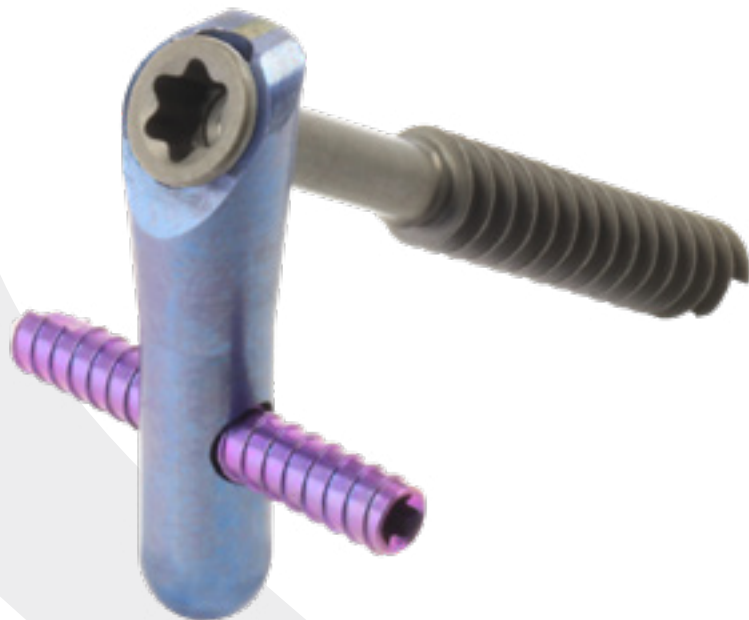


# IntraLock

Patented - Confidential



**Fusion**  
ORTHOPEDICS

First Tarsometatarsal Fusion  
**Surgical Technique**

## DESCRIPTION OF THE MEDICAL DEVICE

IntraLock is a three-part construct consisting of a Locking Post Nail, Static Set Screw, and a Locking Lag Screw. The Post Nail acts as a mating washer component which consists of lengths ranging from 20mm to 28mm. The Set Screw stabilizes and aids the Post Nail and is offered in lengths ranging from 14mm-24mm. Lag Screws are offered in two diameters each with lengths ranging from 22mm to 55mm. The IntraLock Implants are constructed of titanium alloy. The specialized instruments are made of surgical grade stainless steel. Implants are intended for single use only. IntraLock Instruments designed for bone removal are intended for single use only, such as: drill bits, countersinks, reamers, and K-wires.



