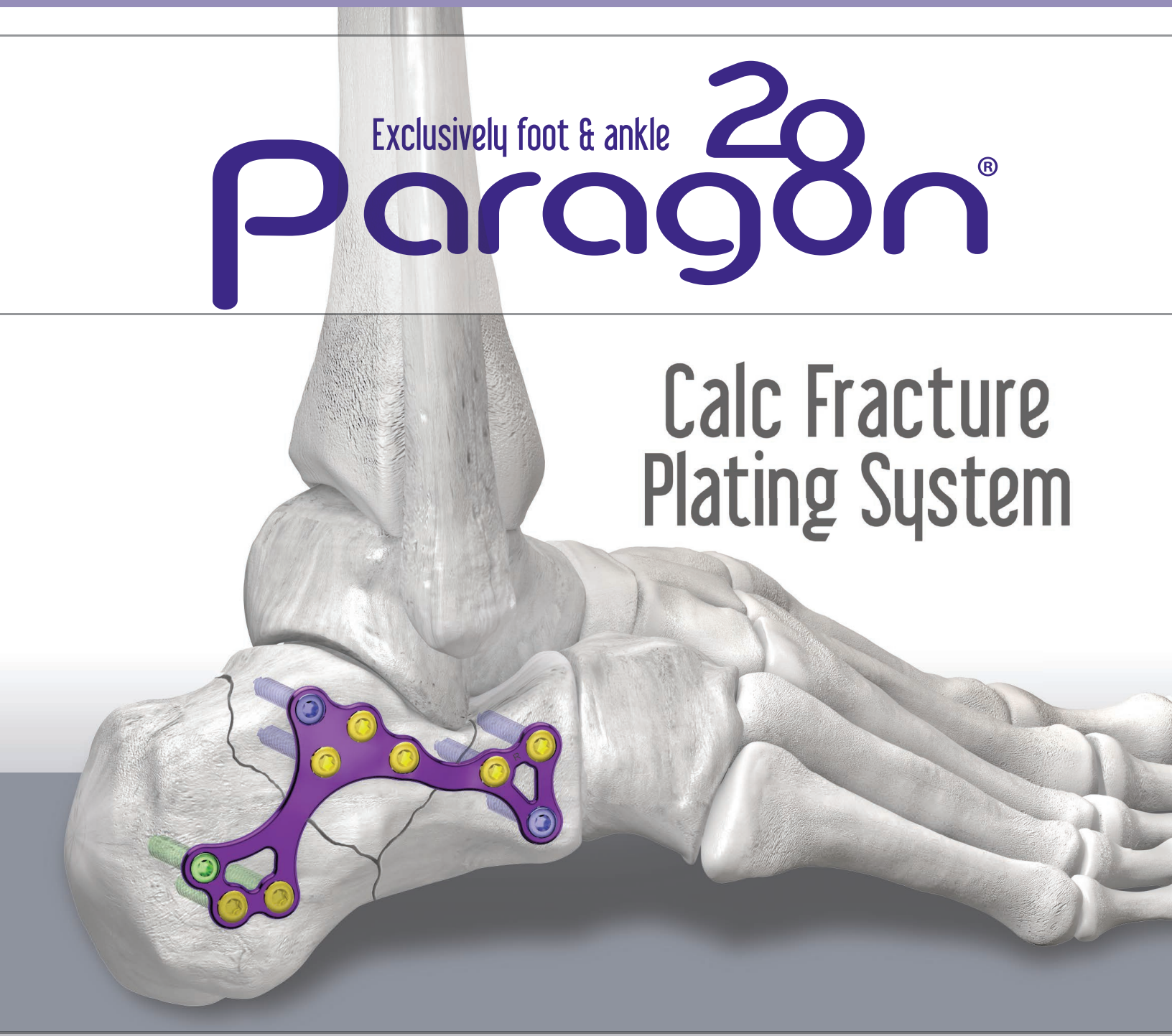
SURGICAL TECHNIQUE GUIDE:

CALCANEAL FRACTURE USING THE GORILLA® SINUS TARSI SUPPORT PLATE

Exclusively foot & ankle

Paragon 28®



Calc Fracture Plating System

GORILLA®

R3CON PLATING SYSTEM

Acknowledgment:

Paragon 28® would like to thank Christopher Zingas, M.D. for his contribution to the development of the surgical technique guide.

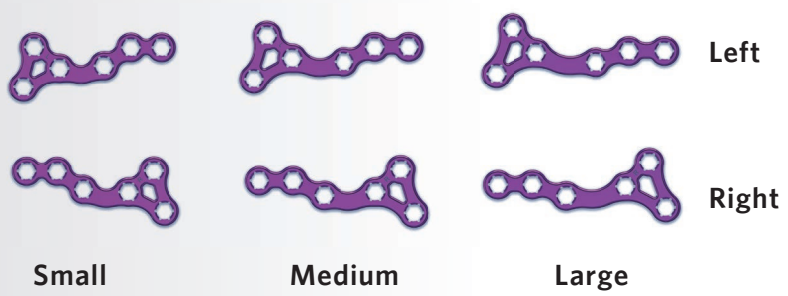
PRODUCT DESCRIPTION

Paragon 28® set out to design the Gorilla® Calc Fracture Plating System to allow for various methods to approach and provide plate fixation for calcaneal fractures. The diversity in plate options allows the surgeon to repair these challenging injuries using either a sinus tarsi or lateral extensile incision. The Gorilla® Calc Fracture Plating System is a part of the Gorilla® R3CON Plating System. All plate holes accommodate 2.7, 3.5 and 4.2 mm locking or non-locking screws. If TUFFNEK® Screw fixation is preferred, refer to the TUFFNEK® Surgical Technique Guide (P50-STG-0001) for proper screw placement technique.

