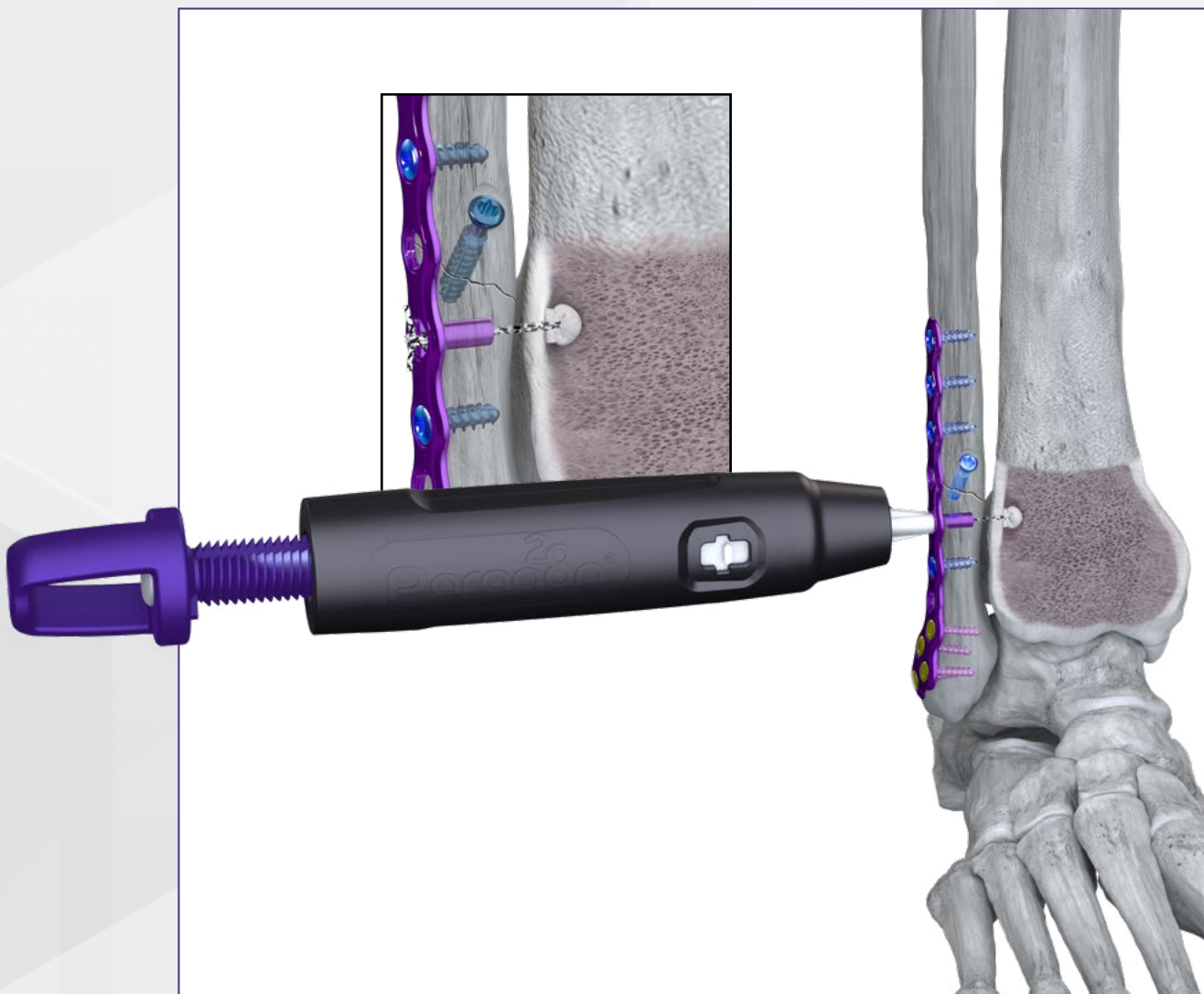


R3FLEX™

STABILIZATION SYSTEM

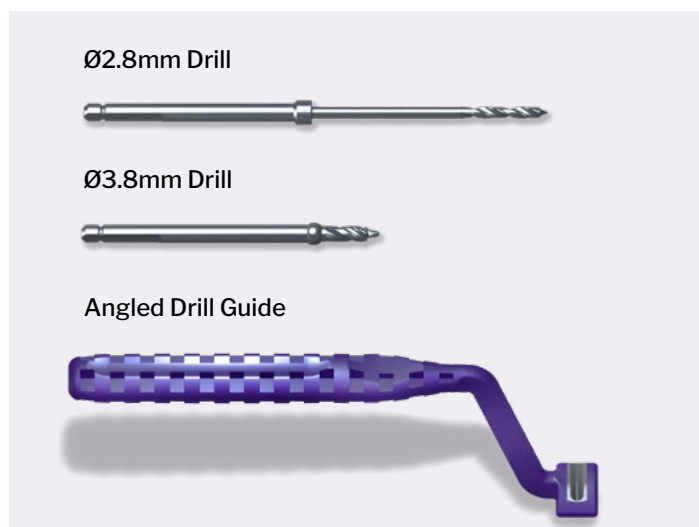
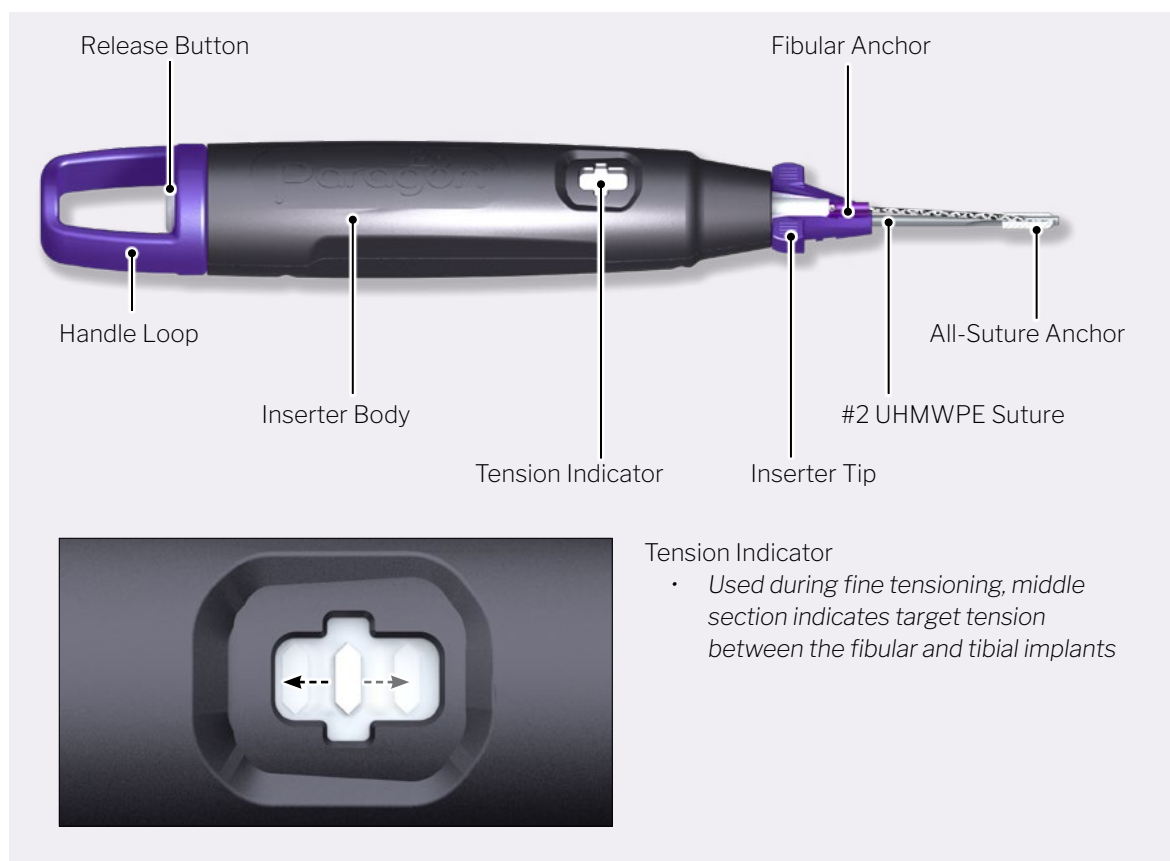


R3FLEX™ | Stabilization System

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 on medial distal tibia. The knotless implant is designed to enable motion across the syndesmosis to better match the native kinematics of the fibula.

