

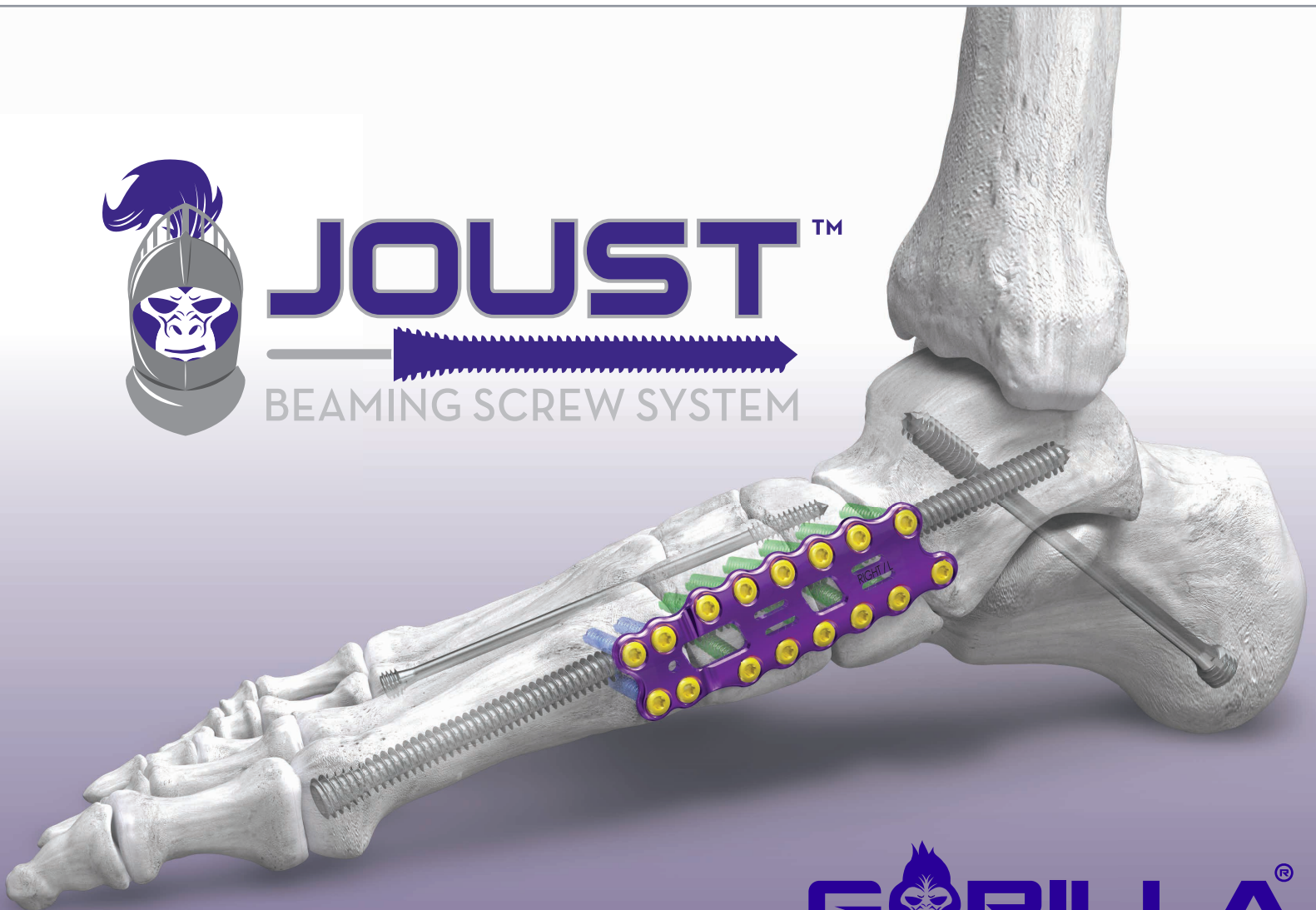
SURGICAL TECHNIQUE GUIDE:

MEDIAL COLUMN BEAMING

Exclusively foot & ankle **Paragon[®] 20**



JOUST[™]
BEAMING SCREW SYSTEM



GORILLA[®]
R3CON PLATING SYSTEM

Acknowledgment:

Paragon 28® would like to thank Michael S. Kerzner, DPM for his contribution to the development of the surgical technique guide.

PRODUCT DESCRIPTION

Paragon 28® designed the Joust™ Beaming Screw System to provide surgeons with options for Charcot neuroarthropathy when surgery is indicated. The Joust™ Beaming Screw System offers 220 beaming screws in 5.0 mm, 5.5 mm and 7.2 mm diameters with solid, cannulated, fully threaded and partially threaded implants, to allow the surgeon to select the preferred implant type for their patient. The Joust™ Beaming Screw System can be used standalone or combined with the Gorilla® Straddle Plate. The Gorilla® Straddle Plate is a 2.0 mm thick plate with a height suitable for the medial column, designed to resist bending and help align the medial column. Like the beaming screws, the Gorilla® Straddle Plate can be used alone, or in combination with the Joust™ Beaming Screw System where a patent-pending Precision® Reduction Guide allows for a beaming screw to be placed between on-axis plate screws without interference.

A Reduction Tube is offered to provide bone apposition along a guide wire in the medial column prior to placing a beaming screw or straddle plate (Figure 1). The surgical technique presented in the subsequent pages demonstrates the use of the Joust™ Beaming Screw placed using the Precision® Reduction Guide, the Reduction Tube, and subsequent Gorilla® Straddle Plate placement via the Precision® Guide Arm (Figure 2). Other methods of using the Joust™ Beaming System can be employed, depending on surgeon preference and patient pathology. The versatility of sizing of the Joust™ Beaming Screw System allows for use in other areas of the foot and ankle (Figure 3 & 4).

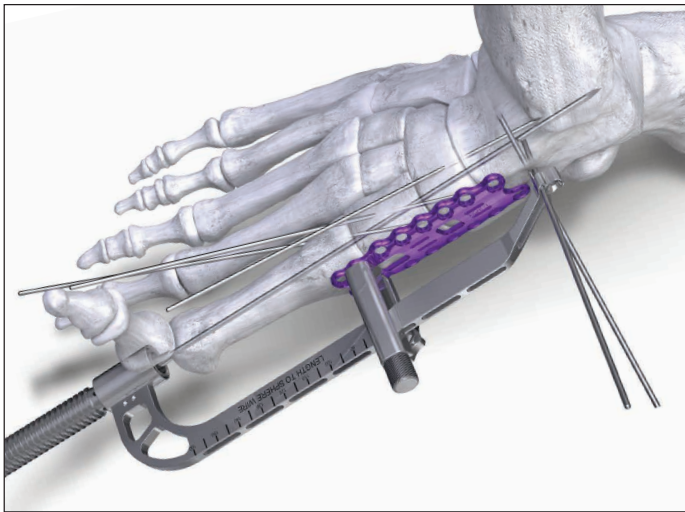


Figure 1

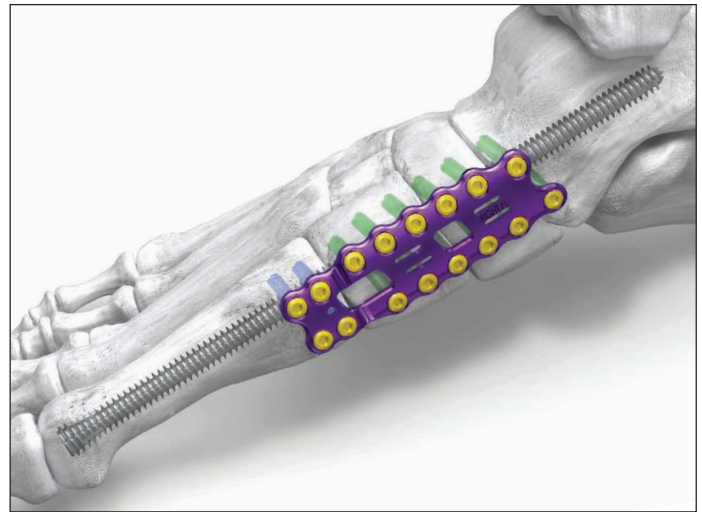


Figure 2



Figure 3




Figure 4

IMPLANT OFFERING

Joust Beaming Screws (220 Unique Implants)

Beaming Screw Features:

- Constructed from Titanium Alloy that is Type II Anodized for improved fatigue strength ¹
- Headless to minimize prominence and help avoid impingement
- Sharp tip

	Ø5.0 mm Beaming Screw	Ø5.5 mm Beaming Screw	Ø7.2 mm Beaming Screw
			
Total Beaming Screws:	60	60	100
Beaming Screw Lengths:	50 mm - 120 mm (5 mm increments)		65 mm - 185 mm (5 mm increments)
Fully and Partially Threaded:	Yes	Yes	Yes
Solid and Cannulated:	Yes	Yes	Yes
K-wire size:	Ø1.4 x 230 mm	Ø1.6 x 230 mm	Ø2.3 x 230 mm Ø2.3 x 300 mm
Drill size:	 Ø3.3 mm	 Ø3.5 mm	 Ø4.6 mm Standard Ø4.6 mm Long
Tap size:	 Ø5.0 mm	 Ø5.5 mm	--
Countersink size:	 Ø5.0 mm	 Ø5.5 mm	 Ø7.2 mm
Driver size:	 TX-20	 TX-25	 TX-30 Standard TX-30 Long

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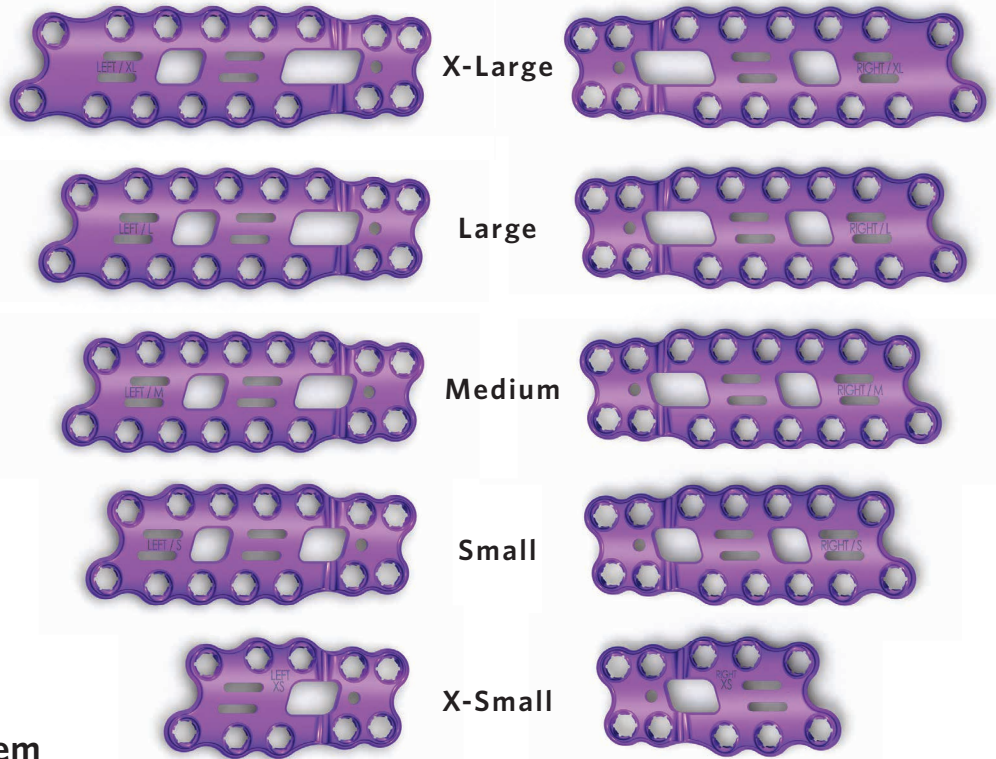
FEATURED INSTRUMENTS

