

FuzeFix

Mini System



Fusion
ORTHOPEDICS

Mini Headed & Headless Screws
Surgical Technique

DESCRIPTION OF THE MEDICAL DEVICE

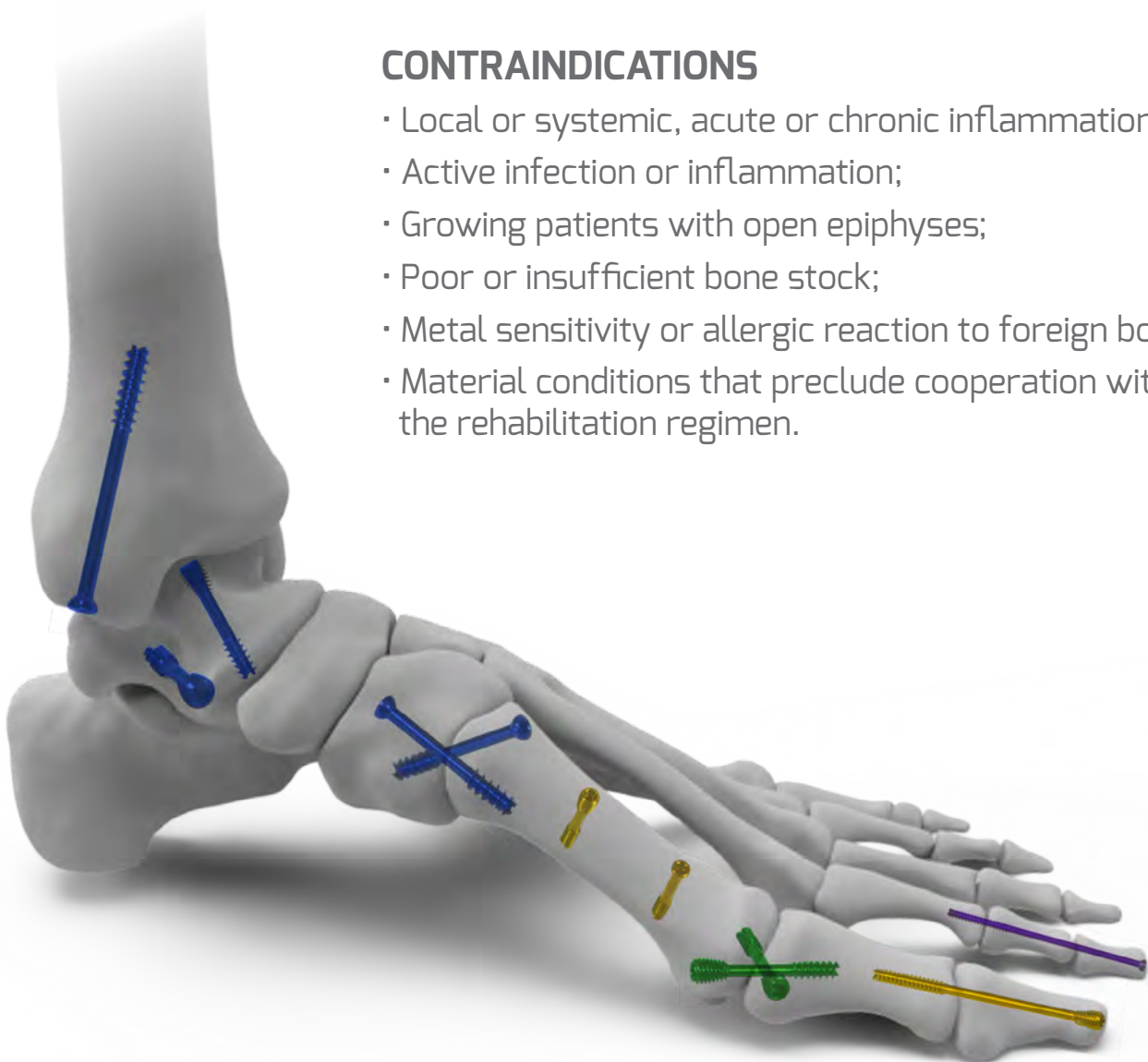
The FuzeFix Mini System consists of threaded bone fixation fasteners for fixation of the hand and foot following trauma and osteotomy with corresponding instrumentation to facilitate insertion. The FuzeFix Mini System includes Mini Cannulated Screws, and Mini Headless Screws. The included cannulated, threaded bone screws are offered in 2.0mm to 4.0mm diameters with lengths ranging from 8mm to 50mm. System instrumentation includes drill bits, countersinks, guide wires, guides, depth gauges, screw removal tools, removal rods, driver shafts, and handles to facilitate the placement of the screws. The implants and guide wires are intended for single use only.

