GRAPPLER®
SUTURE ANCHOR SYSTEM

SURGICAL TECHNIQUE GUIDE

Soft tissue repair using the Grappler® Suture Anchor System

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

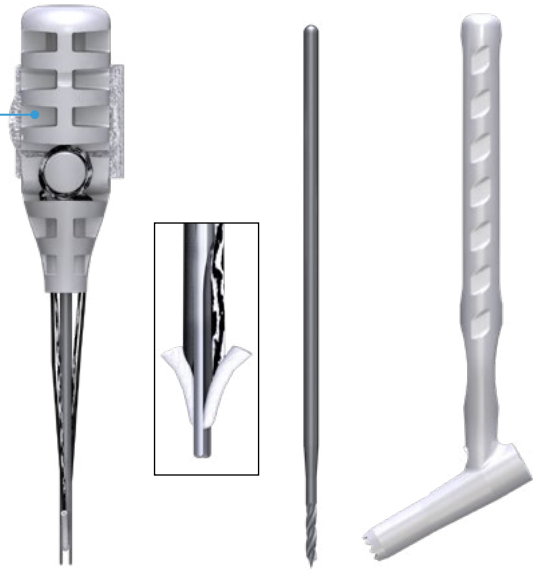
The Grappler® Suture Anchor System was designed to address the challenges that are present when performing soft tissue procedures in foot and ankle. A variety of all-suture anchors, PEEK anchors, titanium anchors, sutures and suture tape provide foot and ankle surgeons the ability to select the appropriate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