Gorilla Straddle Plates

- Left and Right Side Specific

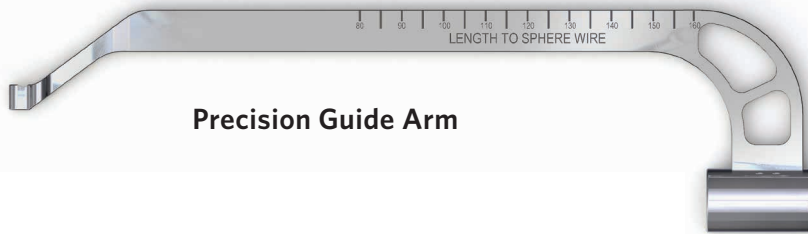
Straddle Plate Features:

- Larger sizes designed to span 1st metatarsal to talus
- 2.0 mm thickness, with a reduction in thickness at the 1st tarsometatarsal to facilitate bending, if necessary
- Open slots allow for visibility in the joint space while placing a Joust Beaming Screw



Precision Reduction Guide System

- Patent-pending system guides the initial placement of the beaming screw insertion point at the first metatarsal head in order to align the trajectory of the beaming screw within the intramedullary canal and along the medial column
- Aligns the straddle plate and beaming screw trajectory, if used together



Precision Guide Arm



Drill Guide



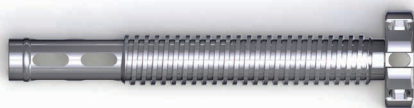
Ø1.4 mm K-wire Guide



Ø1.6 mm K-wire Guide



Ø2.3 mm K-wire Guide



Reduction Tube



Reduction Tube Cap-Large



Reduction Tube Cap-Small



Sphere Wire



U-Clamp



Threaded Knob



Reduction Tube Tommy Bar

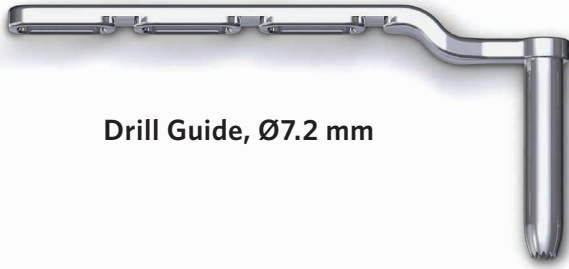


Set Screw

SURGICAL TECHNIQUE GUIDE:

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OTHER INSTRUMENTATION



Drill Guide, Ø7.2 mm



Tissue Protector, Ø7.2 mm



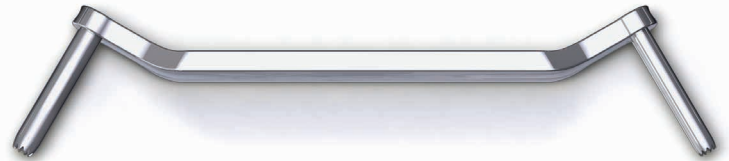
K-wire Guide, Ø5.0 mm



K-wire Guide, Ø5.5 mm



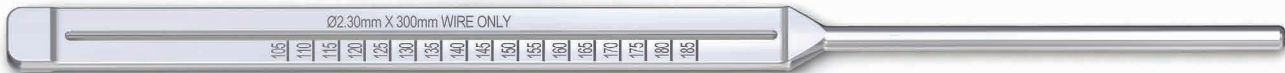
K-wire Guide, Ø7.2 mm



Drill Guide, Ø5.0 mm and Ø5.5 mm



Depth Gauge, Ø5.0 mm and Ø5.5 mm Beaming Screws



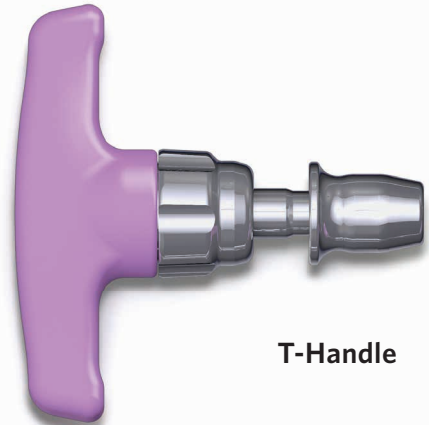
Depth Gauge, Ø7.2 mm Beaming Screws



Jacobs Adapter



Handle



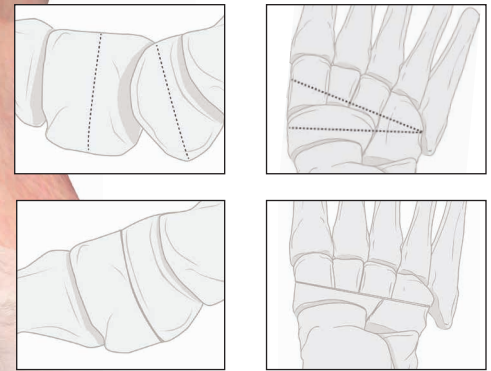
T-Handle

SURGICAL TECHNIQUE GUIDE:

MEDIAL COLUMN BEAMING

INCISION/EXPOSURE

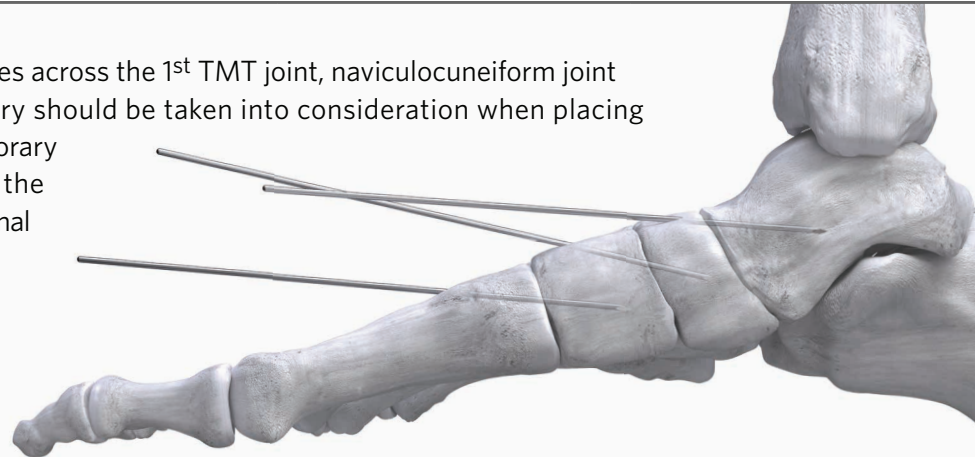
An incision is made at the interval between the tibialis anterior and tibialis posterior tendons. Continue the incision distally across the 1st TMT joint. Soft tissue dissection is carried down to the 1st metatarsal, medial cuneiform, navicula and talus. Joint preparation is performed according to surgeon preference.



Significant bone relocation or an osteotomy may be required in this area to allow for proper plantigrade foot positioning and alignment of the medial column in the sagittal, frontal and transverse planes.

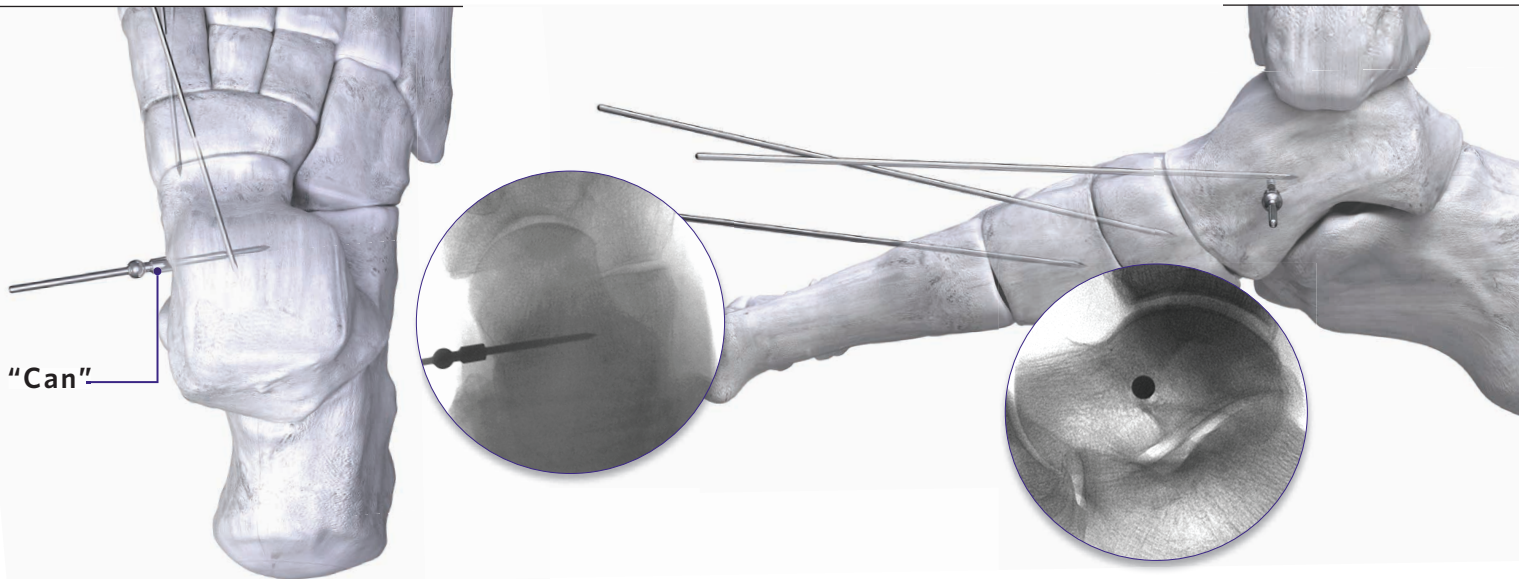
TEMPORARY FIXATION

Temporary fixation is performed by placing K-wires across the 1st TMT joint, naviculocuneiform joint and talonavicular joint. Beaming screw trajectory should be taken into consideration when placing temporary fixation K-wires. Removal of the temporary K-wires and re-pinning may be required during the procedure based on K-wire trajectory and additional beaming screw instrumentation.



SPHERE WIRE PLACEMENT

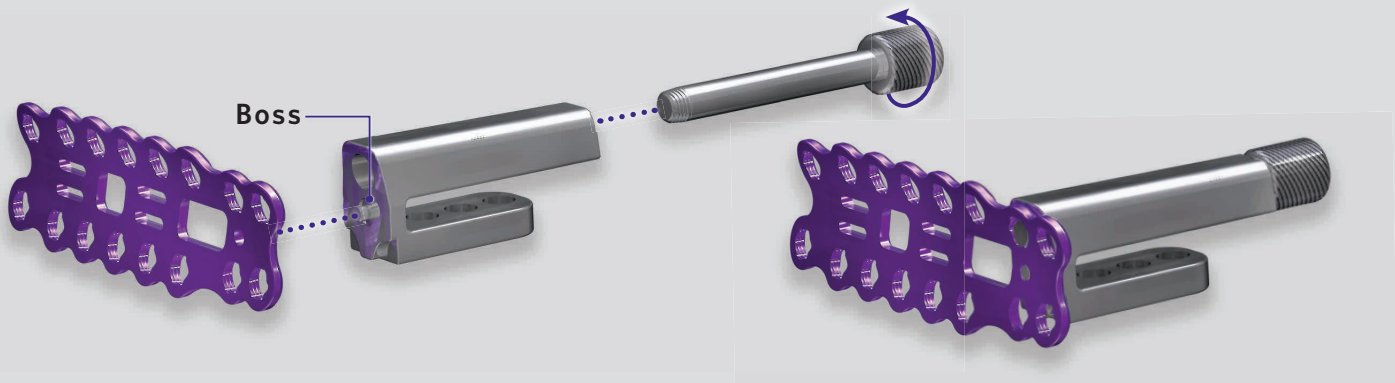
Retrieve the sphere wire. Locate the entry point of the sphere wire at the neck of the talus, centered from dorsal to plantar on the talus. Position the sphere wire perpendicular to the talar neck and perpendicular to the long axis of the medial column, aligned parallel to the floor. Drive the sphere wire into the bone until the "can" portion of the sphere wire contacts the bone.



