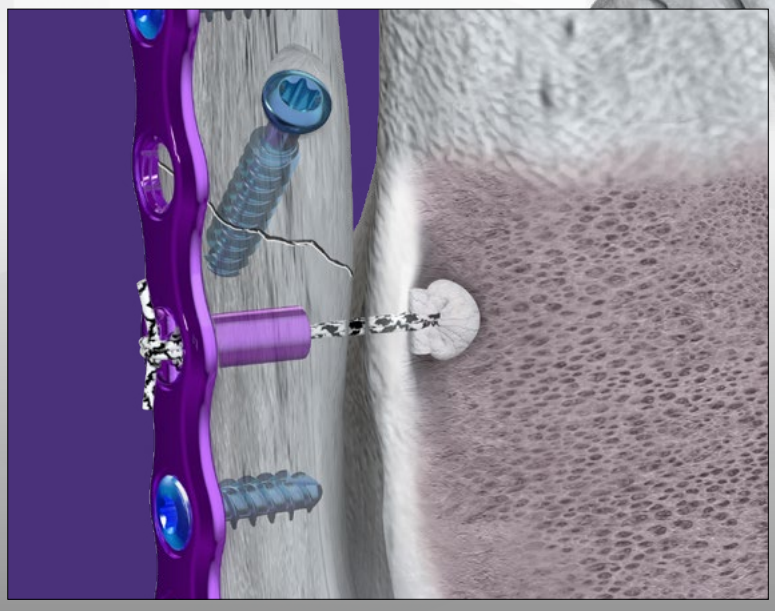
R3FLEX™
STABILIZATION SYSTEM

SURGICAL TECHNIQUE GUIDE

R3FLEX™ Stabilization System



Exclusively foot & ankle
Paragon 28®

Acknowledgment:
Paragon 28® would like to thank Lewis Freed, DPM; Lauren Geaney, MD; John Kwon, MD; and Christopher Zingas, MD for their contribution to the development of the system and surgical technique guide.

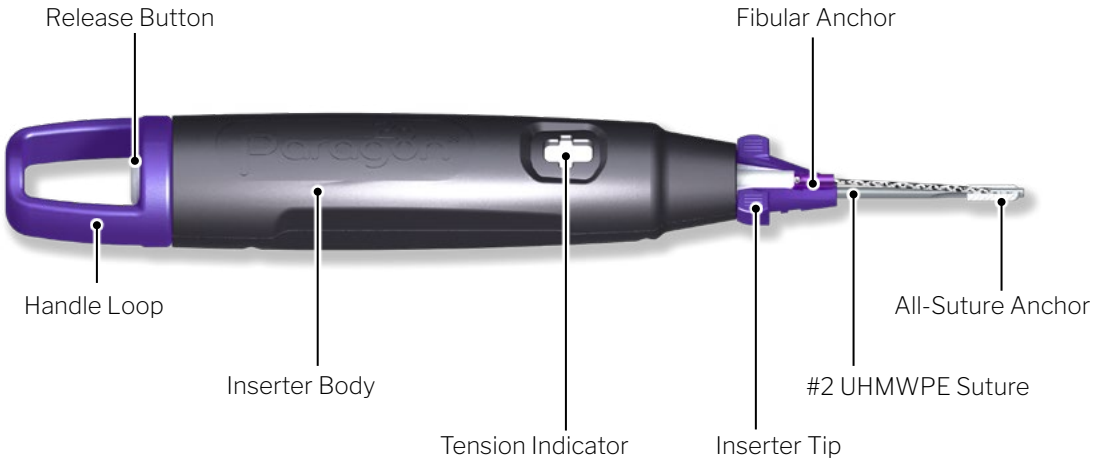
PRODUCT DESCRIPTION

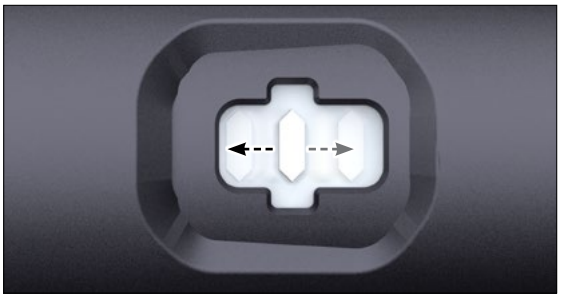
The R3FLEX™ Stabilization System is the next generation of flexible fixation for the syndesmosis. The instrumentation provides surgeons the ability to assess and adjust the tension of the repair intra-operatively. The preparation is performed tri-cortically with a Ø2.8 mm drill bit to alleviate the risk of injury to the saphenous nerve or vein at the distal tibia and preserve the medial cortex in contrast to other systems. The implant is designed to enable motion across the syndesmosis to better match the native kinematics of the fibula.

CONTENTS

SYSTEM OVERVIEW

Inserter and R3FLEX Implant





Tension Indicator
- *Used during fine tensioning, middle section indicates target tension between the fibular and tibial implants*

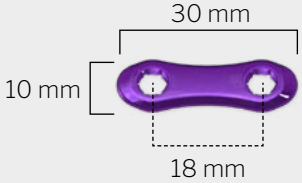
Ø2.8mm Drill

Ø3.8mm Drill

Angled Drill Guide

Available sterile, separate from the R3FLEX kit:

