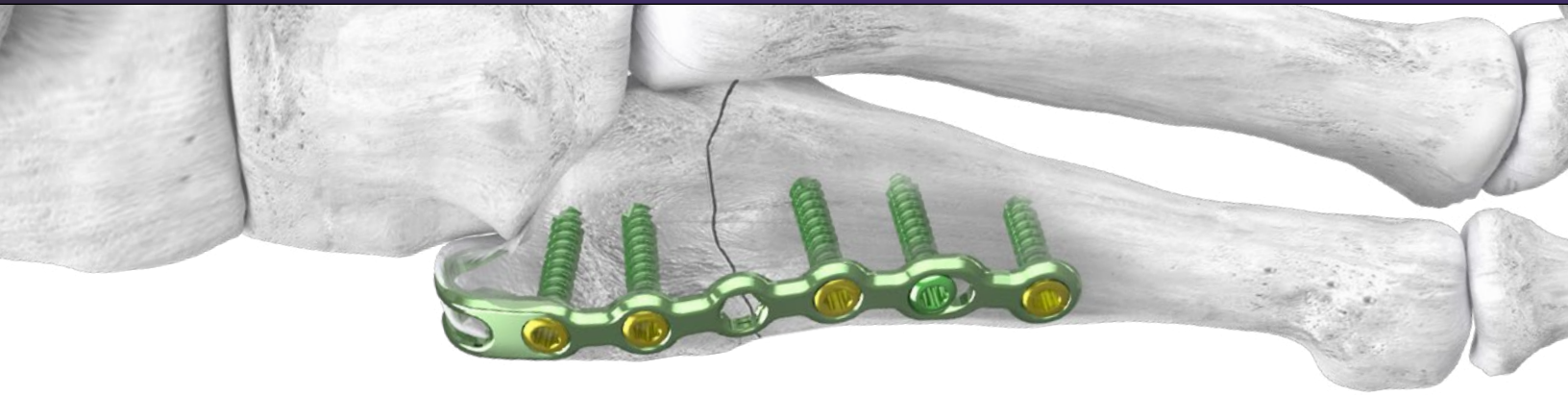
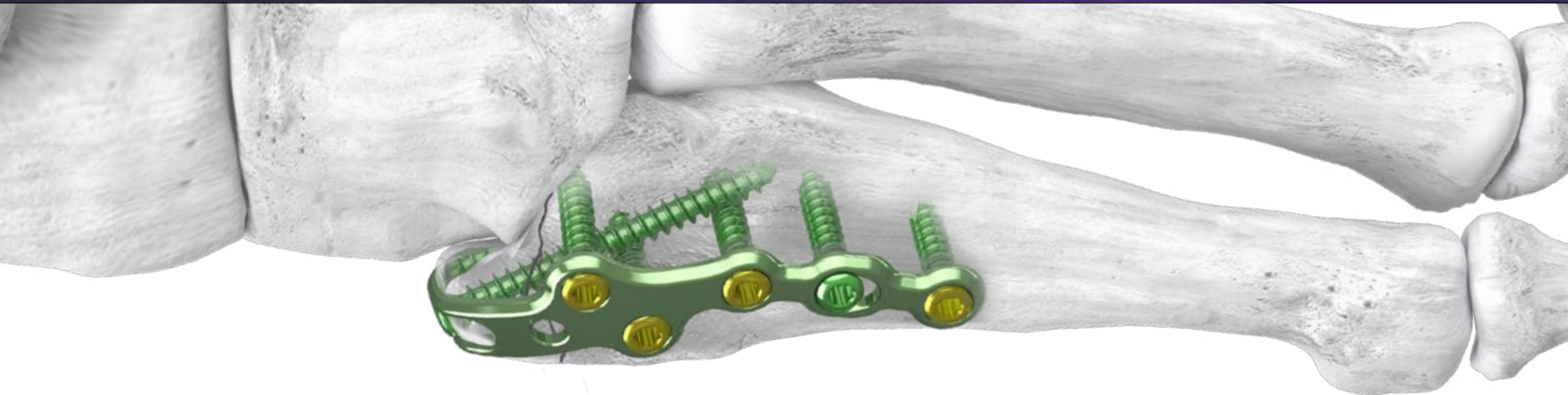




SURGICAL TECHNIQUE GUIDE

5th Metatarsal Fracture

Acknowledgment:

Paragon 28® would like to thank Thomas Harris, MD for his contribution to the development of the system and 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 Ø2.0 mm and Ø2.5 mm plating screws.

