Paragon 28®

a ZIMMER BIOMET company

SURGICAL TECHNIQUE GUIDE

Calcaneal Fracture Using the Gorilla® Sinus Tarsi Support Plate

Gorilla® Calc Fracture Plating System

GORILLA® R3CON PLATING SYSTEM

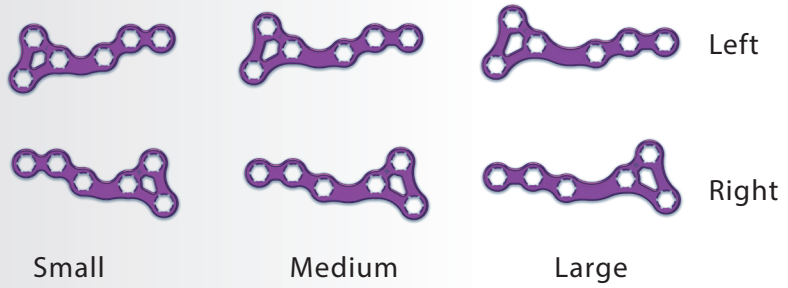
PRODUCT DESCRIPTION

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

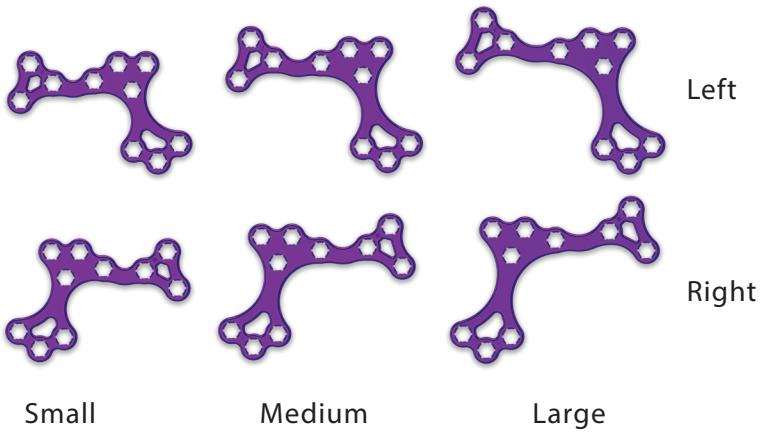
Sinus Tarsi Plate

- 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



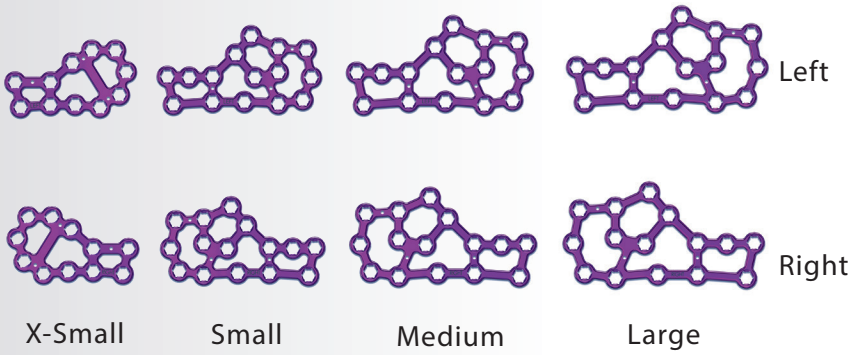
Sinus Tarsi Support Plate

- 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

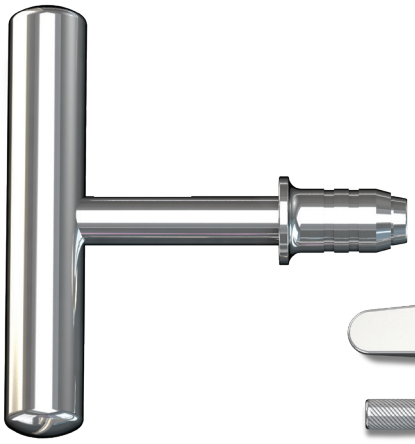
INSTRUMENTS


