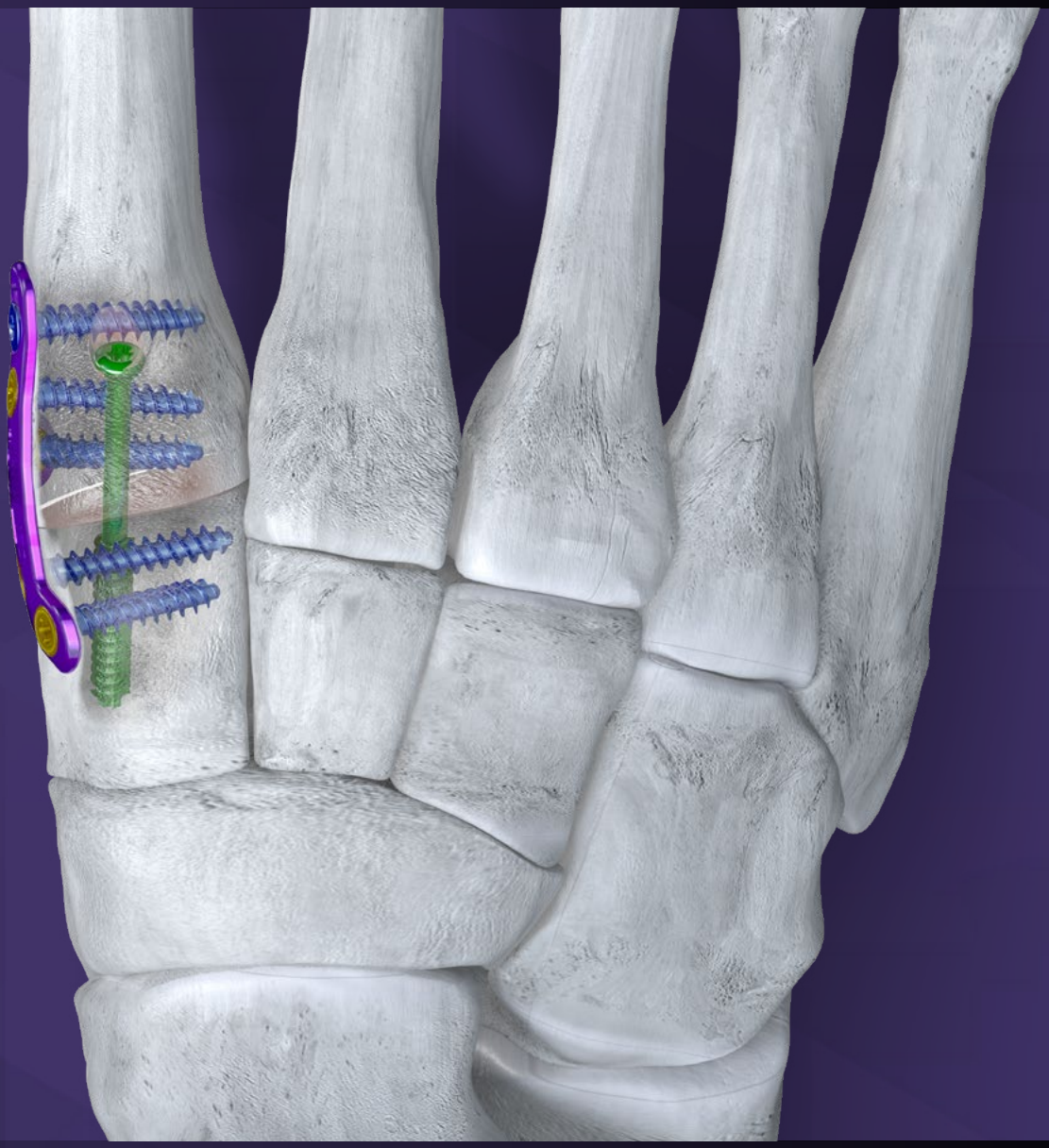
Paragon 28®

a ZIMMER BIOMET company



SURGICAL TECHNIQUE GUIDE

Lapidus Arthrodesis

Gorilla® Lapidus Plating System

GORILLA®
R3CON PLATING SYSTEM

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 2.7, 3.5 and 4.2 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 3.5 mm or 4.0 mm cannulated Mini-Monster® crossing screw or a 4.5 mm cannulated Monster® crossing screw.

