Anchor System, Tap for PEEK Anchor, Ø5.5mm

[P44-960-0055-S]]

GRAPPLER® KNOTLESS ANCHOR SYSTEM STERILE KITS

PROCEDURE KITS

Grappler® Knotless Procedure Kit, Two Ø4.5 mm Anchors w/ Bridgeline™ Tape:

[P44-300-4515-SK]

- Tensioning Driver preloaded with a Ø4.5 mm Knotless Anchor and suture passer
- Additional Ø4.5 mm Knotless Anchor
- Ø3.5 mm Drill Bit
- Ø3.5 mm Drill Guide
- Ø4.5 mm Tap
- UHMWPE Bridgeline™ 4.0 mm Tape

Grappler® Knotless Procedure Kit, Two Ø4.5 mm Anchors w/ Adaptive Bridgeline™ Tape:

[P44-310-4515-SK]

- Tensioning Driver preloaded with a Ø4.5 mm Knotless Anchor and suture passer
- Additional Ø4.5 mm Knotless Anchor
- Ø3.5 mm Drill Bit
- Ø3.5 mm Drill Guide
- Ø4.5 mm Tap
- Adaptive Bridgeline™ 4.0 mm Tape

ANCHORS ONLY

Grappler® Knotless Anchor, Ø4.5 mm Implant-Only Kit:

[P44-131-4515-SK]

- Tensioning Driver preloaded with a Ø4.5 Knotless Anchor and suture passer

Grappler® Knotless Anchor, Ø5.5 mm Implant-Only Kit:

[P44-131-5515-SK]

- Tensioning Driver preloaded with a Ø5.5 Knotless Anchor and suture passer

ANCHORS AND INSTRUMENTS

Grappler® Knotless Anchor, Ø4.5 mm Implant and Instruments Kit:

[P44-130-4515-SK]

- Tensioning Driver preloaded with a Ø4.5 Knotless Anchor and suture passer
- Ø3.5 Drill Bit
- Ø3.5 Drill Guide
- Ø4.5 Tap

Grappler® Knotless Anchor, Ø5.5 mm Implant and Instruments Kit:

[P44-130-5515-SK]

- Tensioning Driver preloaded with a Ø4.5 Knotless Anchor and suture passer
- Ø4.3 Drill Bit
- Ø4.3 Drill Guide
- Ø5.5 Tap

ADDITIONAL STERILE-PACKED COMPONENTS:

Suture passers (Box of 5)

[P44-970-0001-SK]

Bridgeline™ 4.0 mm Tape (UHMWPE)

[P44-300-0004-S]

Adaptive Bridgeline™ 4.0 mm Tape (PGLA/UHMWPE)

[P44-310-0004-S]

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

INDICATIONS FOR USE

The Grappler® Suture Anchor System is intended for the fixation of soft tissue to bone including:

Elbow:
- Biceps Tendon Reattachment
- Lateral Epicondylitis Repair,
- Tennis Elbow Repair

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

Hand/Wrist:
- Scapholunate Ligament Reconstruction
- Ulnar or Radial Collateral Ligament Reconstruction
- TFCC

Foot/Ankle:
- Lateral Stabilization (Brostrom, Brostrom-Gould, Chrisman-Snook Repair)
- Ankle Ligament Repair
- Medial Stabilization (Deltoid Repair, Spring Ligament Reconstruction)
- Achilles Tendon Repair
- Metatarsal Ligament Repair
- Syndesmosis Repair
- Hallux Valgus Reconstruction
- Digital Tendon Transfers
- Mid- foot Reconstruction
- LisFranc Repair

Knee:
- Medial Collateral Ligament Repair
- Lateral Collateral Ligament Repair
- Posterior Oblique Ligament Repair
- Iliotibial Band Tenodesis
- Extra Capsular Reconstruction
- Patellar Ligament and Tendon Avulsion Repair

Hip:
- Capsular Repair
- Acetabular Labral Repair

The plate interacting anchors are only indicated for the above Hand/Wrist and Foot/Ankle indications.

CONTRAINDICATIONS

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

- Active, suspected or latent infection in the affected area
- Patients who are physiologically or psychologically inadequate
- Corpulence; an overweight or corpulent patient can strain the implant to such a degree that stabilization or implant failure can occur
- Patients with a known allergy to the implant material(s)
- Patients previously sensitized to titanium
- Insufficient quantity or quality of bone or soft tissue 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
- Use in cardiac indications
- **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
- 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
- Implant degradation with localized reaction and pain
- Pain, a feeling of malaise or abnormal sensations due to the implant used
- Bone resorption or over-production

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.

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

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 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.
- Avoid K-wires through the implant.
- Avoid flawing implant surfaces to minimize the potential for early fatigue failure.
- **Do not use other manufacturer's instruments or implants in conjunction with the Grappler® Suture Anchor System.**
- **Do not resterilize the Grappler® Suture Anchor System Implants and Instruments.**

MR SAFETY INFORMATION

The Grappler® Suture Anchor 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 Grappler® Suture Anchor System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

GRAPPLER®
SUTURE ANCHOR SYSTEM

GRAPPLER™
KNOTLESS ANCHOR SYSTEM

P44-STG-0001 Rev D [2025-01-31]

Exclusively foot & ankle Paragon 28®
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Australia

Disclaimer:
The purpose of the Grappler® Suture Anchor System and Grappler® Knotless Anchor System Surgical Technique Guide is to demonstrate the optionality and functionality of the Grappler® Suture Anchor System and Grappler® Knotless Anchor System implants and instrumentation.
CAUTION: Federal Law (USA) restricts this device to sale and use by, or on the order of, a physician.