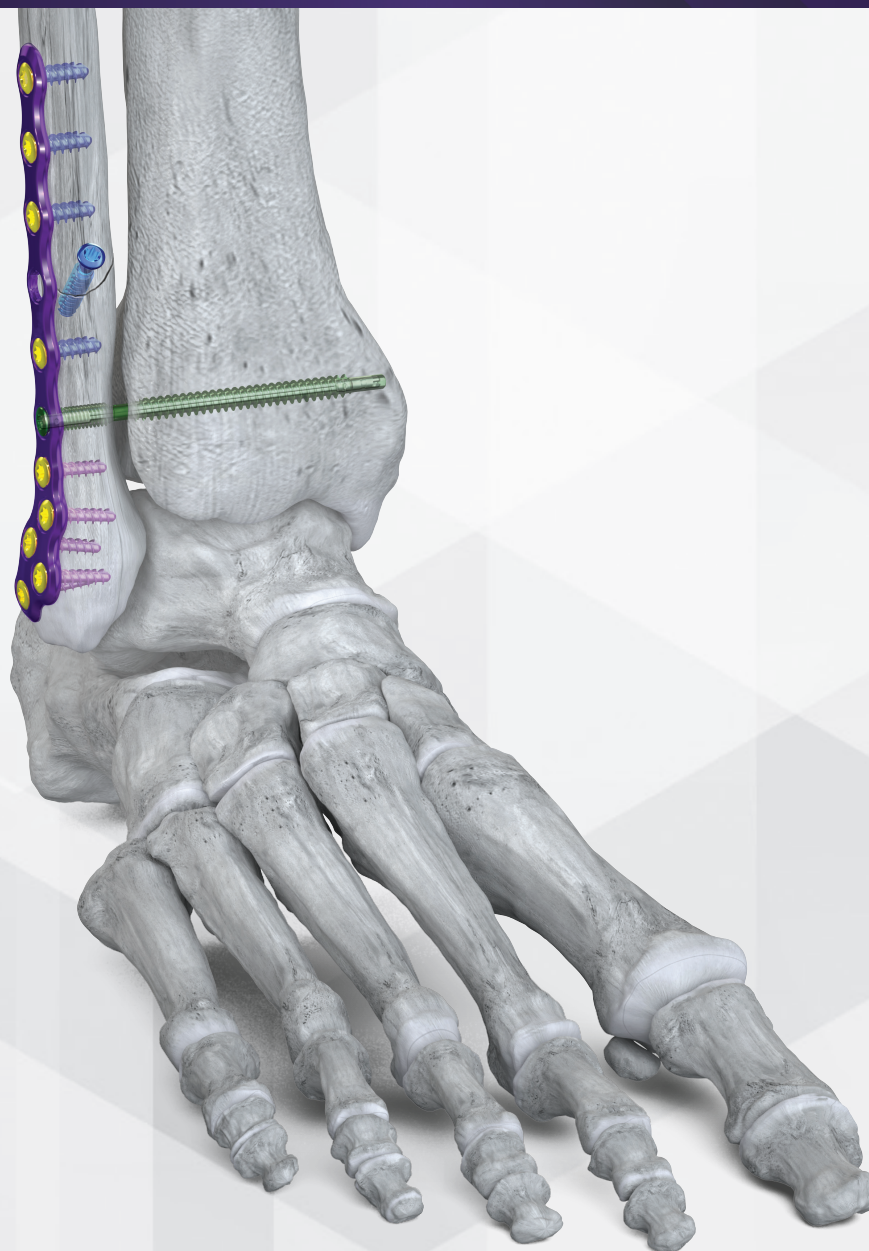
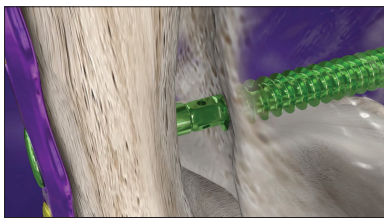


R3ACT™

STABILIZATION SYSTEM



R3ACT™ SCREW FEATURES & BENEFITS



Rigid State



Dynamic State



Dynamic State

CONTROLLED DIASTATIC MOTION — Internal TPU bumper and suture loop work together to help control motion and relieve pressure on the lateral gutter. Internal construct allows for up to 3 mm of diastatic motion, intending to help prevent arthritic changes. This helps provide forgiveness of malreduction upon disengagement and is designed to allow fibular motion in multiple planes.

