MINIBunion™

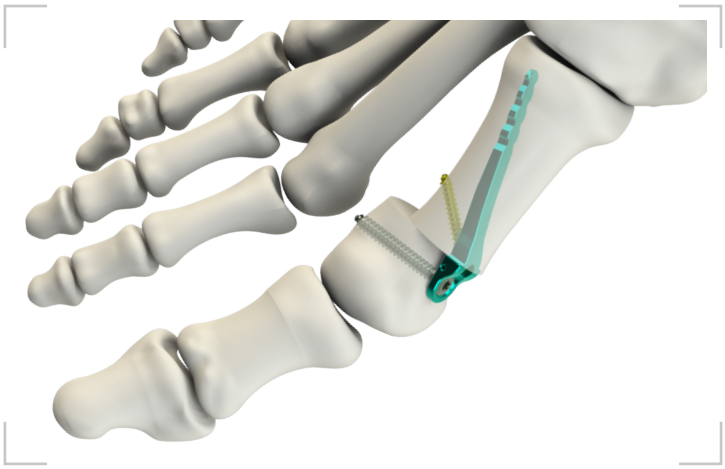
MINIMALLY INVASIVE BUNION SYSTEM

SURGICAL TECHNIQUE

CrossRoads® Extremity Systems

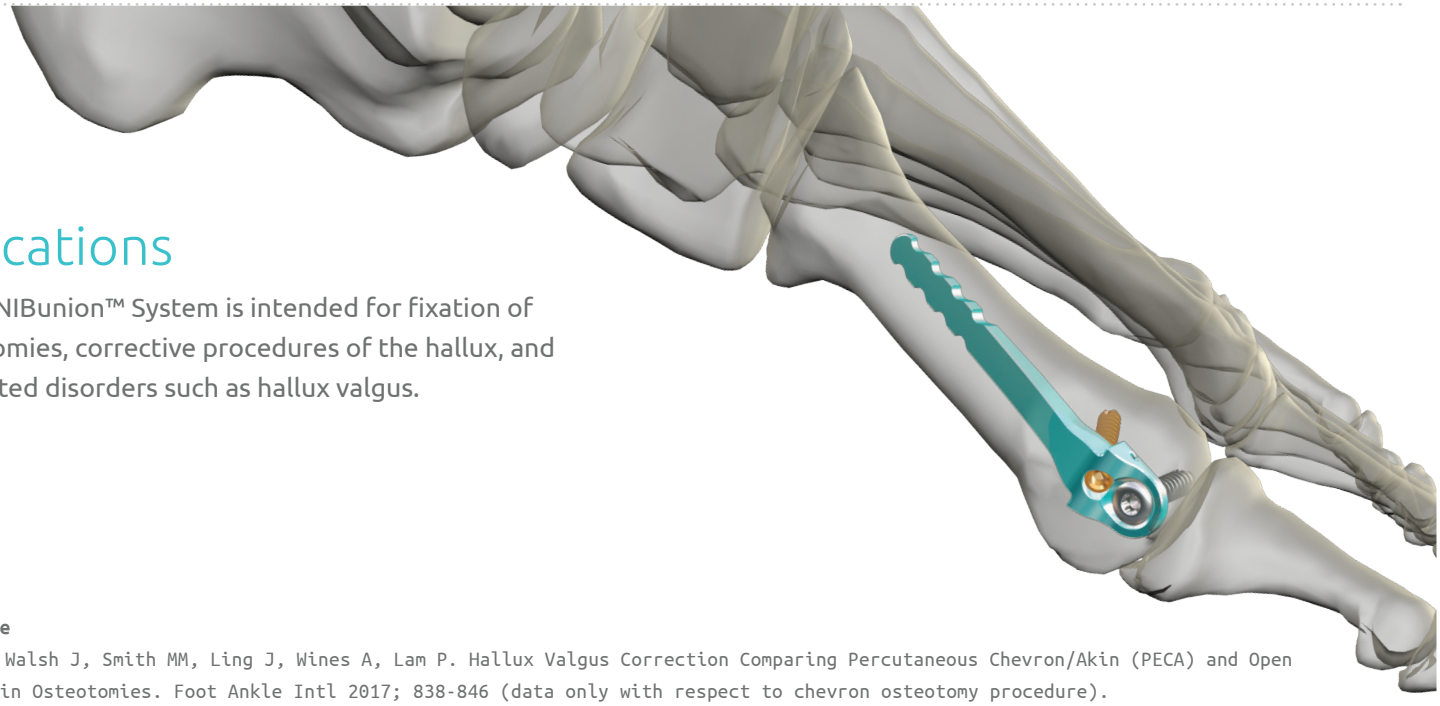
Small Incision, Simple Instrumentation, & Stable Fixation

The CrossRoads MINIBunion™ system provides surgeons with a reproducible surgical technique, minimally invasive instrumentation and stable implant fixation. These features work cooperatively through an approximately 15mm incision to minimize soft-tissue damage and reduce pain.[1]



EcoSmart® Instrumentation

EcoSmart® MINIBunion™ instruments are manufactured from high-quality stainless steel and provided in case-specific sterile packaging. After surgery, they are recovered, restored to new condition and repackaged by CrossRoads® to ensure precision and efficiency for every surgery.



Indications

The MINIBunion™ System is intended for fixation of osteotomies, corrective procedures of the hallux, and associated disorders such as hallux valgus.