SURGICAL TECHNIQUE GUIDE:

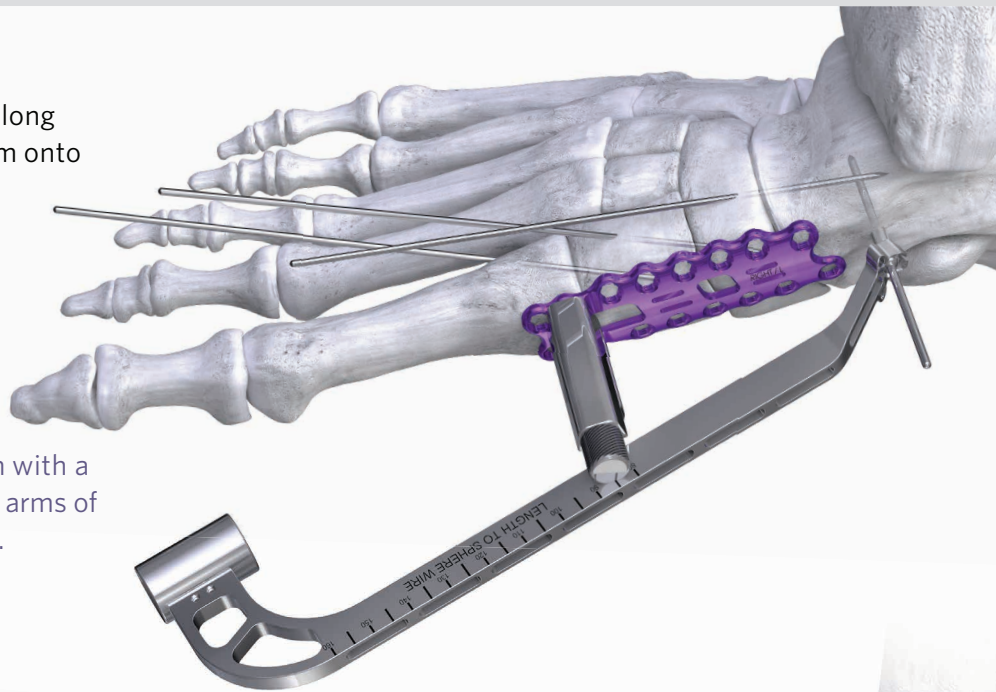
MEDIAL COLUMN BEAMING

PLATE SELECTION AND PRECISION REDUCTION GUIDE ASSEMBLY

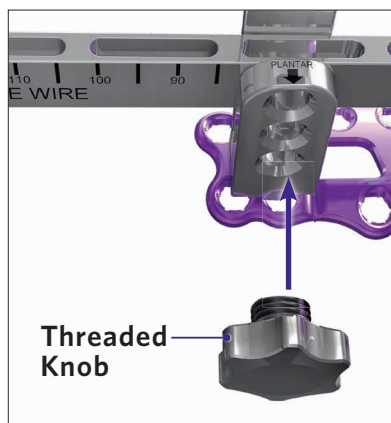


Select the appropriate straddle plate based on the patient's size and the extent of bones fused. Contour the plate at this step, if necessary. Retrieve and attach the U-Clamp to the second most distal dorsal hole on the straddle plate by inserting the boss on the U-Clamp to the adjacent hole in the plate and threading in the set screw into the plate hole in a clockwise fashion. Resect the navicular tuberosity, if required, to allow for flush apposition of plate to bone.

Place the straddle plate/U-Clamp assembly along the medial column. Snap the precision guide arm onto the sphere wire. Position the distal end of the precision guide arm over the 1st MTP joint.



NOTE: For soft bone, hold the sphere wire can with a hemostat or use a freer elevator to spread the arms of the precision guide to ease it onto the sphere wire.



Slide the plate against the medial column, and align the plate such that the plate contacts the bone and is appropriately aligned in the dorsal/plantar and distal/proximal direction. Secure the plate position by inserting the threaded knob into the hole of the U-clamp that corresponds with the precision guide arm height. Rotate the threaded knob clockwise to tighten.



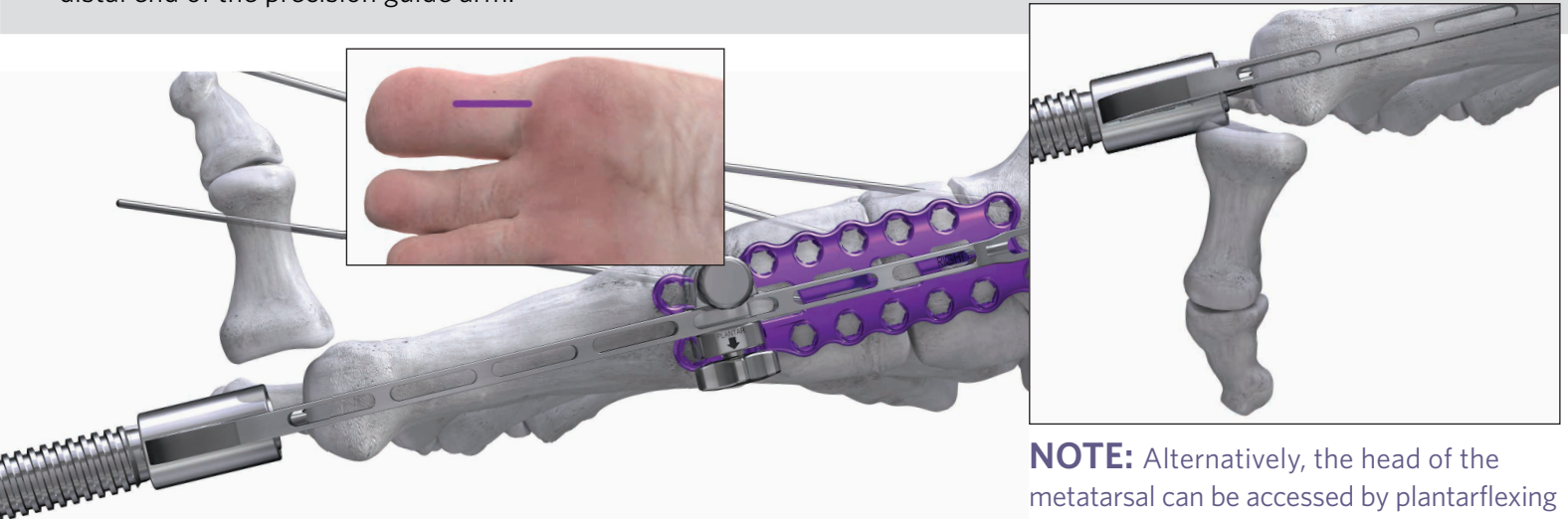
SURGICAL TECHNIQUE GUIDE:

MEDIAL COLUMN BEAMING

SETTING BEAMING SCREW TRAJECTORY



Assemble the reduction tube, drill guide and K-wire guide for a 7.2 mm Beaming Screw. Thread the assembly into the distal end of the precision guide arm.

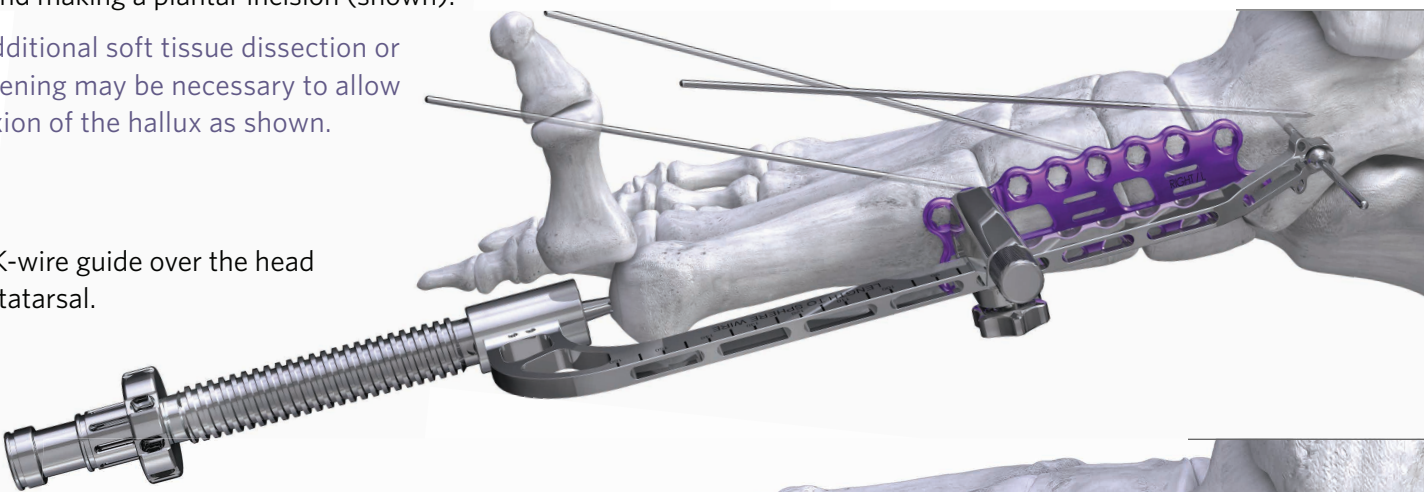


NOTE: Alternatively, the head of the metatarsal can be accessed by plantarflexing the hallux and entering through a dorsal, dorsomedial or medial incision.

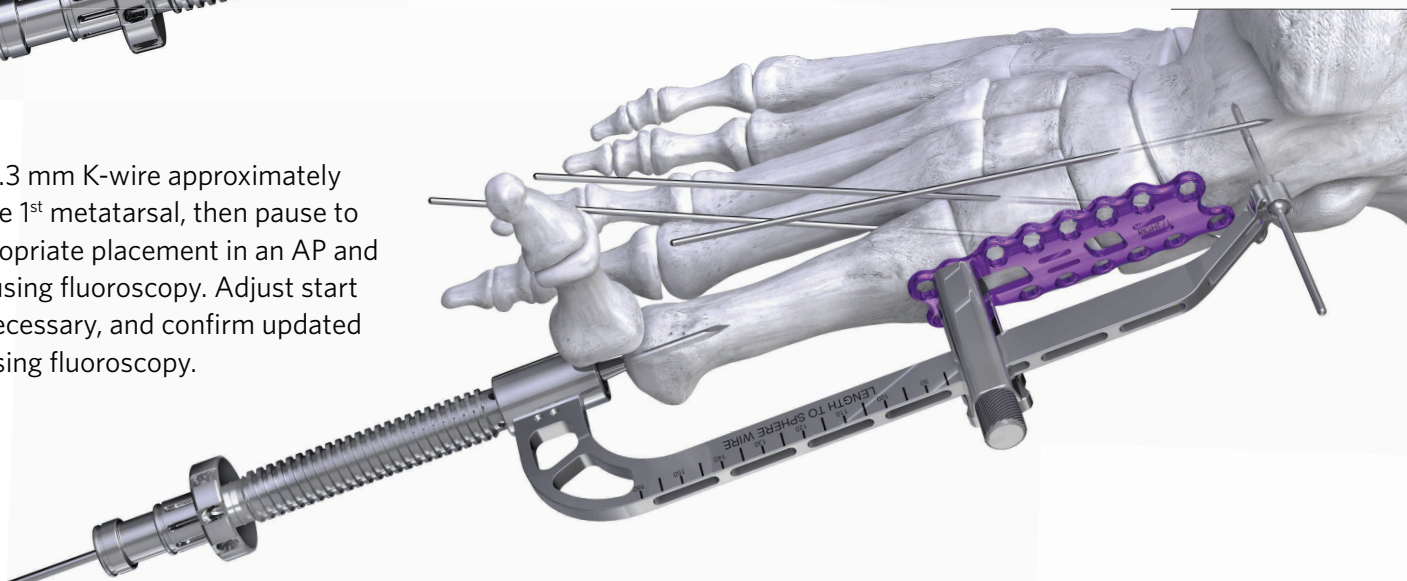
The head of the metatarsal can be accessed by dorsiflexing the hallux and making a plantar incision (shown).

NOTE: Additional soft tissue dissection or capsular opening may be necessary to allow for dorsiflexion of the hallux as shown.

Center the K-wire guide over the head of the 1st metatarsal.



Drive the Ø2.3 mm K-wire approximately 5 mm into the 1st metatarsal, then pause to confirm appropriate placement in an AP and lateral view using fluoroscopy. Adjust start position, if necessary, and confirm updated placement using fluoroscopy.