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
  - Small Plate - 5 mm PRESERVE™ Lapidus Graft (offers compression slot)
  - Medium Plate - 8 mm and 10 mm PRESERVE™ Lapidus Graft
  - Large Plate - 12 mm and 14 mm PRESERVE™ Lapidus Graft

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

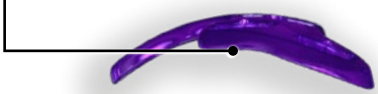
1 mm | 2 mm | 3 mm | 4 mm | 5 mm

PLATE FEATURES

Anatomic Contour

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.

Medial Wall Curvature



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

Plantar Locking Screw Hole

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.

FEATURED INSTRUMENTS

1.2 x 150 mm K-wire

1.2 mm Precision Guide K-wire Sleeve

Mini-Monster® 3.5 mm screw

Mini-Monster® 4.0 mm screw

1.4 mm Precision Guide K-wire Sleeve

Monster® 4.5 mm screw

Precision Guide Set Screw

Precision 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

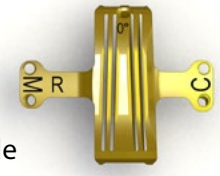
ANCILLARY IMPLANTS AND INSTRUMENTATION

PRESERVE™ Lapidus Angular Length Restoring Graft

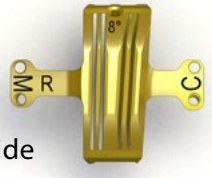
- Can help to restore length for a patient with a short 1st metatarsal, in a case with over-shortening or for revision procedures
- Anatomically shaped to the joint and features biplanar correction to plantar-flex and abduct the 1st metatarsal
- Available in 5 mm x 5°, 8 mm x 8°, 10 mm x 10°, 12 mm x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

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



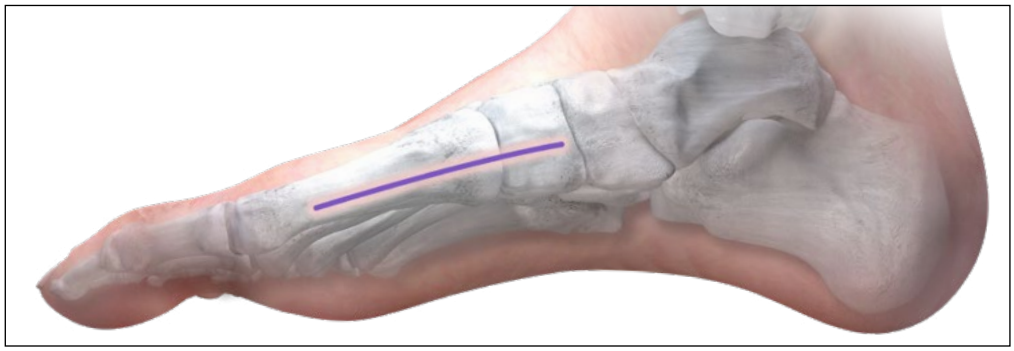
0° Cut Guide



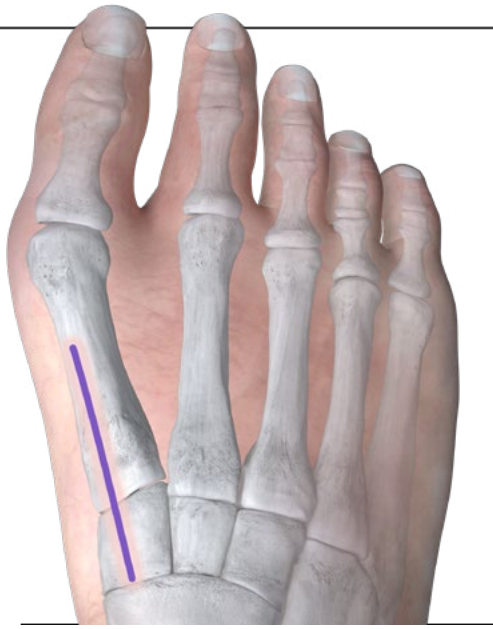
8° Cut Guide

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.