Reference

[1] Lee M, Walsh J, Smith MM, Ling J, Wines A, Lam P. Hallux Valgus Correction Comparing Percutaneous Chevron/Akin (PECA) and Open Scarf/Akin Osteotomies. Foot Ankle Intl 2017; 838-846 (data only with respect to chevron osteotomy procedure).

Contraindications

Contraindications may be relative or absolute and are left to the discretion of the surgeon. Contraindications for the MINIBunion™ System are as follows:

- Comminuted bone surface that would prevent proper implant placement
- Acute or chronic infections, local or systemic
- Physiological or psychological conditions that limit the patient's ability and/or willingness to follow instructions during the healing process.
- Pathological bone conditions that would prevent secure implant fixation
- Inadequate skin, bone, or neurovascular status
- Known allergies or sensitivity to metals, including titanium

Patient Orientation

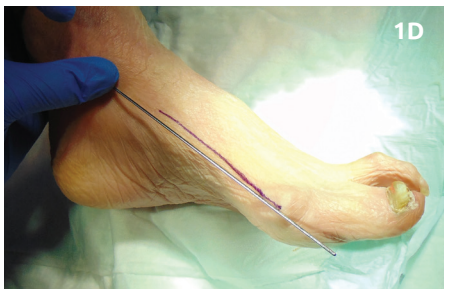
When orienting the patient, make sure to have the patient's foot in an anterior-posterior position that allows for easy access to intraoperative fluoroscopy.

EcoSmart® Instrument Recovery Services

MINIBunion™ is an EcoSMART® product. After use, we re-condition the instruments to new condition, and repackage them in new sterile kits. The EcoSMART® system means reduced costs, less medical waste for your facility, more predictable instrument kits, and improved efficiency.

Step 1 – Setting the Implant Axis

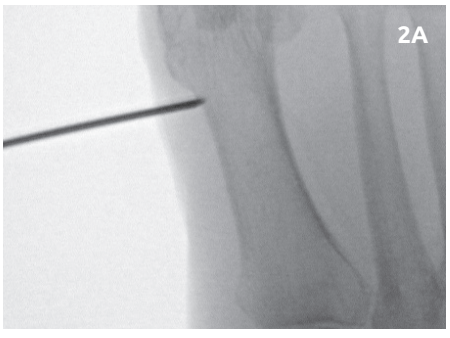
Place the foot on a bump to get a true A/P view parallel to the dorsum of the foot. (Figure 1A) Align the 1.6mm guide wire with the center of the 1st metatarsal shaft and confirm under fluoroscopy. (Figure 1B & 1C) With a skin marker, make a reference line along the guide wire. (Figure 1D)

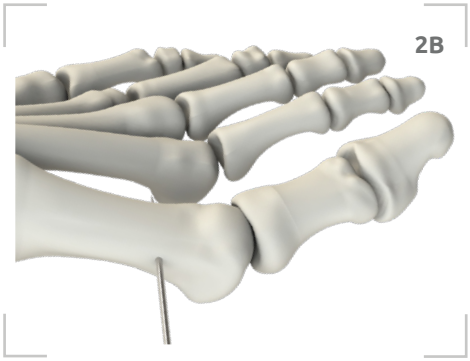


Step 2 – Setting the Osteotomy Location

Under fluoroscopy, dorsally align the guide wire perpendicular to the center of the 1st metatarsal shaft and proximal to the sesamoids and metatarsal neck. (Figure 2A & 2B) With a skin marker, make a reference line along the guide wire. (Figure 2C)

With the crosshair as a guide, place the tip of the long guide wire against the 1st metatarsal at a 90 degree angle to the metatarsal shaft. (Figure 2D) Confirm under fluoroscopy and advance the guide wire until bi-cortical fixation is achieved. (2A, 2B, 2E)

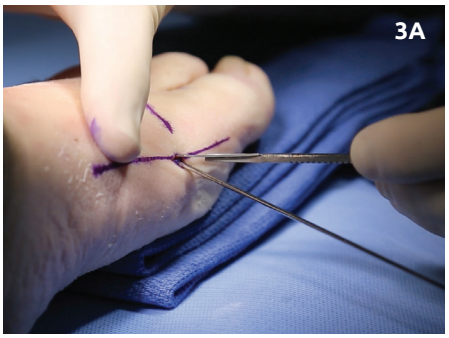




Step 3 – The Incision

Use a #15 blade to make a 1.5cm-2.0cm incision in-line with the original medial reference line drawn in Step 1. The incision should be distally biased to allow for easier insertion of the implant through the distal end of the incision and into the metatarsal. (Fig 3A & 3B)

Bluntly dissect to bone.

