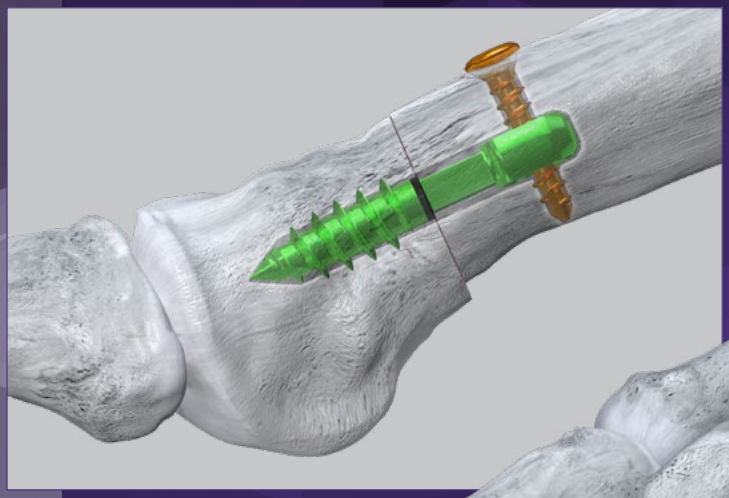
PHANTOM™
Metatarsal Shortening System

SURGICAL TECHNIQUE GUIDE

Phantom® Metatarsal Shortening System



Exclusively foot & ankle
Paragon 28®

Acknowledgment:
Paragon 28® would like to thank Mark Myerson, MD; José A. V. Sanhudo, MD; and Lew Schon, MD for their contribution to the development of the system and surgical technique guide.

PRODUCT DESCRIPTION

The Paragon 28® Phantom® Metatarsal Shortening System was designed to provide fixation for an in-line, parallel shortening osteotomy of the lesser metatarsals. The system was designed to help eliminate potential complications that may arise from alternative osteotomies, such as post-operative floating toe, malunion of the metatarsal head, an altered distal articular surface, opening of the joint capsule, and/or the effects of an open capsulotomy.

The Phantom® Metatarsal Shortening implant is designed to thread into the distal metatarsal head after performing the desired osteotomy. The proximal end of the implant is then inserted into the exposed intramedullary canal and the osteotomy is compressed, completely enveloping the implant. Finally, a Ø2.0 mm crossing screw is driven bicortically through the bone and proximal slot of the implant head to secure the shortening fixation.

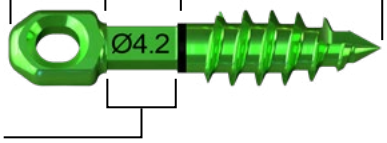
The Phantom® Metatarsal Shortening System was designed with instrumentation to facilitate the procedure from start to finish. Cut Guides are available to allow for measured, parallel cuts, in 1 mm increments that range from 3 mm – 8 mm. Bone canal measurement tools are provided to allow for selection of an appropriately sized implant diameter. Drilling tools are provided to prepare both the distal and proximal aspects of the metatarsal osteotomy for implant placement. A Wire Guide is provided to help place the crossing screw proximally to secure the implant and impart additional stability.

CONTENTS

IMPLANT OFFERINGS

Proximal Head
- Contains slot for crossing screw

Central Shaft
- Four flat faces for Wire Guide attachment and Slot Wrench engagement



Distal Threads
- Driven into distal metatarsal fragment

	Proximal Outer Diameter	Thread Diameter	Pilot Hole Wire Diameter	Implant Length	Ø2.0 mm Baby Gorilla® Crossing Screw Lengths
	**Ø2.7 mm**	Ø3.5 mm	Ø2.25 mm	21 mm	8mm - 16mm (2mm increments)
	**Ø3.5 mm**	Ø3.5 mm	Ø2.25 mm	21 mm	8mm - 16mm (2mm increments)
	**Ø4.2 mm**	Ø4.2 mm	Ø2.75 mm	21 mm	8mm - 16mm (2mm increments)
	**Ø5.0 mm**	Ø4.2 mm	Ø2.75 mm	21 mm	8mm - 16mm (2mm increments)

FEATURED INSTRUMENTATION

Implant Inserters

Ø2.7 mm

Ø3.5 mm

Ø4.2mm

Ø5.0mm

Implant Sizers

Ø2.7 mm

Ø3.5 mm

Ø4.2 mm

Ø5.0 mm

FEATURED INSTRUMENTATION

Pilot Hole Wires

Ø2.25 mm

Ø2.75 mm

Ø1.30 mm x 8cm K-wire

Ø1.10 mm x 5cm K-wire

Wire Guide

Depth Gauge

Cut Guides

3 mm, 5 mm, 7 mm cuts

4 mm, 6 mm, 8 mm cuts

K-wire Ruler

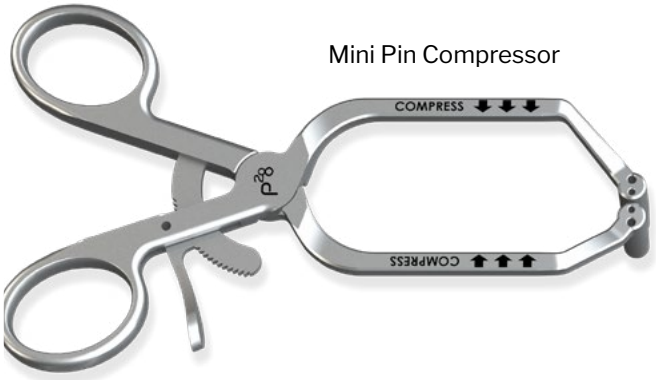
Shmogler Metatarsal Elevator

Slot Wrench

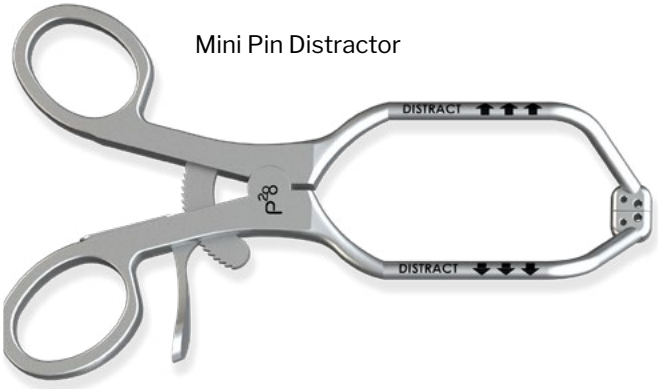
Mini Skin Hook

Ø2.7 mm Reamer

Mini Pin Compressor



Mini Pin Distractor

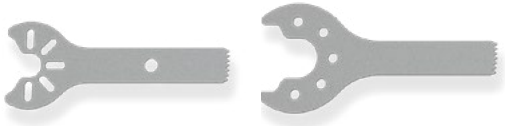


Ratcheting Mini-AO Handle

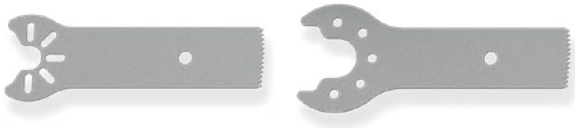
HX7 Solid Driver

Screw Holding Sleeve

Sterile Packed Saw Blades



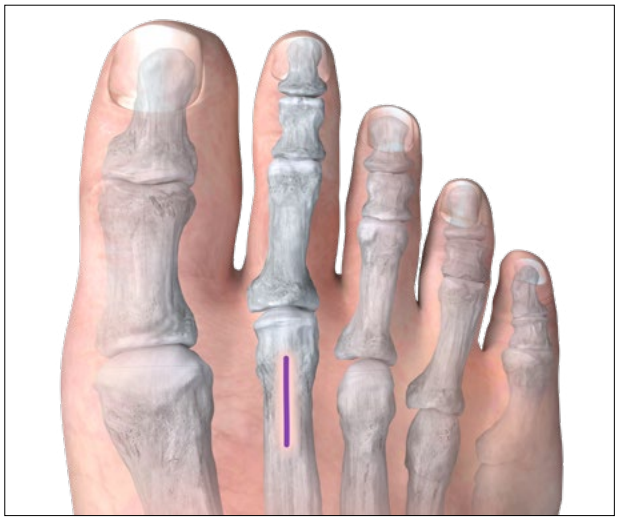
5.5 mm Width



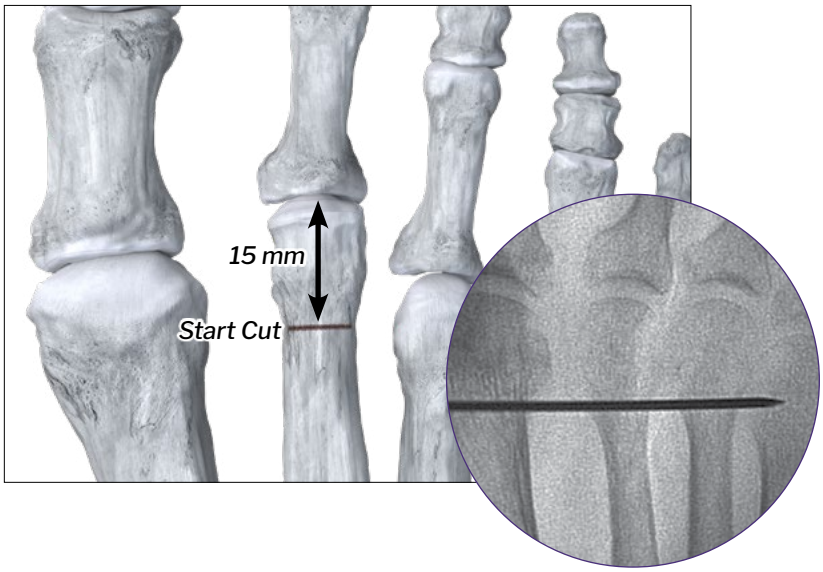
10 mm Width

INCISION/EXPOSURE

Make a longitudinal dorsal incision over the metatarsal that requires shortening. Use blunt soft tissue dissection to expose the dorsal metatarsal bone while taking care to avoid the extensor digitorum longus tendons. Loosen the soft tissue around the osteotomy site to improve access and maneuverability within the space. It is not required to make a capsular incision and expose the metatarsophalangeal (MTP) joint.



