



R3ACT™

STABILIZATION SYSTEM

SURGICAL TECHNIQUE GUIDE

Ankle Fracture with Syndesmotomic Repair

Paragon²⁰®

a  ZIMMER BIOMET company

Shown with use of the:

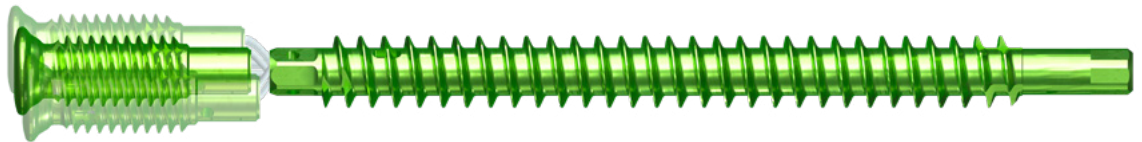
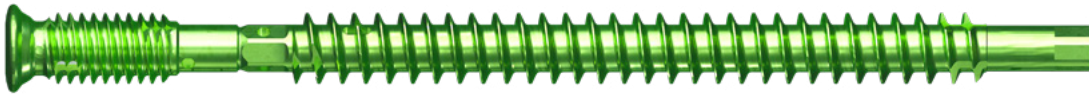
GORILLA®
ANKLE FRACTURE 360™

PRODUCT DESCRIPTION

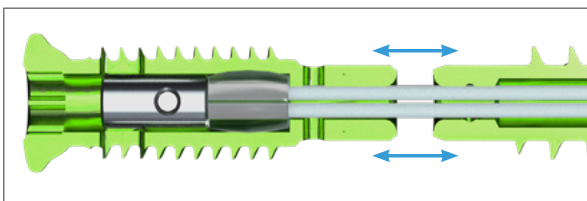
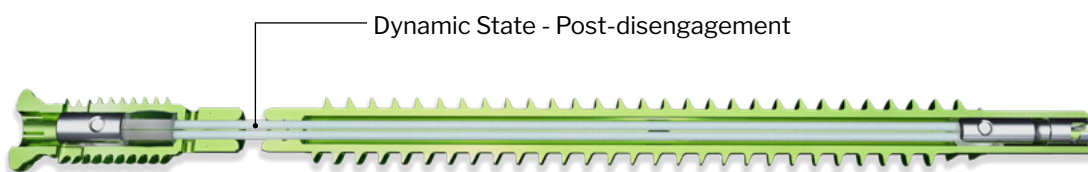
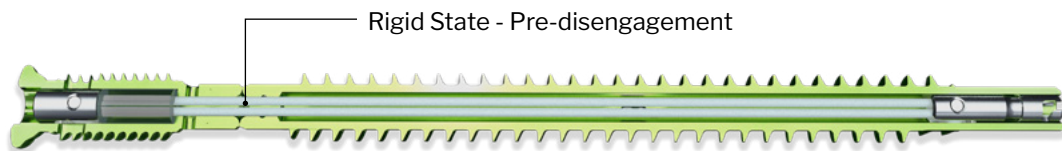
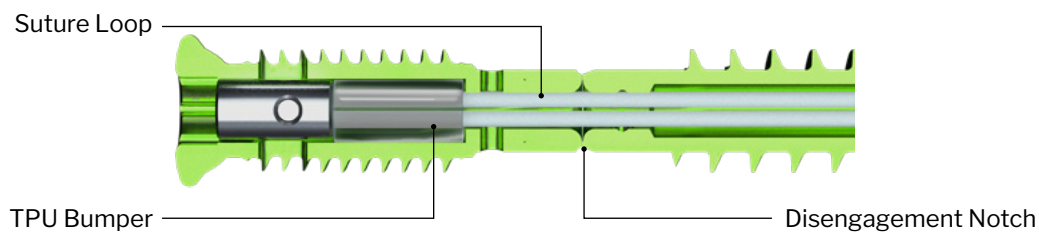
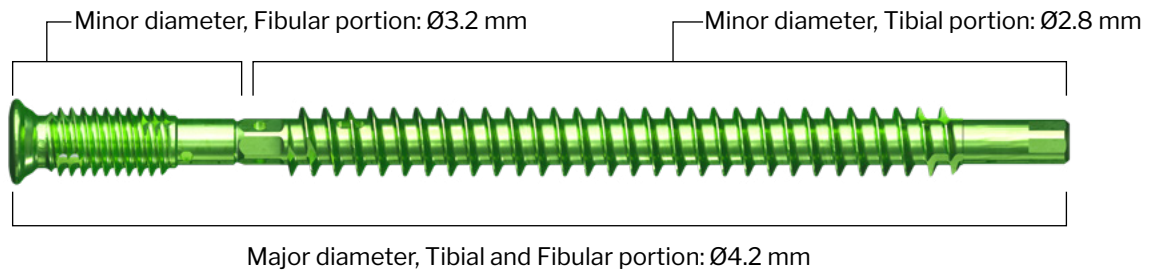
The R3ACT™ Stabilization System was designed to provide a simple solution that allows for multi-stage soft tissue healing following acute or chronic syndesmotic injury. During the period of non-weight bearing following syndesmotic repair, the R3ACT™ Screw is designed to be rigid to support the native ligaments through the crucial early stages of primary healing. Shortly after weight-bearing, the R3ACT Screw is designed such that the outer tibial and fibular components safely disengage in the clear space, where an internal suture-loop and TPU Bumper combine to allow up to 3 mm of diastatic allowance and malreduction forgiveness.

The R3ACT Stabilization System was designed to have the feel and familiar steps of putting in a typical syndesmotic screw. The surgeon can hold the syndesmosis in their desired reduction during screw insertion, which by nature of the screw, will hold that position following insertion.

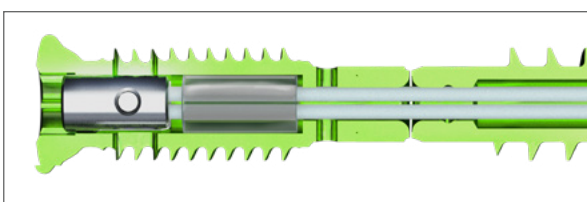
The screw features a unique notch geometry that protects both the surrounding bone and the internal suture, while limiting suture movement to the anatomic axis of the syndesmosis. The screw can be placed in up to 22.5° of angulation in any Paragon 28® Gorilla® Ankle Fracture Plate or can be placed safely outside of a plate without the need for routine removal.



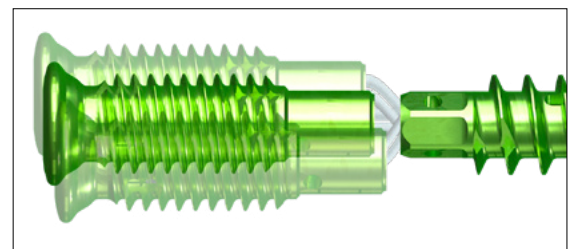
SCREW FEATURES



Dynamic state: TPU Bumper deforms to allow for diastatic motion to occur.



Dynamic state: TPU Bumper returns to original shape to bring tibial and fibular components back to original position.



Dynamic State allows range of motion with movement over time

SCREW FEATURES

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, to help prevent arthritic changes. This helps provide forgiveness of malreduction upon disengagement and is designed to allow fibular motion in multiple planes.

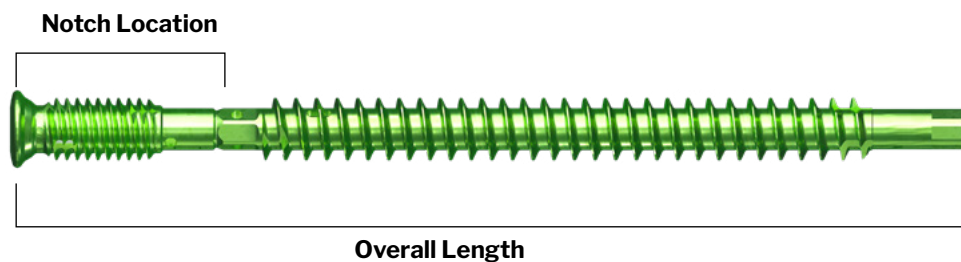
No Medial Soft Tissue Irritation — The R3ACT Implant provides for dynamic syndesmotic correction, while avoiding the need for medial button fixation on the tibia, protecting the soft tissues and neurovascular structures and avoiding a second incision.

