# R3ACT™
## STABILIZATION SYSTEM

GORILLA®
R3CON PLATING SYSTEM

# SURGICAL TECHNIQUE GUIDE

Ankle Fracture with Syndesmotic Repair

Exclusively foot & ankle
Paragon 28®

**ACKNOWLEDGMENTS:**

Paragon 28® would like to thank Lewis Freed, DPM; Lauren Geaney, MD; John Y. Kwon, MD; and Christopher Zingas, MD for their contribution to the development of the R3ACT™ Stabilization System.

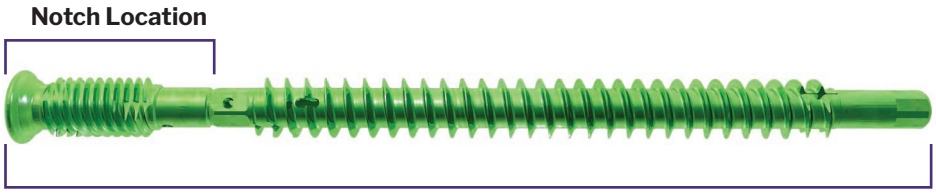
# PRODUCT DESCRIPTION

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 rigid to support the native ligaments through the crucial early stages of primary healing.

Shortly after weight-bearing, the outer tibial and fibular components safely disengage in the clear space, where an internal suture-loop and TPU Bumper combine to allow of 3mm of diastatic allowance and mal-reduction forgiveness.

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




| SCREW SIZE: Ø4.2 mm | | Overall Length | | | | |
|---|---|---|---|---|---|---|
| | | 40 mm | 45 mm | 50 mm | 55 mm | 60 mm |
| Notch Location | 14 mm | ✓ | ✓ | ✓ | ✓ | ✓ |
| | 17 mm | | ✓ | ✓ | ✓ | ✓ |

• **MULTI-STAGE SOFT TISSUE HEALING ----***Initial rigid fixation provides stability for primary healing, then ultimately disengages to allow for controlled physiologic motion.*

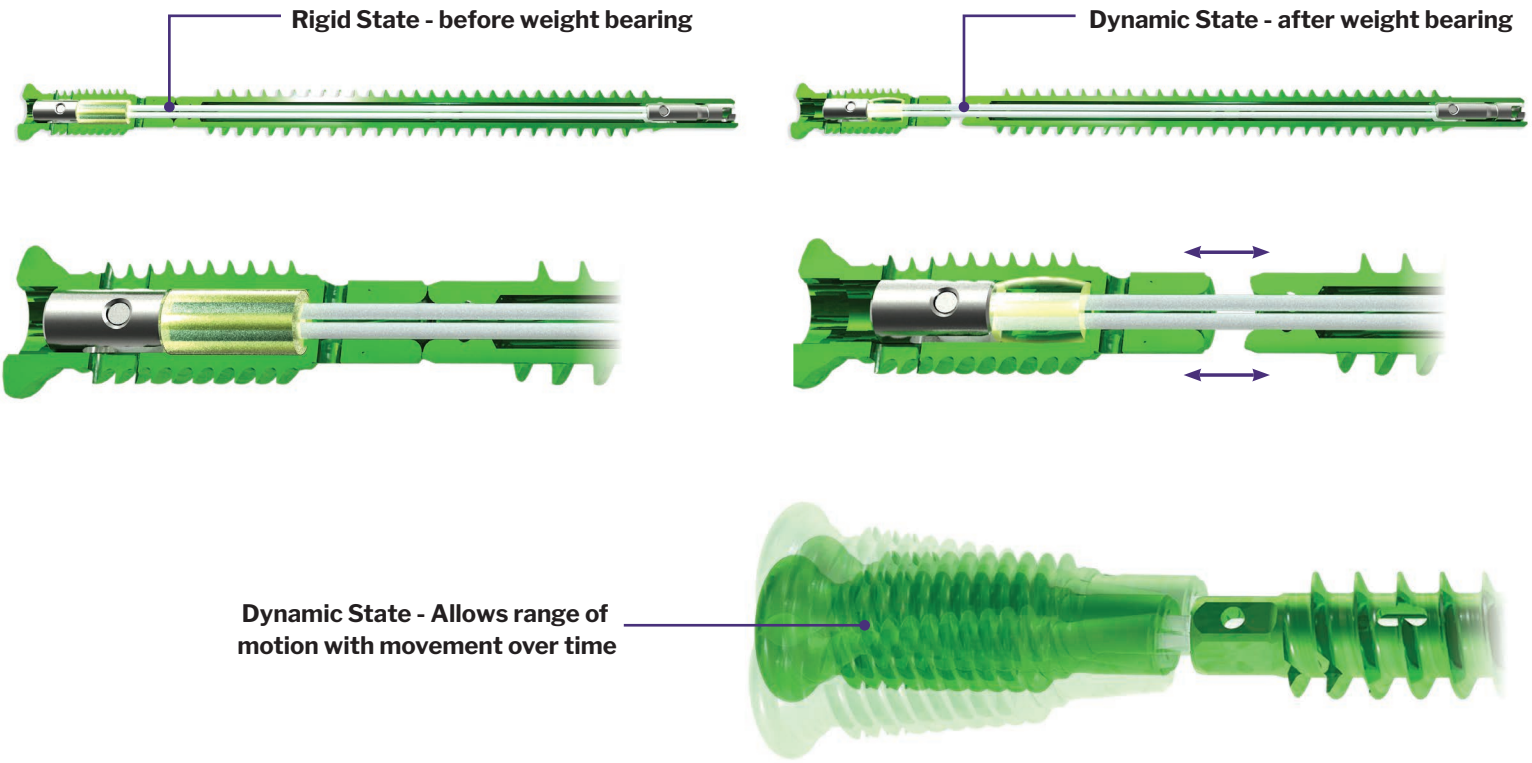
• **CONTROLLED DIASTATIC MOTION** ----*A TPU bumper and suture-loop combine to help control motion and relieve pressure on the lateral gutter by providing up to 3 mm of movement in diastasis.*

• **NO BONE ON SUTURE CONTACT** ----*Unique notch design engineered specifically to protect suture and bone.*

• **MAL-REDUCTION FORGIVENESS** ----*Pre-tensioned suture and TPU Bumper are designed to provide mal-reduction correction upon disengagement, and designed to allow fibular motion in multiple planes.*

• **NOTCH LENGTHS** ----*14 mm and 17 mm notch lengths accommodate a variety of patient anatomy to help ensure the two components safely disengage in the tibio-fibular clear space.*

