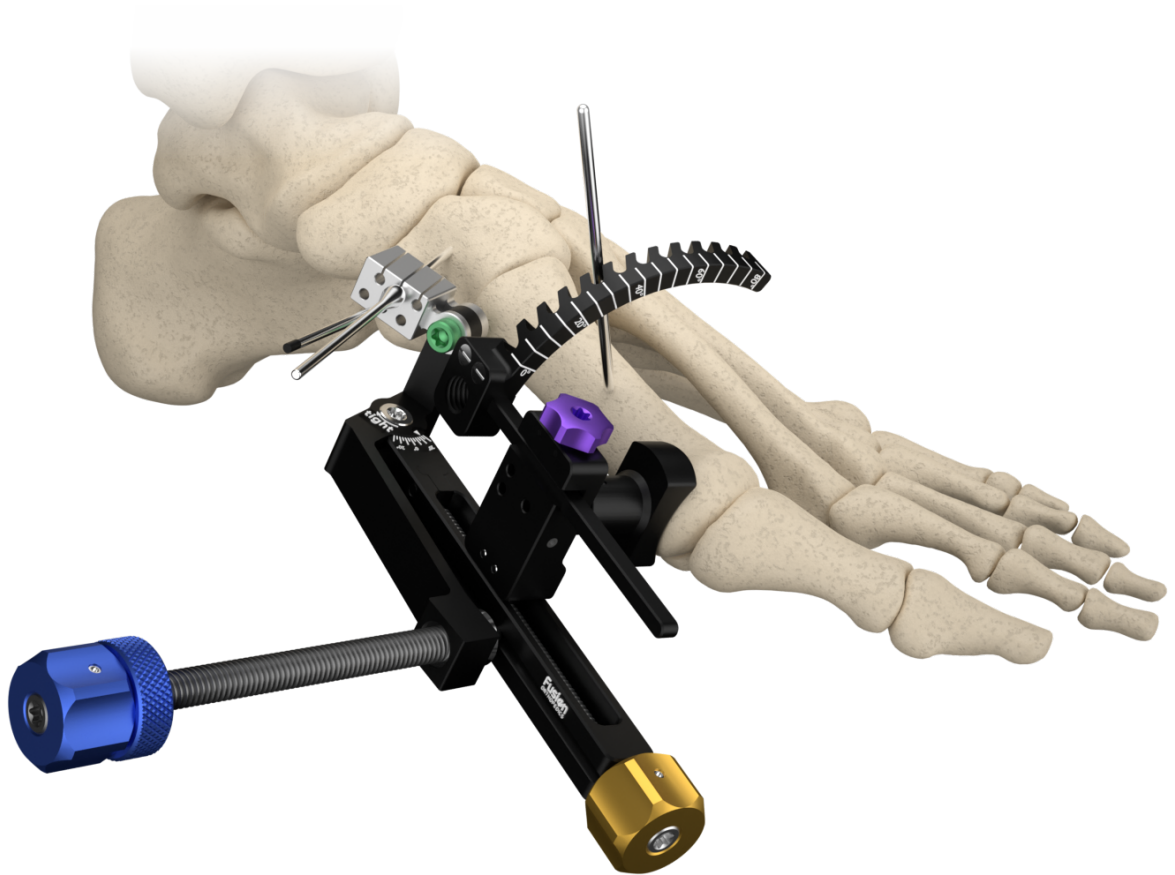


LAPILOCK

4D ADVANCED BUNION CORRECTION

Surgical Technique Guide



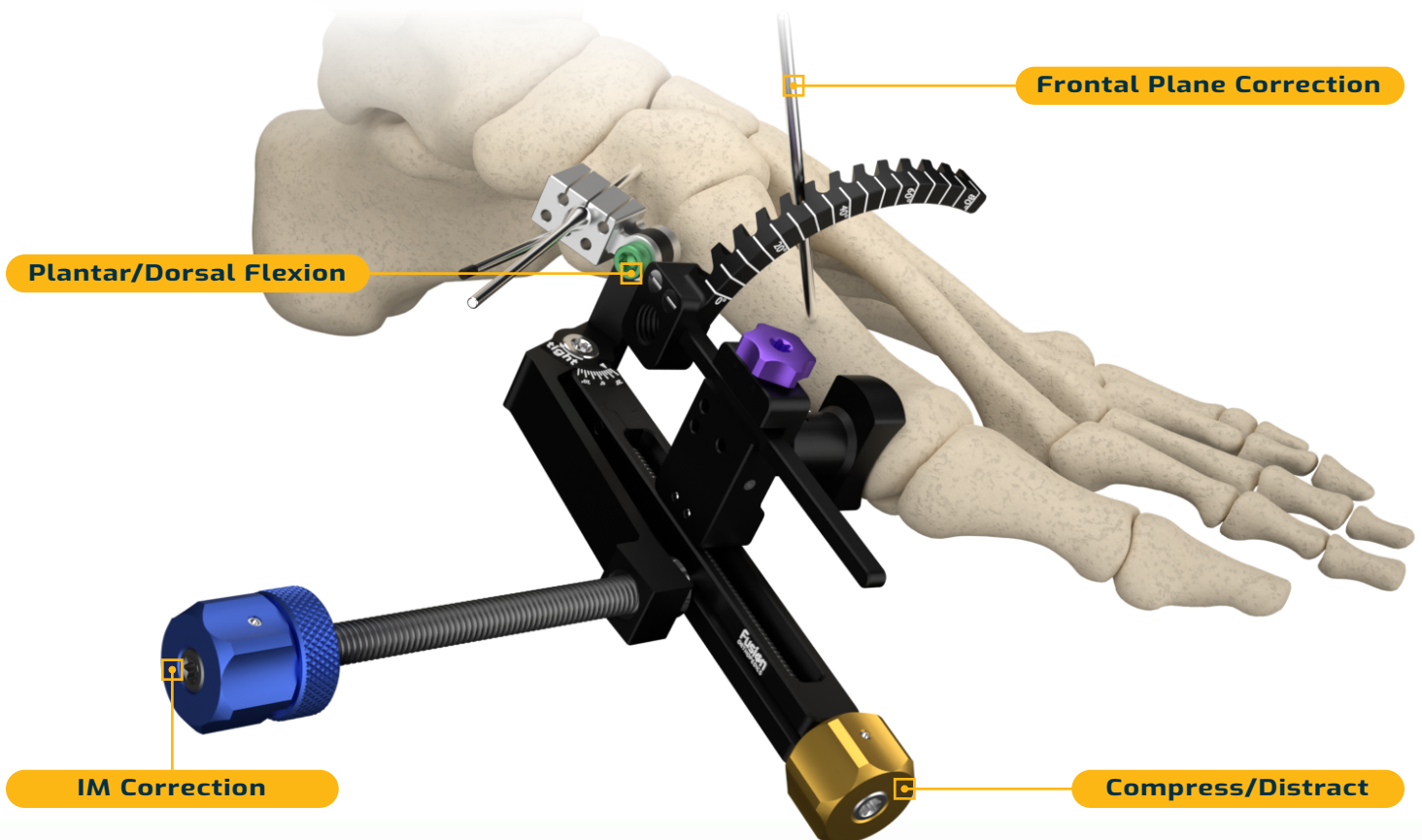
Fusion
ORTHOPEDICS

Patented

LAPILOCK 4D ADVANCED BUNION CORRECTION

- [De] **rotate**. Our proprietary arch allows your surgeon to derotate the bone and hold it in its anatomically correct position.
- [Re] **align**. By turning the blue dial clockwise your surgeon is able to realign and reduce the angle of your bunion.
- [Re] **balance**. The green screw allows your surgeon to rebalance the undesired flexion of your toe.
- [Re] **stabilize**. The gold dial allows your surgeon to restabilize the newly aligned toe by compressing the joint.

The LapiLock tray is equipped with a left foot and a right foot specific Jig.

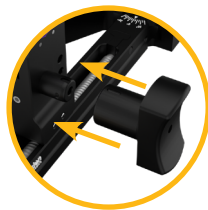


INCISION & INITIAL SETUP:

A: A standard dorsomedial incision is placed over the first metatarsal-cuneiform joint, medial and parallel to the EHL tendon. This should be a straight capsular incision, while protecting the medial dorsal cutaneous nerve. Standard dissection and exposure of the joint is performed. A percutaneous lateral release of the first metatarsophalangeal joint is **optional** and based on surgeon discretion.



B: Attach the percutaneous met cup to the Met Cup Block by aligning the dorsal notches and pressing it in place. Met Cups are single-use and intended to be discarded after the procedure.

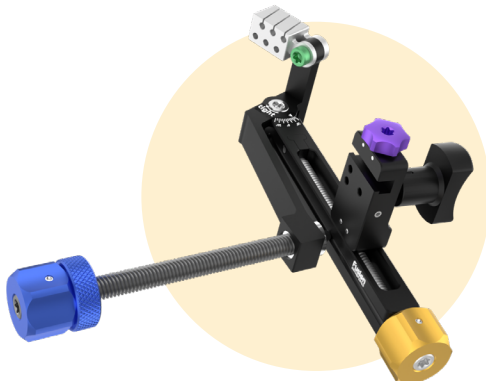


Percutaneous Cup

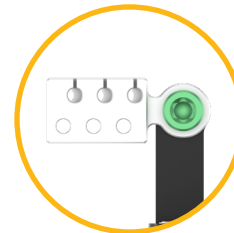


C: Follow the initial jig set up shown below:

Initial Jig Setup:



Buttress the nose of the IM Dial to the rail.

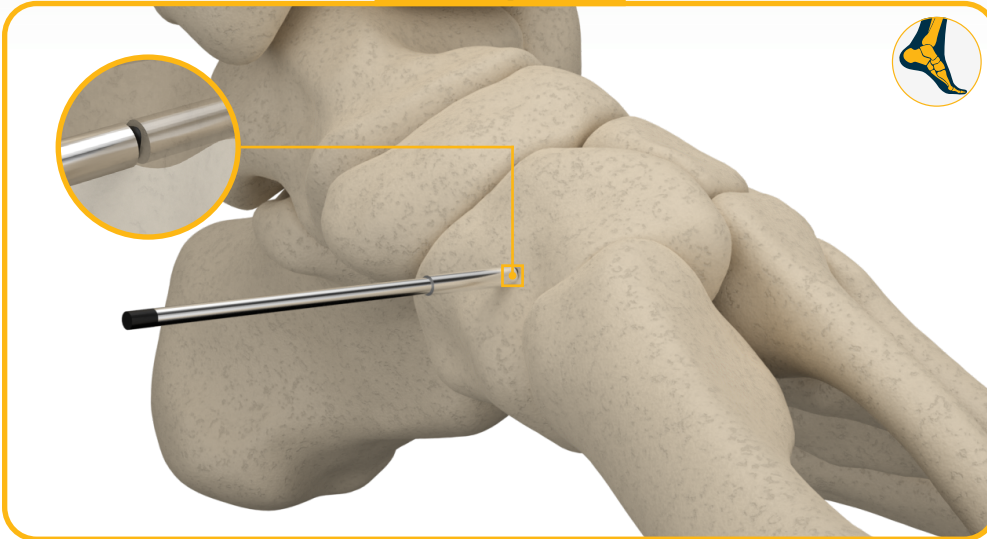


Ensure the cuneiform block is at 90° in relation to the rail.



When you see this icon, it is recommended that you confirm your surgical progress under fluoroscopy, before proceeding further.