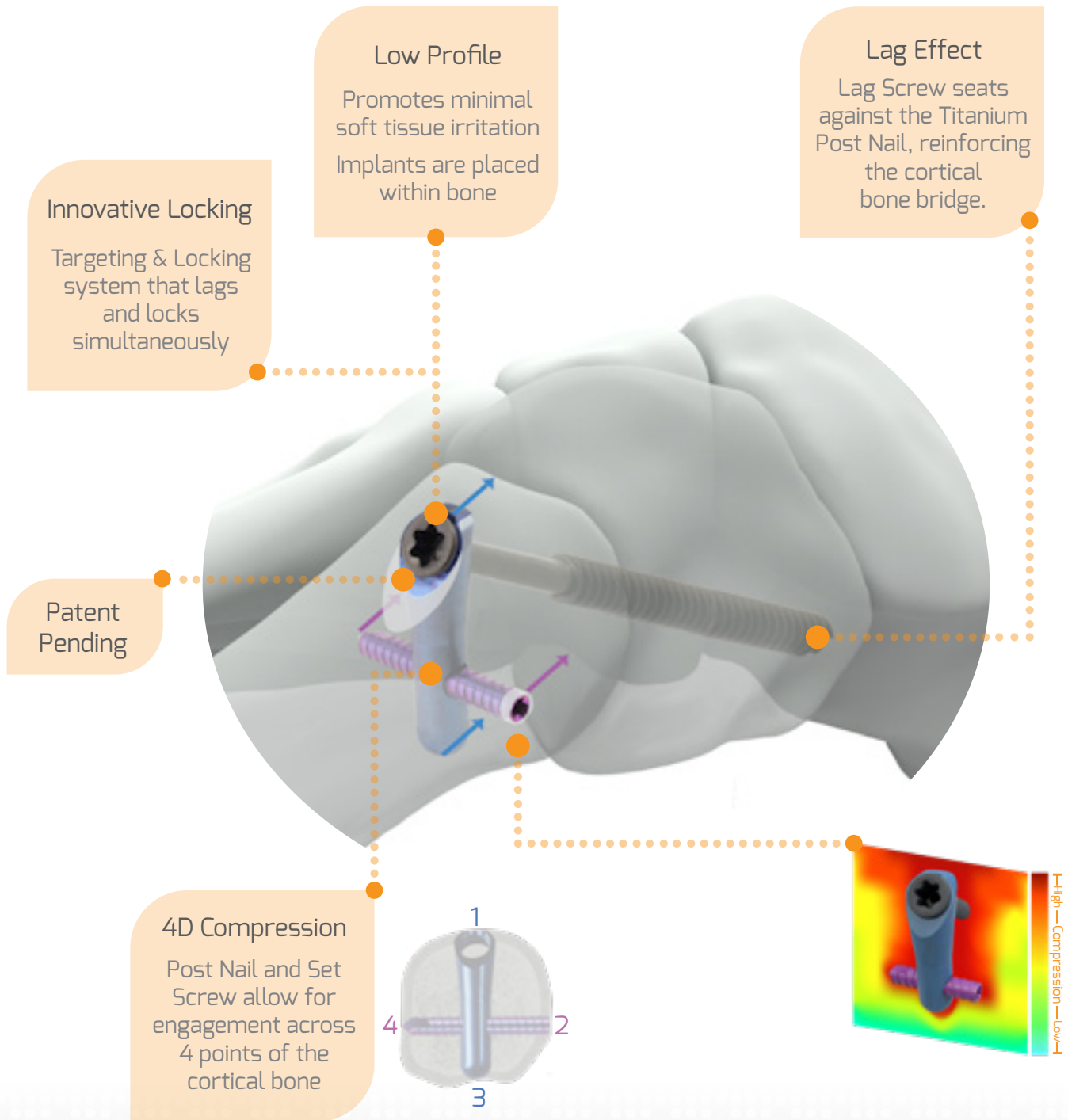
## INDICATIONS FOR USE

IntraLock is indicated for reduction and internal fixation of arthrodeses, osteotomies, intra- and extra-articular fractures, and nonunions of the small bones and joints of the foot. The three-part construct is specifically intended for use in Talonavicular, Calcaneocuboid, and Metatarsocuneiform Arthrodesis.

## 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.

The IntraLock System is designed and indicated to be used with the Post Nail, Set Screw, & Lag Screw as a 3 Piece construct and should not be used alone.

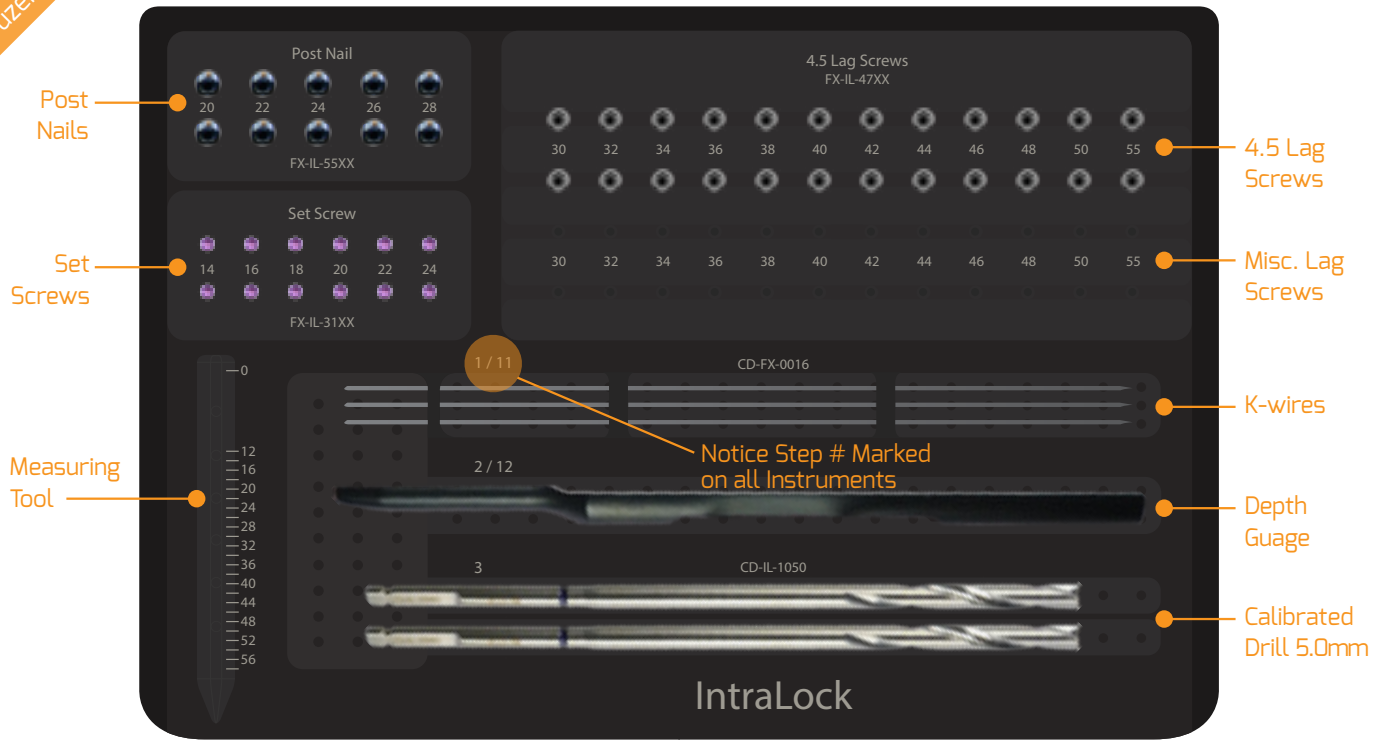


Scan to learn more about our Modular Tray Environment.

