Paragon 28®

a ZIMMER BIOMET company

SURGICAL TECHNIQUE GUIDE

Calcaneal Slide Osteotomy

Gorilla® Calc Slide Plating System

GORILLA® R3CON PLATING SYSTEM

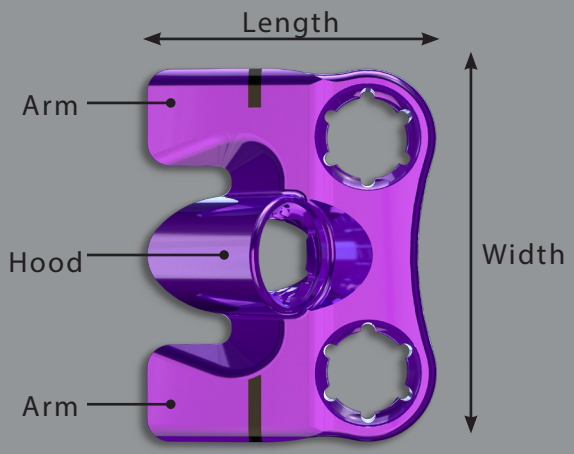
PRODUCT DESCRIPTION

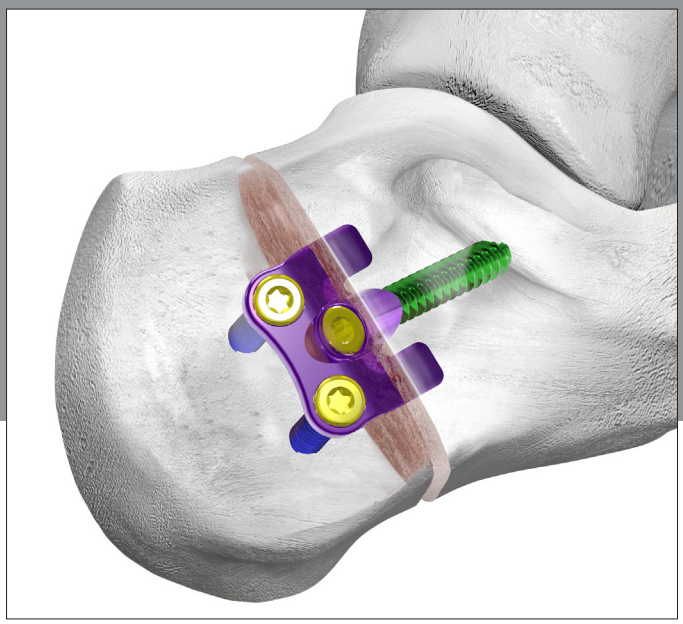
The Calc Slide Plate was developed as an option within the Gorilla® R3CON Plating System to provide fixation for a medial or lateral calcaneal slide osteotomy. The patented shape of the Calc Slide Plate is designed to resist rotation of the calcaneal osteotomy. Use of the Calc Slide Plate in this surgical technique guide is shown using Gorilla R3CON Screws. If TUFFNEK® Screw fixation is preferred, refer to the TUFFNEK® Surgical Technique Guide (P50-STG-0001) for proper screw placement technique.

This surgical technique guide demonstrates a medial calcaneal slide osteotomy. The technique is performed in a similar manner for a lateral calcaneal slide osteotomy, with plate placement shown below.

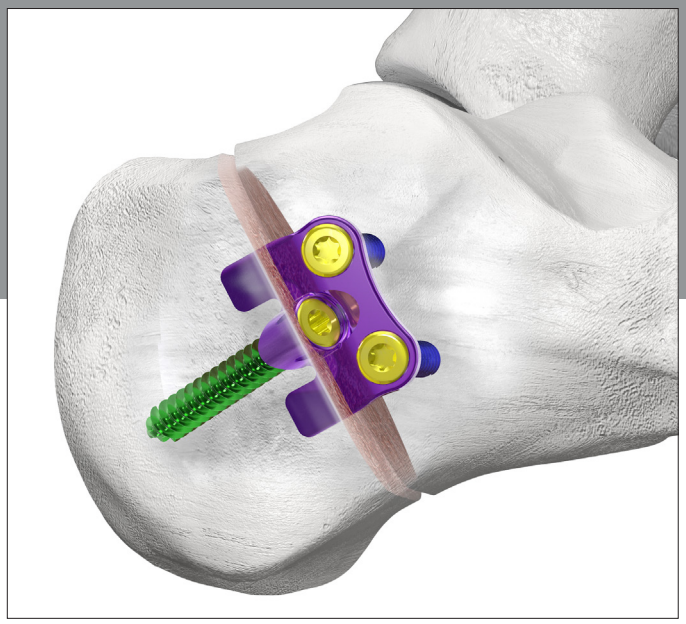
PLATE SPECIFICATIONS

- Universal for right and left
- Universal for medial or lateral calcaneal slide osteotomies
- Hood height less than 5 mm
- Length of plate minimized to help prevent additional dissection and soft tissue disruption during plate insertion
- Sharp arms and hood tip obviates need for broach
- All plate holes accommodate a 2.7, 3.5 or 4.2 mm locking or non-locking screw





