

Exclusively foot & ankle
Paragon²⁰[®]

SURGICAL TECHNIQUE GUIDE



THE PARAGON 28® BABY GORILLA® PLATING SYSTEM

is an “offspring” of the Gorilla® Plating System. This mini plating system addresses a multitude of procedures that may require a specific plate shape with a thinner, narrower profile and smaller screw diameters.

Each and every detail of the system was scrutinized to achieve the following goals:

- 65 unique foot and ankle specific plating options
- All plates within the system are 1.1 mm – 1.4 mm thick
- Allow for selected plates in the system to be “Universal” in application – these plates include the Straight Plates, Y-Plates, L-Plates, T-Plates and Mesh Plate
- Provide anatomically specific plates that require minimal manipulation to achieve necessary fixation – Akin Plates, Navicular Plates, Cuboid Plates, Jones Plates, and 5th Metatarsal Hook Plates
- Include instrumentation sized and designed for foot and ankle procedures likely to be performed with these plates
- Develop screws in sizes that meet the needs of procedures performed with this plating system
- Deliver the system in an all-in-one caddy containing plates, screws and instrumentation

DISCLAIMER

The purpose of the Baby Gorilla® Surgical Technique Guide is to introduce implants and instrumentation in the system and demonstrate their use in a procedure. Although various methods of fixation can be employed for this procedure, the fixation options demonstrated were chosen for simplicity of explanation and demonstration of the unique features of the system.

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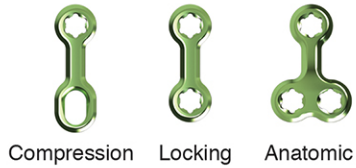
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Baby Gorilla Plating Options