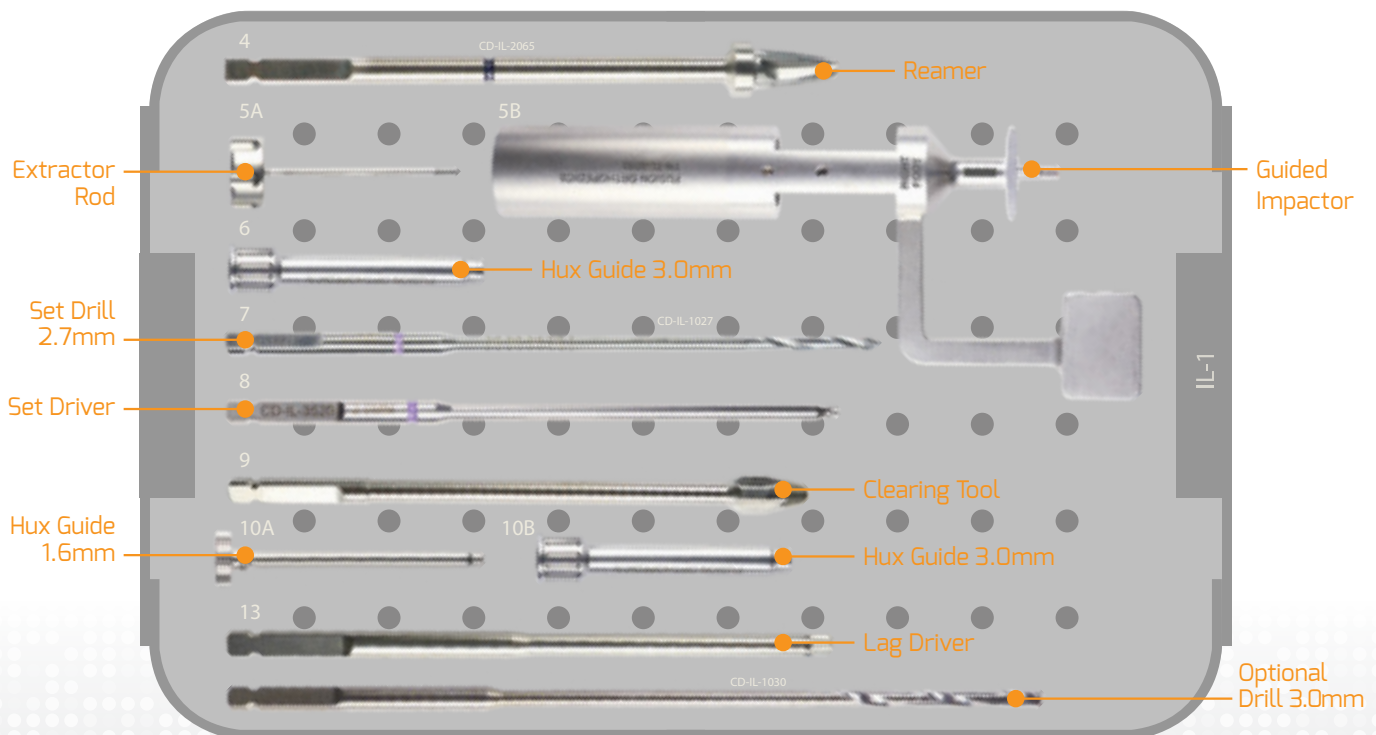


Part Of The FuzeFix Modular Tray

### IL Caddy



### IL Basin



### Editor's Note:

The following technique can be utilized for all Indications of the IntraLock system.



1

After preparing the joint, place the 1.6mm K-wire parallel to the joint surface, between 10-15mm from the osteotomy and centered in the base of the metatarsal.



2

Place the Depth Gauge over the 1.6mm K-wire, and determine the Post Nail length by examining the end of the wire against the graduated depth marks. \*Notice the depth gauge is reversible. Assure side labeled 'POST' is being utilized for Step 2.\*