INDICATIONS FOR USE

The FuzeFix Mini System is intended for use in the stabilization and fixation of bone fractures, osteotomies, non-unions, and reconstruction, tendon reattachment, and arthrodesis of the hand, foot, wrist, and ankle.

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.





HEADED



HANDLE



HEADLESS

Screw Set-Up



Diameter	Color	Drill	Driver	Reamer	K-Wire
2.0mm	Purple	1.7mm	T7	2.0mm	0.9mm
2.5mm	Gold	1.9mm	T8	2.5mm	1.1mm
3.0mm	Green	2.1mm	T10	3.0mm	1.1mm
4.0mm	Blue	2.6mm	T12*	4.0mm	1.1mm

*Custom Made for Fusion

Titanium Alloy

Durable material

Cannulated

Allows for threading

Opposing Thread Directions

Maximizes compression

Self Tapping/Self Drilling

Pre-drilling not necessary

Efficient

Time saving removal system

Comprehensive

Screws are offered in 2.0mm, 2.5mm, 3.0mm, and 4.0mm diameters

Differential Thread Pitch

Between proximal and distal shaft to optimize compression for each screw diameter

Optional Drill and Countersink

Color coordinated to match screw

Color Coded Instrumentation

Assures integration of all instruments with corresponding screw

Torx Star Driver

Maximizes axial force and minimizes stripping



Part Of The
FuzeFix Modular Tray

Scan to learn more
about our Modular
Tray Environment.



