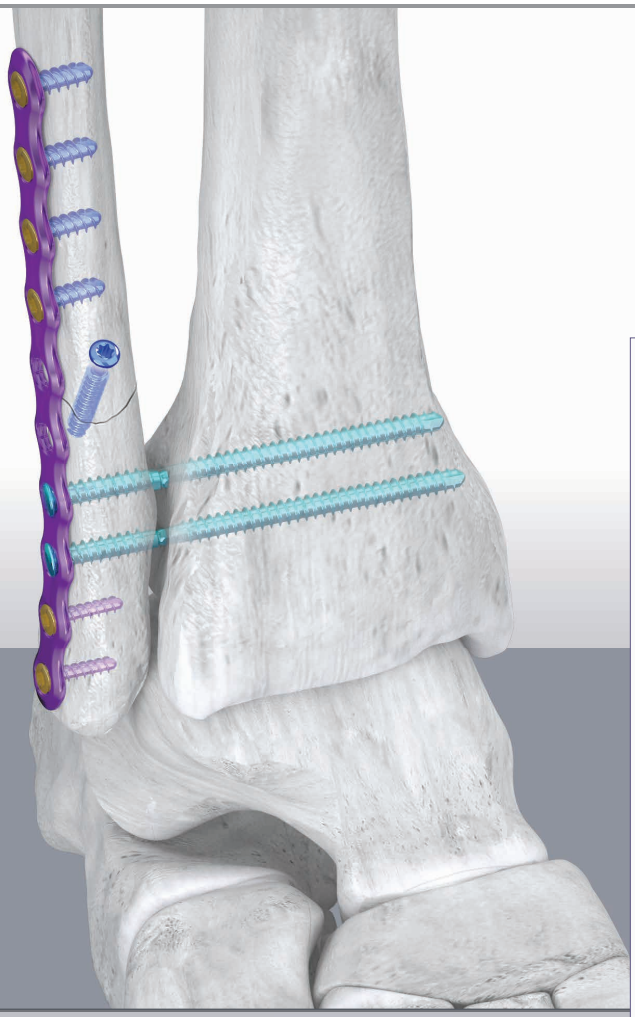
SURGICAL TECHNIQUE GUIDE:
ANKLE FRACTURE WITH SYNDESMOTIC REPAIR

Exclusively foot & ankle

Paragon 28®



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

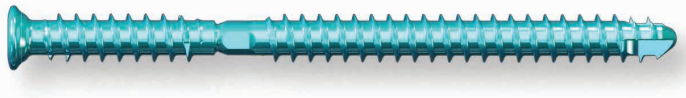
Ø3.9 mm R3LEASE™ Screw - 14 mm Notch Length

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



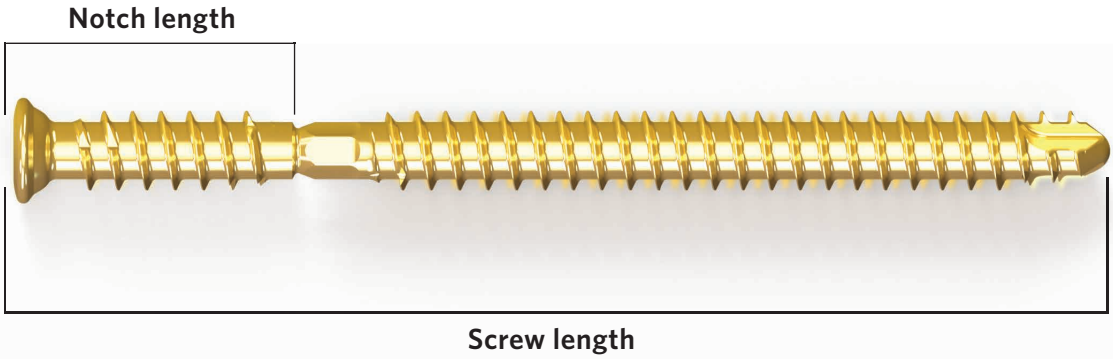
Screw Lengths:

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 and stainless steel (stainless steel is not available in all regions)**



Screw Removal Features:

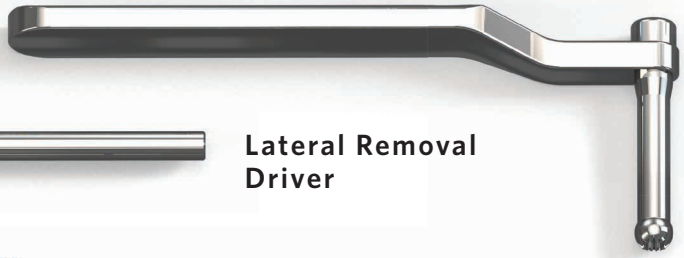
- **Fibular Fragment**
  Can be removed from the lateral side using the standard driver that was used for screw insertion
- **Lateral removal feature**
  Hexagonal shape that mates with a lateral removal driver to allow for removal of the tibial fragment from the lateral side
- **Medial removal feature**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