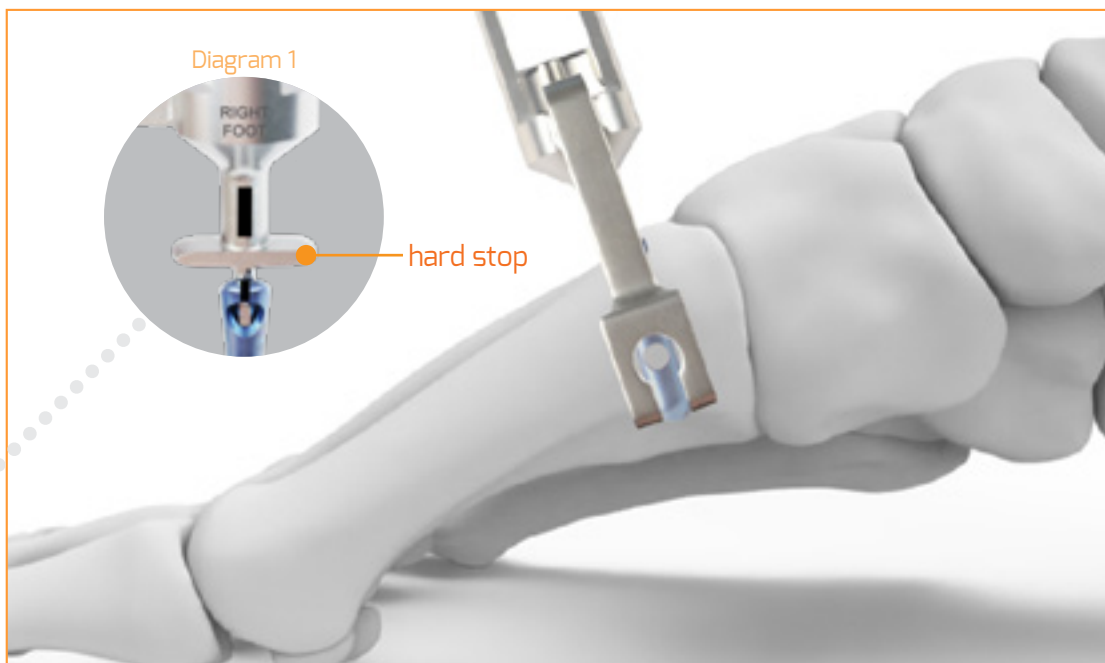
**3** Select the 5.0mm Calibrated Drill. Place the drill over the K-wire and advance through the plantar cortex.



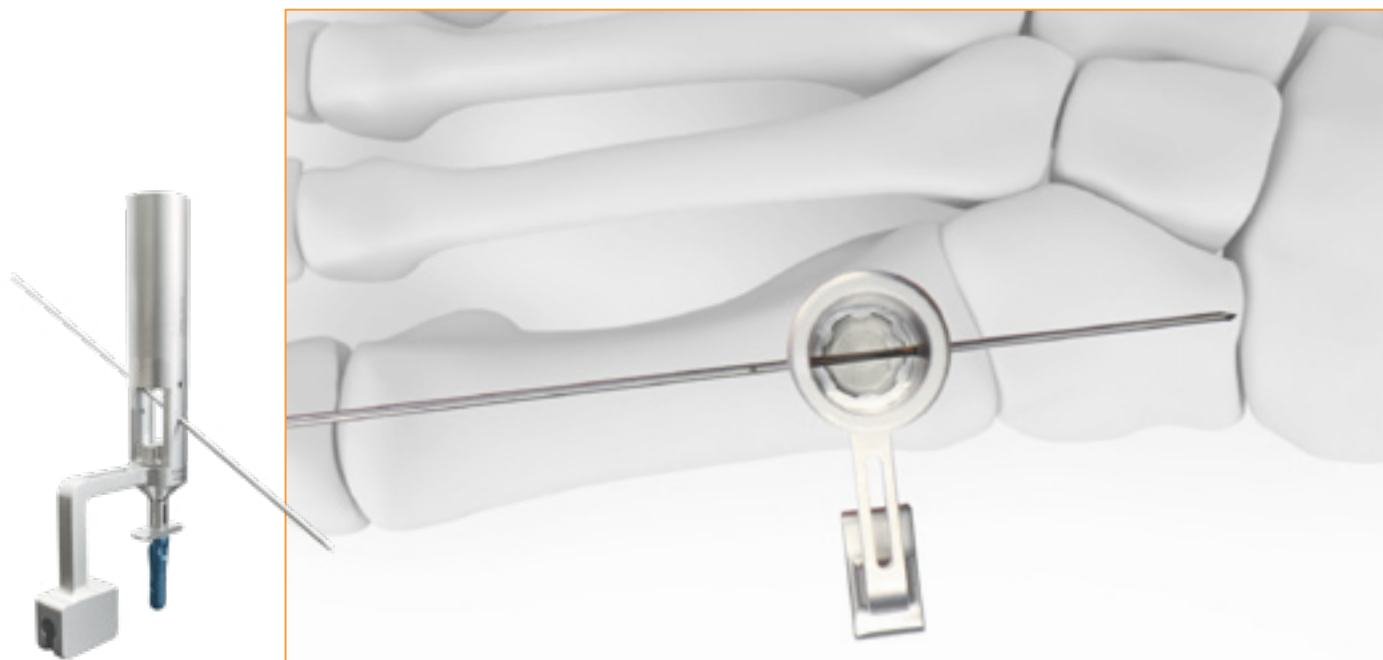
**4** Select the Post Nail Reamer. Place the Reamer over the K-wire and advance until the **hard stop** is flush with the dorsal cortex.