Medial Calcaneal Slide Osteotomy



Lateral Calcaneal Slide Osteotomy

INSTRUMENTS

Calc Slide Inserter

Ø2.5 mm K-wire

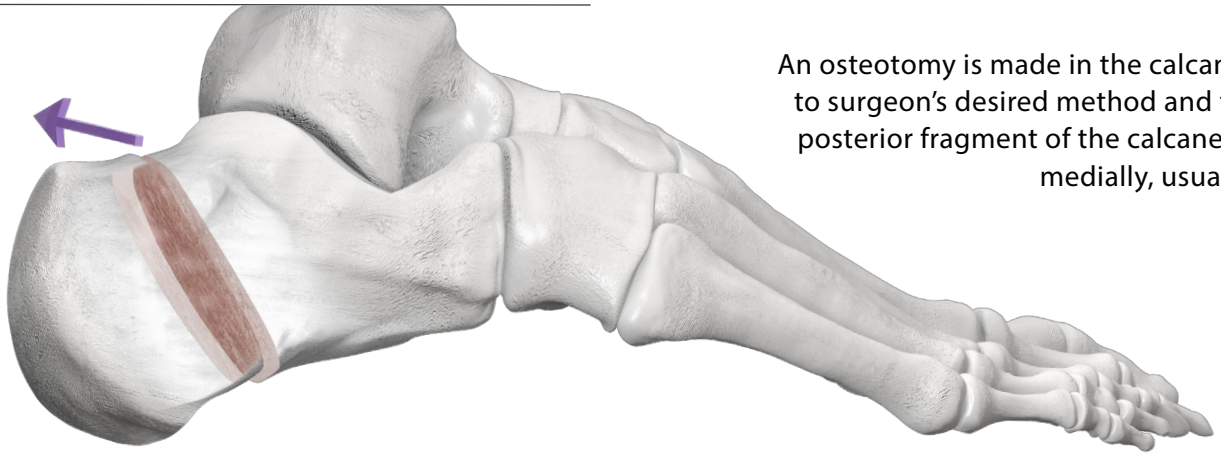
Swivel Guide

INCISION/EXPOSURE

The procedure described can be performed as a sole procedure or combined with various procedures to address Stage II Posterior Tibial Tendon Dysfunction or a pediatric flatfoot at the discretion of the surgeon. This technique will describe only the Medial Calcaneal Slide Osteotomy for flatfoot correction.

Patient positioning in a lateral decubitus or supine position with fluoroscopy available is recommended for this procedure. A standard oblique incision is made over the desired osteotomy site, but can be varied according to surgeon preference. Dissection is carried down to the lateral wall of the calcaneus.