NO MEDIAL SOFT TISSUE IRRITATION — The R3ACT Implant provides for dynamic syndesmotic correction, while avoiding the need for medial button fixation on the tibia, protecting the soft tissues and neurovascular structures and avoiding a second incision.

NO BONE ON SUTURE CONTACT — Bevelled notch designed to protect internal suture and native bone.

STREAMLINED REMOVAL — To remove the R3ACT implant, K-wires are provided to sever the suture-loop, provided drivers allow for removal of tibial component either medially or laterally.

MULTI-STAGE SOFT TISSUE HEALING — The initially rigid construct helps provide stability for primary healing, designed to disengage to allow for controlled physiologic motion.

NOTCH LENGTHS — 14 mm & 17 mm fibular notch length accommodate a variety of patient anatomy.

KEY DESIGN FEATURES

External Screw Shell

Material

- ▶ Ti-6Al-4V ELI

Thread Design

- ▶ Fibular Threads
 - Dual-lead half pitch — inserts at same speed as tibial threads
 - Increases bony purchase across fibula
- ▶ Tibial Threads
 - Same profile as 4.0 Monster® Screw
- ▶ 14 & 17 mm Notch lengths
 - Geometry helps protect native bone and internal suture
 - Designed to limit threads across the clear space

Removal Features

- ▶ Tibial component can be removed medially or laterally, using provided K-wires, trephine and R3ACT™ Removal Driver.

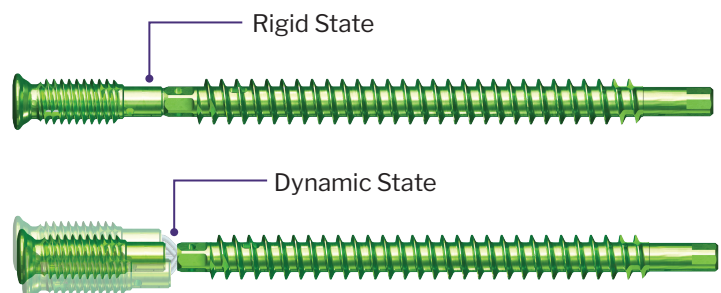
Internal Components

Suture Loop

- ▶ UHMWPE (ultra high molecular weight poly-ethylene)
 - Pre-tensioned to allow consistent fibular motion

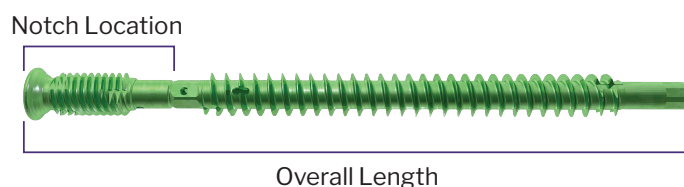
Fibular Bumper

- ▶ Thermoplastic Polyurethane (TPU)
 - Compresses to allow for spring-like fibular motion



SIZE OFFERING

SCREW SIZE: Ø4.2 mm		Overall Length				
		v	45 mm	50 mm	55 mm	60 mm
Notch Location	14 mm	✓	✓	✓	✓	✓
	17 mm		✓	✓	✓	✓



INSTRUMENTATION HIGHLIGHTS

Cone guide

- ▶ The R3ACT™ cone guide is unique to the system and must be used to drill for the screw
- ▶ Allows for 40 degrees of conical angulation

2.8 mm Drill

- ▶ Used to drill across all four cortices

3.2 mm Pilot nose drill

- ▶ 3.2 mm Pilot Nose Drill is designed to drill the fibula only, accounting for the larger inner diameter of the fibula component
 - Pilot nose finds tibial tunnel to ensure proper angulation
- ▶ Depth stops are provided for the different fibular lengths

