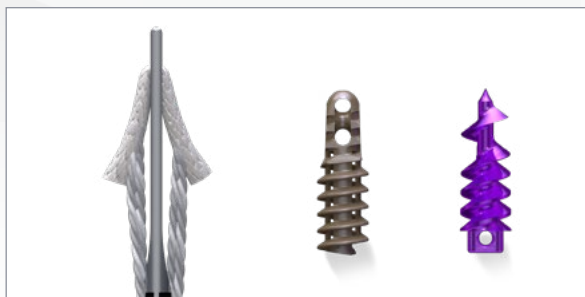


GRAPPLER[®]

SUTURE ANCHOR SYSTEM

SURGICAL TECHNIQUE GUIDE

Soft Tissue repair using the Grappler[®] Suture Anchor System



Exclusively foot & ankle
Paragon²⁰

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.

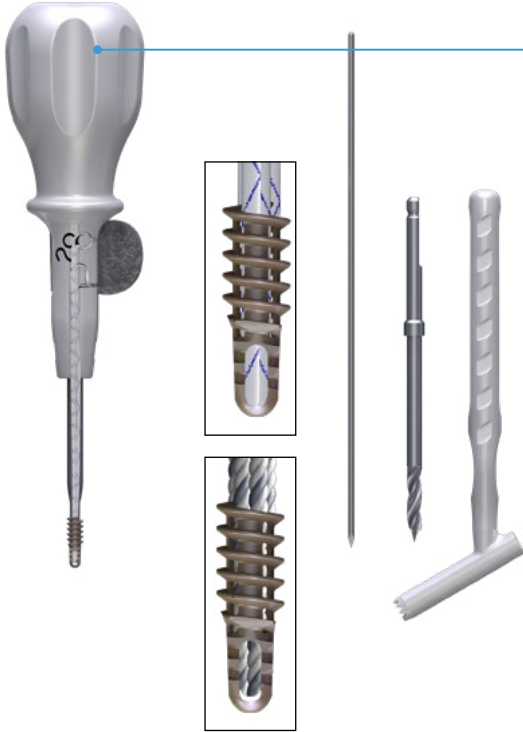
PRODUCT DESCRIPTION

The Grappler® Suture Anchor System was designed to address the challenges that are present when performing soft tissue tensioning and ligament reconstruction in foot and ankle procedures. A variety of soft 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.

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KIT OFFERINGS

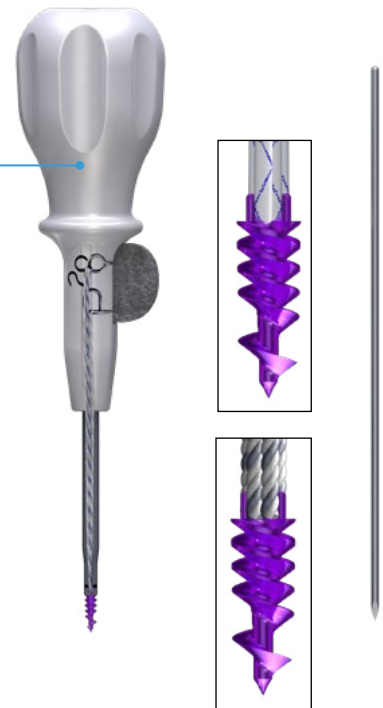


SOLID PEEK ANCHOR KIT

- Ø4.5 mm & Ø5.5 mm Anchor, Pre-loaded with Suture & needles
- K-wire (Ø1.6 mm)
- Drill (Solid, Ø3.5 mm & Ø4.3 mm)
- Driver/Handle
- Tissue Protector
- Double loaded USP 2 Suture
- Single USP 2 Suture + 1.5 mm Tape

TITANIUM ANCHOR KIT

- Ø3.0 mm & Ø4.5 mm Anchor, Pre-loaded with Suture/Needles
- K-wire (Drill, Ø2.0 mm & Ø2.6 mm)
- Driver/Handle
- Double Loaded USP 0 and USP 2 Suture

