

SURGICAL TECHNIQUE GUIDE

Lapidus Arthrodesis

Gorilla® Lapidus Plating System



Lapidus Plate System Overview

Acknowledgment:

Paragon 28® would like to thank Dustin Kruse, DPM for his contribution to the development of the surgical technique guide.

PRODUCT DESCRIPTION:

The Paragon 28® Gorilla Lapidus Plating System was designed to provide surgeons versatility in Plate selection and precise crossing screw placement for Lapidus Arthrodesis procedures. The system has 20 plating options including standard, graft-spanning and medial wall step-off Plates. The Plates embody several features including a medial position with a plantar arm, a ramped edge proximally to avoid tendon irritation and anatomic curvature to provide a bent Plate technique. The 4 hole standard, graft-spanning, and medial wall step-off Plates all feature a patented plantar locking hole to help reduce plantar gapping. All Gorilla® Lapidus Plate holes accommodate Gorilla® R3CON Ø2.7, Ø3.5 and Ø4.2 mm locking and non-locking screws.

The instrumentation provided in the Gorilla® Lapidus Plating System allows for placement of a crossing screw across the arthrodesis while avoiding on-axis locking and non-locking Plate screws within the construct. The patented Precision® Guide provides four trajectories of Guide Wire paths to allow for insertion of a Ø3.5 mm or Ø4.0 mm cannulated Mini-Monster® crossing screw or a 4.5 mm cannulated Monster® crossing screw.

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PLATE OFFERING:

STANDARD PLATES

- Left and Right Side Specific
- 1.3 mm thickness
- Compression slot present on all Plates

3 Hole Standard



4 Hole Standard



GRAFT-SPANNING PLATE

- Left and Right Side Specific
- 1.6 mm thickness
- For use with Paragon 28® PRESERVE™ Grafts
- Large Plate - 12 mm and 14 mm PRESERVE™ Lapidus Graft
- Medium Plate - 8 mm and 10 mm PRESERVE™ Lapidus Graft
- Small Plate - 5 mm PRESERVE™ Lapidus Graft (offers compression slot)

Small



Medium



Large



MEDIAL WALL STEP-OFF PLATES

- Left and Right Side Specific
- 1.4 mm thickness
- Size options include 1 mm step-off increments from 1-5 mm
- Compression slot present on all Plates



1 mm

2 mm

3 mm

4 mm

5 mm

PLATE FEATURES:

- Anatomic Contour
- Medial Wall Curvature
- Plantar Locking Screw Hole









Supports the 1st metatarsal in a corrected position and reduces the adductory force on the 1st metatarsal with Plate fixation during screw insertion, allowing for a "bent Plate" technique.

The Plate fits the curved medial wall of the 1st metatarsal and medial cuneiform.

Provides a stable construct and helps to protect against plantar gapping. This creates a tension band allowing for possible early weightbearing at the surgeon's discretion.

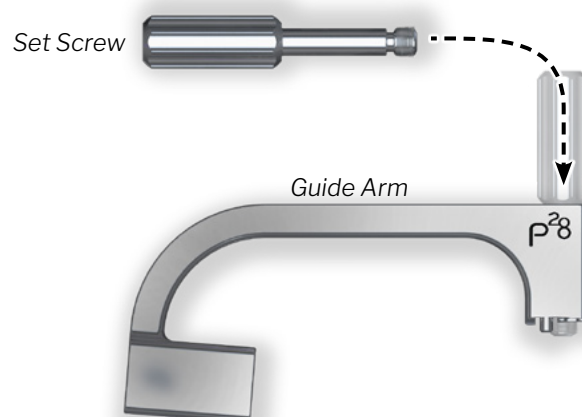
Lapidus Plate System Overview

FEATURED INSTRUMENTATION:

Mini-Monster® Screw Diameters	 Ø3.5 mm screw	 Ø4.0 mm screw	 Ø4.5 mm screw
Precision Guide K-wire Sleeve:	 12 mm sleeve		 14 mm sleeve
K-wire	 Ø1.2 x 150 mm K-wire		

PRECISION™ GUIDE - SET SCREW AND GUIDE ARM

- Patented
- Allows a lag screw to cross the joint and avoid the on-axis locking and non-locking Plate screws in the construct



ANCILLARY IMPLANTS AND INSTRUMENTATION:

PRESERVE™ LAPIDUS ANGULAR LENGTH RESTORING GRAFT

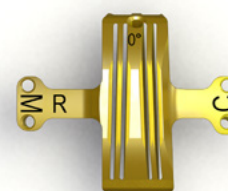
- Can help to restore length for a patient with a short 1st metatarsal, in a case with over-shortening or for revision procedures
- Anatomically shaped to the joint and features biplanar correction to plantarflex and abduct the 1st metatarsal
- Available in 4 mm x 0°, 5 mm x 5°, 8 mm x 8°, 10 mm x 10°, 12 mm x 12° and 14 mm Universal sizes