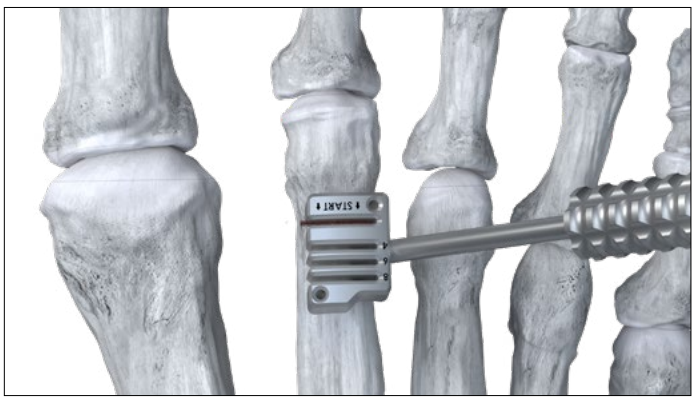
TIP: *Use electrocautery to mark the metatarsal longitudinally and establish the axis (purple line in image). This will help align metatarsal rotation after the cuts have been made.*



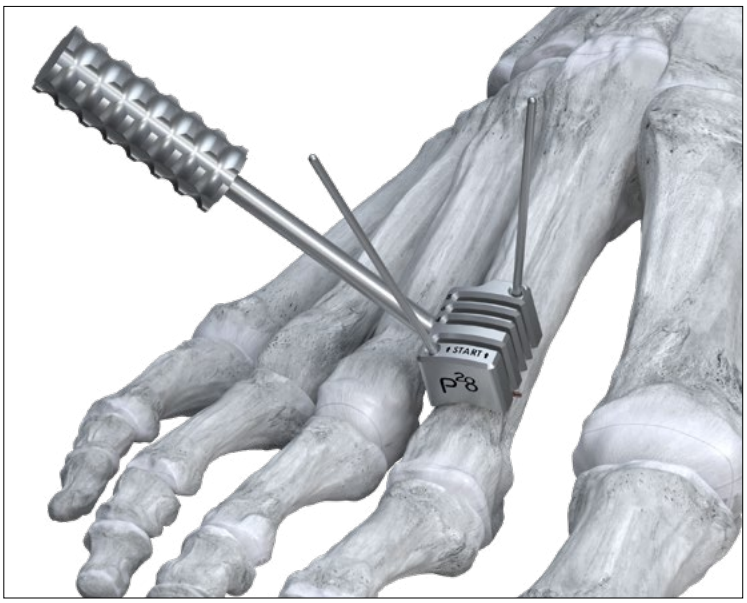
Establish the osteotomy location approximately 15 mm proximal to the MTP joint at the metaphyseal-diaphyseal junction. This can be done by using a K-wire and fluoroscopy, as shown on the left. Mark the desired location dorsally with v (Start Cut).

TIP: *Place a Cut Guide on the metatarsal and confirm the initial slot position and cutting orientation using fluoroscopy.*

OSTEOTOMY

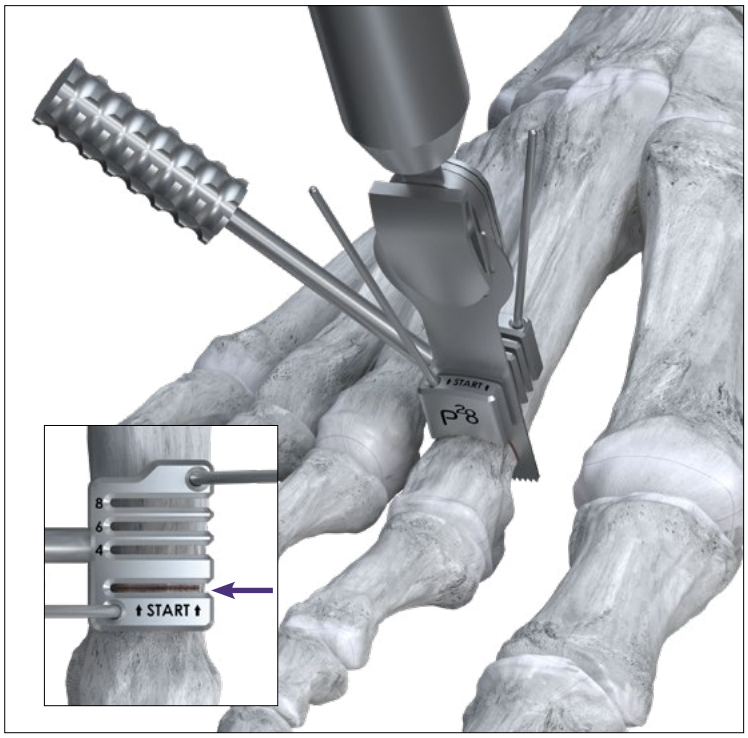


Select the Cut Guide that allows for the desired cut distance. Align the distal (START) slot of the Cut Guide with the perpendicular electrocautery mark.

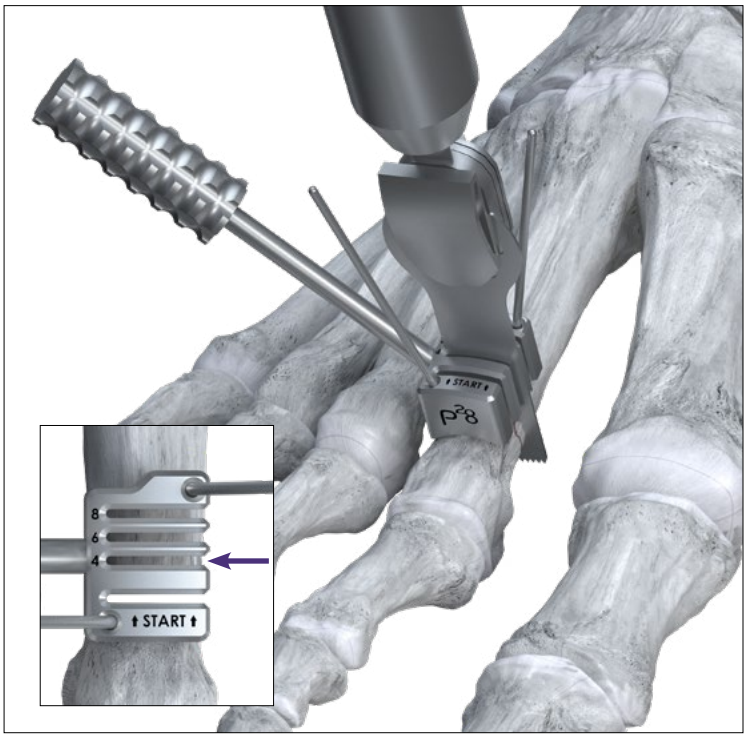


Insert Ø1.10 mm K-wires bicortically through both the distal and proximal oblique K-wire holes of the Cut Guide to secure the Cut Guide to the metatarsal. Before cutting, confirm the cut location using fluoroscopy and reposition if necessary.

OSTEOTOMY



While holding the Cut Guide against the metatarsal, use the provided sterile packed Saw Blade (5.5 mm or 10 mm, per surgeon preference) to create the first cut through the distal (START) slot. Complete this distal cut first to avoid prematurely loosening the metatarsal head.

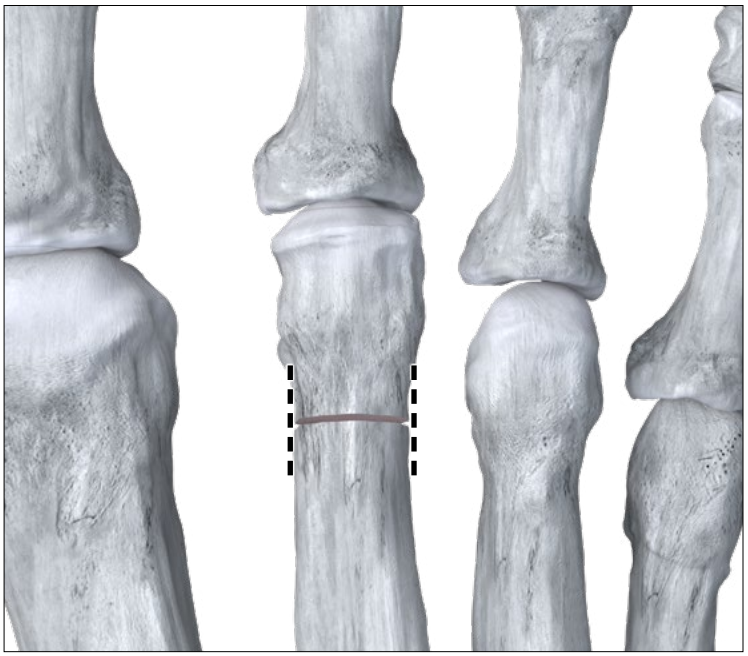


Using the same Saw Blade, make a second cut through the slot at the desired shortening distance (3 mm – 8 mm).

TIP: *Use the Cut Guide to start both cuts, then remove and finish both cuts freehand for more tactile feedback and visibility. The distal cut should be completed first, followed by the proximal cut.*

Remove the bone fragment and confirm that the cut surfaces are congruent when placed together under fluoroscopy. Remove any residual bone spurs or fragments if the cut surfaces are not congruent.