2-Hole Gorilla® Syndesmosis Plate



Washer

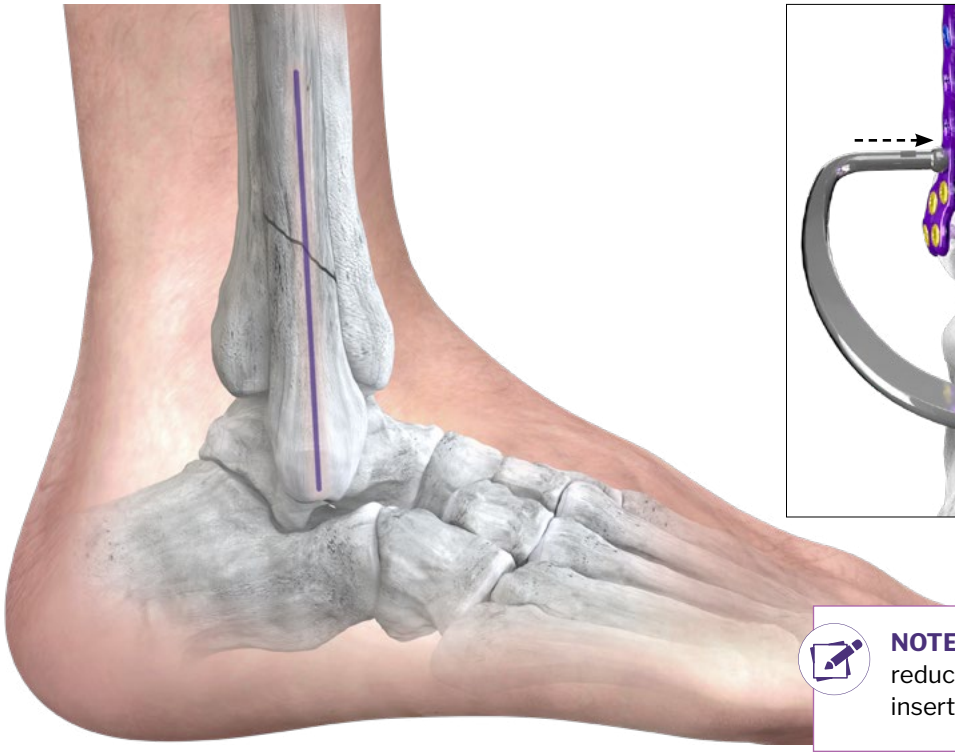
INCISION/EXPOSURE

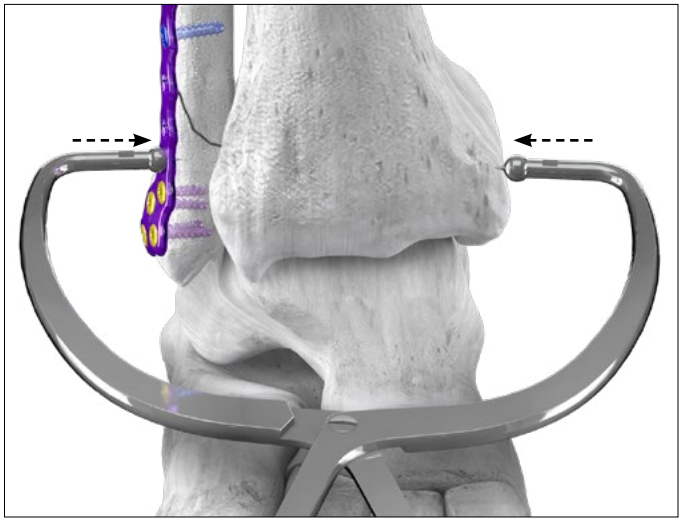
Position the patient supine such that the foot is near the end of the table, or in lateral decubitus, based on surgeon preference or fracture pattern. The incision placement is dependent on surgeon preference for fracture pattern and/or isolated syndesmotic instability as well as anticipated plate length and location(s).

If using the R3FLEX implant through an ankle fracture plate, refer to the Gorilla®Ankle Fracture 360 Surgical Technique Guide (P51-STG-0008) for more specific information on plating options and instruments for ankle fracture reduction and fixation.

The surgeon should address other fractures of the ankle prior to syndesmotic fixation, according to patient injury and surgeon training. If a deltoid injury or medial malleolus fracture is to be repaired, that should be done first. If there is a deltoid ligament injury requiring evaluation or repair, expose the anterior medial ankle and evaluate the joint, and remove any soft tissues in the medial clear space prior to syndesmotic reduction. It is imperative to properly reduce the lateral malleolus prior to placing the syndesmotic device.

Reduction of the syndesmosis is performed per surgeon preference, which can be performed with or without a clamp. The R3FLEX Stabilization System can be used in syndesmotic repair cases without an associated fracture; in such cases, it is required to use a washer or 2-hole plate (see page 5).



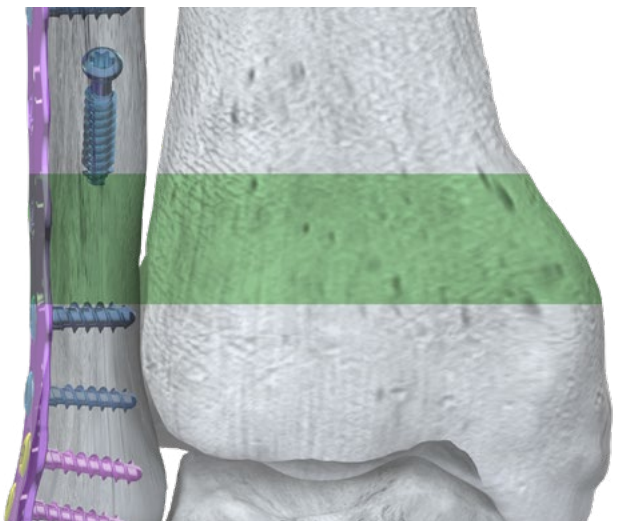


NOTE: Once desired reduction is achieved, reduction must be held in place during implant insertion for appropriate implant tensioning.

PLANNING IMPLANT PLACEMENT

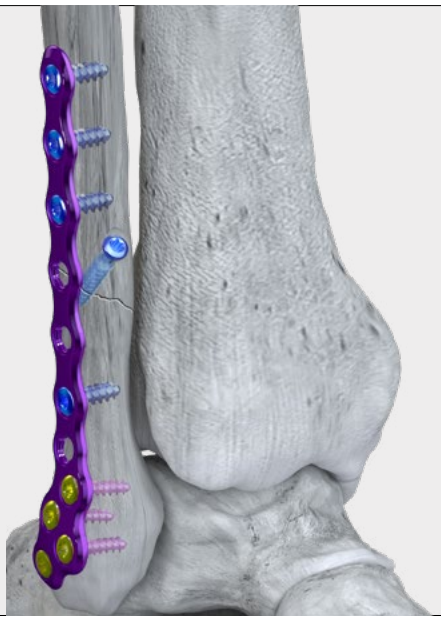
The R3FLEX Implant must be used through a plate hole or washer.

The R3FLEX implant should ideally be placed 1.5cm to 3cm above the ankle joint, depending on if two implants are used, size of patient, hole location in the plate, and the location of the fracture.



