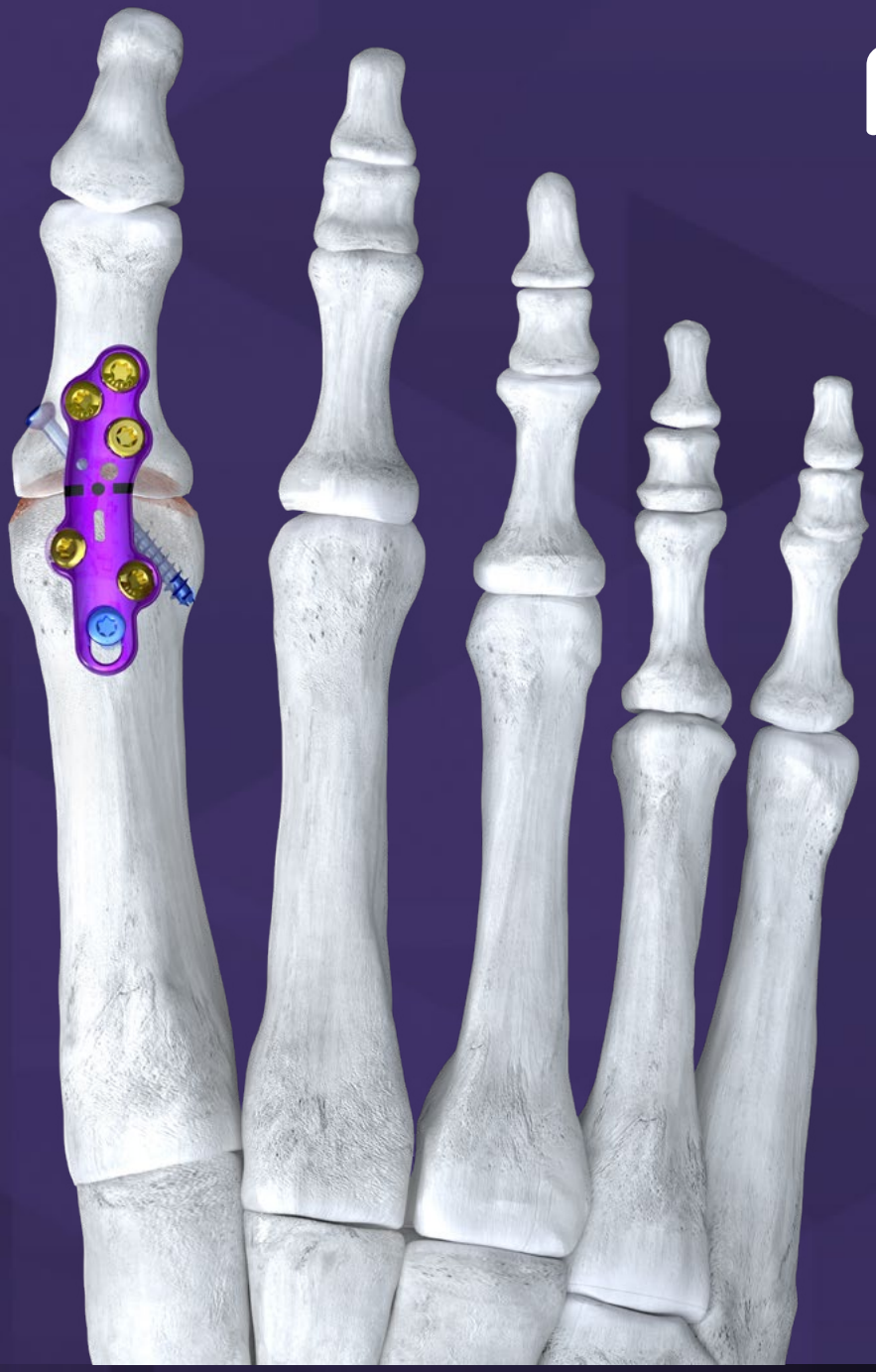
Exclusively foot & ankle

Paragon 28®



SURGICAL TECHNIQUE GUIDE

MTP Arthrodesis

Gorilla® MTP Plating System

GORILLA®
R3CON PLATING SYSTEM

Acknowledgment:

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

PRODUCT DESCRIPTION

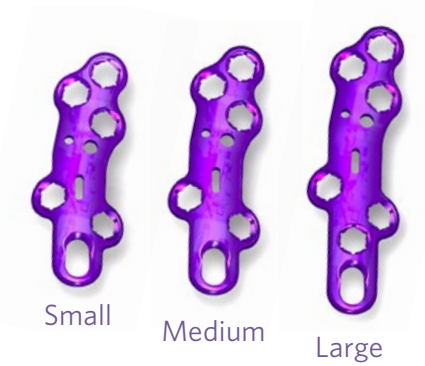
The Paragon 28® Gorilla® MTP Plating System was designed to provide surgeons versatility in plate selection for MTP Arthrodesis procedures, assistance with joint preparation and the ability to position the hallux in all 3 planes during temporary fixation. The system has 32 anatomically contoured plating options to address primary, revision and graft-spanning arthrodesis. The primary and short arthrodesis plates are offered in 0°, 5° and 10° of dorsiflexion to account for differences in anatomy. The revision arthrodesis plates are thicker and provide more holes proximally to avoid previous screw placement. The graft-spanning plates allow for placement of the Paragon 28® PRESERVE™ MTP Length Restoring Graft. All Gorilla® MTP plate holes accommodate Gorilla® R3CON™ 2.7, 3.5 and 4.2 mm locking and non-locking screws.

The instrumentation provided in the Gorilla® MTP Plating System was designed to address joint preparation while facilitating compression and/or stability at the arthrodesis site. The patented Precision® Guide mates with the desired MTP plate to provide five trajectories of guide wire paths to allow for insertion of a 3.0 or 3.5 mm cannulated Mini-Monster® crossing screw across the arthrodesis site, while avoiding on-axis locking and non-locking plate screws within the construct. Spin Guard Reamers are available in the set to assist the surgeon in cartilage removal and joint preparation prior to plate and screw fixation.