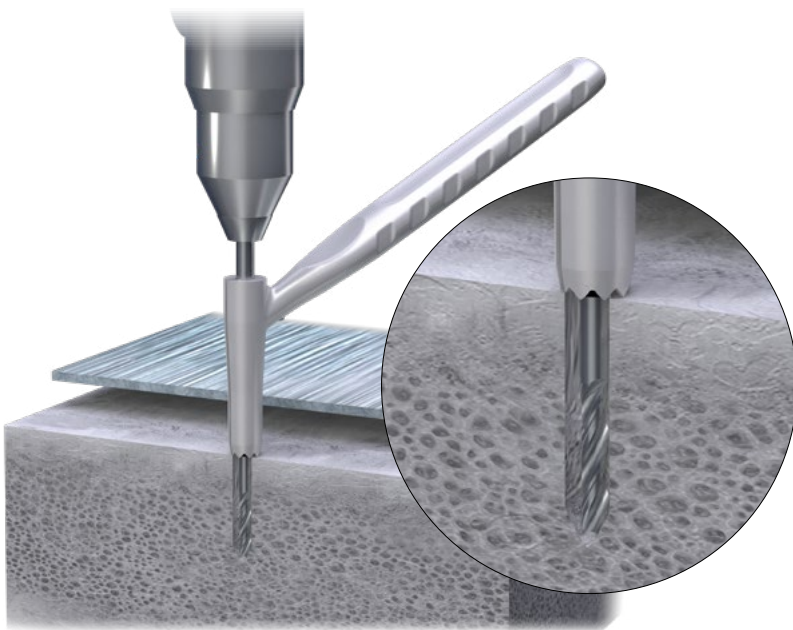


SOFT ANCHOR KIT

- Ø2.8 mm & Ø1.4 mm Anchor, Pre-loaded with Suture/Needles
- K-wire (Ø1.4 mm & Ø2.8 mm)
- Drill/Insertion Guide
- Handle/Insertion Fork
- Single-loaded USP 0 Suture
- Double-loaded USP 2 Suture

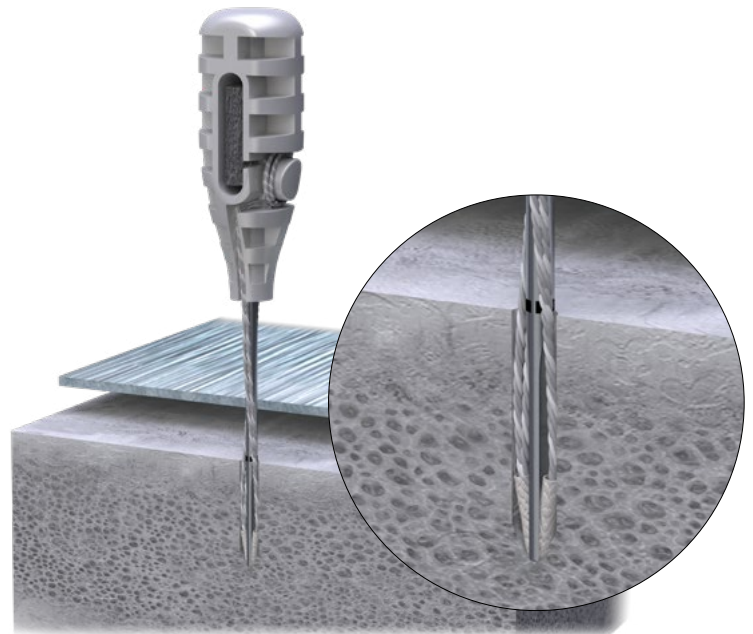


SOFT ANCHOR INSERTION



Place the Drill Guide against bone in the desired position for the first soft anchor insertion site.

