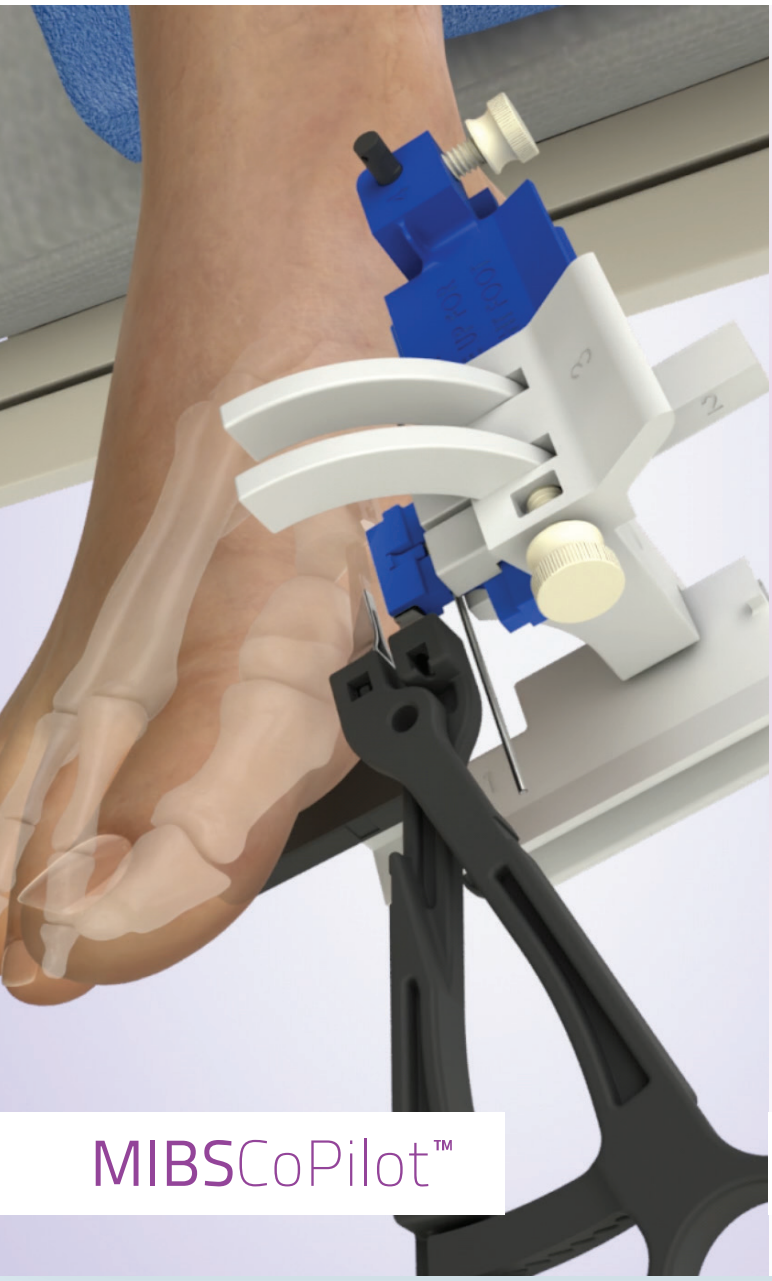
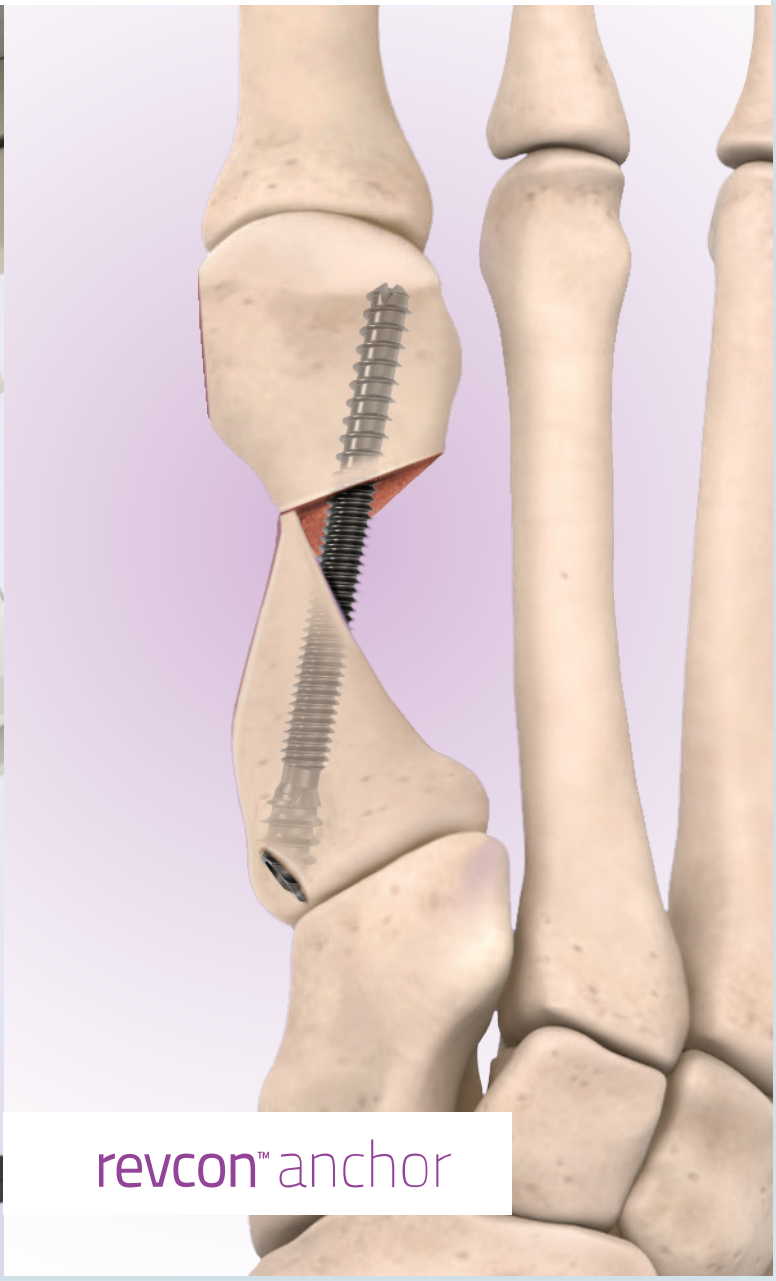
revcon™ minimally invasive screw system

Surgical Technique Guide

Sterile System with MIBS CoPilot™ Shift + Targeting Guide



MIBSCoPilot™



revcon™ anchor

voom™
MEDICAL DEVICES

Table of Contents

Revcon™ Screw System

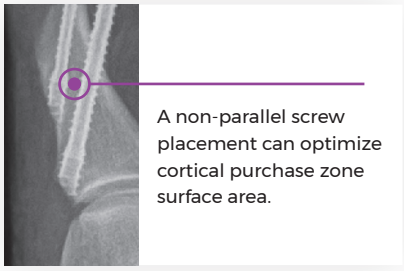
Patented next-evolution design for minimally invasive bunion surgery (MIBS).

Reverse conical shape

Increases thread surface area for bone engagement.

Beveled 42° and 50° angles

Facilitates divergent screw positioning for capture of the cortical purchase zone (CPZ) and cancellous anchor zone (CAZ).

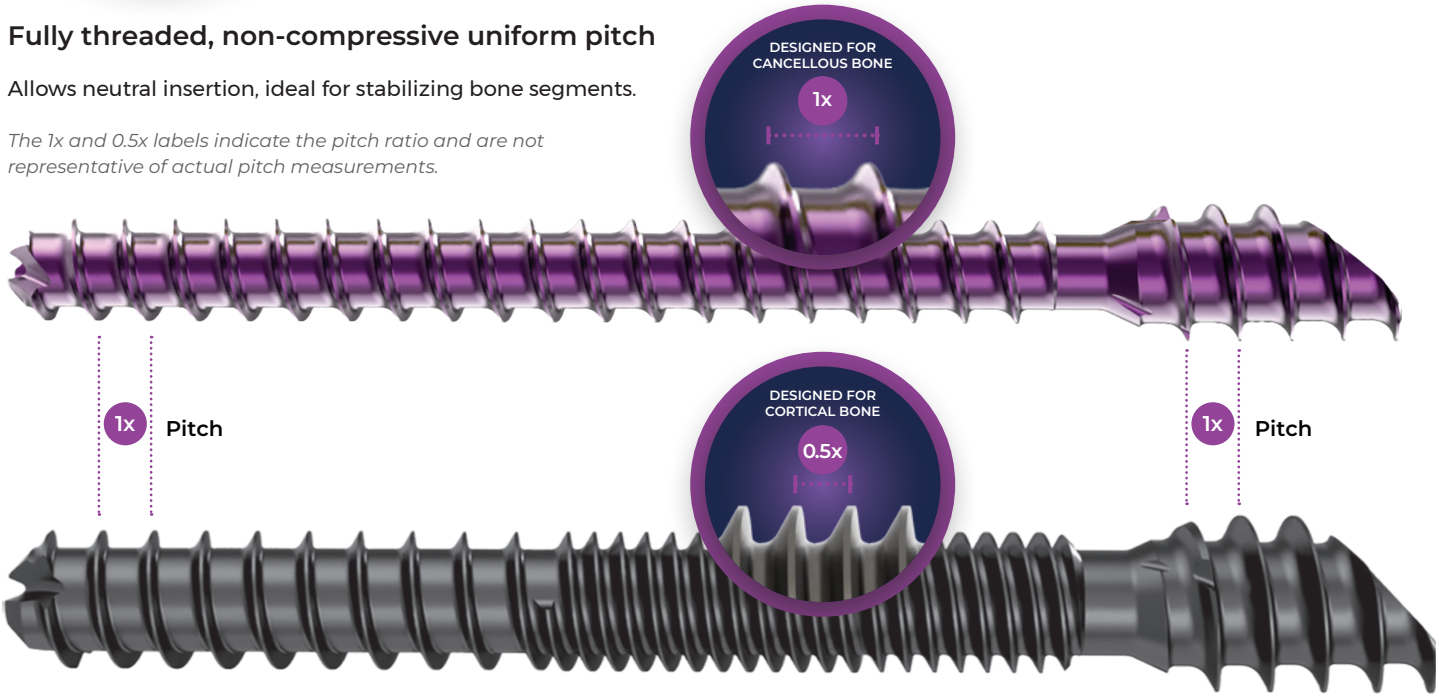


A non-parallel screw placement can optimize cortical purchase zone surface area.

