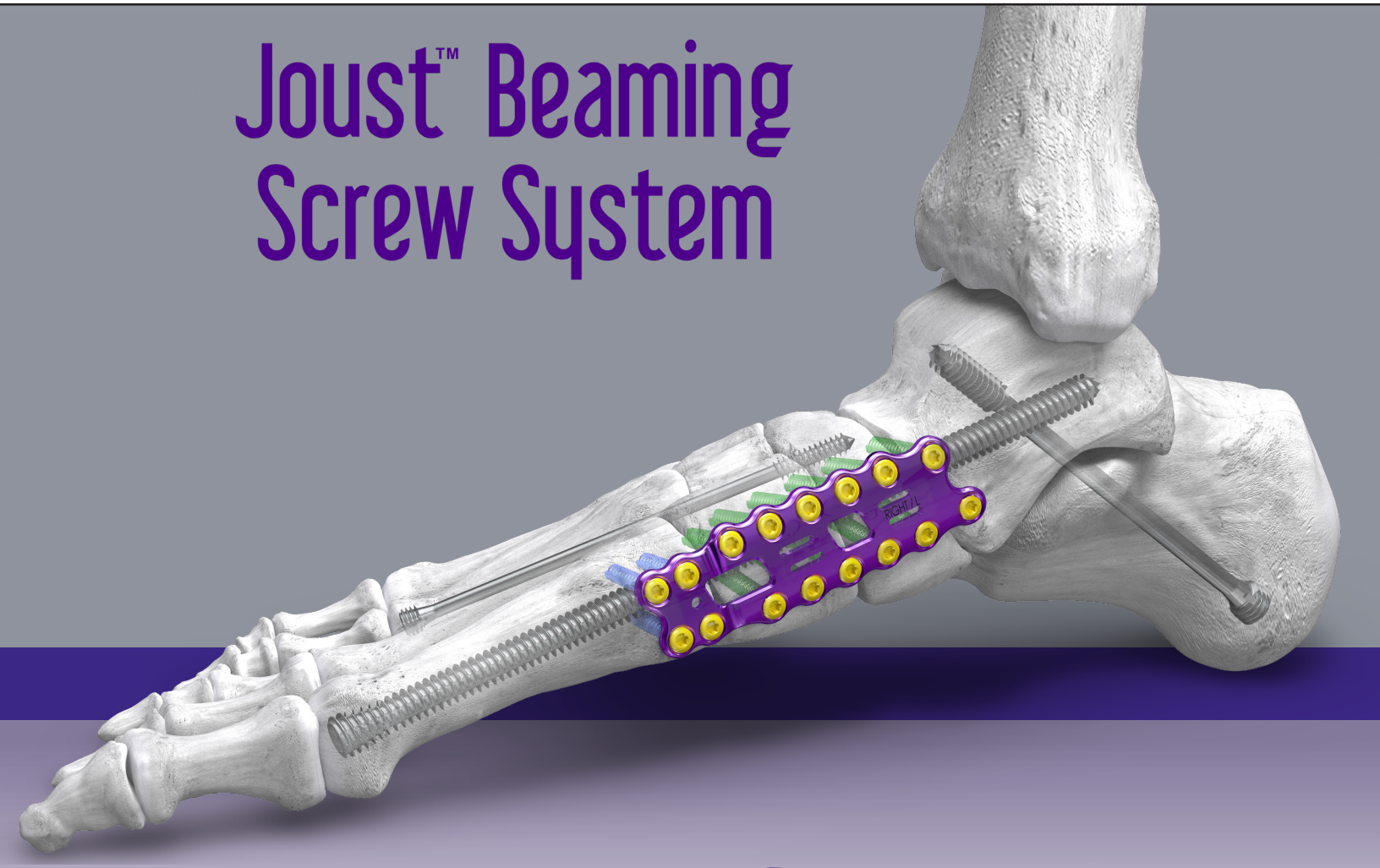
SURGICAL TECHNIQUE GUIDE:

MEDIAL COLUMN BEAMING

Exclusively foot & ankle

Paragon 28®

Joust™ Beaming Screw System



GORILLA® R3CON PLATING SYSTEM

JOUST™ BEAMING SCREW 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 allow surgeons to have options for internal fixation of Charcot Arthropathy cases that may require individualization and variation based on the disease process of the patient. The Joust™ Beaming Screw System can be combined with a robust Gorilla® Straddle Plate that is designed to be used either with a beaming screw or on its own to stabilize the medial column. The 2.0 mm plate thickness and plate height help to resist bending, while assisting in alignment of the medial column. The plate has the ability to set the trajectory for a beaming screw to pass through the plate screws without hitting any on-axis plate screws through a patent-pending Precision® Guide System. (Figure 1)

The Joust™ Beaming Screw System also offers the patent-pending Precision® Guide System as a standalone beaming screw option that is designed to help the surgeon place a medial column beaming screw at a desired trajectory and endpoint. (Figure 2)

Likewise, multiple sizes of beaming screws are offered in this system to allow for use in other areas of the foot. (Figures 3 & 4)

The surgical technique shown in this guide is one of several methods of how to use this system. The method presented works best when good medial column alignment can be achieved in the sagittal and transverse planes and where a straight trajectory can be visualized in both planes for a beaming screw. Other methods of using the Joust™ Beaming System are presented on pages 14-16.

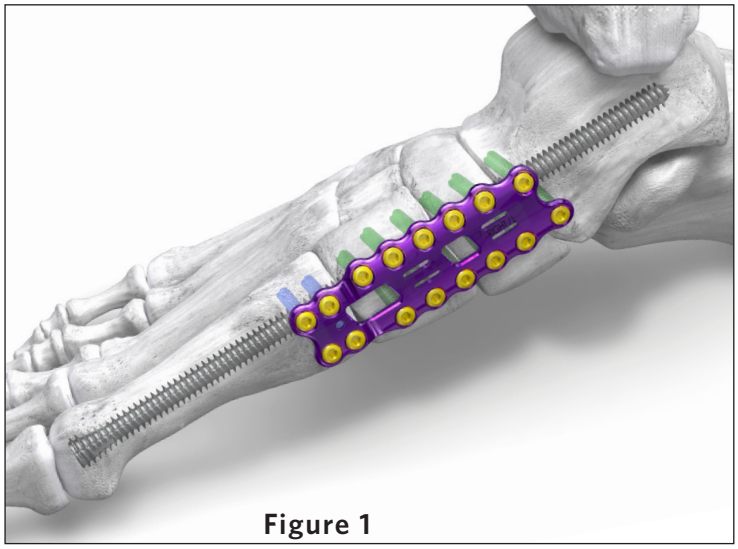


Figure 1

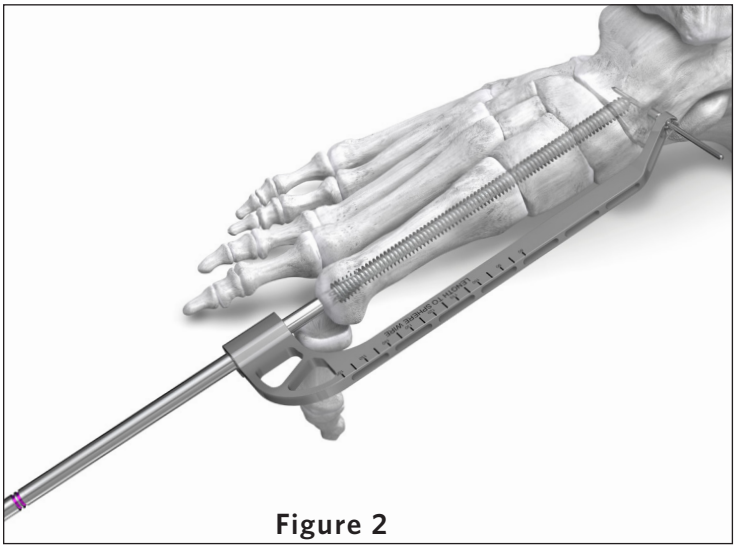


Figure 2

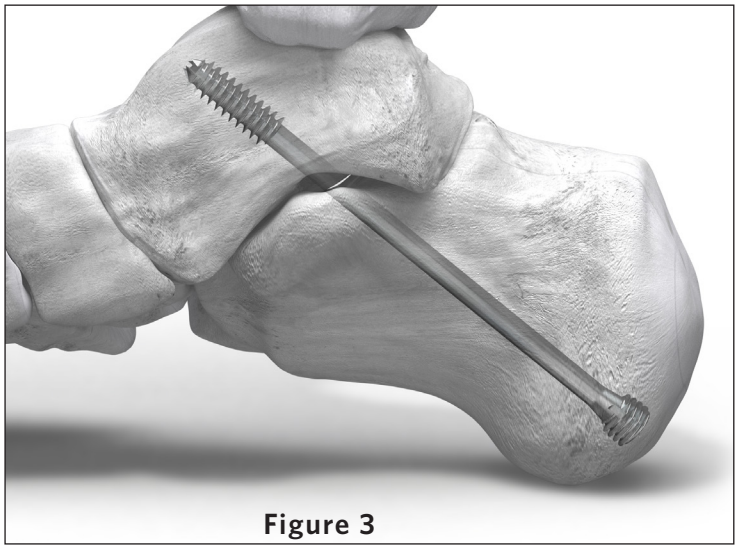


Figure 3

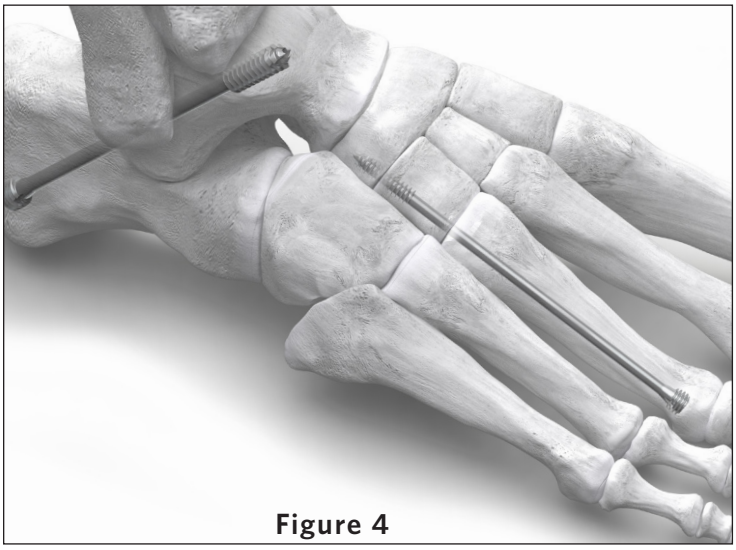
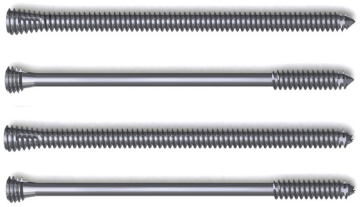
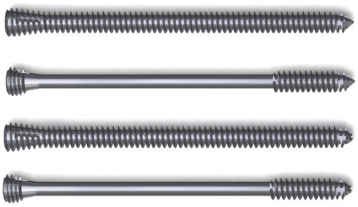
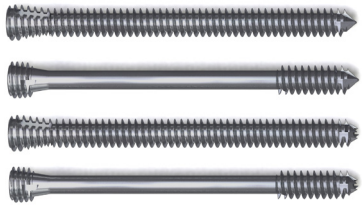


Figure 4

IMPLANT OFFERING

Beaming Screws (220 unique implants)

	5.0 mm Beaming Screw	5.5 mm Beaming Screw	7.2 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

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

Gorilla Straddle Plates - Left and Right Side Specific

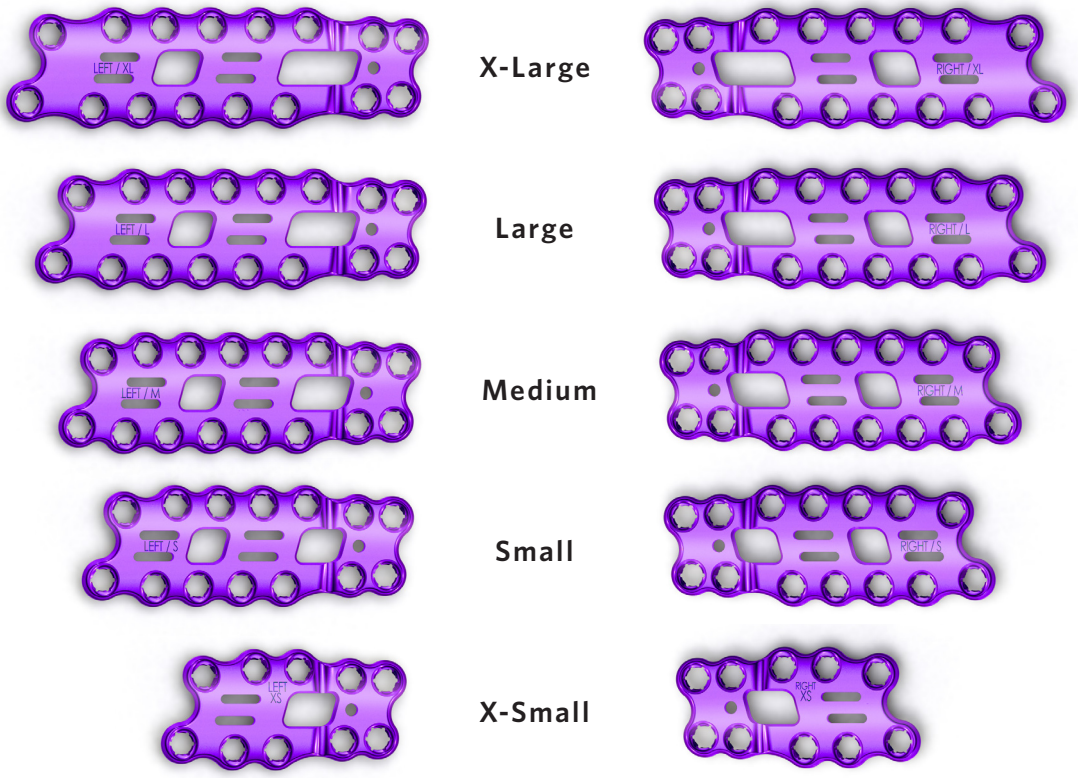


Plate Features:

- 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 joint space while placing a Joust Beaming Screw

FEATURED INSTRUMENTS

Joust Precision Guide

- 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 straddle plate and beaming screw trajectory, if used together
- For use with the 7.2 mm beaming screw only