## SCREW FEATURES




## INSTRUMENTATION OFFERING

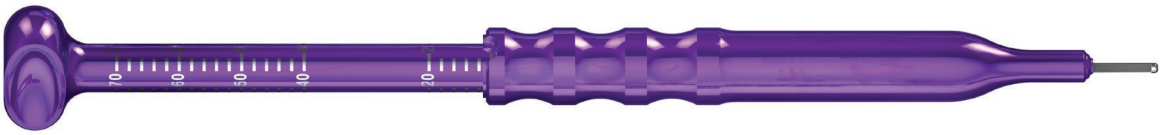

Ø2.8 mm Solid Drill


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

# ADDITIONAL REMOVAL CADDY INSTRUMENTATION


Ø1.2 mm x 100 mm K-wire


Ø0.90 mm Drill Point K-wire


Ø4.2 mm Overdrill


4.0 Monster® Tap

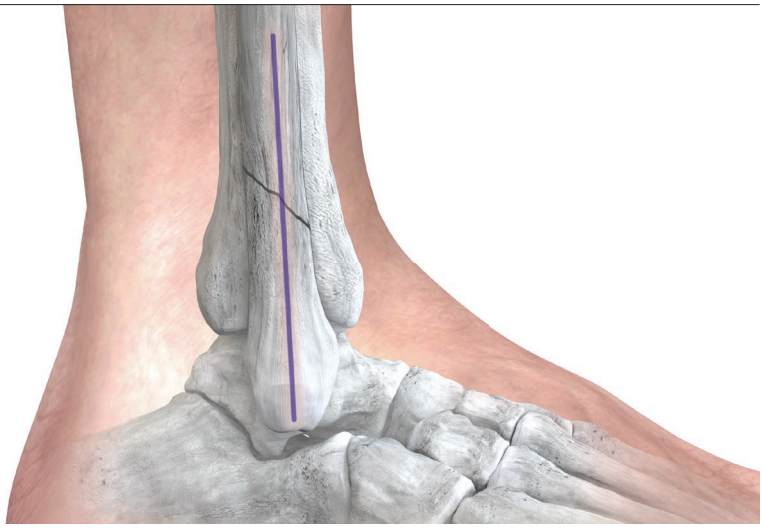

Suture Release Guide Tube


Ø5.5 mm Trephine


R3ACT Removal Driver

# INCISION/EXPOSURE

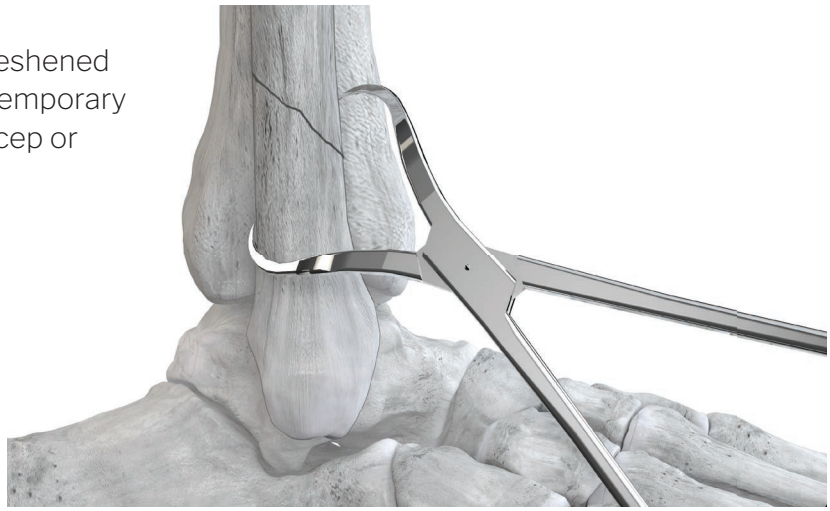
Patient is positioned supine such that the foot is near the end of the table, or in lateral decubitus, based on surgeon preference or fracture extent. A longitudinal incision is made over the central aspect of the fibula, appropriately sized for the fracture pattern and anticipated plate length. Continue soft tissue dissection until the fracture site is visible.



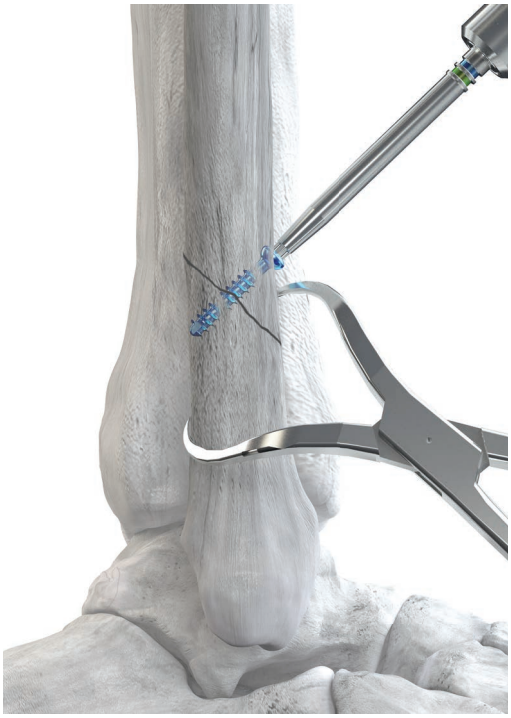
***NOTE:*** *If an isolated syndesmotic injury is present, the R3ACT screw may be placed without a plate or with a washer. Proceed to page 6 of this surgical technique guide for instructions on R3ACT screw placement.*

# FRACTURE REDUCTION AND TEMPORARY FIXATION

The fracture site is cleared and the fracture edges freshened up, as needed. Fracture reduction is performed and temporary stabilization is achieved using a K-wire, reduction forcep or lobster claw clamp, per surgeon preference.

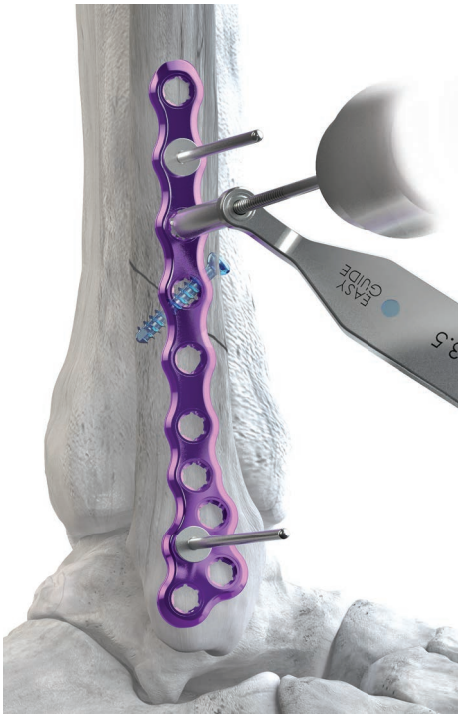


# PERMANENT FIXATION

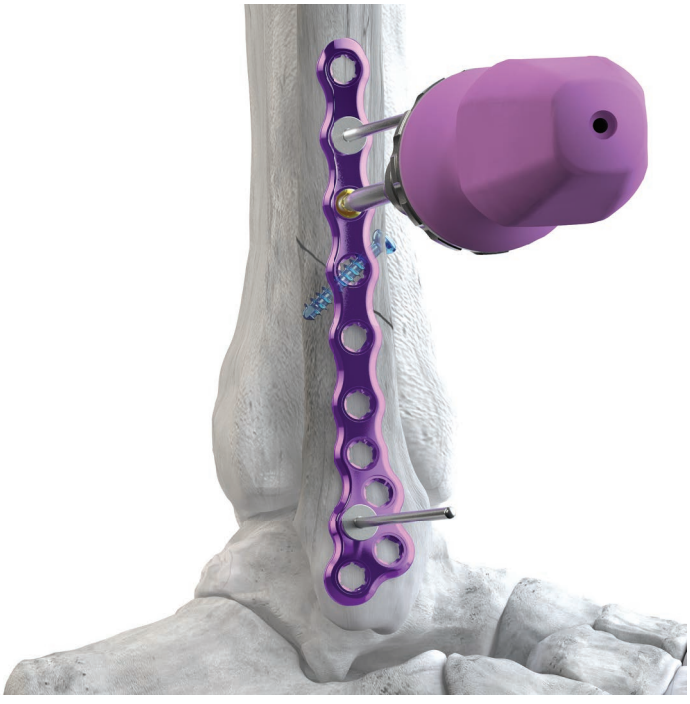


If lag screw fixation is desired across the fracture site, a lag screw can be placed perpendicular to the fracture. In this example, a Ø3.5 mm fully threaded Mini-Monster® Solid Screw is placed using lag screw technique.