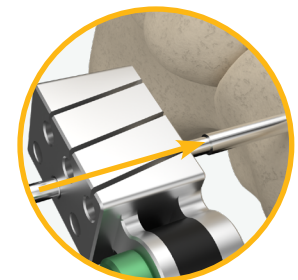
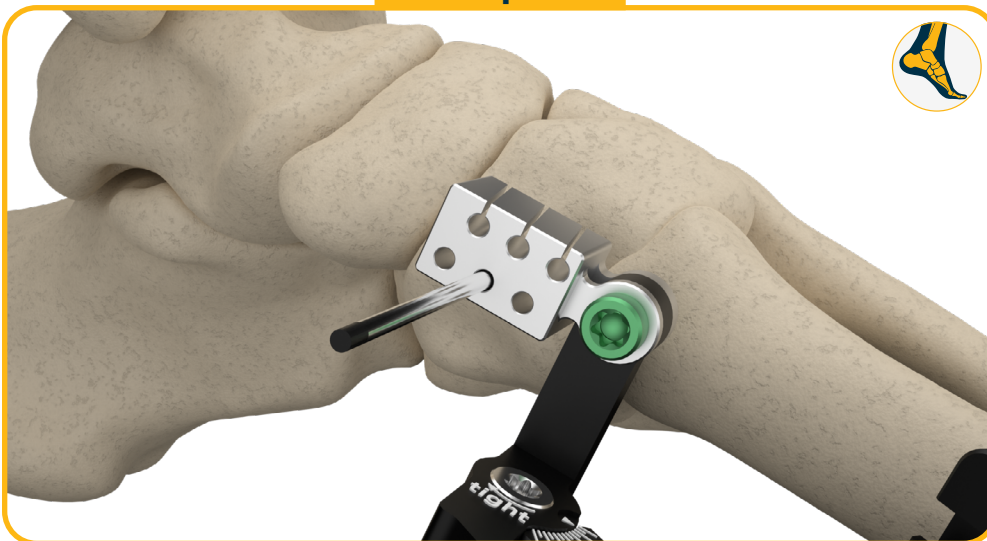
Step 1



Surgeon must consider the Tibialis Anterior Tendon before placing any K-wires.

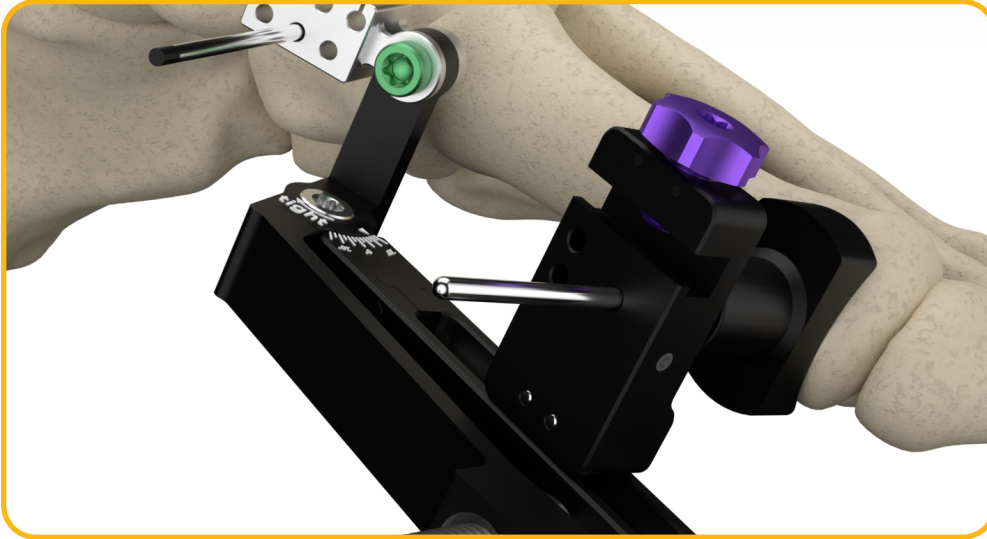
To properly align the Jig, advance a set-wire through the center of the first cuneiform, and into the second cuneiform. Ensure the set-wire is parallel to the weight-bearing surface and perpendicular to the first and second cuneiform. Advance the fluoro notch at the cortex. The fluoro notch placement can be verified under fluoroscopy.