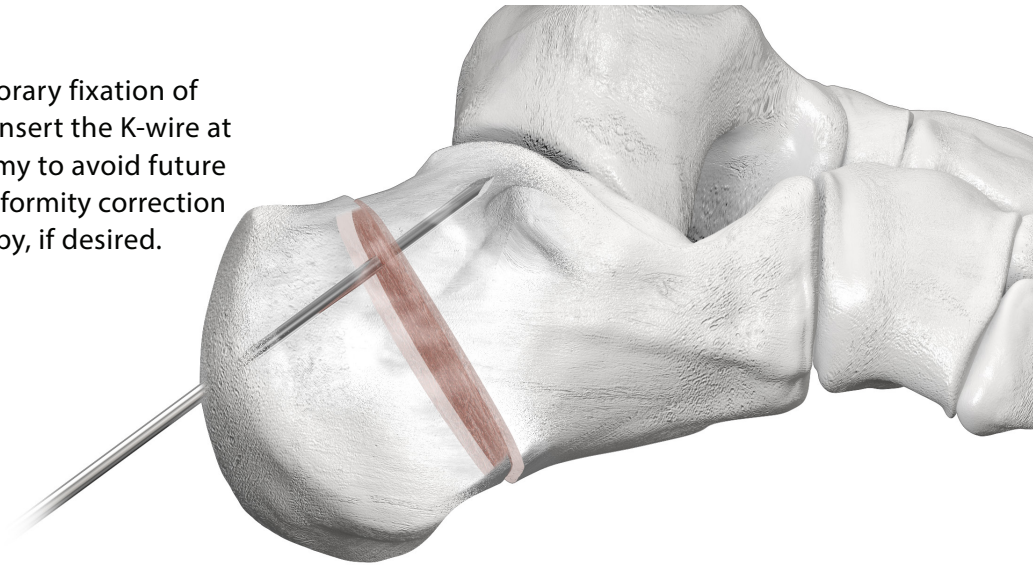
CALCANEAL OSTEOTOMY AND DISPLACEMENT



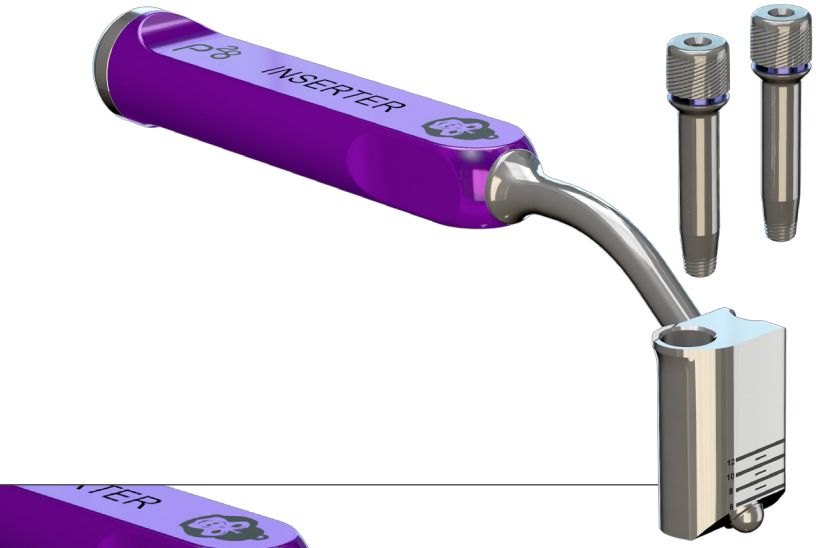
An osteotomy is made in the calcaneus according to surgeon's desired method and technique. The posterior fragment of the calcaneus is displaced medially, usually about 1 cm.

TEMPORARY FIXATION

A K-wire can be used to serve as temporary fixation of the osteotomy. It is recommended to insert the K-wire at the more dorsal aspect of the osteotomy to avoid future plate and screw placement. Confirm deformity correction and K-wire placement using fluoroscopy, if desired.

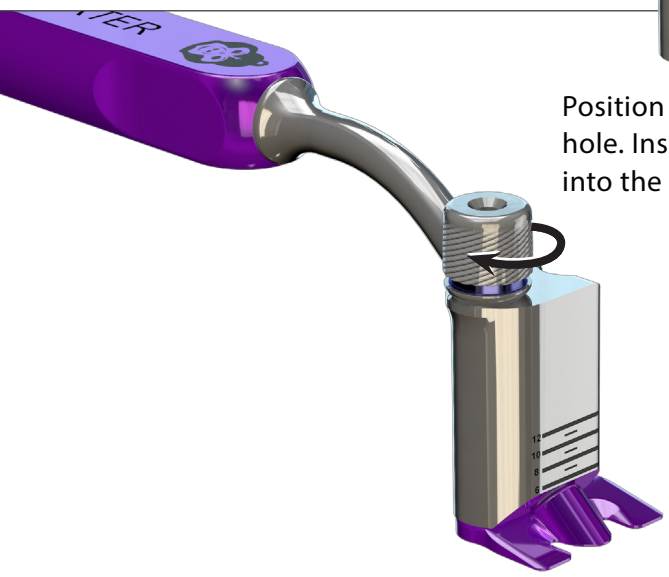


PERMANENT FIXATION USING THE CALC SLIDE PLATE

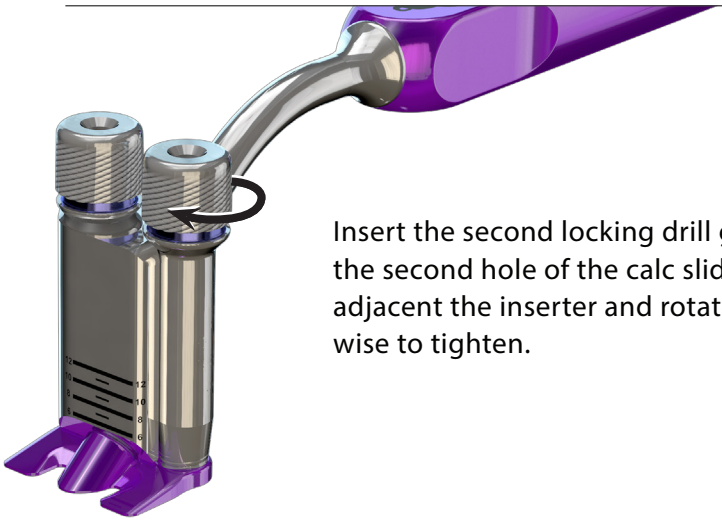


Retrieve the calc slide inserter from the calc slide caddy. Select the two locking drill guides from the Gorilla R3CON Instrument Caddy that correspond to the desired screw diameter(s) for proximal plate fixation.

In this example, two 3.5 mm screws will be placed in the proximal holes, thus two 3.5 mm locking drill guides are used.



