Exclusively foot & ankle

Paragon 28®

PROMO®

PROXIMAL ROTATIONAL METATARSAL OSTEOTOMY

SURGICAL TECHNIQUE GUIDE

Proximal Rotational Metatarsal Osteotomy “PROMO”

CONTENTS

Acknowledgment:

Paragon 28® would like to thank Pablo Wagner, MD and Emilio Wagner, MD for their contribution to the development of the surgical technique guide.

DESIGN RATIONALE

The PROMO concept originated with work performed by Pablo Wagner, MD and Emilio Wagner, MD.

Further reading on their work in this field has been published in the following journal articles:

- Wagner et al. Proximal Oblique Sliding Closing Wedge Osteotomy for Hallux Valgus. Foot Ankle Int (2013); 34(11): 1493-1500.
- Wagner et al. Rotational Osteotomy for Hallux Valgus. A New Technique for Primary and Revision Cases. Tech Foot & Ankle (2017); 16: 3-10.
- Wagner et al. Is the Rotational Deformity Important in Our Decision Making Process for Correction of Hallux Valgus Deformity? Foot Ankle Clin. (2018); 23: 205-217.
- Wagner et al. Using the Center of Rotation of Angulation Concept in Hallux Valgus Correction. Foot Ankle Clin. (2018); 23: 247-256.

The premise of the procedure is based on the understanding that many hallux valgus deformities consist of a combined transverse plane and frontal plane deformity. The goal of hallux valgus correction is to relocate the metatarsal to its original location. To perform this correction, an accurate deformity measurement has to be performed pre-operatively

Clinically and radiographically, the transverse plane deformity manifests as medial migration of the 1st metatarsal away from the 2nd metatarsal and lateral migration of the hallux. Transverse plane deformity is measured by the intermetatarsal angle ("IM ∡") of metatarsals 1 and 2 on an AP radiograph (Fig. 1). The frontal plane rotation angle ("Rotation ∡") can also be measured on an AP radiograph. Wagner et al. defined frontal plane rotation ranges based on the shape of the lateral edge of the 1st metatarsal head.[1] These categories are defined in the table below (Table 1).

If the frontal plane rotation angle cannot be determined prior to the surgery, an average rotation angle of 20-29° should be selected.

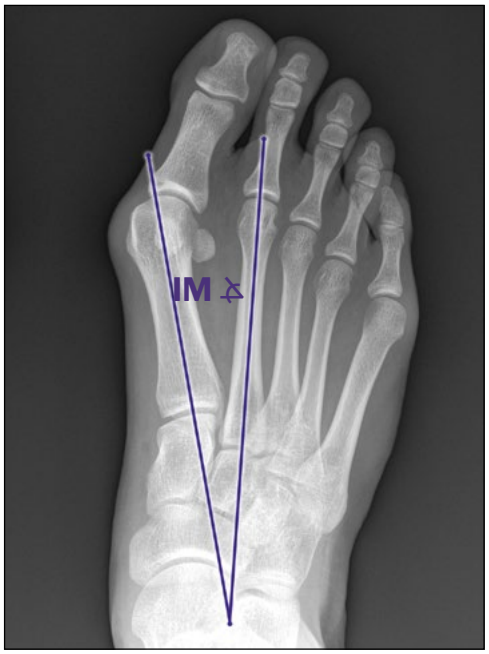
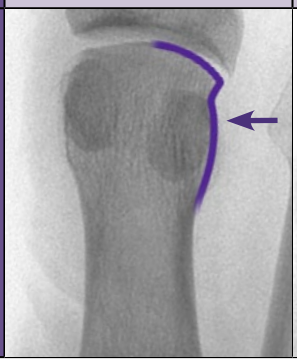
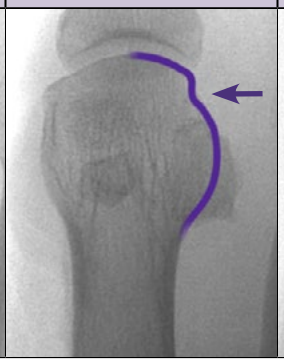
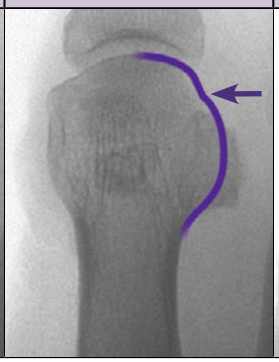
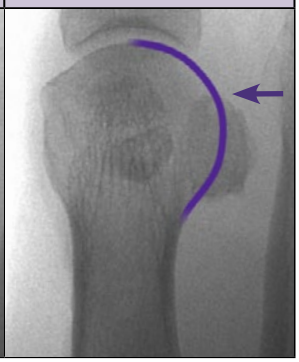


Figure 1

TABLE 1: DETERMINING ROTATION BASED ON 1ST METATARSAL HEAD SHAPE

Rotation Range	0°	10° - 19°	20° - 29°	30° - 39°
Lateral Head Shape	Sharp	Irregular	Rounded	Circular
Lateral Condyle Visiblility	Not Visible	Noteable	Observable	Apparent
Lateral Articular Surface Continuity	None	Step-off	Notched	Smooth
Image Examples (Right 1st Metatarsal)				

DESIGN RATIONALE

The mathematics for calculating the osteotomy cut angle have their roots in trigonometry with adjustments made to increase the correction power. They have been simplified into the following table:

Rotation Angle (°)	Rotation Angle (°)		
	10-19	20-20	30-39
8-10	38	28	23
11-12	47	33	28
13-14	55	38	33
15-17	55	42	38
18-20	55	47	42

Osteotomy Cut Angle

The osteotomy cut angle can be delineated from this table by inputting the IM∡ and rotation∡. For example, a patient with a 12° IM∡ and a 30°-39° rotation∡ would have a 28° osteotomy cut angle.

Paragon 28 has developed instrumentation that facilitates precise and repeatable proximal rotational metatarsal osteotomies of the first metatarsal. A detailed surgical technique using this system is provided in the following pages. Likewise, solutions for fixation of this osteotomy were developed to provide a streamlined method of implant insertion that helps guard against plantar gapping, osteotomy shifting and de-rotation. By using the Paragon 28 patent-pending Precision® Guide PROMO system, a crossing screw can be placed centrally across the osteotomy while a Baby Gorilla® plate buttresses the metatarsal medially. This plate is intended for use with 2.5 mm locking screws.

