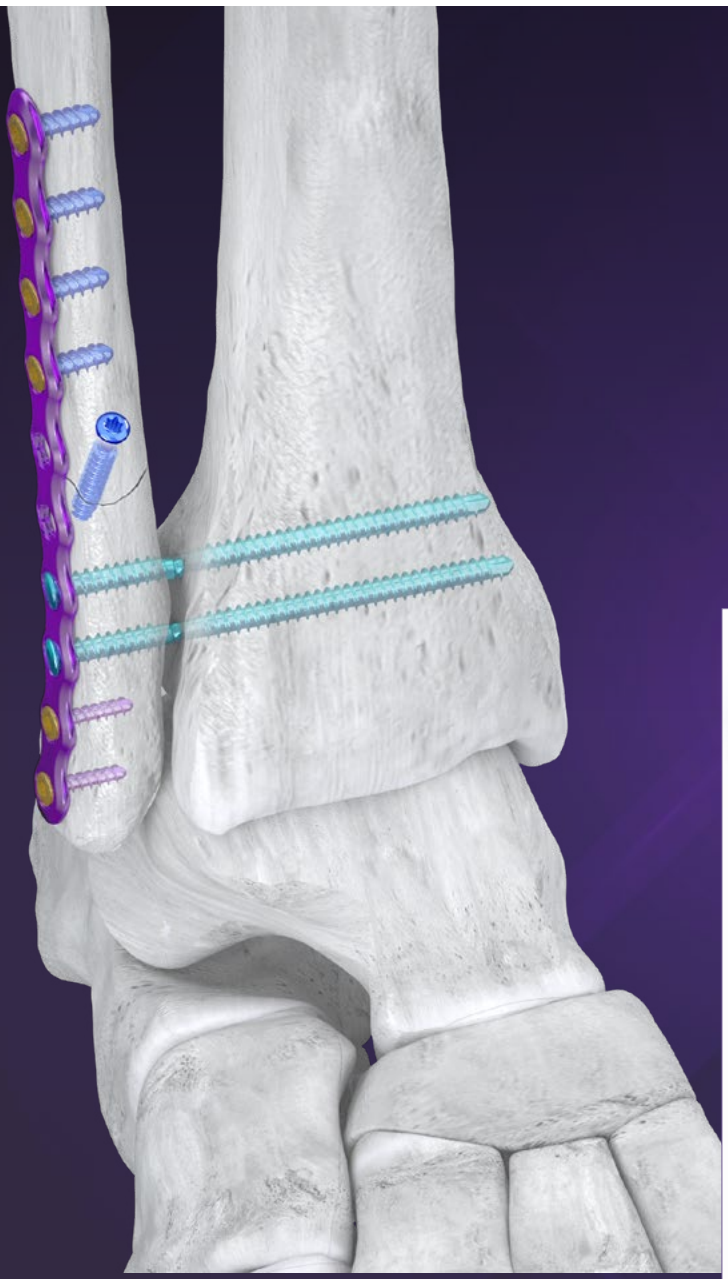
Paragon 28®

a ZIMMER BIOMET company

SURGICAL TECHNIQUE GUIDE

Ankle Fracture with Syndesmotic Repair



R3LEASE™

STABILIZATION SYSTEM

GORILLA®

R3CON PLATING SYSTEM

PRODUCT DESCRIPTION

Paragon 28® set out to provide a simple, improved design to traditional screws for syndesmotic screw fixation. Once a patient begins weightbearing following a period of non-weightbearing postoperatively, traditional syndesmotic screws may break, loosen or cause pain at the syndesmosis. While broken and loose screws have demonstrated improved patient outcomes as compared to intact syndesmotic screws, the location of this screw breakage is unpredictable, with screw breakage within bone or at the cortex potentially causing osteolysis, pain, difficult removal and other consequences.[1] The Gorilla® R3LEASE™ Stabilization System was designed so that if screw breakage occurs, the screw breaks cleanly in the syndesmotic clear space at the notch point. If removal is desired, the lateral removal feature is exposed after removal of the lateral piece. As a secondary solution, the medial screw removal feature can be utilized to remove the medial piece from a medial approach.

Static bending strength and stiffness of the Gorilla® 3.9 mm R3LEASE™ Screw exceeded that of a comparable 3.5 mm solid screw as well as a 4.0 mm cannulated screw made of the same material.[2]

IMPLANT OFFERING

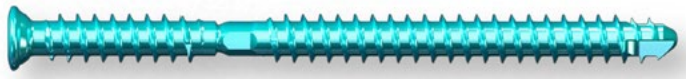
Ø3.9 mm R3LEASE™ Screw - 14 mm Notch Length

Screw Lengths:

40 mm - 45 mm (in 5 mm increments)

48 mm – 64 mm (in 2 mm increments)

Ø3.9 mm R3LEASE™ Screw - 17 mm Notch Length



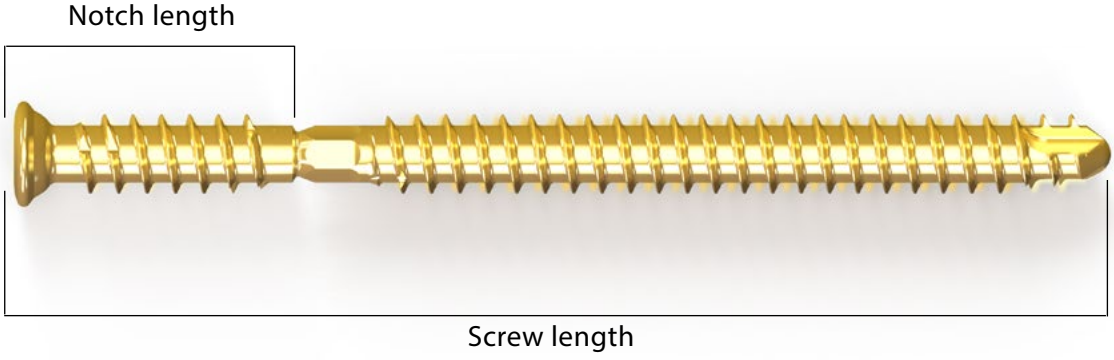
Screw Lengths:

40 mm - 45 mm (in 5 mm increments)

48 mm – 64 mm (in 2 mm increments)

Screw Features:

- Multiple notch lengths: 14 mm and 17 mm
  Address differences in patient anatomy and accommodate use with or without a plate
- Non-locking solid Gorilla® Screw design
- 2 mm increments in 48-64 mm length screws allow for more precision with quadricortical fixation
- Provided in titanium



Screw Removal Features:

- Fibular Fragment
  Can be removed from the lateral side using the standard driver that was used for screw insertion
- Lateral removal feature
  Hexagonal shape that mates with a lateral removal driver to allow for removal of the tibial fragment from the lateral side
- Medial removal feature
  Includes elongated cutting flutes which allow for a specialized medial removal driver to assist in removing the tibial fragment from the medial side

INSTRUMENTATION

Ø2.8 mm Cannulated Drill

Ø2.8 mm Solid Drill

Drill Guide

Lateral Removal Driver

K-wire Depth Gauge

R3LEASE Depth Gauge

Gorilla Driver

1.6 mm x 150 mm K-wire

ADDITIONAL REMOVAL CADDY INSTRUMENTATION

1.2 mm x 100 mm K-wire

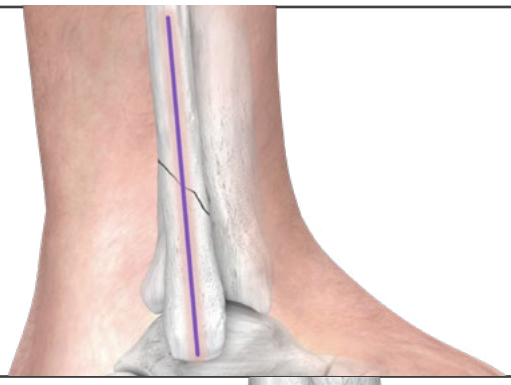
Ø4.2 mm Overdrill

Medial Removal Driver

Ø5.5 mm Trephine

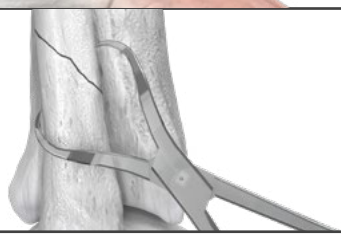
Washer - Available for use when the Titanium R3LEASE Screw is used outside of or without a plate

INCISION/EXPOSURE



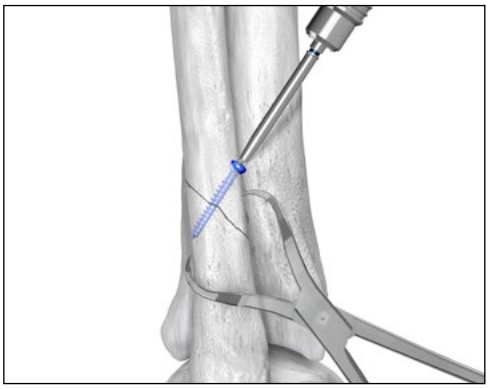
Patient is positioned supine such that the foot is near the end of the table, or in lateral decubitus, based on surgeon preference or fracture extent. A longitudinal incision is made over the central aspect of the fibula, appropriately sized for the fracture pattern and anticipated plate length. Continue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

FRACTURE REDUCTION AND TEMPORARY FIXATION

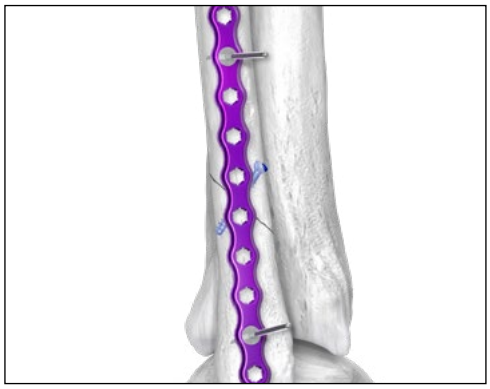


The fracture site is cleared and the fracture edges freshened up, as needed. Fracture reduction is performed and temporary stabilization is achieved using a K-wire, reduction forcep or lobster claw clamp, per surgeon preference.

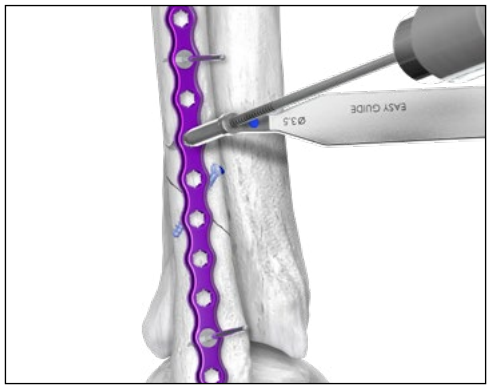
PERMANENT FIXATION



If lag screw fixation is desired across the fracture site, a lag screw can be placed perpendicular to the fracture. In this example, a 3.5 mm fully threaded Mini-Monster® Solid Screw is placed using lag screw technique.