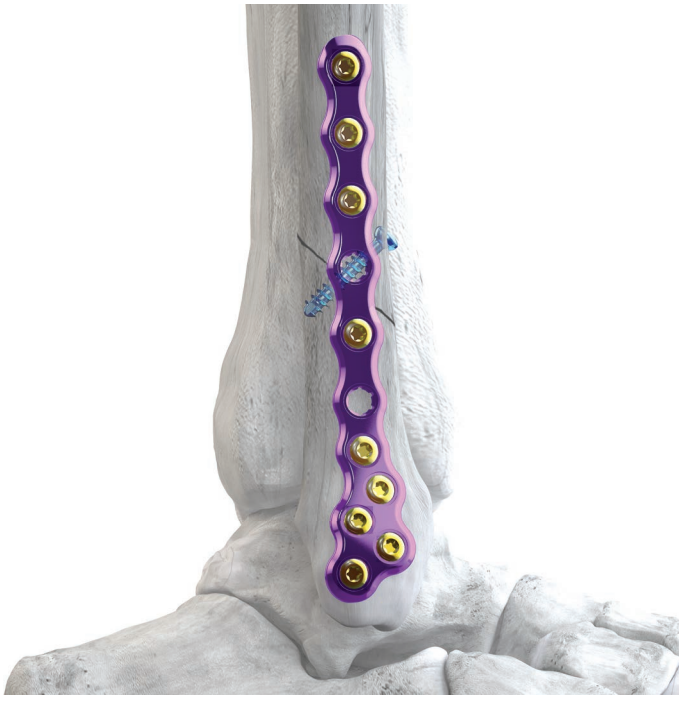
Select the appropriate length plate for stable fixation of the particular fracture type and location. In this example, a Gorilla 10 Hole Straight Fibular Plate is used. Olive wires can be used to secure the plate to bone.




All plate holes accept Ø2.7 mm, Ø3.5 mm, or Ø4.2 mm locking or non-locking screws. Drill through the Drill Guide using the Drill sized for the desired screw diameter. Remove the Drill Guide.



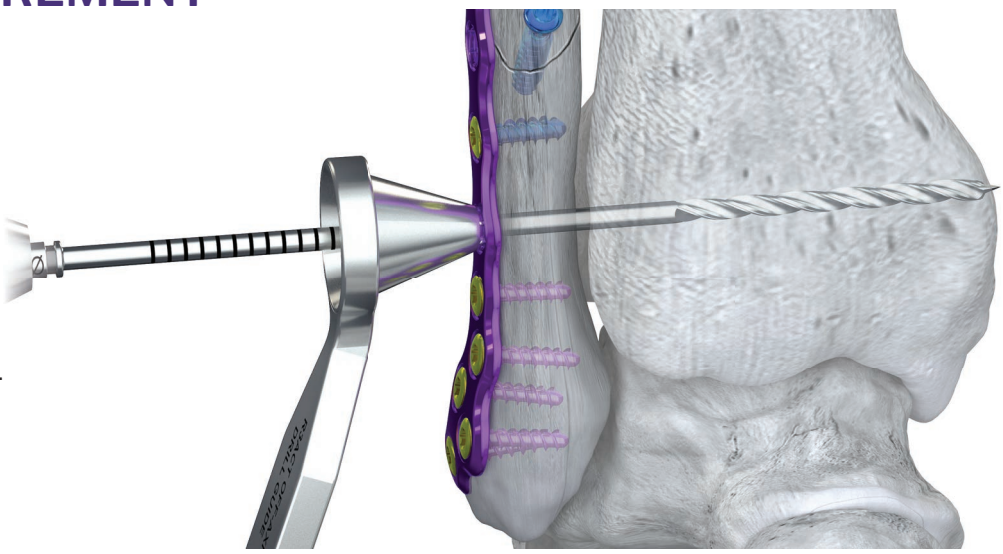
Measure screw length using a Depth Gauge. Insert the selected screw into the drilled hole in the fibula.



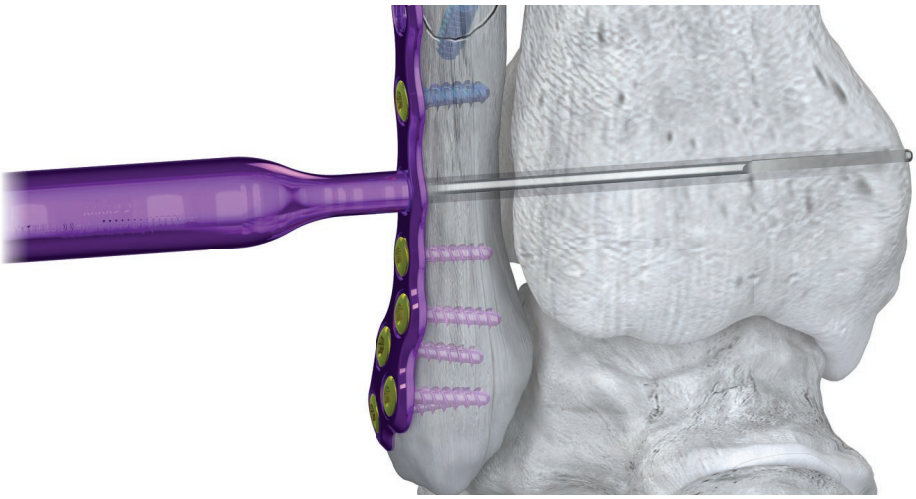
Fill desired plate holes with selected screw sizes, leaving one to two screw holes empty for potential syndesmotic fixation. Confirm plate and screw placement using fluoroscopy.