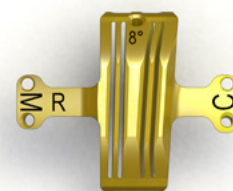
** Do not use excessive force when tamping in the wedge, especially for smaller sizes, to avoid damaging the implant*

LAPIDUS CUT GUIDE SYSTEM

- A patented instrumentation option for joint preparation, enabling surgeons to make congruent cuts while minimizing resection at the 1st TMT joint
- Available in 0° and 8-20° options to achieve appropriate amount of transverse plane correction
- Left and Right side specific



0° Cut Guide



8° Cut Guide

SCREW OFFERING AND INSTRUMENTATION MATRIX:

	Ø2.7 mm R3CON Screws	Ø3.5 mm R3CON Screws	Ø4.2 mm R3CON Screws
Locking:			
Non-locking:			
Screw Lengths:	8 mm - 20 mm in 1 mm increments 22 - 40 mm in 2 mm increments	10 mm - 50 mm in 2 mm increments	10 mm - 50 mm in 2 mm increments 55 mm - 70 mm in 5 mm increments
Drill Size:	 Ø2.0 mm	 *	 Ø2.8 mm
Driver Size:	 HX-10	 HX-10	 HX-10
Locking Drill Guide Size:	 Ø2.7 mm	 Ø3.5 mm	 Ø4.2 mm
Centering Drill Guide Size:	 Ø2.7 mm	 Ø3.5 mm	 Ø4.2 mm
Compression Slot Drill Guide Size:	 Ø2.7 mm	 Ø3.5 mm	 Ø4.2 mm
Cone/Straight Easy Guide Size:	 Ø2.7 mm Easy Guide	 Ø3.5 mm Easy Guide	 Ø4.2 mm Easy Guide
	 Ø2.7 mm Cone Guide	 Ø3.5 mm Cone Guide	 Ø4.2 mm Cone Guide
Tap Size:	 Ø2.7 mm	 Ø3.5 mm	 Ø4.2 mm
Over Drill Size:	 Ø2.7 mm	 Ø3.5 mm	 Ø4.2 mm
Double Ended Drill / Over Drill Guides:	 Ø2.7 mm	 Ø3.5 mm	 Ø4.2 mm

★



NOTE: In hard bone, or if insertion of the Ø3.5 mm screw is difficult, any of the following alternate drills can be used to create a larger pilot hole to assist insertion:

- Ø2.7 mm Overdrill
- Ø2.8 mm Drill

If using an alternate drill, be sure to use the appropriate Drill Guide as well.

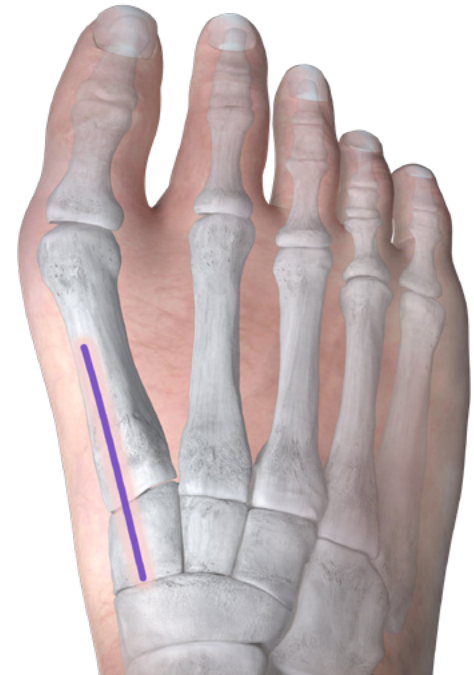
Lapidus Plate Overview - Lapidus Arthrodesis

INCISION/EXPOSURE:

The procedure described can be performed on its own or combined with resection of the medial eminence and lateral release. Supine patient positioning with fluoroscopy available is recommended for this procedure. A dorsomedial or medial incision is recommended when using this Plate. Soft tissue dissection is continued to expose the 1st TMTJ.



