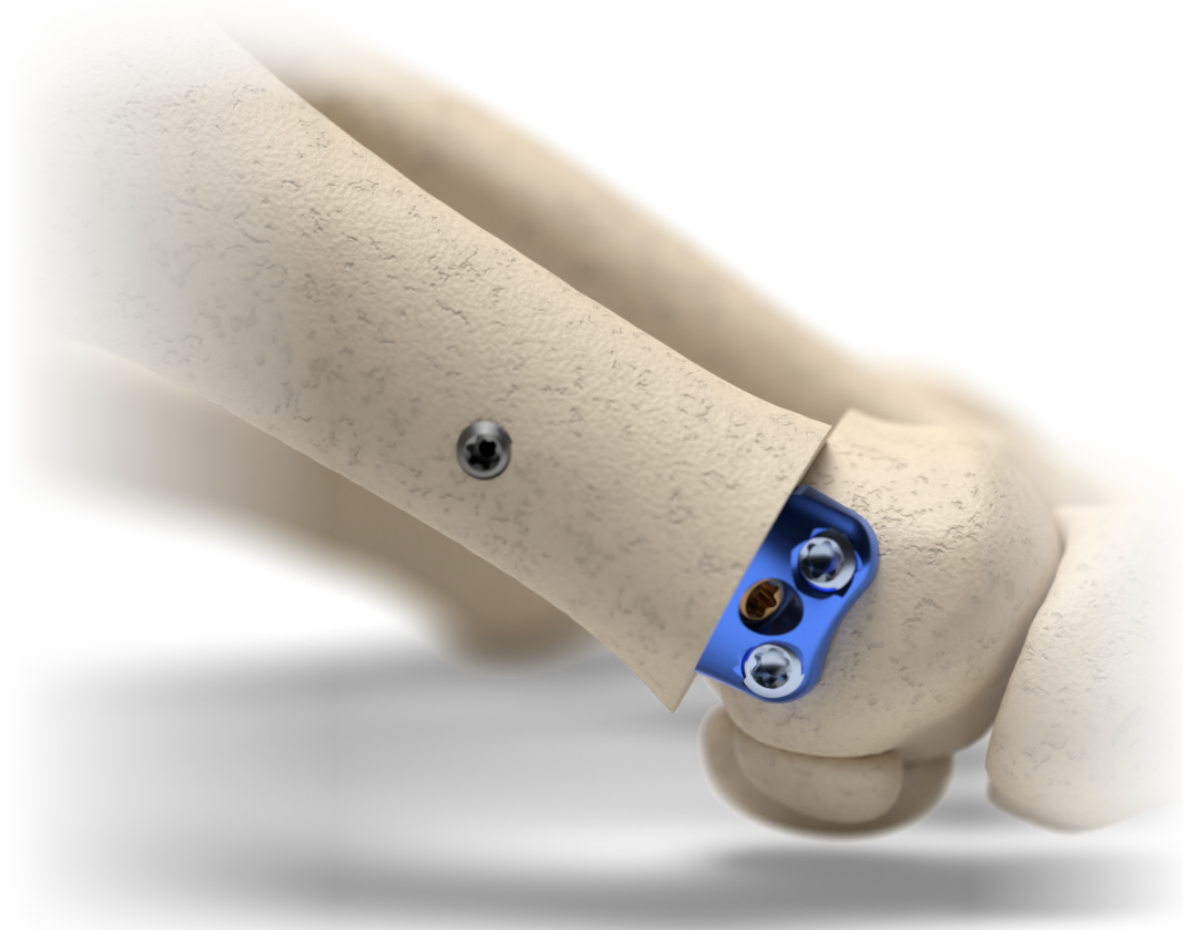


MINILOCK

MINIMALLY INVASIVE BUNION CORRECTION

Surgical Technique Guide



DESCRIPTION OF MEDICAL DEVICE

The PolyLock Plating System consists of various shapes and sizes of plates for the management of small bone orthopedic osteotomies, reconstruction, and trauma. Features include a low profile, limited contact plate capable of dynamic/manual compression, with threaded screw holes accepting both poly-axial and locking screws. The system also consists of poly-axial and locking screws with diameters consisting of 2.0mm, 2.4mm, 2.7mm, 3.5mm and 4.0mm with lengths from 8mm to 60mm. System instrumentation includes: drill bits, countersinks, K-wires, olive wires, depth gauges, reamers, driver shafts, guides, plate benders, clamps, bone positioners (LapiLock) and driver handles to facilitate the placement of the screws. The implants are intended for single use only. Instruments designed for bone removal are intended for single use only, such as: drill bits, countersinks, reamers, K-wires, and olive wires.

INDICATIONS

The PolyLock System is indicated for use in the treatment of bone fractures, osteotomies, arthrodesis, osteochondritis, and interfragmentary indications in the small bones of the hand, foot, and ankle, including the distal tibia, fibula, talus, and calcaneus. Including, fusions of the forefoot and midfoot, stabilization of 1st, 2nd, 3rd, 4th, and 5th tarsometatarsal fusions, intercuneiform, navicular-cuneiform, talo-navicular, calcaneo-cuboid, and medial column fusions, first metatarsal osteotomies for hallux valgus/rigidus correction, first metatarsal fracture fixation, arthrodesis of the first metatarsal cuneiform joint, and arthrodesis/fusion of the first metatarsophalangeal joint.