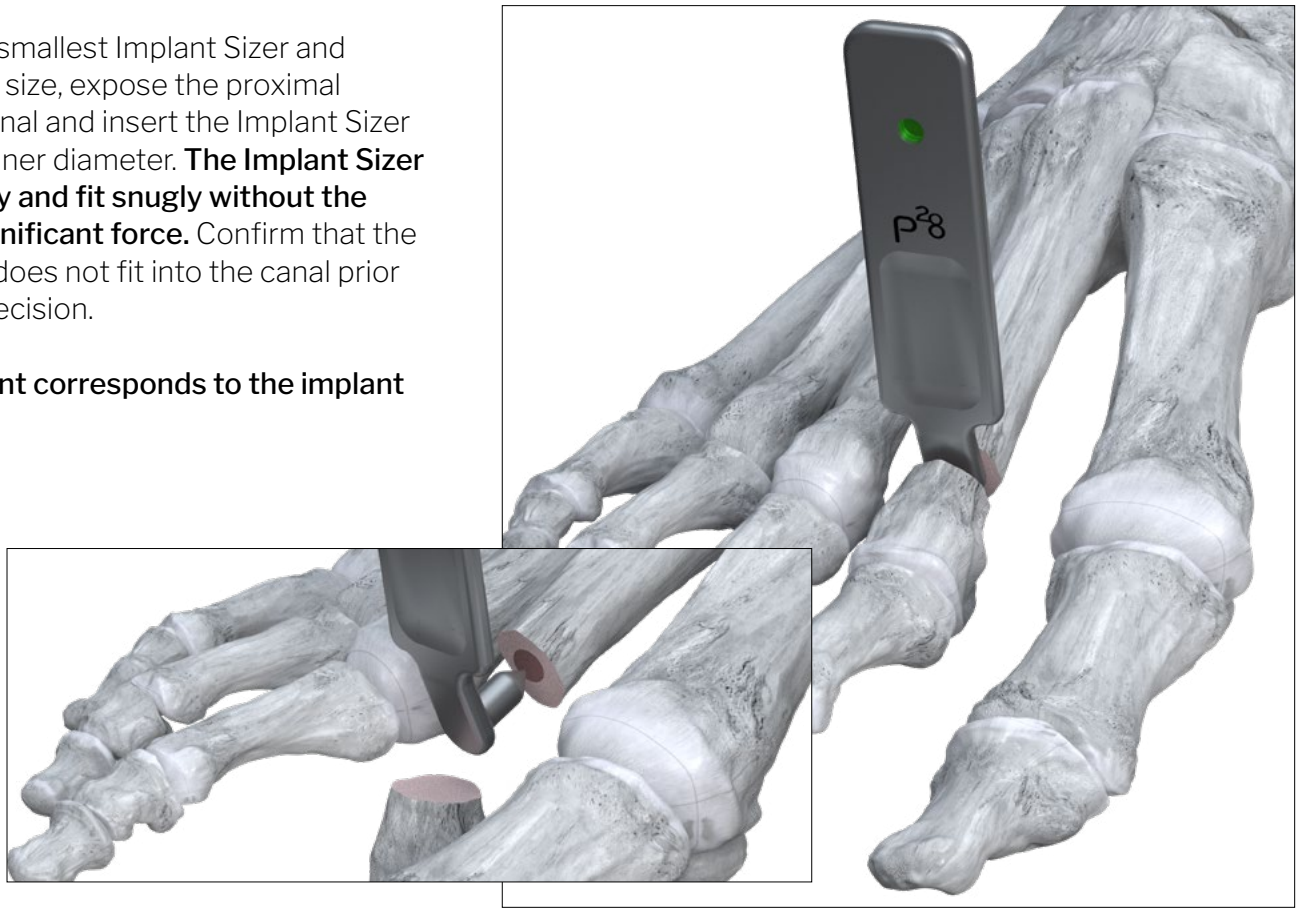
TIP: *A bone fragment is occasionally present on the plantar surface of the metatarsal and can be trimmed with a saw or rongeur.*



IMPLANT SIZING

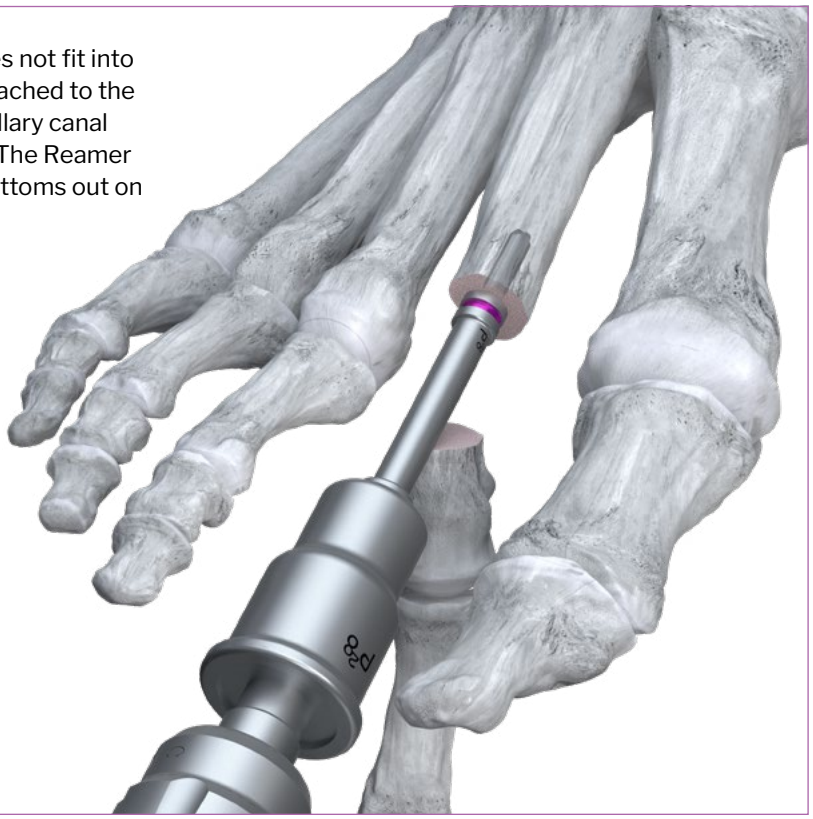
Starting with the smallest Implant Sizer and progressing up in size, expose the proximal intramedullary canal and insert the Implant Sizer to measure the inner diameter. **The Implant Sizer should insert fully and fit snugly without the need to apply significant force.** Confirm that the next largest size does not fit into the canal prior to the final size decision.

This measurement corresponds to the implant size to be used.

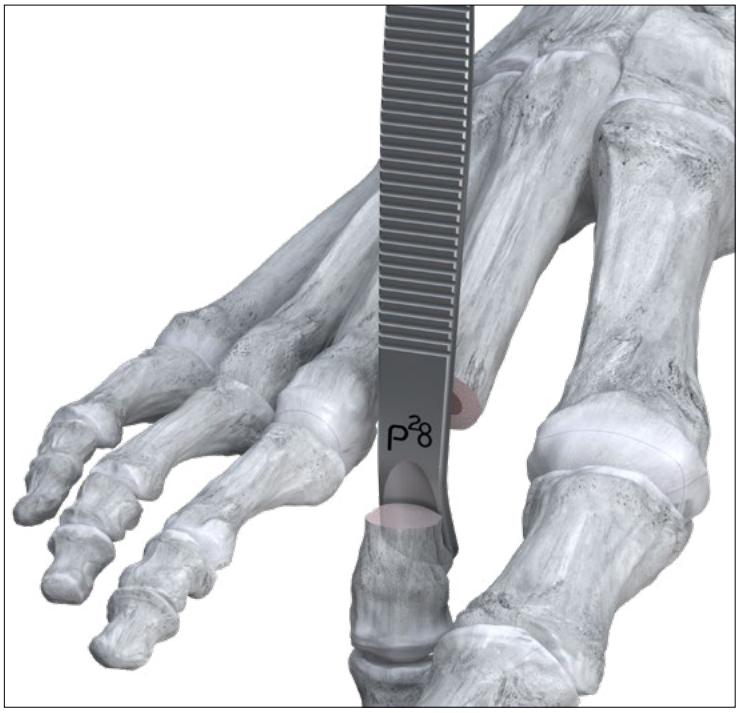


NOTE: In situations where the smallest sizer does not fit into the proximal canal, use the Ø2.7 mm Reamer attached to the provided Mini-AO Handle to ream the intramedullary canal to allow for the Ø2.7 mm implant to be inserted. The Reamer should be rotated clockwise until the Reamer bottoms out on the bone, as shown.

Reaming should be done by hand only, not under power.



IMPLANT SIZING

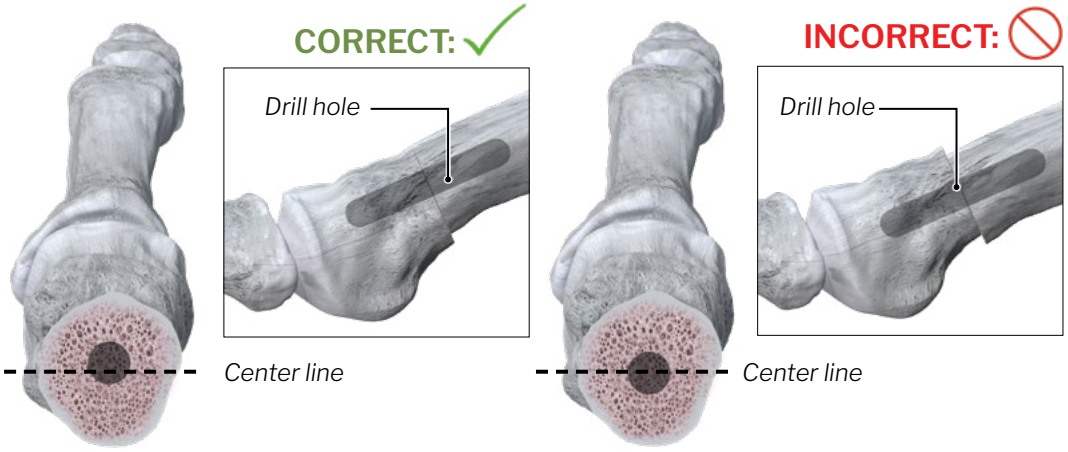


Implant Diameter	Pilot Hole Wire Diameter
Ø2.7 mm	Ø2.25 mm
Ø3.5 mm	Ø2.25 mm
Ø4.2 mm	Ø2.75 mm
Ø5.0 mm	Ø2.75 mm

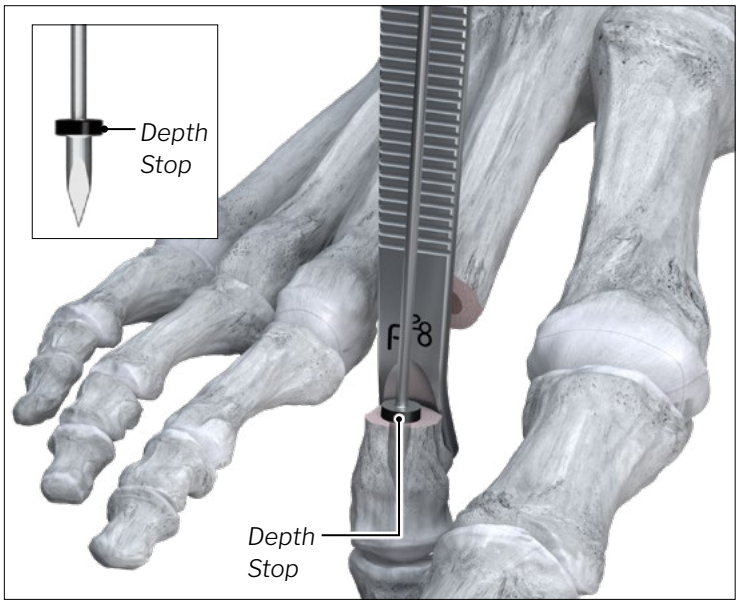
Use the provided Shmogler Metatarsal Elevator (shown) or Mini Skin Hook to expose the cut surface of the distal metatarsal head.