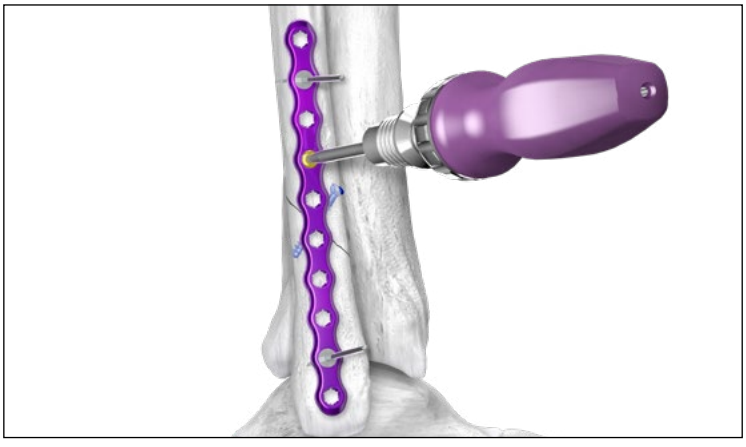


Select the appropriate length plate for stable fixation of the particular fracture type and location. In this example, a Gorilla 10 Hole Straight Fibular Plate is used. Olive wires can be used to secure the plate to bone.

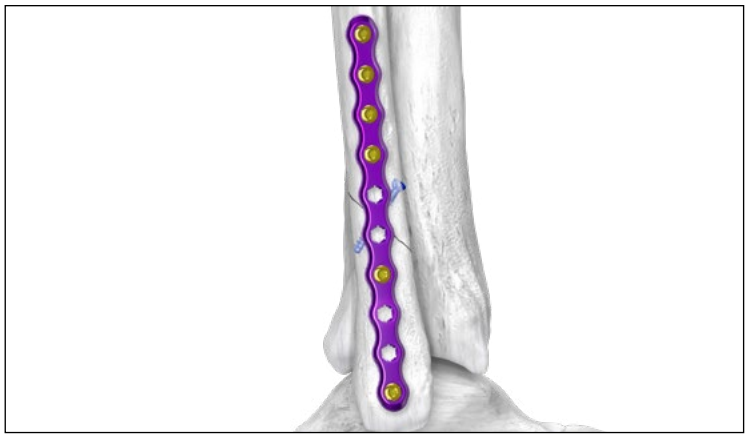


All plate holes accept 2.7 mm, 3.5 mm or 4.2 mm locking or non-locking screws. Drill through the drill guide using the drill sized for the desired screw diameter. Remove the drill guide.

PERMANENT FIXATION



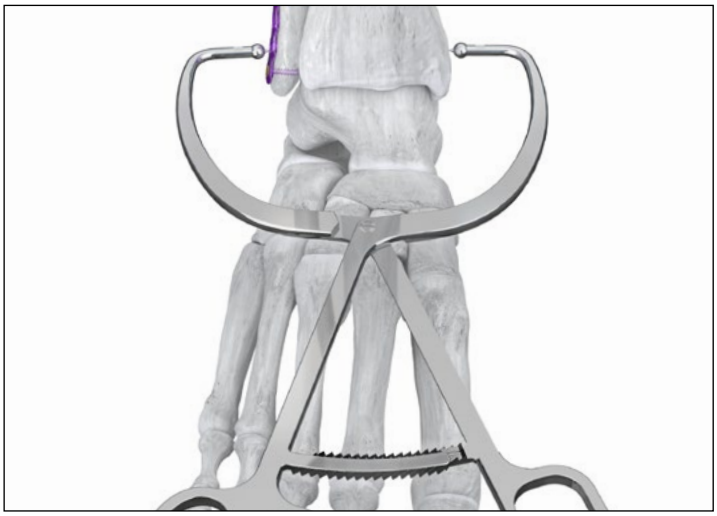
Measure screw length using a depth gauge. Insert the selected screw into the drilled hole in the fibula.



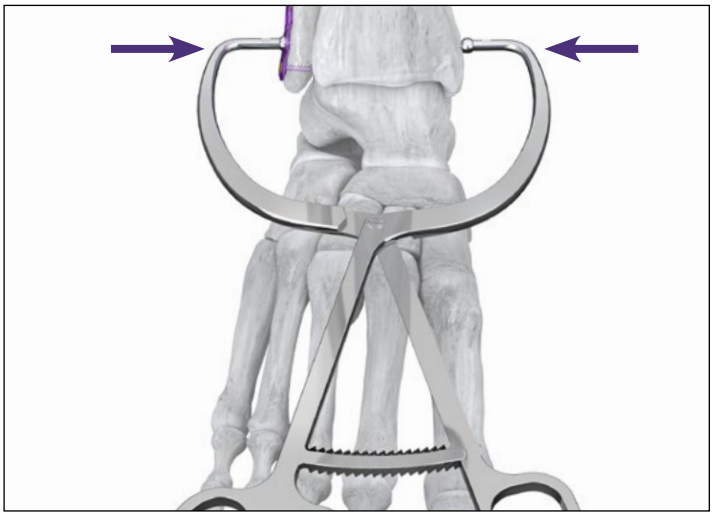
Fill desired plate holes with selected screw sizes, leaving one to two screw holes empty for potential syndesmotic fixation. Confirm plate and screw placement using fluoroscopy.

SYNDESMOTIC REDUCTION

After fibular fixation, test for syndesmotic stability. If syndesmotic fixation is necessary, use a bone tenaculum to provide temporary reduction and stabilization of the syndesmosis. A small stab incision is made over the medial malleolus with blunt dissection continued to bone.



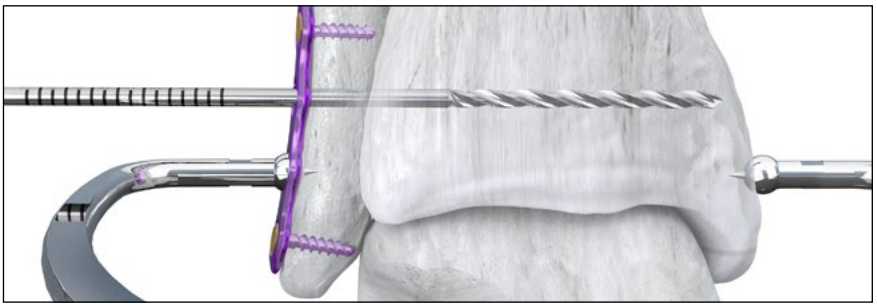
The syndesmotic clamp is placed around the tibia and fibula with placement of the ends of the clamp into the medial and lateral malleoli.