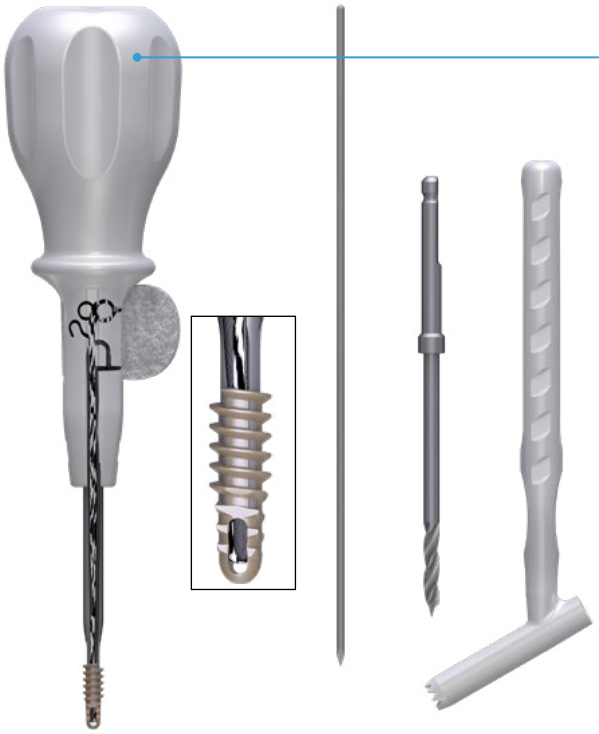
CONTENTS

KIT OFFERINGS

ALL-SUTURE ANCHOR KITS

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





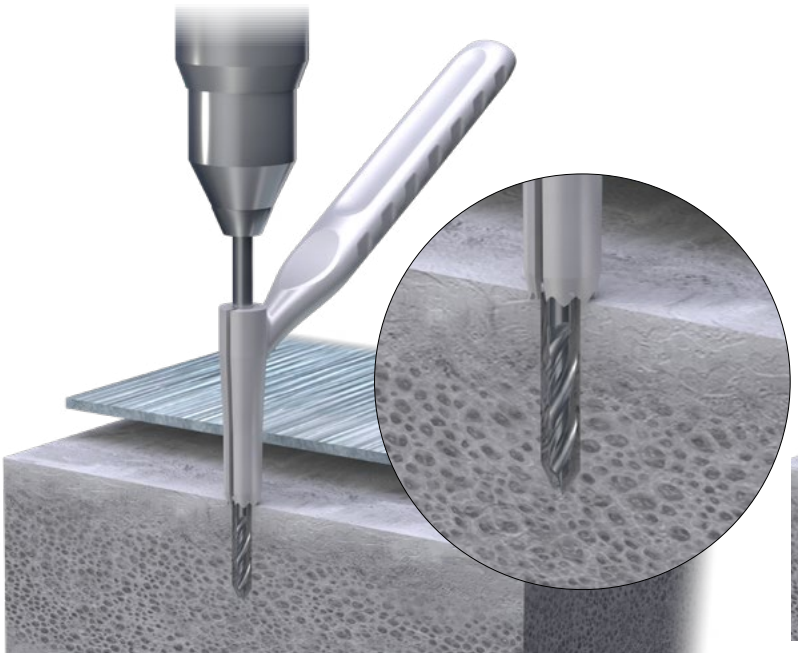
PEEK ANCHOR KITS

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

TITANIUM ANCHOR KITS

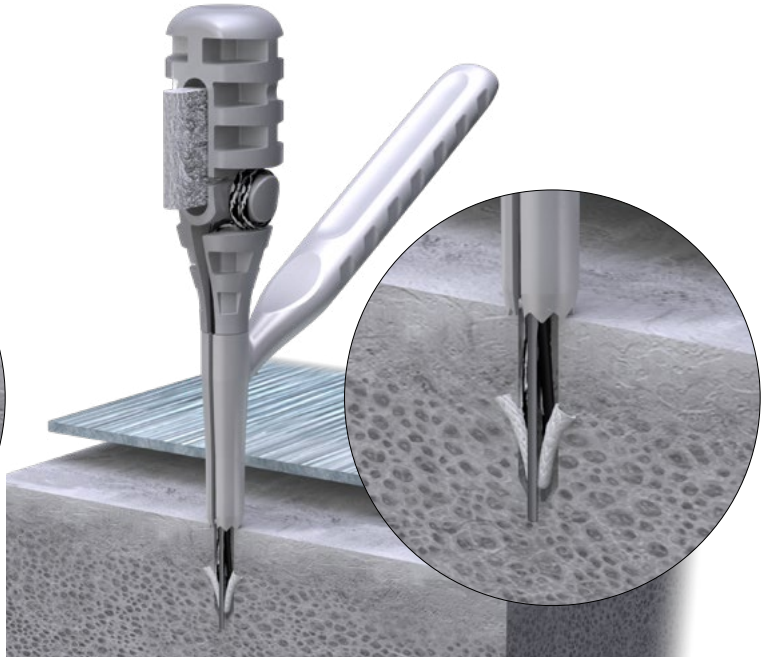
- Titanium Alloy, Ti-6AL-4V
- Ø3.0 mm Anchors:
  - Double-loaded with #0 Suture
  - Ø2.0 mm K-wire
- Ø4.5 mm Anchors:
  - Double-loaded with #2 Suture
  - Ø2.6 mm K-wire

