



PRIMATIX™
SUTURE ANCHORS

GRAPPLER™
KNOTLESS ANCHOR SYSTEM

LATERAL ANKLE INSTABILITY SURGICAL TECHNIQUE GUIDE

Exclusively foot & ankle ²⁰
Paragon®



PRODUCT DESCRIPTION

The PRIMATIX™ 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.

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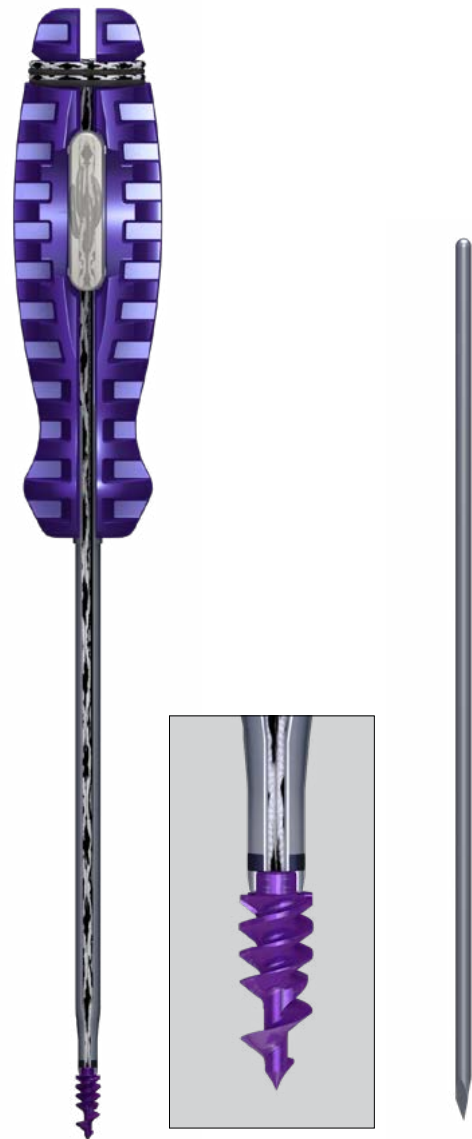
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SYSTEM OVERVIEW



ALL-SUTURE ANCHOR KITS

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

SYSTEM OVERVIEW



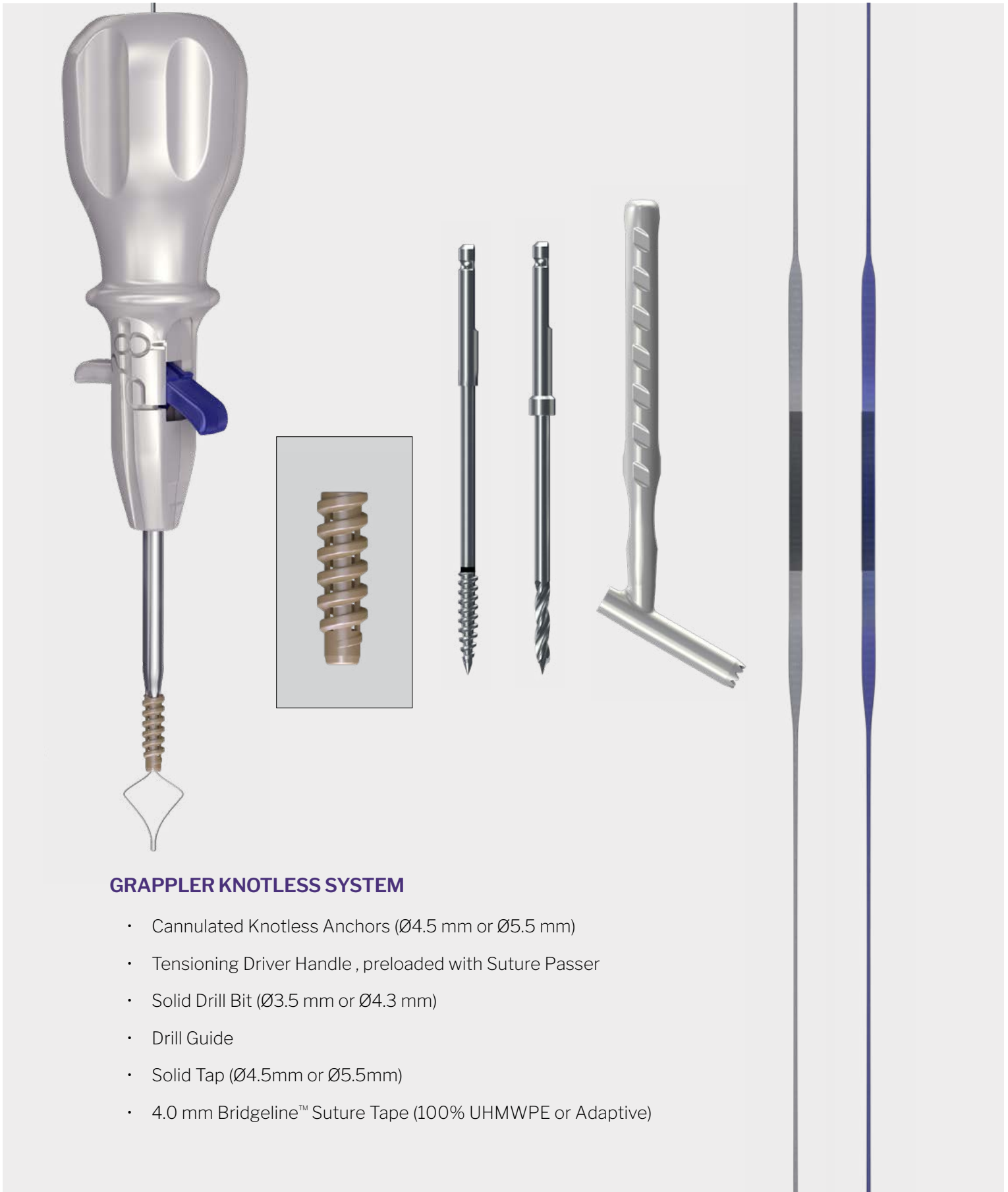
PEEK ANCHOR KITS

- **Ø4.5 mm Anchors:**
 - Double-loaded with #2 Suture
 - or
 - Double-loaded with #2 Suture and 1.5 mm Tape
 - Handle with removable Ø4.5mm Tap Bit
 - Ø3.5 mm Drill Bit
 - Drill Guide
- **Ø5.5 mm Anchors:**
 - Double-loaded with #2 Suture
 - or
 - Double-loaded with #2 Suture and 1.5 mm Tape
 - Handle with removable Ø5.5mm Tap Bit
 - Ø4.3 mm Drill Bit
 - Drill Guide



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

SYSTEM OVERVIEW



GRAPPLER KNOTLESS SYSTEM

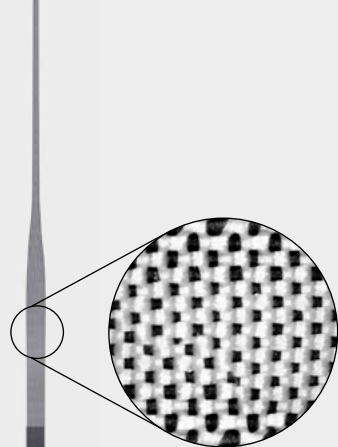
- Cannulated Knotless Anchors (Ø4.5 mm or Ø5.5 mm)
- Tensioning Driver Handle , preloaded with Suture Passer
- Solid Drill Bit (Ø3.5 mm or Ø4.3 mm)
- Drill Guide
- Solid Tap (Ø4.5mm or Ø5.5mm)
- 4.0 mm Bridgeline™ Suture Tape (100% UHMWPE or Adaptive)

SYSTEM OVERVIEW

GRAPPLER KNOTLESS SYSTEM

Tape Features:

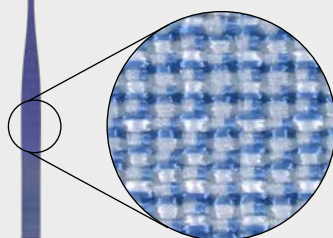
- The central third of each Tape is demarcated by a black tracer strand. This allows the surgeon to plan for appropriate working length of the repair



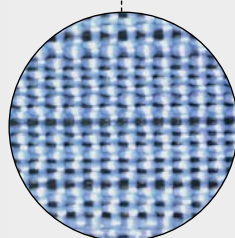
UHMWPE Weave

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

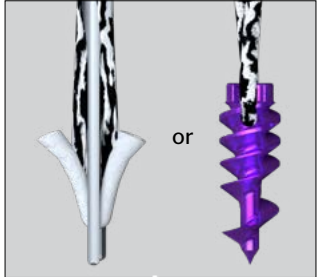
Tensioning Driver Features:

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



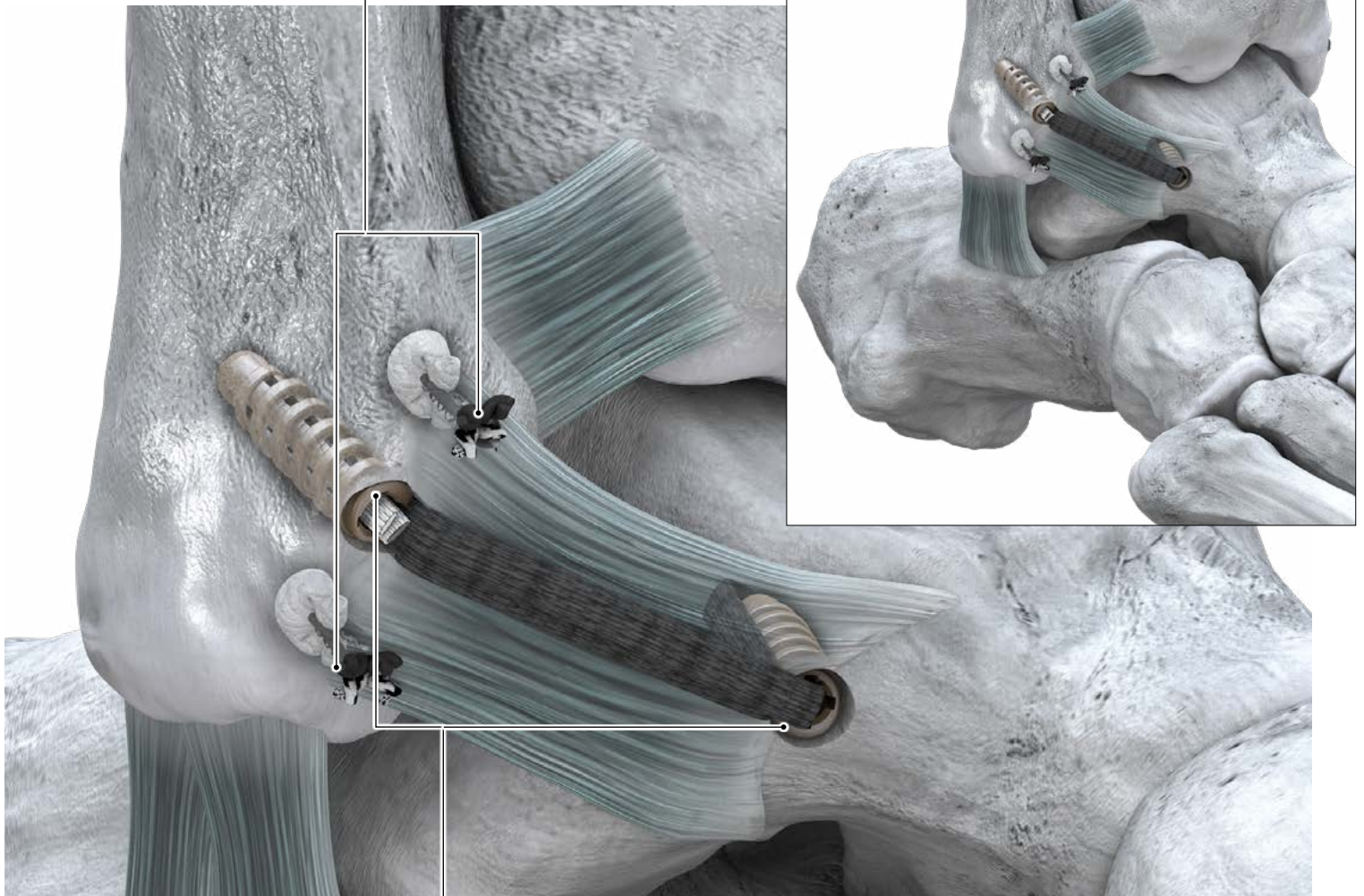
LATERAL ANKLE INSTABILITY: ATFL REPAIR (BROSTROM)

For patients with lateral ankle instability, a repair of the anterior talofibular ligament (ATFL) can be performed using the PRIMATIX™ 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)

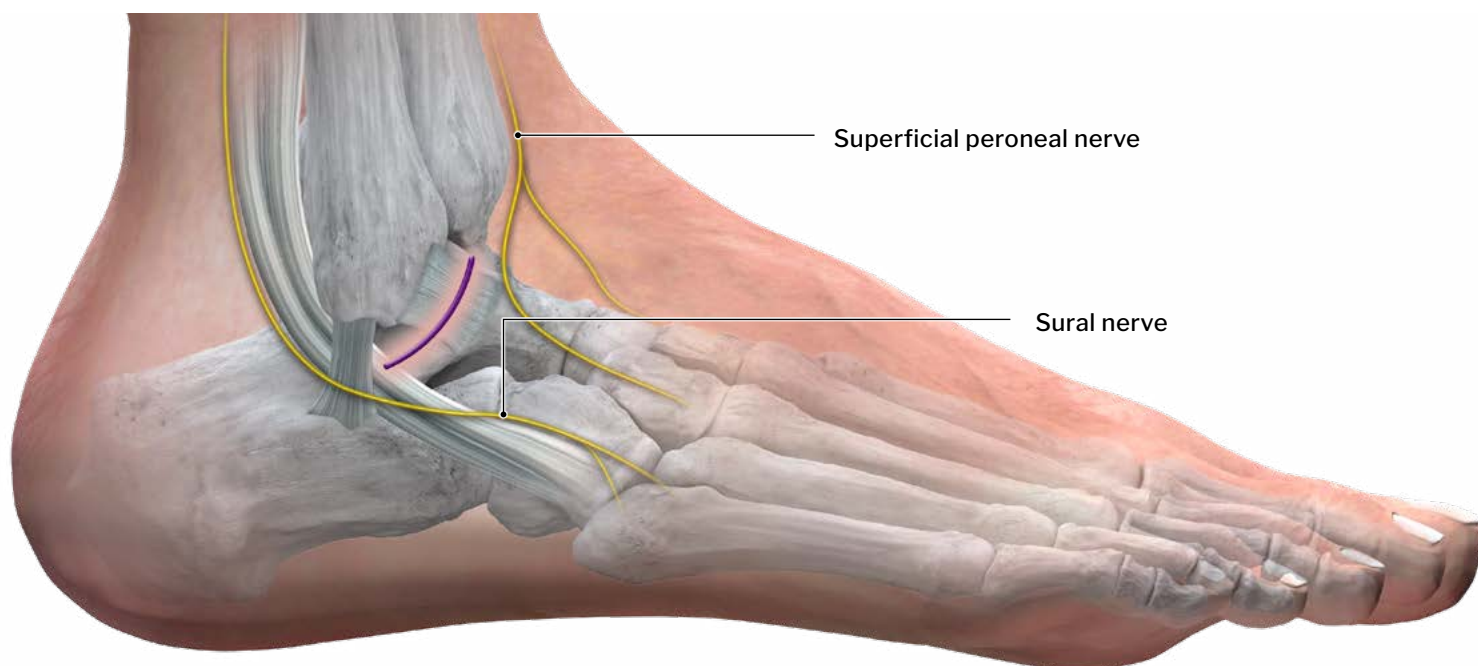


TAPE AUGMENTATION OPTIONS:

- 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

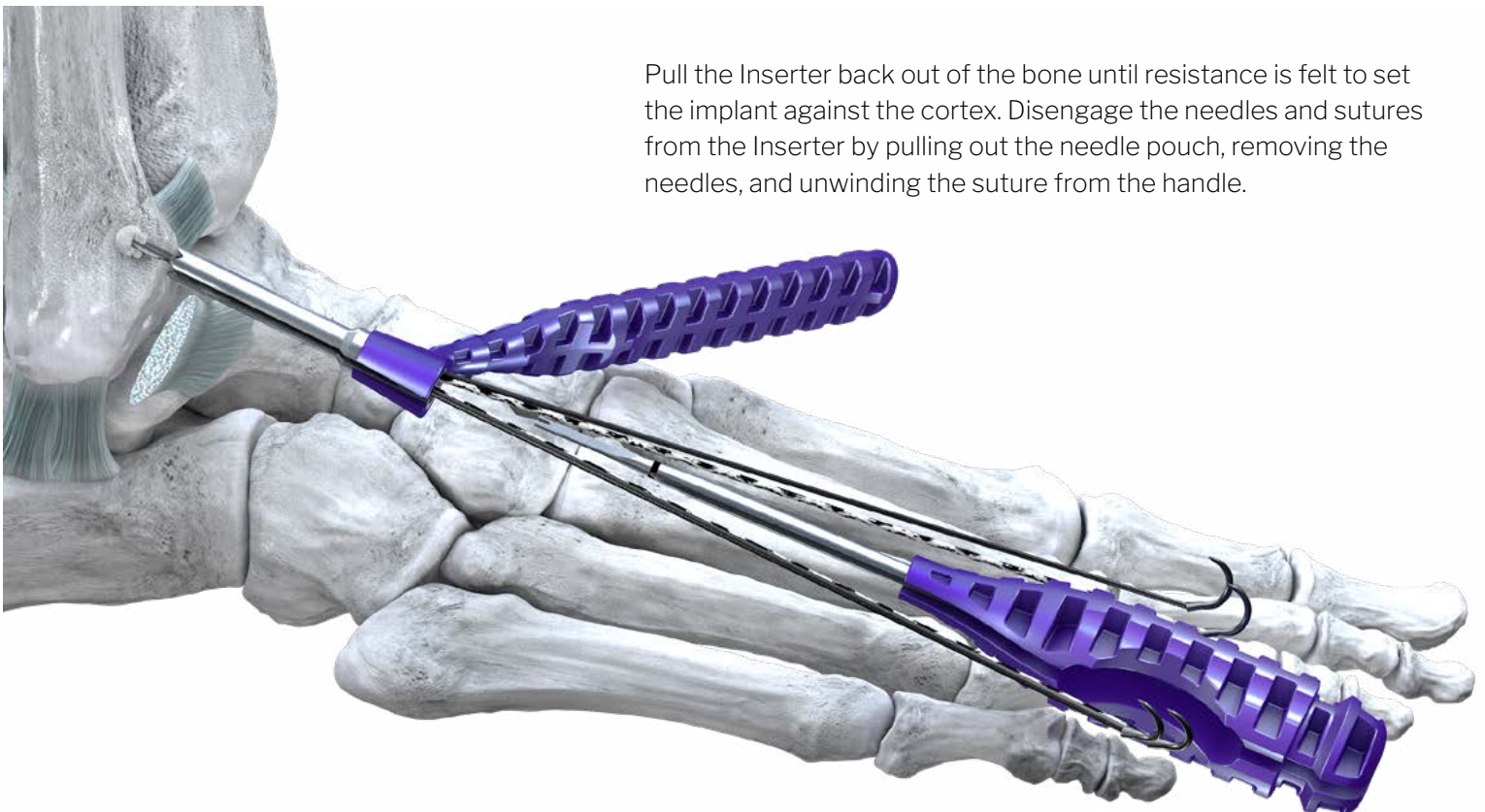
ALL-SUTURE ANCHOR INSERTION



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. Remove the Drill without adjusting the position of the Drill Guide.

