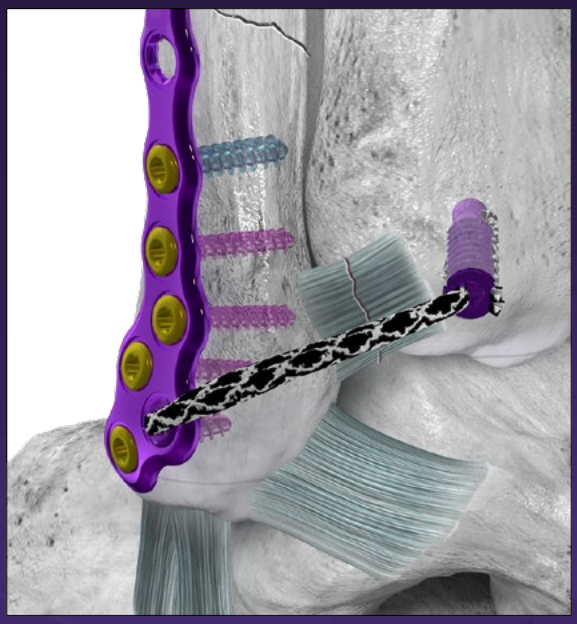
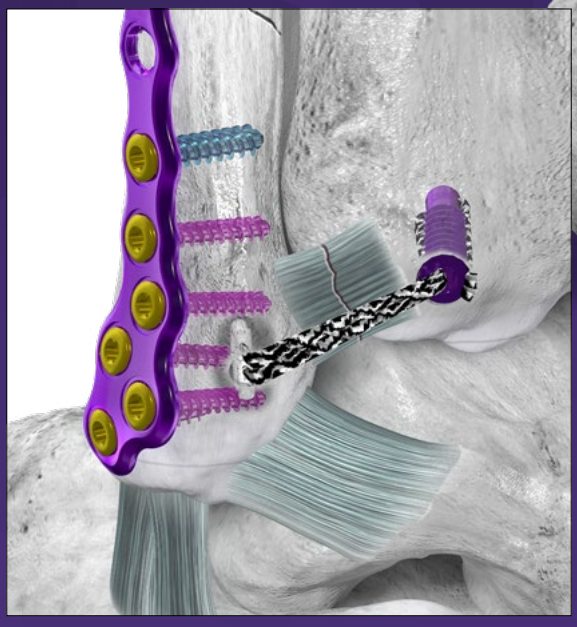
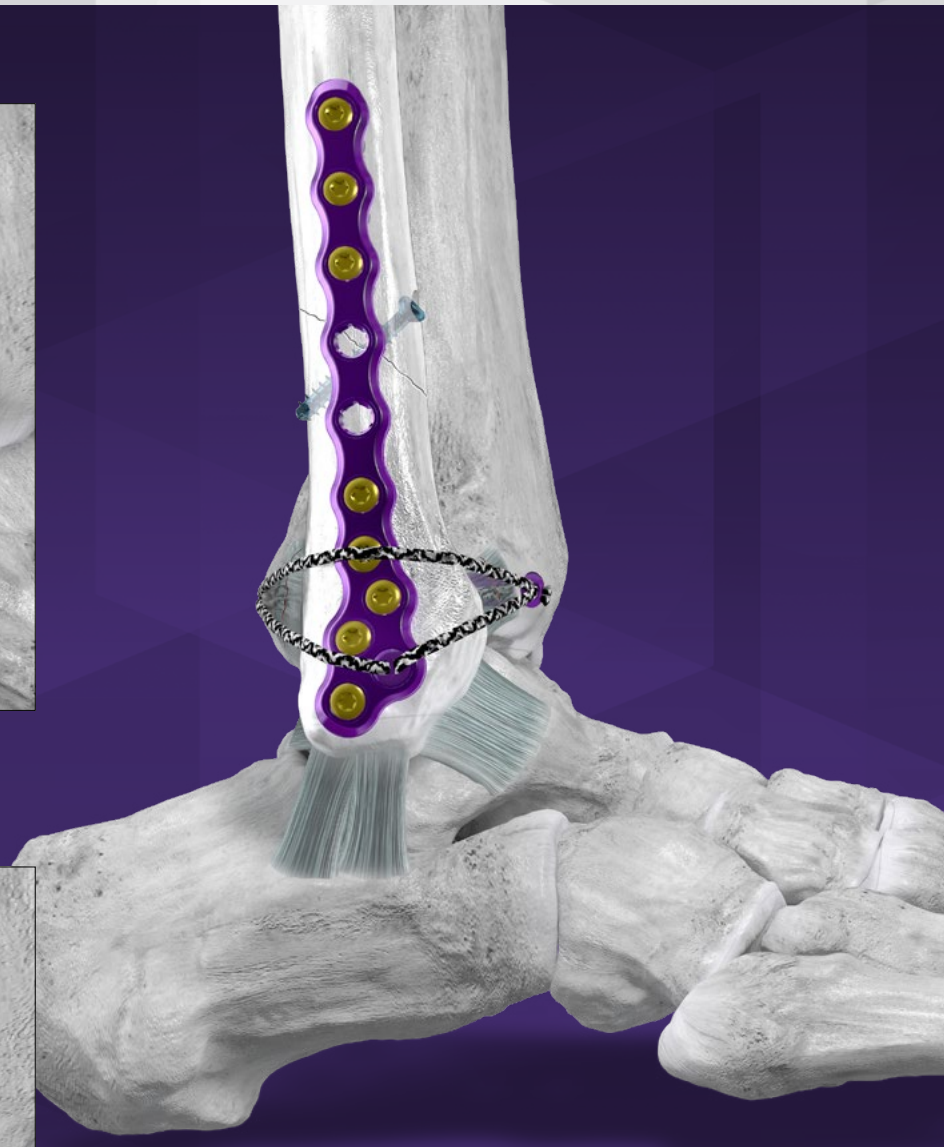
R3INFORCE™
EXTRAOSSEOUS REPAIR SYSTEM

SURGICAL TECHNIQUE GUIDE

Syndesmosis Repair using the Grappler® R3INFORCE™ Extraosseous Repair System







Exclusively foot & ankle 2nd Paragon®

Acknowledgment:

Paragon 28® would like to thank Mr. Kailash Devalia, Mr. Chris Blundell, Mr. Mark Davies, and Cesar de Cesar Netto, MD for their contributions as the surgeon design team.

PRODUCT DESCRIPTION

The Grappler® R3INFORCE™ Extraosseous ("ExO") Repair System was designed to restore ligamentous stability of the ankle during fibula fracture repairs and unstable high ankle sprains. The system can facilitate repair of the AITFL, PITFL, or a combination of the two ligaments, per surgeon preference and patient need. The Grappler® R3INFORCE™ System utilizes an All-suture or Titanium Anchor in combination with Plate-Interfacing Anchors (Ø4.2 mm or Screwless) and separate Ø4.75 mm Dynamic Knotless Anchors to repair the lateral ankle ligaments. Pre-loaded suture tape can be routed and tensioned to address the injured ligament or ligaments. The Dynamic Anchor is designed to create a self-balancing construct that allows for micromotion in the repair to better replicate the mechanics of the native tissue.

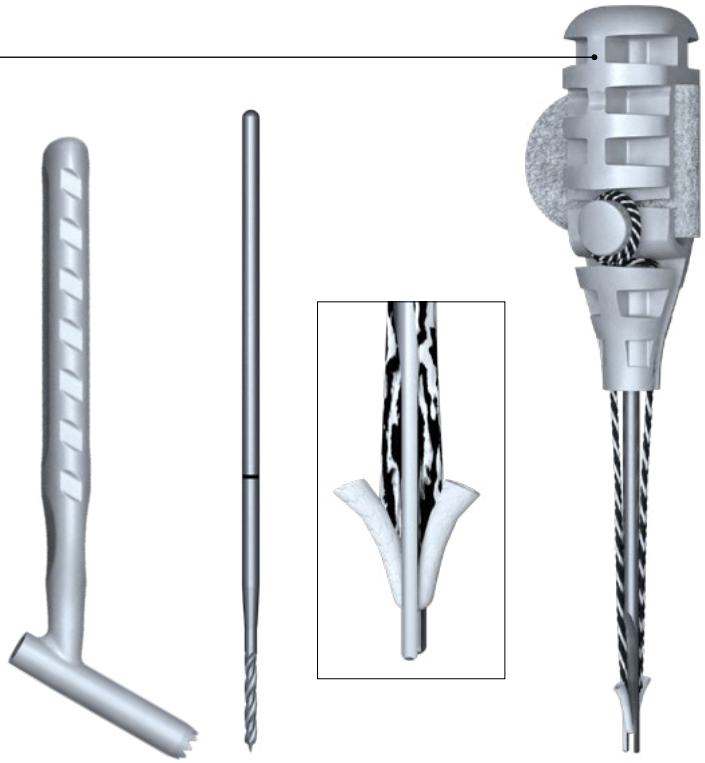
The breadth of anchors and compatibility with the Grappler® Knotless System allows for multiple configurations for surgeons to cater their repairs to their own treatment philosophies.

CONTENTS

SYSTEM OPTIONS

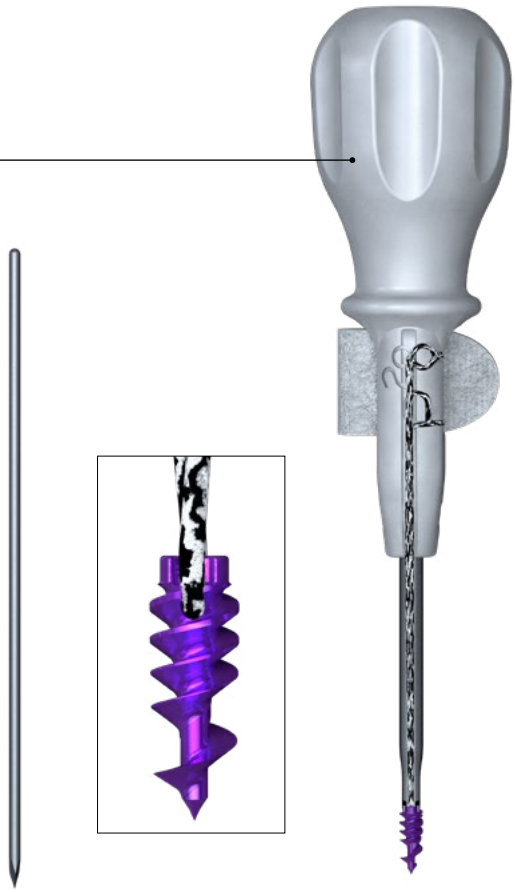
R3INFORCE ExO ALL-SUTURE ANCHOR KIT

- Ø2.8 mm Anchor, pre-loaded with 1.5 mm Passing Suture Tape on Inserter
- Drilling K-wire (Ø2.8 mm)
- Drill/Insertion Guide



R3INFORCE ExO Ø4.5 MM TITANIUM ANCHOR KIT

- Ø4.5 mm x 15 mm Anchor, pre-loaded with 1.5 mm Passing Suture Tape on Driver
- K-wire (Ø2.6 mm)

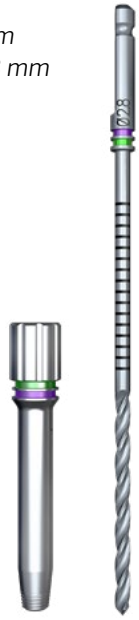


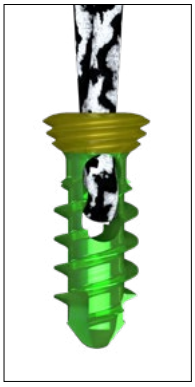
SYSTEM OPTIONS

R3INFORCE ExO LOCKING ANCHOR KIT

- Ø4.2 mm x 12 mm Locking Screw Anchor, pre-loaded with 1.5mm Passing Suture Tape on Driver

NOTE: *Requires the Ø4.2 mm Locking Drill Guide and Ø2.8 mm Drill from the Gorilla® Ankle Fracture 360 System.*





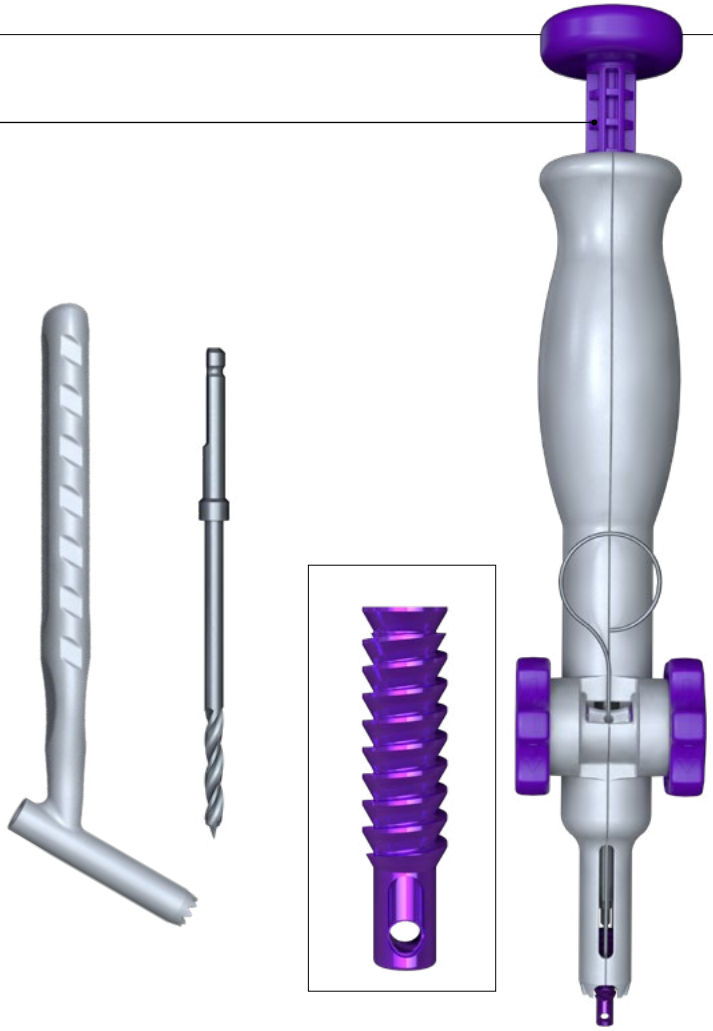
R3INFORCE ExO SCREWLESS HEAD LOCKING ANCHOR KIT

- Screwless Head Locking Anchor, pre-loaded with 1.5 mm Passing Suture Tape on Driver

SYSTEM OPTIONS

Ø4.75 MM X 20 MM DYNAMIC ANCHOR KIT

- Ø4.75 mm x 20 mm Dynamic Anchor, pre-loaded with Suture Passer on Inserter
- Ø3.7 mm Solid Drill
- Drill Guide