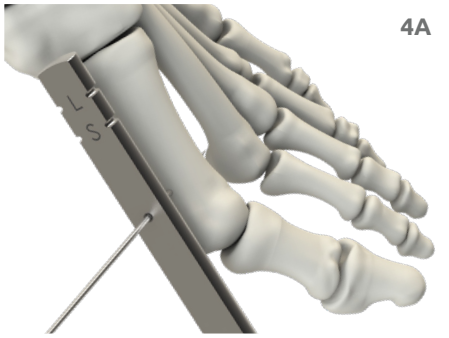


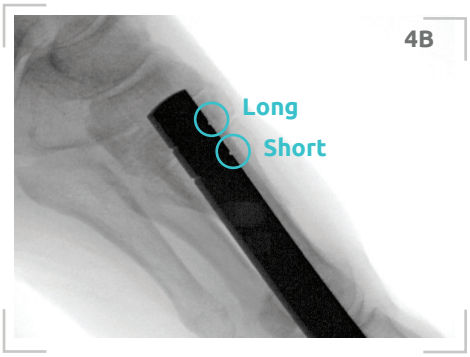
Step 4 – Implant Sizing

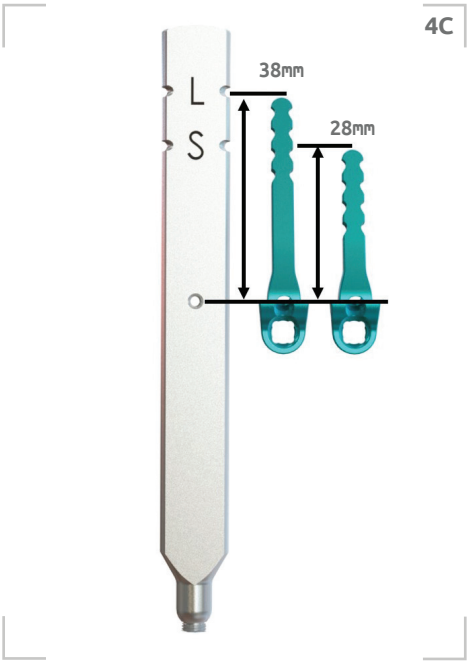
Place the hole of the MINIBunion™ implant handle over the guide wire and utilize fluoroscopy to determine the implant length (short or long), as shown. (Fig 4A & 4B) The implant should fit into the diaphysis of the metatarsal canal without contacting the proximal metaphysis.

Sizing Note: Over 80% of implants used in surgeries are the 28mm short size.

Note: For implant sizing, start with a 3.5mm offset and select a 4.5mm offset if more correction is needed.

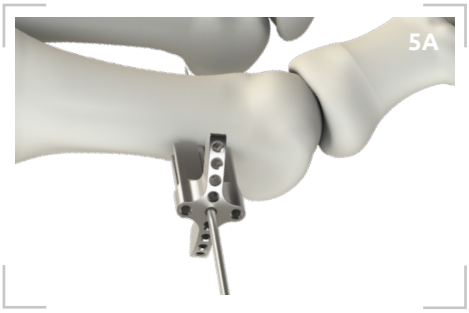


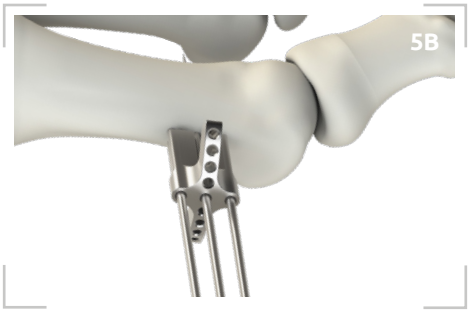


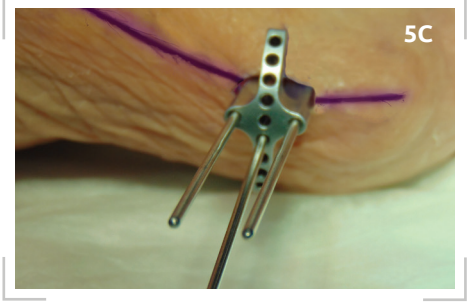


Step 5 – Preparing for the Osteotomy

Place the k-wire guide over the guide wire and advance the guide until it is firmly seated to the bone. (Figure 5A) Ensure the distal and proximal holes on the guide are aligned with the medial reference line drawn in Step 1. Affix the guide to the bone by inserting two short guide wires into the distal and proximal holes. (Figure 5B, 5C)



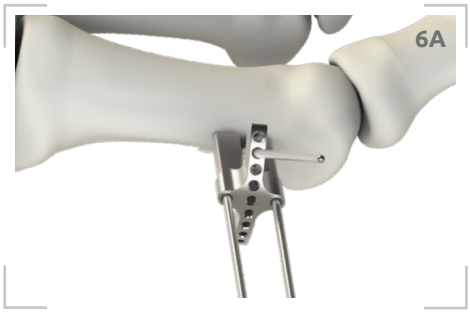


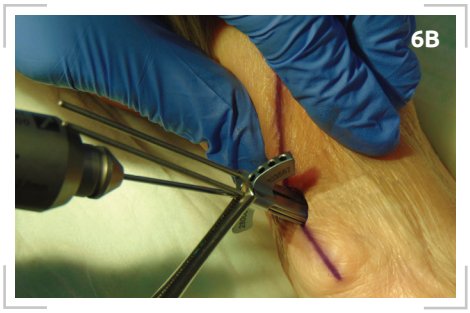


Step 6 Optional – Bone Preparation for the Osteotomy

Remove the long guide wire and use it to drill through the remaining holes on the k-wire guide, making sure each hole is drilled bi-cortical. Irrigating the wire helps it pass through the guide. (Fig 6A & 6B)

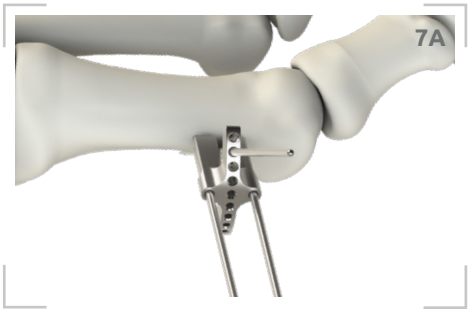
Note: Once seated against the bone, a Kocher forceps can be clamped to one of the wires to keep the guide from migrating (Fig 6B).