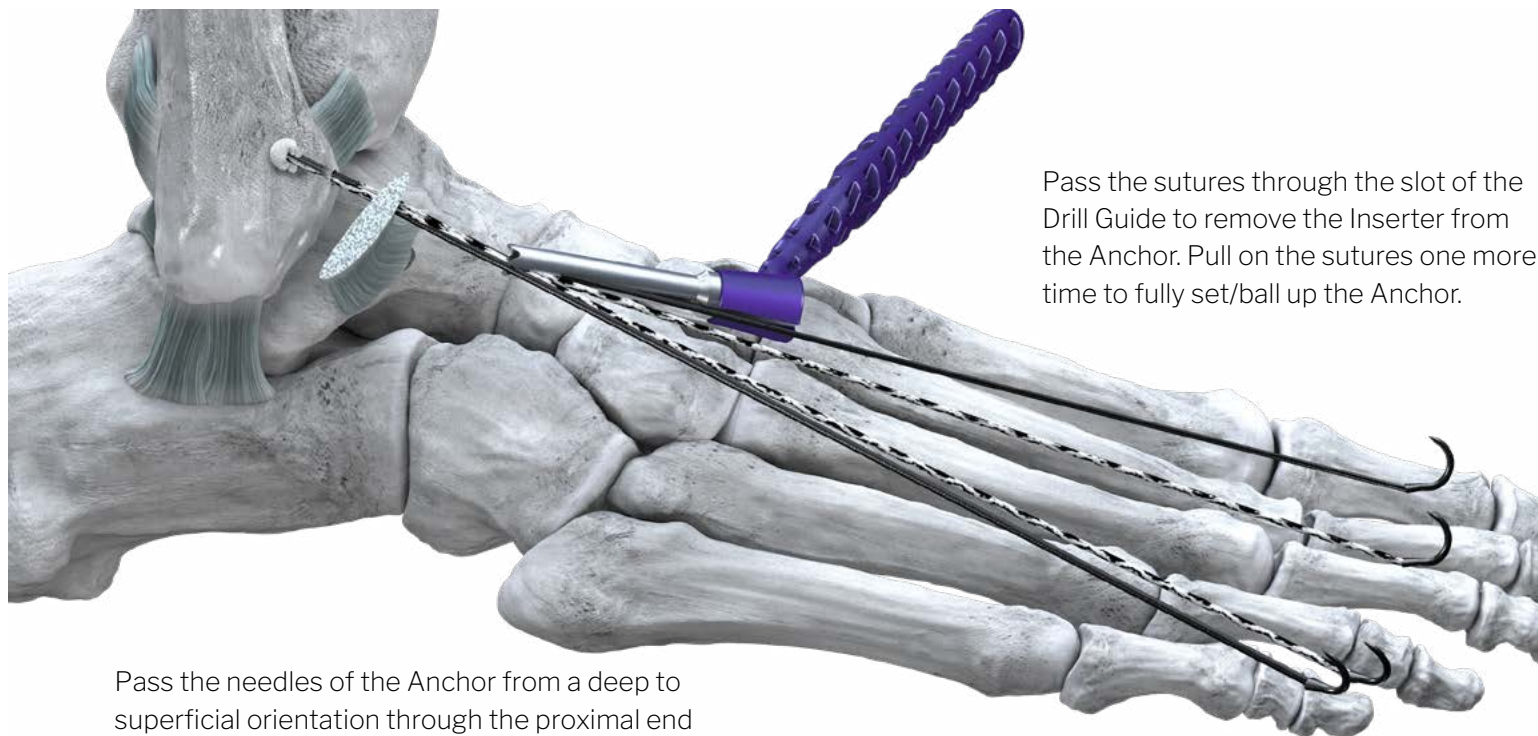


Pass the All-Suture Anchor on the Inserter through the Drill Guide into the bone. Impact with a mallet until the Inserter stops on the Drill Guide.



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 out the needle pouch, removing the needles, and unwinding the suture from the handle.

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

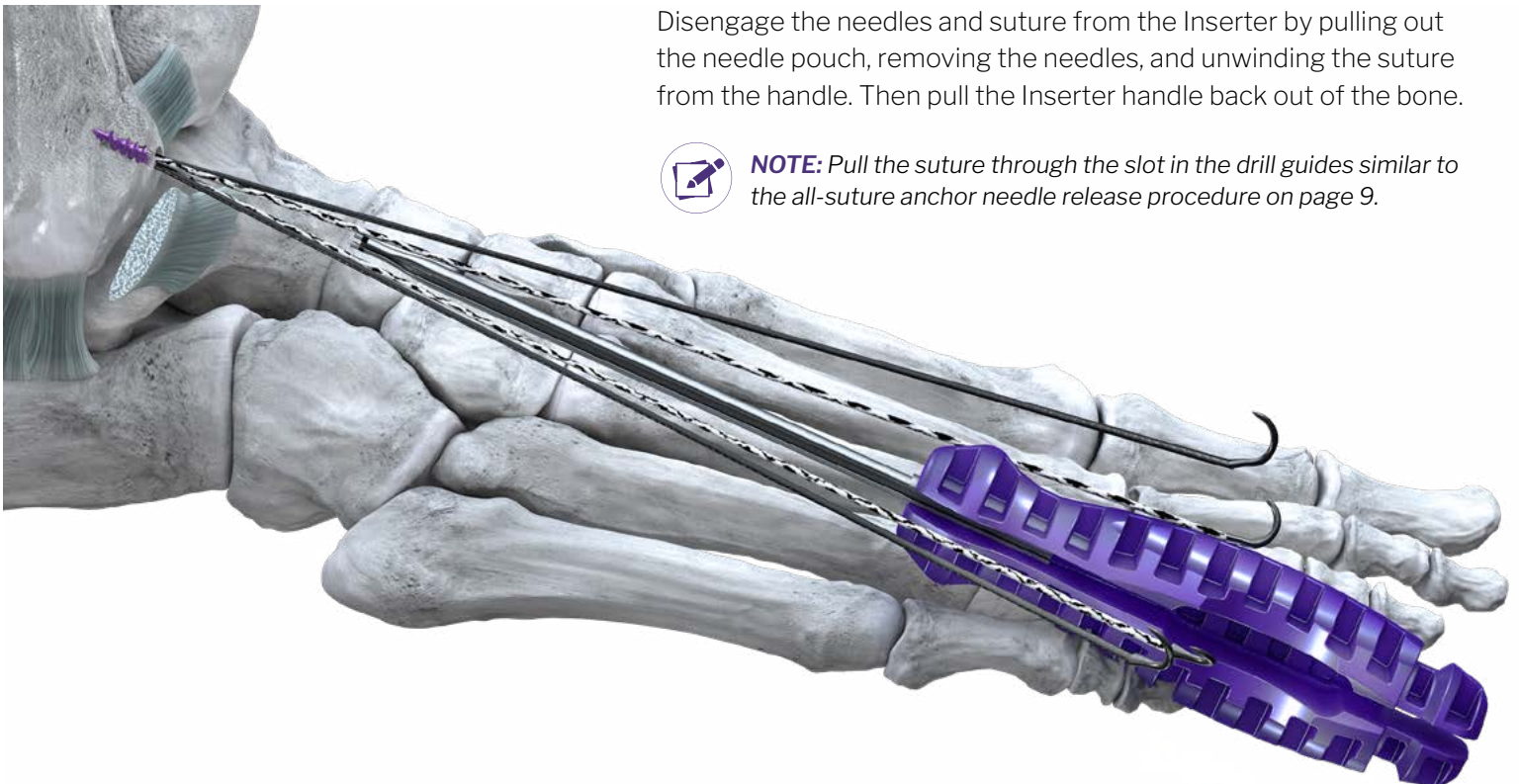
TITANIUM ANCHOR INSERTION



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.

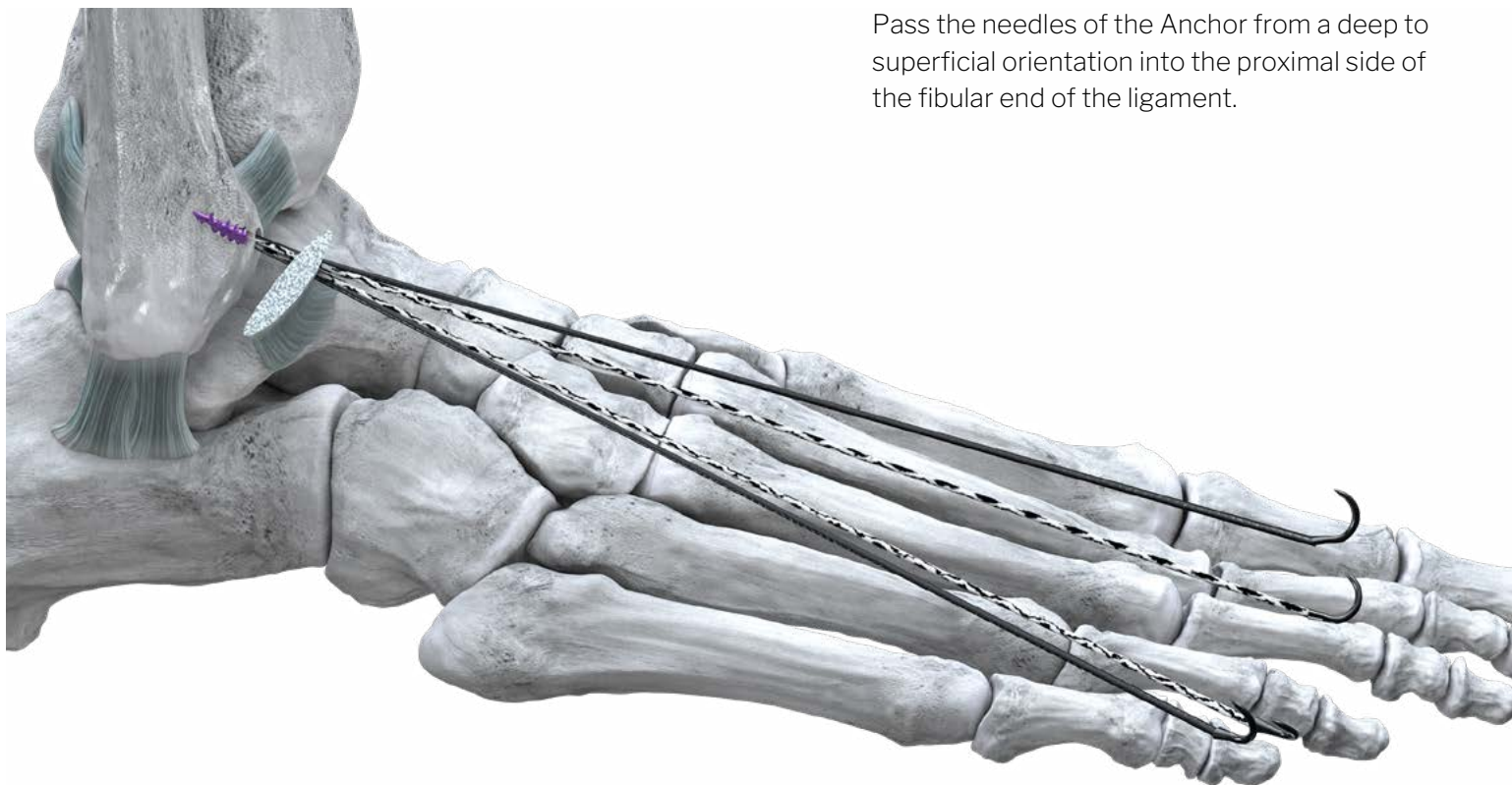


Disengage the needles and suture from the Inserter by pulling out the needle pouch, removing the needles, and unwinding the suture from the handle. Then pull the Inserter handle back out of the bone.