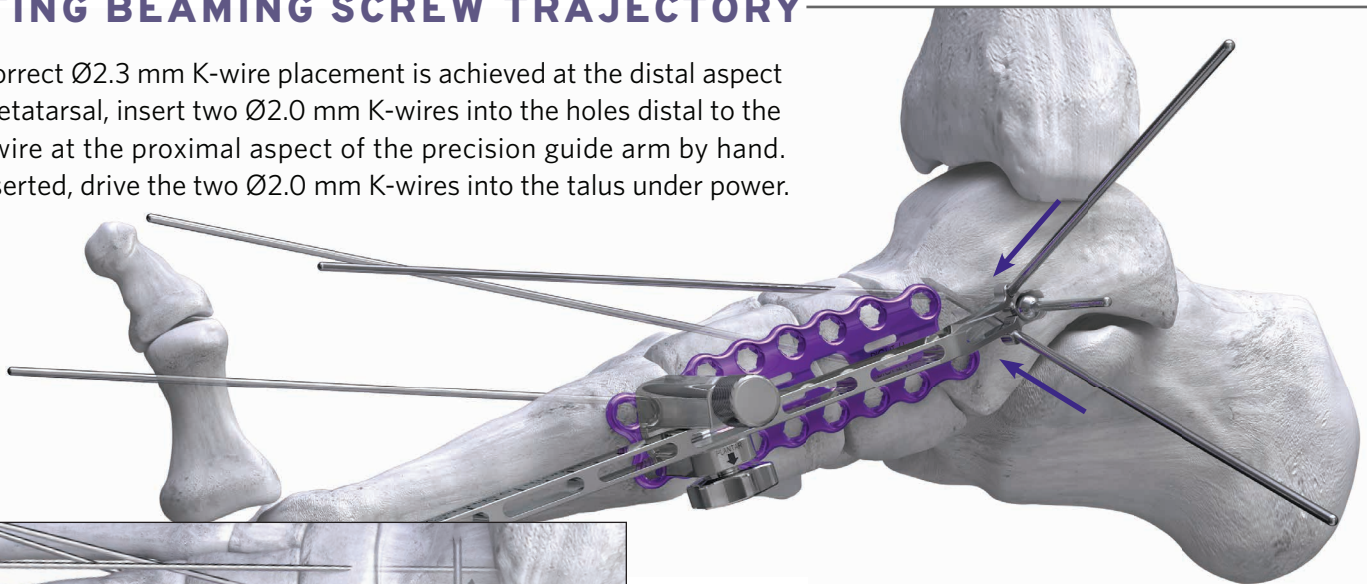


SURGICAL TECHNIQUE GUIDE:

MEDIAL COLUMN BEAMING

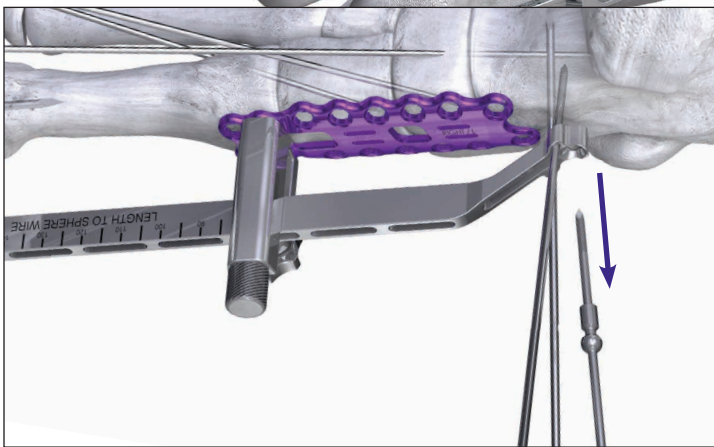
SETTING BEAMING SCREW TRAJECTORY

When correct $\text{\O}2.3$ mm K-wire placement is achieved at the distal aspect of the metatarsal, insert two $\text{\O}2.0$ mm K-wires into the holes distal to the sphere wire at the proximal aspect of the precision guide arm by hand. Once inserted, drive the two $\text{\O}2.0$ mm K-wires into the talus under power.

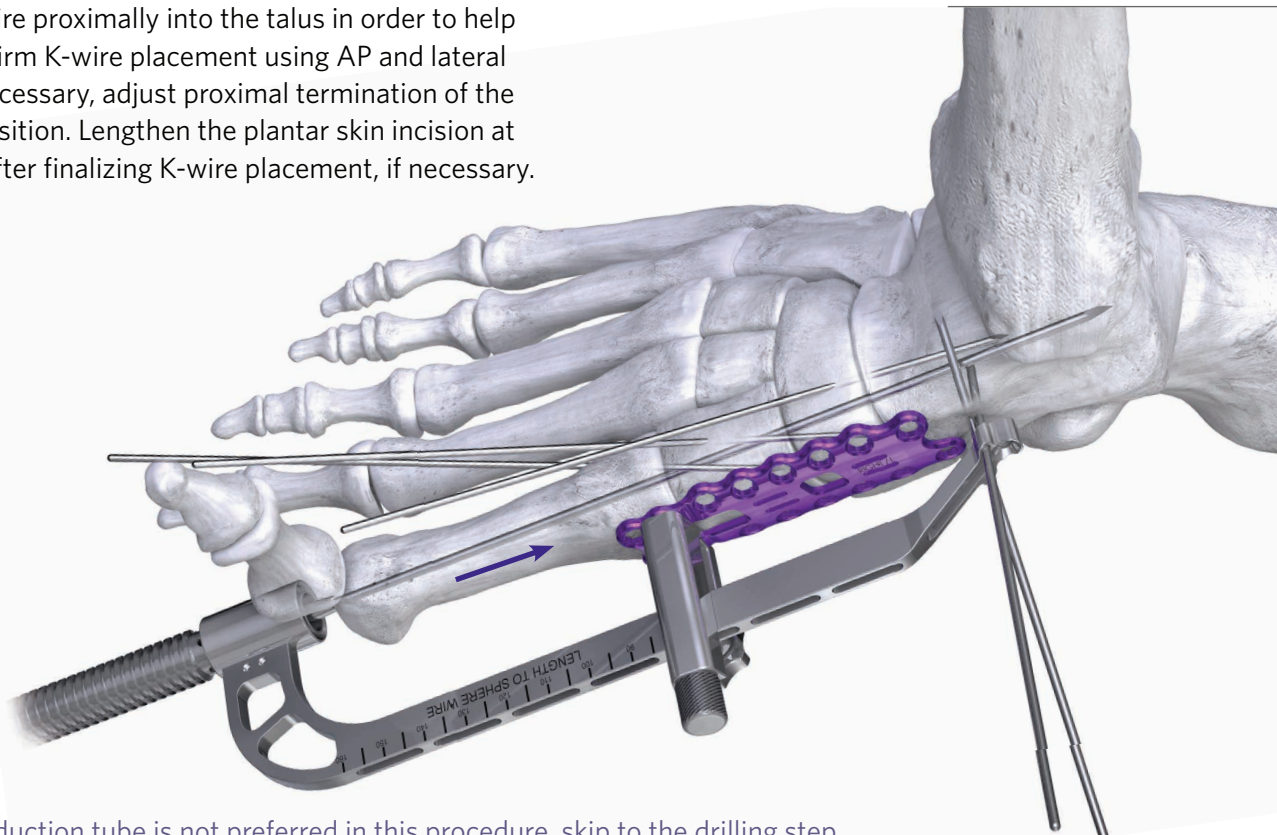


Remove the sphere wire from the talus.

NOTE: Plate position may need to be adjusted a few millimeters distal to intended final plate placement to allow for the $\text{\O}2.0$ mm K-wires to be inserted. Rotate the threaded knob counter-clockwise. Move the plate slightly distal and tighten the threaded knob clockwise to secure.



Drive the $\text{\O}2.3$ mm K-wire proximally into the talus in order to help avoid stress risers. Confirm K-wire placement using AP and lateral fluoroscopic views. If necessary, adjust proximal termination of the K-wire to the desired position. Lengthen the plantar skin incision at the K-wire entry point after finalizing K-wire placement, if necessary.



NOTE: If use of the reduction tube is not preferred in this procedure, skip to the drilling step.

SURGICAL TECHNIQUE GUIDE:

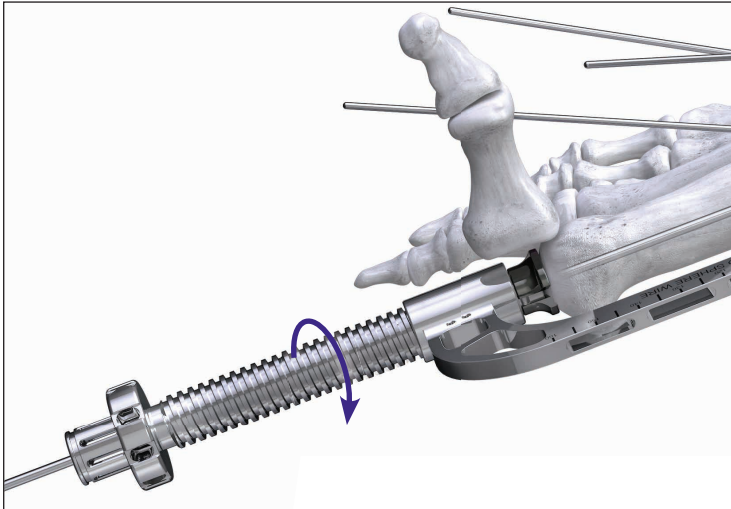
MEDIAL COLUMN BEAMING

MEDIAL COLUMN REDUCTION

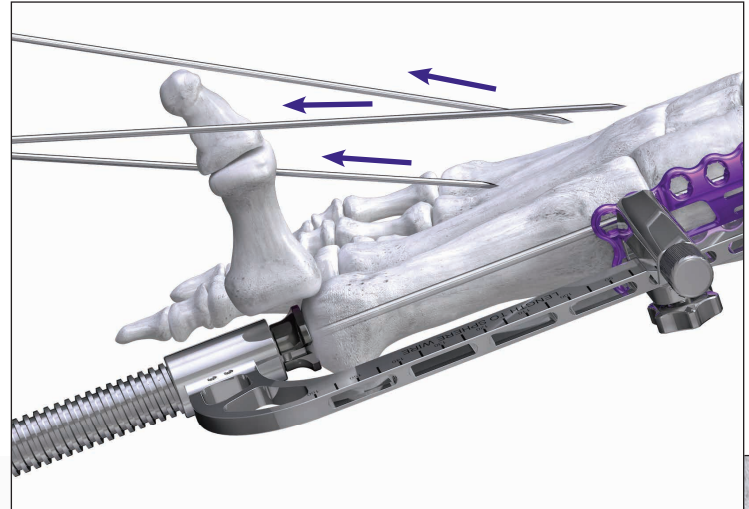


Remove the K-wire guide. Rotate the reduction tube in a clockwise manner until snug against the 1st metatarsal head.

NOTE: The reduction tube cap can be placed at the head of the metatarsal at this time by sliding the slot of the reduction tube cap over the K-wire between the 1st metatarsal and precision guide arm.



K-wires serving as temporary fixation across the joints should be removed prior to final reduction of the medial column.