CONTENTS

Section 1	5TH METATARSAL PLATING SYSTEM OVERVIEW
	IMPLANT OFFERING3
	FEATURED INSTRUMENTATION.....3
	OTHER BABY GORILLA® “UNIVERSAL” OPTIONS FOR 5TH METATARSAL FRACTURES3
	BABY GORILLA® PLATE TECHNOLOGY4
	SCREW OFFERING AND INSTRUMENTATION MATRIX5
Section 2	REPAIR TECHNIQUE
	5TH METATARSAL AVULSION FRACTURE HOOK PLATE.....6-9
	5TH METATARSAL JONES FRACTURE 10-12
Section 3	CADDY AND SAFETY INFORMATION
	CADDY LAYOUT13-14
	INDICATIONS, CONTRAINDICATIONS, WARNINGS.....15-16

IMPLANT OFFERINGS

5th Metatarsal Fracture 8 Hole Compression Plates

- Available in left or right options
- Designed to anatomically fit the 5th metatarsal with the option to be used for:
 - Jones Fractures
 - Revision Jones Fractures
 - 5th Metatarsal Shaft Fractures

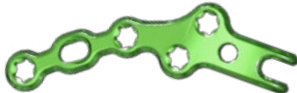


Left Plate



Right Plate

5th Metatarsal Avulsion Fracture Hook Plates



Left Plate



Right Plate

Jones Fracture 6 Hole Hook Plate



Left Plate



Right Plate

FEATURED INSTRUMENTS

5 Hole Plate Pre-Drill Guide



Left Plate



Right Plate

6 Hole Plate Pre-Drill Guide



Left Plate



Right Plate

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



Straight Plates

- 8 plate options



L Plates

- 21 plate options



Y Plates

- 7 plate options

BABY GORILLA® PLATE TECHNOLOGY

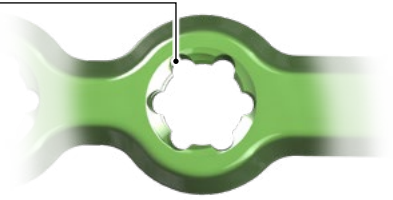
RAMPED COMPRESSION SLOT

Available in most plates for compression capability. Specific plates built with a compression slot to provide compression capability. Either the Ø2.0 or Ø2.5 mm non-locking screw can be inserted into the compression slot eccentrically.



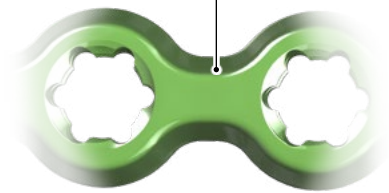
6 SCALLOP HOLES

Initiates threading of the locking screw head into the plate, while allowing for off-axis locking capability.



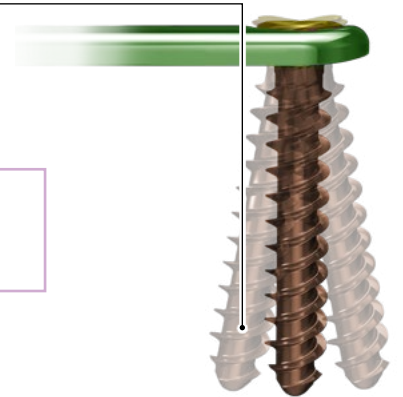
IN-LINE PLATE HOLE SCALLOPS

Provides an advantage in bending strength of the plate to help prevent bending from occurring through a scallop.



VARIABLE ANGLE LOCKING

Creates a locked screw construct up to 15° in every screw hole (with the exception of the compression slot).



TIP: In areas where soft tissue irritation may be a problem over the plate, it is advised to avoid variable angle locking, as the screw head may be proud following insertion.

TAPERED SCREW HEAD

Creates a lag effect to allow locking screws to lag and contour the plate to bone. Do not have to rely solely on non-locking screws for this application.



HEXALOBE DRIVE

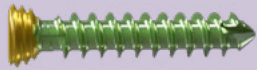
Designed to maximize surface contact and torque transmission between the driver and screw, thus helping to reduce screw head stripping.



BLUNT TIP DESIGN

Helps minimize soft tissue irritation in bicortical fixation.

SCREW OFFERING AND INSTRUMENTATION MATRIX

	Ø2.0 mm Screws	Ø2.5 mm Screws
Locking:		
Non-locking:		
Screw Lengths:	1 mm increments 8-20 mm 2 mm increments 22-40 mm	1 mm increments 8-20 mm 2 mm increments 22-40 mm 5 mm increments 45-50 mm
Drill Size:	 Ø1.3 mm	 Ø1.6 mm
Driver Size:	 HX-7	 HX-7
Locking Drill Guide Size:	 Ø2.0 mm, Ø2.5 mm	 Ø2.0 mm, Ø2.5 mm
Centering Drill Guide Size:	 Ø2.0 mm	 Ø2.5 mm
Compression Slot Drill Guide Size:	 Ø2.0, Ø2.5 mm	 Ø2.0, Ø2.5 mm
Cone/Straight Easy Guide Size:	 Ø2.0 mm, Ø2.5 mm	 Ø2.0 mm, Ø2.5 mm
Over Drill Size:	 Ø2.0 mm	 Ø2.5 mm
Double Ended Drill / Over Drill Guides:	 Ø2.0 mm, Ø2.5 mm	 Ø2.0 mm, Ø2.5 mm

