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.

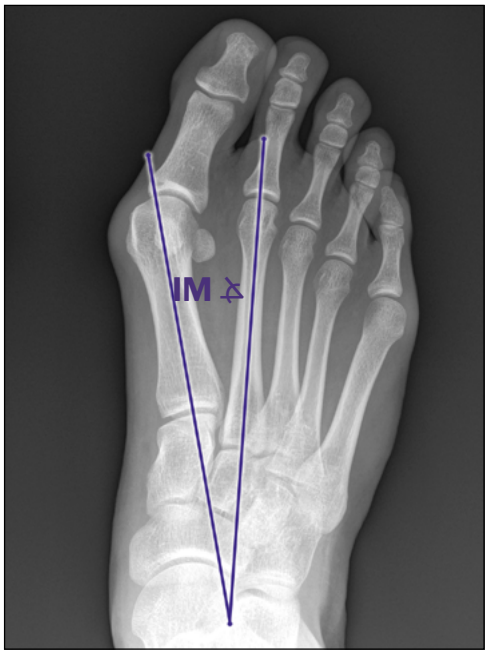
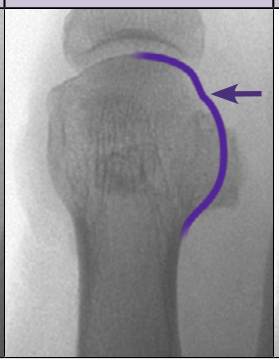


Figure 1

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.

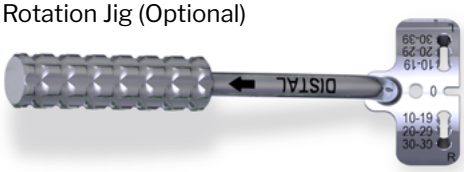
INSTRUMENTATION

Positioning Jig – Left

Positioning Jig – Right

Cutting Jig

Rotation Jig (Optional)



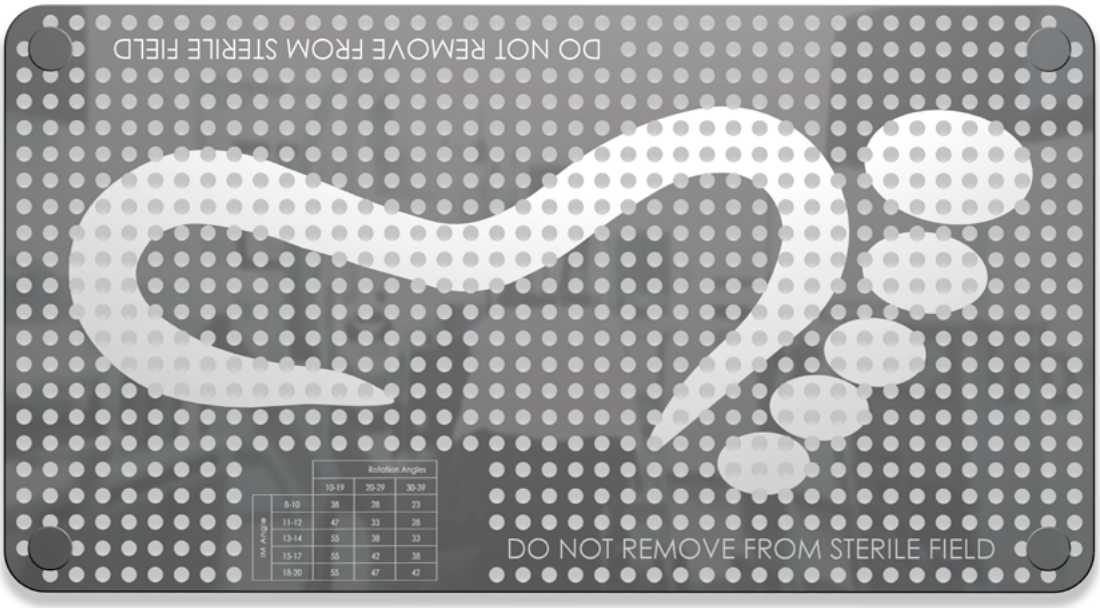
1.0 mm Wire Sleeve

1.2 mm Wire Sleeve

Precision® Guide PROMO

Set Screw

Foot Plate

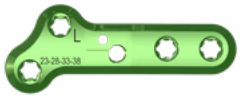


Foot Plate K-wire Guide

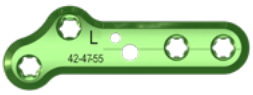
K-wire Guide Retainer

IMPLANTS

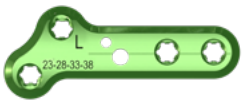
PROMO IMPLANTS - Left and Right Side Specific



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°.

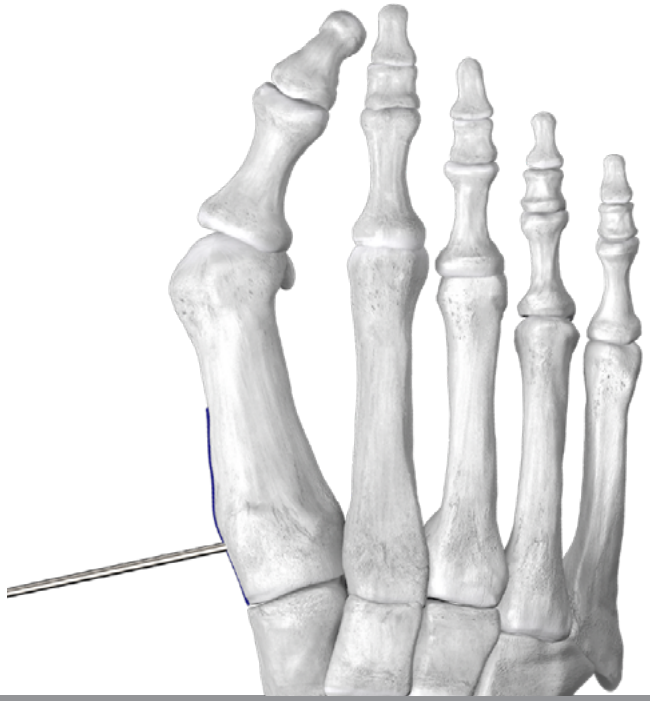
		Rotation Angle		
		10-19	20-20	30-39
IM Angle	8-10	38	28	23
	11-12	47	33	28
	13-14	55	38	33
	15-17	55	42	38
	18-20	55	47	42

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.

