GRAPPLER™
KNOTLESS ANCHOR SYSTEM

SURGICAL TECHNIQUE GUIDE
Soft Tissue Repair Using the Grappler® Knotless Anchor System

Exclusively foot & ankle
Paragon 28®

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

PRODUCT DESCRIPTION

The Grappler® Knotless Anchor System was designed to address the unique challenges that Foot and Ankle surgeons face when repairing soft tissue structures. The Grappler® Knotless Anchor System includes Bridgeline 4mm Suture Tape, cannulated Knotless Anchors, and Foot and Ankle specific instrumentation. Modular kit configurations minimize waste and provide surgeons the ability to address a variety of pathologies with a streamlined technique.

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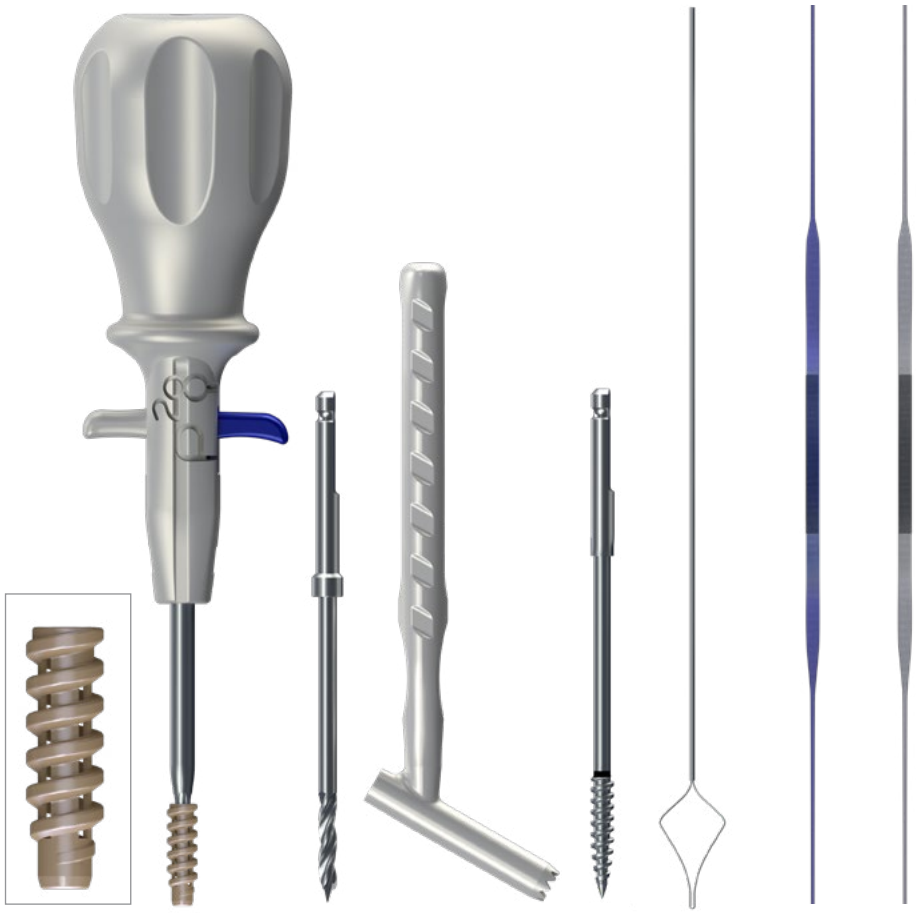
KIT CONTENTS

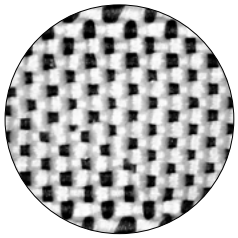


KNOTLESS ANCHOR KIT

- Cannulated Knotless Anchors (Ø4.5 mm & Ø5.5 mm)
- Tensioning Driver Handle
- Drill (Solid, Ø3.5 mm & Ø4.3 mm)
- Tissue Protector/Drill Guide
- Tap (Solid, Ø4.5mm and Ø5.5mm)
- Suture Passer
- 4.0 mm Suture Tape (100% UHMWPE or Adaptive)