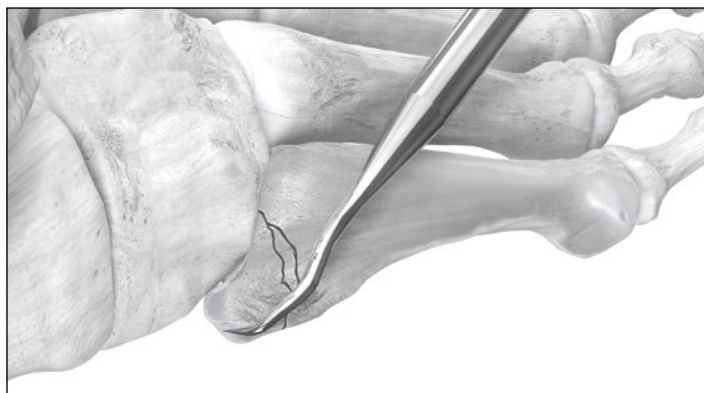
INCISION AND EXPOSURE



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).

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



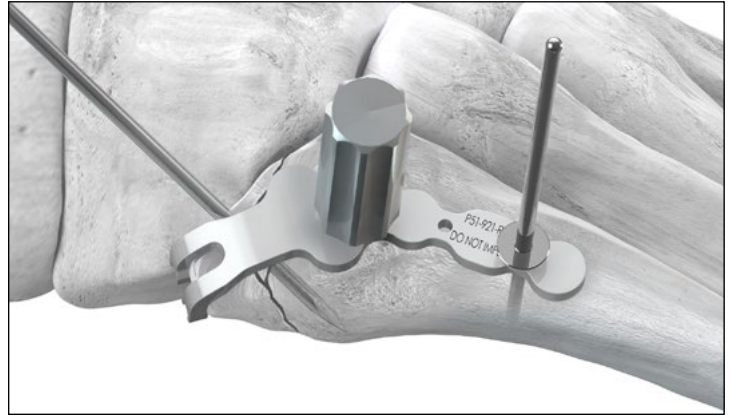
TIP: Pre-drilling is recommended in comminuted fractures or in very hard or soft bone.



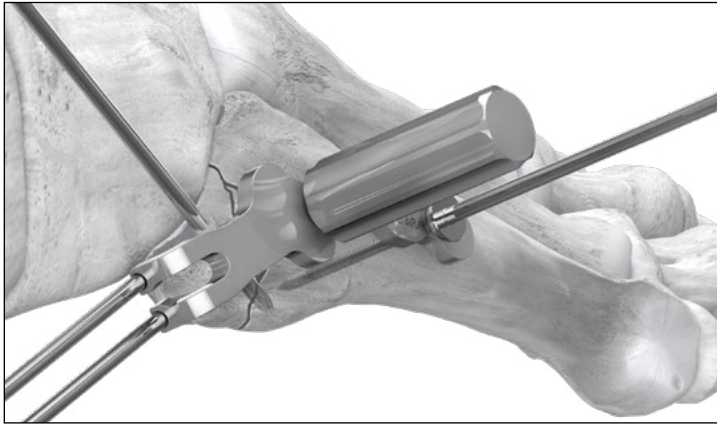
PLATE SELECTION AND INSERTION



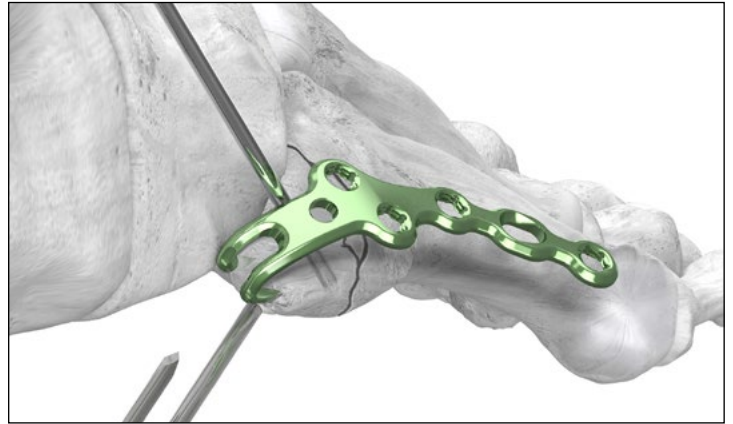
Place the pre-drill guide on the tuberosity to match intended plate position. Hook placement is just plantar to the peroneus brevis insertion, with the plate curvature following the lateral curvature of the 5th metatarsal.