IMPLANT OFFERING

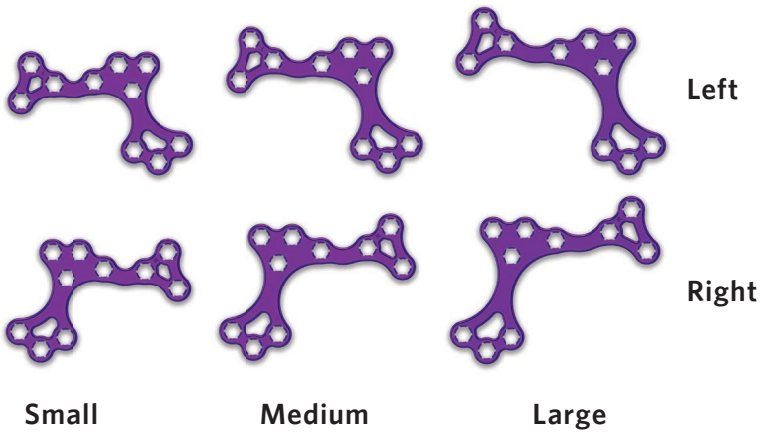
Sinus Tarsi Plate

- Intended for use with a sinus tarsi incision
- Available in 3 sizes
- Right and left specific design
- Minimally invasive and low profile with 1.1 mm thickness
- Made of Titanium Alloy (Ti6Al4V-ELI) for increased strength



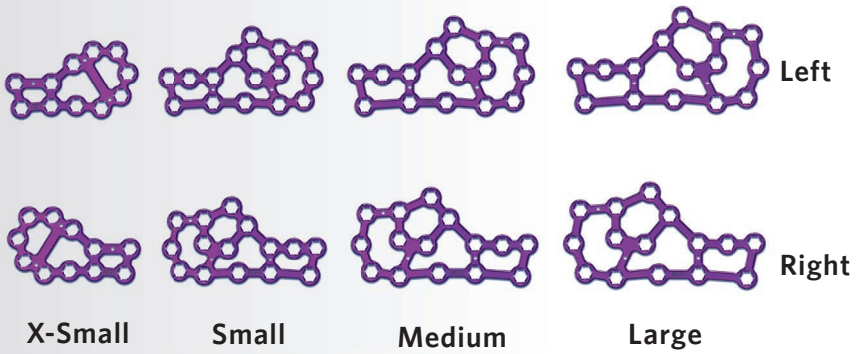
Sinus Tarsi Support Plate

- Intended for use with a sinus tarsi incision
- Available in 3 sizes
- Right and left specific design
- Instrumentation available to assist with incision placement and plate insertion through a sinus tarsi incision
- Minimally invasive and low profile with 1.1 mm thickness
- Made of Titanium Alloy (Ti6Al4V-ELI) for increased strength



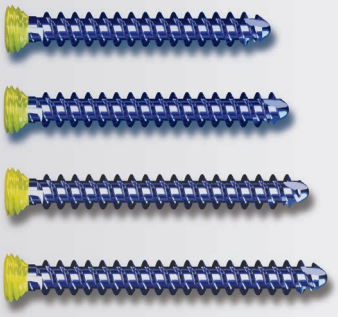
Perimeter Plate

- Intended for use with a lateral extensile incision
- Available in 4 sizes
- Right and left specific design
- Low profile with 1.1 mm thickness and up to 15 screw holes with off-axis locking capability for flexibility of screw placement
- Made of CP Grade 4 Titanium for increased malleability



R3CON Locking Screws

- Additional 3.5 mm R3CON locking screws are available in the most common lengths to supplement the screw offering in the Gorilla Case.



3.5 mm x 26 mm locking screw

3.5 mm x 28 mm locking screw

3.5 mm x 30 mm locking screw

3.5 mm x 32 mm locking screw

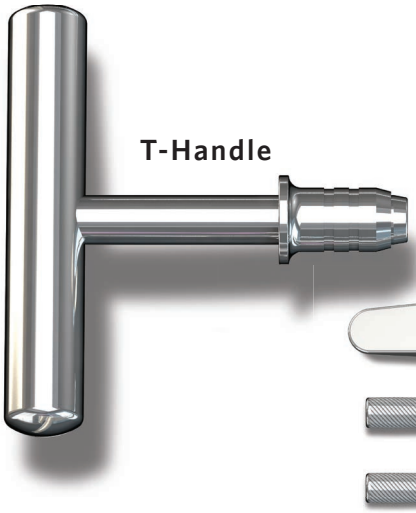
INSTRUMENTS

Ø2.3 mm K-wires

Ø2.9 mm K-wires

Ø4.0 mm Schanz Pins

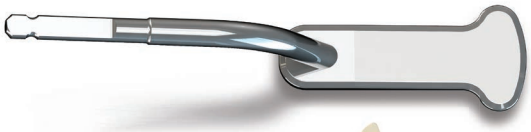
Ø6.0 mm Schanz Pins



T-Handle

Support Plate Inserter

Drill Guides

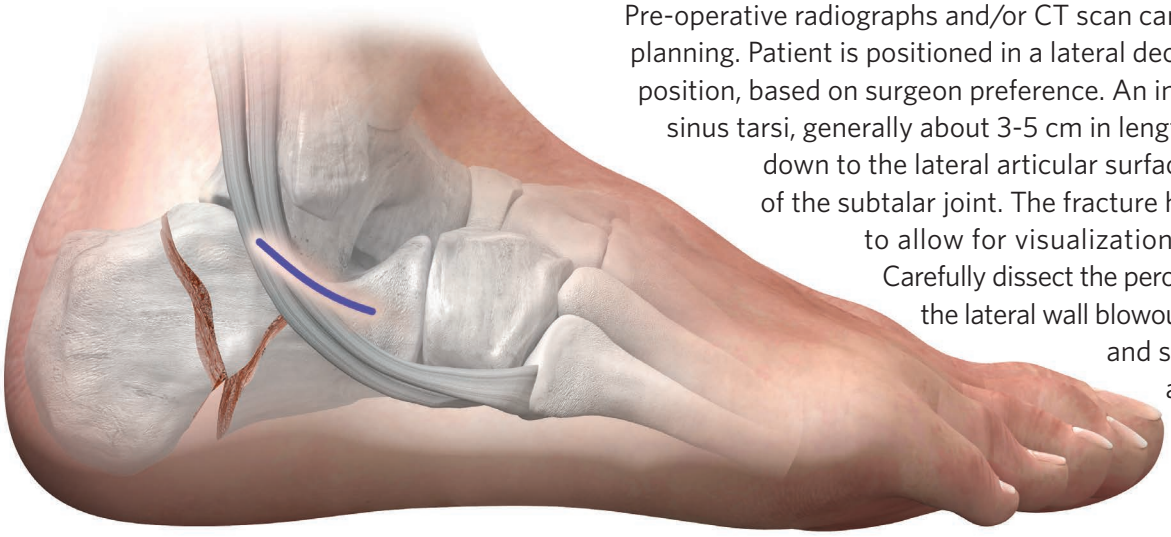


Dissection Tool

Incision Guide
(Available in Small, Medium, and Large)

The surgical technique shown in this guide is for placement of a Gorilla Sinus Tarsi Support Plate.
Use of instrumentation specific to this plate type helps facilitate plate insertion while maintaining a minimally invasive approach.