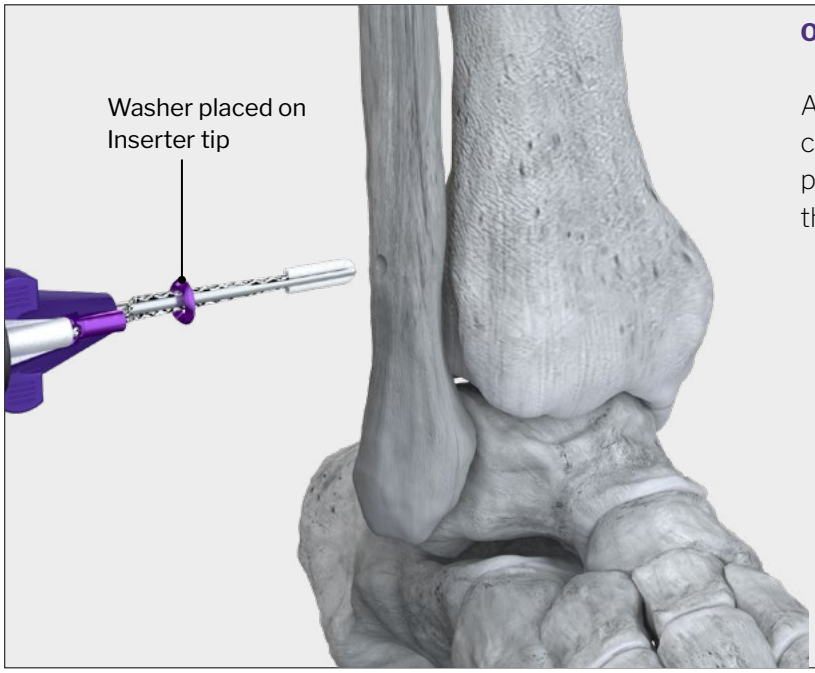
PLATING OPTIONS

NOTE: The R3FLEX implant must be used with a plate or washer.



OPTION #1 FIBULAR PLATE

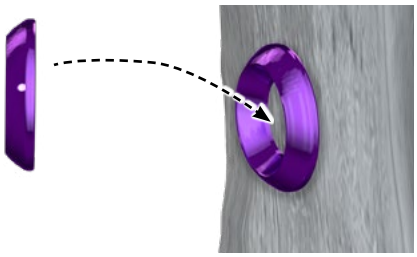
Identify an open hole in the plate that corresponds to an appropriate implant placement, as described on the previous page and avoiding syndesmotic fixation through the fibula fracture.

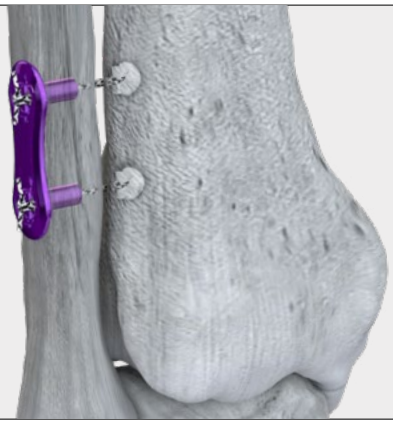


OPTION #2 WASHER

A Gorilla® washer (provided sterile-packaged separately) can be used without the need for a plate, and must be placed directly onto the inserter tip before insertion of the implant.

NOTE: The washer is directional and should be placed with the wider, flat side facing toward the surface of the bone.

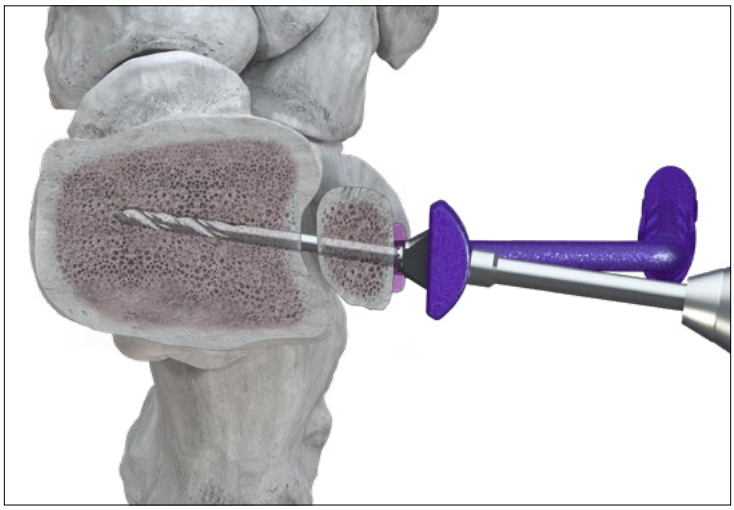




OPTION #3 TWO-HOLE SYNDESMOSIS PLATE

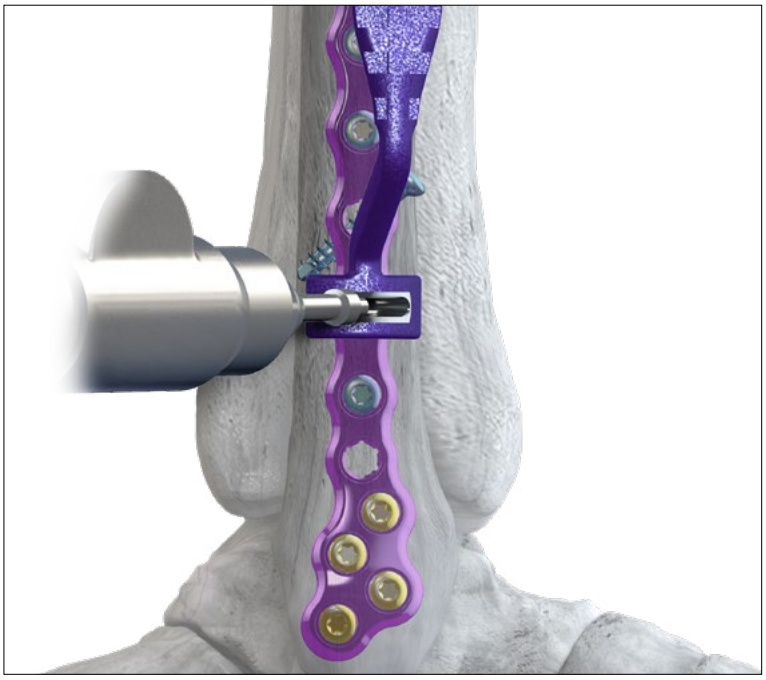
A 2-hole Gorilla® Syndesmosis Plate (sold separately and shipped sterile) can be used without the need for a large plate for purely ligamentous high ankle sprains or Maisonneuve fractures. Secure the plate on the fibula in an appropriate location for syndesmotic fixation using an olive wire. Two R3FLEX implants can be used, or one R3FLEX implant with a Gorilla plate screw in which case the screw should be inserted first.

