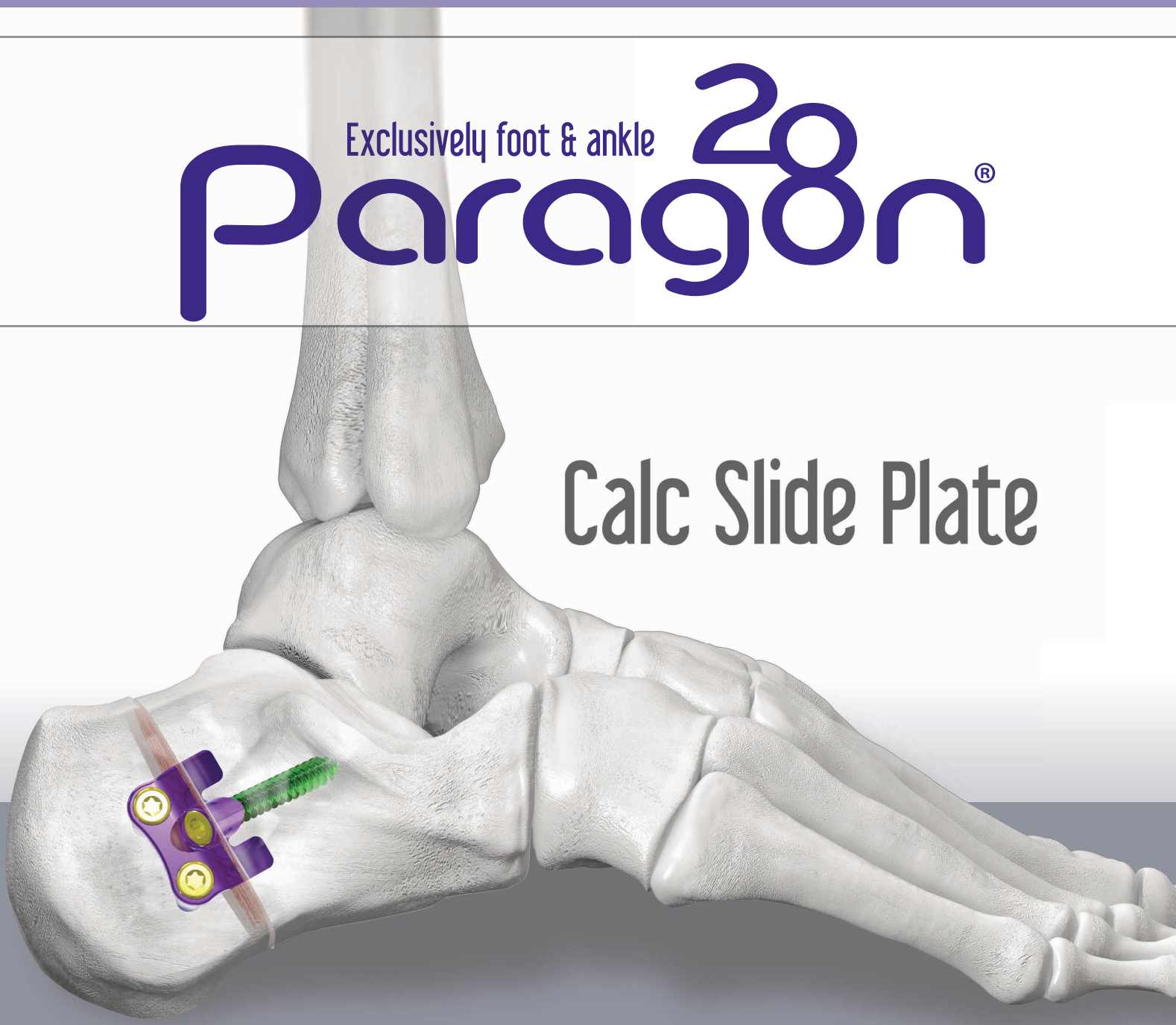
SURGICAL TECHNIQUE GUIDE:
CALCANEAL SLIDE OSTEOTOMY

Exclusively foot & ankle

Paragon 28®

Calc Slide Plate



GORILLA®

R3CON PLATING SYSTEM

Acknowledgment:

Acknowledgment: Paragon 28® would like to thank Thomas Chang, DPM for his contribution to the development of the surgical technique guide.