Tape Features:

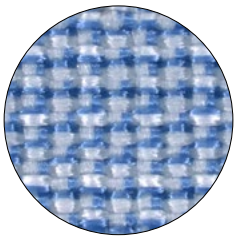
- *The central third of each tape is demarcated by a black tracer strand. This allows the surgeon to plan for appropriate working length of the repair*



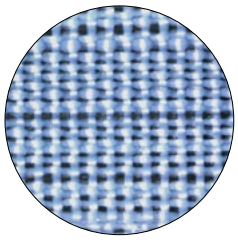
UHMWPE Weave

Adaptive Bridgeline Suture Tape:

- *The tape is partially absorbable. After absorption, the tape has a longer working length which promotes load-sharing with soft tissue structures.*



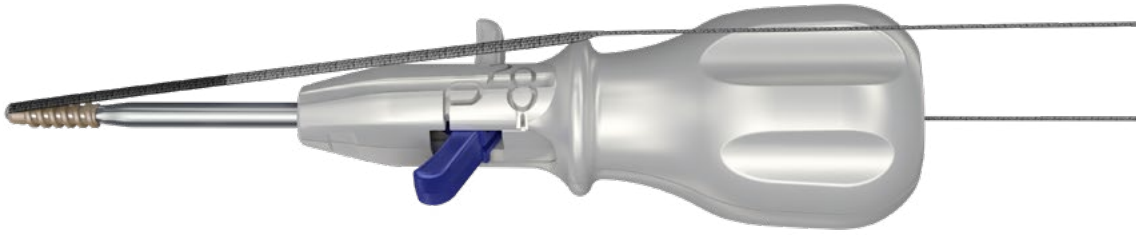
Pre-Absorption



Post-Absorption

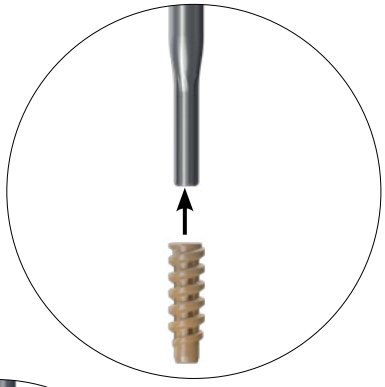
Tensioning Driver Features:

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

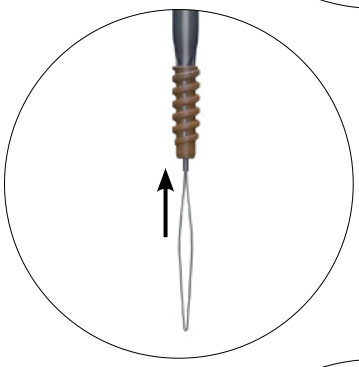


KNOTLESS ANCHOR PREPARATION

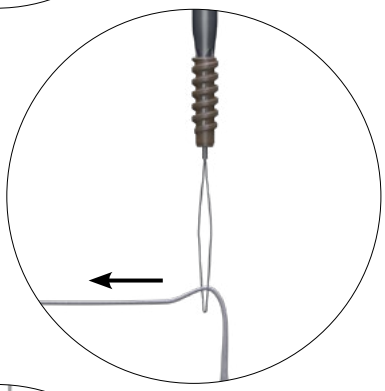
1. If not pre-loaded, place the Knotless Anchor over the tip of the Cannulated Tensioner Driver Handle.



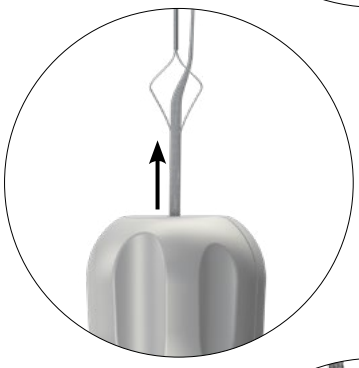
2. If not pre-loaded, pass the Suture Passer through the Anchor and Driver.