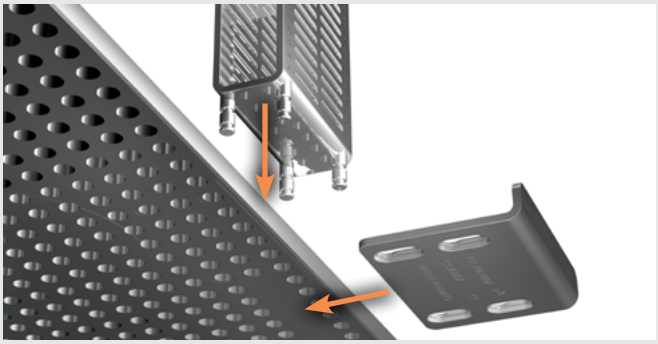
ROTATIONAL CORRECTION

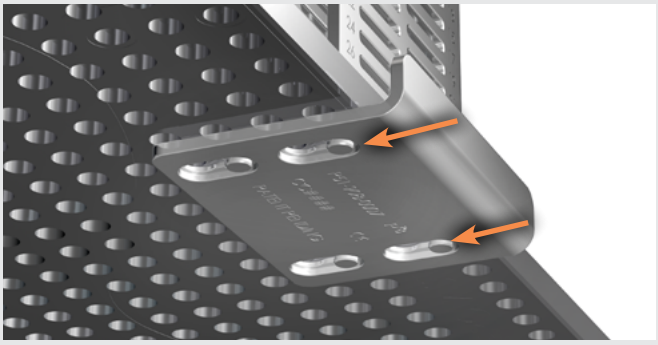
A line is etched along the medial midline of the first metatarsal using a bovie or light skiving with a sagittal saw.



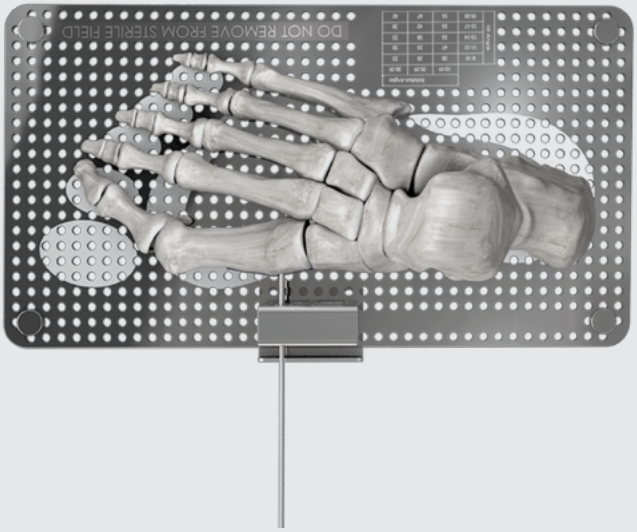
Place a 1.6 mm K-wire through the first metatarsal such that the start point of the K-wire is at the mark corresponding to 1 cm from the 1st tarsometatarsal joint and along the medial midline of the 1st metatarsal.

OPTIONAL: ROTATIONAL CORRECTION



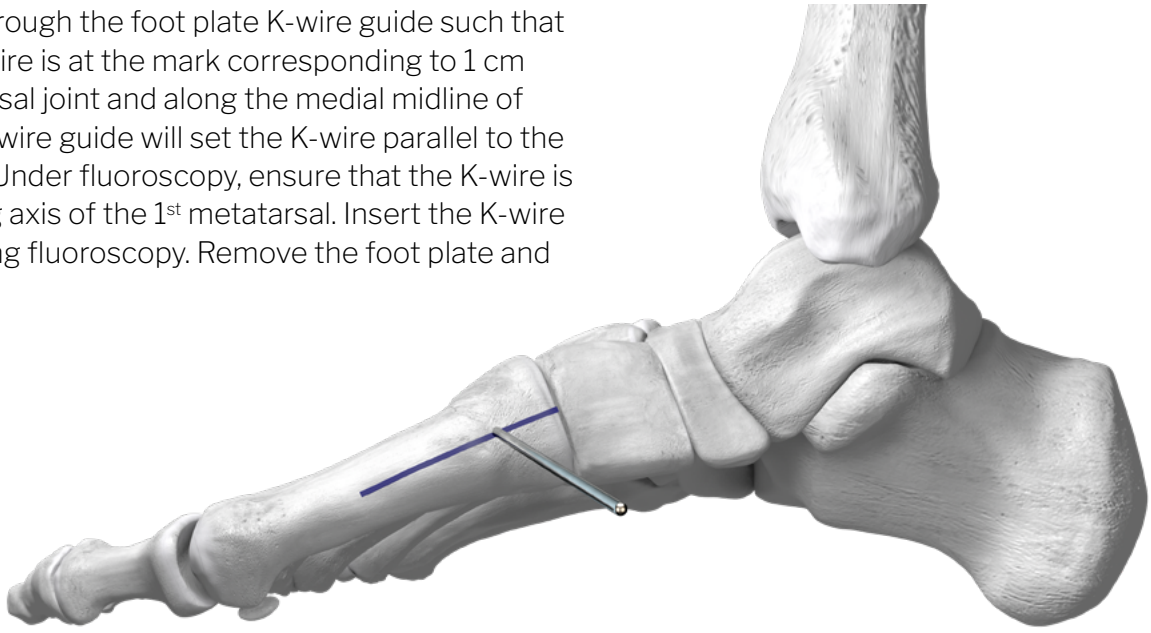


Insert the legs of the foot plate K-wire guide into the edge of the foot plate. Slide the K-wire guide retainer over the legs of the K-wire guide and slide to lock.