Obtain the appropriately-sized Pilot Hole Wire for the implant size to be used (see table above). Use the K-wire Ruler to confirm Pilot Hole Wire diameter before use.

Drill the distal pilot hole with the appropriate Pilot Hole Wire approximately 1 mm dorsal to center and at the same axial trajectory of the proximal metatarsal canal (see Note and images below).



NOTE: Because the distal metatarsal diameter is approximately 1mm wider than the proximal at the level of the osteotomy, if the pilot hole is centered when completing the osteotomy then there will be slight dorsal translation of the metatarsal head.



Insert the Pilot Hole Wire to the Depth Stop. Confirm the wire trajectory under fluoroscopy.

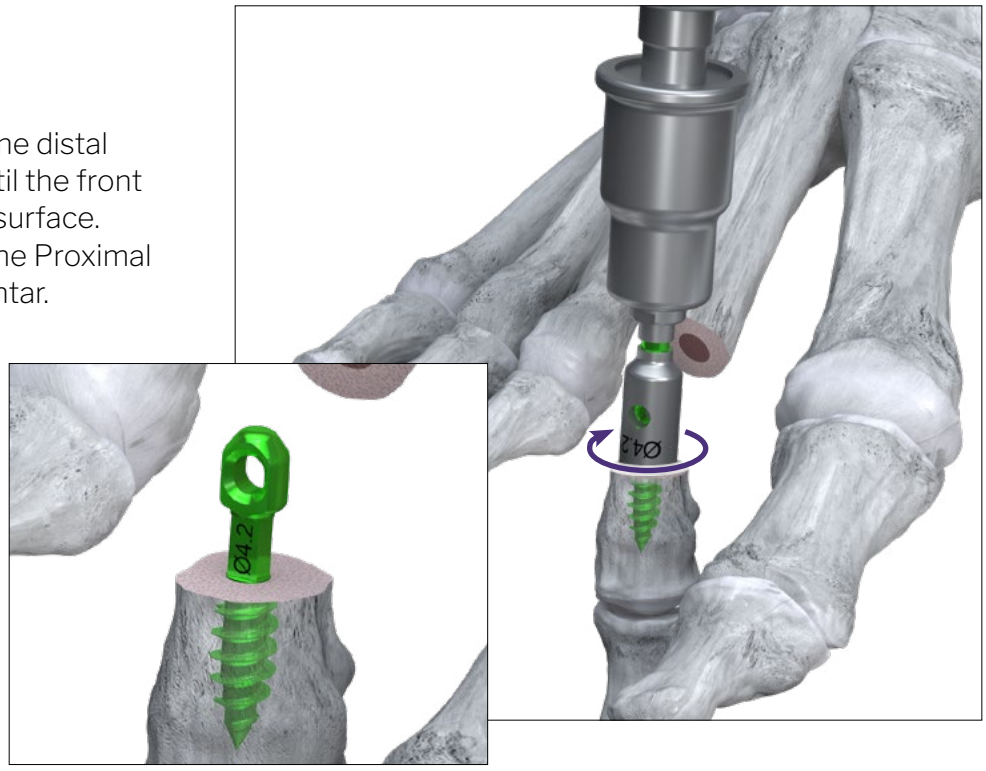
NOTE: For patients with poor bone quality, create a shallower pilot hole (do not drill to the Depth Stop) for more implant thread purchase in the metatarsal head.

IMPLANT INSERTION

Select the Implant Inserter size corresponding to the implant size diameter. Attach the Inserter to the provided AO Handle and then insert the corresponding implant fully into the Inserter, ensuring that it is seated securely.

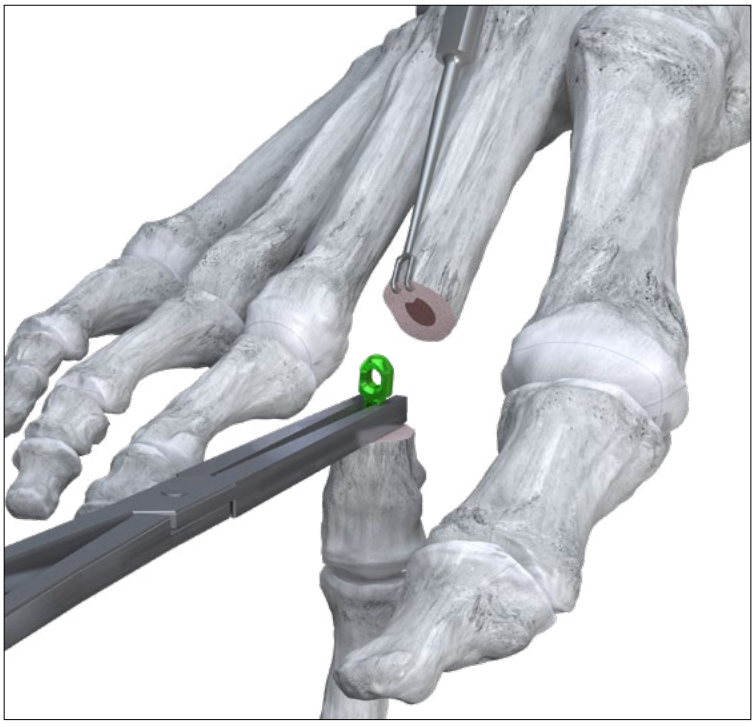
Thread the implant into the pilot hole in the distal metatarsal head by turning clockwise until the front edge of the Inserter is flush with the cut surface. Rotate the implant to ensure the slot in the Proximal Head of the implant is oriented dorsoplantar.

Do not insert the implant under power.



Hold the exposed (proximal) end of the implant with a straight Kelly clamp, or similar instrument. Simultaneously grab the proximal metatarsal shaft with the mini skin hook. Distract the distal metatarsal head and proximal metatarsal shaft to insert the exposed portion of the implant into the intramedullary canal.

Do not fully insert the implant into the proximal canal at this time to allow room for Wire Guide attachment in the next step.

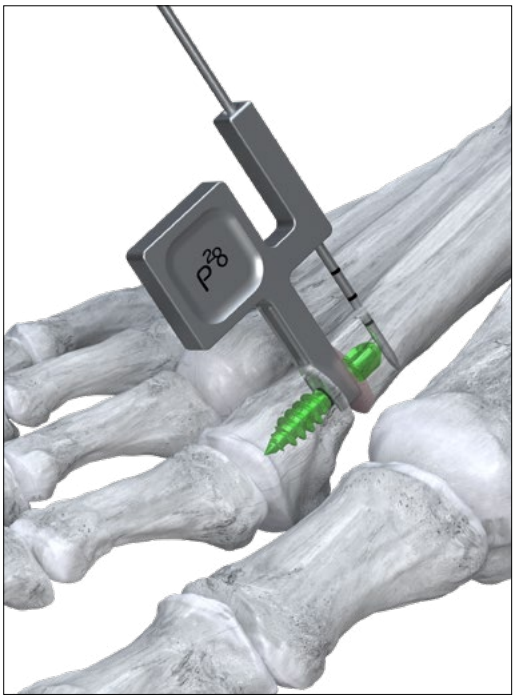


TIP: *If it is difficult to insert the implant into the proximal canal, see page 12 for instructions on how to use the Slot Wrench to assist in this step. A lamina spreader can also be used to open the osteotomy site to assist in implant insertion.*

IMPLANT INSERTION

Attach the Wire Guide to the Central Shaft of the implant, ensuring the Wire Guide is oriented dorsally to the metatarsal with the wire slot proximal. Compress the bone fragments together against the Wire Guide.

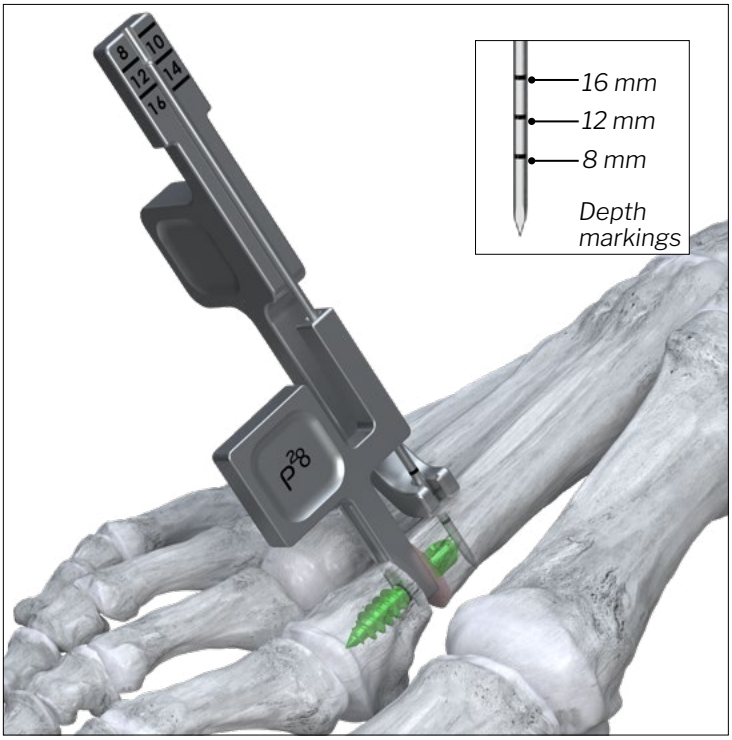
TIP: *If reduction of the bone fragments against the Wire Guide is difficult, see page 12-13 for instructions on how to use the Pin Compressor to assist in this step.*