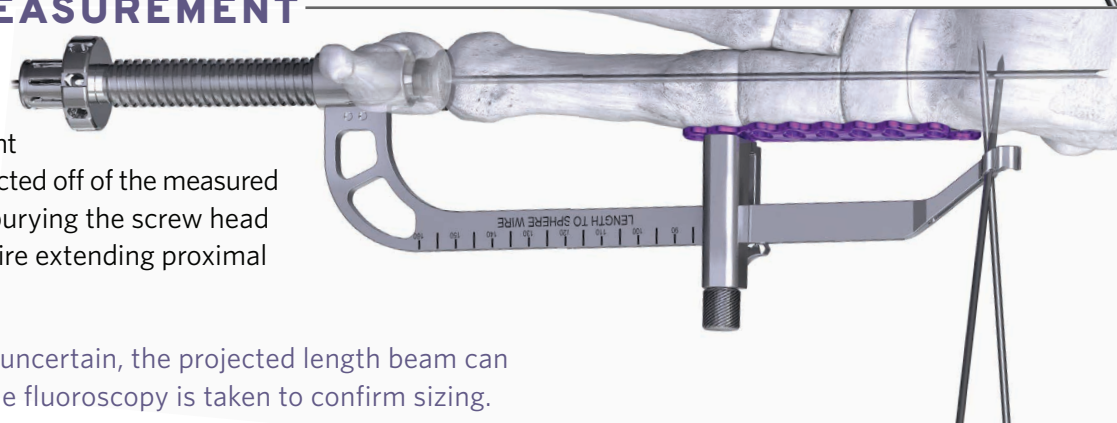
Hand-tighten by rotating the reduction tube in a clockwise direction to allow for reduction of the bones of the medial column.

OPTION: If required, insert the reduction tube tommy bar and rotate until further reduction is appreciated along the medial column.



BEAMING SCREW MEASUREMENT

Measure for the beaming screw length using the laser markings on the precision guide arm. A fixed amount of screw length may need to be subtracted off of the measured depth due to surgeon preference of burying the screw head in the 1st metatarsal, or length of K-wire extending proximal to the precision guide arm.



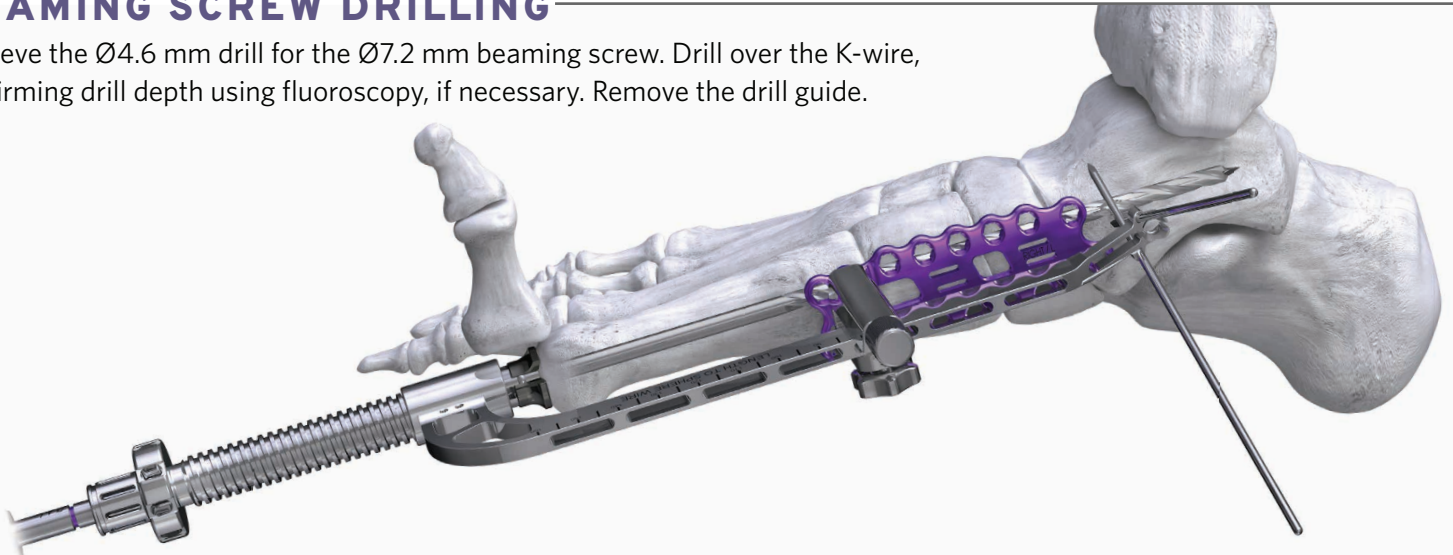
NOTE: If beaming screw length is uncertain, the projected length beam can be held over the medial column while fluoroscopy is taken to confirm sizing.

SURGICAL TECHNIQUE GUIDE:

MEDIAL COLUMN BEAMING

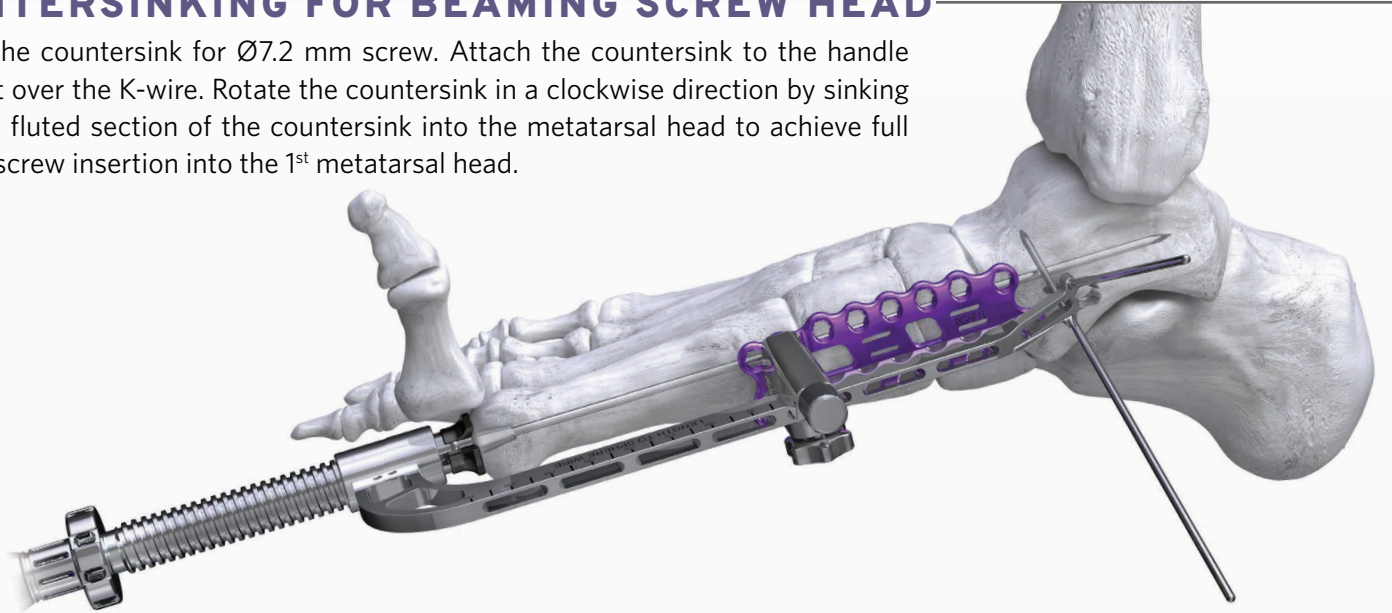
BEAMING SCREW DRILLING

Retrieve the $\text{\O}4.6$ mm drill for the $\text{\O}7.2$ mm beaming screw. Drill over the K-wire, confirming drill depth using fluoroscopy, if necessary. Remove the drill guide.



COUNTERSINKING FOR BEAMING SCREW HEAD

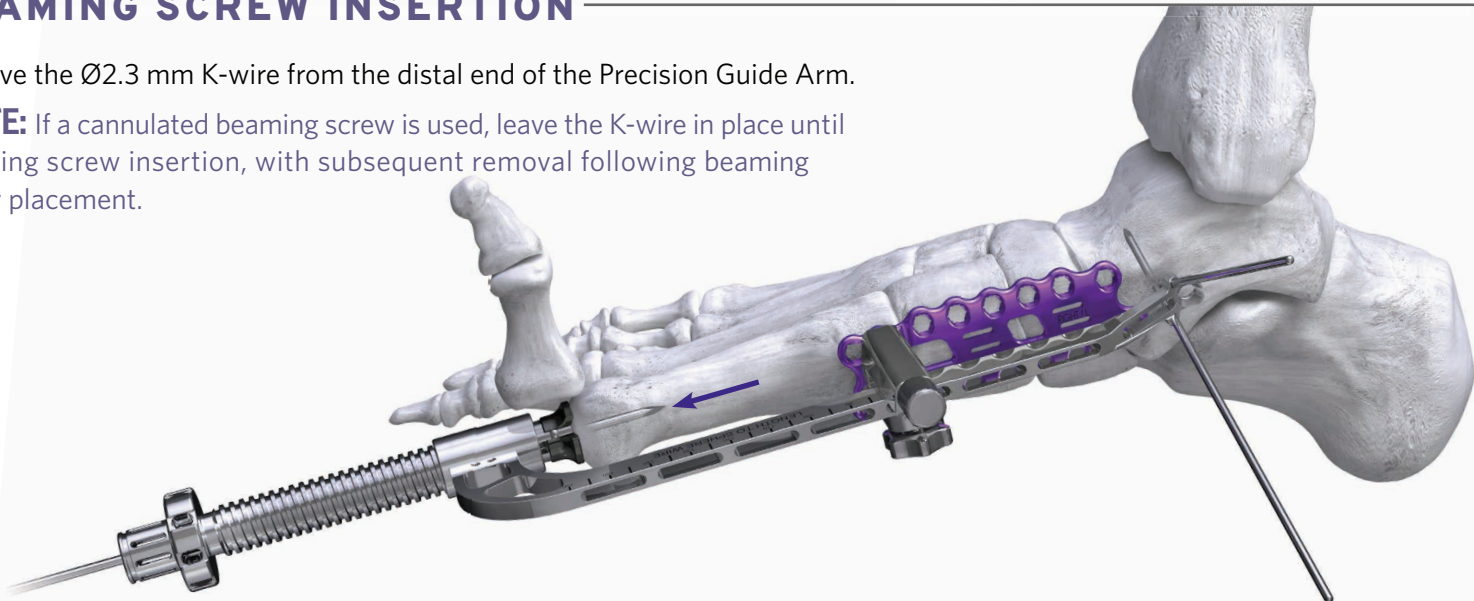
Retrieve the countersink for $\text{\O}7.2$ mm screw. Attach the countersink to the handle and insert over the K-wire. Rotate the countersink in a clockwise direction by sinking the entire fluted section of the countersink into the metatarsal head to achieve full beaming screw insertion into the 1st metatarsal head.



BEAMING SCREW INSERTION

Remove the $\text{\O}2.3$ mm K-wire from the distal end of the Precision Guide Arm.

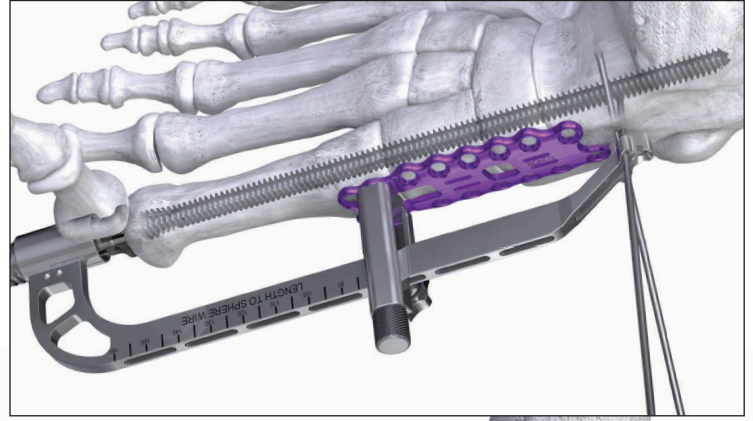
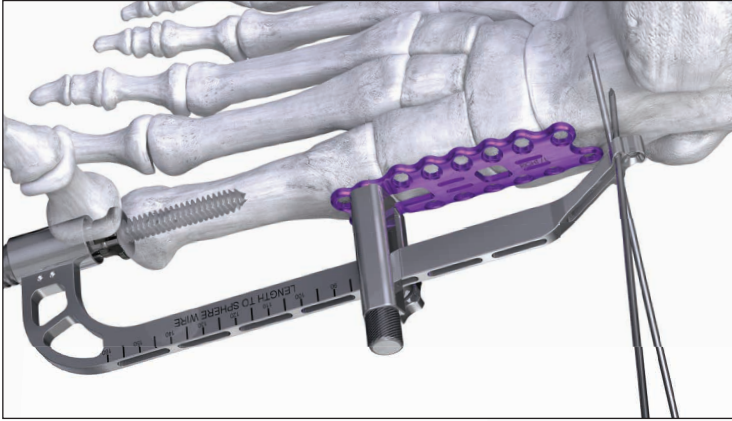
NOTE: If a cannulated beaming screw is used, leave the K-wire in place until beaming screw insertion, with subsequent removal following beaming screw placement.