Caddies

Mini HD & HL and Max FT*



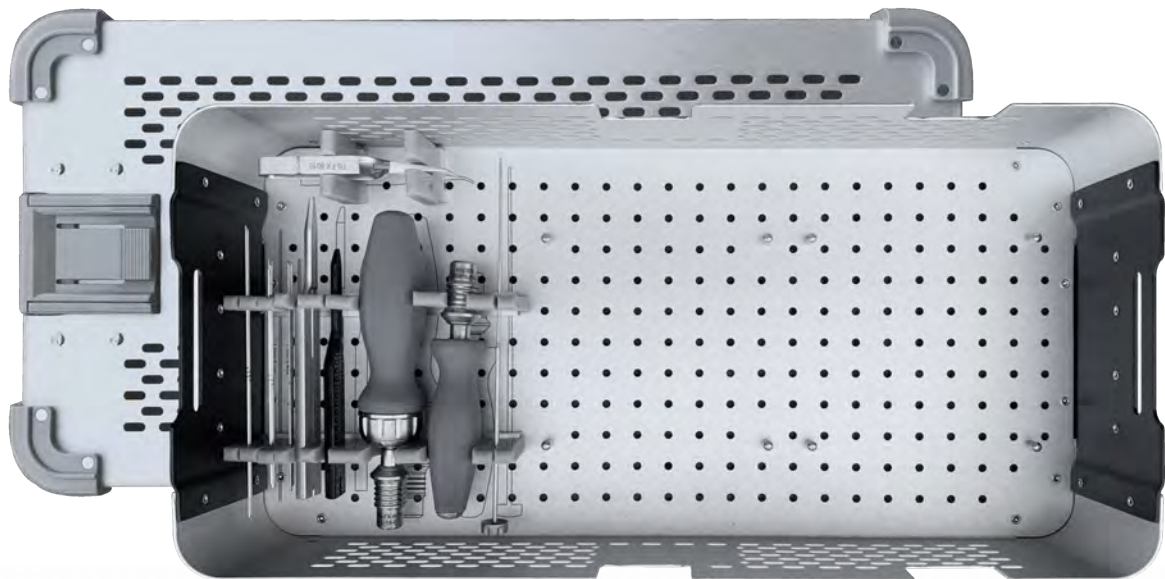
Mini HD Caddies

Mini HL Caddies

Max FT Caddies*

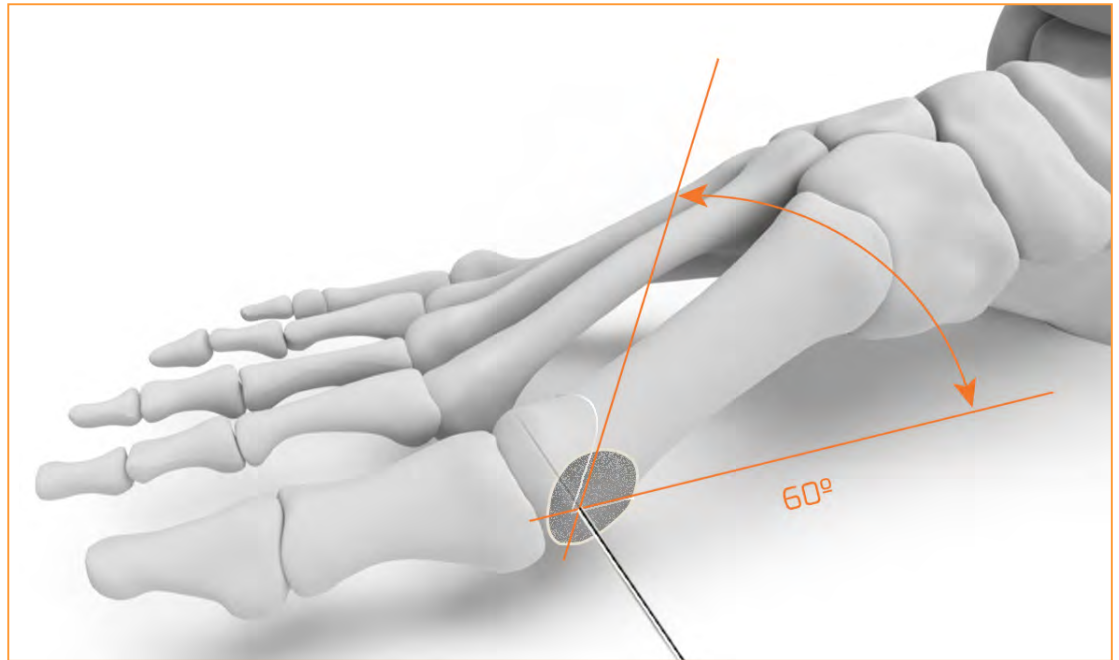
Modular Tray

Fits up to 4 caddies

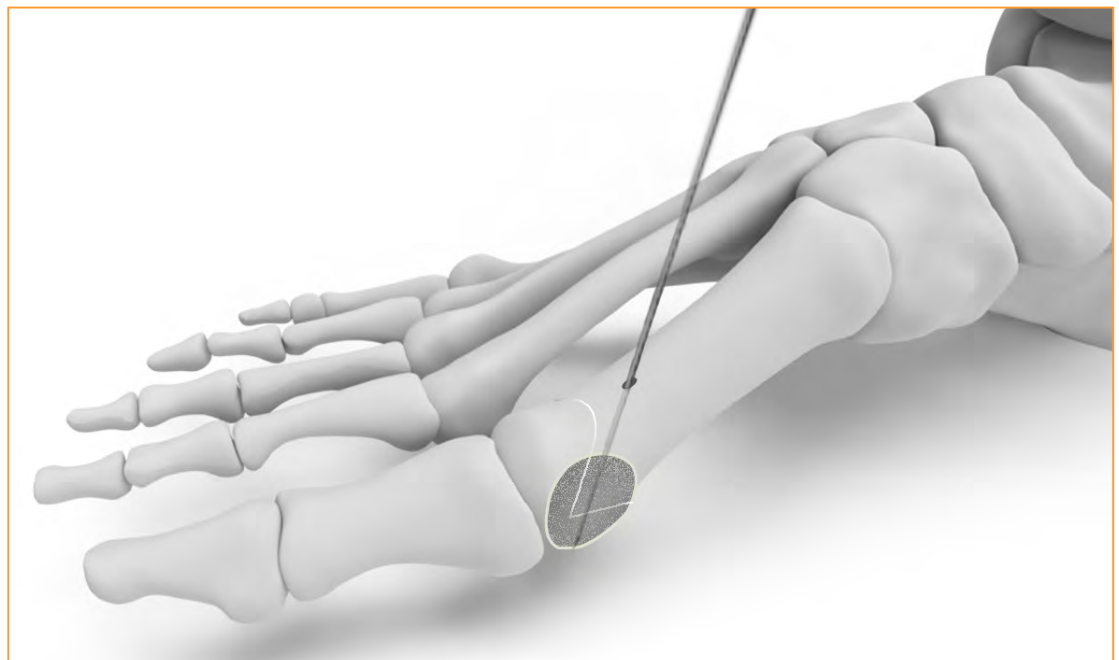


Modular Tray

*Find the Max FT Surgical Technique Guide at fusionorthopedics.com/library

**1**

Resect the medial eminence and insert a K-wire into the center of the metatarsal head. Perform a V-shaped osteotomy in the distal aspect of the first metatarsal with the apex at the wire.

**2**

After translating the capital fragment laterally to correct the deformity, introduce the appropriate sized K-wire aiming at the center of the metatarsal head. Insert the K-wire on power into the distal metatarsal.

For headed screws, countersinking should always be applied BEFORE screw length measurement.



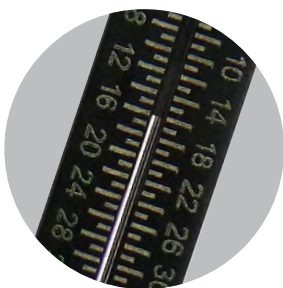
3

To minimize irritation where soft tissue coverage is minimal, slide the appropriately sized countersink over the guide wire until the tip contacts bone and rotate back and forth to create the necessary recess in the bone.



4

Slide the depth gauge over the K-wire until it contacts bone and determine the length of the screw by examining the end of the wire in relation to the graduated laser marks. If the depth gauge is not placed perpendicular to the bone surface, the measurement could be influenced by 1mm-2mm.

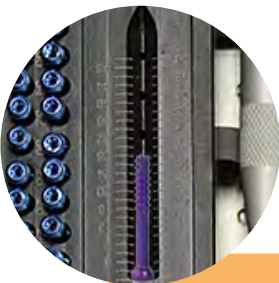


Despite the screw being self drilling, in certain situations or when desiring an oblique approach, drilling may be necessary



5

Especially in dense cortical bone, pre-drilling the near cortex is recommended to reduce the axial force necessary to insert the screw. Slide the corresponding calibrated drill bit over the K-wire and overdrill the K-wire.