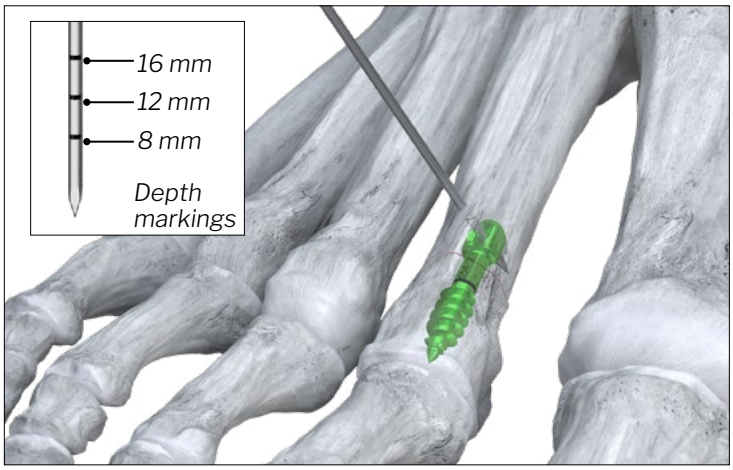
Drive a Ø1.30 mm K-wire through the Wire Guide and both cortices of the metatarsal to create a pilot hole for the Ø2.0 mm Baby Gorilla® crossing screw. Before removing the K-Wire and Wire Guide, use fluoroscopy to ensure the tip of the K-wire is touching the plantar edge of the metatarsal. The K-wire will be proximal to the implant.

Attach the Depth Gauge to the K-wire by wrapping the distal portion around the wire and pushing it against the dorsal surface of the metatarsal. Measure the desired crossing screw length by reading the depth gauge proximally. The laser markings at 8 mm, 12 mm, and 16 mm on the provided Ø1.30 mm K-wire can also be used for depth measurement. If the appropriate crossing screw length is unclear because the wire depth falls between two potential screw lengths, round up to the larger length.

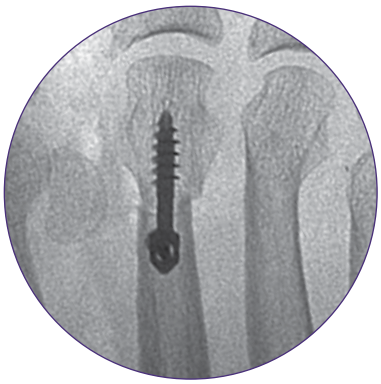
Remove the Depth Gauge, K-wire, and Wire Guide. Compress and hold the bone fragments together.

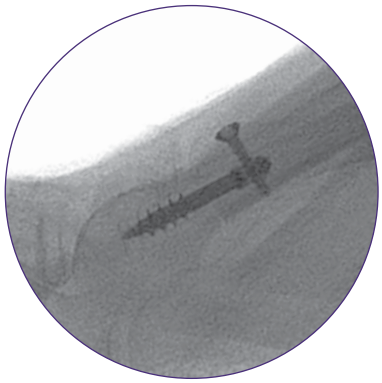


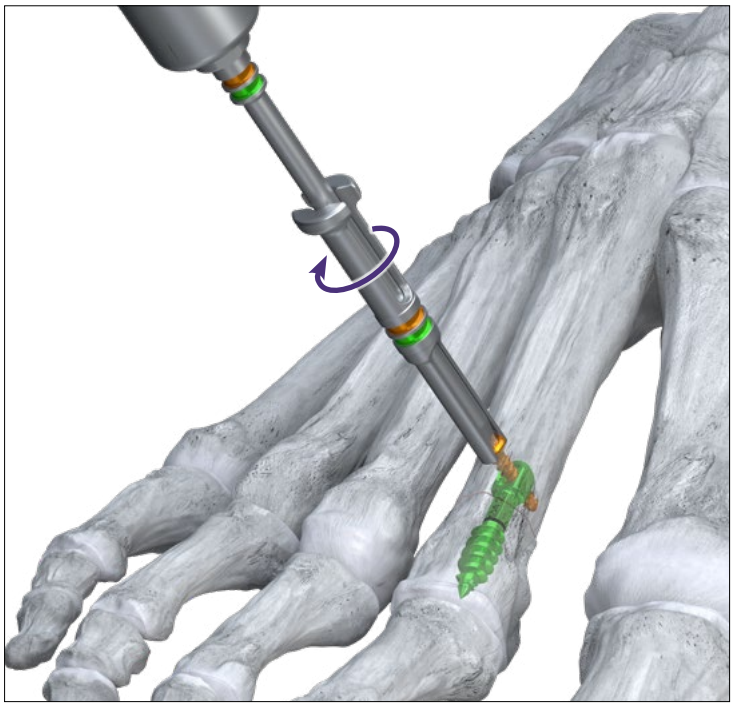
IMPLANT INSERTION



TIP: *Before inserting the crossing screw, the K-wire can be re-inserted though the metatarsal to confirm the screw position is through the implant via fluoroscopy.*





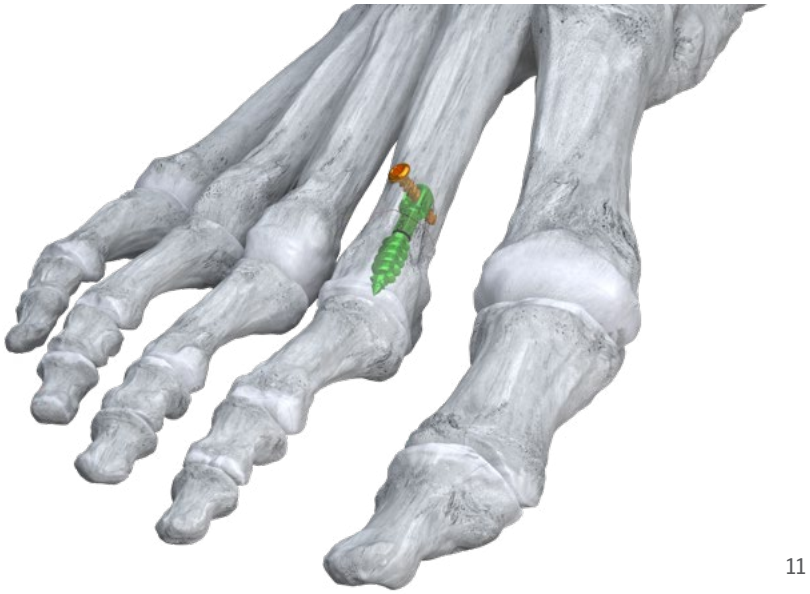


Slide the Screw Holding Sleeve over the HX7 Solid Driver and attach the Driver to the provided AO Handle. Select the appropriate Baby Gorilla® crossing screw based on the measured length. While compressing the bone fragments axially and avoiding dorsiflexion of the toe, insert the crossing screw through the drilled hole in the proximal metatarsal shaft by turning clockwise. Ensure the crossing screw is through the implant slot and has bicortical purchase while confirming final implant position and length using fluoroscopy.

NOTE: The Reamer can be used to countersink the head of the crossing screw, if needed.

CLOSURE

Proceed to incision closure or concomitant procedures at this time.

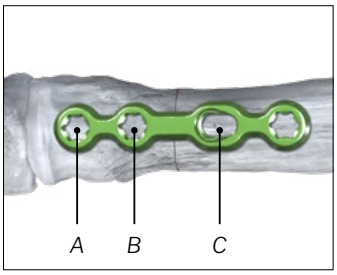


BACKUP PLATING PROCEDURE

In the unlikely event that proper metatarsal apposition cannot be achieved using the implant and crossing screw, the provided Baby Gorilla plates can be used to stabilize the osteotomy.

Select which plate to use based on patient anatomy and position on the dorsal surface of the metatarsal such that at least two screw holes (A and B) are on the metatarsal head and the compression slot (C) is proximal to the osteotomy.

NOTE: If the oblique plate is chosen, refrain from inserting a screw through the hole D if it is close to the osteotomy.



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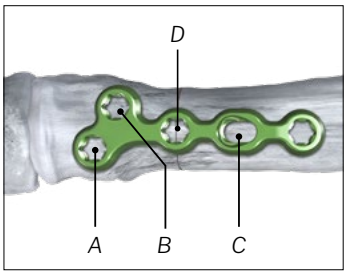