Akin Plates

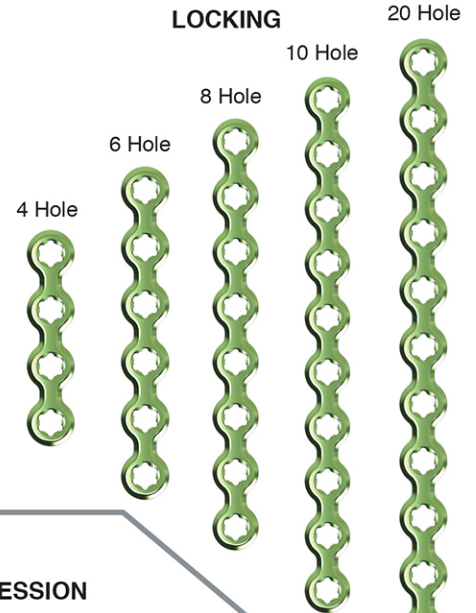


Straight Plates

COMPRESSION

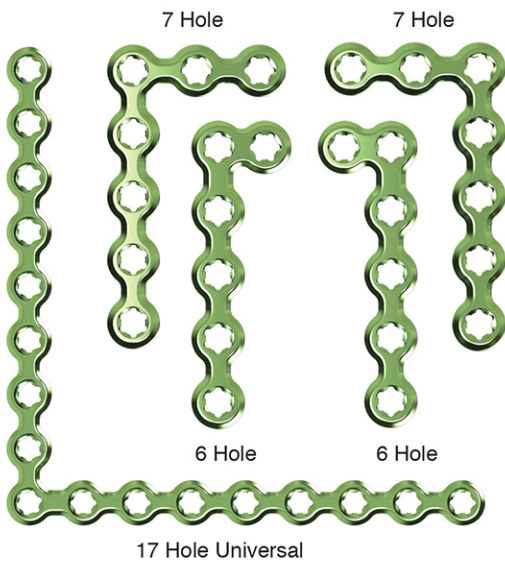


LOCKING

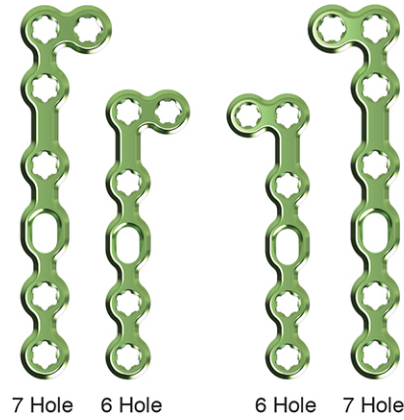


Straight L-Plates

LOCKING

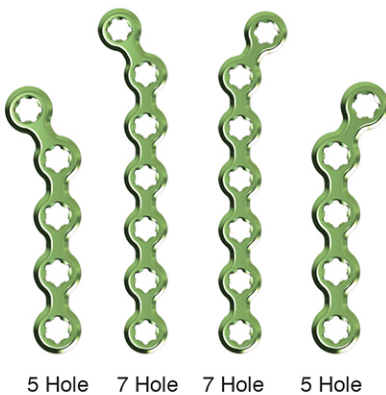


COMPRESSION

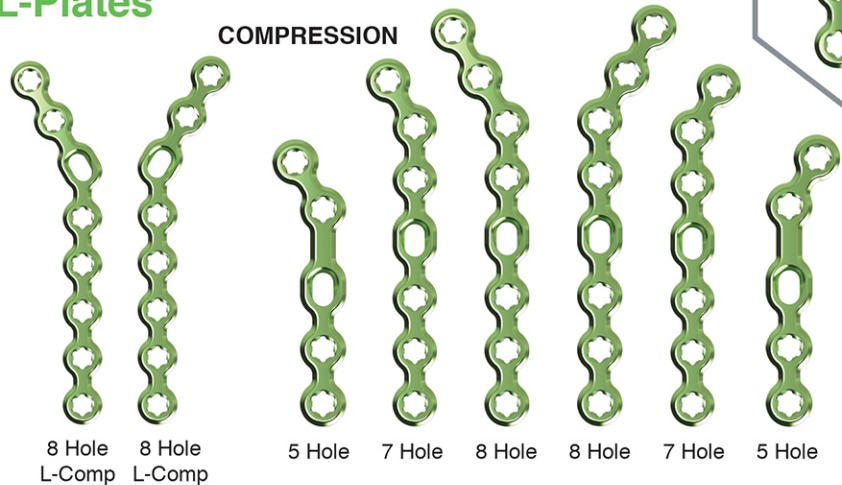


Oblique L-Plates

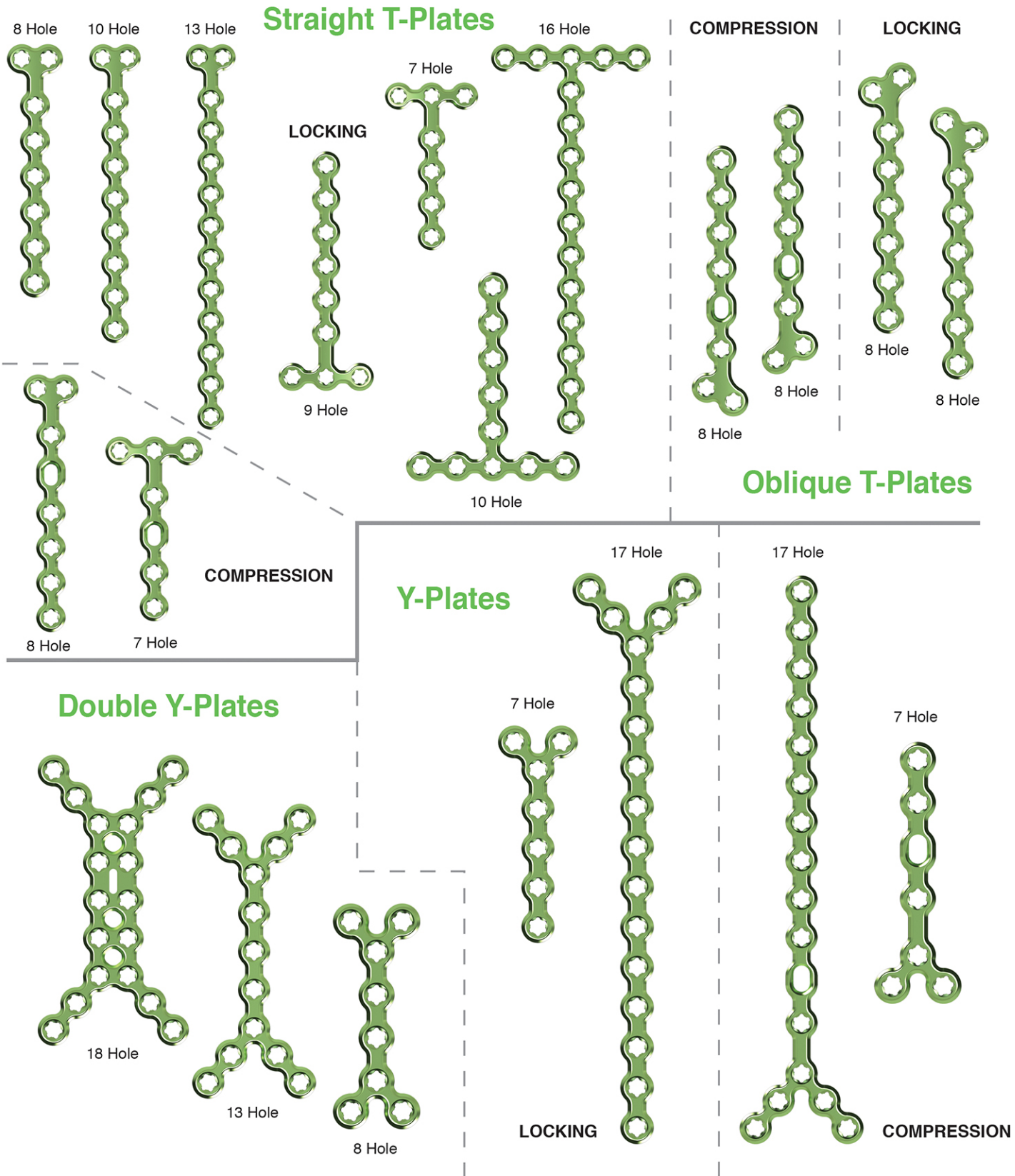
LOCKING



COMPRESSION

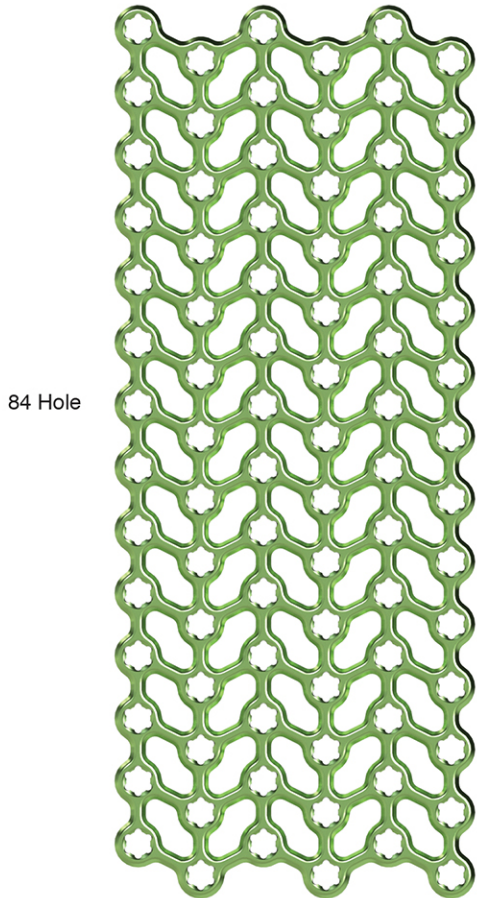


Baby Gorilla Plating Options

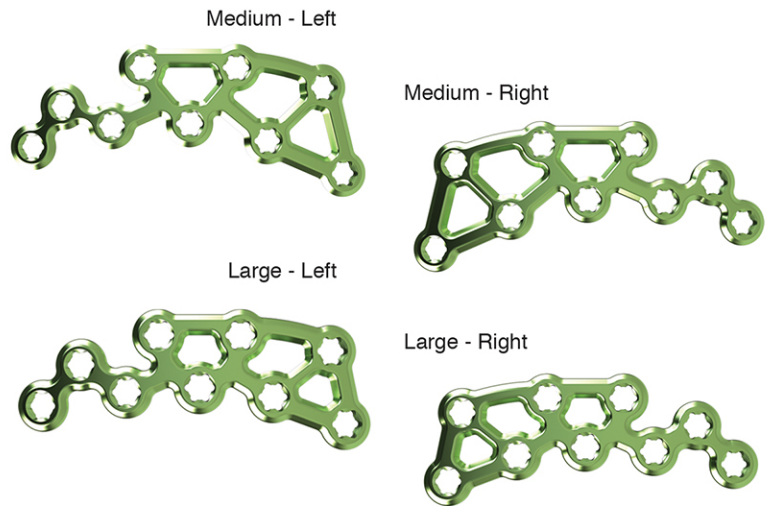


Baby Gorilla Plating Options

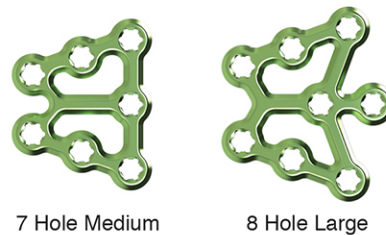
Mesh Plate



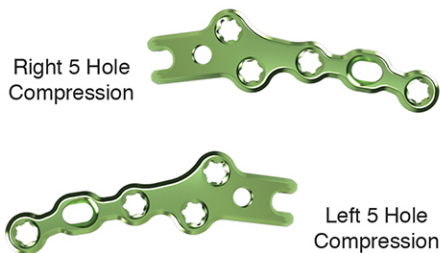
Navicular Plates



Cuboid Plates



5th Metatarsal Hook Plates



Jones Plates

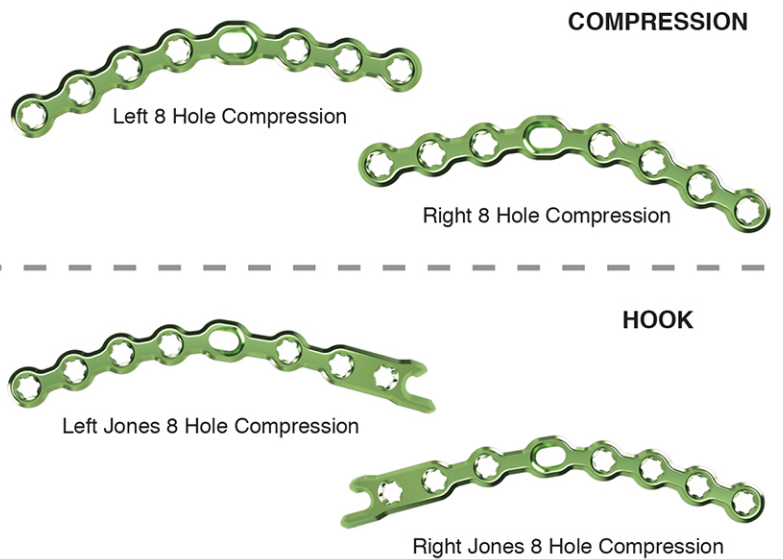


Plate to Procedure Atlas

Procedure	Straight Plates	L-Plates	T-Plates	Y-Plates	Akin Plates	Navicular Plates	Cuboid Plates	Mesh Plate	Jones Plates	Hook Plates