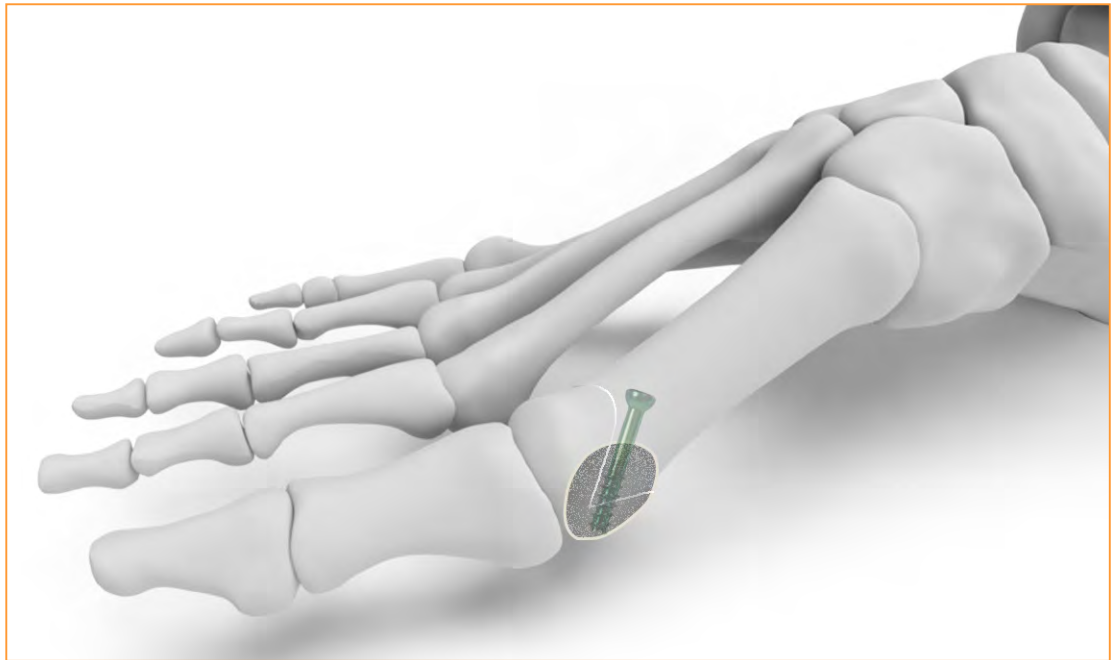


Verify screw length with built in measurement tool on tray.



6

For screw insertion, remove the correct sized cortical screw from the screw block and slide over the K-wire. Load the corresponding Torx Driver onto the Ratcheting Handle. Drive the screw into bone until the desired compression is achieved by turning the driver clockwise. 2-3 finger tightness is recommended. After final insertion remove the driver and verify screw position with fluoroscopy. After final position has been verified, remove and discard the K-wire. Resect the remaining head and neck prominence.