# DRILLING AND MEASUREMENT

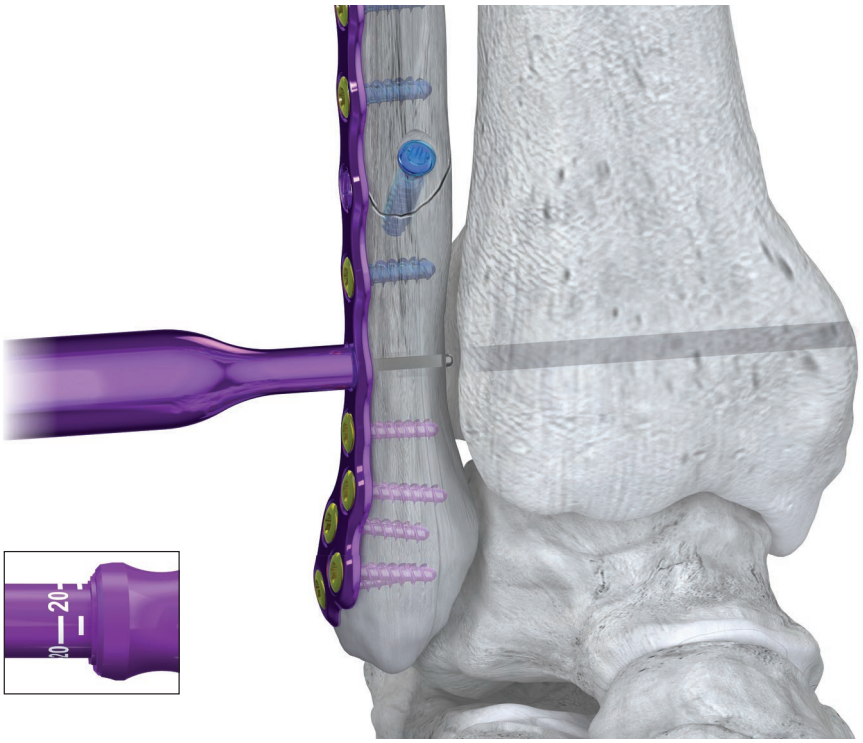
Insert the Cone Guide into an empty plate hole, at the desired level for syndesmotic fixation. Retrieve the Ø2.8 mm Drill. Drill through the Cone Guide, crossing all four cortices of the fibula and tibia. It is recommended to drill using fluoroscopy to ensure correct anticipated screw placement and length.



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



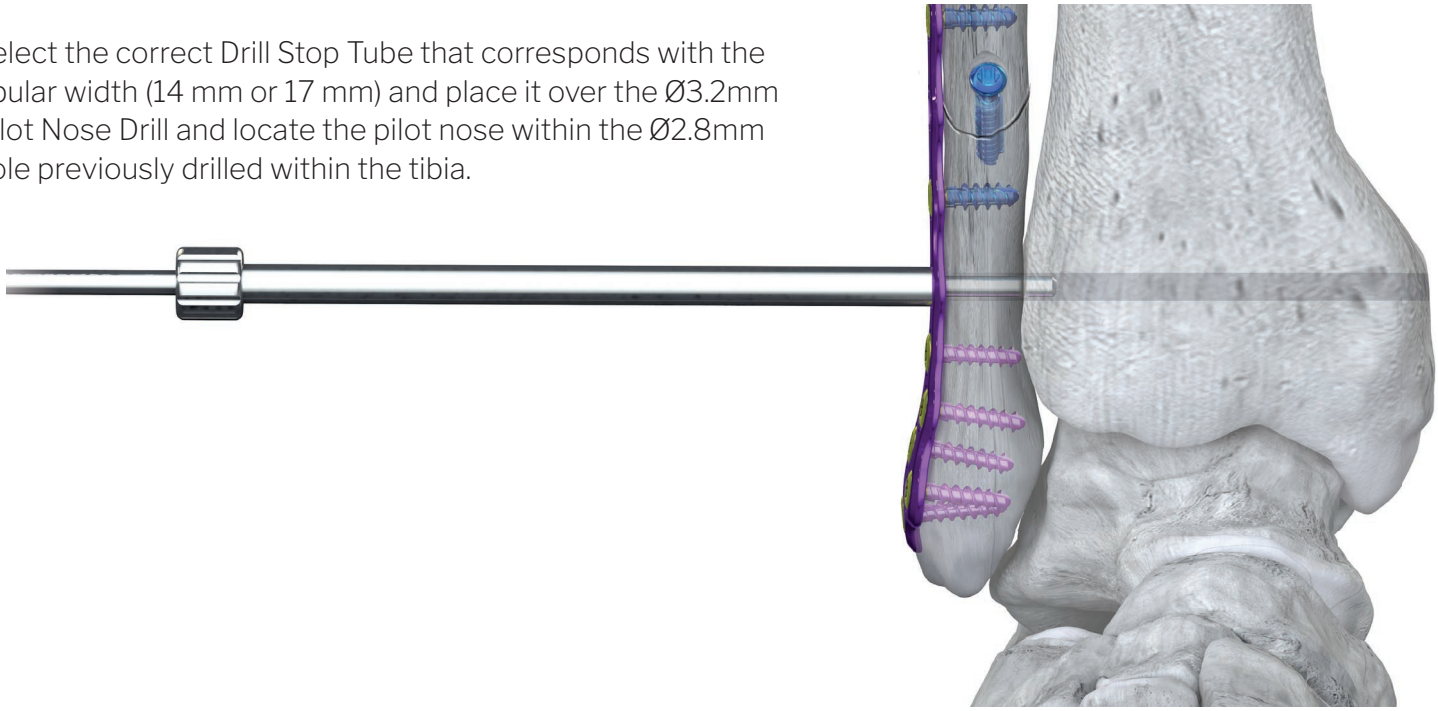
Insert the Depth Gauge and measure the distance to the tibiofibular clear space to determine notch location.



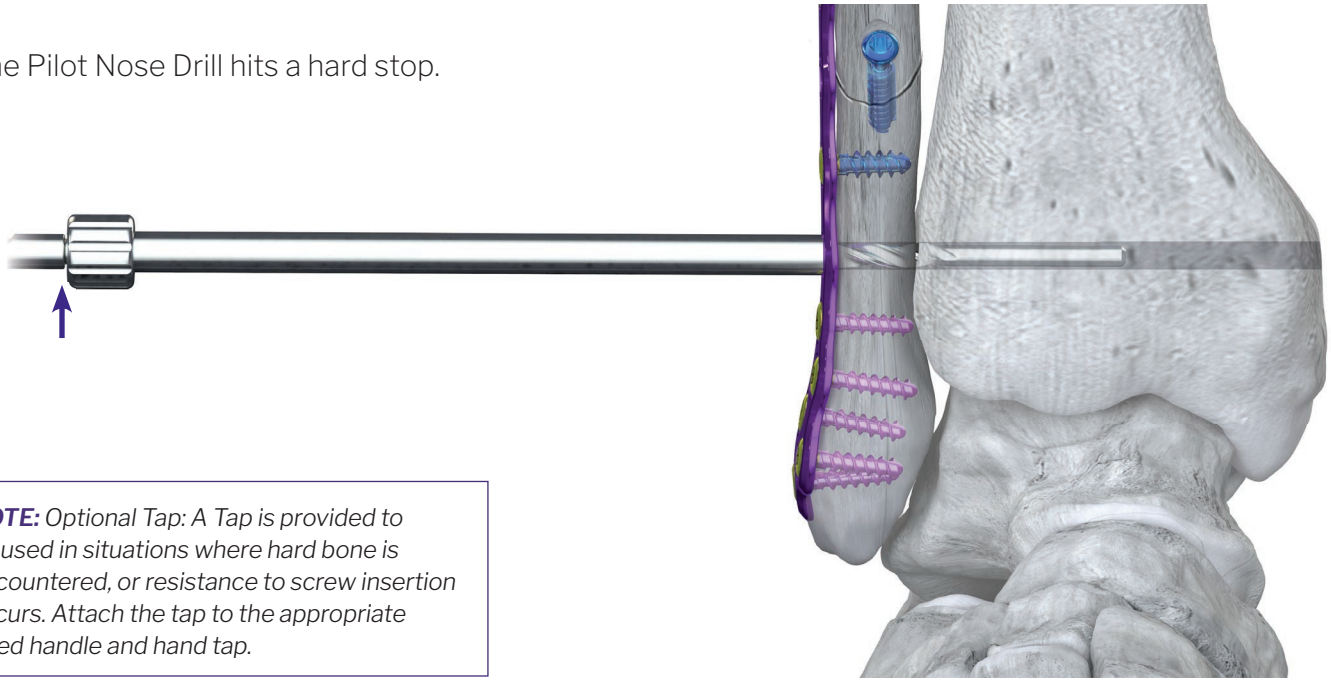
***NOTE:*** *If measuring ≤ 14 mm, use the 14 mm notch length. If measuring > 14 mm, use the 17 mm notch length.*