Step 2

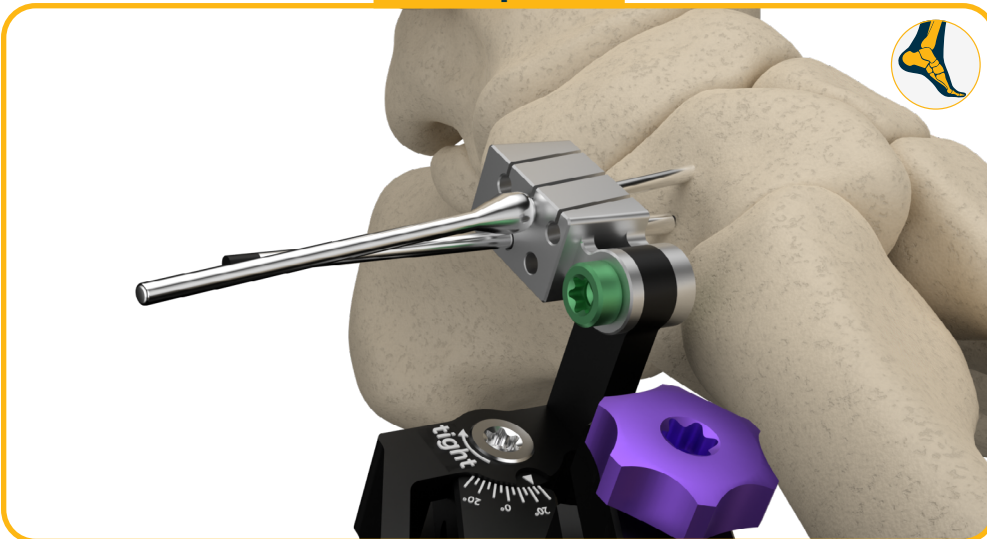


**Advance to
Hard Stop**

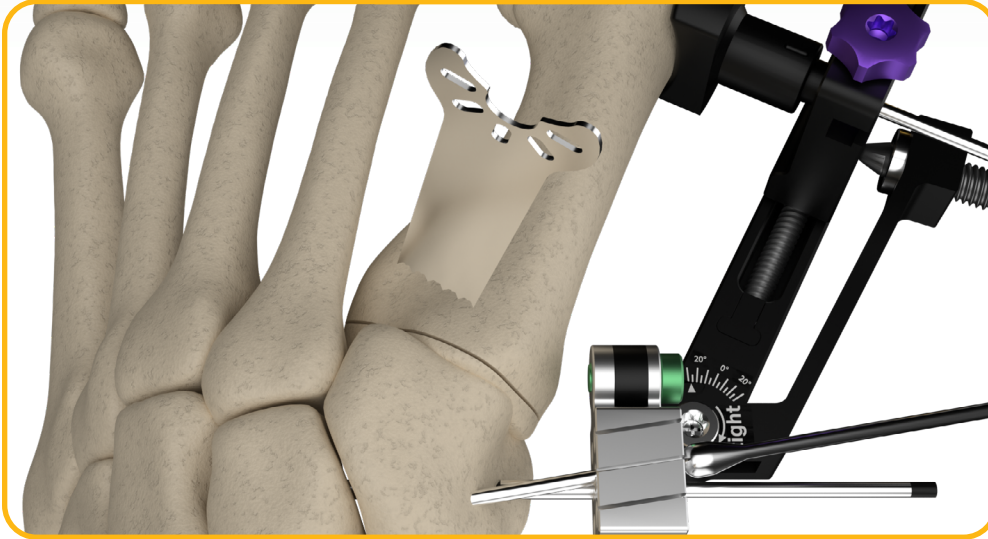
Slide the Cuneiform Block over the set-wire through the center hole in the plantar row, until you reach a **hard stop**. If needed, reposition the Cuneiform Block to assure that the green screw is placed just distal to the joint.

Step 3

Ensure the Jig Rail is parallel to the declination angle of the first metatarsal by placing a temporary short wire through the Met Cup Block, and into the center head of the metatarsal.

Step 4

Advance a non-threaded or threaded olive wire through the most suitable hole in the dorsal row of the Cuneiform Block and into the cuneiform, to secure the Jig.

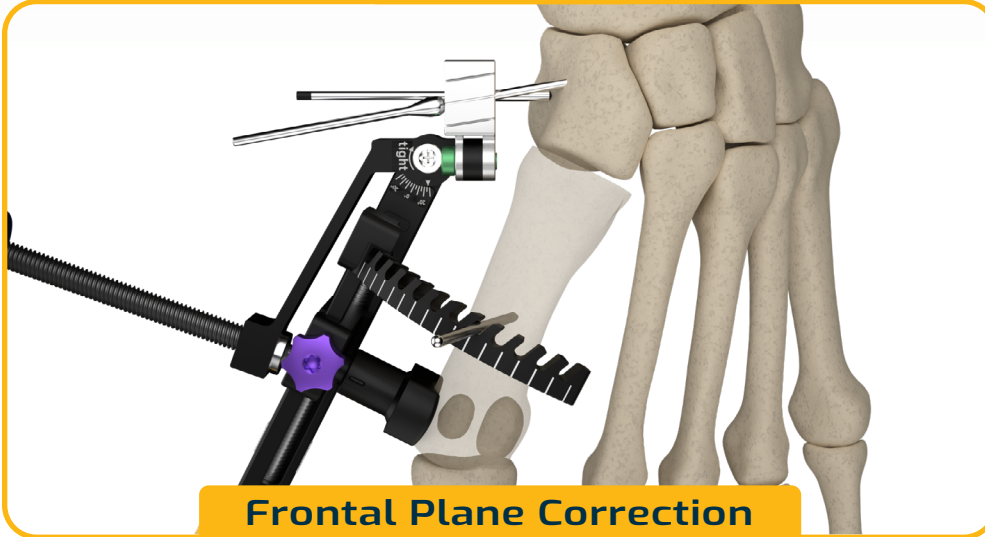
Step 5

Prepare the joint by utilizing a provided chisel, an osteotome or Sagittal Sawblade to free up the joint space. Using a Sagittal Sawblade, cut the subchondral plate off the base of the first metatarsal, perpendicular to the longitudinal axis.

Step 6

Attach the Rotation Arm to the Met Cup Block, and secure it by turning the purple dial. Place a K-wire bicortical through a plantar notch of the Rotation Arm, into the metatarsal. Remove the temporary K-wire from the Met Cup Block so the first metatarsal can freely rotate.

Step 7

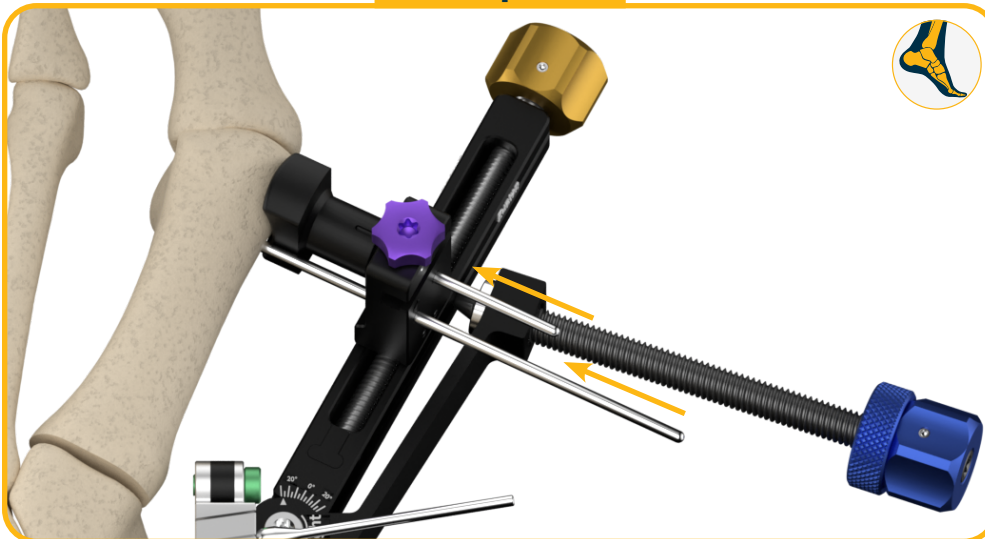


Frontal Plane Correction

Ensure to maintain axial rotation.