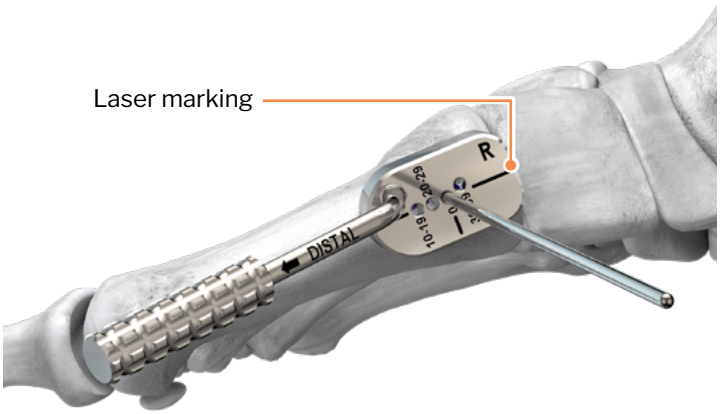


Locate 1 cm from the 1st metatarsal and mark the location with a pen or bovie. Place the foot on the foot plate under fluoroscopy.

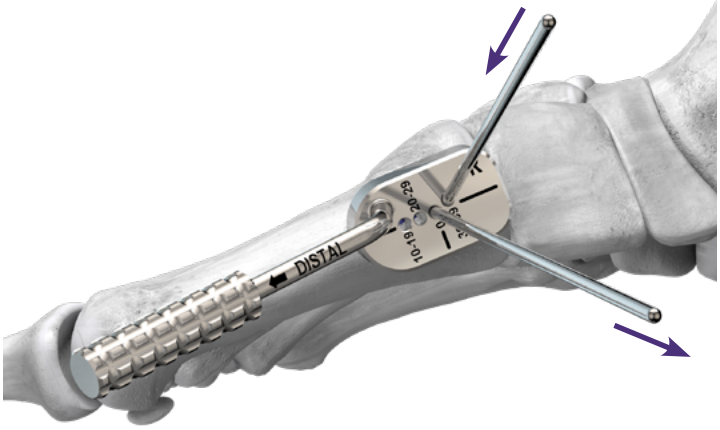
Place a 1.6 mm K-wire through the foot plate K-wire guide such that the start point of the K-wire is at the mark corresponding to 1 cm from the 1st tarsometatarsal joint and along the medial midline of the 1st metatarsal. The K-wire guide will set the K-wire parallel to the weight-bearing surface. Under 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

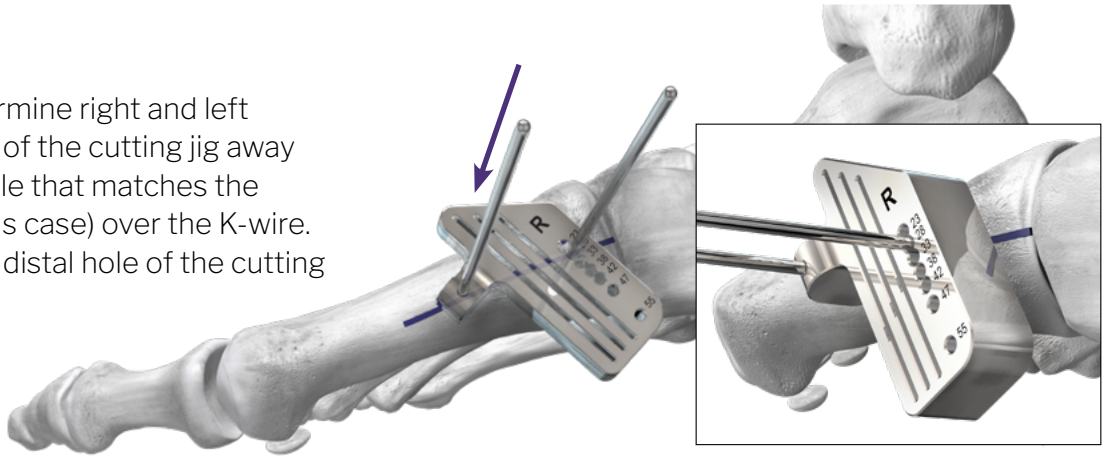


Slide the positioning jig over the K-wire at the “0” hole. This will now be referred to as the “0” K-wire. The laser marking should align with the line etched along the medial midline drawn on the 1st metatarsal.



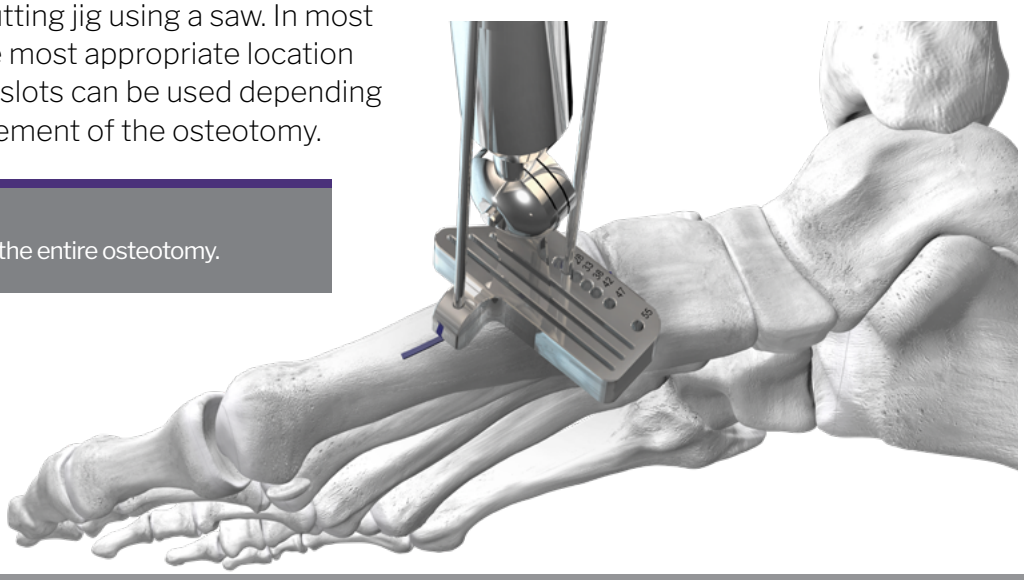
Obtain a second 1.6 mm K-wire. Place the 1.6 mm K-wire into the hole that corresponds to the rotation hole (in this instance, the 30-39 degree hole). Remove the “0” K-wire.

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.



