THE BRACHIATOR
Mini External Fixation System

SURGICAL TECHNIQUE GUIDE
The Brachiator Mini External Fixation System

Paragon 28®
a ZIMMER BIOMET company

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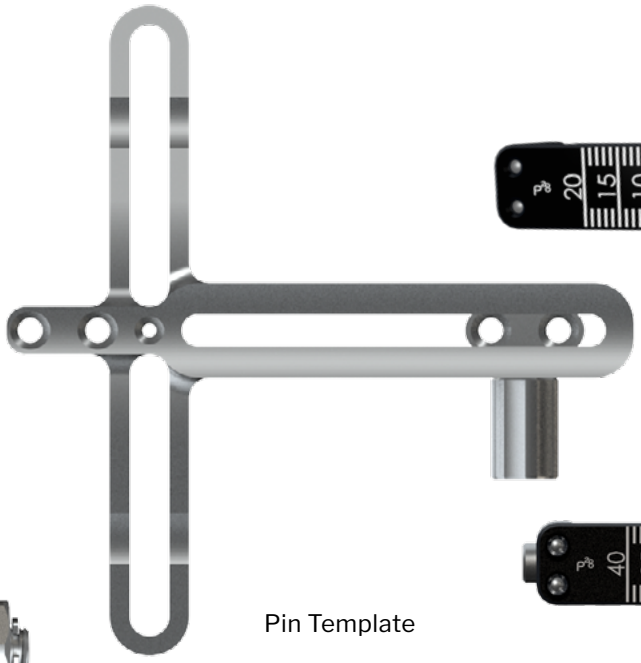


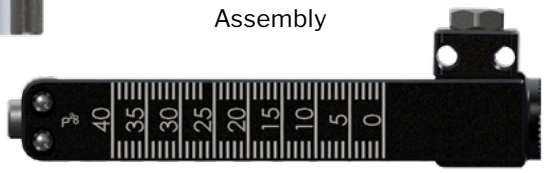
Pin Template

AO Adaptor

Hinged Mini Rail

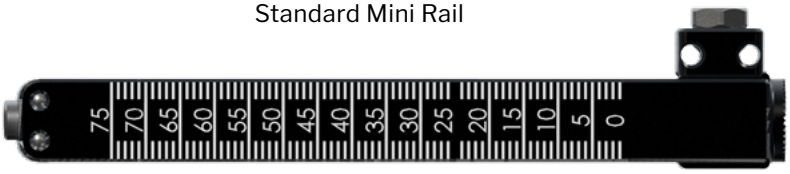
Hinged Rail Locking Assembly

Rotating Adaptor

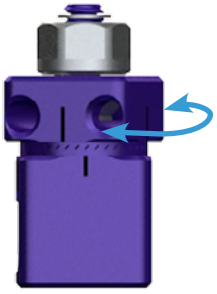


Standard Mini Rail

Static Pin Carriage

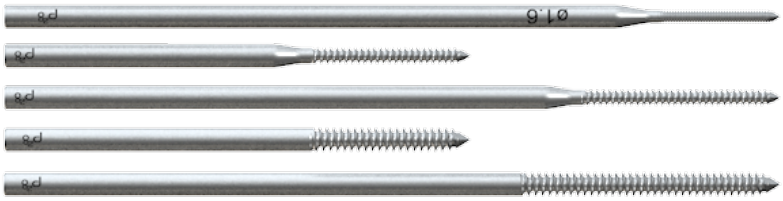


Long Mini Rail



Rotating Pin Carriage

Cut Guide



Half Pins

Available Half Pins		
Diameter	Overall Length	Thread Length
Ø1.6 mm	60 mm	15 mm
Ø2.0 mm	60 mm	20 mm
Ø2.0 mm	100 mm	25 mm
Ø3.0 mm	60 mm	20 mm
Ø3.0 mm	100 mm	33 mm

T-Handle Half Pin/ Hex Driver

Ø1.1 x 150 mm K-wire
Ø1.6 x 100 mm K-wire
Ø1.6 x 150 mm K-wire

K-wires

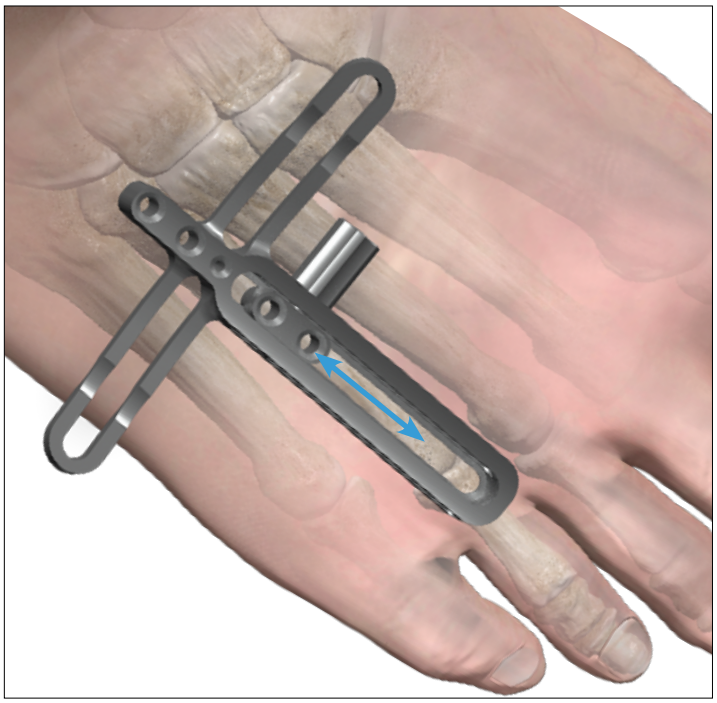
Combination Wrench

Hex Driver

Compression/Distraction Tool

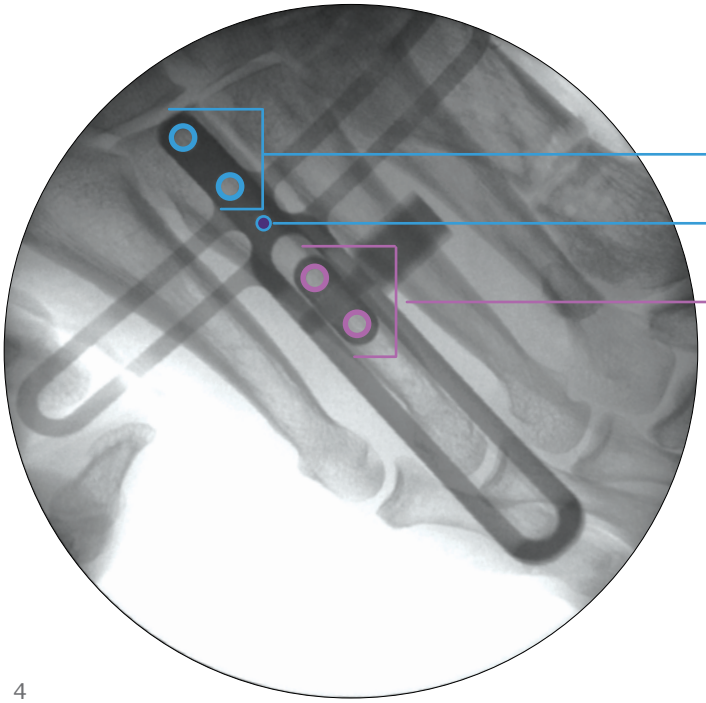
TEMPLATE PLACEMENT

Place the template on the skin above the 4th metatarsal and use fluroroscopy to confirm alignment of the template with the metatarsal and that the pins will be placed in the appropriate position. Adjust the carriage along the template until positioned appropriately on the distal part of the metatarsal.
Place a K-wire sleeve into the most distal hole in the template and place a Ø1.6 mm K-wire through the hole and place it bicortical.
The template also features a Ø1.6 mm K-wire hole to mark the osteotomy site.



NOTE: *Template wires and wire sleeves should be primarily used to predrill and hold position for Ø3.0 mm half pins. If placing Ø1.6 mm or Ø2 mm half pins place the half pin directly through the template for optimal purchase.*

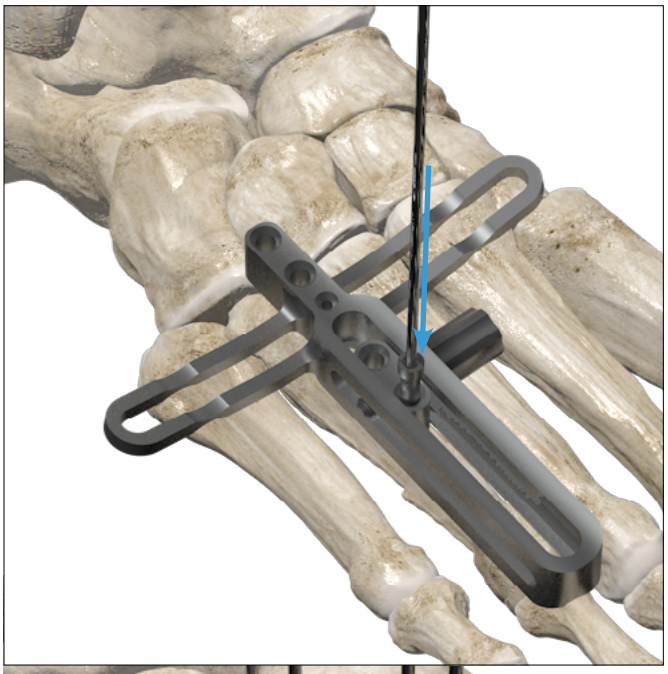
NOTE: *If not wanting to predrill holes with the wires, half pins can be placed directly into the bone through the template.*



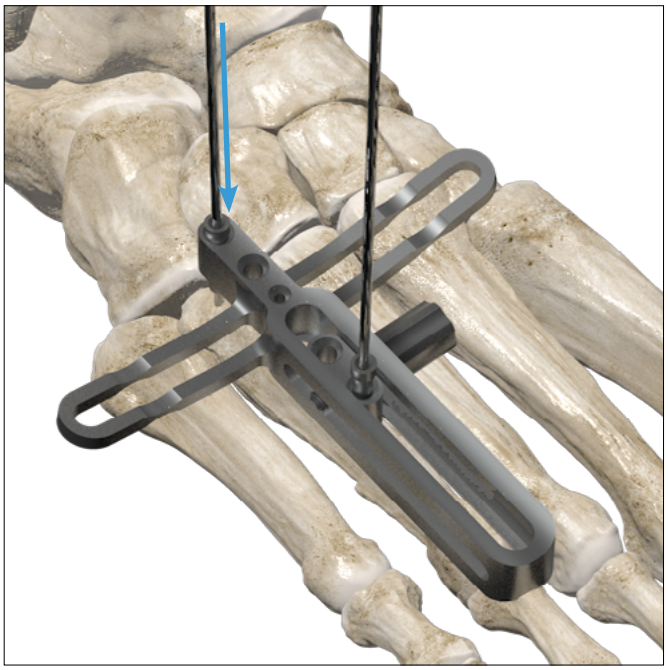
TEMPLATE PLACEMENT

Place a K-wire sleeve into the most distal hole in the template and place a Ø1.6 mm wire through the hole and place it bicortical.