3. Thread smaller tail of the 4.0 mm Tape through the provided Suture Passer.



4. If not pre-loaded, pass the Suture Passer and Tape through the Cannulated Tensioning Driver Handle tip and Cannulated Peek Anchor.

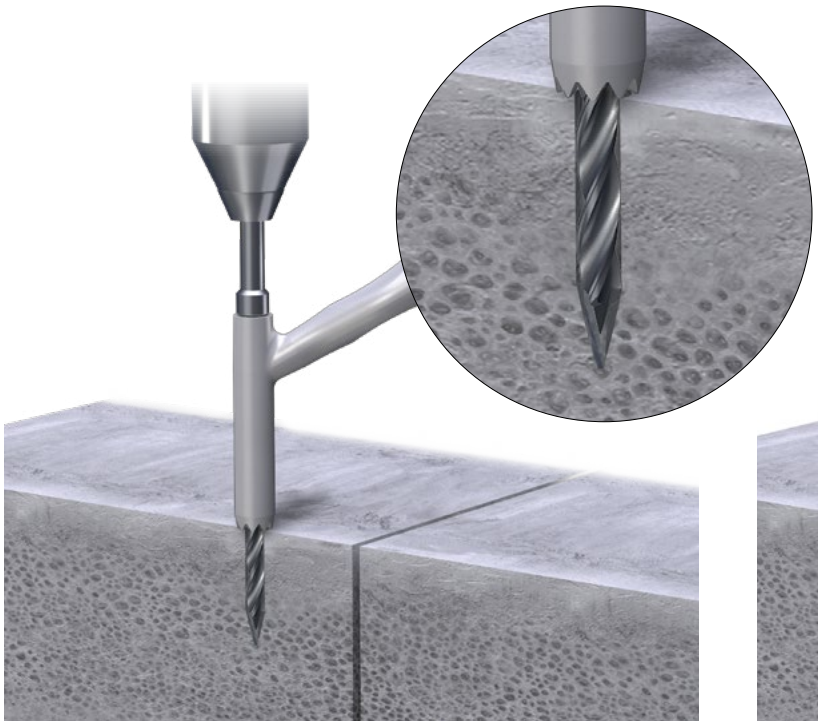


5. Position the tape (e.g. centered, offset, etc.) according to the working length needed to complete the repair.

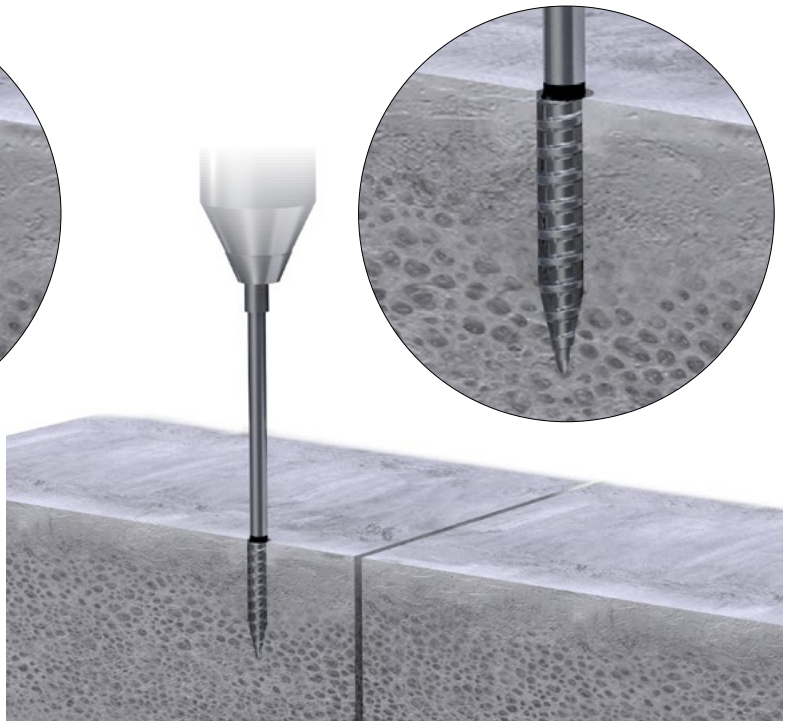
The configuration shown resembles a prepared Tensioning Driver Handle and Tape ready to be placed.