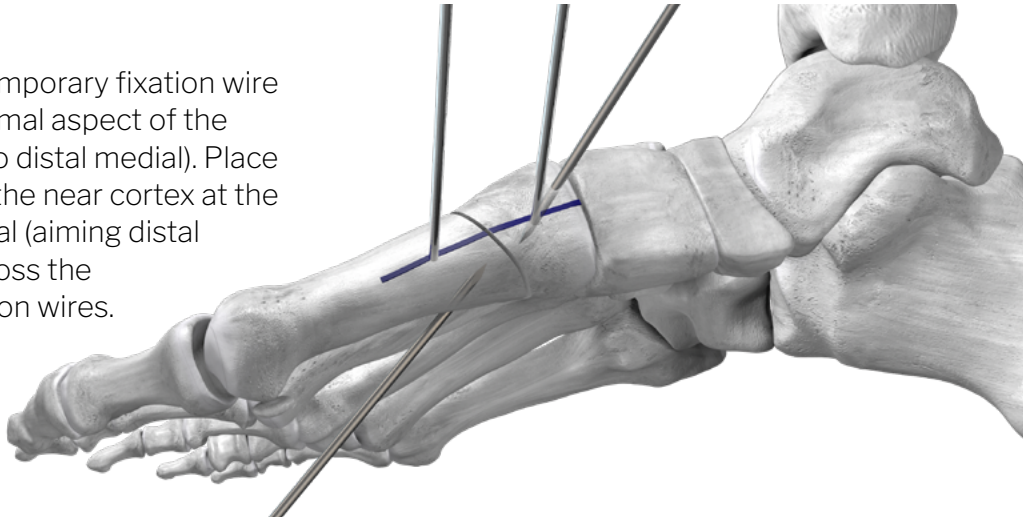
Perform an osteotomy through the cutting jig using a saw. In most instances, the proximal slot will be the most appropriate location for the osteotomy. Either of the three slots can be used depending on surgeon preference and ideal placement of the osteotomy.

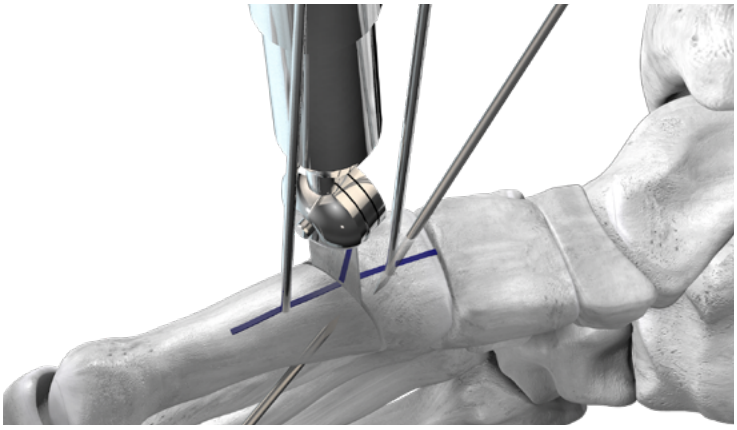
NOTE:
A saw blade may not extend across the entire osteotomy.



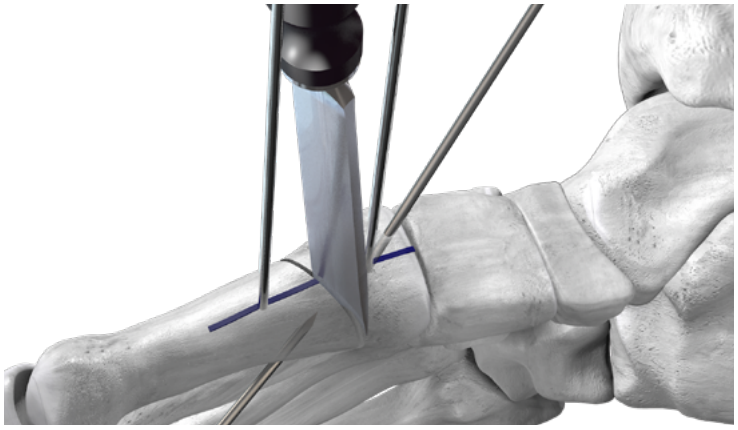
ROTATIONAL CORRECTION

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.

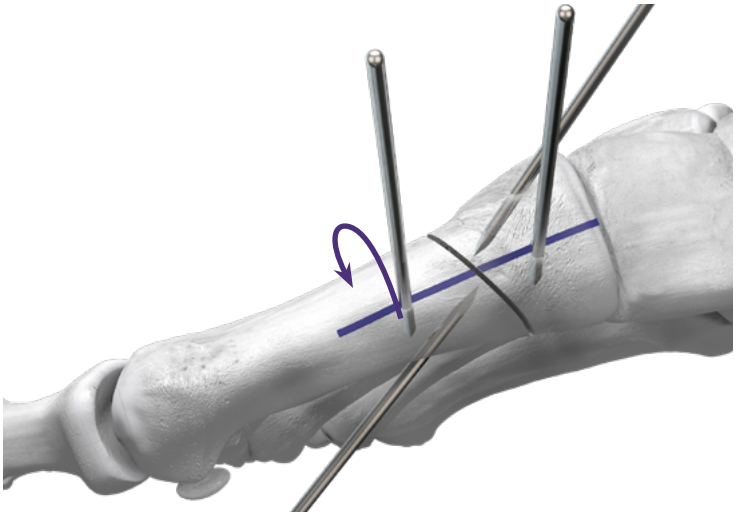


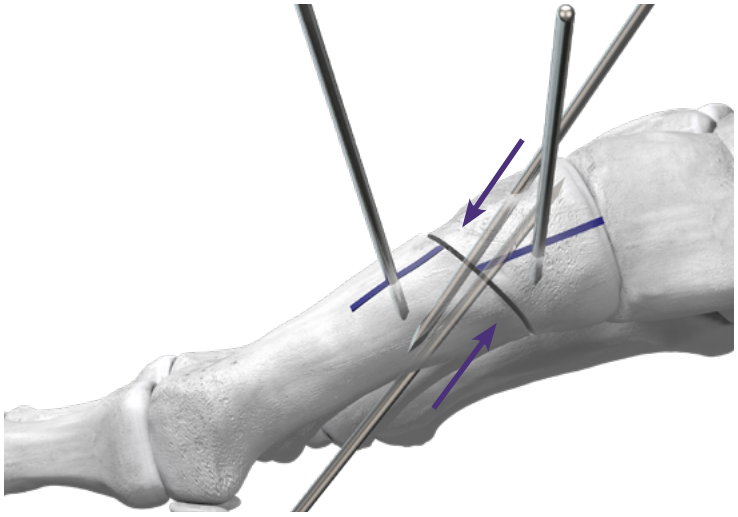


Complete the osteotomy cut.