COMPATIBLE WITH THE GRAPPLER KNOTLESS SYSTEM

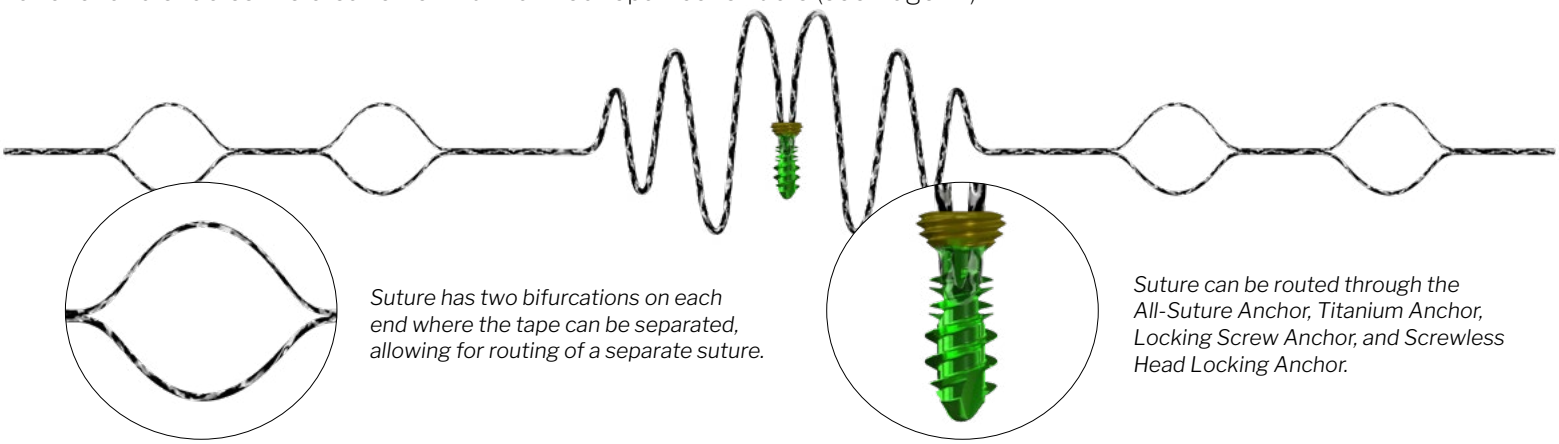
- Ø4.5 mm Knotless PEEK Anchor
- Tensioning Driver Handle , preloaded with Suture Passer
- Ø3.5 mm Solid Drill Bit
- Tissue Protector/Drill Guide
- Ø4.5 mm Solid Tap

NOTE: *More information on the Grappler Knotless System, including the full technique guide and indications, can be found in: P44-STG-0002 Grappler Knotless Anchor STG.*

PRODUCT FEATURES

SUTURE ROUTING WITH PASSING TAPE

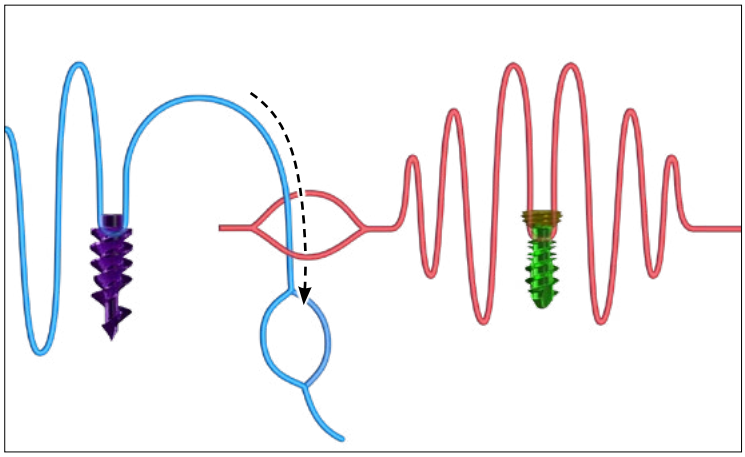
The Ø2.8 mm All-Suture Anchor, Ø4.5 mm Titanium Anchor, Locking Anchor, and Screwless Head Locking Anchor are all pre-loaded with Passing Tape. This tape contains two bifurcations at each end to allow for the routing of repair suture through the anchor and enables the creation of multi-armed repair constructs (see Page 17).



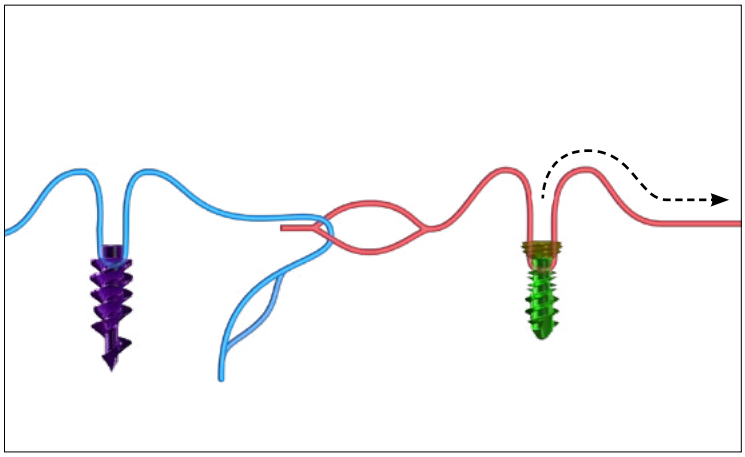
Suture has two bifurcations on each end where the tape can be separated, allowing for routing of a separate suture.

Suture can be routed through the All-Suture Anchor, Titanium Anchor, Locking Screw Anchor, and Screwless Head Locking Anchor.

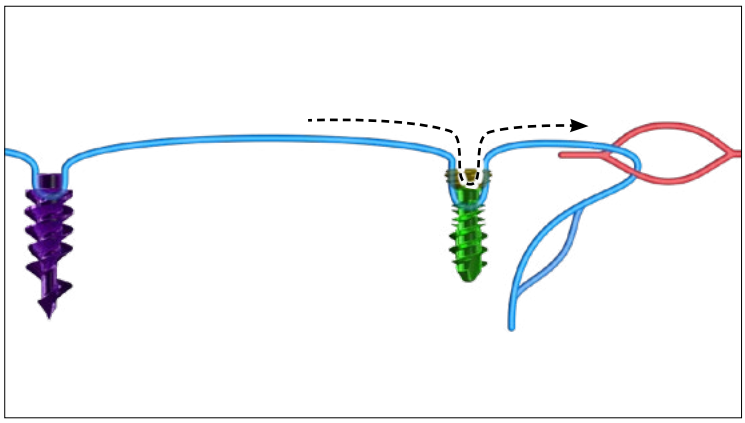
NOTE: *Red/Blue coloration used below to assist in routing demonstration visualization. All R3INFORCE ExO anchors are loaded with identical black-and-white suture tape.*



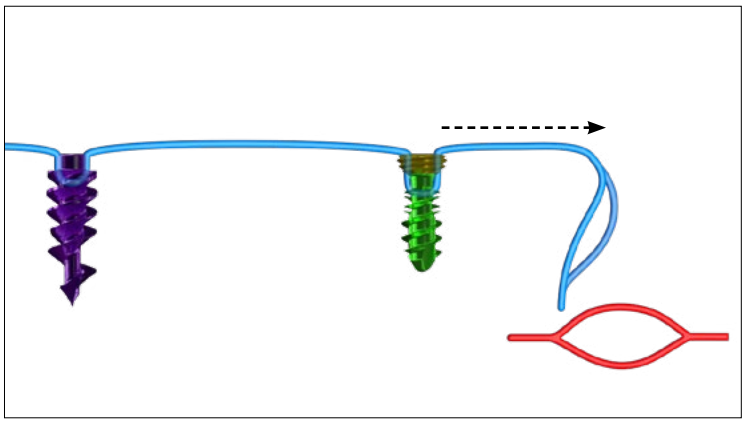
Pass one end of the suture tape to be routed (blue) through a bifurcation of the suture tape coming from the anchor to be routed through (red).



Pull the opposite end of the suture tape from the anchor to be routed through (red), which will pull the captured routing suture tape (blue) toward the anchor.



Continue pulling until the suture tape to be routed (blue) has passed through the anchor.



At this point routing is complete, and the suture tape from the anchor to be routed through (red) can be discarded.

EXAMPLE CONFIGURATIONS

The following are example applications of the Grappler R3INFORCE System for various ligamentous repairs used both in conjunction with or independent of ankle fracture plating.

Titanium Anchor
Pages 15-16

All-Suture Anchor
Page 18

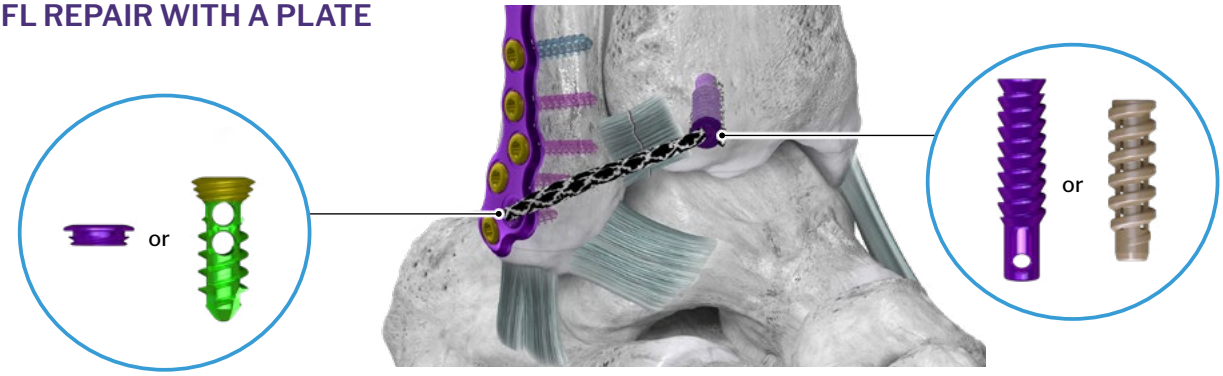
Screwless Head Locking Anchor
Pages 9-10

Locking Anchor
Pages 20-21

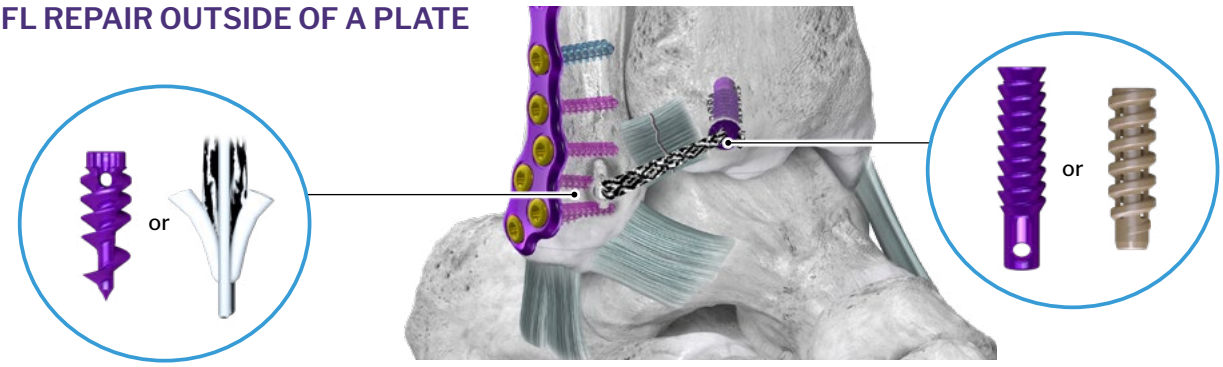
Dynamic Knotless Anchor
Pages 10-14

PEEK Knotless Anchor
(From Grappler Knotless System)

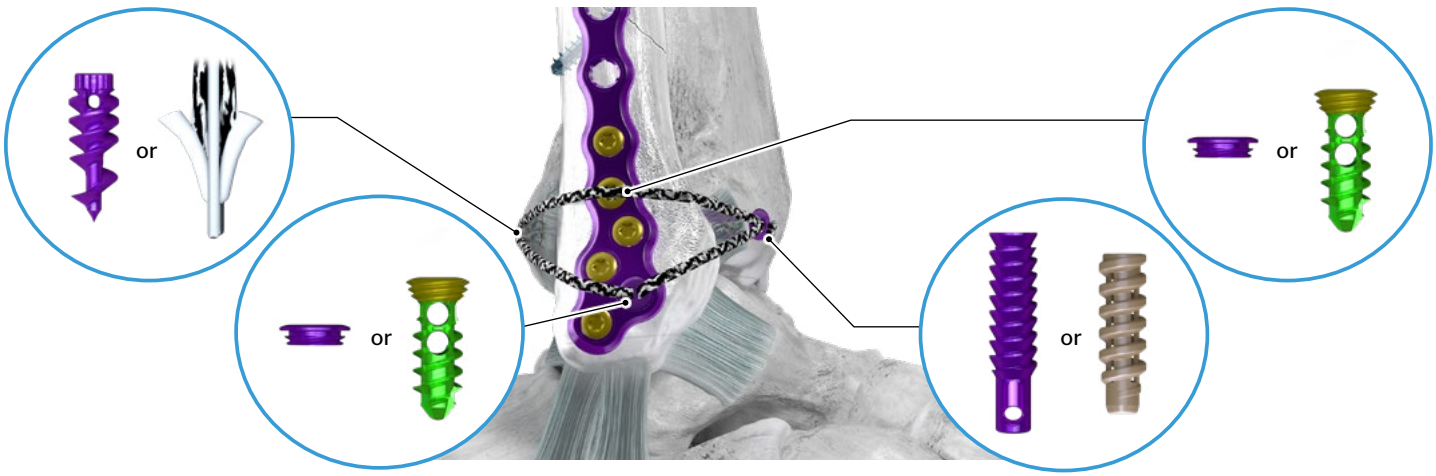
AITFL REPAIR WITH A PLATE



AITFL REPAIR OUTSIDE OF A PLATE



COMBINED AITFL AND PITFL REPAIR IN A PLATE



The following technique describes how to use the Grappler R3INFORCE System to create an AITFL Repair with a Plate construct.

PREPARATION

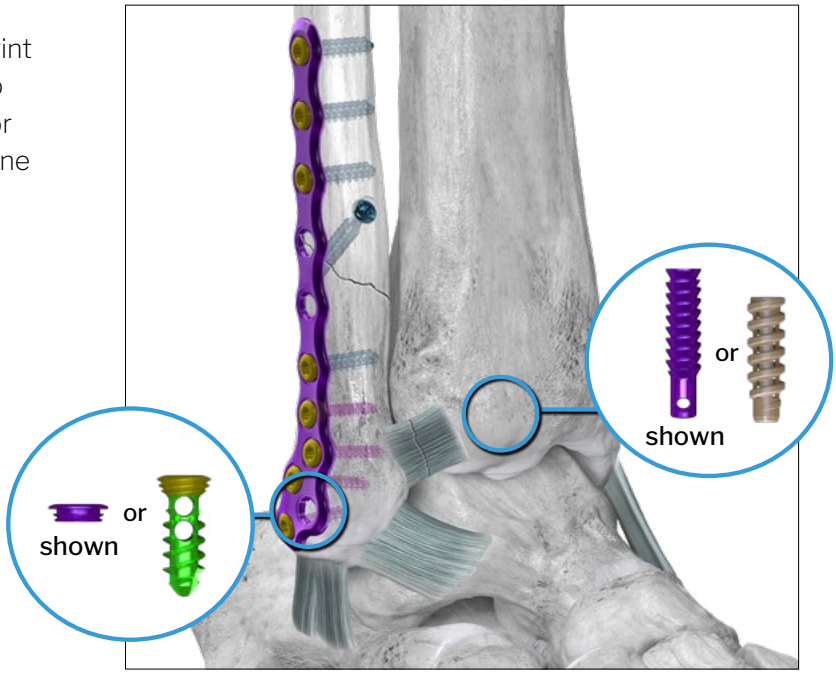
The tape reinforcement should follow the anatomic footprint of the AITFL by utilizing a plate hole that allows the tape to be inline with the native ligament. Similarly, the tibial anchor should be placed in the Chaput tubercle to achieve this inline orientation.