PLATE OFFERING

Primary Plates
- Left and Right Side Specific

- 1.3 mm thickness
- Available in small, medium and large
- 3 holes in proximal phalanx



- Available Plate Angles:


0° dorsiflexion


5° dorsiflexion


10° dorsiflexion

Short Plate
- Left and Right Side Specific

- 1 .3 mm thickness
- 2 holes in proximal phalanx

- Available Plate Angles:


0° dorsiflexion


5° dorsiflexion


10° dorsiflexion

Revision Plates
- Left and Right Side Specific

- 1.6 mm thickness
- Available in small, medium and large

- Plate Angle:


5° dorsiflexion

Graft-Spanning Plate
- Left and Right Side Specific

- 1.6 mm thickness
- Built to span PRESERVE™ MTP Graft

- Plate Angle:


5° dorsiflexion

FEATURED INSTRUMENTS

Patented Female Spin Guard

Female Reamer

Patent Pending Male Spin Guard

Male Reamer

- Available in 17 mm, 19 mm, 21 mm and 23 mm diameters
- Reamers allow for cup and cone engagement of the 1st MTP, providing the ability to adjust hallux position in any plane without re-cutting
  - Helps to remove less bone than flat cuts
- Spin Guard designed to protect adjacent bones while reaming

1.6 x 150 mm K-wire

Precision Guide MTP

1.0 mm Precision Guide K-wire Sleeve

Mini-Monster® 3.0 mm screw

1.2 mm Precision Guide K-wire Sleeve

Mini-Monster® 3.5 mm screw

Precision Guide Set Screw

Precision Guide Arm

- Patented
- Allows a lag screw to cross the joint while avoiding the locking and non-locking plate screws in the construct

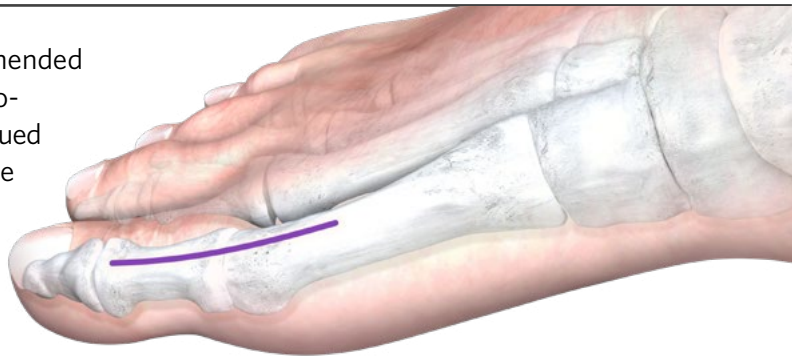
ANCILLARY IMPLANTS

PRESERVE™ MTP Length Restoring Graft

- Can help to restore length in cases of a short 1st metatarsal or revision procedure
- Available in 19 mm diameter with lengths of 5, 8, 10, 15 and 20 mm
- Available in 21 mm diameter with lengths of 5, 8 and 10 mm

INCISION/EXPOSURE

Supine patient positioning with fluoroscopy available is recommended for this procedure. A dorsomedial incision over the 1st metatarsophalangeal joint is recommended. Soft tissue dissection is continued to expose the 1st metatarsophalangeal joint. Release the soft tissue to obtain exposure of the articular surfaces of the 1st metatarsal head and hallux proximal phalanx base.

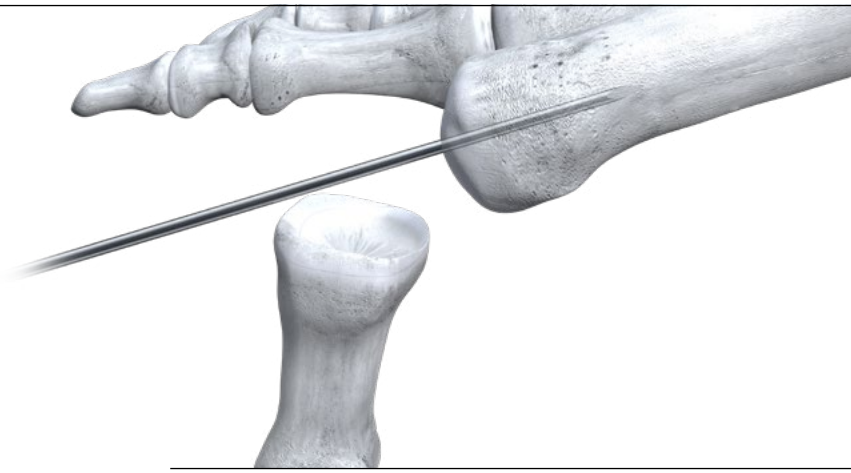


JOINT PREPARATION

After exposing the joint surfaces, remove any osteophytes surrounding the joint using a saw or osteotome. The method of cartilage resection is according to surgeon preference. The method for using the Paragon 28 MTP reamers is described below:

PREPARATION OF THE 1ST METATARSAL HEAD:

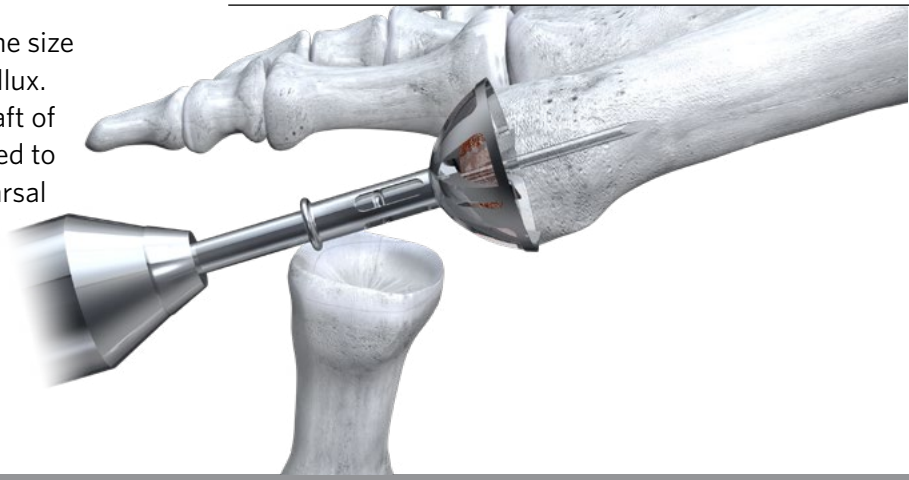
A 1.6 mm K-wire is inserted down the central shaft of the 1st metatarsal head, from distal to proximal. Select the female reamer size based on the 1st metatarsal head size, with the reamer as wide or slightly wider than the diameter of the cartilage covering the 1st metatarsal head.



Connect the matching female spin guard to the end of the female reamer. Attach the construct to a powered driver and slide over the 1.6 mm K-wire. Begin motion of the reamer prior to making contact with the 1st metatarsal head.

Remove all of the cartilage on the 1st metatarsal head, using the reamer in a pulsing motion to facilitate cartilage removal, if necessary. If the outer cartilage remains, go up a reamer size. If the reamer is too large, go down a size. Remove cartilage until bleeding subchondral bone is observed and take care not to over-shorten the 1st metatarsal.