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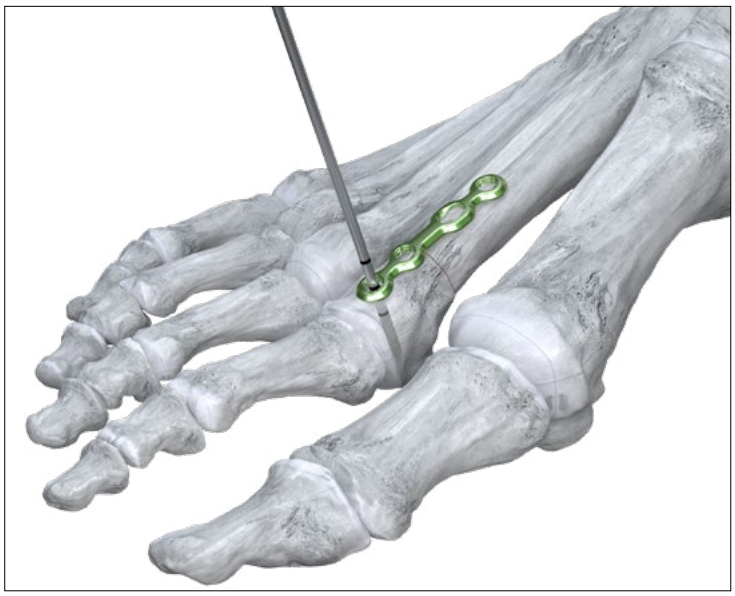
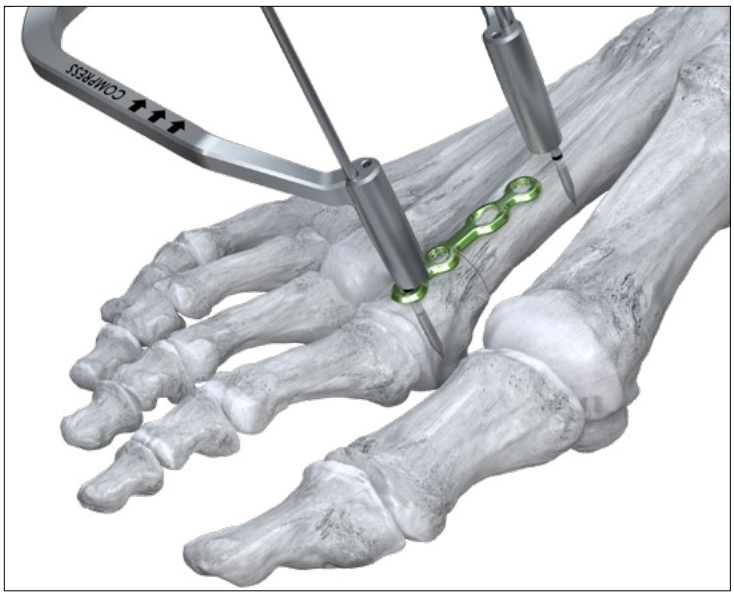
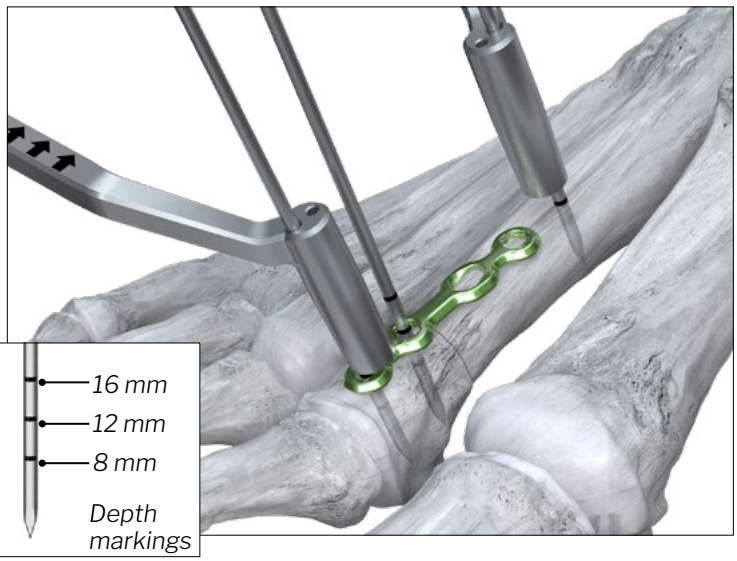


Insert a Ø1.30 mm K-wire into the most distal hole of the plate and into the metatarsal head, avoiding the joint.

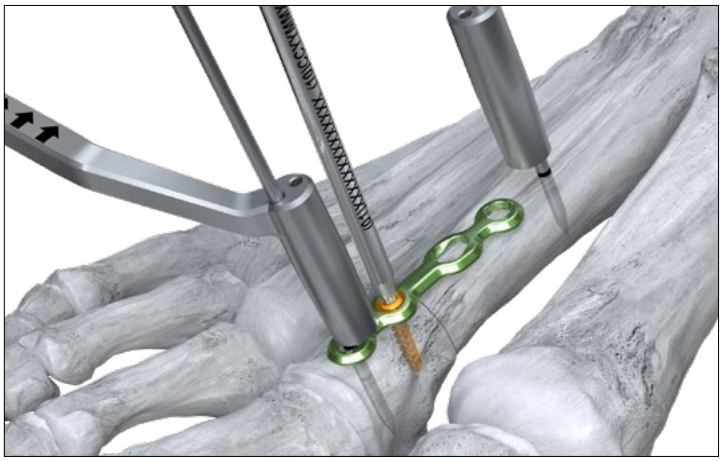


Insert another Ø1.30 mm K-wire into the proximal metatarsal shaft bicortically and proximal to the plate position. Slide the Pin Compressor over the two Ø1.30 mm wires and stabilize/compress the bone fragments together.

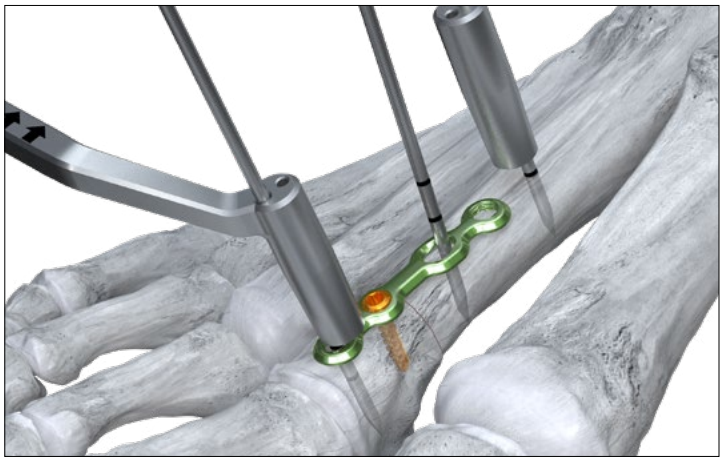
Use a Ø1.30 mm K-wire as a drill for a Ø2.0mm non locking screw provided in the system. Drill the K-wire bicortically into the distal metatarsal head through the open Baby Gorilla plate hole immediately distal to the osteotomy (B). Measure the screw length with the K-wire depth markings.



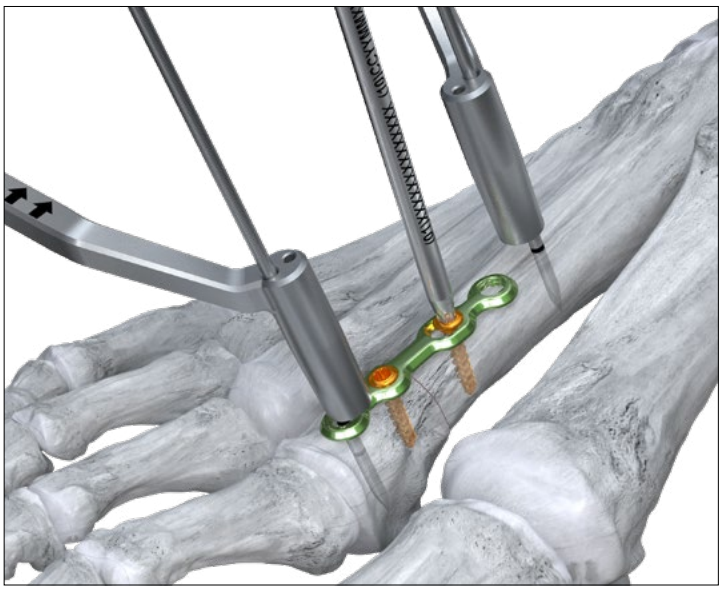
BACKUP PLATING PROCEDURE



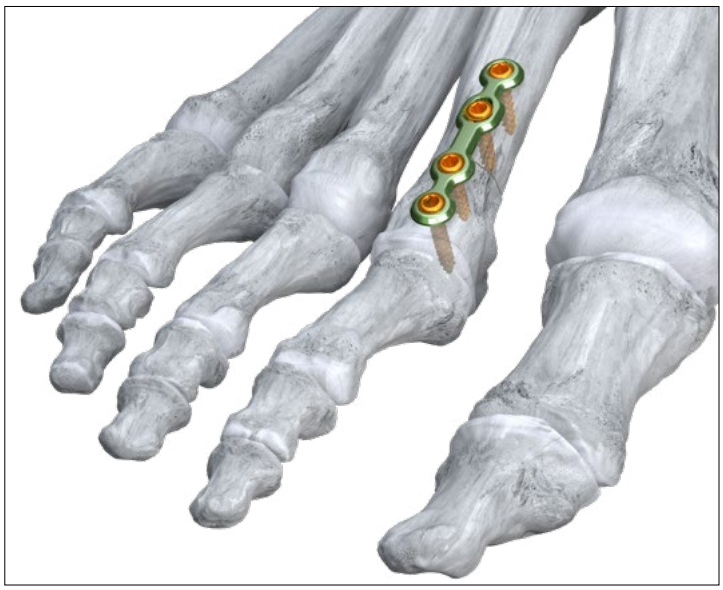
Remove the K-wire and insert the selected Baby Gorilla screw into the distal bone fragment through the same plate hole. Confirm screw position and length using fluoroscopy.



Use the Ø1.30 mm K-wire in the same manner as previously described to drill bicortically for the compression slot (C). If compression across the osteotomy site is desired, drill eccentrically away from the osteotomy site.



When inserting the selected screw, the ratchet may need to be released on the Pin Compressor to allow for the non locking screw to travel in the compression slot of the plate. Repeat the previous steps for screw placement for the remaining proximal plate hole. Ensure screw position and depth using fluoroscopy and confirm fixation and stability of the osteotomy site before fully removing the Pin Compressor and K-wires to allow for access to the final plate hole.

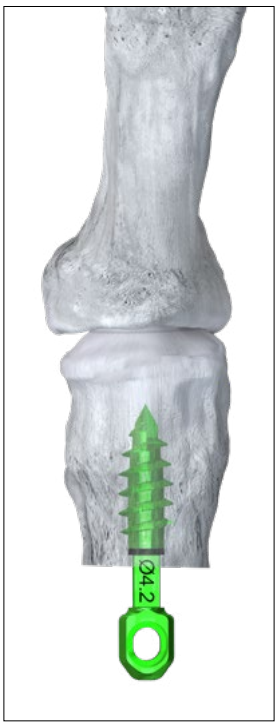


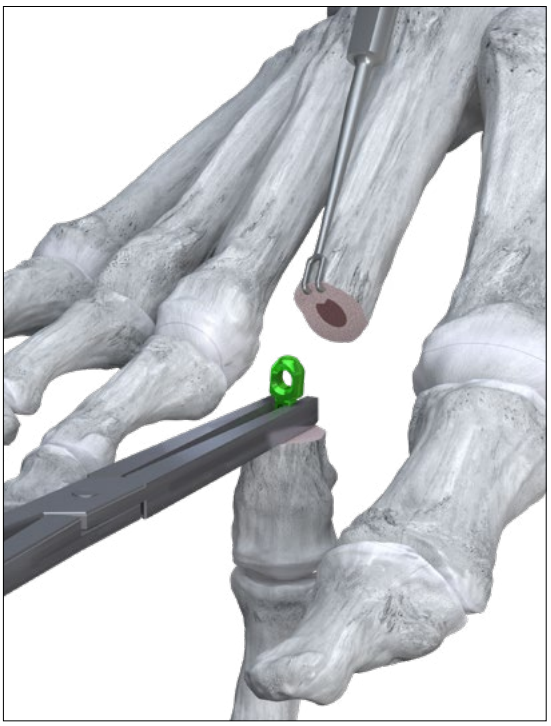
Repeat the previous steps for screw placement for the remaining distal plate hole. If the hole created by the Ø 1.30 mm K-wire in the Pin Compressor is centered, the screw can be placed in the existing hole and drilling with another Ø1.30 K-wire is not necessary.