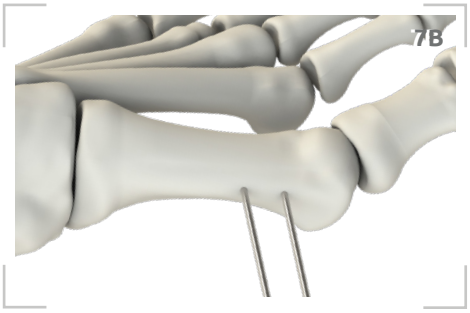


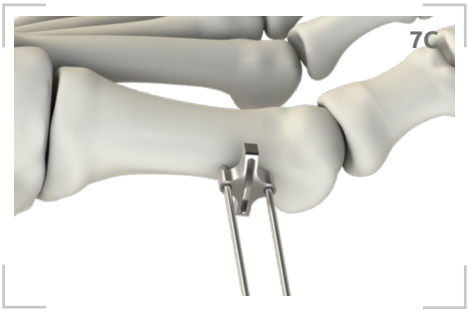


Step 7 – Replace the K-wire Guide with the Osteotomy Guide

Leaving the 2 short guide wires in place, slide off the k-wire guide. (Fig 7A & 7B) Place the osteotomy guide over the 2 short guide wires and advance it until it is flush with the bone. (Fig. 7C & 7D)



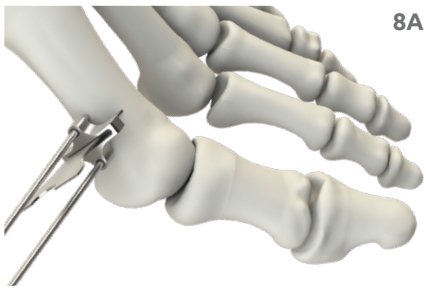




Step 8 – The Osteotomy

Complete the osteotomy with a small sagittal saw until the metatarsal head fragment is released. (Fig 8A & 8B) The guide may need to be removed to complete the osteotomy. Ensure the osteotomy is complete by mobilizing the capital fragment. Ensure there is no remaining dorsal bridge of bone. Confirm under fluoroscopy.

Note: A Ragnell retractor or Hohmann should be used to protect the soft tissues.



8A

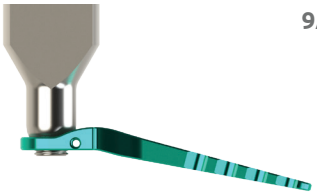
8B

Step 9 – Load the Implant

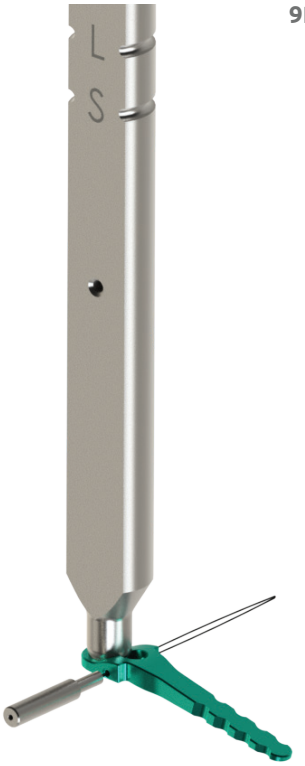
Load the MINIBunion™ implant handle onto the pre-selected implant. Make sure to thread the handle until it is completely secured as shown in image below. (Fig 9A)

Note: If using the suture technique to tighten the capsule, load the suture passer through the 1mm implant hole as shown in image. (Fig 9B)

Sizing Note: Over 80% of the implants used in surgery are the 28mm short size. For offset sizing, start with the 3.5mm offset. If more correction and offset is needed, select the 4.5mm offset.



9A



9B

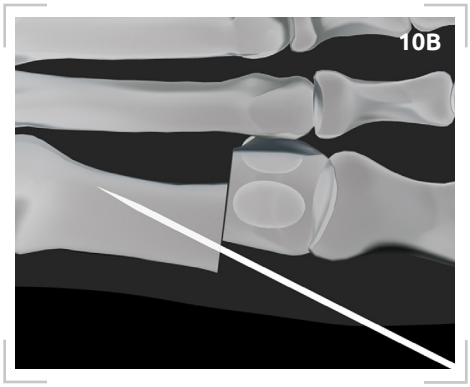
Step 10 – Implantation

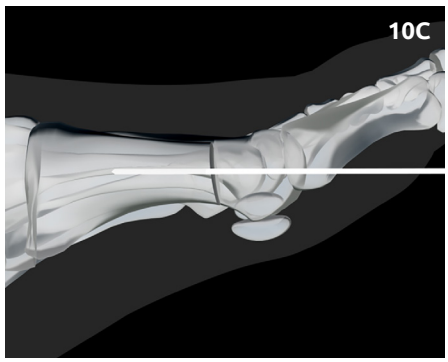
Create a starter hole for the implant using a tapered instrument: mosquito forceps, small curved elevator or k-wire staying parallel to the reference line from Step 1. Confirm the position of the k-wire in both the A/P and lateral planes using fluoroscopy. (Figs 10A, 10B, & 10C)