- **NOTE: If a stainless steel Gorilla R3LEASE Screw is used, it may only be used standalone.**

INSTRUMENTATION

Ø2.8 mm Cannulated Drill

Ø2.8 mm Solid Drill



Drill Guide

Lateral Removal Driver

K-wire Depth Gauge

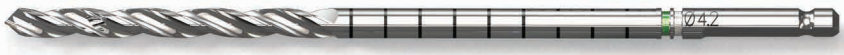
R3LEASE Depth Gauge

Gorilla Driver

1.6 mm x 150 mm K-wire

ADDITIONAL REMOVAL CADDY INSTRUMENTATION

1.2 mm x 100 mm K-wire



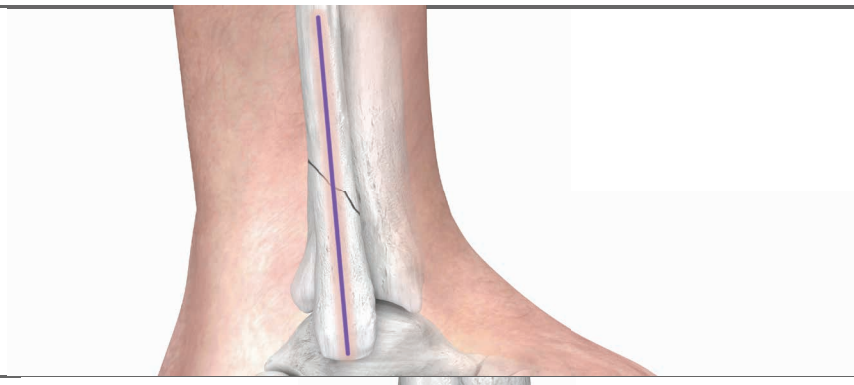
Ø4.2 mm Overdrill

Medial Removal Driver

Ø5.5 mm Trephine

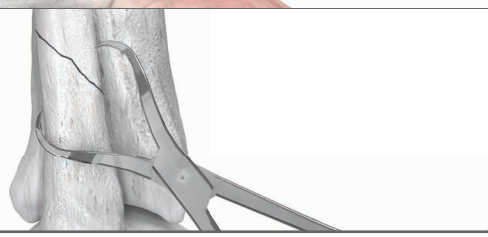
Washer - Available for use when the Titanium R3LEASE Screw is used outside of or without a plate

INCISION/EXPOSURE



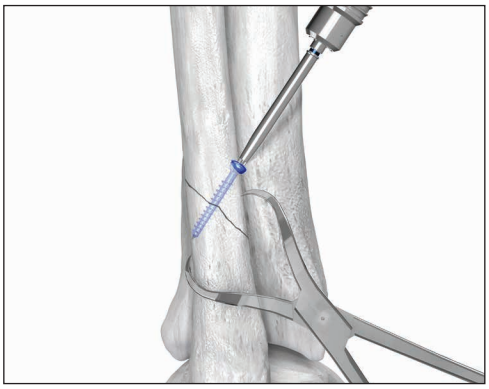
Patient is positioned supine such that the foot is near the end of the table, or in lateral decubitus, based on surgeon preference or fracture extent. A longitudinal incision is made over the central aspect of the fibula, appropriately sized for the fracture pattern and anticipated plate length. Continue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

FRACTURE REDUCTION AND TEMPORARY FIXATION

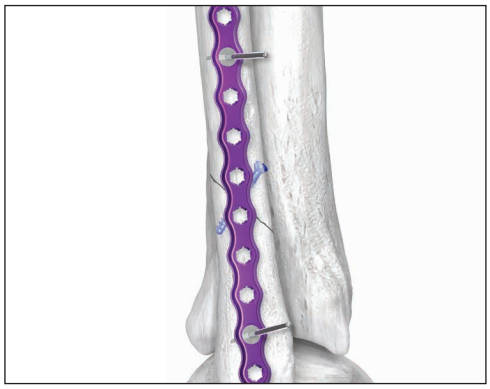


The fracture site is cleared and the fracture edges freshened up, as needed. Fracture reduction is performed and temporary stabilization is achieved using a K-wire, reduction forcep or lobster claw clamp, per surgeon preference.

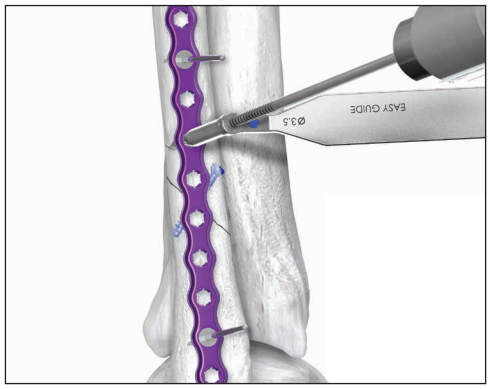
PERMANENT FIXATION



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.