CONTRAINDICATIONS

- Local or systemic, acute or chronic inflammation
- Active infection or inflammation
- Growing patients with open epiphyses
- Poor or insufficient bone stock
- Metal sensitivity or allergic reaction to foreign bodies
- Material conditions that preclude cooperation with the rehabilitation regimen.

PRE-OP PREPARATION

- If the bunion is reducible, proceed to step A. If the bunion is semi-reducible or not reducible then a medial exostectomy should be performed.
- Perform 2cm incision over the medial bump. A typical dissection is carried out of the capsule and periosteum tissue.
- Using a high-torque low-speed burr or sagittal saw remove the medial bump **JUST ENOUGH*** to make the bunion reducible. Proceed to step B.

Just enough dissection is taken place to perform the osteotomy.

INCISION & INITIAL SETUP:

Step A



Use a 1cm incision if using a high-torque low-speed burr. Use a 2cm incision if using a sagittal saw.

Adductor release may be performed on bunions with a hallux valgus angle (HVA) 30 degrees or more, perform a lateral capsulotomy.

A standard 1-2cm longitudinal, medial incision is placed proximal of the first metatarsophalangeal joint. According to surgeon preference and the patient's anatomy, incision may vary.

Step B



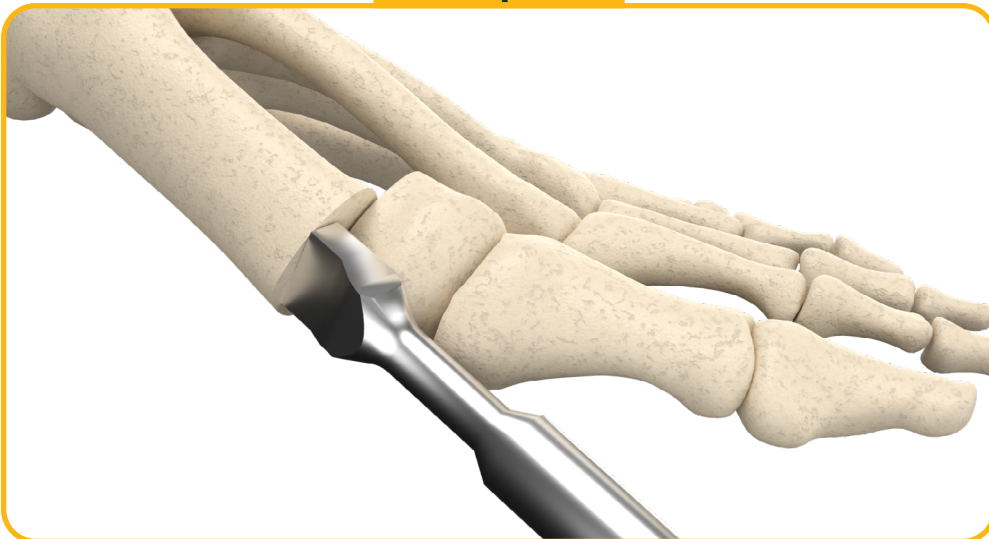
Utilizing the drill turrets, attach the desired MiniLock Plate to the orientation appropriate placement guide. The drill turrets will engage with the screw interfaces on the plate.