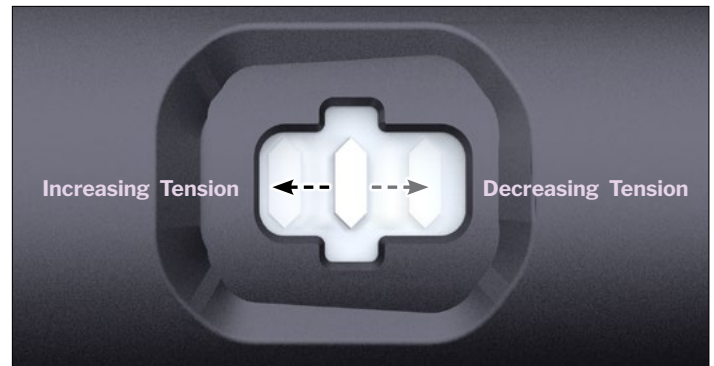
SYSTEM OVERVIEW

Insertor and R3FLEX Implant



Measurable and Adjustable Tensioning

- ▶ Tension indicator allows surgeon to visualize and optimize the tension of the construct to each patient.
- ▶ Inserter allows the surgeon to precisely increase or decrease tension across the implant with micro and macro adjustments.



No Medial Button/Tri-Cortical

- ▶ No medial incision needed- saving procedural time.
- ▶ Decreases risk to the greater saphenous neurovasculature because the drill does not need to go quad cortical, and no implant is placed on the medial tibia.

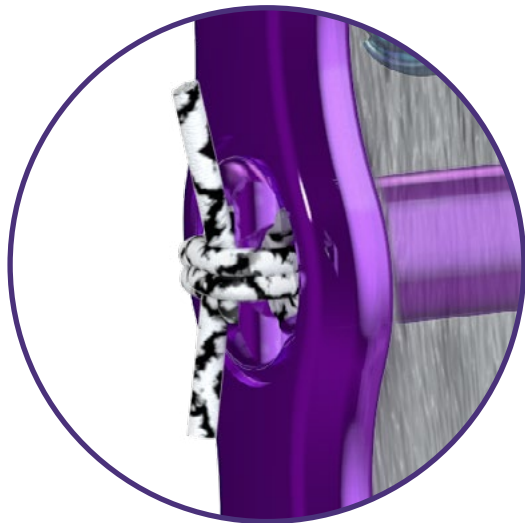
Malreduction Forgiveness

- ▶ Flexible design allows the fibula to find its native location in the incisura upon implantation.



Controlled Fibular Motion

- The thermoplastic urethane (TPU) bumper and suture-loop allows for up to 2 mm of motion in the construct so that the fibula can translate and rotate naturally.