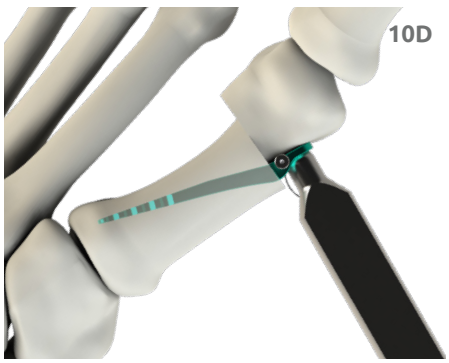
Staying parallel to the reference line from Step 1, insert the tip of the implant into the osteotomy to displace the metatarsal head laterally to the desired offset. (Fig 10D & 10E)

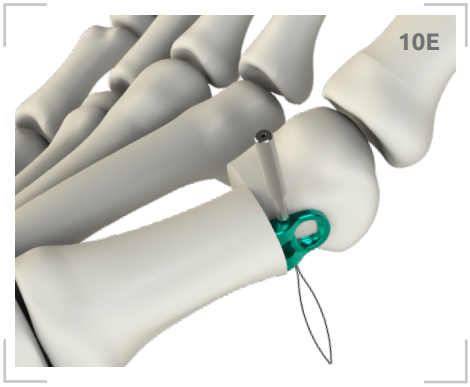
Fluoroscopy must be used in both A/P and lateral planes to verify accurate implant position. (Fig 10G & 10H)

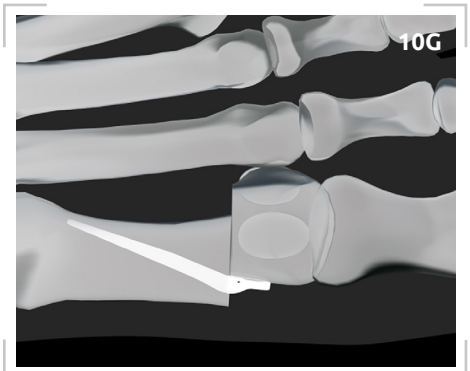
Tip: A mallet can be used to gently tap the base of the MINIBunion™ implant handle to assist with implant insertion. (Fig 10F)

