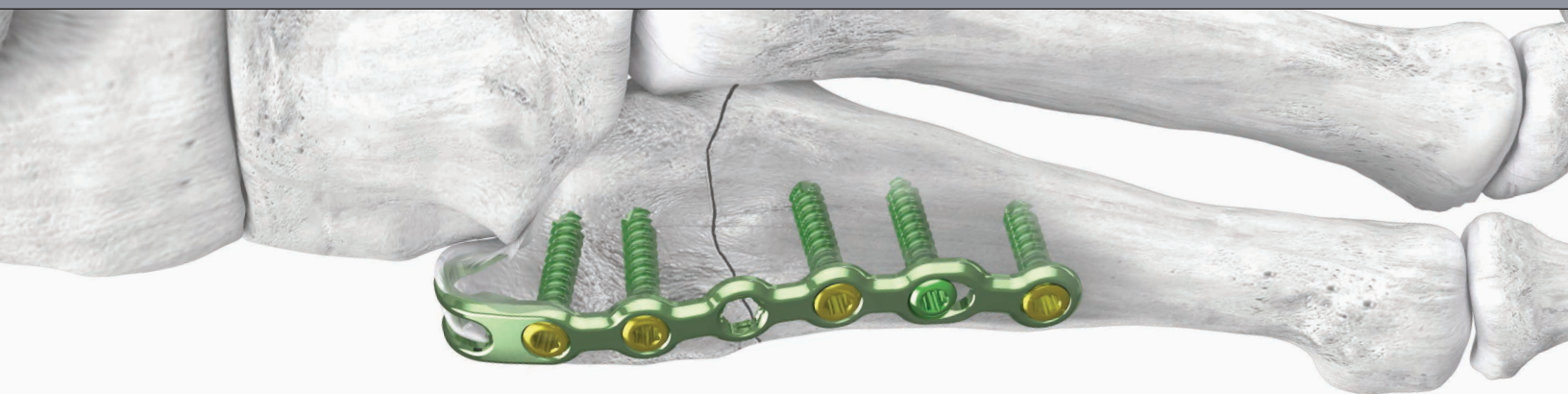


SURGICAL TECHNIQUE GUIDE:

5th METATARSAL FRACTURE

Exclusively foot & ankle 20
Paragon®



5th METATARSAL PLATING SYSTEM

BABY
GORILLA®
MINI PLATING SYSTEM

Acknowledgment:

Paragon 28® would like to thank Thomas Harris, MD for his contribution to the development of the surgical technique guide.

PRODUCT DESCRIPTION

The Baby Gorilla® Plating System offers an extensive line of 65 unique mini-plates for use in a multitude of procedures. Some plates in the system are “universal” in application where they may be used in multiple areas of the foot. Other anatomically specific plates are provided that require minimal manipulation to achieve the necessary fixation, including the 5th metatarsal fracture plates shown in this surgical technique guide. System-specific instrumentation is designed to address foot and ankle fracture reduction and joint preparation, while also easing insertion of 2.0 mm and 2.5 mm plating screws.

IMPLANT OFFERING

5th Metatarsal Fracture 8 Hole Compression Plates



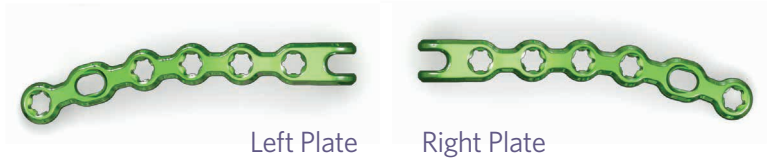
Designed to anatomically fit the 5th metatarsal with the option to be used for:

- Jones Fractures
- Revision Jones Fractures
- 5th Metatarsal Shaft Fractures

5th Metatarsal Avulsion Fracture Hook Plates



Jones Fracture 6 Hole Hook Plate

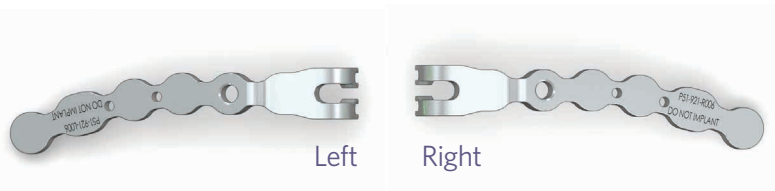


FEATURED INSTRUMENTS

5 Hole Plate Pre-Drill Guide



6 Hole Plate Pre-Drill Guide



Hook Screw Drill Guide



Threaded Knob for Pre-Drill Guides



Single Tamp



Double Tamp

OTHER BABY GORILLA® “UNIVERSAL” OPTIONS FOR 5TH METATARSAL FRACTURES



T Plates
13 plate options in this family



Straight Plates
8 plate options in this family

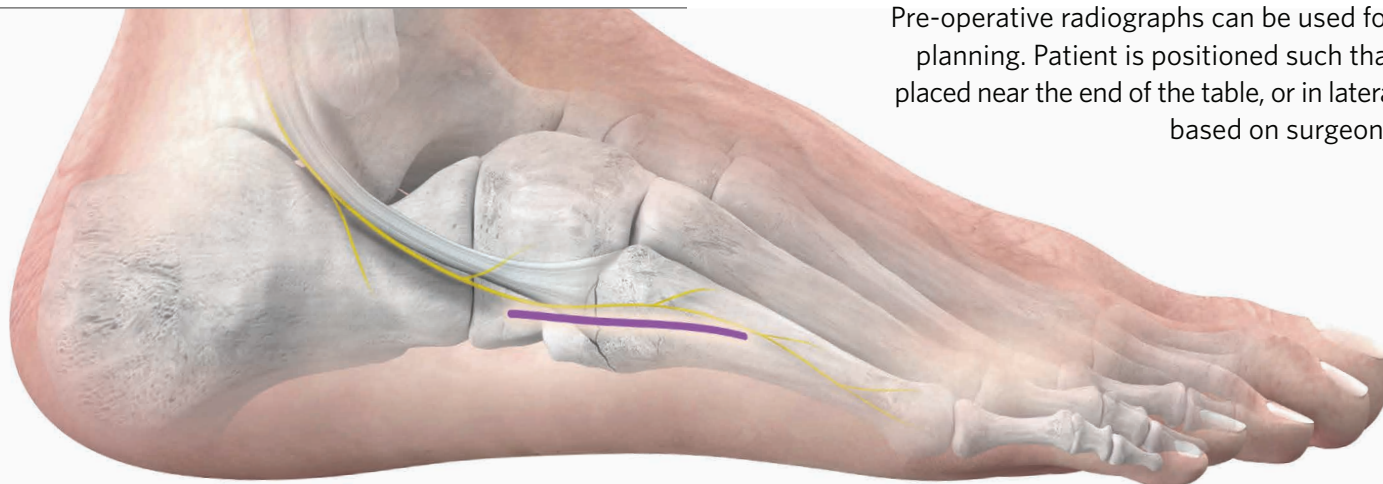


L Plates
21 plate options in this family



Y Plates
7 plate options in this family

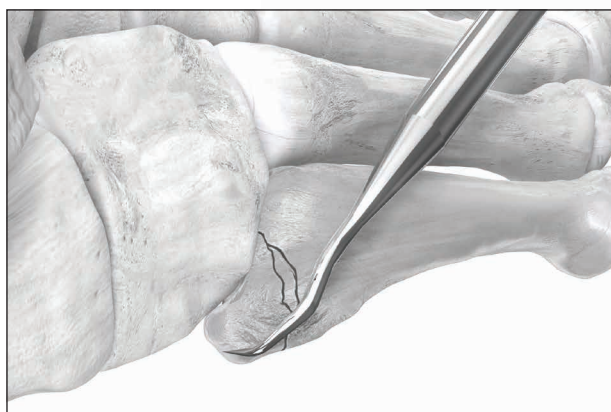
INCISION/EXPOSURE



Pre-operative radiographs can be used for procedure planning. Patient is positioned such that the foot is placed near the end of the table, or in lateral decubitus, based on surgeon preference.

A longitudinal incision is made over the lateral aspect of the 5th metatarsal encompassing the base of the 5th metatarsal and fracture site. Identify and protect the sural nerve. Soft tissue dissection is carried down until the fracture site is visible and adequate exposure of the 5th metatarsal tuberosity is achieved for plate fit.

FRACTURE REDUCTION



The fracture site can be refreshed and cleared using a curette provided in the Baby Gorilla™ Case. A dental pick (shown), lobster claw clamp and pointed reduction forcep are provided for fracture reduction.



Temporary stabilization of the fracture site can be performed at this time using a K-wire, if preferred.

PLATE SELECTION AND INSERTION

A 5 Hole 5th Metatarsal Avulsion Fracture Hook Plate is recommended for a 5th metatarsal avulsion fracture. The hooks on the plate can be placed with or without drilling. If drilling is not performed, the plate can be inserted by threading a locking drill guide onto the plate and pushing or manually tamping the hooks of the plate into the base of the 5th metatarsal (not shown).

TIP: Pre-drilling is recommended in comminuted fractures or in very hard or soft bone.

Place the threaded knob into the 5 Hole Pre-Drill Guide by rotating the knob in a clockwise direction.