Medial Incision



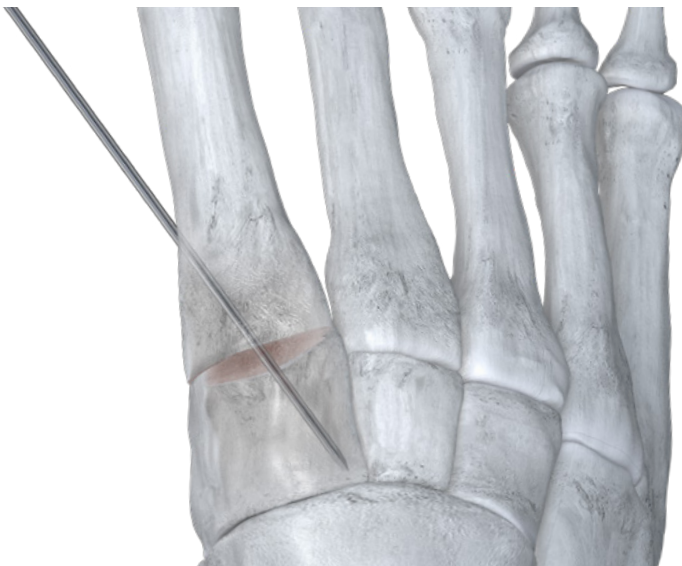
Dorsomedial Incision

JOINT PREPARATION:

After exposure of the joint surfaces at the 1st TMTJ, the method of cartilage resection is according to surgeon preference. Paragon 28 Lapidus Cut Guides can be used for this step, preferably through a dorsomedial incision. Subchondral bone preparation is recommended following joint resection using the Paragon 28 Subchondral Drill or surgeon's preferred technique.

If used, bone grafting material or a PRESERVE Lapidus Length Restoring Wedge can be inserted at this time.

TEMPORARY FIXATION:



The correct alignment of the 1st metatarsal is achieved per surgeon preference. A K-wire is recommended to be inserted from plantar medial distal to dorsal lateral proximal to avoid future Plate and screw placement. A second K-wire can be used if additional stabilization is desired.

PLATE SELECTION:

An appropriately sized “Left” or “Right” Lapidus arthrodesis Plate is selected at this time. Position the Plate along the long axis of the 1st ray in the sagittal plane.

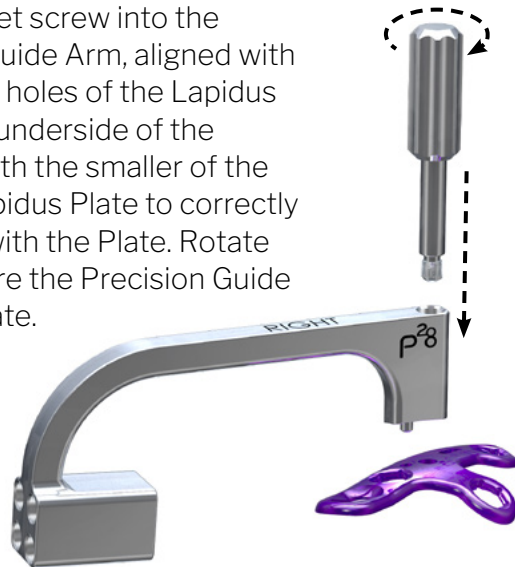


NOTE: If a thicker Plate is desired for a patient that may have difficulty with restricted weight-bearing following the procedure, a small graft spanning Plate (thickness 1.6 mm) may be used in lieu of a standard Plate (thickness 1.3 mm).



PERMANENT FIXATION:

Insert the Precision Guide set screw into the “Right” or “Left” Precision Guide Arm, aligned with the larger of the two central holes of the Lapidus Plate. The small peg on the underside of the Precision Guide will mate with the smaller of the two central holes on the Lapidus Plate to correctly orient the Precision Guide with the Plate. Rotate the Knob clockwise to secure the Precision Guide set screw to the Lapidus Plate.

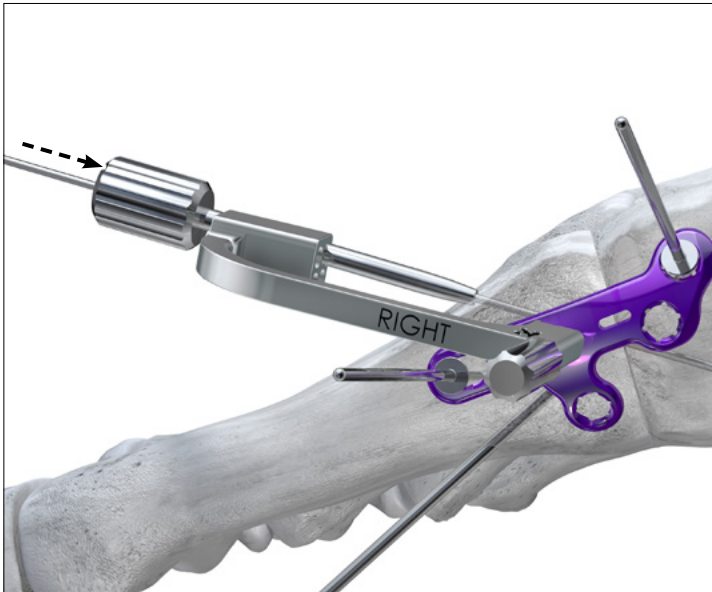


NOTE: If Use of the Precision Guide Lapidus is optional. It may be used as demonstrated below, or it may be attached to the Plate after Plate screw fixation. In the latter case, a fully threaded crossing screw is recommended.