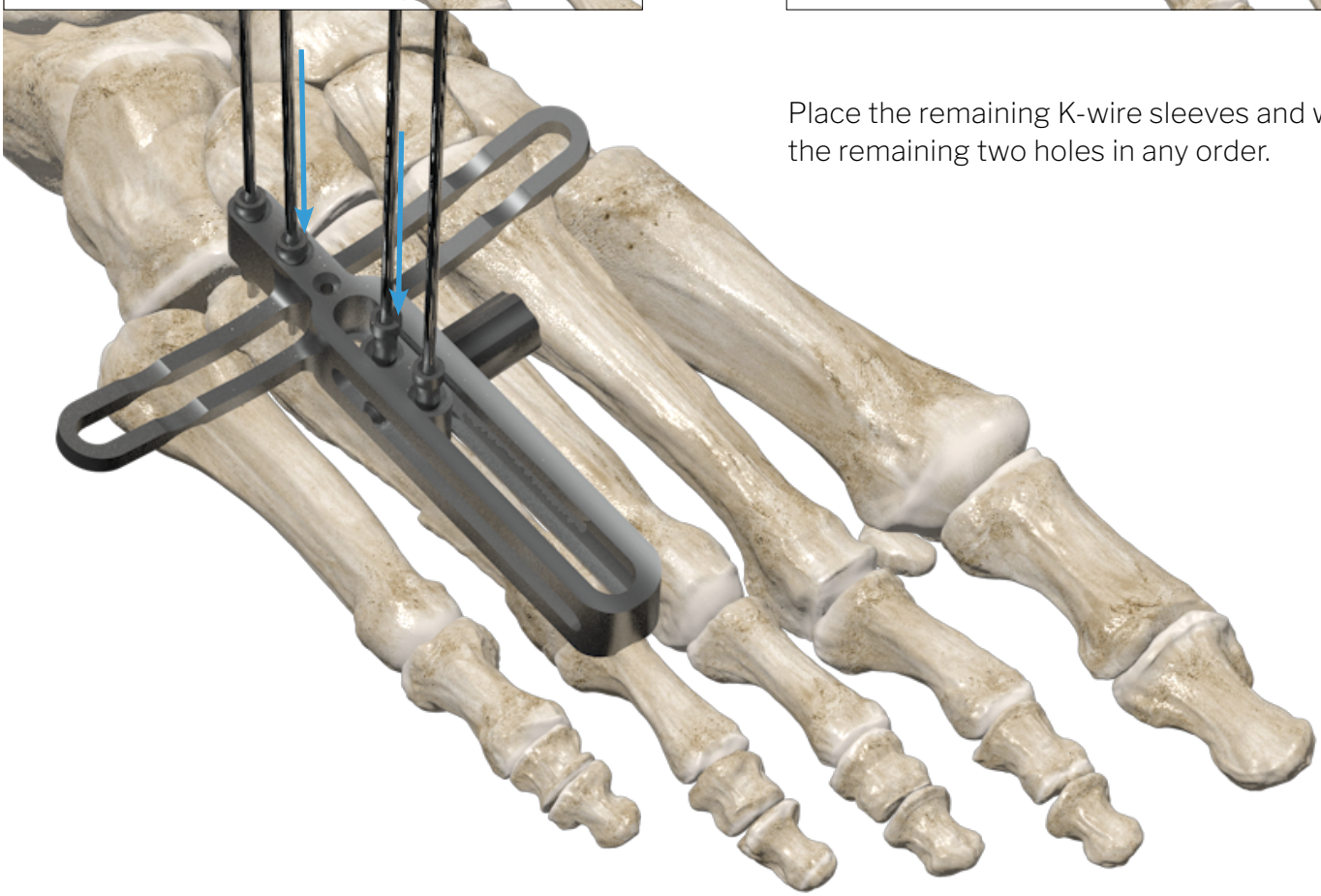
After placing the wire, confirm appropriate positioning of the proximal pin/wire holes and there is room between the pins for an osteotomy.



After confirming appropriate placement, place a K-wire sleeve into the most proximal hole in the template and place a Ø1.6 mm wire through the hole and place it bicortical.



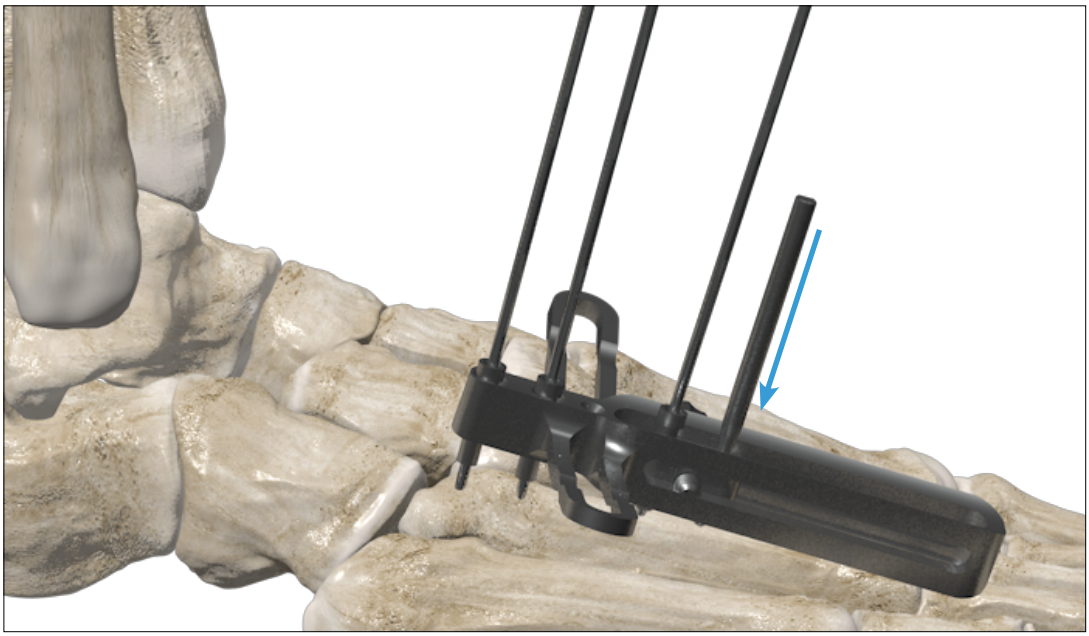
Place the remaining K-wire sleeves and wires in the remaining two holes in any order.



PIN PLACEMENT

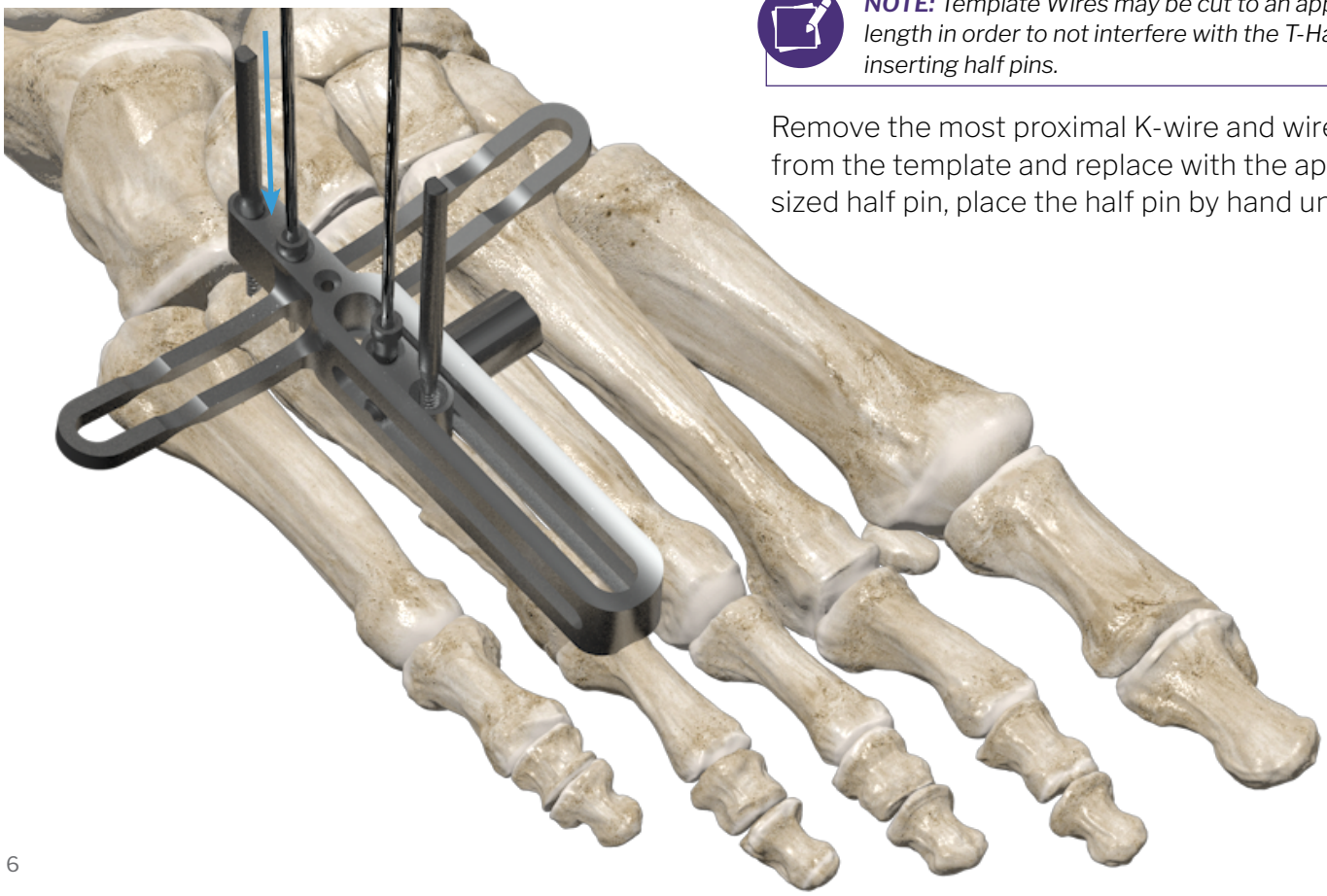
Remove the most distal wire and wire sleeve from the template and replace with the appropriately sized half pin, place the half pin by hand using the provided T-handle until bicortical.

Half Pin



NOTE: *An AO adaptor is provided if there are clearance issues with the pins.*

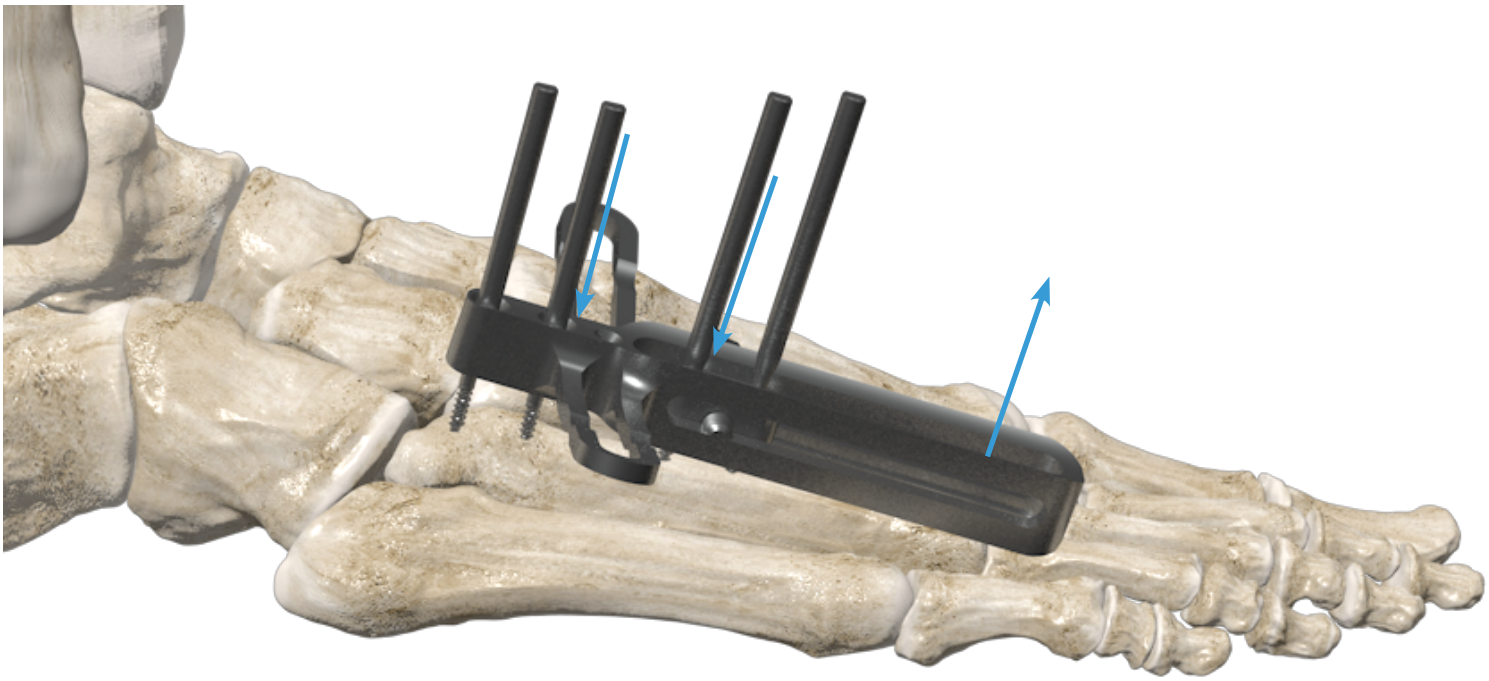
NOTE: *Template Wires may be cut to an appropriate length in order to not interfere with the T-Handle when inserting half pins.*



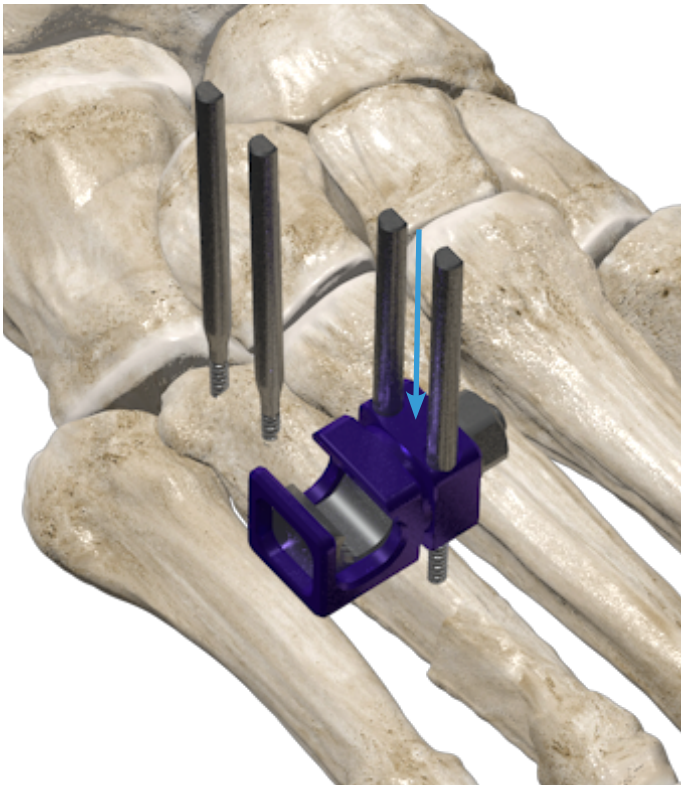
Remove the most proximal K-wire and wire sleeve from the template and replace with the appropriately sized half pin, place the half pin by hand until bicortical.