NOTE: Pull the suture through the slot in the drill guides similar to the all-suture anchor needle release procedure on page 9.

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.



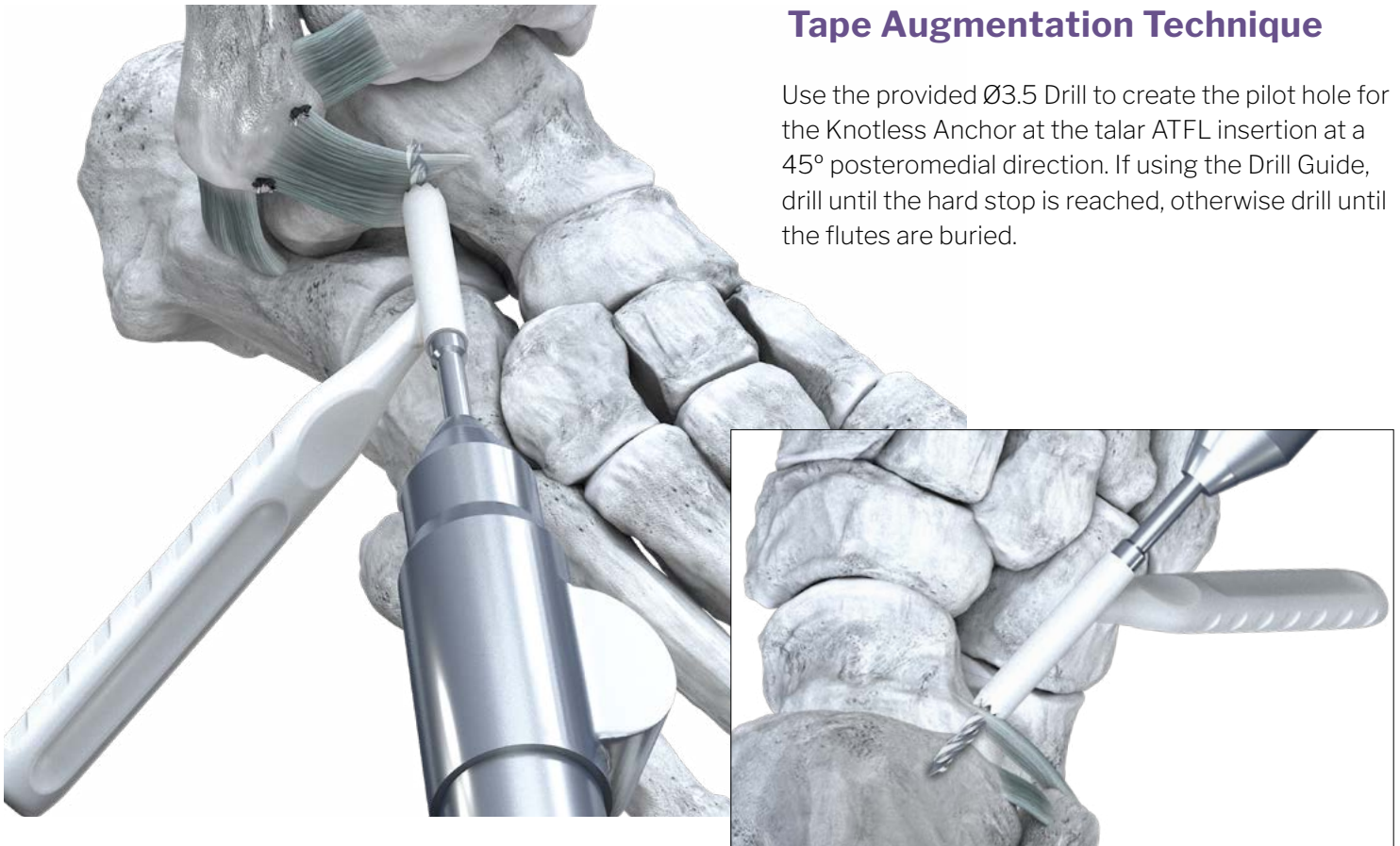
After tensioning the Anchor suture tails, tie knots to secure the ligament to the bone and cut the excess suture to complete the repair.

Continue on page 11 for Knotless Anchor Insertion

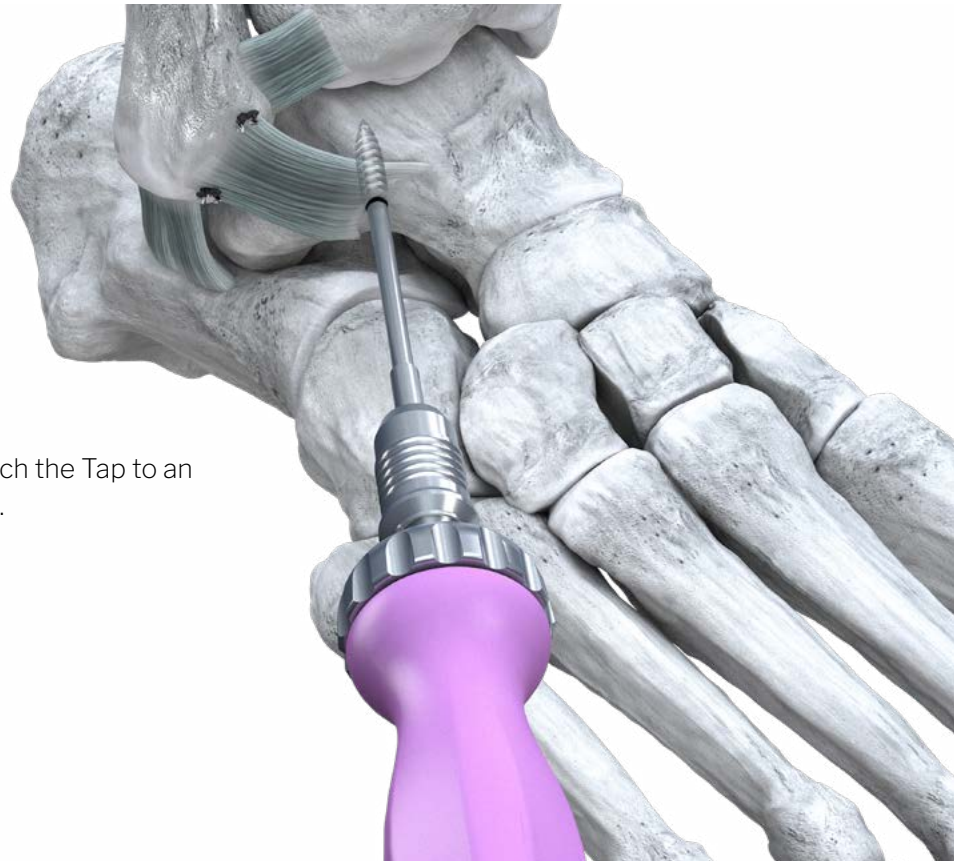
KNOTLESS ANCHOR INSERTION

Tape Augmentation Technique

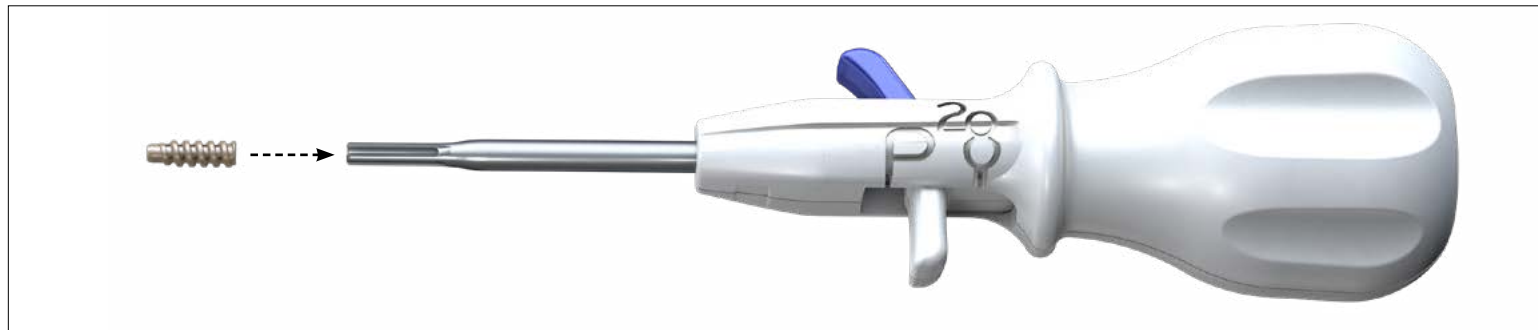
Use the provided Ø3.5 Drill to create the pilot hole for the Knotless Anchor at the talar ATFL insertion at a 45° posteromedial direction. If using the Drill Guide, drill until the hard stop is reached, otherwise drill until the flutes are buried.