No Bone on Suture Contact — Unique notch design engineered specifically to help protect 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 and help ensure the two components safely disengage in the tibio-fibular clear space.



SCREW SIZE: Ø4.2 mm		Overall Length									
		40 mm	42.5 mm	45 mm	47.5 mm	50 mm	52.5 mm	55 mm	57.5 mm	60 mm	62.5 mm
Notch Location	14 mm	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	17 mm			✓	✓	✓	✓	✓	✓	✓	✓

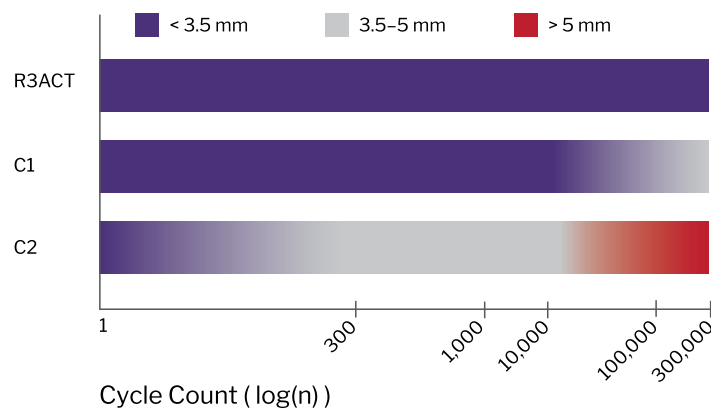
* Sizes may vary by international market. Contact your representative for available sizing options.

RESEARCH

CYCLIC TESTING

Cyclic loading data at 300,000 cycles demonstrated improved results for the R3ACT™ Stabilization System in limiting displacement versus two suture constructs at a clinically significant load.¹

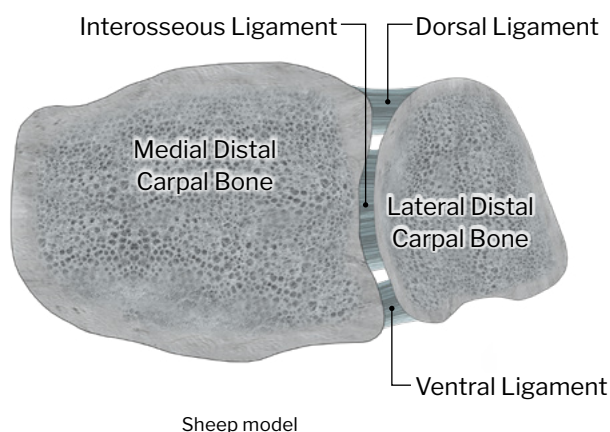
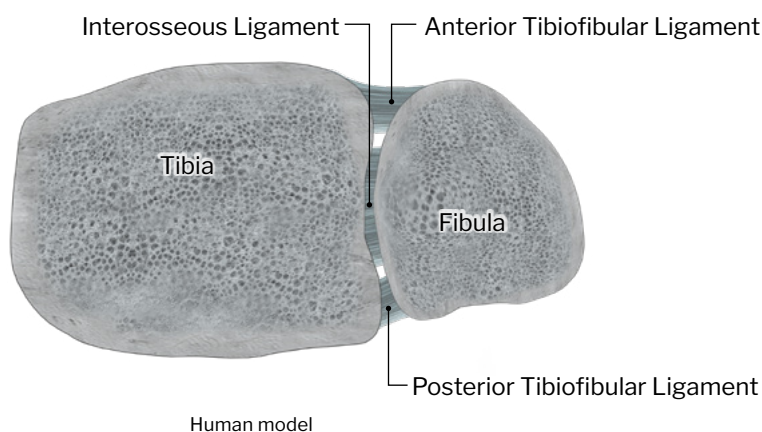
Over 300,000 cycles, R3ACT™ exhibited displacement of less than 3.5 mm (within functional range of displacement at the joint for native function) whereas both suture constructs fell outside this range.



Displacement of devices at half load during cyclic testing (range: 90–93N). Color corresponds to device displacement: 0–3.5 mm (purple), 3.5–5.0 mm (gray), 5.0 mm+ (red).

ANIMAL MODEL FOR SYNDESMOTIC RESEARCH

A large animal model (sheep) was developed to aid in the understanding of orthopedic foot and ankle research. Large animal models present relevant translation to human models by having similar bone structures, rates of healing, and metabolic rates. Additionally, large animal models provide physical sizing that is similar enough to humans to allow for testing of implants that are designed for use in humans.



In this particular study, sheep distal carpal bones were used as a model for syndesmotic ligament healing in humans. The dorsal ligament in the sheep was transected, analogous to the anterior inferior tibiofibular ligament (AITFL) being torn during a syndesmotic injury. The lateral and medial distal carpal bones of the sheep were fixed using a cannulated screw, to mimic trans-syndesmotic screw fixation in humans for a syndesmotic injury. At 6 weeks, greater than 1/2 of all animals had reconnection of the transected dorsal ligament. At 10 weeks, all but one animal had reconnection of this ligament. Histologic examination demonstrated well-organized collagen structures at the soft tissues around the dorsal carpal bones.

The authors concluded that the ability to heal the dorsal ligament in this study is analogous to healing of acute injuries of the AITFL using trans-syndesmotic screws. This healing ability helps explain why resultant widening of the syndesmosis does not occur when trans-syndesmotic screws are removed routinely in the post-operative period.

The R3ACT Stabilization System allows for initial rigidity to the syndesmosis to provide an environment for initial connection and collagen alignment of the ligament to occur, in the absence of an abundance of scar tissue. Once that primary healing has taken place, the R3ACT Screw transitions to a dynamic state that allows range of motion of this joint to occur within physiologic bounds.

*Animal studies may not be indicative of actual clinical performance

INSTRUMENTATION OFFERING



Ø2.8 mm Solid Drill



Ø3.2 mm Solid Drill with Ø2.8mm Pilot



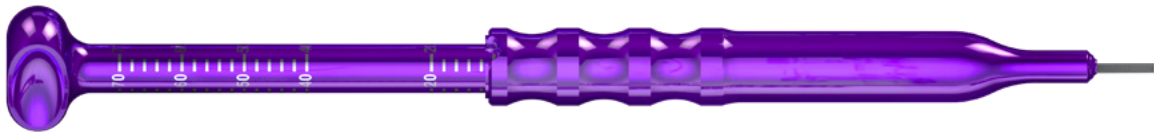
Drill Cone Guide



Pilot Nose Drill Stop Tube, 14 mm



Pilot Nose Drill Stop Tube, 17 mm



Syndesmotic Depth Gauge



Gorilla® Driver



Ø1.2 mm x 100 mm K-wire



Ø0.90 mm Drill Point K-wire



Ø4.2 mm Overdrill



4.0 Monster® Tap



Suture Release Guide Tube



Ø5.5 mm Trephine



R3ACT Removal Driver

INCISION/EXPOSURE

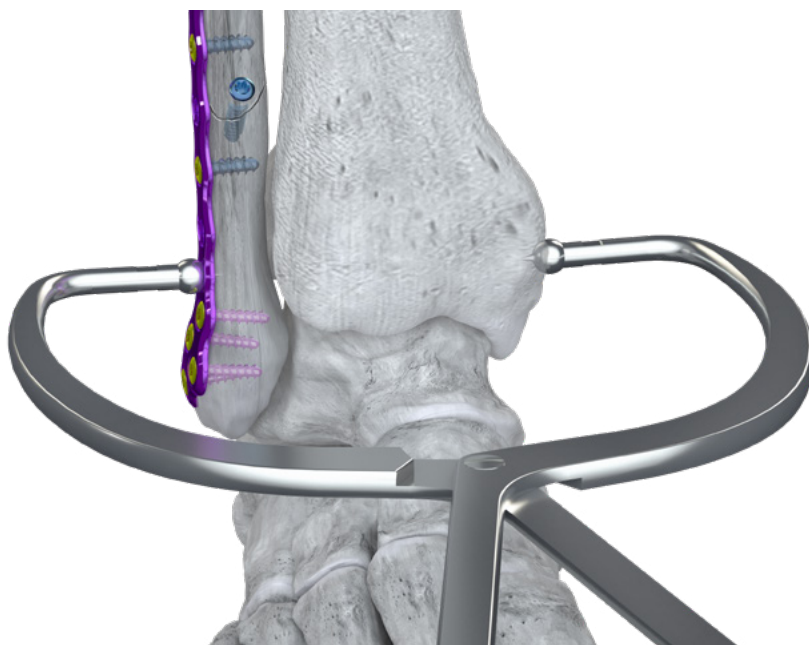
Patient is positioned supine such that the foot is near the end of the table, or in lateral decubitus, based on surgeon preference or fracture pattern. The approach to the fibula is dependent on surgeon preference for fracture pattern and anticipated plate length and location(s).