SURGICAL TECHNIQUE GUIDE:

MEDIAL COLUMN BEAMING

BEAMING SCREW INSERTION



Retrieve the long TX-30 driver. Insert the long TX-30 driver into the provided standard handle or T-handle. Insert the desired beaming screw through the Reduction Tube, while engaging the screw head with the driver. Rotate the screw in a clockwise manner until the screw is fully seated.

Confirm screw length and position using fluoroscopy.

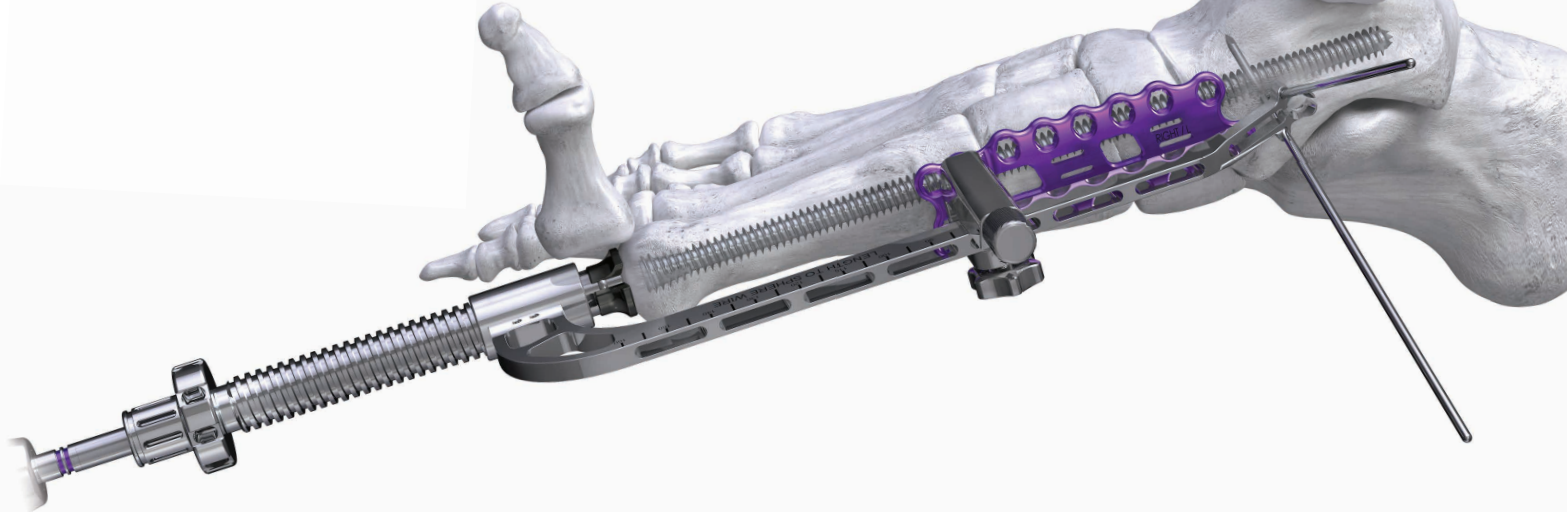
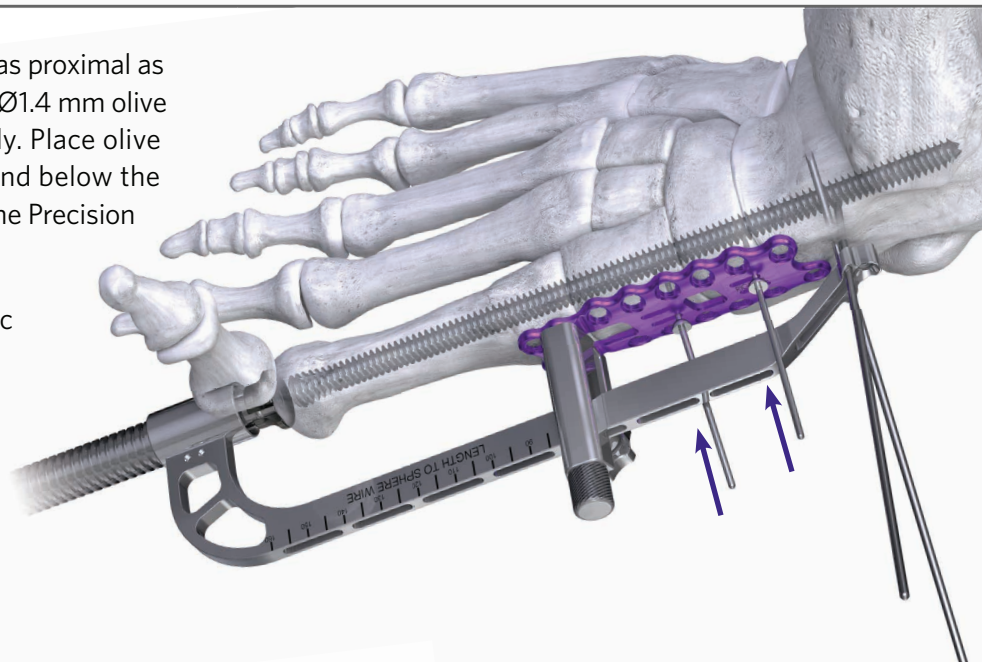


PLATE FIXATION

Position the plate along the Precision Guide Arm as proximal as possible prior to placing olive wires. Retrieve two Ø1.4 mm olive wires from the Gorilla R3CON Instrument Caddy. Place olive wires into the proximal end of the slots above and below the Precision Guide, angling the olive wires to avoid the Precision Guide Arm.

Confirm plate placement on a lateral fluoroscopic view to confirm dorsal to plantar position.

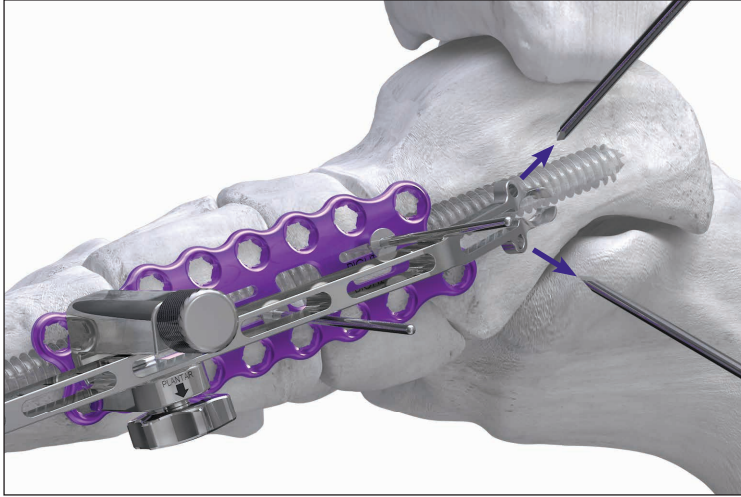
NOTE: The precision guide arm should remain in place until temporary fixation of the plate is achieved, to allow for relative positioning of the plate to the beaming screw.



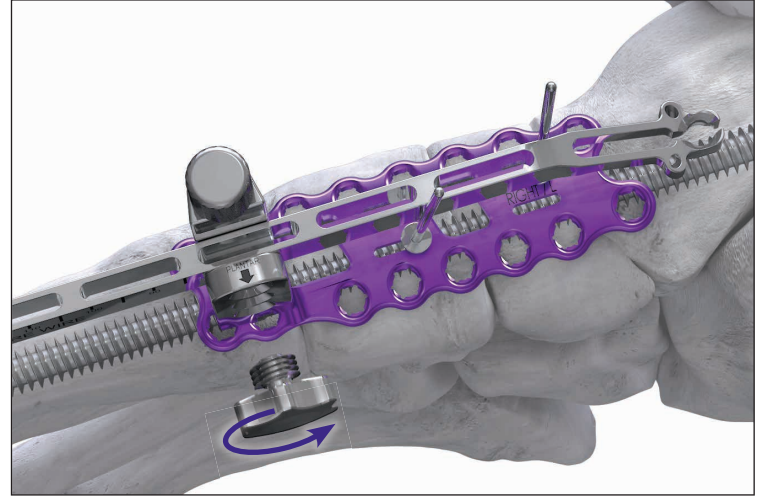
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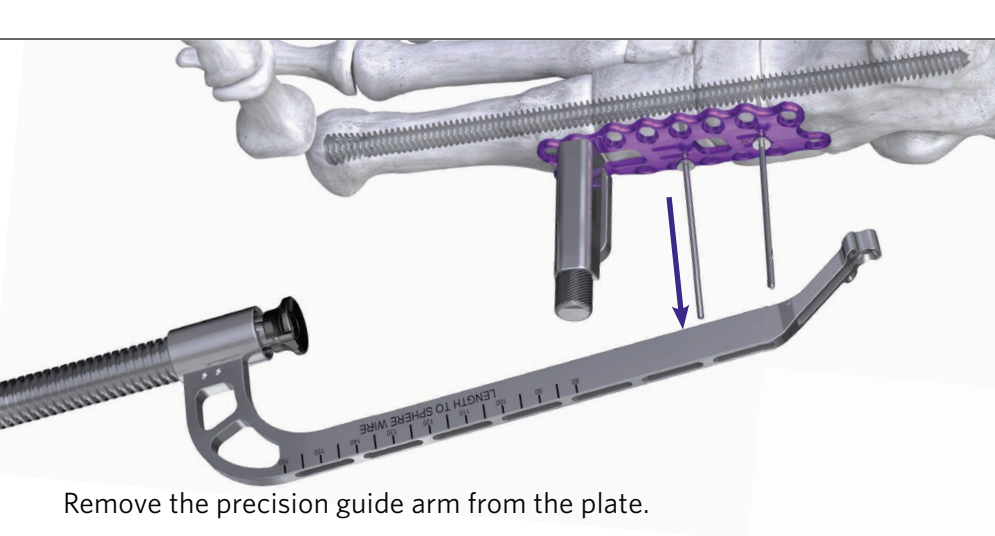
PLATE FIXATION



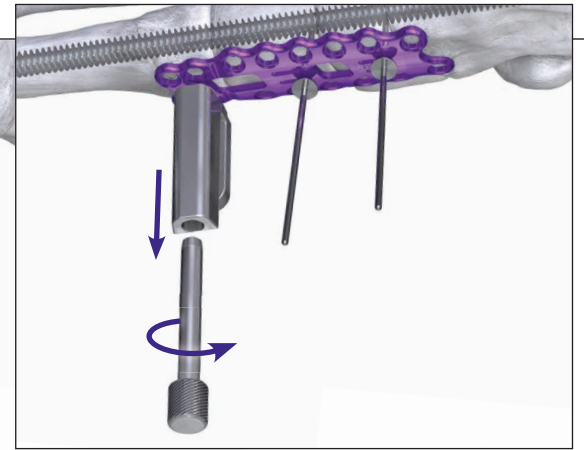
Remove the $\text{\O}2.0$ mm wires from the proximal end of the precision guide arm.



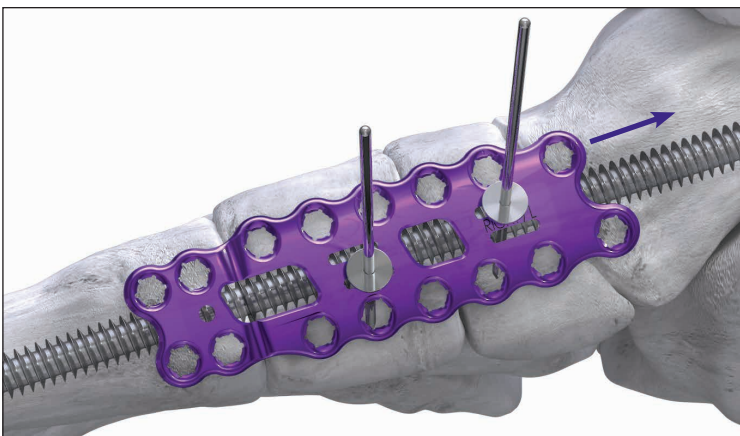
Rotate the threaded knob counterclockwise to loosen engagement of the precision guide arm.