Fibular Plate Anchor Options:

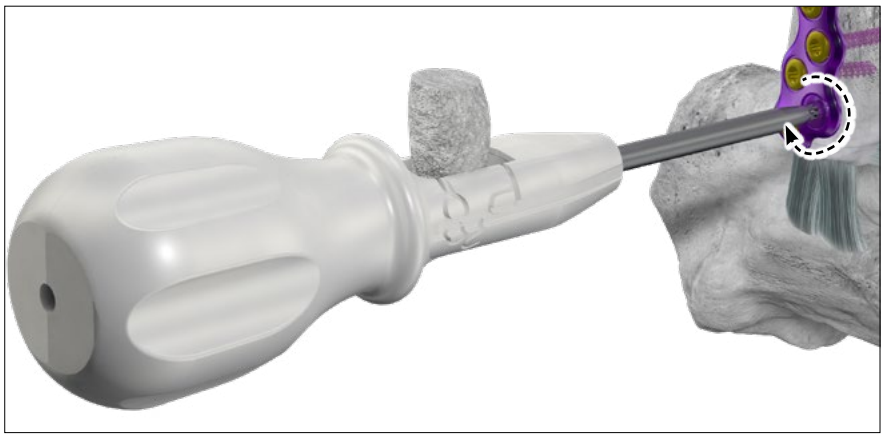
- Screwless Head Locking Anchor (shown here)
- Locking Anchor (shown on page 20)

Anterior Tibia Anchor Options:

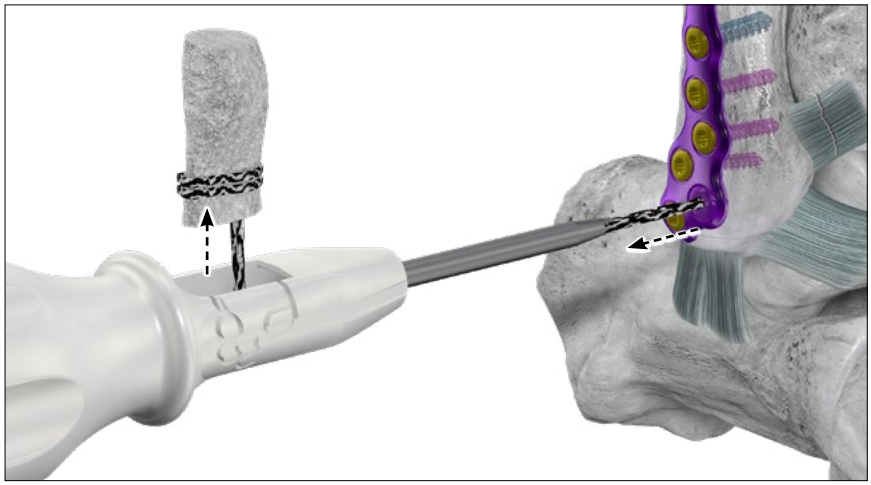
- Dynamic Knotless Anchor (shown here)
- Grappler Knotless Anchor (from the Grappler Knotless System)



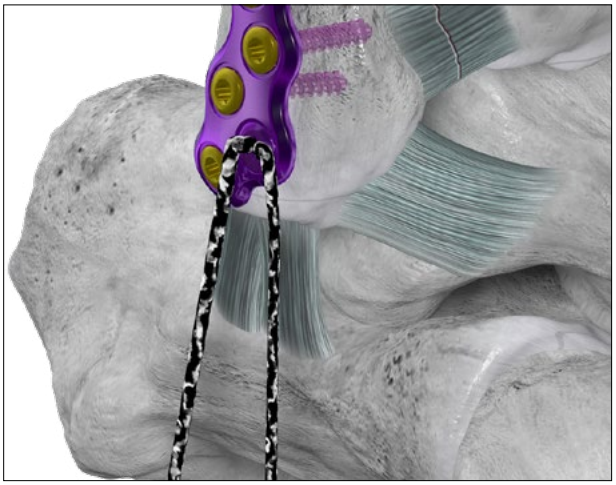
SCREWLESS HEAD LOCKING ANCHOR INSERTION



Using the preloaded Screwless Head Locking Anchor Driver, implant the anchor into the desired hole on the fibula plate by turning clockwise until the anchor is flush with the plate and secure.



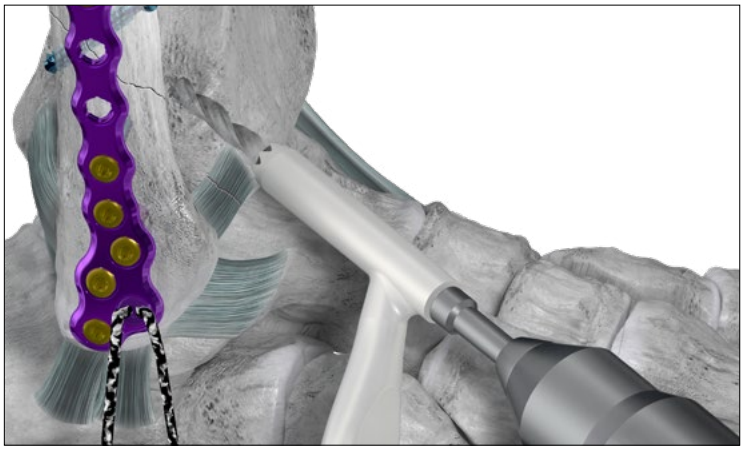
Disengage the driver from the implant by removing the foam suture holder, unwinding the suture, and then pulling back on the driver.

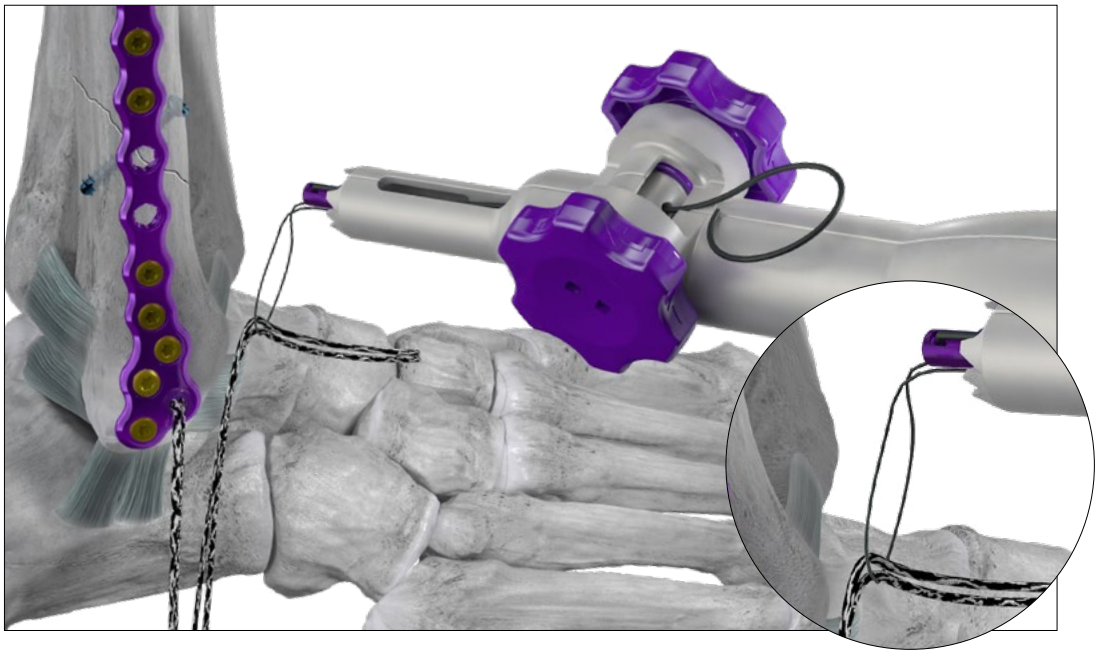


Remove the driver and securely place suture strands out of the incision.

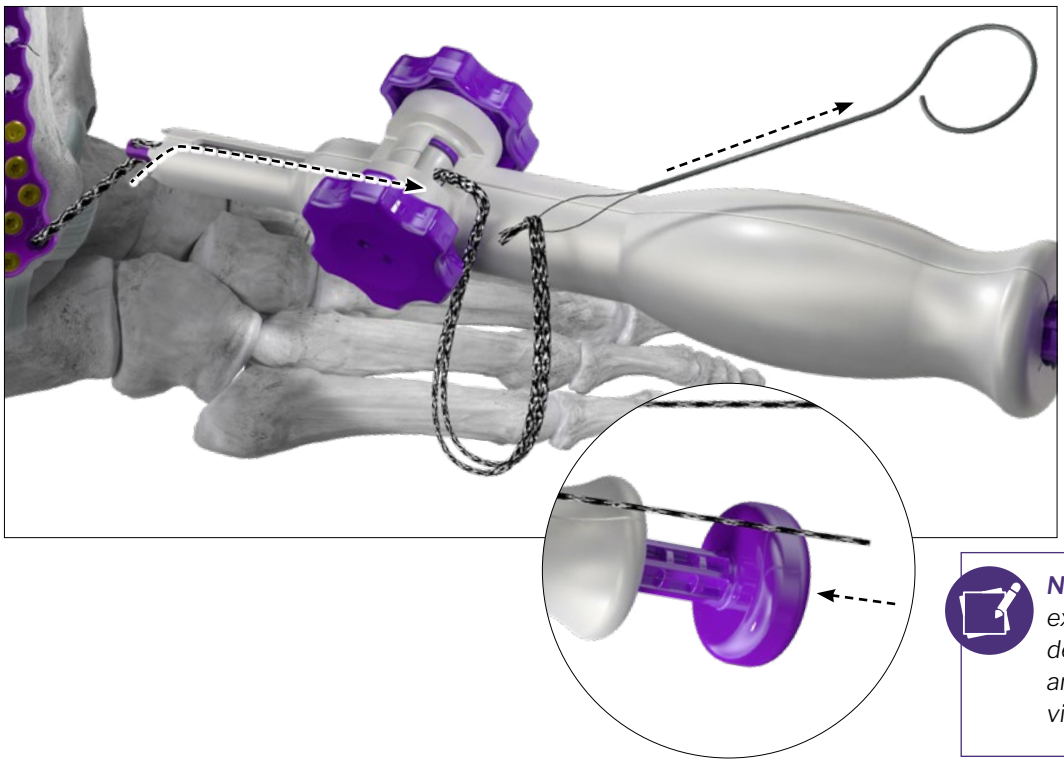
DYNAMIC ANCHOR INSERTION

The tibial anchor should be placed in the Chaput tubercle in the foot print of the AITFL so that the tape will be in line with the native AITFL. Drill with the Ø3.7 mm drill bit through the drill guide, away from the joint, until the hard stop is reached.





Capture both ends of the repair suture from the plate anchor through the suture passer preloaded in the Dynamic Knotless Anchor inserter. Only capture about the first 3cm of each suture strand in the passer to reduce difficulty when routing the suture through the inserter in the next step.

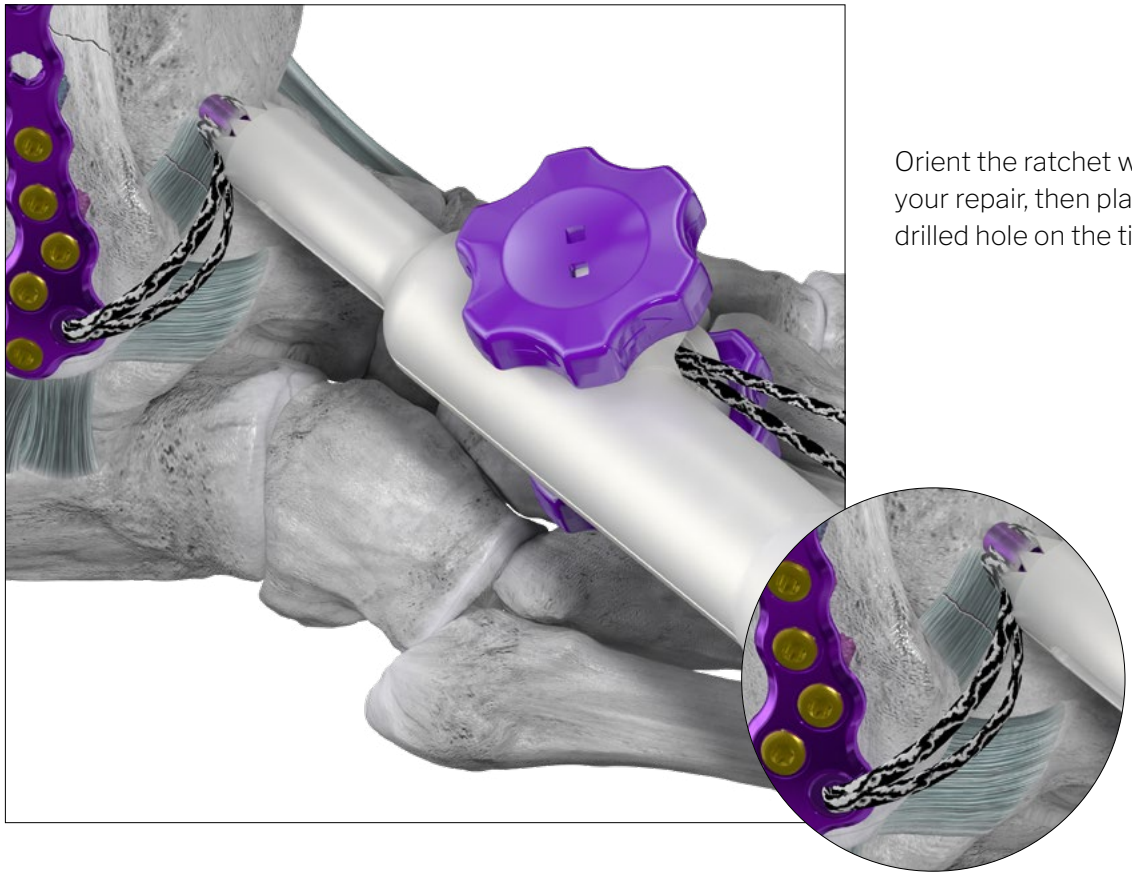


With the ends of the repair suture captured, pull back on the suture passer ring located near the ratchet wheels until the repair suture is fully routed through anchor, and out of the inserter ratchet.

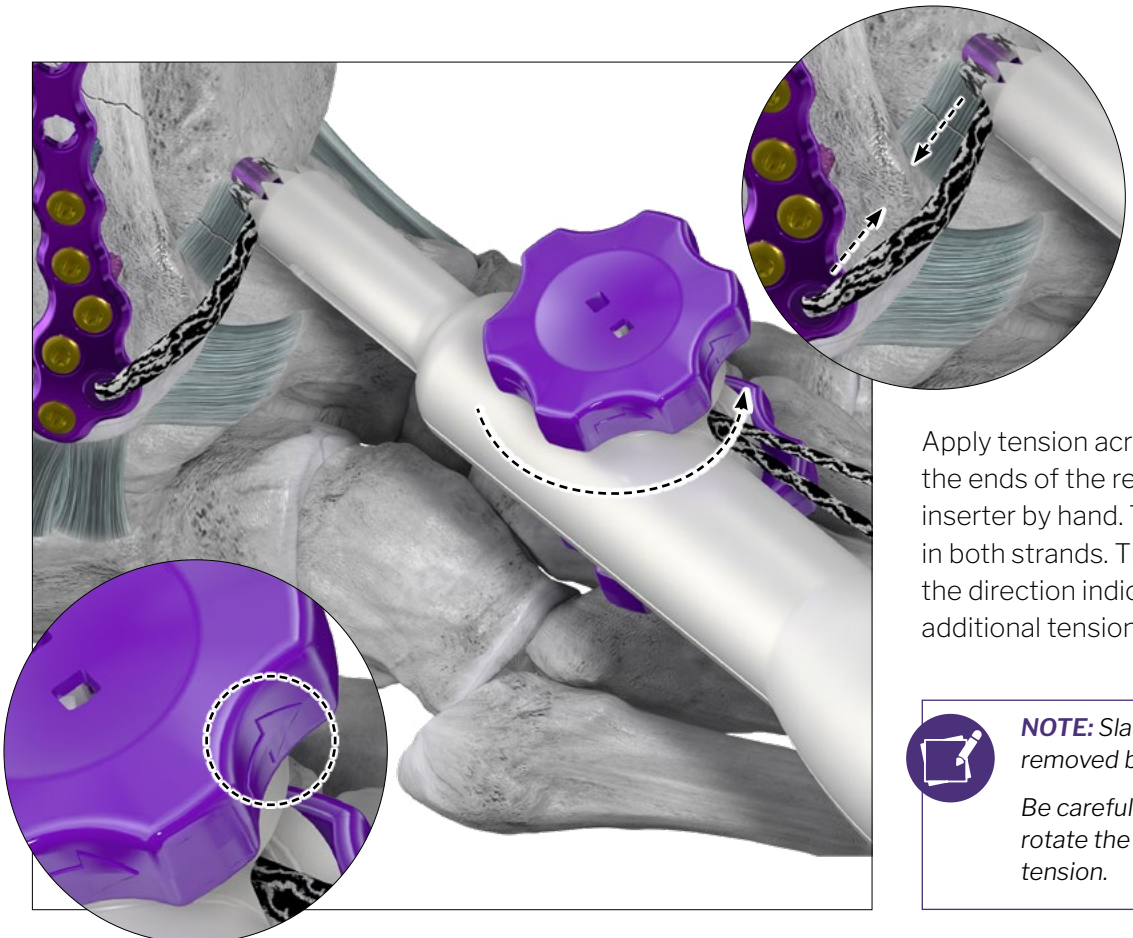
Discard the passer.