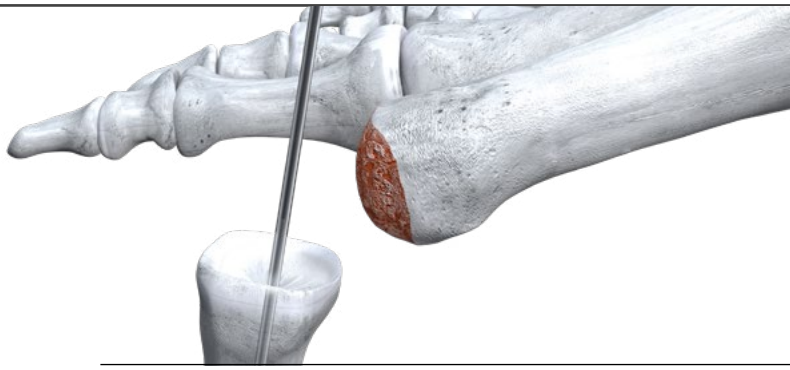
Take note of the last reamer size used, as this will be the size designated for reaming the proximal phalanx of the hallux. When finished, remove the K-wire from the central shaft of the 1st metatarsal. A rongeur or curette can be employed to resect any cartilage or rough edges from the 1st metatarsal head joint surface.



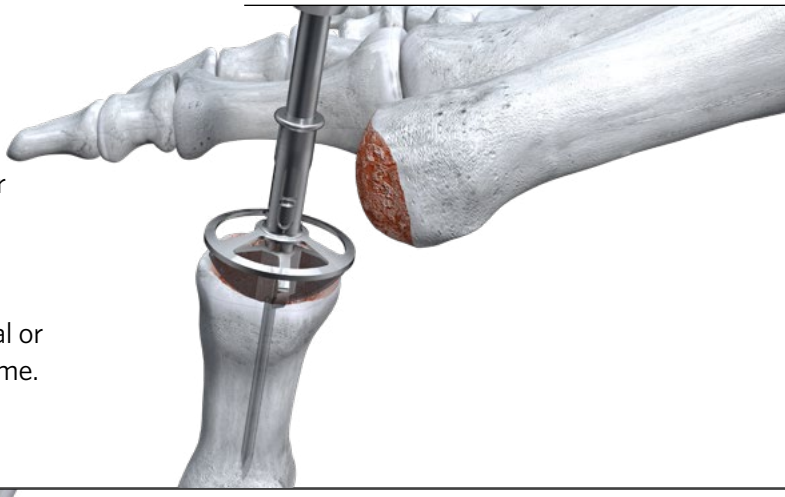
JOINT PREPARATION

PREPARATION OF THE PROXIMAL PHALANX BASE:

Insert the same 1.6 mm K-wire down the central shaft of the hallux proximal phalanx, from proximal to distal. The convex male reamer is selected to match the last size of reamer used on the 1st metatarsal head.

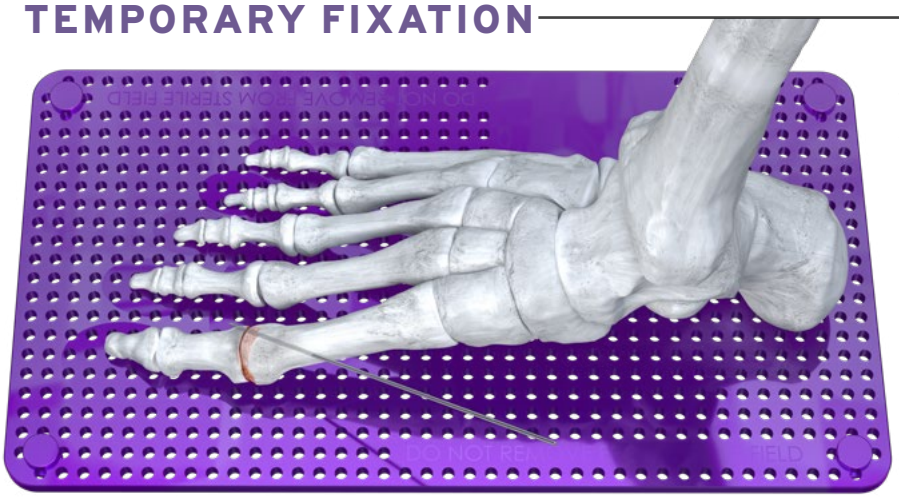


Attach the matching male spin guard to the end of the male reamer. The male reamer is placed over the K-wire and is secured to the powered driver. Begin motion of the reamer prior to contact with the proximal phalanx.



Remove all of the cartilage from the base of the hallux proximal phalanx until bleeding subchondral bone is observed. Remove the K-wire from the base of the hallux proximal phalanx. A rongeur or curette can be employed to resect any additional cartilage from the edges or joint surface. Subchondral bone preparation can be performed following reaming using the Paragon 28 subchondral drill or surgeon's preferred technique. If used, bone grafting material or a PRESERVE MTP Length Restoring Graft can be inserted at this time.

TEMPORARY FIXATION



The correct alignment of the hallux can be determined with the assistance of the Paragon 28 Foot Plate. A K-wire is recommended to be inserted from proximal medial to distal lateral to serve as temporary fixation.