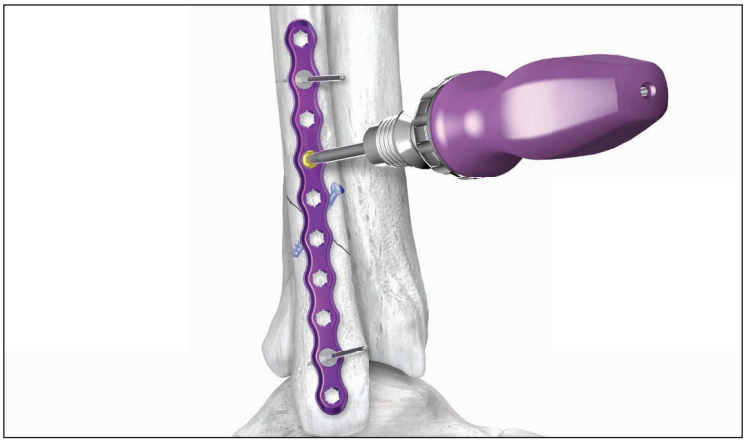


Select the appropriate length plate for stable fixation of the particular fracture type and location. In this example, a Gorilla 10 Hole Straight Fibular Plate is used. Olive wires can be used to secure the plate to bone.

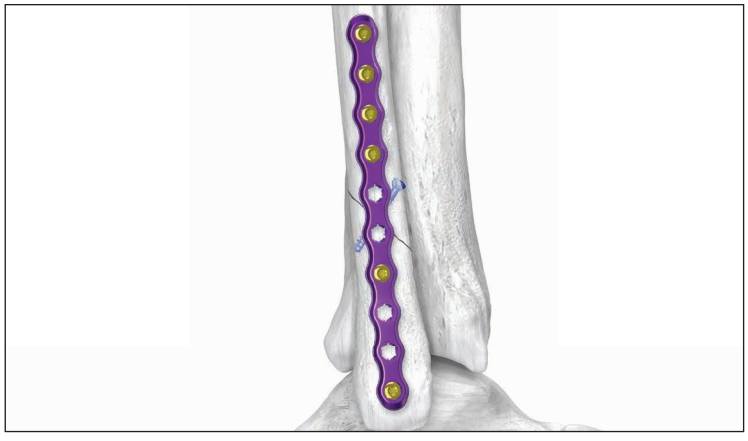


All plate holes accept 2.7 mm, 3.5 mm or 4.2 mm locking or non-locking screws. Drill through the drill guide using the drill sized for the desired screw diameter. Remove the drill guide.

PERMANENT FIXATION



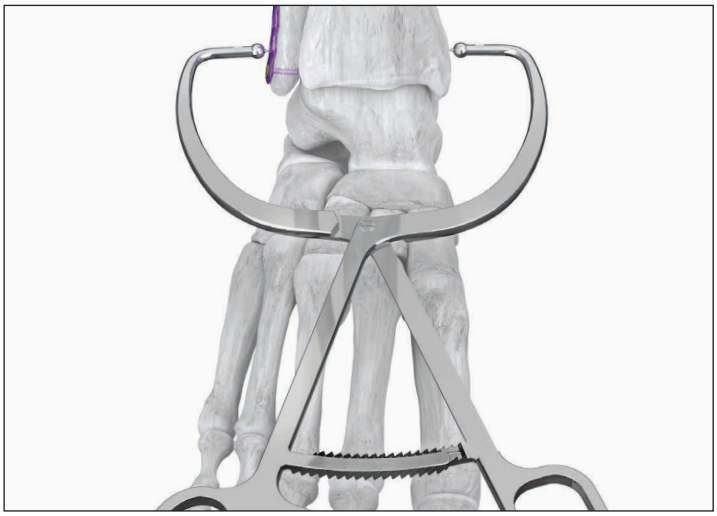
Measure screw length using a depth gauge. Insert the selected screw into the drilled hole in the fibula.



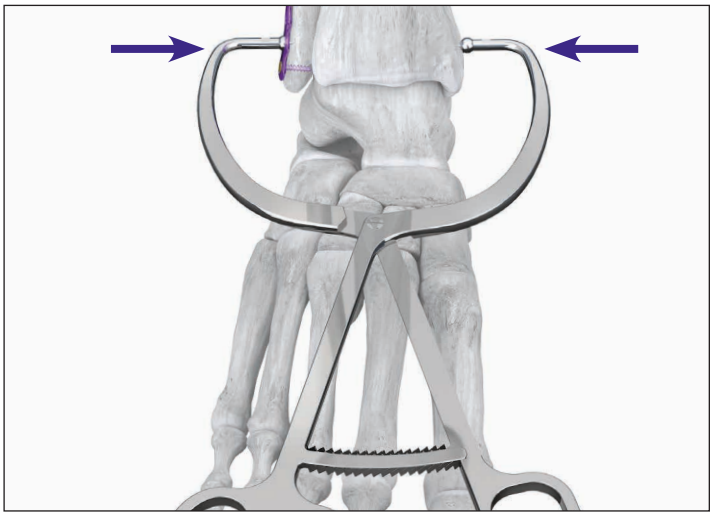
Fill desired plate holes with selected screw sizes, leaving one to two screw holes empty for potential syndesmotic fixation. Confirm plate and screw placement using fluoroscopy.