Fully threaded, non-compressive uniform pitch

Allows neutral insertion, ideal for stabilizing bone segments.

The 1x and 0.5x labels indicate the pitch ratio and are not representative of actual pitch measurements.



From end to end, the Revcon™ screw is designed for smooth, quick percutaneous insertion, bone purchase, and strength.

Hexagonal recess

Forward cutting flutes

Cannulated design

End-to-end features are depicted here using Revcon™ Neutra screw for optimal visibility, but are consistent across the Revcon™ Neutra and Revcon™ Anchor screw lines.

Revcon™ Screw System

Instructions for Use

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.


Single Use Only

Device description

The REVCON™ Screws are intended for use in bone reconstruction, osteotomy, arthrodesis, fracture repair, and fracture fixation of bones appropriate for the size of the device, to allow surgeons to perform a bunion osteotomy and fixation of the osteotomy with a minimally invasive surgical technique. The REVCON™ Screw System contains fully threaded, cannulated screws offered in a variety of diameters and lengths. The REVCON™ RSN 30xx-S and RSA 40xx-S screws are manufactured from medical grade titanium alloy (Ti-6Al-4V-ELI) as per ASTM F136 and are provided sterile and ready for use.

Indications for use

The REVCON™ Screw System is indicated for fixation of bone surgery involving reconstruction. Examples include:

- Mono or Bi-Cortical osteotomies in the foot or hand
- Distal or Proximal metatarsal or metacarpal osteotomies
- Weil osteotomy
- Fusion of the first metatarsophalangeal joint and interphalangeal joint
- Fixation of osteotomies for Hallux Valgus treatment
- Akin type osteotomy
- Arthrodesis base first metatarsal cuneiform joint to reposition and stabilize metatarsus varus primus
- Calcaneus/cuboid arthrodesis
- Talar/navicular arthrodesis.

The REVCON™ Screw System is not intended for spinal use.

Contraindications

The REVCON™ Screw System should not be used in the following scenarios:

- Infection
- Physiologically or psychologically inadequate patient
- Irreparable tendon system
- Possibility for conservative treatment
- Growing patients with open epiphyses
- Patients with high levels of activity
- Vascular insufficiency
- Poor bone quality
- Open epiphyses
- Noncompliant patient
- Allergy to device components
- Possibility for non-surgical treatment

Warnings and precautions

The surgeon should be familiar with the procedure and use of the REVCON™ Screw System instruments prior to surgery.

The outcome and results obtained from this surgical procedure, as with any surgery, are highly dependent on the knowledge of surgical techniques, placement and sizes of implants used, management of the patient both pre and post operation, including the general health of the patient.

The implants used in the system are manufactured from medical grade titanium alloy, Ti-6Al-4V (ASTM F-136) and use with implants of other metallic materials is not recommended.

REVCON™ Screw System has not been evaluated for safety and compatibility in the MR environment. It has not been

Revcon™ Screw System

Instructions for Use

tested for heating, migration, or image artifact in the MR environment. The safety of REVCON™ Screw System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

The REVCON™ Screw System implants are single use devices and should never be re-used.

Potential adverse events.

Potential Adverse Events for use of the REVCON™ Screw System includes, but is not limited to:

- Infection, early or late
- Fracture of the implant
- Foreign body (allergic) reaction to implants.
- Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, necrosis, and/or pain. Bursitis. Tissue or nerve damage caused by improper positioning and placement of implants or instruments.
- Loosening or dislocation of the implant requiring revision surgery.
- Nonunion, delayed union
- Allergic reaction to the implant material
- Migration of particle wear debris possibly resulting in a bodily response
- Embolism

Care and handling of instruments

The REVCON™ Screw System 3.0MM instrument Kit (RIK30-S) and 4.0MM Instrument Kit (RIK40-S) are provided sterile and must be stored in their original packaging until ready to use. As these kits are provided sterile, they are single use only.

How to use

Reference the Revcon™ Surgical Technique - Sterile document (RSN-STE2) available on the Voom™ Website for how to use the Revcon™ Screw System.

Product complaints

Any healthcare professional (e.g., customer or user) who has a complaint or who has experienced any dissatisfaction in the product quality, durability, reliability, safety, effectiveness, and/or performance should notify the distributor and/or Voom™ Medical Devices.

783 Old Hickory Blvd., Suite 155
Brentwood, TN 37207
+844.372.5489
info@voomdevices.com

When reporting a complaint, please provide the unique device identification number (UDI) or the lot number and serial number, your name and phone number, and the nature of the problem.

The surgical technique is available at no charge upon request.

Symbol {Reference Number)	Description of symbol	Standard of origin
	Indicates the medical device manufacturer	ISO 15223 - 1 Medical Device - Symbols to be used with medical device labels, labeling and information to be supplied - Part: General Requirements
	Indicates the manufacturer's batch code so that the batch or lot can be identified	
	Indicates the manufacturer's catalogue number so that the medical device ca be identified	
	Indicates a medical device that has been subjected to a Radiation sterilization process.	
	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure	
	Indicates the need for the user to consult the instructions for use	
	Indicates that the device is intended for prescription use only	21 CFR 801.109

Surgical Technique

Distal First Metatarsal Osteotomy

1 Step 1: Identifying Landmarks + Incisions

Under fluoroscopic guidance and using a the straight elevator for triangulation, mark the location for the distal incisions.

The distal incision location is medial at the first metatarsal neck, just proximal to the flare of the medial eminence (figure 1).

Bluntly dissect soft tissues down to the bone. Care is taken to avoid any neurovascular structures related to the incision placement.

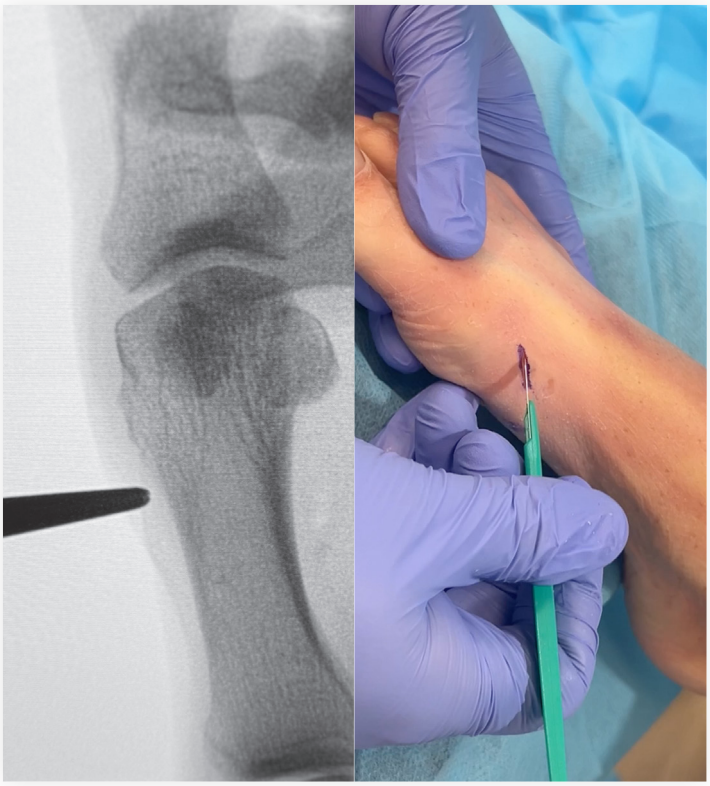


Figure 1: Distal incision location.

2 Step 2: Dissection + Soft Tissue Release

The straight elevator is used to create a plane between the bone of the first metatarsal neck and the dorsal, plantar, and medial soft tissue structures (figure 2). Avoid aggressive plantar dissection as this may increase risk for injury to the blood supply to the first metatarsal head.

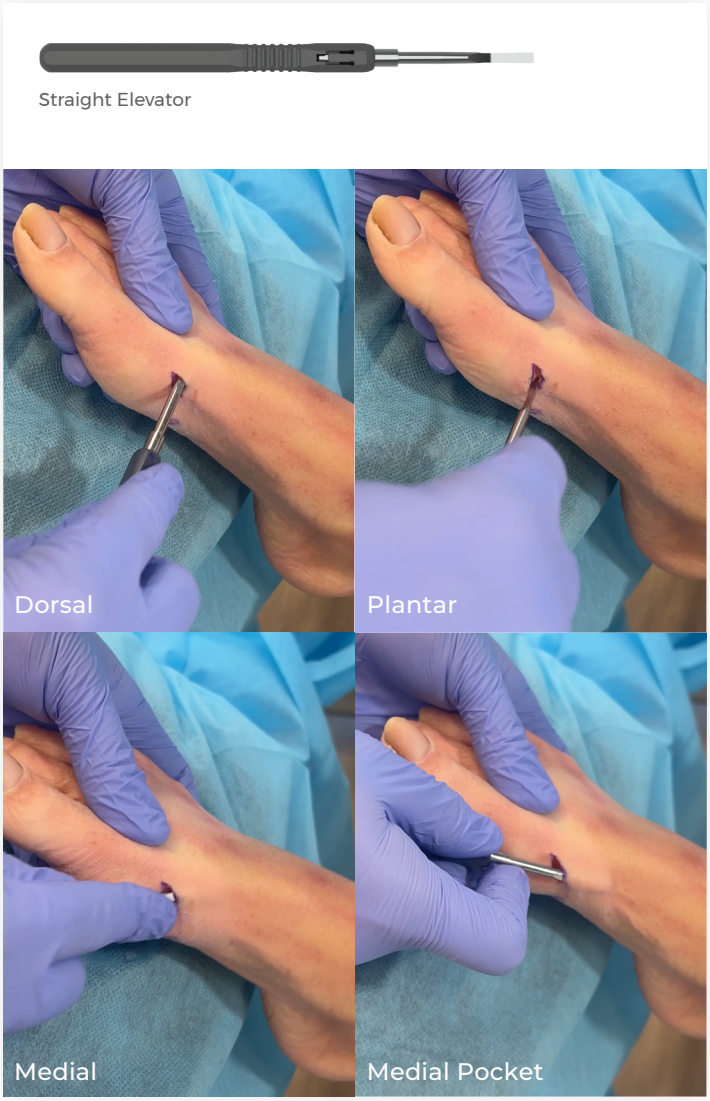


Figure 2: Periosteum release with straight elevator.

3 Step 3: Midshaft Osteotomy

Perfom the Transveron™ osteotomy using a 2.0mm x 16mm Shannon bur under irrigation and fluoroscopic guidance (figures 3 and 4).

Depending on the surgeon's goal for correction, orienting the osteotomy distally will lengthen the first metatarsal whereas orienting the osteotomy proximal will shorten it.