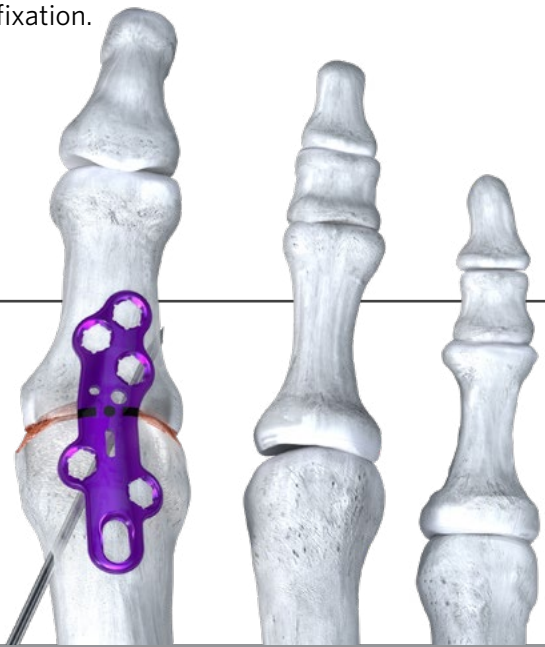


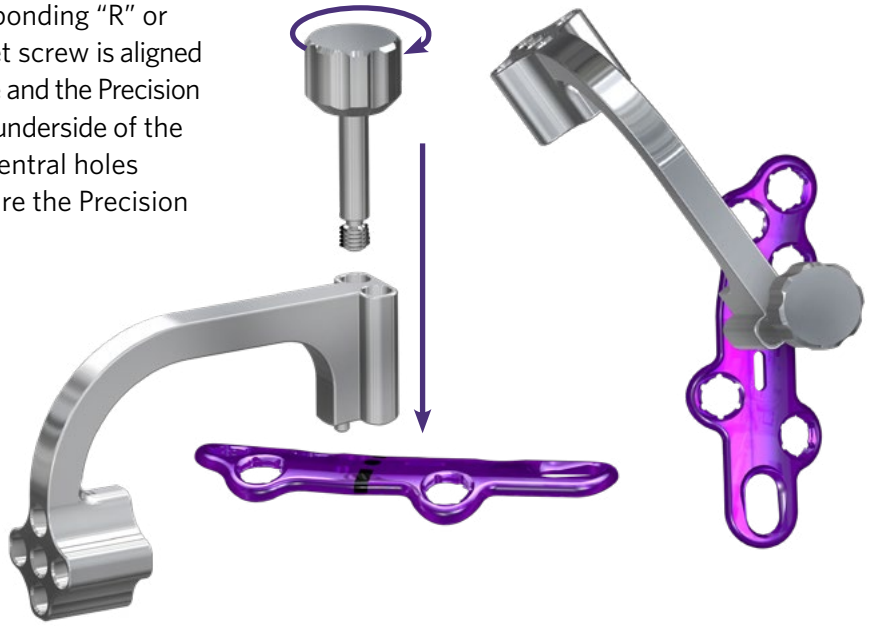
PLATE SELECTION

An appropriately sized "Left" or "Right" MTP arthrodesis plate is selected at this time. The laser markings at the central aspect of the plate should align with the joint.

TIP: If a thicker plate is desired for a patient that may have difficulty with restricted weight-bearing following the procedure, a small revision plate (thickness 1.6 mm) may be used in lieu of a medium primary plate (thickness 1.3 mm), as the length is comparable.

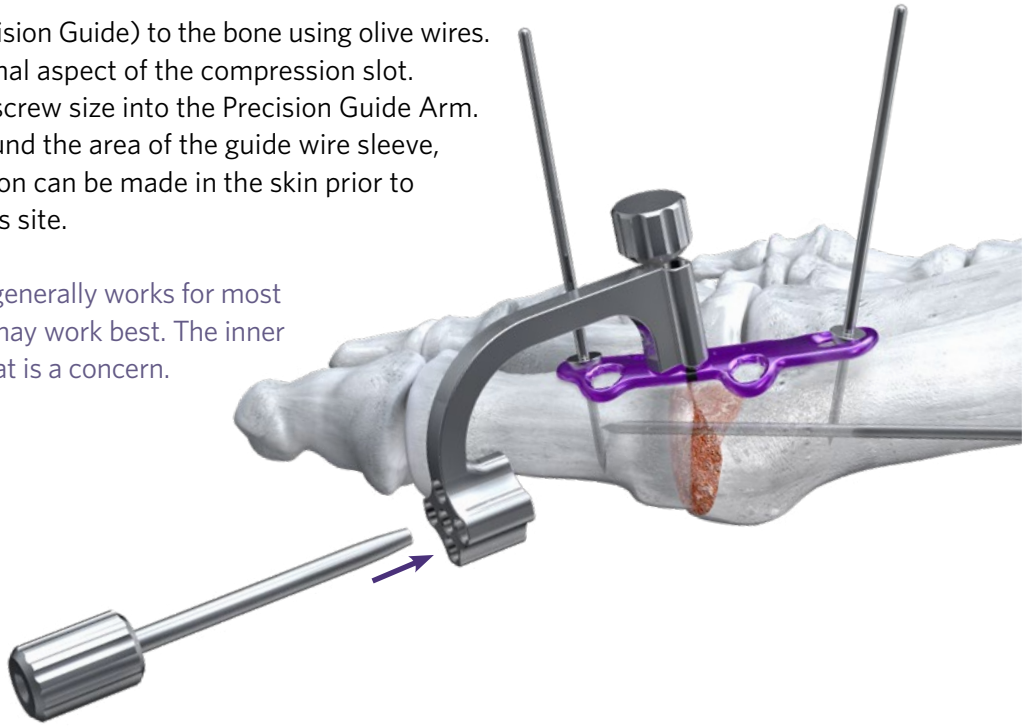
PERMANENT FIXATION

Insert the Precision Guide set screw into the corresponding "R" or "L" hole of the Precision Guide Arm such that the set screw is aligned with the larger of the two central holes of the MTP Plate and the Precision Guide Arm is oriented medially. The small peg on the underside of the Precision Guide mates with the smaller of the two central holes of the MTP Plate. Rotate the knob clockwise to secure the Precision Guide set screw to the MTP plate.

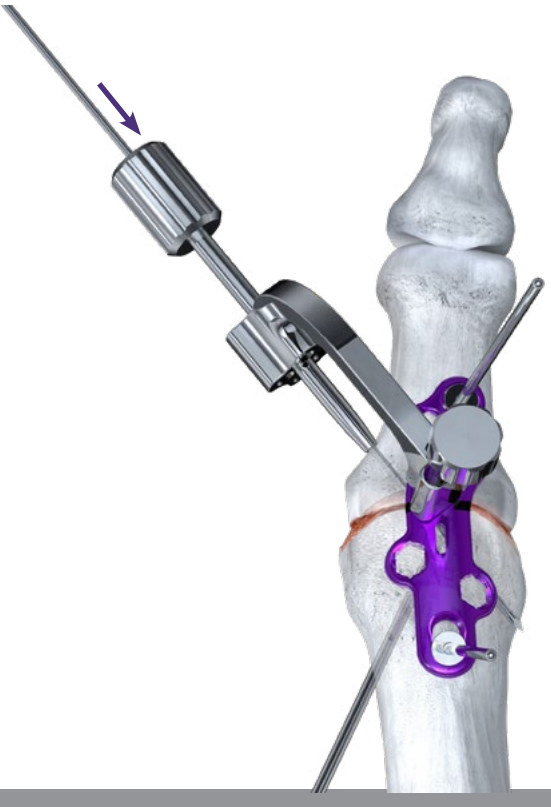


NOTE: Use of the Precision Guide MTP is optional. It may be used as demonstrated below, or it may be attached to the plate after plate screw fixation. In the latter case, a fully threaded crossing screw is recommended.