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.



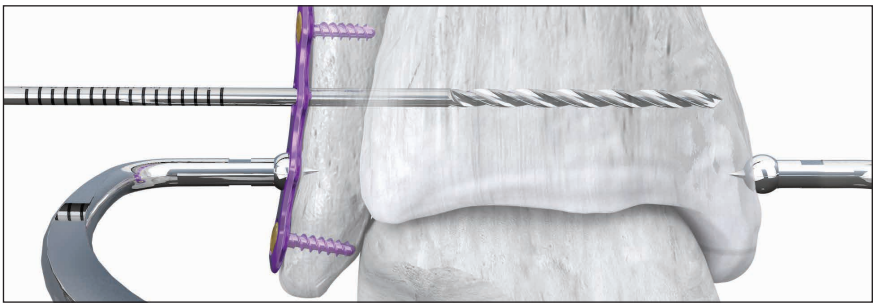
The syndesmotic clamp is placed around the tibia and fibula with placement of the ends of the clamp into the medial and lateral malleoli.



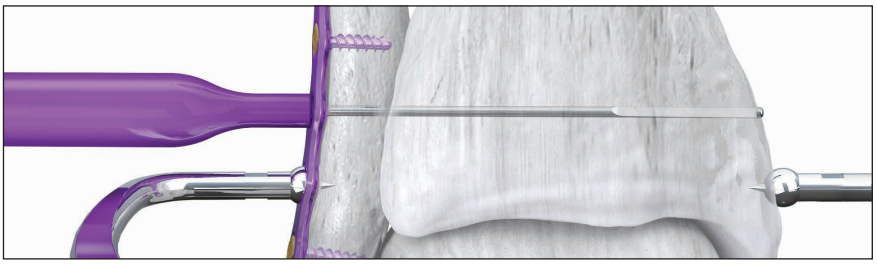
Reduction of the syndesmosis is performed by closing the handles together and allowing the ratcheting mechanism to maintain position of the clamp once appropriate reduction is achieved. Care should be taken not to overcompress the syndesmosis.

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

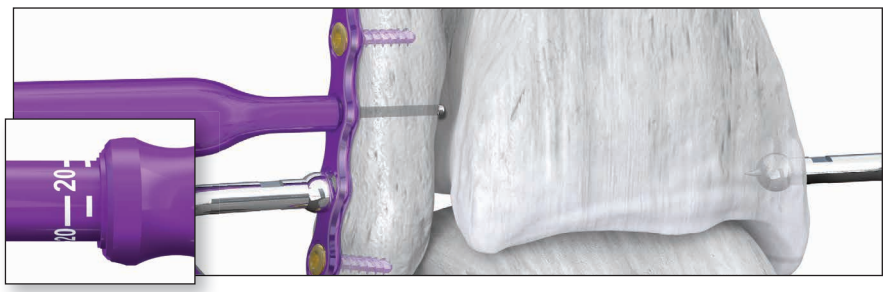
SYNDESMOTIC FIXATION - SOLID DRILLING TECHNIQUE



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.

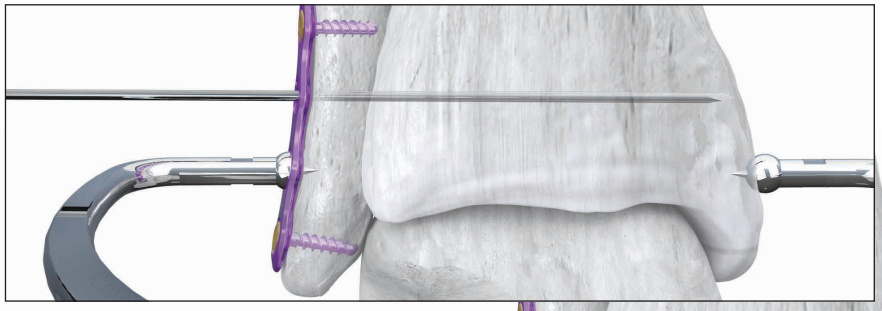


Insert the R3LEASE Depth Gauge and measure the distance to the tibiofibular clear space to determine notch location.