Diagram 2



**5** Place the Post Nail on the Guided Impactor aligning the corresponding laser marks (Diagram 1). Feed the Extrator Rod through the Guided Impactor and tighten the Extrator Rod to fasten the Post Nail on to the Guided Impactor (Diagram 2). Tamp in the Post Nail until the dorsal cortex is flush with the **hard stop** of the Guided Impactor.



**5+** Feed a K-wire through the pre-cut holes on the Guided Impactor to project the angle of the Lag Screw. Turn the Guided Impactor until you are satisfied with the projected angle .



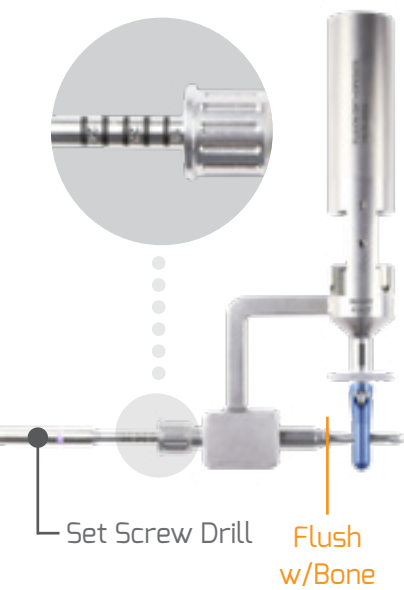
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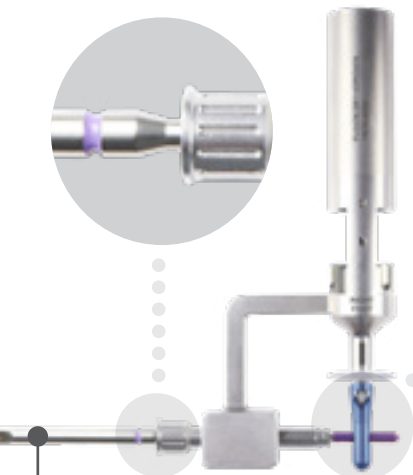
Slide the 3.0mm Hux Guide through the side arm of the Guided Impactor. Hux Guide should sit flush with the bone. Ensure it remains flush with the bone through Step 8.



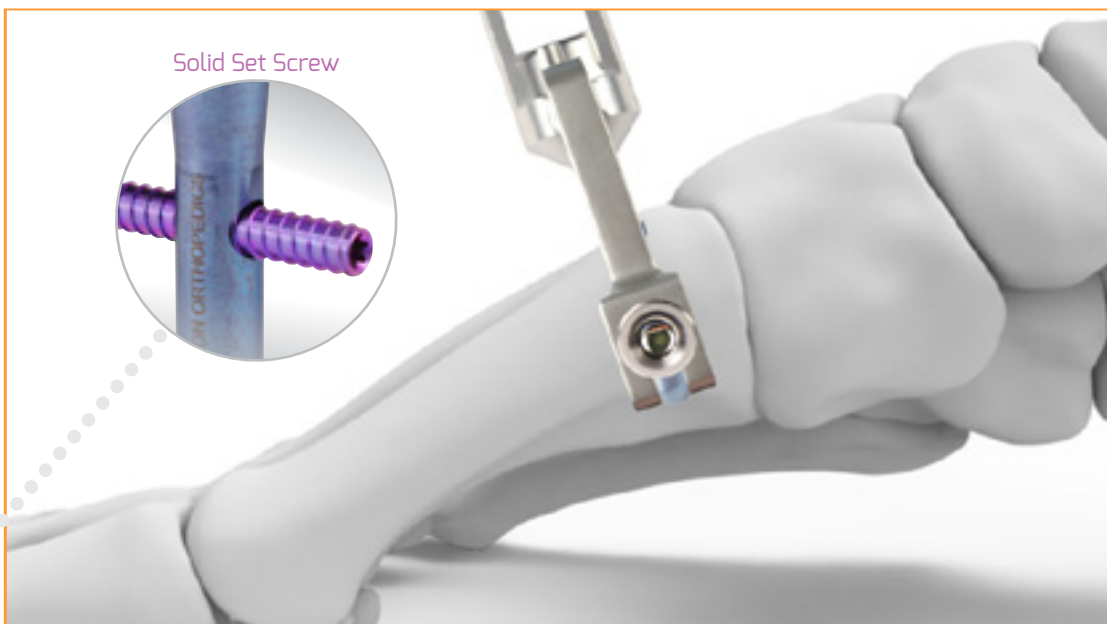
7

Using the Set Screw Drill, drill through the 3.0mm Hux Guide until you breach the lateral cortex. Using the laser lines on the drill, and the 3.0mm Hux Guide, determine the length of the Set Screw that will be utilized.