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

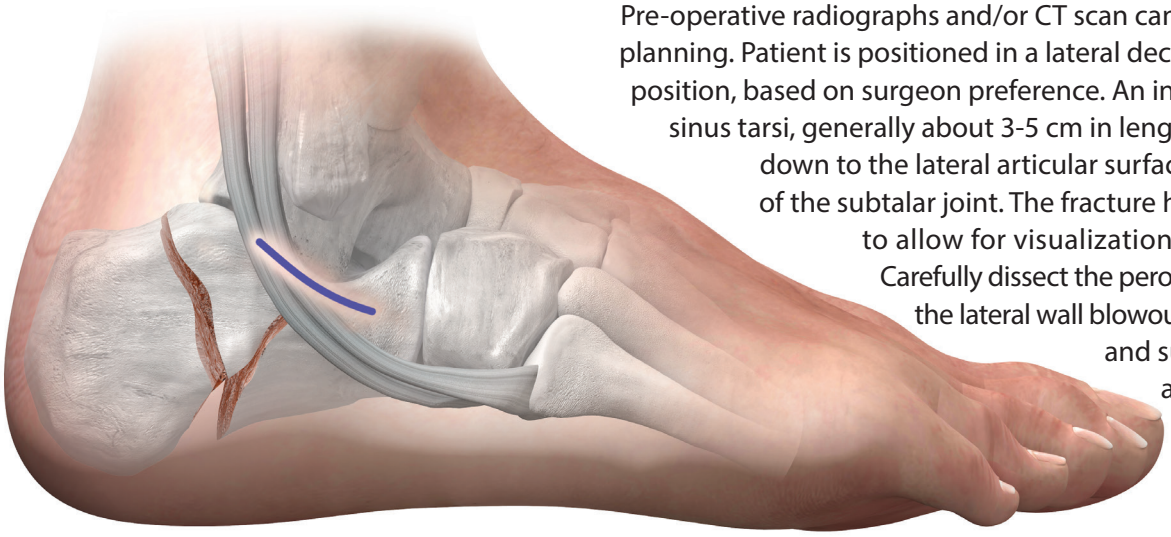

Drill Guides


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.

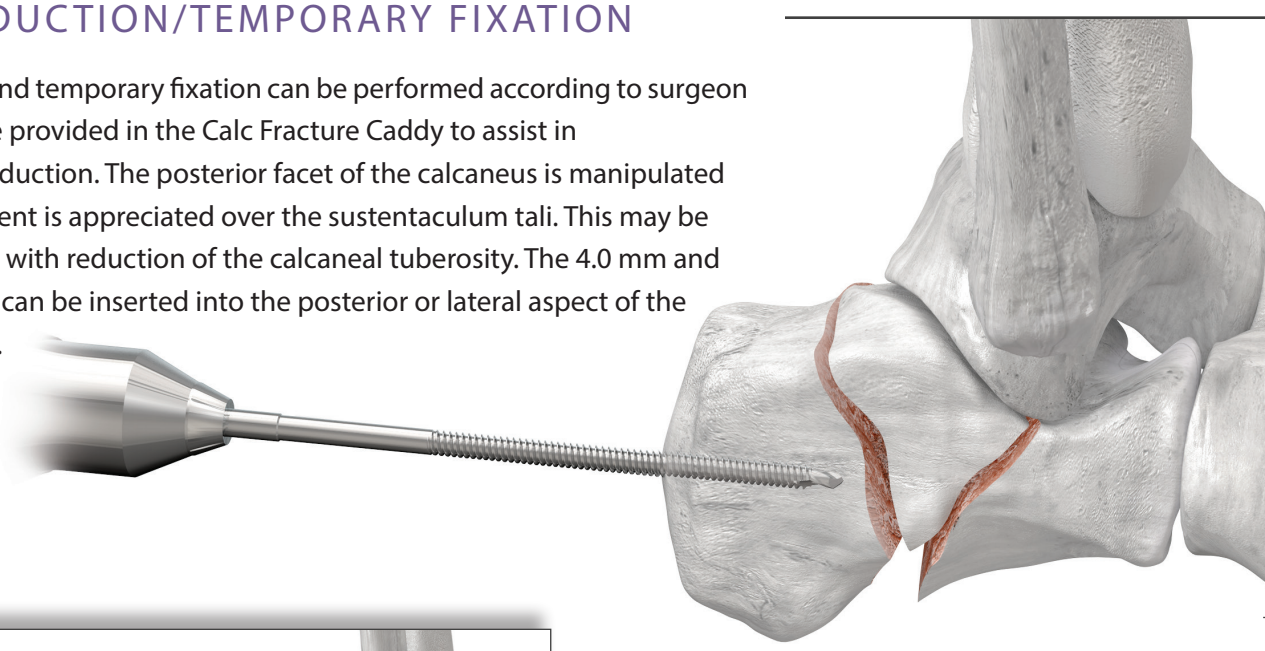
INCISION/EXPOSURE

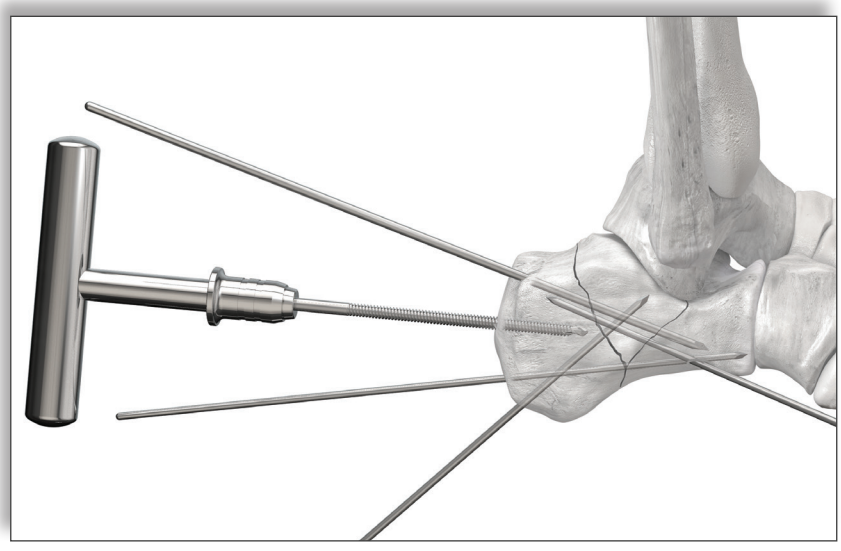


Pre-operative radiographs and/or CT scan can be used for procedure planning. Patient is positioned in a lateral decubitus, prone or supine position, based on surgeon preference. An incision is made over the sinus tarsi, generally about 3-5 cm in length. Dissection is carried down to the lateral articular 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.