Precision Guide Arm

Threaded Knob

U-Clamp

Drill Guide Sleeve

K-wire Sleeve

Set Screw

Sphere Wire

OTHER INSTRUMENTATION

Ø3.3 mm Drill for 5.0 mm Beaming Screw

Ø3.5 mm Drill for 5.5 mm Beaming Screw

Ø4.6 mm Drill for 7.2 mm Beaming Screw

Ø4.6 mm Long Drill for 7.2 mm Beaming Screw

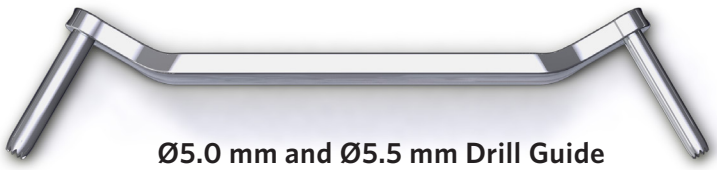
Ø5.0 mm Tap

Ø5.5 mm Tap

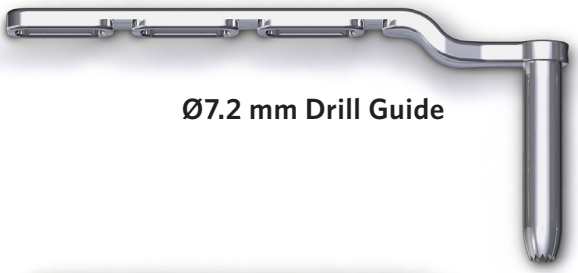
5.0 mm Countersink

5.5 mm Countersink

7.2 mm Countersink



Ø5.0 mm and Ø5.5 mm Drill Guide



Ø7.2 mm Drill Guide

K-wire Guide Ø5.0 mm

K-wire Guide Ø5.5 mm

K-wire Guide Ø7.2 mm

Tissue Protector

OTHER INSTRUMENTATION

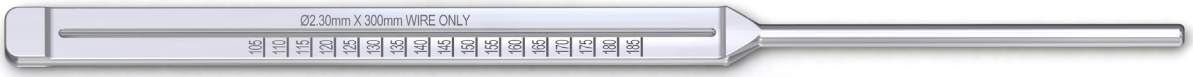
1.4 x 230 mm K-wire

1.6 x 230 mm K-wire

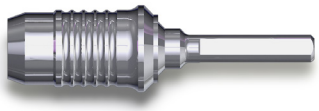
2.3 x 230 mm K-wire

2.3 x 300 mm K-wire

Depth Gauge, 5.0 mm and 5.5 mm Beaming Screws

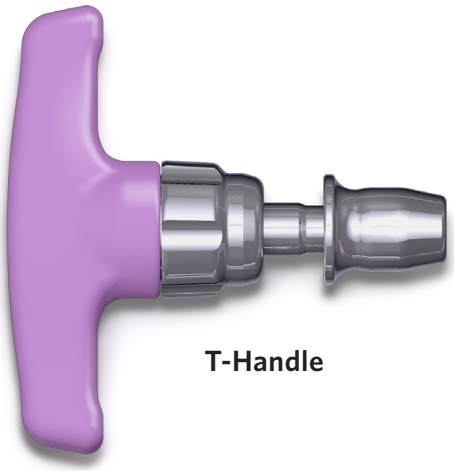


Depth Gauge, 7.2 mm Beaming Screws



Jacobs Adapter

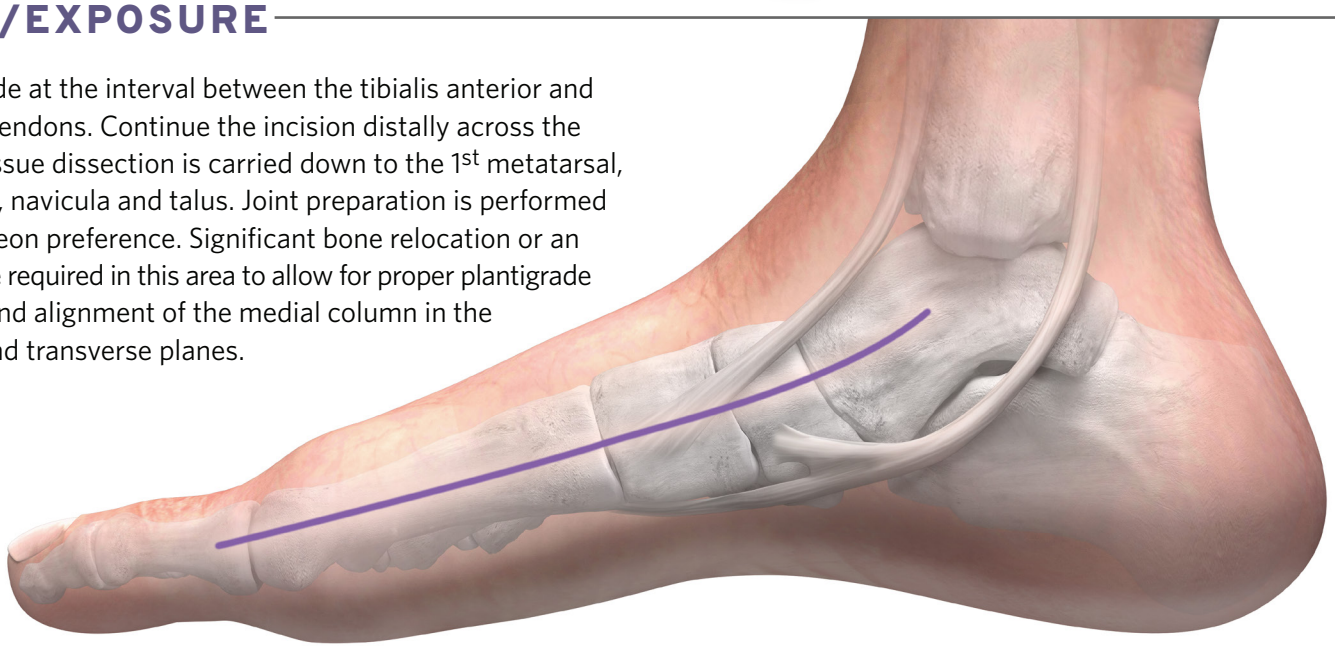
Handle



T-Handle

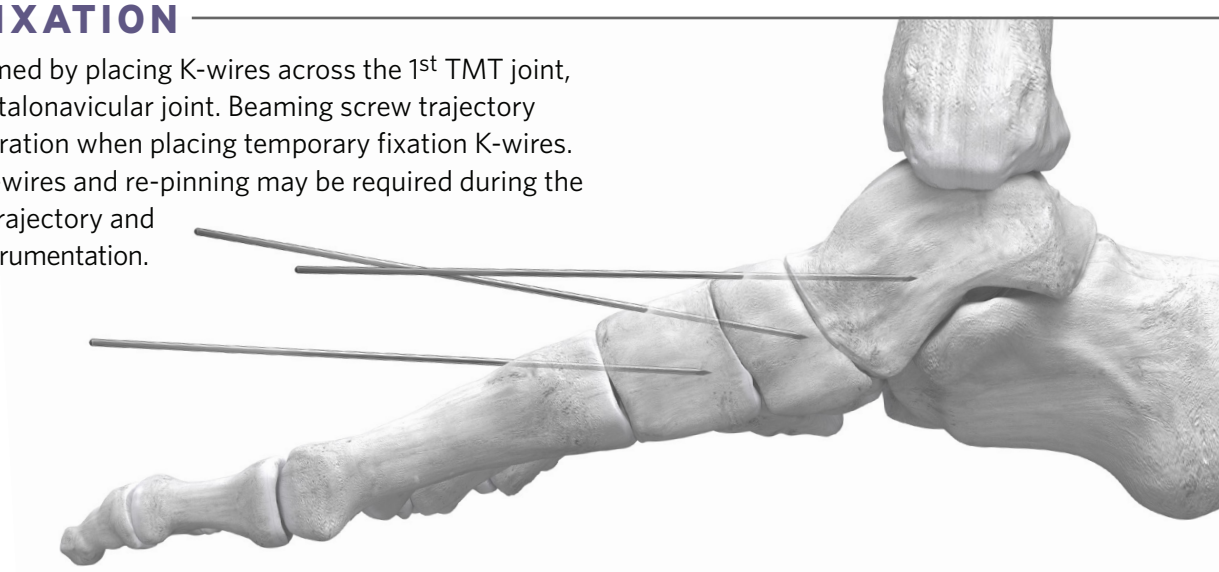
INCISION/EXPOSURE

An incision is made at the interval between the tibialis anterior and tibialis posterior tendons. Continue the incision distally across the MTP 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.



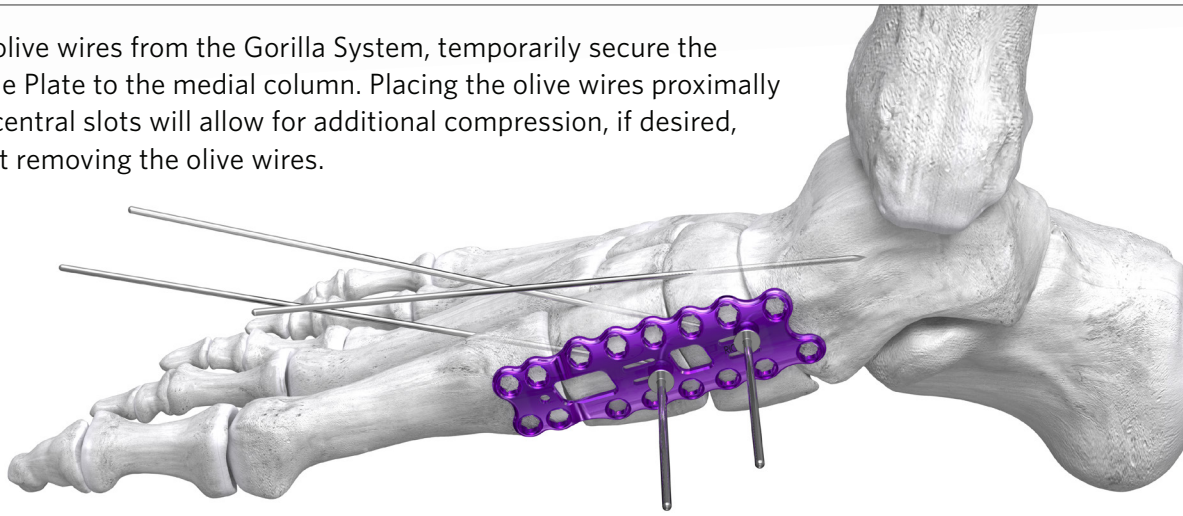
TEMPORARY FIXATION

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.



1 Freehand Straddle Plate + Precision Guide Beaming Screw

Using olive wires from the Gorilla System, temporarily secure the Straddle Plate to the medial column. Placing the olive wires proximally in the central slots will allow for additional compression, if desired, without removing the olive wires.



It is important that the plate is centered on the metatarsal base and maintains orientation with respect to the medial column to allow the beaming screw to pass through to the proximal portion of the reconstruction at the talus.

PLATE FIXATION

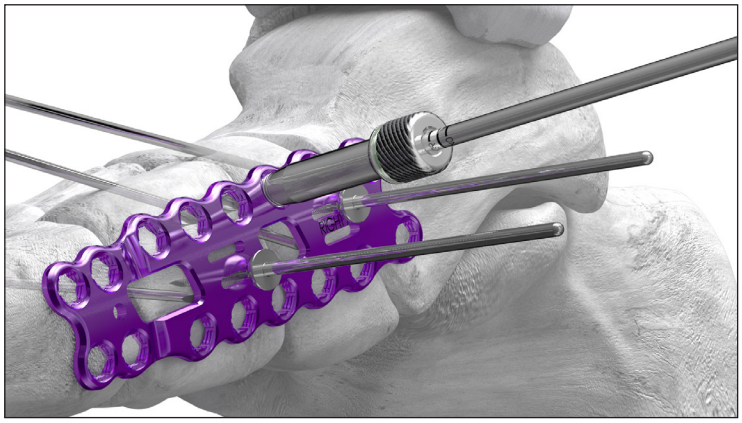
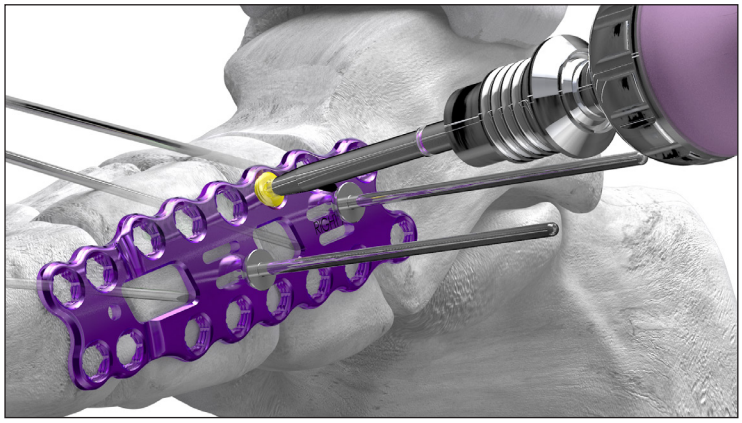


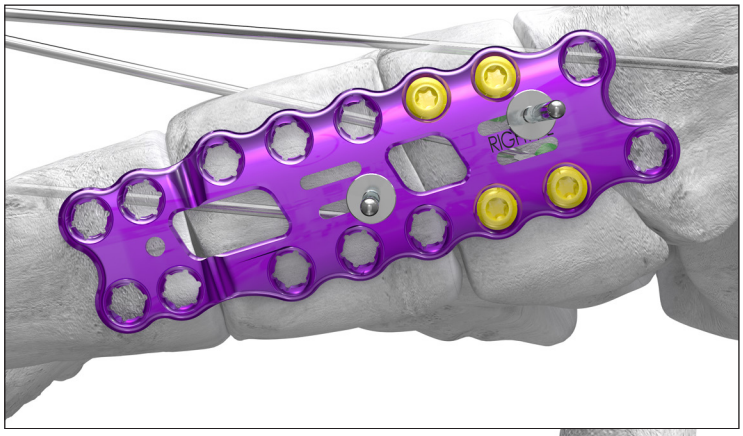
Plate fixation should begin at the central portion of the medial column first, where the plate best fits the bone surface. Using Gorilla plate screws, insert a threaded drill guide in a central hole of the plate. Drill using the drill sized for the desired screw diameter.