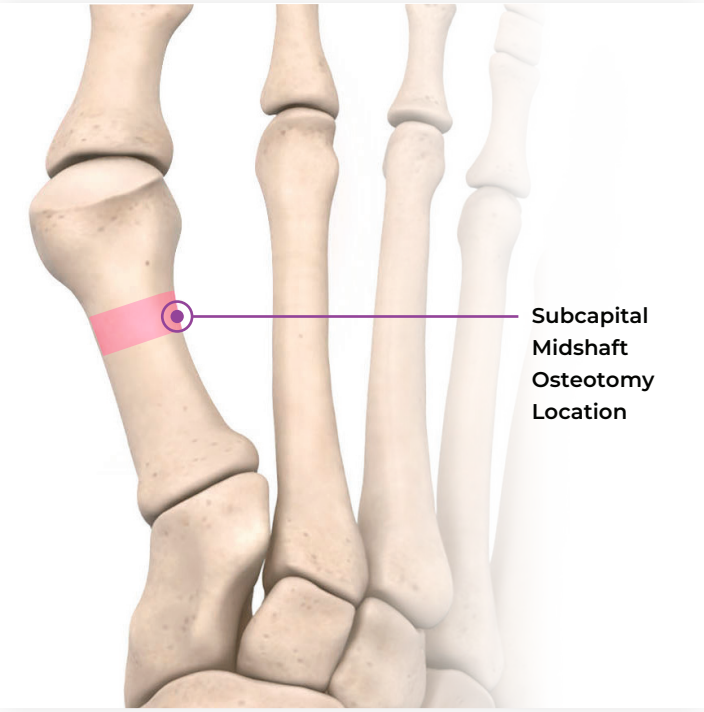


Figure 3: The Transveron™ osteotomy may be placed distally or proximally in the apical transition zone of the first metatarsal.

Shannon Bur, 2.0mm x 16mm

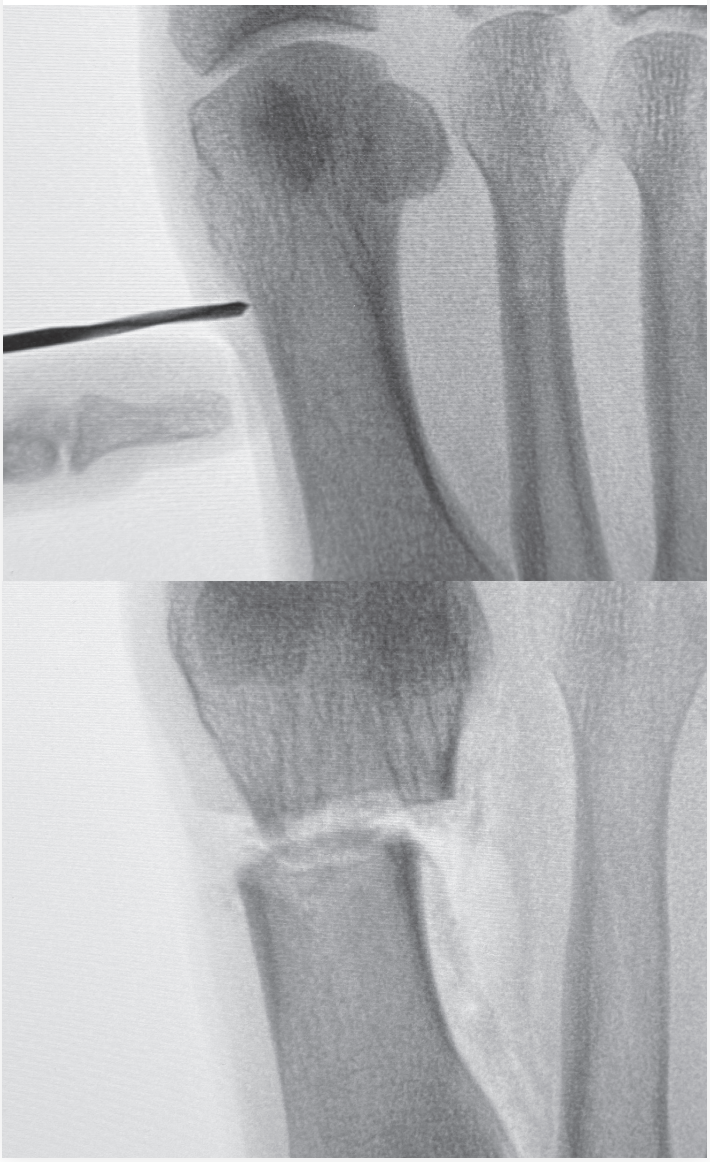


Figure 4: Starting (top); complete osteotomy (bottom).

4 Step 4: Shift Preparation + Mock Reduction

After the osteotomy is verified to be complete, place the curved periosteal elevator across the osteotomy site to mobilize the lateral soft tissue allowing for translation (figure 5). Perform multiple times if necessary to achieve desired mobility.

Perform mock reduction by placing the straight periosteal elevator into the metatarsal shaft. Lever distal and lateral under fluoroscopy (figure 6). This will give you a future reference for the target final shift location for the patient. Use the instruments as shown in figures 5 and 6 to avoid plantarflexing the metatarsal head.

Curved Elevator

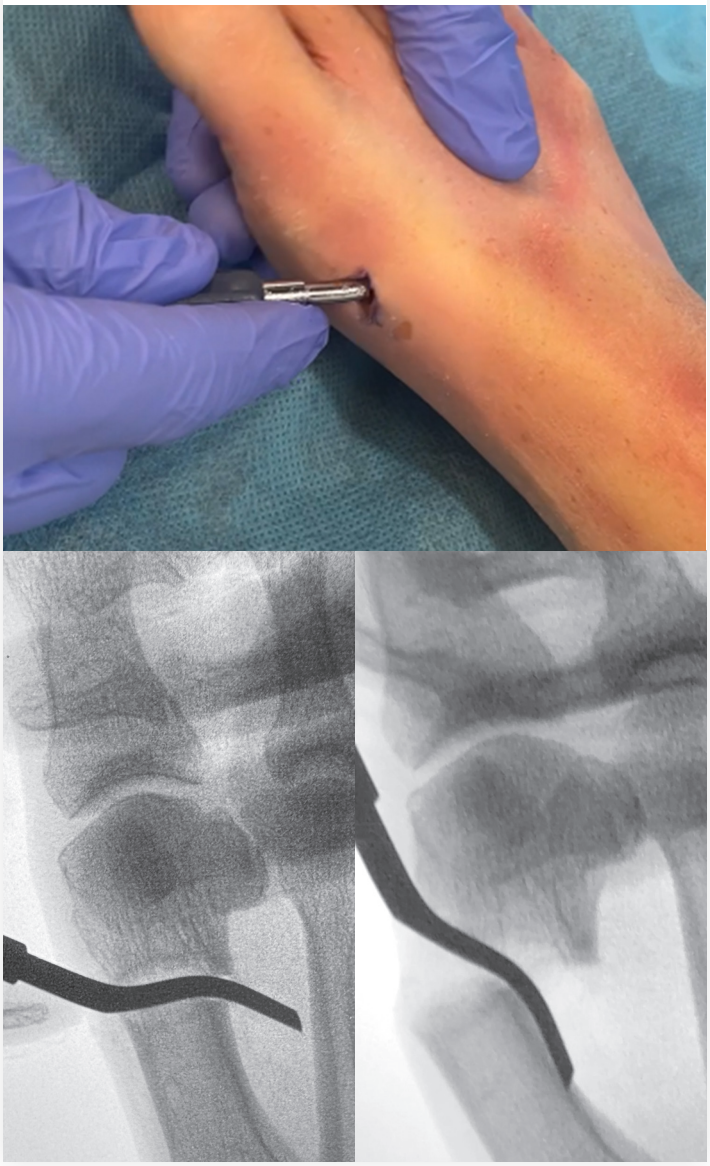


Figure 5: Levering the curved elevator both distally and medially will loosen the soft tissues surrounding the metatarsal.

Straight Elevator

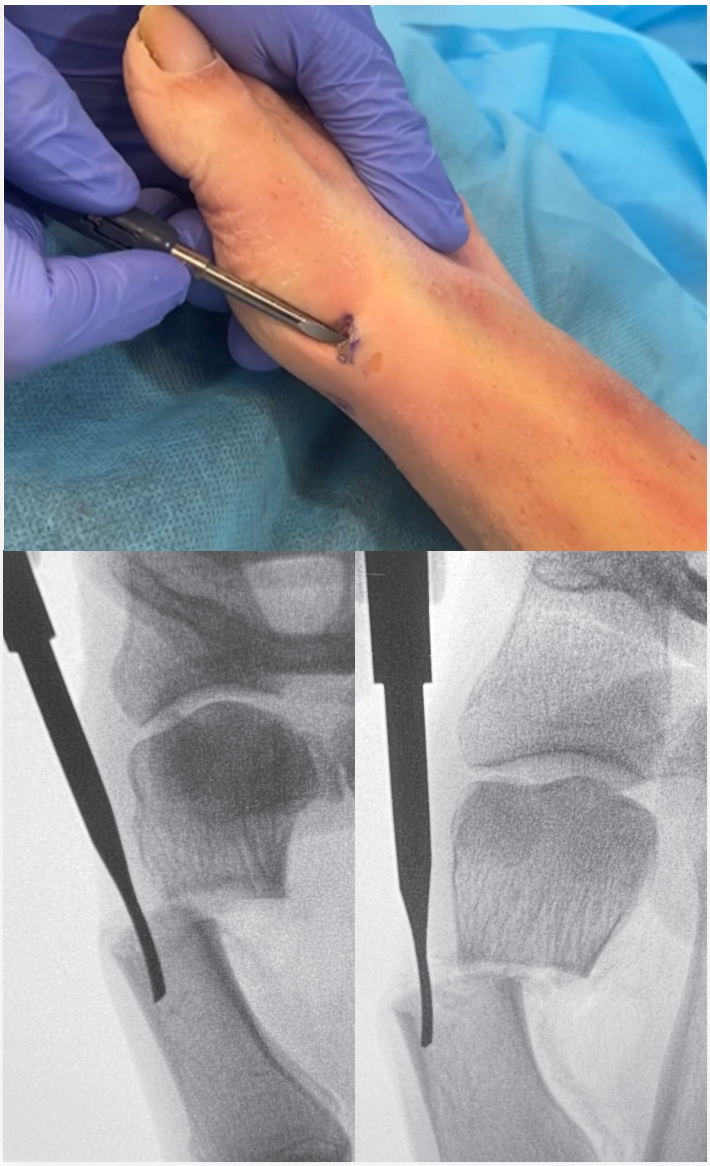


Figure 6: Levering the straight elevator will give you a reference target for the final shift location.