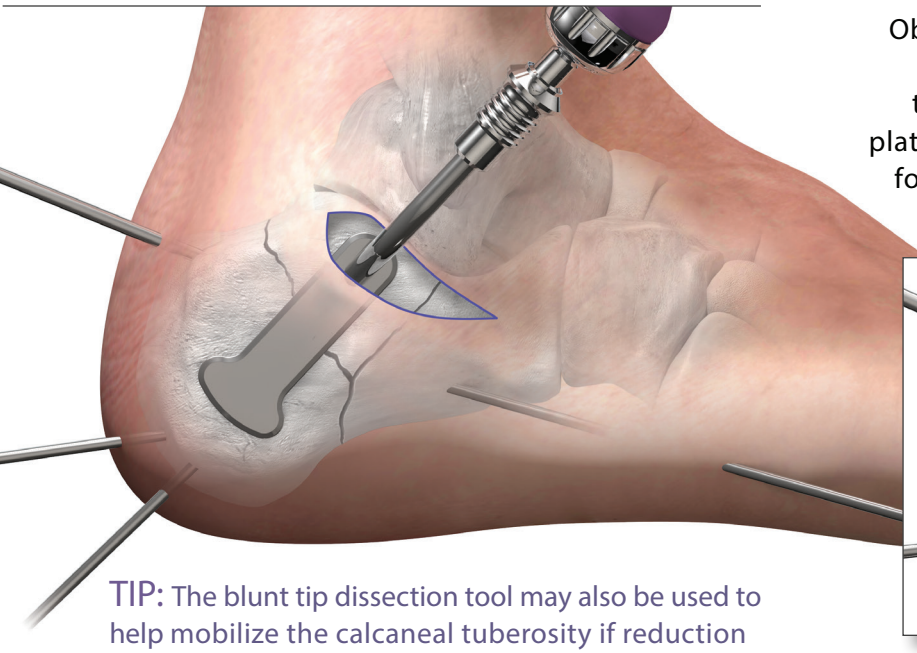


Once inserted, the T-handle can be attached to the Schanz pin to pull the calcaneal tuberosity out of varus, out to length and reduced with respect to the sustentacular fragment.

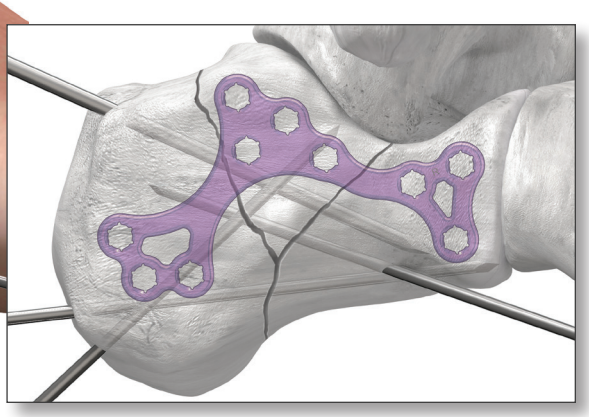
2.3 mm and 2.9 mm K-wires are used to provide temporary stabilization of the fracture fragments.

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



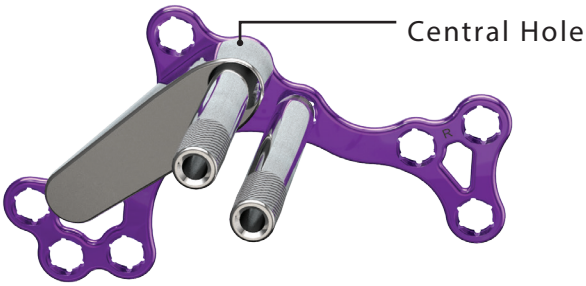
Obtain the blunt tip dissection tool. Use the blunt tip dissection tool to separate the soft tissue at the lateral aspect from the bone in the area of plate placement. This tool is designed to help allow for minimally invasive plate insertion of the Sinus Tarsi Support Plate along the lateral calcaneus.