NOTE: *If excessive resistance is experienced during suture routing, depress the plunger to expose anchor and provide additional visibility/access.*

DYNAMIC ANCHOR INSERTION



Orient the ratchet wheels away from your repair, then place the anchor into the drilled hole on the tibia.

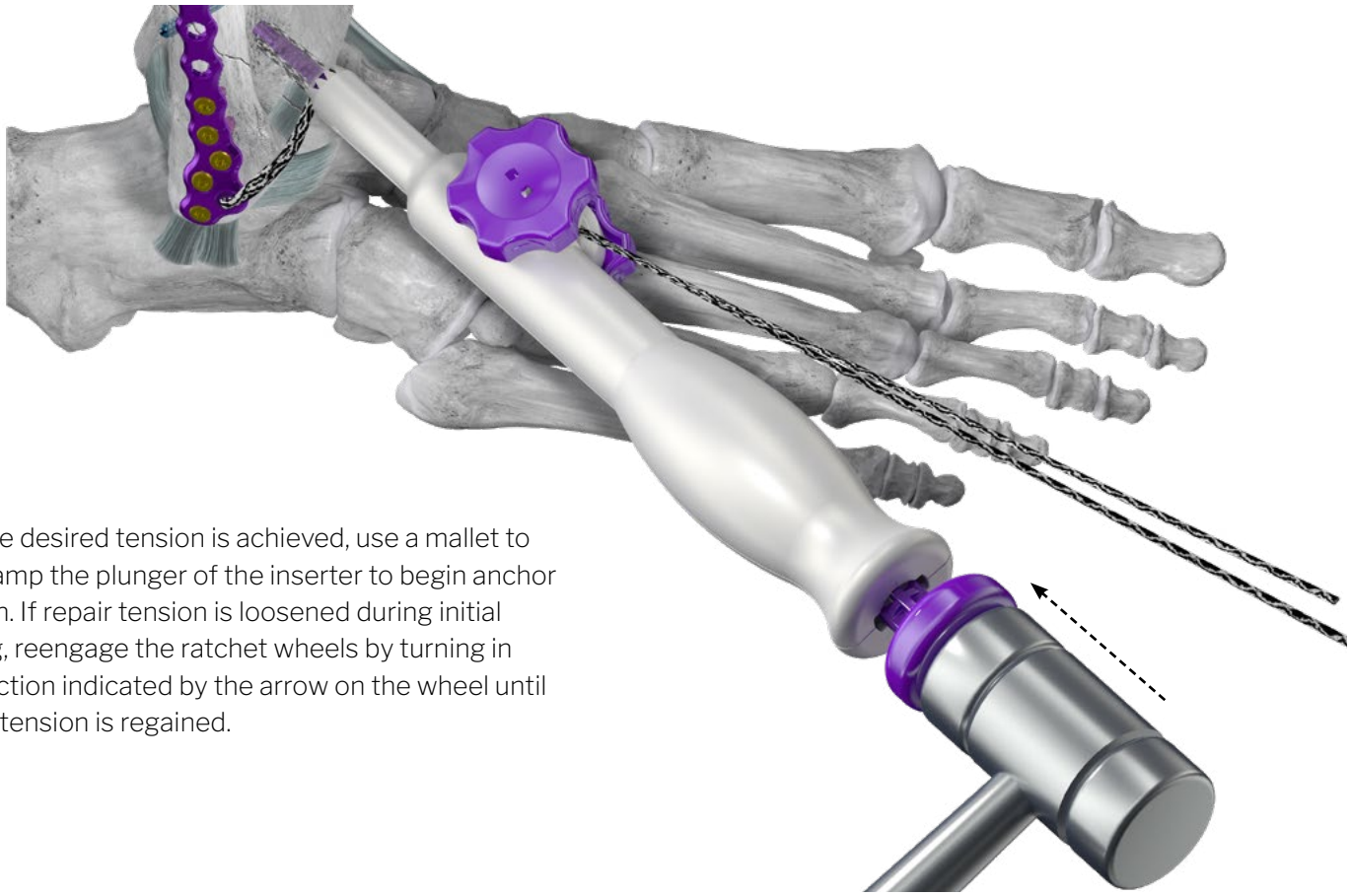


Apply tension across the tape by evenly pulling the ends of the repair suture through the inserter by hand. There should be equal tension in both strands. The ratchet can be turned in the direction indicated on the wheel to apply additional tension.

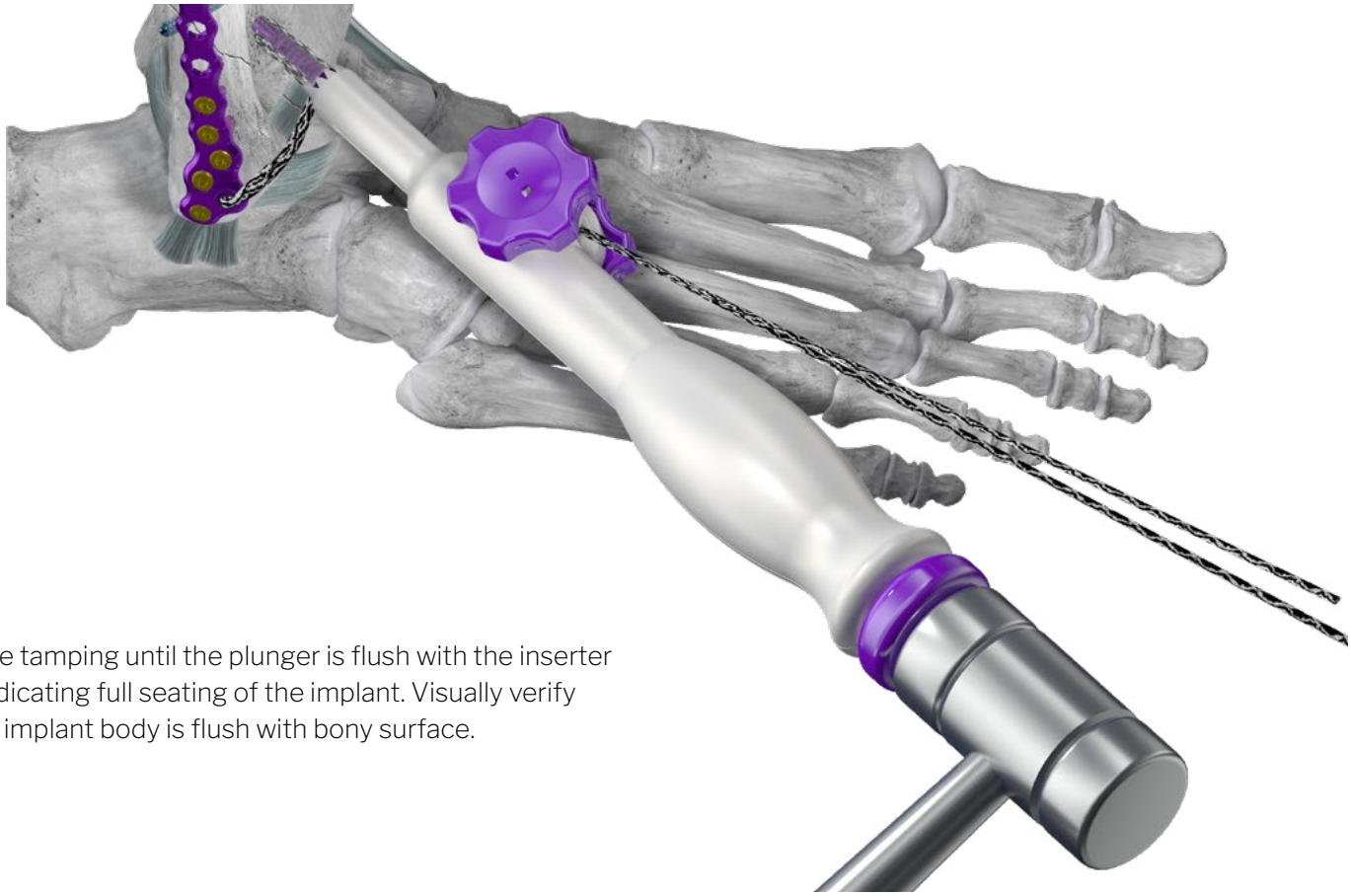
NOTE: *Slack in the repair suture must be removed before the ratchet will function*

Be careful not to over-reduce/internally rotate the fibula by adding too much tension.

DYNAMIC ANCHOR INSERTION

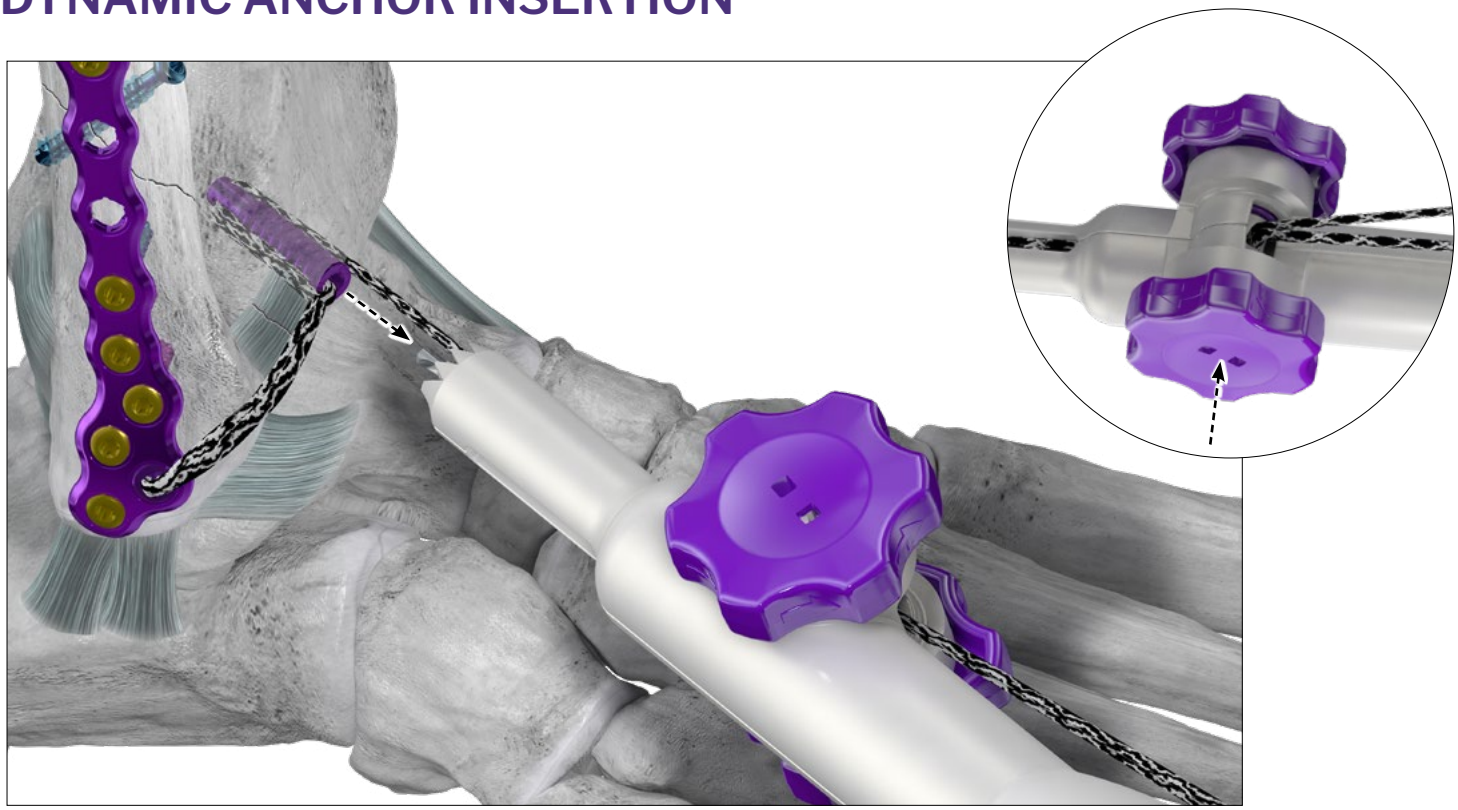


Once the desired tension is achieved, use a mallet to lightly tamp the plunger of the inserter to begin anchor insertion. If repair tension is loosened during initial tamping, reengage the ratchet wheels by turning in the direction indicated by the arrow on the wheel until desired tension is regained.

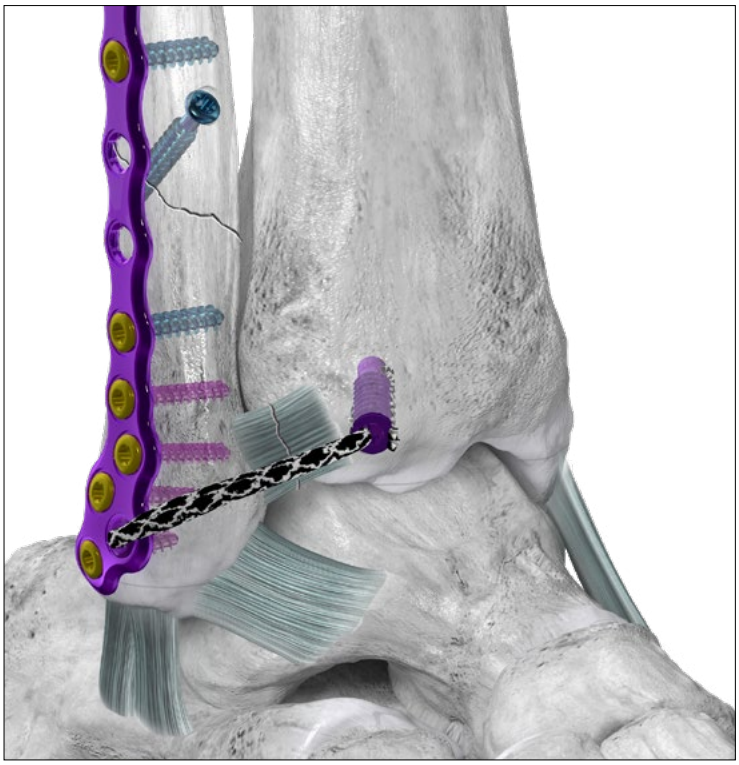


Continue tamping until the plunger is flush with the inserter body, indicating full seating of the implant. Visually verify that the implant body is flush with bony surface.

DYNAMIC ANCHOR INSERTION



Disengage the inserter by pressing in on the Ratcheting Knob to release the ratchet feature and then pulling the inserter away from the implant site. You may have to manually rotate the ratchet wheels opposite of the tensioning direction to assist in release.