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.

NOTE: If an isolated syndesmotic injury is present, the R3ACT screw may be placed without a plate or with a washer.

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. It is imperative to properly reduce the lateral malleolus prior to placing the syndesmotic screw.

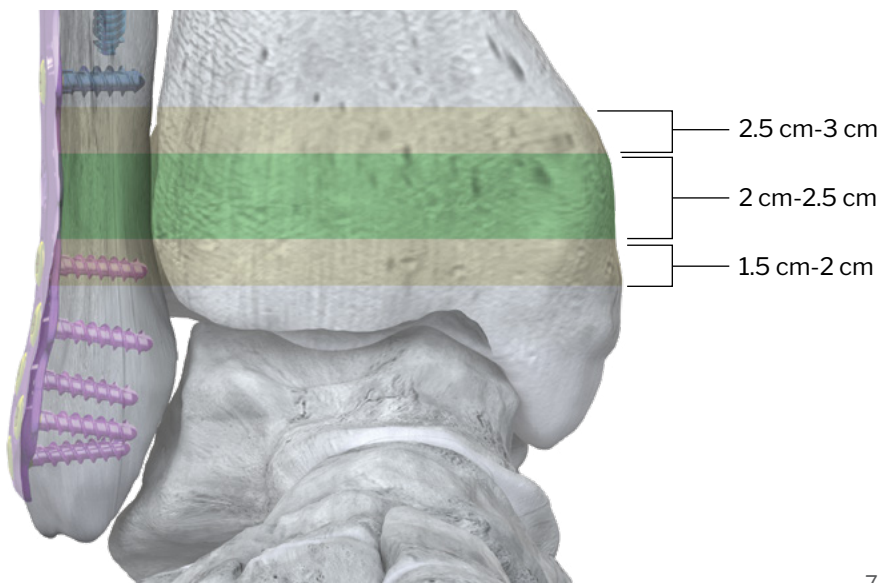
Reduction of the syndesmosis is per surgeon preference. A syndesmotic clamp can be used, if desired.



PLANNING SCREW PLACEMENT

If the R3ACT Screw is used in isolation or through a plate, principles of placement remain the same:

The R3ACT Screw should ideally be placed 2 cm-2.5 cm above the ankle joint, but may range from 1.5 cm-3 cm, depending on if two screws are used, size of patient, hole location in the plate, and the location of the fracture.

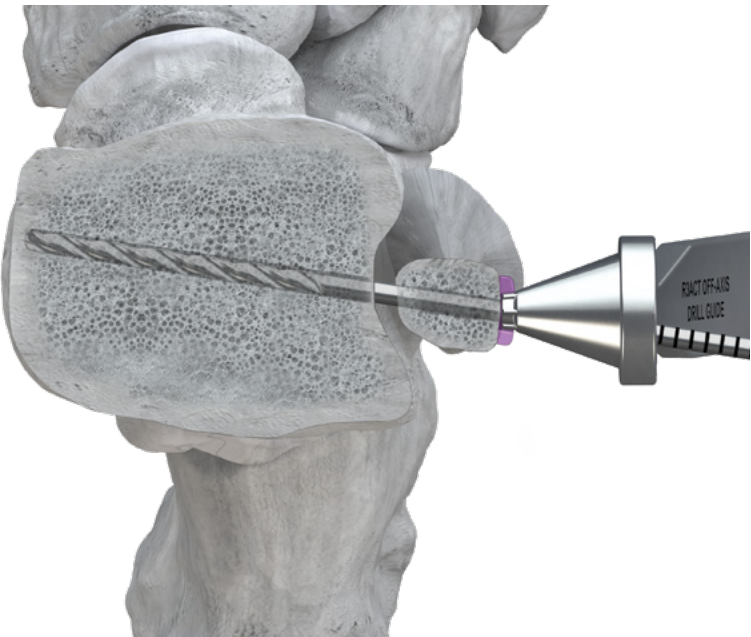
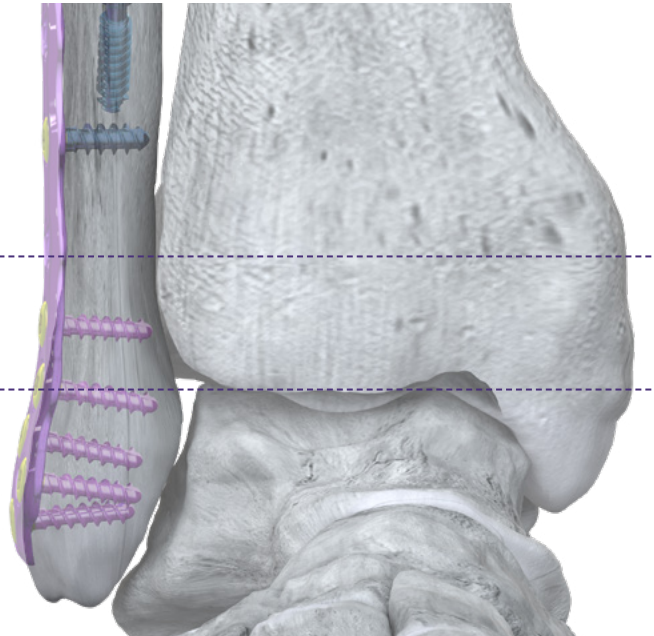


PLANNING SCREW PLACEMENT

The R3ACT Screw should be placed parallel to the ankle joint line.

Screw placement

Ankle joint



The surgeon should angle the R3ACT screw 15-20° from posterior to anterior relative to the coronal plane of the lower extremity.

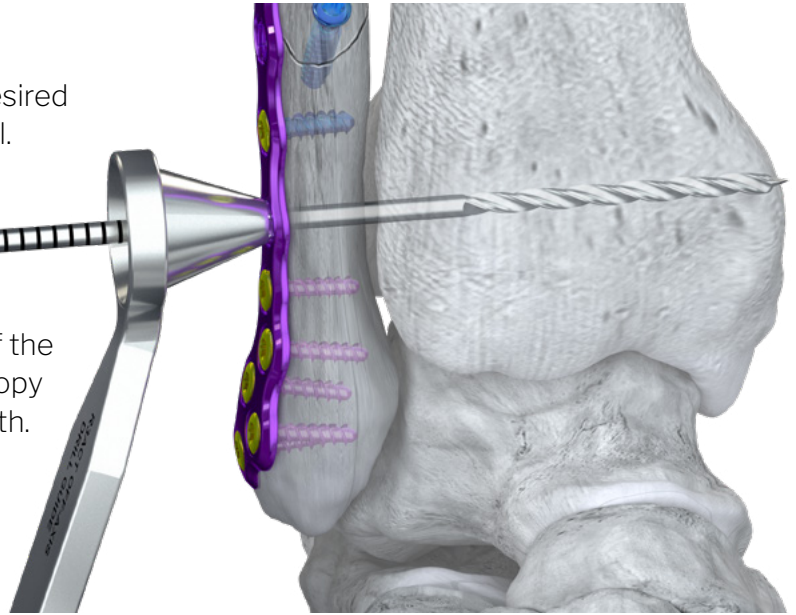
PLACEMENT OF R3ACT SCREW

Insert the Cone Guide into an empty plate hole, at the desired level for syndesmotic fixation. Retrieve the Ø2.8 mm Drill.