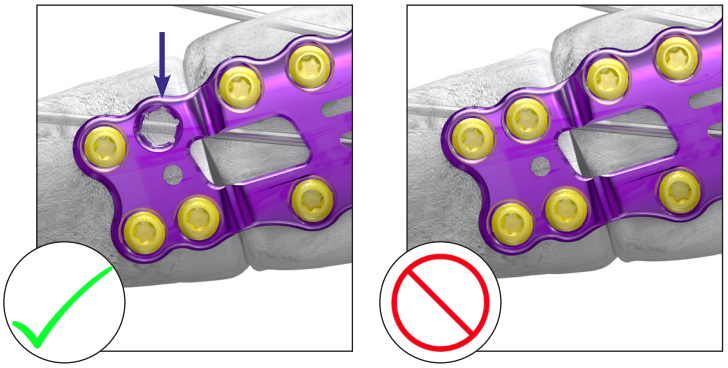
Measure for screw length using the depth gauge. Insert the selected screw into the plate hole using the driver and handle provided.

PLATE FIXATION

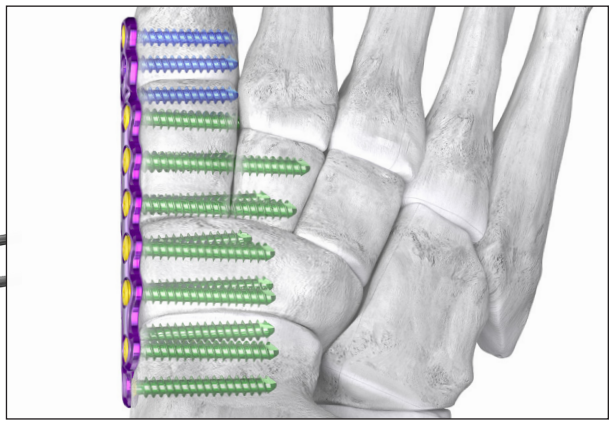
Continue screw fixation using the technique just described to place plate screws distal and proximal from initial screw placement.



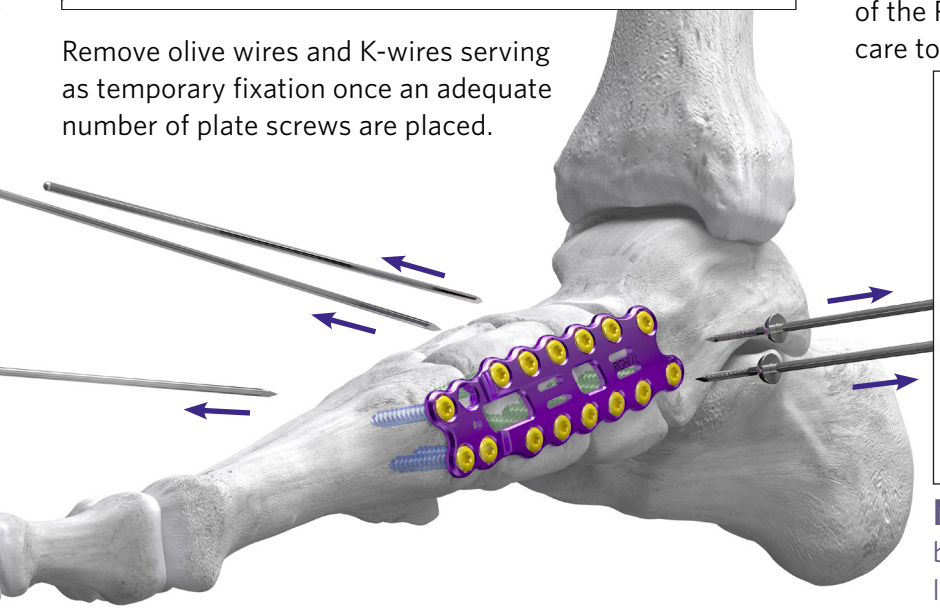
Ensure adequate reduction and compression of the bones and joints before placing additional plate screws.



Hole location for initial plate fixation is important for use of the Precision Guide Arm. In the first metatarsal, take care to avoid the above identified hole.



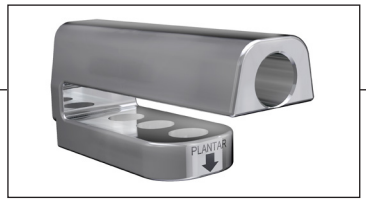
Remove olive wires and K-wires serving as temporary fixation once an adequate number of plate screws are placed.



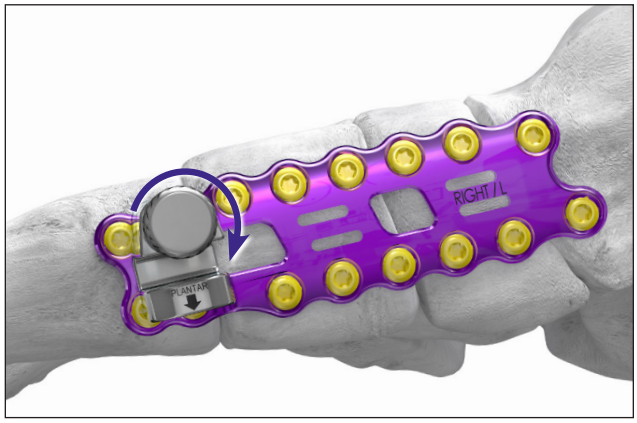
NOTE: The appropriate length screws should extend beyond medial column across the midfoot based on level of deformity, correction and bone involvement.

ATTACHING PRECISION GUIDE ARM TO PLATE

Retrieve the U-Clamp.

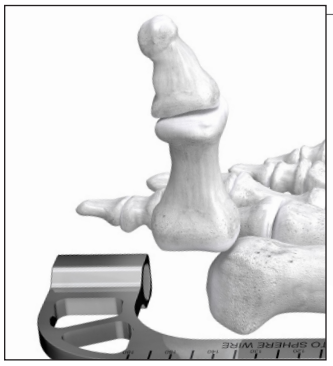


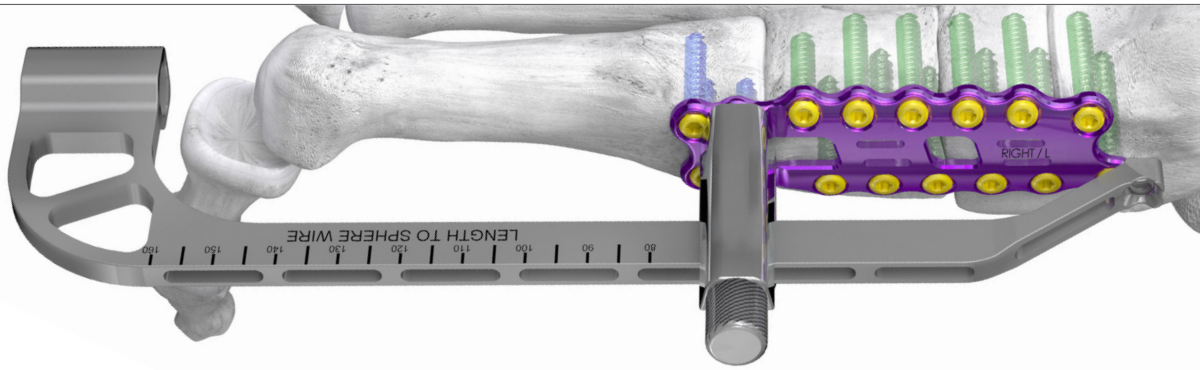
Attach the U-Clamp to the plate by inserting the boss into the hole in the plate between the two proximal plate holes on the 1st metatarsal.



Insert the set screw through the U-Clamp and thread into the empty plate hole at the dorsal proximal 1st metatarsal.

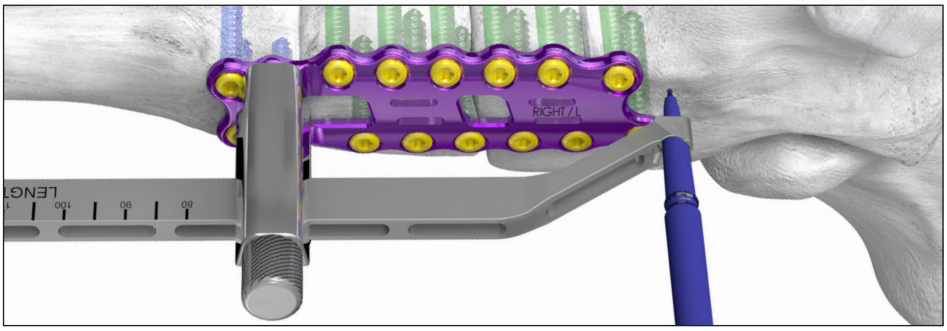
ATTACHING PRECISION GUIDE ARM TO PLATE





NOTE: For the purposes of this surgical technique guide, a plantarflexed hallux and dorsal approach is shown. A dorsiflexed hallux and plantar approach is an alternative per surgeon preference.

Retrieve the Precision Guide Arm. Slide the Precision Guide Arm within the U-Clamp to establish sphere wire placement from proximal to distal within the incision.

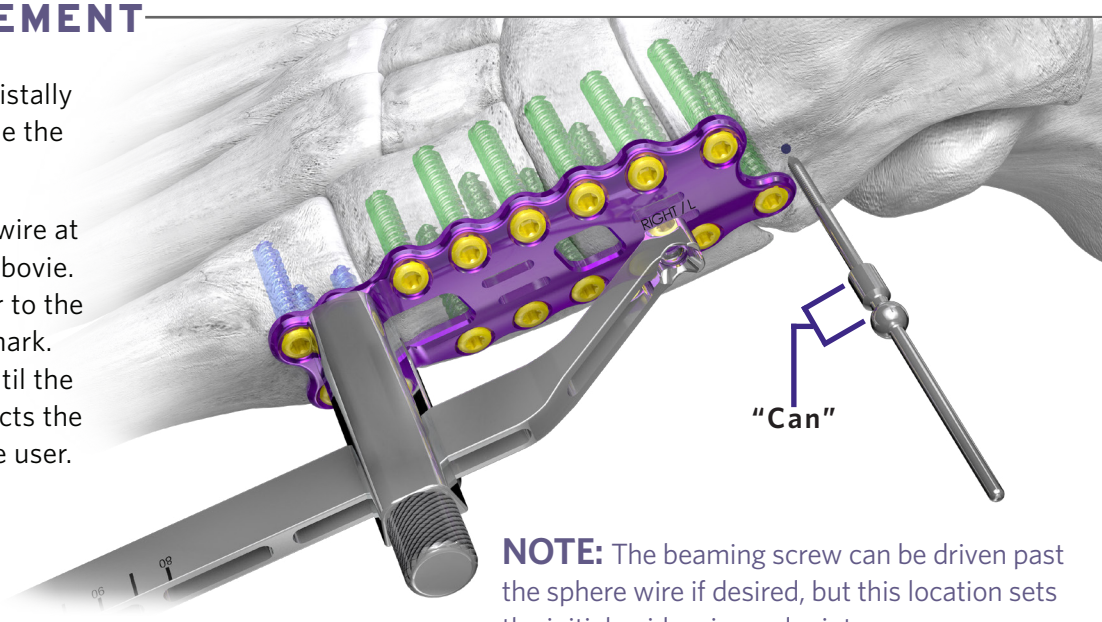


Once desired sphere wire placement has been established, mark the location through the Precision Guide with a marking pen or bovie.

SPHERE WIRE PLACEMENT

The Precision Guide Arm can be slid distally or off of the U-Clamp temporarily while the sphere wire is retrieved and placed.

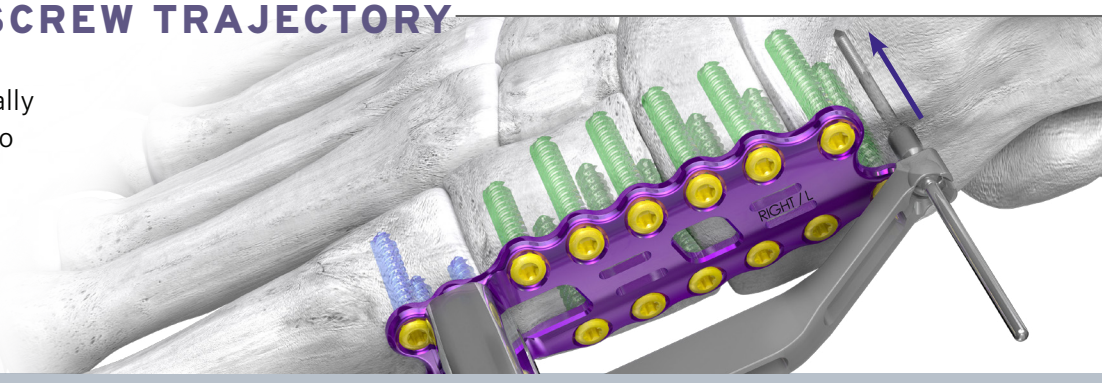
Position the entry point of the sphere wire at the point made by the marking pen or bovie. Position the sphere wire perpendicular to the talus with the tip at the pen or bovie mark. Drive the sphere wire into the bone until the "can" portion of the sphere wire contacts the bone. A hard stop should be felt by the user.



NOTE: The beaming screw can be driven past the sphere wire if desired, but this location sets the initial guide wire endpoint.

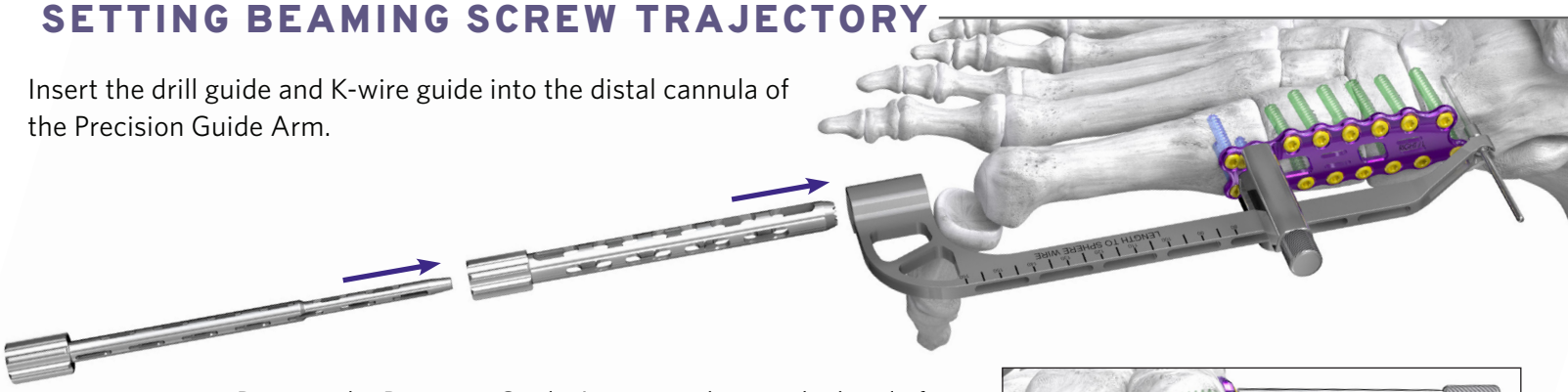
SETTING BEAMING SCREW TRAJECTORY

Slide the Precision Guide Arm proximally and snap the Precision Guide Arm onto the sphere wire.