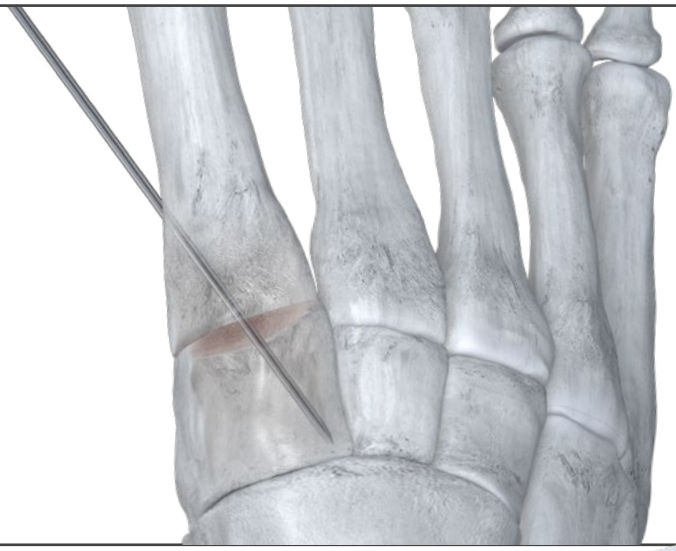


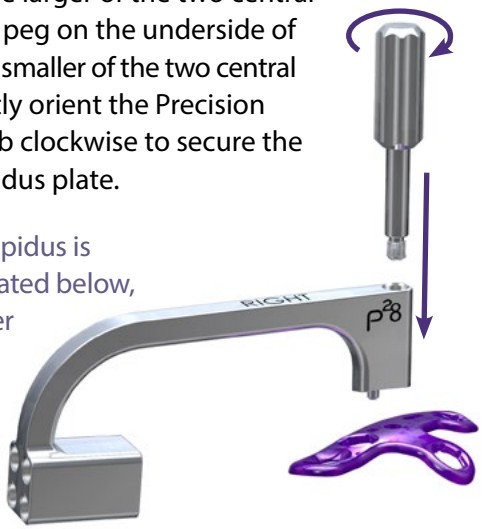
PLATE SELECTION

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.

TIP: 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).