Drill through the Cone Guide, crossing all four cortices of the fibula and tibia. It is recommended to drill using fluoroscopy to ensure correct anticipated screw placement and length.

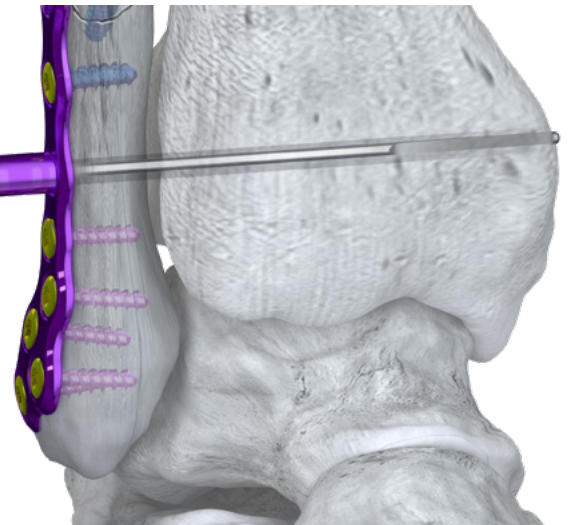
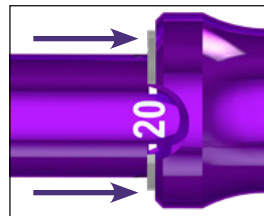


NOTE: The drill may be passed through the hole several times in hard bone to help avoid the need to tap.

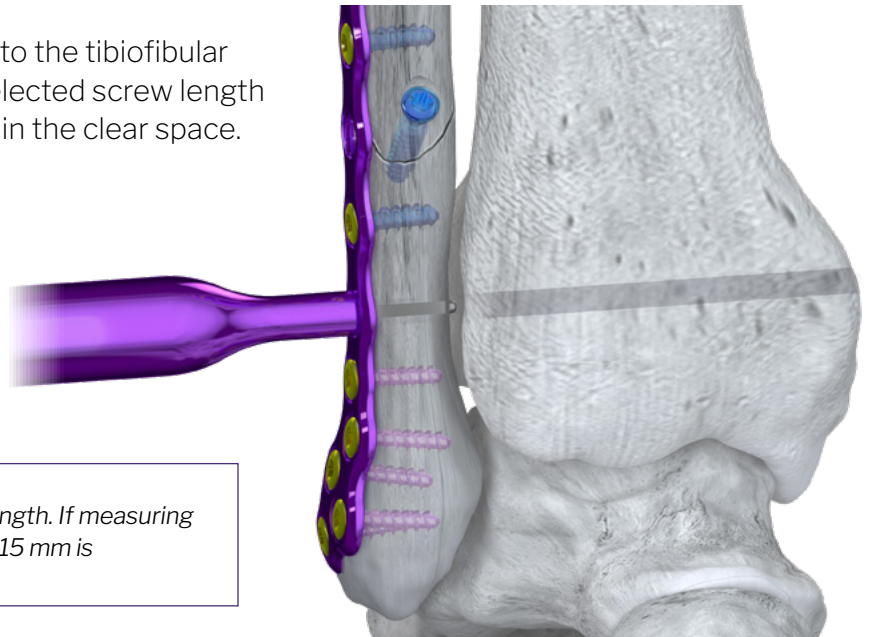


Insert the Depth Gauge and measure to the far tibial cortex for total screw length.

Measure depth from straight silver line.
The divot allows for reading the number only.



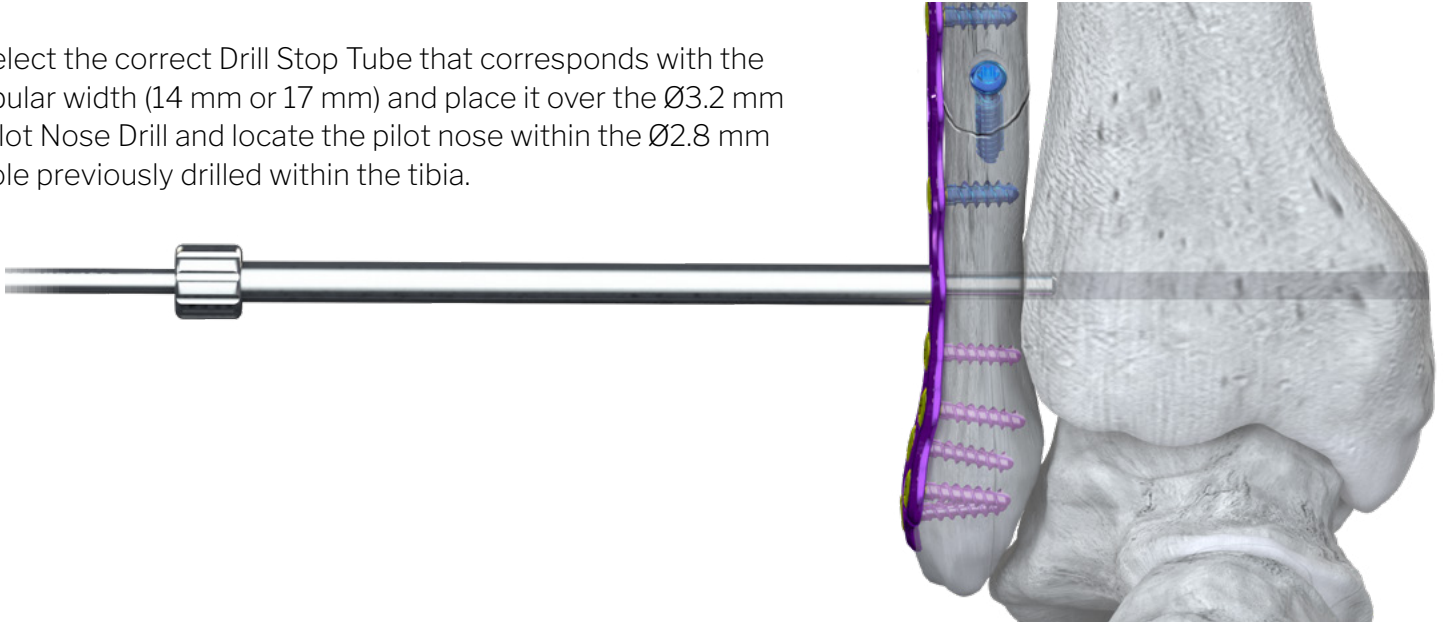
Insert the Depth Gauge and measure the distance to the tibiofibular clear space to determine notch location. Ensure selected screw length engages both cortices of the tibia and the notch is in the clear space.