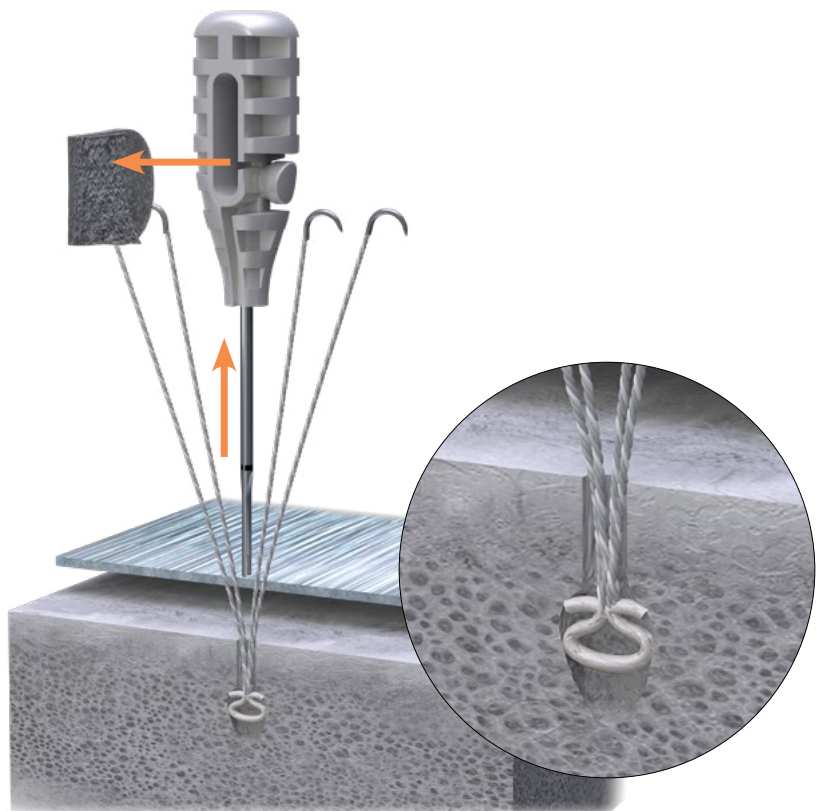
Drill through the Drill Guide with the provided Ø2.8 mm fluted K-wire for the corresponding Ø2.8 mm soft anchor. Remove the Drill without adjusting the position of the Drill Guide.



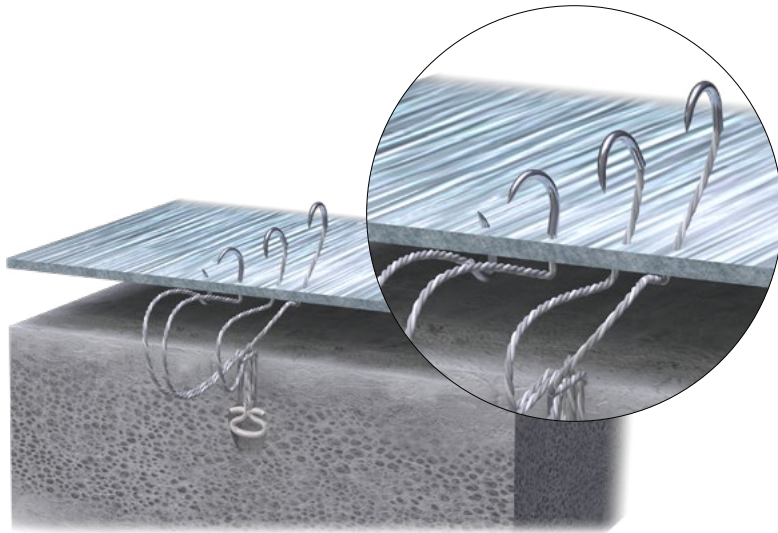
Retrieve the Inserters with the attached soft anchor (Ø2.8 mm) and insert through the Drill Guide into bone until reaching a physical stop against the Drill Guide. If necessary, lightly tap the inserter down.

Pull the Inserters distally and against the bone insertion site to set the implant against the cortex.

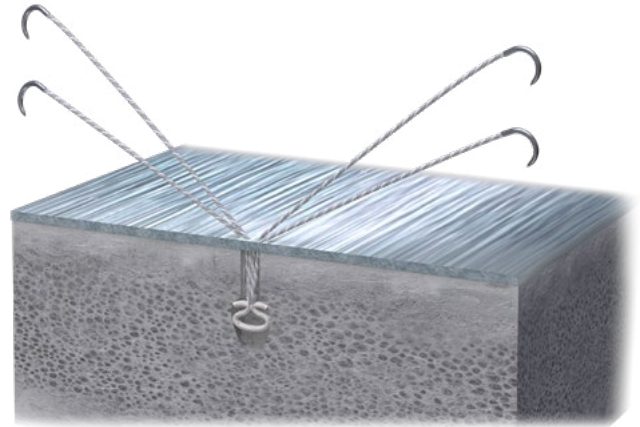
Disengage the needles and sutures from the Inserters by pulling the foam block.