4.0 mm Monster Tap (Optional)

- ▶ For hard bone

Torque Limiting Driver

- ▶ Crucial for insertion of the screw, the torque limiting driver helps prevent the screw from disengaging prematurely
- ▶ Handle is grey to help distinguish from other P28 drivers



Ø2.8 mm Solid Drill



Ø3.2 mm Solid Drill with Ø2.8 mm Pilot



4.0 Monster® Tap



Pilot Nose Drill Stop Tube, 14 mm



Pilot Nose Drill Stop Tube, 17 mm



ADDITIONAL REMOVAL INSTRUMENTATION

1.2 mm K-wire

- ▶ For use with 5.5 mm Trepine

0.9 mm Drill Point K-Wire

- ▶ Inserted laterally through the Suture Release Guide Tube, the wire cuts the suture and allows for removal of the fibular component

Suture Release Guide Tube

- ▶ Fits in head of the screw, set trajectory to cut suture

4.2 mm Overdrill

- ▶ Used to overdrill the fibula when performing lateral removal

Ø1.2 mm x 100 mm K-wire



Ø5.5 mm Trepine



Ø.90 mm Drill Point K-wire



Suture Release Guide Tube



Ø4.2 mm Overdrill



R3ACT Removal Driver



TECHNIQUE PEARLS

Drilling

- ▶ Use only the provided R3ACT™ cone guide
- ▶ If drilling through a plate, ensure the slots are fully seated in the plate

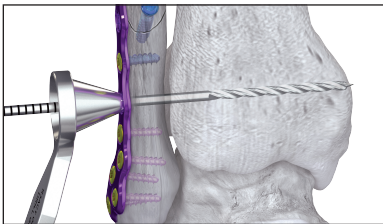
Measuring Screw length

- ▶ When in between sizes, use the next smallest increment of 5
 - Example: Measuring: 53 mm Sugg. Screw Size: 50 mm
- ▶ For the Fibula, when the measurement is > 14 mm, use 17 mm Notch Length

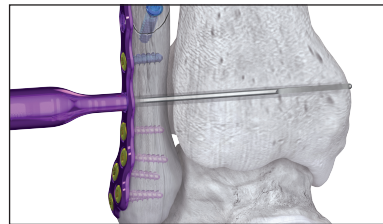
Insertion

- ▶ Maintain reduction until screw is fully seated, the screw will not compress
- ▶ Use the tap, in instances of hard bone or when the torque limiter engages before the screw is fully seated

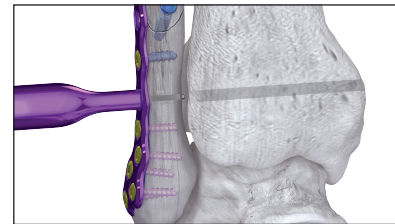
TECHNIQUE HIGHLIGHTS



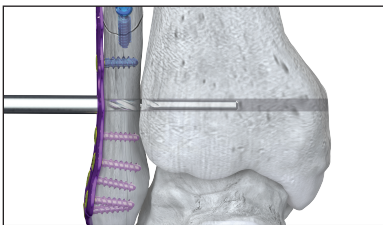
2.8 mm drill is inserted through cone guide, drilling across all four cortices.



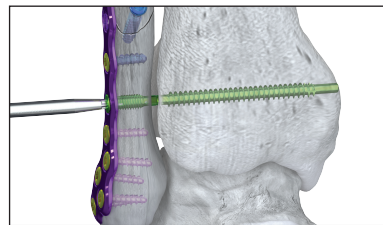
Measure to the far tibial cortex for total screw length.



Measure the distance to the tibiofibular clear space to determine notch location.



Drill Fibula with 3.2 mm Pilot Nose drill and corresponding Drill Stop Tube.



Using the torque limiting driver, fully insert the screw.

NOTE: Pilot nose should locate tibial tunnel before drilling.


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>



www.Paragon28.com

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