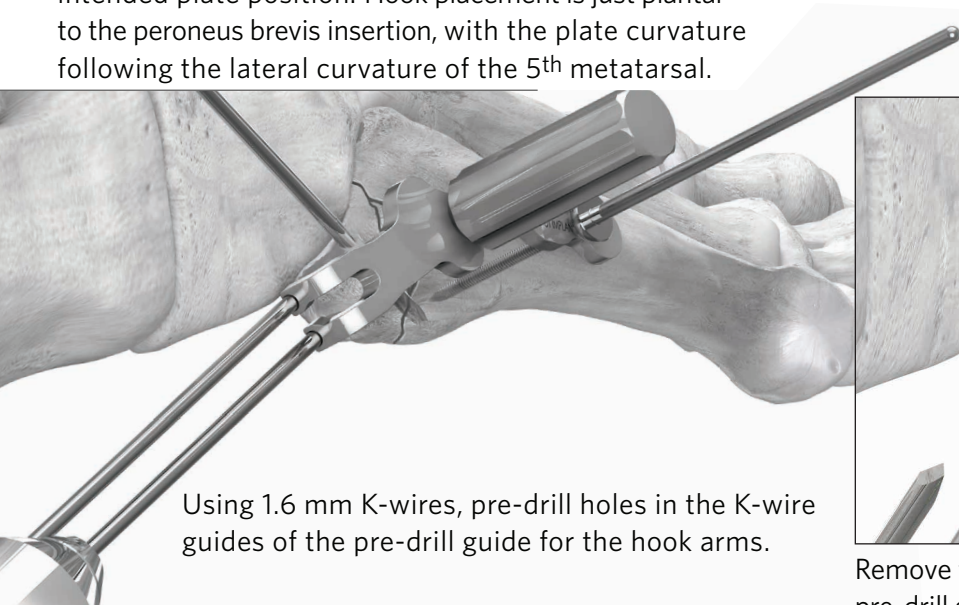
PLATE SELECTION AND INSERTION



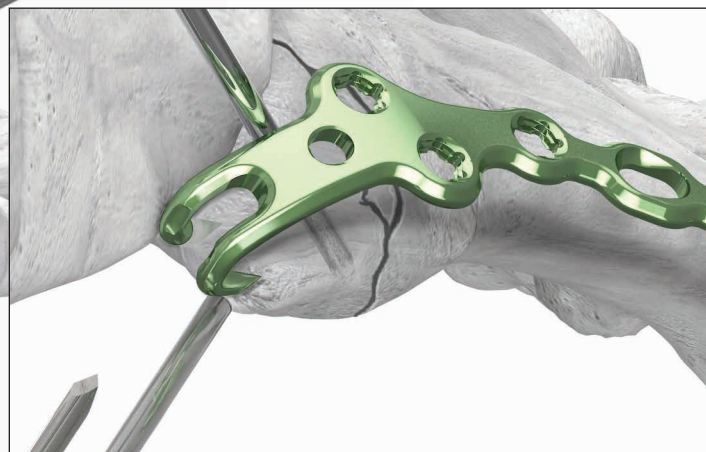
Place the pre-drill guide on the tuberosity to match intended plate position. Hook placement is just plantar to the peroneus brevis insertion, with the plate curvature following the lateral curvature of the 5th metatarsal.



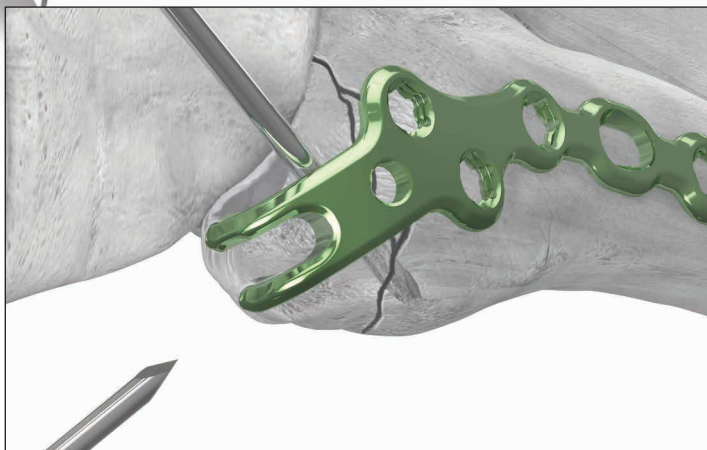
Secure the pre-drill guide with an olive wire, if preferred.



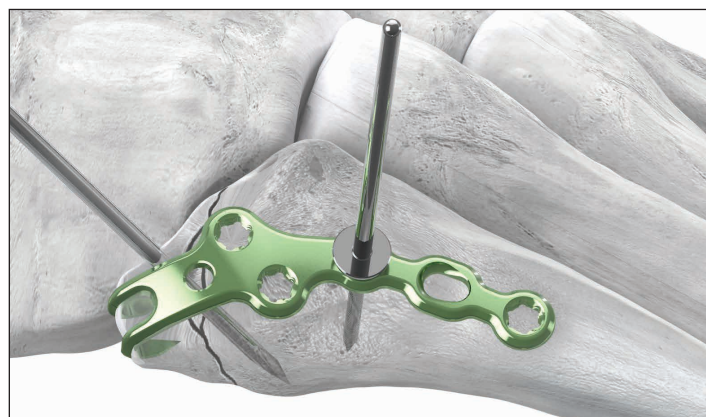
Using 1.6 mm K-wires, pre-drill holes in the K-wire guides of the pre-drill guide for the hook arms.



Remove the olive wire from the pre-drill guide and slide the pre-drill guide off the K-wires. Remove the K-wires one at a time, while replacing the first K-wire removed with the first hook.

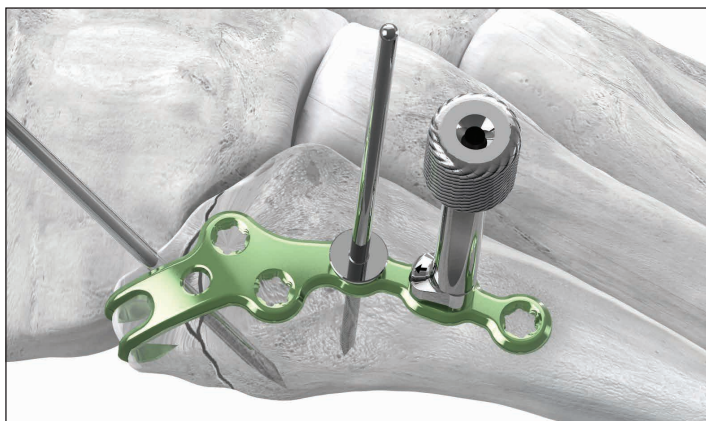


Removal of the second K-wire is performed while filling the second hole with the second hook.