5 Step 5: Guide Clamp Application + Attaching Guide Rail

Use the straight elevator to expose the IM canal. Insert the metal end of the clamp, placing the straight leg IM and the curved leg subcutaneous and extramedullary with the medial cortex in between the legs. Confirm with AP fluoroscopy that the medial cortex is between the two legs of the clamp.

Advance the clamp proximally until the curved leg is 3-5mm proximal to the osteotomy site (figure 7). **Do not tighten the clamp at this time.**

Snap the preassembled guide rail and K-wire targeter into the clamp as shown in figure 8.

The guide is marked to show which side faces up based on right or left patient anatomy. The white knob on the guide should always be proximal (figure 8). **Do not tighten the clamp at this time.**

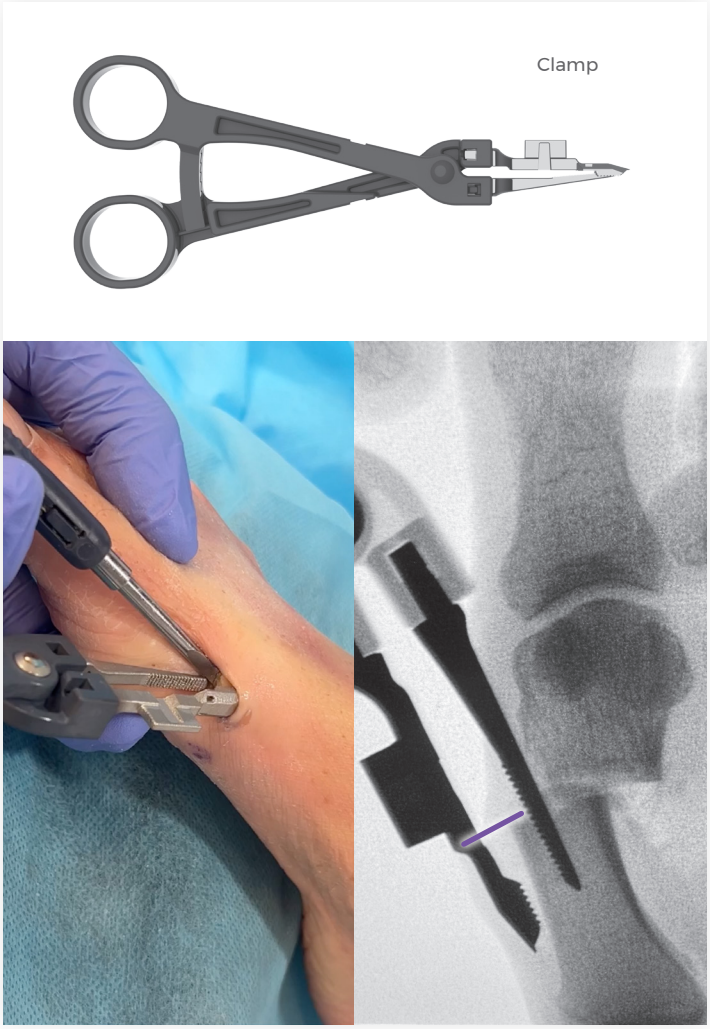


Figure 7: 3-5mm is the optimal depth to maintain the stability of the clamp throughout the procedure and remain a safe distance from the osteotomy. site.

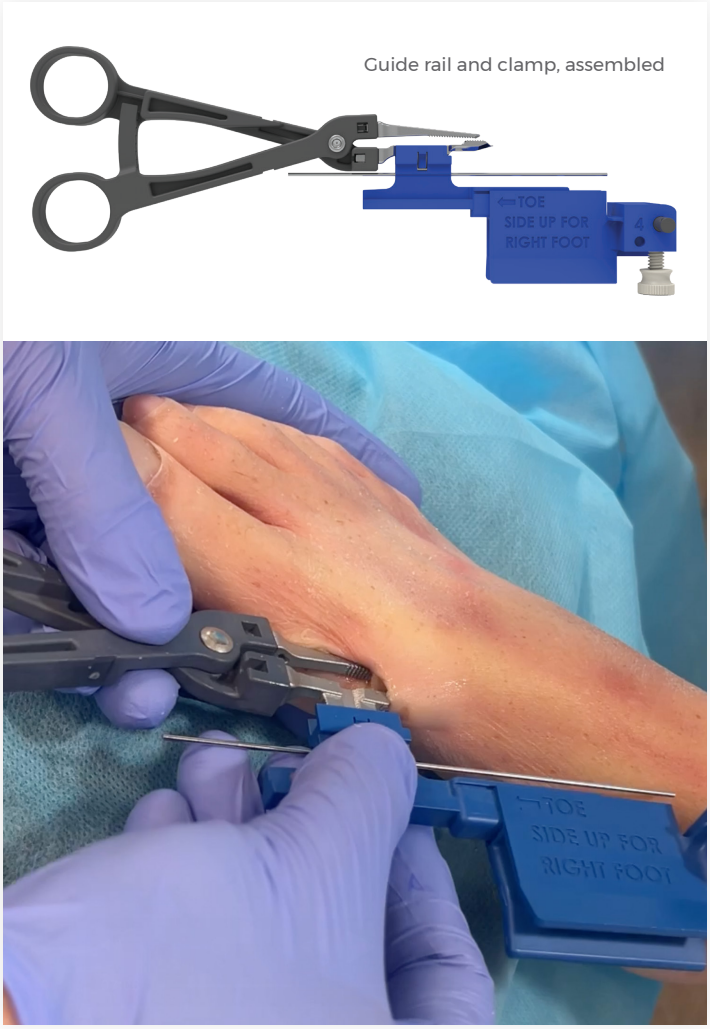


Figure 8: Correct guide rail orientation.

6 Step 6: Lateral Alignment + Metatarsal Shifter Application

Position the fluoroscopy for a lateral view. **Ensure that you are viewing the foot in a true lateral.**

While maintaining the true lateral view, adjust the clamp under live fluoroscopy to ensure the clamp is in the middle of the IM canal and rotated so that both windows on the curved leg of the clamp are visible under fluoroscopy. Ensure the external K-wire trajectory is parallel to the center of the IM canal and central to the apex at the tip of the clamp. Once the position is confirmed, tighten the clamp to hold the guide securely in place (figure 9)

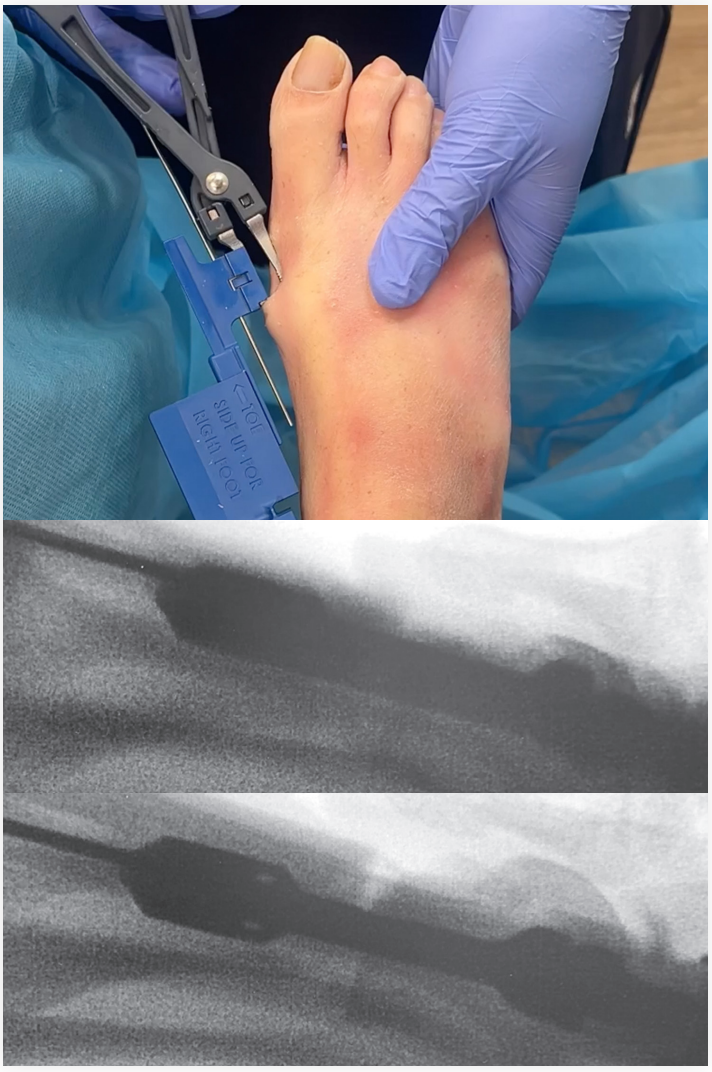


Figure 9: Foot alinged in true lateral (top); foot positioned in true lateral with guide misaligned (middle); both foot and guide in true lateral with trajectory in the middle of the IM canal and windows visible (bottom).

7 Step 7: Setting the Starting Point

Place the blunt tip wire in the dorsal hole in the proximal end of the wire targeter. Place a 1.4mm K-wire in the central hole of the wire positioner, directly underneath the blunt wire. Under AP fluoroscopy, move the guide to the starting position at the medial flare of the metatarsal base and rotate the K-wire into the desired trajectory.

Note: Trajectory may be adjusted later in the case after shifting the metatarsal head, if needed.

Advance the central K-wire percutaneously to the starting position.

From medial, place a securing K-wire in the center of the medial slot into the navicular for added stability (figure 10).