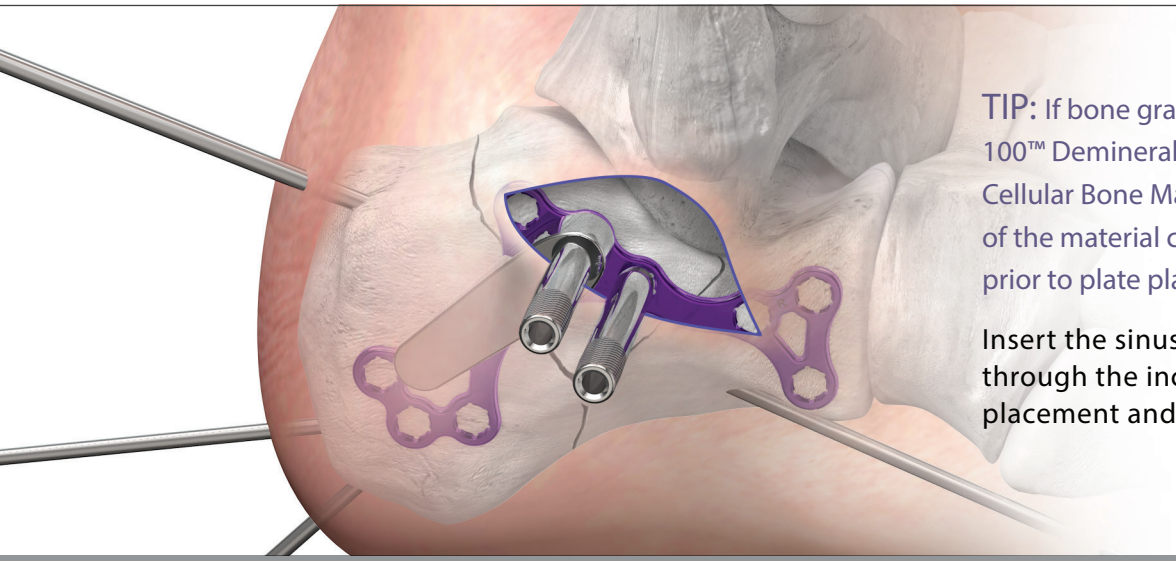
TIP: The blunt tip dissection tool may also be used to help mobilize the calcaneal tuberosity if reduction cannot be performed using the Schanz pins alone, especially in cases where bone healing has started and release of scar tissue along the lateral wall may be required.

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



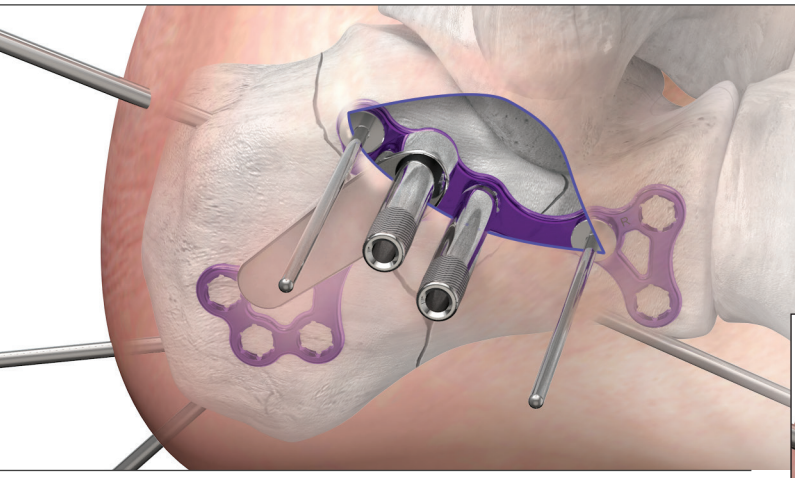
Place the plate inserter such that the boss extends into the hole below the three-hole cluster and the opening aligns with the central hole of the three hole cluster. Insert the two provided drill guides into the holes, as shown, with the drill guide extending into the central hole and also passing through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



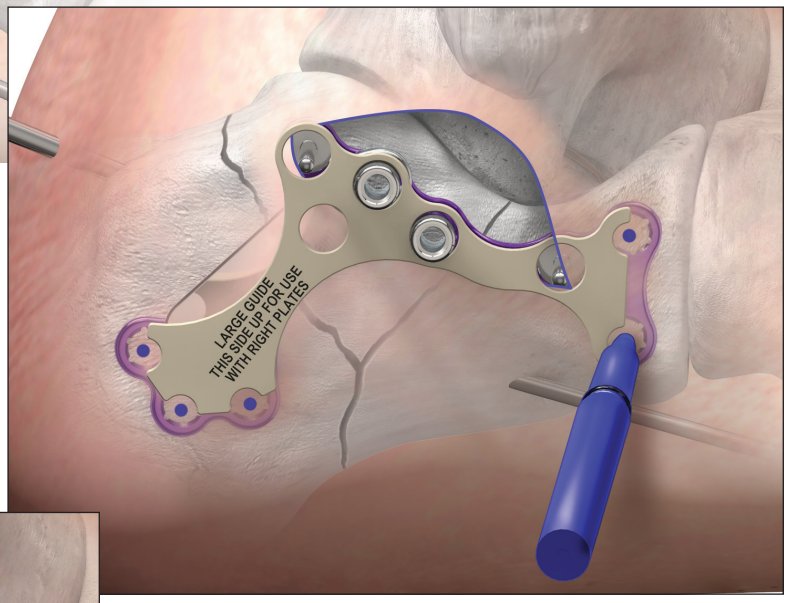
TIP: If bone graft or use of Paragon 28 Beast 100™ Demineralized Bone Matrix or V92™ Cellular Bone Matrix is necessary, insertion of the material can be performed prior to plate placement.