Step 1



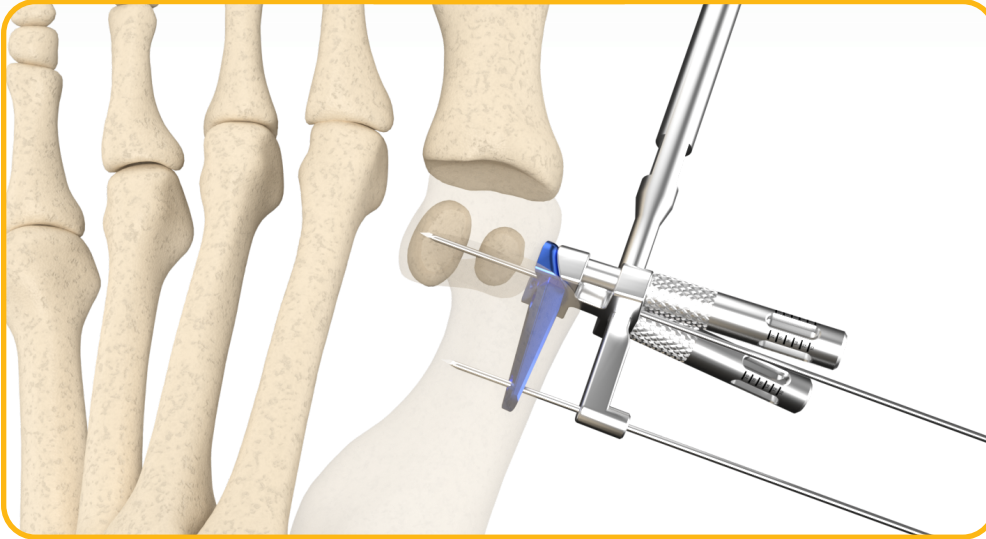
Perform a transverse osteotomy through the first metatarsal, typically at the surgical neck, utilizing a sagittal saw or high-torque low-speed burr.

Step 2



Insert the broach into the proximal medullary canal, concurrently sliding the capital fragment laterally. If needed, **gently** use a small mallet to assist with broaching.

Step 3



On occasion, the capsule or bump is too thick/ prominent which can push the capital fragment too lateral. To counter this issue, you may need to burr down the proximal medial aspect of the dorsal medial bump. To avoid over correction it may be pertinent to remove the bump.