Secure the MTP plate (with the attached Precision Guide) to the bone using olive wires. One olive wire should be placed in the proximal 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.



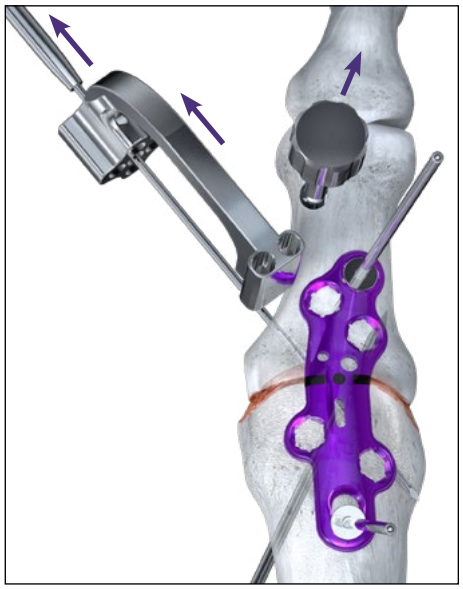
TIP: The central hole of the Precision Guide generally works for most patients. For larger patients, the plantar hole may work best. The inner and outer holes may help prevent skiving if that is a concern.



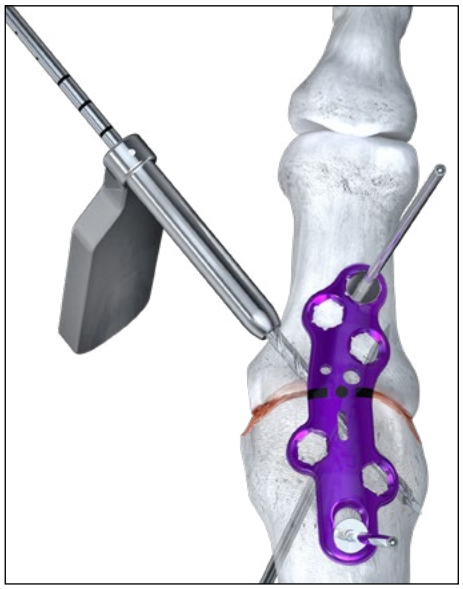
Insert the guide wire for the selected crossing screw size into the guide wire sleeve such that it crosses the arthrodesis site at a desired location.

The Precision Guide can be used during initial permanent fixation. In this case (as shown), no further compression across the arthrodesis site should be attempted following crossing screw placement, as this will result in loosening of the crossing screw.

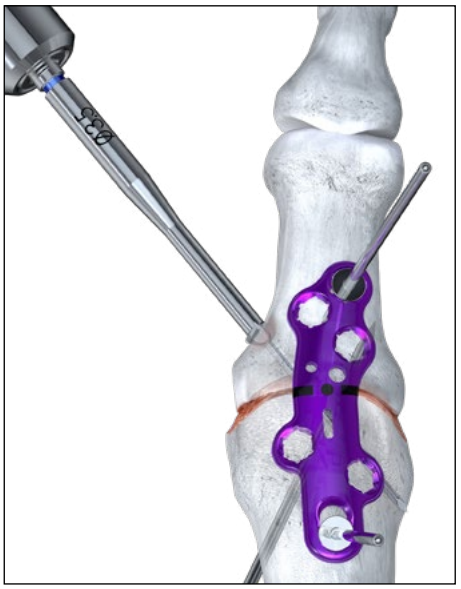
PERMANENT FIXATION



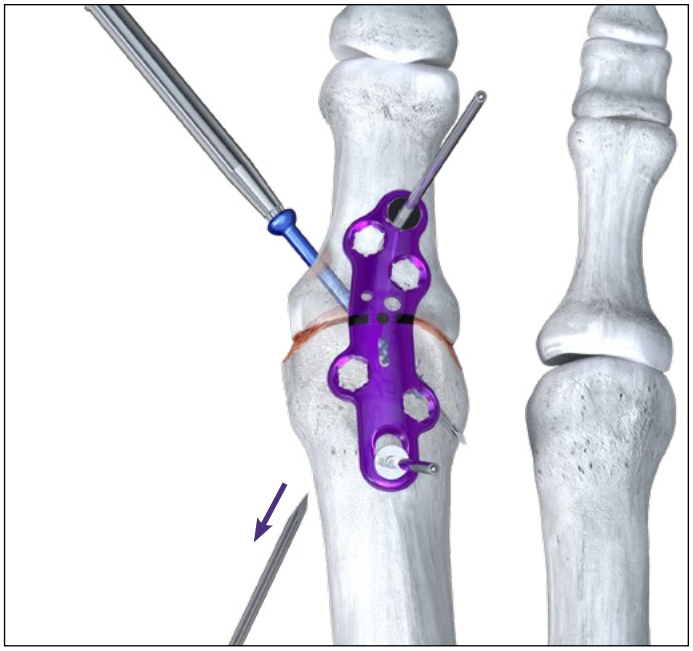
The position and length of the guide wire is confirmed using fluoroscopy. When correct, remove the Precision Guide from the plate by rotating the set screw in a counter-clockwise manner and sliding the Precision Guide Arm off of the guide wire.



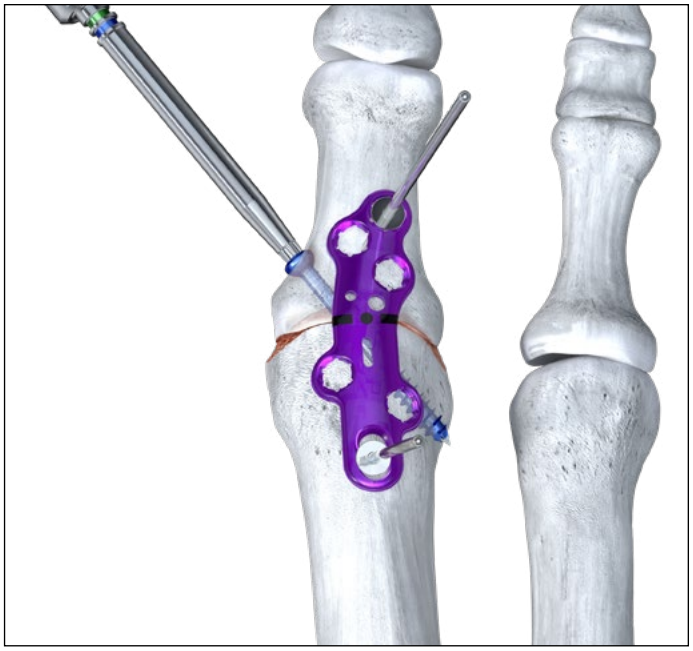
The drill and drill guide for the selected crossing screw diameter are slid over the guide wire and drilling is performed.