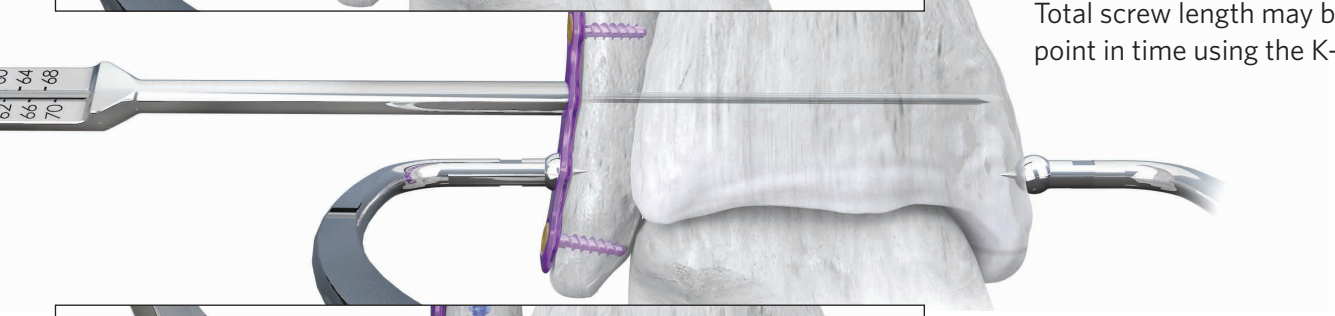
NOTE:

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

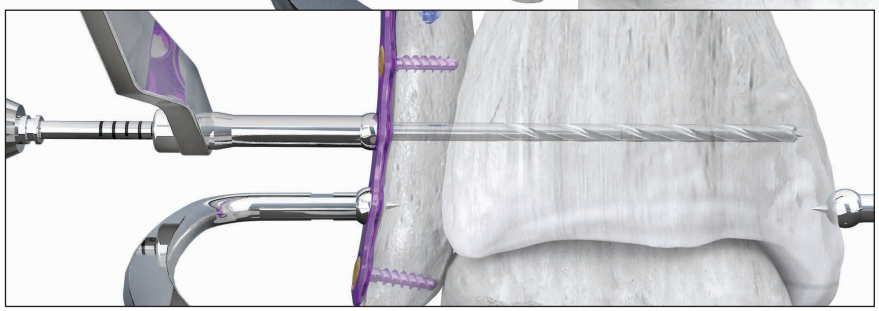
SYNDESMOTIC FIXATION - CANNULATED DRILLING TECHNIQUE



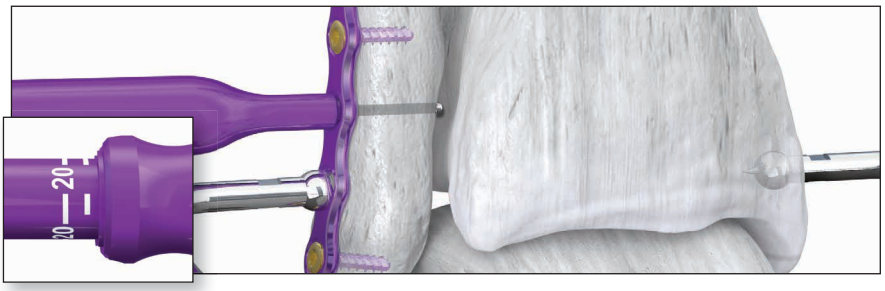
The R3LEASE Stabilization System may be used for tricortical or quadricortical fixation. Insert a 1.6 mm K-wire to the desired screw length.
Check K-wire position and length using fluoroscopy.



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



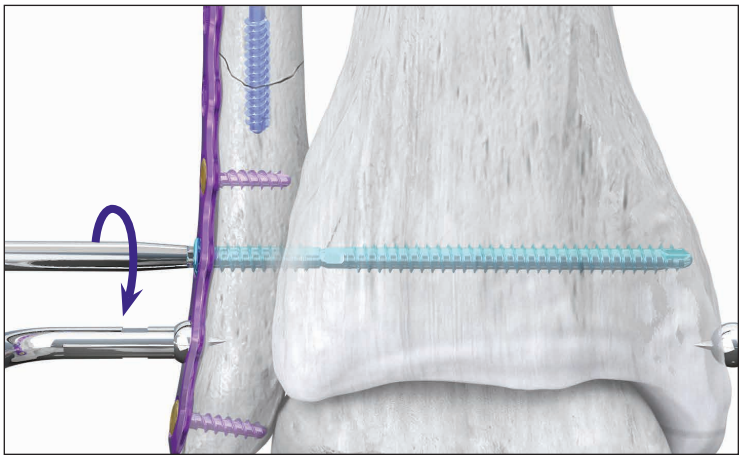
Using the Drill Guide and Ø2.8 mm Cannulated Drill, drill to the K-wire depth. Remove the K-wire.