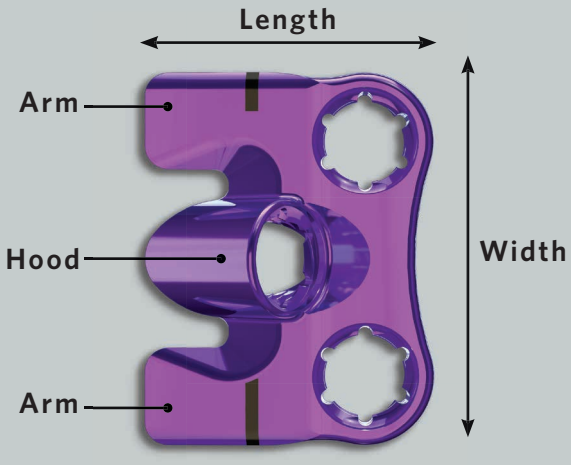
PRODUCT DESCRIPTION

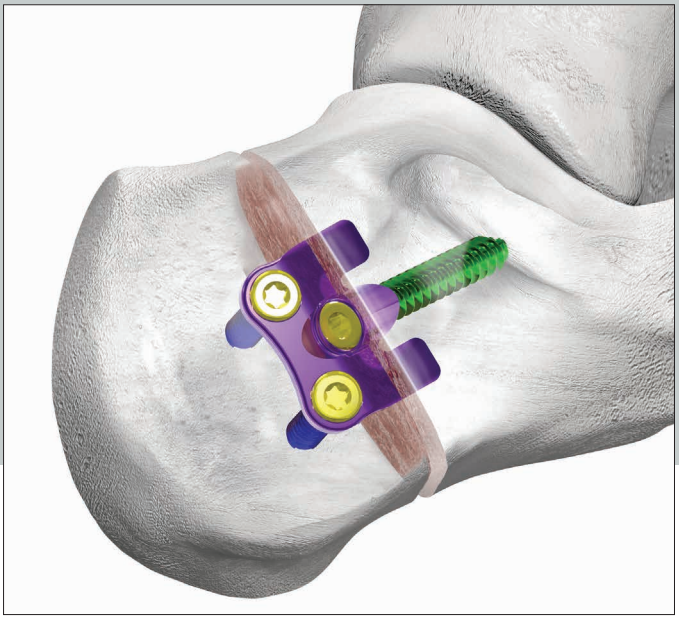
The Calc Slide Plate was developed as an option within the Gorilla® R3CON Plating System to provide fixation for a medial or lateral calcaneal slide osteotomy. The patent pending shape of the Calc Slide Plate is designed to resist rotation of the calcaneal osteotomy. Use of the Calc Slide Plate in this surgical technique guide is shown using Gorilla R3CON Screws. If TUFFNEK® Screw fixation is preferred, refer to the TUFFNEK® Surgical Technique Guide (P50-STG-1001) 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.

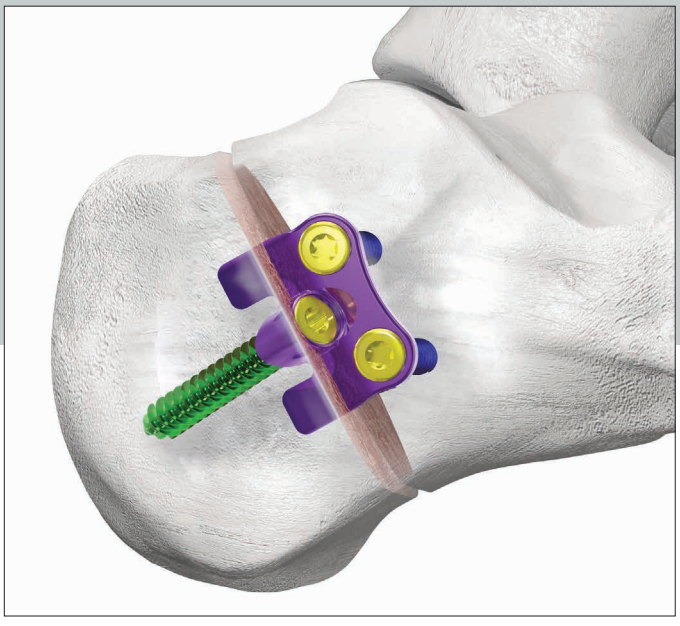
PLATE SPECIFICATIONS

- 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

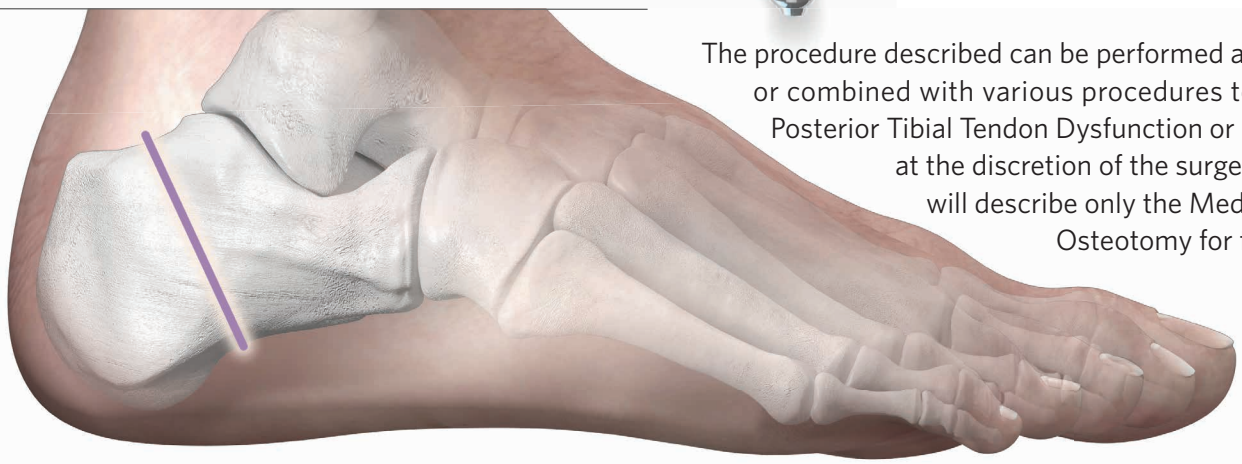
INSTRUMENTS

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.