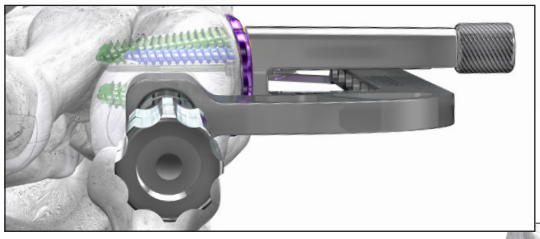


SETTING BEAMING SCREW TRAJECTORY

Insert the drill guide and K-wire guide into the distal cannula of the Precision Guide Arm.

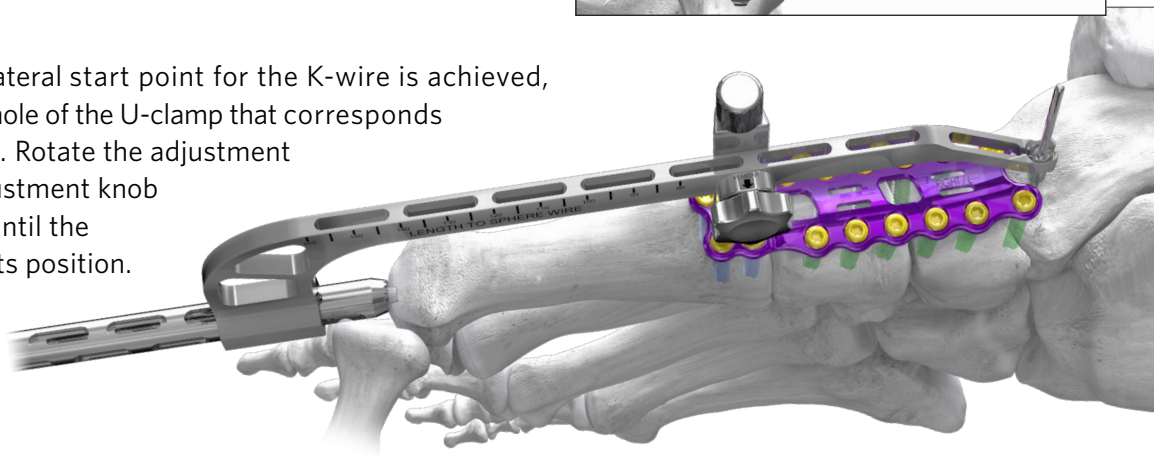


Position the Precision Guide Arm cannula over the head of the 1st metatarsal at the desired beaming screw entry point.



Retrieve the threaded knob for the Precision Guide Arm.

When the appropriate medial to lateral start point for the K-wire is achieved, insert the threaded knob into the hole of the U-clamp that corresponds with Precision Guide Arm height. Rotate the adjustment knob clockwise to tighten the adjustment knob against the Precision Guide Arm until the Precision Guide Arm is secure in its position.

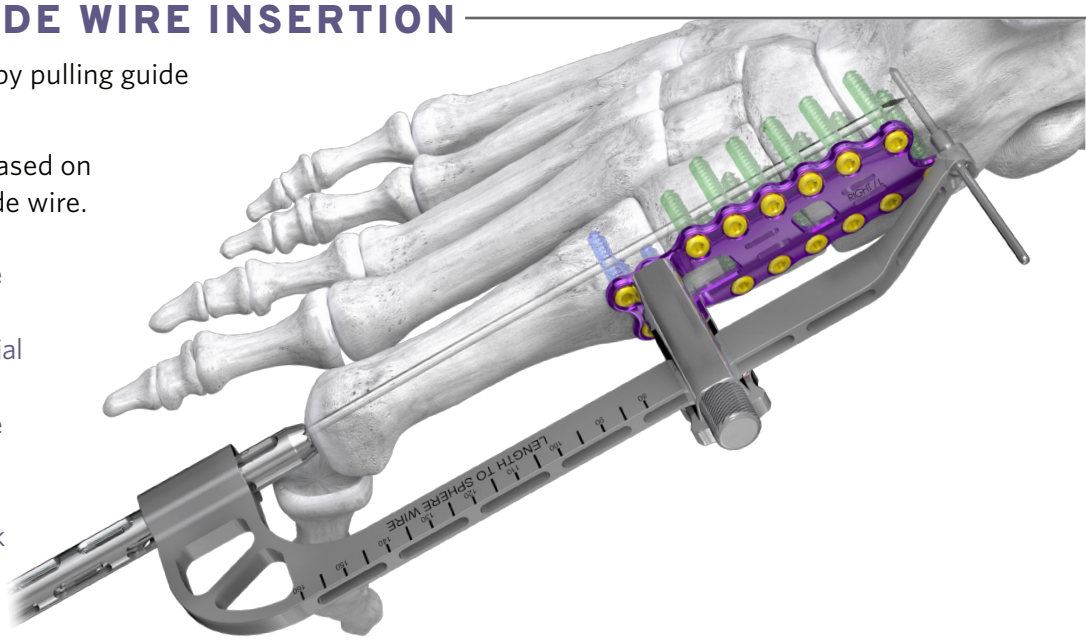


BEAMING SCREW GUIDE WIRE INSERTION

Guide wire entry point can be checked by pulling guide tubes back slightly.

Ensure desired guide wire entry point based on metatarsal shaft. Begin insertion of guide wire.

NOTE: The guide wire should terminate at the transition point between the thread and shaft of the sphere wire. If more medial placement of the guide wire is desired, remove the Precision Guide Arm from the sphere wire and back the sphere wire out medially until intended sphere wire end point. Place the Precision Guide Arm back on the sphere wire once moved.

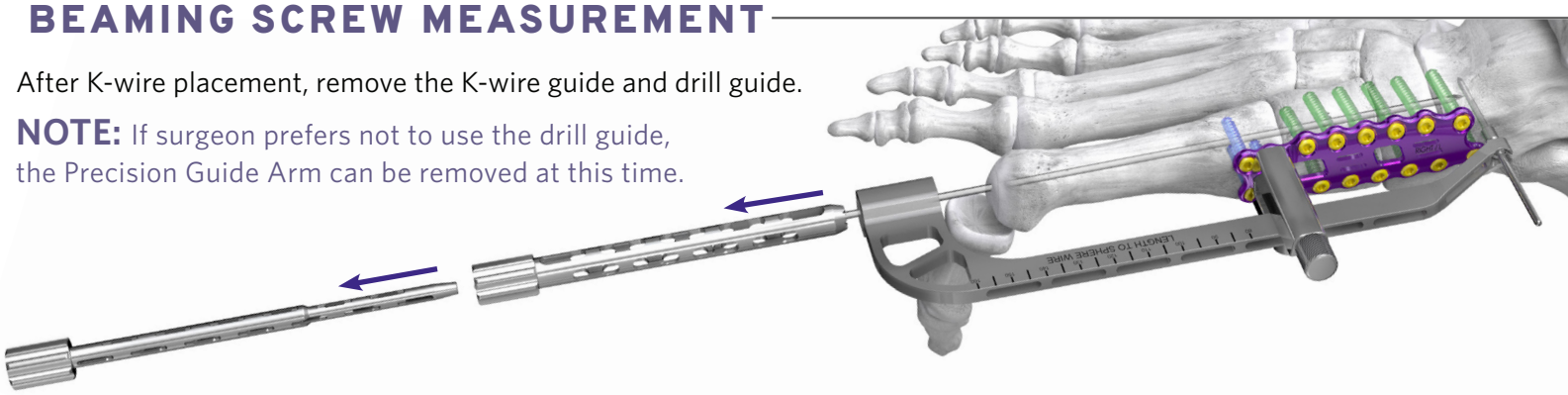


Although the Precision Guide Arm is designed to aid in insertion of guide wire, progress of wire insertion can be checked under fluoroscopy. Complete guide wire insertion. The guide wire is designed to contact the sphere wire at the point of thread to shaft transition; however, because of deflection due to hard bone at the joints, this may not always occur.

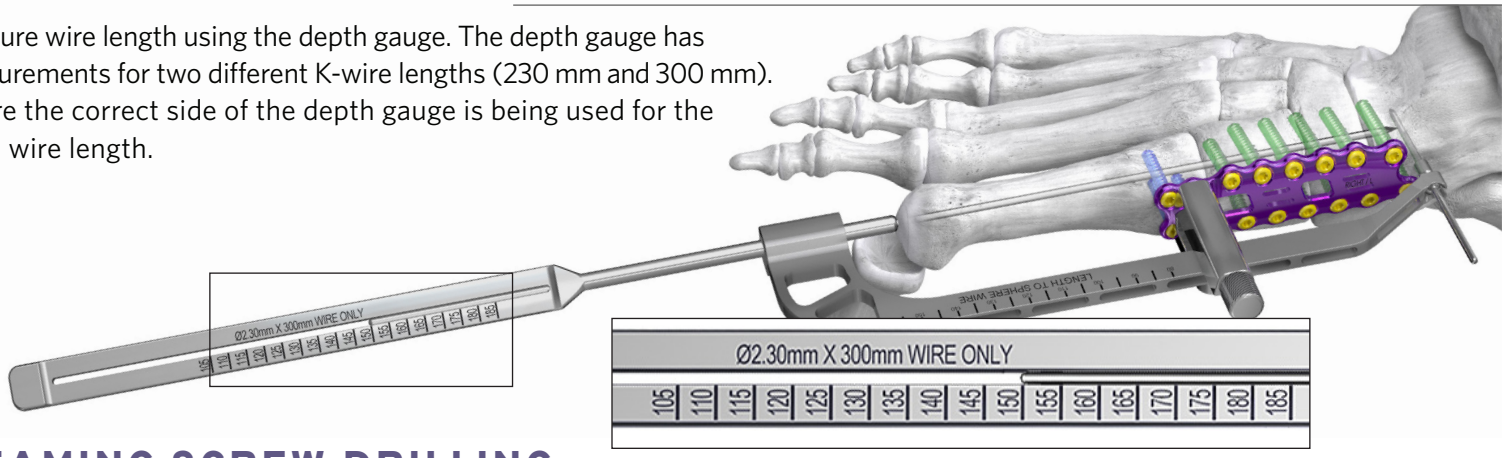
BEAMING SCREW MEASUREMENT

After K-wire placement, remove the K-wire guide and drill guide.

NOTE: If surgeon prefers not to use the drill guide, the Precision Guide Arm can be removed at this time.

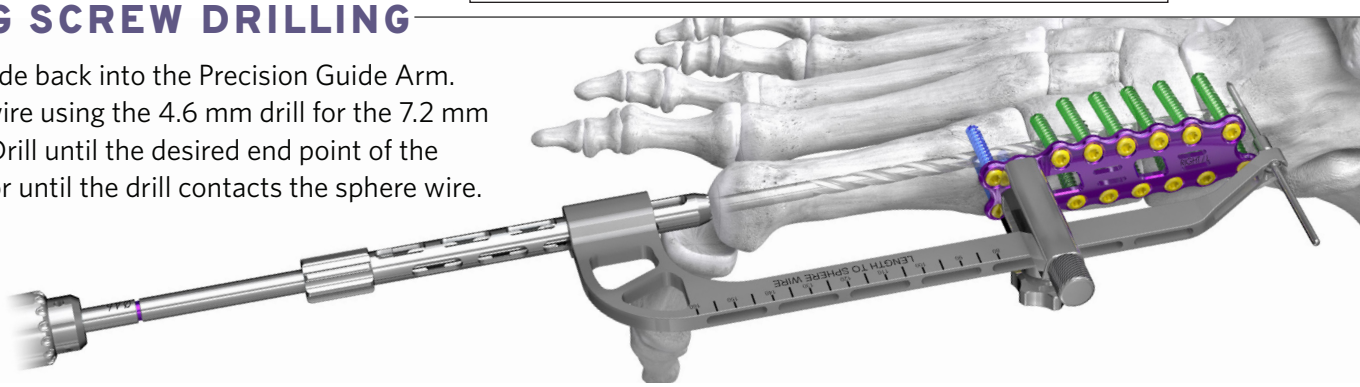


Measure wire length using the depth gauge. The depth gauge has measurements for two different K-wire lengths (230 mm and 300 mm). Ensure the correct side of the depth gauge is being used for the guide wire length.



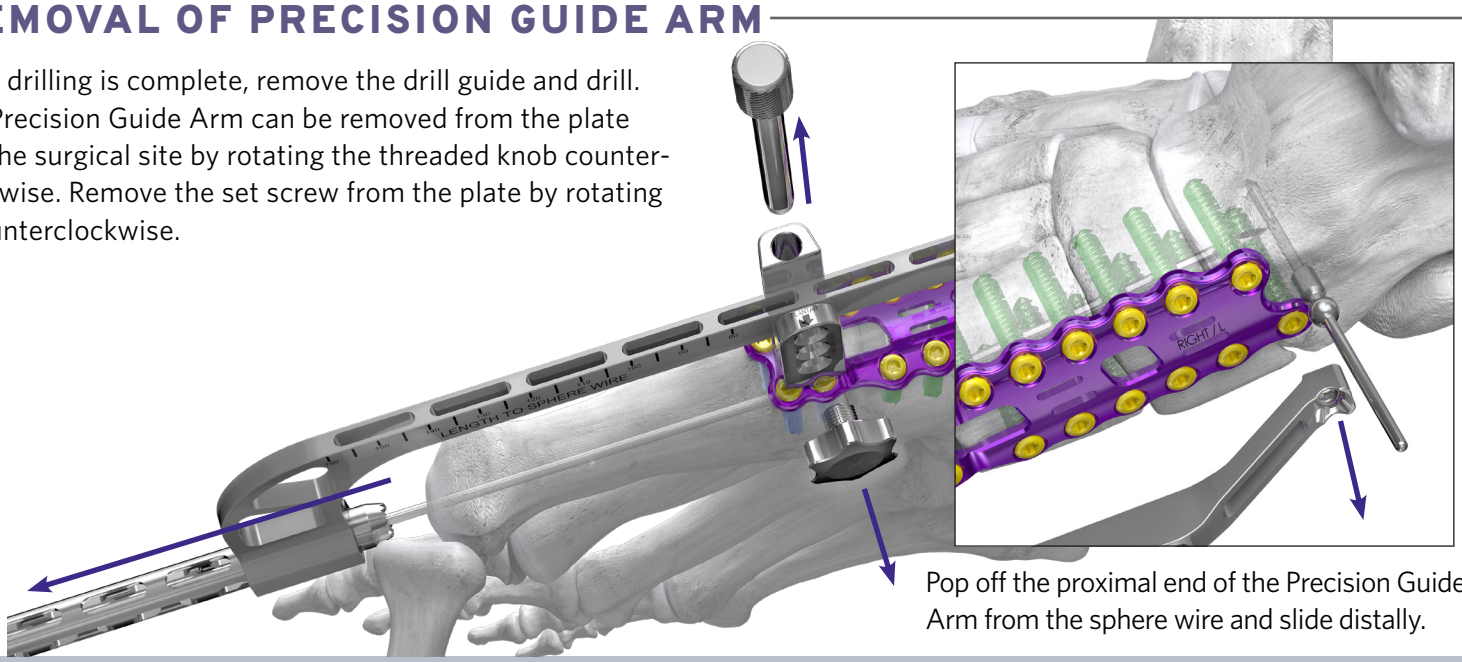
BEAMING SCREW DRILLING

Place the drill guide back into the Precision Guide Arm. Drill over the K-wire using the 4.6 mm drill for the 7.2 mm beaming screw. Drill until the desired end point of the beaming screw, or until the drill contacts the sphere wire.