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

PERMANENT FIXATION

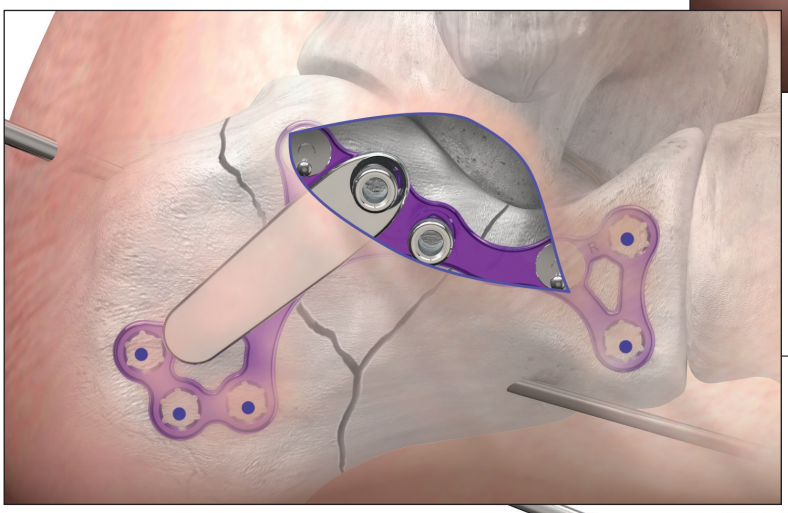


Once plate placement is correct,
olive wires can be used to hold plate position.

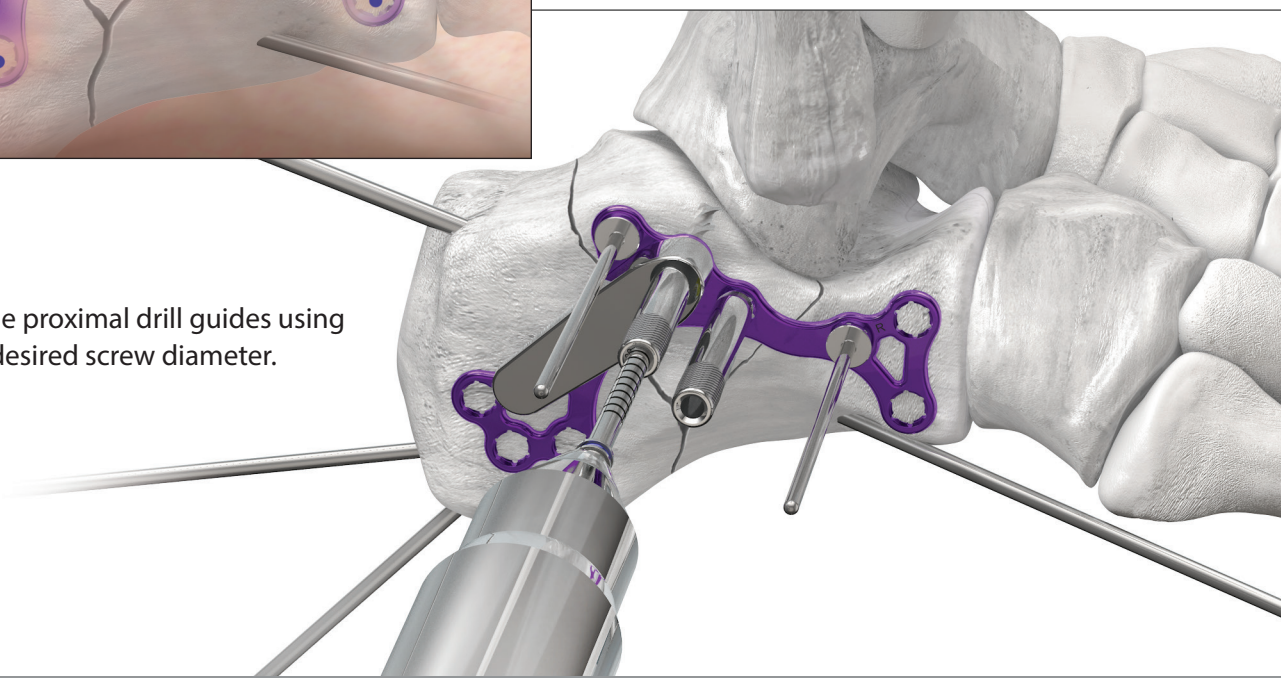


Obtain the incision guide that matches the chosen plate size. Place the incision guide over the drill holes such that the drill guides go through the same two central proximal holes as the plate.

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

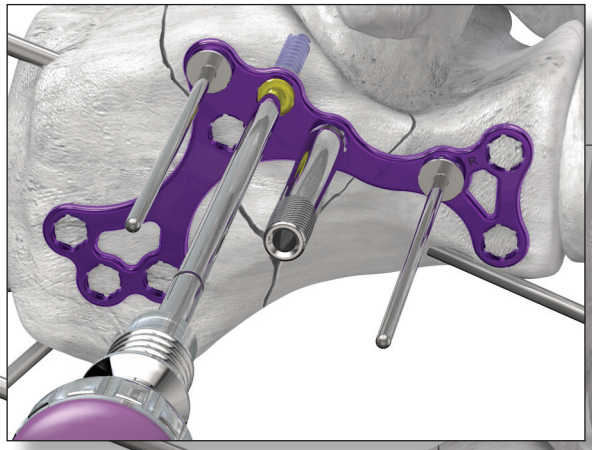


Alternatively, stab incisions can be made while the incision guide is on to allow for drilling and screw placement in these areas.