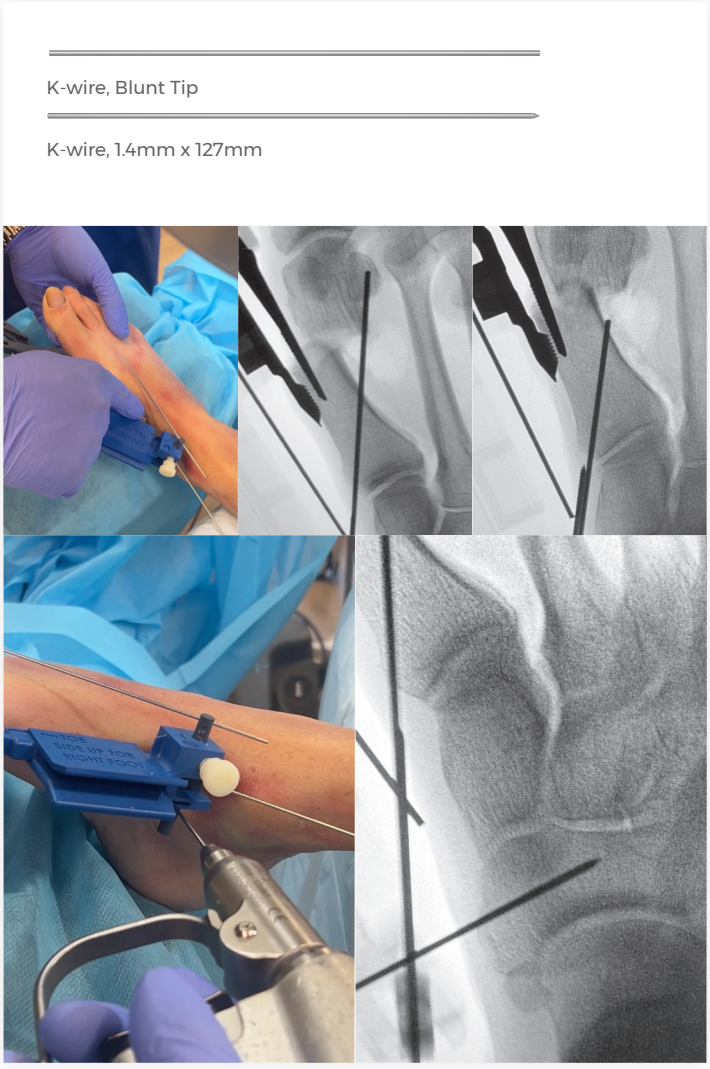


Figure 10: Starting point established and navicular wire applied.

8 Step 8: Securing the Starting Point

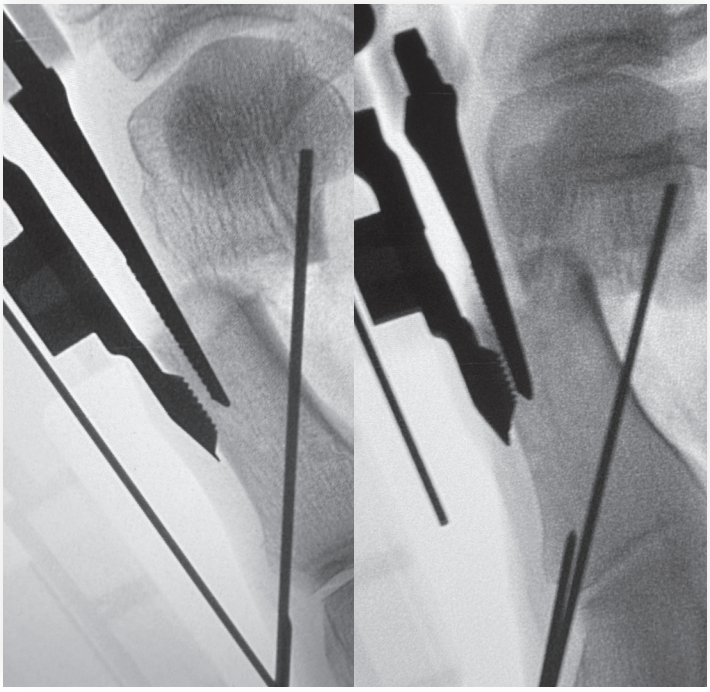


Figure 11: Advancing the K-wire into the medial flare.

Place the wire driver over the central K-wire and advance the tip into the cortex of the medial flare to maintain starting point for later in the case (figure 11).

Make the proximal incision around the K-wire and bluntly dissect the soft tissue (figure 12)

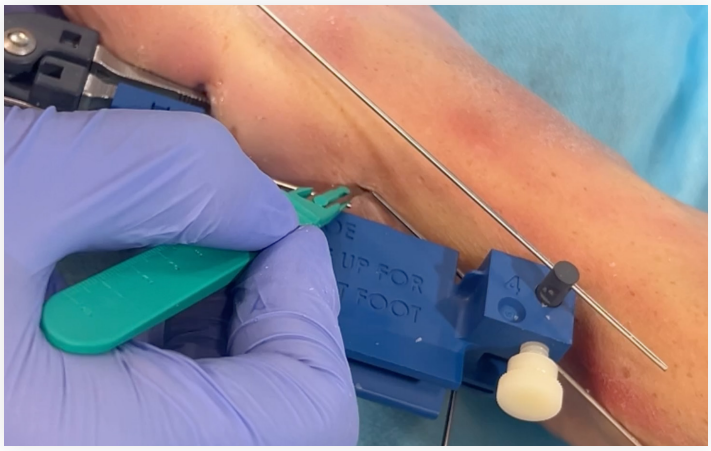


Figure 12: Proximal incision location.

9 Step 9: Setting the Sagittal Plane Alignment

Place a 1.4mm K-wire just dorsal to the top of the extramedullary clamp, aimed plantar and into the metatarsal head. Stop the wire proxmimal to the osteotomy (figure 13).

Asses sagittal plane alignment under lateral fluoroscopy and manually adjust the metarsal head until desired sagittal plane alignment is achieved. Hold the position and advance the K-wire distal into the metatarsal head to temporarily maintain sagittal alignment (figure 13).

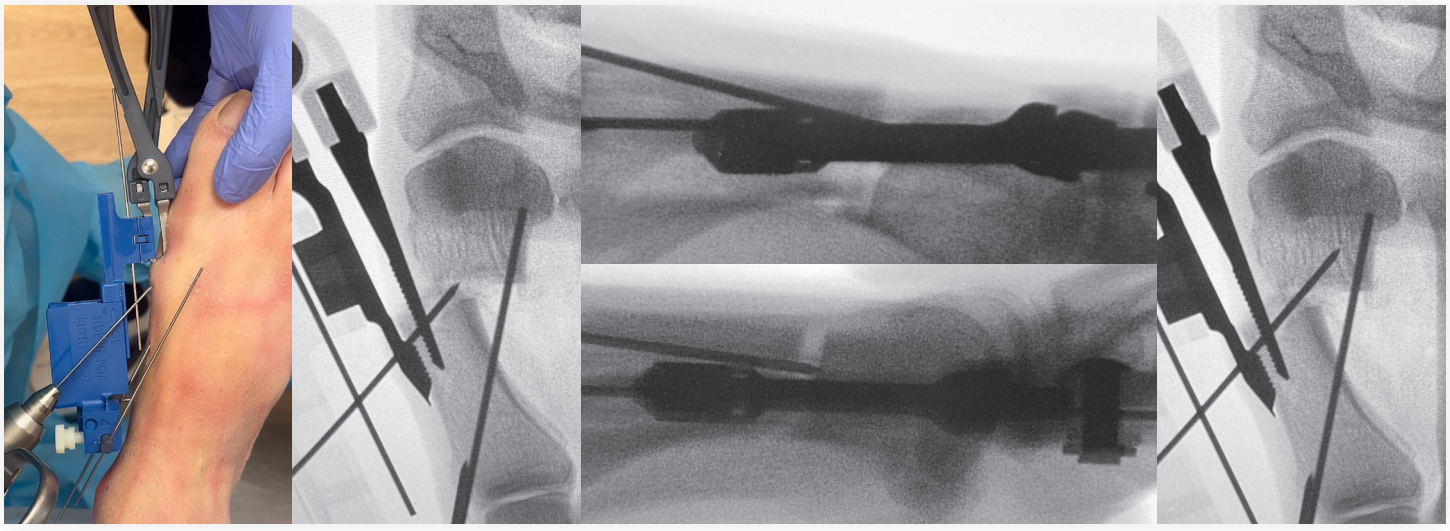


Figure 13: Placing the 1.4mm K-wire proximal to the osteotomy; manual setting the sagittal plane; K-wire advacned to the metatarsal head.

10 Step 10: Aligning the Metatarsal Shifter and Sagittal Plane Support

Slide the metatarsal shifter distal to proximal over the distal end of the guide rail. The “C” shape should always face lateral.

Unscrew the medial screw and advance the 1.6mm K-wire to the skin as shown. Under AP fluoroscopy, adjust the shifter until the wire is in the center of the metatarsal head.

Hold the plantar paddle steady and twist the plantar knob until the paddle is taught. This will support sagittal alignment (figure 14).

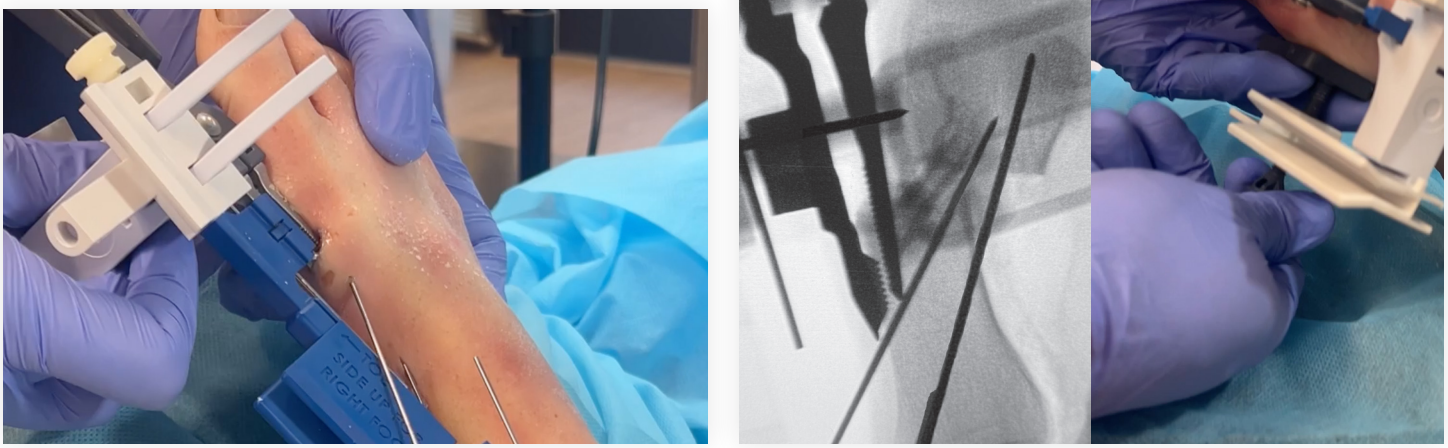


Figure 14: Applying the metatarsal shifter distal to proximal (left); shifter aligned to the center of the metatarsal head and sagittal support applied (right).

11 Step 11: Transverse Plane Alignment

Advance the 1.6mm K-wire into the metatarsal head, stopping when the line is at the skin. Apply a hemostat at the line and against the skin to form a buttress.