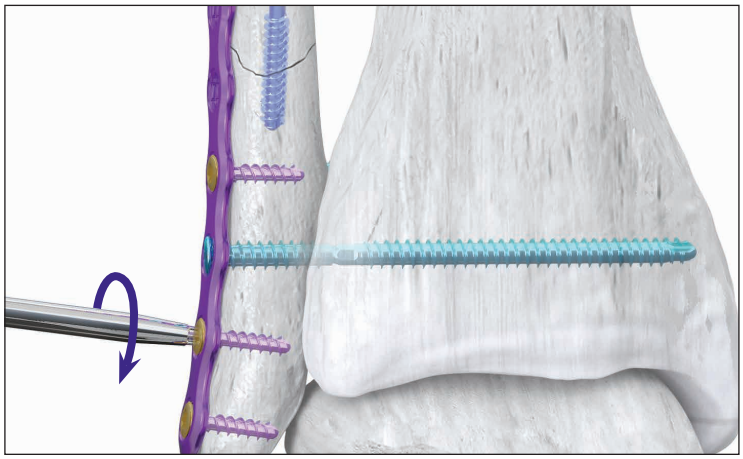
Insert the R3LEASE Depth Gauge and measure the distance to the tibiofibular clear space to determine notch location.

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

SCREW INSERTION

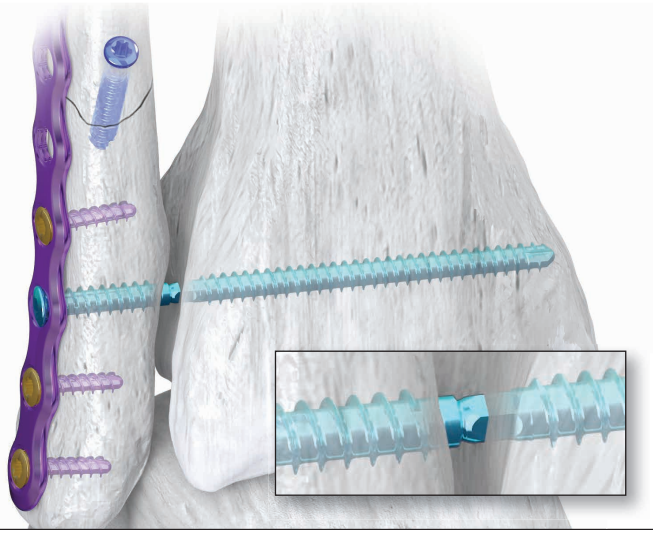


Select desired screw length. Attach the driver to the handle and use the driver to insert the screw until fully seated. Remove the syndesmotic clamp.



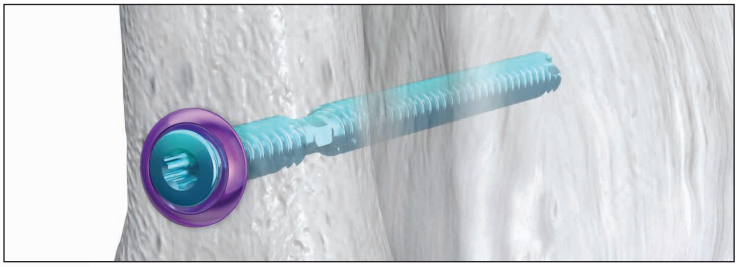
Place a final Gorilla plate screw in the remaining open plate hole(s).

SCREW INSERTION

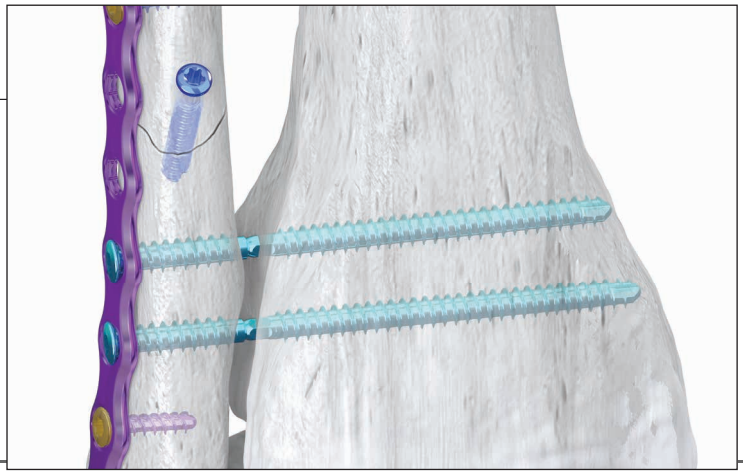


Using fluoroscopy, check that the R3LEASE Screw notch is visible in the clear space between the fibula and tibia.

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.

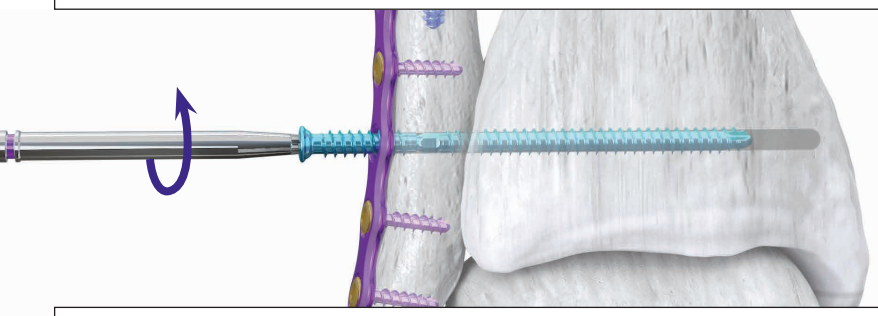


CLOSURE

Proceed to incision closure or concomitant procedures at this time.