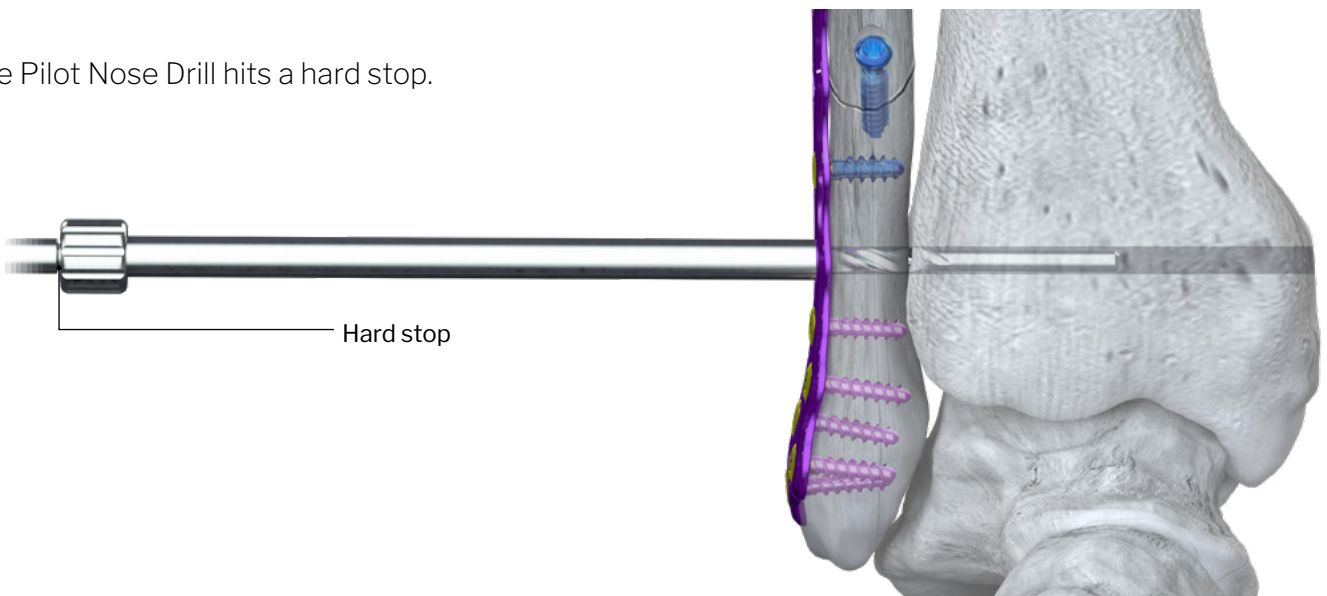
NOTE: If measuring ≤ 14 mm, use the 14 mm notch length. If measuring > 14 mm, use the 17 mm notch length. For example, if 15 mm is measured, use a 17 mm notch length.

PLACEMENT OF R3ACT SCREW

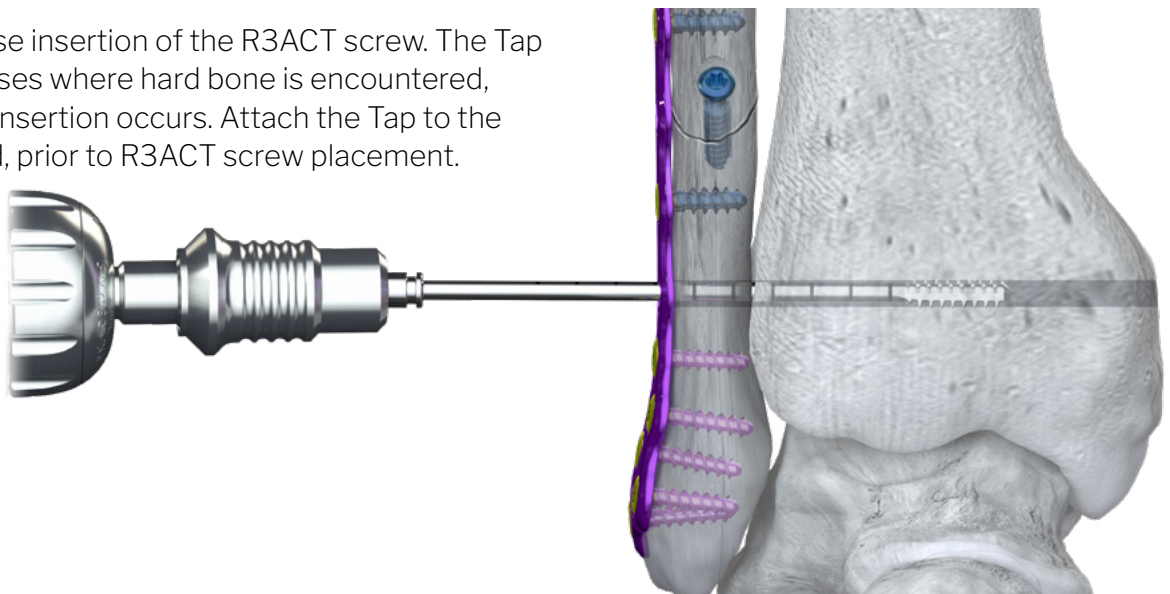
Select the correct Drill Stop Tube that corresponds with the fibular width (14 mm or 17 mm) and place it over the Ø3.2 mm Pilot Nose Drill and locate the pilot nose within the Ø2.8 mm hole previously drilled within the tibia.



Drill until the Pilot Nose Drill hits a hard stop.



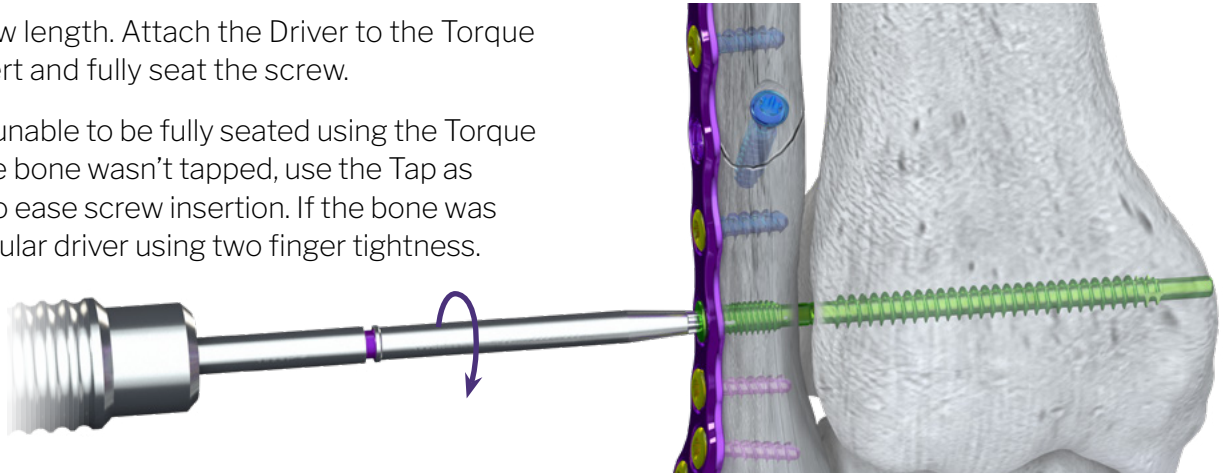
A Tap is provided to ease insertion of the R3ACT screw. The Tap should be used in all cases where hard bone is encountered, or resistance to screw insertion occurs. Attach the Tap to the Handle and tap by hand, prior to R3ACT screw placement.



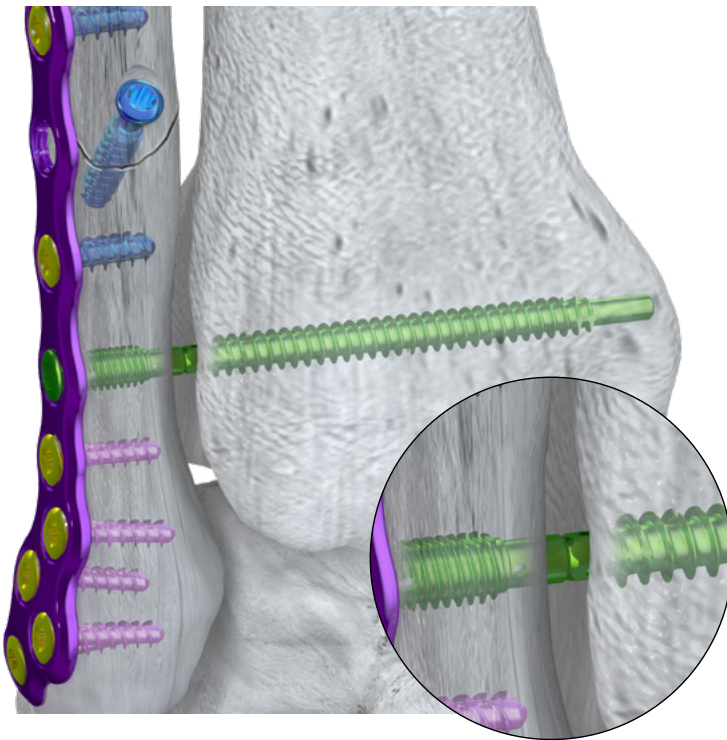
PLACEMENT OF R3ACT SCREW

Select measured screw length. Attach the Driver to the Torque Limited Handle to insert and fully seat the screw.