Secure the Lapidus Plate (with the attached Precision Guide) to the bone using Olive Wires. One Olive Wire should be placed in the distal aspect of the compression slot. Insert the Guide Wire Sleeve for the selected screw size into the Precision Guide Arm. If soft tissue dissection is not performed around the area of the Guide Wire Sleeve, a stab incision with blunt soft tissue separation can be made in the skin prior to driving the Guide Wire through the arthrodesis site.



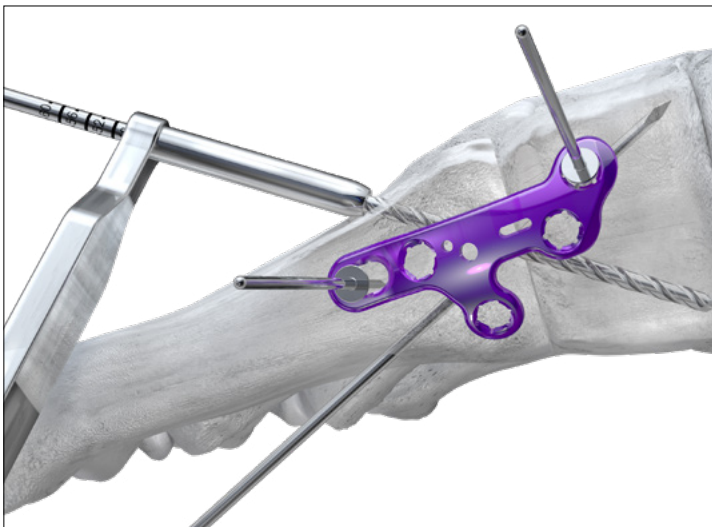
PERMANENT FIXATION:



Insert the Guide Wire for the selected crossing screw size into the Guide Wire Sleeve such that it crosses the arthrodesis site at the desired location. The position and length of the Guide Wire is confirmed using fluoroscopy.



When the Guide Wire position is correct, remove the Precision Guide from the Plate by rotating the set screw in a counter-clockwise manner and slide the Precision Guide Arm off the K-wire of the Guide Wire.

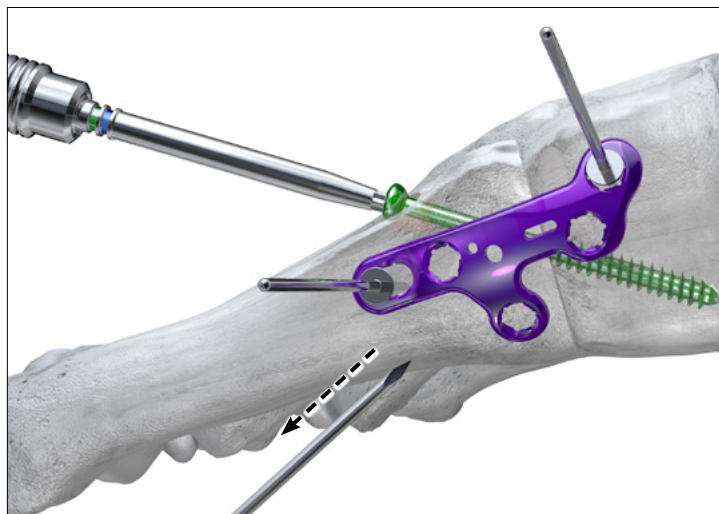


The Drill and Drill Guide for the selected crossing Screw diameter are slid over the Guide Wire and drilling is performed.

