

GRAPPLER™
KNOTLESS ANCHOR SYSTEM

BRIDGELINE™
TAPE

Grapppler® Knotless Anchor
and Bridgeline™ Tape Systems
Hospital Registration Memo

———— by ————

Exclusively foot & ankle
paragon²⁰



The mission of Paragon 28®

Our mission is to strategically build a company around the core principles that **drive innovation and quality**. Relentlessly working to advance the science behind foot and ankle surgery, Paragon 28 is passionate about and committed to:



Blending different surgical philosophies from various global thought leaders to develop biomechanically and clinically relevant surgical solutions.



A customer service based, dedicated, and highly-trained distribution network to the foot and ankle market.



Meeting the needs of increasing pricing pressures and reimbursement while continuing to develop cutting-edge surgical implants.



Creating complete surgeon-centric systems, specialty instruments, and next generation implants to solve real world issues faced by foot and ankle surgeons.



Improving clinical outcomes through meaningful and unbiased research. We are ready to embrace research data regardless of marketing impact.

Paragon 28® History

In 2010, Paragon 28® was established as an orthopedic foot and ankle company. The name “Paragon 28” was chosen to show that we are exclusively a foot and ankle company, with the “28” representing the number of bones in the foot. We will remain true to that vision. Paragon 28 was started as a small, family-based company and we have kept those core ideals as we have grown.

Our first product was the Monster® Screw System, followed by the Gorilla® Plating System. As we continue to add more products, we maintain a fine level of detail to every feature of every product we design. The goal is to give options to the foot and ankle surgeon, knowing there is more than one way to achieve a great result. We have listened to surgeons and will continue to do so in order to understand and address their specific needs.



The product development team is pleased to announce the launch of the Grappler® Knotless Anchor System and Bridgeline™ Tape further expanding its foot and ankle specific soft tissue offering

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 with the ability to address a variety of pathologies with a streamlined technique.

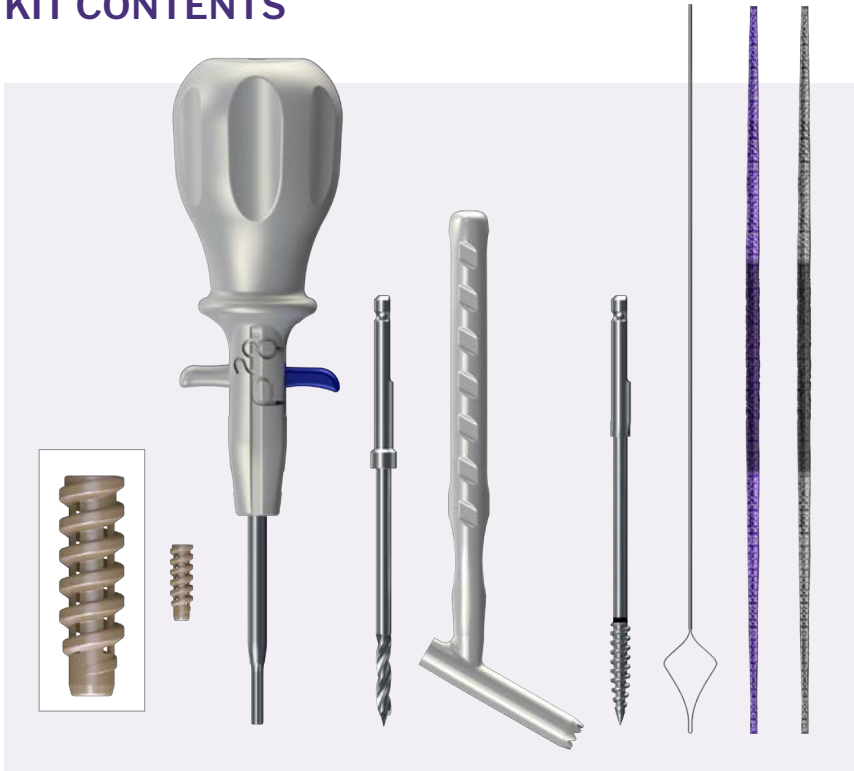
There are inherent challenges in completing soft tissue balancing procedures of the foot and ankle including:

- ▶ Pull-out of suture or anchor in poor bone
- ▶ Diverse bony and soft tissue anatomy requiring varied sized implants and augment materials
- ▶ Post-operative stiffness and subtalar stiffness related to implant tension and scarring
- ▶ Instability due to implant stretch or failure of repair

The Grappler® Knotless Anchor System and Bridgeline™ Tape were designed to address the unique challenges surgeons face when repairing soft tissue structures in the foot and ankle. The cannulated PEEK anchors are vented to maximize driver engagement and designed to allow for bony growth. The anchors come preloaded with either tape or suture on an elegantly designed handle intended to maximize surgeon control in restoring soft tissue anatomy to the appropriate tension following insertion of the anchor. The Bridgeline™ Tape offers surgeons a first in kind semi-resorbable suture tape construct which stretches following resorption and which is designed to transition load to the native anatomy. The tape is four millimeters wide allowing for broader tissue surface interaction than competitive offerings. The Grappler® Suture Anchor System comes sterile packed with all instrumentation needed to complete the case in multiple configurations reducing waste and interoperative complexity.