Back the temporary stabilization wire from the metatarsal head proximal to the osteotomy to free the metatarsal for transverse plane shift.

Slide the medial screw over the 1.6mm K-wire and tighten the screw until the desired shift is achieved (figure 15).

Note: Thumb screw must be tightened several rotations to contact the blunt end of the K-wire. Once the thumb screw is in contact with the K-wire, shifting will occur.

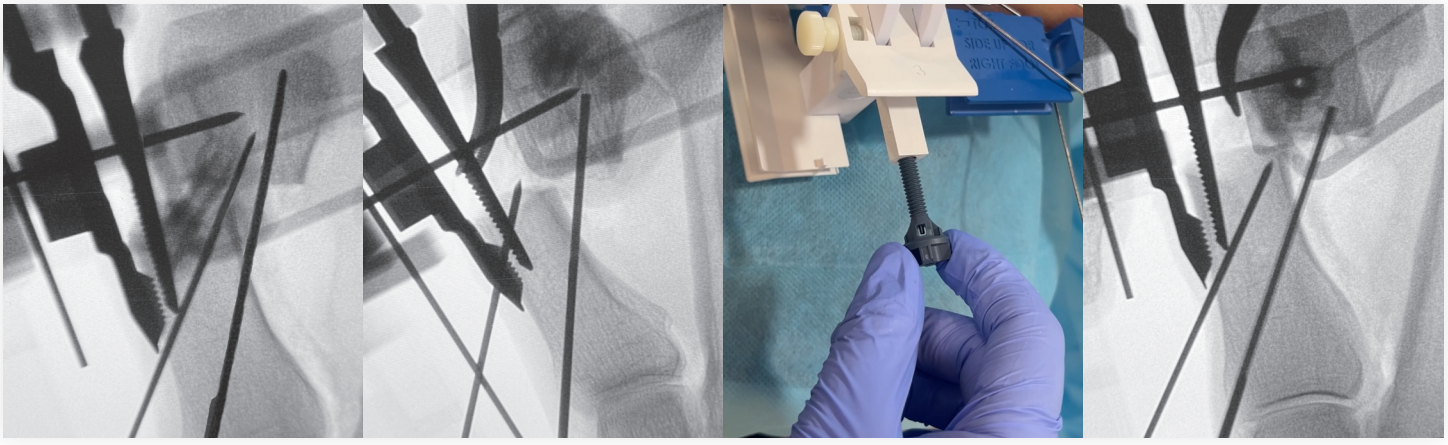
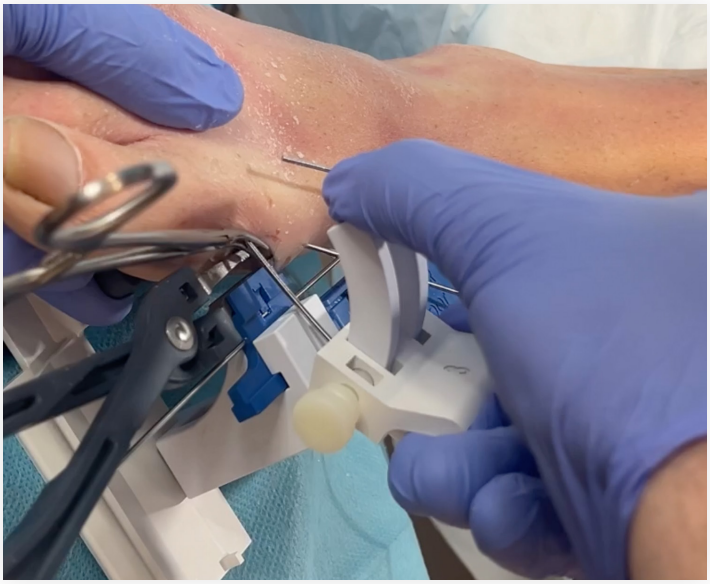


Figure 15: Medial K-wire inserted; clamp butress applied; medial screw tightened to achieve desired shift

12 Step 12: Frontal Plane Correction

If sesamoid rotation is necessary, loosen the screw securing the paddle to the dorsal arc. Advance the paddle up the arc under fluoroscopy to perform sesamoid rotation .

When desired location is achieved, re-tighten the screw to hold placement (figure 16).



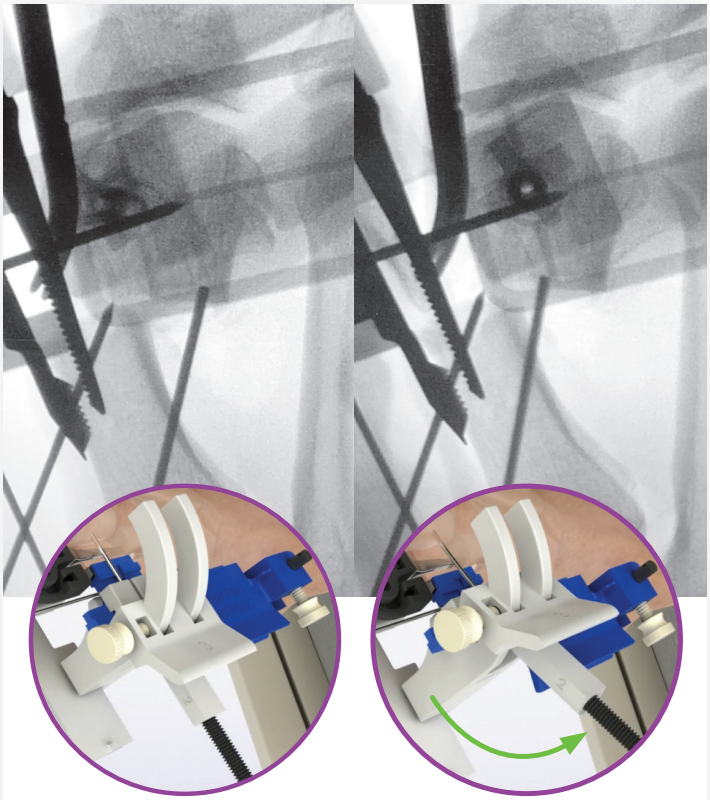


Figure 16: Advancing and securing desired frontal plane correction.

13 Step 13: K-wire Advancement Through Lateral Cortex

Under AP fluoroscopy, reassess the post-shift K-wire trajectory. Adjust trajectory as needed to target the wire from the medial flare to the lateral third of the metatarsal head. The alignment should target a minimum of 1cm proximal to the osteotomy on the lateral wall of the proximal metatarsal.

Secure the trajectory by tightening the medial knob. Advance the K-wire up to the lateral cortex and stop to confirm trajectory.

To advance through the lateral cortex, hold steady pressure and let the tip of the K-wire spin on the lateral cortex until it successfully penetrates through the cortex. **Do not apply forward pressure to prevent skiving** (figure 17).

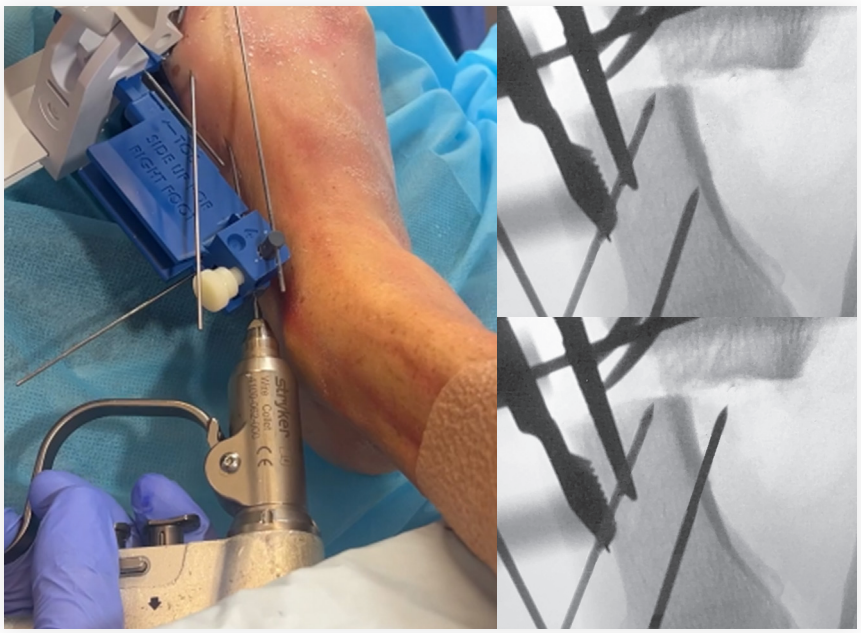


Figure 17: K-wire advanced to the lateral cortex, then through the lateral cortex.

14 Step 14: Final K-wire Placement

Remove the navicular wire and blunt K-wire from the dorsal hole. Squeeze the tabs of the wire targeter and slide it proximally and medial over the inserted K-wire to expose more working length of the K-wire.

Advance the K-wire into the metatarsal head, stopping approximately 4mm from the MTP joint (figure 18).

15 Step 15: Implanat Selection

Measure the 4.0mm Revcon™ Anchor screw length by placing the depth gauge over the K-wire and advancing it to the bone (figure 19).

Note: If the K-wire is advanced near the MTP joint, deduct 4mm from the measurement to ensure the implant is safely away from the joint. The 3.0mm Neutra screws are available if a second screw is desired.

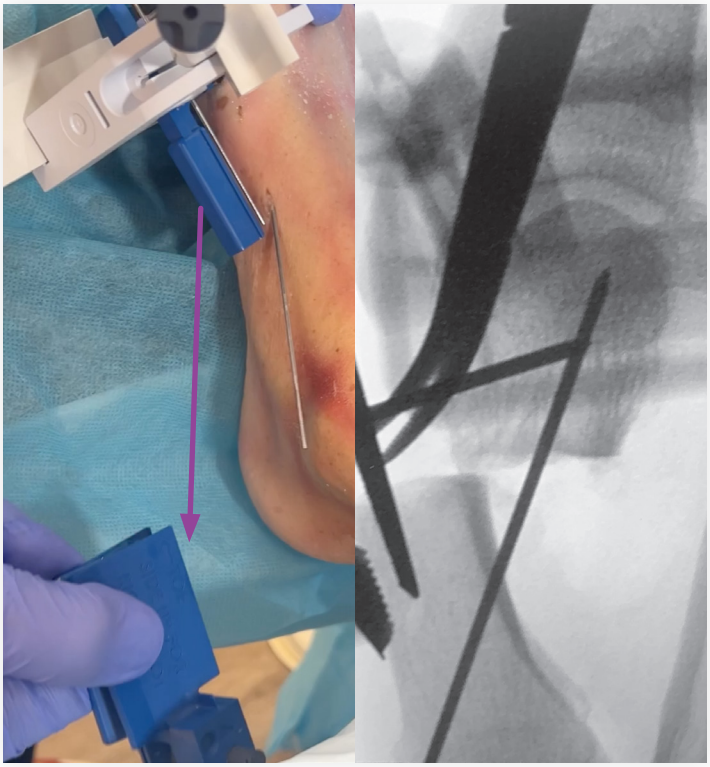


Figure 18: Removal of wire targeter.