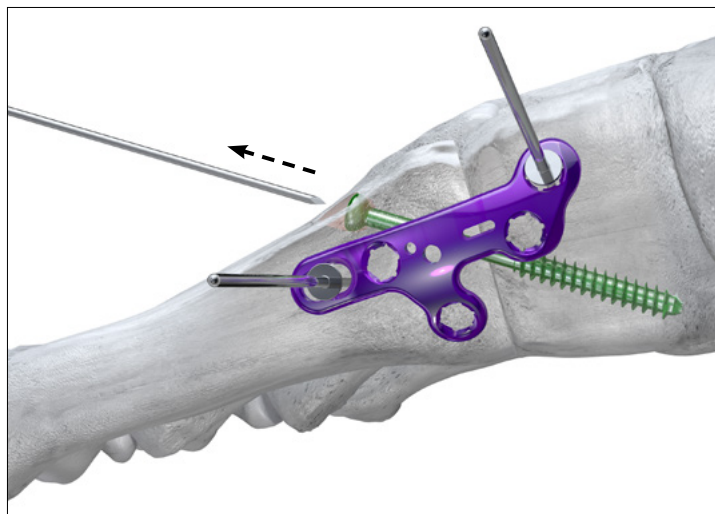


Countersinking for the Headed Screw is performed. If using a Headless Screw, countersink after measuring. The Depth Gauge is used to determine screw length.

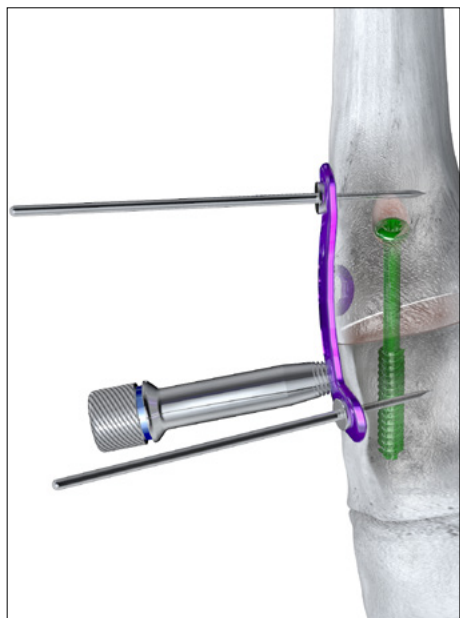
PERMANENT FIXATION:



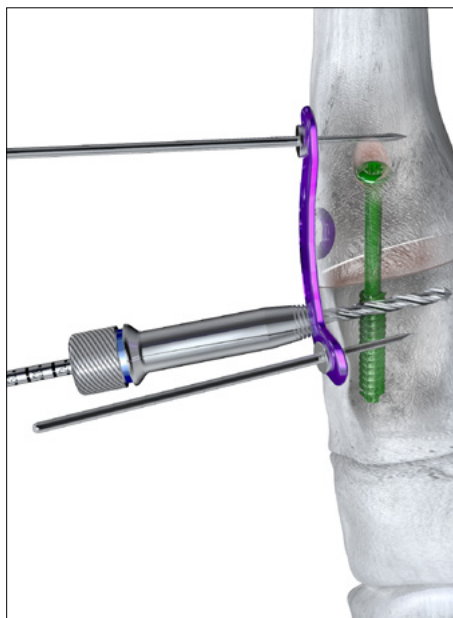
The selected Screw is inserted over the Guide Wire across the arthrodesis site. Remove temporary fixation prior to fully seating the Screw.



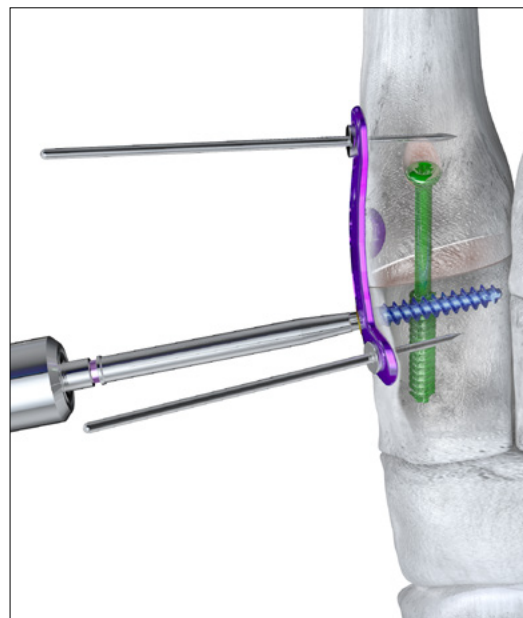
Remove the K-wire serving as temporary fixation just prior to fully seating the Lag Screw. Complete Screw insertion. Remove the Guide Wire.



Insert a Threaded Drill Tower into one of the proximal screw holes corresponding to desired Plate Screw diameter.



Drill using the Drill corresponding to the desired Plate Screw diameter.



Screw length can be measured using the provided Depth Gauge or by measuring off the Drill using the Drill Guide. Insert the Plate Screw using the provided Driver. Continue to fill the Plate holes with Locking Screws while removing the Olive Wires, according to surgeon preference.