SOFT ANCHOR INSERTION



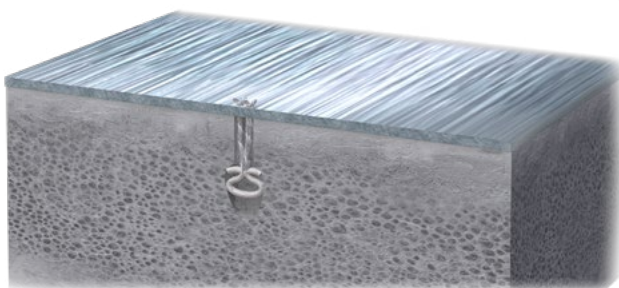
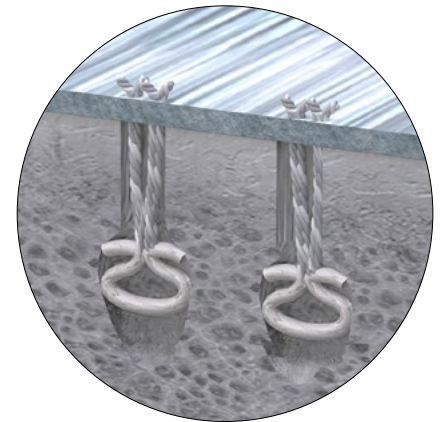
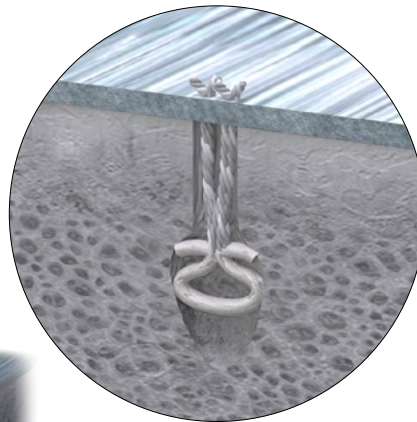
Pass the needles from a deep to superficial orientation in the desired locations of the ligament.



The soft anchor implants have four suture tails with four 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.



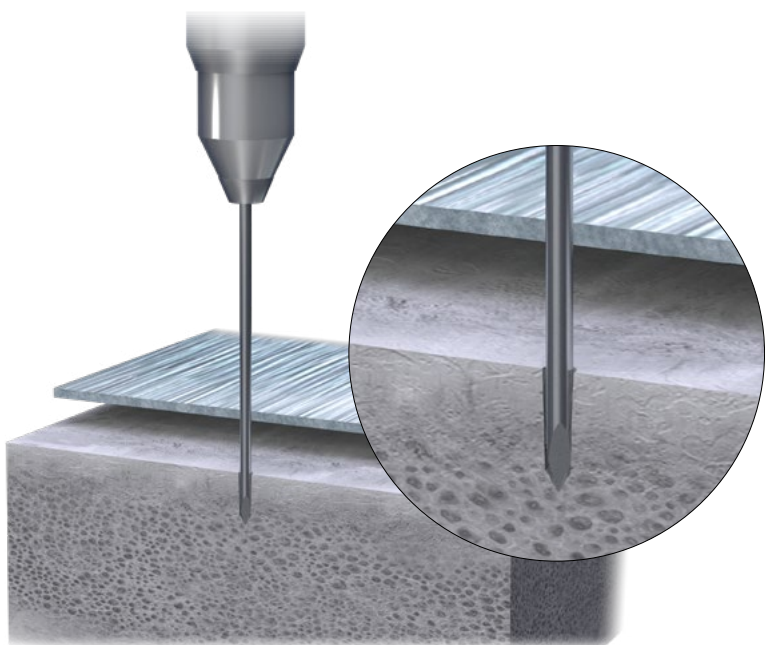
After tensioning the anchor suture tails, tie a knot to secure the ligament to the bone and cut the excess suture to complete the repair.

Repeat the above steps to place a second soft anchor if desired.