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



The selected crossing screw is inserted over the guide wire into the proximal phalanx.

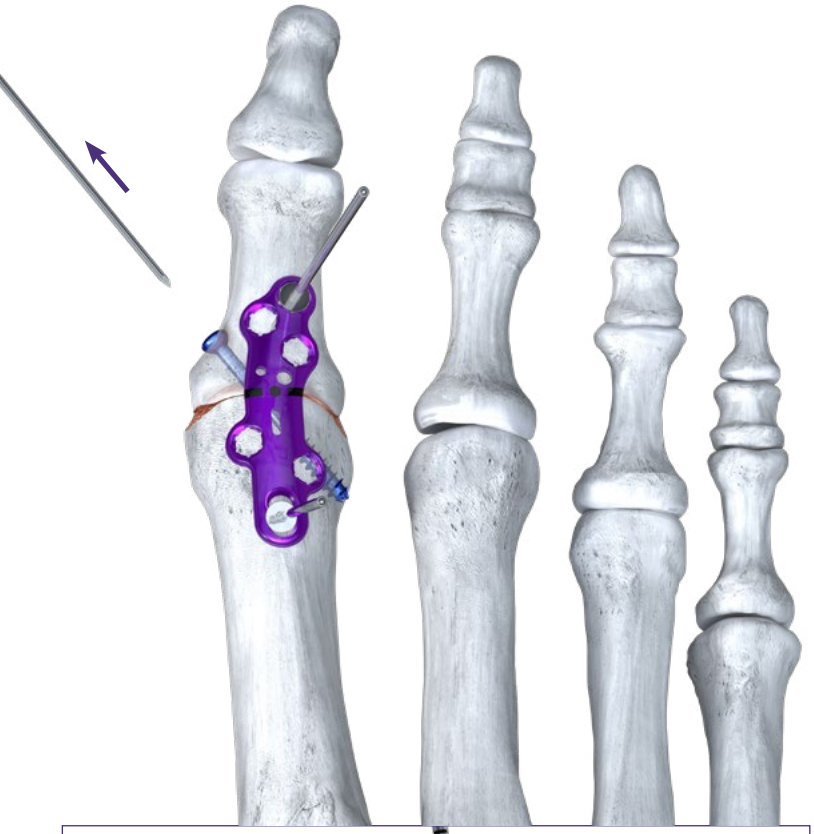


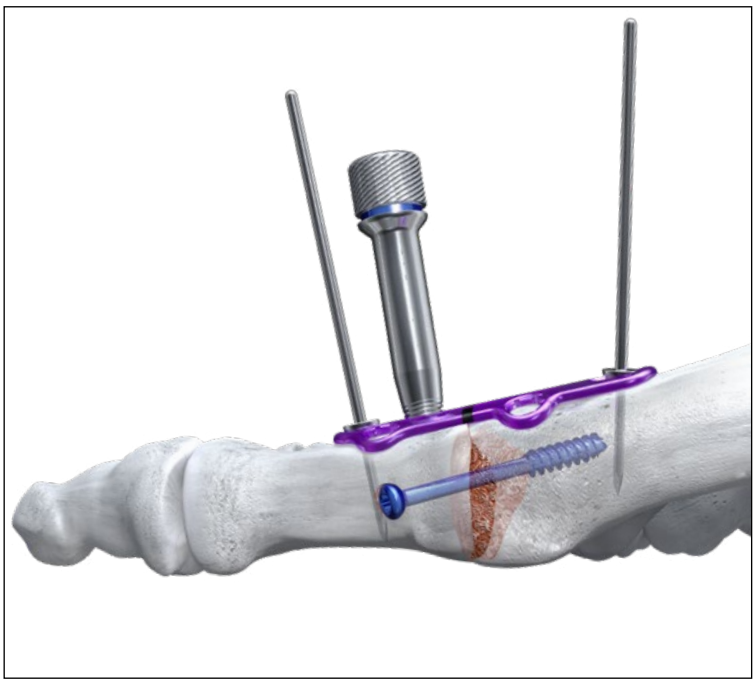
Complete screw insertion.

TIP: If a surgeon prefers to not use a crossing screw, or if a crossing screw is unable to be placed, eccentric drilling of the compression slot can be performed and compression can be achieved in this manner or by external compression of the joint prior to locking screw placement.

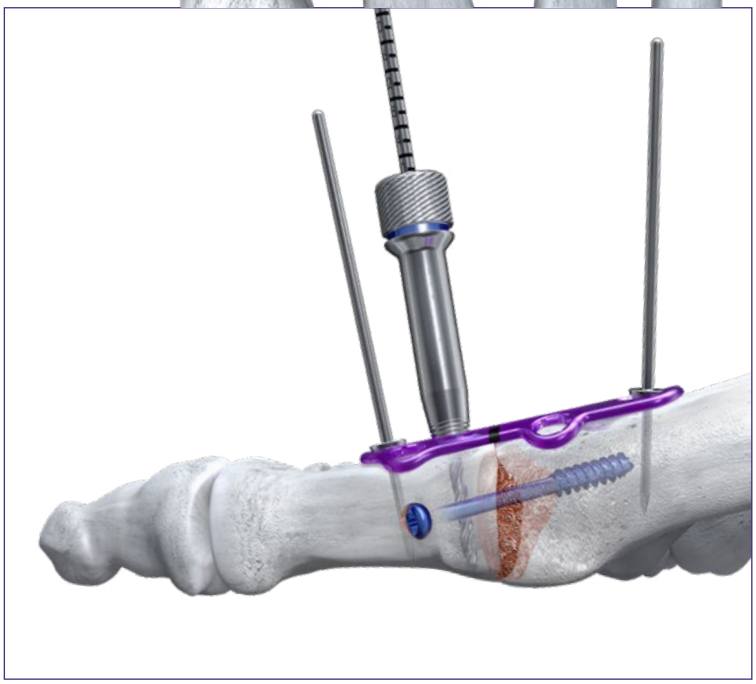
PERMANENT FIXATION

Remove the guide wire.