Akin Osteotomy					✓					
1st Metatarsal Osteotomy for Hallux Valgus	✓	✓	✓	✓						
1st MTP Arthrodesis	✓	✓	✓	✓						
Metatarsal Deformity Correction	✓	✓	✓	✓						
Tarsometatarsal Joint Arthrodesis	✓	✓	✓	✓						
Medial Column Arthrodesis	✓	✓	✓	✓				✓		
Lateral Column Arthrodesis	✓	✓	✓	✓				✓		
Lisfranc Fracture/Dislocation	✓	✓	✓	✓				✓		
Metatarsal Fracture	✓	✓	✓	✓						
Cuboid Fracture				✓			✓			
Calcaneal Fracture				✓				✓		
Navicular Fracture	✓					✓				
5th Metatarsal Fracture	✓	✓	✓	✓					✓	✓

Plate Features



6 Scallop Holes

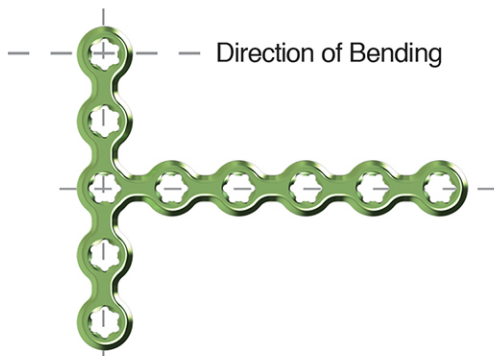
Quickly initiates threading of the locking screw head into the plate, while allowing for off-axis locking capability.



Ramped Compression Slot

Specific plates built with a compression slot to provide compression capability. Either the 2.0 or 2.5 mm non-locking screw can be inserted into the compression slot eccentrically to allow for 1.6 mm of total compression.

Alignment of Scallops



In-Line Plate Hole Scallops

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

Baby Gorilla Screw Optionality

LOCKING SCREW



OPTIONALITY:

All sizes of locking screws fit into the circular holes on the plate.

Diameter	Lengths	Drill Size
2.0 mm	1 mm increments, 8-20 mm; 2 mm increments, 22-40 mm	1.3 mm
2.5 mm	1 mm increments, 8-20 mm; 2 mm increments, 22-40 mm; 5 mm increments; 45-50 mm	1.6 mm



NON-LOCKING SCREW



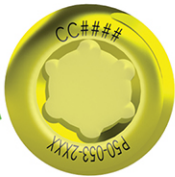
OPTIONALITY:

All sizes of the non-locking screws fit into the circular holes and the oblong compression slot on the plate. Washers are available for use when non-locking screws are used outside of the plate.