Fibular implant with TPU Bumper



Unloaded TPU Bumper



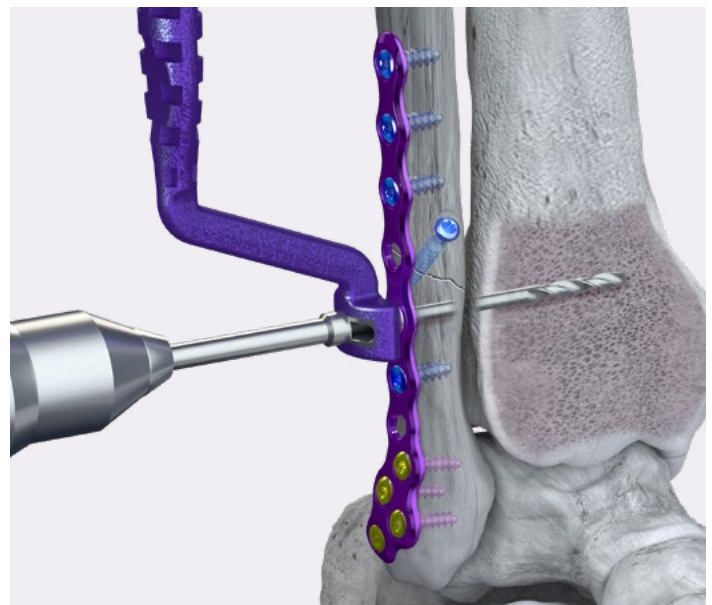
Loaded TPU Bumper

Shorter Working Length

- Reduced working length results in a more stable construct – competitive devices must extend across the entire tibia resulting in increased stretch when loaded and may experience creep over time.

Narrower Drill Tunnel in the Tibia

- The Ø2.8 mm drill tunnel may reduce the risk of tibial fractures and decrease the chance of hitting other hardware compared to a larger drill tunnel.



ORDERING INFO

R3FLEX™ Implant and Instruments

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 2-hole Syndesmosis Plate



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

- ▶ Sterile Washer



COMPLIMENTARY PRODUCTS

R3INFORCE™ Extraosseous Repair System

The Grappler® R3INFORCE Extraosseous Repair System was designed to repair and reinforce the syndesmosis with a variety of anchors as well as seamlessly integrate with the Gorilla Plating System during fracture fixation cases. 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. The Anterior Inferior Tibiofibular Ligament (AITFL), Posterior Inferior Tibiofibular Ligament (PITFL), or both ligaments can be anatomically addressed with the system.