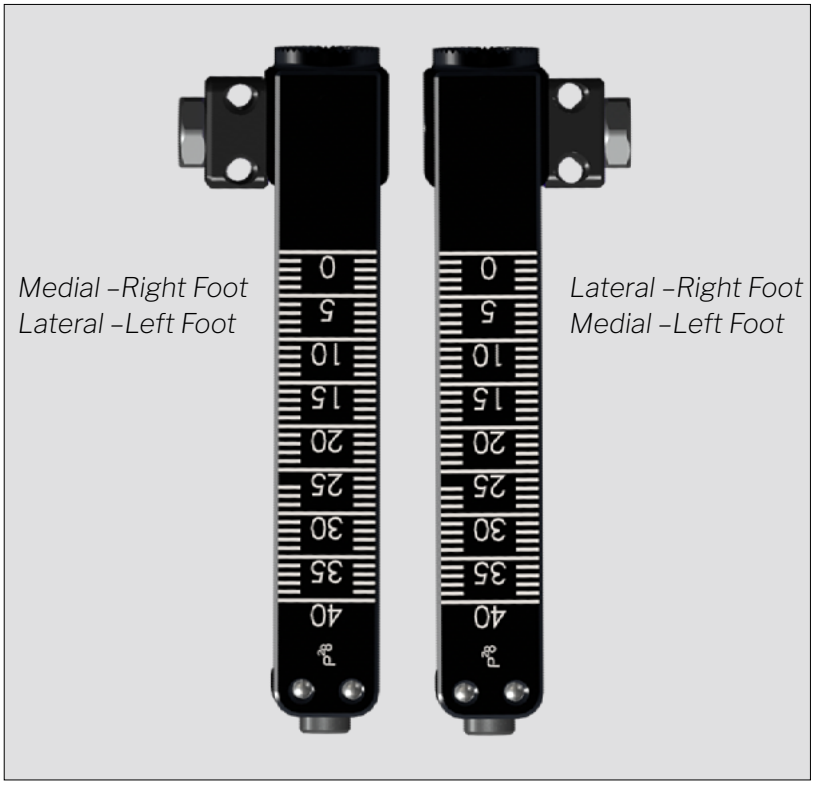
PIN/CARRIAGE PLACEMENT

Remove the remaining wires and replace with the appropriately sized half pins. After placing the remaining pins, remove the template by sliding it off the pins.



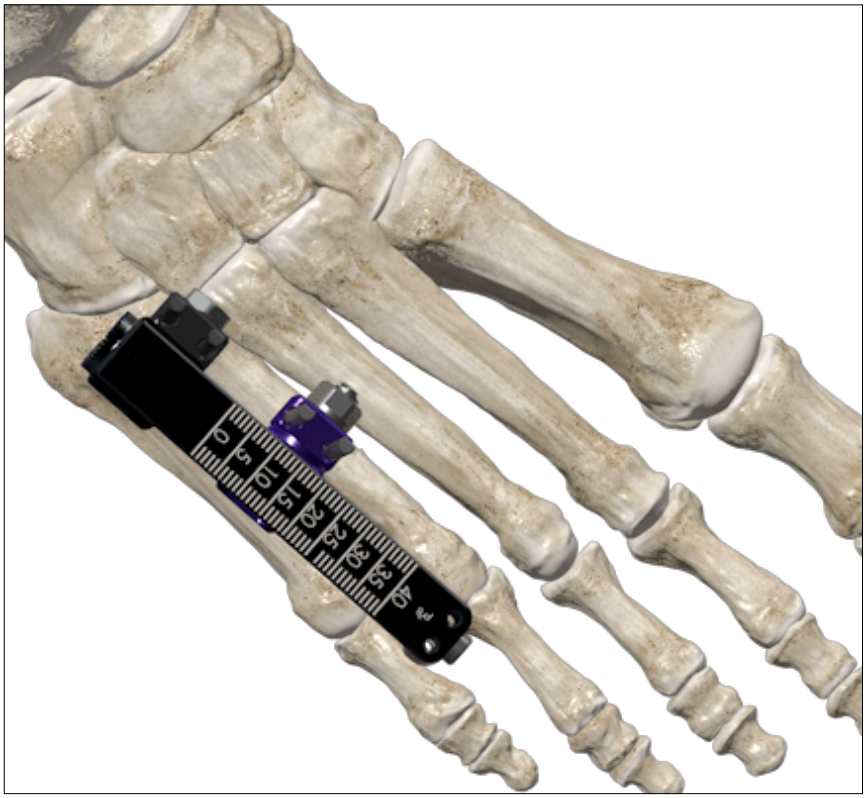
Slide the appropriate carriage over the 2 distal pins so the opening of the carriage is facing up and the carriage is either medial or lateral (shown) to the metatarsal according to surgeon preference. Prepare the proximal pin portion of the rail to accommodate the medial or lateral placement, so the length markings are visible and facing up. The pin portion on the rail can be unthreaded, moved, and tightened to either side of the rail.



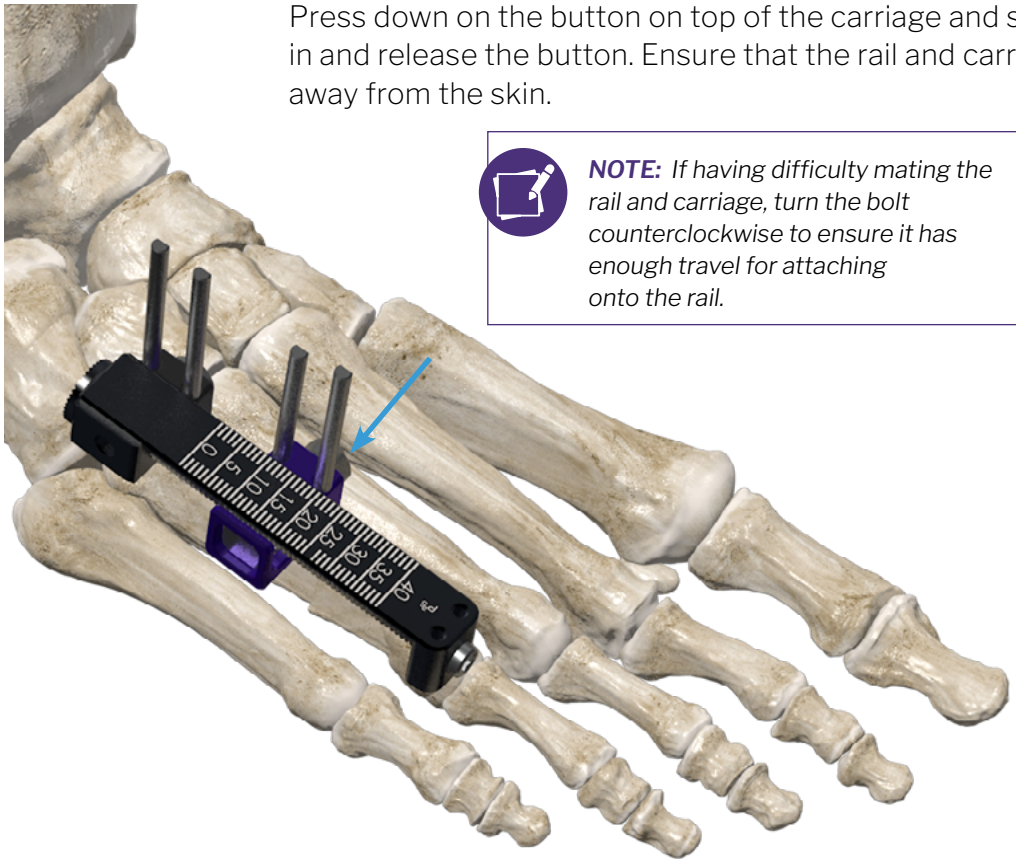


MINI RAIL PLACEMENT

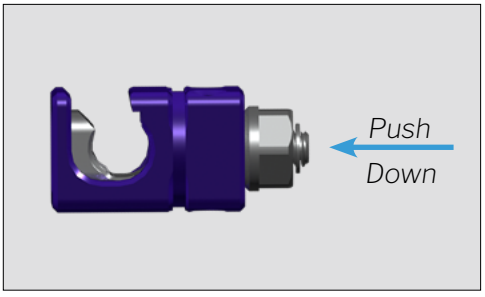
Slide the appropriately sized rail over the 2 proximal pins and slide down to the carriage.

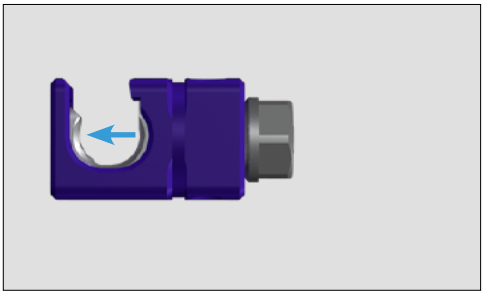


Press down on the button on top of the carriage and slide it onto the rail until it clicks in and release the button. Ensure that the rail and carriage are at least 1 centimeter away from the skin.



NOTE: *If having difficulty mating the rail and carriage, turn the bolt counterclockwise to ensure it has enough travel for attaching onto the rail.*

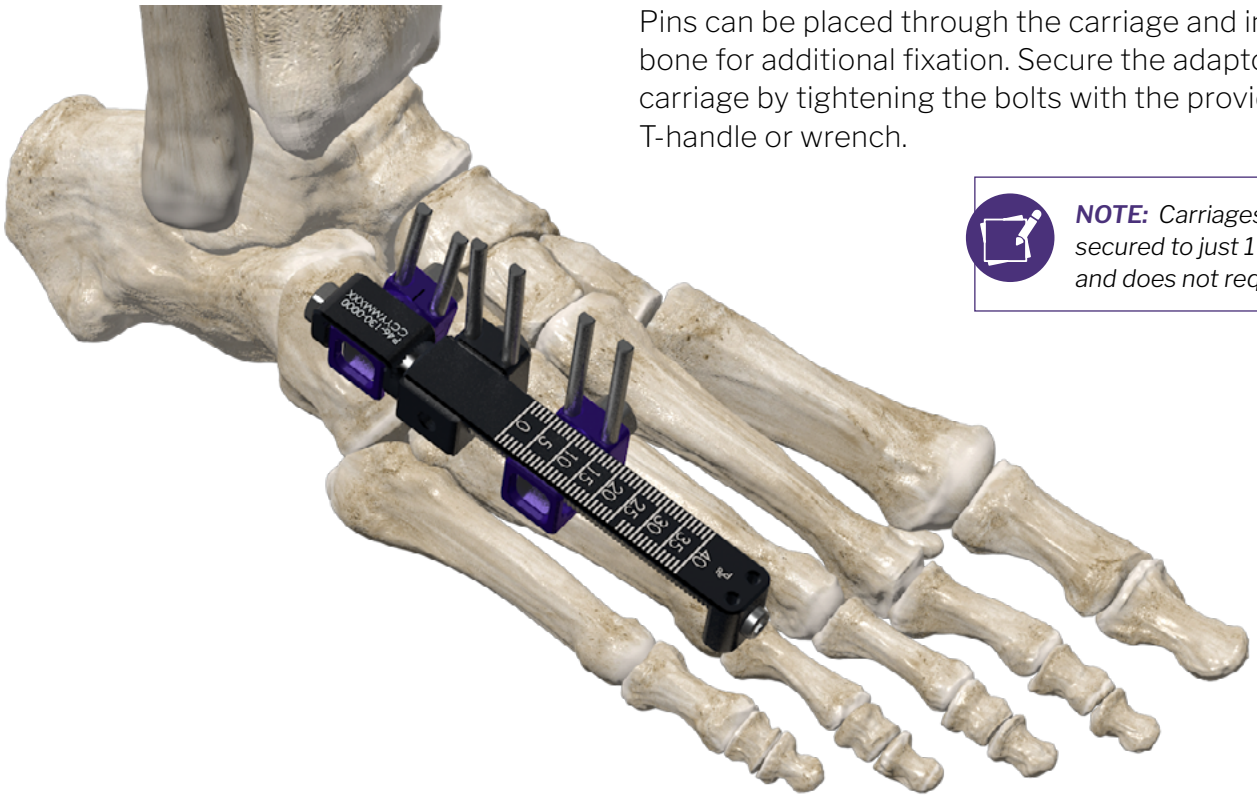




ROTATING ADAPTOR PLACEMENT

Optional: If additional proximal fixation is preferred, the rotating adaptor can be threaded into the proximal end of the rail and secured using the wrench.