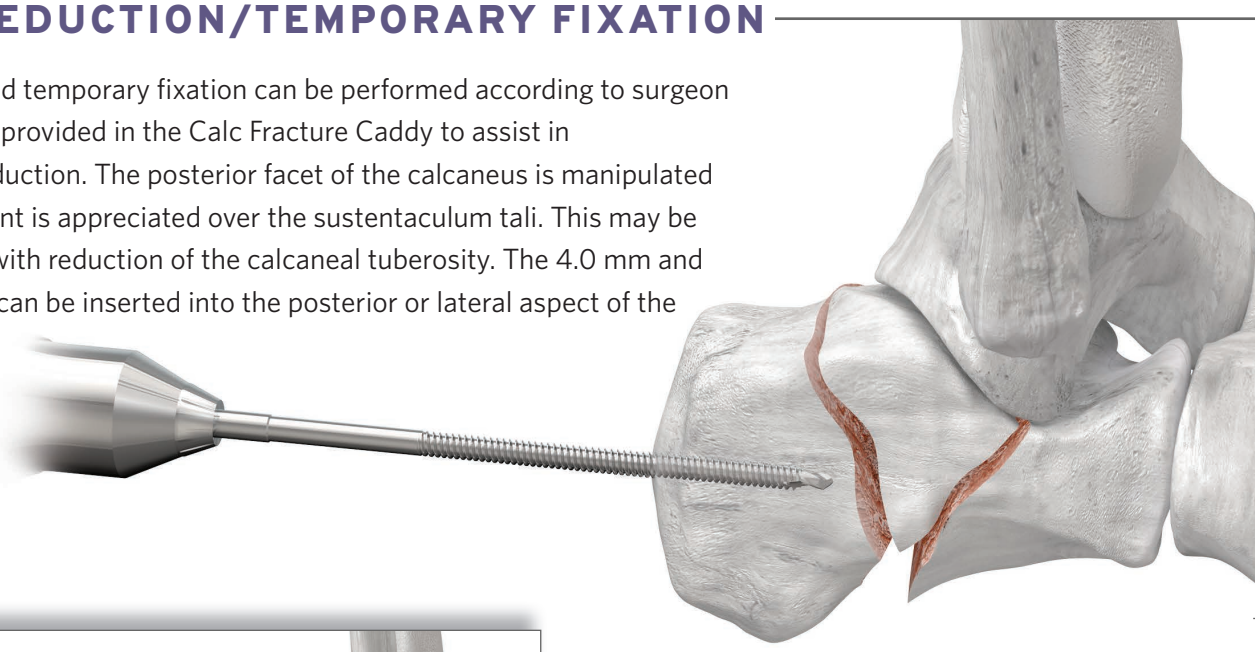
INCISION/EXPOSURE

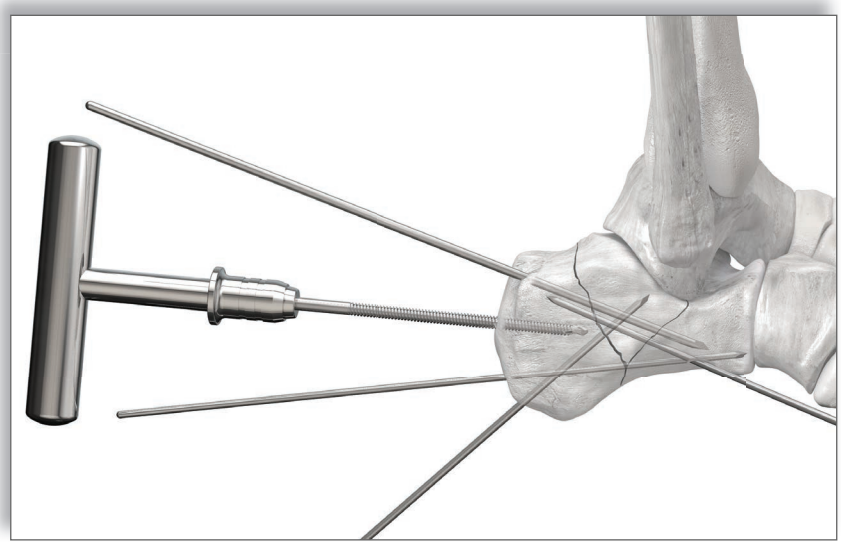


Pre-operative radiographs and/or CT scan can be used for procedure planning. Patient is positioned in a lateral decubitus, prone or supine position, based on surgeon preference. An incision is made over the sinus tarsi, generally about 3-5 cm in length. Dissection is carried down to the lateral articular surface of the posterior facet of the subtalar joint. The fracture hematoma is evacuated to allow for visualization of the posterior facet. Carefully dissect the peroneal tendons away from the lateral wall blowout. The peroneal tendons and sural nerve are retracted and protected plantarly.

FRACTURE REDUCTION/TEMPORARY FIXATION

Fracture reduction and temporary fixation can be performed according to surgeon preference. Tools are provided in the Calc Fracture Caddy to assist in calcaneal fracture reduction. The posterior facet of the calcaneus is manipulated until correct placement is appreciated over the sustentaculum tali. This may be done in conjunction with reduction of the calcaneal tuberosity. The 4.0 mm and 6.0 mm Schanz pins can be inserted into the posterior or lateral aspect of the calcaneal tuberosity.



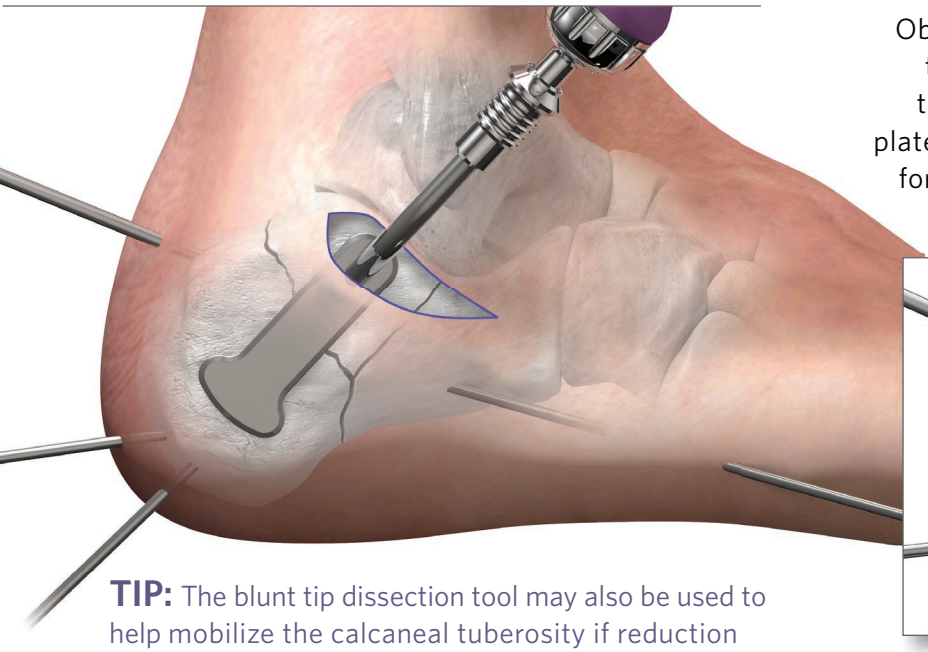


Once inserted, the T-handle can be attached to the Schanz pin to pull the calcaneal tuberosity out of varus, out to length and reduced with respect to the sustentacular fragment.