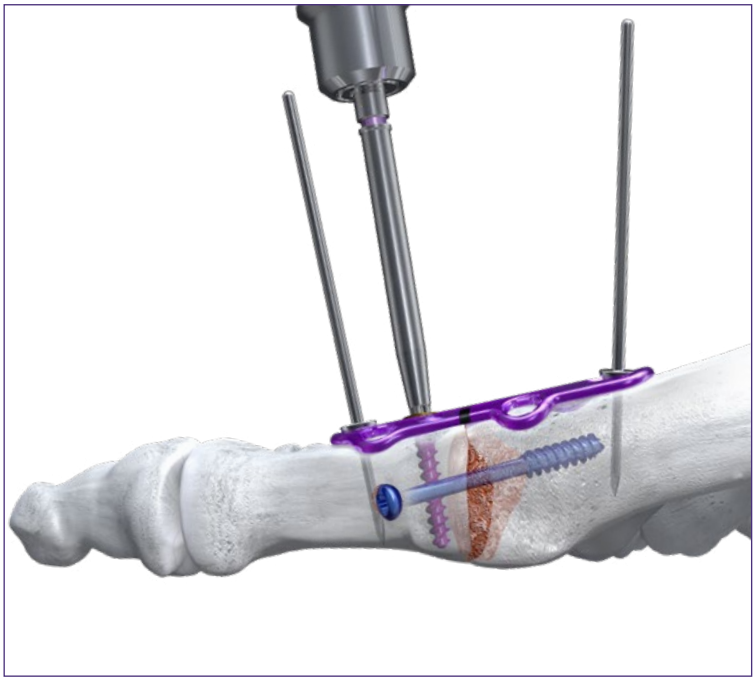




Insert a threaded drill tower into one of the distal screw holes corresponding to desired plate screw diameter.

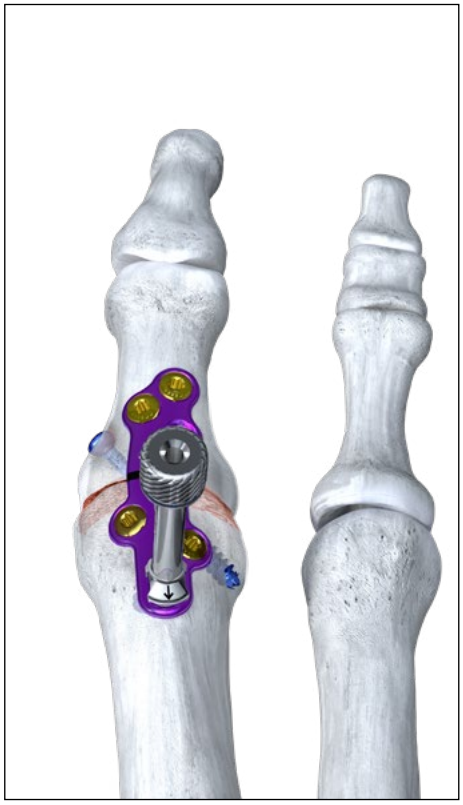


Drill using the drill corresponding to the desired plate screw diameter.

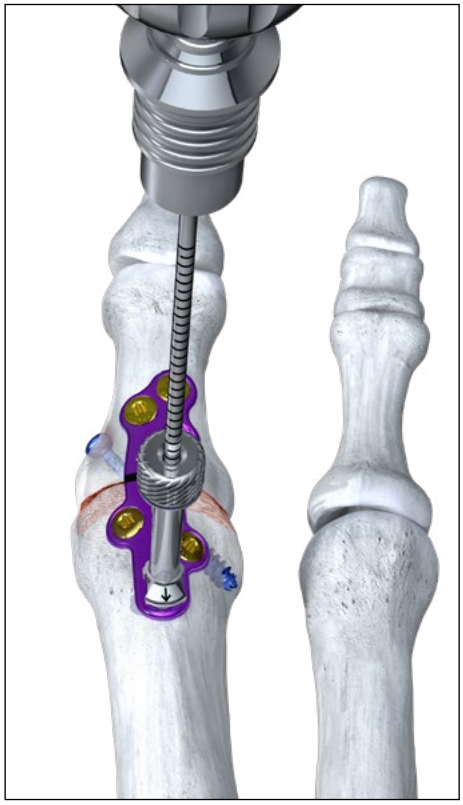


Screw length can be measured using the provided depth gauge or by measuring off of the drill using the drill guide. Insert the plate screw using the provided driver. It is advised to avoid final tightening of the distal plate screws into the locked position until proximal plate screws are inserted.

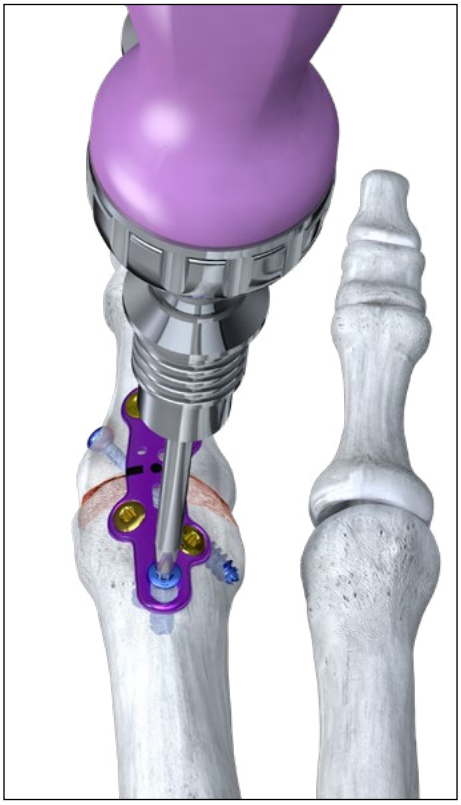
PERMANENT FIXATION



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.

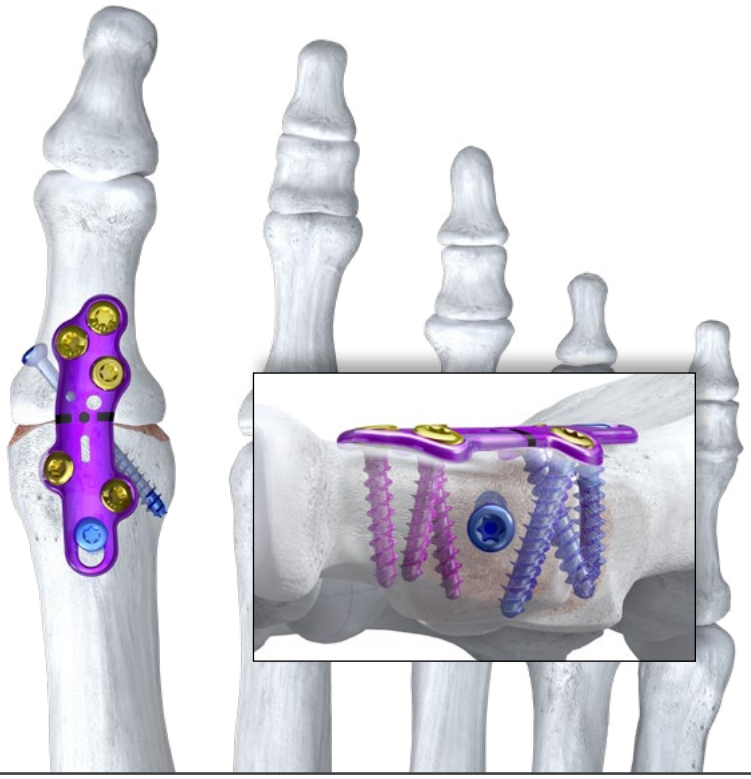


Drill using the drill corresponding to the desired screw diameter.