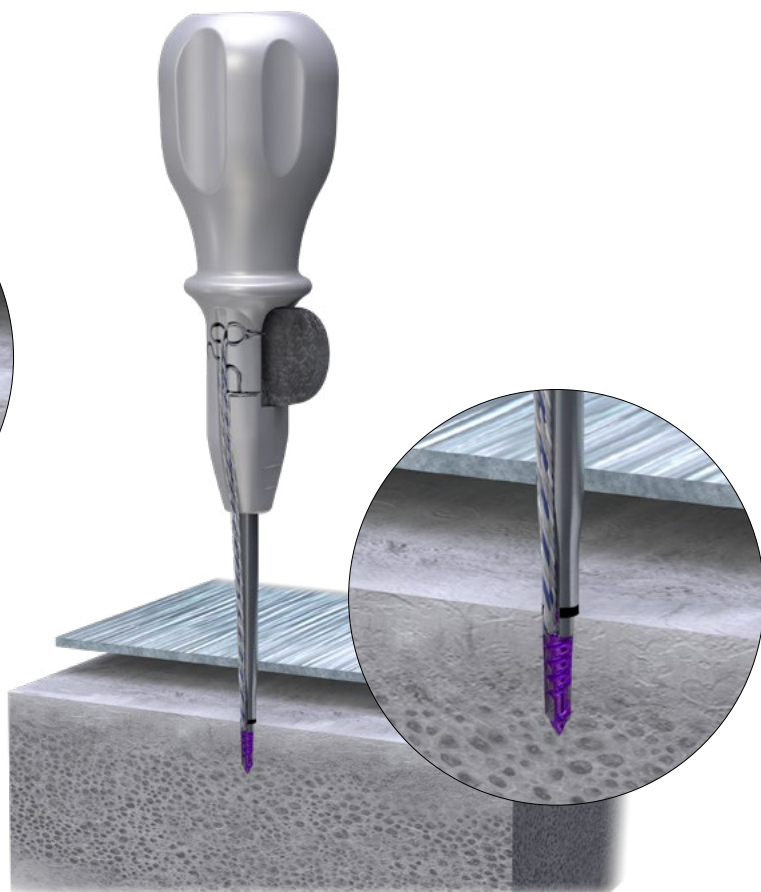


NOTE: If a central PEEK or titanium anchor is intended, space the soft anchors appropriately and proceed to next steps. If a PEEK or titanium anchor is not intended, proceed to implant tensioning and closure.

TITANIUM ANCHOR INSERTION

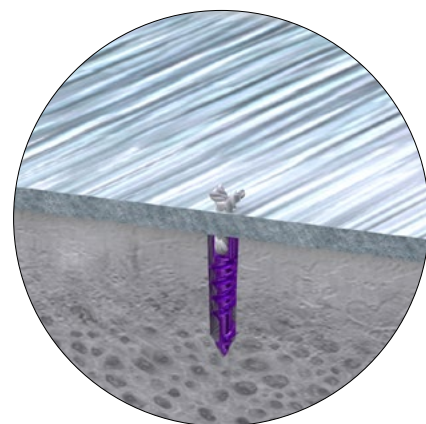
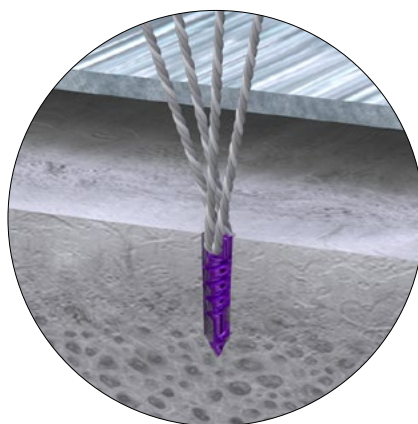
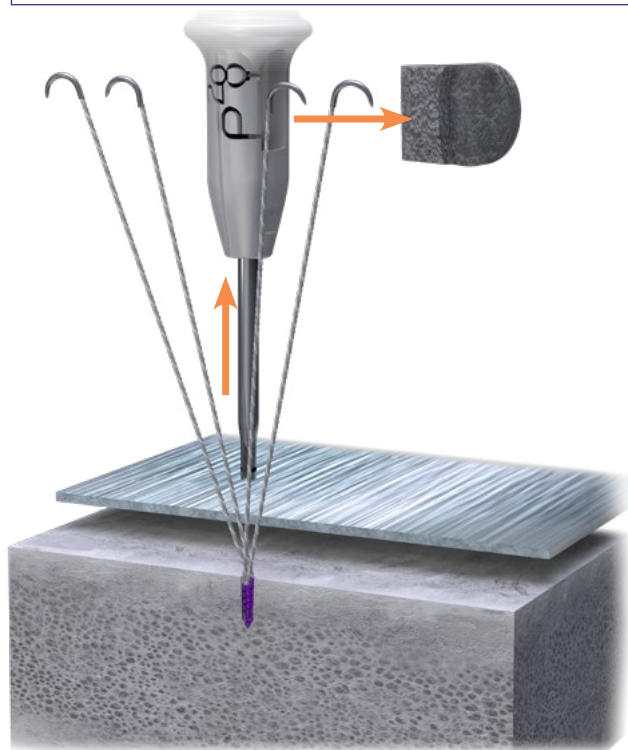