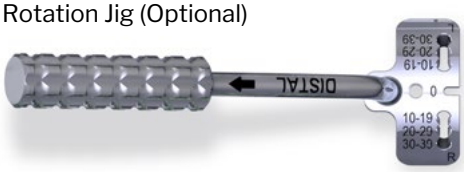
INSTRUMENTATION

Positioning Jig – Left

Positioning Jig – Right

Cutting Jig

Rotation Jig (Optional)



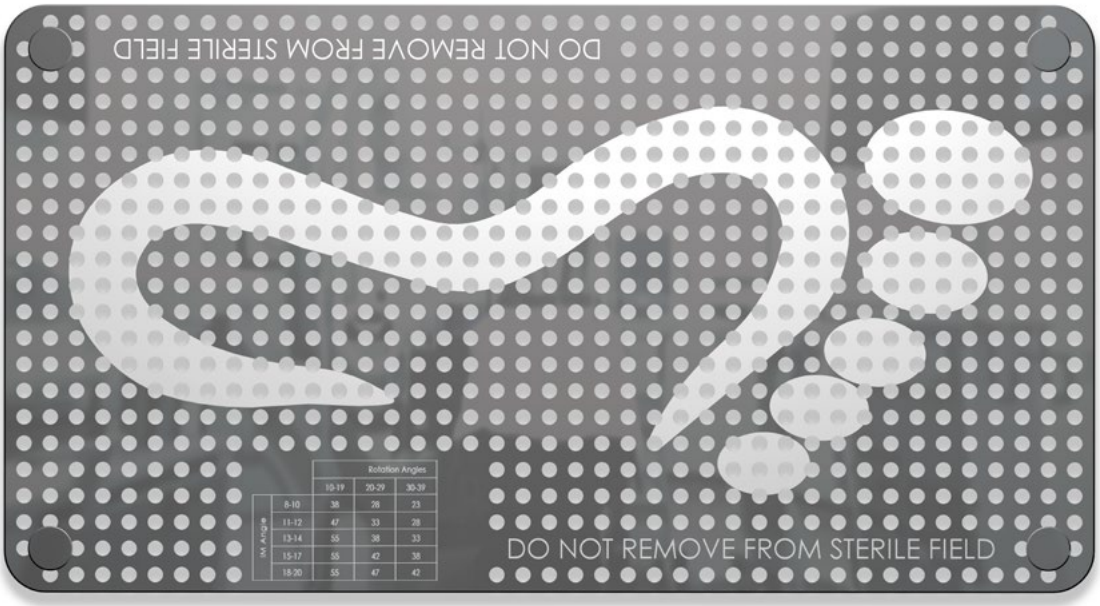
1.0 mm Wire Sleeve

1.2 mm Wire Sleeve

Precision® Guide PROMO

Set Screw

Foot Plate

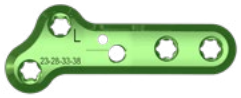


Foot Plate K-wire Guide

K-wire Guide Retainer

IMPLANTS

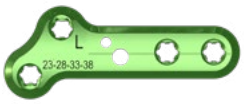
PROMO IMPLANTS - Left and Right Side Specific



Straight 23-28-33-38* PROMO Plate



Straight 42-47-55* PROMO Plate



Angled 23-28-33-38* PROMO Plate



Angled 42-47-55* PROMO Plate

** Plate numbers correspond to osteotomy cut angles*

BABY GORILLA PLATE SCREWS


2.5 mm Locking Baby Gorilla Plate Screws


2.5 mm Non-locking Baby Gorilla Plate Screws


2.0 mm Locking Baby Gorilla Plate Screws


2.0 mm Non-locking Baby Gorilla Plate Screws

A Mini-Monster® cannulated screw caddy is available in 3.0 mm or 3.5 mm for cross-screw fixation of the osteotomy.


3.0 mm Mini-Monster® Cannulated Screw


3.5 mm Mini-Monster® Cannulated Screw

AKIN ANCILLARY FIXATION:


2.0 mm Mini-Monster® Cannulated Screw


2.5 mm Mini-Monster® Cannulated Screw

Baby Gorilla® 2 Hole Akin Plate

8 mm JAWS™ Staple

10 mm JAWS™ Staple

Baby Gorilla® 2 Hole Akin Plate with Compression

Baby Gorilla® Anatomic Medial Akin Plate

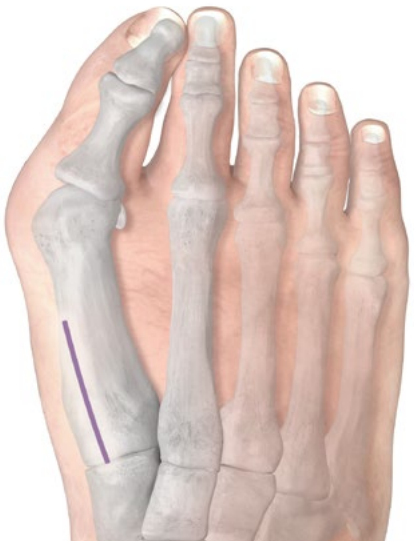
PRE-OPERATIVE PLANNING

ATTENTION:
Measurement of IM ∡ and rotation ∡ are performed pre-operatively and should be recorded or known prior to beginning the procedure. The surgical technique presented here is for a hallux valgus deformity that pre-operatively measured 30°-39° of metatarsal rotation and an IM angle of 12°, resulting in an osteotomy cut angle of 28°.

		Rotation Angle		
		10-19	20-20	30-39
IM Angle	8-10	38	28	23
	11-12	47	33	28
	13-14	55	38	33
	15-17	55	42	38
	18-20	55	47	42