Insert the screw using the driver provided.

TIP: If the surgeon prefers to create compression via the compression slot, insert distal 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 cross screw would be placed last in this scenario.



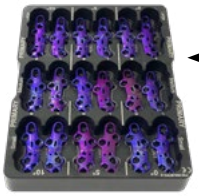
Insert screws in the remaining screw holes, as desired. Confirm final screw length and placement using fluoroscopy.

CLOSURE

Proceed to incision closure or concomitant procedures at this time.

MTP Caddy

The Gorilla® MTP Plating Caddy includes 32 varieties of Gorilla® MTP plates, MTP reamers in 4 sizes and 1.6 mm K-wires for use with the MTP reamers. The Precision® Guide MTP is also located in this caddy.



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 procedures performed in addition to an MTP Arthrodesis case.

Mini-Monster® Screw Caddy

The Gorilla® Case can accommodate one Mini-Monster® Screw Caddy for a 3.0 mm or 3.5 mm Mini-Monster® screw to be used during an MTP Arthrodesis procedure.

Gorilla® 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 Caspar Compression/Distraction 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.

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 bone plates and bone screws of the Baby Gorilla®/Gorilla® Plating System are indicated for use in stabilization and fixation of fractures or osteotomies; intra and extra articular fractures, joint depression, and multi-fragmentary fractures; revision procedures, joint fusion and reconstruction of small bones of the toes, feet and ankles including the distal tibia, distal fibula, talus, and calcaneus. The system can be used in both adult and pediatric patients.

In addition, the non-locking, titanium alloy (Ti6Al4V ELI) screws and washers are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair and fracture fixation of the foot and ankle, including the tibia, fibula, tarsus, metatarsals, and phalanges, appropriate for the size of the device.

CONTRAINDICATIONS

Use of the Baby Gorilla®/Gorilla® Plating System is contraindicated in cases of inflammation, cases of active or suspected sepsis / infection and osteomyelitis; or in patients with certain metabolic diseases.

All applications that are not defined by the indications are contraindicated. In addition, surgical success can be adversely affected by:

- Acute or chronic infections, local or systemic
- Vascular, muscular or neurological pathologies that compromise the concerned extremity
- All concomitant pathologies that could affect the function of the implant
- Osteopathies with reduced bone substance that could affect the function of the implant
- Any mental or neuromuscular disorder that could result in an unacceptable risk of failure at the time of fixation or complications in post-operative treatment
- Known or suspected sensitivity to metal
- Corpulence; an overweight or corpulent patient can strain the implant to such a degree that stabilization or implant failure can occur
- Whenever the use of the implant comes into conflict with the anatomical structures of physiological status

Other medical or surgical pre-conditions that could compromise the potentially beneficial procedure, such as:

- The presence of tumors
- Congenital abnormalities
- Immunosuppressive pathologies
- Increased sedimentation rates that cannot be explained by other pathologies
- Increased leukocyte (WBC) count
- Pronounced left shift in the differential leukocyte count

POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS

In any surgical procedure, the potential for complications and adverse reactions exist. The risks and complications with these implants include:

- Loosening, deformation or fracture of the implant
- Acute post-operative wound infections and late infections with possible sepsis
- Migration, subluxation of the implant with resulting reduction in range of movement
- Fractures resulting from unilateral joint loading
- Thrombosis and embolism
- Wound hematoma and delayed wound healing
- Temporary and protracted functional neurological perturbation
- Tissue reactions as the result of allergy or foreign body reaction to dislodged particles
- Corrosion with localized tissue reaction and pain
- Pain, a feeling of malaise or abnormal sensations due to the implant used
- Bone loss due to stress shielding

All possible complications listed here are not typical of Paragon 28®, Inc. products but are in principle observed with any implant. Promptly inform Paragon 28®, Inc. as soon as complications occur in connection with the implants or surgical instruments used. In the event of premature failure of an implant in which a causal relationship with its geometry, surface quality or mechanical stability is suspected, please provide Paragon 28®, Inc. with the explant(s) in a cleaned, disinfected and sterile condition. Paragon 28®, Inc. cannot accept any other returns of used implants. The surgeon is held liable for complications associated with inadequate asepsis, inadequate preparation of the osseous implant bed in the case of implants, incorrect indication or surgical technique or incorrect patient information and consequent incorrect patient behavior.

WARNINGS AND PRECAUTIONS

- Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
- Use of an undersized plate or screw in areas of high functional stresses may lead to implant fracture and failure.
- Plates and screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
- The implants and guide wires are intended for single use only.
- Instruments, guide wires and screws are to be treated as sharps.
- Patient risk as a result of the Baby Gorilla®/Gorilla® Plating System in the MR environment has been minimized.
- **Do not use other manufacturer's instruments or implants in conjunction with the Baby Gorilla®/Gorilla® Plating System.**
- **Do not implant the instruments.**

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

MRI SAFETY INFORMATION

A person 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.

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 Spatial 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 SAW [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.

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

INDICATIONS FOR USE: MONSTER® SCREW SYSTEM

The Monster® Screw System is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, ligament fixation, fracture repair and fracture fixation of the foot and ankle, including the tibia, fibula, tarsus, metatarsals, and phalanges and the joints and ligaments coupling said bones, appropriate for the size of the device.

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

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.**

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

MRI SAFETY INFORMATION

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

Name/Identification of Device	Paragon 28® Monster® Screw System
Nominal value(s) of Static Magnetic Field [T]	1.5 T or 3 T
Maximum Spatial 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 SAW [W/kg]	2.0 W/kg (Normal Operating Mode)
Limits on Scan Duration	All anatomic 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 20mm

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

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Gorilla® MTP Plating System

PATENTED, DESIGNED & EXCLUSIVELY DISTRIBUTED BY

Exclusively foot & ankle Paragon 28®

P51-STG-3002 Rev B [2024-05-15]

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DISCLAIMER

The purpose of the MTP Arthrodesis Surgical Technique Guide is to demonstrate use of the MTP Plates in the Gorilla® Recon 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.