Diameter	Lengths	Drill Size
2.0 mm	1 mm increments, 8-20 mm; 2 mm increments, 22-40 mm	1.3 mm
2.5 mm	1 mm increments, 8-20 mm; 2 mm increments, 22-40 mm; 5 mm increments; 45-50 mm	1.6 mm



SCREW FEATURES

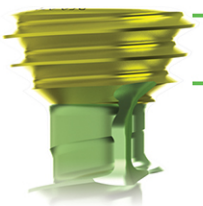


Hexalobe Drive

- Designed to maximize surface contact and torque transmission between the driver and screw
- Helps to reduce screw head stripping
- Same driver used for 2.0 and 2.5 mm screws

Hard Headed

- Locking screw has a titanium nitride (TiN) coating
- Helps to prevent screw head stripping during variable angle locking



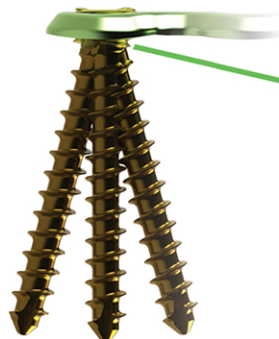
Tapered Screw Head

- 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



Blunt Tip Design

- Helps minimize soft tissue irritation in bicortical fixation



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.

Baby Gorilla Featured Instrumentation

PLATE BENDING



THREADED PLATE BENDING BARS

- Thread into plate holes to allow for preservation of plate threads when contouring plate

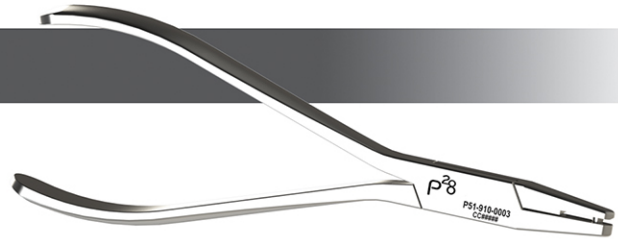


PLATE BENDING PLIERS

- Allows for bending of plate through hole without damage to plate hole threads
- Protrusion on one end of plier engages with top end of the locking screw hole while flat end receives protrusion on the bottom of the plate

FRACTURE REDUCTION AND JOINT PREPARATION



PERIOSTEAL ELEVATOR



CURETTE

- Large and small sizes available to accommodate different areas of the foot
- Angled 20° for better joint space access



OSTEOTOMES

- End of handles designed for use with mallet
- Straight or curved
- Available widths: 6 mm, 9 mm and 12 mm



BONE REDUCTION CLAMP

- Curved with pointed tip



LOBSTER CLAW

- Curved with serrated jaws



HY MINI PIN DISTRACTOR

- Low profile pin distractor for accessibility to clean out joint space

SAN GIO RETRACTOR

- Retractors sized for forefoot and midfoot applications



HY MINI PIN COMPRESSOR

- Allows for compression through plate

BONE HOOK



Baby Gorilla Featured Instrumentation

PLATE AND SCREW PLACEMENT



THREADED DRILL TOWER

- Sized for both 2.0 and 2.5 mm screw drills
- Provides best trajectory for locking screw
- Accepts 1.3 mm long olive wire to help minimize shifting of plate while temporarily fixing plate to bone



COMPRESSION SLOT DRILL GUIDE

- Aligns drill within compression slot
- Point arrow toward bone interface where compression is desired



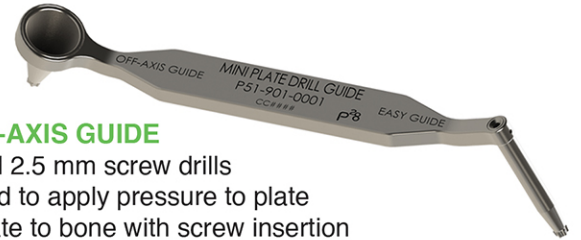
CENTERING DRILL GUIDE

- Available when placing a non-locking screw outside of the plate
- Fits inside overdrill hole to center drill hole during lag screw technique
- Available for use with 2.0 mm and 2.5 mm screw sizes



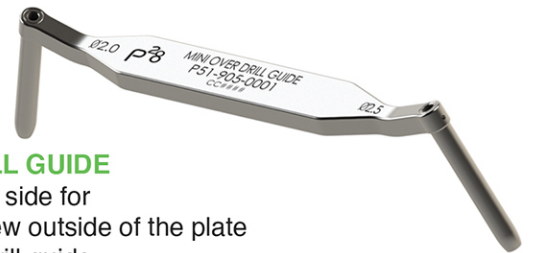
SCREW GRIPPER

- Interfaces directly with driver
- Firmly retains 2.0 or 2.5 mm locking or non-locking screws