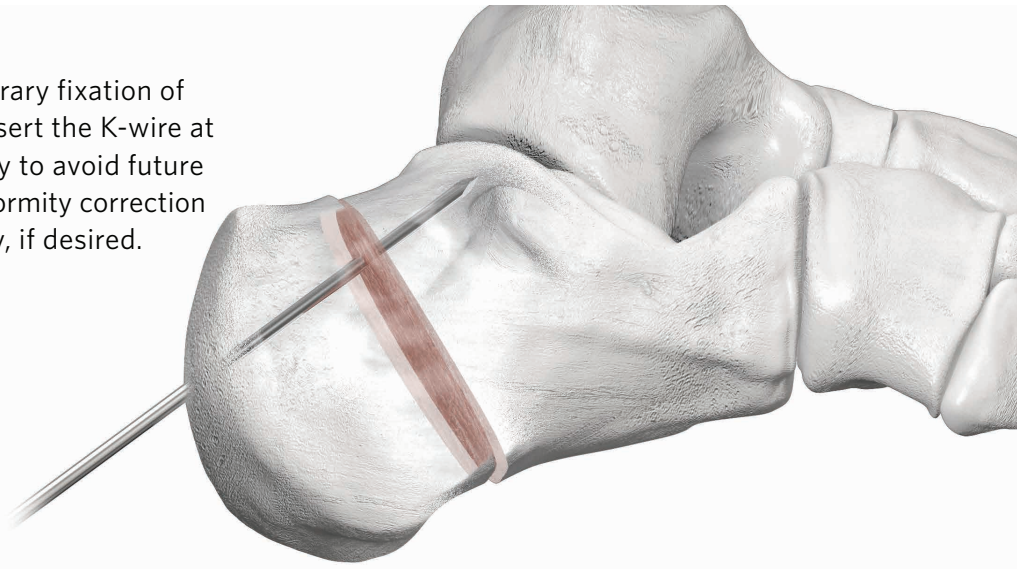
Patient positioning in a lateral decubitus or supine position with fluoroscopy available is recommended for this procedure. A standard oblique incision is made over the desired osteotomy site, but can be varied according to surgeon preference. Dissection is carried down to the lateral wall of the calcaneus.

CALCANEAL OSTEOTOMY AND DISPLACEMENT

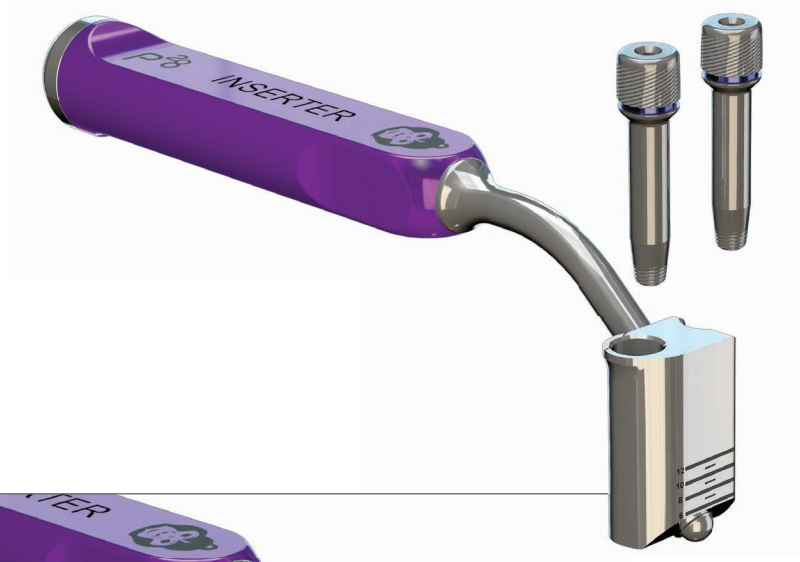
An osteotomy is made in the calcaneus according to surgeon's desired method and technique. The posterior fragment of the calcaneus is displaced medially, usually about 1 cm.

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.

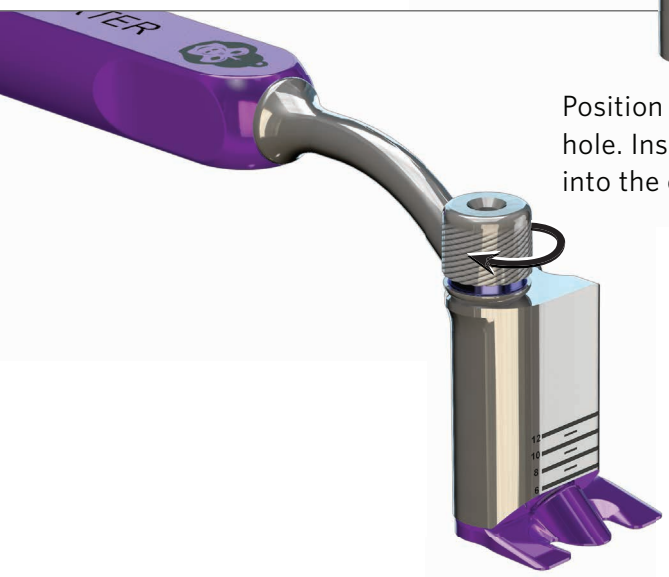


PERMANENT FIXATION USING THE CALC SLIDE PLATE



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.