ALL-SUTURE ANCHOR INSERTION

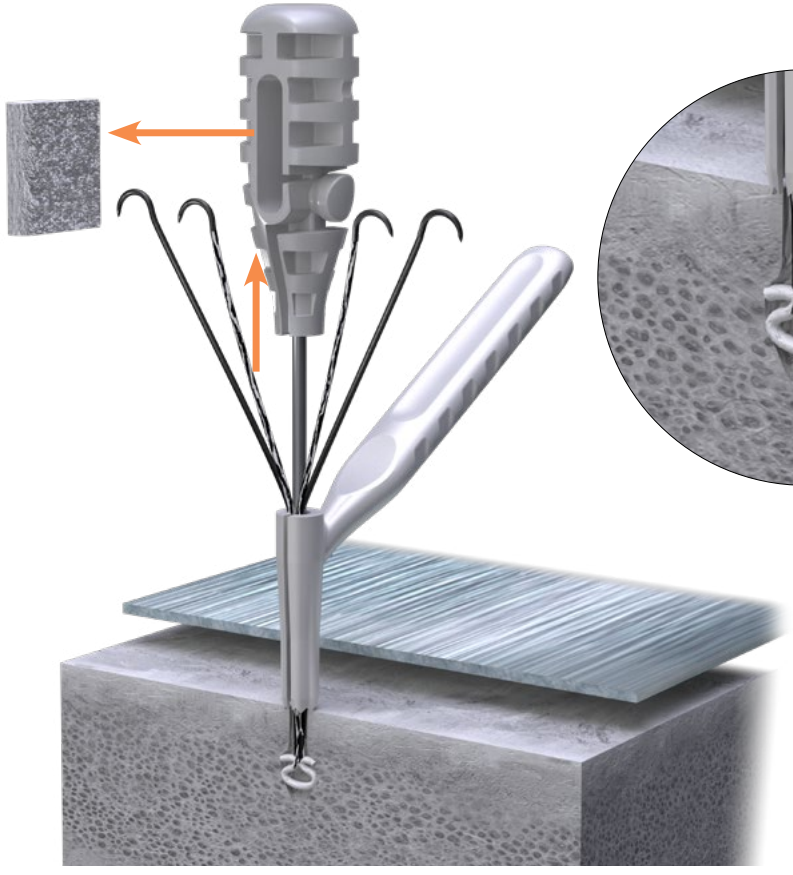


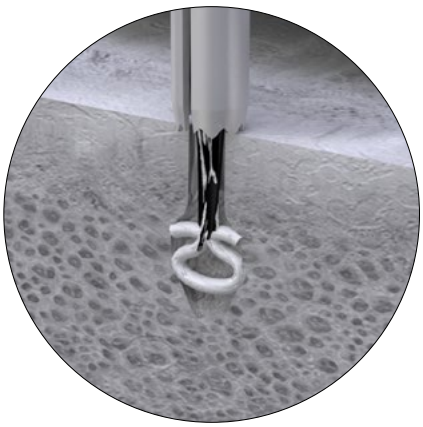
Place the drill guide against bone in the desired position for the anchor.

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 until it stops against the drill guide. If necessary, lightly tap the inserter down.