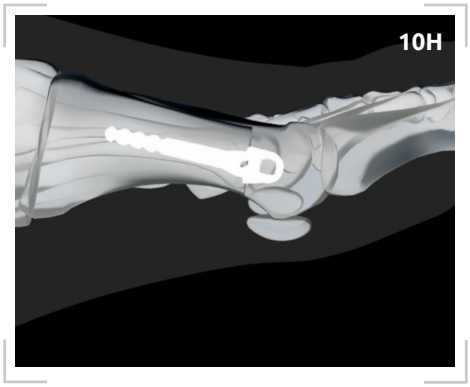








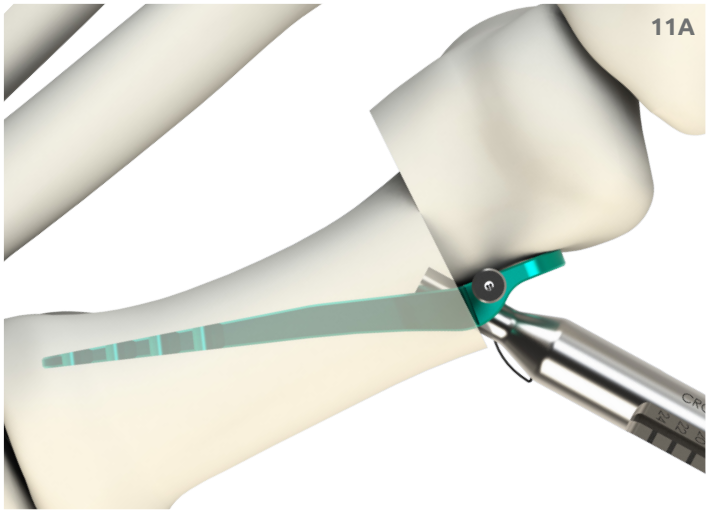


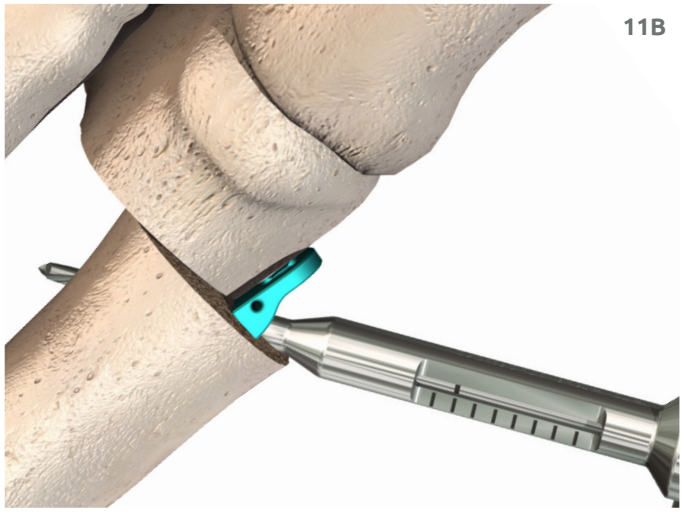


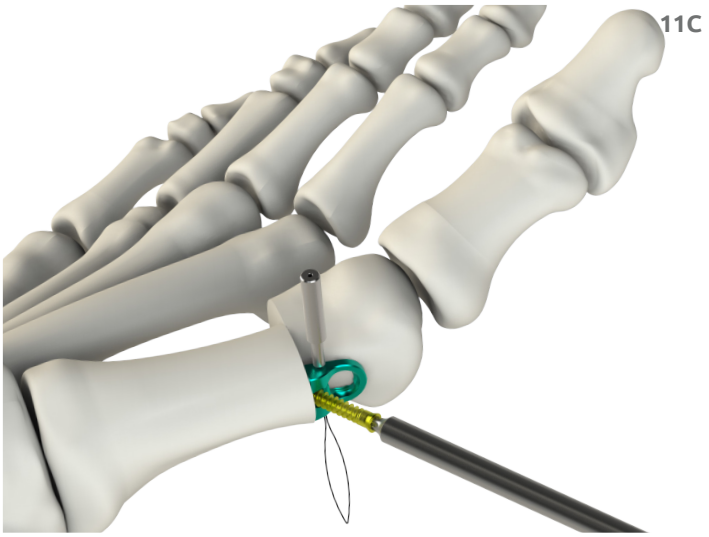
Step 11 – Insert the Oblique Proximal Screw

Remove the MINIBunion™ implant handle from the implant and attach it to the non-locking guide. Insert the guide into the oblique hole in the implant. (Fig 11A) Proper alignment should be verified under fluoroscopy. Using the provided 2.0mm reamer, insert the reamer through the guide until the lateral cortex is penetrated and confirm on fluoroscopy. (Fig 11B) Verify screw length through the window in the sleeve. (Fig 11B)

Advance a 2.7mm non-locking screw through the oblique hole and into the lateral cortex.
Do not overtighten the screw. (Fig 11C & 11D)


11A


11B


11C

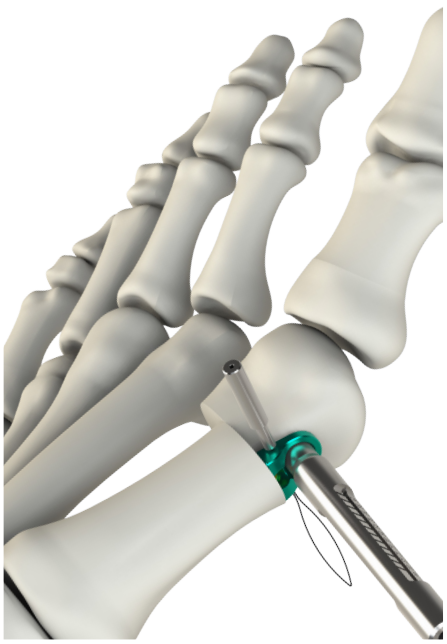

11D

Step 12 – Frontal & Sagittal Plane Correction

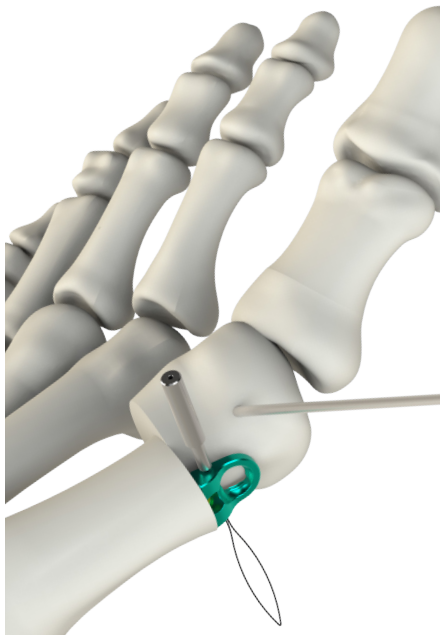
Attach the threaded guide into the distal locking hole. (Fig 12A) For frontal plane correction, insert a k-wire dorsal medial into the capital fragment. (Fig. 12B) Externally rotate the capital fragment until the sesamoids are under the metatarsal. (Fig. 12C) Ensure sagittal plane correction as well. Confirm with fluoroscopy. It is common for the soft-tissues to pull the capital fragment plantarly. Ensure the fragment is aligned with the metatarsal using fluoroscopy for a lateral view.

Note: Lateral fluoroscopy is critical to ensure alignment of the capital fragment with the metatarsal axis. Verify the capital fragment is not plantarly or dorsally displaced.