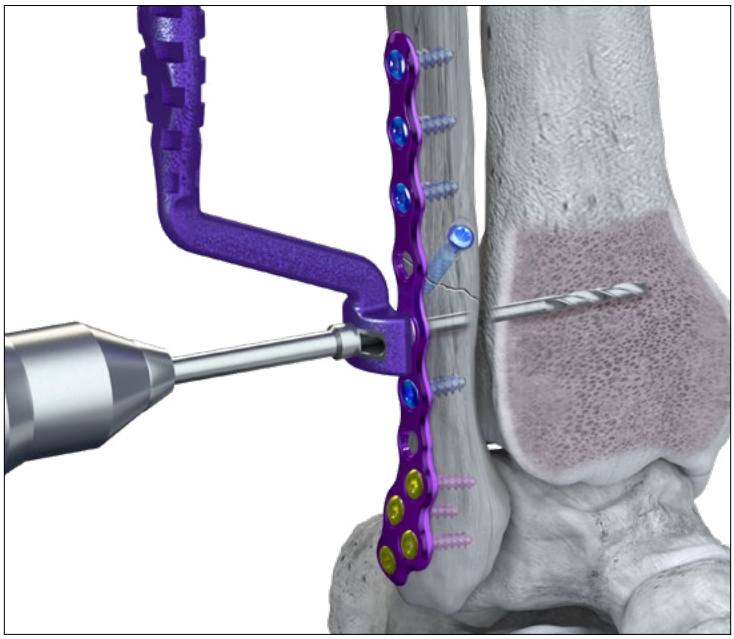
PREPARATION



Place the end of the Angled Drill Guide into the selected hole on the fibular plate or washer. Using the Ø2.8mm bit, drill through the guide parallel to the tibiotalar joint and bi-cortically into the fibula. Verify drill trajectory using fluoroscopy as needed.

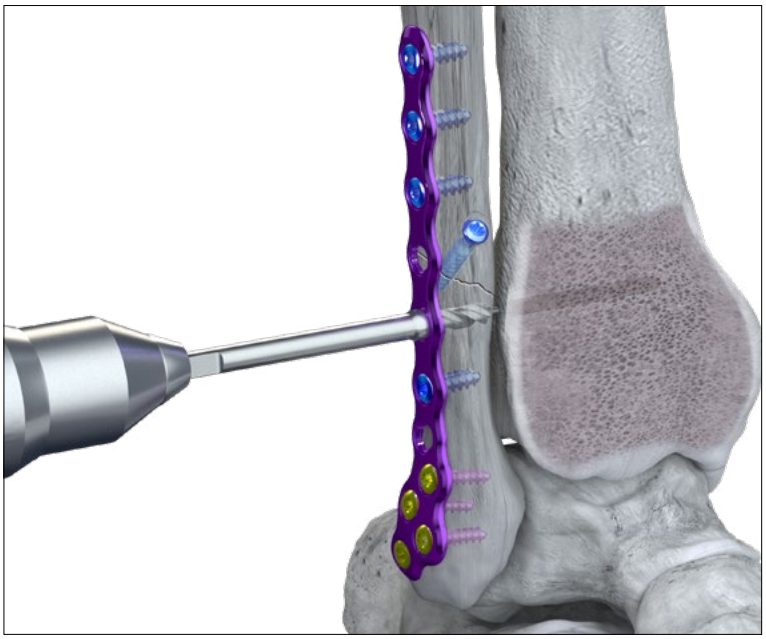
The Angled Drill Guide allows for 30 degrees of axial plane angulation in both directions. The initial Ø2.8mm drill bit should be directed from the center of the fibula toward the center of the tibia, which will typically be angled from 25-30 degrees posterior to anterior.





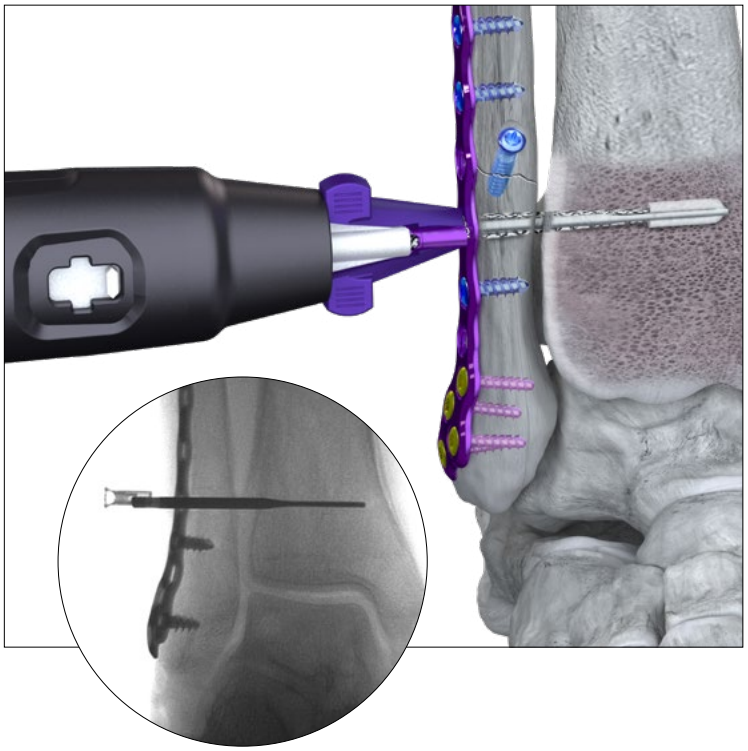
Continue drilling along the same trajectory until the physical stop is reached. Use fluoroscopy to verify that the drilling path is parallel to the joint line.