R3INFORCE ExO
Ø4.2 mm x 12 mm Locking
Anchor Kit



R3INFORCE ExO
Screwless Head Locking
Anchor Kit



R3INFORCE ExO
Ø2.8 mm All-Suture
Anchor



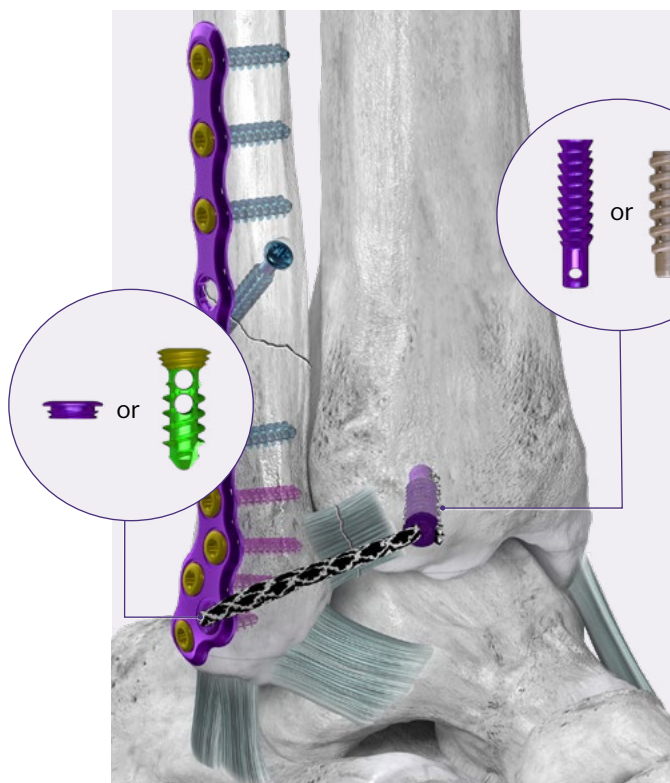
R3INFORCE ExO
Ø4.5 mm
Titanium Anchor



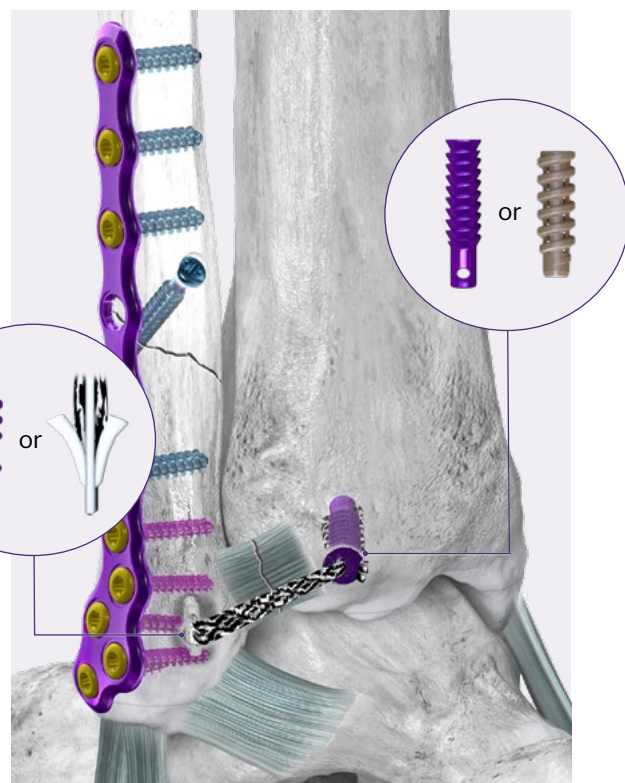
R3INFORCE ExO
Ø4.75 x 20 mm
Dynamic Anchor



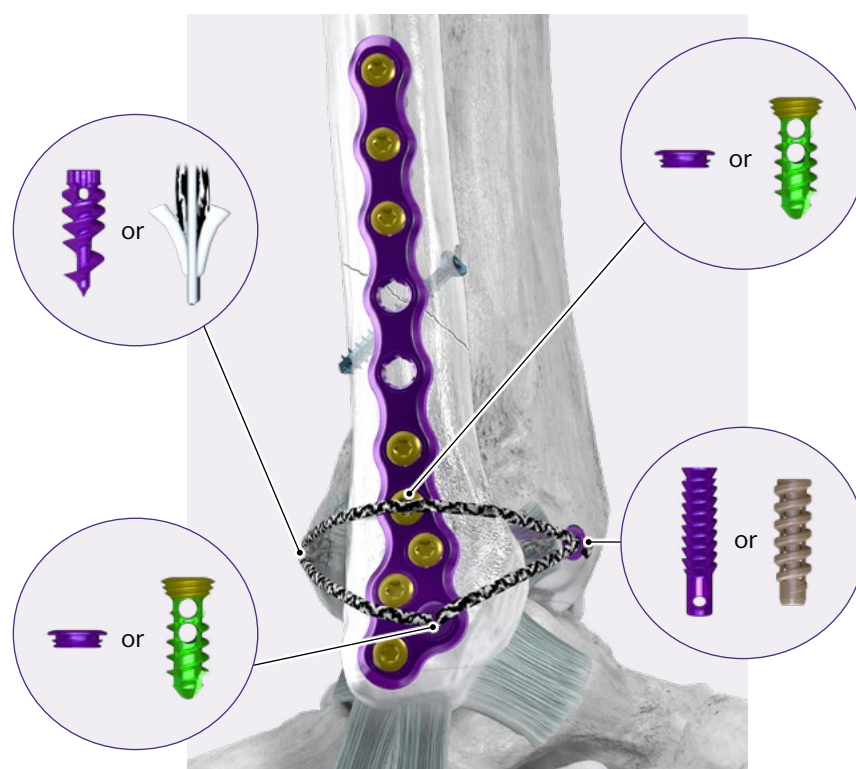
SAMPLE CONSTRUCTS



AITFL R3INFORCE Repair with a Plate



AITFL R3INFORCE Repair Outside of a Plate




"Diamond" Construct – Combined AITFL and PITFL Repair

R3FLEX™

STABILIZATION SYSTEM

P28-R3FLX-BRO-01 Rev A
2024-08-21

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For the contraindications, potential complications and adverse reactions, warnings and precautions associated with this device, please refer to the device specific instructions for use at <http://www.paragon28.com/ifus>