A static or rotating (shown) carriage can then be attached to the adaptor. The angle of the carriage/adaptor can be adjusted to best accommodate the anatomy.



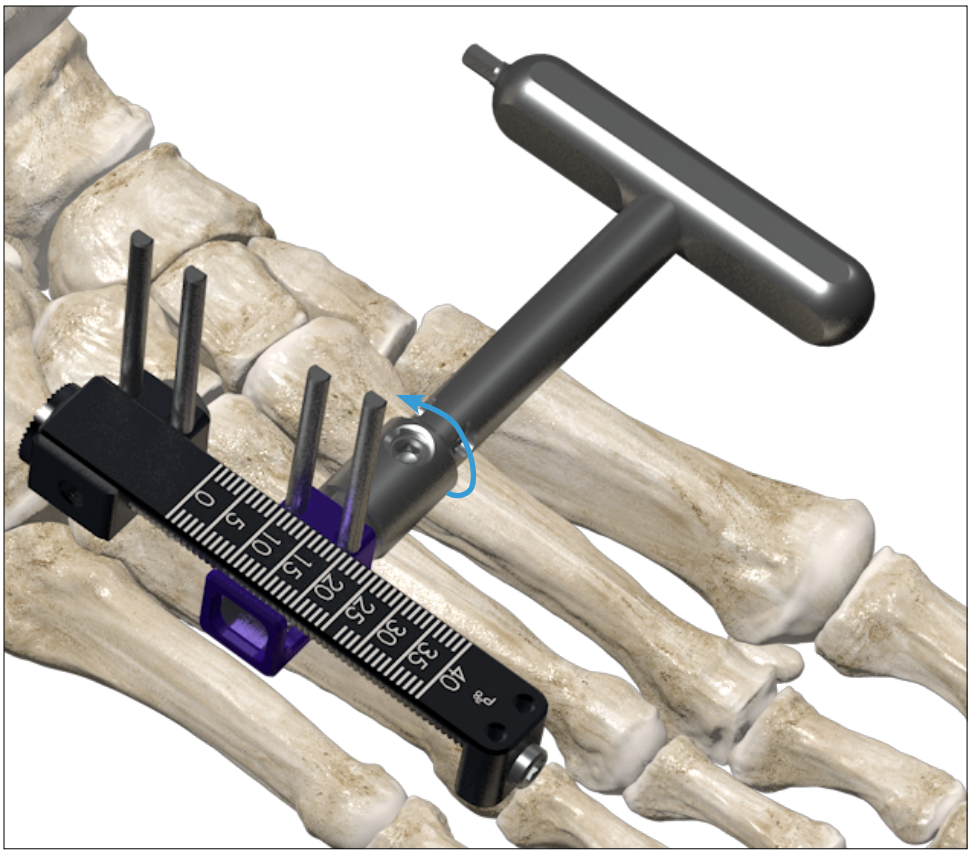
Pins can be placed through the carriage and into bone for additional fixation. Secure the adaptor and carriage by tightening the bolts with the provided T-handle or wrench.

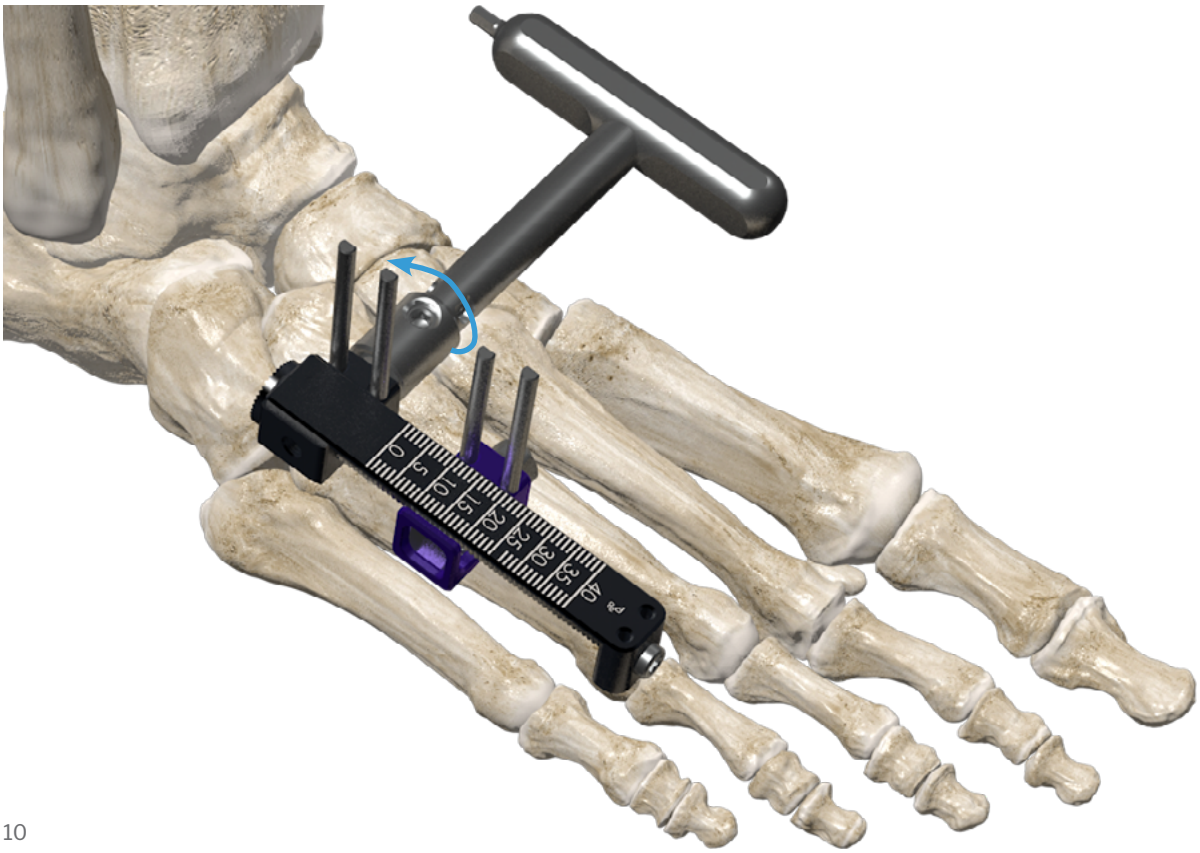
NOTE: *Carriages can be secured to just 1 pin and does not require 2.*

MINI RAIL PLACEMENT

Secure the position of the rail and carriage by tightening the bolts with the provided T-handle and turning them clockwise to tighten.

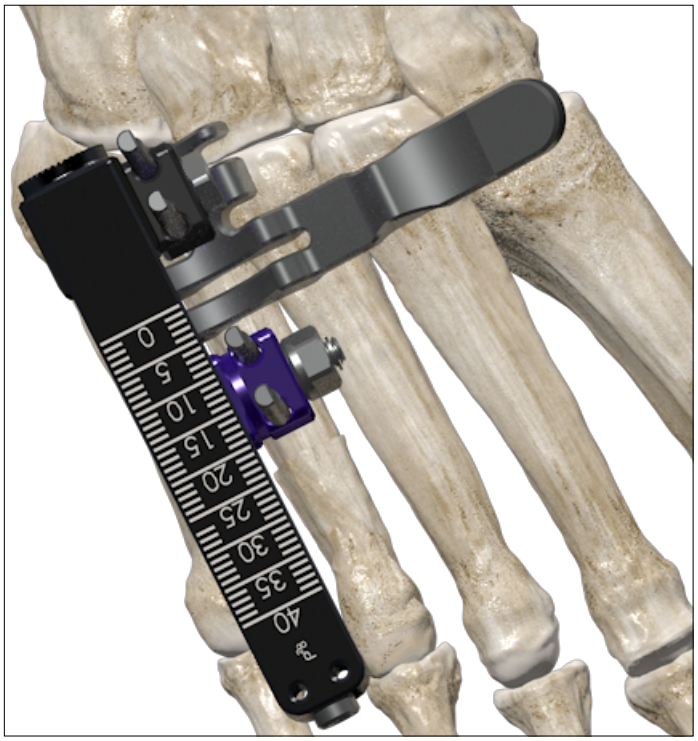
T-handle Half Pin / Hex Driver

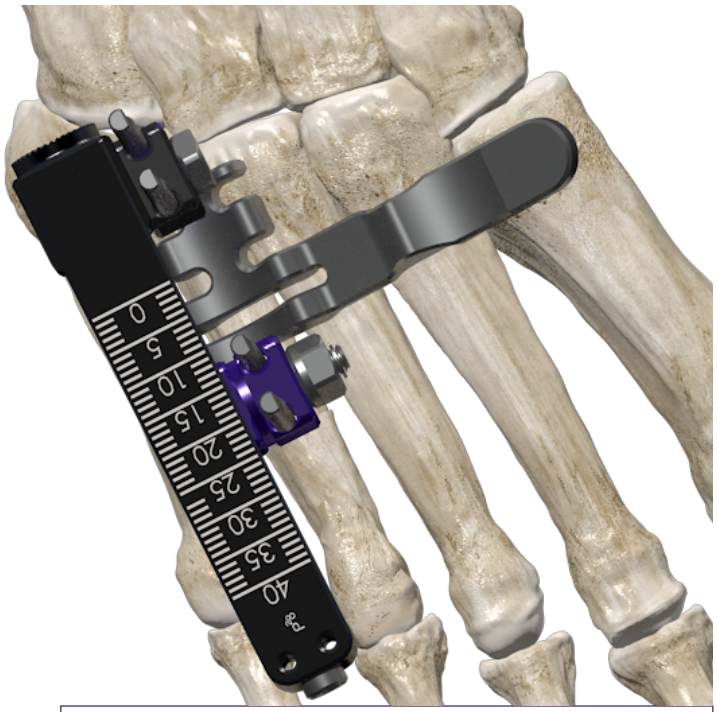




OSTEOTOMY

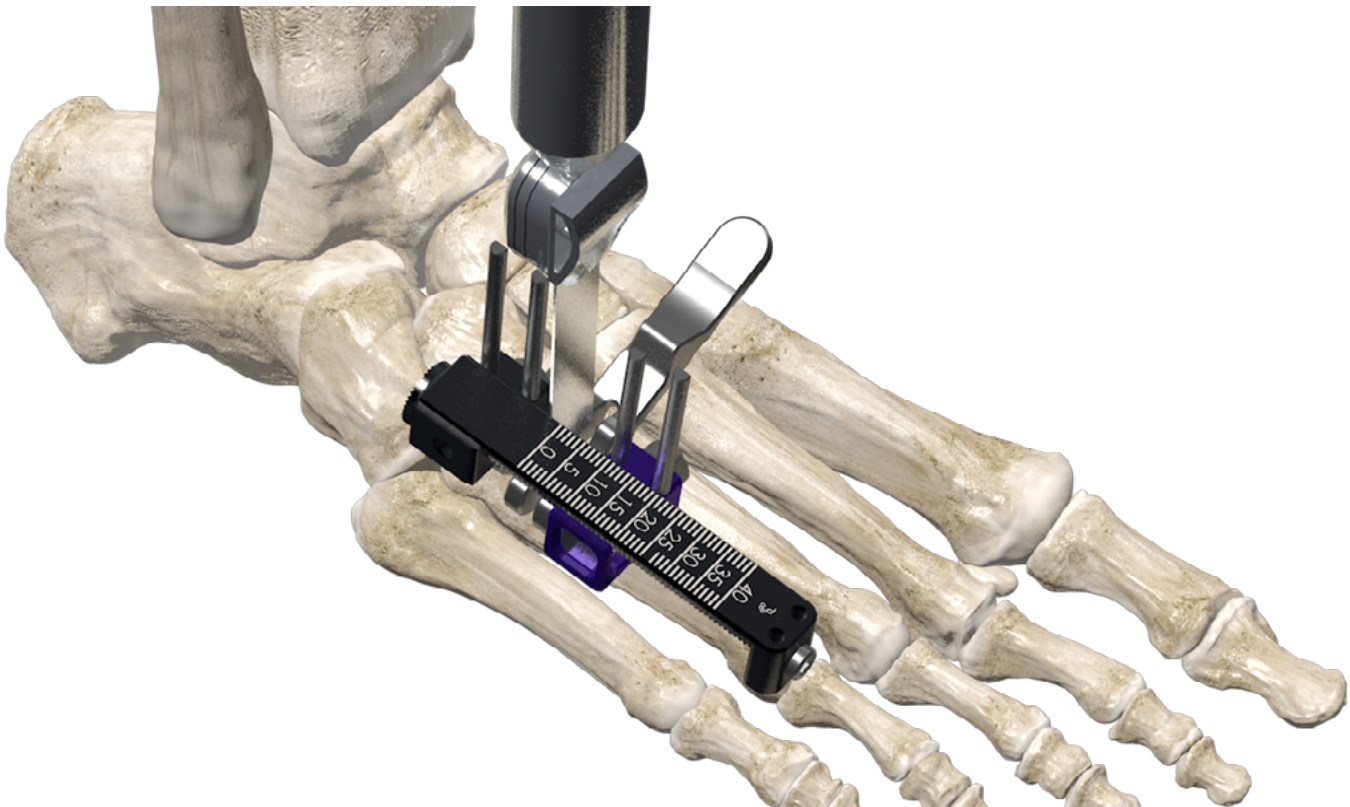
Slide the cut guide over a pair of pins in the orientation that puts the cut at the appropriate location per surgeon preference. The guide can be placed from either the lateral or medial side to accommodate surgeon preference and surgical access.