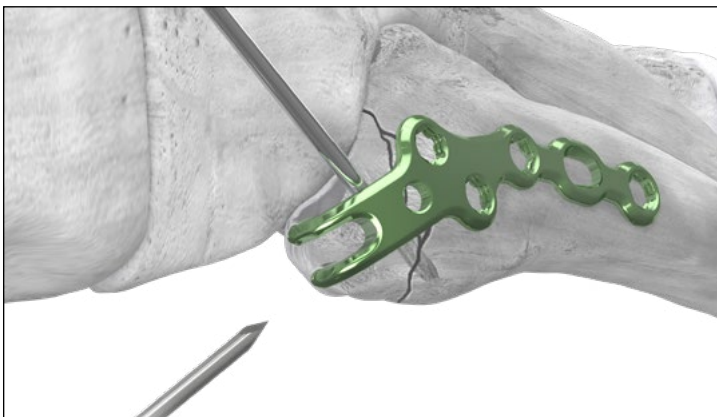
Secure the pre-drill guide with an olive wire, if preferred.



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.



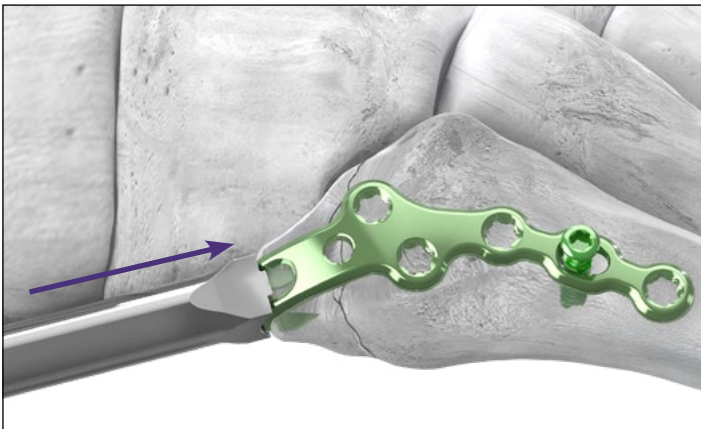
Drill through the compression drill guide eccentrically and distal from the fracture using the drill sized to desired screw diameter.



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.

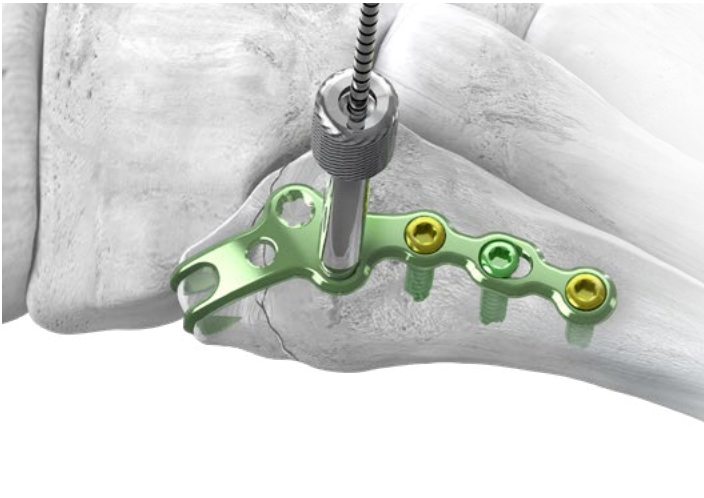


While maintaining pressure on the hooks with the tamp, tighten and fully seat the compression screw in the compression slot once better hook position is achieved.



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.

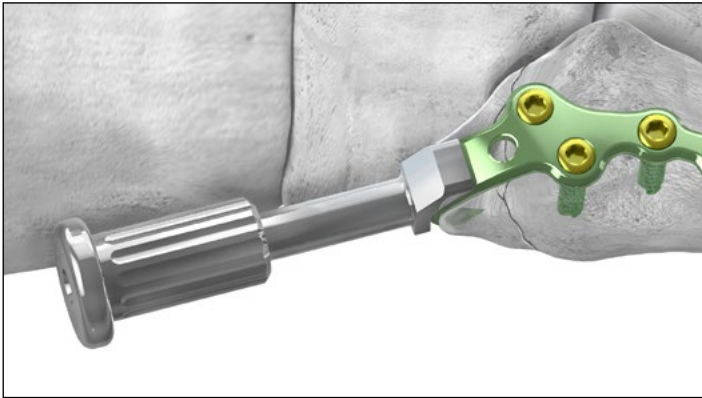
PLATE FIXATION AND COMPRESSION



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.