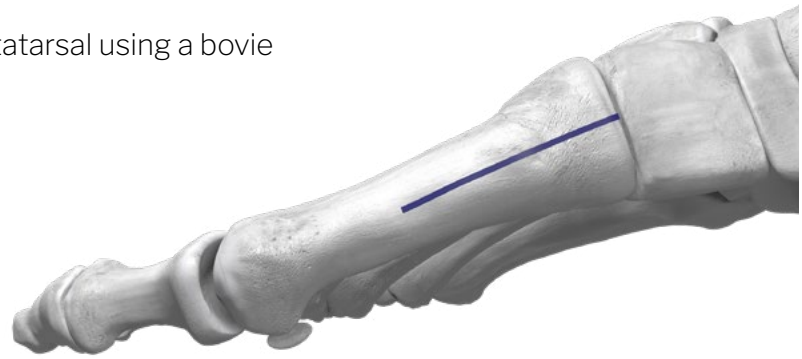
INCISION/EXPOSURE

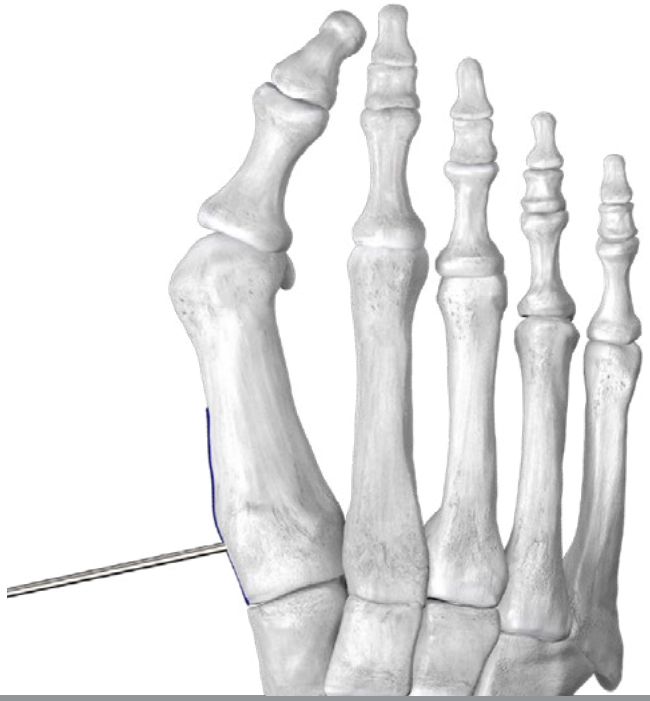
The procedure may be combined with a lateral release for hallux valgus correction, if desired. A medial or dorsomedial incision is made over the proximal 1st metatarsal, per surgeon preference. Dissection is carried down to the base of the first metatarsal.



ROTATIONAL CORRECTION

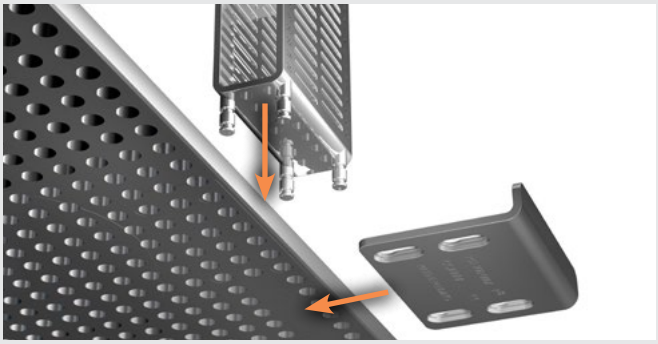
A line is etched along the medial midline of the first metatarsal using a bovie or light skiving with a sagittal saw.

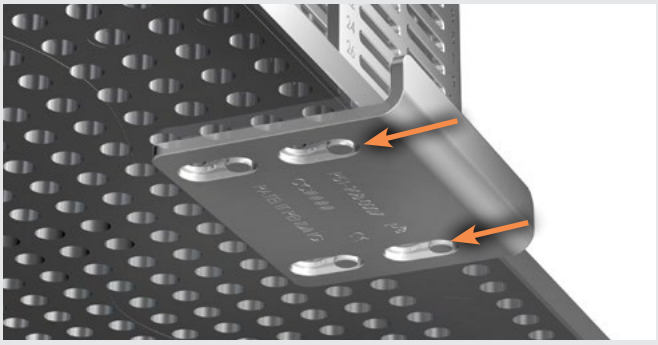




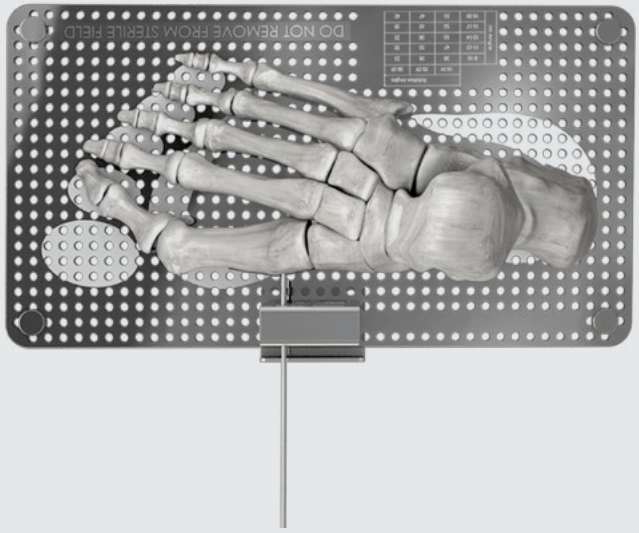
Place a 1.6 mm K-wire through the first metatarsal such that the start point of the K-wire is at the mark corresponding to 1 cm from the 1st tarsometatarsal joint and along the medial midline of the 1st metatarsal.

OPTIONAL: ROTATIONAL CORRECTION



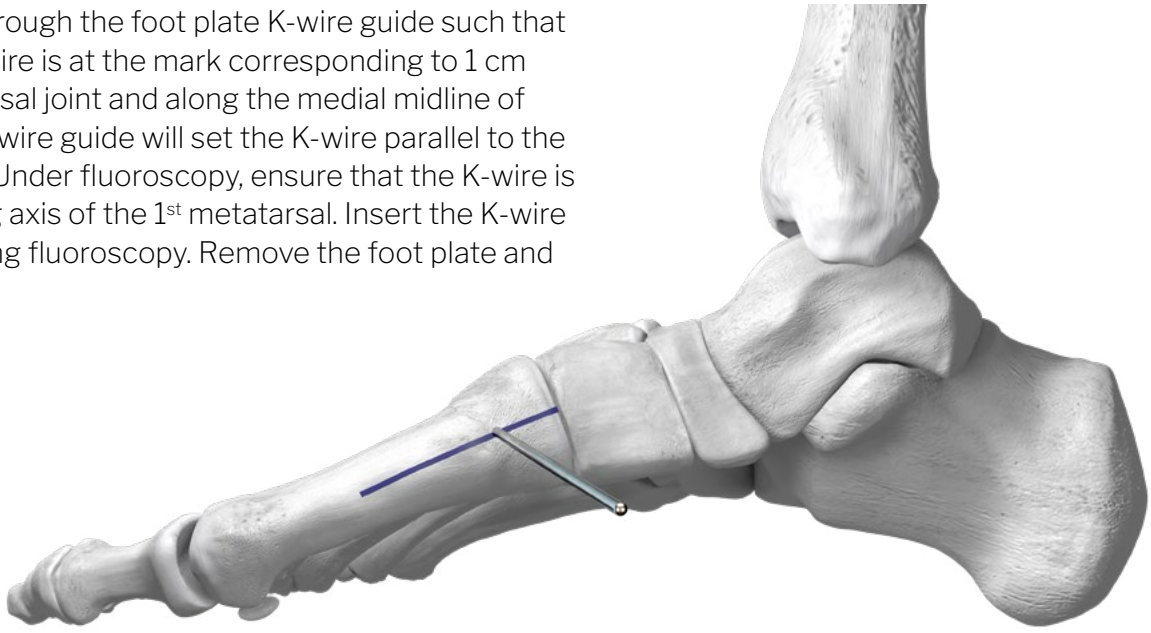


Insert the legs of the foot plate K-wire guide into the edge of the foot plate. Slide the K-wire guide retainer over the legs of the K-wire guide and slide to lock.