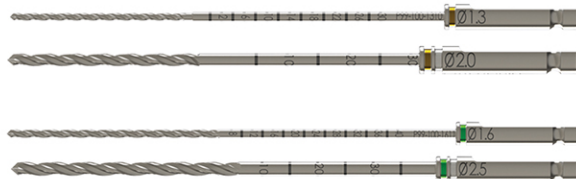
DOUBLE ENDED EZ OFF-AXIS GUIDE

- Both sides accept 2.0 and 2.5 mm screw drills
- EZ guide side can be used to apply pressure to plate while drilling to lag the plate to bone with screw insertion
- Off-Axis Guide limits off-axis drilling capability to 15° in any direction



DOUBLE ENDED OVER DRILL GUIDE

- Has 2.0 mm side and 2.5 mm side for overdrilling a non-locking screw outside of the plate
- Can be used with centering drill guide



1.3 MM DRILL, 2.0 MM OVER DRILL

- For 2.0 mm screw placement



1.6 MM DRILL, 2.5 MM OVER DRILL

- For 2.5 mm screw placement



HANDLE SELECTION

- Ratcheting and non-ratcheting handles available



OLIVE WIRES



1.3 mm Smooth Olive Wire

- For use in plate holes



1.3 mm Threaded Olive Wire

- For use in plate holes



1.3 mm Long Olive Wire

- For use with a threaded drill tower to help minimize shifting of plate when placing olive wire
- Tip of olive wire is 1.3 mm such that the olive wire will not over-drill for a 2.0 mm screw



1.6 mm Standard Olive Wire

- Has central recess in the sphere to accept HY Mini Pin Compressor outside of the plate
- Should not be used in plate holes if intending to use a 2.0 mm screw

Surgical Technique Guide

2nd TAROMETATARSAL JOINT ARTHRODESIS

The purpose of this portion of the surgical technique guide is to demonstrate the general use of a Baby Gorilla plate, while highlighting the instrumentation available and built-in plate features of the Baby Gorilla Plating System.

INCISION/EXPOSURE

A longitudinal incision is made over the 2nd tarsometatarsal joint. Dissection is carried down to the 2nd tarsometatarsal joint while identifying and retracting the neurovascular bundle. (A) Straight and curved osteotomes are available to remove any osteophytes present on the dorsal aspect of the joint. The osteotomes are available in 6, 9, and 12 mm widths.

JOINT PREPARATION

A HY Mini Pin Distractor is obtained. The holes in the distractor are sized to accept either a 1.2 mm or a 1.6 mm K-wire. Insert K-wires into the HY Mini Pin Distractor on either side of the joint. (B) The HY Mini Pin Distractor is opened to expose the joint surfaces. Cartilage removal can be performed according to surgeon preference. 20° handled curettes are available in two sizes to assist in cartilage removal. Straight and curved osteotomes are available as well. Remove the HY Mini Pin Distractor once adequate joint preparation has been achieved.

PLATE SELECTION

Plating options in the Baby Gorilla Plating System for a 2nd Tarsometatarsal Joint arthrodesis include Straight Plates, L-Plates, T-Plates and Y-Plates. In this example, a 6 Hole L2 Compression Plate is chosen. This particular plate has a bridge at the arrow for placement over a tarsometatarsal joint and allows for 3 screws to be placed in the cuneiform. (C) Plate bending is performed according to surgeon preference. Two threaded plate bender bars are available as well as two plate bending pliers.

Attach a threaded drill tower to a screw hole on the opposite end of the compression slot, on the "L" side of the 6 Hole L2 Compression plate. (D) Retrieve a 1.3 mm long olive wire that fits inside of the drill tower. (E) Place the 6 Hole L2 Compression plate over the 2nd TMT joint, positioning the plate using the threaded drill tower. When an appropriate position of the plate is obtained, insert the 1.3 mm long olive wire into the threaded drill tower such that the plate is secured to the bone. (F) A second olive wire can be placed into a round hole at the opposite end of the plate to secure the plate to the 2nd metatarsal. (G)