An optional knot can be tied if desired. Cut the suture ends flush to the anchor.

Check final reduction and fixation using fluoroscopy. Proceed to incision closure at this time.

The following technique describes how to use the Grappler R3INFORCE System to create an AITFL Repair outside of a Plate construct.

PREPARATION

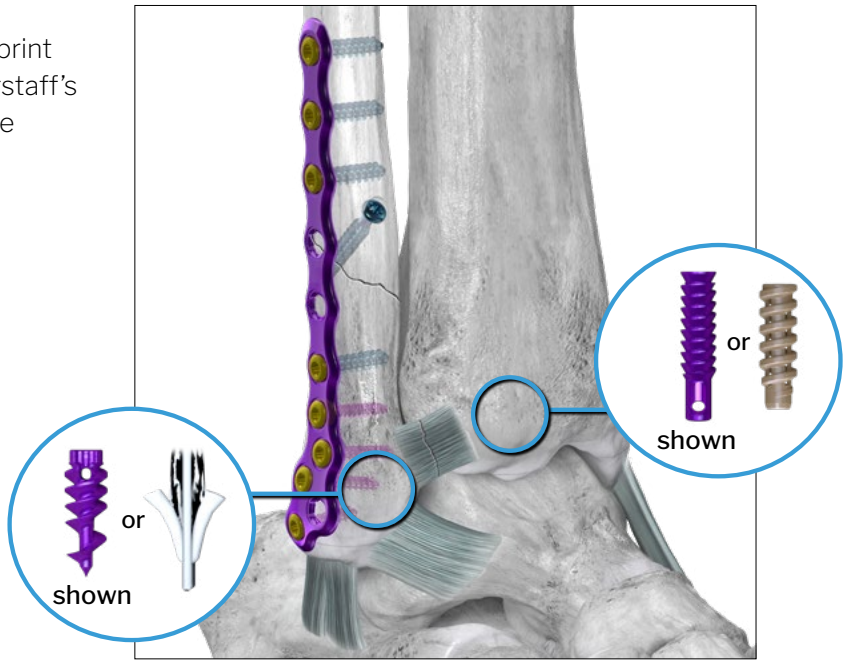
The tape reinforcement should follow the anatomic footprint of the AITFL. The fibular anchor should be placed in Wagstaff's tubercle whereas the tibial anchor should be placed in the Chaput tubercle.

Fibular Anchor Options:

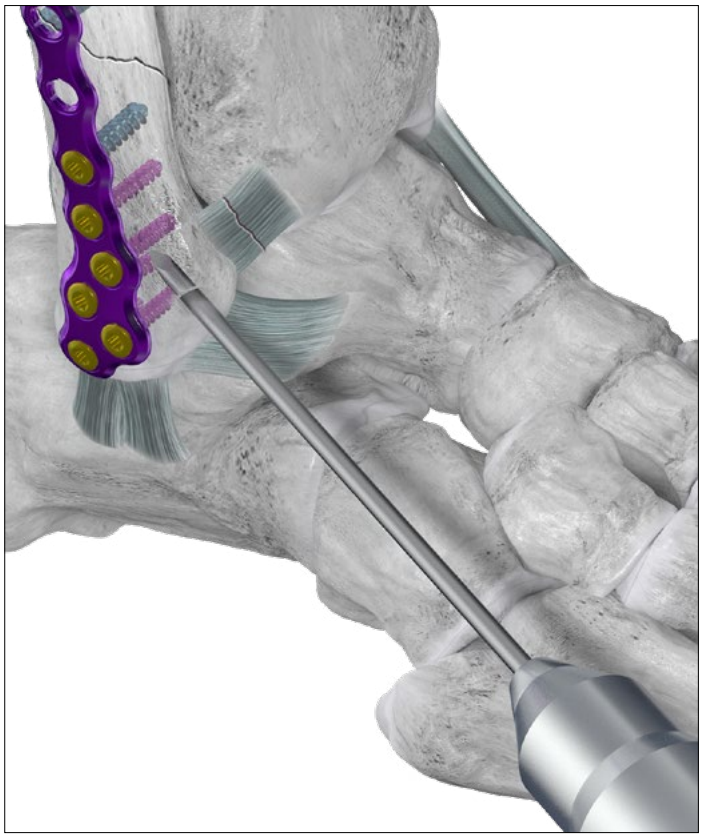
- Titanium Anchor (shown here)
- All-Suture Anchor (shown on page 18)

Anterior Tibia Anchor Options:

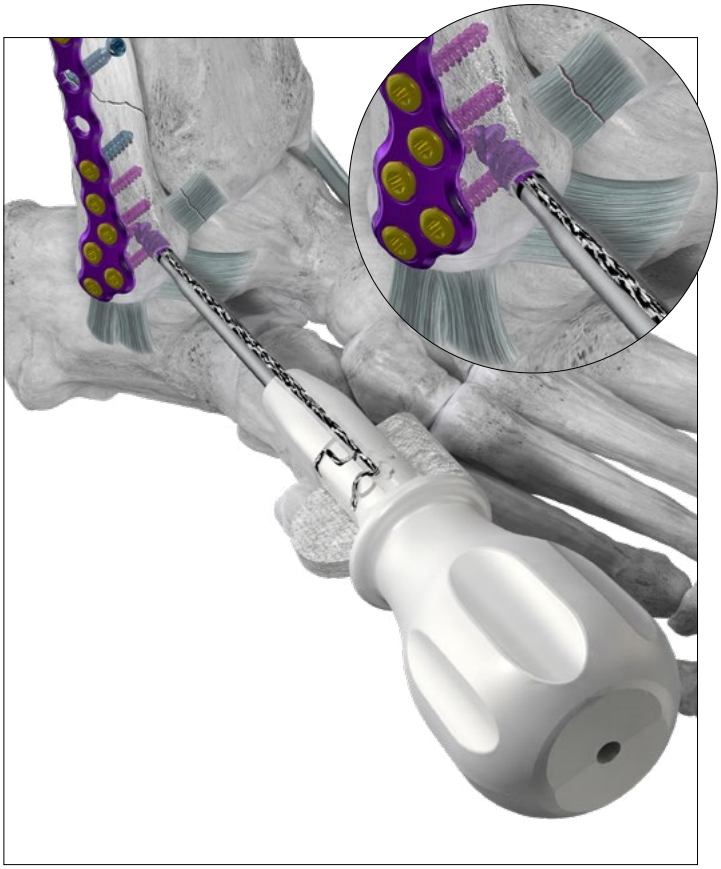
- Dynamic Knotless Anchor (shown here)
- Grappler Knotless Anchor (from the Grappler Knotless System)



TITANIUM ANCHOR INSERTION

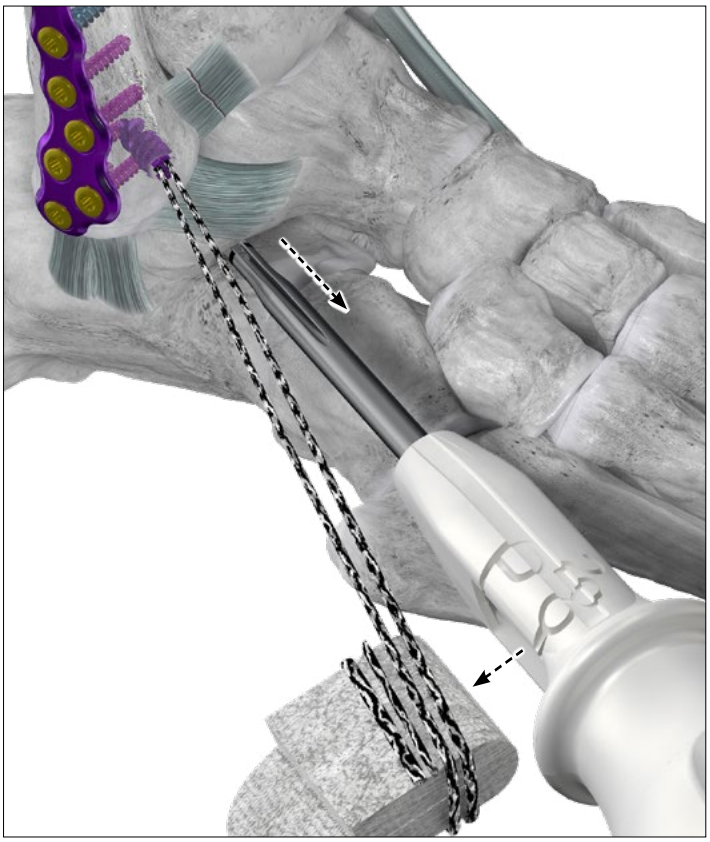


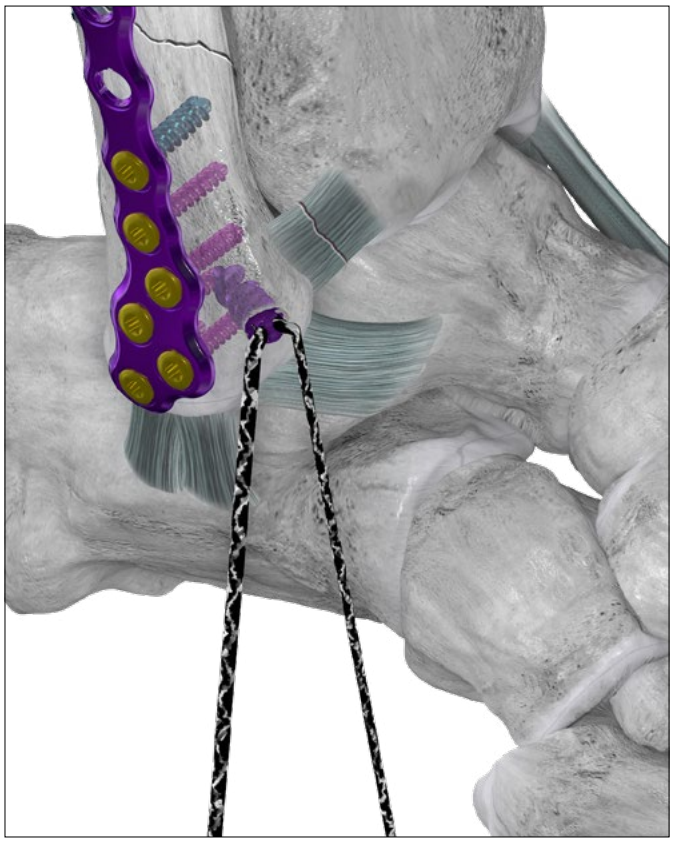
Drill with the Ø2.6 mm K-wire about 15mm into Wagstaff's tubercle, angling away from the lateral gutter.



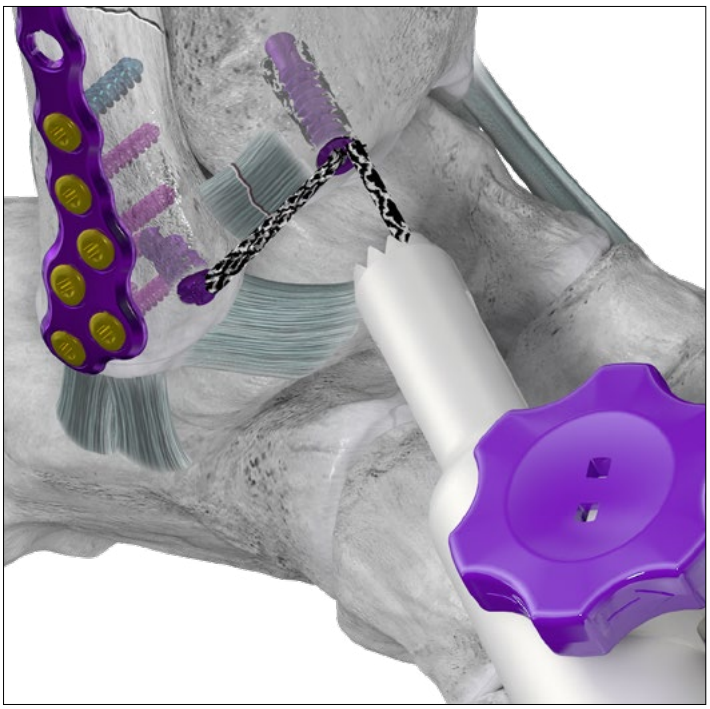
Implant the Titanium anchor on the preloaded driver into the drill hole by turning clockwise until visually confirming that the anchor head is flush with the bone. The laser mark on the driver indicates the level of the anchor head.

TITANIUM ANCHOR INSERTION

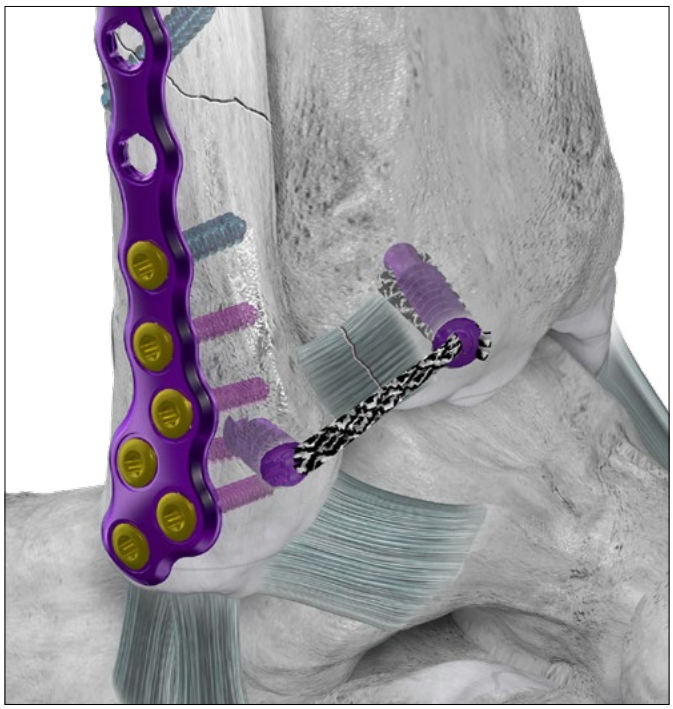




Disengage the driver from the implant by removing the foam suture holder, unwinding the suture, and then pulling back on the driver.



Follow the instructions shown previously on page 10 to complete the construct using a Dynamic Knotless Anchor.

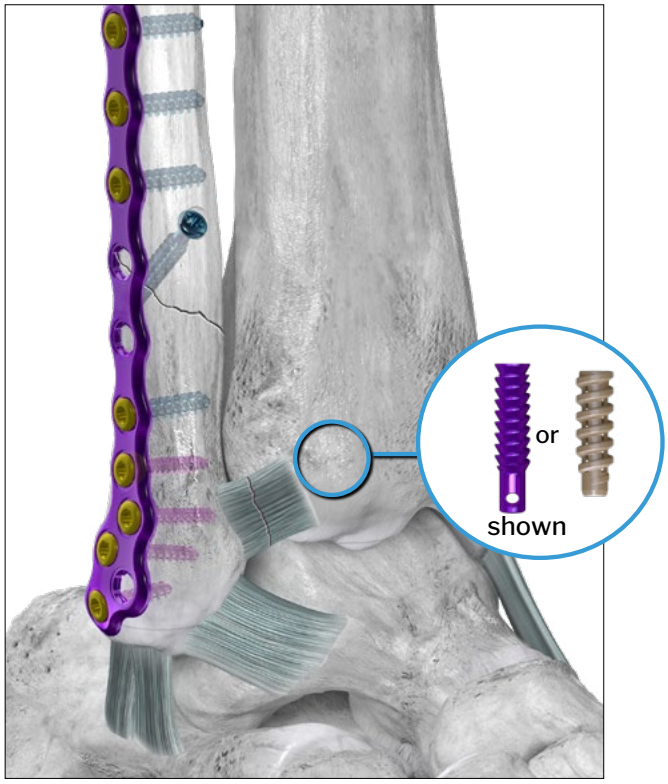


An optional knot can be tied if desired. Cut the suture ends flush to the anchor. Check final reduction and fixation using fluoroscopy. Proceed to incision closure at this time.