SPECIALIZED INSTRUMENT USE

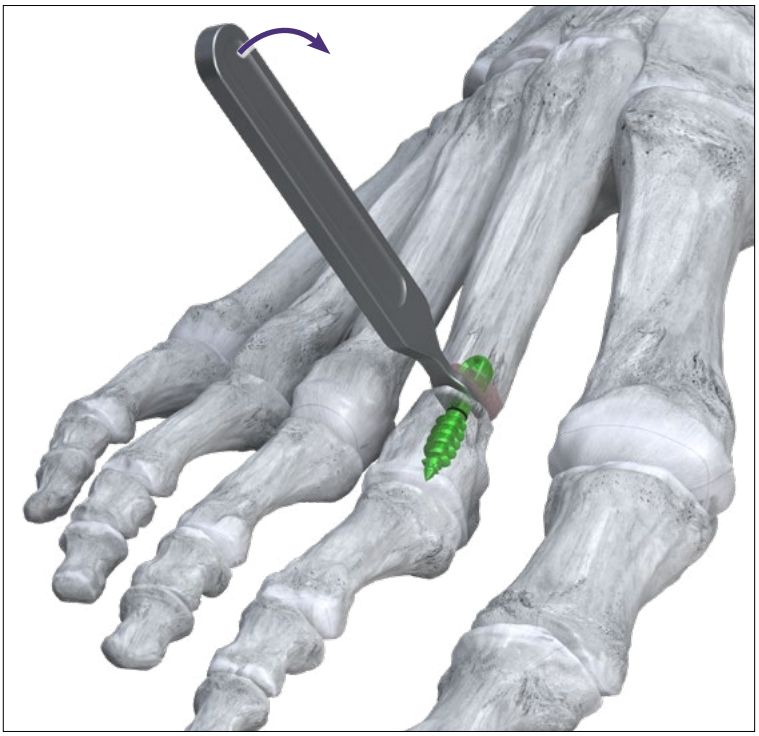
SLOT WRENCH

If it is difficult to get the exposed proximal portion of implant into the proximal canal (page 9), use the Implant Inserter to advance the threads distally. **Be mindful that the implant threads do not advance through the MTP joint,** and do not exceed one full (360°) turn of the Inserter.





Once able to insert the proximal end of the implant, use the Slot Wrench to back out the implant by rotating clockwise from a distal perspective. Back out the implant the same rotational amount as further inserted previously, such that the distal edge of the implant's Central Shaft is flush with the distal cut surface, and the slot of the Proximal Head is oriented dorsoplantar.

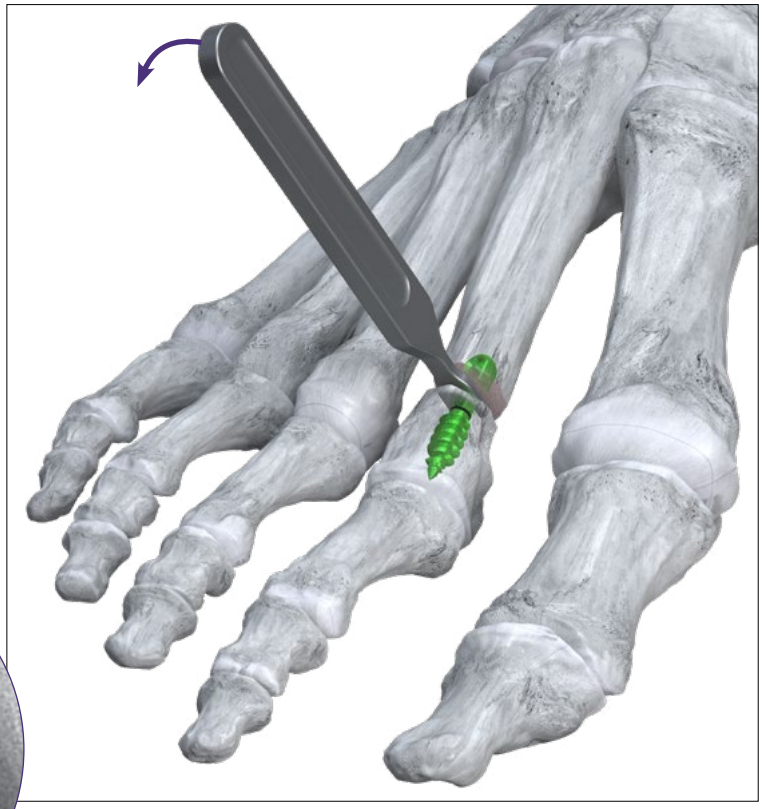


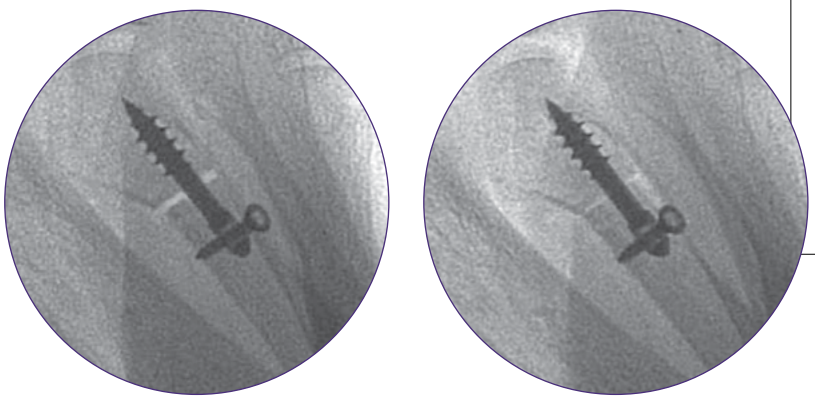
SPECIALIZED INSTRUMENT USE

SLOT WRENCH (CONTINUED)

If a gap remains between the two bone segments after crossing screw insertion, remove the screw and use the Slot Wrench to rotate the implant one half turn (180°) or one full turn (360°) counter-clockwise from a distal perspective, based on gap size. Ensure the implant is clocked properly to accept the crossing screw. **Be mindful that the implant threads do not advance through the MTP joint.**

Apply compression to oppose the bone fragments and re-insert the crossing screw into the screw hole to allow for improved bone apposition upon seating the screw.

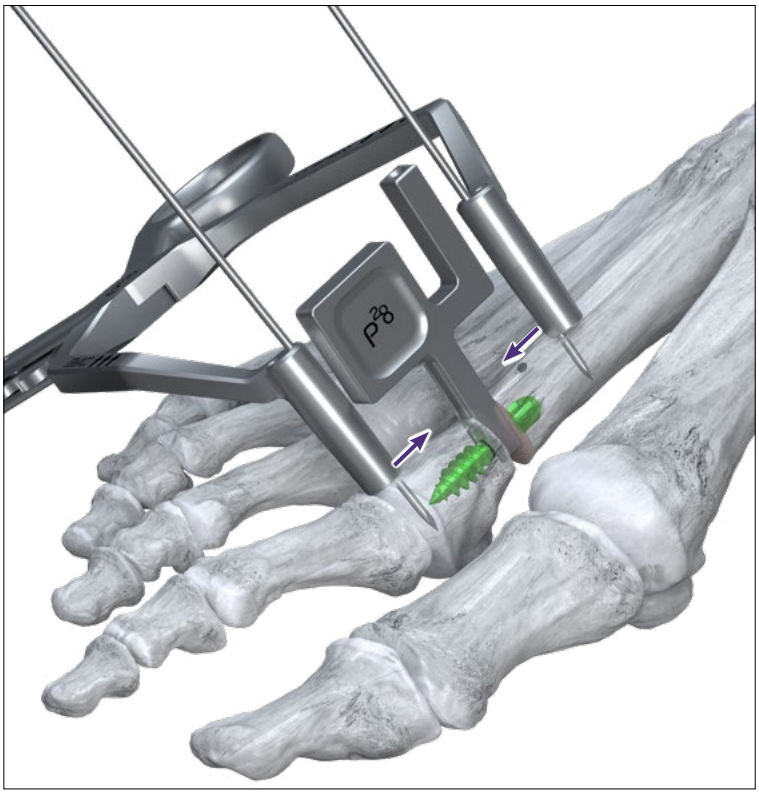




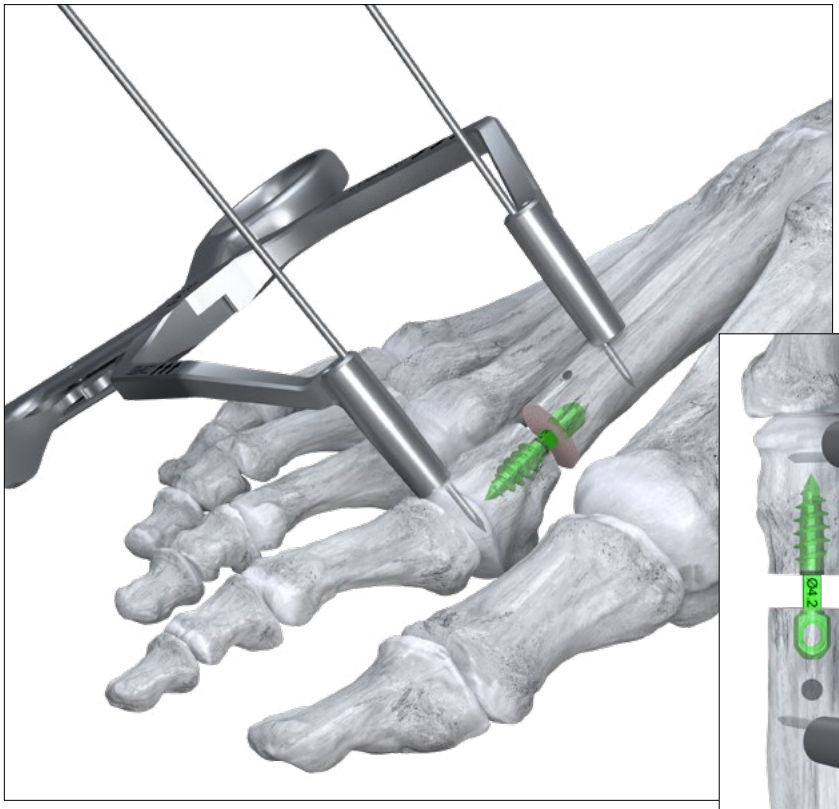
Implant inserted further into the distal metatarsal head

PIN COMPRESSOR

If assistance is needed when compressing the bone fragments together against the Wire Guide (page 10), insert a Ø1.30 mm K-wire at an oblique angle into the distal metatarsal head, avoiding the joint, distal of the implant threads. Insert another Ø1.30 mm K-wire at the same oblique angle into the proximal metatarsal shaft, bicortical, proximal to the Wire Guide. Slide the Pin Compressor over the two Ø1.30 mm wires and compress the bone fragments together against the Wire Guide.