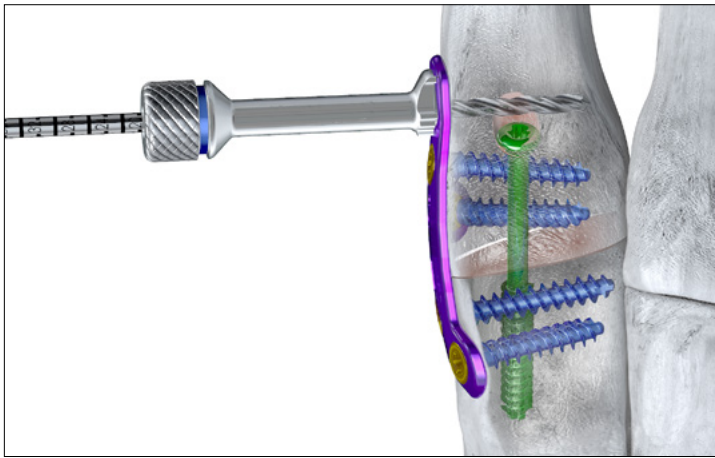
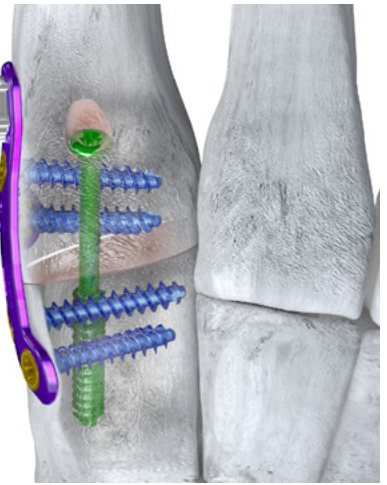
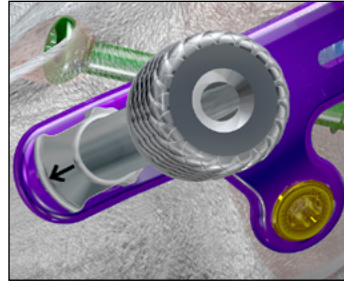
Lapidus Plate Overview - Lapidus Arthrodesis

PERMANENT FIXATION:

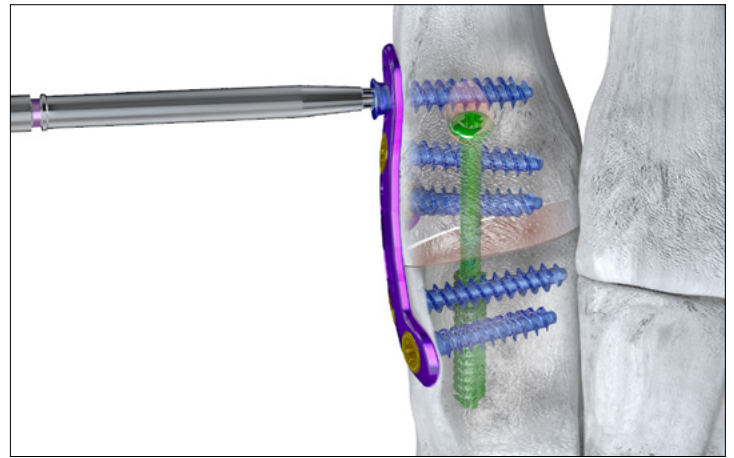
Insert an oblong Drill Guide into the Plate compression slot. The Oblong Drill Guide can be reversed, with the arrow pointing away from the joint (as shown) to insert a Non-Locking Screw into the compression slot without creating compression.