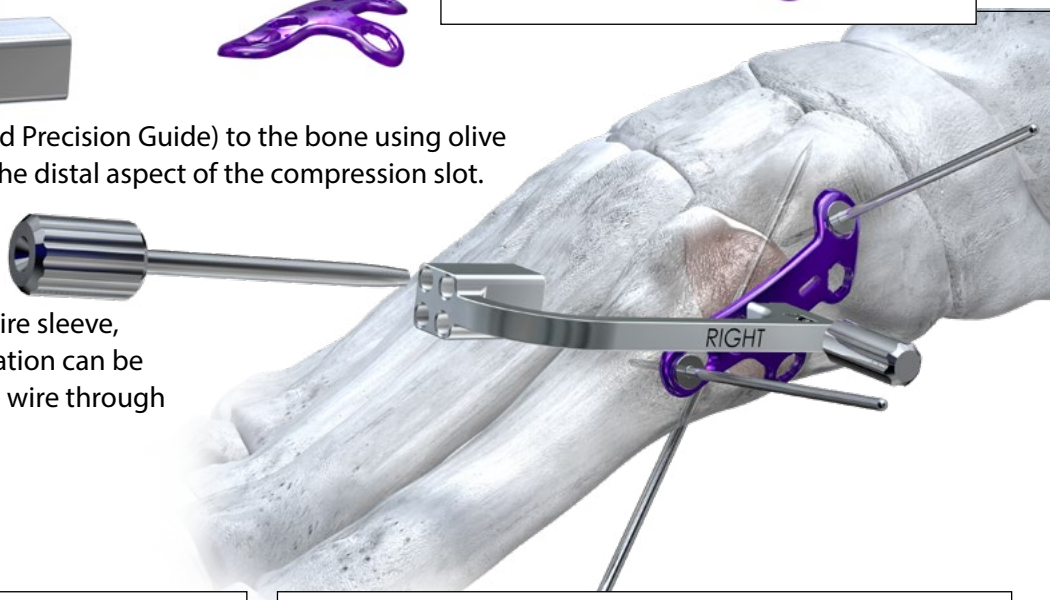
PERMANENT FIXATION

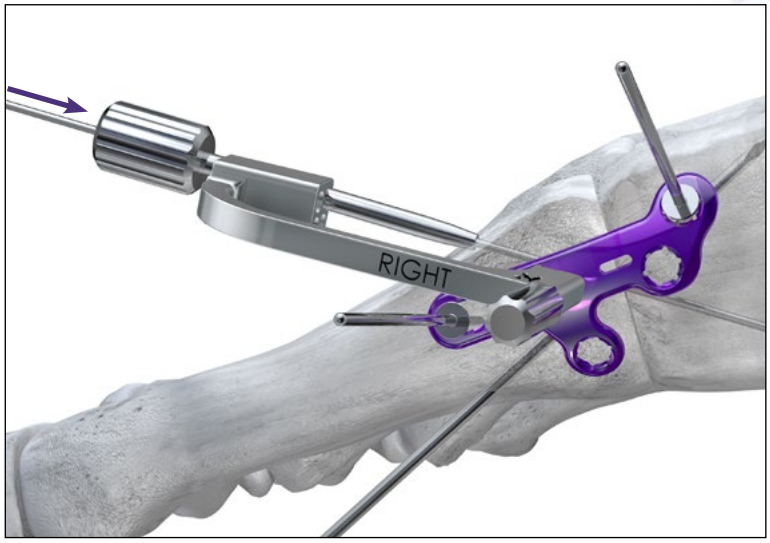
Insert the Precision Guide set screw into the "Right" or "Left" Precision Guide Arm, aligned with the larger of the two central holes of the Lapidus plate. The small peg on the underside of the Precision Guide will mate with the smaller of the two central holes on the Lapidus plate to correctly orient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



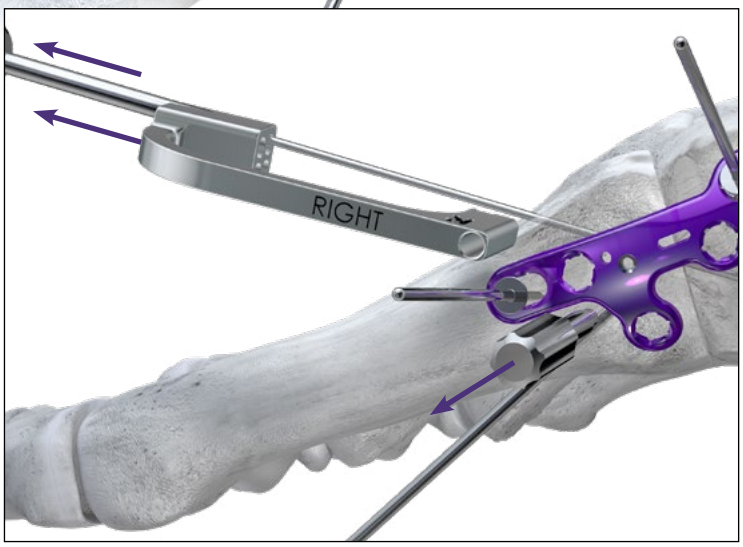
NOTE: Use of the Precision Guide Lapidus is optional. It may be used as demonstrated below, or it may be attached to the plate after plate screw fixation. In the latter case, a fully threaded crossing screw is recommended.

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.



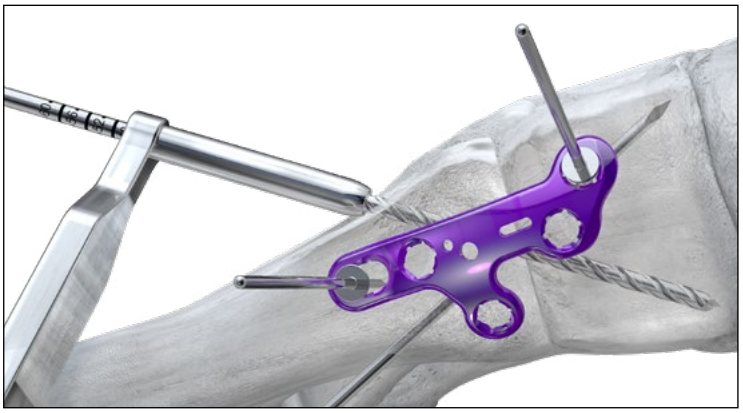


Insert the guide wire for the selected crossing screw size into the guide wire sleeve such that it crosses the arthrodesis site at the desired location. The position and length of the guide wire is confirmed using fluoroscopy.