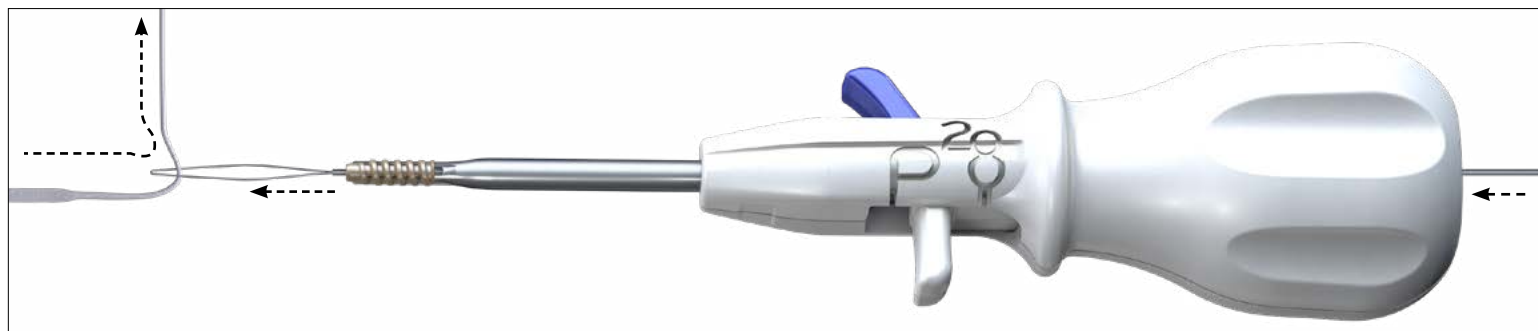
A Tap is provided to aid in insertion. Attach the Tap to an AO Handle and hand tap to the laser line.



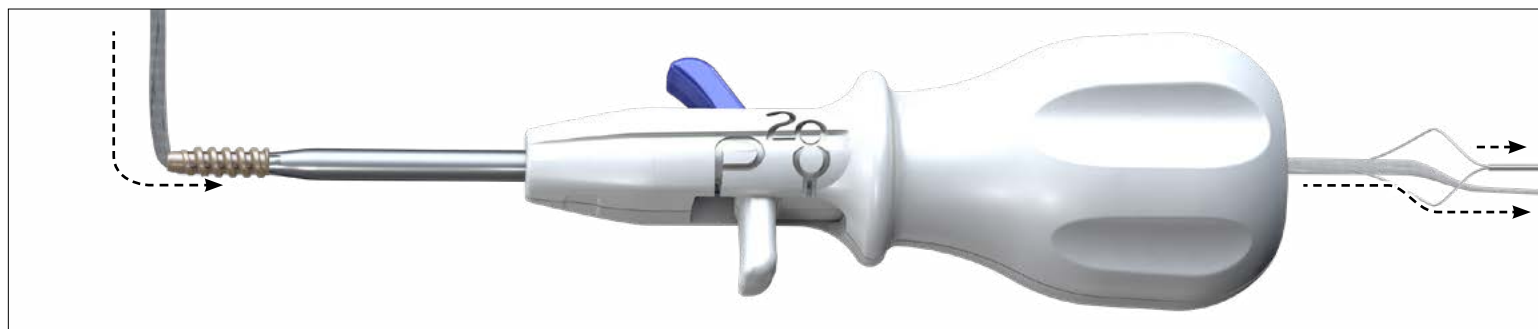
KNOTLESS ANCHOR INSERTION



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



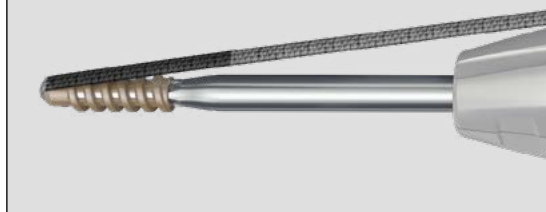
2. Pass the Suture Passer through the Tensioning Driver Handle. Feed 3-5 cm of the Suture Tape through the Suture Passer.



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

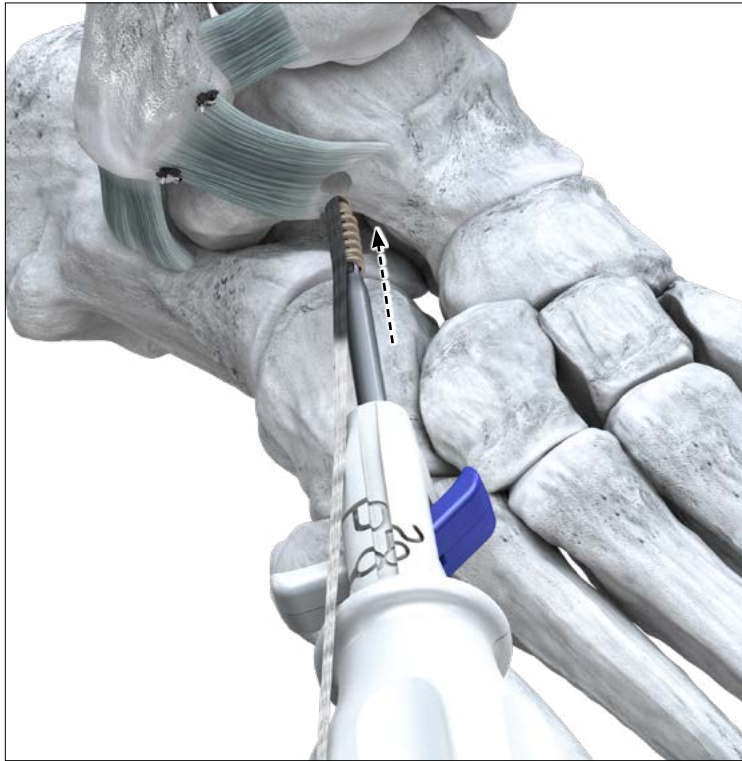


NOTE: Pull the Tape through until about 1 cm of the black portion of the Tape is past the Anchor.



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.

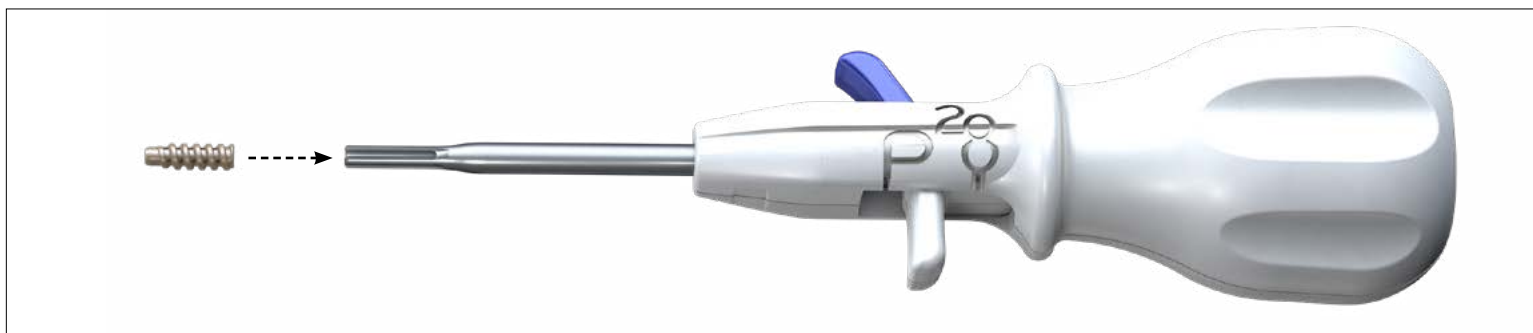


Examine the Tape to ensure it is not twisted so it can be smoothly passed through the second Knotless Anchor.

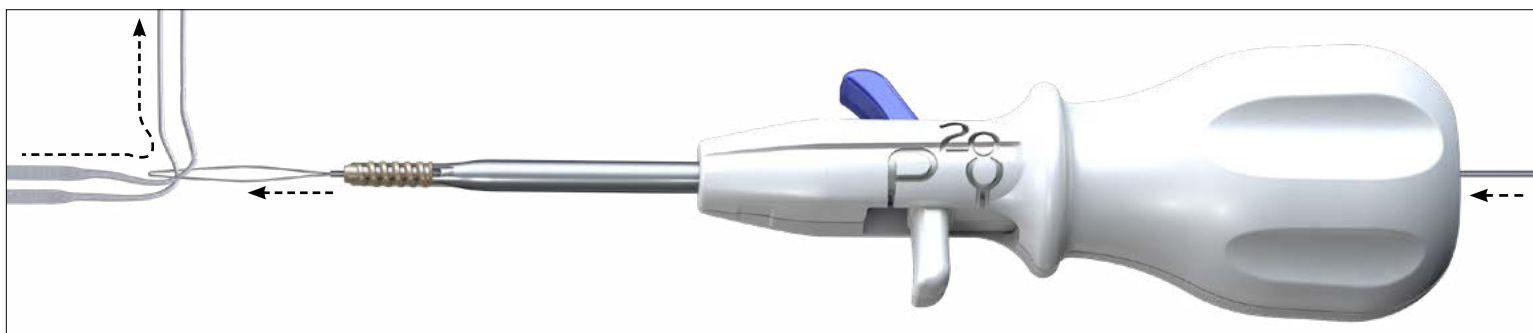
KNOTLESS ANCHOR INSERTION



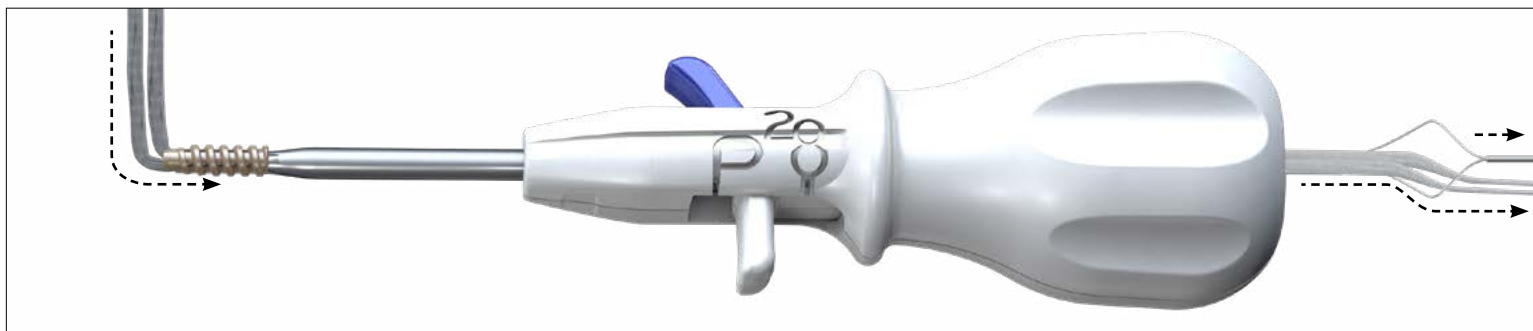
Once the first Knotless Anchor has been placed, use the provided Drill, Drill Guide, and Tap to create a second pilot hole for the second Anchor in the fibula at the origin of the ATFL.