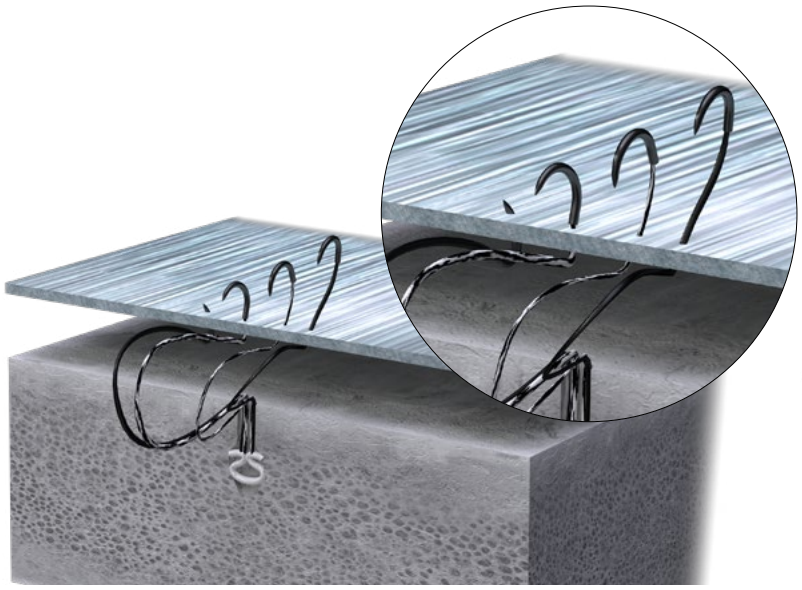




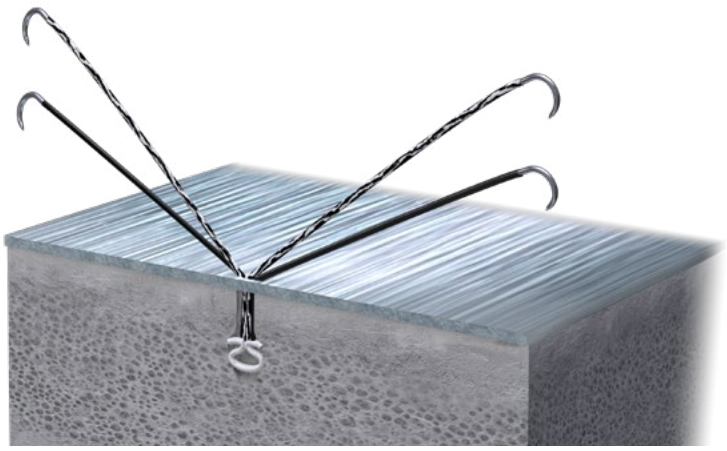
Pull the inserter back out of the bone until resistance is felt to set the implant against the cortex. Disengage the needles and sutures from the inserter by pulling the foam block.

Pass the sutures through the slot of the drill guide to remove the inserter from the anchor.

ALL-SUTURE ANCHOR INSERTION

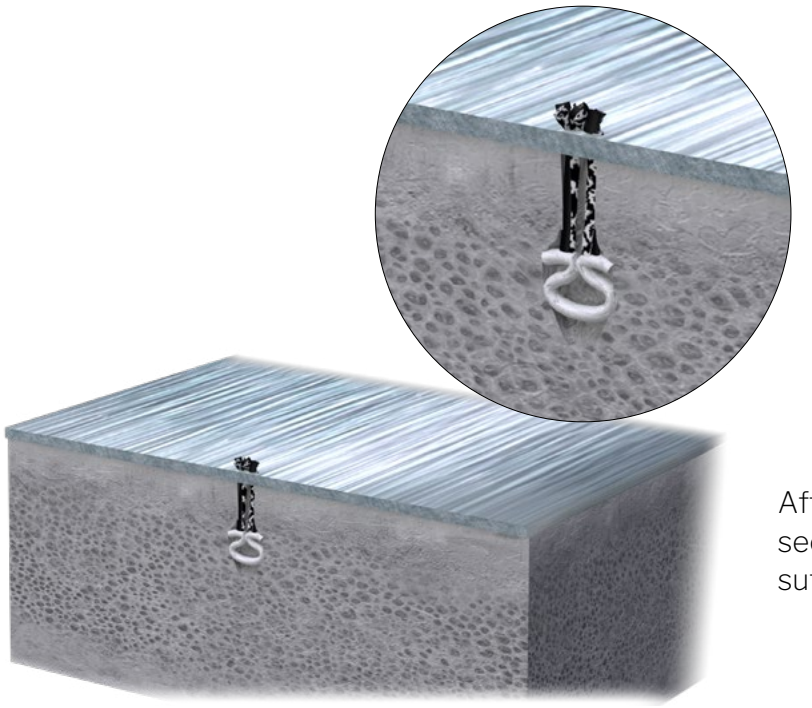


Pass the needles from a deep to superficial orientation in the desired locations of the ligament.



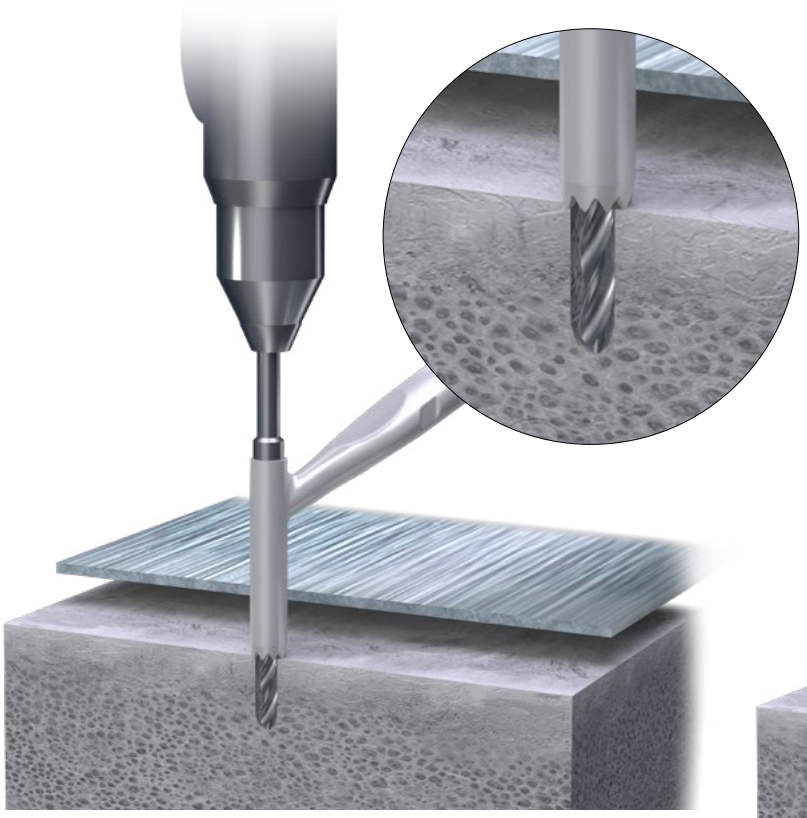
The Ø2.8 mm all-suture anchors have four suture tails with four needles while the Ø1.4 mm all-suture anchors have two tails and two needles.