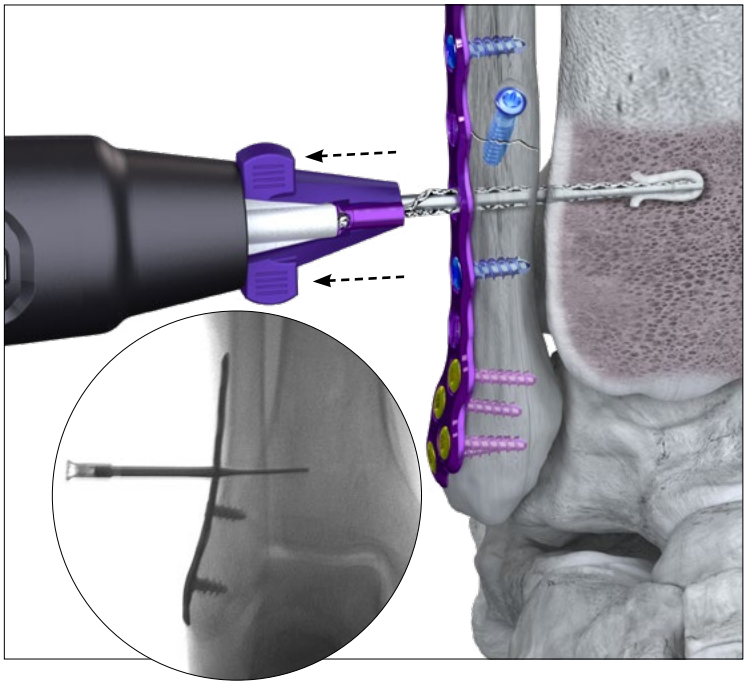
TIP: With smaller anatomies, drill under fluoroscopy up to the medial tibial cortex instead of relying on the drill stop. The working length of the drill bit is approximately 47 mm.



Remove the Angled Drill Guide. Prepare the fibula for the body of the fibular implant by drilling with the Ø3.8mm drill bit until the drill stop hits the plate. It is recommended to drill in-line with the Ø2.8mm tunnel, but the design of the implant allows for some variability.

IMPLANTATION



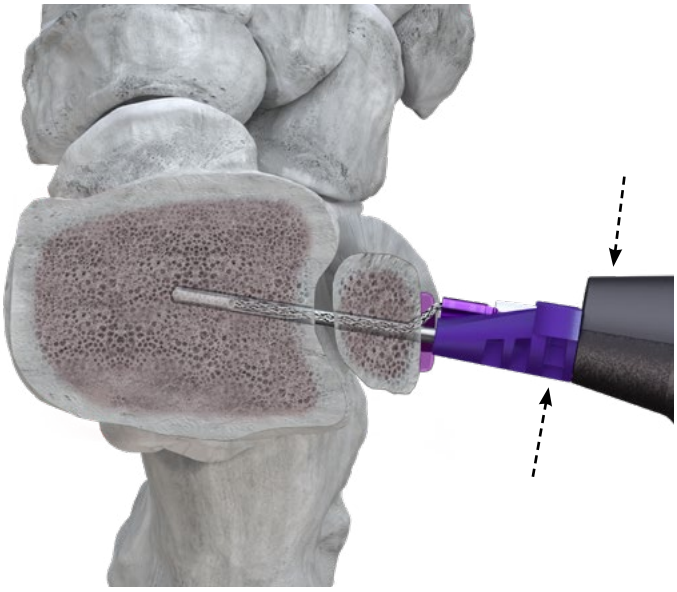


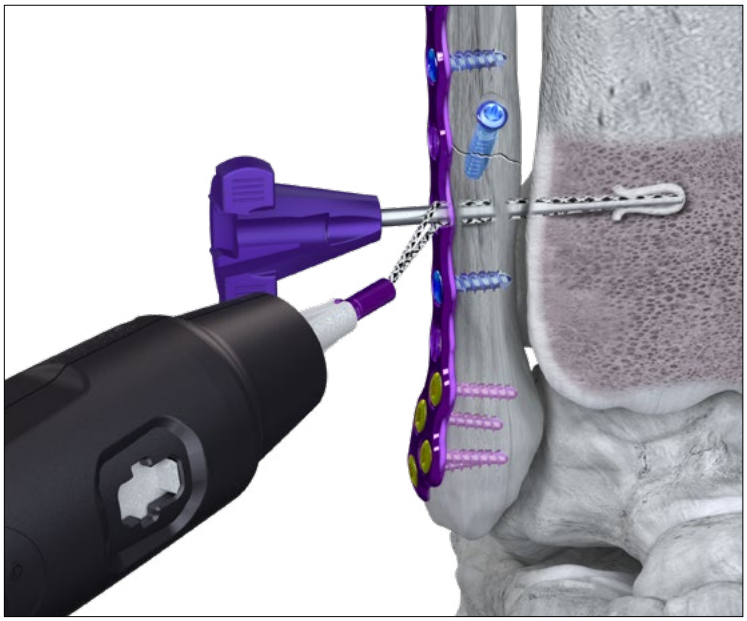
Check that the Inserter Tip is still engaged to the grey Inserter Body after impaction. Set the tibial anchor by pulling on the grey Inserter Body away from the fibula. This should be a quick motion to pull the all-suture anchor toward the lateral tibial cortex. The space between the purple portion of the Inserter Tip and the plate will increase.

The location of the tibial anchor can be determined with fluoroscopy by noting the location of the taper on the Inserter Tip on an A/P image. The end of the anchor is approximatively half way down the flat portion of the tip.

With the Tension Indicator facing anterior, insert the R3FLEX Inserter Tip and R3FLEX Implant into the prepared drill tunnel with mallet impaction until the purple portion of the Inserter Tip contacts the plate. Fluoroscopy can be used to check the positioning of the implant. At minimum, the tapered portion of the Inserter Tip should be in or past the lateral tibial cortex.

TIP: With a free hand, apply counteracting pressure to the purple Inserter Tip and Inserter Body during impaction to prevent premature disengagement of the Inserter Tip.