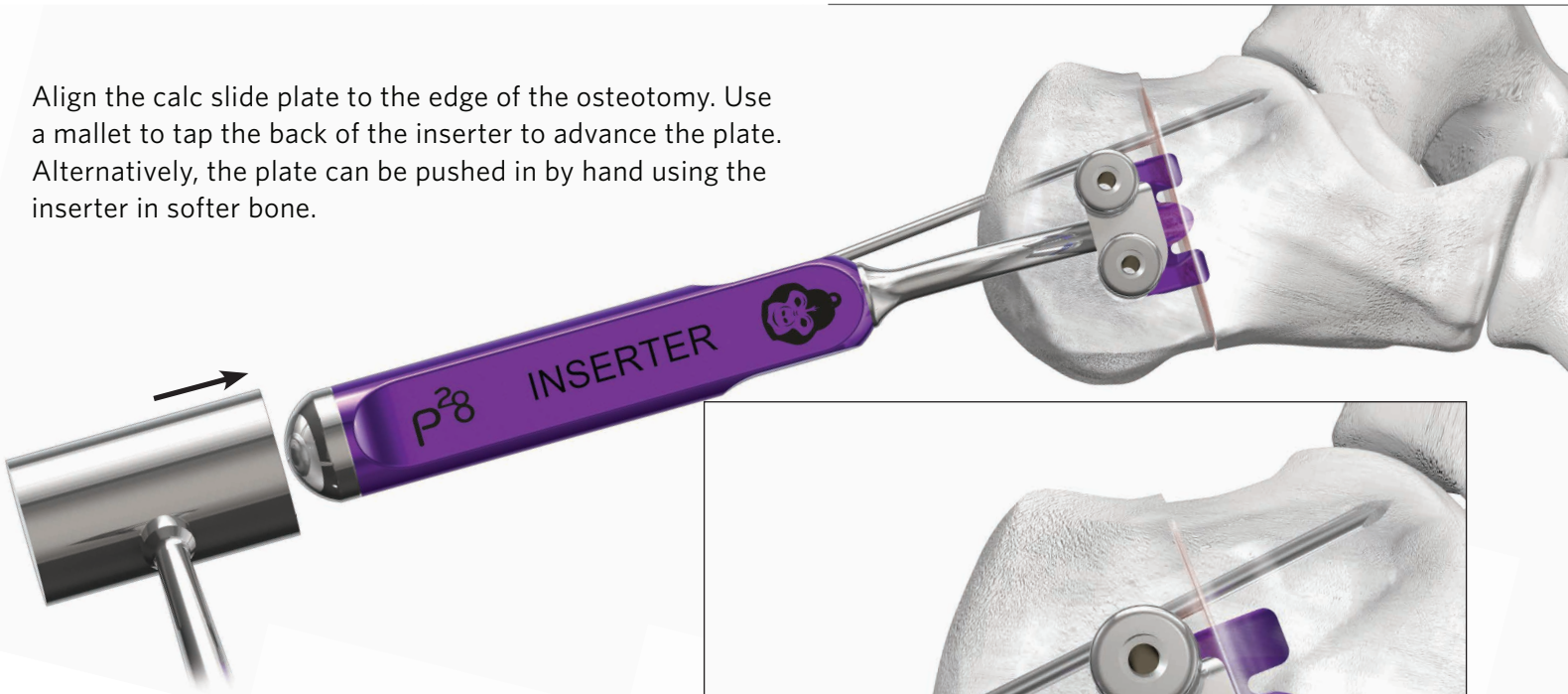


Position the ball on the front of the inserter into the hooded hole. Insert a locking drill guide through the calc slide inserter into the calc slide plate and rotate clockwise to tighten.

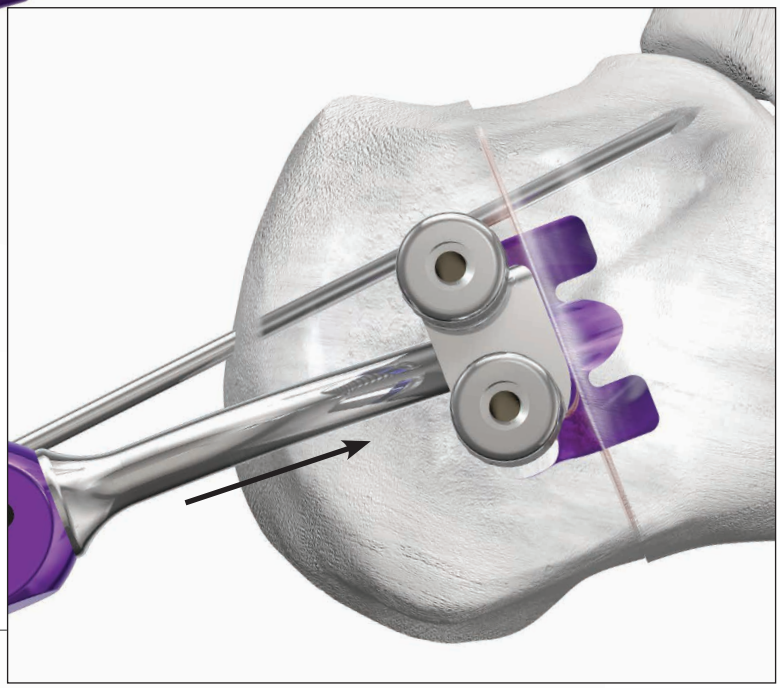
Insert the second locking drill guide into the second hole of the calc slide plate adjacent the inserter and rotate clockwise to tighten.