KIT CONTENTS



Knotless Anchor Kit

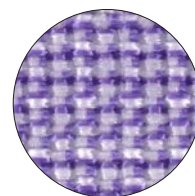
- Cannulated Knotless Anchors (Ø4.5 mm and Ø5.5 mm)
- Tensioning Driver Handle
- Drill (Solid, Ø3.5 mm and Ø4.3 mm)
- Tissue Protector/Drill Guide
- Tap (Solid, Ø4.5 mm and Ø5.5 mm)
- Suture Passer
- 4.0 mm Suture Tape (100% UHMWPE or Adaptive)

BRIDGELINE™ TAPE:

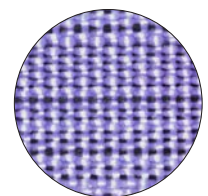
Bridgeline™ Tape is offered in conventional UHMWPE as well as the novel Adaptive version which is a first in kind semi-resorbable suture tape construct which stretches following resorption and which is designed to transition load to the native anatomy. Both are four millimeters wide allowing for broader tissue surface interaction than competitive offerings.

Adaptive Bridgeline™ Tape:

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



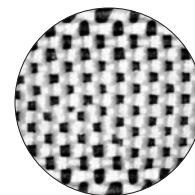
Pre-Absorption



Post-Absorption

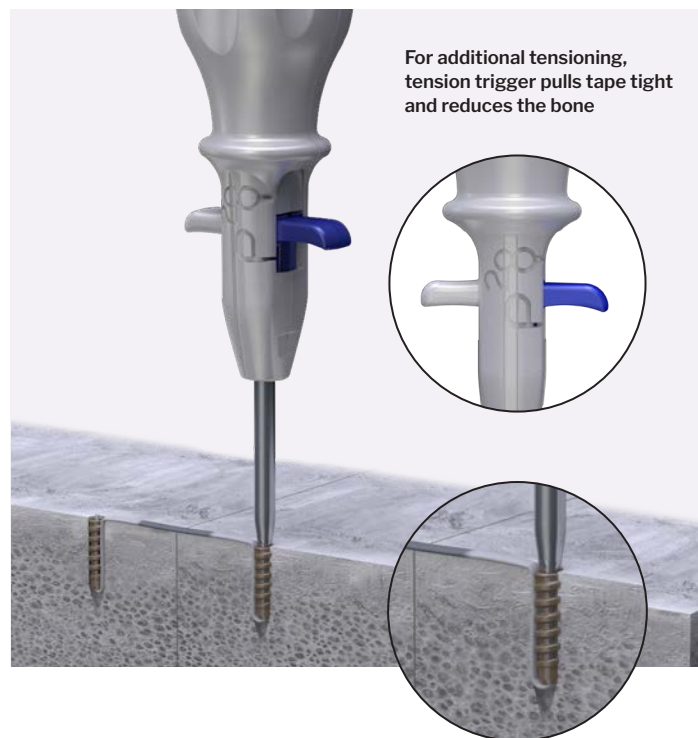
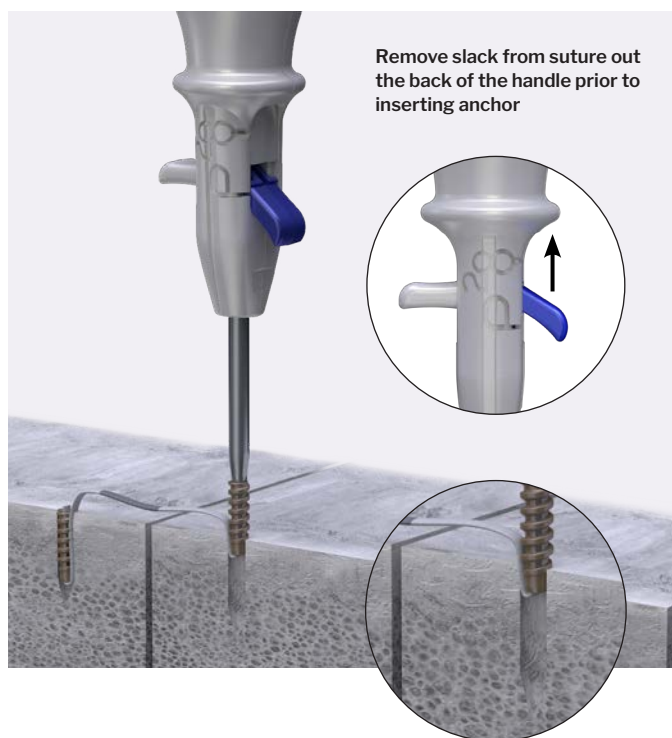
UHMWPE Bridgeline™ Tape Features:

- 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

Tensioning Driver Functionality



KIT CONFIGURATIONS

Grappler Knotless Anchor Two Ø4.5 mm Implant Kit:

- ▶ Tap
- ▶ Ø3.5 mm Drill Bit
- ▶ 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 or Ø5.5 mm Knotless Anchor and suture passer

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

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

Additional Sterile-packed Components:

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

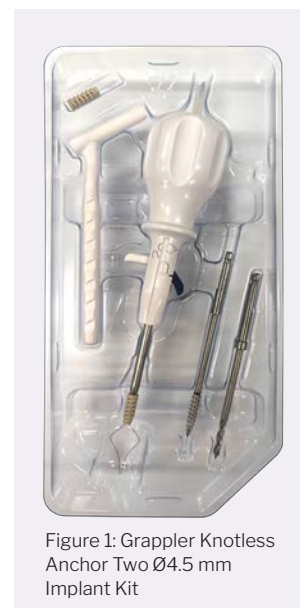




Figure 1: Drill

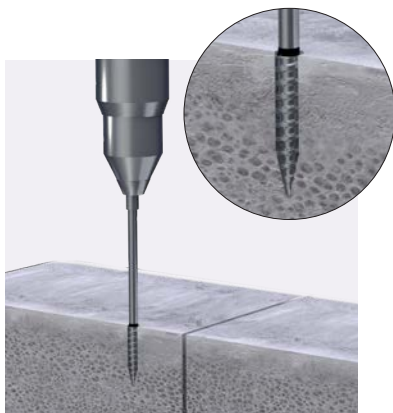


Figure 2: Tap

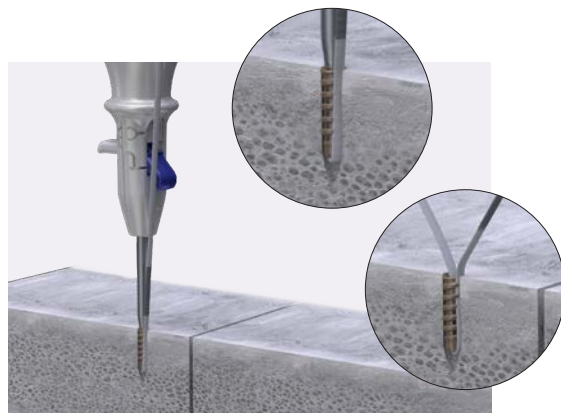


Figure 3: Insert Anchor in Bone Tunnel and Remove Driver

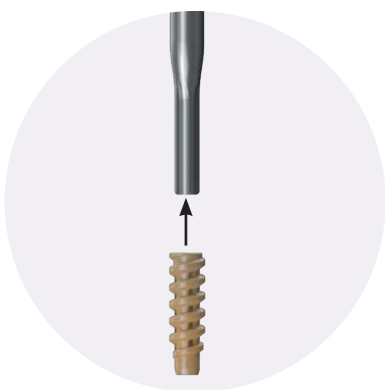


Figure 4: Load 2nd Implant on Driver

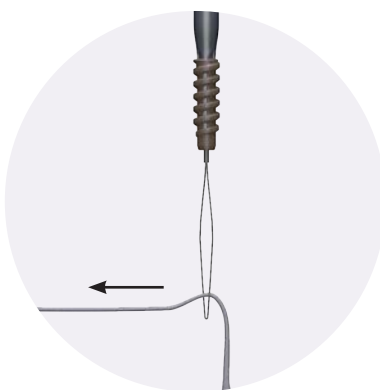


Figure 5: Load Tape through Suture Passer

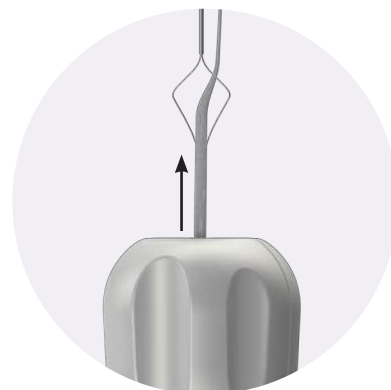


Figure 6: Pull Tape through Driver

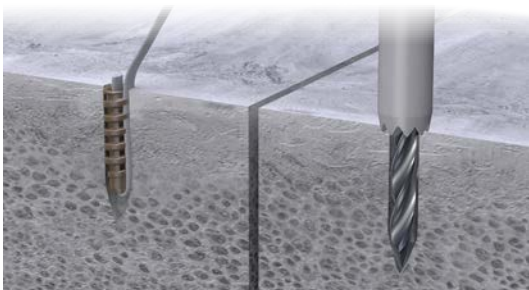


Figure 7: Drill and Tap for 2nd Anchor

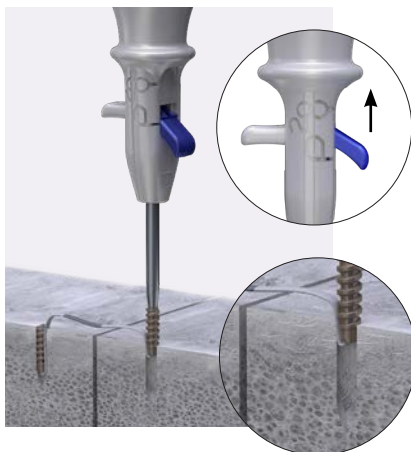


Figure 8: Pull Slack Out of Back of Driver. For Additional Tension, Pull on Both Tensioning Triggers

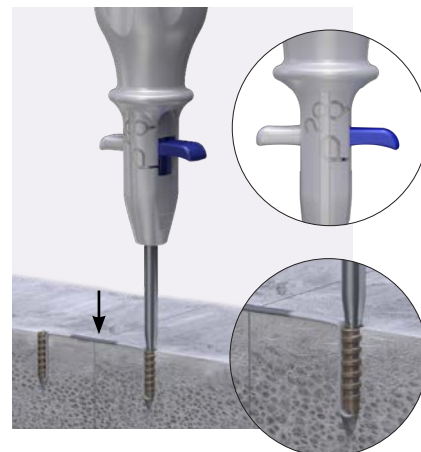


Figure 9: Full Seat Anchor

GSASKL-XXX, GRAPPLER KNOTLESS/BRIDGELINE TAPE (BLACK BOX)

PART #	DESCRIPTION	QUANTITY
P44-130-4515-SK	Knotless Anchor, PEEK, 4.5 x 15mm, Sterile Kit w/Tap+Wire, Grappler®	3
P44-130-5515-SK	Knotless Anchor, PEEK, 5.5 x 15mm, Sterile Kit w/Tap+Wire, Grappler®	2
P44-131-4515-SK	Knotless Anchor, PEEK, 4.5 x 15mm, Anchor/Driver Only, Sterile Kit, Grappler®	3
P44-131-5515-SK	Knotless Anchor, PEEK, 5.5 x 15mm, Anchor/Driver Only, Sterile Kit, Grappler®	2