Depth Gauge

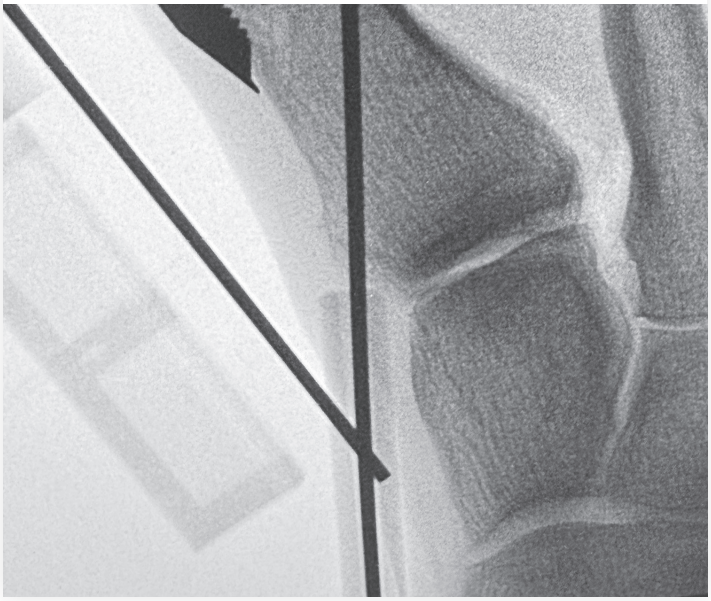


Figure 19: Depth gauge advanced to the bone.

revcon™ neutra

revcon™ anchor

Design Feature	Revcon™ Neutra Ø3.0mm	Revcon™ Anchor Ø4.0mm
Hex Driver	2.0mm	2.5mm
Guide Wire	0.9mm	1.4mm
Drill	2.2mm	3.0mm
Lengths	20mm - 30mm, 36mm - 48mm	46mm - 60 mm

16 Step 16: Implant Placement

Place tissue protector over the K-wire and down to the bone. Use the 3.0mm cannulated drill to drill over the K-wire to prepare for implant insertion (figure 20).

Prior to removing the drill bit, slide the wire pusher into the back of the cannulated drill and advance until you feel it engage the inside of the cannulated drill bit. Provide counter pressure on the wire pusher handle while removing the drill bit. This will ensure that the K-wire stays in place while the drill is being removed.

Load the 4.0mm Revcon™ Anchor screw onto the 2.5mm hex driver, with the flat side of the driver aligned with the beveled side of the screw. This provides a visual reference of the beveled head direction when the implant is advanced beneath the skin. Advance the screw manually using the handle or using low speed power. When fully implanted the beveled side of the screw should face medial **Advancing the screw using high speed power is not recommended.**

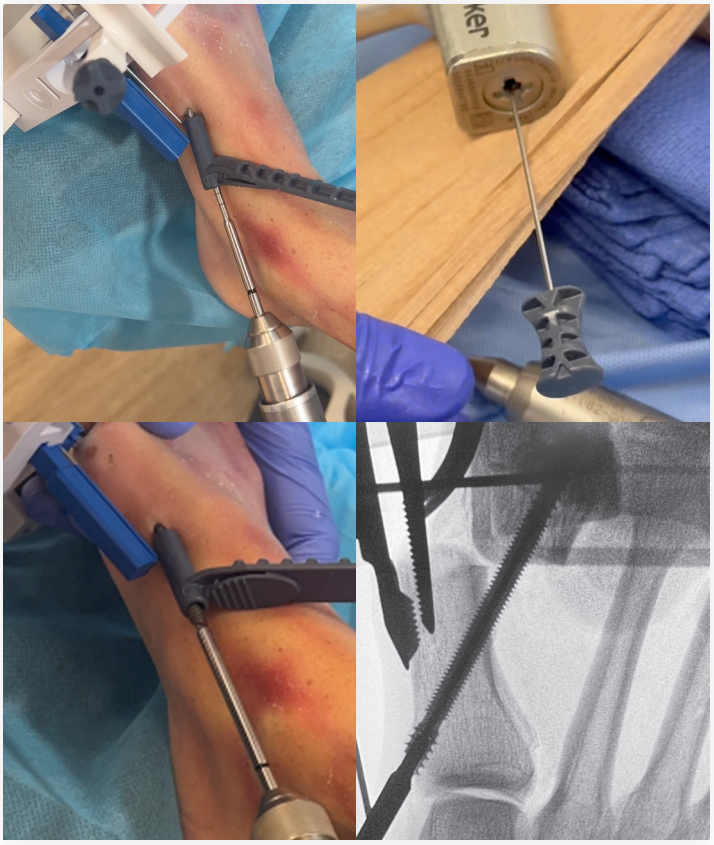
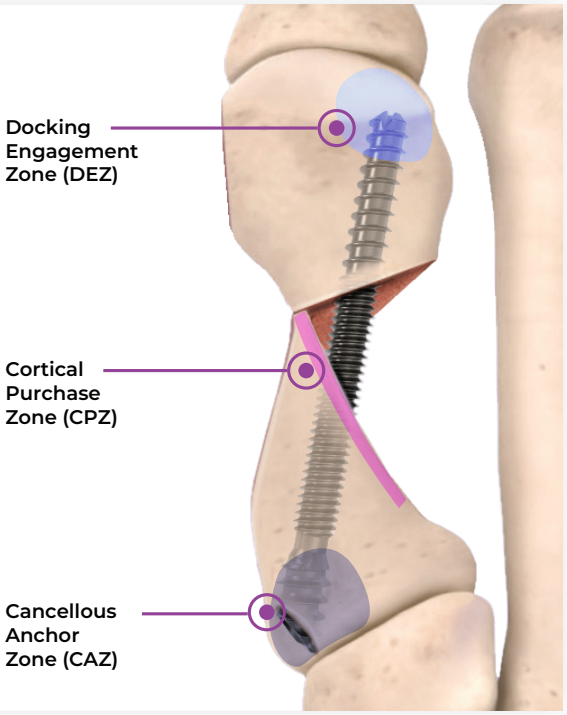


Figure 20: Drilling over 1.4mm K-wire; wire pusher inserted; screw advanced.

Anchor Ø4.0mm



The Revcon™ Anchor screw instrumentation (left); fixation using the Revcon™ Anchor screw, which is design-optimized for single screw fixation (right).

The Revcon™ Screw System is designed for capture of cortical and cancellous bone.

17 Step 17: Guide Removal / Final Implant Confirmation

Remove the medial thumb screw from the metatarsal shifter and remove 1.6mm K-wire from the metatarsal head. Loosen the clamp to remove guide (figure 21).

Assess final implant under fluoroscopy in both the AP and lateral views (figure 21).

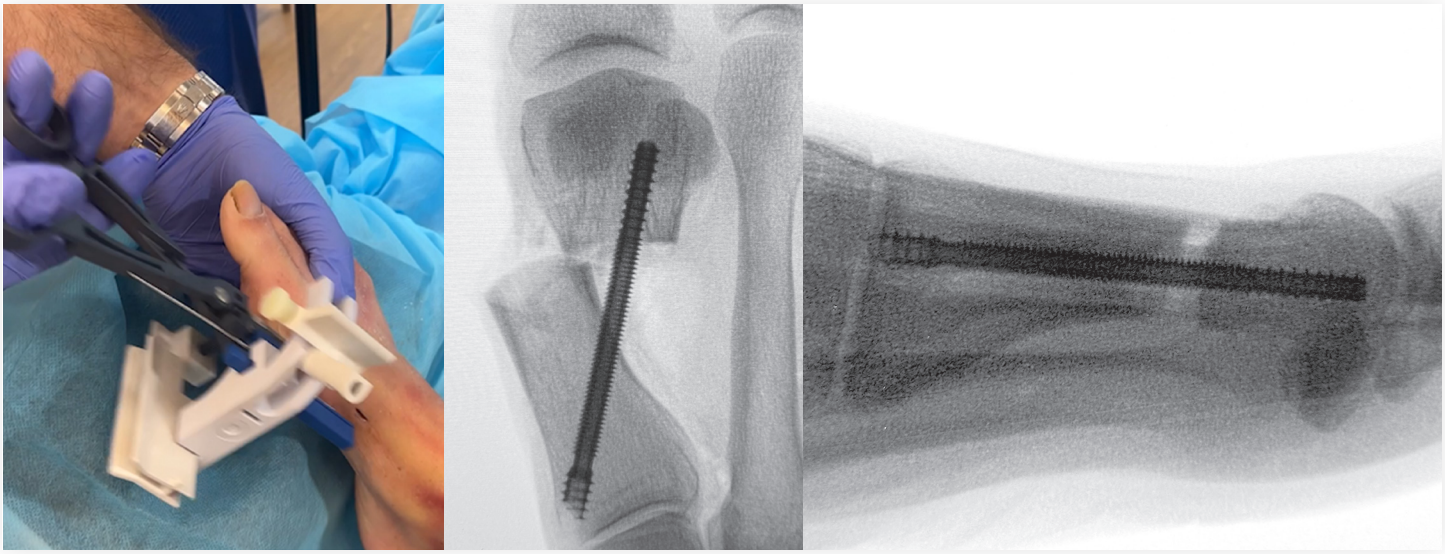


Figure 21: K-wire removed from distal fragment and clamp loosened for removal (left); Final implant placement (middle, right).

18 Step 18: NervPreserv™ Medial Ledge Resection

Use the 3.1mm x 13mm wedge bur to perform NervPreserv™ medial ledge resection as shown in training. Remove resected medial ledge fragment through the distal incision as shown in figure 22.