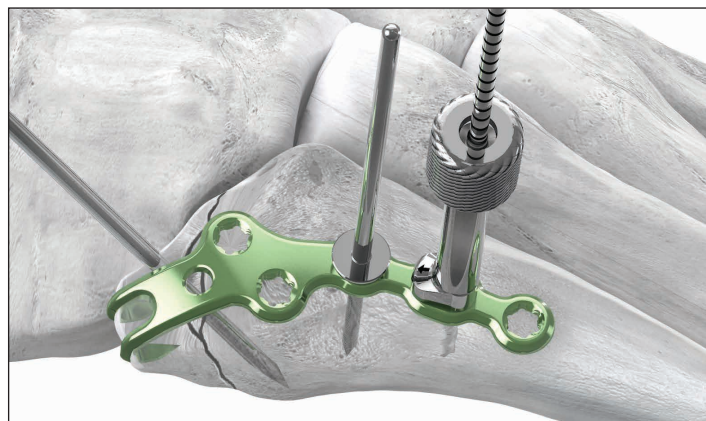


If desired, an olive wire may be placed into any circular hole of the plate. Confirm plate size and placement using fluoroscopy.

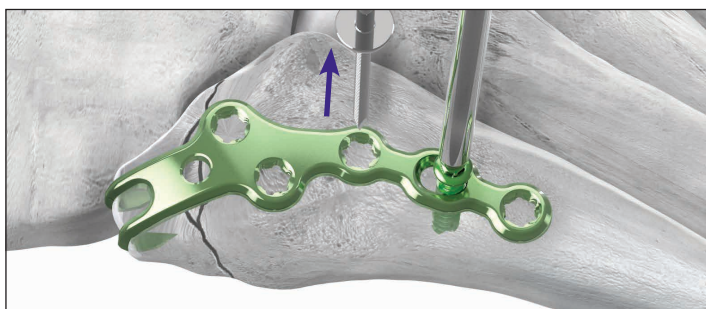
PERMANENT FIXATION



Retrieve the Compression Slot Drill Guide. Place the drill guide into the compression slot with the arrow pointing towards the fracture site.



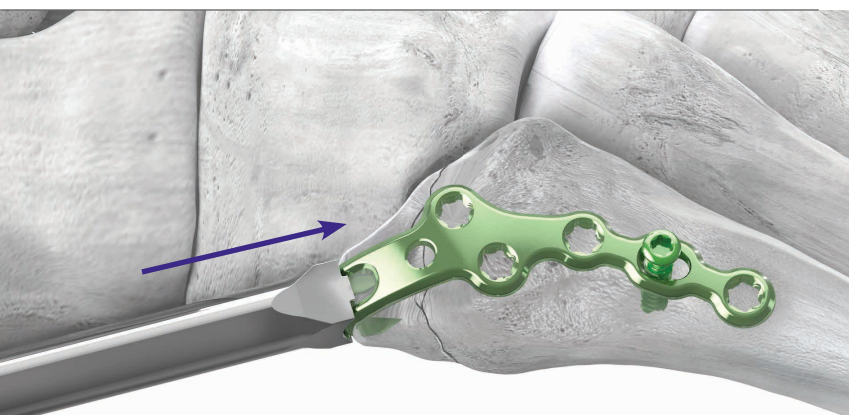
Drill through the compression drill guide eccentrically and distal from the fracture using the drill sized to desired screw diameter.



Measure screw length. Insert a non-locking screw into the compression slot, stopping before the screw neck reaches the plate to remove any temporary fixation or olive wires.



Complete screw insertion into the compression slot. Confirm plate and screw position using fluoroscopy.



TIP: If adequate compression of the fracture site or plate seating is not achieved through the compression slot, back out the compression screw at least one quarter turn. Tamp the hooks of the plate using either the single hook tamp or double hook tamp to seat the plate on the tuberosity.



While maintaining pressure on the hooks with the tamp, tighten and fully seat the compression screw in the compression slot once better hook position is achieved.