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

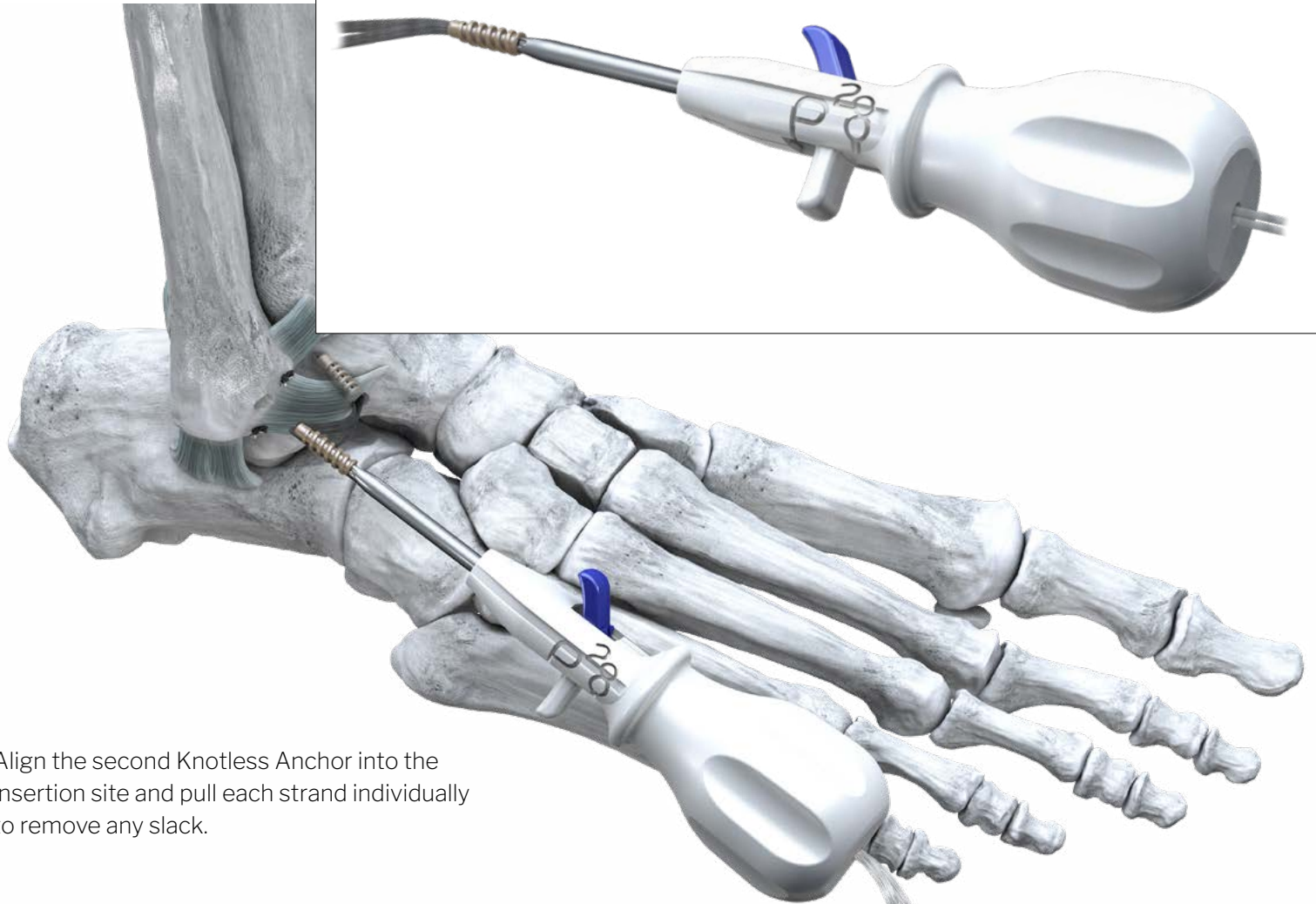
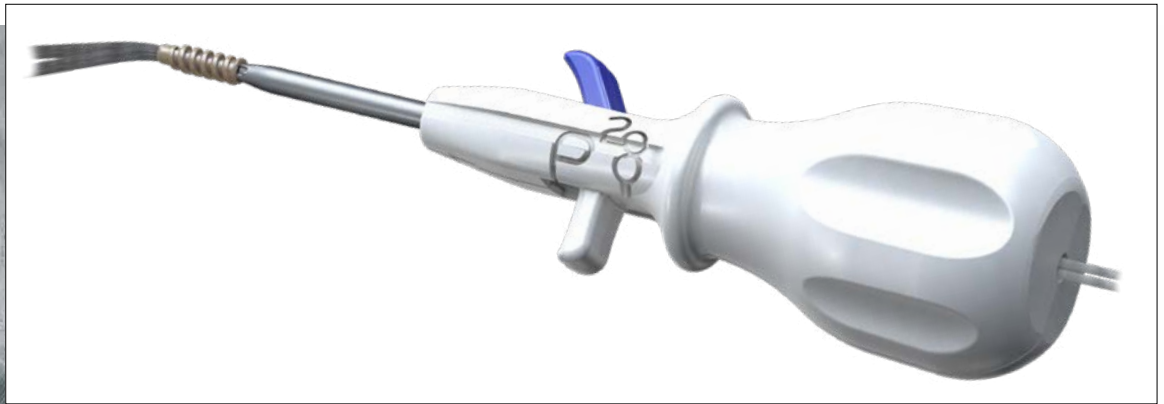


2. Pass the Suture Passer through the Tensioning Driver Handle. Feed 3-5 cm of the Suture Tape through the Suture Passer.

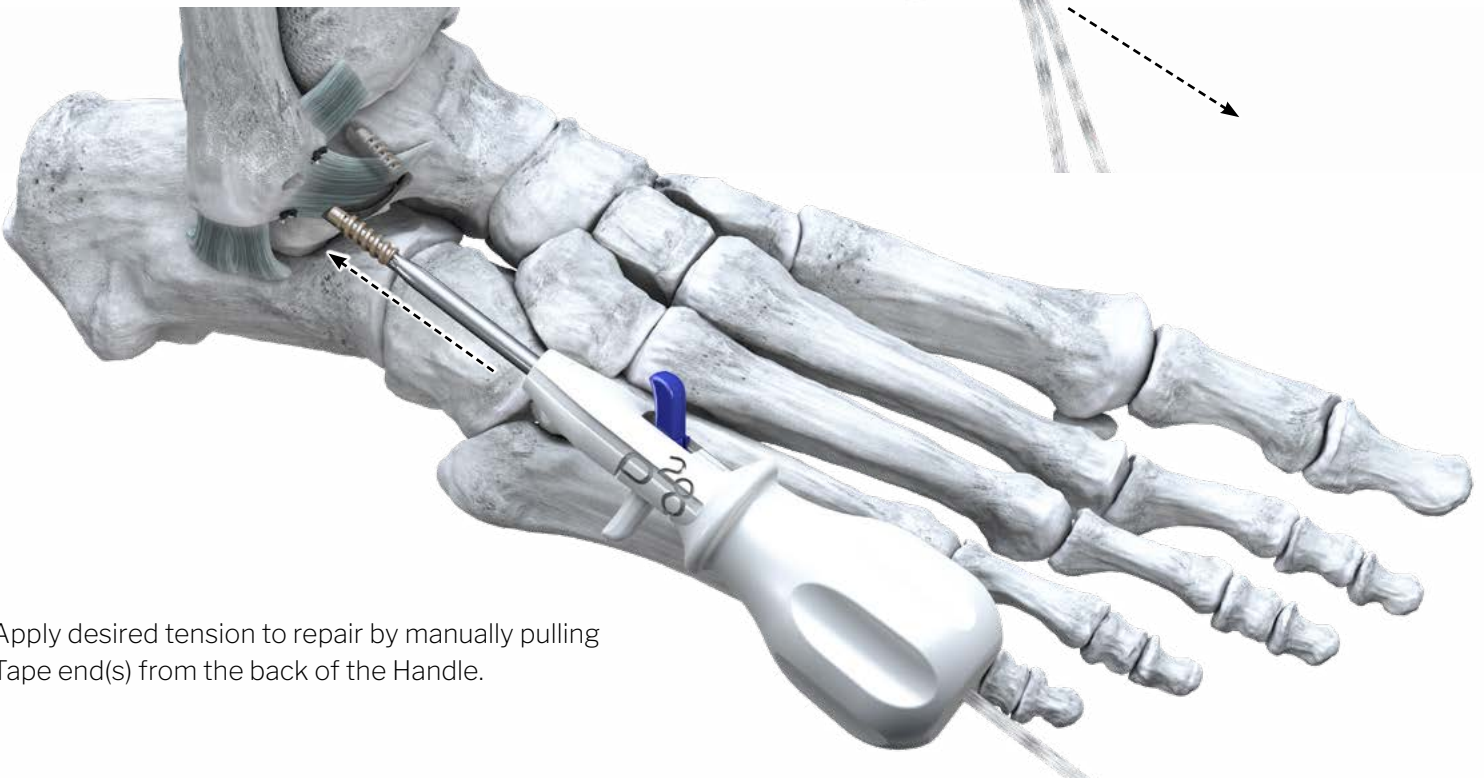


3. Pull the Suture Passer back through the center of the Tensioning Driver Handle to pass the Tape through the Knotless Anchor and Handle.