# DRILLING AND MEASUREMENT

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



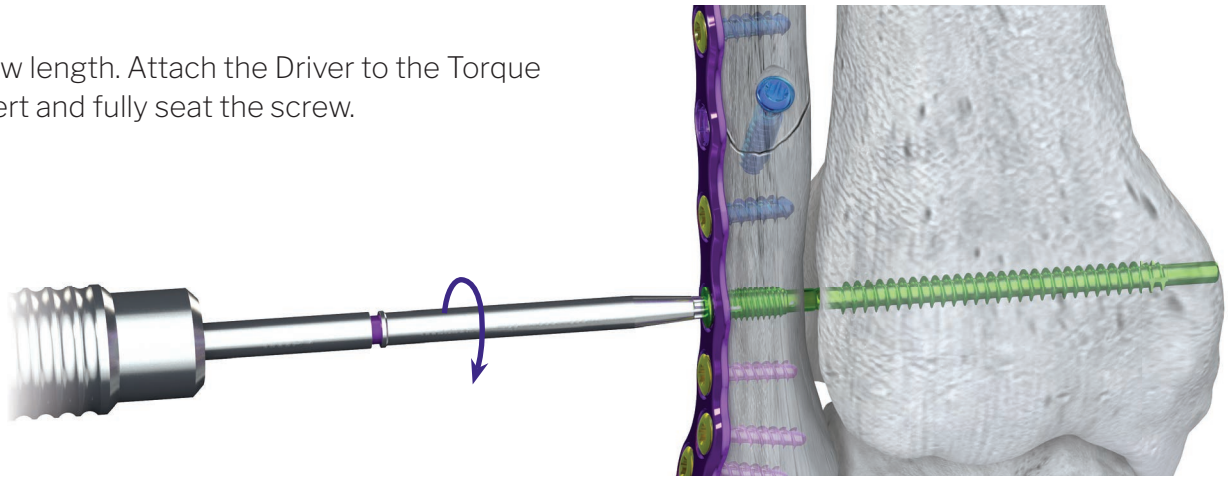
Drill until the Pilot Nose Drill hits a hard stop.



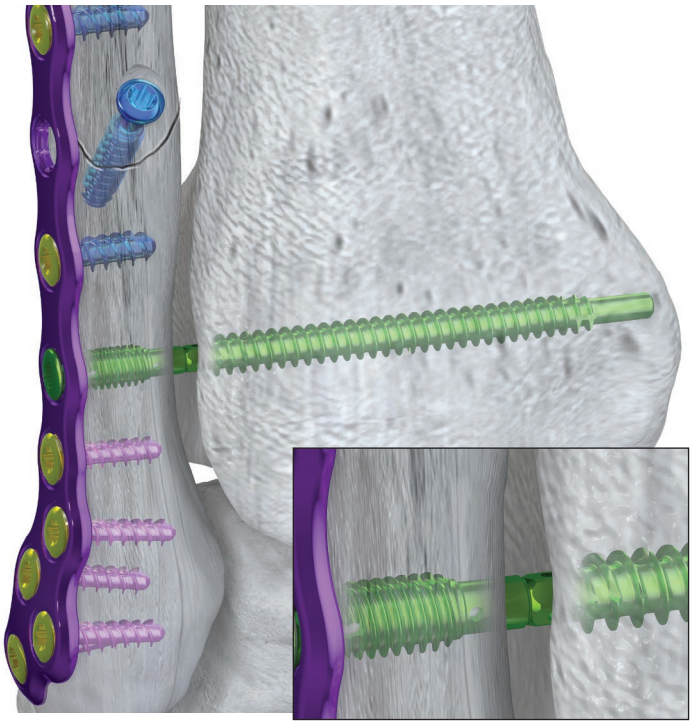
***NOTE:*** *Optional Tap: A Tap is provided to be used in situations where hard bone is encountered, or resistance to screw insertion occurs. Attach the tap to the appropriate sized handle and hand tap.*

# FIBULA DRILLING AND SCREW INSERTION

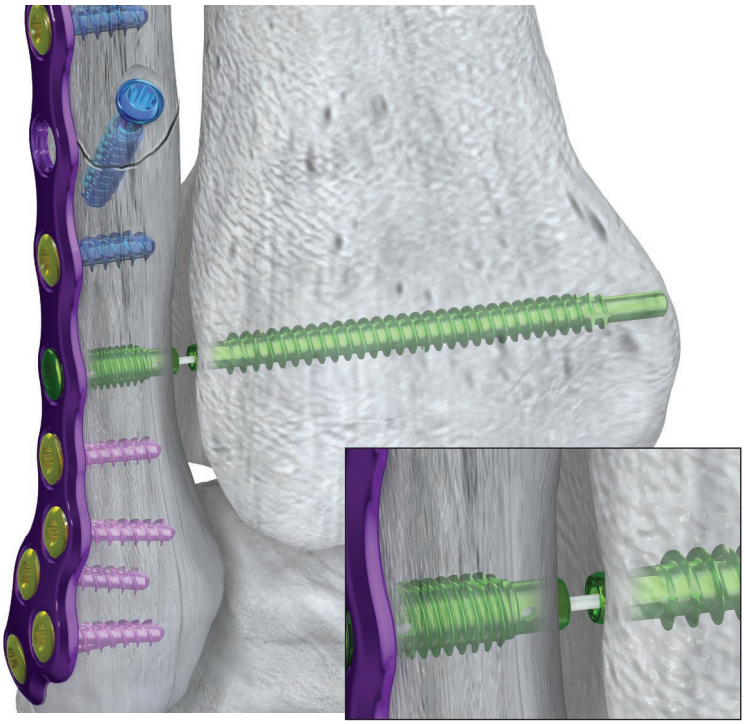
Select measured screw length. Attach the Driver to the Torque Limited Handle to insert and fully seat the screw.