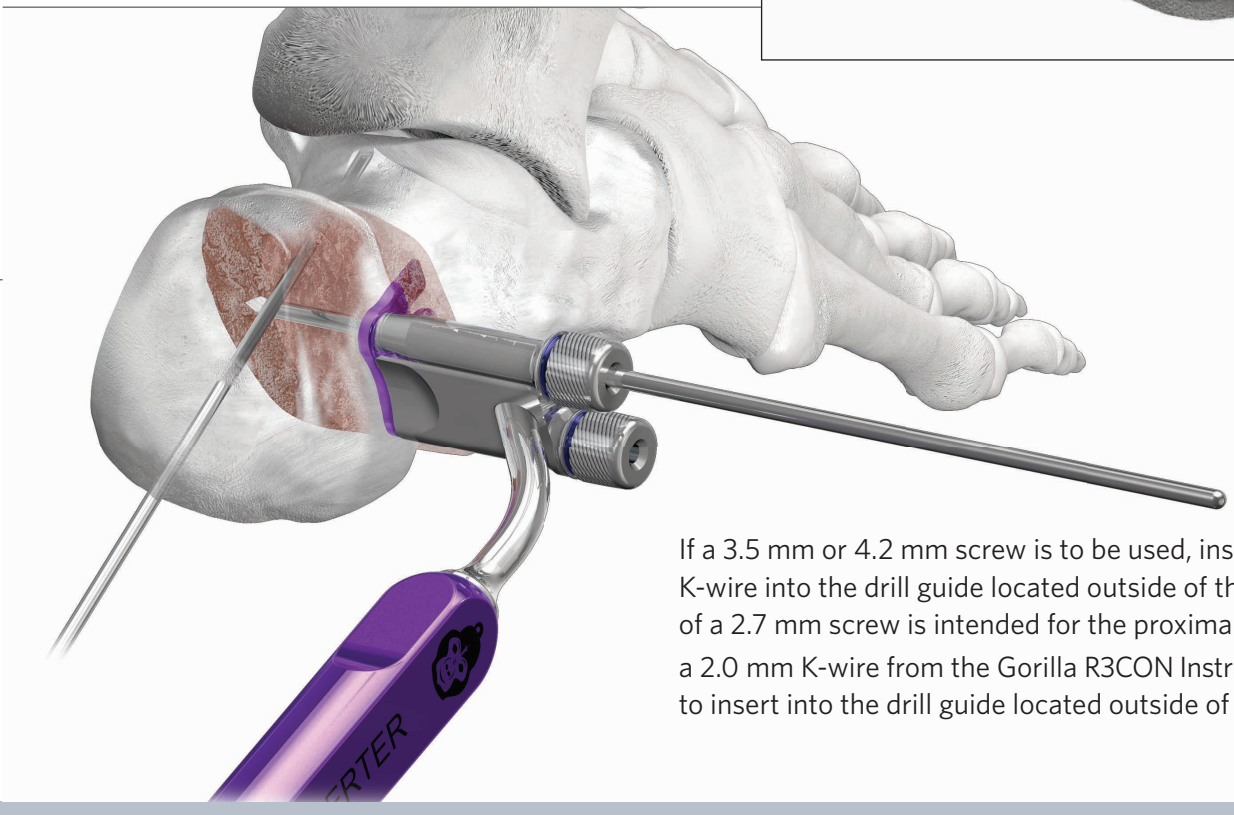
PERMANENT FIXATION USING THE CALC SLIDE PLATE

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.



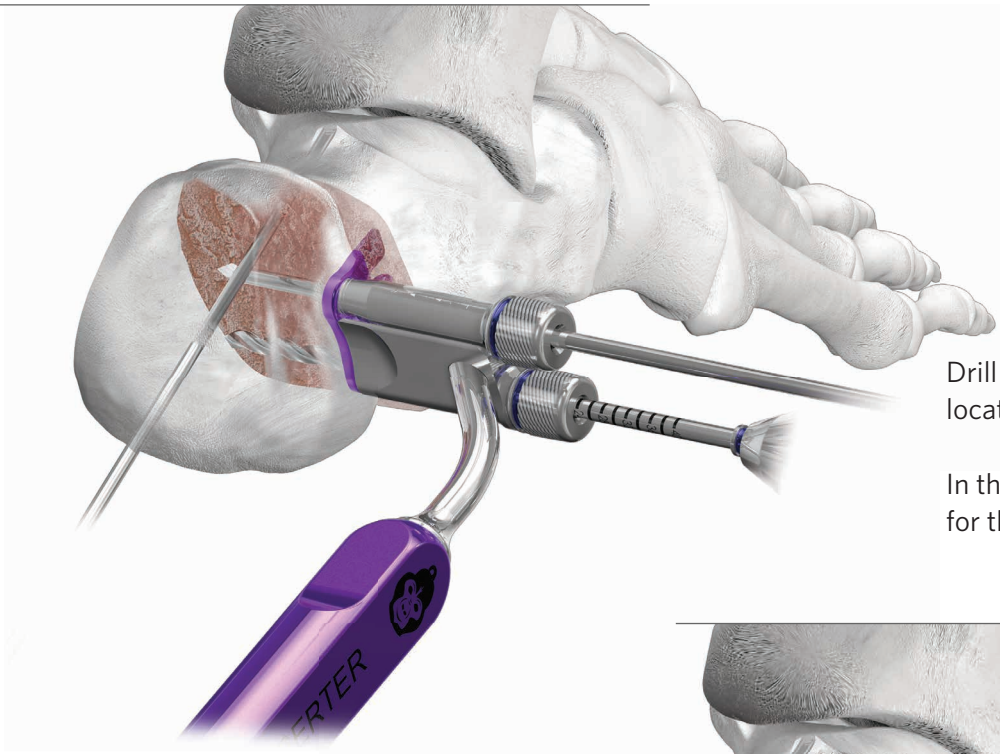
Advance the plate until the stop at the front of the inserter is flush to the anterior side of the osteotomy.