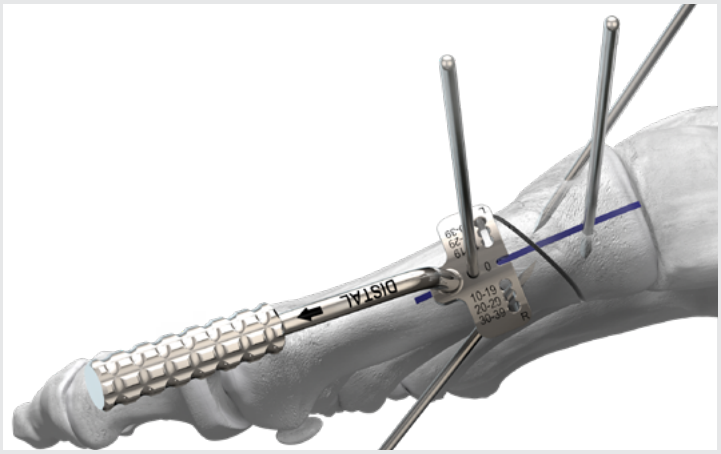
A flat or curved osteotome can be levered back and forth to free bone and soft tissue. Prepare the plantar soft tissue plantar and distal to osteotomy to allow for purchase of the Lobster Claw or Forceps.



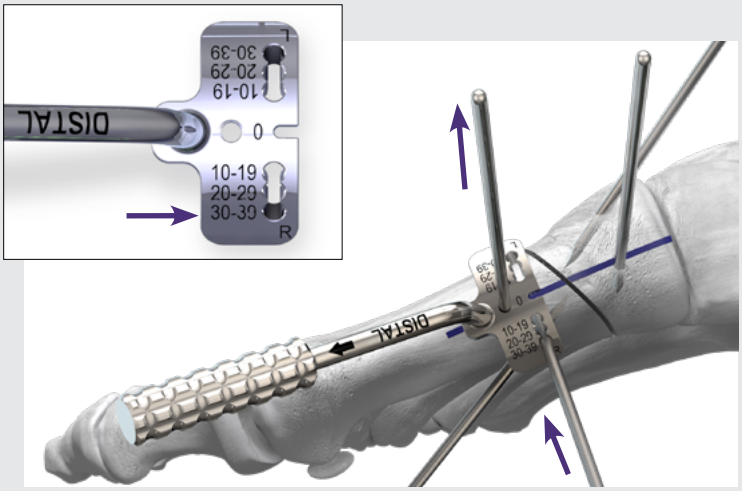


Use a lobster claw clamp or pointed reduction forceps to grasp the distal metatarsal if preferred. Rotate the distal 1st metatarsal out of varus until the distal K-wire is parallel with the proximal K-wire along the medial aspect of the 1st metatarsal. Place temporary fixation wires across the osteotomy.

ALTERNATIVE: DE-ROTATION OF OSTEOTOMY AND TEMPORARY FIXATION

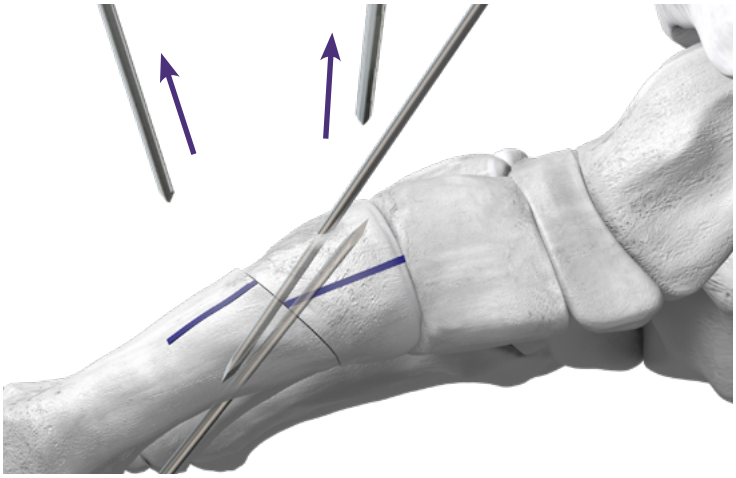


Remove the cutting jig. Insert the rotation guide on the distal K-wire of the metatarsal at the “0” measurement.

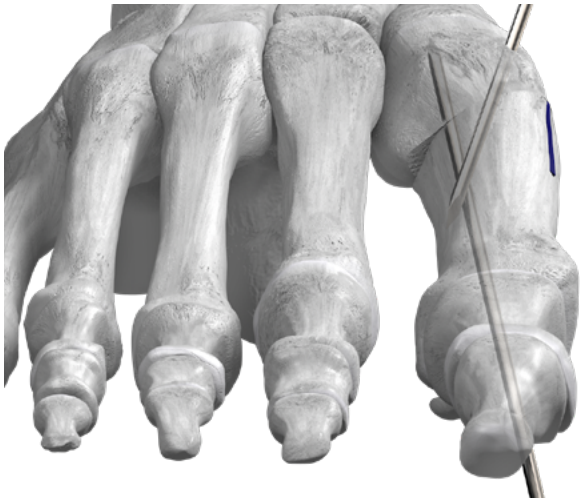


Place a second K-wire in the hole that corresponds to the rotation ∡ (30-39° in this case) that is below the centerline. Remove the K-wire at the “0” measurement.