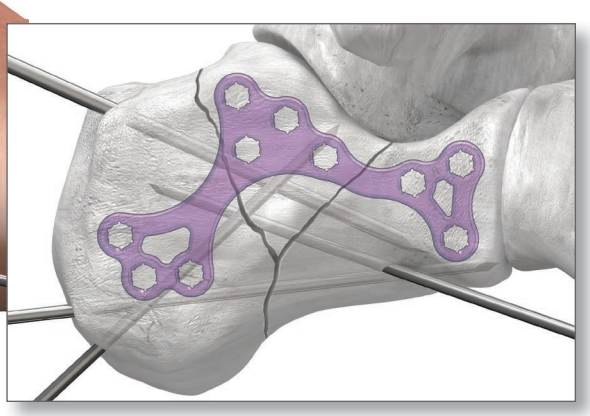
2.3 mm and 2.9 mm K-wires are used to provide temporary stabilization of the fracture fragments.

Ensure that Bohler's angle and the critical angle of Gissane have been re-established using fluoroscopy. Proceed with plate selection and placement once proper fracture reduction is achieved.

PLATE SELECTION AND PLACEMENT



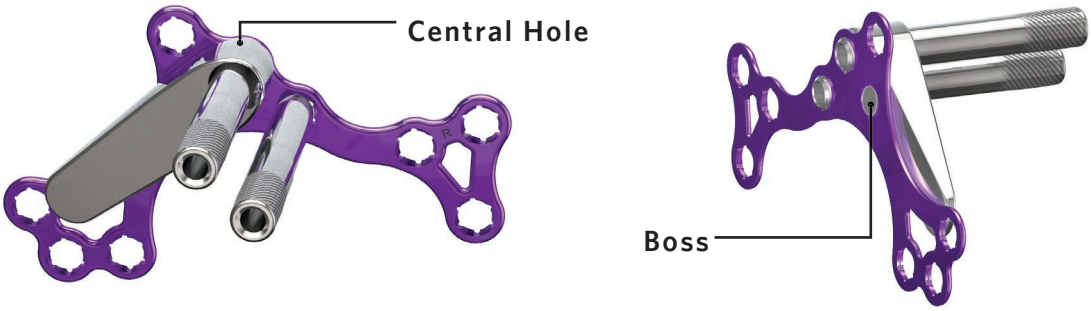
Obtain the blunt tip dissection tool. Use the blunt tip dissection tool to separate the soft tissue at the lateral aspect from the bone in the area of plate placement. This tool is designed to help allow for minimally invasive plate insertion of the Sinus Tarsi Support Plate along the lateral calcaneus.



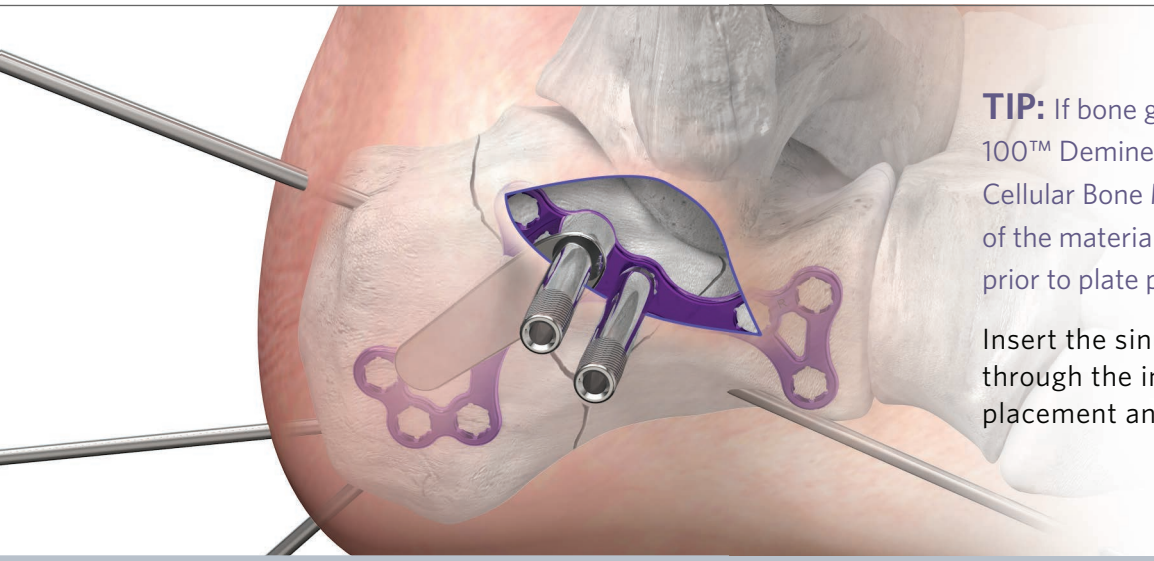
TIP: The blunt tip dissection tool may also be used to help mobilize the calcaneal tuberosity if reduction cannot be performed using the Schanz pins alone, especially in cases where bone healing has started and release of scar tissue along the lateral wall may be required.

Determine plate size clinically or with fluoroscopy. Plate benders from the Gorilla Case can be used to contour the plate at this time, if necessary.

PERMANENT FIXATION



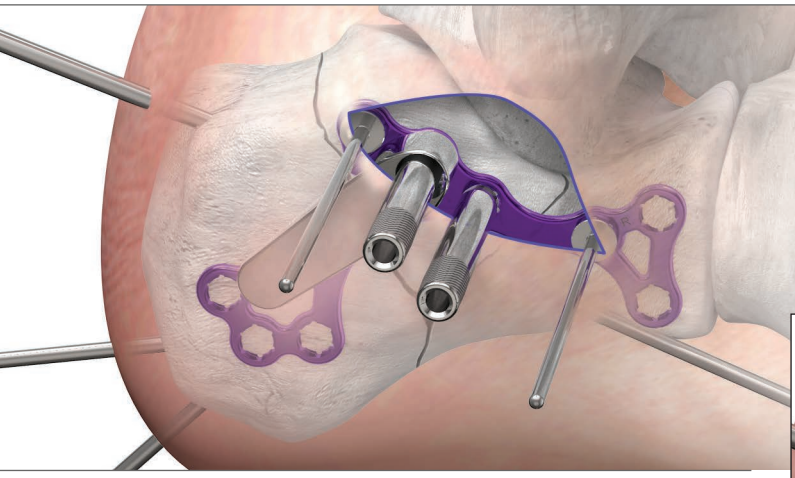
Place the plate inserter such that the boss extends into the hole below the three-hole cluster and the opening aligns with the central hole of the three hole cluster. Insert the two provided drill guides into the holes, as shown, with the drill guide extending into the central hole and also passing through the plate inserter.