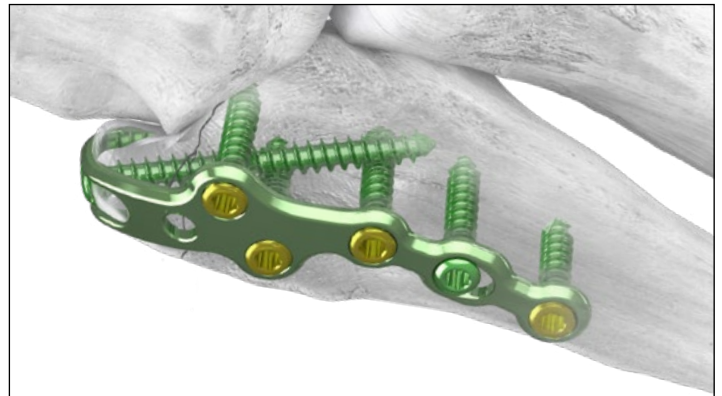


Drill through the hooks to desired length.



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

Confirm position using fluoroscopy.



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

CLOSURE

Proceed to incision closure or concomitant procedures at this time.

INCISION AND 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.



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

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).

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



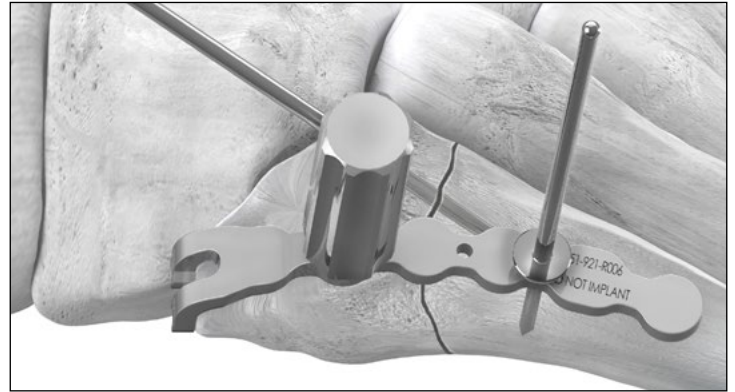
TIP: Pre-drilling is recommended in comminuted fractures or in very hard or soft bone.



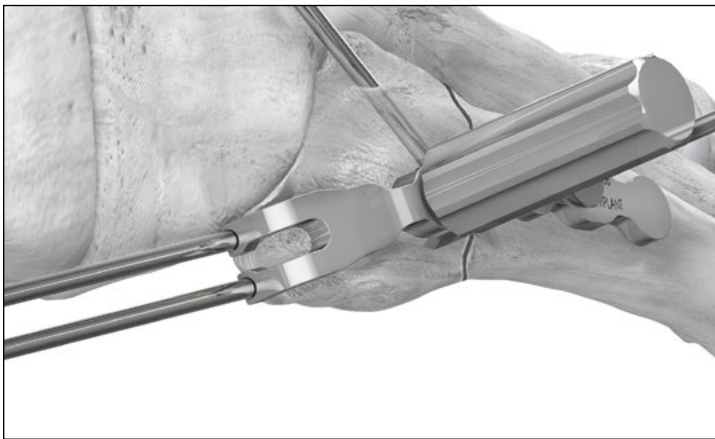
PLATE SELECTION AND INSERTION



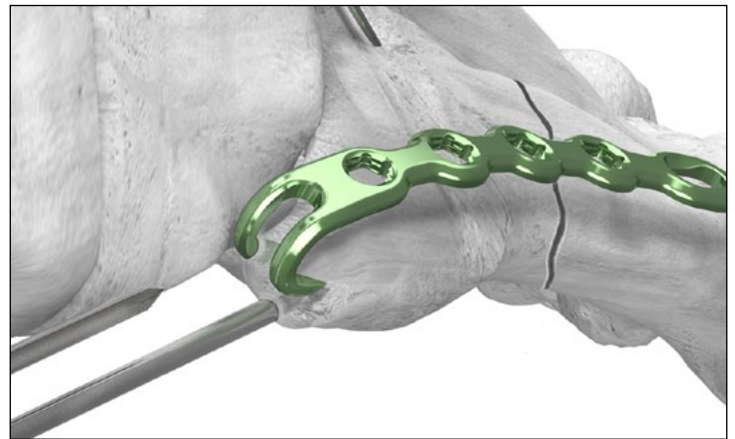
Place the pre-drill guide on the tuberosity to match intended plate position. Hook placement is just plantar to the peroneus brevis insertion, with the plate curvature following the lateral curvature of the 5th metatarsal.