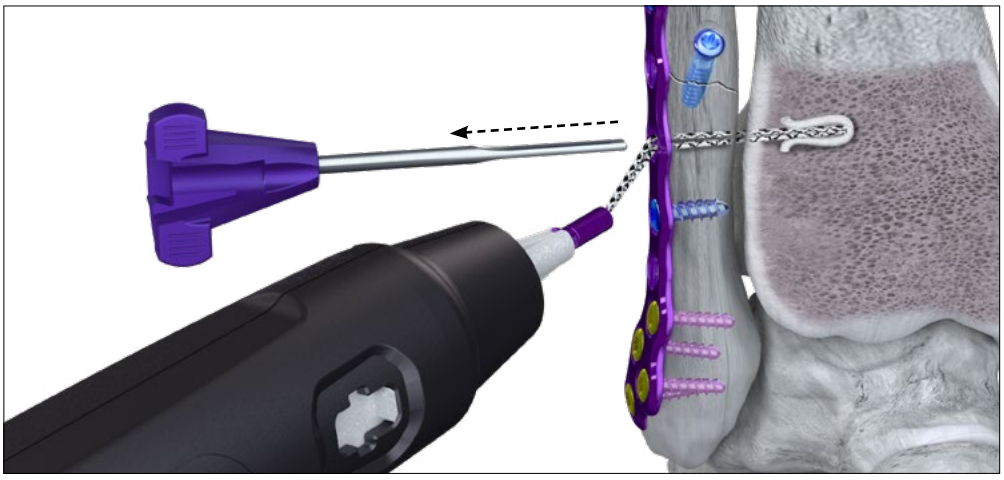


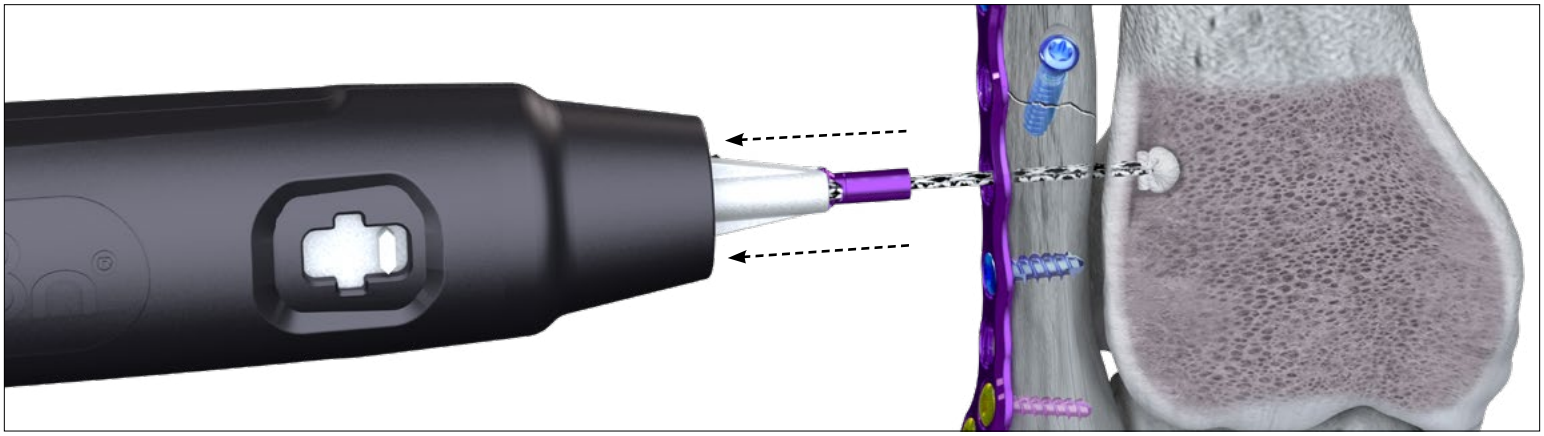


Slide the grey inserter body anteriorly to disengage from the Inserter Tip.

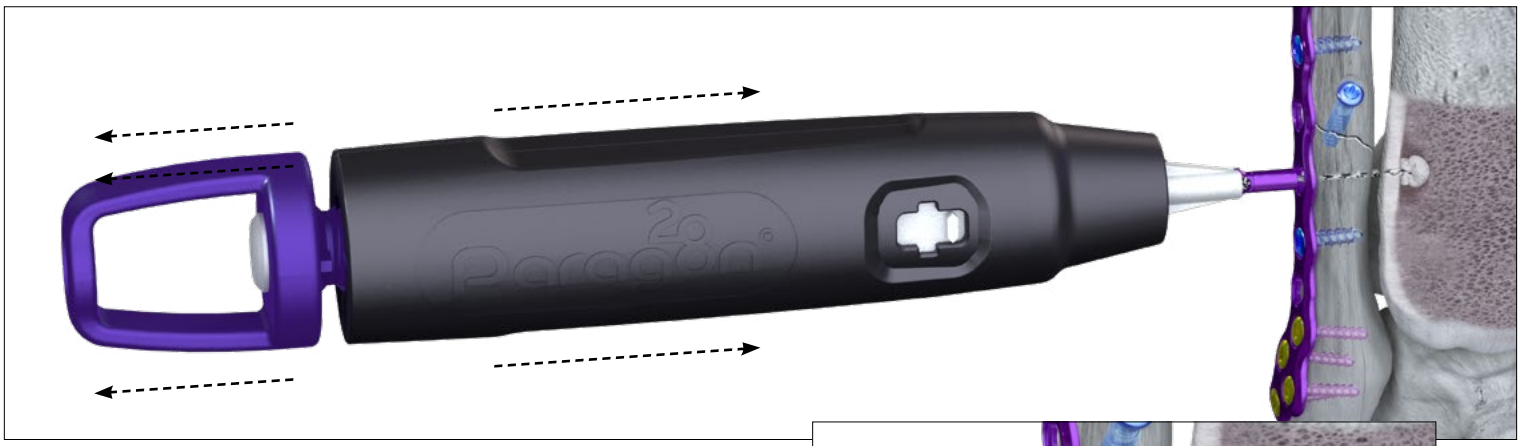
IMPLANTATION

Remove the Inserter Tip from the fibula by pulling directly out.

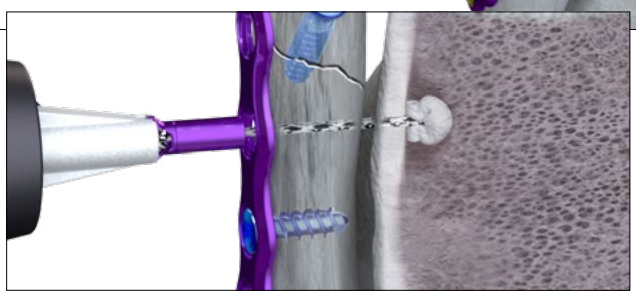




Perform a final set of the tibial anchor by pulling the grey Inserter Body away from the fibula. The tibial anchor should now be seated against the lateral cortex of the tibia.



While pulling back on the purple Handle Loop, push the grey inserter body towards the fibula. The body of the fibular anchor should sit within the fibula. Manually guide the body of the fibula anchor into the plate hole if needed.