To use a titanium anchor, drill with the provided K-wire (Ø2.0 mm or Ø3.4 mm) into the desired anchor insertion site.



NOTE: Per surgeon preference, the titanium anchors do not require a pilot hole. They can be inserted directly with the Driver in a clockwise direction.

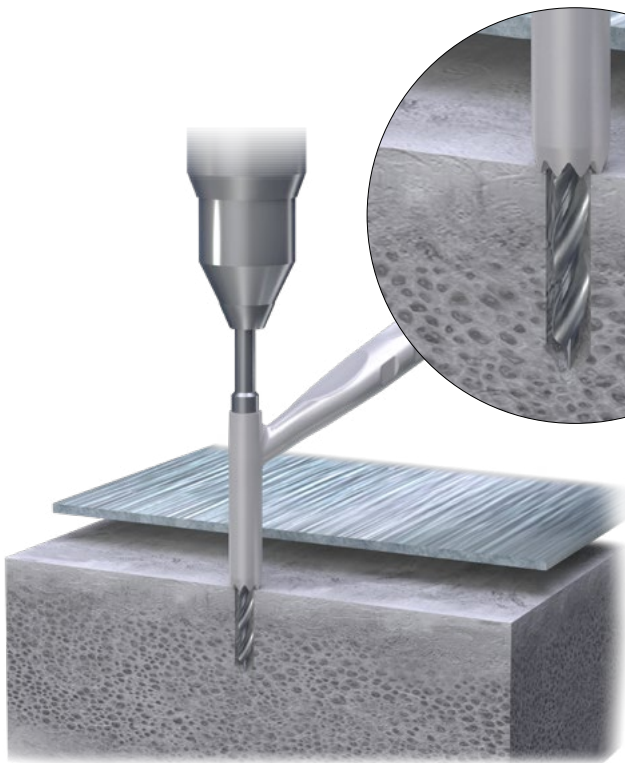
Insert the corresponding titanium anchor (Ø3.0 mm or Ø4.5 mm) by turning the Driver clockwise until flush with the bone.