Use the K-wire as a joystick to de-rotate the first metatarsal until it is in a neutral position. Temporarily hold the frontal plane by placing the K-wire in one of the rotation arm notches.

Step 8

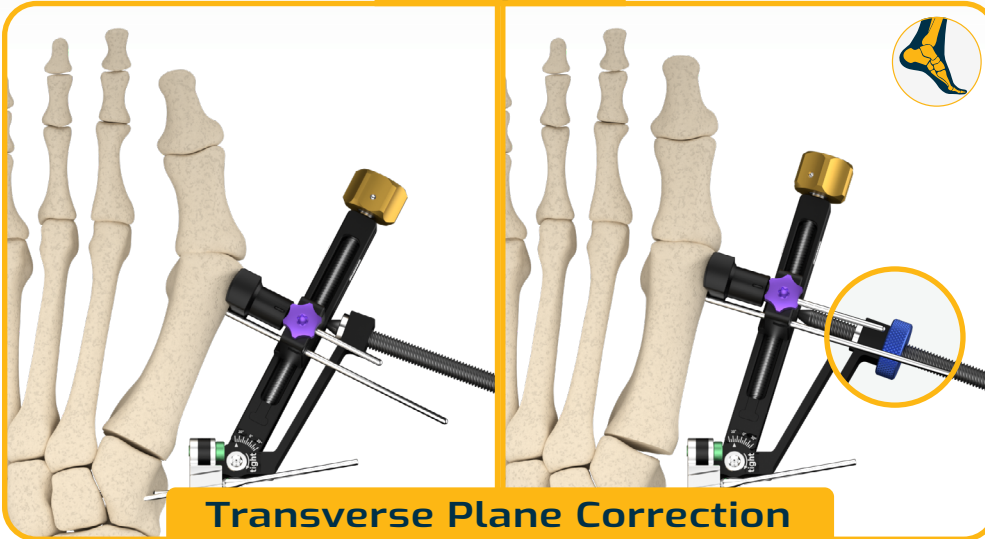


To allow for intermetatarsal angle correction, compression, and distraction, ensure K-wires do not cross into the second metatarsal.

In order to secure correction, 2 k-wires need to be pinned in the metatarsal at all times.

Place a bicortical short wire into the first metatarsal head through the Met Cup Block, and a k-wire proximal to the short wire, to lock the frontal plane rotation. Remove the joystick k-wire and the rotation arm.

Step 9



Transverse Plane Correction

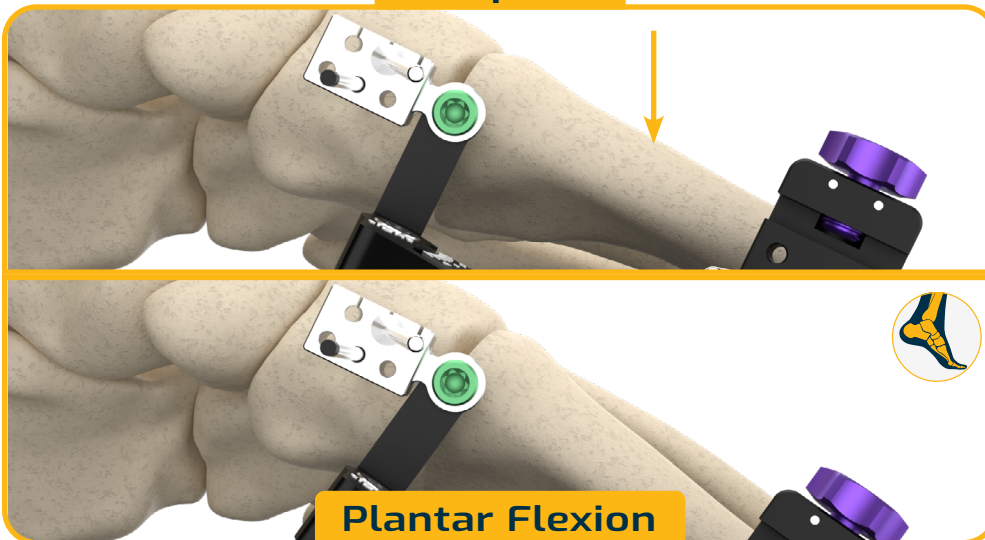
LapiLock is a fulcrum-less system that does not require placement of any instruments between the first and second metatarsal during IM Correction.



The protractor may be utilized to estimate IM deformity and intraoperative achieved correction.

- A:** Correct the intermetatarsal (IM) angle by turning the blue dial clockwise.
- B:** As the IM angle closes, the base of the metatarsal may compress against the cuneiform, causing tension on the blue dial. Distract by turning the gold dial counter-clockwise to relieve the tension and continue properly positioning.
- C:** Repeat as necessary to gain proper IM correction.
- D:** Finger-tighten the blue IM Lock upon achieving IM Correction.