Set Screw Driver



Solid Set Screw

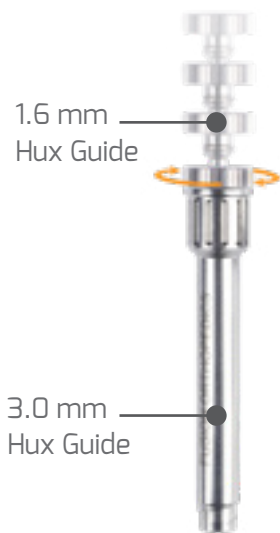
8

Using the Set Screw Driver, drive in the Set Screw to the hard stop.

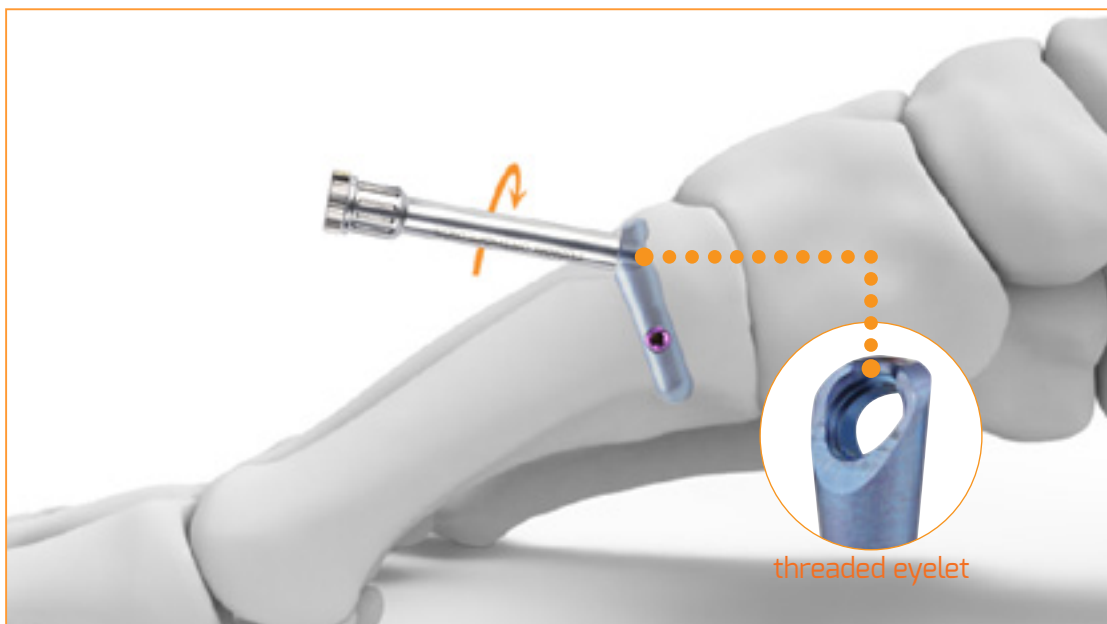


9

Unscrew the Extractor Rod from the Guided Impactor and remove the Guided Impactor from the Post Nail. Remove any bone obstruction above the Post Nail by using the Clearing Tool. Rotate the Clearing Tool until Post Nail eyelet is clearly visible.



Hux Guide Construct



**10** Twist the 1.6mm Hux Guide into the 3.0mm Hux Guide as shown to the left. The threaded end of the Hux Guide Construct is then screwed into the **threaded eyelet** of the Post Nail with a half turn clockwise. The Hux Guide will help ensure the Lag Screw will properly seat into the post.



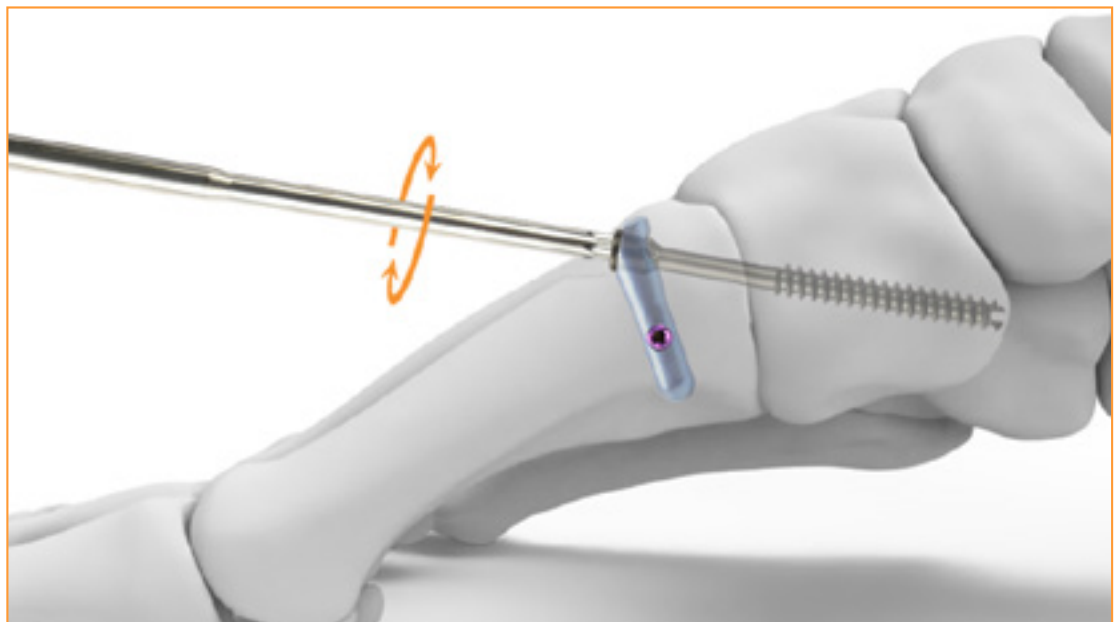
**11** Insert the K-Wire through the Hux Guide Construct until the far cortex of the cuneiform is reached. Confirm placement under fluoroscopy.