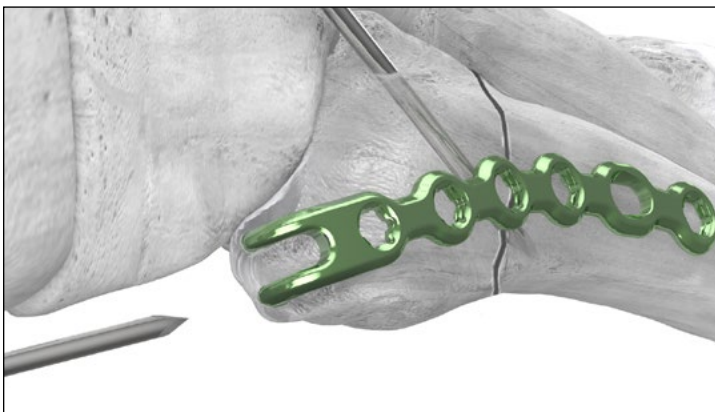
Secure the pre-drill guide with an olive wire, if preferred.



Using Ø1.6 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.

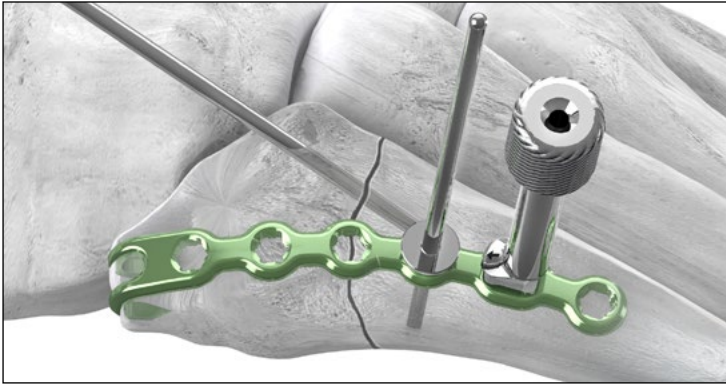


Removal of the second K-wire is performed while filling the second hole with the second hook.

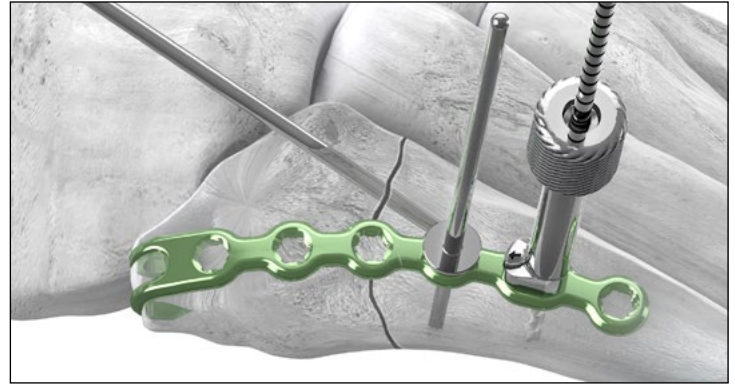


If desired, an olive wire may be placed into any circular hole of the plate. Confirm plate size and placement using fluoroscopy.

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.



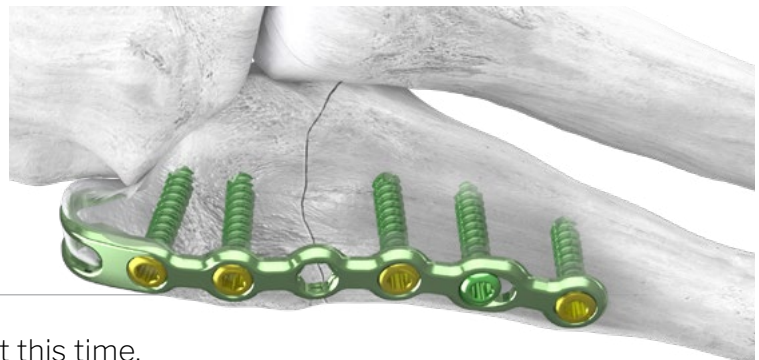
While maintaining pressure on the hooks with the tamp, tighten and fully seat the compression screw in the compression slot once better hook position is achieved.

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.