P44-300-4515-SK	Knotless Anchor, 4.5mm PEEK + Bridgeline Tape, Sterile Procedure Kit	4
P44-300-0004-S	BridgeLine Suture Tape, 4mm, UHMWPE, Sterile	2
P44-970-0001-SK	Suture Passer, Sterile, Grappler®, Box of 5	1

GSASKR-XXX, GRAPPLER KNOTLESS/BRIDGELINE ADAPTIVE TAPE (BLACK BOX)

PART #	DESCRIPTION	QUANTITY
P44-130-4515-SK	Knotless Anchor, PEEK, 4.5 x 15mm, Sterile Kit w/Tap+Wire, Grappler®	3
P44-130-5515-SK	Knotless Anchor, PEEK, 5.5 x 15mm, Sterile Kit w/Tap+Wire, Grappler®	2
P44-131-4515-SK	Knotless Anchor, PEEK, 4.5 x 15mm, Anchor/Driver Only, Sterile Kit, Grappler®	3
P44-131-5515-SK	Knotless Anchor, PEEK, 5.5 x 15mm, Anchor/Driver Only, Sterile Kit, Grappler®	2
P44-310-4515-SK	Knotless Anchor, 4.5mm PEEK + Bridgeline Adaptive Tape, Sterile Procedure Kit	4
P44-310-0004-S	BridgeLine Adaptive Suture Tape, 4mm, UHMWPE/ PGLA, Sterile	3
P44-970-0001-SK	Suture Passer, Sterile, Grappler®, Box of 5	1

GRAPPLER™

KNOTLESS ANCHOR SYSTEM

BRIDGELINE™

TAPE

Grappler® Knotless Anchor and Bridgeline™ Tape Systems

Additional Information


Thank you for taking time to consider offering the Grappler Knotless Anchor and Bridgeline™ Tape Systems in in your facility. Please reference the enclosed documents for additional information on the system:

- ▶ Surgical Technique Guide
- ▶ Pricelist
- ▶ System Brochure

The Instructions for Use (IFU) for the Grappler® Knotless Anchor and Bridgeline™ Tape Systems can be found in P44.IFU.0001 (<http://www.paragon28.com/ifus/>).

For additional information on Paragon 28® and its products please visit: <http://www.paragon28.com>.

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Exclusively foot & ankle **28**
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