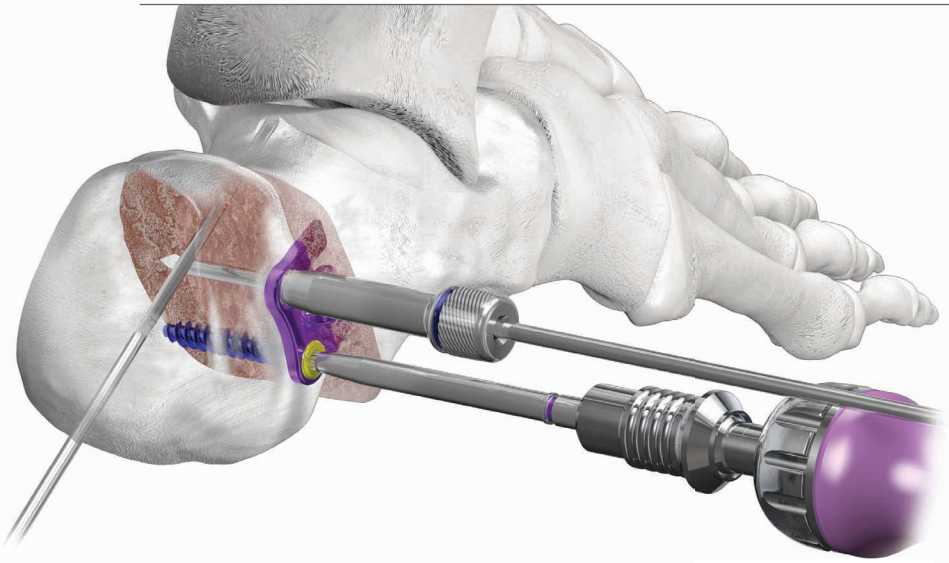
If a 3.5 mm or 4.2 mm screw is to be used, insert the 2.5 mm K-wire into the drill guide located outside of the inserter. If use of a 2.7 mm screw is intended for the proximal screw, retrieve a 2.0 mm K-wire from the Gorilla R3CON Instrument Caddy to insert into the drill guide located outside of the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

PERMANENT FIXATION USING THE CALC SLIDE PLATE

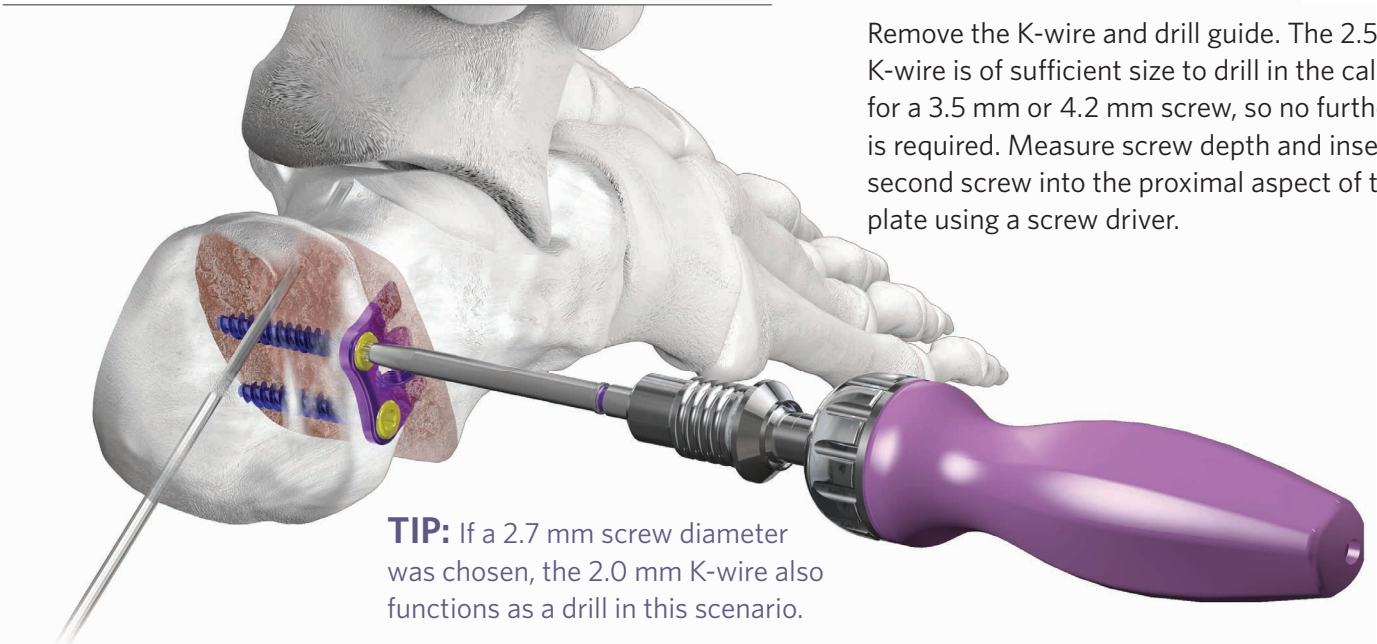


Drill through the drill guide that is located within the inserter.

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.