NOTE: *It is recommended to wait to tension and tie off these strands until all anchors have been placed to ensure for a balanced final construct.*

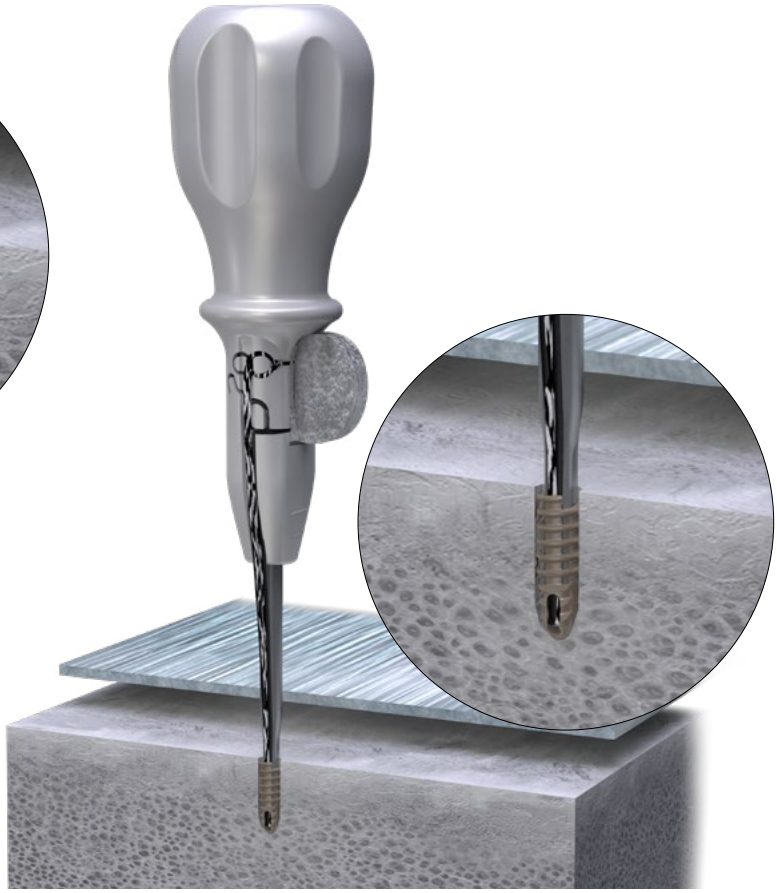


After tensioning the anchor suture tails, tie a knot to secure the ligament to the bone and cut the excess suture to complete the repair.