NOTE: *The black portion of the Suture indicates the middle third section of the Tape.*

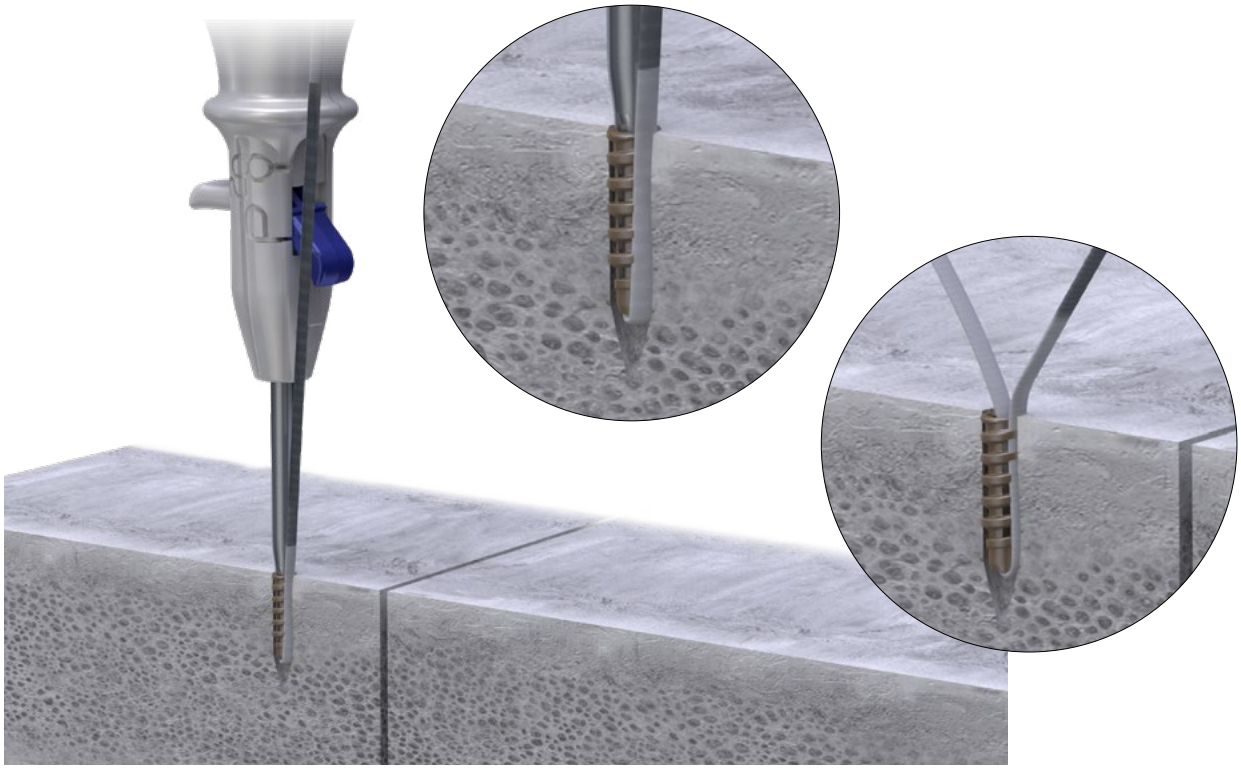
KNOTLESS ANCHOR INSERTION



Before inserting the Knotless anchor, use the provided Drill to create the pilot hole for the Knotless Anchor at the desired bone insertion site. If using the Drill Guide, drill until hard stop is reached, otherwise drill until flutes are buried.



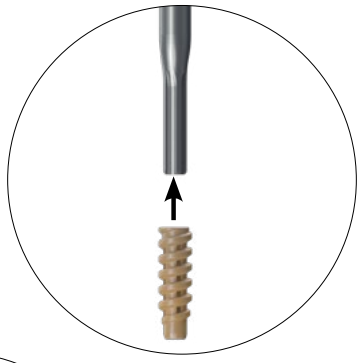
A Tap is provided to aid in insertion. Attach the Tap to the appropriate sized Handle and hand tap to the laser line.