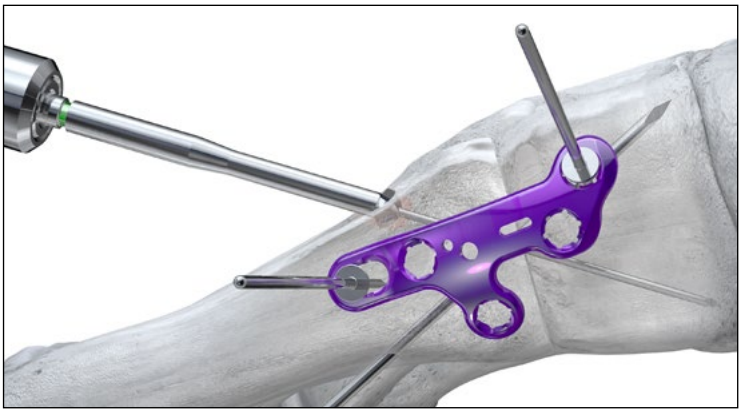


When the guide wire position is correct, remove the Precision Guide from the plate by rotating the set screw in a counter-clockwise manner and slide the Precision Guide Arm off the K-wire of the guide wire.

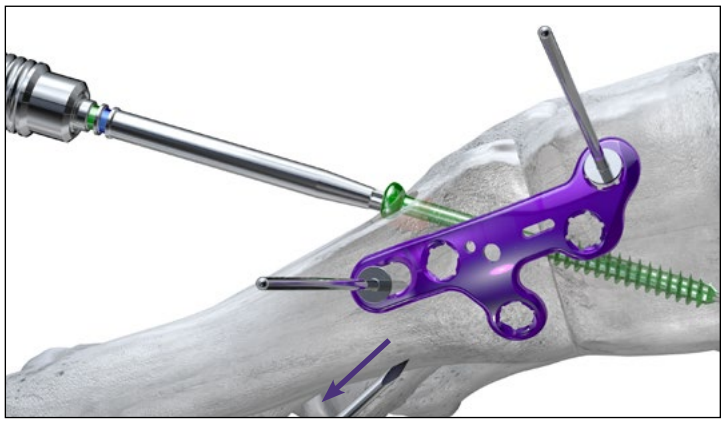
PERMANENT FIXATION



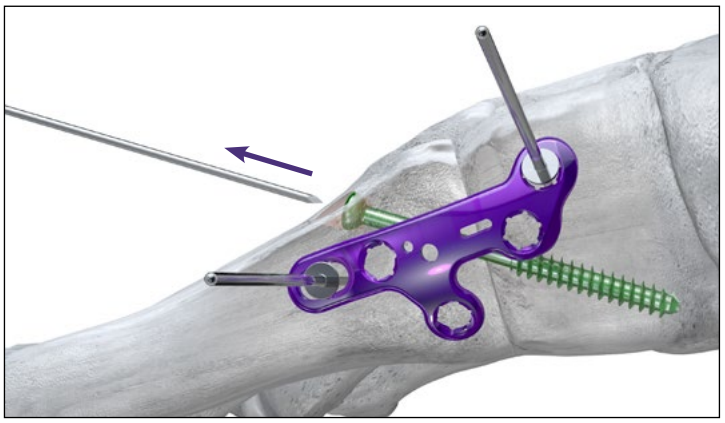
The drill and drill guide for the selected crossing screw diameter are slid over the guide wire and drilling is performed.



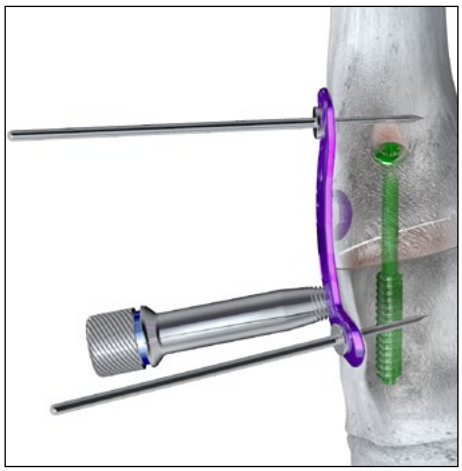
Countersinking for the headed screw is performed. If using a headless screw, countersink after measuring. The depth gauge is used to determine screw length.



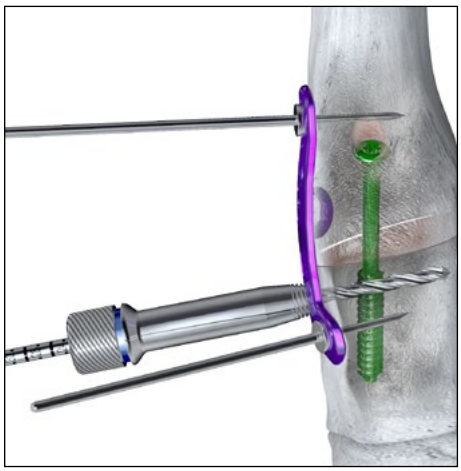
The selected screw is inserted over the guide wire across the arthrodesis site. Remove temporary fixation prior to fully seating the screw.