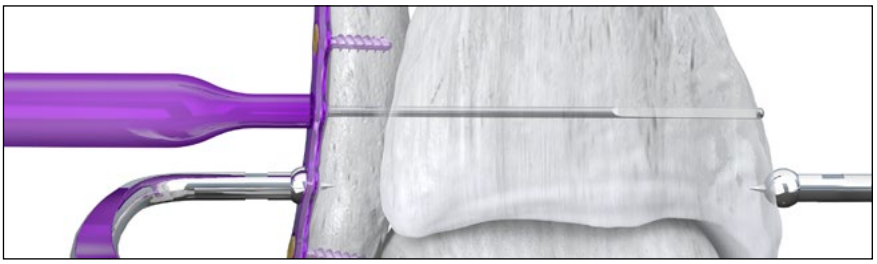
Reduction of the syndesmosis is performed by closing the handles together and allowing the ratcheting mechanism to maintain position of the clamp once appropriate reduction is achieved. Care should be taken not to overcompress the syndesmosis.

A cannulated or solid drilling technique can be performed following reduction, as outlined below.

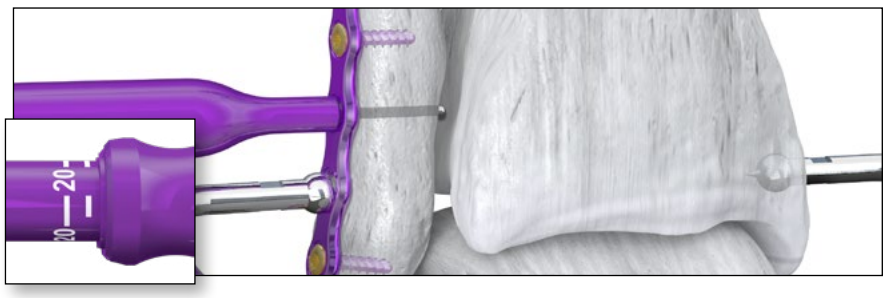
SYNDESMOTIC FIXATION - SOLID DRILLING TECHNIQUE



The R3LEASE Stabilization System may be used for tricortical or quadricortical fixation. Using the Drill Guide and the Ø2.8 mm Solid Drill, drill to the desired screw length. It is recommended to drill under fluoroscopy to ensure correct anticipated screw placement and length.



Insert the R3LEASE Depth Gauge and measure for total screw length.

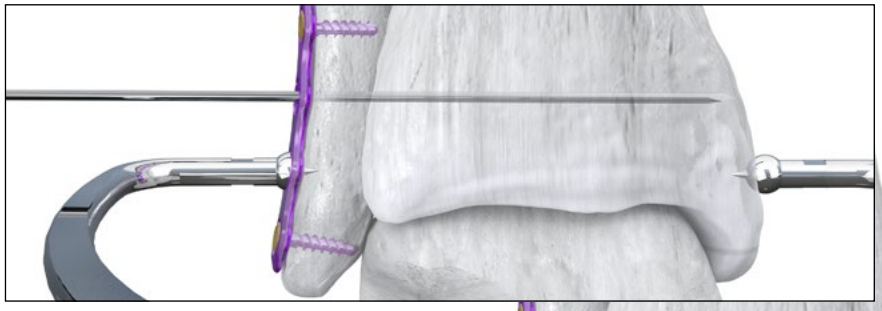


Insert the R3LEASE Depth Gauge and measure the distance to the tibiofibular clear space to determine notch location.

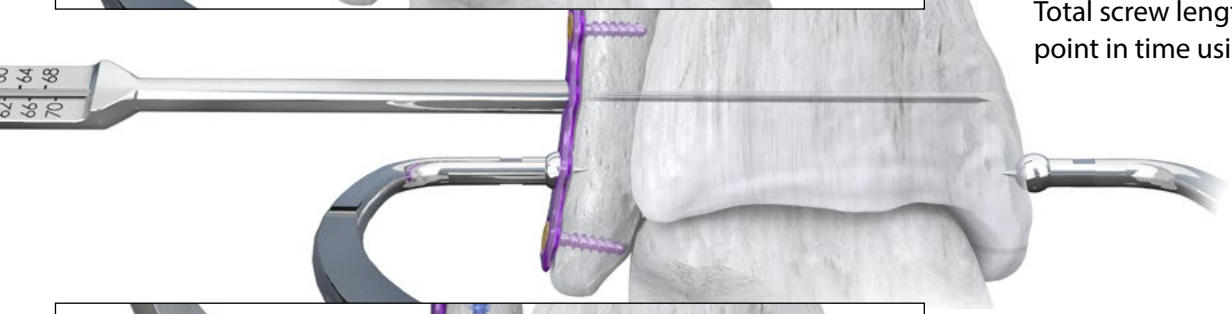
NOTE:

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

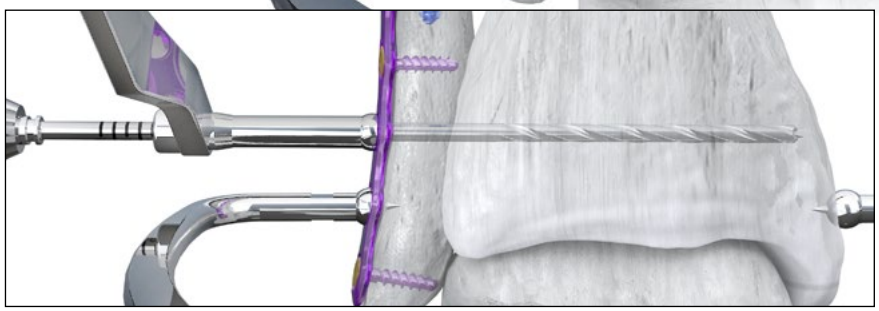
SYNDESMOTIC FIXATION - CANNULATED DRILLING TECHNIQUE



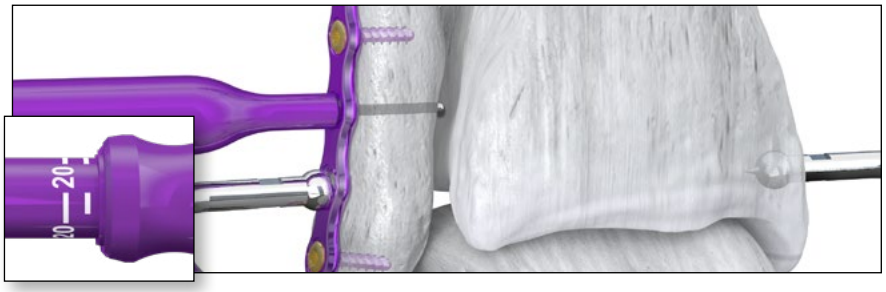
The R3LEASE Stabilization System may be used for tricortical or quadricortical fixation. Insert a 1.6 mm K-wire to the desired screw length.
Check K-wire position and length using fluoroscopy.



Total screw length may be measured at this point in time using the K-wire Depth Gauge.



Using the Drill Guide and Ø2.8 mm Cannulated Drill, drill to the K-wire depth. Remove the K-wire.

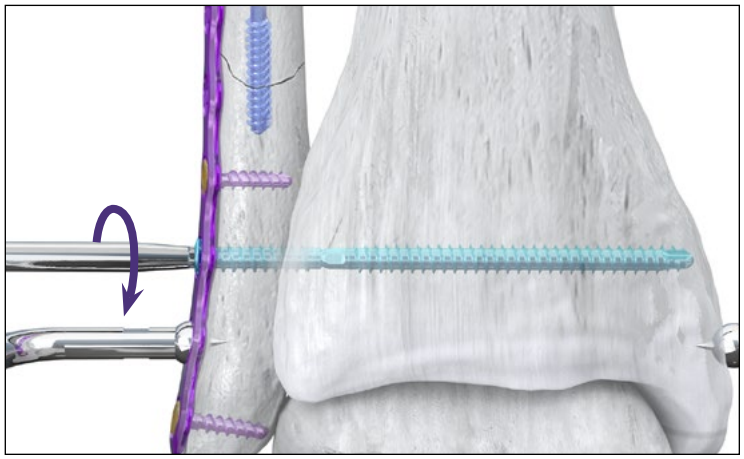


Insert the R3LEASE Depth Gauge and measure the distance to the tibiofibular clear space to determine notch location.

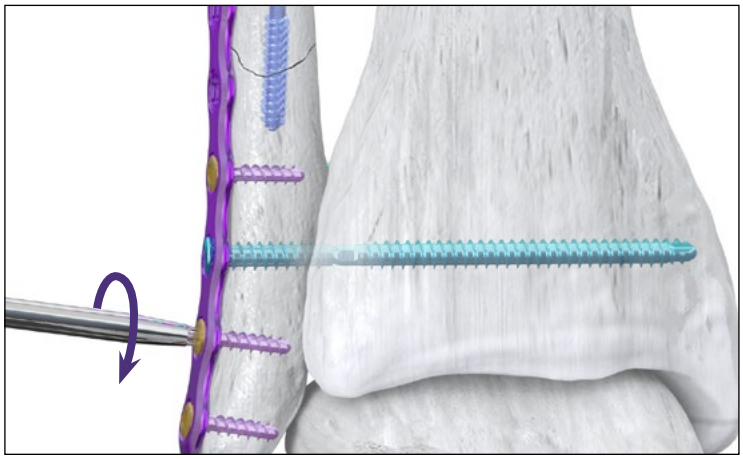
NOTE:

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

SCREW INSERTION

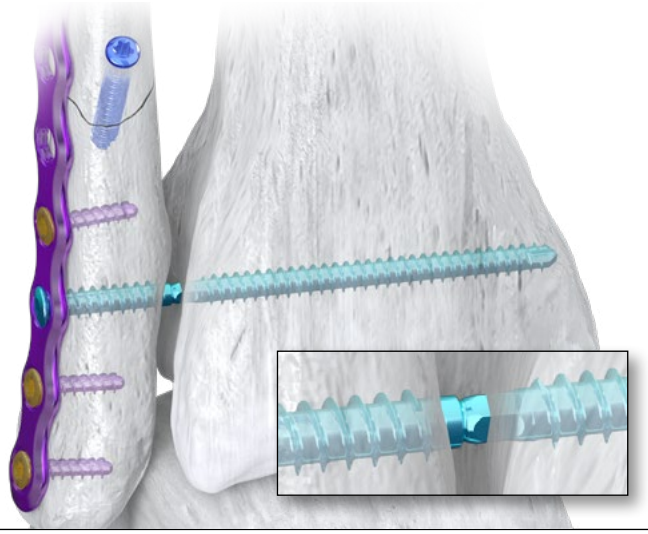


Select desired screw length. Attach the driver to the handle and use the driver to insert the screw until fully seated. Remove the syndesmotic clamp.



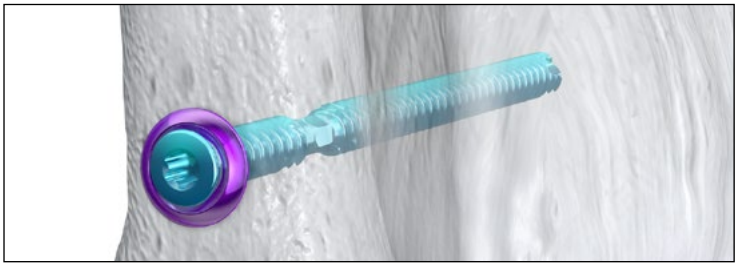
Place a final Gorilla plate screw in the remaining open plate hole(s).