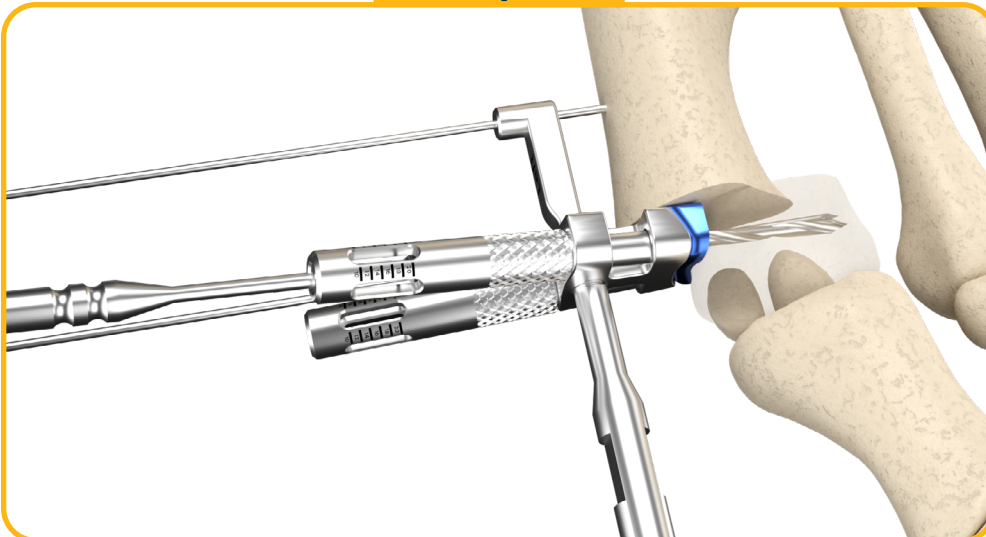
Guide holes are provided on the placement guide. Insert the previously assembled plate construct into the canal created and temporarily secure the placement of the assembly with two K-wires.

A: Insert proximal k-wire first.

B: Rotate the hallux out of valgus to a rectus position using a K-wire as a joystick.

C: Then insert the distal k-wire to secure the correction.

Step 4

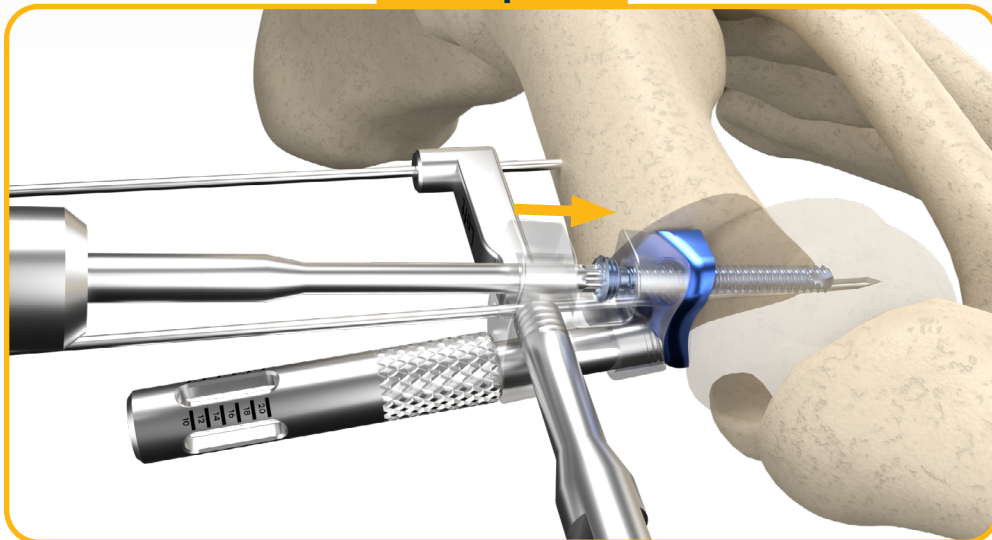


Appropriate screw length may be difficult to determine, but one can count the lines from the proximal aspect end of the turret going distal. Each line indicates a 2mm increment starting from 10mm going to 20mm. (For example: 3 marks from the top mark is 16mm)

Locking screws are usually 18mm in length and rarely 20mm.

Insert the 2.4mm drill through either drill turret to prepare for distal screw placement. Drill through the first cortex until you hit the lateral cortex then stop. Correspond the laser mark on the drill with the laser marks on the drill turret to determine appropriate screw length. Then finish drilling through the lateral cortex.