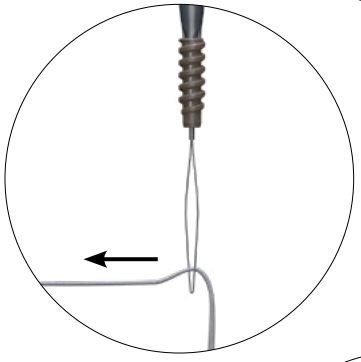
Insert the anchor with the pre-loaded 4.0 mm Suture Tape, turning the Driver in a clockwise direction. Ensure that the tape is flat/not twisted when inserting the anchor to prevent complications with insertion.

KNOTLESS ANCHOR INSERTION

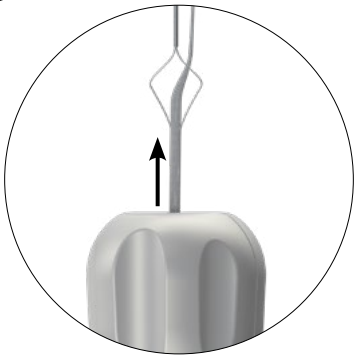
1. Prepare the second Knotless Anchor over the Tensioning Driver Handle tip.

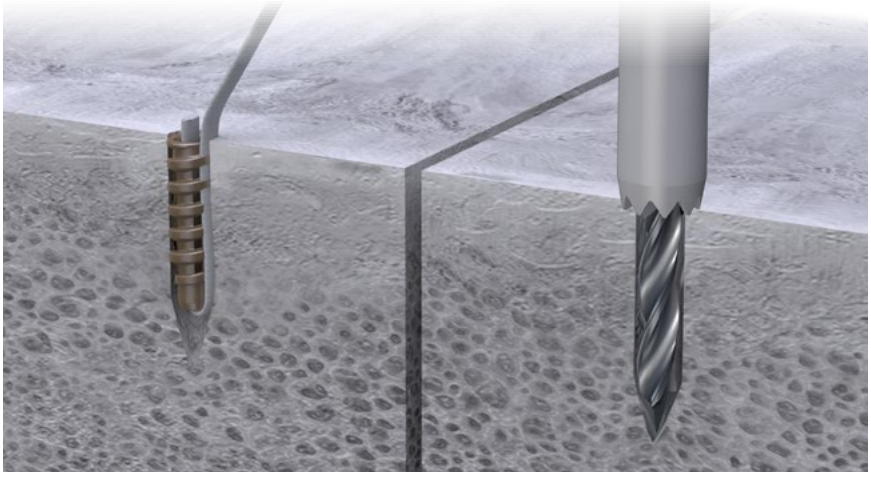


2. Pass the Suture Passer through the Tensioning Driver Handle. Feed the tail of the Suture Tape through the Suture Passer.



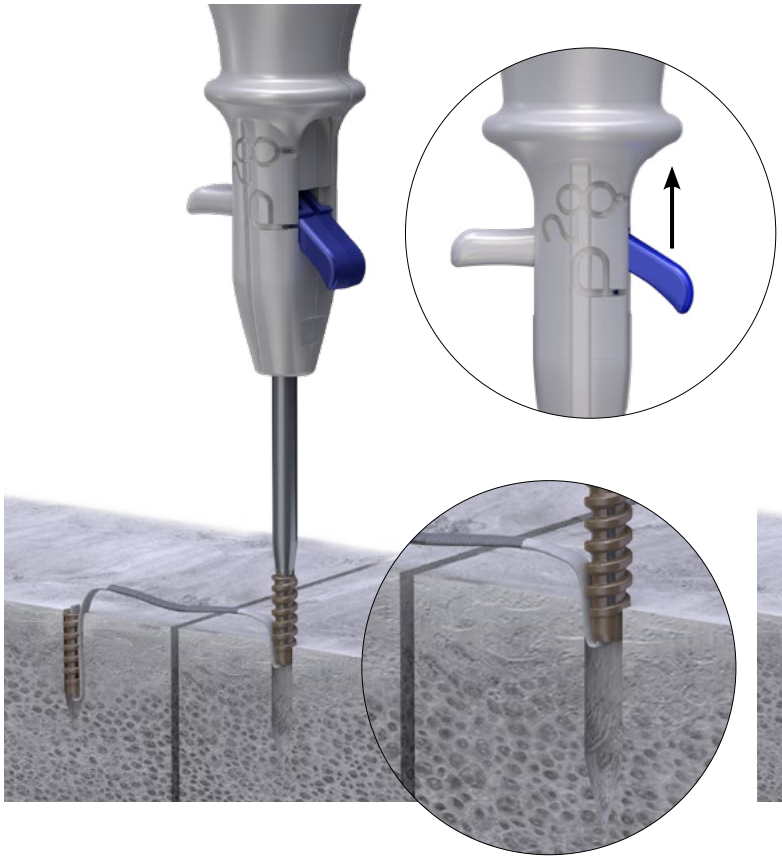
3. Pull the Suture Passer back through the center of the Tensioner Driver Handle to retrieve and reload the Tape.