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

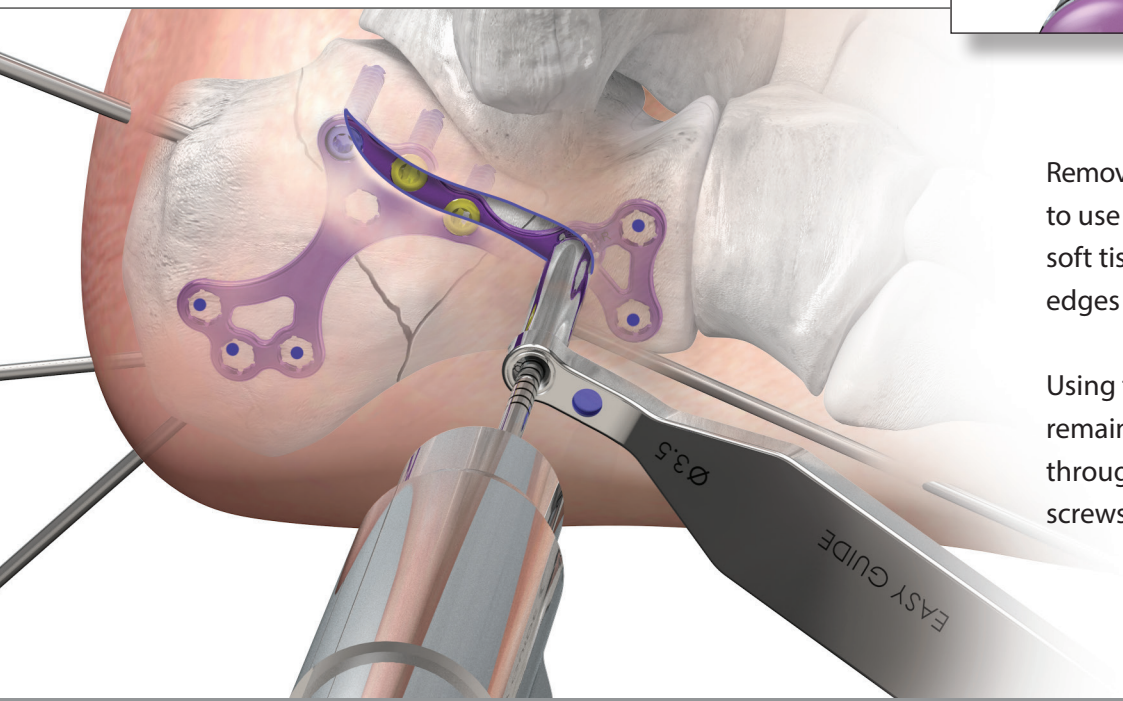
PERMANENT FIXATION



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

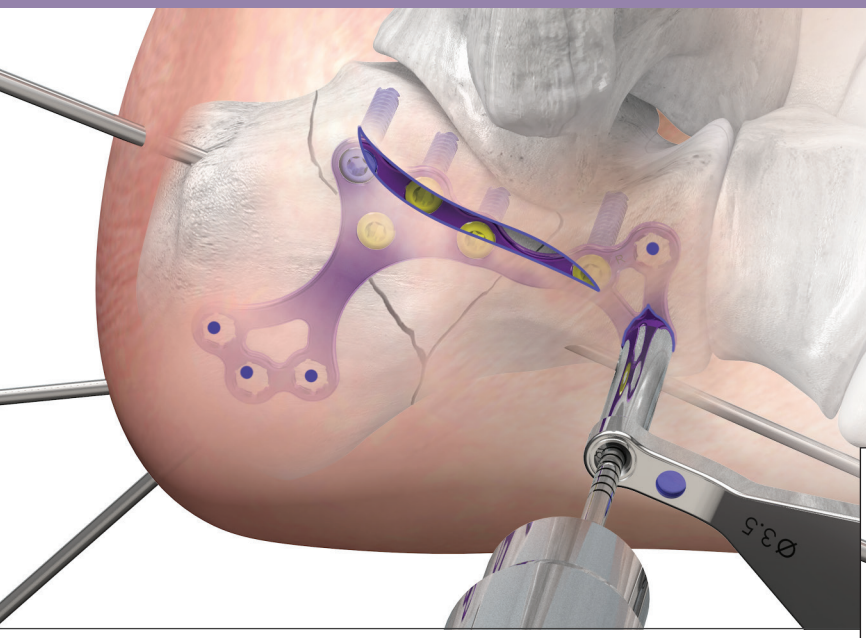
Repeat these steps for the second proximal drill guide.

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.