REMOVAL OF PRECISION GUIDE ARM

Once drilling is complete, remove the drill guide and drill. The Precision Guide Arm can be removed from the plate and the surgical site by rotating the threaded knob counter-clockwise. Remove the set screw from the plate by rotating it counterclockwise.

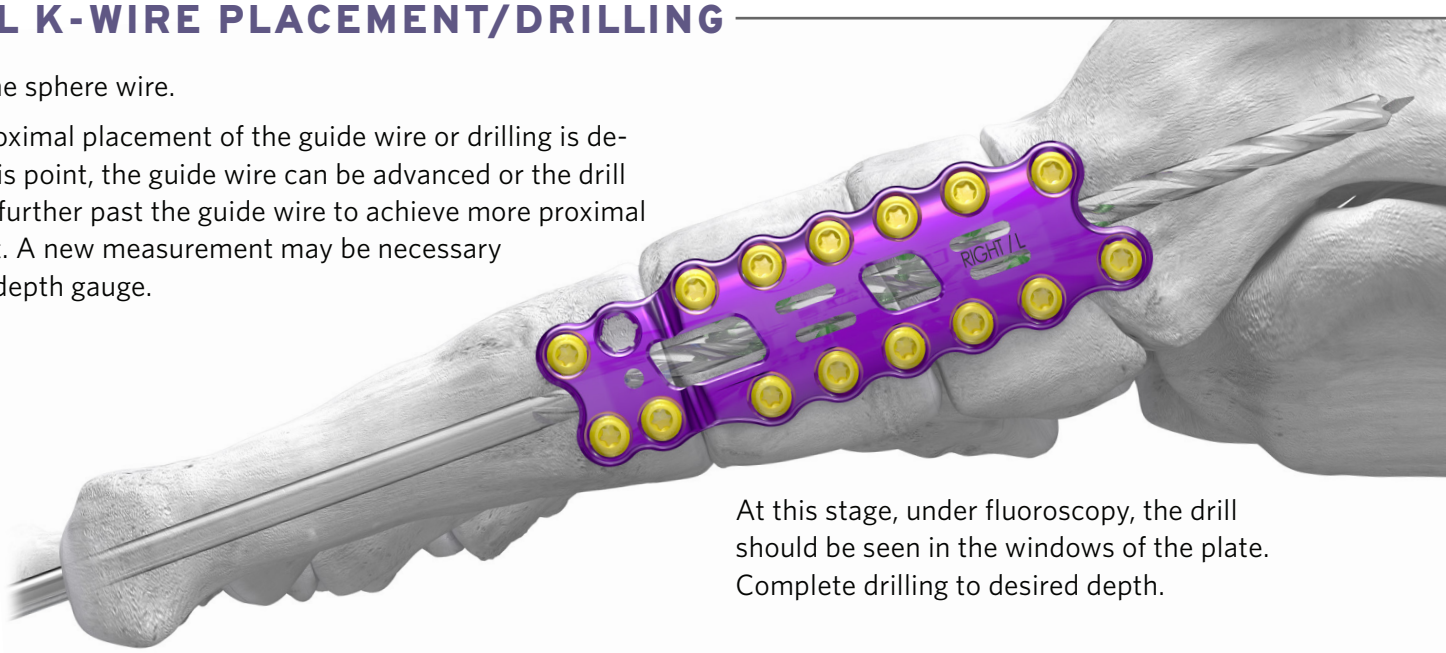


Pop off the proximal end of the Precision Guide Arm from the sphere wire and slide distally.

FINAL K-WIRE PLACEMENT/DRILLING

Remove the sphere wire.

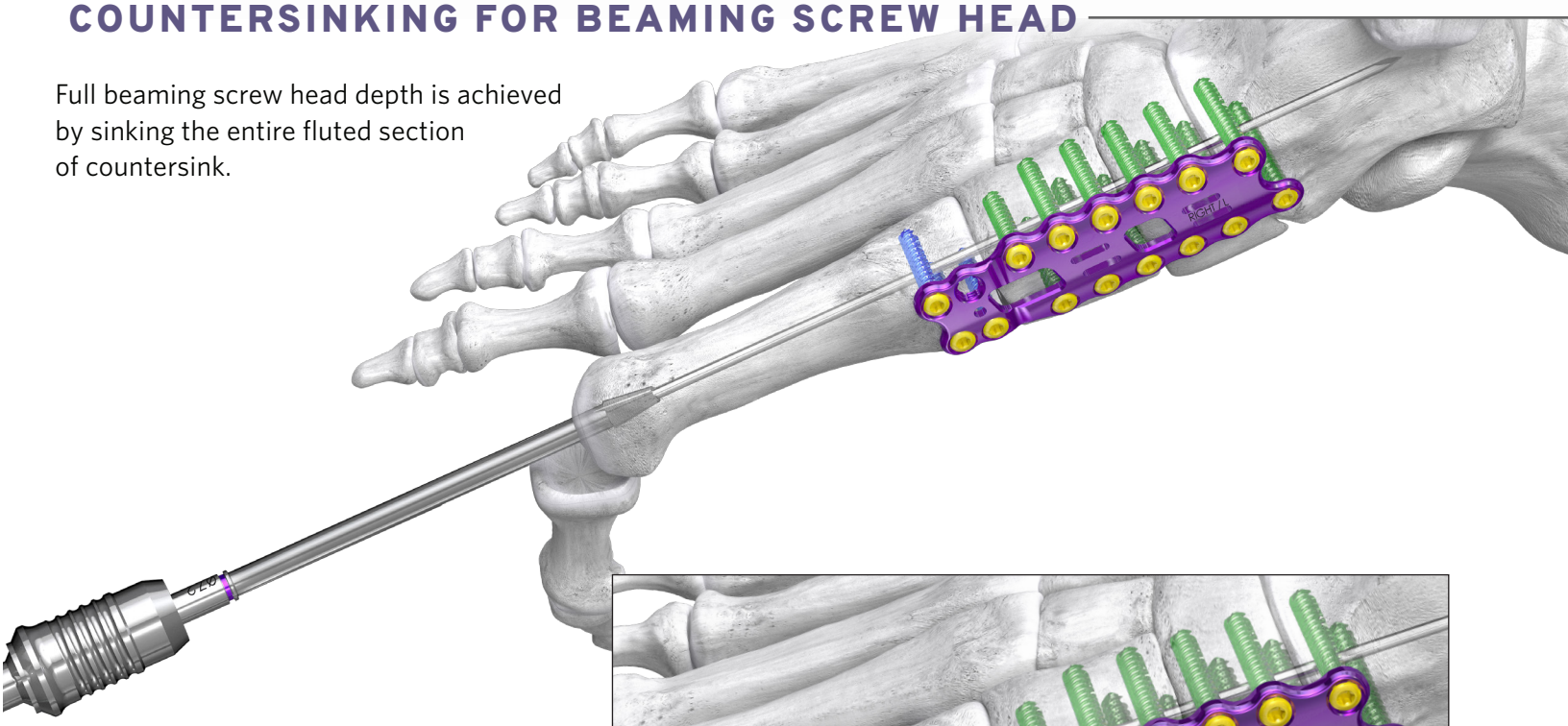
If more proximal placement of the guide wire or drilling is desired at this point, the guide wire can be advanced or the drill advanced further past the guide wire to achieve more proximal placement. A new measurement may be necessary using the depth gauge.

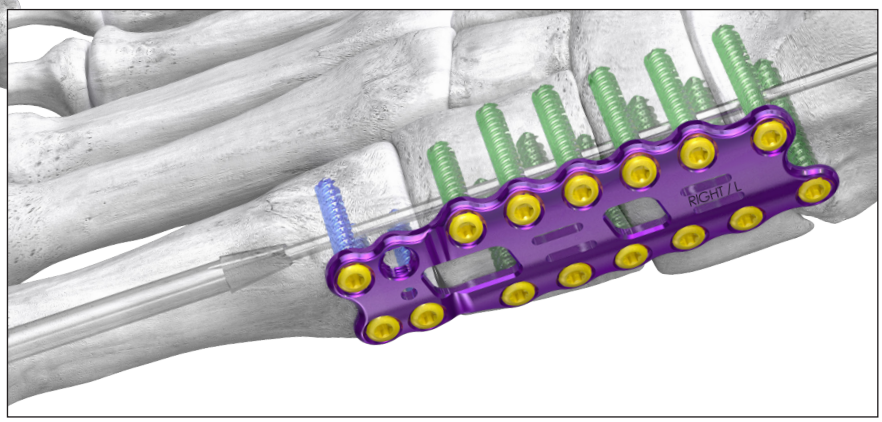


At this stage, under fluoroscopy, the drill should be seen in the windows of the plate. Complete drilling to desired depth.

COUNTERSINKING FOR BEAMING SCREW HEAD

Full beaming screw head depth is achieved by sinking the entire fluted section of countersink.



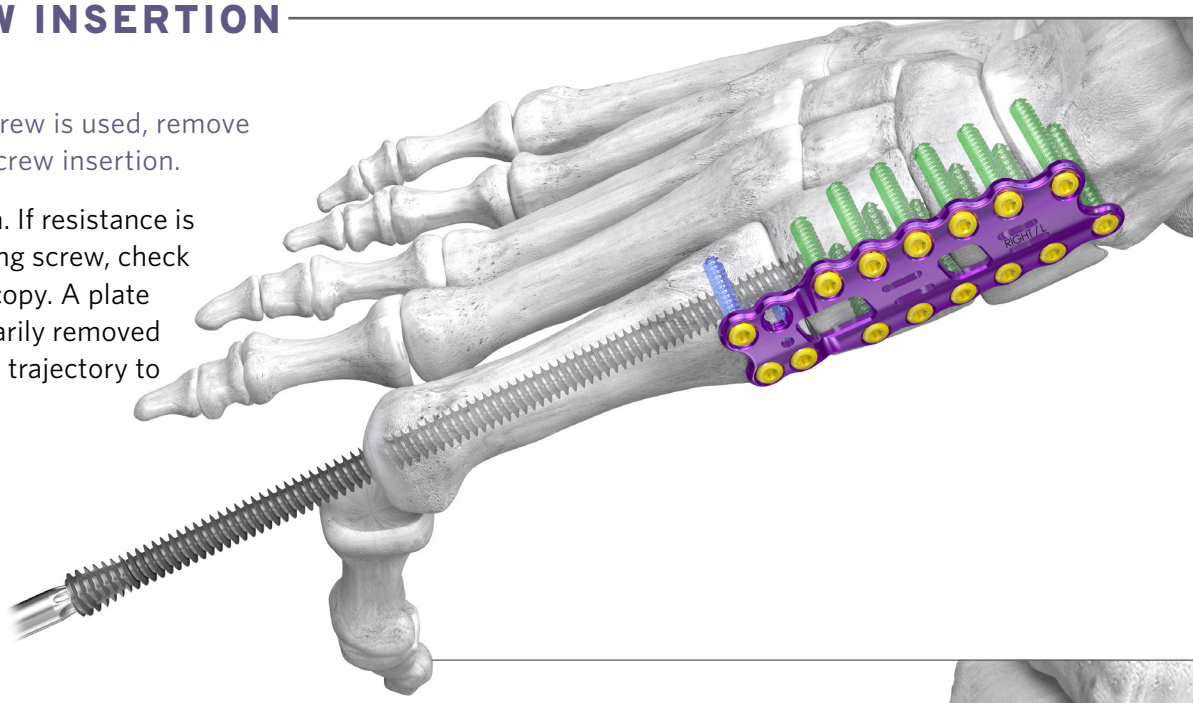


OPTION: The countersink is designed with an extended shaft length to allow for deep countersinking of the beaming screw into the metatarsal, if desired. If the beaming screw is placed more proximally into the metatarsal, ensure that the appropriate amount is subtracted from the original beaming screw length measured.