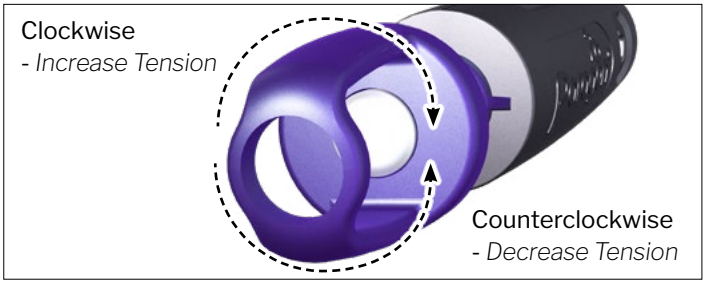


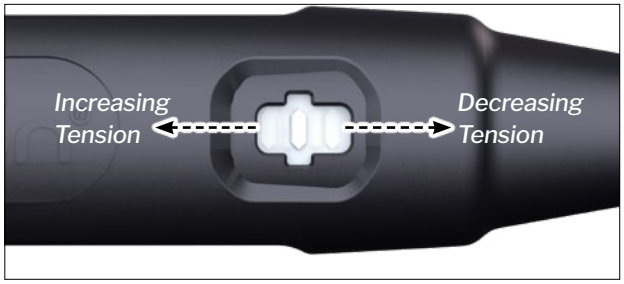
IMPLANTATION

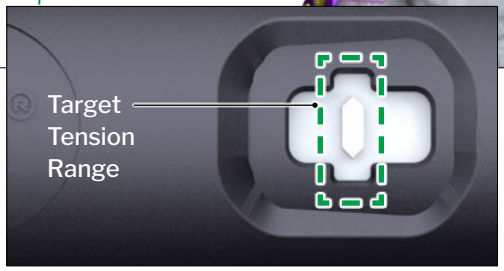
Continue pulling on the purple Handle Loop to grossly tension the R3FLEX implant while holding the grey Inserter Body.

To finely adjust the tension, the purple Handle Loop can be rotated clockwise to increase tension or counter-clockwise to decrease tension while holding the grey Inserter Body.

NOTE: Turning the Handle Loop will not provide tactile feedback on the tension across the syndesmosis because of the inserter's mechanical advantage. The syndesmosis should be clinically evaluated for stability.

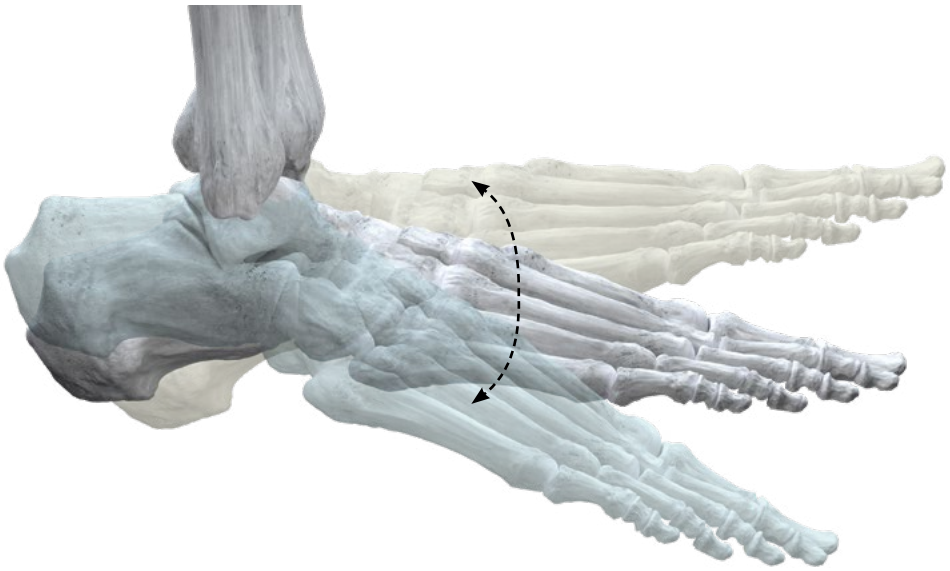






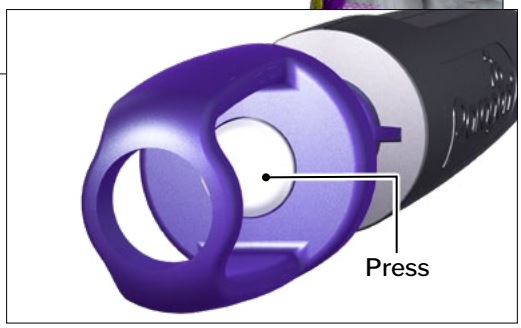
Utilize the tension indicator to monitor the tension across the implant. The target tension is within the middle window.

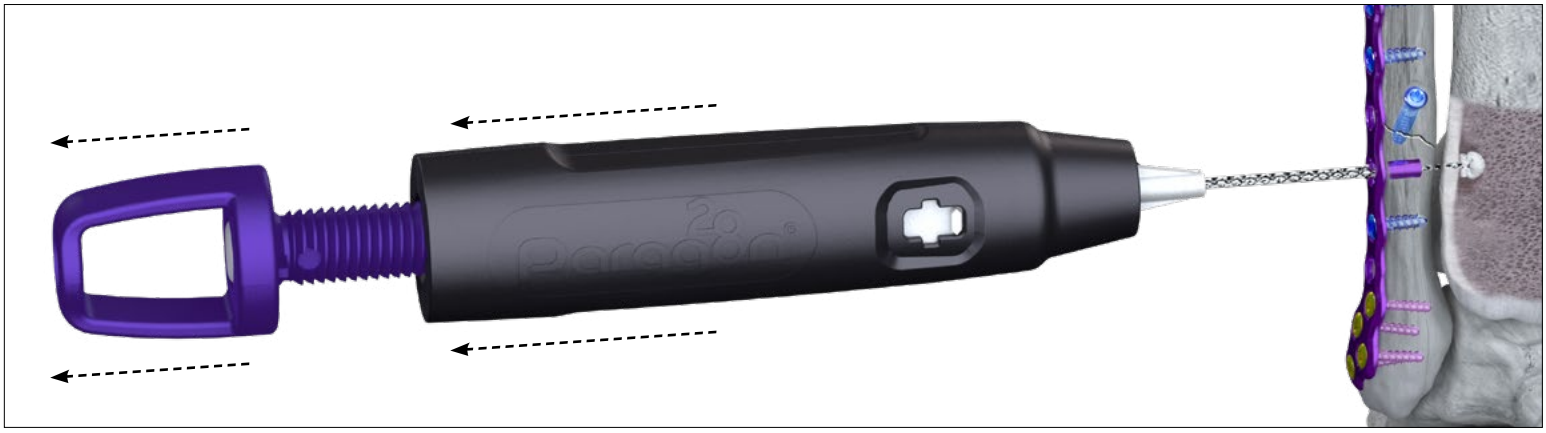
IMPLANTATION



Plantarflex and dorsiflex the foot multiple times to ensure that the suture in the repair is properly balanced. The tension indicator may decrease so the tension should be increased again to the target tension.