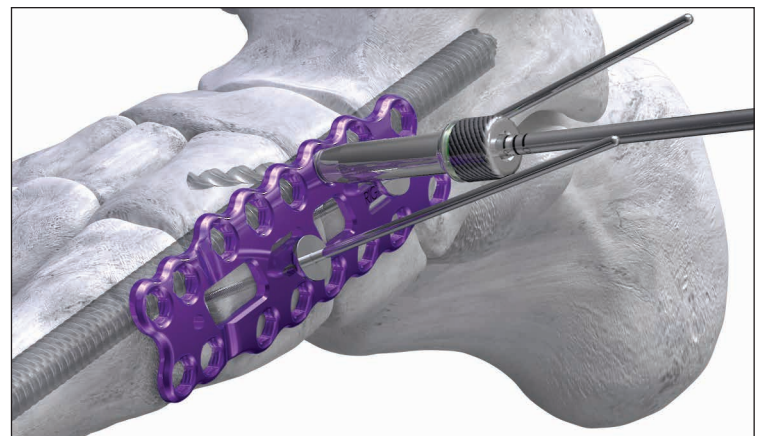
Remove the precision guide arm from the plate.



Rotate the set screw in a counterclockwise manner to release the U-clamp from the plate.



If necessary, slide plate position proximally along the slots to allow for talar screw holes to be appropriately positioned over the talus. Surgeon may use in situ plate benders to contour plate.



It is recommended to begin plate fixation at the central portion of the medial column, where the plate best fits the bone surface. Insert a threaded drill guide in a central hole of the plate. Drill using the drill sized for the desired Gorilla plate screw diameter.

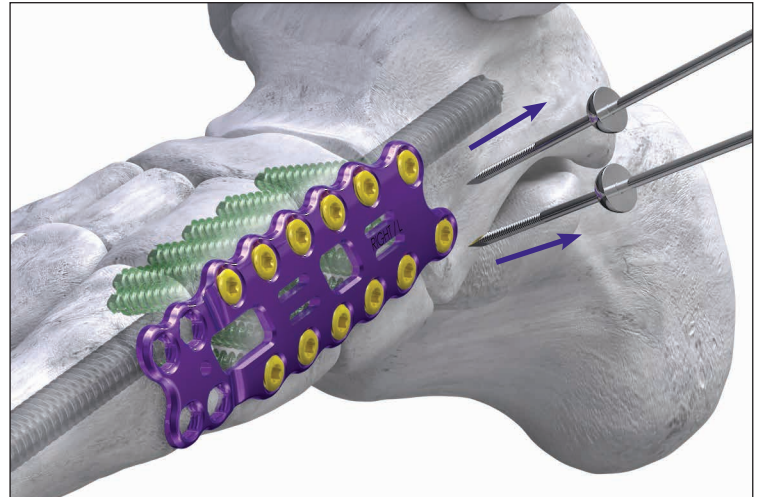
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MEDIAL COLUMN BEAMING

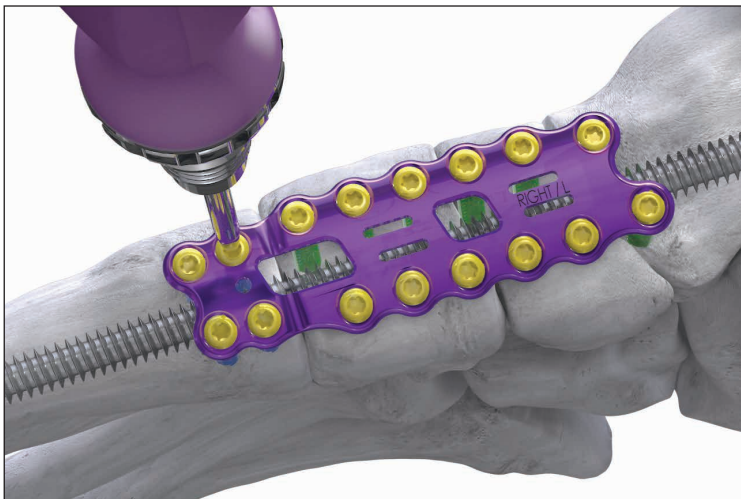
PLATE FIXATION



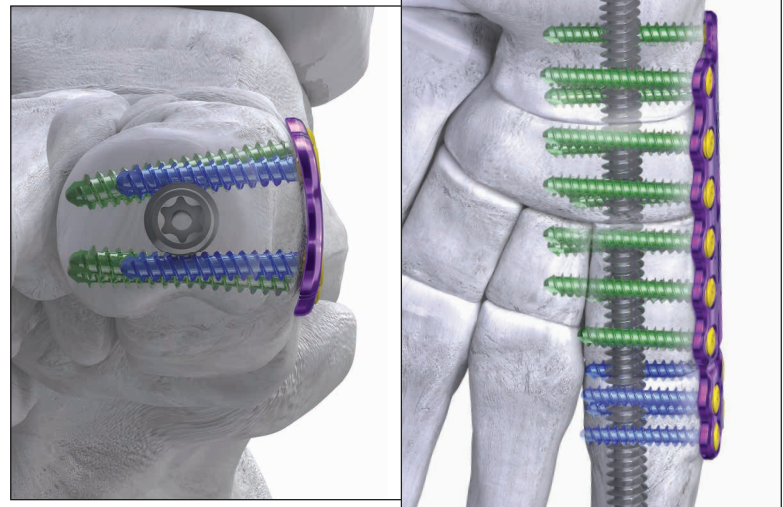
Measure for screw length using the provided depth gauge. Insert the selected screw into the plate hole using the provided driver and handle.



Continue screw fixation using the technique just described to place plate screws distal and proximal from initial screw placement. Remove olive wires when an adequate number of plate screws are placed.



Complete plate screw insertion.

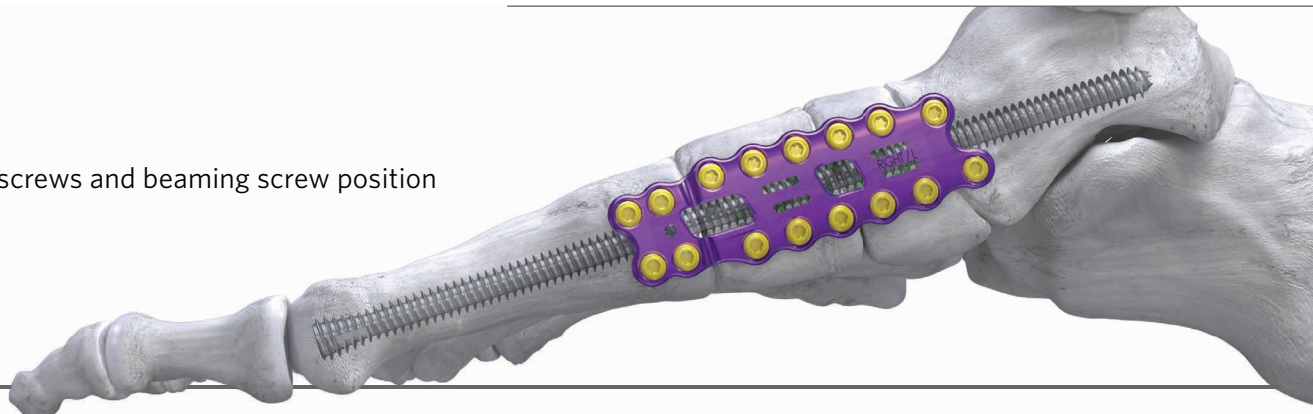


NOTE: The locking screws have 15° (in any direction) off-axis locking capability. Care should be taken to avoid the beaming screw with plate screws. The plate has been designed to accept 4.2 mm screws in all plate holes on-axis.

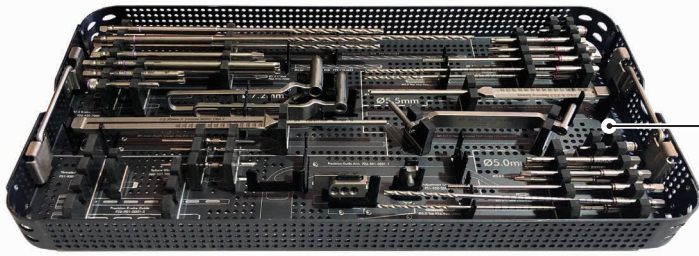
Confirm plate, plate screws and beaming screw position using fluoroscopy.

CLOSURE

Proceed to incision closure or concomitant procedures at this time.

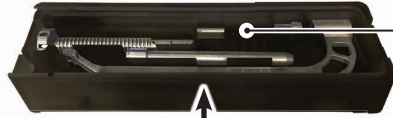


JOUST™ BEAMING SCREW SYSTEM



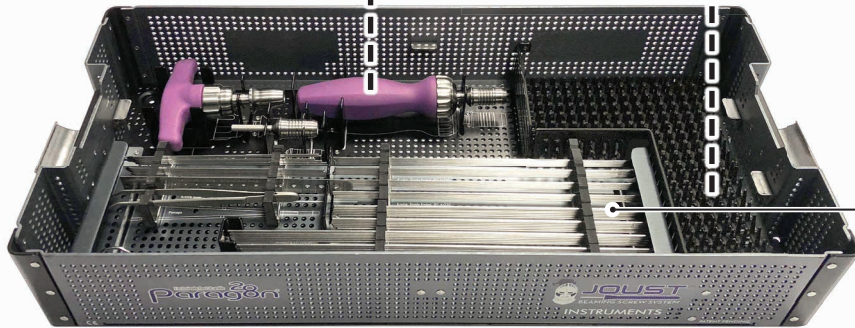
Instrument Tray

The U-Clamp, threaded knob, set screw, depth gauges, tissue protectors, drivers, drills, countersinks and taps for each size of Joust™ Beaming Screws are located in the top Instrument Tray.



Precision Reduction Guide Caddy

The Precision® Guide arm, reduction tube, drill guide tube, K-wire guide tubes, tommy bar and reduction tube caps are located within the Precision® Reduction Guide Caddy.

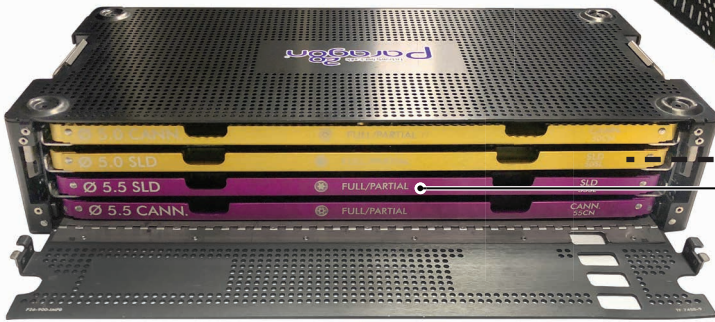
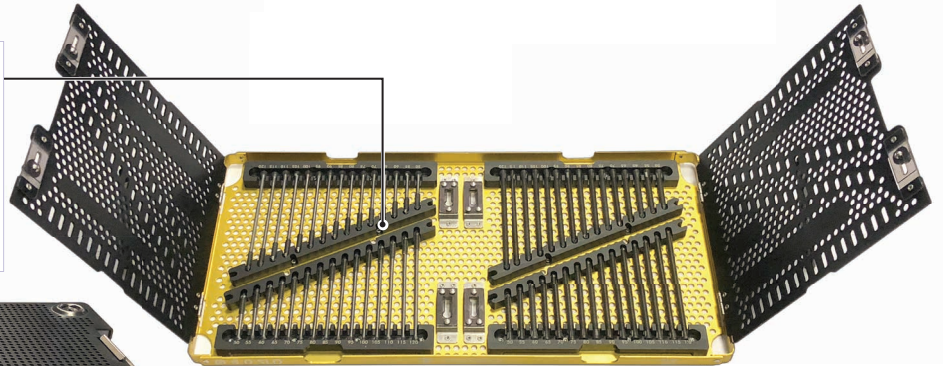


Instrument Case

A Jacobs adapter, handle, T-handle, cleaning stylets, forceps and K-wires are located at the bottom of the Joust™ Beaming Screw Instrument Case.