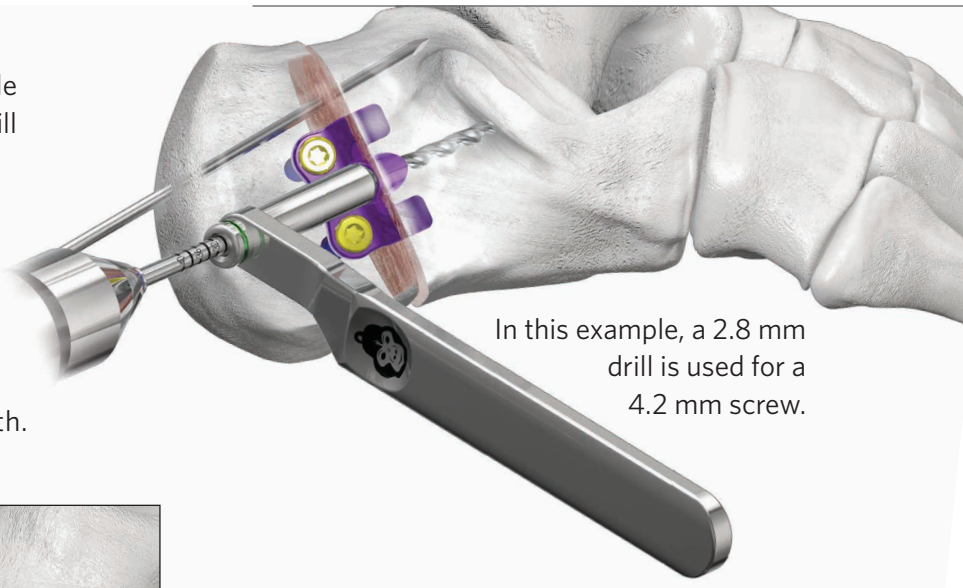


Remove the K-wire and drill guide. The 2.5 mm K-wire is of sufficient size to drill in the calcaneus for a 3.5 mm or 4.2 mm screw, so no further drilling is required. Measure screw depth and insert the second screw into the proximal aspect of the plate using a screw driver.

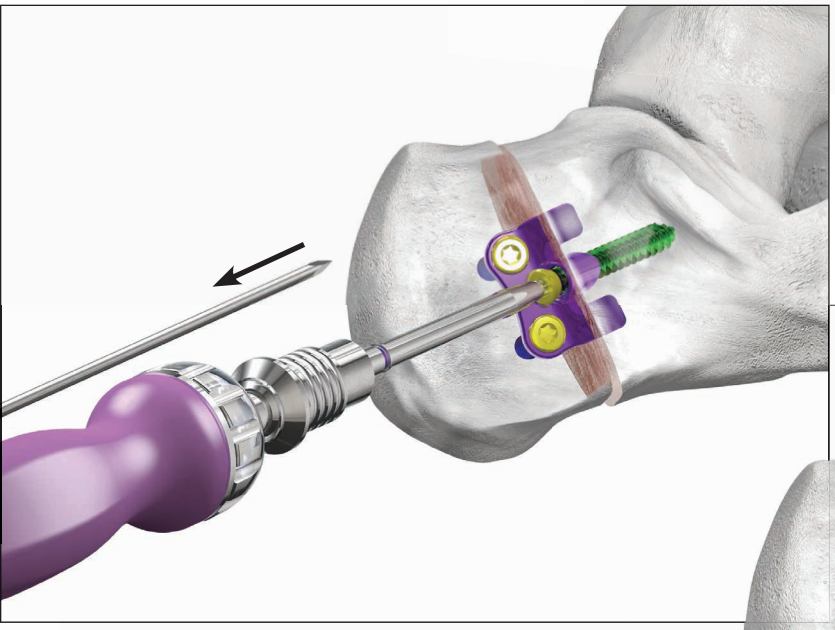
TIP: If a 2.7 mm screw diameter was chosen, the 2.0 mm K-wire also functions as a drill in this scenario.