The following technique describes how to use the Grappler R3INFORCE System to create a Combined AITFL and PITFL Repair in a Plate construct.

PREPARATION

The tape reinforcement should follow the anatomic footprints of the AITFL and PITFL. The distal fibular anchor is placed to ensure the tape is in line with the AITFL and PITFL fibers whereas the proximal fibular anchor helps to distribute the compression forces over a larger surface area of the fibula. The anterior tibial anchor should be placed in the Chaput tubercle and the posterior tibial anchor in the Volkmann tubercle.



Posterior Tibia Options:

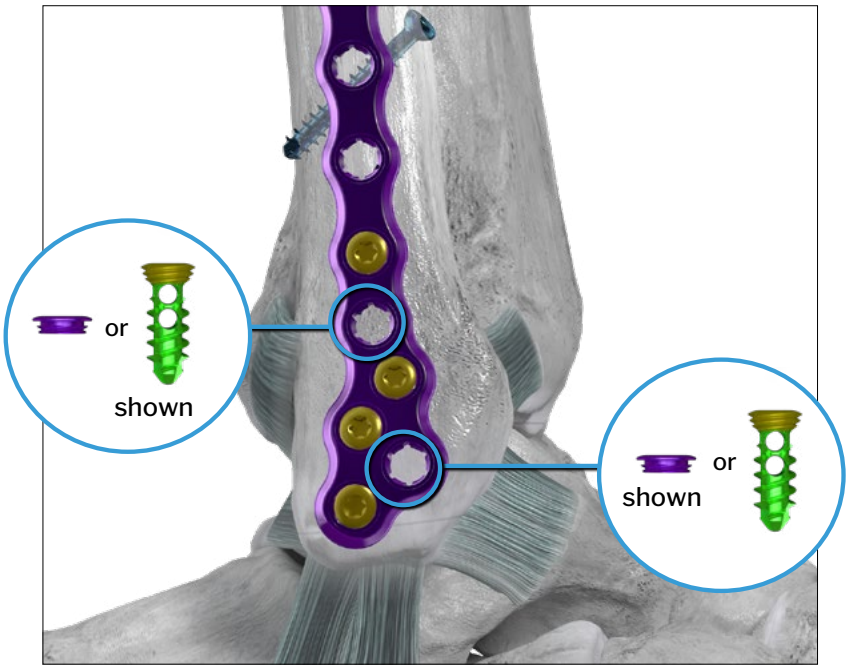
- Titanium Anchor (shown here)
- All-Suture Anchor (shown here)

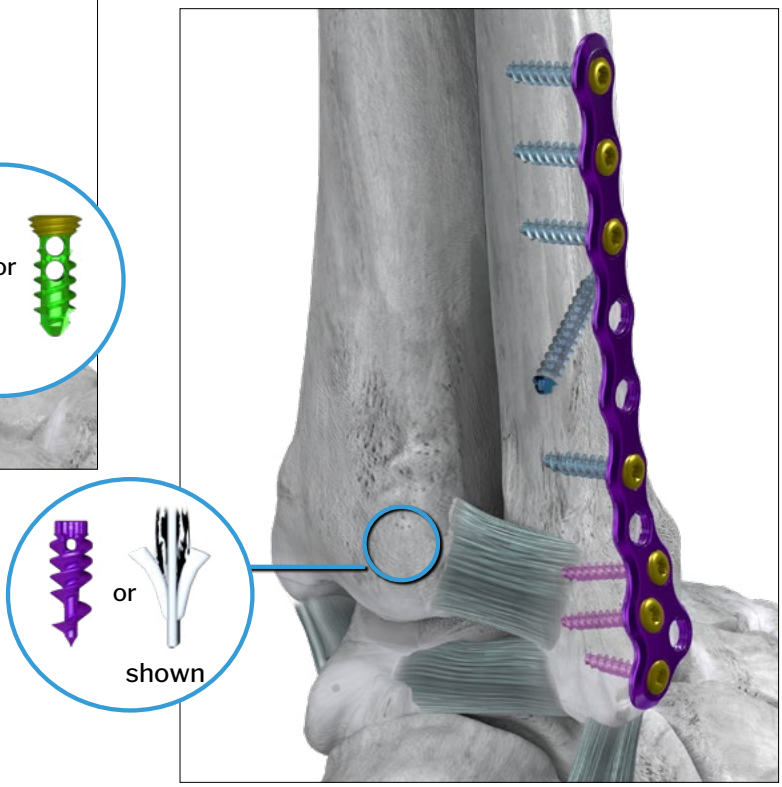
Fibular Plate Anchor Options:

- Screwless Head Locking Anchor (shown on page 13)
- Locking Anchor (shown here)

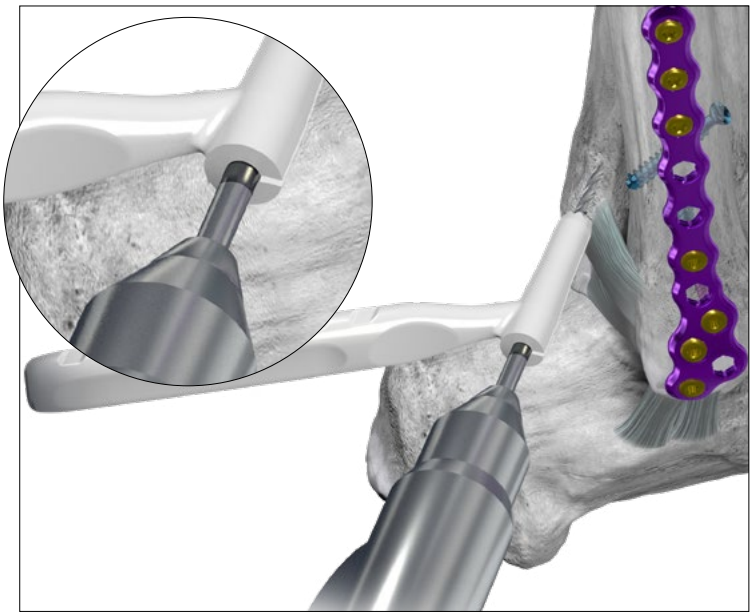
Anterior Tibia Anchor Options:

- Dynamic Knotless Anchor (shown here)
- Grappler Knotless Anchor (from the Grappler Knotless System)

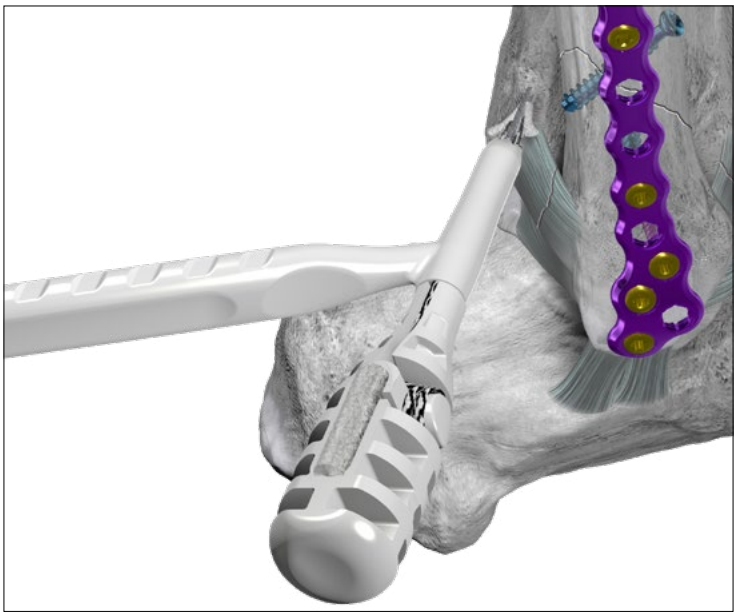




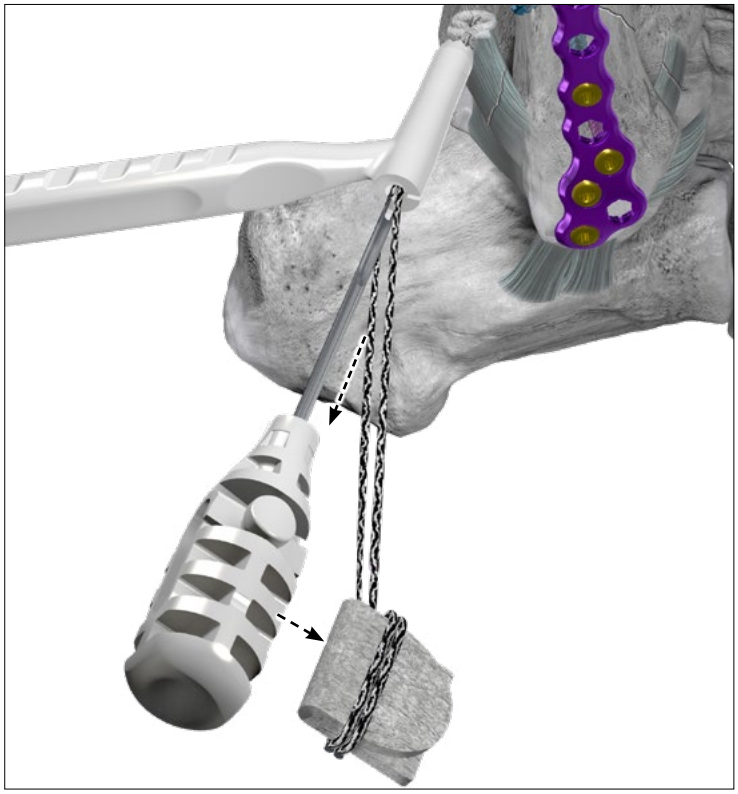
ALL-SUTURE ANCHOR INSERTION

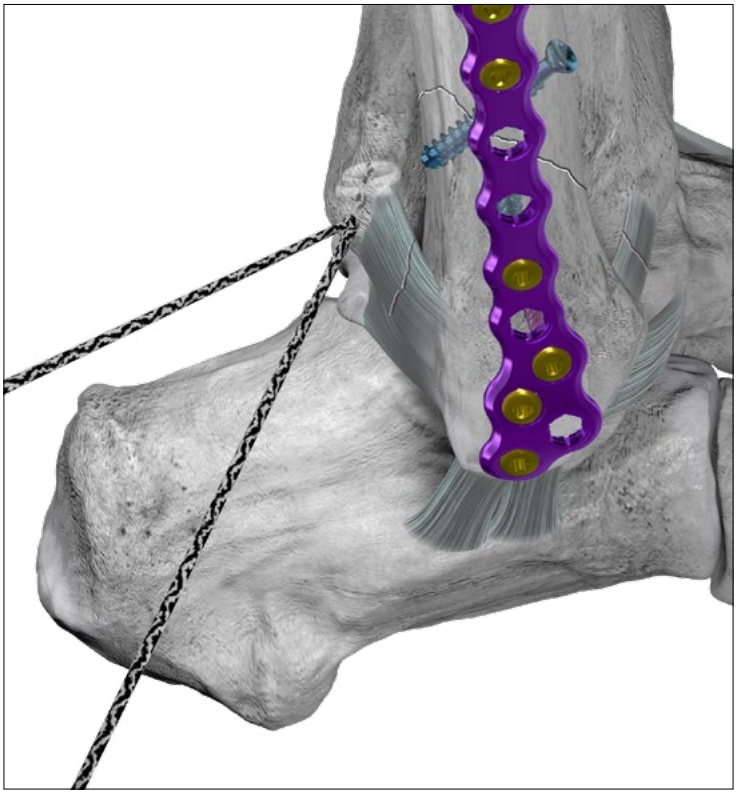


Position the drill guide on the Volkmann tubercle and aim away from the joint and towards the anterior medial aspect of the tibia. Drill with the Ø2.8mm drill-tip K-wire through the Drill Guide until the laser mark on the K-wire reaches the back of the guide. Remove the K-wire, leaving the Drill Guide in place.



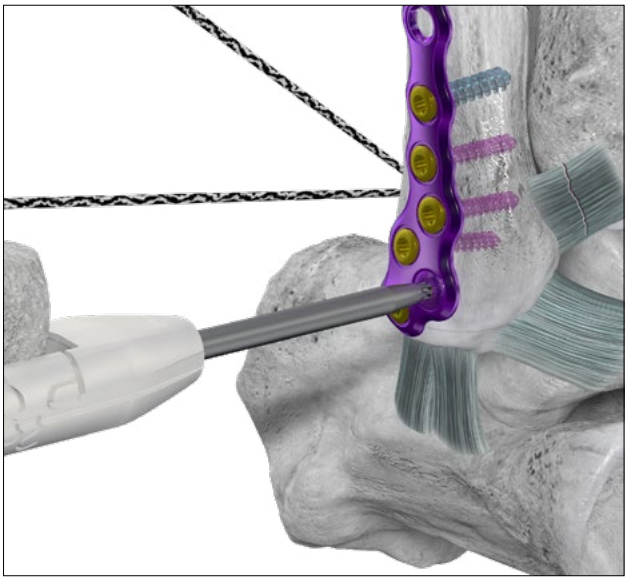
Insert the pre-loaded All-Suture Anchor Inserter through the Drill Guide into bone. Impact with a mallet until the inserter contacts the drill guide.



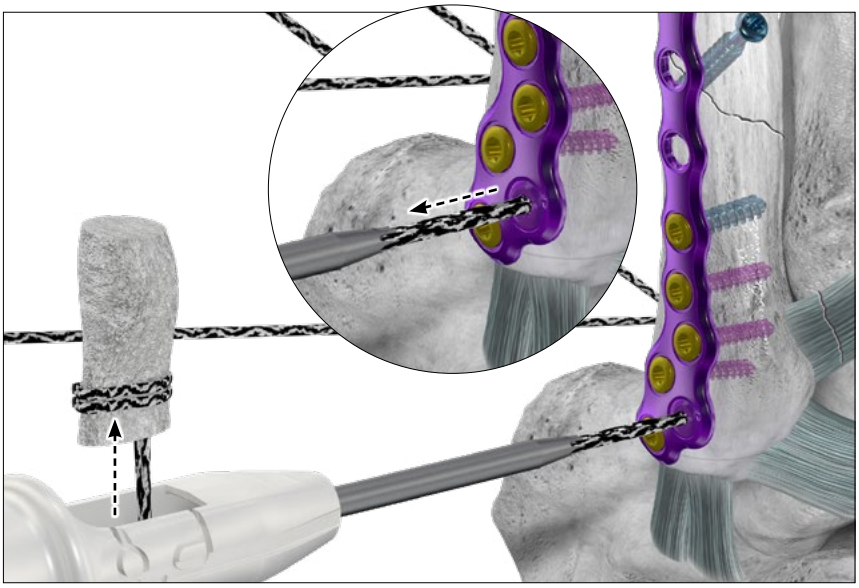


Pull the Inserter away to set the implant against the cortex. Pull the foam block out of the inserter, unwrap the suture, then pull the inserter out of the anatomy.