IMPLANT REMOVAL

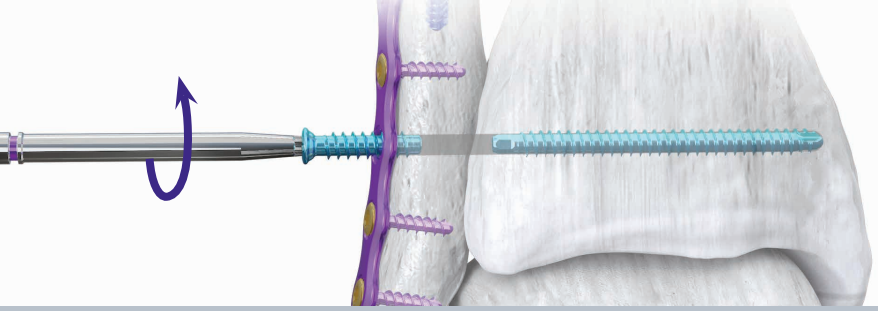
REMOVAL OF INTACT R3LEASE SCREW:



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:

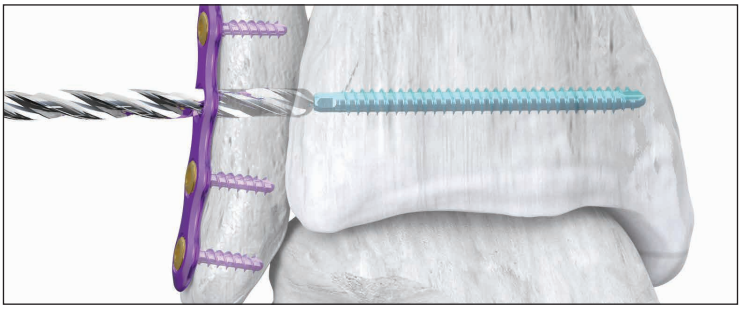


Make a lateral incision at the site of the R3LEASE Screw. Using the Gorilla driver, back the fibular screw remnant out by rotating the driver in a counterclockwise direction.

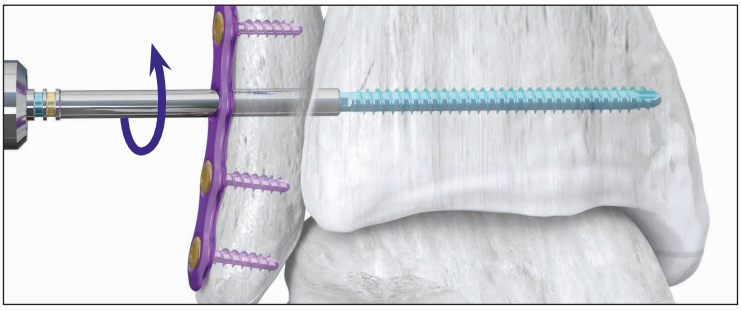
IMPLANT REMOVAL

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.

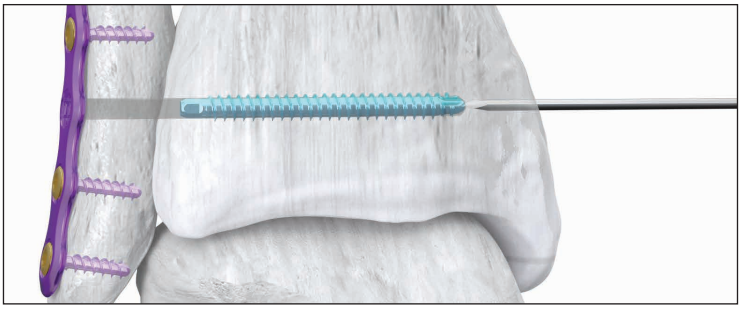


Insert the Lateral Removal Driver through the fibula and engage the lateral removal feature on the tibial remnant. Confirm removal using fluoroscopy.

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.

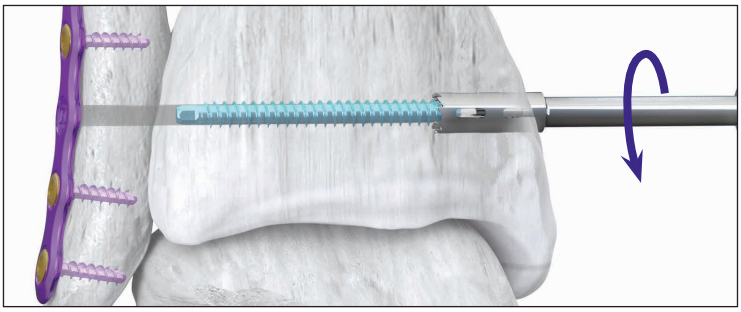
Back the remnant out through the fibular hole by rotating the lateral removal driver in a counterclockwise direction.