PERMANENT FIXATION USING THE CALC SLIDE PLATE

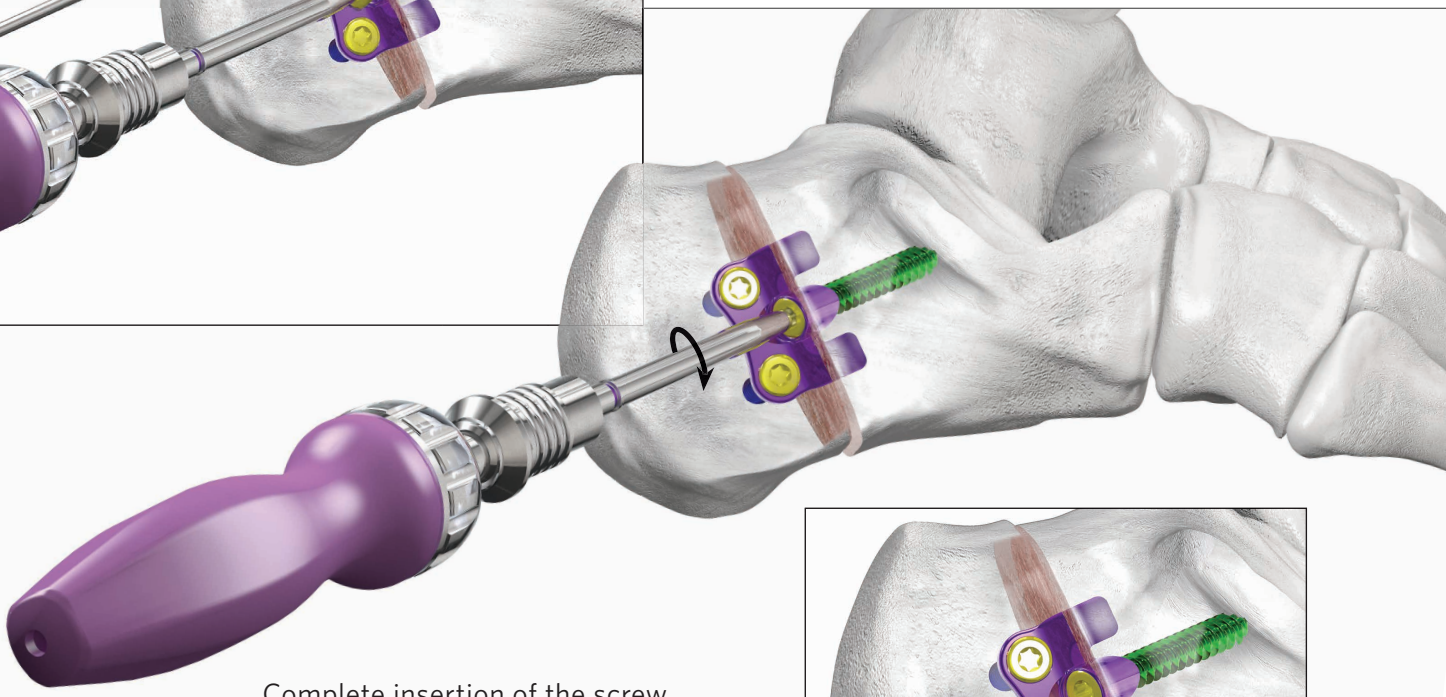
Retrieve the swivel guide for use in the hooded hole. Insert the swivel guide into the hooded hole and rotate the swivel guide such that the drill will aim toward the sustentaculum tali. The hooded hole placement is designed such that on-axis drilling of this hole should be directed towards the sustentaculum 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.



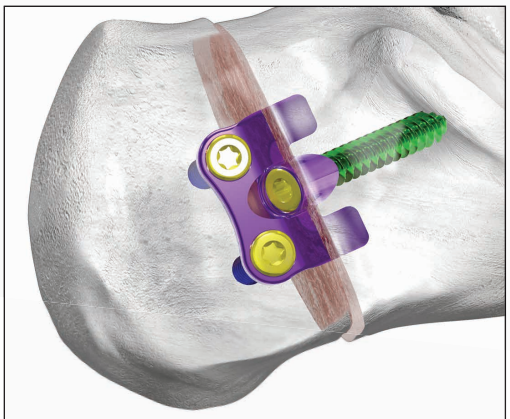
In this example, a 2.8 mm drill is used for a 4.2 mm screw.



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.

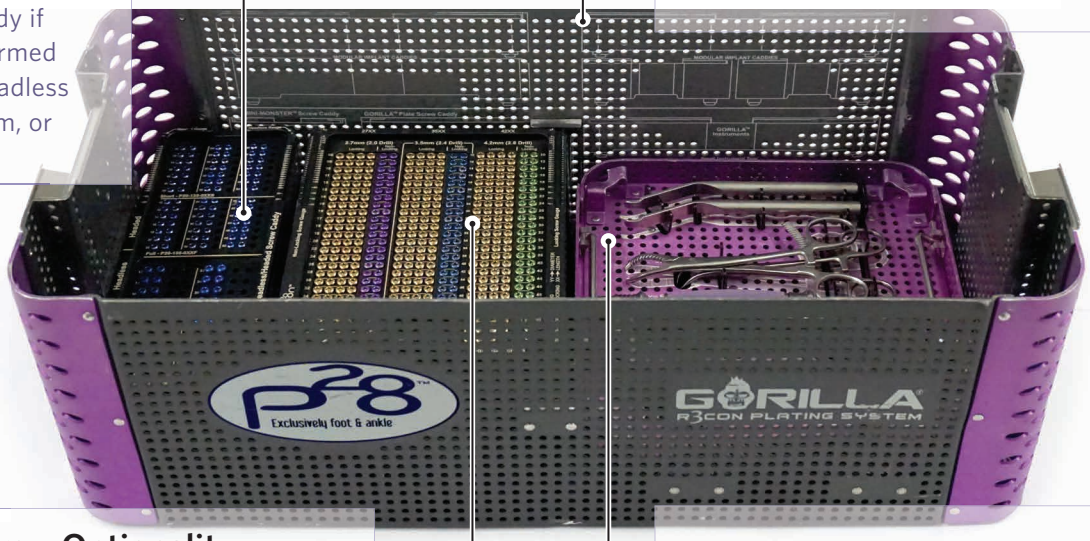
Additional Gorilla® Caddies

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.

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.

GORILLA®
R3CON PLATING SYSTEM

Calc Slide Plate

PATENTED, DESIGNED & EXCLUSIVELY DISTRIBUTED BY

Exclusively foot & ankle
Paragon 28®

www.PARAGON28.com

P51-STG-1004 RevC

Patents: www.paragon28.com/patents

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DISCLAIMER

The purpose of the Calcaneal Slide Osteotomy Surgical Technique Guide is to demonstrate the use of the Calc Slide 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.