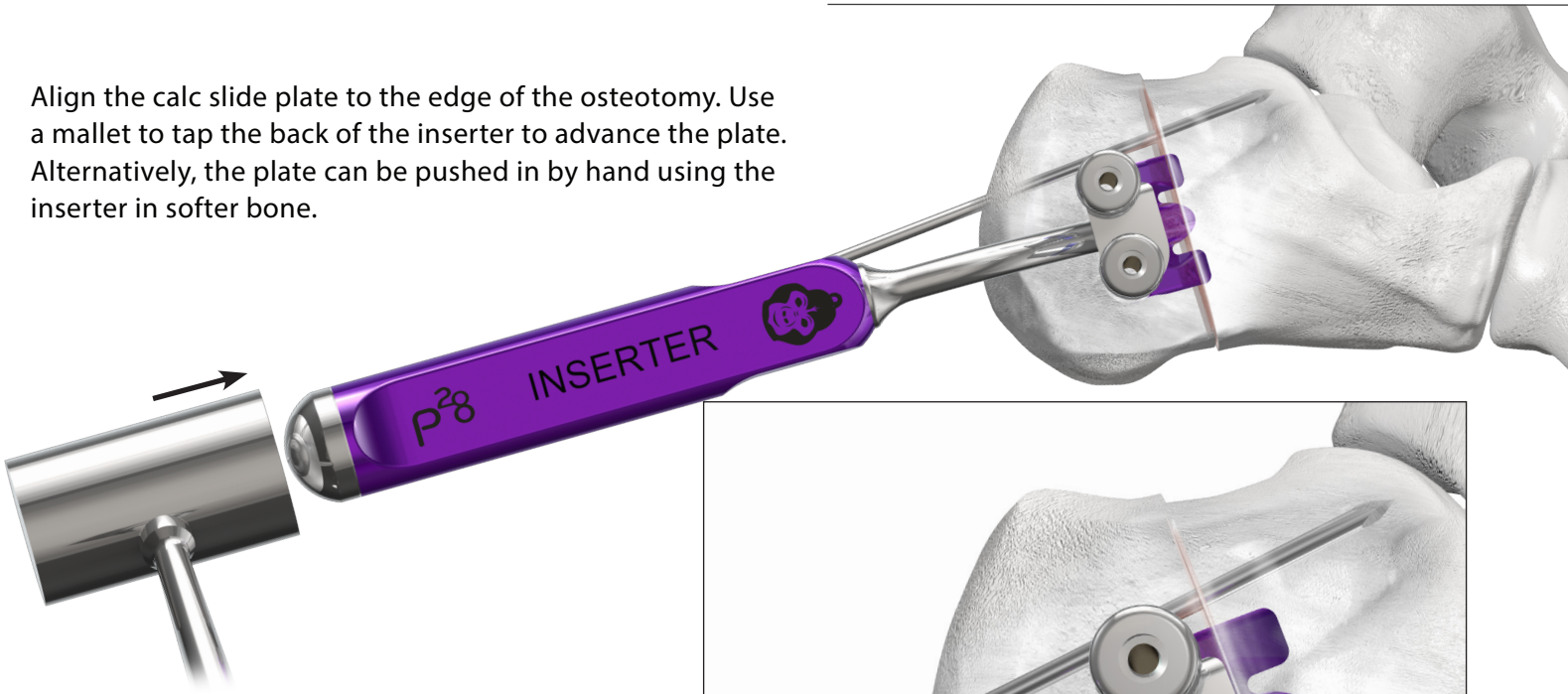
Position the ball on the front of the inserter into the hooded hole. Insert a locking drill guide through the calc slide inserter into the calc slide plate and rotate clockwise to tighten.

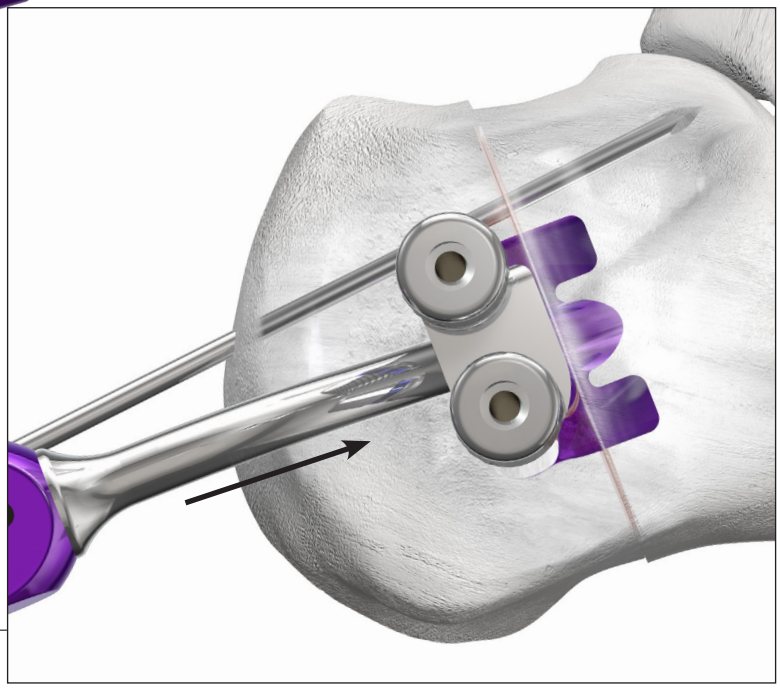


Insert the second locking drill guide into the second hole of the calc slide plate adjacent the inserter and rotate clock-wise to tighten.