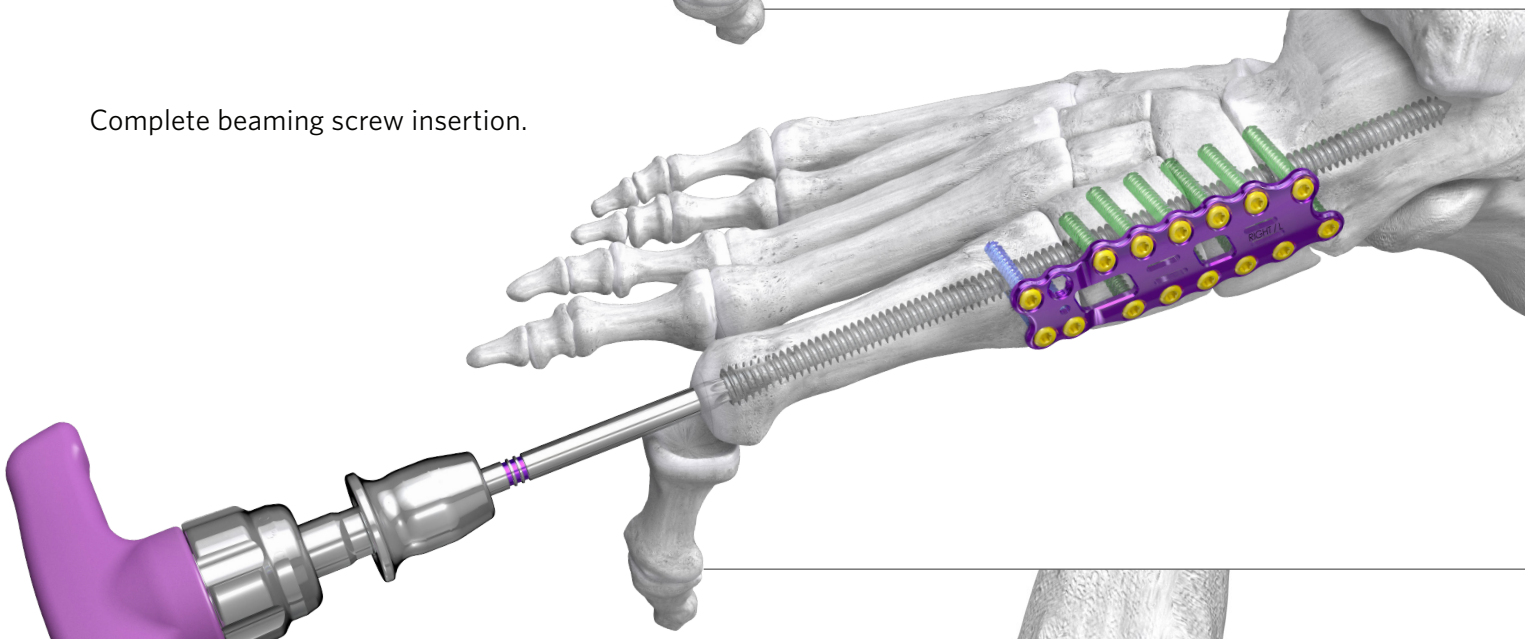
BEAMING SCREW INSERTION

NOTE: If a solid beaming screw is used, remove the K-wire prior to beaming screw insertion.

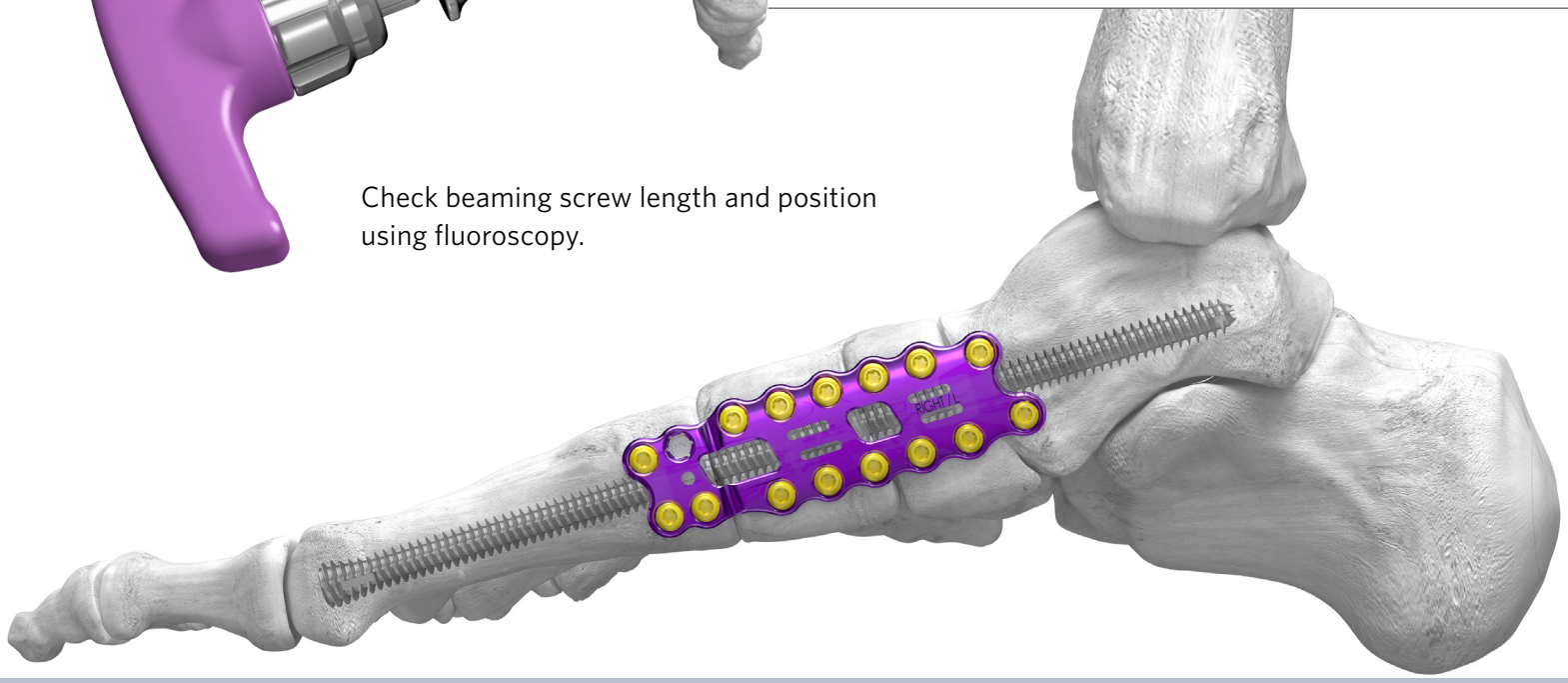
Begin beaming screw insertion. If resistance is felt while putting in the beaming screw, check area in question using fluoroscopy. A plate screw may need to be temporarily removed and replaced later using a new trajectory to avoid the beaming screw.



Complete beaming screw insertion.

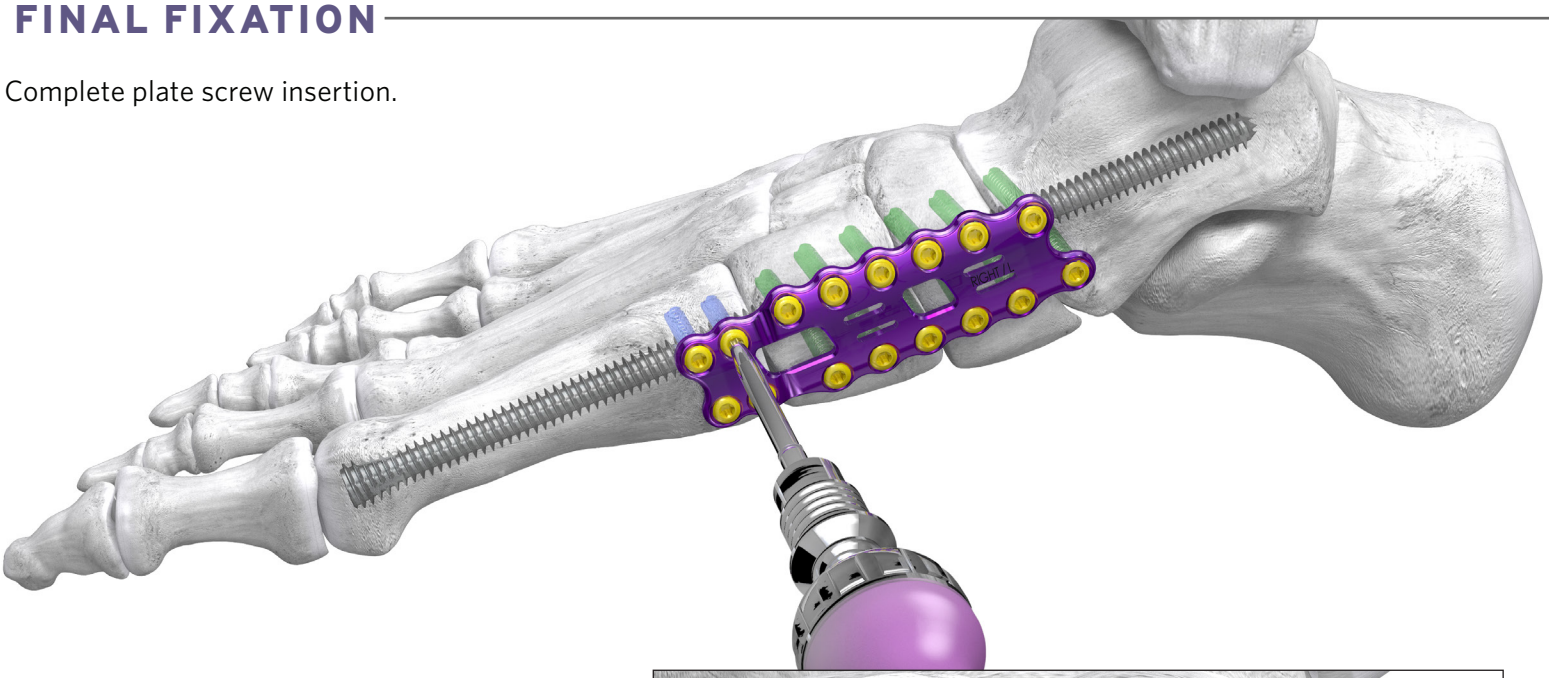


Check beaming screw length and position using fluoroscopy.

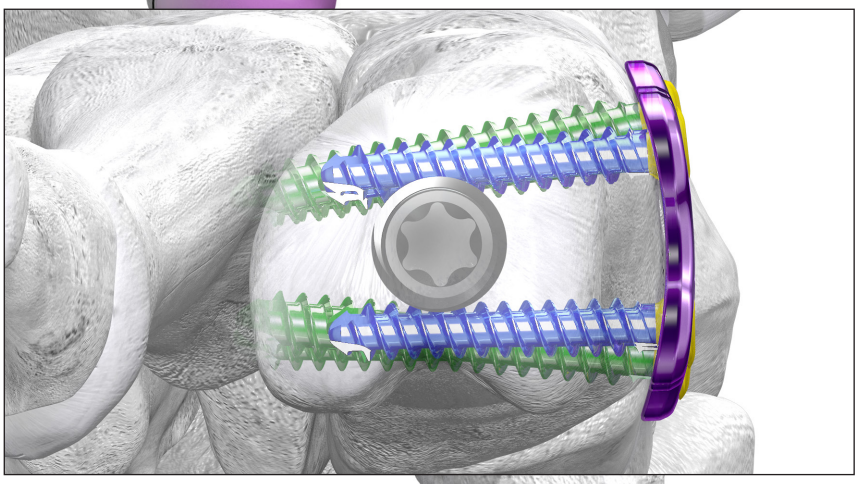


FINAL FIXATION

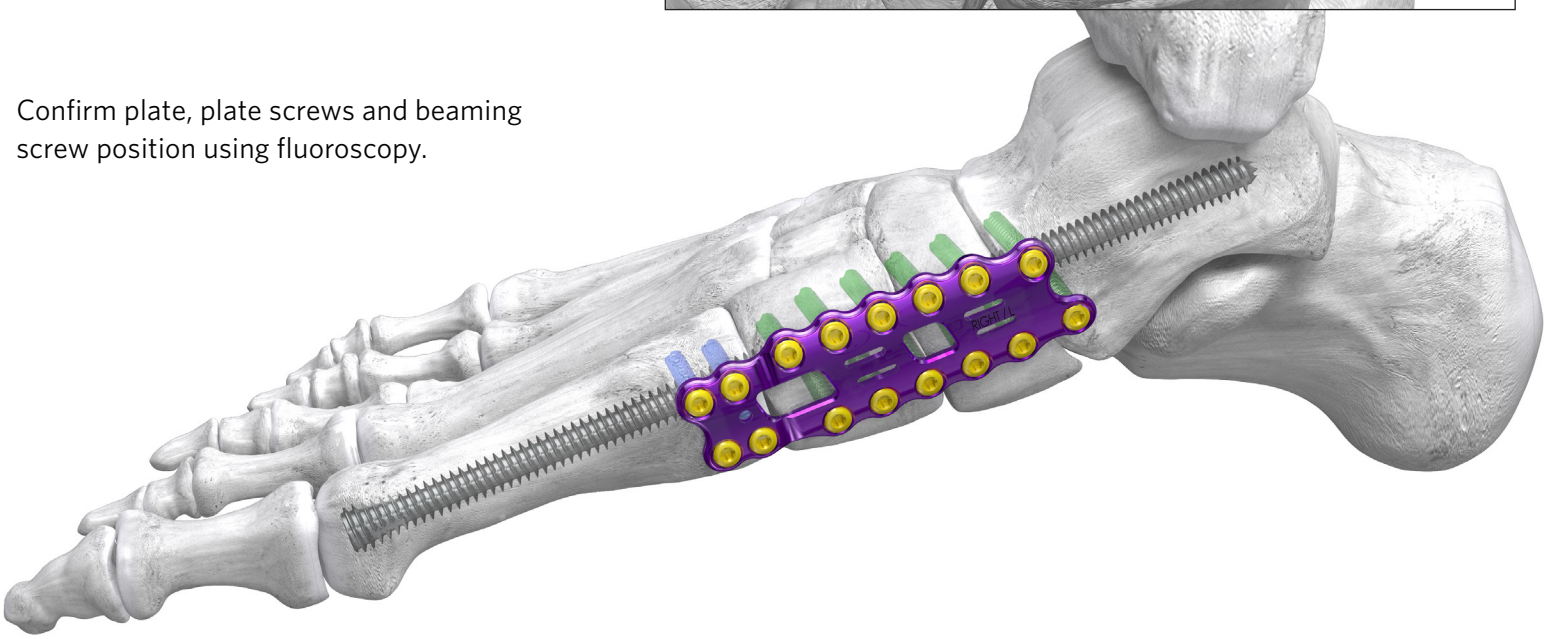
Complete plate screw insertion.



NOTE: The locking screws have 15° (in any direction) off-axis locking capability. Care should to 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.