Ø5.0 & Ø5.5 Beaming Screw Tray

Two Ø5.0 mm and Ø5.5 mm Joust™ Beaming Screws are available in each length in their specific Joust™ Beaming Screw Tray. Beaming screw trays are separated by diameter, cannulated/solid and thread type.

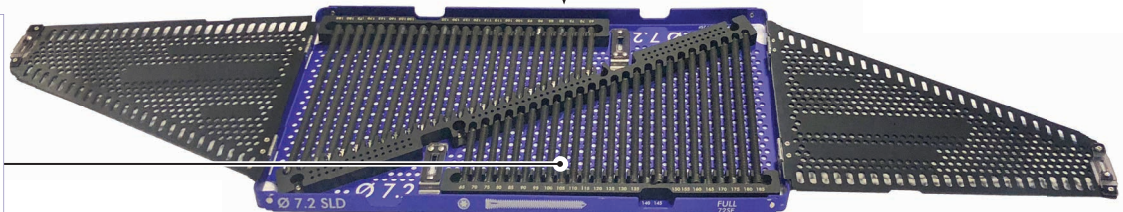


Beaming Screw Case

Joust™ Beaming Screw Trays are available in the Joust™ Beaming Screw Case.

Ø7.2 Beaming Screw Tray

Two Ø7.2 mm Joust™ Beaming Screws are available in each length in their specific Joust™ Beaming Screw Tray. Beaming screw trays are separated by diameter, cannulated/solid and thread type.



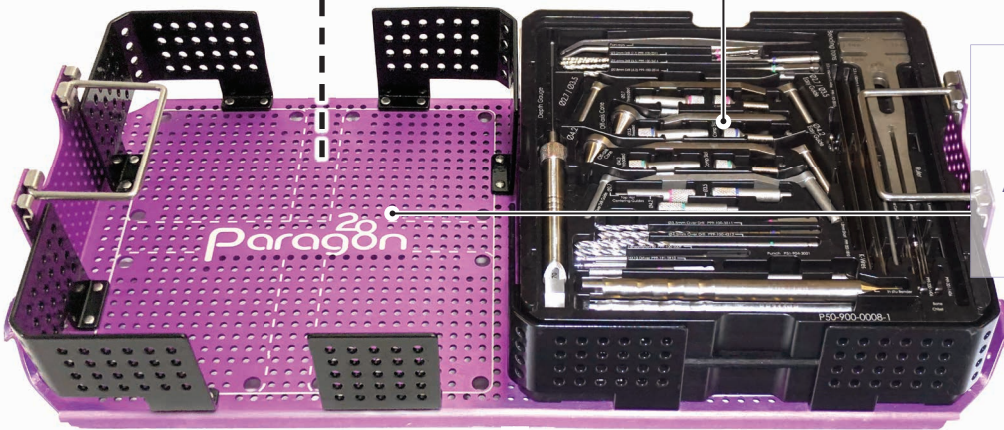
Medial Column Caddy

The Gorilla® Medial Column Caddy contains all sizes of the Straddle Plates, 1.5 mm and 2.0 mm Rescue Plates, 1.5 mm and 2.0 mm Arch Plates and Extended Arch Plates.



Gorilla® R3CON Instrument Caddy

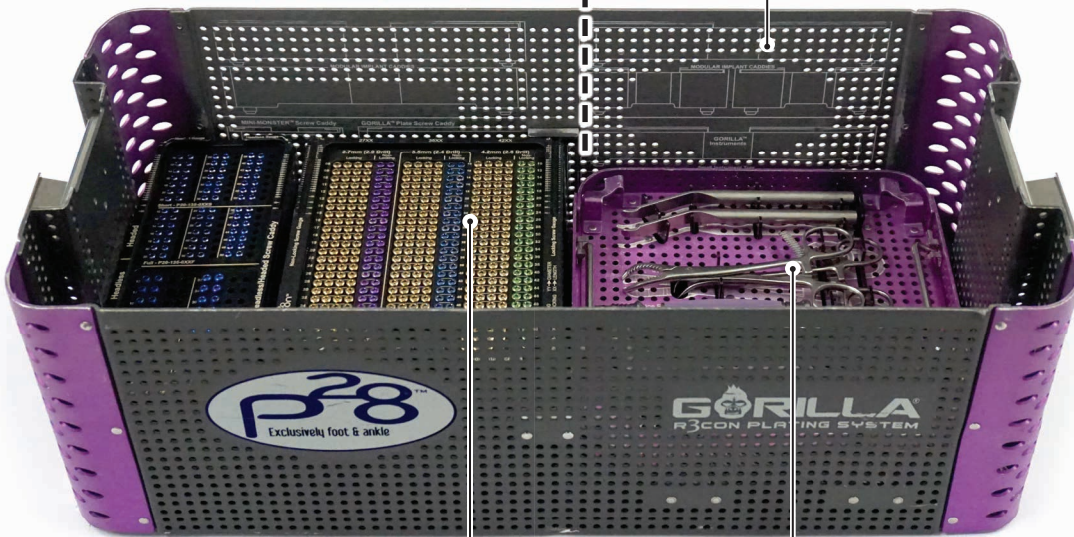
Drills, drill guides, centering guides, olive wires, plate benders, drivers, K-wires and a depth gauge are located in the Gorilla® R3CON Instrument Caddy.



Additional Gorilla® Caddies



The Gorilla® Case has room for additional Gorilla® Plate Caddies or PRESERVE™ Allgraft caddies that may be needed for additional procedures performed in addition to medial column beaming.

Gorilla® Case



Gorilla® Screw Optionality

The Gorilla® 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.

SURGICAL TECHNIQUE GUIDE: INDICATIONS, CONTRAINDICATIONS, AND WARNINGS

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

INDICATIONS FOR USE (GORILLA®)

The Baby Gorilla®/Gorilla® Bone Plates and Bone Screws of the Baby Gorilla®/Gorilla® Plating System are indicated for use in stabilization and fixation of fractures or osteotomies; intra and extra articular fractures, joint depression, and multi-fragmentary fractures; revision procedures, joint fusion and reconstruction of small bones of the toes, feet and ankles including the distal tibia, talus, and calcaneus, as well as the fingers, hands, and wrists. The system can be used in both adult and pediatric patients. Specific examples include:

Forefoot:

- Arthrodesis of the first metatarsalcuneiform joint (Lapidus Fusion)
- Metatarsal or phalangeal fractures and osteotomies
- Lesser metatarsal shortening osteotomies (e.g. Weil)
- Fifth metatarsal fractures (e.g. Jones Fracture)

Mid/Hindfoot:

- LisFranc Arthrodesis and/or Stabilization
- 1st (Lapidus), 2nd, 3rd, 4th, and 5th Tarsometatarsal (TMT) Fusions
- Intercuneiform Fusions
- Navicular-Cuneiform (NC) Fusion
- Talo-Navicular (TN) Fusion
- Calcaneo-Cuboid (CC) Fusion
- Subtalar Fusion
- Medial Column Fusion
- Cuneiform Fracture
- Cuboid Fracture
- Navicular Fracture

In addition, the non-locking, titanium screws and washers are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair and fracture fixation, appropriate for the size of the device.

Ankle:

- Lateral Malleolar Fractures
- Syndesmosis Injuries
- Medial Malleolar Fractures and Osteotomies
- Bi-Malleolar Fractures
- Tri-Malleolar Fractures
- Posterior Malleolar Fractures
- Distal Anterior Tibia Fractures
- Vertical Shear Fractures of the Medial Malleolus
- Pilon Fractures
- Distal Tibia Shaft Fractures
- Distal Fibula Shaft Fractures
- Distal Tibia Periarticular Fractures
- Medial Malleolar Avulsion Fractures
- Lateral Malleolar Avulsion Fractures
- Tibiotalocalcaneal Joint Arthrodesis
- Tibiotalar Joint Arthrodesis
- Tibiocalcaneal Arthrodesis
- Supramalleolar Osteotomy
- Fibular Osteotomy

First metatarsal osteotomies for hallux valgus correction including:

- Opening base wedge osteotomy
- Closing base wedge osteotomy
- Crescentic Osteotomy
- Proximal Osteotomy (Chevron and Rotational Oblique)
- Distal Osteotomy (Chevron/Austin)

Arthrodesis of the first metatarsophalangeal joint (MTP) including:

- Primary MTP Fusion due to hallux rigidus and/or hallux valgus
- Revision MTP Fusion
- Revision of failed first MTP Arthroplasty implant

Flatfoot:

- Lateral Column Lengthening (Evans Osteotomy)
- Plantar Flexion Opening Wedge Osteotomy of the Medial Cuneiform (Cotton Osteotomy)
- Calcaneal Slide Osteotomy

Charcot:

- Medial column fusion (talus, navicular, cuneiform, metatarsal) for neuropathic osteoarthropathy (Charcot)
- Lateral column fusion (calcaneus, cuboid, metatarsal) for neuropathic osteoarthropathy (Charcot)

CONTRAINDICATIONS

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

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

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

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

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

POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS

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

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

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

WARNINGS AND PRECAUTIONS

- Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
- Use of an undersized plate or screw in areas of high functional stresses may lead to implant fracture and failure.
- Plates and screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
- The implants and guide wires are intended for single use only.
- Instruments, guide wires and screws are to be treated as sharps.
- Do not use other manufacturer's instruments or implants in conjunction with the Baby Gorilla®/Gorilla® Plating System.
- If a stainless steel Gorilla® R3LEASE™ Screw is used, it may only be used standalone.
- The device should only be used in pediatric patients where the growth plates have fused or in which active growth plates will not be crossed by the system implants or instrumentation.

MR SAFETY INFORMATION

The Baby Gorilla®/Gorilla® Plating System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Baby Gorilla®/Gorilla® Plating System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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

INDICATIONS FOR USE (MONSTER®)

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

Fractures and Osteotomies

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

Hallux Valgus Correction

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

Arthrodesis/Deformity Correction

- 1st MTP arthrodesis
- Metatarsal deformity correction
- Tarsometatarsal joint arthrodesis
- Naviculocuneiform joint arthrodesis
- Talonavicular arthrodesis
- Subtalar joint arthrodesis
- Triple arthrodesis
- Medial column arthrodesis
- Subtalar joint distraction arthrodesis
- Ankle arthrodesis
- Lateralizing calcaneal osteotomy
- Lateral column lengthening
- Hammertoe

Fusion resulting from neuropathic osteoarthopathy (Charcot) such as:

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

CONTRAINDICATIONS

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

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

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

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

- The presence of tumors
- Congenital abnormalities
- Immunosuppressive pathologies
- Increased sedimentation rates that cannot be explained by other pathologies
- Increased leukocyte (WBC) count
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POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS

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- Plates and screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
- The implants and guide wires are intended for single use only. Re-use may cause product failure and could lead to disease transmission.
- Instruments, guide wires and screws are to be treated as sharps.
- **Do not use other manufacturer's instruments or implants in conjunction with the Monster® Screw System.**

MR SAFETY INFORMATION

The Monster® Screw System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Monster® Screw System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.



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Endnotes:


- ¹ Whitten, Andy. Evaluation of the Effects of Anodization on the Fatigue Performance of Titanium Alloy. *Fatigue and Fracture of Medical Metallic Materials and Devices*, STP 1559. West Conshohocken, PA: ASTM International; 2013: 109-121.

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DISCLAIMER

The purpose of the Joust™ Beaming Screw System Surgical Technique Guide is to demonstrate the optionality and functionality of the Joust™ Beaming Screw System and Straddle Plate in the Gorilla® R3CON Plating System. Although variations in placement and use of the Joust™ Beaming Screw 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 Joust™ Beaming Screw System can be employed, appropriate for the size of the device. Federal law (U.S.A.) restricts this device to sale and use by, or on order of, a physician.