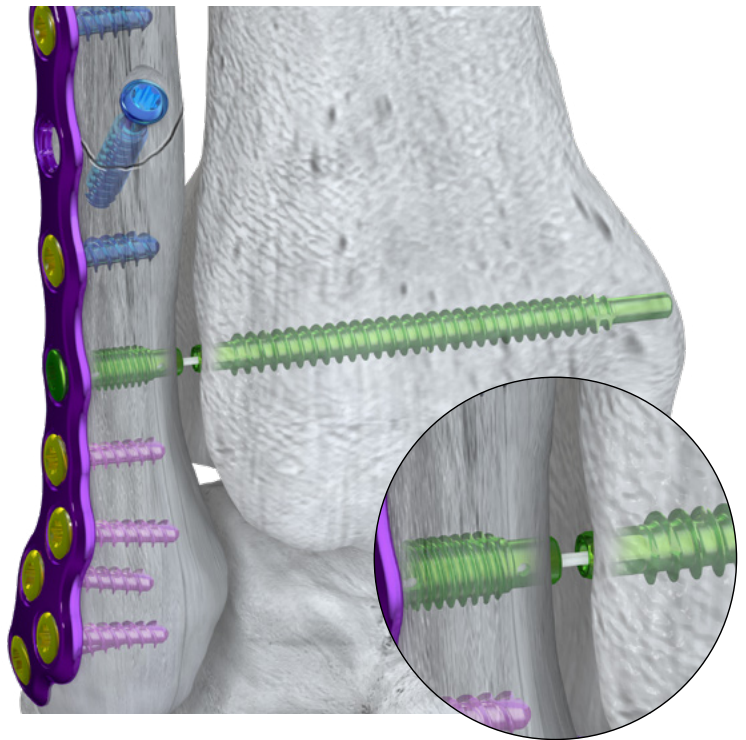
If the R3ACT screw is unable to be fully seated using the Torque Limited Handle and the bone wasn't tapped, use the Tap as previously described to ease screw insertion. If the bone was tapped, switch to a regular driver using two finger tightness.



Using fluoroscopy, check that the R3ACT Screw notch is visible in the clear space between the fibula and tibia.



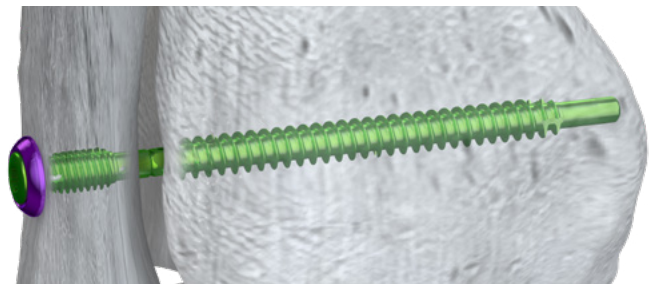
Rigid State



Dynamic State



NOTE: A Washer may be used if necessary when a R3ACT Screw is used outside of a plate. When measuring fibular length or overall length using the Depth Gauge, add 1 mm to the measured value to account for washer thickness.



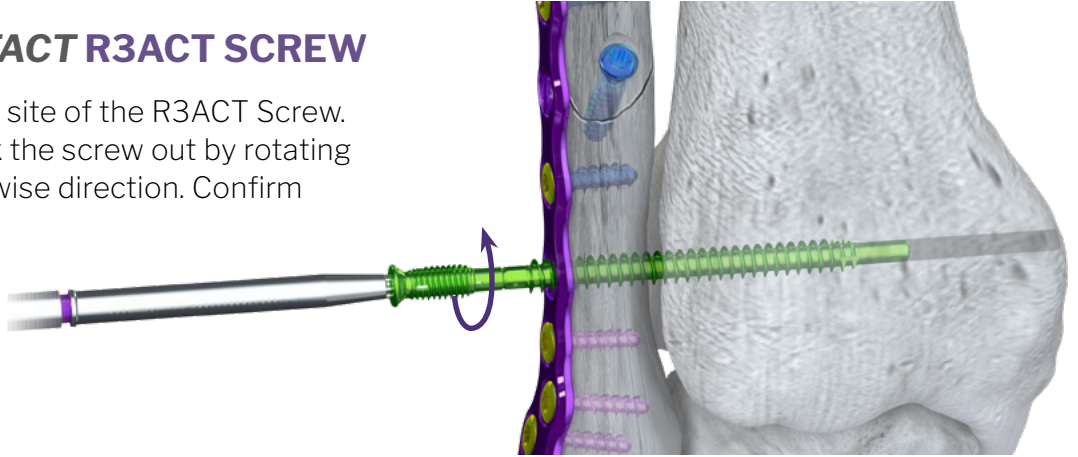
CLOSURE

Proceed to incision closure or concomitant procedures at this time.

IMPLANT REMOVAL

REMOVAL OF AN *INTACT* R3ACT SCREW

Make a lateral incision at the site of the R3ACT Screw. Using the Gorilla Driver, back the screw out by rotating the Driver in a counterclockwise direction. Confirm removal using fluoroscopy.



REMOVAL OF *DISENGAGED* R3ACT SCREW COMPONENTS:

REMOVAL OF THE FIBULAR COMPONENT:

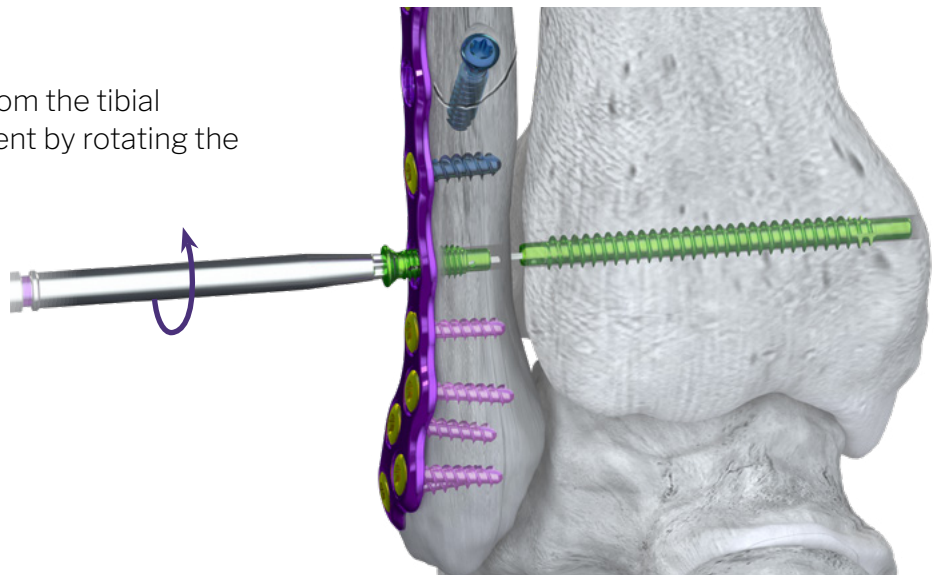
Make a lateral incision at the site of the R3ACT Screw. If the device is released at the notch, first try to remove the R3ACT Screw with the Driver to determine if both fibular and tibial components are backing out when rotating the Driver in a counterclockwise motion.

If this method is not successful, place the Lateral Suture Release K-wire Guide into the bore within the head of the R3ACT Screw. Insert the Drill Point K-wire through the K-wire Guide and into the Fibular Tensioning Post of the Screw until it stops.



Spin the Drill Point K-wire using a K-wire Driver until it frays the suture material and the fibular component is separated from the tibial component.

Upon releasing the fibular component from the tibial component, remove the fibular component by rotating the Driver in a counterclockwise fashion.