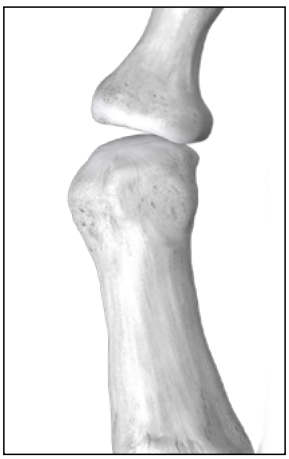
DE-ROTATION OF OSTEOTOMY AND TEMPORARY FIXATION

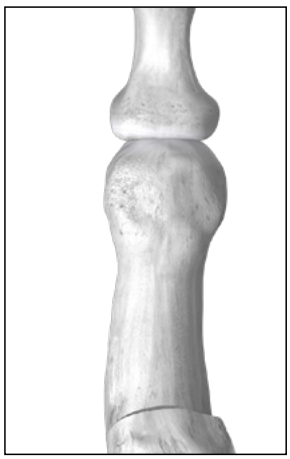


Remove the two K-wires along the medial axis.



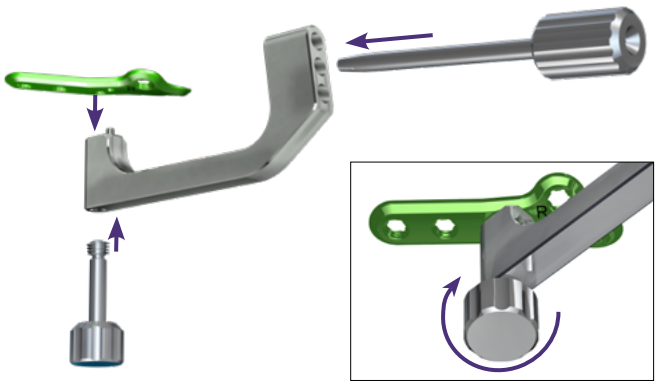
Ensure that the medial cortex is flush without step-off medially. A dorsal step-off may occur.





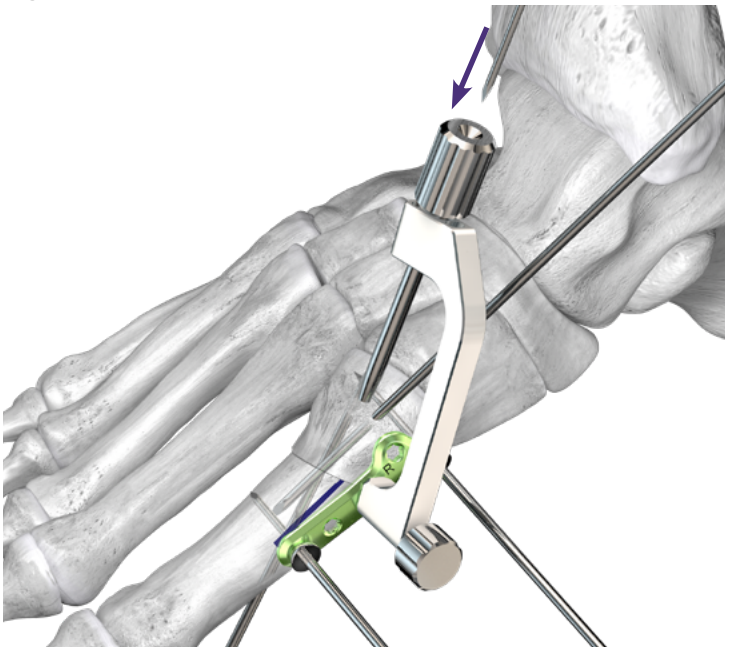
TIP:
If under correction is observed, check to ensure that accidental de-rotation did not occur. If it did not and additional correction is desired, displace the metatarsal segment laterally to decrease the intermetatarsal angle. Do not increase rotation beyond the pre-operative planned angle as the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

PERMANENT FIXATION



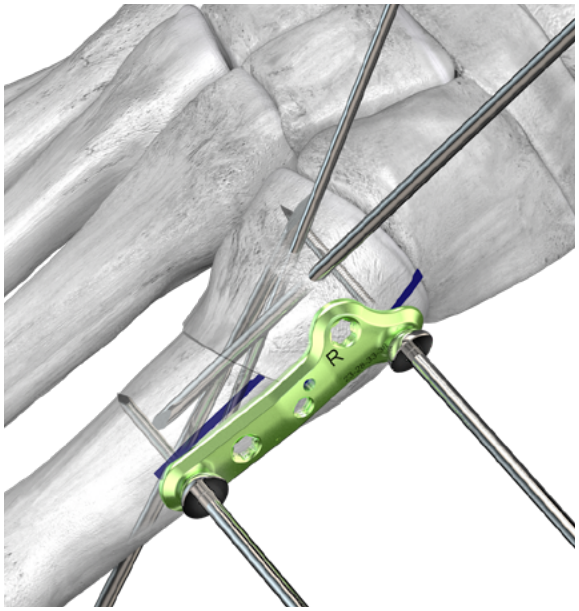
Retrieve the Baby Gorilla PROMO plate that corresponds with the osteotomy cut angle (in this situation, the Angled 23-28-33-38 PROMO Plate). Attach the Precision Guide to the plate by threading the set screw into the central threaded hole of the plate while the alignment peg is inserted into the alignment 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.

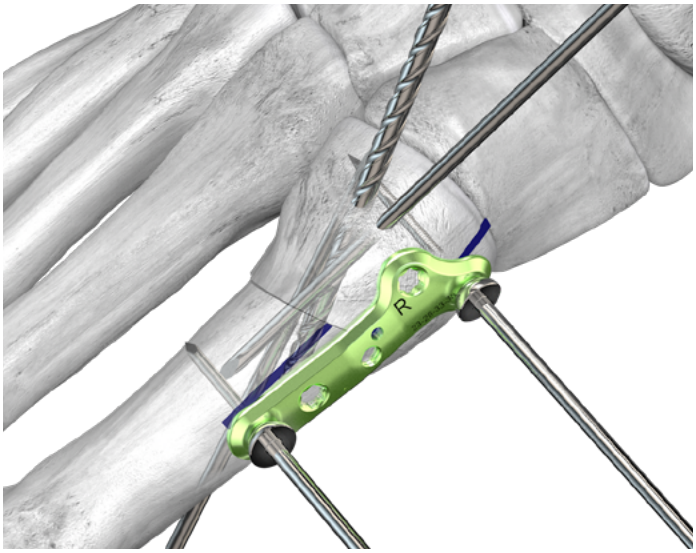


Retrieve a K-wire corresponding to the diameter of Mini-Monster screw used. In this instance, a 1.2 mm K-wire is selected for use with a 3.5 mm Mini-Monster cannulated screw. Drive the K-wire through the K-wire guide, into the bone and across the osteotomy. Check wire position and length using fluoroscopy. 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.