Step 5

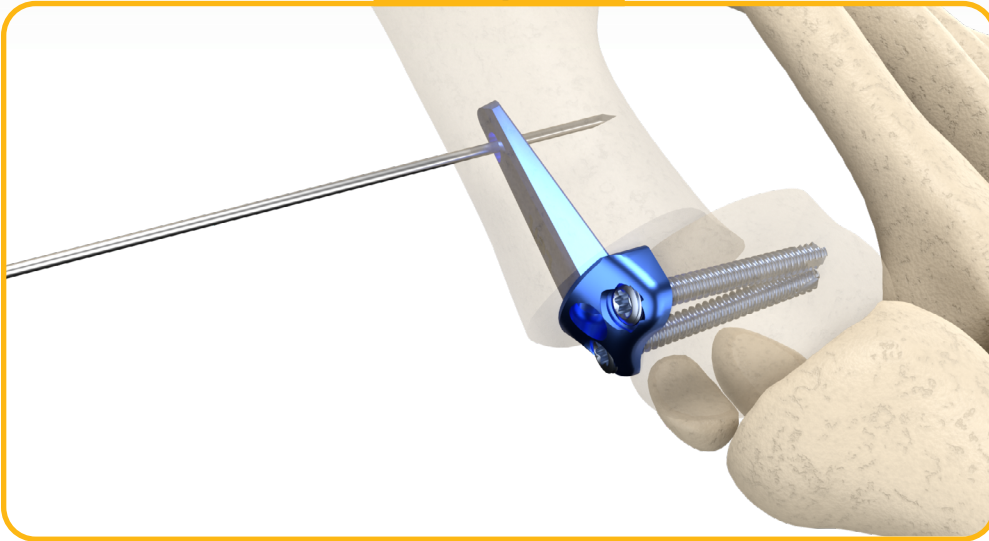


Remove the drill turret and insert the 2.4mm locking screw through the placement guide.