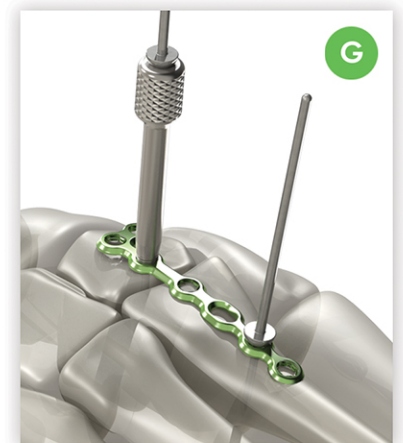
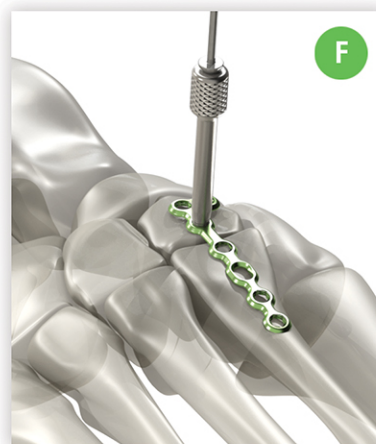
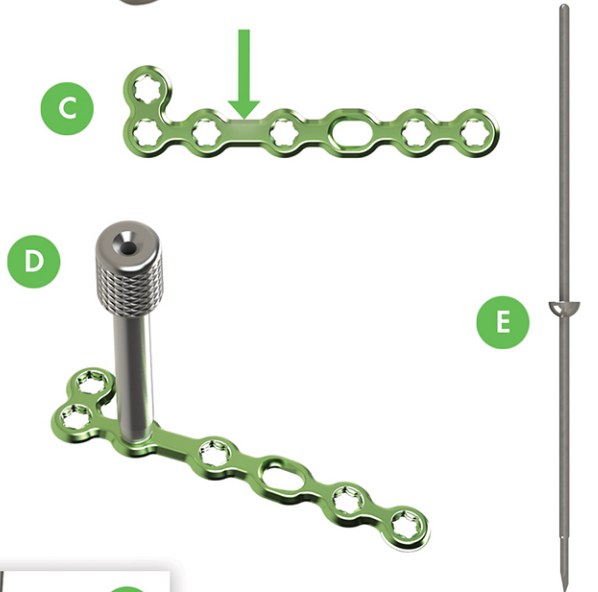
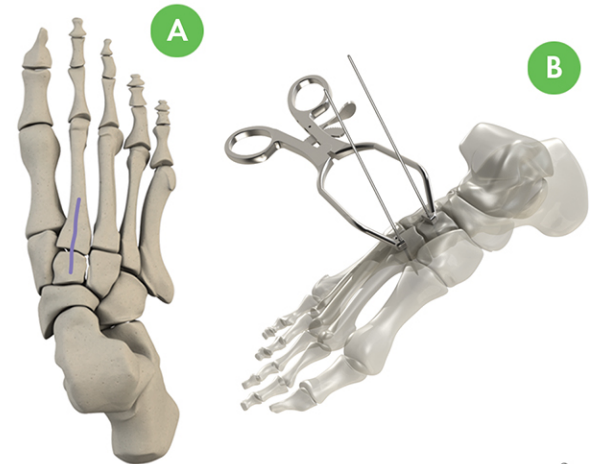


PLATE SELECTION

Insert a threaded tower into another open hole on the intermediate cuneiform. To insert a 2.5 mm diameter screw, select the 1.6 mm drill. Drill through the drill guide. (H) Remove the drill and threaded tower and pass from the operative field. Measure screw length using the depth gauge. (I) Retrieve the appropriately sized 2.5 mm screw and insert into the screw hole. Remove the distal olive wire.