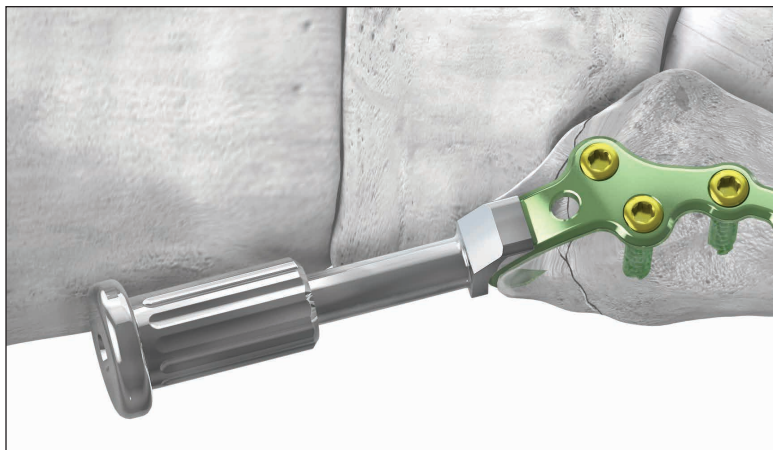
PLATE FIXATION AND COMPRESSION



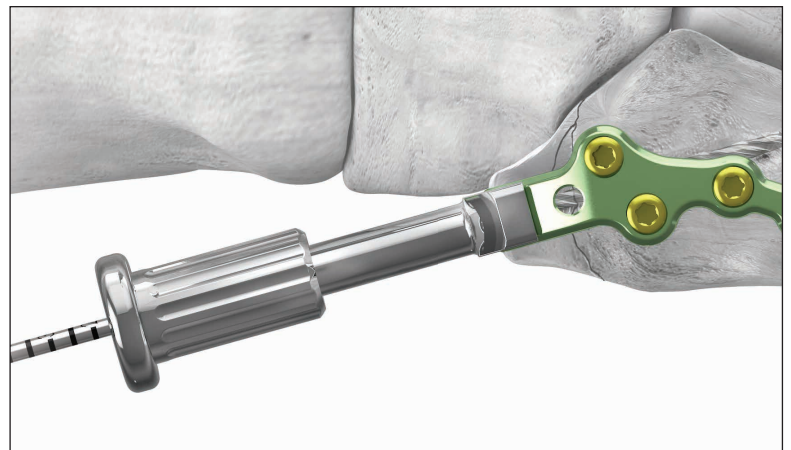
Fill the remaining plate screw holes as desired. Use of a threaded drill guide is preferred at the two most proximal screw holes if the intent is to put a cross screw through the hooks for additional stabilization. This guide helps to prevent screw interference.

Confirm plate and screw placement using fluoroscopy, if desired.

OPTIONAL CROSS SCREW



Place the hook screw drill guide in between the hooks on the tuberosity.



Drill through the hooks to desired length.



Measure the screw length using the depth gauge. Insert selected screw through the hooks.

NOTE: The screw can achieve bi-cortical fixation if sized to cross the medial 5th metatarsal cortex.

Confirm position using fluoroscopy.

CLOSURE

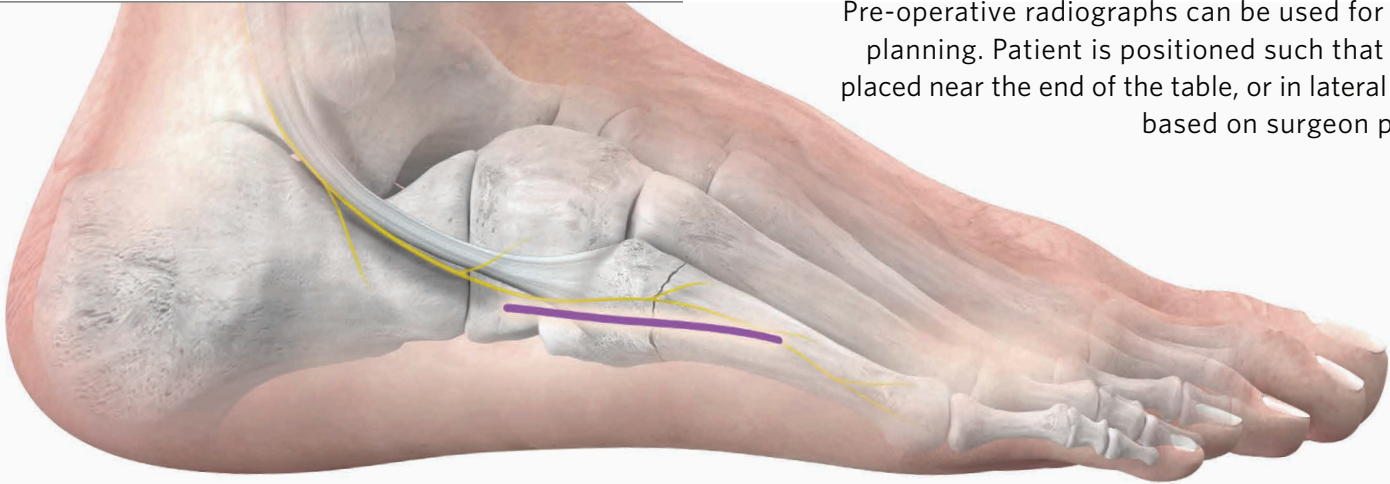
Proceed to incision closure or concomitant procedures at this time.



SURGICAL TECHNIQUE GUIDE: 5th METATARSAL JONES FRACTURE

JONES FRACTURE HOOK PLATE

INCISION/EXPOSURE



Pre-operative radiographs can be used for procedure planning. Patient is positioned such that the foot is placed near the end of the table, or in lateral decubitus, based on surgeon preference.

A longitudinal incision is made over the lateral aspect of the 5th metatarsal encompassing the base of the 5th metatarsal and fracture site. Identify and protect the sural nerve. Soft tissue dissection is carried down until the fracture site is visible and adequate exposure of the 5th metatarsal tuberosity is achieved for plate fit.