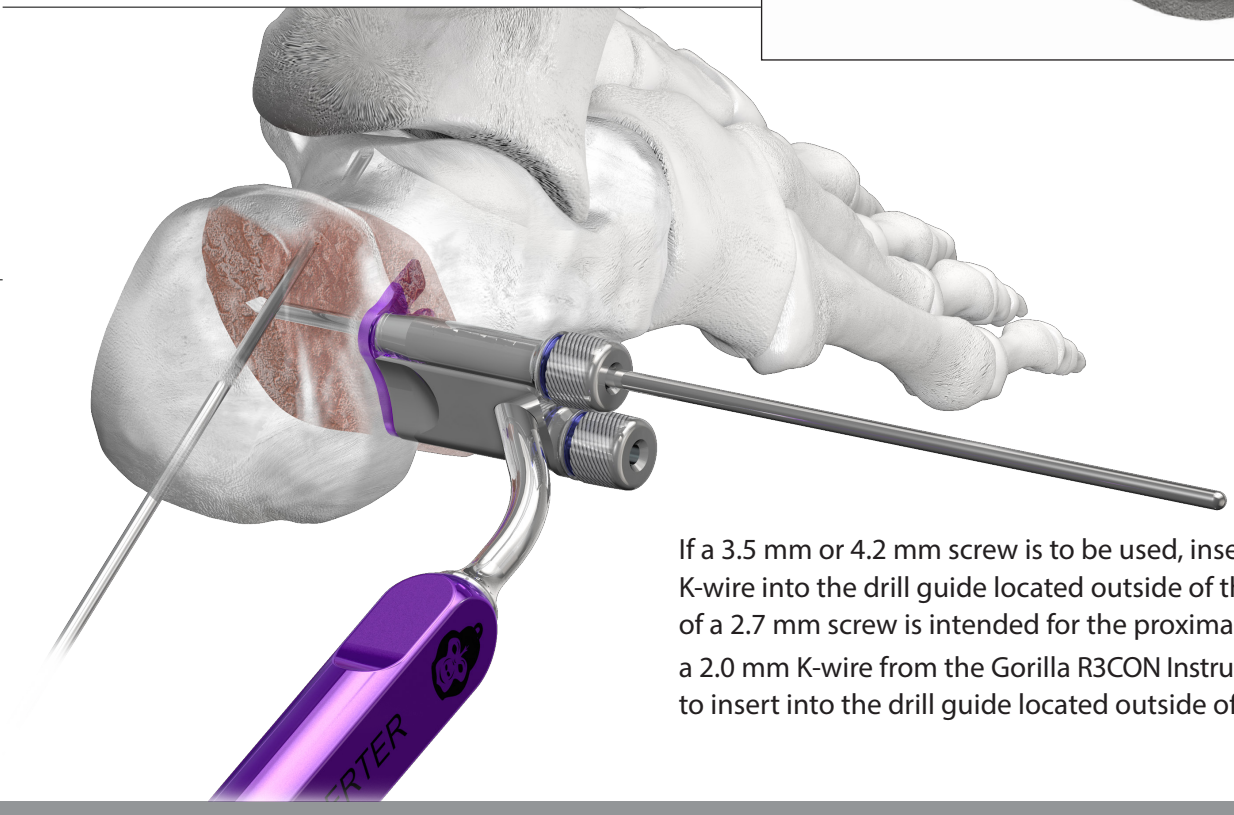
PERMANENT FIXATION USING THE CALC SLIDE PLATE

Align the calc slide plate to the edge of the osteotomy. Use a mallet to tap the back of the inserter to advance the plate. Alternatively, the plate can be pushed in by hand using the inserter in softer bone.



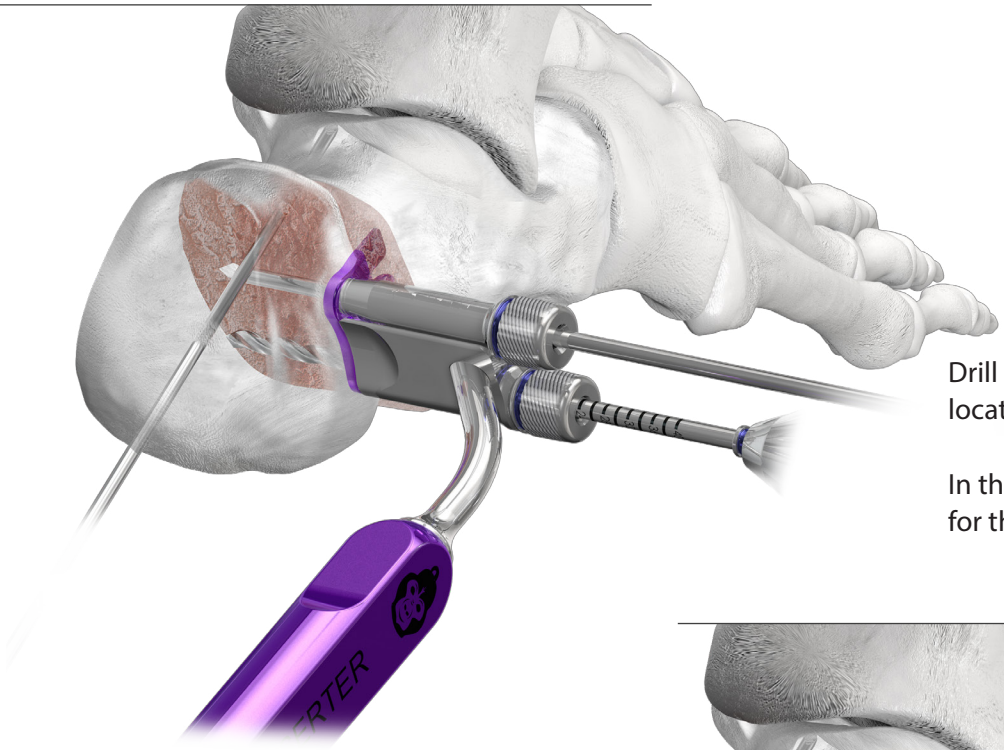


Advance the plate until the stop at the front of the inserter is flush to the anterior side of the osteotomy.