IMPLANT REMOVAL

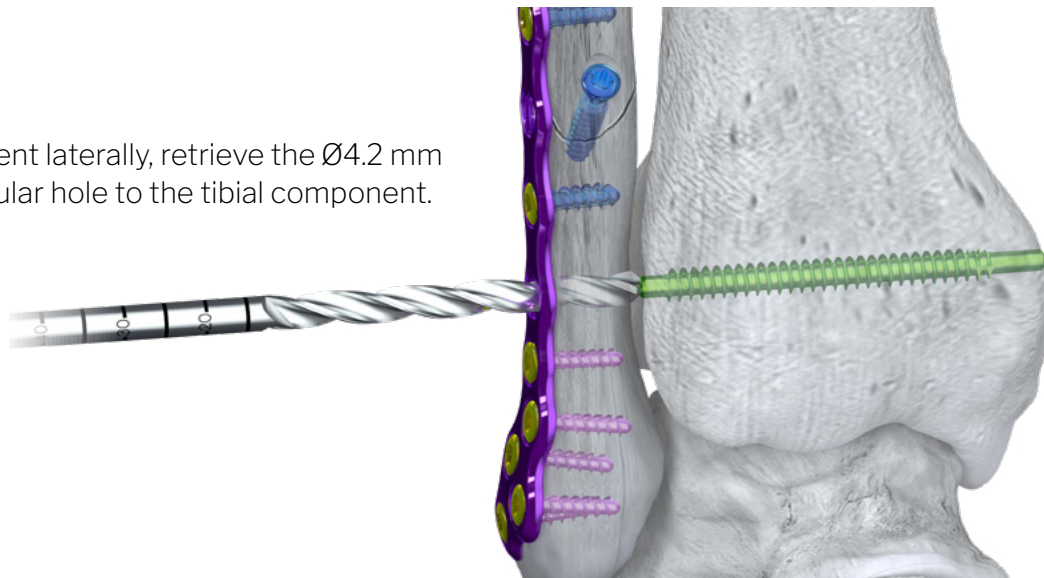
REMOVAL OF **DISENGAGED** R3ACT SCREW COMPONENTS:

REMOVAL OF THE TIBIAL SCREW COMPONENT:

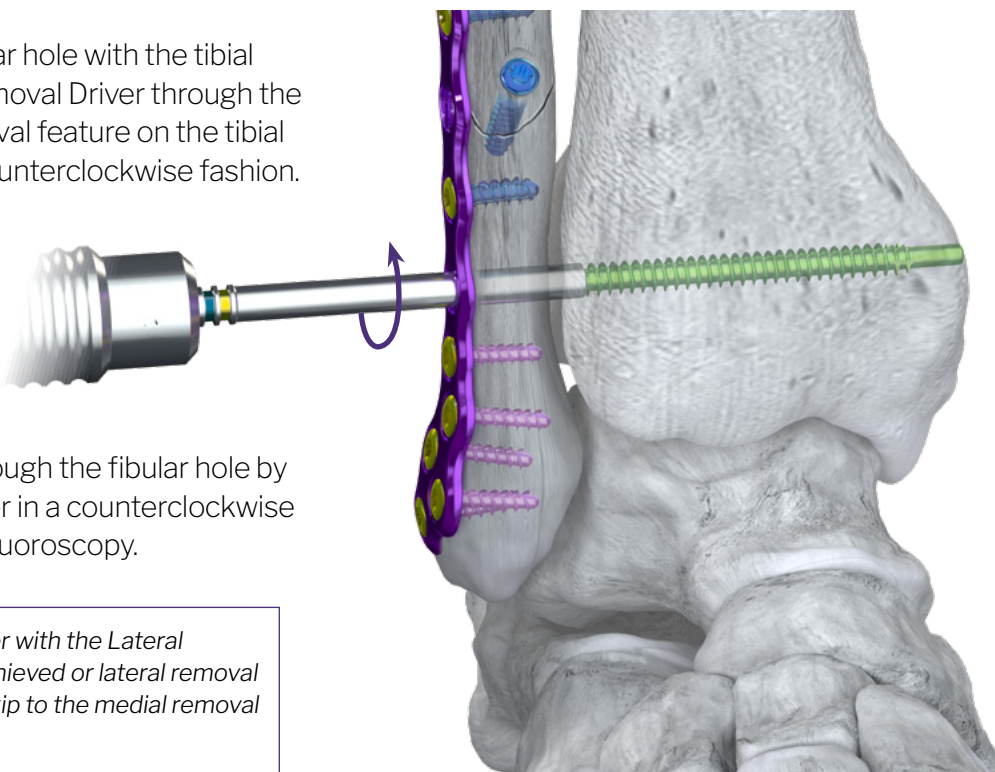
The tibial component has two removal techniques when disengaged from the fibular component:

LATERAL REMOVAL:

To remove the tibial component laterally, retrieve the Ø4.2 mm Overdrill. Drill through the fibular hole to the tibial component.



While attempting to align the fibular hole with the tibial component, insert the R3ACT Removal Driver through the fibula and engage the lateral removal feature on the tibial component. Turn the Driver in a counterclockwise fashion.



Back the tibial component out through the fibular hole by rotating the R3ACT Removal Driver in a counterclockwise direction. Confirm removal using fluoroscopy.

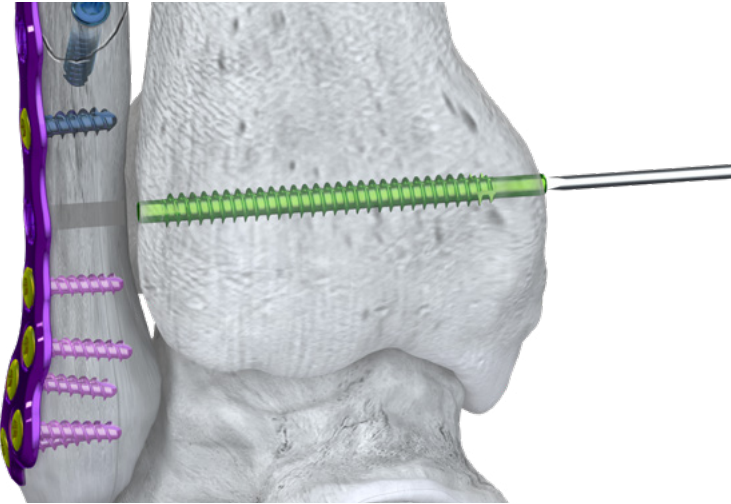


NOTE: If alignment of the Driver with the Lateral Removal Feature cannot be achieved or lateral removal proves difficult/not possible, skip to the medial removal technique on page 14.

IMPLANT REMOVAL

REMOVAL OF SEPARATED R3ACT SCREW COMPONENTS:

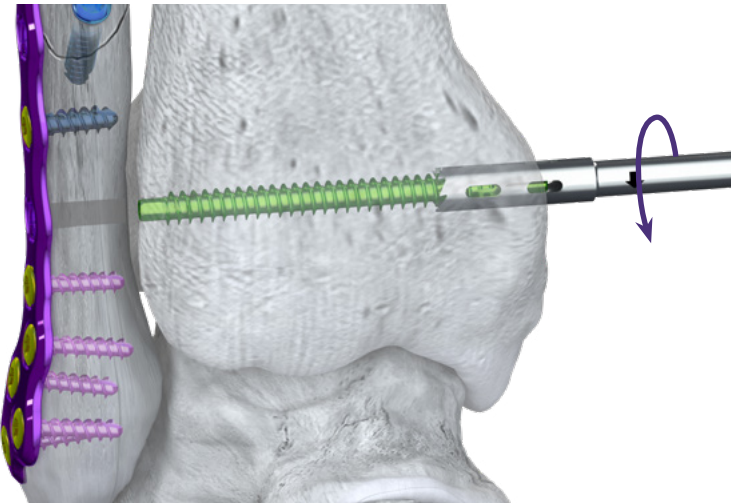
MEDIAL REMOVAL:



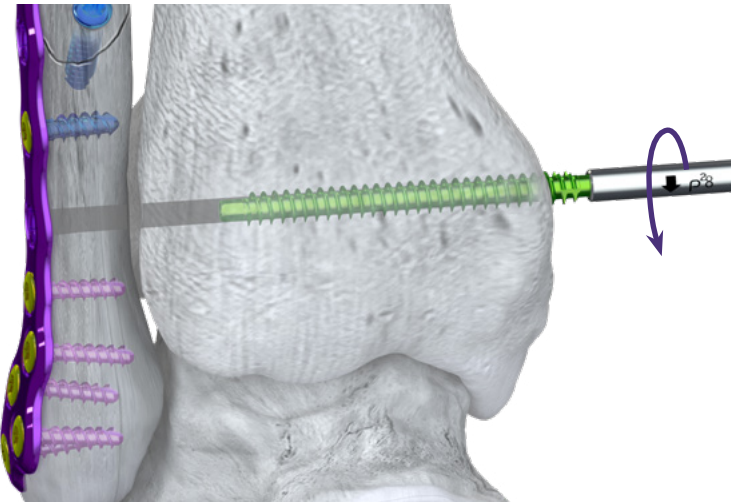
Retrieve the Removal Trephine. The Trephine is cannulated and can be used with a Ø1.2 mm K-wire to help guide orientation of the Trephine with respect to screw position. Use fluoroscopy to insert the Ø1.2 mm K-wire at the medial location of the screw. Make an incision and bluntly dissect to bone.