KNOTLESS ANCHOR INSERTION

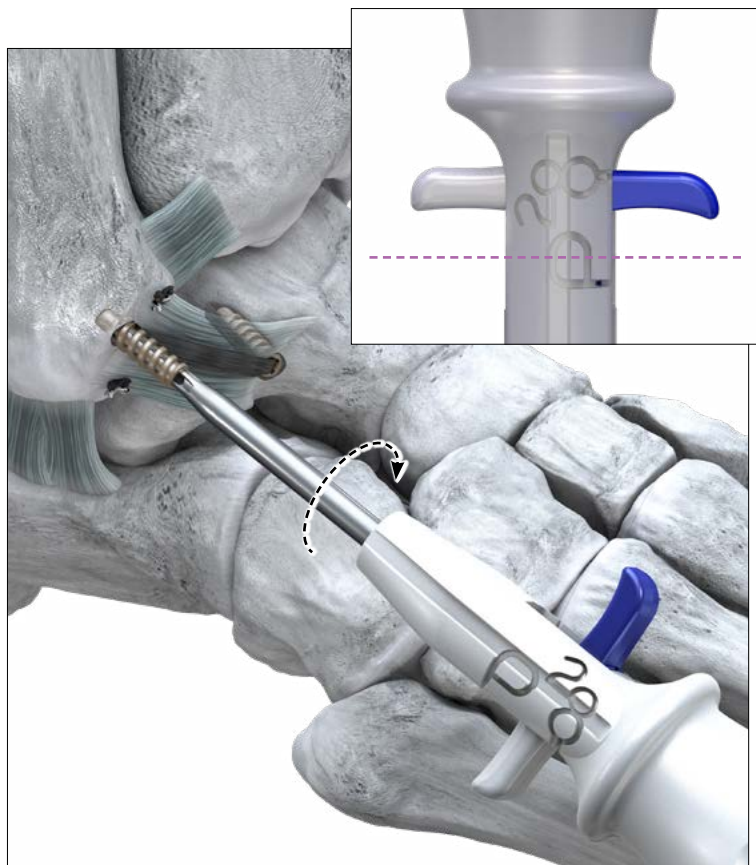
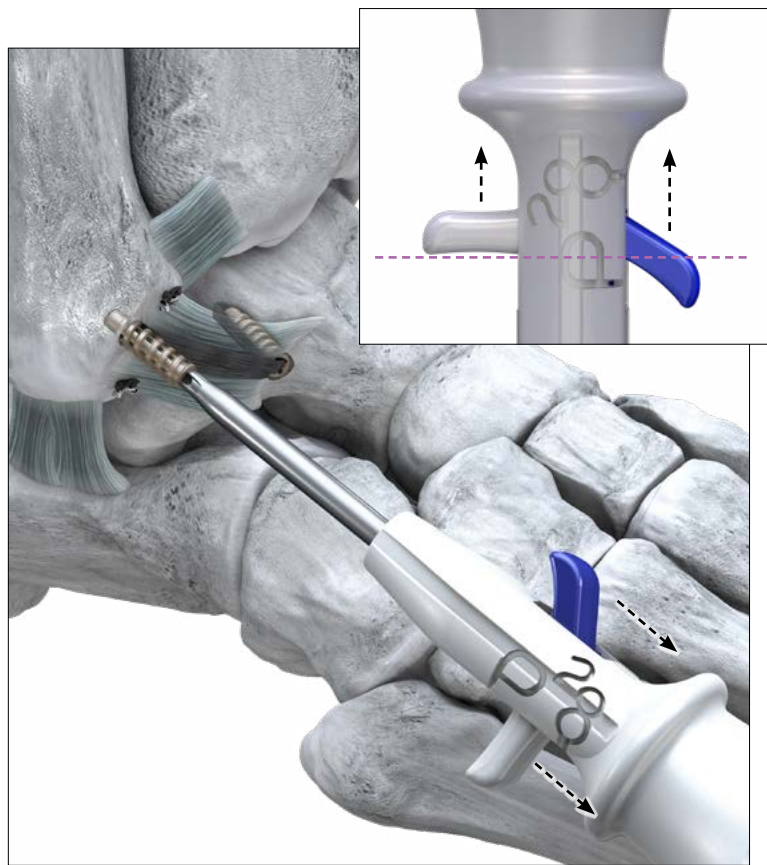


Align the second Knotless Anchor into the insertion site and pull each strand individually to remove any slack.

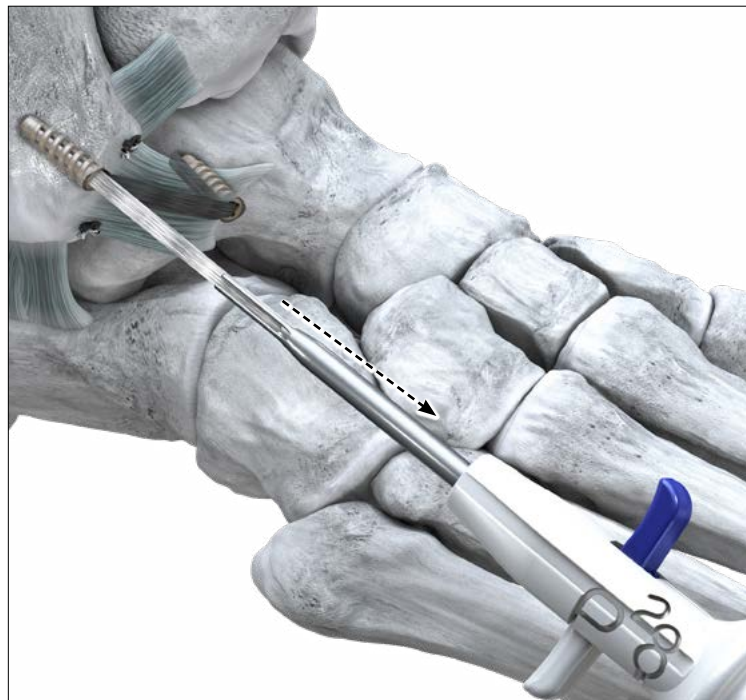


Apply desired tension to repair by manually pulling Tape end(s) from the back of the Handle.

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

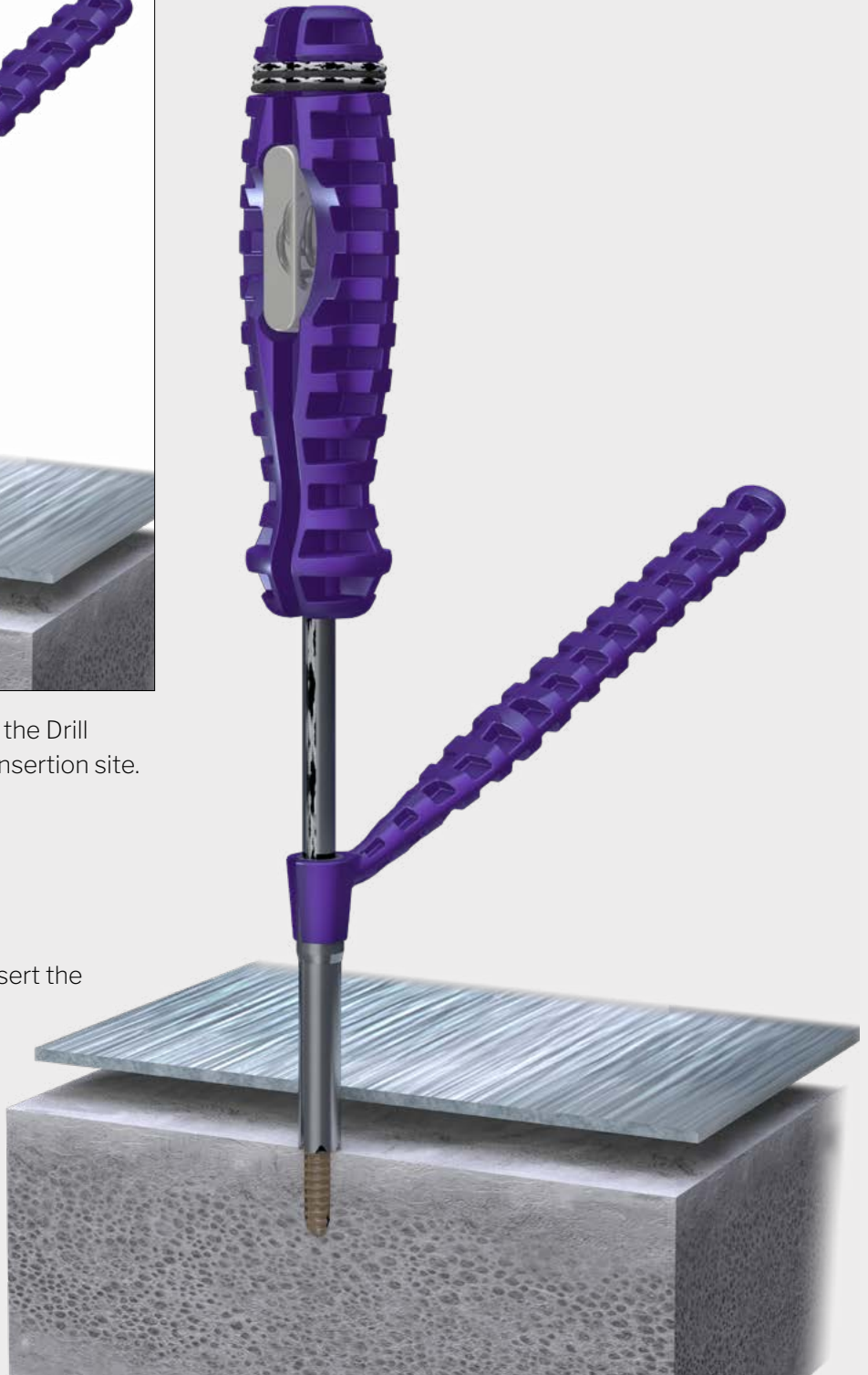


NOTE: PEEK Anchors due to their size offerings are not recommended for use in the Brostrom technique, therefore instructions for their general use is provided here.