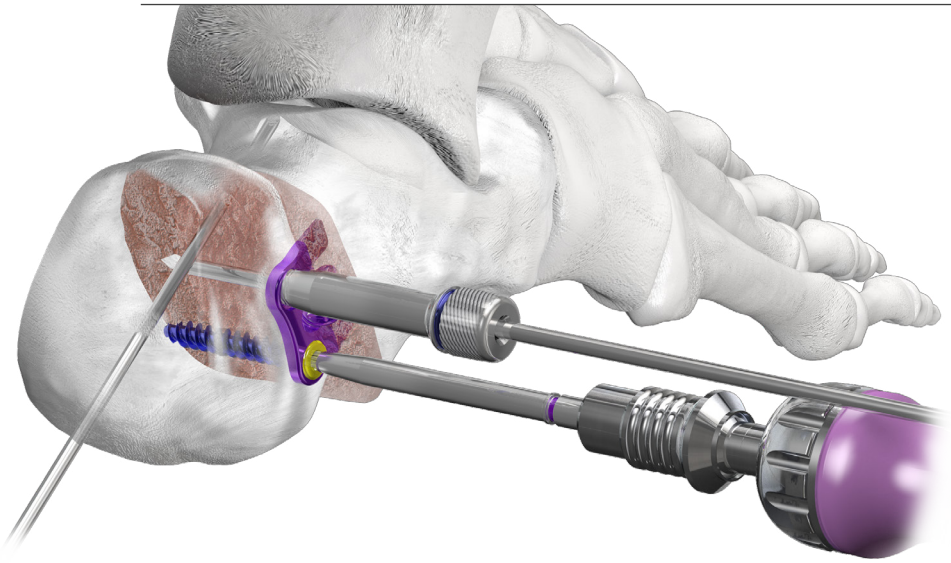
If a 3.5 mm or 4.2 mm screw is to be used, insert the 2.5 mm K-wire into the drill guide located outside of the inserter. If use of a 2.7 mm screw is intended for the proximal screw, retrieve a 2.0 mm K-wire from the Gorilla R3CON Instrument Caddy to insert into the drill guide located outside of the inserter.

PERMANENT FIXATION USING THE CALC SLIDE PLATE

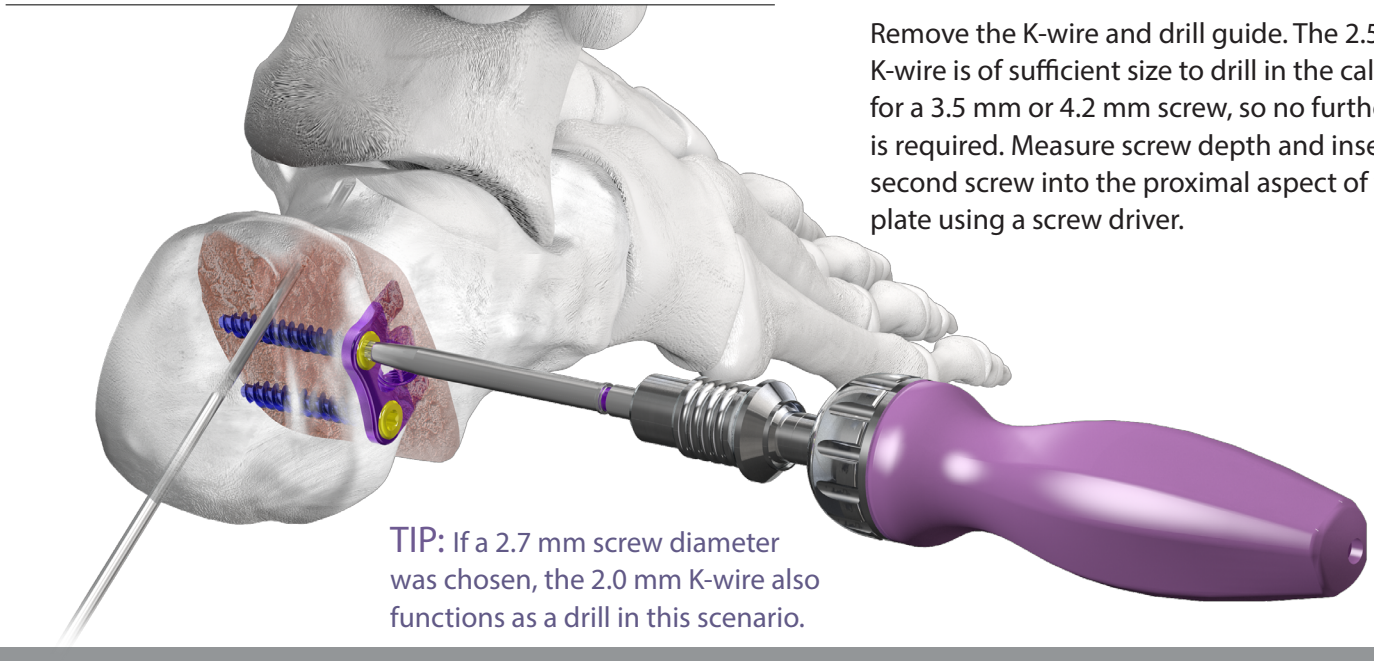


Drill through the drill guide that is located within the inserter.