FRACTURE REDUCTION



The fracture site can be refreshed and cleared using a curette provided in the Baby Gorilla™ Case. A dental pick (shown), lobster claw clamp and pointed reduction forcep are provided for fracture reduction.

NOTE: Bone grafting can be added to a prior non-union site, if needed, prior to fixation.

Temporary stabilization of the fracture site can be performed at this time using a K-wire, if preferred.

PLATE SELECTION AND INSERTION

A 6 Hole Jones Fracture Hook Plate is recommended for a Jones Fracture. The hooks on the plate can be placed with or without drilling. If drilling is not performed, the plate can be inserted by threading a locking drill guide onto the plate and pushing or manually tamping the hooks of the plate into the base of the 5th metatarsal (not shown).

TIP: Pre-drilling is recommended in comminuted fractures or in very hard or soft bone.

Place the threaded knob into the 6 Hole Pre-Drill Guide by rotating the knob in a clockwise direction.

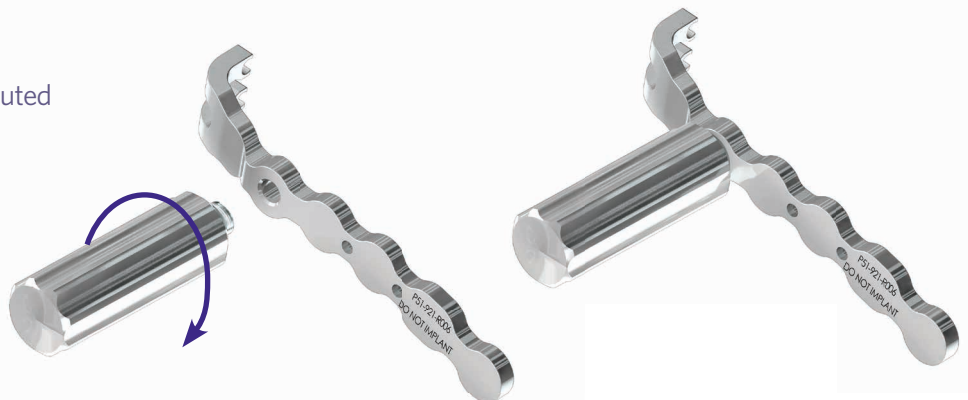
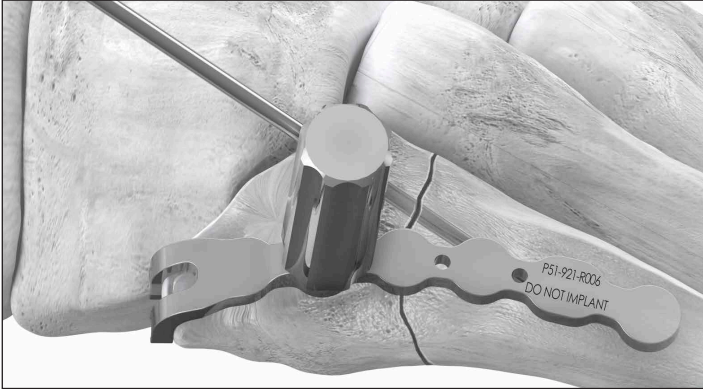
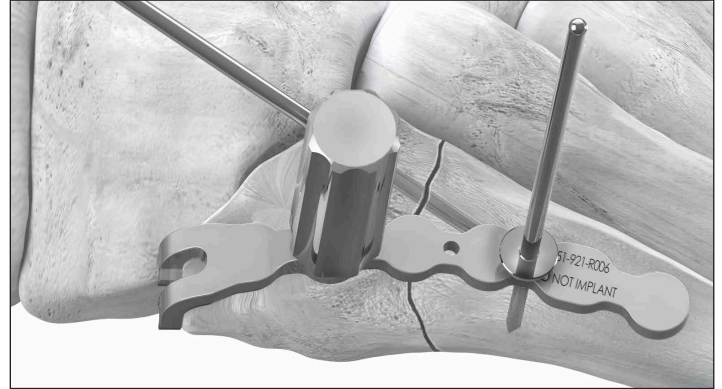


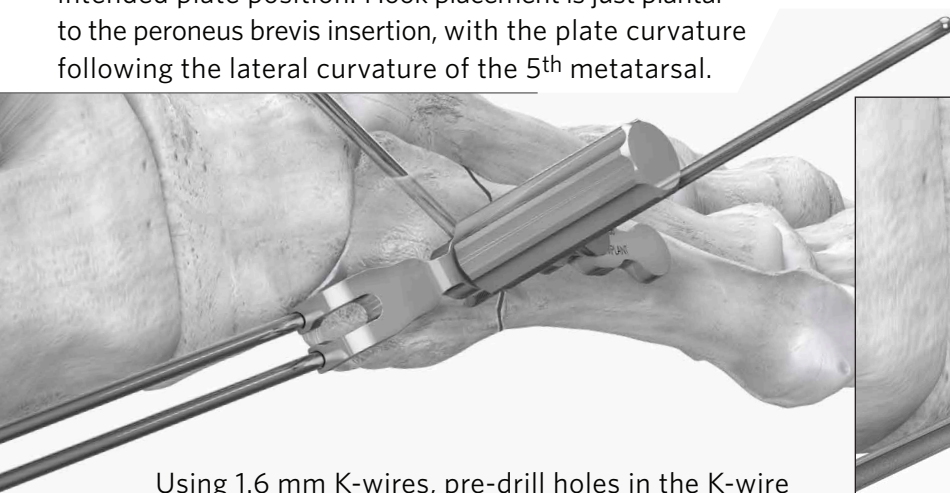
PLATE SELECTION AND INSERTION



Place the pre-drill guide on the tuberosity to match intended plate position. Hook placement is just plantar to the peroneus brevis insertion, with the plate curvature following the lateral curvature of the 5th metatarsal.