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.

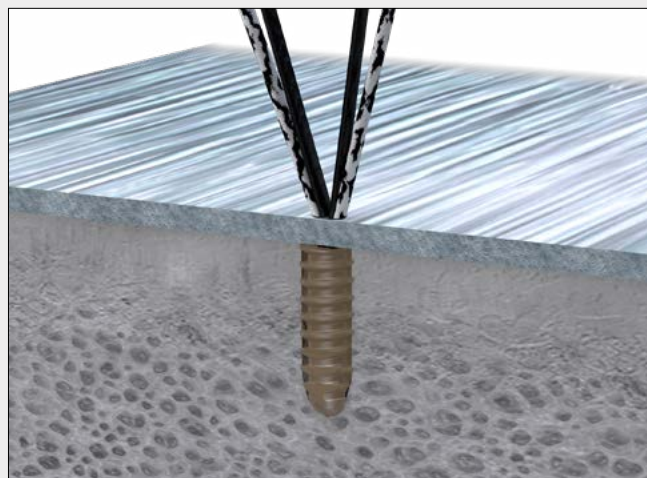
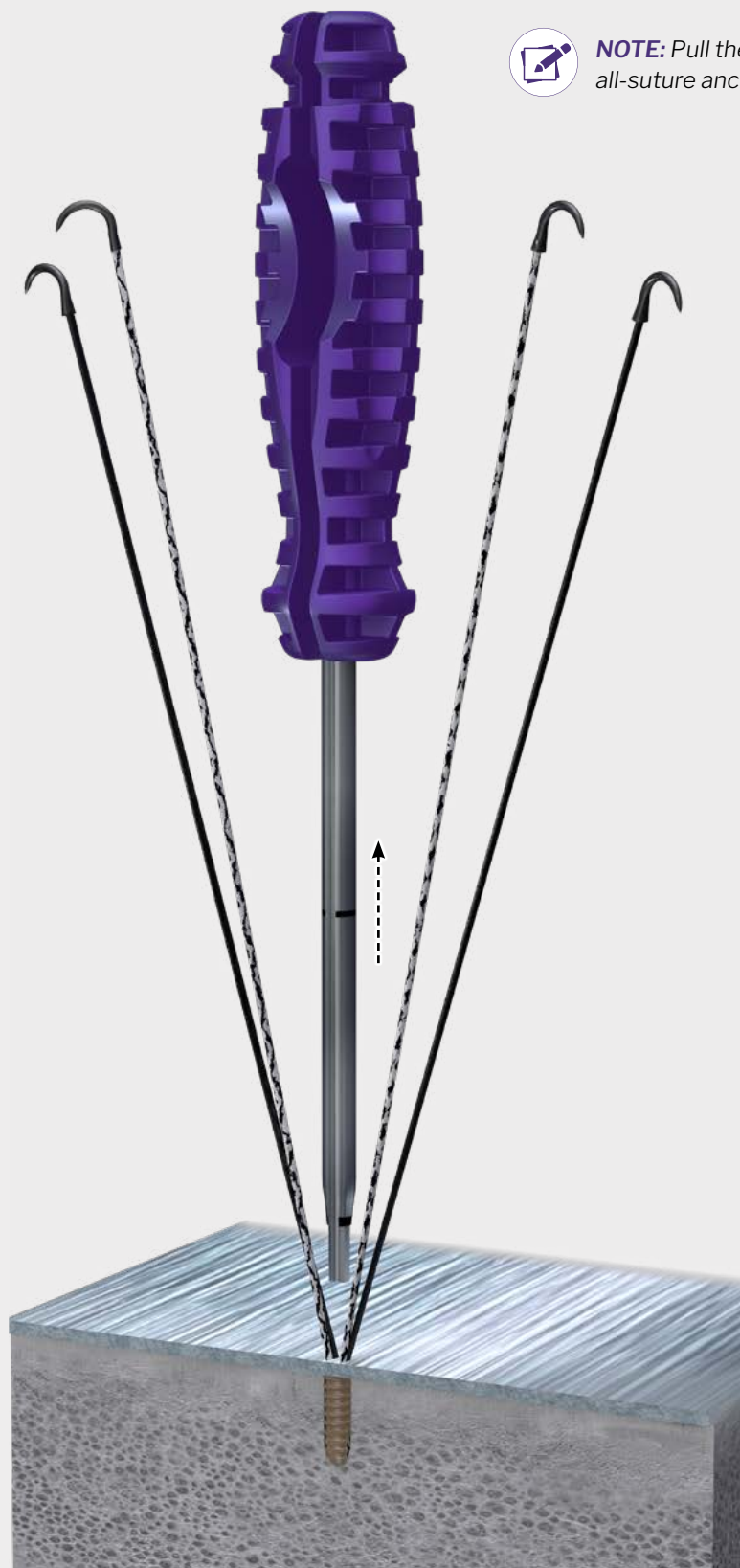


PEEK ANCHOR INSERTION

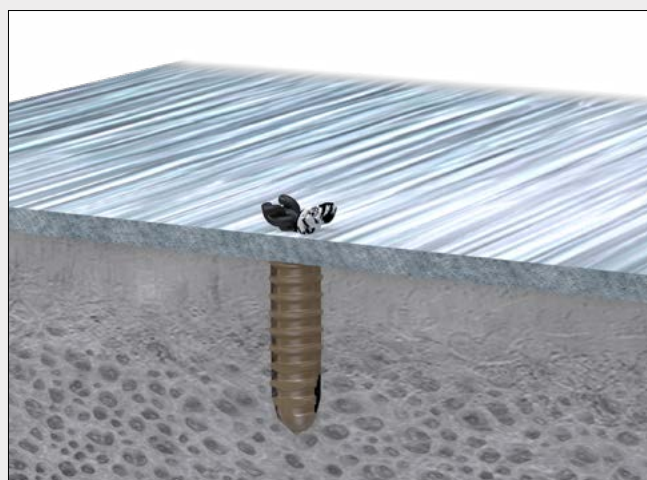
Disengage the needles and suture from the driver by pulling out the needle pouch, removing the needles, and unwinding the suture from the handle.



NOTE: Pull the suture through the slot in the drill guides similar to the all-suture anchor needle release procedure on page 9.



Proceed to pass the needles from a deep to superficial orientation in the desired location of the ligament.



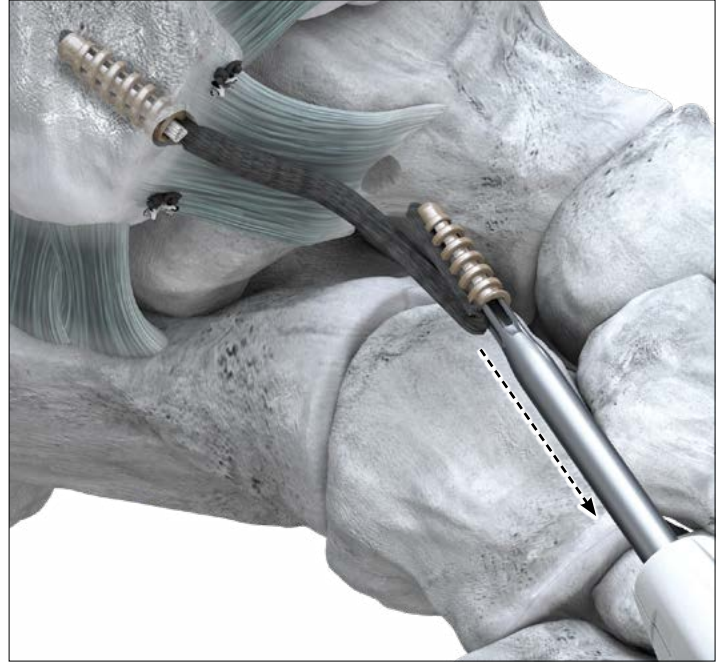
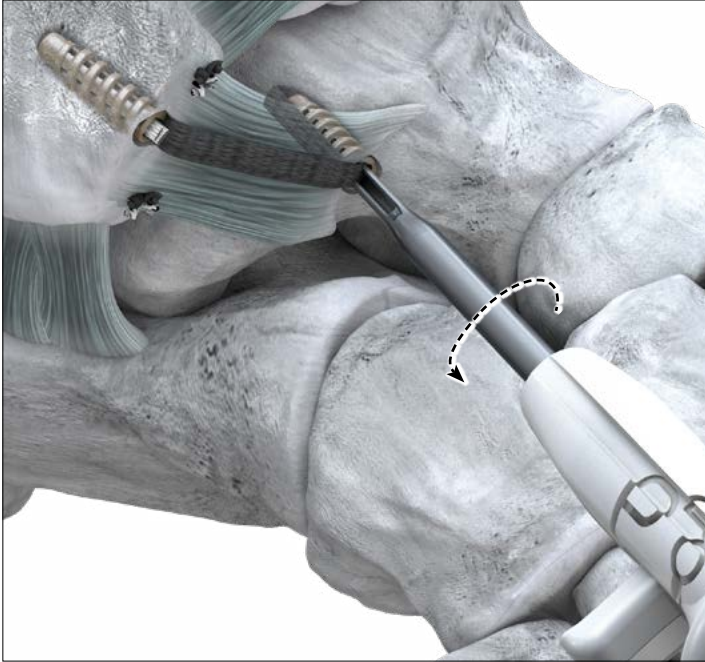
After tensioning the Anchor suture tails, tie a knot to secure the ligament to the bone and cut the excess suture to complete the repair.

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.



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

MR SAFETY INFORMATION



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



This image shows a full page of blank, lined paper. It features approximately 20 evenly spaced horizontal grey lines across its entire width, typical of notebook or composition paper. The background is white, and there are no margins, text, or other markings present.

This image shows a single sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.



PRIMATIX™
SUTURE ANCHORS

GRAPPLER™
KNOTLESS ANCHOR SYSTEM

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Disclaimer:

The purpose of the PRIMATIX™ Suture Anchor System and Grappler® Knotless Anchor System Surgical Technique Guide is to demonstrate the optionality and functionality of the PRIMATIX™ 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.