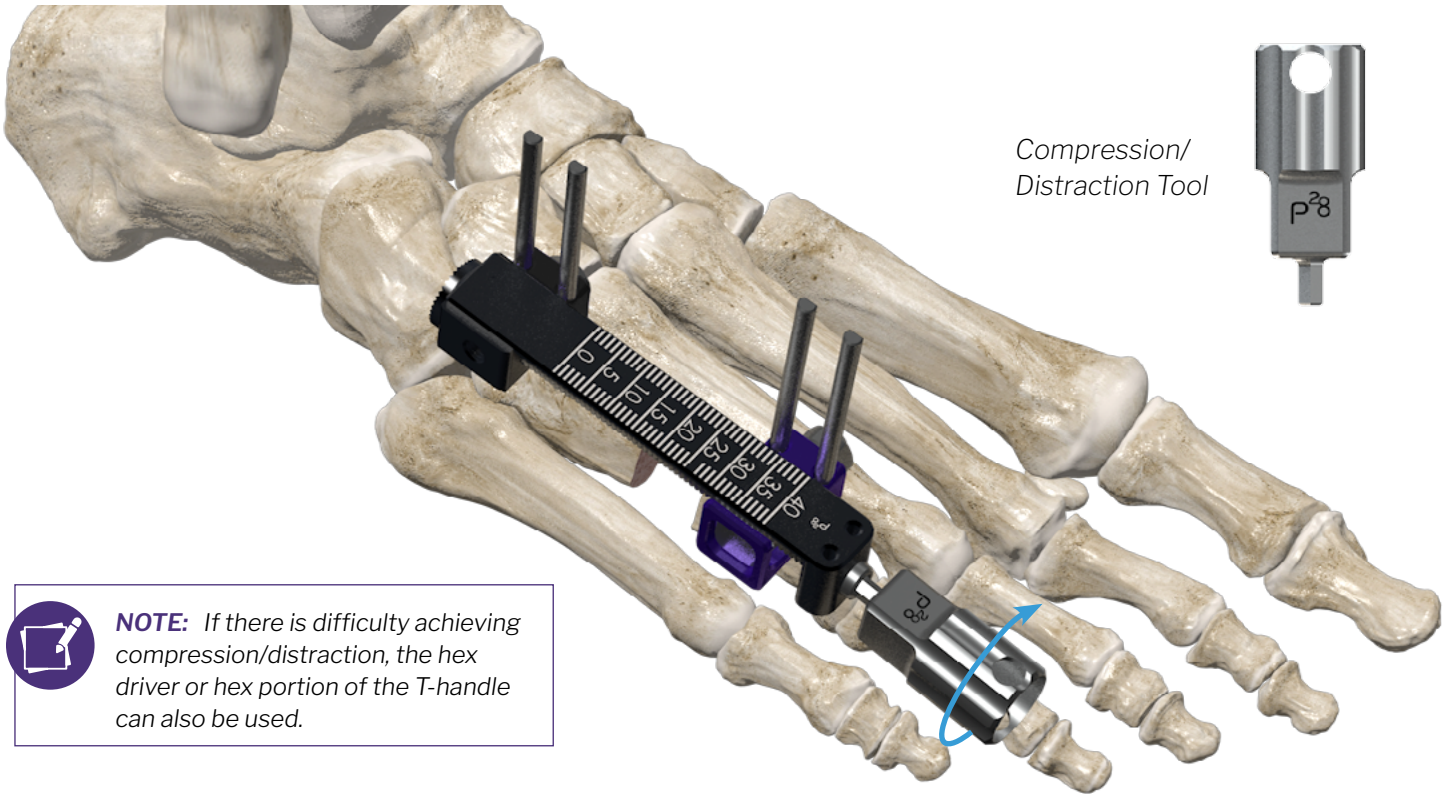
NOTE: *The cut guide also accommodates up to a Ø2.0 mm burr.*

Make an incision at the planned osteotomy location and use skin hooks to retract soft tissues. Use a saw to cut through the guide. Use fluoroscopy to ensure the cut is complete and has not violated adjacent structures.



MINI RAIL COMPRESSION/DISTRACTION

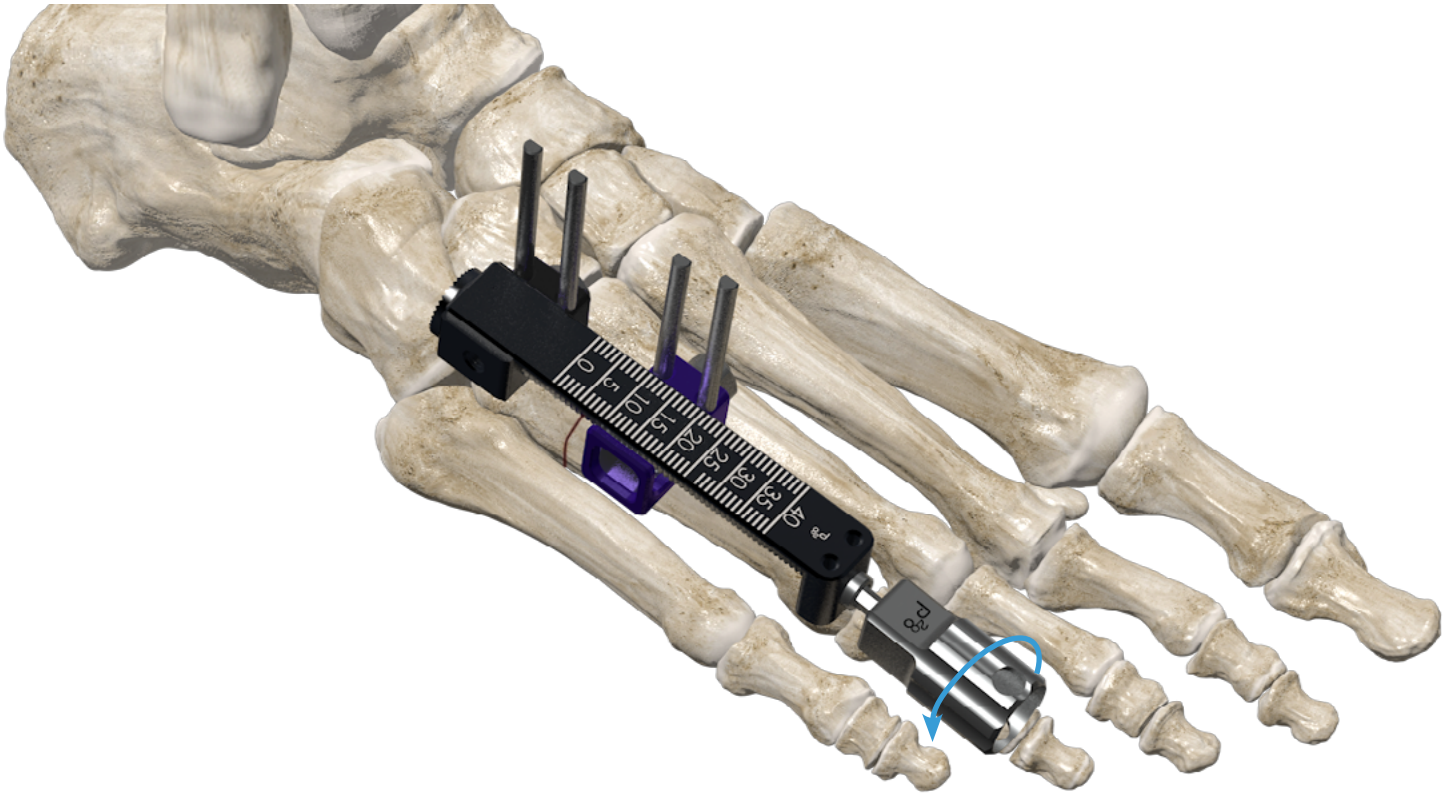
Place the compression/distraction tool into the distal end of the rail and turn it clockwise to distract the fragment and ensure that bone fragment is free to move. Each quarter turn is 0.25 mm of travel.



Compression/ Distraction Tool

NOTE: *If there is difficulty achieving compression/distraction, the hex driver or hex portion of the T-handle can also be used.*

After confirming the fragment can move, turn the driver counterclockwise to compress it back to the proximal part of the metatarsal



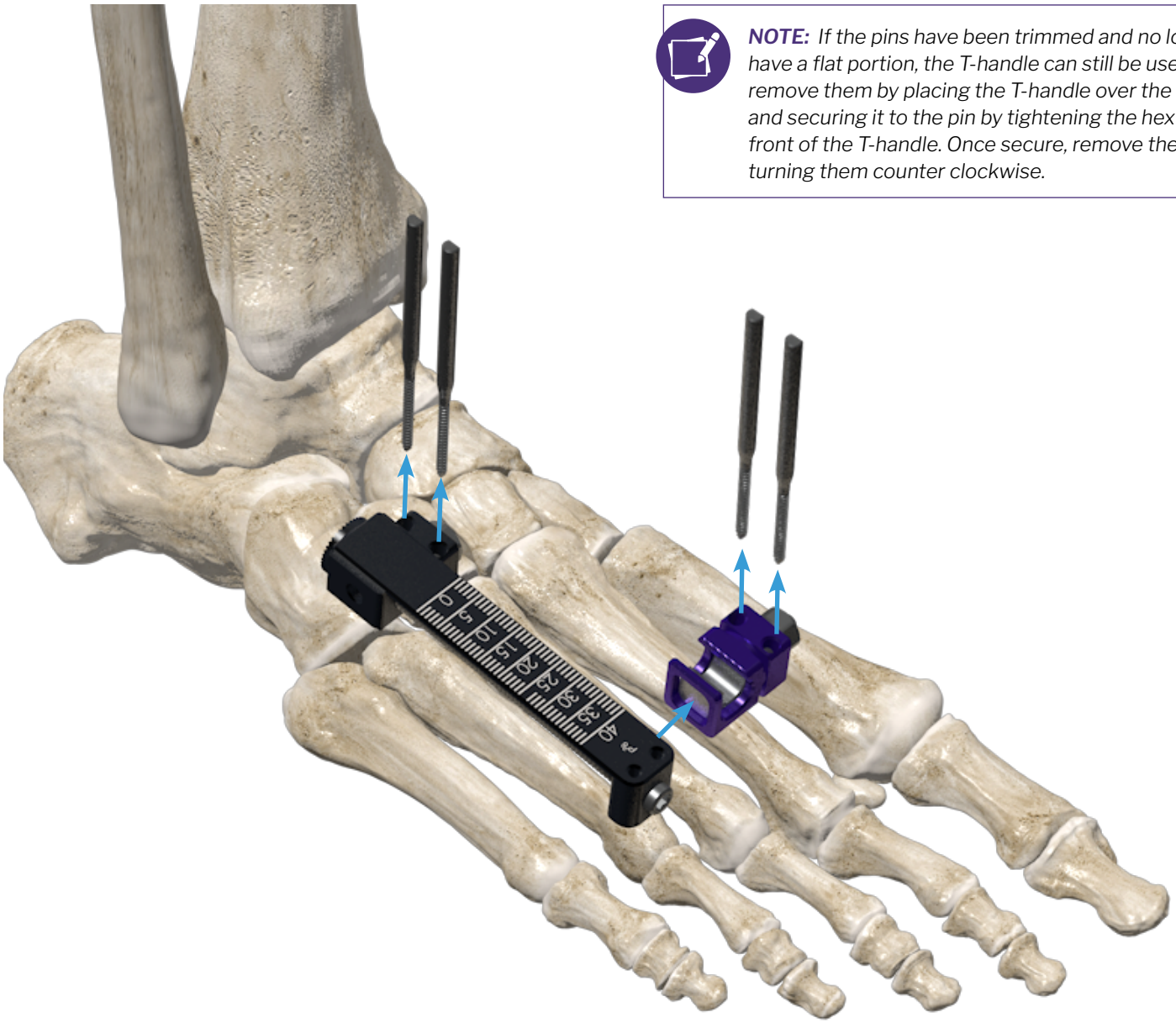
CLOSURE

Proceed to incision closure and concomitant procedures. Provide the patient with their prescribed treatment plan and the compression/distraction tool.

REMOVAL

To remove the device, loosen the bolts on the mini rail and carriage and slide them off the pins.