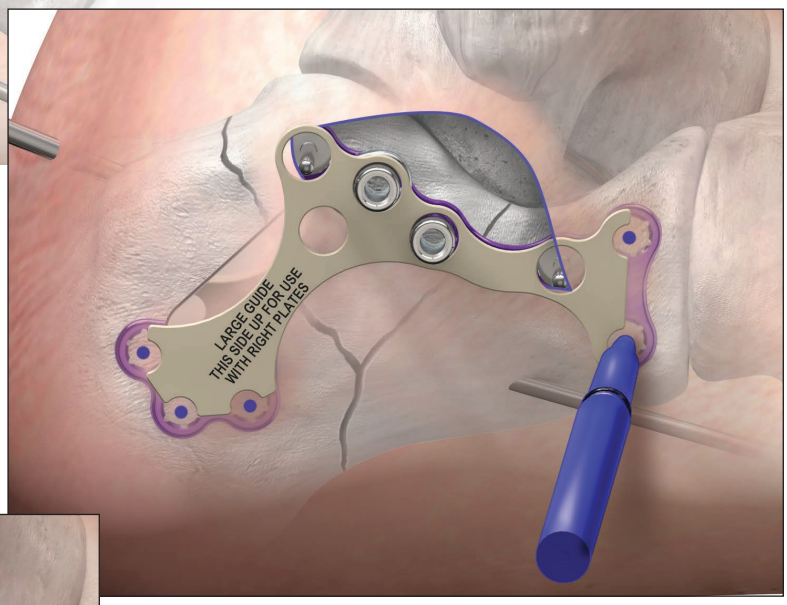
TIP: If bone graft or use of Paragon 28 Beast 100™ Demineralized Bone Matrix or V92™ Cellular Bone Matrix is necessary, insertion of the material can be performed prior to plate placement.

Insert the sinus tarsi support plate through the incision and confirm plate placement and size using fluoroscopy.

PERMANENT FIXATION

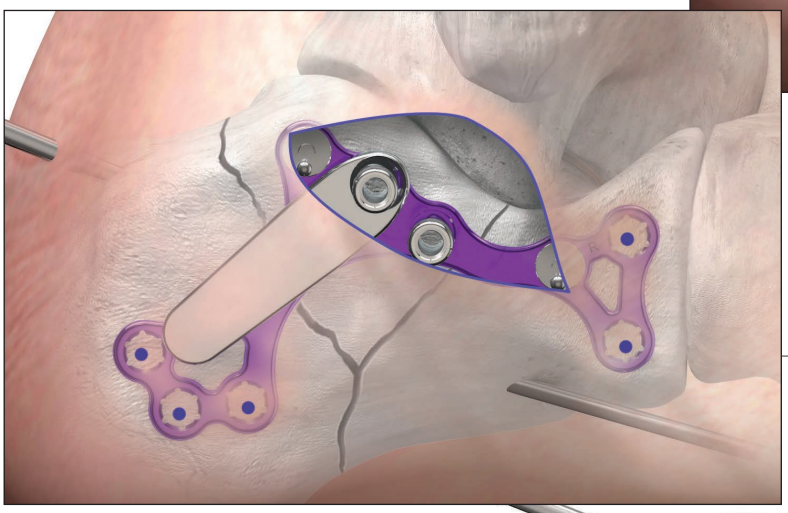


Once plate placement is correct,
olive wires can be used to hold plate position.

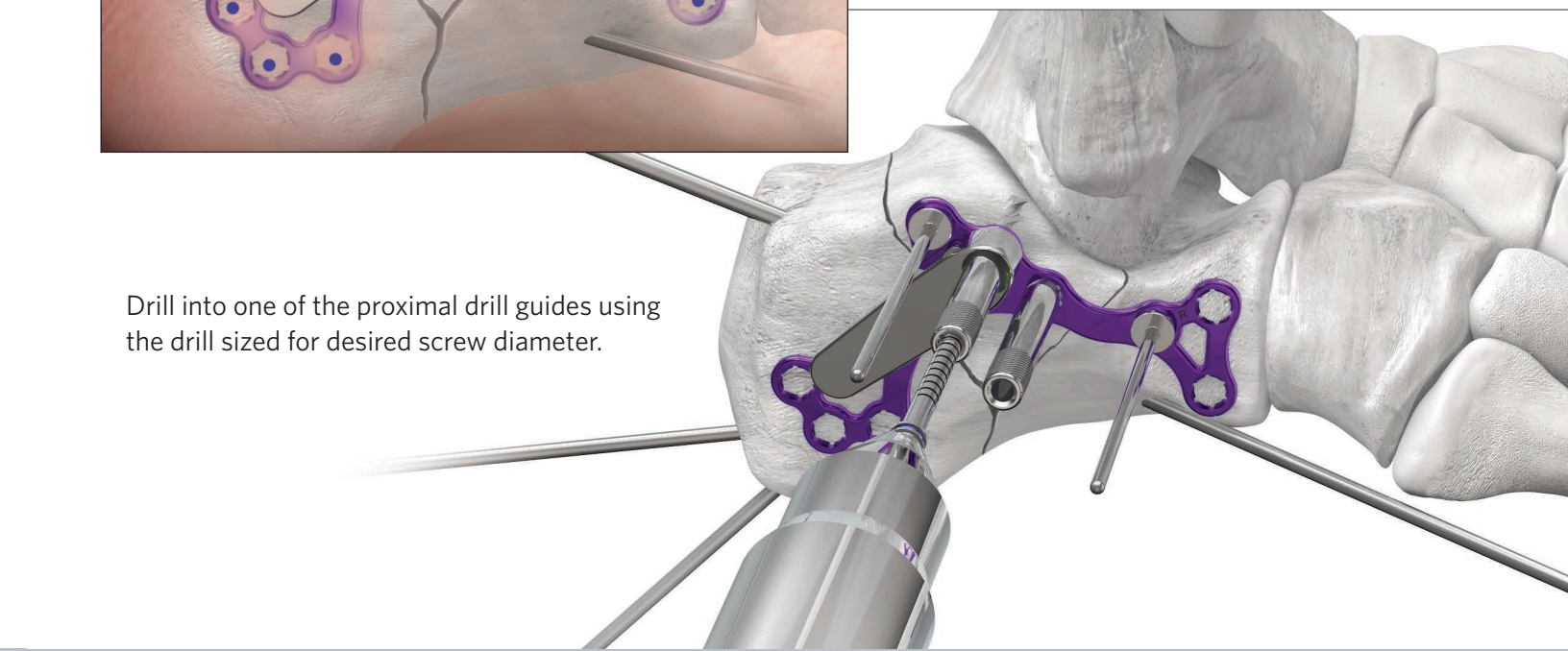


Obtain the incision guide that matches the chosen plate size. Place the incision guide over the drill holes such that the drill guides go through the same two central proximal holes as the plate.