Secure the pre-drill guide with an olive wire, if preferred.



Using 1.6 mm K-wires, pre-drill holes in the K-wire guides of the pre-drill guide for the hook arms.



Remove the olive wire from the pre-drill guide and slide the pre-drill guide off of the K-wires. Remove the K-wires one at a time, while replacing the first K-wire removed with the first hook.

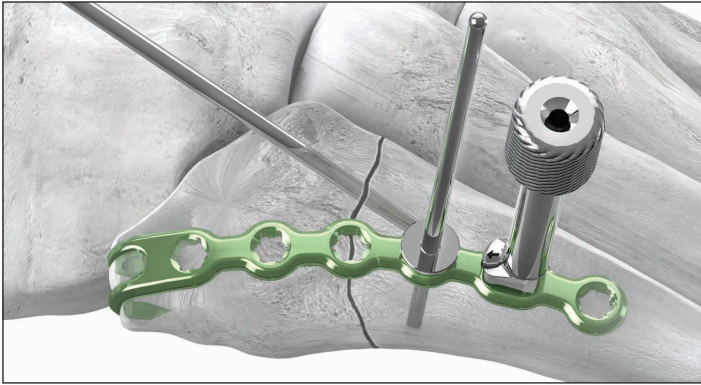


Removal of the second K-wire is performed while filling the second hole with the second hook.

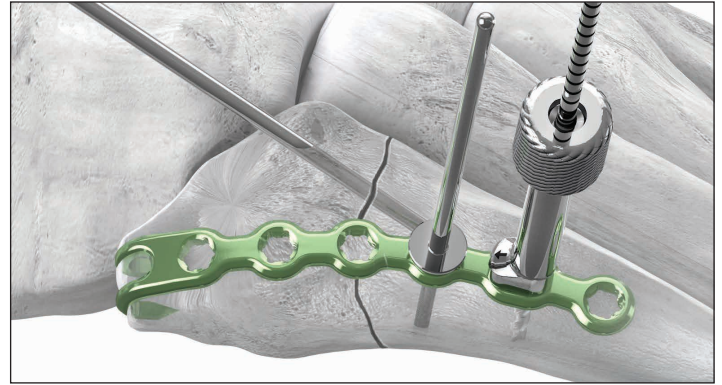


If desired, an olive wire may be placed into any circular hole of the plate. Confirm plate size and placement using fluoroscopy.

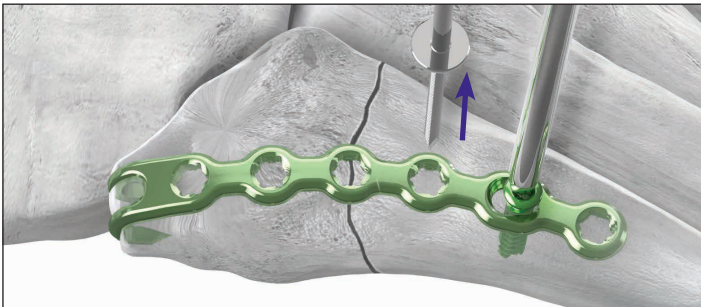
PERMANENT FIXATION



Retrieve the Compression Slot Drill Guide. Place the drill guide into the compression slot with the arrow pointing towards the fracture site.



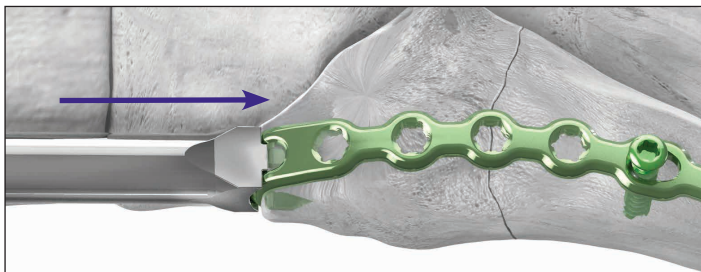
Drill through the compression drill guide eccentrically and distal from the fracture using the drill sized to desired screw diameter.



Measure screw length. Insert a non-locking screw into the compression slot, stopping before the screw neck reaches the plate to remove any temporary fixation or olive wires.



Complete screw insertion into the compression slot. Confirm plate and screw position using fluoroscopy.

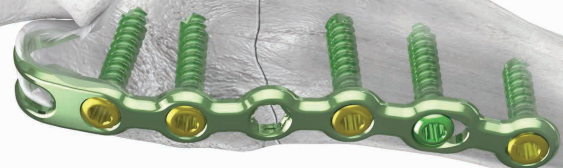


TIP: If adequate compression of the fracture site or plate seating is not achieved through the compression slot, back out the compression screw at least one quarter turn. Tamp the hooks of the plate using either the single hook tamp or double hook tamp to seat the plate on the tuberosity.