In this example, a 2.4 mm drill is used for the 3.5 mm screw.



Remove the drill, drill guide, and inserter. Screw length can be measured using the provided depth gauge or by measuring off of the drill using the drill guide. Insert the appropriate length locking or non-locking screw into the hole.

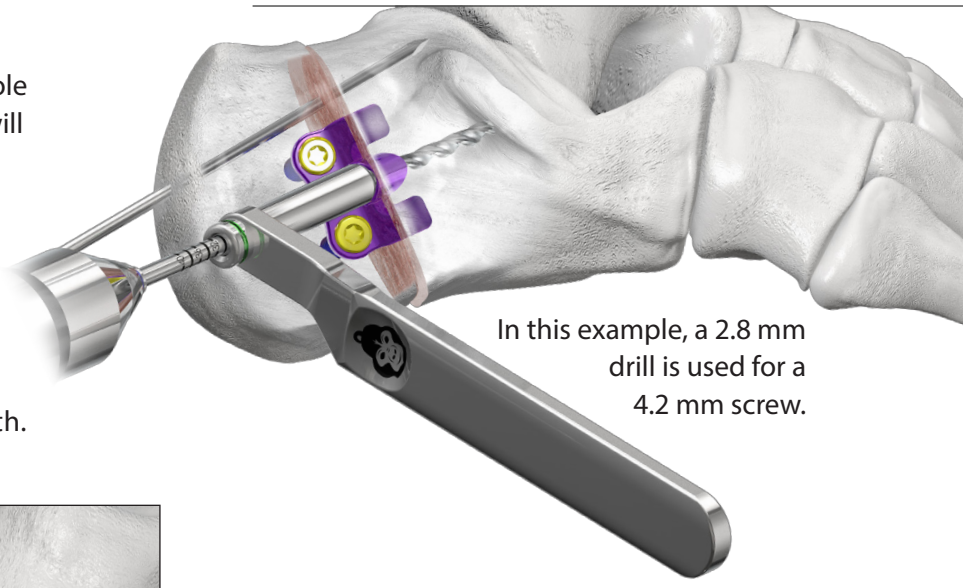


Remove the K-wire and drill guide. The 2.5 mm K-wire is of sufficient size to drill in the calcaneus for a 3.5 mm or 4.2 mm screw, so no further drilling is required. Measure screw depth and insert the second screw into the proximal aspect of the plate using a screw driver.

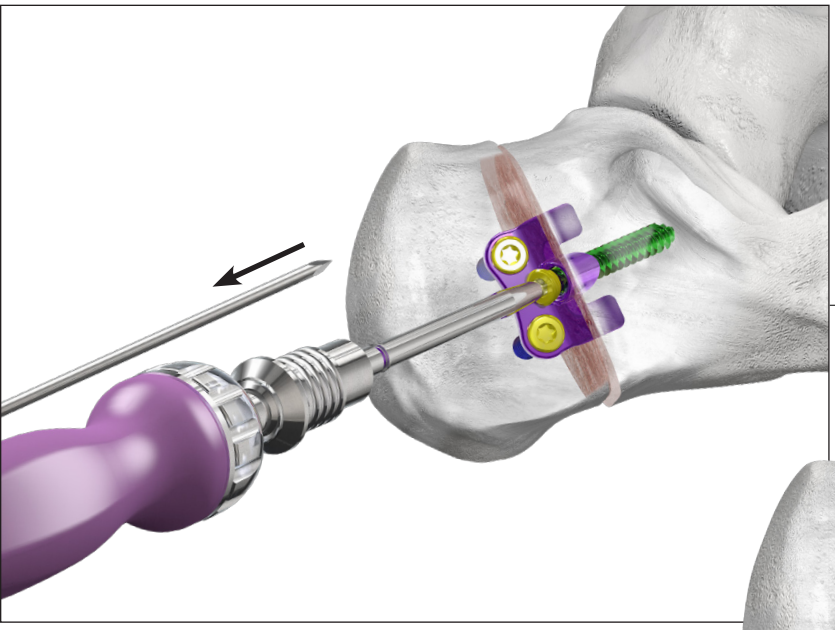
TIP: If a 2.7 mm screw diameter was chosen, the 2.0 mm K-wire also functions as a drill in this scenario.