Use the incision guide to mark the hole positions distally and plantarly on the plate.

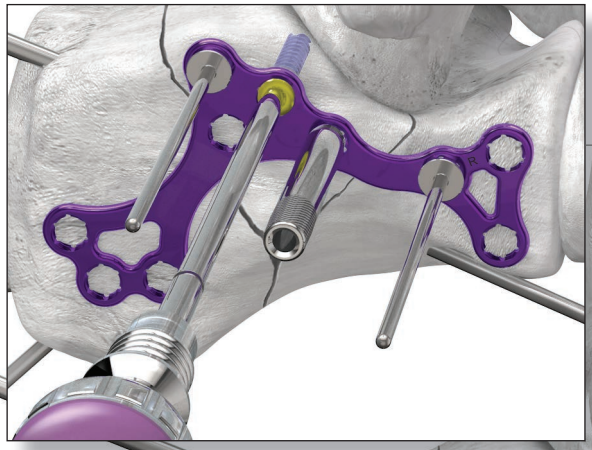


Alternatively, stab incisions can be made while the incision guide is on to allow for drilling and screw placement in these areas.



Drill into one of the proximal drill guides using the drill sized for desired screw diameter.

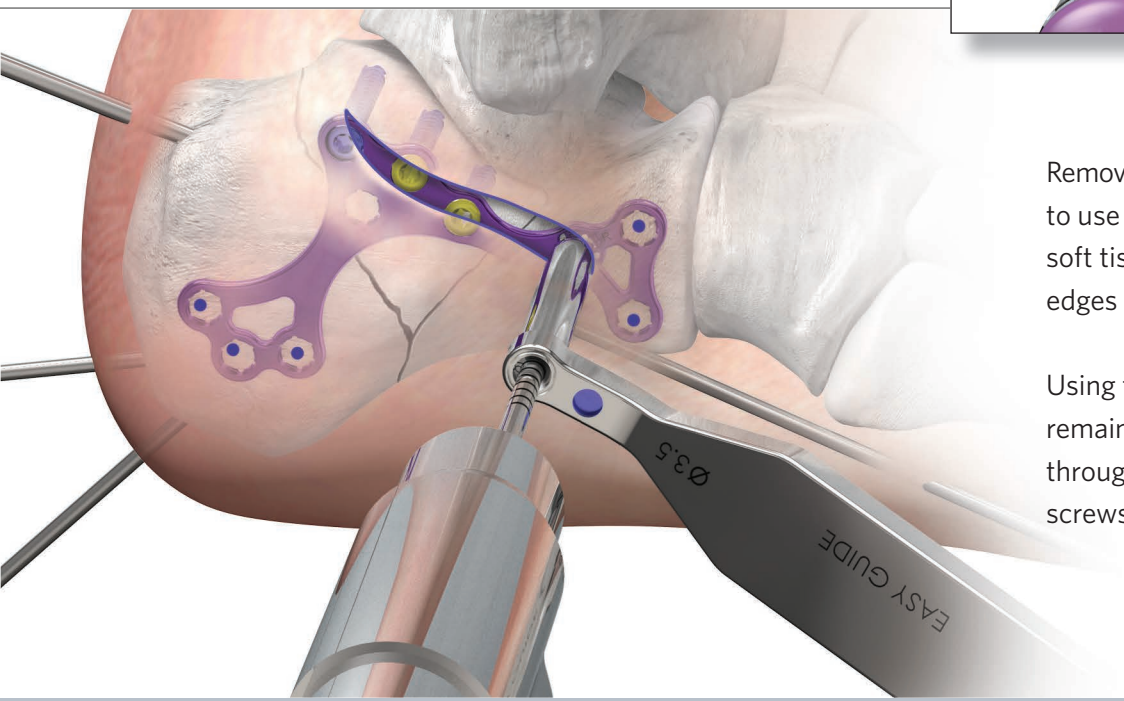
PERMANENT FIXATION



Remove the drill guide and plate inserter, measure screw length and insert the appropriate length screw using a screw driver.

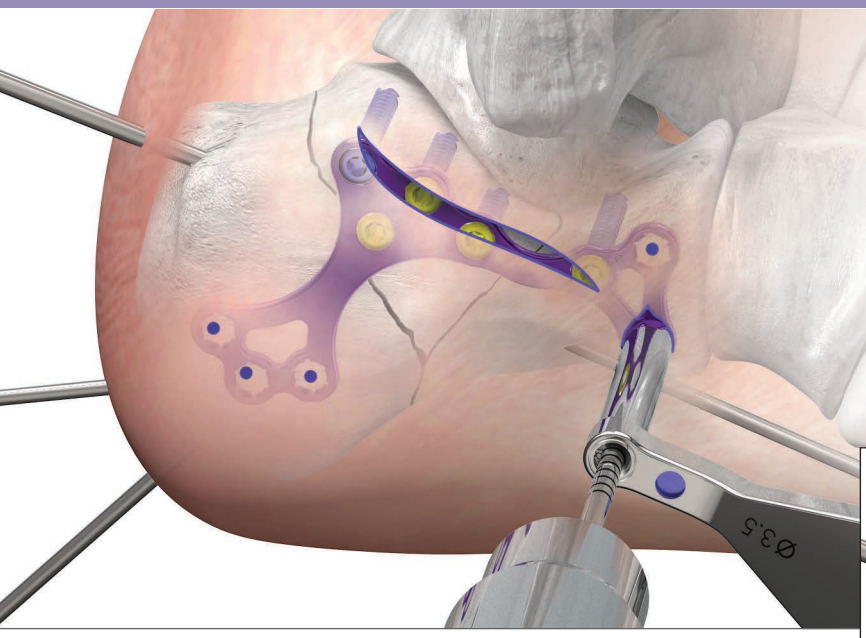
Repeat these steps for the second proximal drill guide.

TIP: A Harris-Beath projection view can be taken during the steps of screw placement to confirm screw length and to ensure the calcaneus is out of varus.