NOTE: Alternatively, the Trephine can be used without use of a Ø1.2 mm K-wire.



Insert the Trephine and cut in reverse approximately 5 mm past the screw tip to expose the medial removal feature.



Retrieve the R3ACT Removal Driver. Using the R3ACT Removal Driver, engage the medial removal feature and back the tibial component out by rotating the medial removal feature in a counterclockwise direction. Confirm removal using fluoroscopy.

R3ACT™ AND GORILLA® SYSTEM CADDY

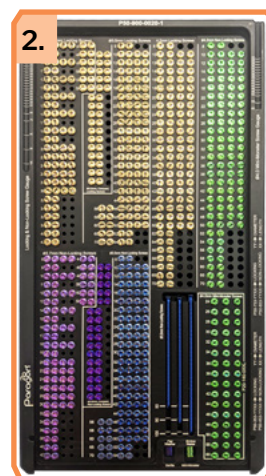


R3ACT™ SCREW CADDY

1. The Gorilla® R3ACT™ Non-Sterile Instrument Stabilization System Caddy contains Solid Drills, Solid Drills with Pilot Nose, Depth Gauge, Drill Cone Guide, Pilot Nose Drill Stop Tubes, Gorilla R3CON Drivers, Torque Limiting Handle, K-wires, Removal Driver, Trephine, and Gorilla Washers. It contains all instruments required to facilitate insertion and removal of the sterile-packaged R3ACT implant.

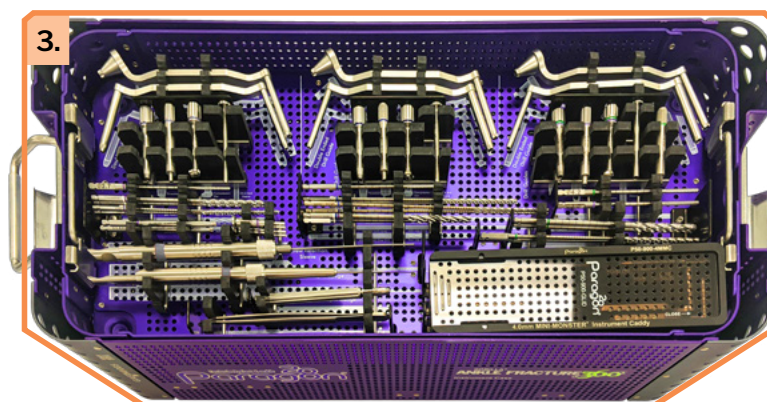
2. ANKLE FRACTURE 360™ SCREW CADDY

The Ankle Fracture 360™ Screw Caddy accommodates Ø2.7 mm, Ø3.5 mm and Ø4.2 mm R3CON Locking and Non-locking Screws. As well as Gorilla R3CON Ø3.5 mm Compact Locking and Non-locking screws and Ø4.0 mm Mini Monster Screws.



3. GORILLA® ANKLE FRACTURE 360™ INSTRUMENT TRAYS

Drills, Drill guides, Centering Guides, Taps, Drivers, Plate Bending instrumentation, K-wires, Olive Wires, Handles and Ø4.0 Mini Monster instrumentation.



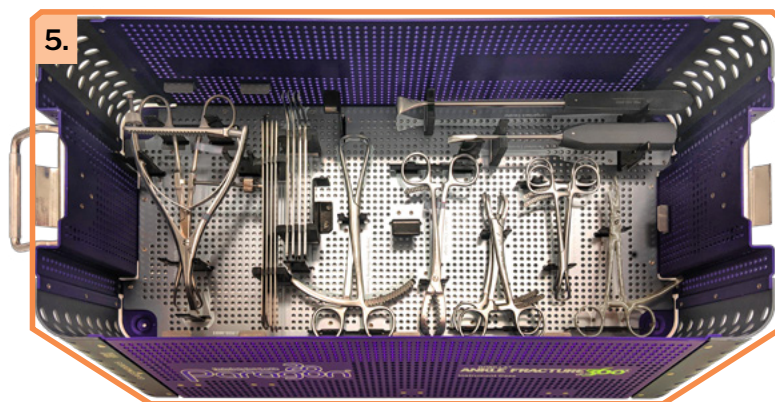
4. ADDITIONAL GORILLA® CADDIES

The Ankle Fracture 360™ Implant Case has room for additional Gorilla® Plate Caddies that may be needed for additional procedures performed in addition to an Ankle Fracture.



5. ANKLE FRACTURE 360™ INSTRUMENT CASE

Reduction clamps, joint preparation instrumentation and retractors are located at the bottom of the Ankle Fracture 360 Instrument Case Base.



R3ACT™ STABILIZATION SYSTEM - IMPLANTS

Part #	Description	Use
P40-142-14[40-62]-S	R3ACT Stabilization System Implant, Ø4.2 X 40-62mm, 14mm Notch, Ti-6Al-4V ELI, Sterile	Single-use
P40-142-17[45-62]-S	R3ACT Stabilization System Implant, Ø4.2 X 40-62mm, 17mm Notch, Ti-6Al-4V ELI, Sterile	Single-use

*2.5mm increments

R3ACT STABILIZATION SYSTEM - INSTRUMENTS

Part #	Description	Use
P80-900-2814	Ø2.8mm Solid Drill	Reusable
P80-930-2800	Ø2.8mm Drill Cone Guide	Reusable
P80-950-0080	Syndesmosis Depth Gauge	Reusable
P80-900-32PN	Ø3.2mm Solid Drill with Ø2.8mm Pilot Nose	Reusable
P80-930-32PN-14	Pilot Nose Drill Stop Tube, 14mm Depth	Reusable
P80-930-32PN-17	Pilot Nose Drill Stop Tube, 17mm Depth	Reusable
P99-191-TR10	Gorilla R3CON Driver, Solid, HX10X68MM, SS	Reusable
P99-000-TQ08	Torque Limiting Handle, 8 in.-lb., petite	Reusable
P80-940-3903	R3ACT Suture Release Guide Tube	Reusable
P99-307-0910	Ø0.90mm Drill Point K-Wire	Single-use
P80-940-3904	R3ACT Removal Driver	Reusable
P80-960-5500	Ø5.5mm OD Breakaway Trephine	Single-use
P99-100-4212	Ø4.2mm OD, 12cm Length, Solid Drill	Reusable
P99-192-1210	Ø1.2mm x 100mm K-wire	Single-use
P50-153-WS00	Gorilla Washer Standard	Single-use
P20-920-4000	Ø4.0mm Single Lead Tap	Reusable

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

R3ACT™ AND GORILLA® MR INFORMATION

Indications, Contraindications, Warnings and Precautions relevant to the R3ACT Stabilization System are contained in the Instructions for Use document of the R3ACT™ Stabilization System P80-IFU-0001.

MR SAFETY INFORMATION

The R3ACT™ Stabilization 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 R3ACT™ Stabilization System in the MR environment is unknown. MR scanning of a patient who has this device may result in patient injury.

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

R3ACT™

STABILIZATION SYSTEM

Shown with use of the:



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References:

1. Data on file at Paragon 28®, internal testing.

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