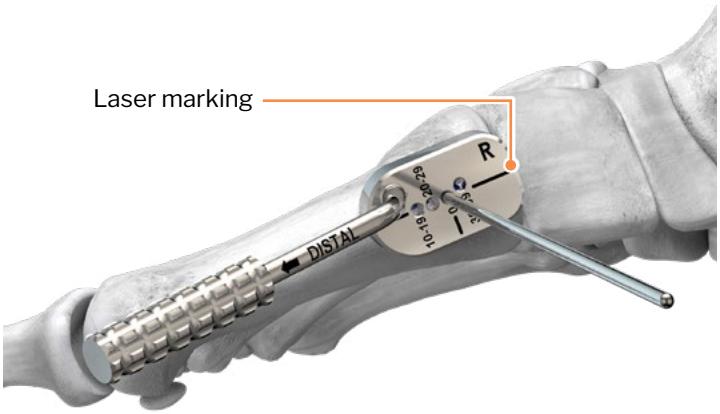


Locate 1 cm from the 1st metatarsal and mark the location with a pen or bovie. Place the foot on the foot plate under fluoroscopy.

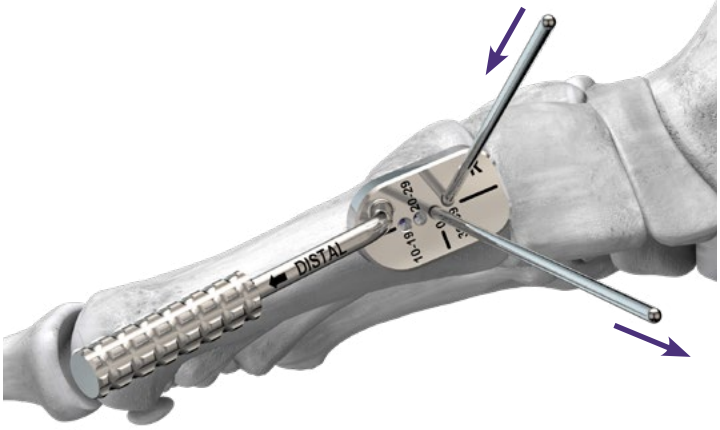
Place a 1.6 mm K-wire through the foot plate K-wire guide such that the start point of the K-wire is at the mark corresponding to 1 cm from the 1st tarsometatarsal joint and along the medial midline of the 1st metatarsal. The K-wire guide will set the K-wire parallel to the weight-bearing surface. Under fluoroscopy, ensure that the K-wire is perpendicular to the long axis of the 1st metatarsal. Insert the K-wire and confirm position using fluoroscopy. Remove the foot plate and foot plate K-wire guide.



ROTATIONAL CORRECTION

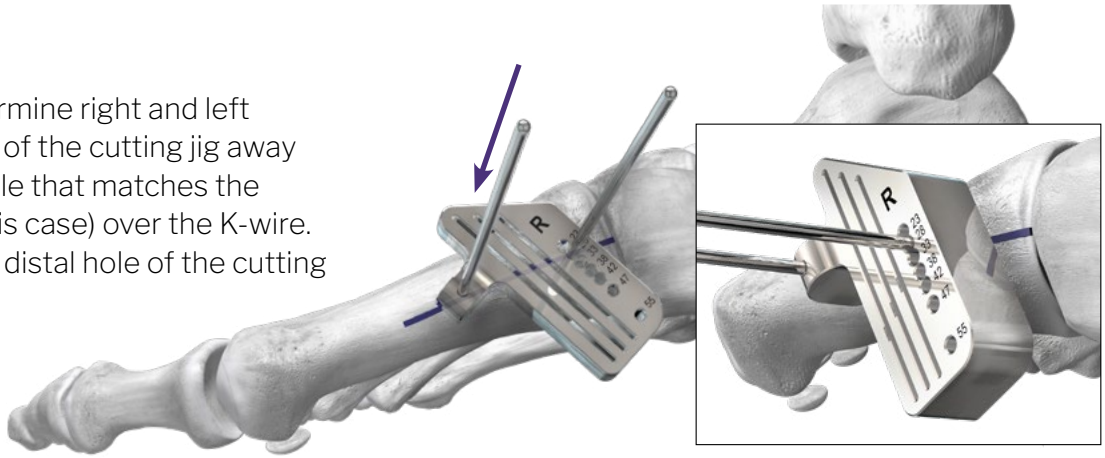


Slide the positioning jig over the K-wire at the “0” hole. This will now be referred to as the “0” K-wire. The laser marking should align with the line etched along the medial midline drawn on the 1st metatarsal.



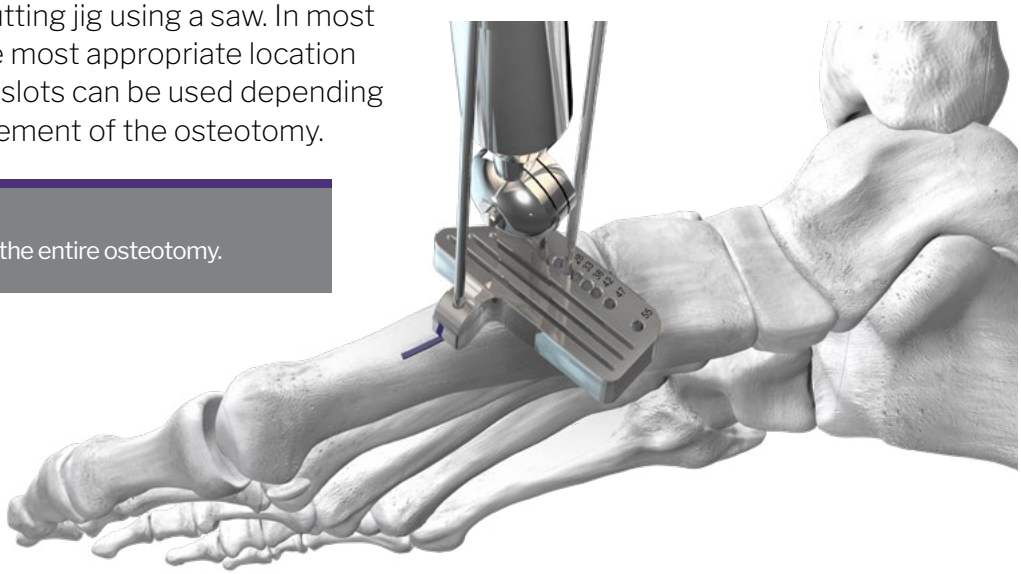
Obtain a second 1.6 mm K-wire. Place the 1.6 mm K-wire into the hole that corresponds to the rotation hole (in this instance, the 30-39 degree hole). Remove the “0” K-wire.

Obtain the cutting jig and determine right and left sides. Place the operative side of the cutting jig away from the bone and slide the hole that matches the osteotomy cut angle (28° in this case) over the K-wire. Place a second K-wire into the distal hole of the cutting jig along the marked midline.