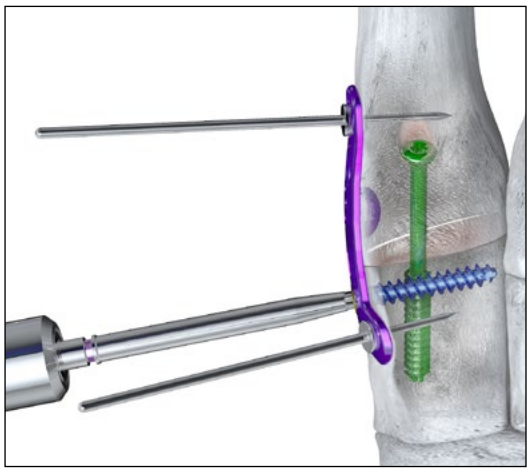
Remove the K-wire serving as temporary fixation just prior to fully seating the lag screw. Complete screw insertion. Remove the guide wire.



Insert a threaded drill tower into one of the proximal screw holes corresponding to desired plate screw diameter.



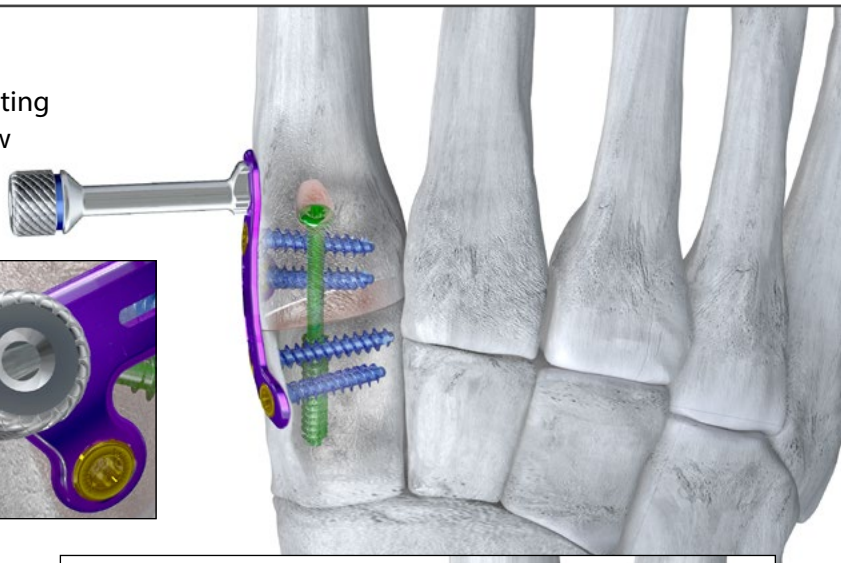
Drill using the drill corresponding to the desired plate screw diameter.



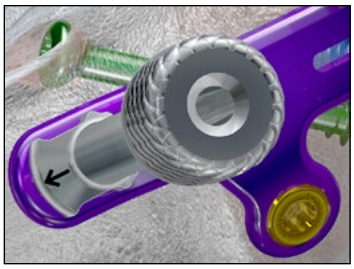
Screw length can be measured using the provided depth gauge or by measuring off the drill using the drill guide. Insert the plate screw using the provided driver. Continue to fill the plate holes with locking screws while removing the olive wires, according to surgeon preference.

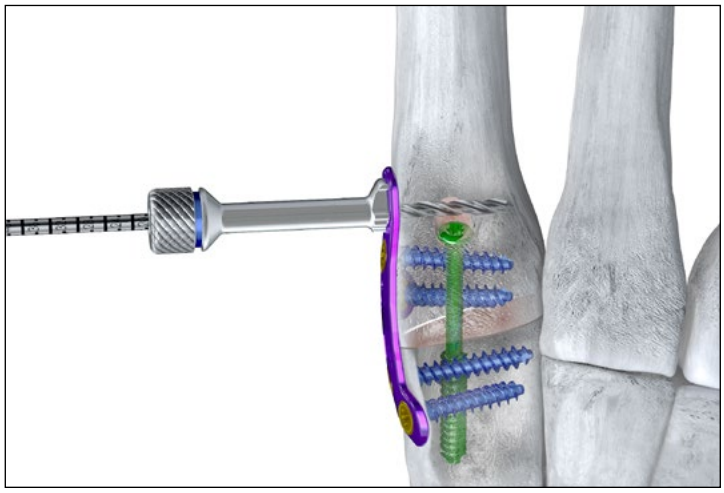
PERMANENT FIXATION

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.