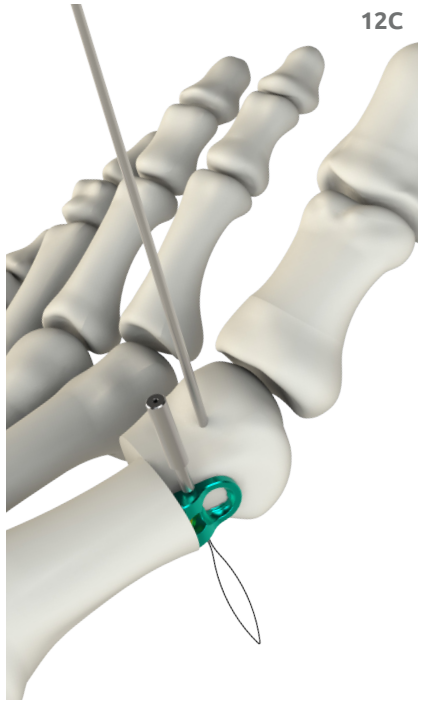
12A



12B



12C

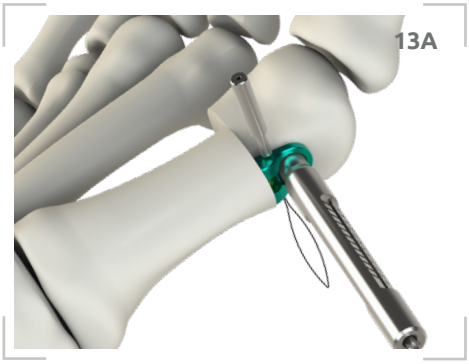


Step 13 – Insert the Distal Screw

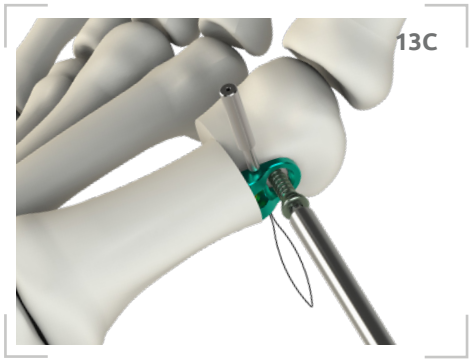
Utilize the provided 2.0mm reamer to prepare for the 3.0 locking screw; ensure the lateral cortex has been penetrated and confirm on fluoroscopy. (Fig 13A) Verify screw length through the window in the sleeve and remove the threaded guide. (Fig 13B)

Advance a 3.0mm locking screw into the 1st metatarsal head and lock it into the implant. (Fig 13C)

Note: It is recommended that a k-wire be used to temporarily hold the metatarsal head in place prior to preparing for the locking screw. A more distal trajectory can be taken to avoid the osteotomy.


13A


13B

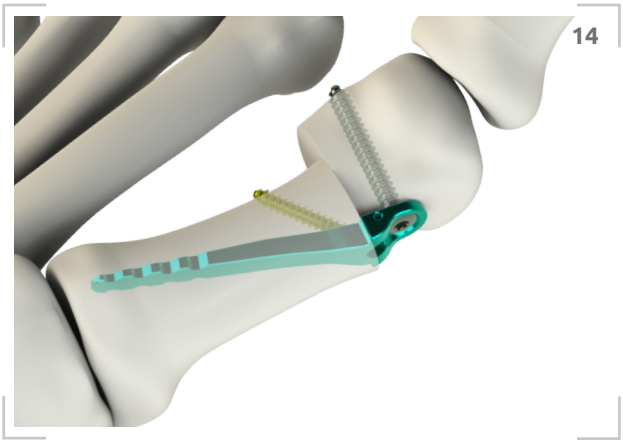

13C

Step 14 – Final Implant Stabilization

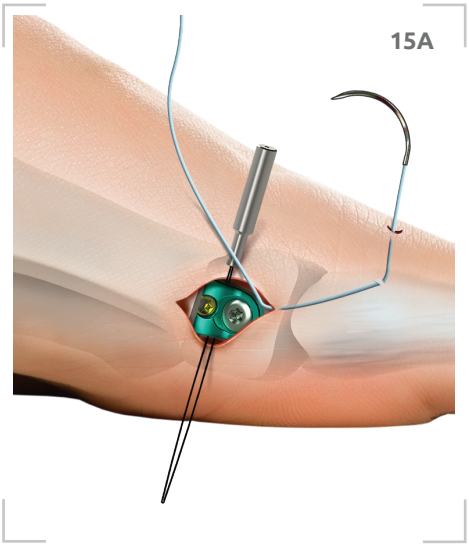
Once the distal screw is seated, the oblique screw can be tightened to help further stabilize the construct. (Fig 14) Additional turning of the oblique screw can help fine-tune the lateral position of the metatarsal head.

Note: Please place all EcoSMART® eligible instruments into the collection container for return to CrossRoads.

EcoSmart® Instrument Recovery Services

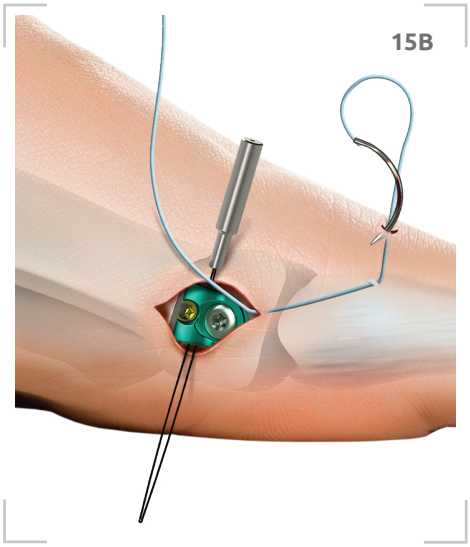

14

Step 15 Medial Capsule Tightening



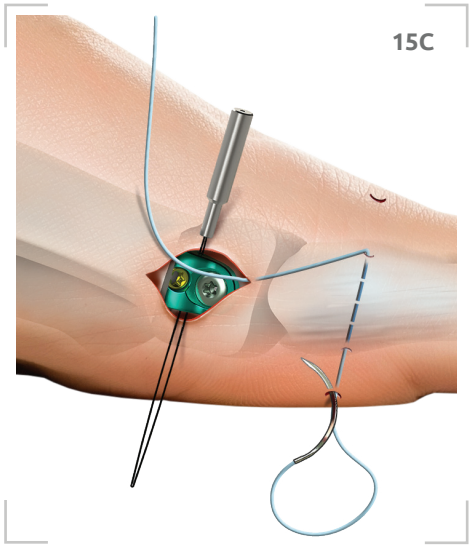
STEP 15A

A 2.0 PDS suture on a CT needle is passed through the osteotomy incision into the proximal medial dorsal 1st MTPJ capsule and out of the dorsal medial capsule and dermis.