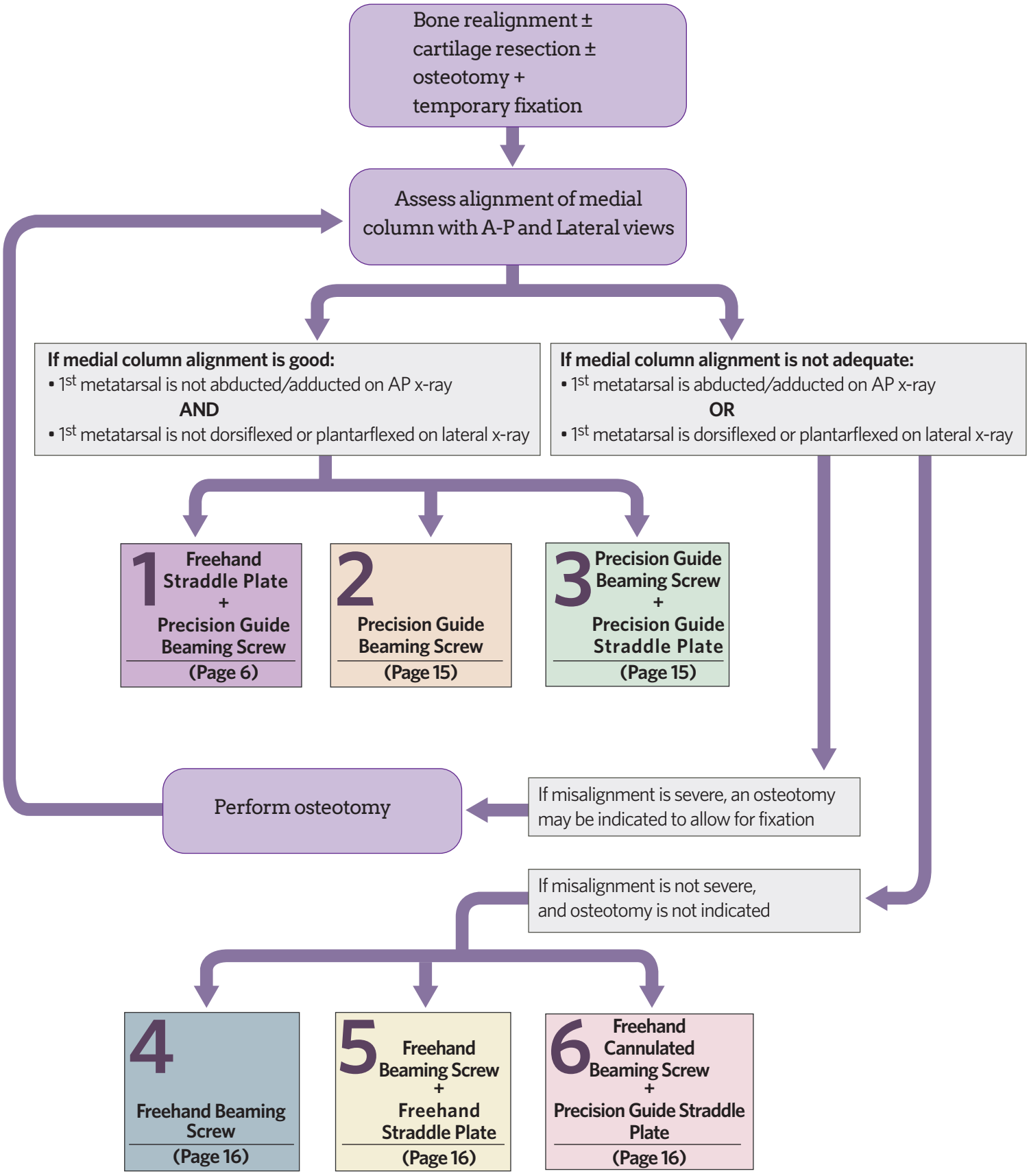


CLOSURE

Proceed to incision closure or concomitant procedures at this time.

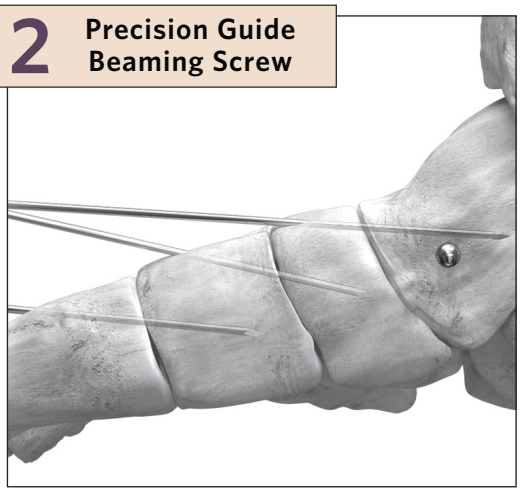
DECISION MATRIX FOR FIXATION

The previous technique described may not be feasible for all cases of medial column beaming due to foot shape and bone alignment. The following decision matrix helps to outline options for situations that may not be as straightforward, as well as provide insight into the versatility of the system.

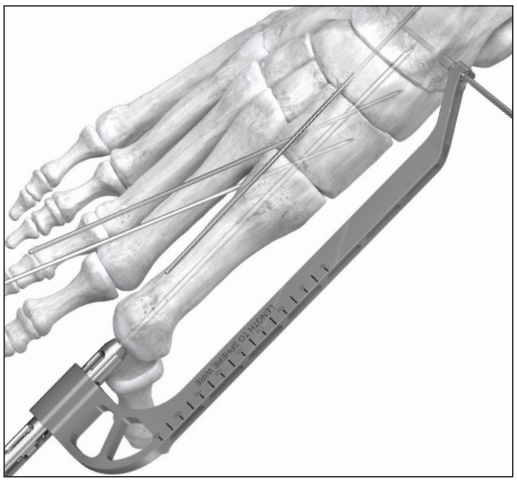


FINAL FIXATION

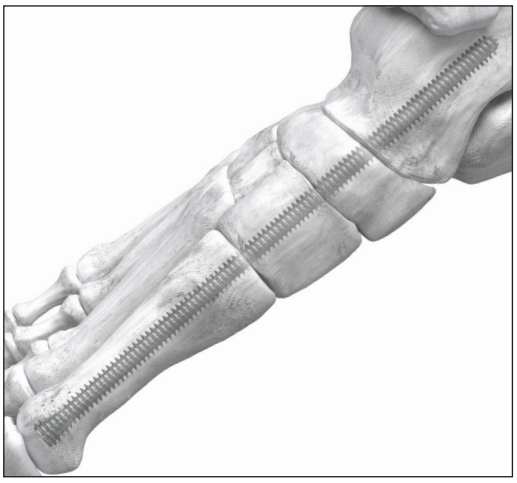
2 Precision Guide Beaming Screw



Place the sphere wire perpendicular to the talus at the talar neck. Drive the sphere wire into the bone until the can portion of the sphere wire contacts bone.

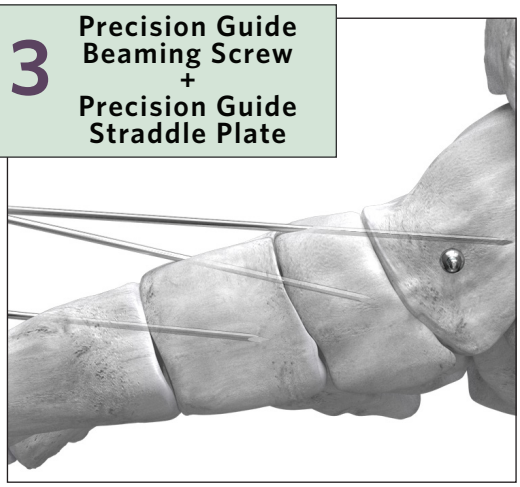


Snap the Precision Guide Arm onto the sphere wire and position the Precision Guide Arm cannula to allow for desired beaming screw entry point at the head of the 1st metatarsal.

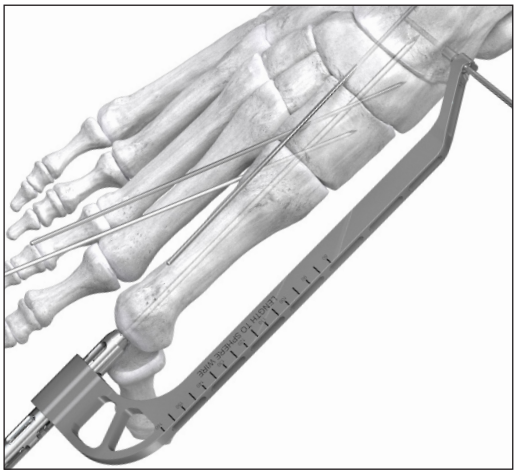


Insert a cannulated or solid beaming screw as described in the surgical technique steps on pages 9-12.

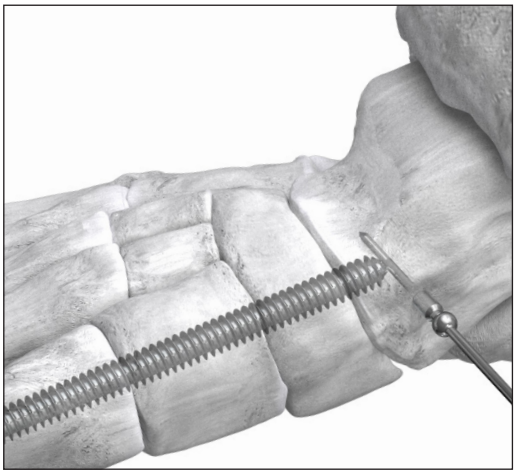
3 Precision Guide Beaming Screw + Precision Guide Straddle Plate



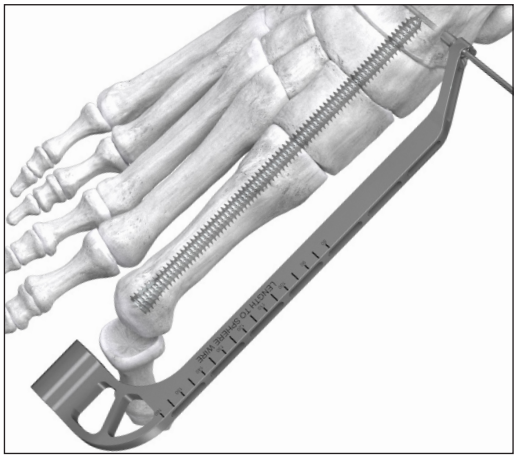
Place the sphere wire perpendicular to the talus at the talar neck. Drive the sphere wire into the bone until the can portion of the sphere wire contacts bone.



Snap the Precision Guide Arm onto the sphere wire and position the Precision Guide Arm cannula to allow for desired beaming screw entry point at the head of the 1st metatarsal.

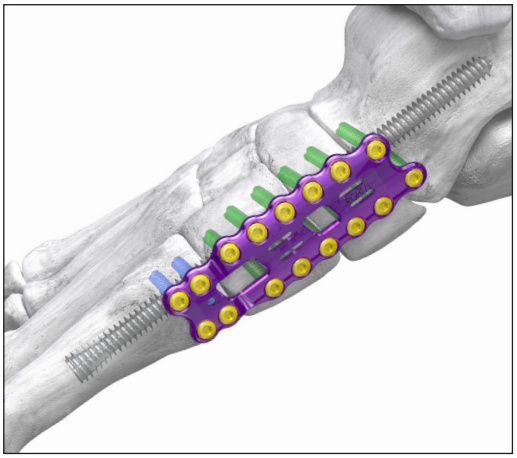


Insert a cannulated or solid beaming screw as described in the surgical technique steps on pages 9-12, while keeping the sphere wire in place.



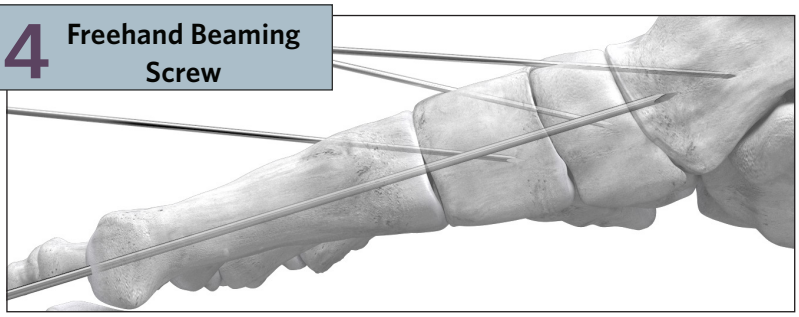
Reattach the Precision Guide Arm to the sphere wire.

Assemble the U-Clamp to the straddle plate. Attach the Precision Guide Arm to the U-Clamp and secure the Precision Guide Arm once desired plate placement is achieved.

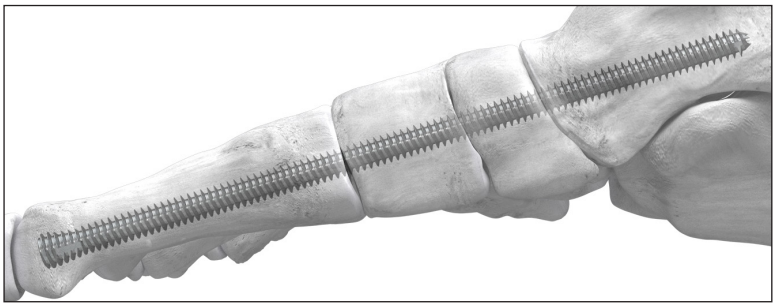


Affix the straddle plate to the medial column with plate screws. If more proximal beaming screw placement is desired, drive beaming screw proximally once sphere wire is removed.

4 Freehand Beaming Screw

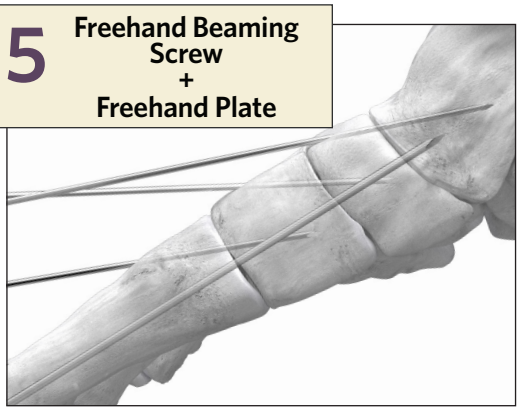


Insert K-wire for beaming screw into the medial column.

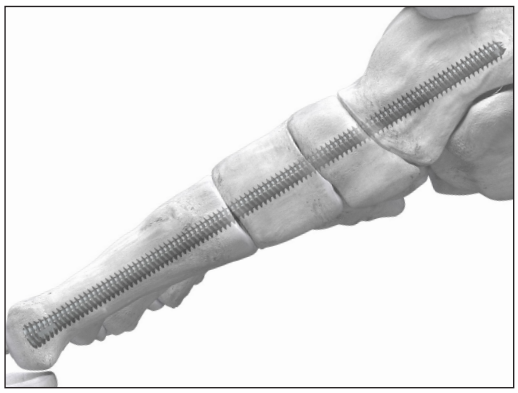


Using standard techniques, insert a cannulated or solid beaming screw. Remove K-wire once position is confirmed using fluoroscopy.

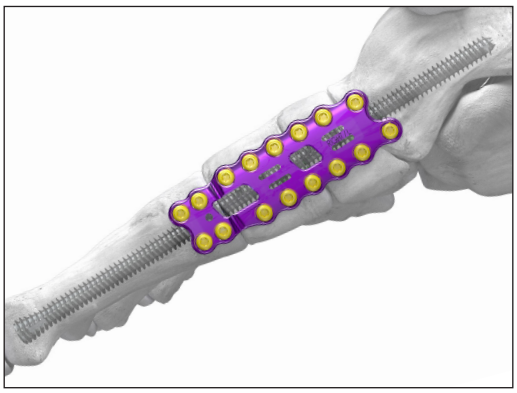
5 Freehand Beaming Screw + Freehand Plate



Insert K-wire for beaming screw into the medial column.