12

Utilize the 'LAG' side of the Depth Gauge to measure the desired Lag Screw length. Remove the Hux Guide Construct from the Post Nail after drilling to prepare for placement of the Lag Screw. If surgeon prefers drilling: Only remove the 1.6mm Hux Guide, not the entire Hux Guide Construct and proceed to the note in Step 13.

Optional: Select the 3.0mm Calibrated Drill. Drill through the 3.0mm Hux guide to the desired depth. After drilling, remove 3.0mm Hux Guide.



13

Select the Lag Screw Driver. Insert the desired Lag Screw over the K-wire and through the Post Nail until tactile compression is felt, and/or the rim of the Lag Screw sits flush with the eyelet of the Post Nail.

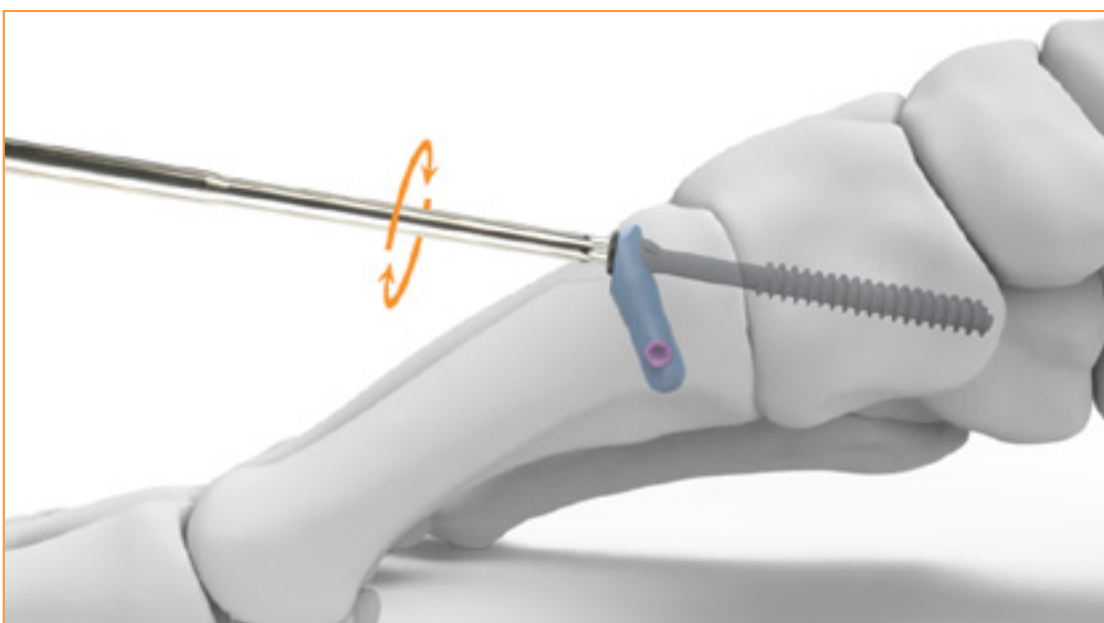


14

Verify final placement under fluoroscopy.



**1** Using a Rongeur, clear any bone or tissue ingrowth, revealing the Lag Screw interface.



**2** Insert the Lag Screw Driver into the Lag Screw head and explant the screw through the Post Nail by turning it counter-clockwise..

If removal of the implant is required do to revision or failure of the device, the surgeon should contact Fusion Orthopedics using the contact information found at the end of this manual to receive instructions for returning the explanted device for investigation.



3

Insert the Guided Impactor into the Post Nail. Introduce the Extractor Rod through the Guided Impactor and turn Extractor Rod clock-wise to fasten the Post Nail onto the Guided Impactor.



4

Insert Set Screw Driver through the side arm of the Guided Impactor and turn counter-clockwise to remove the Set Screw


If removal of the implant is required do to revision or failure of the device, the surgeon should contact Fusion Orthopedics using the contact information found at the end of this manual to receive instructions for returning the explanted device for investigation.