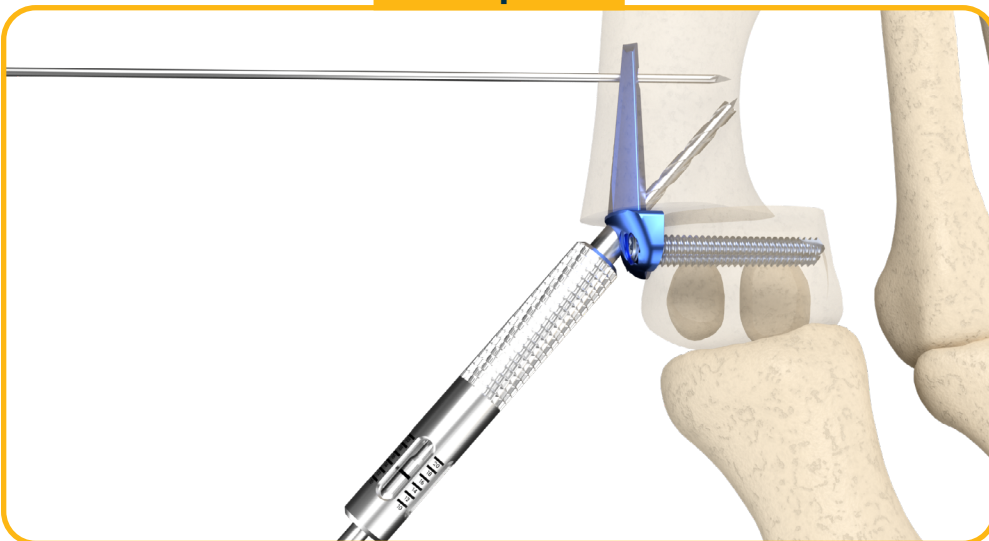
Step 6



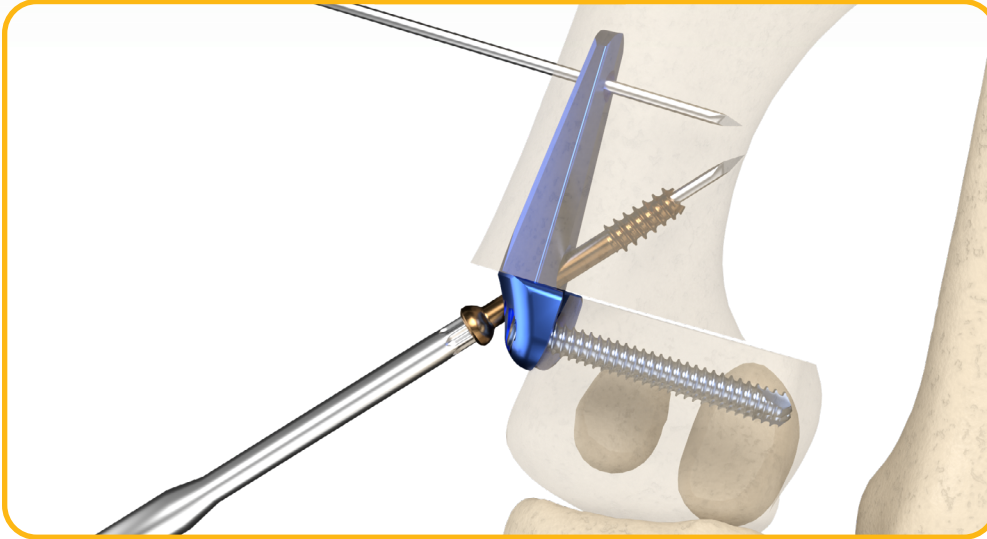
Repeat steps 4 & 5 for the second distal screw.

Step 7

Remove the distal K-wire from the placement guide and slide the guide off of the proximal k-wire, leaving the proximal K-wire inserted.

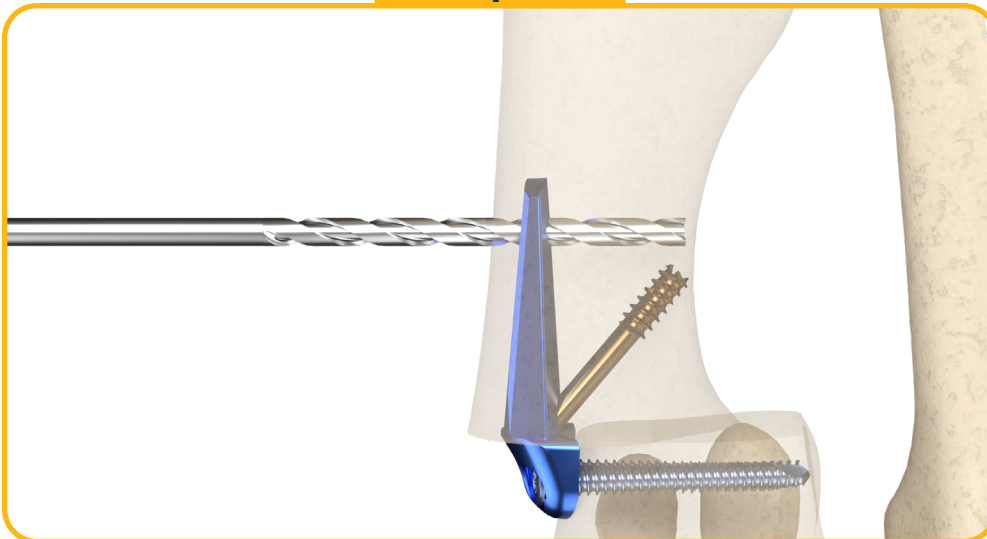
Step 8

To insert the interfrag screw, attach the interfrag drill turret to the remaining hole on the MiniLock plate. Insert a 1.1mm k-wire through the drill turret to confirm placement of the screw. Using the 2.5mm cannulated drill, drill over the top of the k-wire. Utilizing the corresponding laser marks, determine appropriate screw length.

Step 9


Can be measured with wire gauge if desired.