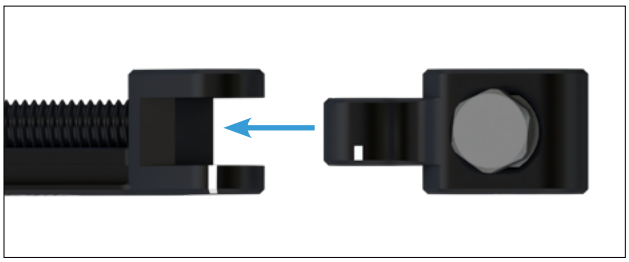
Remove the pins by hand or with power.

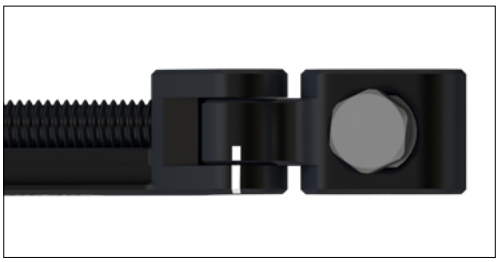


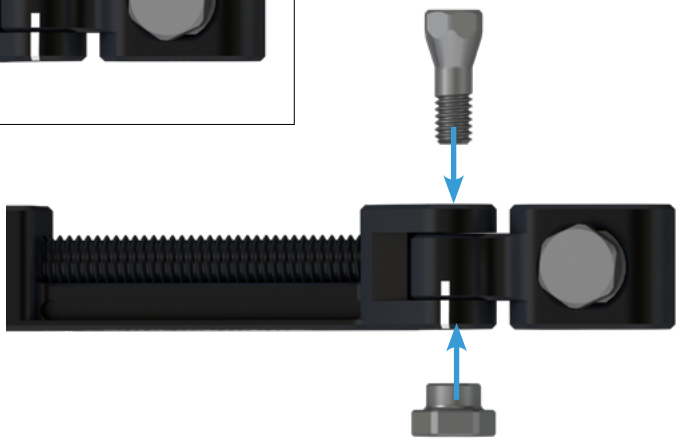
NOTE: *If the pins have been trimmed and no longer have a flat portion, the T-handle can still be used to remove them by placing the T-handle over the cut pin and securing it to the pin by tightening the hex on the front of the T-handle. Once secure, remove the pin by turning them counter clockwise.*

HINGED RAIL ASSEMBLY

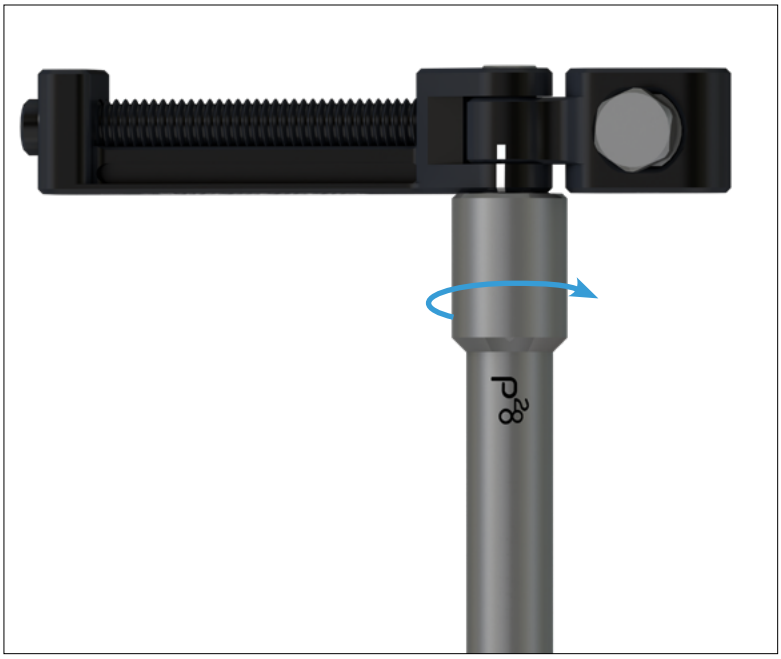
To create a hinged rail assembly, retrieve the appropriate male or female hinged rail, male or female short segment, and locking assembly. The chosen hinged rail and short segment will depend on limb laterality. A Ø1.6 mm K-wire can be used to help guide assembly of the construct.





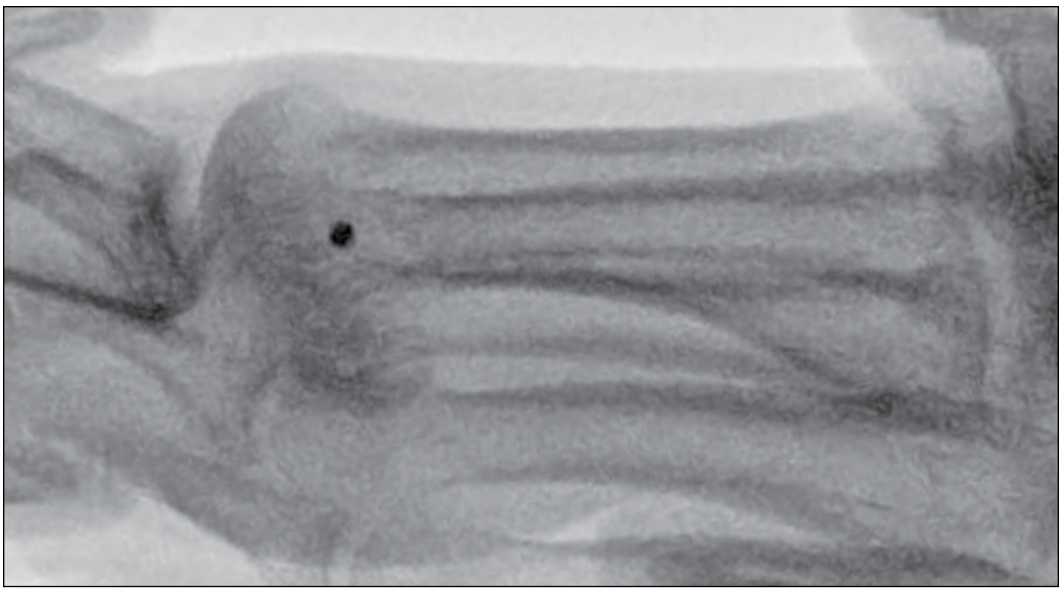


Secure the construct/lock the hinge motion by tightening the bolt with the provided T-handle and turning it clockwise to tighten.

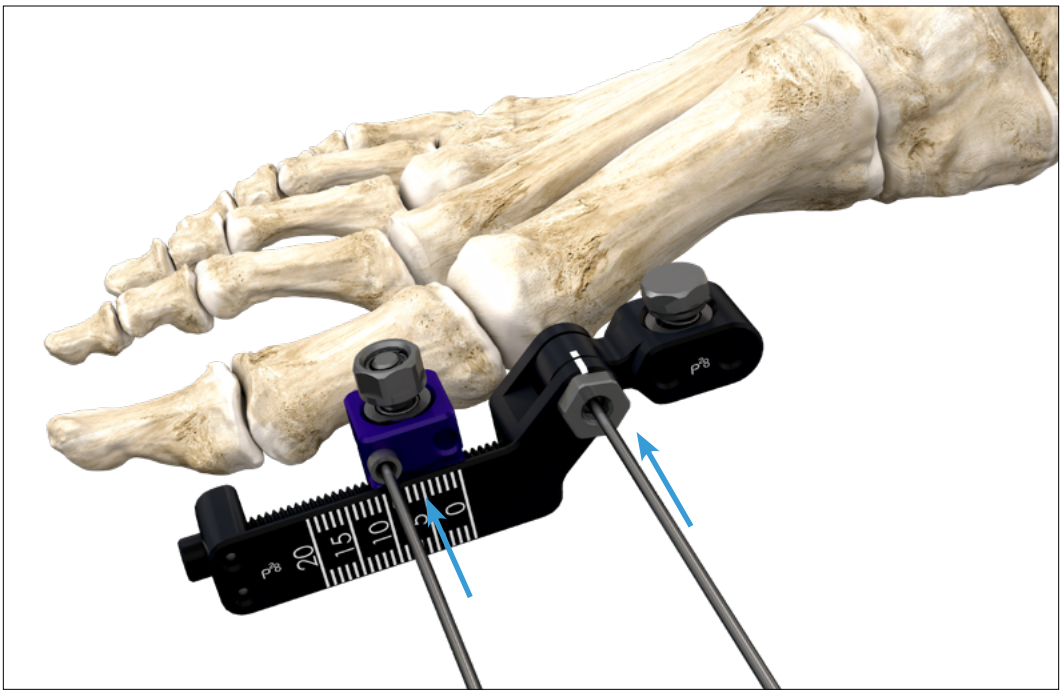


WIRE PLACEMENT

Prepare the joint per surgeon preference. Use fluoroscopy to determine the center of rotation of the metatarsophalangeal joint in the metatarsal head. Mark the location and place a wire bicortical in the metatarsal head in the center of rotation of the joint.



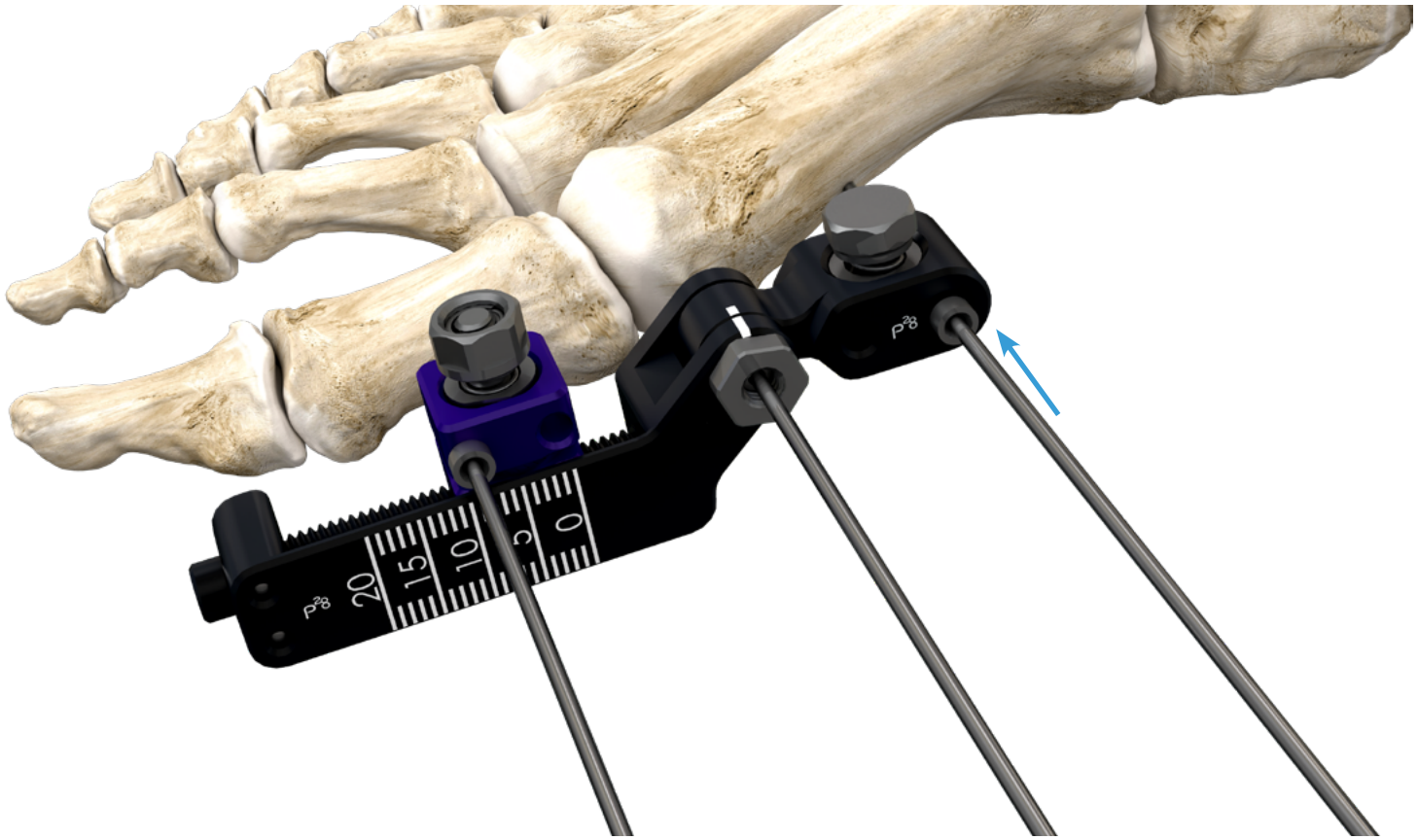
Slide the articulating joint of the mini rail over the wire. Orient the rail so that the rail portion is distal and over the phalanx. If wanting to predrill with a Ø1.6 K-wire for Ø3.0 pins, place a wire sleeve in the most distal hole in the carriage and place a wire through the sleeve and into the phalanx.