5

Explant the Post Nail by using the Guided Impactor as leverage to unseat the Post Nail from the bone.

If removal of the implant is required do to revision or failure of the device, the surgeon should contact Fusion Orthopedics using the contact information found at the end of this manual to receive instructions for returning the explanted device for investigation.

Post Nail	Description	Non-Sterile
	Locking Post Nail 20mm	FX-IL-5520
	Locking Post Nail 22mm	FX-IL-5522
	Locking Post Nail 24mm	FX-IL-5524
	Locking Post Nail 26mm	FX-IL-5526
	Locking Post Nail 28mm	FX-IL-5528

Set Screw	Description	Non-Sterile
	Static Set Screw 3.0mm x 14mm	FX-IL-3114
	Static Set Screw 3.0mm x 16mm	FX-IL-3116
	Static Set Screw 3.0mm x 18mm	FX-IL-3118
	Static Set Screw 3.0mm x 20mm	FX-IL-3120
	Static Set Screw 3.0mm x 22mm	FX-IL-3122
	Static Set Screw 3.0mm x 24mm	FX-IL-3124

4.0mm Lag Screw



Description	Non-Sterile
Locking Lag Screw 4.0mm x 22mm	FX-IL-4222
Locking Lag Screw 4.0mm x 24mm	FX-IL-4224
Locking Lag Screw 4.0mm x 26mm	FX-IL-4226
Locking Lag Screw 4.0mm x 28mm	FX-IL-4228
Locking Lag Screw 4.0mm x 30mm	FX-IL-4230
Locking Lag Screw 4.0mm x 32mm	FX-IL-4232
Locking Lag Screw 4.0mm x 34mm	FX-IL-4234
Locking Lag Screw 4.0mm x 36mm	FX-IL-4236
Locking Lag Screw 4.0mm x 38mm	FX-IL-4238
Locking Lag Screw 4.0mm x 40mm	FX-IL-4240
Locking Lag Screw 4.0mm x 42mm	FX-IL-4242
Locking Lag Screw 4.0mm x 44mm	FX-IL-4244
Locking Lag Screw 4.0mm x 45mm	FX-IL-4245
Locking Lag Screw 4.0mm x 46mm	FX-IL-4246
Locking Lag Screw 4.0mm x 48mm	FX-IL-4248
Locking Lag Screw 4.0mm x 50mm	FX-IL-4250
Locking Lag Screw 4.0mm x 55mm	FX-IL-4255

4.5mm Lag Screw



Description	Non-Sterile
Locking Lag Screw 4.5mm x 22mm	
Locking Lag Screw 4.5mm x 24mm	
Locking Lag Screw 4.5mm x 26mm	
Locking Lag Screw 4.5mm x 28mm	
Locking Lag Screw 4.5mm x 30mm	
Locking Lag Screw 4.5mm x 32mm	
Locking Lag Screw 4.5mm x 34mm	
Locking Lag Screw 4.5mm x 36mm	
Locking Lag Screw 4.5mm x 38mm	
Locking Lag Screw 4.5mm x 40mm	
Locking Lag Screw 4.5mm x 42mm	
Locking Lag Screw 4.5mm x 44mm	
Locking Lag Screw 4.5mm x 45mm	
Locking Lag Screw 4.5mm x 46mm	
Locking Lag Screw 4.5mm x 48mm	
Locking Lag Screw 4.5mm x 50mm	
Locking Lag Screw 4.5mm x 55mm	

Instruments	Description	Non-Sterile
Step 1	K-Wire Standard 1.6mm	CD-FX-0016
Step 2	Depth Gauge IL	TN-IL-8050
Step 3	Calibrated Drill Cannulated 5.0mm	CD-IL-1050
Step 4	Proximal Reamer Cannulated	CD-IL-2065
Step 5A	Screw Extractor Rod Post Nail	CD-IL-6540
Step 5B	Guided Impactor Nail	TN-IL-5050
Step 6	Hux Guide Sleeve 3.0mm	TN-IL-5030
Step 7	Calibrated Drill Set Screw 2.7mm	CD-IL-1027
Step 8	Driver Torx Solid Set Screw	CD-IL-3520
Step 9	Clearing Tool 6.5mm	TN-IL-2065
Step 10A	Hux Guide Wire Sleeve 1.6mm	TN-IL-5016
Step 10B	Hux Guide Sleeve 3.0mm	TN-IL-5030
Step 11	K-Wire Standard 1.6mm	CD-FX-0016
Step 12	Depth Gauge IL	TN-IL-8050
Step 13	Driver Hex Lag 3.0mm	CD-IL-3040
Optional	Calibrated Drill Cannulated 3.0mm	CD-IL-1030

\*Trays have corresponding Step # labeled next to instrument

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Rev 1



4135 South Power Road, #118

Mesa, Arizona 85212, U.S.A.

800-403-6876

[info@fusionorthopedics.com](mailto:info@fusionorthopedics.com)

[fusionorthopedics.com](http://fusionorthopedics.com)