PERMANENT FIXATION USING THE CALC SLIDE PLATE

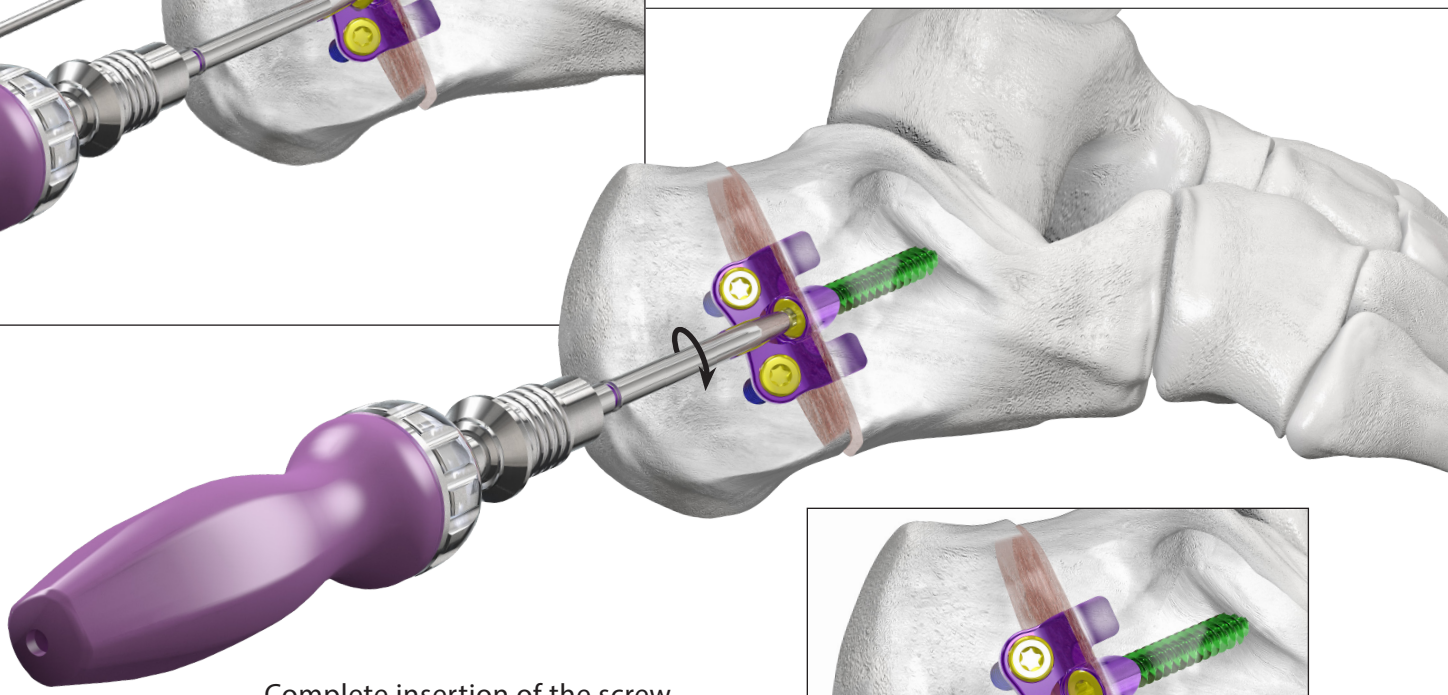
Retrieve the swivel guide for use in the hooded hole. Insert the swivel guide into the hooded hole and rotate the swivel guide such that the drill will aim toward the sustentaculum tali. The hooded hole placement is designed such that on-axis drilling of this hole should be directed towards the sustentaculum tali in most cases. Use the drill sized for the desired screw diameter to drill the hooded hole through the swivel guide, stopping if dense cortical bone is felt along the medial calcaneal wall. Measure screw length.



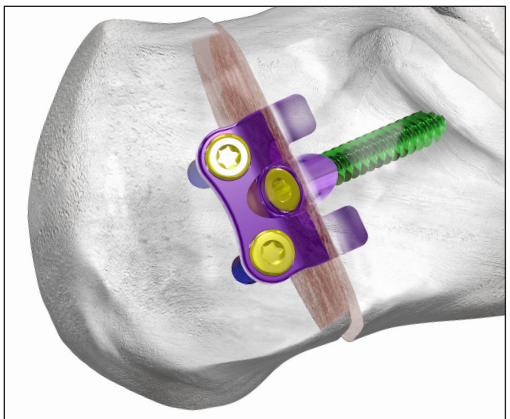
In this example, a 2.8 mm drill is used for a 4.2 mm screw.



Insert an appropriately sized locking or non-locking screw into the hooded hole until the neck of the screw is just entering the hood. Stop to remove the K-wire serving as temporary fixation across the osteotomy.



Complete insertion of the screw into the hooded hole.



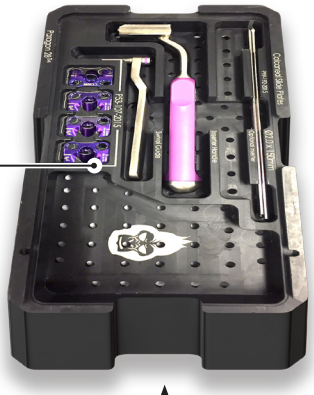
Confirm screw and plate placement using fluoroscopy, if desired.

CLOSURE

Proceed to incision closure or concomitant procedures at this time.

Gorilla® Calc Slide Caddy

The Gorilla® Calc Slide Caddy contains four Calc Slide Plates and instrumentation needed for plate insertion including the calc slide plate inserter, the swivel guide, and 2.5 mm K-wires.



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 a calcaneal slide osteotomy.

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 R3CON PLATING SYSTEM - CALC SLIDE CADDY:

Part #	Description	Use
P51-907-0002	Calcaneal Slide, Inserter	Reusable
P51-907-0006	Calcaneal Slide, Swivel Guide	Reusable
P53-107-2015	Calcaneal Slide, Plate	Single-use
P99-192-2515	K-Wire, Single Ended Trocar Tip, Smooth, 2.5 x 150 mm	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: 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.

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 Slide Plating System

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