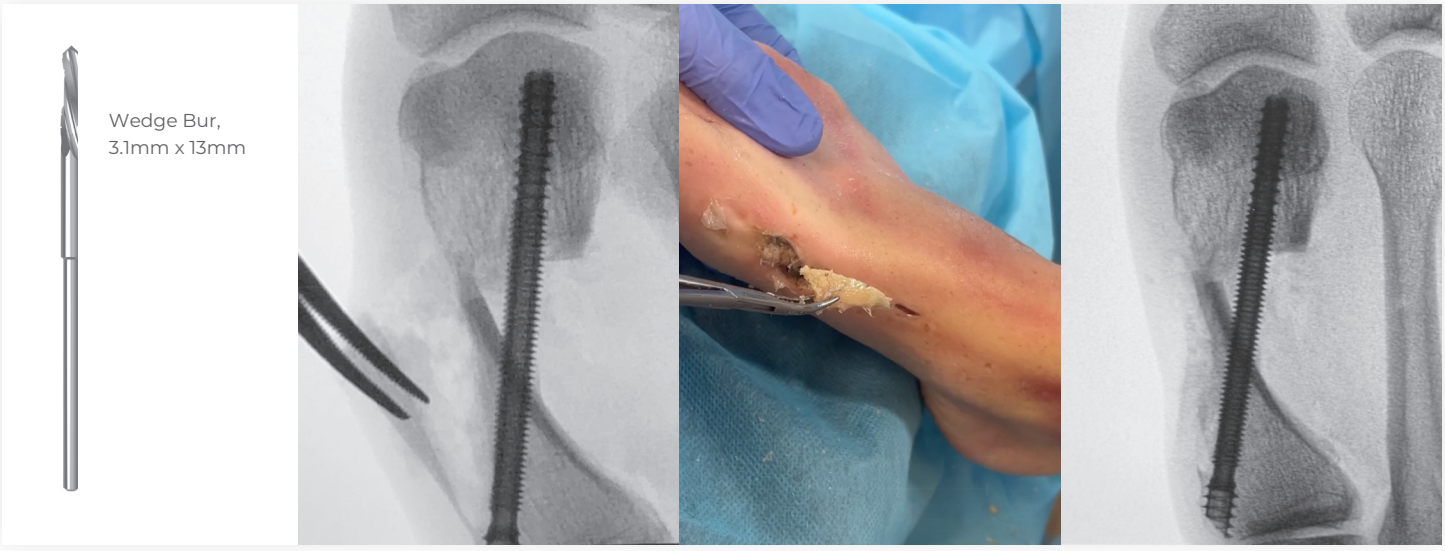


Figure 22: Resected medial ledge and final implant placement.

Surgical Technique

Akin Osteotomy

1 Step 1: Identifying landmarks + Incision

After the distal first metatarsal osteotomy procedure is completed there may be residual hallux interphalangeus deformity that the surgeon may deem to correct with an Akin osteotomy. The Akin procedure can also be performed as an independent procedure for isolated hallux interphalangeus.

Under fluoroscopic guidance and using a metallic instrument for triangulation, the medial proximal metaphyseal-diaphyseal junction should be marked out. A small longitudinal incision measuring approximately 2-3mm is made directly over this area and carried down deep to the bone. Care is taken to avoid the dorsomedial cutaneous nerve. The periosteal elevator is used to create a plane between the bone and dorsal extensor tendon complex and plantar flexor complex.

2 Step 2: Osteotomy

The osteotomy can be performed with a rotary shannon-type burr or a saw, under irrigation. A Shannon bur has the advantage of removing bone with cutting allowing for a wedge to be created. The osteotomy should be performed under fluoroscopic guidance and irrigation. The osteotomy can be transverse or angled distal medial to proximal plantar depending on surgeon preference. Perform the osteotomy from medial to lateral and dorsal to plantar, and the lateral cortex can remain intact or broken for additional correction.

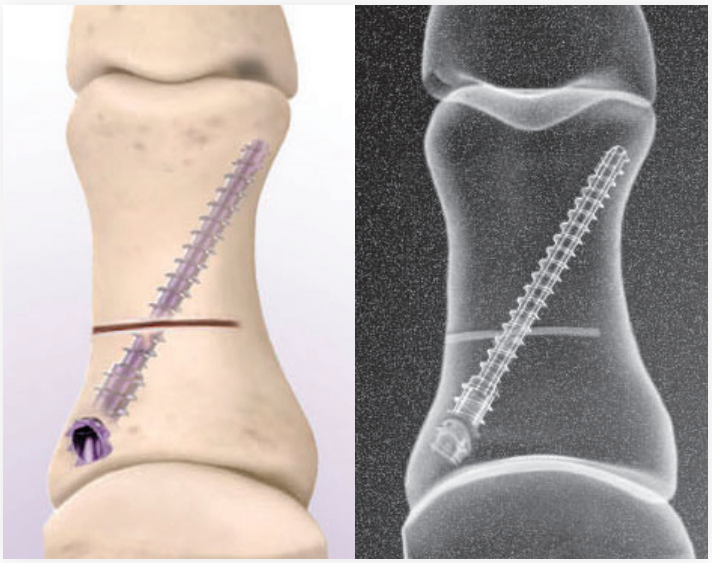


Figure 23: Akin osteotomy and 3.0mm screw placement.

3 Step 3: K-wire Placement

The Akin osteotomy is fixated with a 3.0mm Revcon™ screw. Percutaneously place a 0.9mm K-wire from the medial base of the proximal phalanx to the distal lateral cortex under fluoroscopic guidance. Once the position of the correction is confirmed on AP and lateral fluoroscopic views, the depth gauge is used to measure off of the guide wire. For added security of the K-wire during over drilling, it can be advanced laterally through the skin and clamped with a hemostat.

4 Step 4: Revcon™ Screw Fixation

Drill over the 0.9mm K-wire with the 2.2mm cannulated drill for the 3.0mm Revcon™ screw. Place the 3.0mm Recon™ screw over the K-wire. The head of the screw should be flush with the medial cortex of the proximal phalanx base. Remove the K-wire (figure 23).

Surgical Technique

Closure + Dressings

1 Step 1: Closure

After irrigation, incisions are closed with sutures or steri-strips.

2 Step 2: Dressings

A non-adherent dressing should be placed over the incisions, followed by 4x4 gauze and 4-inch conforming bandage. The hallux should be splinted rectus. A cohesive bandage or ACE wrapped on top.

Revcon™ Screw System

Ordering Information

revcon™ neutra

Length	Revcon™ Neutra Ø3.0mm	Qty.
20mm	RSN3020-S	3
22mm	RSN3022-S	3
24mm	RSN3024-S	3
26mm	RSN3026-S	3
28mm	RSN3028-S	3
30mm	RSN3030-S	3
36mm	RSN3036-S	2
38mm	RSN3038-S	2
40mm	RSN3040-S	2
42mm	RSN3042-S	2
44mm	RSN3044-S	2
46mm	RSN3046-S	2
48mm	RSN3048-S	2

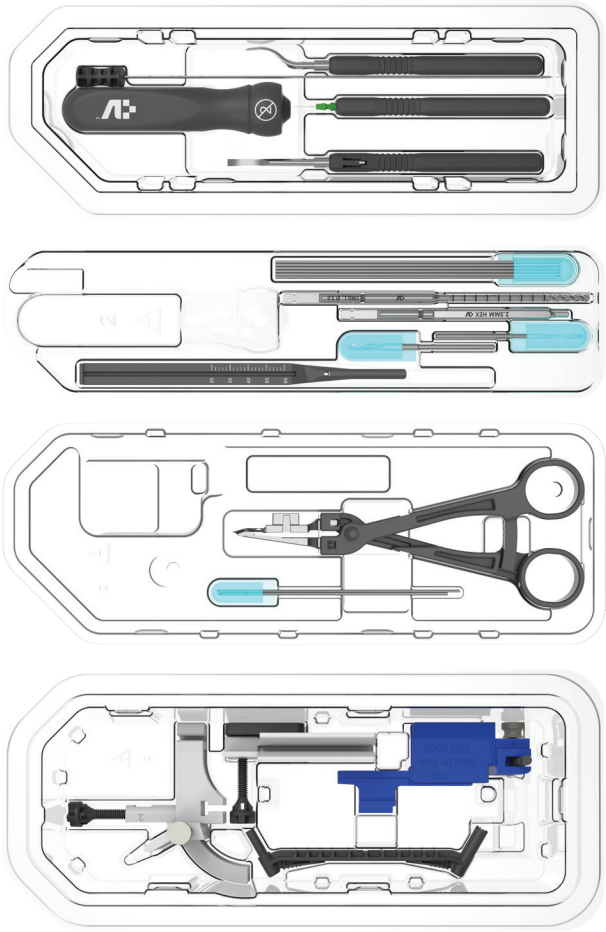
revcon™ anchor

Length	Revcon™ Anchor Ø4.0mm	Qty.
46mm	RSA4046-S	2
48mm	RSA4048-S	2
50mm	RSA4050-S	4
52mm	RSA4052-S	4
54mm	RSA4054-S	4
56mm	RSA4056-S	4
58mm	RSA4058-S	2
60mm	RSA4060-S	2

Revcon™ Screw System

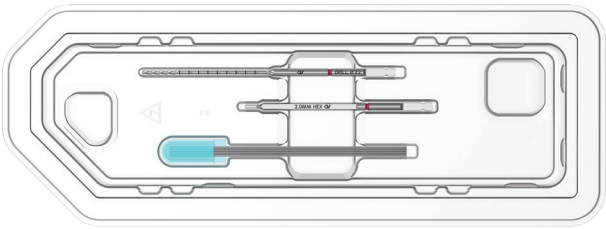
Ordering Information

Anchor Ø4.0mm



Part No.	Description	Qty.
RIK40-S	Revcon™ Instrument Kit, 4.0mm, Sterile	1
	Instrument Kit Components	
	Axial Handle, Cannulated	1
	Elevator, Curved	1
	Elevator, Straight	1
	Depth Gauge	1
	Beaver Blade Assembly	1
	Drill, Cannulated, 3.0mm	1
	Hex Driver, Cannulated, 2.5mm	1
	Shannon Bur, 2.0mm x 16mm	1
	Wedge Bur, 3.1mm x 13mm	1
	Wire Pusher	1
	K-wire, 1.4mm x 127mm	6
	Guide Clamp	1
	Smooth Tip K-wires	2
	1.6mm K-wire	1
	Drill Sleeve / Tissue Protector	1
	Guide Rail / Wire Targeter Assembly	1
	Metatarsal Shifter Medial Component	1
	Metatarsal Shifter Plantar Component	1

Neutra Ø3.0mm



Part No.	Description	Qty.
RIK30-S	Revcon™ Instrument Kit, 3.0mm, Sterile	1
	Instrument Kit Components	
	Hex Driver, Cannulated, 2.0mm	1
	Drill, Cannulated, 2.2mm	1
	K-wire, 0.9mm x 127mm	6

MEDICAL DEVICES

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