NOTE: *Template wires and wire sleeves should be primarily used to predrill and hold position for Ø3.0 mm half pins. If placing Ø1.6 mm or Ø2 mm half pins place the half pin directly through the template for optimal purchase.*

HINGED RAIL PLACEMENT

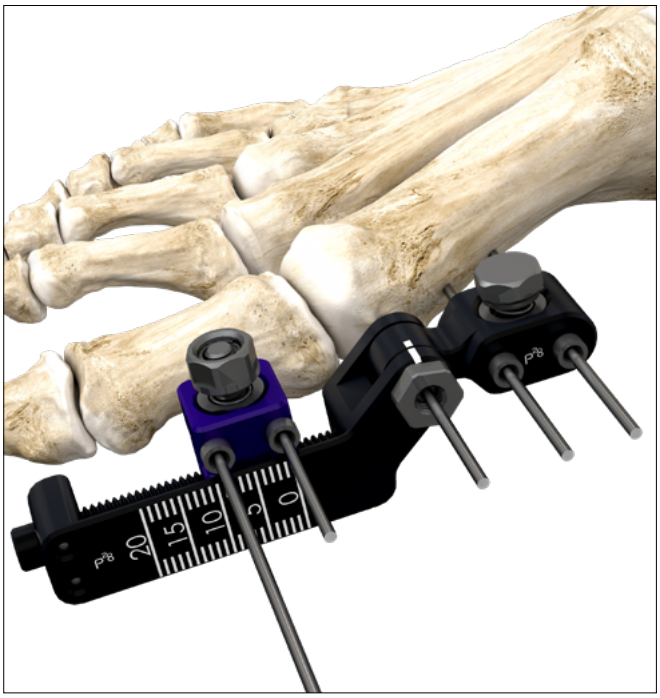
Confirm appropriate orientation of the rail over the phalanx and metatarsal, remove the distal wire and reposition if needed. After confirming appropriate location, place a K-wire sleeve in the most proximal hole in the segment over the metatarsal at the appropriate location according to surgeon preference. Place a K-wire through the sleeve and into the metatarsal until bicortical.

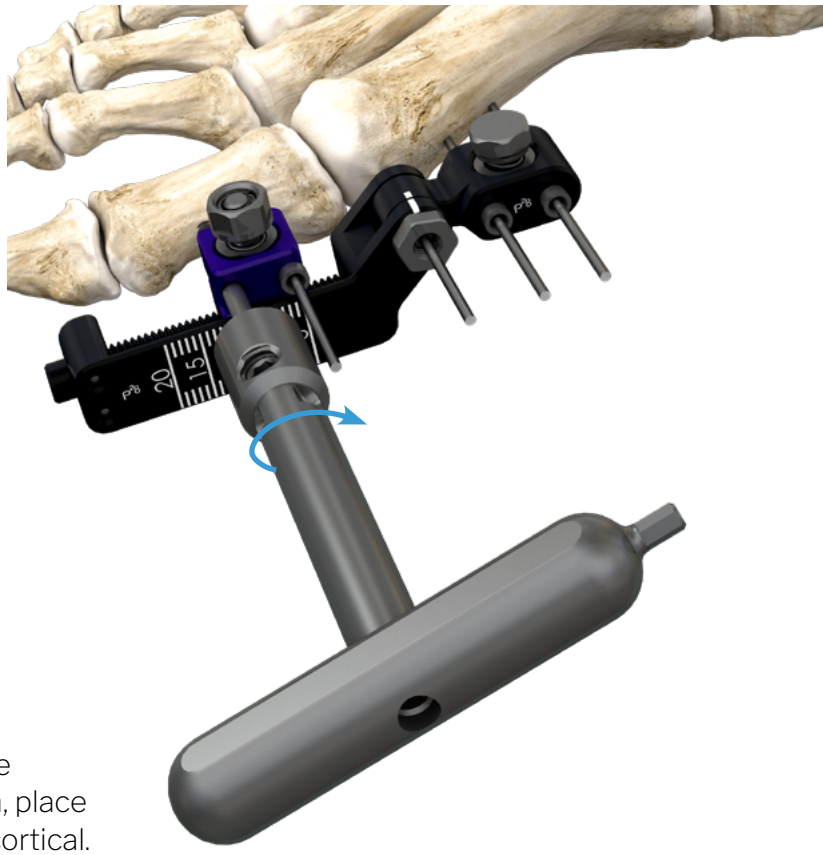


Place the remaining sleeves and wires in the phalanx and metatarsal

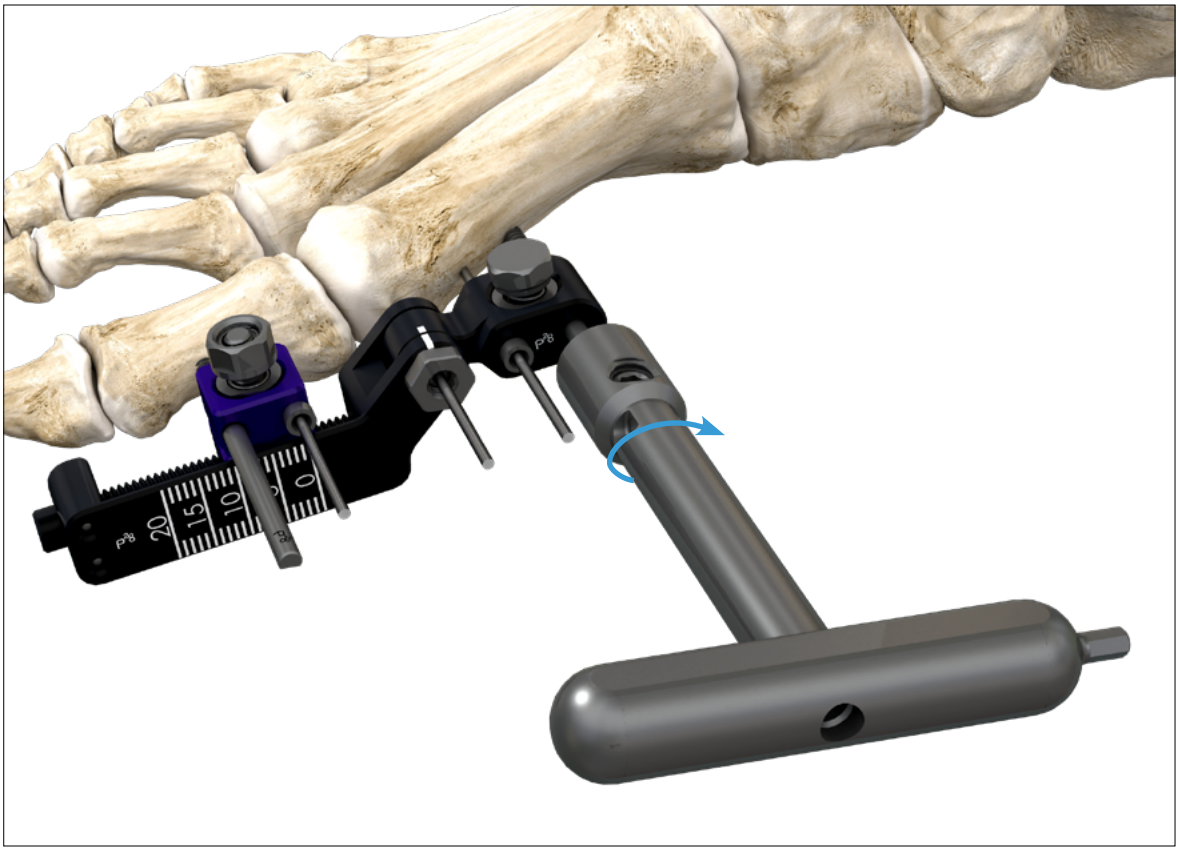
PIN PLACEMENT

Remove the most distal wire and wire sleeve from the carriage and replace with the appropriately sized half pin, place the half pin by hand using the provided T-handle until bicortical.



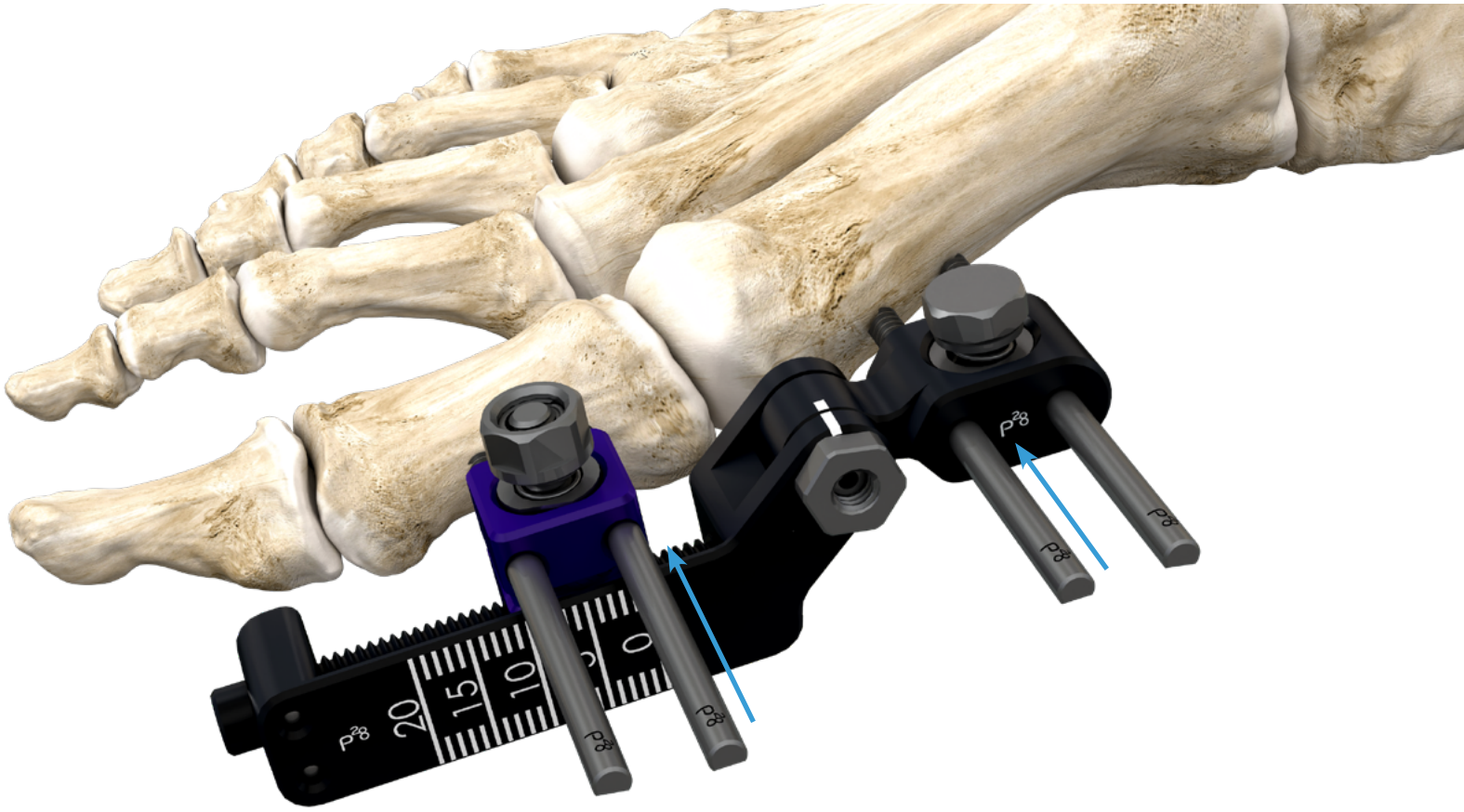


Remove the most proximal wire and wire sleeve from the carriage and replace with the appropriately sized half pin, place the half pin by hand using the provided T-handle until bicortical.