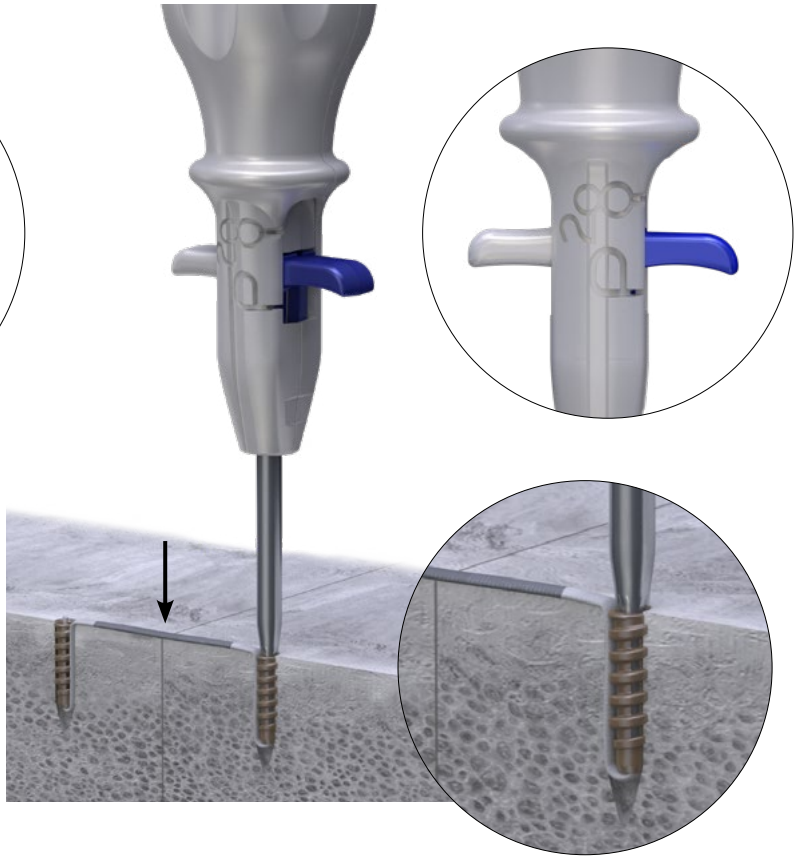


Once the first Anchor has been placed, use the provided Drill, Drill Guide, and Tap to create a second pilot hole for the second PEEK anchor at the desired bone insertion site to reduce the bone.