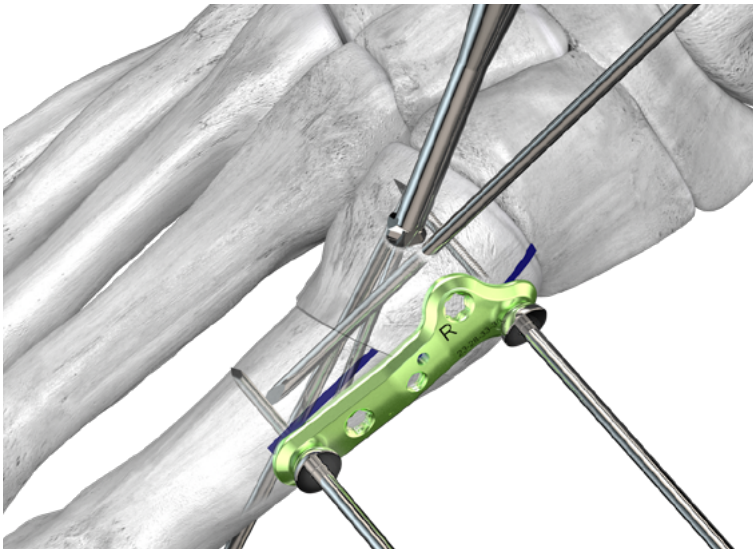
TIP:
If it is desired to place the crossing screw from plantar to dorsal as opposed to dorsal to plantar (shown), drive the K-wire plantarly such that only the tip of the wire remains at the dorsal aspect of the first metatarsal. The subsequent steps would then be performed through the plantar aspect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



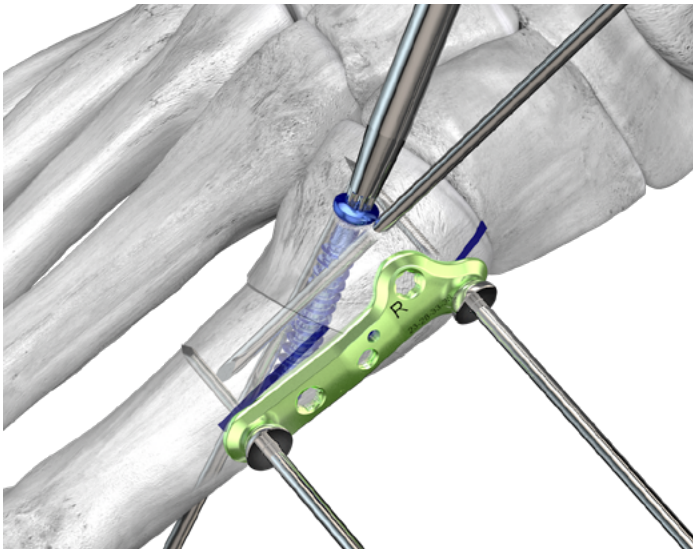
PERMANENT FIXATION



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.

BABY GORILLA PLATING SYSTEM - PROMO PLATING CASE

Part #	Description	Use
P99-000-AORC	Mini-AO Racheting Handle Streamline Cannulated	Reusable
P99-000-AOMN	Mini-AO Ratcheting Handle Streamline, Cannulated, Medium	Reusable
P99-150-0013	Sharp Tip Bone Reduction Clamp	Reusable
P99-150-0017	Lobster Claw	Reusable
P51▯910▯0003	Plate Bending Pliers	Reusable
P99-900-1008	Radiolucent Plantigrade Foot Plate, V1.5	Reusable

BABY GORILLA PLATING SYSTEM - PROMO PLATE AND INSTRUMENT CADDY I

Part #	Description	Use
P53-014-L001	PROMO Plate Left Size 1	Single-use
P53-014-L002	PROMO Plate Left Size 2	Single-use
P53-014-L003	PROMO Plate Left Size 3	Single-use
P53-014-L004	PROMO Plate Left Size 4	Single-use
P53-014-R001	PROMO Plate Right Size 1	Single-use
P53-014-R002	PROMO Plate Right Size 2	Single-use
P53-014-R003	PROMO Plate Right Size 3	Single-use
P53-014-R004	PROMO Plate Right Size 4	Single-use
P53-001-1010	Akin Plate, Straight, 10 mm	Single-use
P53-001-1C10	Akin Plate, w/Compression, 10 mm	Single-use
P53-001-2010	Akin Plate, Medial, Anatomic, 10 mm	Single-use
P51-908-R001	PROMO Placement Jig Right	Reusable
P51-908-L001	PROMO Placement Jig Left	Reusable
P51-908-0002	PROMO Cut Guide	Reusable
P51-908-0003	PROMO Rotation Jig	Reusable
P51-908-0004	Foot Plate K-Wire Guide	Reusable
P51-908-0006	PROMO Precision Guide	Reusable
P51-908-0007	Foot Plate K-Wire Guide Retainer	Reusable
P51-950-0001	Precision Guide Set Screw	Reusable
P51-950-0010	Guidewire Sleeve 1.0 mm	Reusable
P51-950-0012	Guidewire Sleeve 1.2 mm	Reusable
P99-200-1307	1.3, smooth olive, 7 cm	Single-use
P99-201-1307	1.3, threaded olive, 7 cm	Single-use
P99-192-1615	K-wire, Single Ended Trocar Tip, SMOOTH, 1.6 x 150 mm	Single-use
P99-192-1610	K-wire, Single Ended Trocar Tip, SMOOTH, 1.6 x 100 mm	Single-use

BABY GORILLA PLATING SYSTEM - PROMO PLATE AND INSTRUMENT CADDY II

Part #	Description	Use
P51-908-R011	PROMO Positioning Jig Right	Reusable
P51-908-L011	PROMO Positioning Jig Left	Reusable
P51-908-0012	PROMO Cut Guide	Reusable
P51-908-0013	PROMO Rotation Jig	Reusable