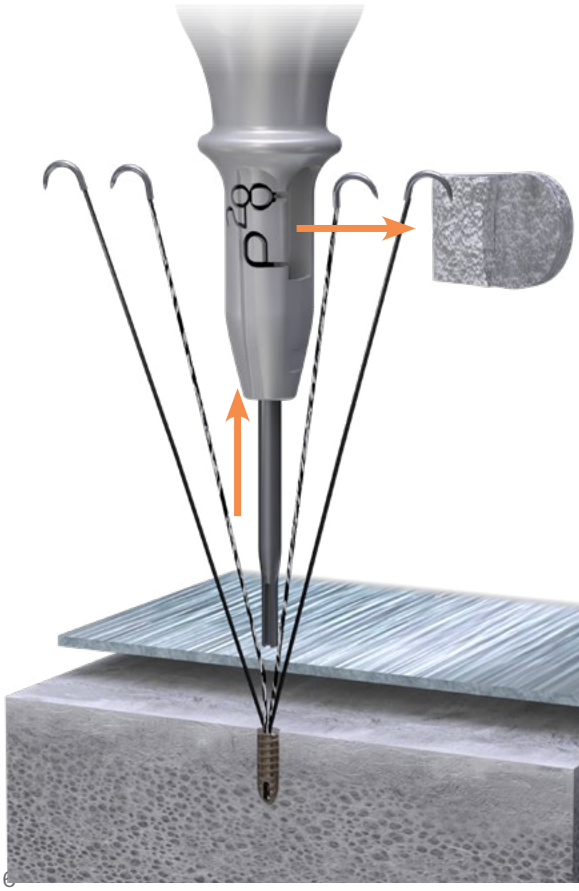
PEEK ANCHOR INSERTION

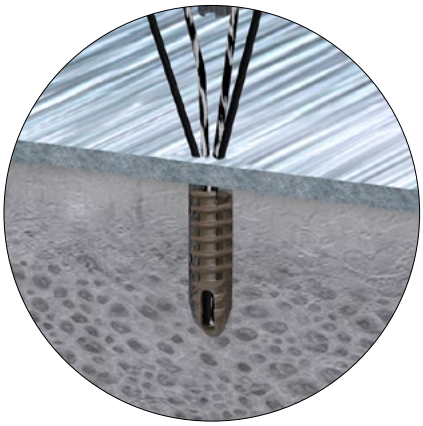


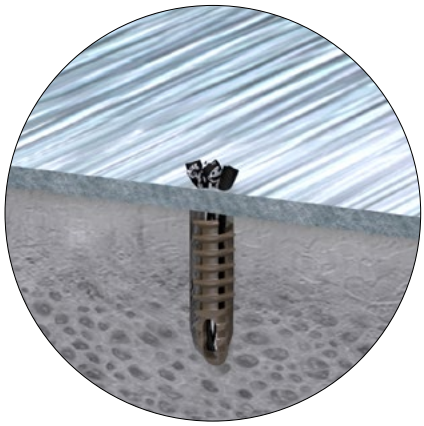
Drill with the provided solid drill bit through the drill guide to the hard stop at the desired bone insertion site.