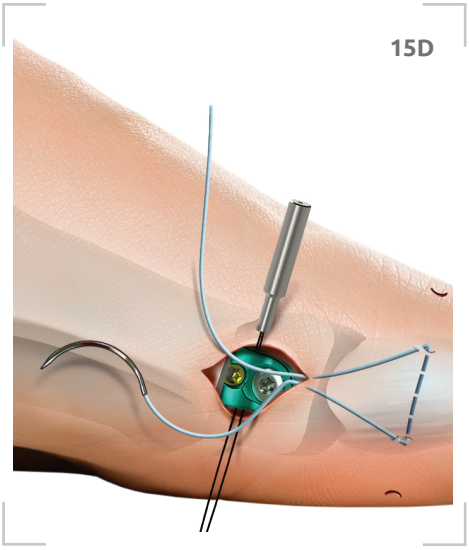
STEP 15B

The suture is passed back through the suture hole in the dermis and the dorsal medial capsule.



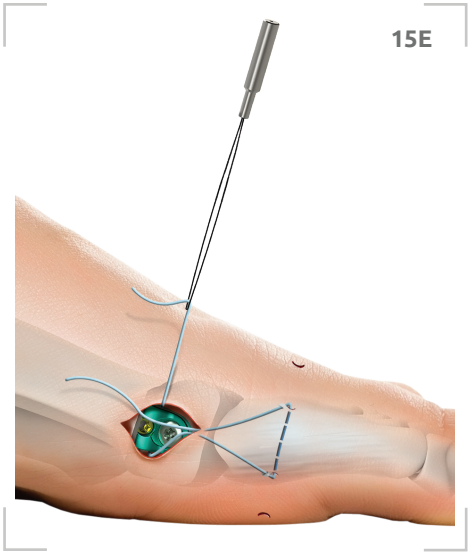
STEP 15C

The suture is then passed through the plantar medial capsule and out of the adjacent dermis. It is then passed back through the hole in the dermis, into the plantar medial capsule and out of the starting osteotomy incision.



STEP 15D

Feed the plantar capsule suture through the suture passer.



STEP 15E

Use the suture passer to pull the plantar suture through the hole in the implant neck. Tighten and tie the suture ends to the implant to hold the hallux in the rectus position.

Pre-Operative

Post-Operative

Postoperative Protocol

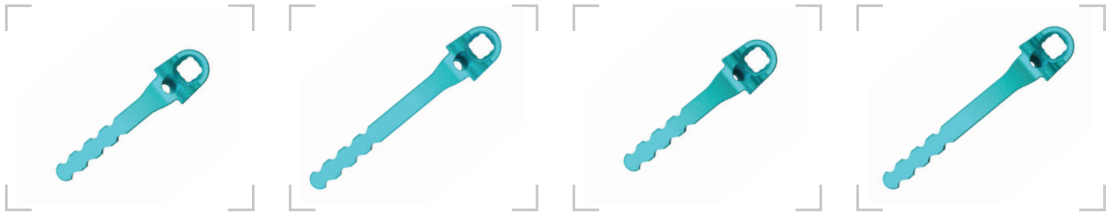
BRADLEY LAMM, DPM

Paley Orthopedic & Spine Institute. West Palm Beach, Florida

Insert a spacer between the first and second toes (folded 4 x 4 in fours). Apply gauze and Webroll with an Ace wrap and a wooden-bottom surgical shoe. Elevate and ice 20 minutes on and 20 minutes off during daytime hours. The dressing needs to stay clean and dry for 5 to 7 days until first follow-up. For pain relief, Tylenol® or ibuprofen is recommended. Additionally, an oxycodone is typically prescribed for pain but generally only required for one to two days.

MINIBUNION™

Short & Long Plates



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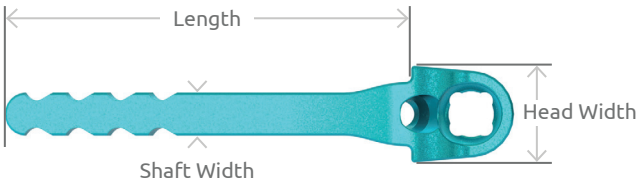
OFFSET	3.5mm	3.5mm	4.5mm	4.5mm
LENGTH	28.0mm	38.0mm	28.0mm	38.0mm
SHAFT WIDTH	4.0mm	4.0mm	4.0mm	4.0mm
HEAD WIDTH	9.0mm	9.0mm	9.0mm	9.0mm



MINIBUNION™

Locking & Non-Locking Screws

	3.0mm LOCKING	2.7mm NON-LOCKING
PART NUMBER	3100-3014LK to 3100-3024LK	3100-2714NL to 3100-2724NL
SIZE RANGE	14-24mm (2mm increments)	14-24mm (2mm increments)
DRIVER	H8 (Hexalobe)	H8 (Hexalobe)
THREAD DIAMETER	3.0mm	2.7mm
REAMER DIAMETER	2.0mm	2.0mm

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