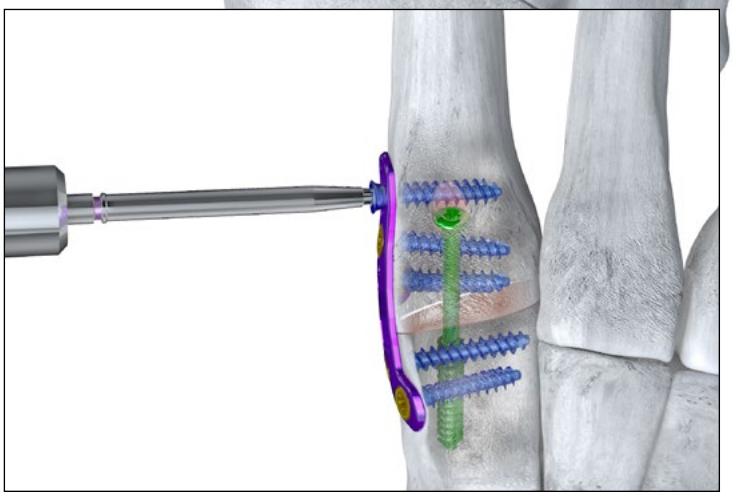


TIP: If the surgeon prefers to create compression via the compression slot, insert proximal plate screw(s) first. Use the compression drill guide with the arrow pointing towards the joint to eccentrically drill. Place a non-locking screw to achieve compression. The crossing screw would be placed last in this scenario.

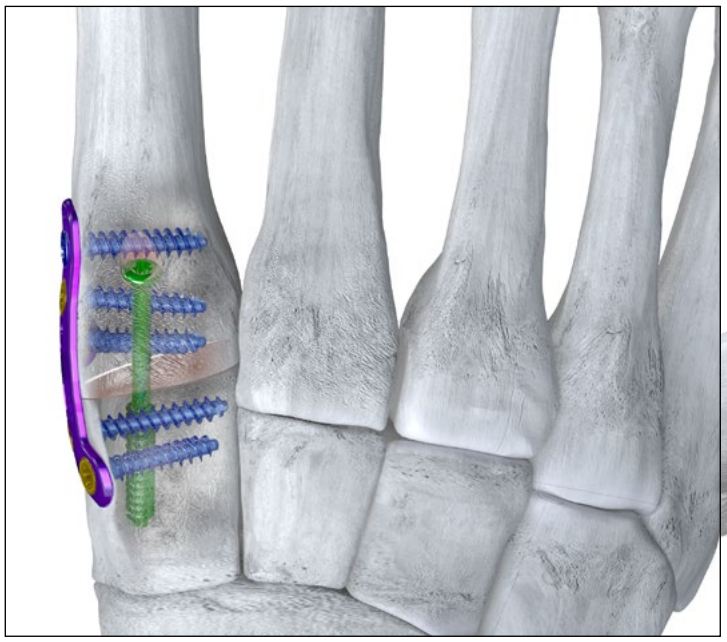


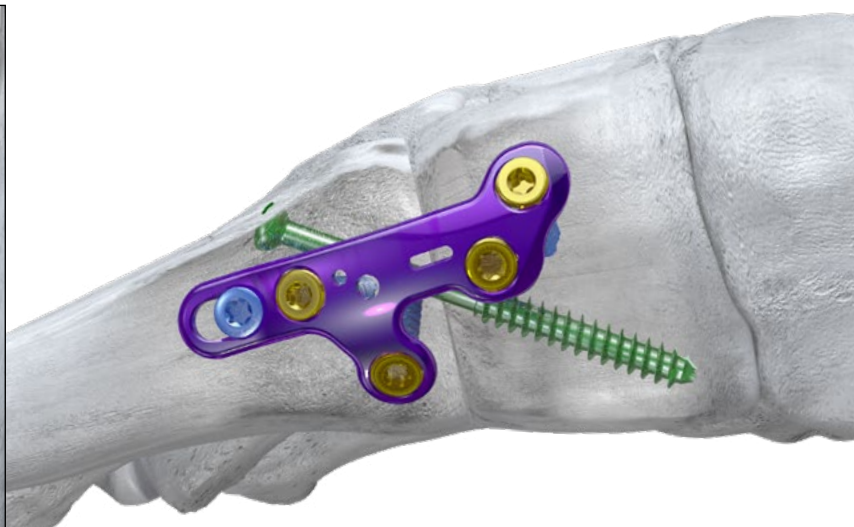


Drill using the drill corresponding to the desired screw diameter.