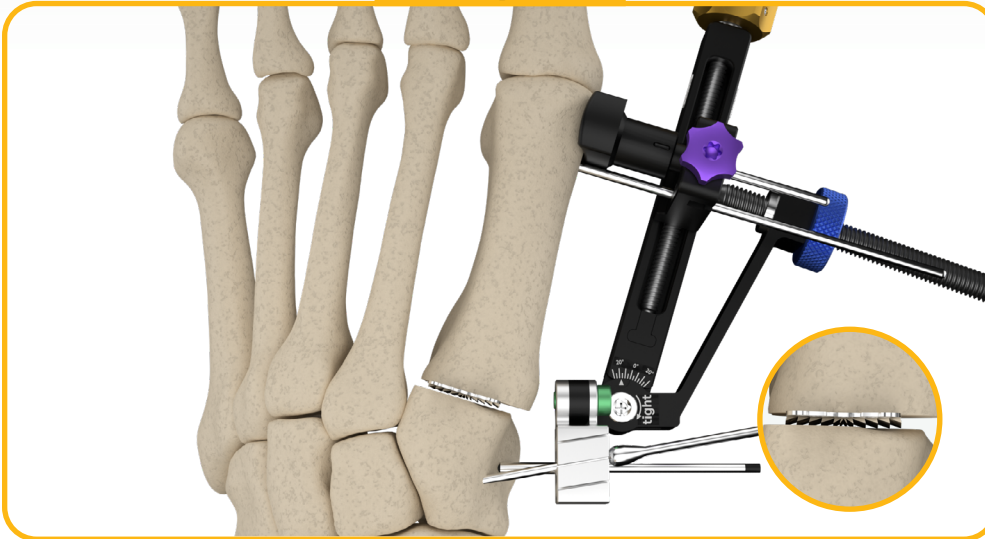
Step 10



Plantar Flexion

As needed, LapiLock allows for plantar flexion of the first metatarsal. If correction is needed after a lateral view of the metatarsal, slightly distract the joint, loosen the green screw and manually adjust the metatarsal to the desired position. Tighten the green screw to lock in the adjustment.

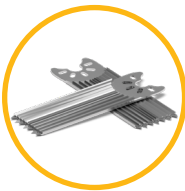
Step 11



Utilize saline in the joint space while resecting with either cutting technique.

The YOCO Power Curette may require cleaning of the cutting flutes during joint resection.

Distract the joint utilizing the gold dial. Select from a choice of cutting techniques and follow the individual steps outlined below:



Single YOCO Power Curette:

Insert the Single YOCO Power Curette into the joint space with the cutting surface facing the cuneiform. Resect the cuneiform joint surface, by using the base of the metatarsal as a guide. This achieves parallel coaptive cuts in the joint. Irrigate and clear the joint at surgeon discretion.

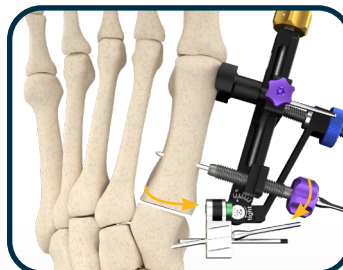
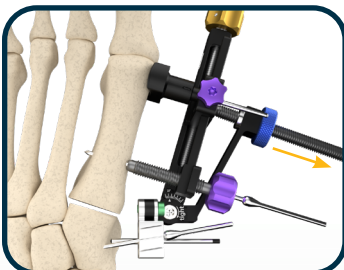
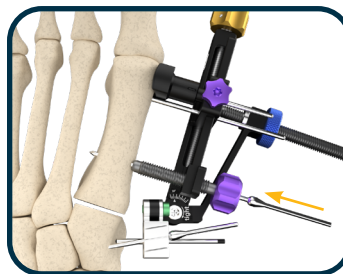
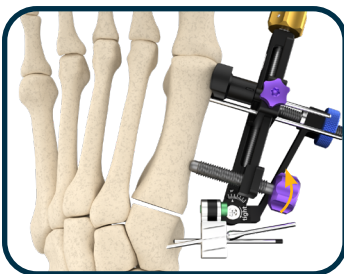


Sagittal Sawblade:

Utilizing a traditional Sagittal Sawblade, create a parallel resection on the cuneiform in relationship to the base of the metatarsal.

Optional Step 11-B

According to surgeon discretion, utilize the Met Positioner for precise placement of the metatarsal base:



A: Attach the Metatarsal Positioner to the Met Cup Block and ensure that the nose of the metatarsal positioner is buttressed against the metatarsal. Distract the joint.

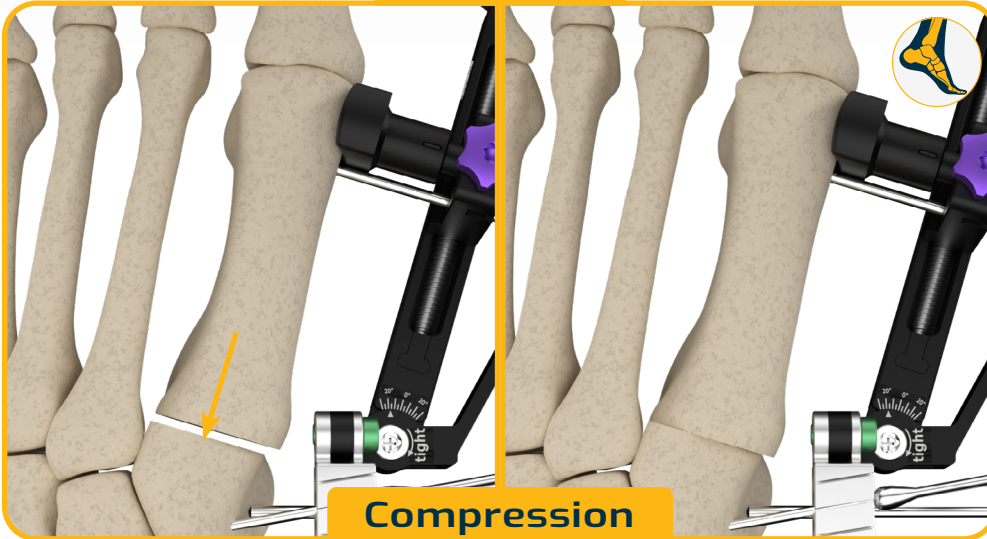
B: Advance the Met Positioner Olive Wire through the Purple Dial and bi-cortically into the metatarsal.