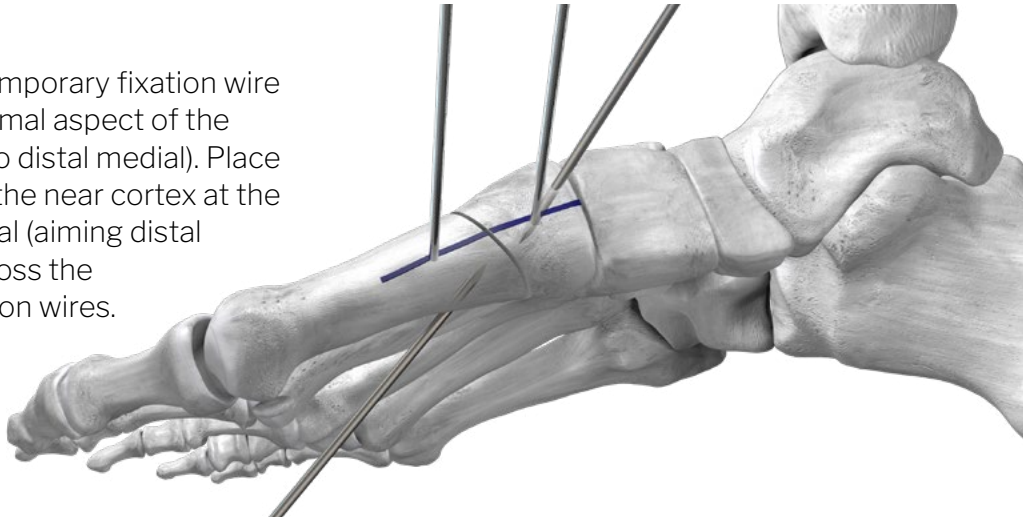
Perform an osteotomy through the cutting jig using a saw. In most instances, the proximal slot will be the most appropriate location for the osteotomy. Either of the three slots can be used depending on surgeon preference and ideal placement of the osteotomy.

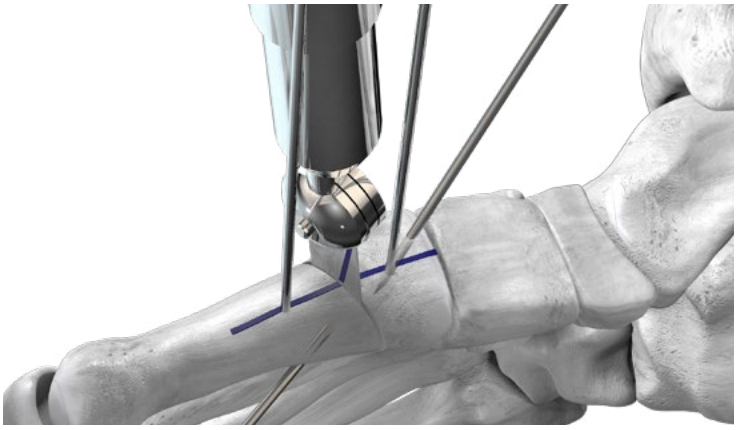
NOTE:
A saw blade may not extend across the entire osteotomy.



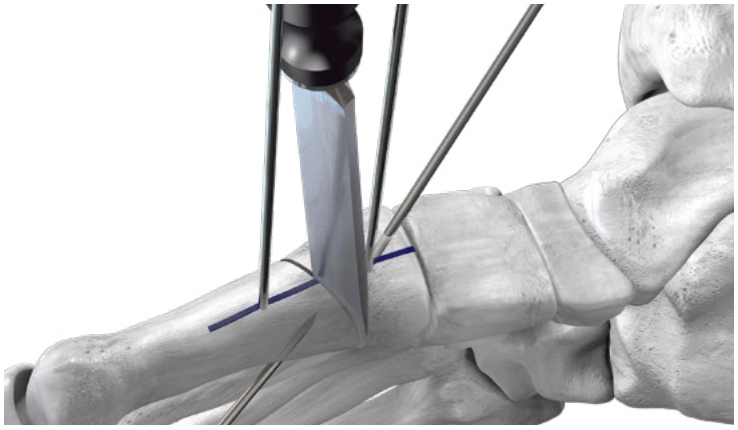
ROTATIONAL CORRECTION

Remove the cutting jig. Place one temporary fixation wire in the near cortex at the lateral proximal aspect of the metatarsal (aiming proximal lateral to distal medial). Place a second temporary fixation wire in the near cortex at the distal medial aspect of the metatarsal (aiming distal medial to proximal lateral). Do not cross the osteotomy with the temporary fixation wires.

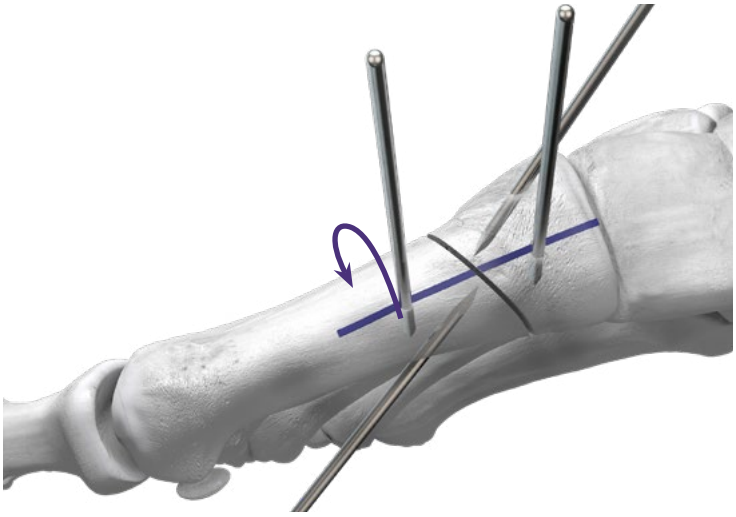


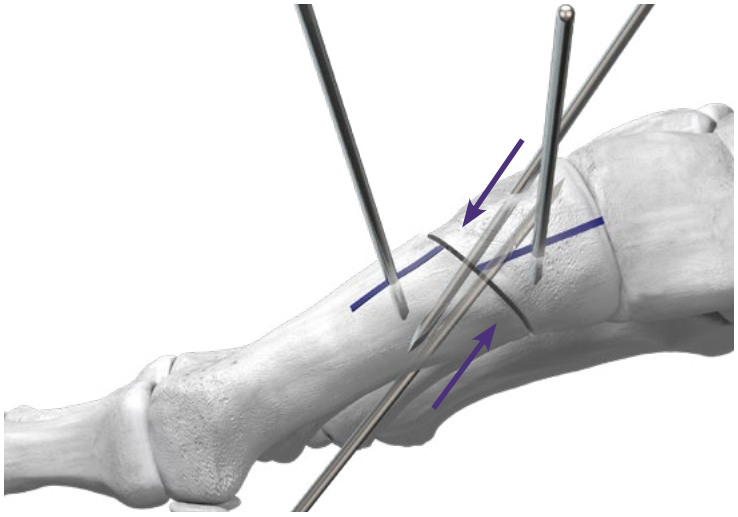


Complete the osteotomy cut.