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



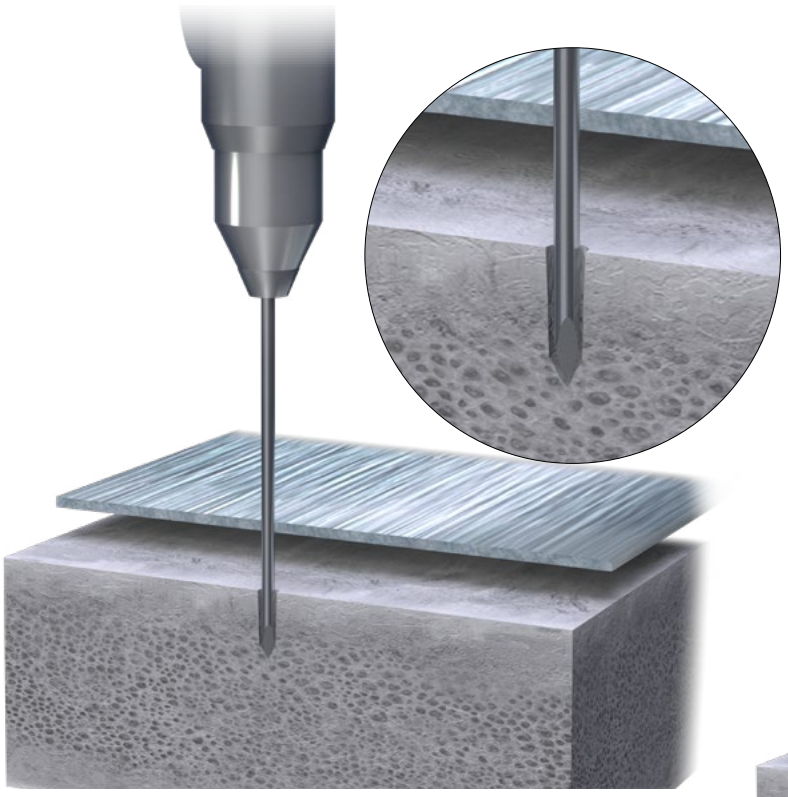




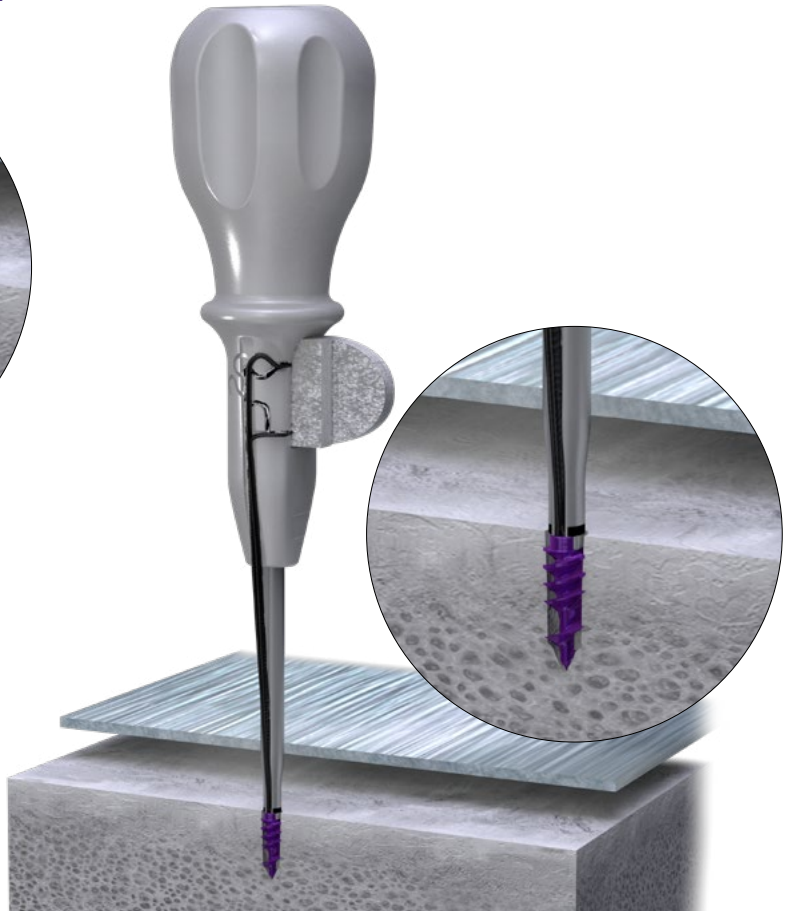
Disengage the needles and suture from the driver by pulling the foam block. Proceed to pass the needles from a deep to superficial orientation in the desired location of the ligament.

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.