While maintaining pressure on the hooks with the tamp, tighten and fully seat the compression screw in the compression slot once better hook position is achieved.

Fill the remaining plate screw holes as desired. Confirm plate and screw placement using fluoroscopy, if desired.



CLOSURE

Proceed to incision closure or concomitant procedures at this time.

SURGICAL TECHNIQUE GUIDE:

5th METATARSAL FRACTURE SCREW SYSTEM

5th Metatarsal Plating System Caddy

The Baby Gorilla® 5th Metatarsal Plate Caddy contains the left and right 5th Metatarsal Fracture 8 hole Compression Plates, Jones Fracture Hook Plates and 5th Metatarsal Avulsion Fracture Hook Plates. Single and double hook tamps, plate pre-drill guides, hook screw drill guide and threaded knobs are also included in this caddy.

Baby Gorilla® Additional Caddies

The Baby Gorilla® Case comes standard with additional Baby Gorilla® Plate Caddies that may be needed for procedures performed in addition to fixation of a 5th metatarsal fracture. Universal plate options are available as a backup for a 5th metatarsal fracture.

Baby Gorilla® Instruments Caddy

Drill guides, threaded bar plate benders, drills, overdrills, forceps, K-wire ruler, book hook, depth gauge, K-wires and olive wires are located within the Baby Gorilla™ Instruments Caddy.

Baby Gorilla® Screw Caddy


The Baby Gorilla® Screw Caddy contains locking and non-locking screws in 2.0 mm and 2.5 mm diameters. Drivers and holding sleeves are contained in the screw caddy.

Baby Gorilla® Instrument Tray

The plate bending pliers, San Gio Baby Bennetts, lobster claw, bone reduction clamp, Wurapa distractor and Wurapa compressor are all located within the Baby Gorilla™ Instruments Tray.

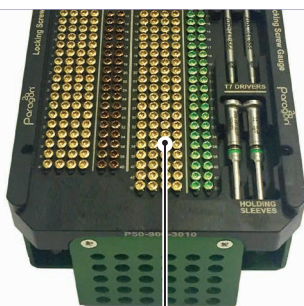
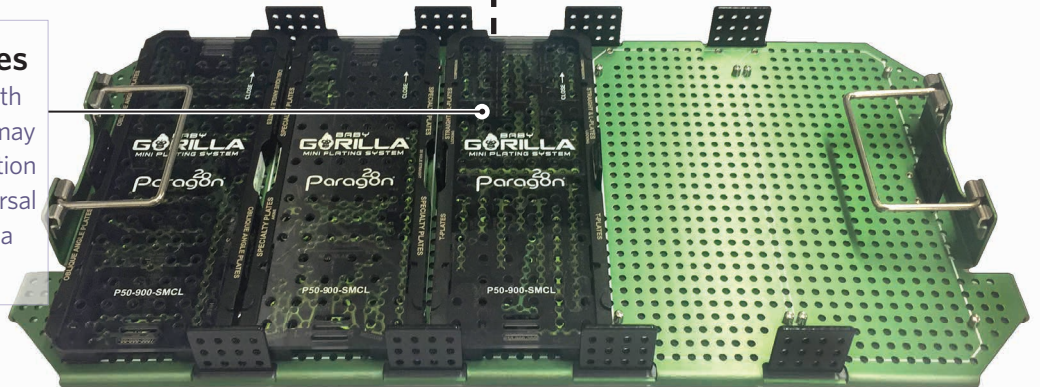
Baby Gorilla® Screw Optionality

The Baby Gorilla® screw length options for both locking and non-locking are as follows:

| | | |
|--------|---------------------------|---|
| 2.0 mm | 1 mm increments, 8-20 mm |  |
| 2.0 mm | 2 mm increments, 22-40 mm |  |
| 2.5 mm | 1 mm increments, 8-20 mm |  |
| 2.5 mm | 2 mm increments, 22-40 mm |  |
| 2.5 mm | 5 mm increments, 45-50 mm |  |

Baby Gorilla® Case

The ultra-mini AO Ratchet handle and mini streamline AO handle are located under the screw caddy. The plate cutter, periosteal elevator, rasp, curettes and osteotomes are located within the Baby Gorilla® Case, under the Instruments Tray.



SURGICAL TECHNIQUE GUIDE: INDICATIONS, CONTRAINDICATIONS, AND WARNINGS

Refer to www.paragon28.com/ifu 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.

BABY GORILLA[®] MINI PLATING SYSTEM

PATENTED, DESIGNED & EXCLUSIVELY DISTRIBUTED BY

Exclusively foot & ankle 28[®]
Paragon[®]


www.PARAGON28.com

P53-STG-1002 RevB

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DISCLAIMER

The purpose of the Baby Gorilla[®] 5th Metatarsal Fracture Surgical Technique Guide is to demonstrate the optionality and functionality of the Baby Gorilla[®] 5th Metatarsal Fracture implants and instrumentation. Although variations in placement and use of the Baby Gorilla[®] 5th Metatarsal Fracture implants can be performed, the fixation options demonstrated in this technique were chosen to demonstrate the functionality of the system and for simplicity of explanation. Other uses for the Baby Gorilla[®] 5th Metatarsal Fracture can be employed, appropriate for the size of the device.