SCREW INSERTION

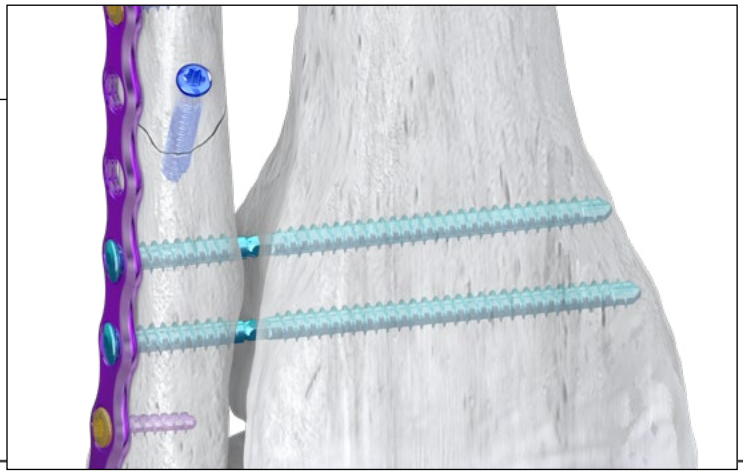


Using fluoroscopy, check that the R3LEASE Screw notch is visible in the clear space between the fibula and tibia.

OPTIONAL: An optional second R3LEASE Screw can be added in the proximal plate hole if additional syndesmotic stabilization is required.



NOTE: A Washer may be used if necessary when a titanium 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.

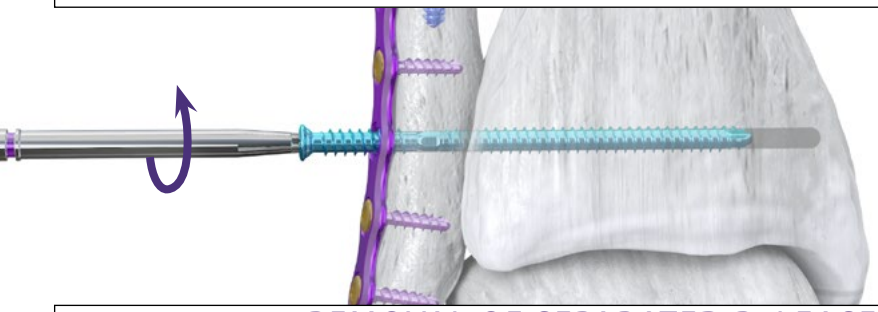


CLOSURE

Proceed to incision closure or concomitant procedures at this time.

IMPLANT REMOVAL

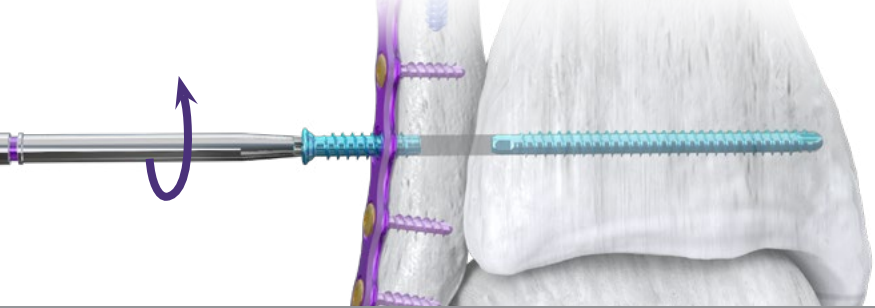
REMOVAL OF INTACT R3LEASE SCREW:



Make a lateral incision at the site of the R3LEASE Screw. Using the Gorilla driver, back the screw out by rotating the driver in a counterclockwise direction. Confirm removal using fluoroscopy.

REMOVAL OF SEPARATED R3LEASE SCREW REMNANTS:

REMOVAL OF THE FIBULAR SCREW REMNANT:

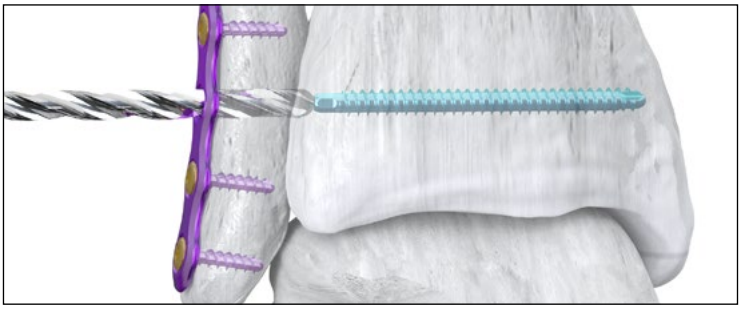


Make a lateral incision at the site of the R3LEASE Screw. Using the Gorilla driver, back the fibular screw remnant out by rotating the driver in a counterclockwise direction.

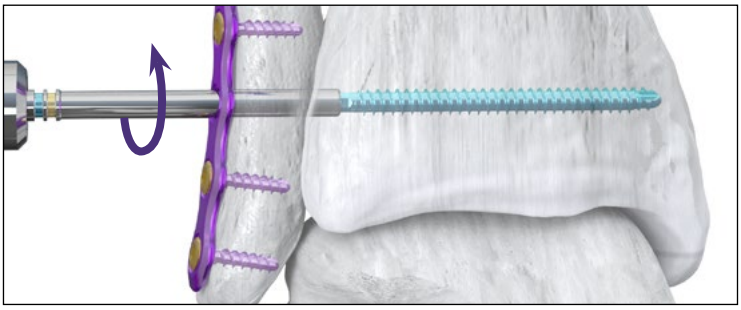
IMPLANT REMOVAL

REMOVAL OF THE TIBIAL SCREW REMNANT: The tibial screw remnant has two removal techniques:

Lateral Removal:



To remove the tibial screw remnant laterally, align the fibular screw remnant hole with the tibial remnant. Using the 4.2 mm overdrill, drill through the fibular hole to the tibial remnant.