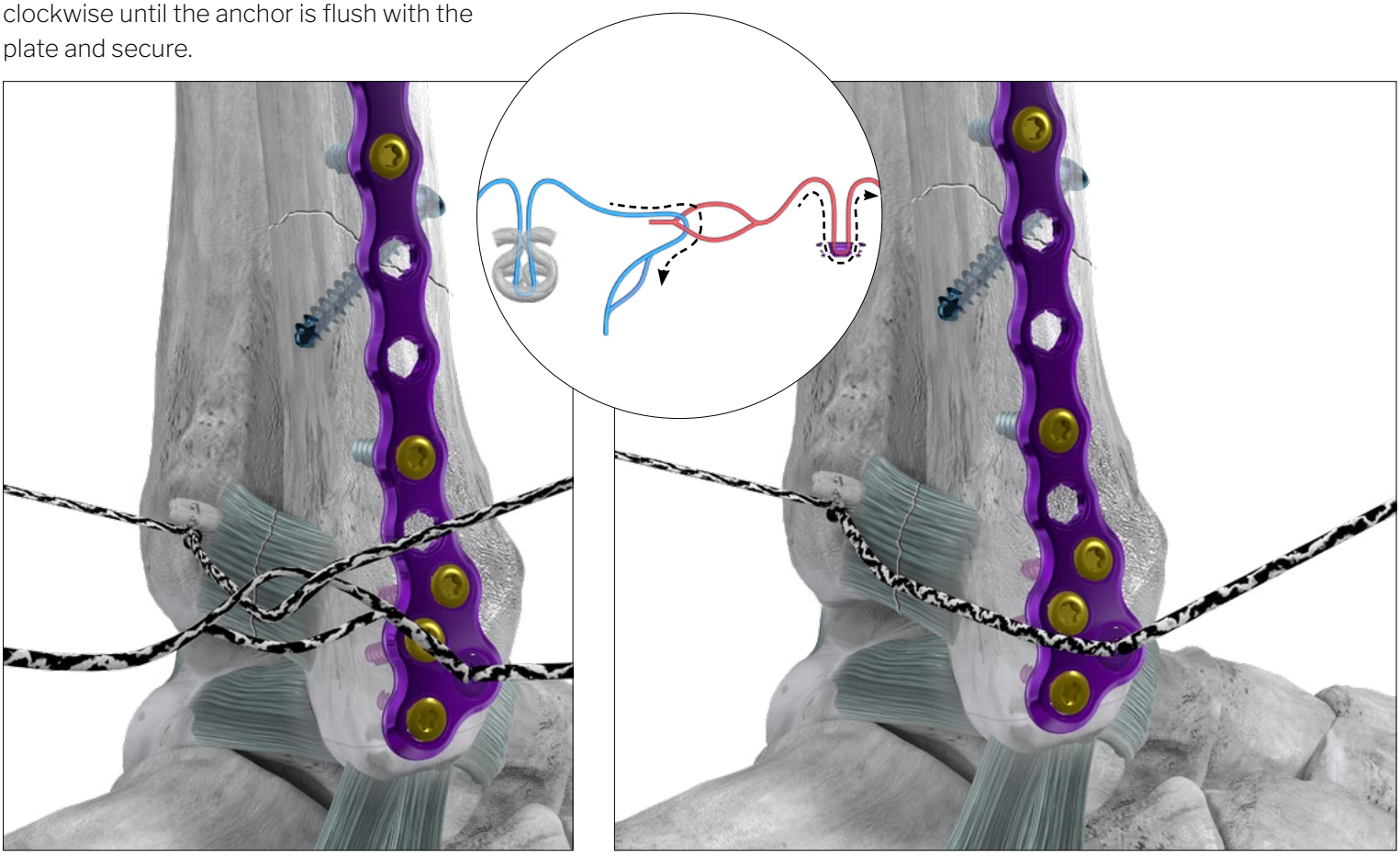
SCREWLESS HEAD LOCKING ANCHOR INSERTION



Using the preloaded Screwless Head Locking Anchor Driver, implant the anchor into the appropriate hole on the fibula plate by turning clockwise until the anchor is flush with the plate and secure.

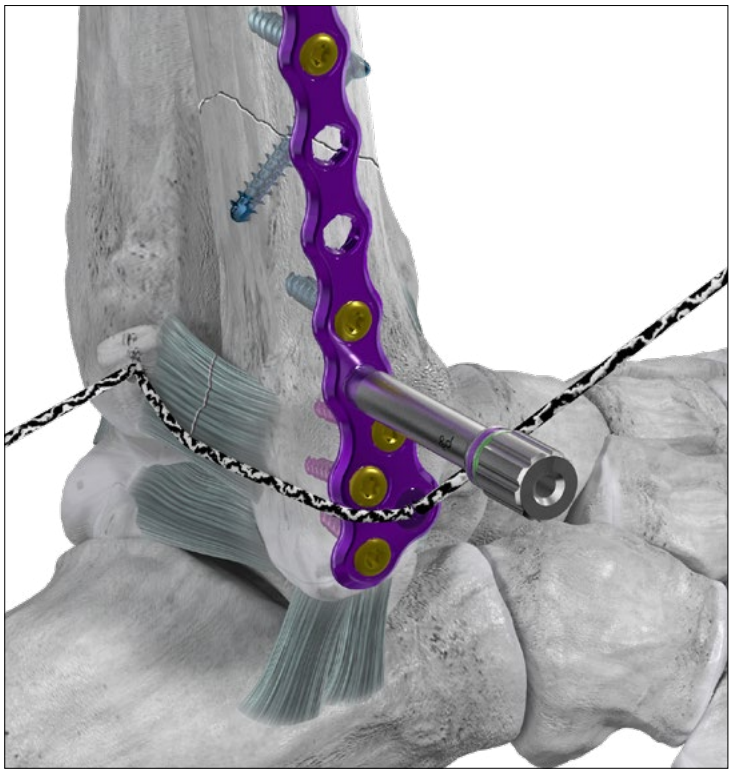


Disengage the driver from the implant by removing the foam suture holder, unwrapping the suture, then pulling back on the driver until the entirety of the suture has been freed.

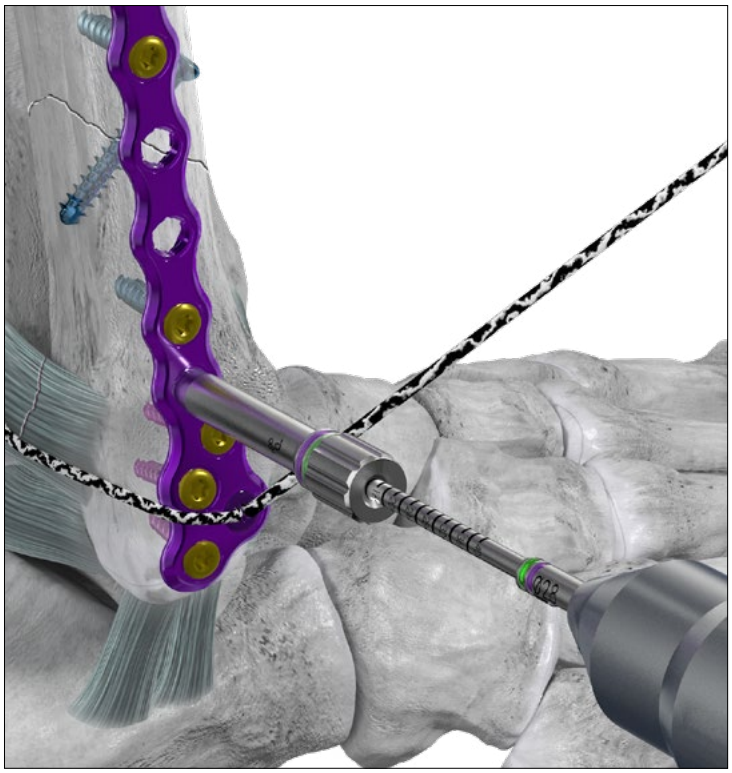


Route one end of the repair suture from the posterior anchor through the Screwless Head Locking Anchor (see page 6 for suture routing technique).

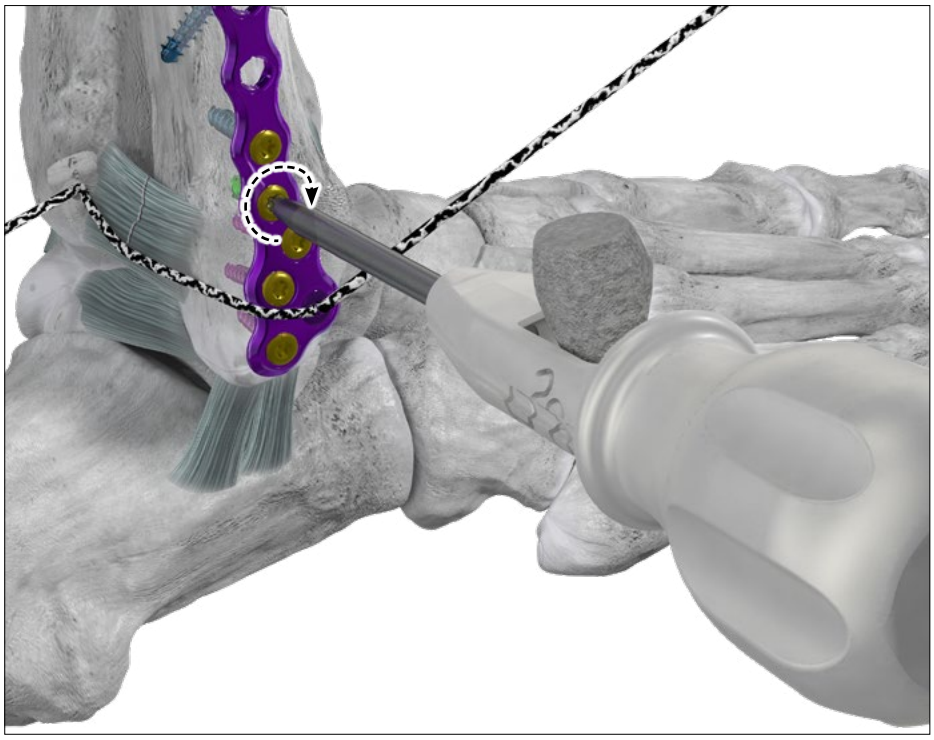
STANDARD LOCKING ANCHOR INSERTION



Place the Ø4.2 mm Threaded Drill Tower in the desired hole in the plate and screw in clockwise.

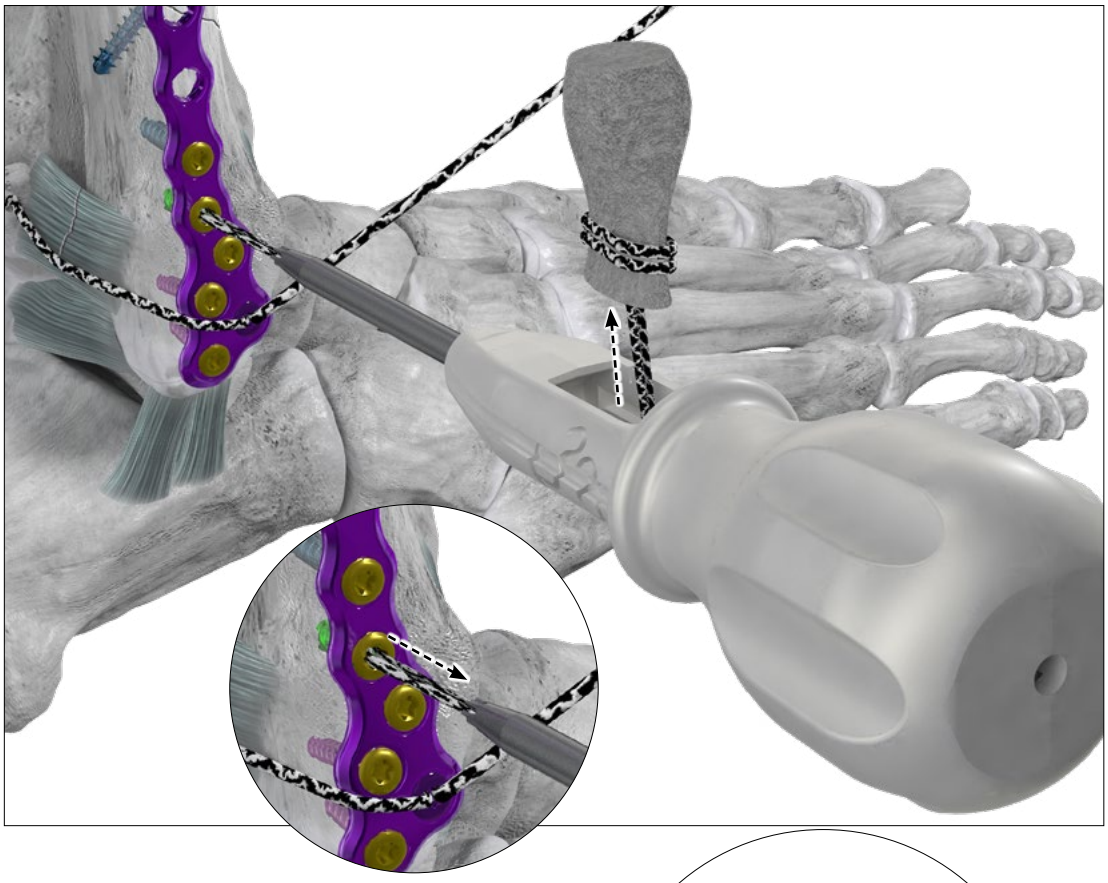


Drill approximately 12 mm through the drill tower using the Ø2.8 mm drill, using the depth markings on the drill as reference. Remove the drill tower.

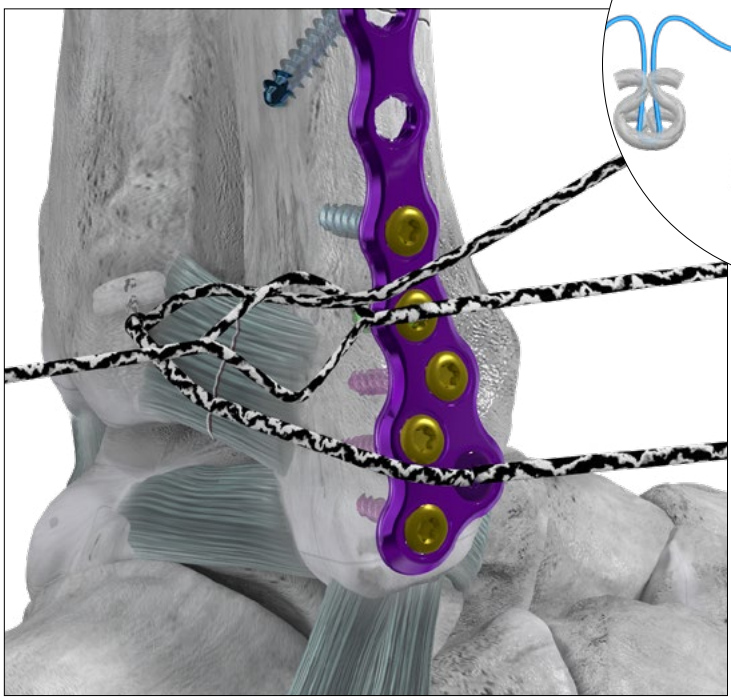


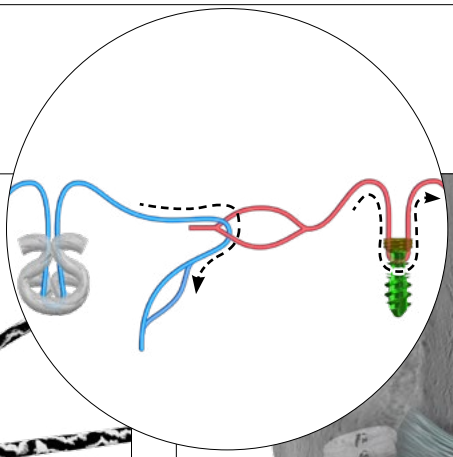
Implant the preloaded Ø4.2 mm x 12 mm Locking Screw Anchor into the drilled hole on the fibula plate by turning clockwise until the anchor is flush with the plate and secure.