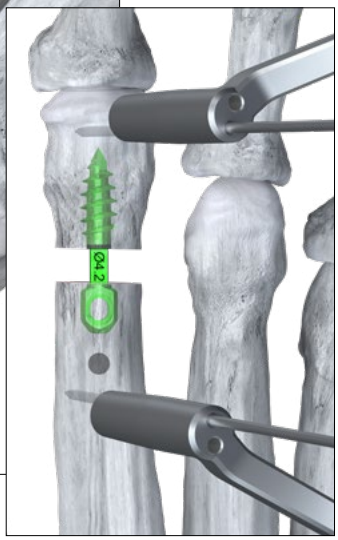


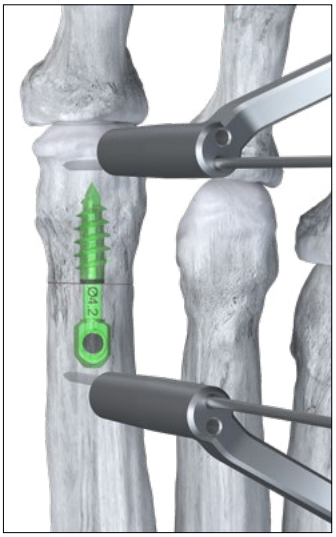
SPECIALIZED INSTRUMENT USE



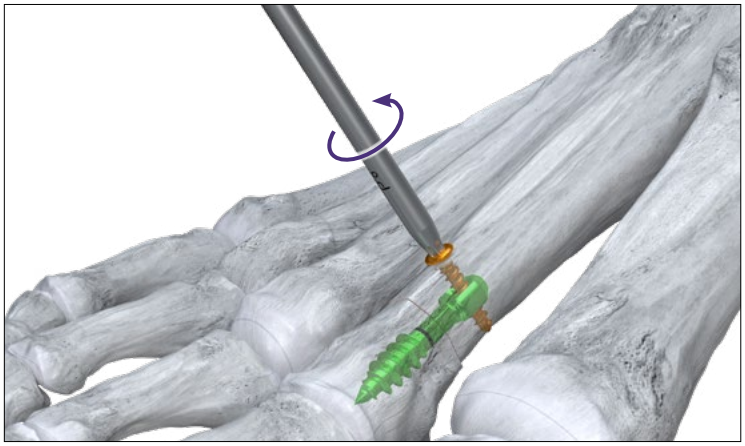
PIN COMPRESSOR (CONTINUED)

After making the pilot hole for the crossing screw and using the Depth Gauge to measure the desired screw length, continue to use the Pin Compressor to compress the bone surfaces and fully seat the proximal implant before placing the crossing screw.

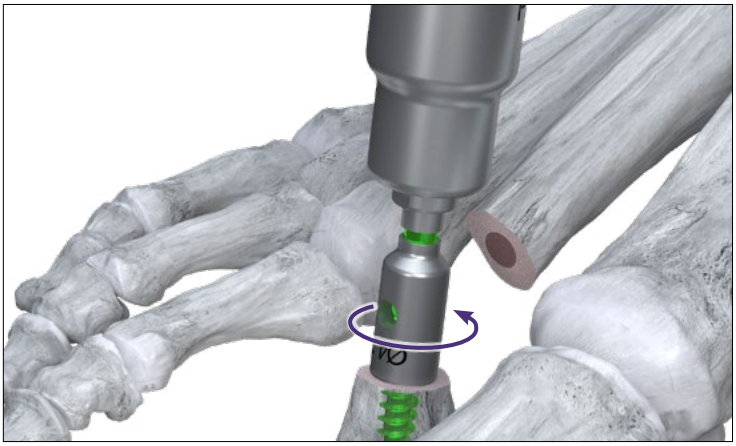




IMPLANT REMOVAL



If implant removal is required, attach the HX7 Solid Driver to the provided AO Handle. Identify the head of the screw at the dorsal-proximal end of the implant. Insert the Driver and rotate counterclockwise to remove the crossing screw. Pass the crossing screw from the operative site.



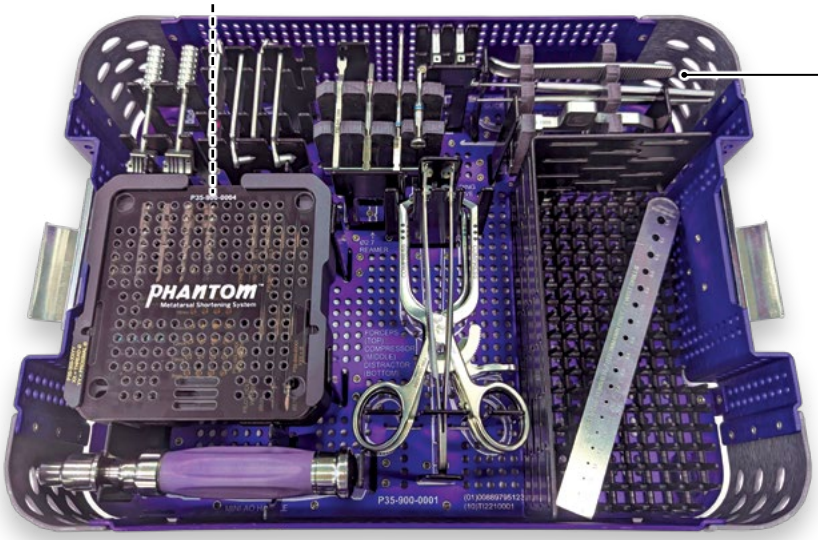
Distract the osteotomy site to expose the proximal end of the implant. If bone healing has occurred, create an osteotomy around the central aspect of the implant, then distract the osteotomy to expose the proximal end of the implant. The provided Pin Distractor can be used to assist in this step, if needed.

Assemble the provided AO Handle to the appropriate Implant Inserter based on implant size. Connect the exposed (proximal) end of the implant to the Implant Inserter and rotate counterclockwise until the implant is removed. Confirm complete implant removal under fluoroscopy.

PHANTOM® METATARSAL SHORTENING CASE

PHANTOM® METATARSAL SHORTENING CADDY

The Implants, Crossing Screws, Implant Inserters, K-wires, Baby Gorilla plates, and Pilot Hole Wires are located within the caddy.



PHANTOM® METATARSAL SHORTENING CASE

The Cut Guides, Implant Sizers, Slot Wrench, Ø2.7 Reamer, HX7 Solid Driver, Screw Holding Sleeve, Wire Guide, Shmogler Metatarsal Elevator, Mini Skin Hook, Depth Gauge, Mini Pin Compressor, Mini Pin Distractor, Forceps, Ratcheting Mini-AO Handle and K-wire Ruler are located within the metal tray.

Reusable Items Include:

- Implant Inserters
- Implant Sizers
- Wire Guide
- Cut Guides
- Ratcheting Mini-AO Handle
- Mini Pin Compressor
- Mini Pin Distractor
- Forceps
- Depth Gauge
- Ø2.7 Reamer
- Slot Wrench
- Screw Holding Sleeve
- Mini Skin Hook
- Shmogler Metatarsal Elevator
- HX7 Solid Driver
- K-Wire Ruler

Single Use Items Include:

- Implants
- Crossing Screws
- Saw Blades
- K-Wires
- Pilot Hole Wires
- Baby Gorilla Plates

NOTE: Saw Blades are delivered sterile-packed and separate from the case.

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

INDICATIONS FOR USE (PHANTOM®)

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

- Metatarsal and phalangeal osteotomies
- Metatarsal deformity correction
- Hammertoe
- Revision hammertoe
- Claw toe
- Mallet toe
- Proximal Interphalangeal Joint Arthrodesis
- Distal Interphalangeal Joint Arthrodesis

CONTRAINDICATIONS

Use of the Phantom Metatarsal Shortening 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 wires are intended for single use only. Re-use may cause product failure and could lead to disease transmission.
- Instruments, wires and screws are to be treated as sharps.
- Do not use other manufacturer's instruments or implants in conjunction with the Phantom Metatarsal Shortening System.

MR SAFETY INFORMATION

The Phantom Metatarsal Shortening 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 Phantom Metatarsal Shortening 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 (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

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 ridgidus 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)

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.

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

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:

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- Vascular, muscular or neurological pathologies that compromise the concerned extremity
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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.

PHANTOM™
Metatarsal Shortening System

Phantom® Metatarsal Shortening System Surgical Technique Guide

PATENTED, DESIGNED & EXCLUSIVELY DISTRIBUTED BY

Exclusively foot & ankle
Paragon 28®

P35-STG-0001 RevB [2023-08-15]

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DISCLAIMER

The purpose of the Phantom® Metatarsal Shortening Surgical Technique Guide is to demonstrate the optionality and functionality of the Phantom® Metatarsal Shortening implants and instrumentation. CAUTION: Federal Law (USA) restricts this device to sale and use by, or on the order of, a physician.