C: Remove the most proximal wire from the **Met Cup Block**.

D: Turn the Purple Dial counter-clockwise until desired position of the metatarsal is achieved. *Each full rotation creates 1mm of space between the first and second metatarsal.*

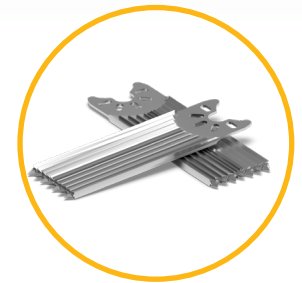
E: The Metatarsal Position can remain attached until the conclusion of the case.

Step 12



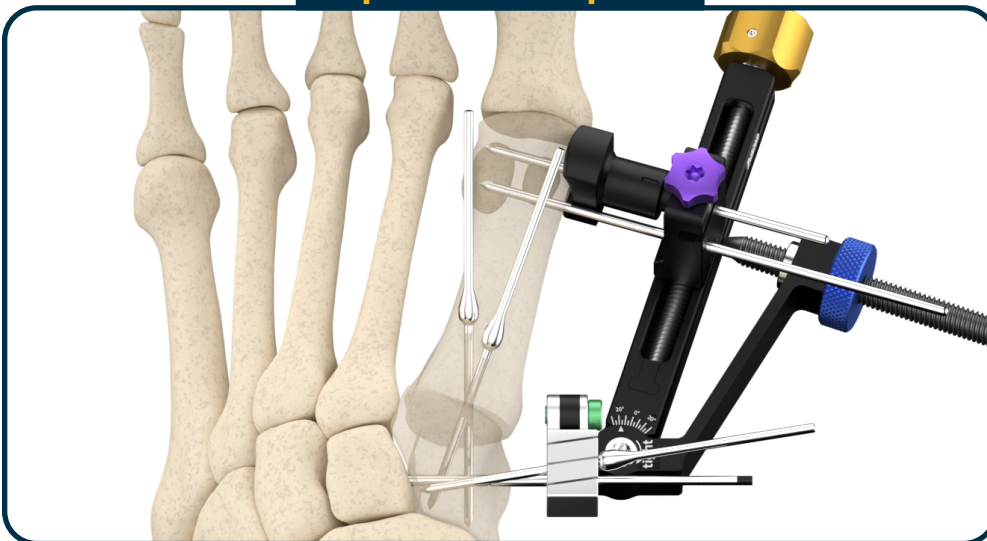
Compression

Compress the joint and confirm proper alignment and bone on bone apposition, under fluoroscopy from an anteroposterior (AP) and lateral perspective. If needed, repeat Step 11.



Double YOCO Power Curette:
 The Double YOCO Power Curette creates resections on both the first metatarsal base and the cuneiform, simultaneously. If needed, utilize the Double YOCO to adjust and perfect joint preparation.

Optional Step 13



Temporary fixation and removal of the LapiLock Jig may be required to reduce the risk of interference with chosen fixation. Temporarily fixate the fusion site using non-threaded or threaded olive pins. Follow the removal steps to remove the jig.

Fixations

Pictured is an example of final fixation utilizing the LapiLock and PolyLock U-Plate.

LapiLock can be used with over 13 forms of fixation from Fusion Orthopedics.

Once the desired corrected position is achieved, fixate according to surgeon preference.

SURGEONS CHOICE OF 13+ FIXATION OPTIONS

U-Plate



Dual Slim Constructs



IntraLock



DynaBridge Staple



Maverick Plate



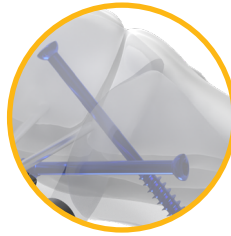
Neutral Lapidus Plate



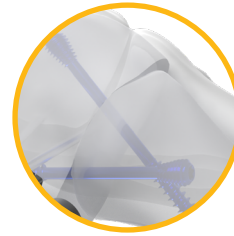
T-Plate



HD Screws



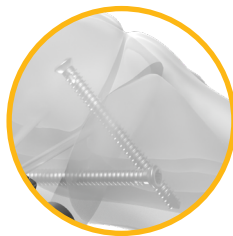
HL Screws



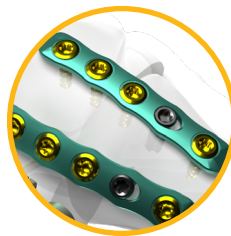
FT Screws



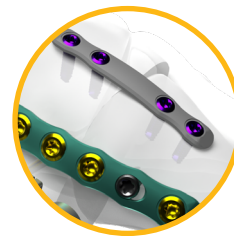
3.5 & 4.0 Solid Screws



Dual Lapidus Plates

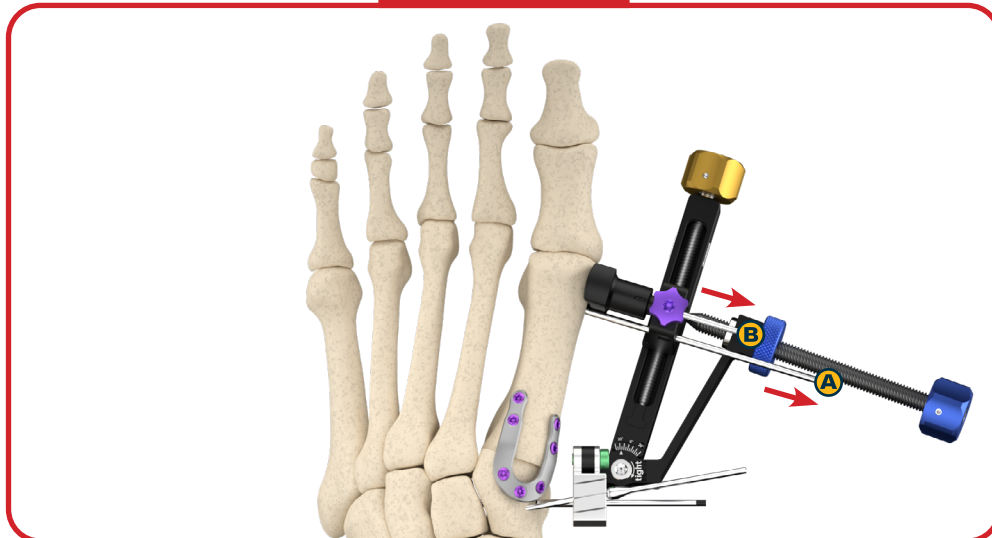


Two Plate Construct



Removal Technique

R-1



Remove K-wires (A) and (B) prior to removing K-Wires from the Cuneiform Pin Guide.