BABY GORILLA PLATING SYSTEM - PROMO PLATE AND INSTRUMENT CADDY II

Part #	Description	Use
P51-908-0004	Foot Plate K-Wire Guide	Reusable
P51-908-0010	PROMO Precision Guide, 6 Barrel	Reusable
P51-908-0007	Foot Plate K-Wire Guide Retainer	Reusable
P51-950-0001	Precision Guide Set Screw	Reusable
P51-950-0010	Guidewire Sleeve 1.0 mm	Reusable
P51-950-0012	Guidewire Sleeve 1.2 mm	Reusable
P53-014-L002	PROMO Plate Left, Straight, Short	Single-use
P53-014-L003	PROMO Plate Left, Straight, Long	Single-use
P53-014-L021	PROMO Plate, Left, Angled, Short	Single-use
P53-014-L022	PROMO Plate, Left, Angled, Long	Single-use
P53-014-R002	PROMO Plate Right, Straight, Short	Single-use
P53-014-R003	PROMO Plate Right, Straight, Long	Single-use
P53-014-R021	PROMO Plate,Right, Angled, Short	Single-use
P53-014-R022	PROMO Plate, Right, Angled, Long	Single-use
P53-001-1010	Akin Plate, Straight, 10 mm	Single-use
P53-001-1C10	Akin Plate, w/Compression, 10 mm	Single-use
P53-001-2010	Akin Plate, Medial, Anatomic, 10 mm	Single-use
P99-200-1307	1.3, smooth olive, 7 cm	Single-use
P99-201-1307	1.3, threaded olive, 7 cm	Single-use
P99-250-1608	1.6, smooth olive, 8 cm	Single-use
P99-192-1615	K-wire, Single Ended Trocar Tip, SMOOTH, 1.6 x 150 mm	Single-use
P99-192-1610	K-wire, Single Ended Trocar Tip, SMOOTH, 1.6 x 100 mm	Single-use

BABY GORILLA PLATING SYSTEM - PROMO SCREW CADDY

Part #	Description	Use
P20-910-2000	Countersink, 2.0 Headed	Reusable
P20-915-2000	Countersink, 2.0 Headless	Reusable
P20-910-2500	Countersink, 2.5/2.7 Headed	Reusable
P20-915-2500	Countersink, 2.5 Headless	Reusable
P20-920-2500	Tap, 2.5/2.7, Cannulated	Reusable
P20-951-2040	Depth Gauge (2.0 - 4.0 mm)	Reusable
P99-110-1712	Drill, 1.7 x 120mm, Cannulated, AO	Single-use
P99-192-0915	K-wire, Single Ended Trocar Tip, SMOOTH, 0.9 x 150 mm	Single-use
P99-292-0915	K-wire, Double Ended Trocar Tip, SMOOTH, 0.9 x 150 mm	Single-use
P20-941-2025	Drill Guide, 2.0/2.5	Reusable
P99-191-TS07	Screw Driver Attachment, Solid, AO, TX-7	Reusable
P99-191-SL07	Mini-Screw Gripper	Reusable
P99-190-TX06	Modified Tx 6 Screw Driver Attachment, Cannulated	Reusable
P99-191-TX06	Screw Driver Attachment, Solid, AO, HX-6	Reusable
P99-190-SL06	Holding Sleeve, HX-6	Reusable
P50-153-WM00	Baby Gorilla, Washer	Single-use
P20-020-DW00	Washer, 2.0 Headed	Single-use

BABY GORILLA PLATING SYSTEM - PROMO SCREW CADDY

Part #	Description	Use
P20-025-DW00	Washer, 2.5 Headed	Single-use
P50-053-20[08-36]	BG Locking Screw, 2.0 x 8-36mm	Single-use
P50-153-20[08-36]	BG Non-Locking Screw 2.0 x 8-36mm	Single-use
P50-053-25[08-36]	BG Locking Screw, 2.5 x 8-36mm	Single-use
P50-153-25[08-36]	BG Non-Locking Screw 2.5 x 8-36mm	Single-use
P20-120-0[10-36]S	Mini-Monster Cannulated, Short Thread Screw, Headed, 2.0 x 10 mm	Single-use
P20-125-0[10-36]S	Mini-Monster Cannulated, Short Thread Screw, Headed, 2.5 x 10 mm	Single-use
P20-520-0[10-36]S	Mini-Monster Cannulated, Short Thread Screw, Headless, 2.0 x 10 mm	Single-use
P20-525-0[10-36]S	Mini-Monster Cannulated, Short Thread Screw, Headless, 2.5 x 10 mm	Single-use

*See the complete Baby Gorilla Plating System Surgical Technique Guide (P53-STG-1001) for general instrument information

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

Indications, Contraindications, Warnings and Precautions relevant to the PROMO® Plating system are contained in the Instructions for Use document of the Gorilla® Plaiting System P51-IFU-1001.

MRI SAFETY INFORMATION

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

Name/Identification of device	Baby Gorilla®/Gorilla® Plating System Implant
Static Magnetic Field Strength [B0]	1.5 T or 3 T
Maximum Spatial Field Gradient	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
Limits on Scan Duration	2.0 W/kg or whole body average SAR for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks)
MR Image Artifact	32mm

Refer to www.paragon28.com/ifus for the complete and most current Instructions for Use document.

INSTRUCTIONS FOR USE: MONSTER® SCREW SYSTEM

Indications, Contraindications, Warnings and Precautions relevant to the PROMO® Plating system are contained in the Instructions for Use document of the Monster® Screw system P20-IFU-1001.

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 to the patient.

Name/Identification of device	Paragon 28® Monster® Screw System
Static Magnetic Field Strength [B0]	1.5 T or 3.0 T
Maximum Spatial Field Gradient	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 from the implant.

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

PROMO®

PROXIMAL ROTATIONAL METATARSAL OSTEOTOMY

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Exclusively foot & ankle Paragon 28®

Paragon 28, Inc.
14445 Grasslands Dr.
Englewood, CO 80112
(855) 786-2828

CE 2797	Class Ir, IIa, IIb
CE	Class I Self Certify

EC REP
Emergo Europe
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

CH REP
MedEnvoy Switzerland
Gotthardstrasse 28
6302 Zug
Switzerland

UK Responsible Person
MedEnvoy UK Ltd
85 Great Portland St.
London, W1W 7LT,
UK

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.

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.