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

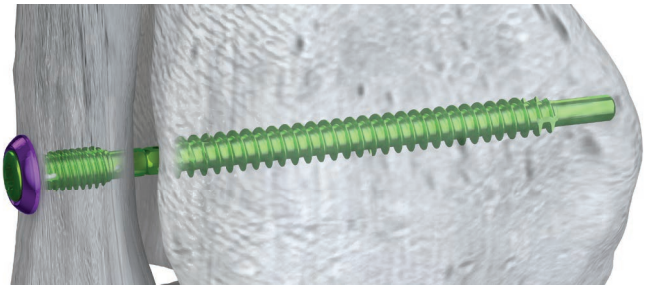


Rigid State



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.*



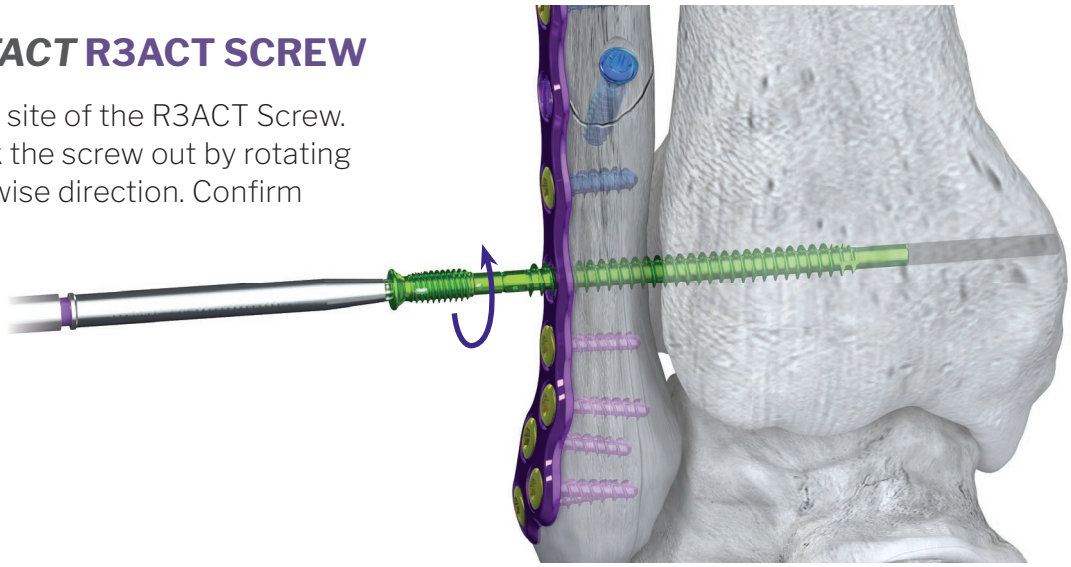
# CLOSURE

Proceed to incision closure or concomitant procedures at this time.

# IMPLANT REMOVAL

## REMOVAL OF AN *INTACT* R3ACT SCREW

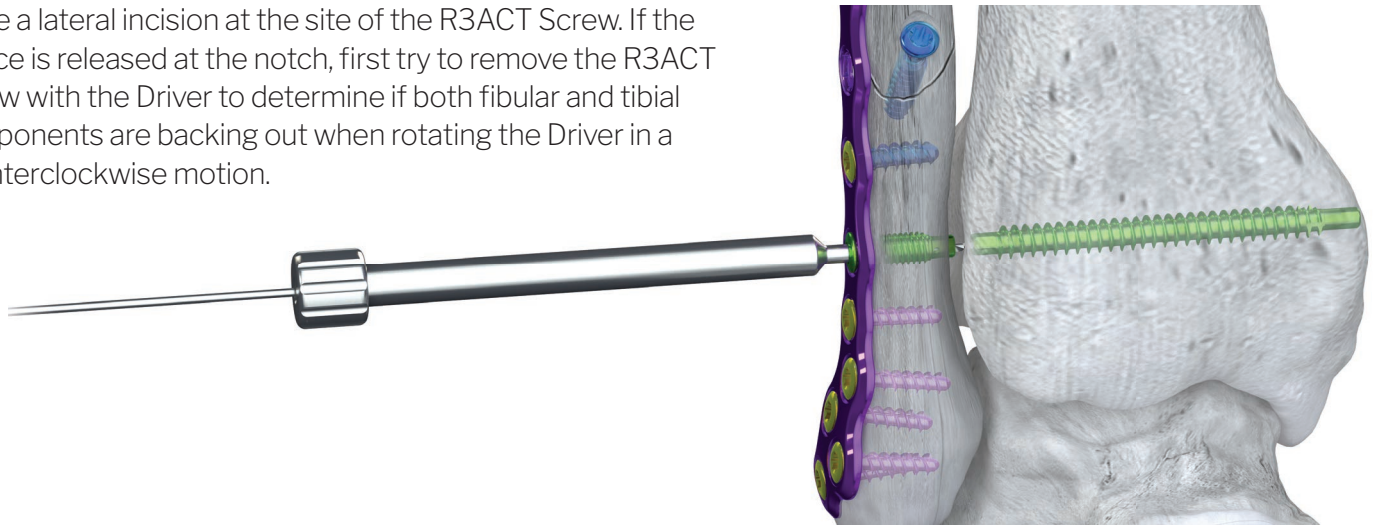
Make a lateral incision at the site of the R3ACT Screw. Using the Gorilla Driver, back the screw out by rotating the Driver in a counterclockwise direction. Confirm removal using fluoroscopy.



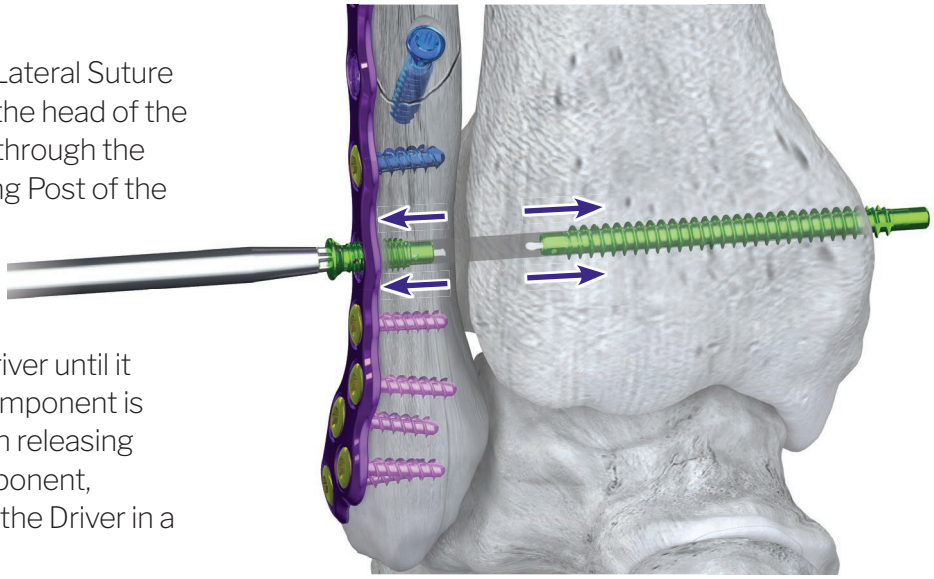
## REMOVAL OF *DISENGAGED* R3ACT SCREW COMPONENTS:

### 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

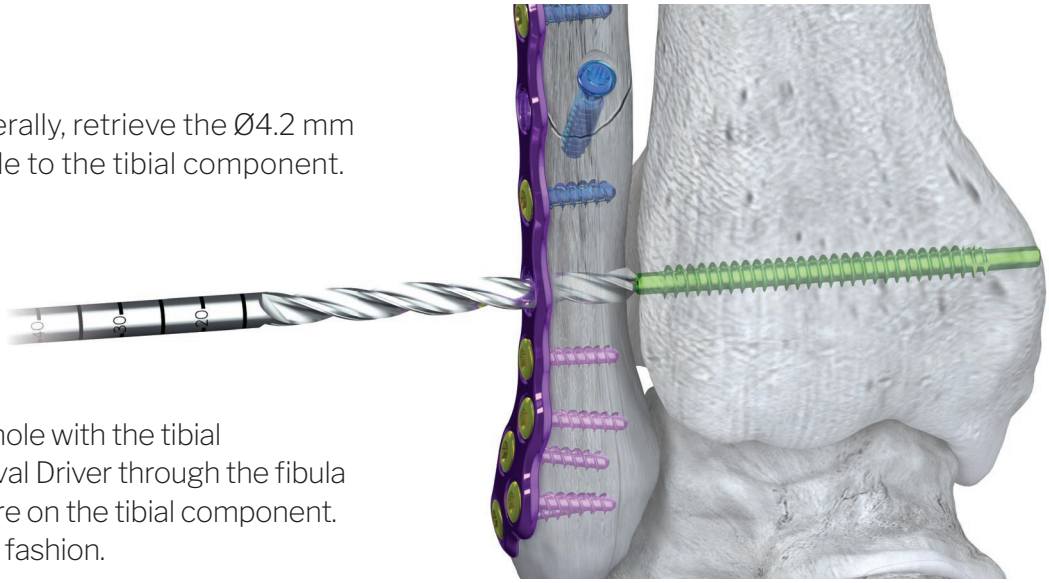
## REMOVAL OF *DISENGAGED* R3ACT SCREW COMPONENTS:

### REMOVAL OF THE TIBIAL SCREW COMPONENT:

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

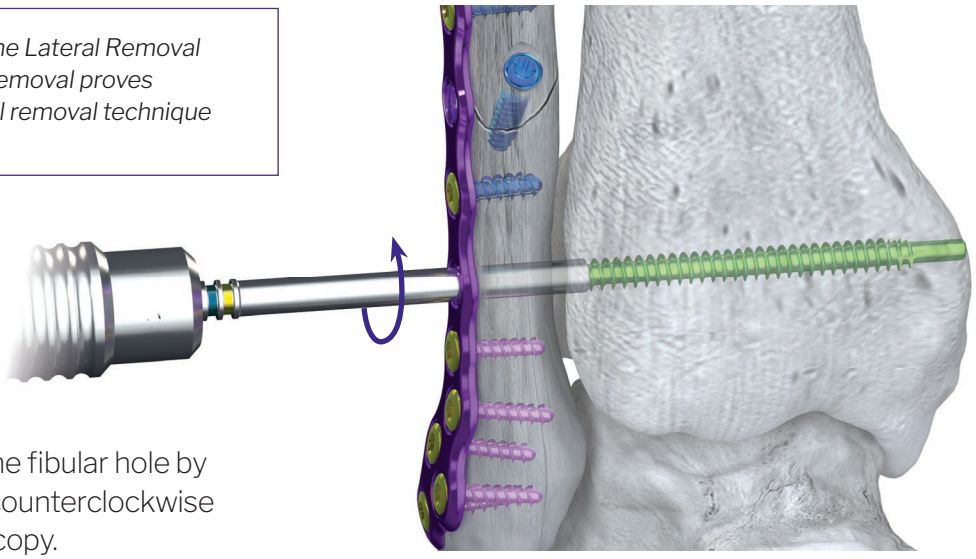
#### LATERAL REMOVAL:

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.

> ***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 9.*

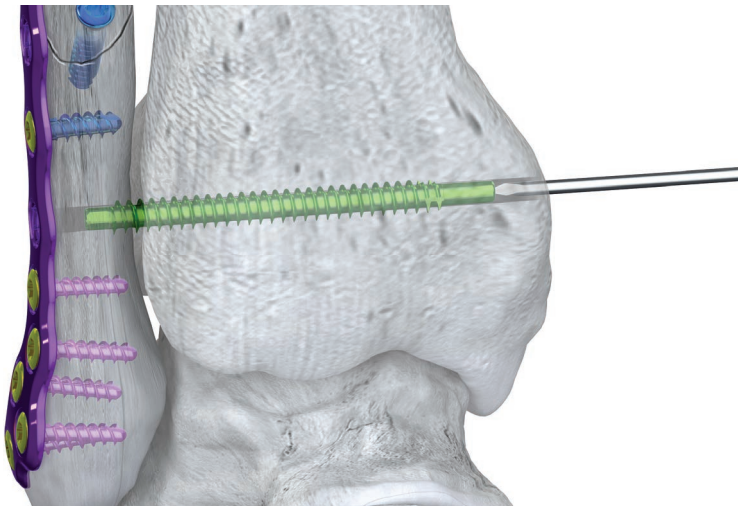


Back the tibial component out through the fibular hole by rotating the R3ACT Removal Driver in a counterclockwise direction. Confirm removal using fluoroscopy.

# IMPLANT REMOVAL

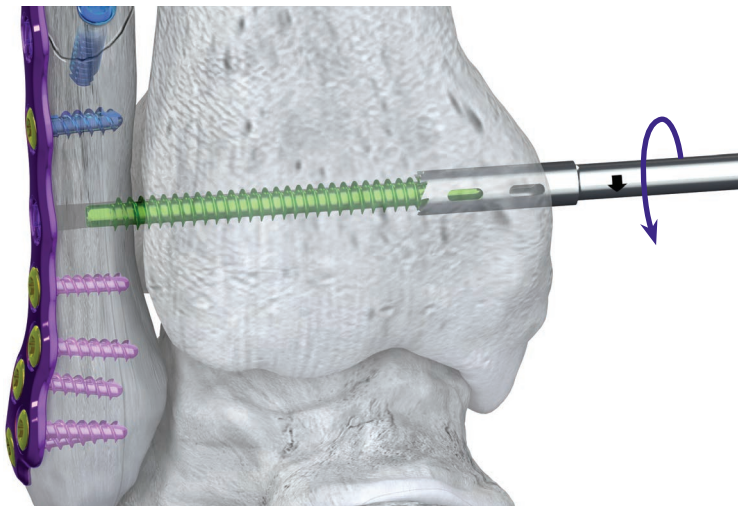
## REMOVAL OF SEPARATED R3ACT SCREW COMPONENTS:

### MEDIAL REMOVAL:

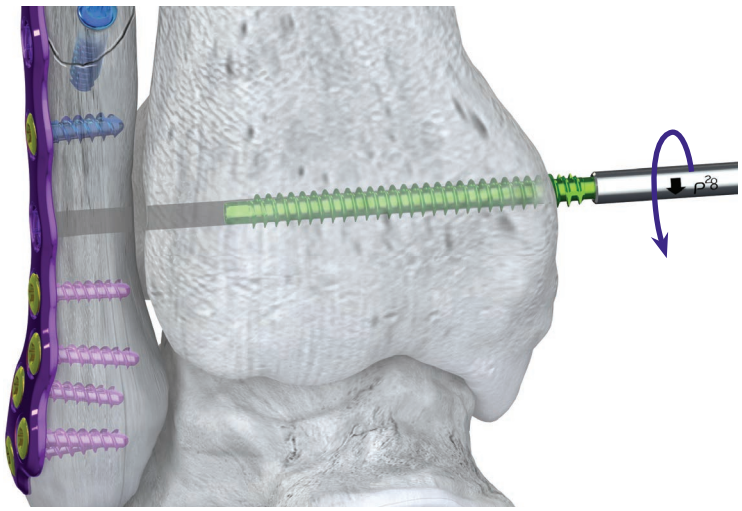


Retrieve the Removal Trephine. The Trephine is cannulated and can be used with a Ø1.2 mm K-wire to help guide orientation of the Trephine with respect to screw position. Use fluoroscopy to insert the Ø1.2 mm K-wire at the medial location of the screw. Make an incision and bluntly dissect to bone.

***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.

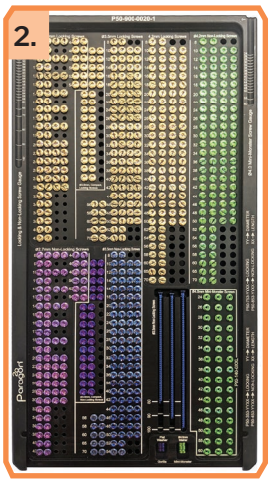


Retrieve the R3ACT Removal Driver. Using the R3ACT Removal Driver, engage the medial removal feature and back the tibial component out by rotating the medial removal feature in a counterclockwise direction. Confirm removal using fluoroscopy.

# 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.

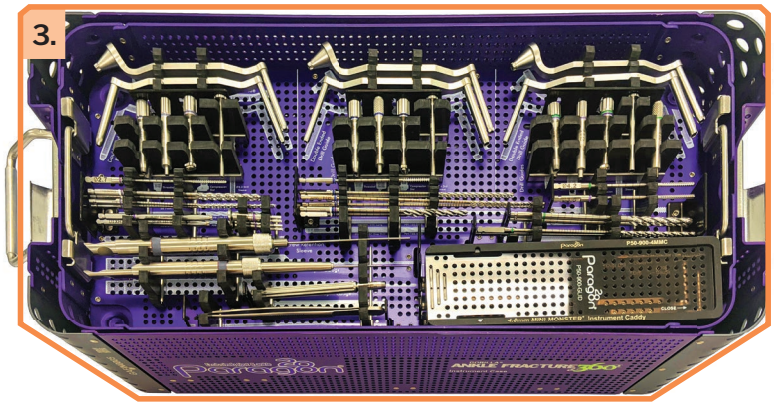



## 2. ANKLE FRACTURE 360™ SCREW CADDY

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.

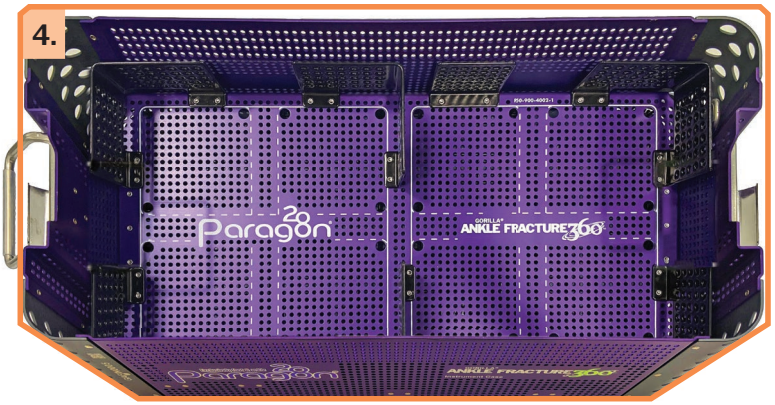
## 3. GORILLA® ANKLE FRACTURE 360™ INSTRUMENT TRAYS

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



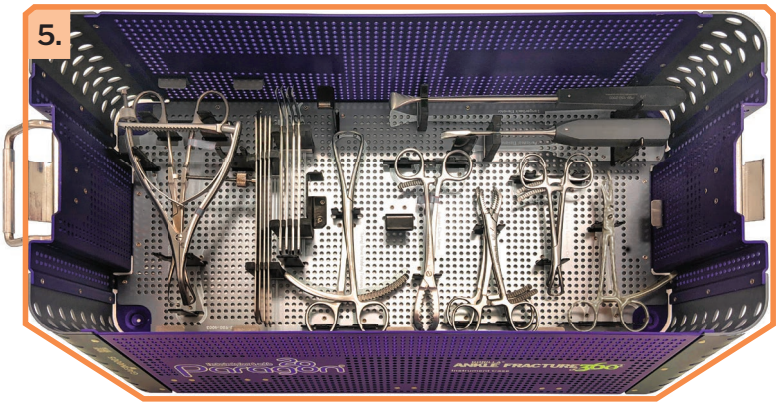

## 4. ADDITIONAL GORILLA® CADDIES

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.



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

## INDICATIONS FOR USE (R3ACT™)

The R3ACT™ Stabilization System is intended as an adjunct in fracture repair and ligamentous injuries of small bones of the feet and ankles including the distal tibia, distal fibula, talus, and calcaneus, and as an adjunct in external and intramedullary fixation systems involving plates and rods. Specifically, the R3ACT™ Stabilization System is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle fractures.

## CONTRAINDICATIONS

Use of the R3ACT™ Stabilization 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 implant materials
- 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, migration, subluxation, 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 or 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.
- The implants and guide wires are intended for single use only.
- Guide wires and screws are to be treated as sharps.
- Do not use other manufacturer's instruments or implants in conjunction with the R3ACT™ Stabilization System.
- Do not re-sterilize the R3ACT™ Stabilization System Implants or Instruments.

## 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.

**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 first 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

**First 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 first metatarsophalangeal joint (MTP) including:**

- Primary MTP Fusion due to hallux ridgidus and/or hallux valgus
- Revision MTP Fusion
- Revision of failed first 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.

## 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

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

## 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.

# R3ACT™
## STABILIZATION SYSTEM

GORILLA®
R3CON PLATING SYSTEM

**PATENTED, DESIGNED & EXCLUSIVELY DISTRIBUTED BY**

Exclusively foot & ankle Paragon 28®

P80-STG-0001 RevA [2022-03-24]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## DISCLAIMER

The purpose of the Gorilla® R3ACT™ Stabilization System Surgical Technique Guide is to demonstrate the optionality and functionality of the R3ACT™ Stabilization System implants and instrumentation in the Gorilla® R3CON Plating System. Although various methods can be employed for these procedures, the fixation options demonstrated were chosen for simplicity of explanation and demonstration of the unique features of our device. Federal law (U.S.A.) restricts this device to sale and use by, or on order of, a physician.