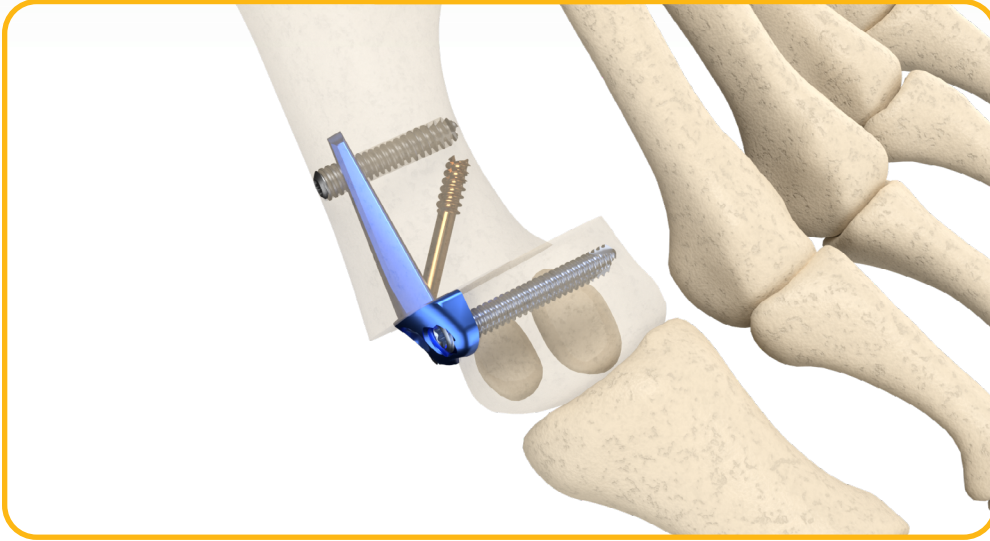
Remove the drill turret and insert the 2.5mm headed screw through the MiniLock plate.

Step 10


It is helpful to "rainbow" the c-arm in order to get a true AP view of the proximal screw to ensure that the screw is flush with the bone.

Almost always 14mm or 16mm are utilized.

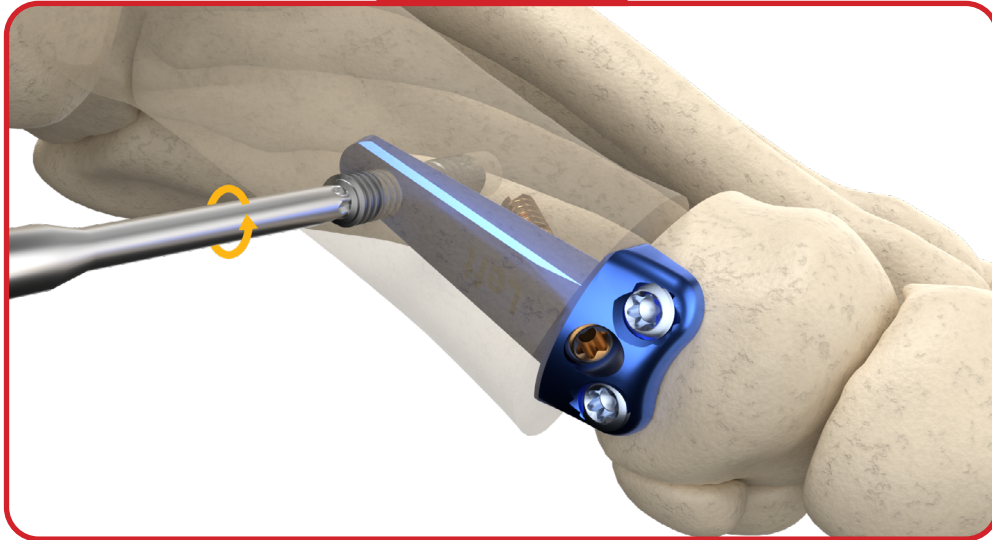
Measure the proximal screw length needed with the provided depth gauge. Drill over the K-wire utilizing the 2.5mm fully threaded drill.

Step 11

Insert the 2.5mm fully threaded screw over the K-wire. Remove the K-wire and close the surgical site.