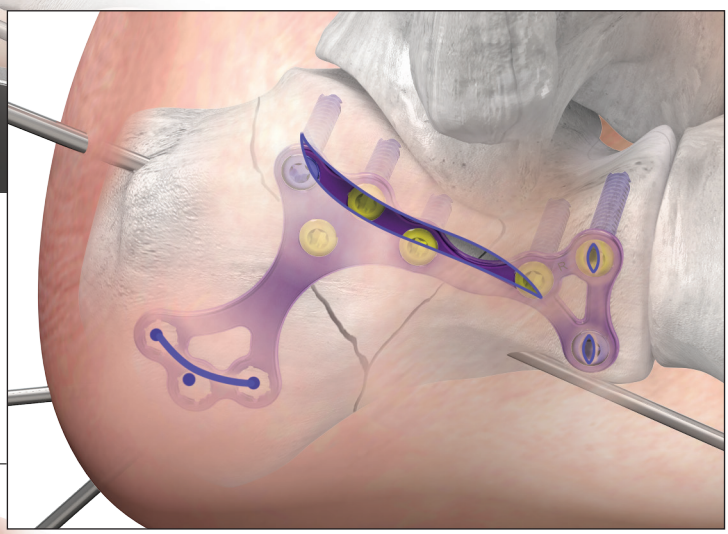


Remove the olive wires. It is recommended to use the Easy Drill Guide to help retract soft tissue while drilling the holes at the edges of the incision.

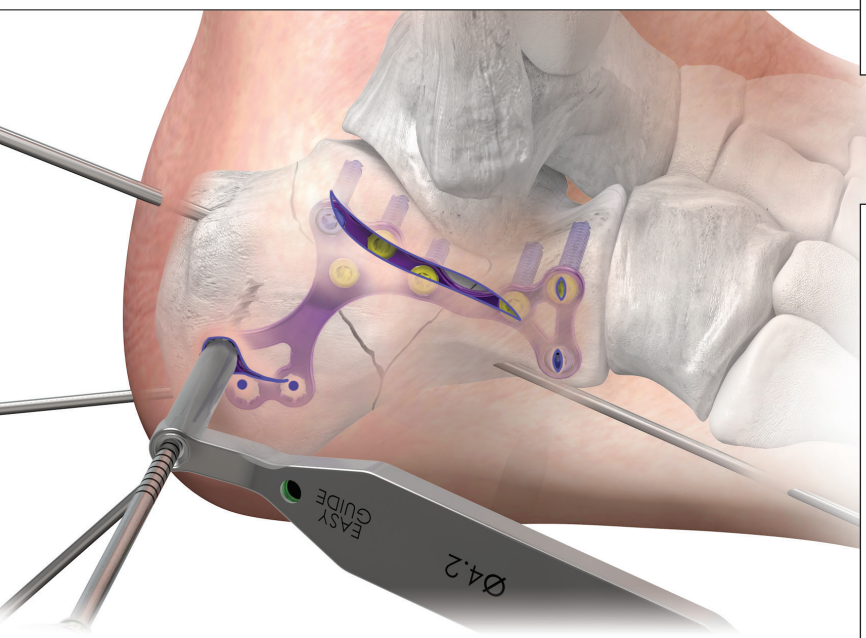
Using the Easy Drill Guide, drill the remaining holes that are accessible through the main incision and insert screws as described above.



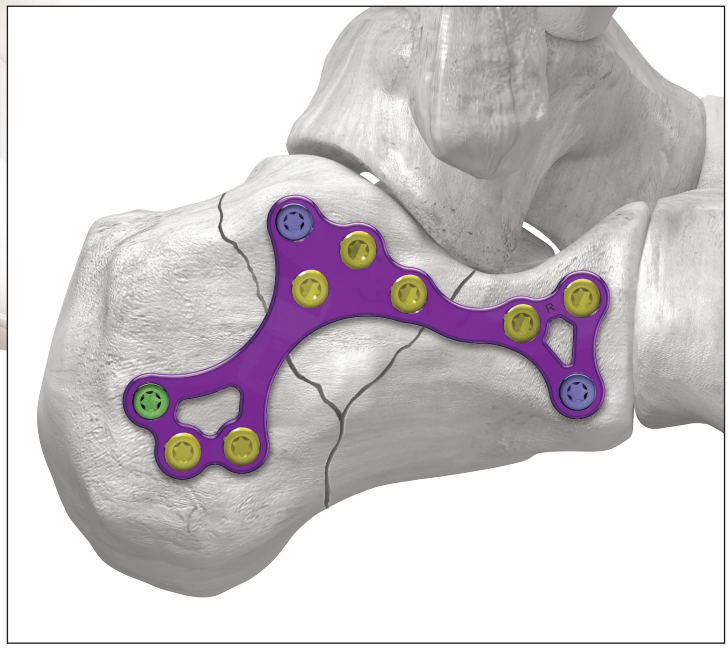
An incision or multiple stab incisions are made in the location of the marked holes distally and plantarly. A series of stab incisions are made over these holes or a single incision is made joining these marks.



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.



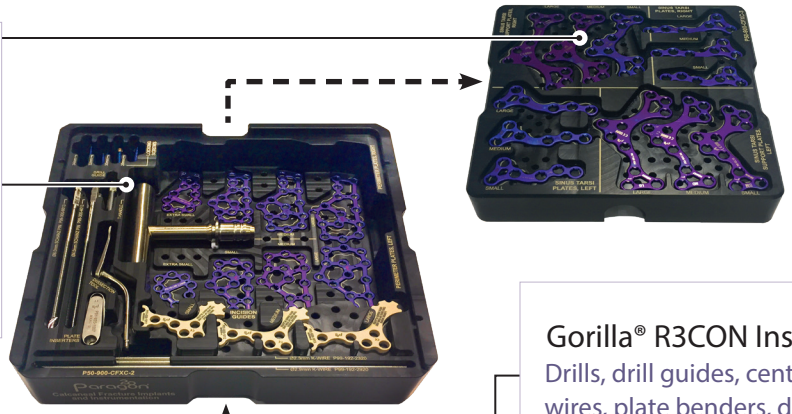
Repeat these steps to fill the remaining holes. Confirm implant placement using fluoroscopy.