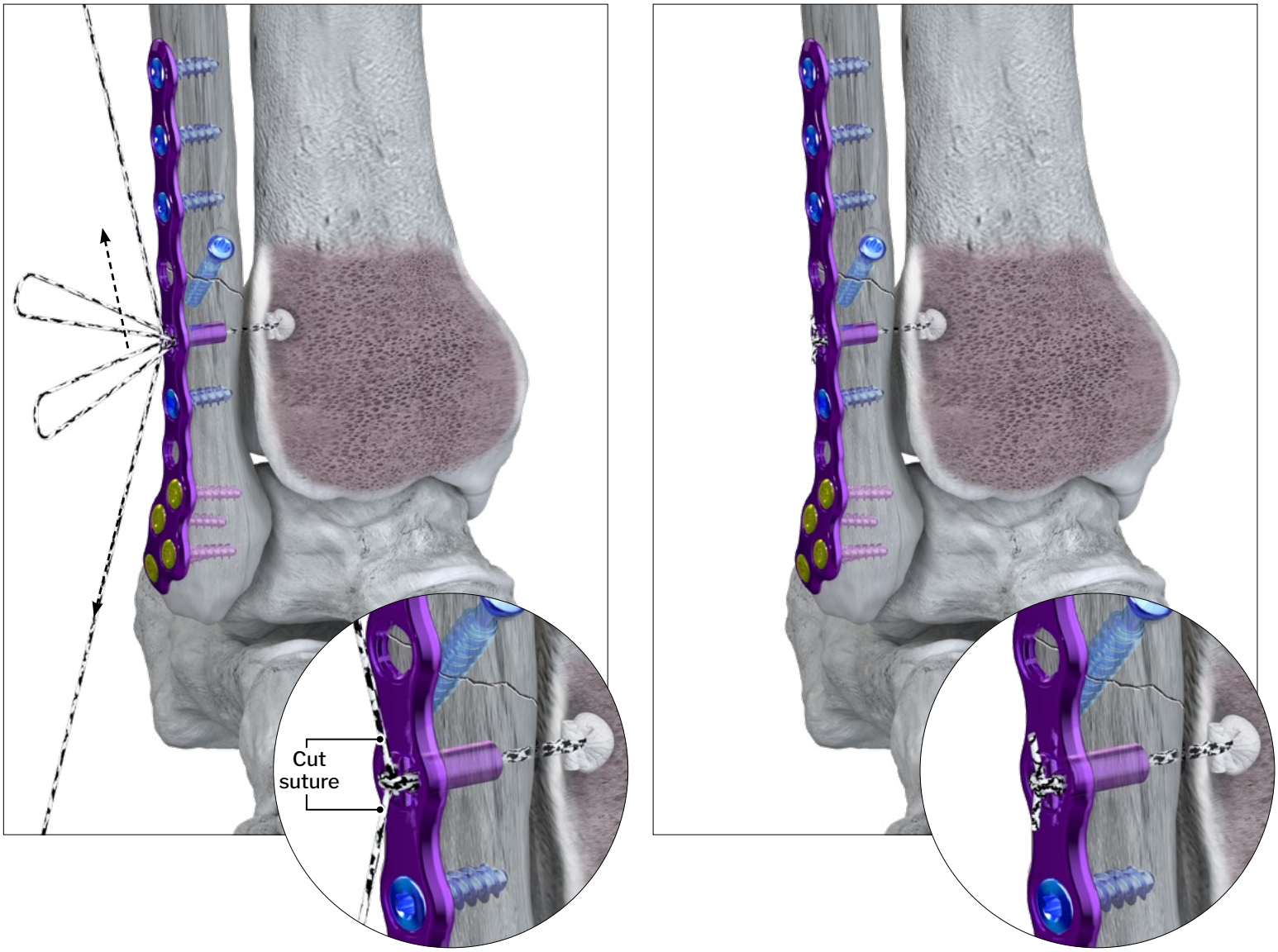
Clinical evaluation of the syndesmosis should be the final check to determine the tension required. When the desired tension is achieved, press the white release button and pull the grey inserter body away from the fibula.





When the handle is pulled away, the pre-tied knot within the handle will move towards the plate.

FINAL CONSTRUCT



Tighten the suture lock down to the plate by divergently pulling the unlooped suture strands superiorly and inferiorly. Cut the ends of the suture off by the plate leaving 1-2 mm of tail.

NOTE: If the implant is over-tensioned (white indicator is beyond the window), the Inserter is designed to release the suture before pushing the white button. In this scenario, knots must be tied to complete implantation.

REMOVAL

Using a scalpel, cut through the exposed suture on the top of the fibular anchor. Remove any loose suture strands. Utilizing a blunt, narrow tipped instrument (i.e. Hohmann Retractor) lever the anchor head away from the surface of the plate. Grasp the head of the fibular anchor with an instrument such as a rongeur and pull away from the plate to remove the implant and suture loop. A Freer or other similar instrument may be used as a wedge under the plate to assist in removal if desired. The sleeve of the all-suture anchor will remain in the tibia. If it is necessary to remove, a hook or small arthroscopic grasper can be used to remove.

STERILE KIT

R3FLEX™ STABILIZATION SYSTEM KIT:
P82-001-1237-SK

- R3FLEX Implant on Inserter
- Ø2.8 mm Solid Drill
- Ø3.8 mm Solid Drill
- Angled Drill Guide

GORILLA® 2-HOLE SYNDESMOSIS PLATE
P53-201-1002-S

- Sterile-packed

GORILLA® STANDARD 8MM WASHER
P50-153-WS00-S

- Sterile-packed

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

The following are the indications for the entire Grappler Suture Anchor System family of products. Indications relevant to the R3FLEX Stabilization System are in bold.

INDICATIONS FOR USE (GRAPPLER®):

The Grappler® Suture Anchor System is intended for the fixation of soft tissue to bone including:

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

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

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.

R3FLEX™
STABILIZATION SYSTEM

R3FLEX™ Stabilization System

P82-STG-0002 RevC [2024-10-31]

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

Disclaimer:
The purpose of the Grappler® R3FLEX™ Stabilization System Surgical Technique Guide is to demonstrate the optionality and functionality of the Grappler® R3FLEX™ Stabilization System implants and instrumentation. CAUTION: Federal Law (USA) restricts this device to sale and use by, or on the order of, a physician.