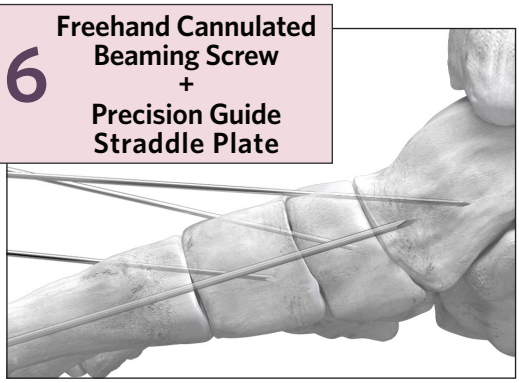


Using standard techniques, insert a cannulated or solid beaming screw. Remove K-wire once position is confirmed using fluoroscopy.

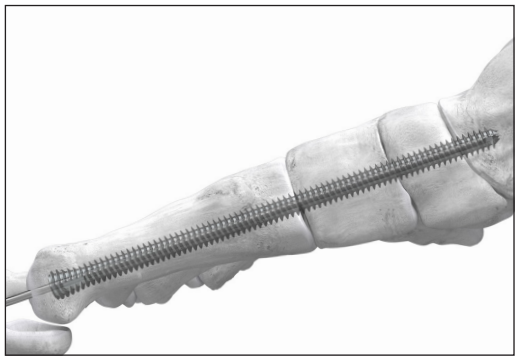


Affix the straddle plate to the medial column with plate screws. Off-axis screw placement may be required on some of the plate screws to avoid interference with the beaming screw.

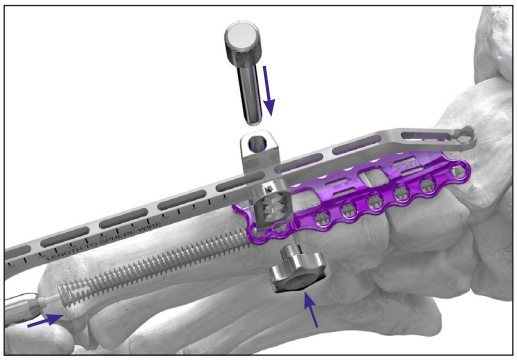
6 Freehand Cannulated Beaming Screw + Precision Guide Straddle Plate



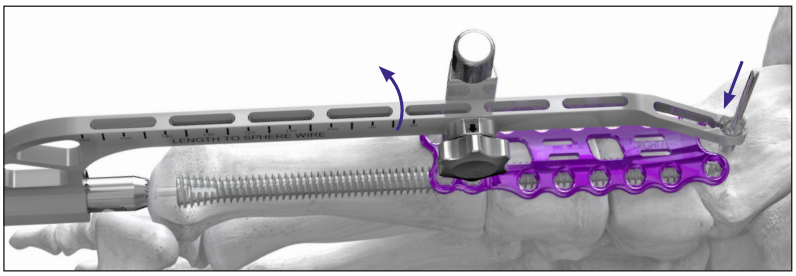
Insert K-wire for the beaming screw into the medial column.



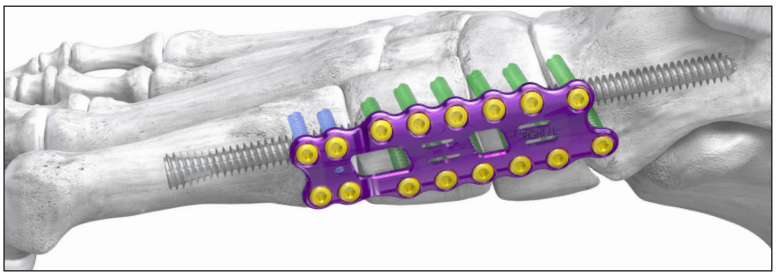
Using standard techniques, insert a cannulated beaming screw over the K-wire. Retain K-wire in the beaming screw.



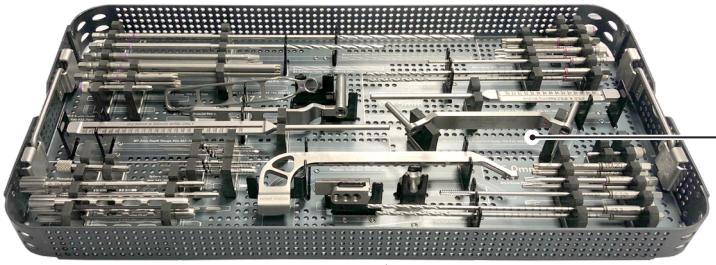
Assemble the U-Clamp to the straddle plate. Insert the Precision Guide Arm into the U-Clamp and affix the Precision Guide Arm to the U-Clamp using the threaded knob.



Allow the Precision Guide and plate to rotate around the beaming screw (up to 60°) until desired plate placement is achieved. Insert the sphere wire at the proximal end of the Precision Guide Arm. Snap the Precision Guide Arm onto the sphere wire.

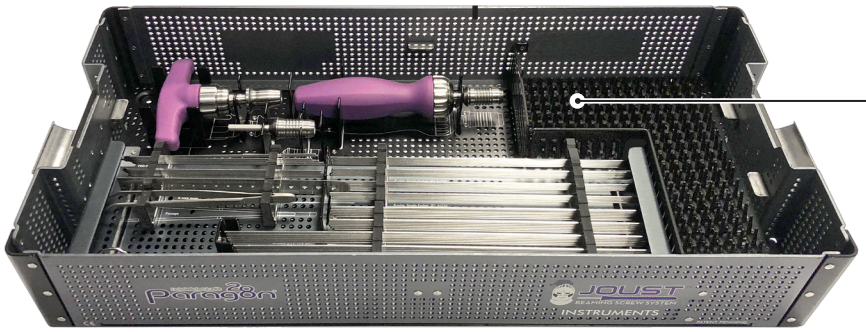


Affix the straddle plate to the medial column with plate screws. Off-axis screw placement may be required on some of the plate screws to avoid interference with the beaming screw. If more proximal beaming screw placement is desired, drive beaming screw proximally once sphere wire is removed.



Instrument Tray

The Precision® Guide, U-Clamp, threaded knob, K-wire guides, drill guides, sphere wires, 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.

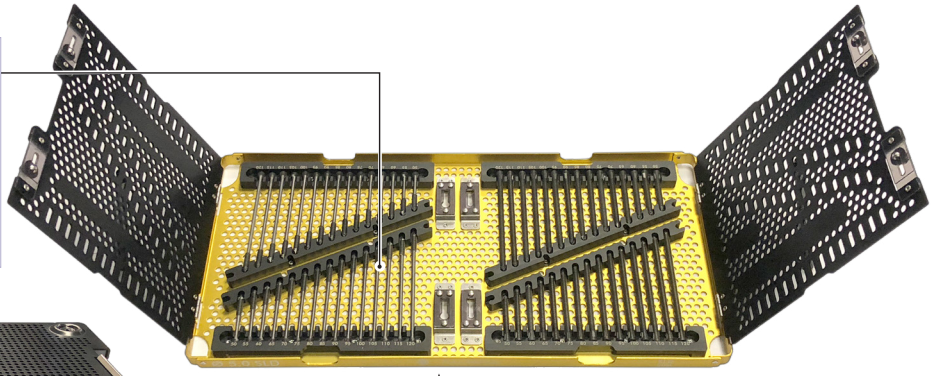


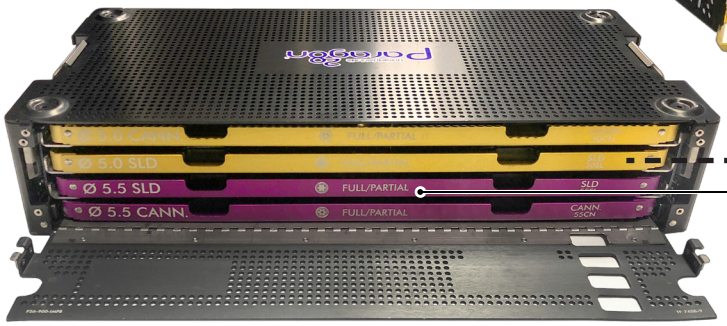
Instrument Case

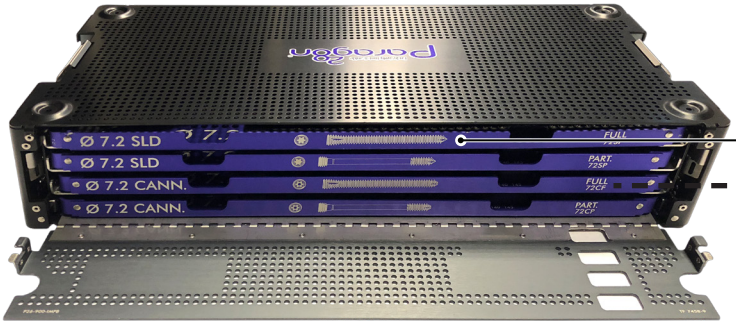
A Jacobs adapter, handle, T-handle, cleaning stylets, forceps and K-wires are located at the bottom of the Joust™ Beaming Screw Instrument Case.

Ø5.0 & Ø5.5 Beaming Screw Tray

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





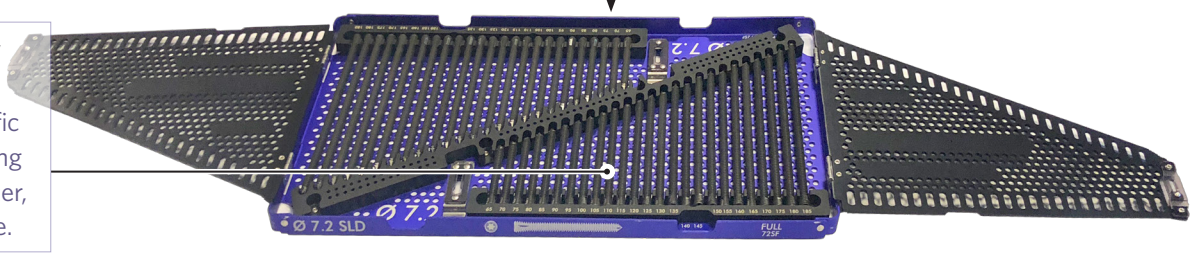


Beaming Screw Case

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

Ø7.2 Beaming Screw Tray

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

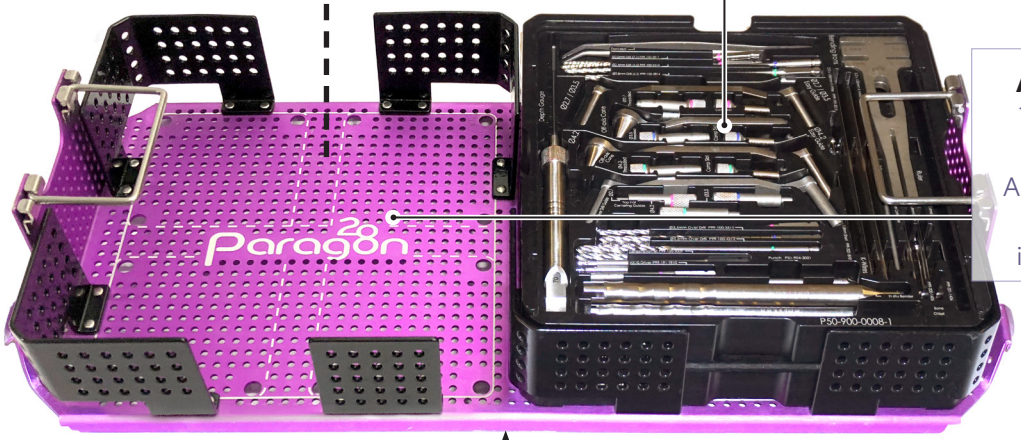


Medial Column Caddy

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

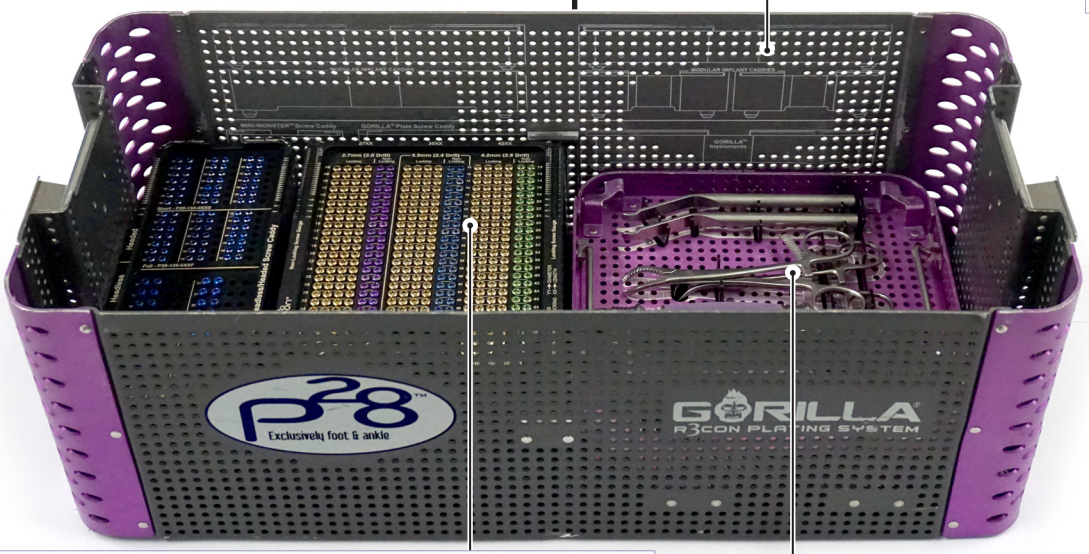
Drills, drill guides, centering guides, olive wires, plate benders, drivers, K-wires and a depth gauge are located in the Gorilla® R3CON Instrument Caddy.



Additional Gorilla® Caddies

The Gorilla® Case has room for additional Gorilla® Plate Caddies or PRESERVE™ Allograft 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.

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 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.
- 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.
- **Do not use other manufacturer's instruments or implants in conjunction with the Monster Screw System.**

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. The system can be used in both adult and pediatric patients.

In addition, the non-locking 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.

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

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

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- 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.
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- 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 Breakaway 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.

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JOUST™
BEAMING SCREW SYSTEM

GORILLA®
R3CON PLATING SYSTEM

PATENTED, DESIGNED & EXCLUSIVELY DISTRIBUTED BY

Exclusively foot & ankle
Paragon 28®

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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.