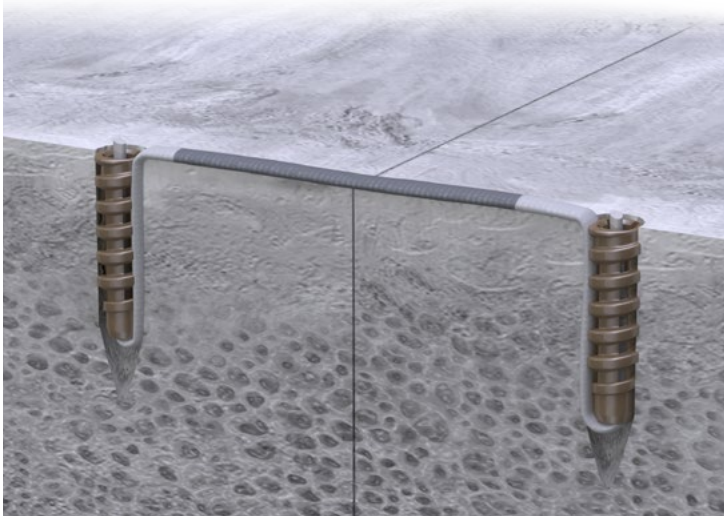
KNOTLESS ANCHOR INSERTION



Align the second Knotless Anchor into the insertion site and pull suture slack out of the back of the Handle. Apply desired tension to repair by manually pulling tape end(s) from the back of the Handle.



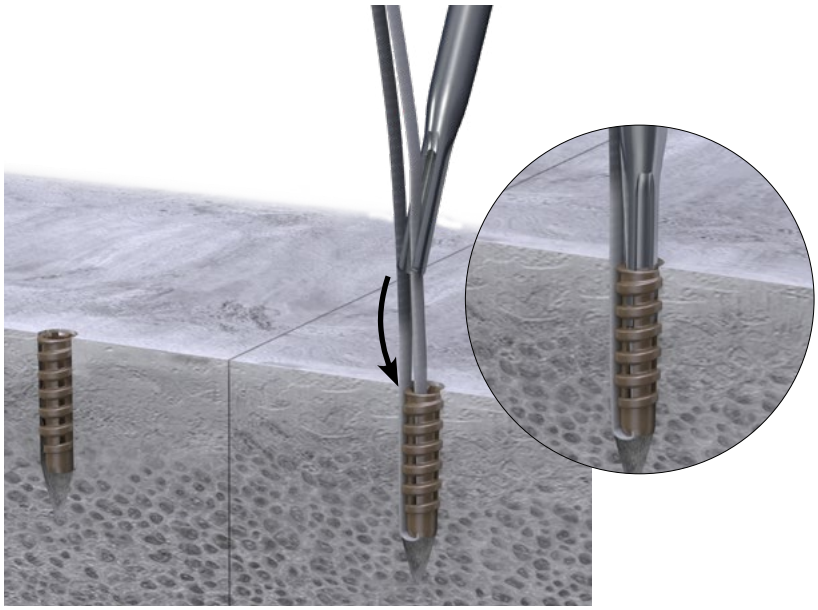
For additional tensioning, using the Tensioning Trigger on the Handle, pull to obtain the desired tension which pulls the Tape tight and reduced the bone. When proper tension is achieved, fully insert the Knotless anchor into the insertion site by driving in clockwise.



Once the Anchors and Tape are placed and tensioned, cut the excess Tape bound to the Anchors. Bone should be reduced after tensioning the anchored Tape.

KNOTLESS ANCHOR REMOVAL (IF NECESSARY)

The Knotless 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.



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.*

THE GRAPPLER® KNOTLESS SYSTEM STERILE CADDY

Grappler Knotless Anchor Two Ø4.5 mm Implant Kit:

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

Grappler Knotless Anchor Ø4.5 mm and Ø5.5 mm Implant - Only Kits:

- Tensioning Driver preloaded with Ø4.5/Ø5.5 mm Knotless Anchor and suture passer

Grappler Knotless Anchor Ø4.5 mm and Ø5.5 mm Implant + Instrumentation Kit:

- Tap
- Ø3.5 /Ø4.3 mm Drill
- Drill Guide
- Tensioning Driver Handle preloaded with Ø4.5/Ø5.5 mm Knotless Anchor and suture passer

Additional Sterile-packed Components:

- Suture passers (5X individually sterilized)
- Suture Tape (100% UHMWPE or Adaptive)

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

PATENTED, DESIGNED & EXCLUSIVELY DISTRIBUTED BY

Exclusively foot & ankle Paragon 28®

P44-STG-0002 RevB [2023-05-17]

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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.