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.

GORILLA PLATING SYSTEM - CALCANEAL FRACTURE CADDY, IMPLANTS:

Part #	Description	Use
P50-353-3528	Gorilla, R3CON™ Plate Screw, Locking, 3.5 x 28 mm, TiA	Single-use
P50-353-3530	Gorilla, R3CON™ Plate Screw, Locking, 3.5 x 30 mm, TiA	Single-use
P50-353-3532	Gorilla, R3CON™ Plate Screw, Locking, 3.5 x 32 mm, TiA	Single-use
P50-353-3534	Gorilla, R3CON™ Plate Screw, Locking, 3.5 x 34 mm, TiA	Single-use
P53-102-L000	Gorilla, Calcaneal Fracture, Perimeter Plate, Extra Small, Left, Ti	Single-use
P53-102-L001	Gorilla, Calcaneal Fracture, Perimeter Plate, Small, Left, Ti	Single-use
P53-102-L002	Gorilla, Calcaneal Fracture, Perimeter Plate, Medium, Left, Ti	Single-use
P53-102-L003	Gorilla, Calcaneal Fracture, Perimeter Plate, Large, Left, Ti	Single-use
P53-102-L101	Gorilla, Calcaneal Fracture, Sinus Tarsi+Support Plate, Small, Left, TiA	Single-use
P53-102-L102	Gorilla, Calcaneal Fracture, Sinus Tarsi+Support Plate, Medium, Left, TiA	Single-use
P53-102-L103	Gorilla, Calcaneal Fracture, Sinus Tarsi+Support Plate, Large, Left, TiA	Single-use
P53-102-L201	Gorilla, Calcaneal Fracture, Sinus Tarsi Plate, Small, Left, TiA	Single-use
P53-102-L202	Gorilla, Calcaneal Fracture, Sinus Tarsi Plate, Medium, Left, TiA	Single-use
P53-102-L203	Gorilla, Calcaneal Fracture, Sinus Tarsi Plate, Large, Left, TiA	Single-use
P53-102-R000	Gorilla, Calcaneal Fracture, Perimeter Plate, Extra Small, Right, Ti	Single-use
P53-102-R001	Gorilla, Calcaneal Fracture, Perimeter Plate, Small, Right, Ti	Single-use
P53-102-R002	Gorilla, Calcaneal Fracture, Perimeter Plate, Medium, Right, Ti	Single-use
P53-102-R003	Gorilla, Calcaneal Fracture, Perimeter Plate, Large, Right, Ti	Single-use
P53-102-R101	Gorilla, Calcaneal Fracture, Sinus Tarsi+Support Plate, Small, Right, TiA	Single-use
P53-102-R102	Gorilla, Calcaneal Fracture, Sinus Tarsi+Support Plate, Medium, Right, TiA	Single-use
P53-102-R103	Gorilla, Calcaneal Fracture, Sinus Tarsi+Support Plate, Large, Right, TiA	Single-use
P53-102-R201	Gorilla, Calcaneal Fracture, Sinus Tarsi Plate, Small, Right, TiA	Single-use
P53-102-R202	Gorilla, Calcaneal Fracture, Sinus Tarsi Plate, Medium, Right, TiA	Single-use
P53-102-R203	Gorilla, Calcaneal Fracture, Sinus Tarsi Plate, Large, Right, TiA	Single-use

GORILLA PLATING SYSTEM - CALCANEAL FRACTURE CADDY, INSTRUMENTS:

Part #	Description	Use
P51-920-1006	Gorilla, Calcaneal Fracture, Dissection Tool, SS	Reusable
P51-920-1007	Gorilla, Calcaneal Fracture, Sinus Tarsi, Support Plate Inserter	Reusable
P51-920-1010	Gorilla, Calcaneal Fracture, Sinus Tarsi, Drill Guide, Locking	Reusable
P51-920-1011	Gorilla, Calcaneal Fracture, Sinus Tarsi, Incision Guide, Small	Reusable
P51-920-1012	Gorilla, Calcaneal Fracture, Sinus Tarsi, Incision Guide, Medium	Reusable
P51-920-1013	Gorilla, Calcaneal Fracture, Sinus Tarsi, Incision Guide, Large	Reusable
P99-000-AOTH	P28, T-Handle, AO Non-ratcheting, Solid, SS	Reusable
P99-300-4013	P28, Schanz Pin, Ø4.0mm, AO Connect, SS	
P99-300-6013	P28, Schanz Pin, Ø6.0mm, AO Connect, SS	
P99-192-2320	P28, K-wire, Ø2.3 x 200mm, Smooth, SS	Single-use
P99-192-2920	P28, K-wire, Ø2.9 x 200mm, Smooth, SS	Single-use

*See the complete Gorilla Plating Surgical Technique Guide (P51-STG-0001) for general instrument information

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

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.

Gorilla® Calc Fracture Plating System

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Paragon 28®

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