R-2



Remove the olive pin (C), then slide the entire Jig off, before removing K-wire (D). Note: Do not remove Set-Wire (D) through the Cuneiform Pin Guide.

DESCRIPTION OF MEDICAL DEVICE

LapiLock is a non-powered orthopedic manual surgical instrument. This system uses 2.0mm guide wires and olive wires to manipulate various bones in the foot. LapiLock's intended use is for the lapius bunion correction.

INDICATIONS

LapiLock is intended for tissue and bone manipulation. This bone positioner is specifically used to help position and prepare the 1st Metatarsocunieform joint for arthrodesis. Previously cleared Fusion Orthopedics fixation (class 2 medical devices) should be used in conjunction with LapiLock to fuse the 1st Metatarsocunieform joint.

CONTRAINDICATIONS

- Any active or suspected latent infection or marked local inflammation around the affected area.
- Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site.
- Bone stock compromised by disease, infection or prior implantation that can not provide adequate fixation of the devices.
- Material sensitivity, documented or suspected.
- Obesity. An overweight or obese patient can produce loads on the implant that can lead to failure of the fixation of the device or to failure of the device itself.
- Patients having inadequate tissue coverage over the operative site.
- Implant utilization that would interfere with anatomical structures or physiological performance.
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complication in postoperative care.

IMPLANT SYSTEMS

Product #	Description
DB-LL-7000	LapiLock DynaBridge Implant System
FX-LL-7000	LapiLock FuzeFix Implant System
IL-LL-7000	LapiLock IntraLock Implant System
PL-LL-7000	LapiLock PolyLock Implant System
XY-LL-7000	LapiLock Universal Implant System

INSTRUMENTATION

Product #	Description	Product #	Description
CD-LL-0040	LapiLock Olive Wires Threaded	CD-LL-9001-SC	YOCO Lapidus Double Conmed (Sterile)
CD-LL-0045	LapiLock Olive Wires Non-Threaded	CD-LL-9002-SC	YOCO Lapidus Single Conmed (Sterile)
CD-LL-0020	LapiLock K-Wire 2.0mm	CD-LL-0030	LapiLock Olive Wire Threaded (Short)
TN-LL-9991	Metatarsal Positioner	CD-IL-3040	Driver Torx LL/IL
CD-LL-9901	LapiLock Osteotome Angled	TN-FX-8025	Depth Gauge Max FT
CD-LL-0991	MP Oliver Wire Non-Threaded	CD-FX-0009	K-Wire Standard 0.9mm
TN-LL-5860	IntraLock LapiLock Tissue Protector Window 6mm	CD-FX-0011	K-Wire 1.1mm
TN-LL-7000-15P	LapiLock Met Cup Percutaneous	CD-FX-0014	K-Wire Standard 1.4mm
CD-LL-9001-S	YOCO Lapidus Double Sided (Sterile)	TN-LL-5861	IntraLock Reese Guide 6mm
CD-LL-9002-S	YOCO Lapidus Single (Sterile)	TN-LL-7920	LapiLock Drill Guide
CD-LL-0001	LapiLock Set Wire	TN-FX-9110	Tissue Protector Handle
TN-LL-7100	LapiLock Jig Right	CD-FX-6040	Screw Extractor Rod 3.0mm & 4.0mm
TN-LL-7000	LapiLock Jig Left	TN-FX-6010	Driver Handle Ratcheting
CD-LL-0002	LapiLock Short Wire	TN-FX-6020	Driver Handle Non-Ratcheting
CD-LL-1020	LapiLock Fenestration Drill 2.0mm	TN-TR-0041	LapiLock Triplanar Correction System Tray

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ORTHOPEDICS

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STG015 10272023

A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Surgeons should rely on their lapidus bunionectomy education and professional training, as the LapiLock instruments and technique augments a traditional lapidus bunionectomy. Fusion Orthopedics, and its affiliates ("Fusion") does not dispense medical advice and while Fusion recommends that surgeons be trained in the use of any particular Fusion product before using it in surgery, surgeons must still rely on their professional training and expertise. The information presented is for general education and intended to demonstrate the breadth of Fusion's product offerings. A surgeon and patient must always refer to the complete LapiLock written surgical technique guide released on September 01, 2022 or newer, package insert, product label, and instructions for use before using any Fusion product. Products and associated accessories may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your representative if you have questions about the availability of products in your area. Patients must solely rely on advice from their surgeon regarding the risks and all steps of a lapidus bunionectomy with the utilization of the LapiLock instruments. As with any surgery, individual results and recovery time vary. Recovery time may range from months to years. Known risks associated with a lapidus bunionectomy are, but not limited to, significant scarring, nerve damage, mal-union, long-term pain, implant pain, failed implant hardware, misalignment, loss of motion, subsequent development of hallux rigidus/limitus, TMT joint non-union, improper dorsal/plantar flexion of the first ray, shortening of the first ray, insufficient intermetatarsal angle correction, insufficient frontal plane correction, infections, swelling, stiffness, bone fracture, and subsequent required amputation. These works and its contents are protected by U.S. and International copyright laws. Reproduction and/or distribution of these works, and its contents, without the express written consent of Fusion Orthopedics USA, LLC is prohibited. © 2023 Fusion Orthopedics USA, LLC