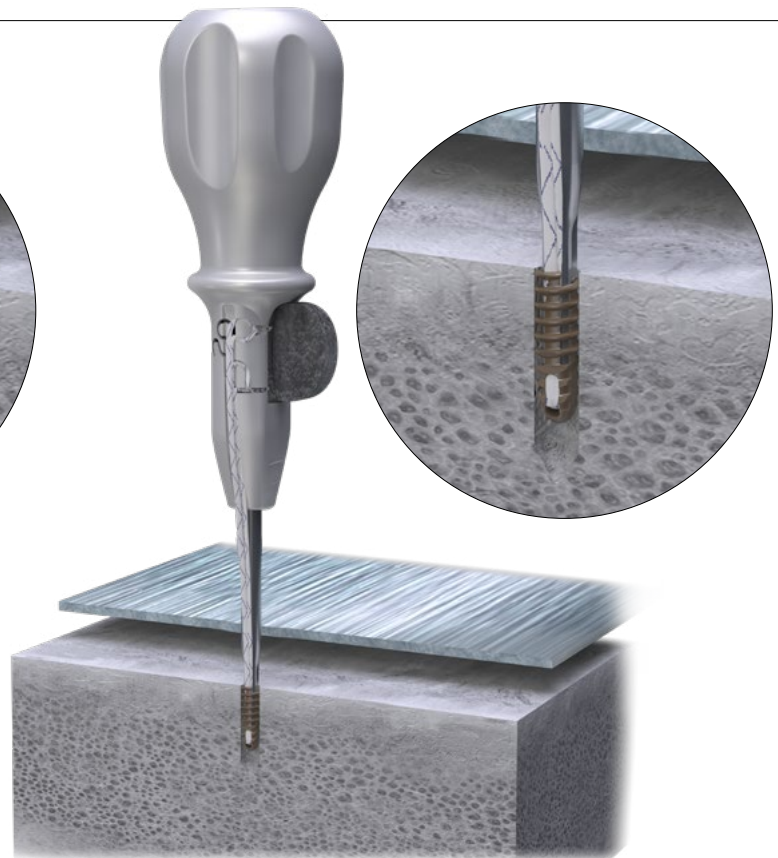
Disengage the needles and suture from the Inserter by pulling the foam block. Proceed to pass the needles from a deep to superficial orientation in the desired location of the ligament.

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.

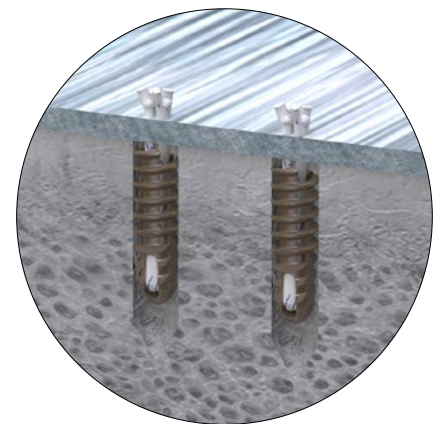
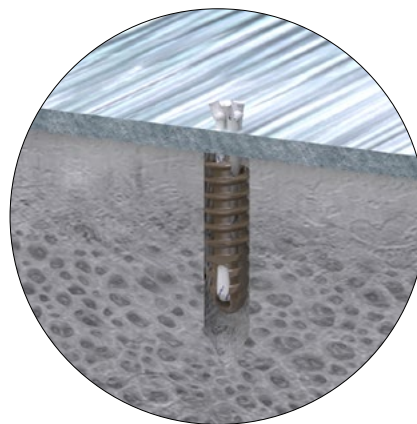
PEEK ANCHOR INSERTION



If inserting a PEEK anchor, use the provided Ø3.5 mm or Ø4.3 mm solid Drill, drill through the Drill Guide at the desired bone insertion site.



Insert the anchor with the pre-loaded 1.5 mm suture tape, turning the Driver in a clockwise direction.



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.

For the placement of the second titanium or PEEK anchor repeat the process of drilling described above at the desired location.

THE GRAPPLER® SYSTEM STERILE CADDY



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

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

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

- Suture (USP 2) and Needles (qty 4)
- Ø2.8 mm x 15 cm K-wire (qty 1)
- Drill Guide



Grappler Suture Anchor, Titanium, Ø3.0 x 10 mm

- Suture (USP 0) and Needles (qty 4)
- Ø2.0 mm x 15 cm K-wire (qty 1)

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

- Suture (USP 2) and Needles (qty 4)
- Ø2.6 mm x 15 cm K-wire (qty 1)



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

- Suture (USP 2) and 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

- Suture (USP 2) and Needles (qty 4)
- Ø1.6 mm x 15 cm K-wire (qty 1)
- Ø3.5 mm Drill (qty 1)
- Drill Guide

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

- Suture (USP 2) and 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

- Suture (USP 2) and 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 counter clockwise. Removal instrumentation can be supplied upon request.



NOTE: Sterile packed 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.

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.

GRAPPLER®

SUTURE ANCHOR SYSTEM

PATENTED, DESIGNED & EXCLUSIVELY DISTRIBUTED BY


Exclusively foot & ankle
Paragon²⁸®

P44-STG-0001 RevA [2021-12-13]

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Patents: www.paragon28.com/patents

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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.

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