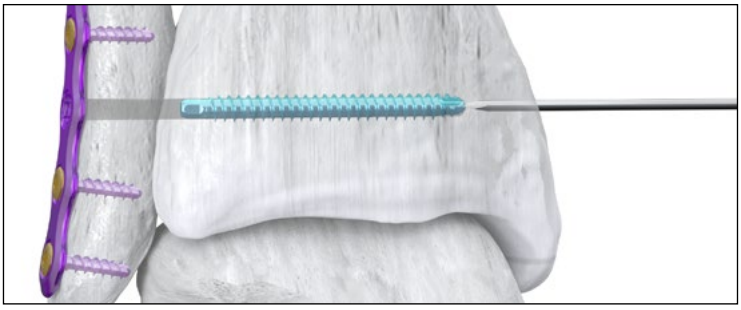


Insert the Lateral Removal Driver through the fibula and engage the lateral removal feature on the tibial remnant. Confirm removal using fluoroscopy.

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.

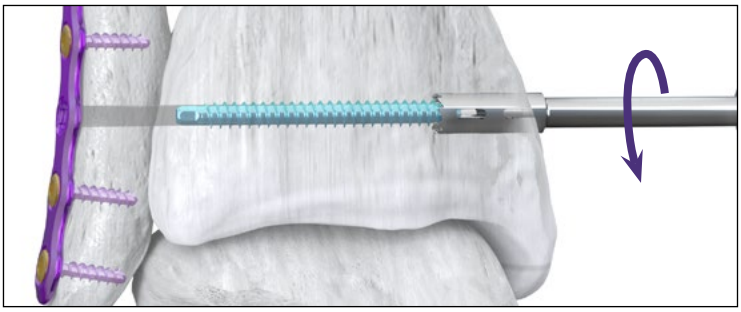
Back the remnant out through the fibular hole by rotating the lateral removal driver in a counterclockwise direction.

Medial Removal:

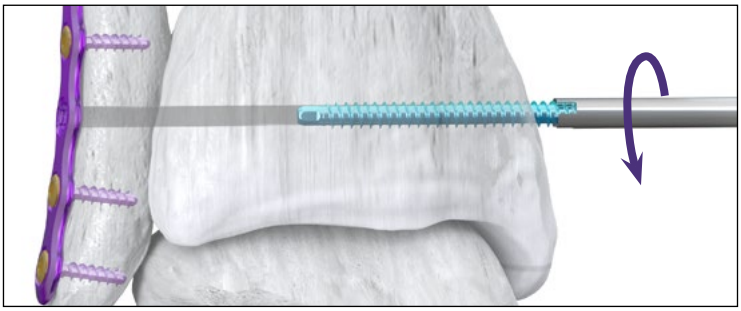


The trephine is cannulated and can be used with a 1.2 mm K-wire to help guide orientation of the trephine with respect to screw position. Use fluoroscopy to insert the 1.2 mm K-wire at the medial location of the screw. Make an incision and bluntly dissect to bone.

NOTE: Alternatively, the trephine can be used without use of a 1.2 mm K-wire.



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



Using the medial removal driver, engage the medial removal feature and back the tibial remnant out by rotating the medial removal feature in a counterclockwise direction. Confirm removal using fluoroscopy.

R3LEASE™ Screw Caddy

The Gorilla® R3LEASE™ Screw Caddy contains all R3LEASE™ Screw size options. The R3LEASE™ Depth Gauge and K-wire Depth Gauge are also included in this caddy. An instrument tray is located below the screw caddy. The instrument tray contains Gorilla® washers, cannulated and solid drills, Gorilla® drivers, the lateral removal driver, K-wires and a drill guide.

Gorilla® Ankle Fracture Caddy

The Gorilla® Ankle Fracture Plate Caddy contains the right and left Anatomic Fibular, Straight Fibular and the Medial Malleolus plate options. The K-wire guide, threaded plate positioning towers, olive wires and additional 3.5 mm R3CON locking and non-locking screws are also included in this caddy.

Gorilla® R3CON Instrument Caddy

Drills, drill guides, centering guides, olive wires, plate benders, drivers, K-wires and a depth gauge are located in the Gorilla® R3CON Instrument Caddy.

Additional Gorilla® Caddies

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

Gorilla® Case

Gorilla® Screw Optionality

The Gorilla® screw length options for both locking and non-locking screws are as follows:

2.7 mm	1 mm increments, 8-20 mm	
2.7 mm	2 mm increments, 22-40 mm	
3.5 mm	2 mm increments, 10-50 mm	
4.2 mm	2 mm increments, 10-50 mm	
4.2 mm	5 mm increments, 55-70 mm	

Gorilla® R3CON Instruments

The Caspar Compression/Distraction device, osteotomes, baby Bennet retractors, bone reduction clamps, periosteal elevator, cartilage removal device, pin distractor and handles are located at the bottom of the Gorilla® Case.