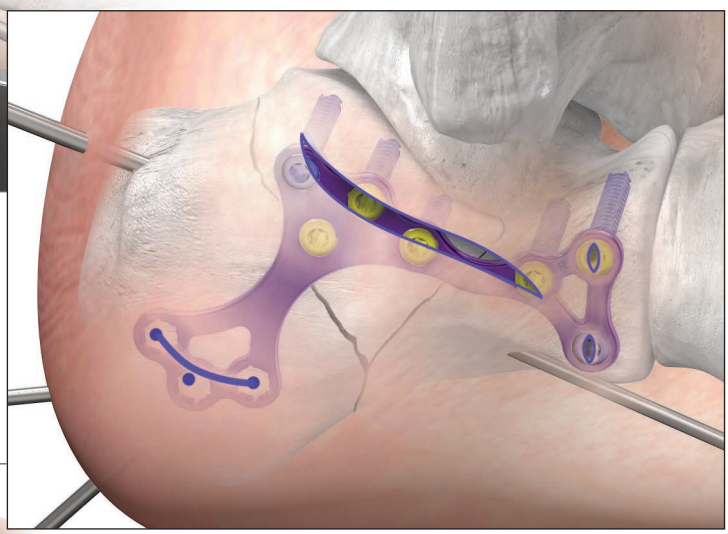


Remove the olive wires. It is recommended to use the Easy Drill Guide to help retract soft tissue while drilling the holes at the edges of the incision.

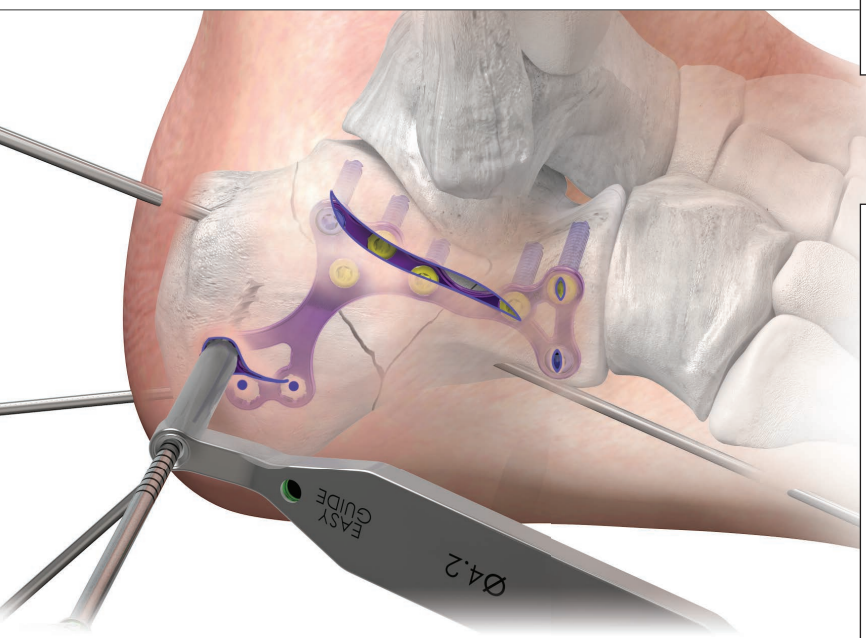
Using the Easy Drill Guide, drill the remaining holes that are accessible through the main incision and insert screws as described above.



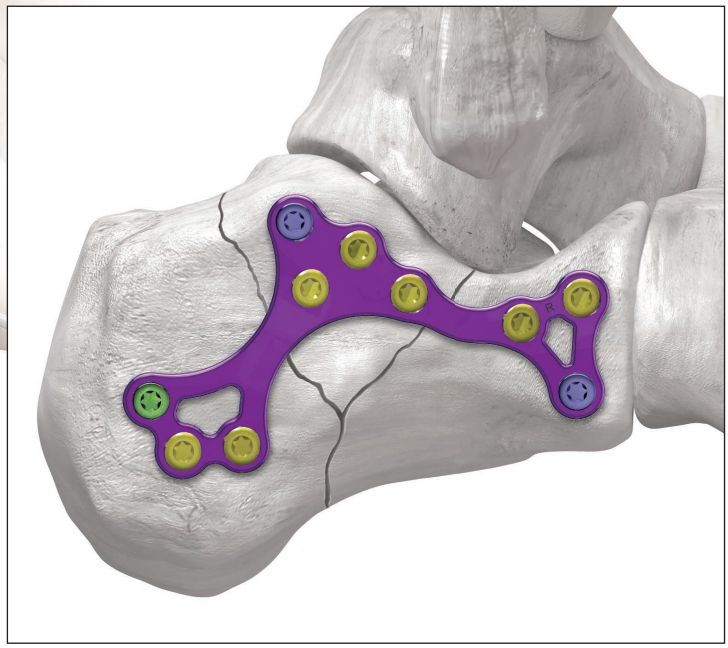
An incision or multiple stab incisions are made in the location of the marked holes distally and plantarly. A series of stab incisions are made over these holes or a single incision is made joining these marks.



TIP: If a single incision is made over the plantar holes, the incision should be straightened out slightly to avoid skin necrosis caused by a flap created by an incision that is too curved.



Place the Easy Drill Guide into one of the remaining distal or plantar holes. Using the drill for the selected screw diameter, drill through the drill guide. Measure screw length using a depth gauge. Insert the appropriate length screw using a screw driver.



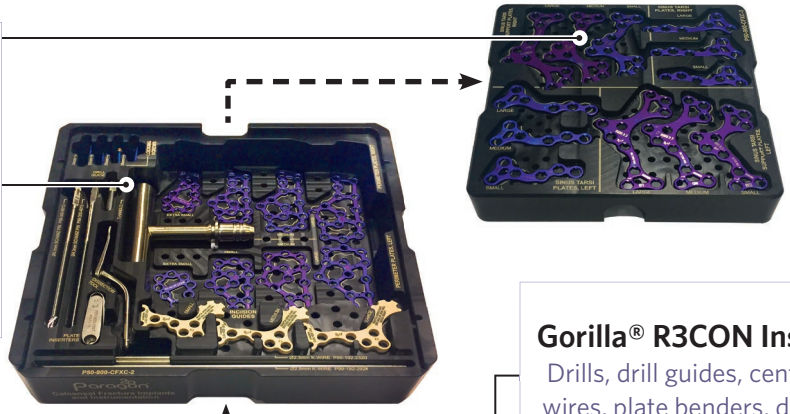
Repeat these steps to fill the remaining holes. Confirm implant placement using fluoroscopy.

CLOSURE

Proceed to incision closure or concomitant procedures at this time.

Gorilla® Calc Fracture Caddy

Calcaneal fracture plates, additional 3.5 mm locking screws and supporting instrumentation including Schanz pins, drill guides, incision guides, dissection tool, T-Handle, Support Plate Inserters and K-wires can be found in the Gorilla® Calc Fracture Caddy.