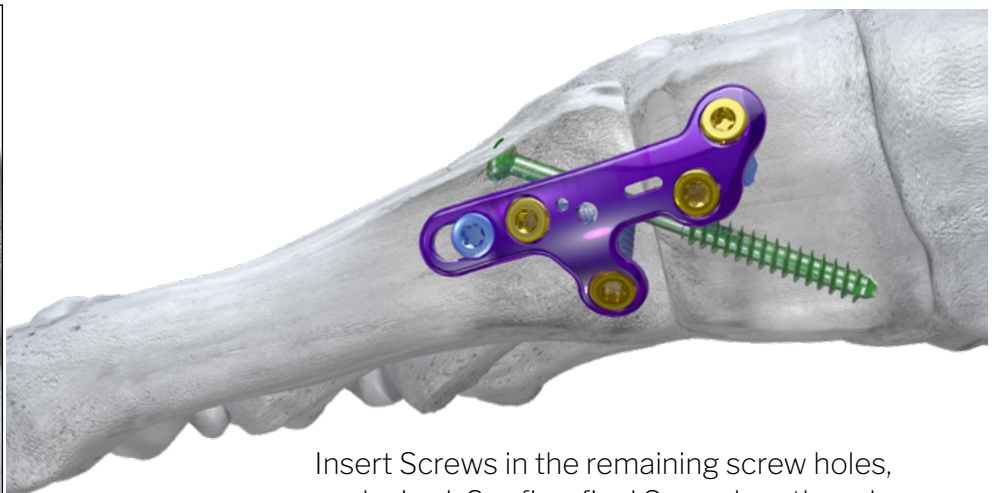
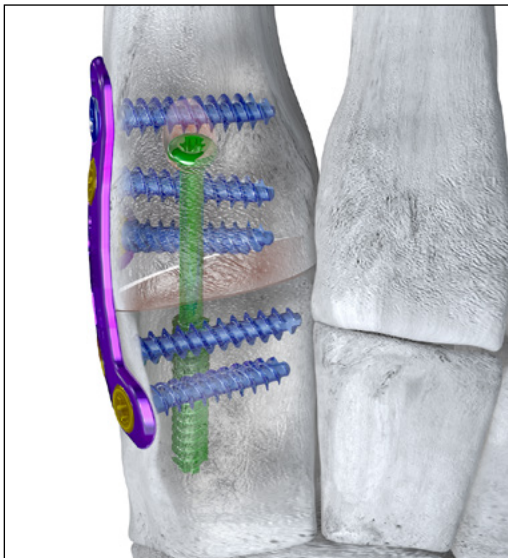
NOTE: If the surgeon prefers to create compression via the compression slot, insert proximal Plate Screw(s) first. Use the compression Drill Guide with the arrow pointing towards the joint to eccentrically drill. Place a Non-Locking Screw to achieve compression. The Crossing Screw would be placed last in this scenario.



Drill using the Drill corresponding to the desired screw diameter.



Insert the Screw using the provided Driver.



Insert Screws in the remaining screw holes, as desired. Confirm final Screw length and placement using fluoroscopy.

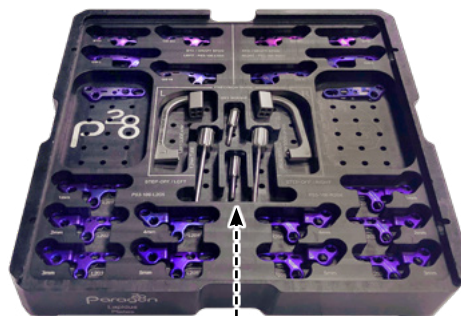
CLOSURE:

Proceed to incision closure or concomitant procedures at this time.

GORILLA R3CON PLATING SYSTEM - LAPIDUS CADDY:

1. GORILLA® LAPIDUS PLATING CADDY

The Gorilla® Lapidus Plating Caddy includes 20 varieties of Gorilla® Lapidus Plates with the Precision® Guide Lapidus for use with the Plates.



2. 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 Lapidus Arthrodesis case.

3. 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.



3. GORILLA® CASE

4. MINI-MONSTER® SCREW CADDY

The Gorilla® Case can accommodate one Mini-Monster® Screw Caddy if a Ø3.5 mm or Ø4.0 mm cannulated screw is needed during a Lapidus Arthrodesis case.

5. GORILLA® R3CON INSTRUMENTS

The Casper Compression/Distractor device, osteotomes, baby Bennet retractors, bone reduction clamps, periosteal elevator, cartilage removal device, pin distractor and handles are located at the bottom of the Gorilla® Case.

Gorilla® Lapidus Plating System Caddy and Contents

GORILLA R3CON PLATING SYSTEM - LAPIDUS CADDY:

Part #	Description	Use
P51-950-0002	Precision™ Guide Set Screw, Long	Reusable
P51-950-0012	Guidewire Sleeve, 1.2 mm	Reusable
P51-950-0014	Guidewire Sleeve, 1.4 mm	Reusable
P51-950-L106-01	Lapidus Precision™ Guide Arm, Left	Reusable
P51-950-R106-01	Lapidus Precision™ Guide Arm, Right	Reusable
P53-106-L001	Lapidus, 4-Hole Standard, Compression Plate, Left, Precision™ Guide	Single-use
P53-106-L002	Lapidus, Graft Span Small, for 5-8 mm Grafts, 4-Hole w/ Comp, Left	Single-use
P53-106-L003	Lapidus, Graft Span Medium, for 10-12 mm Grafts, 5-Hole, Left	Single-use
P53-106-L005	Lapidus, Graft Span Large, for 14 mm Grafts, 5-Hole, Left	Single-use
P53-106-L101	Lapidus, 3-Hole Standard, Compression Plate, Left, Precision™ Guide	Single-use
P53-106-L201	Lapidus, Graft Span Small, for 5-8 mm Grafts, 4-Hole w/ Comp, Left	Single-use
P53-106-L202	Lapidus, Graft Span Medium, for 10-12 mm Grafts, 5-Hole, Left	Single-use
P53-106-L203	Lapidus, Graft Span Large, for 14 mm Grafts, 5-Hole, Left	Single-use
P53-106-L204	Lapidus, 4 mm Step Plate, Left	Single-use
P53-106-L205	Lapidus, 5 mm Step Plate, Left	Single-use
P53-106-R001	Lapidus, 4-Hole Standard, Compression Plate, Right, Precision™ Guide	Single-use
P53-106-R002	Lapidus, Graft Span Small, for 5-8 mm Grafts, 4-Hole w/ Comp, Right	Single-use
P53-106-R003	Lapidus, Graft Span Medium, for 10-12 mm Grafts, 5-Hole, Right	Single-use
P53-106-R005	Lapidus, Graft Span Large, for 14 mm Grafts, 5-Hole, Right	Single-use
P53-106-R101	Lapidus, 3-Hole Standard, No Arm, Compression Plate, Rt, Precision™ Guide	Single-use
P53-106-R201	Lapidus, 1 mm Step Plate, Right, Precision™ Guide	Single-use
P53-106-R202	Lapidus, 2 mm Step Plate, Right, Precision™ Guide	Single-use
P53-106-R203	Lapidus, 3 mm Step Plate, Right, Precision™ Guide	Single-use
P53-106-R204	Lapidus, 4 mm Step Plate, Right	Single-use
P53-106-R205	Lapidus, 5 mm Step Plate, Right	Single-use

*See the complete Gorilla Plating Surgical Technique Guide (P51-STG-0001) for general instrument information

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

INDICATIONS FOR USE (GORILLA®)

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 1st 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

1st 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 1st metatarsophalangeal joint (MTP) including:

- Primary MTP Fusion due to hallux rigidus and/or hallux valgus
- Revision MTP Fusion
- Revision of failed 1st 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.

Indications, Contraindications and Warnings

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.

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

INDICATIONS FOR USE (MONSTER®)

The Monster® Screw System is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, ligament fixation, fracture repair and fracture fixation, appropriate for the size of the device. Specific examples include:

Fractures and Osteotomies

- Fractures of the tarsals, metatarsals and other fractures of the foot (i.e. LisFranc)
- Avulsion fractures and fractures of the 5th metatarsal (i.e. Jones Fracture)
- Talar fractures
- Ankle fractures
- Navicular fractures
- Fractures of the fibula, malleolus, and calcaneus
- Metatarsal and phalangeal osteotomies
- Weil osteotomy
- Calcaneal osteotomy

Hallux Valgus Correction

- Fixation of osteotomies (i.e. Akin, Scarf, Chevron)
- Interphalangeal (IP) arthrodesis
- Proximal, midshaft, or distal osteotomy
- Lapidus arthrodesis

Arthrodesis/Deformity Correction

- MTP arthrodesis
- Metatarsal deformity correction
- Tarsometatarsal joint arthrodesis
- Naviculocuneiform joint arthrodesis
- Talonavicular arthrodesis
- Subtalar joint arthrodesis
- Triple arthrodesis
- Medial column arthrodesis
- Subtalar joint distraction arthrodesis
- Ankle arthrodesis
- Lateralizing calcaneal osteotomy
- Lateral column lengthening
- Hammertoe

Fusion resulting from neuropathic osteoarthopathy (Charcot)

such as:

- Medial and lateral column
- Subtalar, talonavicular, and calcaneocuboid

CONTRAINDICATIONS

Use of the Monster® Screw 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

Indications, Contraindications and Warnings

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

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® 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® with the explant(s) in a cleaned, disinfected and sterile condition. Paragon 28® 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 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. Re-use may cause product failure and could lead to disease transmission.
- Instruments, Guide Wires and screws are to be treated as sharps.
- Do not use other manufacturer's instruments or implants in

conjunction with the Monster® Screw System.

MR SAFETY INFORMATION

The Monster® Screw 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 the Monster® Screw System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

NOTES:

NOTES:

This image shows a single sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.



SURGICAL TECHNIQUE GUIDE

Gorilla® Lapidus Plating System

P51-STG-0003 RevG [2025-04-25]

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Exclusively foot & ankle ²⁸
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Disclaimer:

The purpose of the Lapidus Arthrodesis Surgical Technique Guide is to demonstrate use of the Lapidus Plates 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.