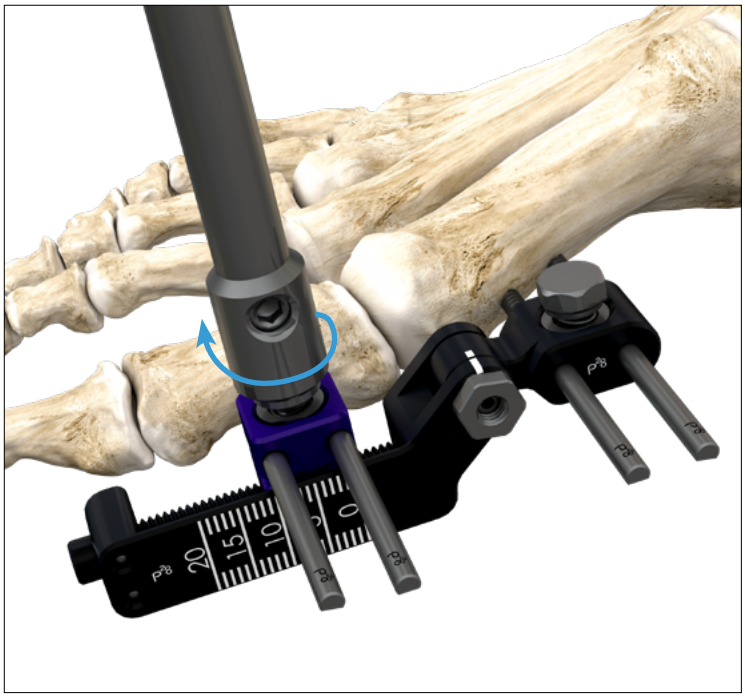


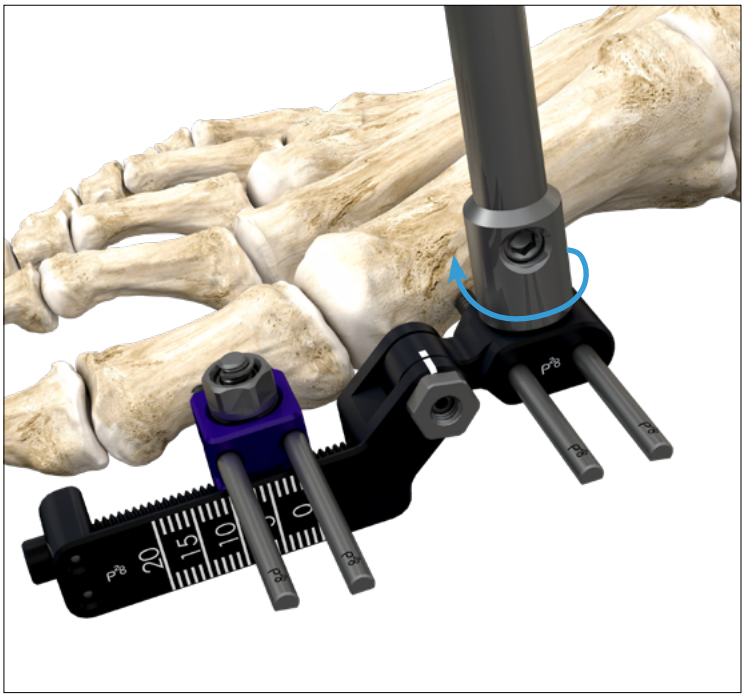
PIN PLACEMENT

Remove the remaining wires and sleeves and replace with the appropriately sized half pins.



Use the provided T-handle to secure the clamp to the rail and the segment to the pins

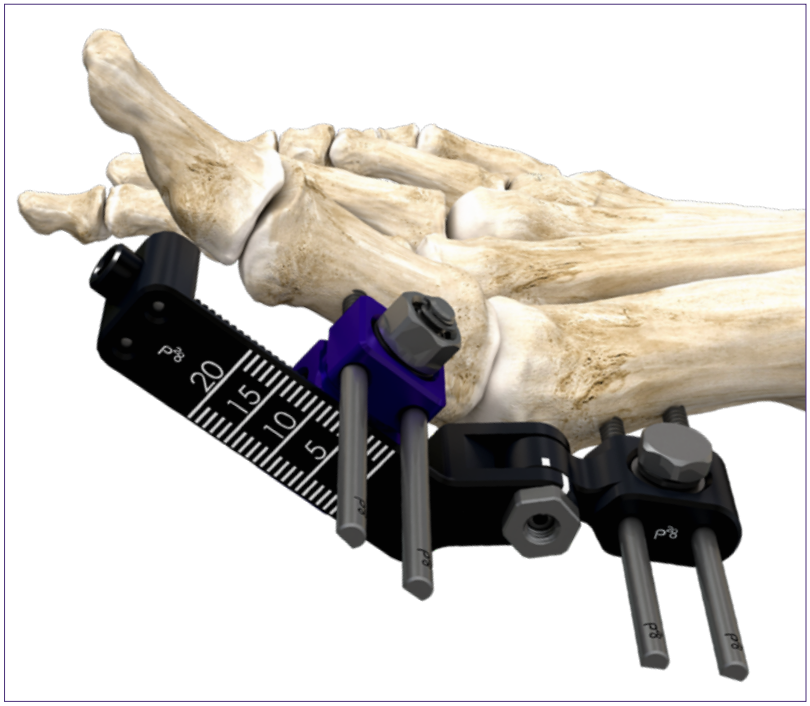




HINGED RAIL ARTICULATION

After securing the construct to the pins, use the provided T-handle to loosen the hinge by turning it counterclockwise. Confirm appropriate range of motion of the joint and construct.

After confirming appropriate range of motion. Tighten the bolt on the hinge to lock the motion of the hinge by turning it clockwise.



HINGED RAIL DISTRACTION

Place the compression/distraction tool into the distal end of the rail and turn it clockwise to distract the joint. Each quarter turn is 0.25 mm of travel. Clockwise is distraction and counterclockwise is compression.

NOTE: *If there is difficulty achieving compression/ distraction, the hex driver or hex portion of the T-handle can also be used.*

No Distraction

Distracted

CLOSURE

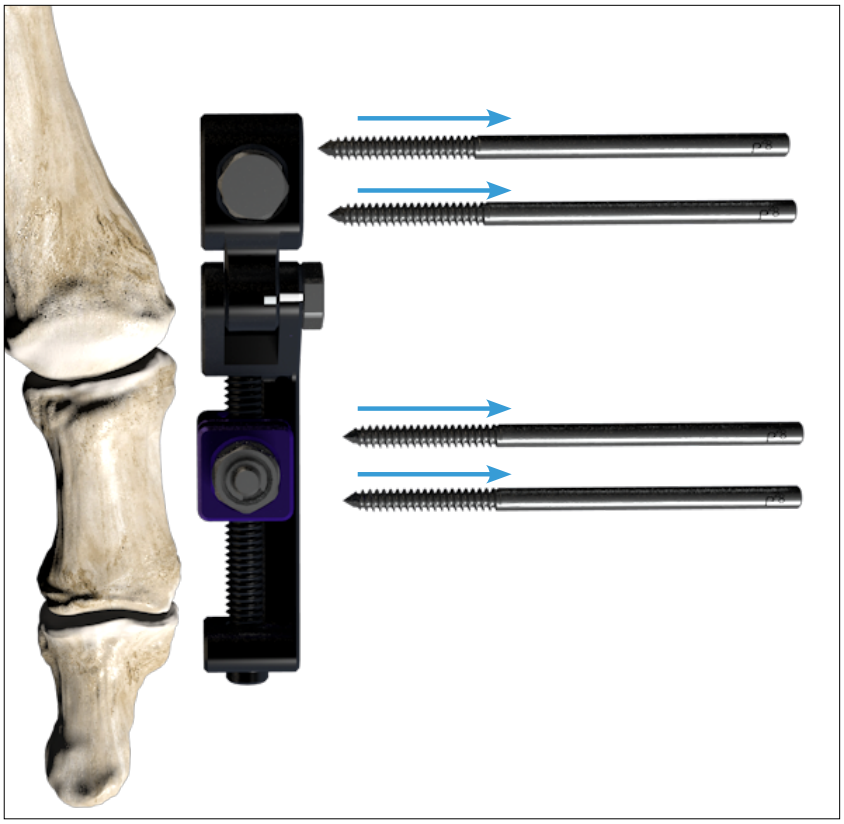
Proceed to incision closure and concomitant procedures. Provide the patient with their prescribed treatment plan and the compression/distraction tool.

REMOVAL

To remove the device, loosen the bolts on the mini rail and carriage and slide them off the pins.

Remove the pins by hand or with power.

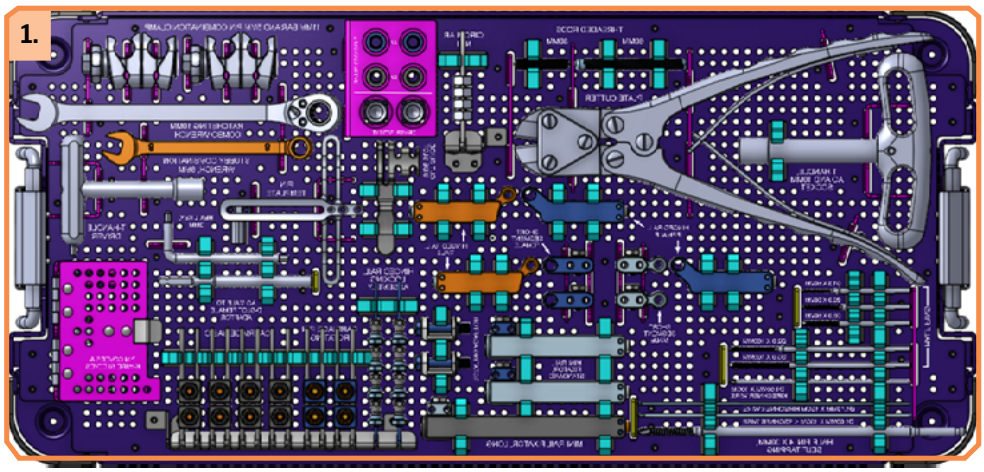
NOTE: *If the pins have been trimmed and no longer have a flat portion, the T-handle can still be used to remove them by placing the T-handle over the cut pin and securing it to the pin by tightening the hex on the front of the T-handle. Once secure, remove the pin by turning them counter clockwise.*



BRACHIATOR EXTERNAL FIXATION CADDY AND CASE

1. BRACHIATOR CASE

The Brachiator Mini Rail External Fixation System tray contains the straight rails, hinged rails, hinged rail assembly, carriages, threaded rods, threaded pillars, M6 nuts, combination clamps, half pins, K-wires, pin covers, T-handle, compression/distraction tool, AO adaptor, combination wrench, K-wire sleeves, pin template, cut guide, plate cutter, and 10mm wrench



THE BRACHIATOR MINI EXTERNAL FIXATION SYSTEM

Part #	Description	Use
P46-100-0075	Mini Rail Fixator, Long 75 mm of travel	Single Use
P46-100-0040	Mini Rail Fixator, Standard 40 mm of travel	Single Use
P46-101-1020	Hinged Rail, 20 mm of travel, female	Single Use
P46-101-2020	Hinged Rail, 20 mm of travel, male	Single Use
P46-101-1000	Hinged Rail, Short Segment, male	Single Use
P46-101-2000	Hinged Rail, Short Segment, female	Single Use
P46-101-3000	Hinged Rail, Locking Assembly	Single Use
P46-130-0000	Rotating Adaptor	Single Use
P46-121-0000	Carriage Basic	Single Use
P46-122-0000	Carriage Pin Rotating	Single Use
P45-310-0030	Threaded Rod, 30 mm	Single Use
P45-310-0060	Threaded Rod, 60 mm	Single Use
P45-330-1030	Threaded Pillar, 30 mm	Single Use
P45-330-1050	Threaded Pillar, 50 mm	Single Use
P45-940-1001	M6 Bevel Nut, 10 mm Hex	Single Use
P85-310-1105	11 mm Bar and 5 mm Pin Combination Clamp	Single Use
P46-310-3033	Half Pin, Ø3.0 x 100 mm OAL x 33 mm THD	Single Use
P46-306-3020	Half Pin, Ø3.0 x 60 mm OAL x 20 mm THD	Single Use
P46-310-2025	Half Pin, Ø2.0 x 100 mm OAL x 25 mm THD	Single Use
P46-306-2020	Half Pin, Ø2.0 x 60 mm OAL x 20 mm THD	Single Use
P46-306-1615	Half Pin, Ø1.6 x 60 mm OAL x 15 mm THD	Single Use
P47-210-430S	Half Pin, 4 x 30 mm, Self-Tapping	Single Use
P99-192-1115	Ø1.10 mm X 15 cm Kirschner Wire, 316 LVM	Single Use
P99-192-1610	Ø1.60 mm X 10 cm Kirschner Wire, 316 LVM	Single Use
P99-192-1615	Ø1.60 mm X 15 cm Kirschner Wire, 316 LVM	Single Use
P46-300-0001	Pin Covers	Single Use
P46-900-0001	8mm and D-slot Female T-Handle Driver with Male 3 mm Hex	Reusable
P46-900-0002	Compression/Distraction Tool	Reusable
P46-900-0003	Hex L Key, 3 mm	Reusable
P46-900-0004	Stubby Combination Wrench, 8 mm	Reusable
P46-910-0001	AO Male to D-slot Female Adaptor	Reusable
P46-920-0001	K-wire Sleeve	Reusable
P46-930-0001	Pin Template, 40 mm of Travel	Reusable
P46-930-0002	Cut Guide, Side Slot	Reusable
P99-150-0016	Plate Cutter, Double Action 230 mm, Straight	Reusable
P45-513-0010	Ratcheting 10 mm Combo Wrench	Reusable
P47-940-0001	T-Handle, AO and 10 mm Socket	Reusable

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

MR SAFETY INFORMATION

The Brachiator Mini External Fixation System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the Brachiator Mini External Fixation System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

THE BRACHIATOR
Mini External Fixation System

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P46-STG-0001 RevB [2026-1-20]

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DISCLAIMER

The purpose of the Brachiator Mini External Fixation System Surgical Technique Guide is to demonstrate the optionality and functionality of the Brachiator Mini External Fixation System implants and instrumentation. Although variations in placement and use of the Brachiator Mini External Fixation System implants 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 Brachiator Mini External Fixation System can be employed, appropriate for the size of the device. CAUTION: Federal Law (USA) restricts this device to sale and use by, or on the order of, a physician.