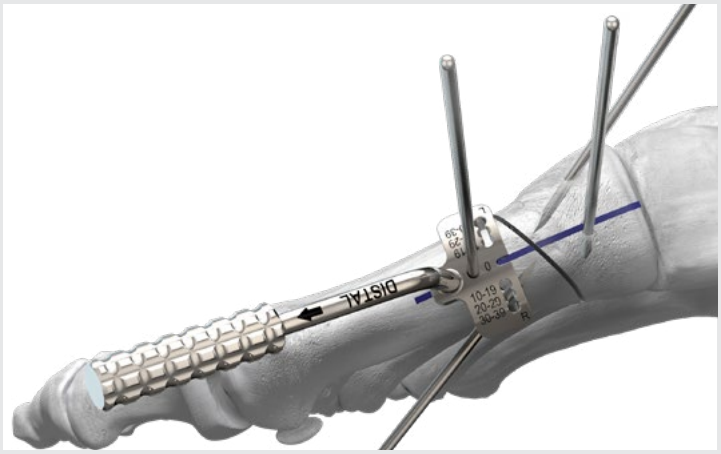
A flat or curved osteotome can be levered back and forth to free bone and soft tissue. Prepare the plantar soft tissue plantar and distal to osteotomy to allow for purchase of the Lobster Claw or Forceps.



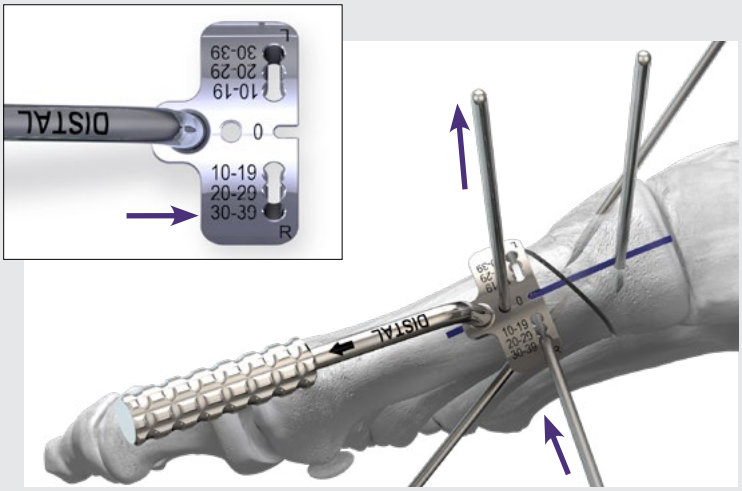


Use a lobster claw clamp or pointed reduction forceps to grasp the distal metatarsal if preferred. Rotate the distal 1st metatarsal out of varus until the distal K-wire is parallel with the proximal K-wire along the medial aspect of the 1st metatarsal. Place temporary fixation wires across the osteotomy.

ALTERNATIVE: DE-ROTATION OF OSTEOTOMY AND TEMPORARY FIXATION

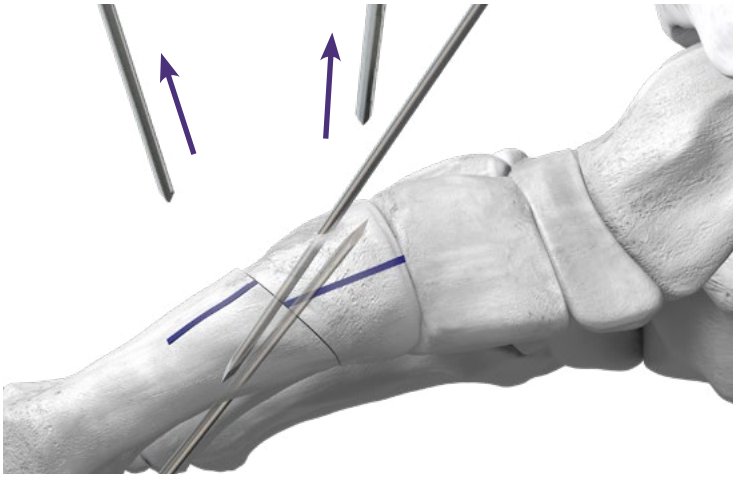


Remove the cutting jig. Insert the rotation guide on the distal K-wire of the metatarsal at the “0” measurement.

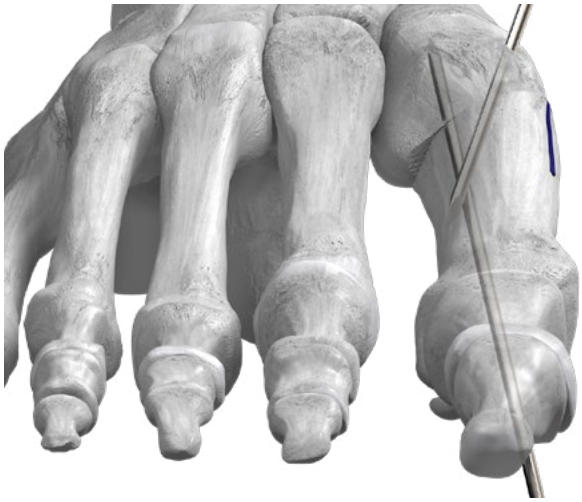


Place a second K-wire in the hole that corresponds to the rotation ∡ (30-39° in this case) that is below the centerline. Remove the K-wire at the “0” measurement.

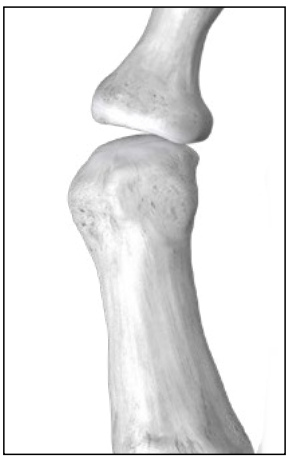
DE-ROTATION OF OSTEOTOMY AND TEMPORARY FIXATION

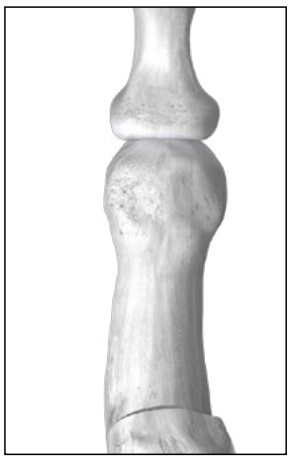


Remove the two K-wires along the medial axis.