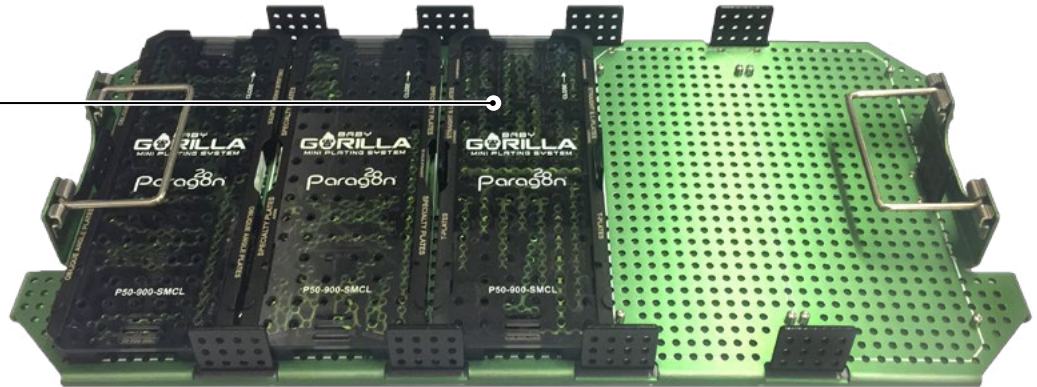
BABY GORILLA® CADDY AND CASE SYSTEM

BABY GORILLA® CADDIES

All caddy options include:

BABY GORILLA® ADDITIONAL CADDIES

The Baby Gorilla® Case comes standard with additional Baby Gorilla® Plate Caddies that may be needed for procedures.



BABY GORILLA® INSTRUMENTS CADDY

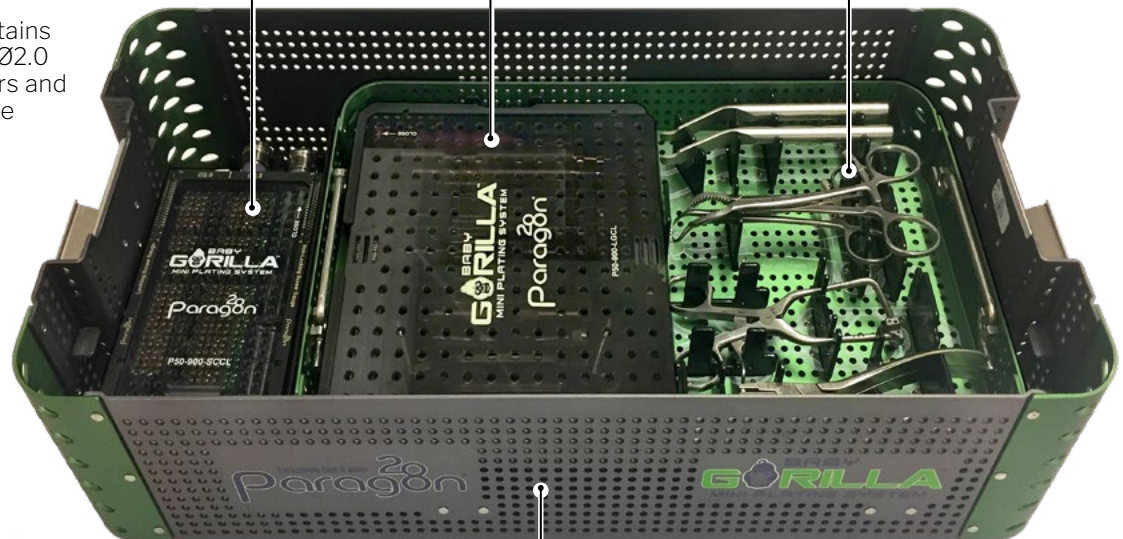
Drill guides, threaded bar plate benders, drills, overdrills, forceps, K-wire ruler, book hook, depth gauge, K-wires and olive wires are located within the Baby Gorilla Instruments Caddy.

BABY GORILLA® 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 CADDY

The Baby Gorilla Screw Caddy contains locking and non-locking screws in Ø2.0 mm and Ø2.5 mm diameters. Drivers and holding sleeves are contained in the screw caddy.



BABY GORILLA® SCREW OPTIONALITY

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

Ø2.0 mm	1 mm increments, 8-20 mm	
Ø2.0 mm	2 mm increments, 22-40 mm	
Ø2.5 mm	1 mm increments, 8-20 mm	
Ø2.5 mm	2 mm increments, 22-40 mm	
Ø2.5 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.