Medial Removal:

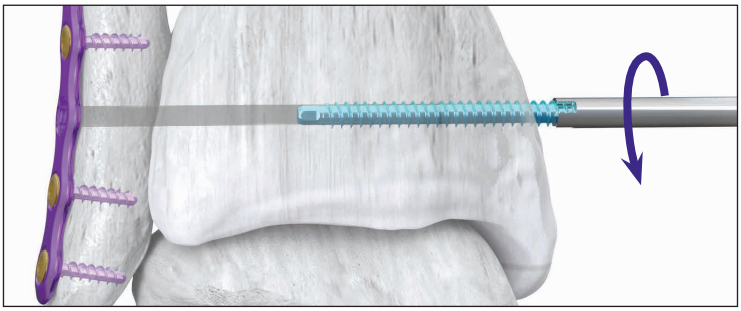


The trephine is cannulated and can be used with a 1.2 mm K-wire to help guide orientation of the trephine with respect to screw position. Use fluoroscopy to insert the 1.2 mm K-wire at the medial location of the screw. Make an incision and bluntly dissect to bone.

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

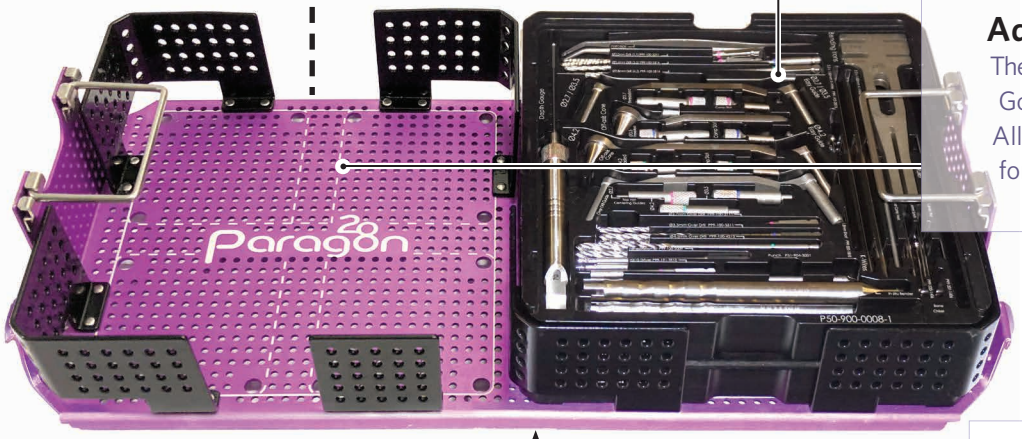
The Gorilla® Ankle Fracture Plate Caddy contains the right and left Anatomic Fibular, Straight Fibular and the Medial Malleolus plate options. The K-wire guide, threaded plate positioning towers, olive wires and additional 3.5 mm R3CON locking and non-locking screws are also included in this caddy.

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.

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

INDICATIONS FOR USE (GORILLA®)

The 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, distal fibula, talus, and calcaneus. The system can be used in both adult and pediatric patients.

In addition, the non-locking, titanium alloy (Ti6Al4V ELI) screws and washers are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair and fracture fixation of the foot and ankle, including the tibia, fibula, tarsus, metatarsals, and phalanges, 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

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.
- Patient risk as a result of the Baby Gorilla®/Gorilla® Plating System in the MR environment has been minimized.
- Do not use other manufacturer's instruments or implants in conjunction with the Baby Gorilla®/Gorilla® Plating System.
- Do not implant the instruments.

MR SAFETY INFORMATION

The Baby Gorilla®/Gorilla® Plating System has 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® Plating System in the MR environment is unknown. Scanning 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 (MONSTER®)

The Monster® Screw System is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, ligament fixation, fracture repair and fracture fixation of the foot and ankle, including the tibia, fibula, tarsus, metatarsals, and phalanges and the joints and ligaments coupling said bones, appropriate for the size of the device.

CONTRAINDICATIONS

Use of the Monster® Screw 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

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

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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 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. Re-use may cause product failure and could lead to disease transmission.
- Instruments, guide wires and screws are to be treated as sharps.
- **Do not use other manufacturer's instruments or implants in conjunction with the Monster® Screw System.**

MR SAFETY INFORMATION

The Monster® Screw System has 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 Monster® Screw System in the MR Environment is unknown. Scanning a patient who has this device may result in patient injury.

GORILLA®
R3CON PLATING SYSTEM

R3LEASE™
STABILIZATION SYSTEM

PATENTED, DESIGNED & EXCLUSIVELY DISTRIBUTED BY

Exclusively foot & ankle
Paragon 28®

www.PARAGON28.com

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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DISCLAIMER

If a stainless steel Gorilla® R3LEASE™ Screw is used (not available in all regions), it may only be used standalone.

The purpose of the Gorilla® R3LEASE™ Stabilization System Surgical Technique Guide is to demonstrate the optionality and functionality of the R3LEASE™ 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.