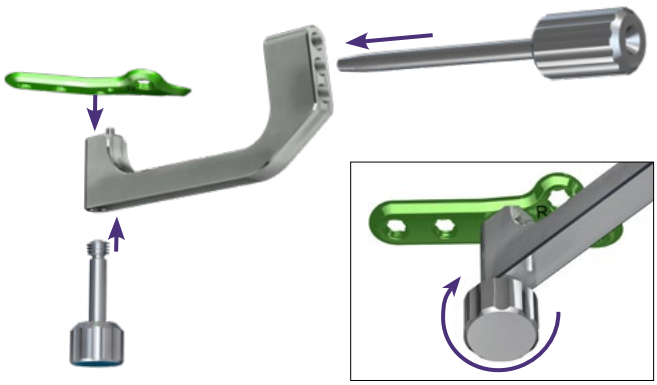
Ensure that the medial cortex is flush without step-off medially. A dorsal step-off may occur.





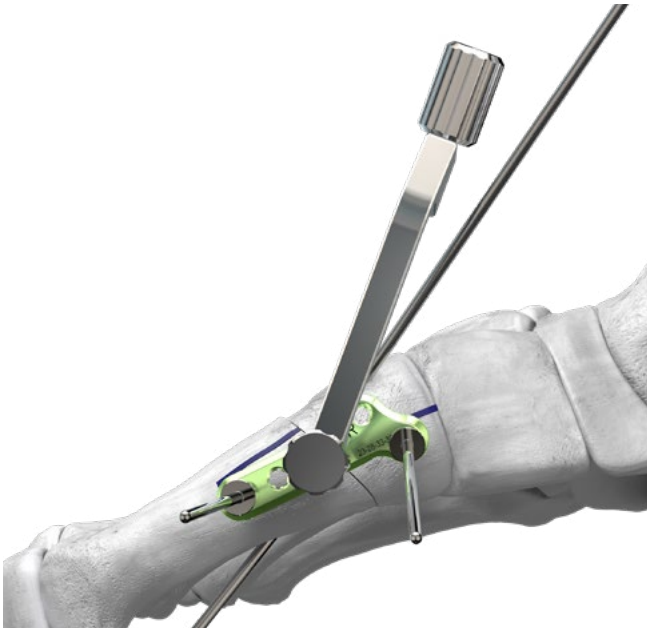
TIP:
If under correction is observed, check to ensure that accidental de-rotation did not occur. If it did not and additional correction is desired, displace the metatarsal segment laterally to decrease the intermetatarsal angle. Do not increase rotation beyond the pre-operative planned angle as the metatarsal can become over plantarflexed.

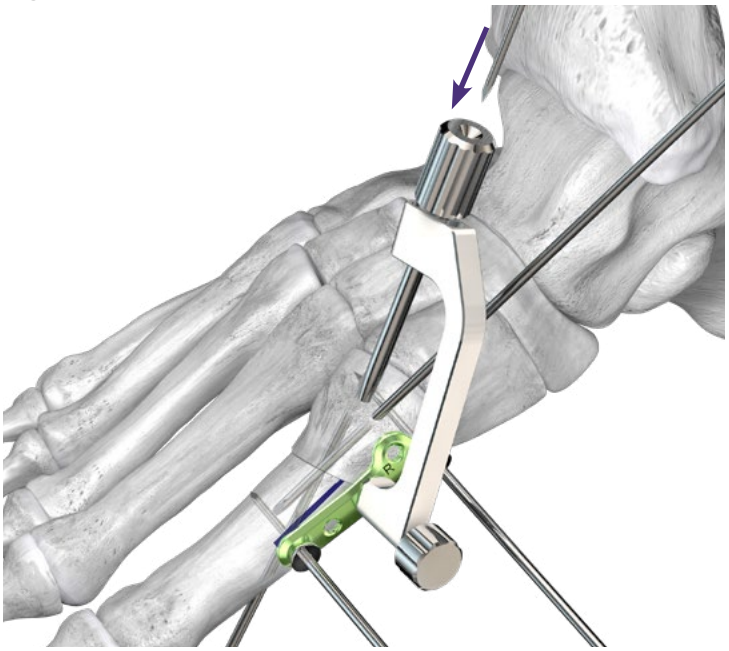
PERMANENT FIXATION



Retrieve the Baby Gorilla PROMO plate that corresponds with the osteotomy cut angle (in this situation, the Angled 23-28-33-38 PROMO Plate). Attach the Precision Guide to the plate by threading the set screw into the central threaded hole of the plate while the alignment peg is inserted into the alignment hole to ensure proper orientation of the Precision Guide. Rotate the set screw clockwise to secure the Precision Guide to the plate. Insert the 1.0 mm or 1.2 mm K-wire guide depending on desired cross-screw diameter (3.0 mm or 3.5 mm, respectively).

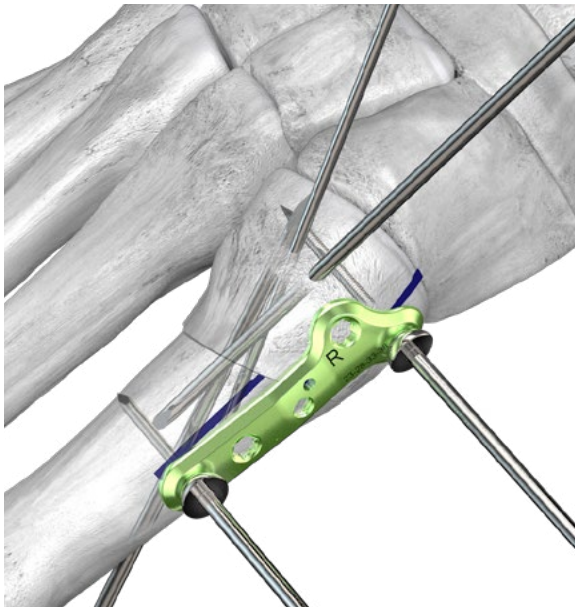
Position the Baby Gorilla PROMO Plate/Precision Guide medially on the 1st metatarsal, centering the plate along the long axis of the 1st metatarsal with the plate holes approximately equidistant from the osteotomy. Secure the plate to the bone using two olive wires. Check plate placement using fluoroscopy.