BABY GORILLA PLATING SYSTEM - 5TH MET PLATING CADDY

Part #	Description	Use
P53-007-LC08	Baby Gorilla, Plate, Jones, 8 Hole, Comp., Left, 1.4mm, TiA	Single-use
P53-007-RC08	Baby Gorilla, Plate, Jones, 8 Hole, Comp., Right, 1.4mm, TiA	Single-use
P53-008-LC05	Baby Gorilla, Plate, Hook, 5 Hole, Comp., Left, 1.2mm, TiA	Single-use
P53-008-RC05	Baby Gorilla, Plate, Hook, 5 Hole, Comp., Right, 1.2mm, TiA	Single-use
P53-008-LC06	Baby Gorilla, Plate, Hook, 6 Hole, Comp., Left, 1.2mm, TiA	Single-use
P53-008-RC06	Baby Gorilla, Plate, Hook, 6 Hole, Comp., Right, 1.2mm, TiA	Single-use
P51-921-0001	Baby Gorilla, Tamp, Single Hook	Reusable
P51-921-0002	Baby Gorilla, Tamp, Double Hook	Reusable
P51-921-L005	Baby Gorilla, 5 th Met, Plate Template, 5-Hole, Left	Reusable
P51-921-R005	Baby Gorilla, 5 th Met, Plate Template, 5-Hole, Right	Reusable
P51-921-L006	Baby Gorilla, 5 th Met, Plate Template, 6-Hole, Left	Reusable
P51-921-R006	Baby Gorilla, 5 th Met, Plate Template, 6-Hole, Right	Reusable
P51-921-0009	Baby Gorilla, 5 th Met, Drill Guide, Hook Screw	Reusable
P51-950-0004	Threaded Knob, M3	Reusable

*See the complete Baby Gorilla Plating System Surgical Technique Guide (P53-STG-0001) for general instrument information

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 Baby Gorilla®/Gorilla® 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, talus, and calcaneus, as well as the fingers, hands, and wrists. The system can be used in both adult and pediatric patients. Specific examples include:

Forefoot:

- Arthrodesis of the first metatarsalcuneiform joint (Lapidus Fusion)
- Metatarsal or phalangeal fractures and osteotomies
- Lesser metatarsal shortening osteotomies (e.g. Weil)
- Fifth metatarsal fractures (e.g. Jones Fracture)

Mid/Hindfoot:

- LisFranc Arthrodesis and/or Stabilization
- 1st (Lapidus), 2nd, 3rd, 4th, and 5th Tarsometatarsal (TMT) Fusions
- Intercuneiform Fusions
- Navicular-Cuneiform (NC) Fusion
- Talo-Navicular (TN) Fusion
- Calcaneo-Cuboid (CC) Fusion
- Subtalar Fusion
- Medial Column Fusion
- Cuneiform Fracture
- Cuboid Fracture
- Navicular Fracture

Ankle:

- Lateral Malleolar Fractures
- Syndesmosis Injuries
- Medial Malleolar Fractures and Osteotomies
- Bi-Malleolar Fractures
- Tri-Malleolar Fractures
- Posterior Malleolar Fractures
- Distal Anterior Tibia Fractures
- Vertical Shear Fractures of the Medial Malleolus
- Pilon Fractures
- Distal Tibia Shaft Fractures
- Distal Fibula Shaft Fractures
- Distal Tibia Periarticular Fractures
- Medial Malleolar Avulsion Fractures
- Lateral Malleolar Avulsion Fractures
- Tibiotalocalcaneal Joint Arthrodesis
- Tibiotalar Joint Arthrodesis
- Tibiocalcaneal Arthrodesis
- Supramalleolar Osteotomy
- Fibular Osteotomy

First metatarsal osteotomies for hallux valgus correction including:

- Opening base wedge osteotomy
- Closing base wedge osteotomy
- Crescentic Osteotomy
- Proximal Osteotomy (Chevron and Rotational Oblique)
- Distal Osteotomy (Chevron/Austin)

Arthrodesis of the first metatarsophalangeal joint (MTP) including:

- Primary MTP Fusion due to hallux rigidus and/or hallux valgus
- Revision MTP Fusion
- Revision of failed first MTP Arthroplasty implant

Flatfoot:

- Lateral Column Lengthening (Evans Osteotomy)
- Plantar Flexion Opening Wedge Osteotomy of the Medial Cuneiform (Cotton Osteotomy)
- Calcaneal Slide Osteotomy

Charcot:

- Medial column fusion (talus, navicular, cuneiform, metatarsal) for neuropathic osteoarthropathy (Charcot)
- Lateral column fusion (calcaneus, cuboid, metatarsal) for neuropathic osteoarthropathy (Charcot)

In addition, the non-locking, titanium screws and washers are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair and fracture fixation, appropriate for the size of the device.

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

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.
- Do not use other manufacturer's instruments or implants in conjunction with the Baby Gorilla®/Gorilla® Plating System.
- If a stainless steel Gorilla® R3LEASE™ Screw is used, it may only be used standalone.
- The device should only be used in pediatric patients where the growth plates have fused or in which active growth plates will not be crossed by the system implants or instrumentation.

MR SAFETY INFORMATION:

The Baby Gorilla®/Gorilla® Plating System has not 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 Baby Gorilla®/Gorilla® Plating System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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PATENTED, DESIGNED & EXCLUSIVELY DISTRIBUTED BY

Exclusively foot & ankle
Paragon²⁸®

P53-STG-0002 RevE [2024-12-05]

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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.

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