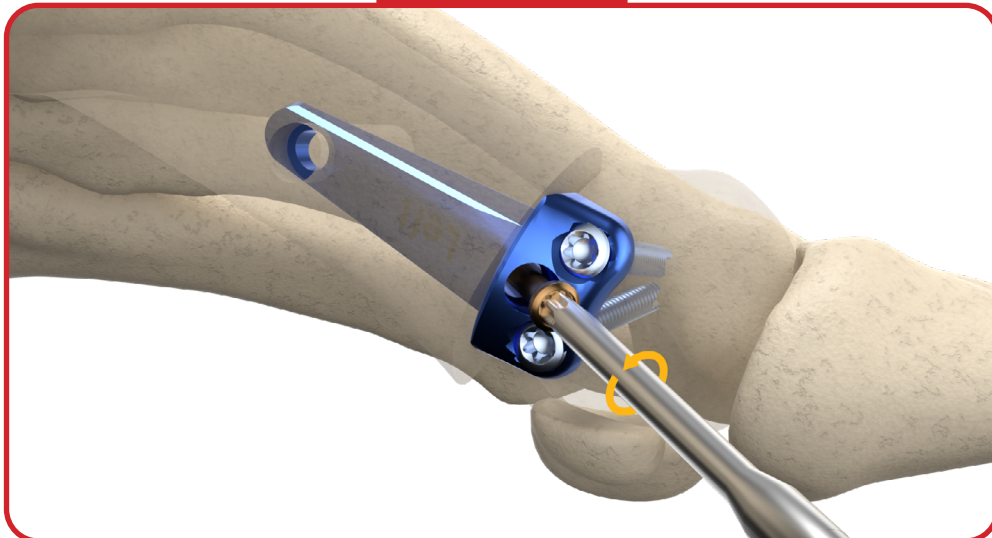
Removal Technique

R-1



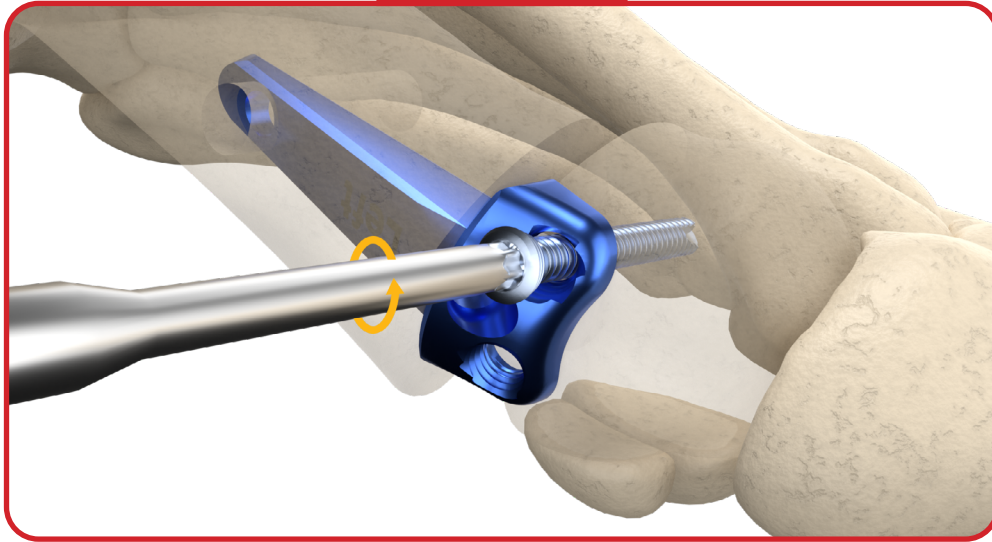
Using the 2.5mm fully threaded driver, carefully remove the grey 2.5mm fully threaded screw.

R-2



After removing the grey 2.5mm fully threaded screw, use the 2.5mm headed driver to carefully remove the bronze 2.5mm headed screw.

R-3



Lastly, use the 2.4mm small bone driver to carefully remove the two silver 2.4mm locking screws.

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