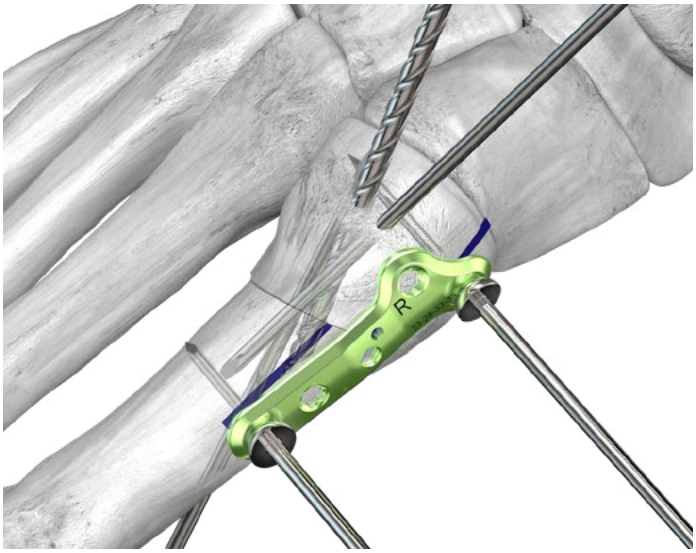


Retrieve a K-wire corresponding to the diameter of Mini-Monster screw used. In this instance, a 1.2 mm K-wire is selected for use with a 3.5 mm Mini-Monster cannulated screw. Drive the K-wire through the K-wire guide, into the bone and across the osteotomy. Check wire position and length using fluoroscopy. Once correct, remove the Precision Guide from the plate by rotating the set screw counterclockwise and sliding the Precision Guide off the 1.2 mm K-wire.

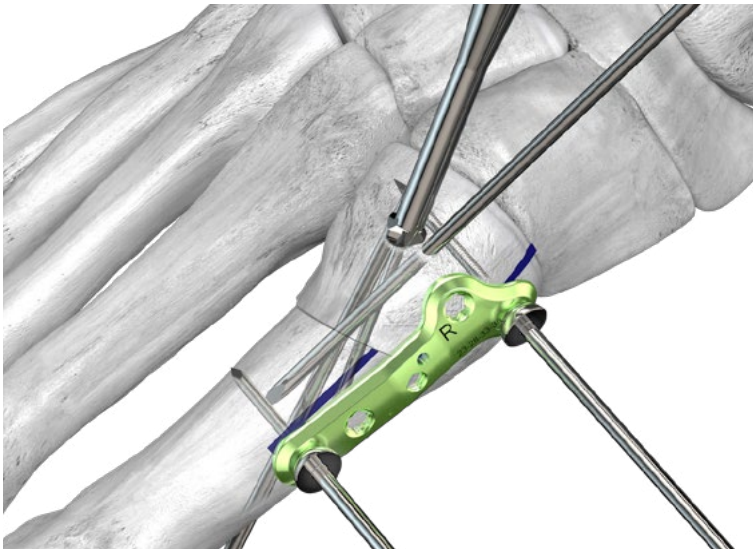
TIP:
If it is desired to place the crossing screw from plantar to dorsal as opposed to dorsal to plantar (shown), drive the K-wire plantarly such that only the tip of the wire remains at the dorsal aspect of the first metatarsal. The subsequent steps would then be performed through the plantar aspect of the 1st metatarsal.



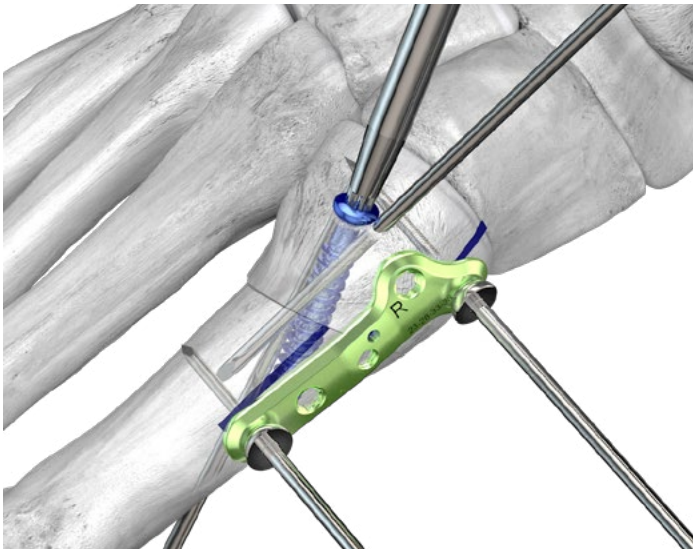
PERMANENT FIXATION



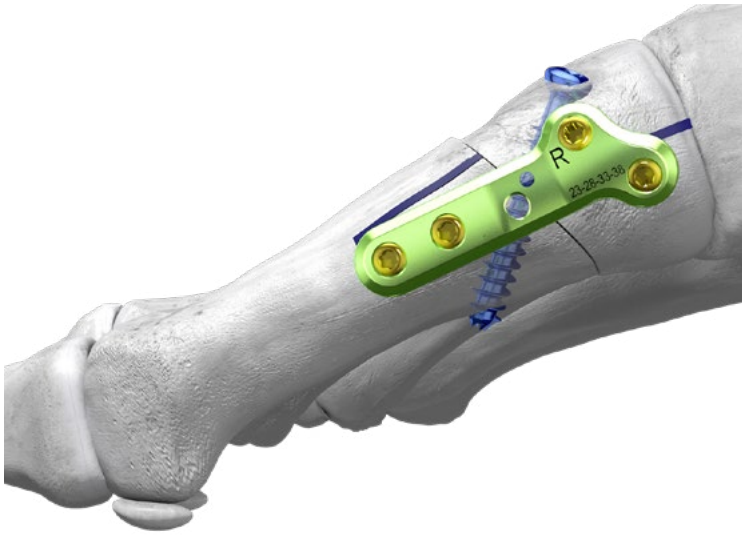
Retrieve the cannulated drill for the 3.5 mm Mini-Monster screw. Drill over the K-wire.



Use the countersink for the 3.5 mm Mini-Monster screw that corresponds to a headed or headless screw, depending on surgeon preference. If using a headed screw, measure following countersinking. If using a headless screw, measure prior to countersinking.



Insert the appropriate length Mini-Monster screw across the osteotomy.



Remove the 1.2 mm K-wire from the Mini-Monster cannulated screw. Fill plate holes with 2.5 mm locking or non-locking screws. Confirm screw position and length using fluoroscopy.

CLOSURE

Proceed to incision closure or concomitant procedures at this time.

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.

PROMO®

PROXIMAL ROTATIONAL METATARSAL OSTEOTOMY

PATENTED, DESIGNED & EXCLUSIVELY DISTRIBUTED BY

Exclusively foot & ankle Paragon 28®

P53-STG-3003 RevB [2024-05-15]

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1. Wagner et al. Is the Rotational Deformity Important in Our Decision Making Process for Correction of Hallux Valgus Deformity? Foot Ankle Clin. (2018); 23: 205-217.

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DISCLAIMER

The purpose of the PROMO™ Surgical Technique Guide is to demonstrate the optionality and functionality of the PROMO™ implants and instrumentation. Although variations in placement and use of the PROMO™ System can be performed, the fixation options demonstrated in this technique were chosen to demonstrate the functionality of the system and for simplicity of explanation. Other uses for the PROMO™ System can be employed, appropriate for the size of the device.