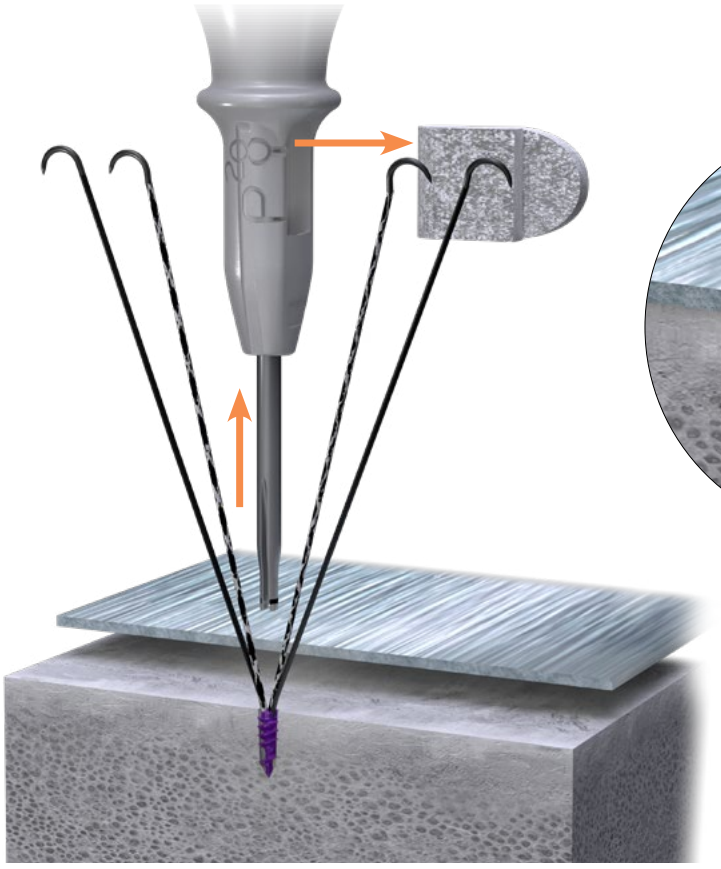
TITANIUM ANCHOR INSERTION

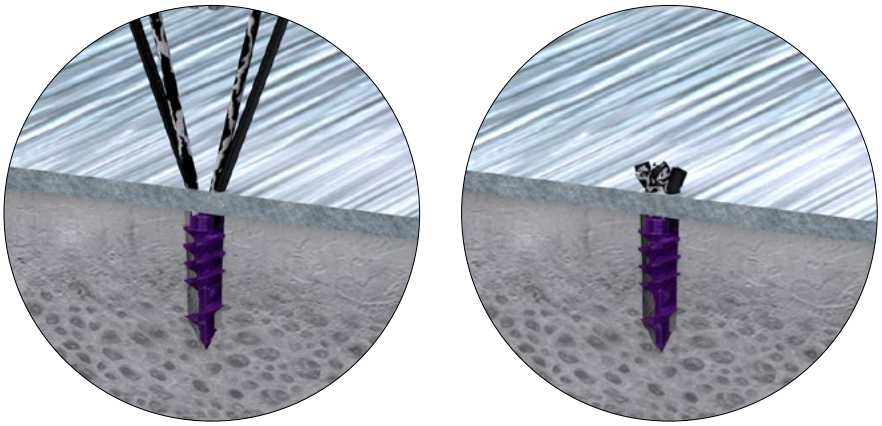


Drill with the provided K-wire into the desired anchor insertion site. For reference, the Ø3.0 mm anchor is 12 mm long and the Ø4.5 mm anchor is 15 mm long.



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. 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.

STERILE KIT OPTIONS

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

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

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

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

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

- Two #0 Suture w/ Needles (qty 4)
- Ø2.0 mm x 1 5cm K-wire (qty 1)

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

- Two #2 Suture w/ Needles (qty 4)
- Ø2.6 mm x 1 5cm K-wire (qty 1)

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

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

Grappler Suture Anchor, PEEK, Ø4.5 x 15 mm, W/ Tape

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

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

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

Grappler Suture Anchor, PEEK, Ø5.5 x 15 mm, W/ Tape

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

IMPLANT REMOVAL (IF NECESSARY)

The titanium and PEEK anchors may be removed using the accompanying drivers. To remove, engage the drive feature of the anchor and turn counterclockwise. Removal instrumentation can be supplied upon request.

NOTE: *Sterile packed Cannulated Drills and Taps are available for the PEEK anchors per surgeon preferences.*

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

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**

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
- 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.

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

PATENTED, DESIGNED & EXCLUSIVELY DISTRIBUTED BY

Exclusively foot & ankle Paragon 28®

P44-STG-0001 RevC [2024-03-05]

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DISCLAIMER

The purpose of the Grappler® Suture Anchor System Surgical Technique Guide is to demonstrate the optionality and functionality of the Grappler® Suture Anchor System implants and instrumentation. Although variations in placement and use of the Grappler® Suture Anchor System 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® Suture Anchor System Screws can be employed, appropriate for the size of the device. CAUTION: Federal Law (USA) restricts this device to sale and use by, or on the order of, a physician.