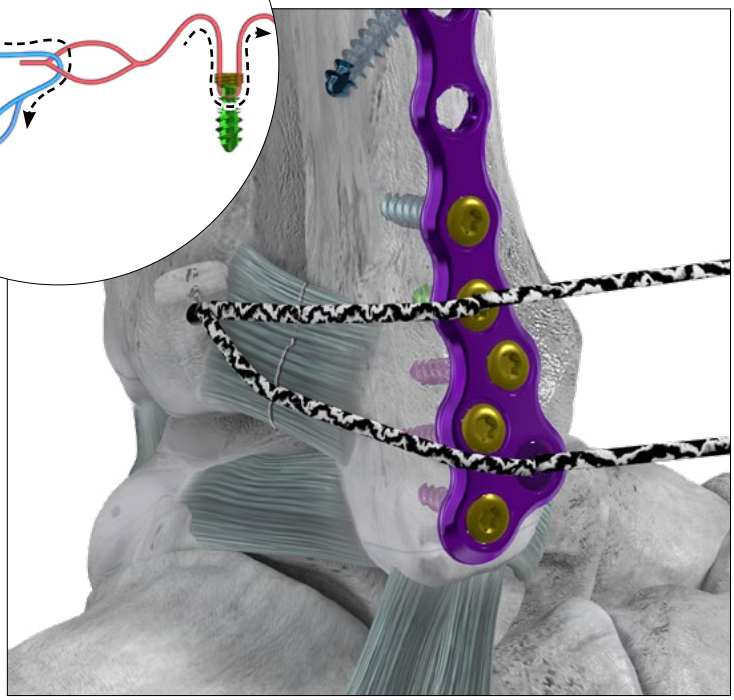
STANDARD LOCKING ANCHOR INSERTION



Disengage the inserter from the implant by removing the foam suture holder, unwrapping the suture, then pulling back on the inserter until the entirety of the suture has been freed.

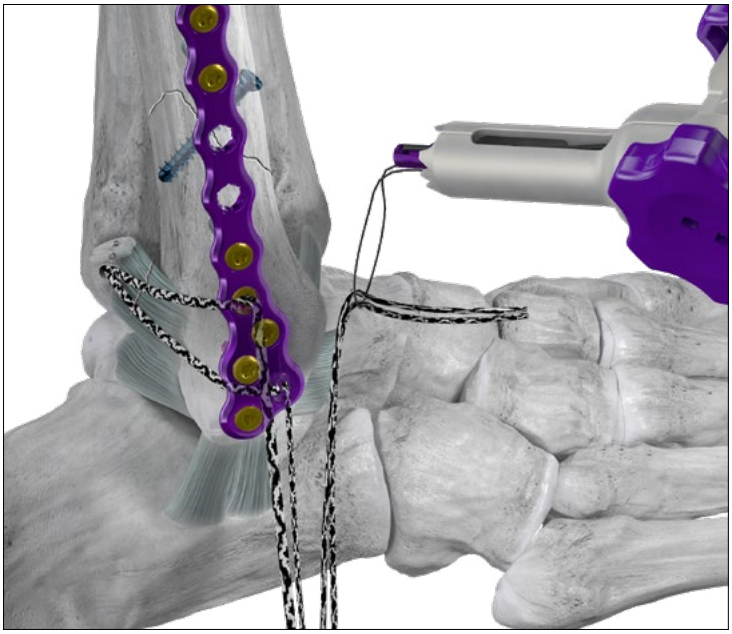


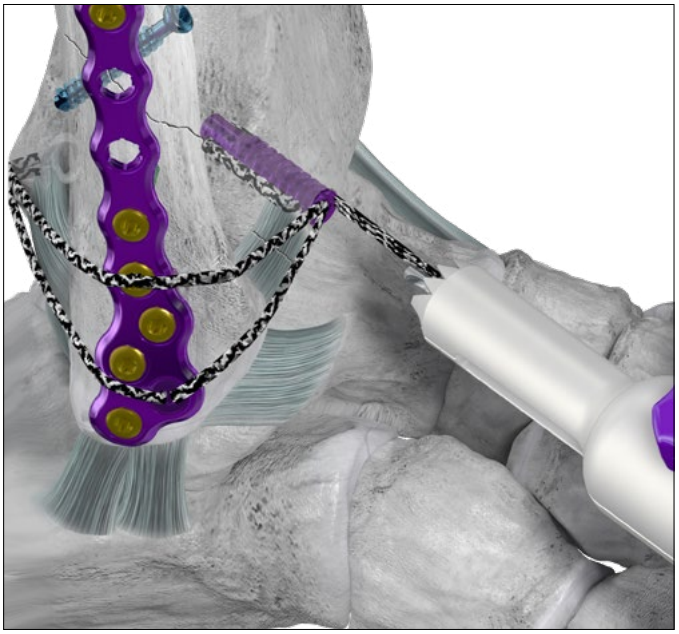




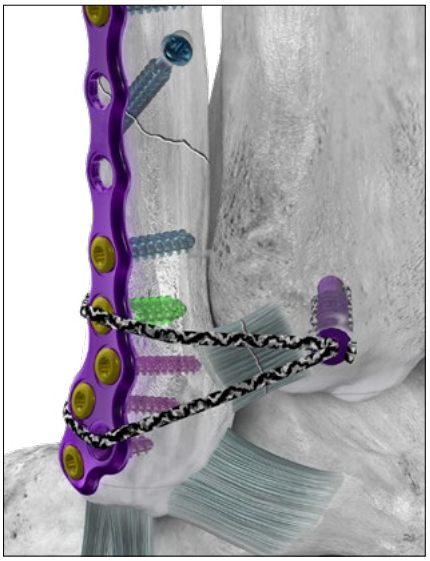
Route the remaining end of the repair suture from the posterior anchor through Locking Anchor (see page 6 for suture routing technique).

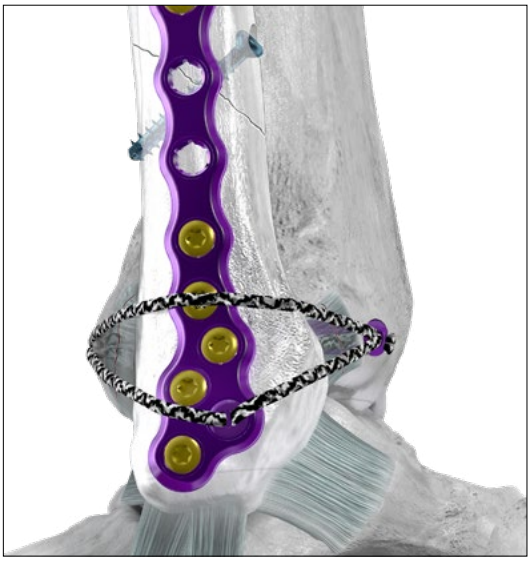
DYNAMIC KNOTLESS ANCHOR INSERTION

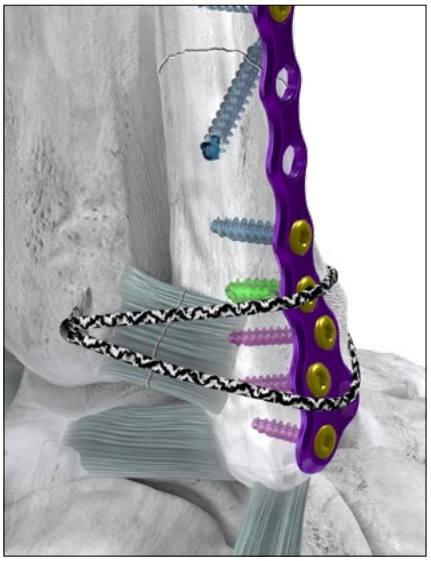




Follow the instructions shown on page 10 to complete the construct using a Dynamic Knotless Anchor, beginning by capturing the suture strand ends from each plate anchor through the suture passer.







An optional knot may be tied in the suture ends to secure repair. The suture may be cut flush with implant body.

Check final reduction and fixation using fluoroscopy. Proceed to incision closure at this time.

IMPLANT REMOVAL (IF NECESSARY)

Removal of the Locking Anchor, Screwless Head Locking Anchor, and Dynamic Knotless Anchor is achieved by cutting the repair suture and using their corresponding inserters or a T10 Gorilla® driver to rotate the anchor counterclockwise until fully unscrewed. The All-Suture anchor is removed by pulling the suture out of the anatomy.

STERILE KITS

Grappler R3INFORCE Ø2.8mm All-Suture Anchor:

[P82-211-0028-SK]

- Ø2.8 mm All-Suture Anchor, pre-loaded with 1.5 mm Passing Suture Tape on Inserter
- K-wire (Ø2.8 mm)
- Drill/Insertion Guide

Grappler R3INFORCE, Ø4.5mm x 15mm Titanium Anchor

[P82-111-4515-SK]

- Ø4.5 mm Titanium Anchor, pre-loaded with 1.5 mm Passing Suture Tape on Driver
- K-wire (Ø2.6 mm)

Grappler R3INFORCE Screwless Head Locking Anchor

[P82-230-3500-SK]

- Screwless Head Locking Anchor, pre-loaded with 1.5 mm Passing Suture Tape on Driver

Grappler R3INFORCE Locking Anchor:

[P82-220-4212-SK]

- Ø4.2 mm x 12 mm Locking Screw Anchor pre-loaded with Passing Suture Tape on Driver

Grappler R3INFORCE, Ø4.75mm x 20mm Dynamic Knotless Anchor:

[P82-240-4820-SK]

- Ø4.75 mm x 20 mm Dynamic Anchor, pre-loaded with Suture Passer on Inserter
- Ø3.7 mm Solid Drill
- Drill Guide

Grappler Knotless System: (From Grappler Knotless System)

[P44-130-4515-SK]

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

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

INDICATIONS FOR USE (GRAPPLER®)

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.

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

INDICATIONS FOR USE (GORILLA®)

The Baby Gorilla®/Gorilla® Bone Plates and Bone Screws of the Baby Gorilla®/Gorilla® Plating System are indicated for use in stabilization and fixation of fractures or osteotomies; intra and extra articular fractures, joint depression, and multi-fragmentary fractures; revision procedures, joint fusion and reconstruction of small bones of the toes, feet and ankles including the distal tibia, talus, and calcaneus, as well as the fingers, hands, and wrists. The system can be used in both adult and pediatric patients. Specific examples include:

Forefoot:

- Arthrodesis of the 1st metatarsalcuneiform joint (Lapidus Fusion)
- Metatarsal or phalangeal fractures and osteotomies
- Lesser metatarsal shortening osteotomies (e.g. Weil)
- Fifth metatarsal fractures (e.g. Jones Fracture)

Mid/Hindfoot:

- LisFranc Arthrodesis and/or Stabilization
- 1st (Lapidus), 2nd, 3rd, 4th, and 5th Tarsometatarsal (TMT) Fusions
- Intercuneiform Fusions
- Navicular-Cuneiform (NC) Fusion
- Talo-Navicular (TN) Fusion
- Calcaneo-Cuboid (CC) Fusion
- Subtalar Fusion
- Medial Column Fusion
- Cuneiform Fracture
- Cuboid Fracture
- Navicular Fracture

Ankle:

- Lateral Malleolar Fractures
- Syndesmosis Injuries
- Medial Malleolar Fractures and Osteotomies
- Bi-Malleolar Fractures
- Tri-Malleolar Fractures
- Posterior Malleolar Fractures
- Distal Anterior Tibia Fractures
- Vertical Shear Fractures of the Medial Malleolus
- Pilon Fractures
- Distal Tibia Shaft Fractures
- Distal Fibula Shaft Fractures
- Distal Tibia Periarticular Fractures
- Medial Malleolar Avulsion Fractures
- Lateral Malleolar Avulsion Fractures
- Tibiotalocalcaneal Joint Arthrodesis
- Tibiotalar Joint Arthrodesis
- Tibiocalcaneal Arthrodesis
- Supramalleolar Osteotomy
- Fibular Osteotomy

1st metatarsal osteotomies for hallux valgus correction including:

- Opening base wedge osteotomy
- Closing base wedge osteotomy
- Crescentic Osteotomy
- Proximal Osteotomy (Chevron and Rotational Oblique)
- Distal Osteotomy (Chevron/Austin)

Arthrodesis of the 1st metatarsophalangeal joint (MTP) including:

- Primary MTP Fusion due to hallux ridgidus and/or hallux valgus
- Revision MTP Fusion
- Revision of failed 1st MTP Arthroplasty implant

Flatfoot:

- Lateral Column Lengthening (Evans Osteotomy)
- Plantar Flexion Opening Wedge Osteotomy of the Medial Cuneiform (Cotton Osteotomy)
- Calcaneal Slide Osteotomy

Charcot:

- Medial column fusion (talus, navicular, cuneiform, metatarsal) for neuropathic osteoarthropathy (Charcot)
- Lateral column fusion (calcaneus, cuboid, metatarsal) for neuropathic osteoarthropathy (Charcot)

In addition, the non-locking, titanium screws and washers are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair and fracture fixation, appropriate for the size of the device.

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

CONTRAINDICATIONS

Use of the Baby Gorilla®/Gorilla® Plating System is contraindicated in cases of inflammation, cases of active or suspected sepsis/infection and osteomyelitis; or in patients with certain metabolic diseases.

All applications that are not defined by the indications are contraindicated. In addition, surgical success can be adversely affected by:

- Acute or chronic infections, local or systemic
- Vascular, muscular or neurological pathologies that compromise the concerned extremity
- All concomitant pathologies that could affect the function of the implant
- Osteopathies with reduced bone substance that could affect the function of the implant
- Any mental or neuromuscular disorder that could result in an unacceptable risk of failure at the time of fixation or complications in post-operative treatment
- Known or suspected sensitivity to metal
- Corpulence; an overweight or corpulent patient can strain the implant to such a degree that stabilization or implant failure can occur
- Whenever the use of the implant comes into conflict with the anatomical structures of physiological status

Other medical or surgical pre-conditions that could compromise the potentially beneficial procedure, such as:

- The presence of tumors
- Congenital abnormalities
- Immunosuppressive pathologies
- Increased sedimentation rates that cannot be explained by other pathologies
- Increased leukocyte (WBC) count
- Pronounced left shift in the differential leukocyte count

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 wound infections and late infections with possible sepsis
- Migration, subluxation of the implant with resulting reduction in range of movement
- Fractures resulting from unilateral joint loading
- Thrombosis and embolism
- Wound hematoma and delayed wound healing
- Temporary and protracted functional neurological perturbation
- Tissue reactions as the result of allergy or foreign body reaction to dislodged particles
- Corrosion with localized tissue reaction and pain
- Pain, a feeling of malaise or abnormal sensations due to the implant used
- Bone loss due to stress shielding

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 undersized plate or screw in areas of high functional stresses may lead to implant fracture and failure.
- Plates and screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
- The implants and guide wires are intended for single use only.
- Instruments, guide wires and screws are to be treated as sharps.
- Do not use other manufacturer's instruments or implants in conjunction with the Baby Gorilla®/Gorilla® Plating System.
- If a stainless steel Gorilla® R3LEASE™ Screw is used, it may only be used standalone.
- The device should only be used in pediatric patients where the growth plates have fused or in which active growth plates will not be crossed by the system implants or instrumentation.

MR SAFETY INFORMATION

The Baby Gorilla®/Gorilla® Plating 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 Baby Gorilla®/Gorilla® Plating System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

R3INFORCE™
EXTRAOSSEOUS REPAIR SYSTEM

SURGICAL TECHNIQUE GUIDE

Syndesmosis Repair using the
Grappler® R3INFORCE Extraosseous Repair System

P82-STG-0001 Rev B [2024-04-15]

Exclusively foot & ankle
Paragon 28®
www.Paragon28.com

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Disclaimer:
The purpose of the Grappler® R3INFORCE Stabilization System Surgical Technique Guide is to demonstrate the optionality and functionality of the Grappler® R3INFORCE Stabilization System implants and instrumentation. Although variations in placement and use of the Grappler® R3INFORCE Stabilization 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® R3INFORCE Stabilization 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.