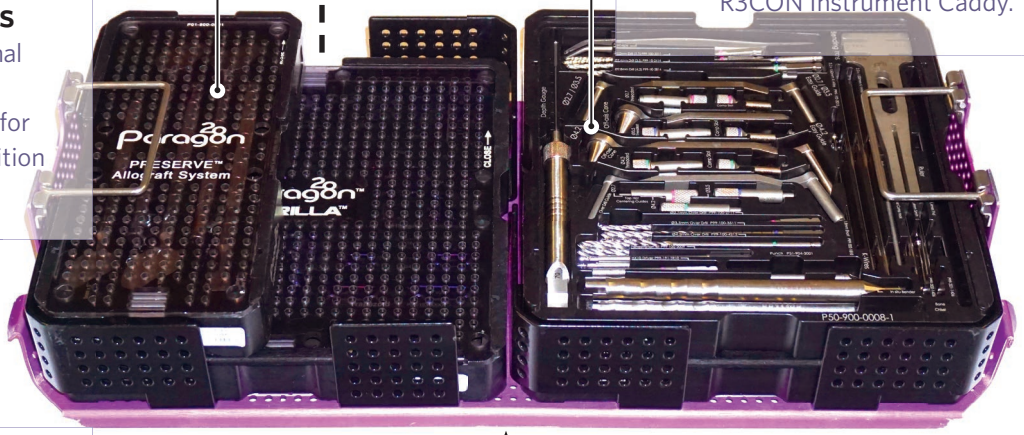


Gorilla® R3CON Instrument Caddy

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

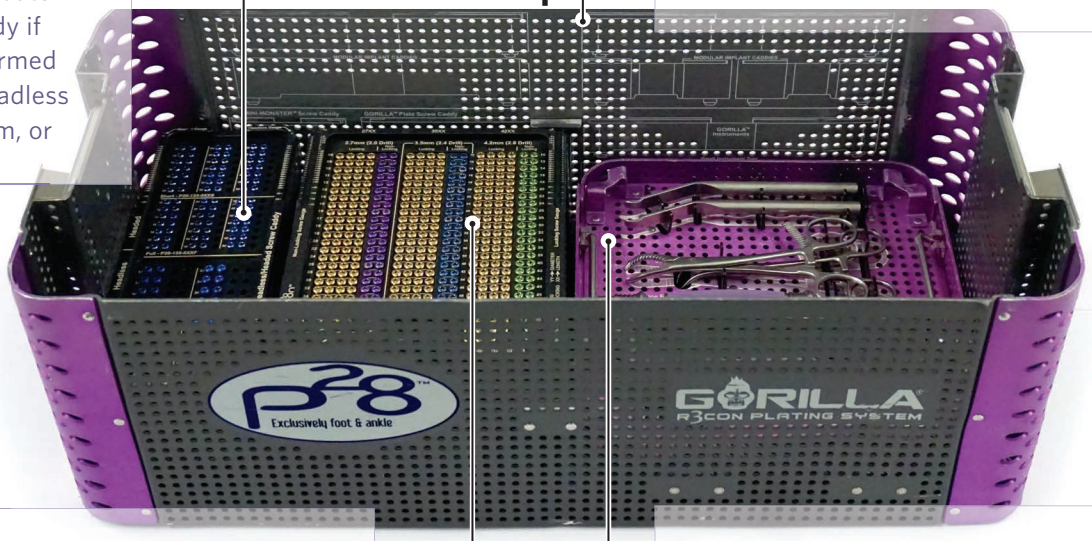
The Gorilla® Case has room for additional Gorilla® Plate Caddies or PRESERVE® Allograft Caddies that may be needed for additional procedures performed in addition to fixation of a calcaneal fracture.



Mini-Monster® Screw Caddy

The Gorilla® Case can accommodate one Mini-Monster® Screw Caddy if another procedure is being performed that would require a headed or headless 2.0 mm, 2.5 mm, 3.0 mm, 3.5 mm, or 4.0 mm cannulated screw.

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: BABY GORILLA®/GORILLA® PLATING SYSTEM

The bone plates and bone screws of the Baby Gorilla®/Gorilla® Plating System are indicated for use in bone reconstruction/ osteotomies, arthrodesis/joint fusion, and fracture repair/fracture fixation of the foot and ankle, appropriate for the size of the device.

System(s)	Indications	Intended Population(s)
Gorilla Plating System Plates and Bone Screws in Diameters: 2.7 mm, 3.5 mm, and 4.2 mm	The Gorilla plates and bone screws of the Gorilla Plating System are indicated for use in the foot and ankle for: - Bone Reconstruction Osteotomy - Arthrodesis/Joint Fusion - Fracture Repair/Fracture Fixation	Adult and Pediatric Patients
Baby Gorilla Plating System Plates and Bone Screws in Diameters: 2.0 mm and 2.5 mm	The Baby Gorilla plates and bone screws of the Gorilla Plating System are indicated for use in the foot for: - Bone Reconstruction/ Osteotomy - Arthrodesis/Joint Fusion - Fracture Repair/Fracture Fixation	Adult and Pediatric Patients
Silverback Plating System Plates and Bone Screws in Diameters: 4.5 mm, 4.7 mm, 5.2 mm	The Silverback plates and bone screws of the Gorilla plating System are indicated for use in the ankle for: - Arthrodesis/joint fusion	Adult Patients
R3LEASE Stabilization System Solid Screws and Washers in 3.9 mm Diameter	The R3LEASE Stabilization Screws of the Gorilla Plating System are indicated for use in the ankle for: - Fracture repair/fracture fixation	Adult Patients
Non-locking Screws and Washers Diameters: 2.0 mm, 2.5 mm, 2.7 mm, 3.5 mm, 4.2 mm, 4.5 mm, 4.7 mm, 5.2 mm, and 5.5 mm	The Non-Locking Bone Screws and Washers of the Gorilla Plating System are indicated for use in the foot and ankle for: - Bone Reconstruction Osteotomy - Arthrodesis/Joint Fusion - Fracture Repair/Fracture Fixation	Adult and Pediatric Patients

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

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

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.

GORILLA®
R3CON PLATING SYSTEM

Calc Fracture Plating System

PATENTED, DESIGNED & EXCLUSIVELY DISTRIBUTED BY

Exclusively foot & ankle
Paragon 28®

www.PARAGON28.com

P51-STG-1006 RevD [2022-07-10]

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DISCLAIMER

The purpose of the Calc Fracture Plate Surgical Technique Guide is to demonstrate the use of the Calc Fracture Plate in the Gorilla® R3CON Plating System. Although various methods can be employed for this procedure, 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.