GORILLA ANKLE FRACTURE 360 PLATING SYSTEM - R3LEASE STABILIZATION SYSTEM CADDY

PART #	DESCRIPTION	USE
P80-239-1440	R3LEASE Screw Ø3.9 X 40mm, 14mm Notch, Ti-6Al-4V ELI	Single-use
P80-239-1740	R3LEASE Screw Ø3.9 X 40mm, 17mm Notch, Ti-6Al-4V ELI	Single-use
P80-239-1445	R3LEASE Screw Ø3.9 X 45mm, 14mm Notch, Ti-6Al-4V ELI	Single-use
P80-239-1745	R3LEASE Screw Ø3.9 X 45mm, 17mm Notch, Ti-6Al-4V ELI	Single-use
P80-239-1448	R3LEASE Screw Ø3.9 X 48mm, 14mm Notch, Ti-6Al-4V ELI	Single-use
P80-239-1748	R3LEASE Screw Ø3.9 X 48mm, 17mm Notch, Ti-6Al-4V ELI	Single-use
P80-239-1450	R3LEASE Screw Ø3.9 X 50mm, 14mm Notch, Ti-6Al-4V ELI	Single-use
P80-239-1750	R3LEASE Screw Ø3.9 X 50mm, 17mm Notch, Ti-6Al-4V ELI	Single-use
P80-239-1452	R3LEASE Screw Ø3.9 X 52mm, 14mm Notch, Ti-6Al-4V ELI	Single-use
P80-239-1752	R3LEASE Screw Ø3.9 X 52mm, 17mm Notch, Ti-6Al-4V ELI	Single-use
P80-239-1454	R3LEASE Screw Ø3.9 X 54mm, 14mm Notch, Ti-6Al-4V ELI	Single-use
P80-239-1754	R3LEASE Screw Ø3.9 X 54mm, 17mm Notch, Ti-6Al-4V ELI	Single-use
P80-239-1456	R3LEASE Screw Ø3.9 X 56mm, 14mm Notch, Ti-6Al-4V ELI	Single-use
P80-239-1756	R3LEASE Screw Ø3.9 X 56mm, 17mm Notch, Ti-6Al-4V ELI	Single-use
P80-239-1458	R3LEASE Screw Ø3.9 X 58mm, 14mm Notch, Ti-6Al-4V ELI	Single-use
P80-239-1758	R3LEASE Screw Ø3.9 X 58mm, 17mm Notch, Ti-6Al-4V ELI	Single-use
P80-239-1460	R3LEASE Screw Ø3.9 X 60mm, 14mm Notch, Ti-6Al-4V ELI	Single-use
P80-239-1760	R3LEASE Screw Ø3.9 X 60mm, 17mm Notch, Ti-6Al-4V ELI	Single-use
P80-239-1462	R3LEASE Screw Ø3.9 X 62mm, 14mm Notch, Ti-6Al-4V ELI	Single-use
P80-239-1762	R3LEASE Screw Ø3.9 X 62mm, 17mm Notch, Ti-6Al-4V ELI	Single-use
P80-239-1464	R3LEASE Screw Ø3.9 X 64mm, 14mm Notch, Ti-6Al-4V ELI	Single-use
P80-239-1764	R3LEASE Screw Ø3.9 X 64mm, 17mm Notch, Ti-6Al-4V ELI	Single-use
P50-153-WS00	Gorilla Washer	Single-use
P80-910-2814	2.8mm Cannulated Drill	Reusable
P80-900-2814	2.8mm Solid Drill	Reusable
P80-930-3900	R3LEASE Ø3.9mm Drill Guide	Reusable
P80-940-3902	R3LEASE Lateral Removal Driver	Reusable
P80-950-0080	Syndesmosis Depth Gauge	Reusable
P80-950-0081	Syndesmosis Depth Gauge, K-wire Measuring	Reusable
P99-191-TR10	Gorilla R3CON Driver, Solid, HX10 X 68 MM, SS	Reusable
P99-192-1615	Ø1.6 x 150mm K-Wire, Smooth	Single-use

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

INSTRUCTIONS FOR USE: BABY GORILLA®/GORILLA® PLATING SYSTEM

Indications, Contraindications, Warnings and Precautions relevant to the Baby Gorilla®/Gorilla® Plating System are contained in the Instructions for Use document of the Baby Gorilla®/Gorilla® Plating System P51-IFU-3001.

A patient with the Paragon 28® Baby Gorilla®/Gorilla® Plating System may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.	
NAME/IDENTIFICATION OF DEVICE	**PARAGON 28® BABY GORILLA®/GORILLA® PLATING SYSTEM**
Nominal value(s) of Static Magnetic Field [T]	1.5 T or 3 T
Maximum Spacial Field Gradient [T/m and gauss/cm]	30 T/m (3000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body transmit coil, Head RF transmit-receive coil
Operating Mode	Normal Operating Mode
Maximum Whole Body SAR [W/kg]	2.0 W/kg (Normal Operating Mode)
Limits on Scan Duration	2.0 W/kg whole body average SAR for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact
If information about a specific parameter is not included, there are no conditions associated with that parameter.	

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

INSTRUCTIONS FOR USE: MONSTER®/MINI-MONSTER® SCREW SYSTEM

Indications, Contraindications, Warnings and Precautions relevant to the Monster® Screw System are contained in the Instructions for Use document of the Monster® Screw System P20-IFU-3001.

A patient with the Paragon 28® Monster® Screw System may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

NAME/IDENTIFICATION OF DEVICE	PARAGON 28® MONSTER® SCREW SYSTEM
Nominal value(s) of Static Magnetic Field [T]	1.5 T or 3 T
Maximum Spacial Field Gradient [T/m and gauss/cm]	30 T/m (3000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body transmit coil, Head RF transmit-receive coil
Maximum Whole Body SAR [W/kg]	2.0 W/kg (Normal Operating Mode)
Limits on Scan Duration	All anatomical regions can be safely scanned under the following conditions: 2.0 W/kg whole body average SAR for 5 minutes of continuous RF (a sequence or back to back series/scan without breaks) with a 20 minute cooling period between scans for an hour long scanning session
	Scanning of the knees and all anatomy superior to the knees can be safely scanned under the following conditions: 2.0 W/kg whole body average SAR for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact of 20 mm

If information about a specific parameter is not included, there are no conditions associated with that parameter.

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GORILLA®
R3CON PLATING SYSTEM

R3LEASE
STABILIZATION SYSTEM

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1. Manjoo, Ajay, et al. "Functional and Radiographic Results of Patients with Syndesmotic Screw Fixation: Implications for Screw Removal." J Orthop Trauma 24.1 (2010): 2-6.
2. Internal data on file, TR-17102601

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For indications, contraindications, warnings, precautions, potential adverse effects and patient counseling information, see the instructions for use or contact your local representative; visit www.paragon28.com for additional product information.

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