Insert the screw using the driver provided.





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® 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.

Gorilla® R3CON Instrument Caddy

Drills, drill guides, centering guides, olive wires, plate benders, drivers, K-wires and a depth gauge are located in the Gorilla® R3CON Instrument Caddy.

Additional Gorilla® Caddies

The Gorilla® Case has room for additional Gorilla® Plate Caddies or PRESERVE™ Allograft caddies that may be needed for additional procedures performed in addition to a Lapidus Arthrodesis case.

Gorilla® Case

Mini-Monster® Screw Caddy

The Gorilla® Case can accommodate one Mini-Monster® Screw Caddy if a 3.5 mm or 4.0 mm cannulated screw is needed during a Lapidus Arthrodesis case.

Gorilla® R3CON Screw Optionality

The Gorilla® R3CON screw length options for both locking and non-locking screws are as follows:

2.7 mm	1 mm increments, 8-20 mm
2.7 mm	2 mm increments, 22-40 mm
3.5 mm	2 mm increments, 10-50 mm
4.2 mm	2 mm increments, 10-50 mm
4.2 mm	5 mm increments, 55-70 mm

Gorilla® R3CON Instruments

The 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 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.

INSTRUCTIONS FOR USE: MONSTER®/MINI-MONSTER® SCREW SYSTEM

Indications, Contraindications, Warnings and Precautions relevant to the Monster® Screw System are contained in the Instructions for Use document of the Monster® Screw System P20-IFU-3001.

A patient with the Paragon 28® Monster® Screw System may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Name/Identification of Device	Paragon 28® Monster® Screw System
Nominal value(s) of Static Magnetic Field [T]	1.5 T or 3 T
Maximum Spacial Field Gradient [T/m and gauss/cm]	30 T/m (3000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body transmit coil, Head RF transmit-receive coil
Maximum Whole Body SAR [W/kg]	2.0 W/kg (Normal Operating Mode)
Limits on Scan Duration	All anatomical regions can be safely scanned under the following conditions: 2.0 W/kg whole body average SAR for 5 minutes of continuous RF (a sequence or back to back series/scan without breaks) with a 20 minute cooling period between scans for an hour long scanning session
	Scanning of the knees and all anatomy superior to the knees can be safely scanned under the following conditions: 2.0 W/kg whole body average SAR for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact of 20 mm

If information about a specific parameter is not included, there are no conditions associated with that parameter.

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

INSTRUCTIONS FOR USE: BABY GORILLA®/GORILLA® PLATING SYSTEM

Indications, Contraindications, Warnings and Precautions relevant to the Baby Gorilla®/Gorilla® Plating System are contained in the Instructions for Use document of the Baby Gorilla®/Gorilla® Plating System P51-IFU-3001.

A patient with the Paragon 28® Baby Gorilla®/Gorilla® Plating System may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Name/Identification of Device	Paragon 28® Baby Gorilla®/Gorilla® Plating System
Nominal value(s) of Static Magnetic Field [T]	1.5 T or 3 T
Maximum Spacial Field Gradient [T/m and gauss/cm]	30 T/m (3000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body transmit coil, Head RF transmit-receive coil
Operating Mode	Normal Operating Mode
Maximum Whole Body SAR [W/kg]	2.0 W/kg (Normal Operating Mode)
Limits on Scan Duration	2.0 W/kg whole body average SAR for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact

If information about a specific parameter is not included, there are no conditions associated with that parameter.

Gorilla® Lapidus Plating System

PATENTED, DESIGNED & EXCLUSIVELY DISTRIBUTED BY

Paragon 28®

a ZIMMER BIOMET company

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Zimmer Biomet does not practice medicine. This technique was developed in conjunction with healthcare professionals. This document is intended for surgeons and is not intended for laypersons. Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training surgeons have received. As with all surgical procedures, the product/technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Results will vary based on health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure. Caution: Federal (USA) law restricts this device to sale by or on the order of a surgeon. Rx only. ©2025 Zimmer Biomet.

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