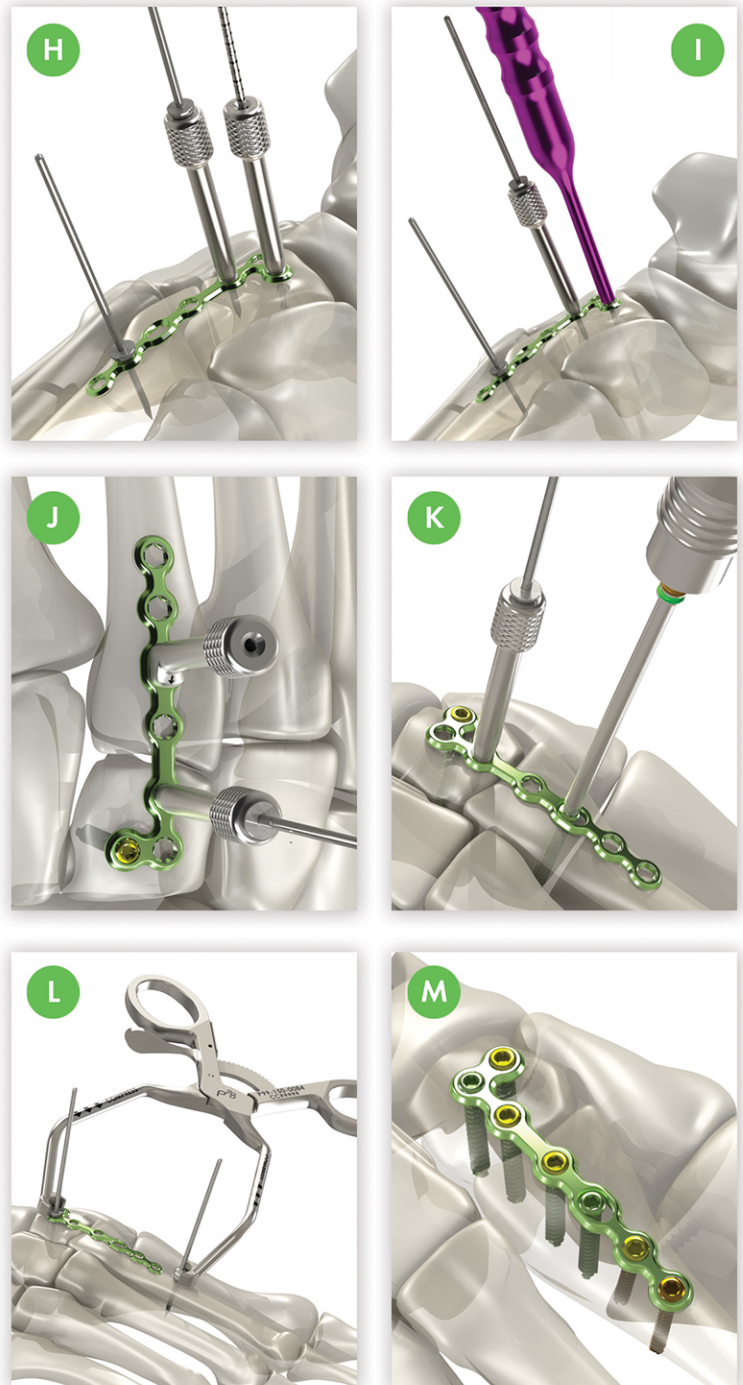
At this time, retrieve the compression drill guide. Insert the compression drill guide into the slot on the metatarsal side of the plate with the arrow pointing toward the arthrodesis site. (J) Drill through the compression drill slot, using a 1.6 mm drill if a 2.5 mm diameter screw is being used. Remove the drill and compression drill guide. Insert a 2.5 mm screw into the compression slot. (K)

TIP: If a surgeon prefers to gain compression through or external to the plate, a HY Mini Pin Compressor can be used. Two 1.3 mm smooth or threaded olive wires can be placed eccentrically in two plate holes on either side of the arthrodesis and the compressor can be placed around these olive wires to compress. Place a locking or non-locking screw on either side of the arthrodesis to maintain compression. Alternatively, place one 1.3 mm smooth or threaded olive wire on the proximal portion of the plate and place the 1.6 mm standard olive wire distal to the plate, as shown in Figure L. Place the HY Mini Pin Compressor over the two olive wires. (L) Squeeze the handled portion together to create compression across the arthrodesis. Place a locking or non-locking screw on either side of the arthrodesis to maintain compression created by the HY Mini Pin Compressor. Remove the HY Mini Pin Compressor.

Remove the remaining olive wire and continue to fill plate holes, as desired. If using a 2.0 mm screw, the 1.3 mm drill should be used. Confirm plate and screw placement using fluoroscopy, if desired. (M)

CLOSURE

Proceed to incision closure or concomitant procedures at this time.



Indications, Contraindications, and Warning:

Indications For Use:

CAUTION: Federal Law (USA) restricts this device to sale and use by, or on order of, a physician.

The Baby Gorilla® Bone Plates and Bone Screws of the Baby 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. 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, appropriate for the size of the device

Contraindications:

Use of the Baby 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

Indications, Contraindications, and Warning:

- 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 Precaution:

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, screws and 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.

The Baby Gorilla® Plating System has not been evaluated for safety and compatibility in the MR environment. The Baby Gorilla® Plating System has not been tested for heating, migration or image artifact in the MR environment. The safety of the Baby Gorilla® Plating System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Do not use other manufacturer's instruments or implants in conjunction with the Baby Gorilla® Plating System.

Maintaining Device Effectiveness

The surgeon should have specific training, experience, and thorough familiarity with the use of screw/plating systems.

The surgeon must exercise reasonable judgment when deciding which plate and screw type to use for specific indications.

The Baby Gorilla® plates and screws are not intended to endure excessive abnormal functional stresses.

The Baby Gorilla® plates and screws are intended for temporary fixation only until osteogenesis occurs.

Failure to use dedicated, unique Baby Gorilla® Plating System instruments for every step of the implantation technique may compromise the integrity of the implanted device, leading to premature device failure and subsequent patient injury. Failed devices may require re-operation and removal.

Carefully inspect the implants prior to use; inspect the instruments before/after each procedure to assure they are in proper operational condition. Instruments, which are faulty, damaged or suspect should not be used.

Paragon 28® Inc. recommends the use of Paragon 28® Inc. products in a sterile environment.

Please contact company for product inquiries, cleaning instructions and surgical techniques, or to report any adverse event.