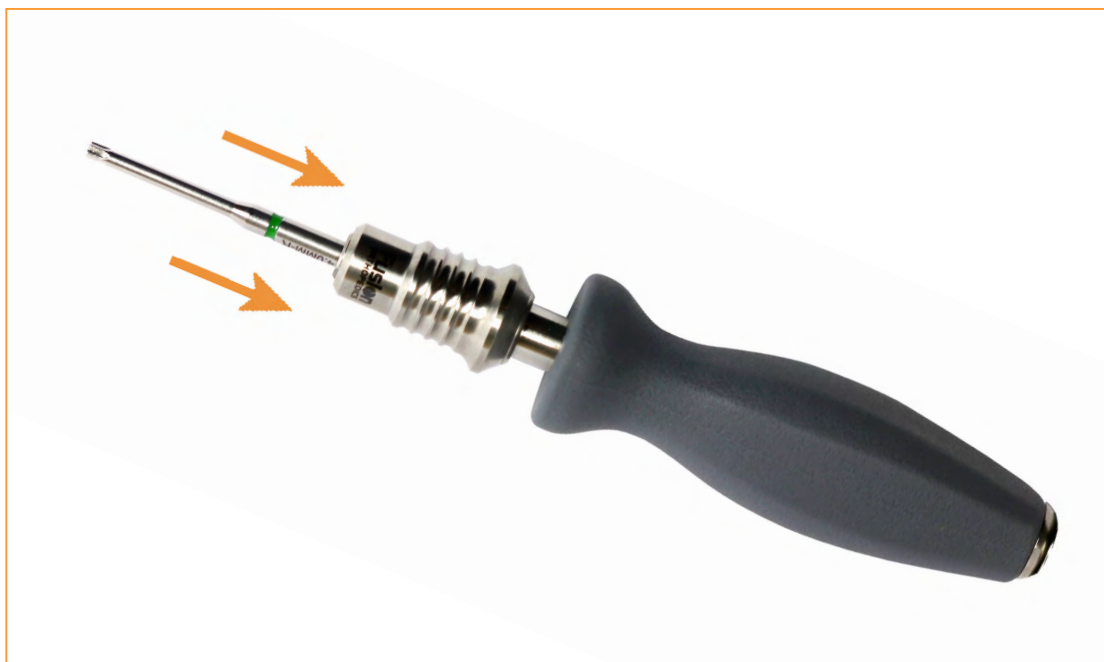
7

After final insertion remove the driver and verify screw position with fluroscopy. After final position has been verified, remove and discard the K-wire and resect the remaining metatarsal head and neck prominence.



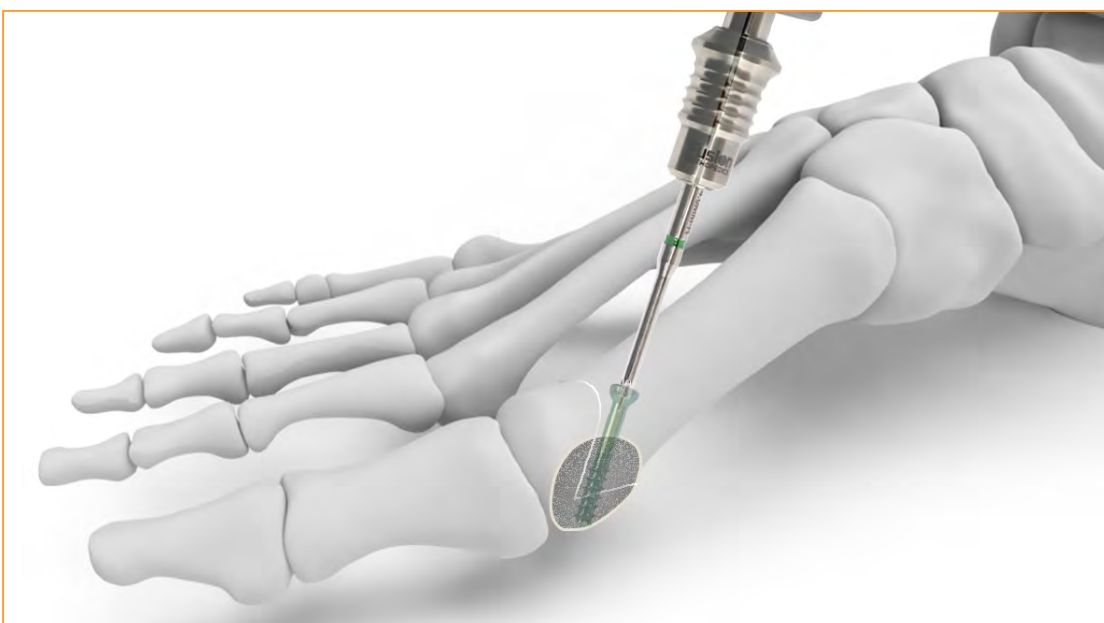
8

If additional fixation is required, repeat steps 2-7.



1

To utilize the FuzeFix Removal System, Insert the Removal Driver on to the Non-Ratcheting Handle.



2

Place the torx driver interface into the screw head and introduce the Removal Rod through the cannulation of the handle, driver, and 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.



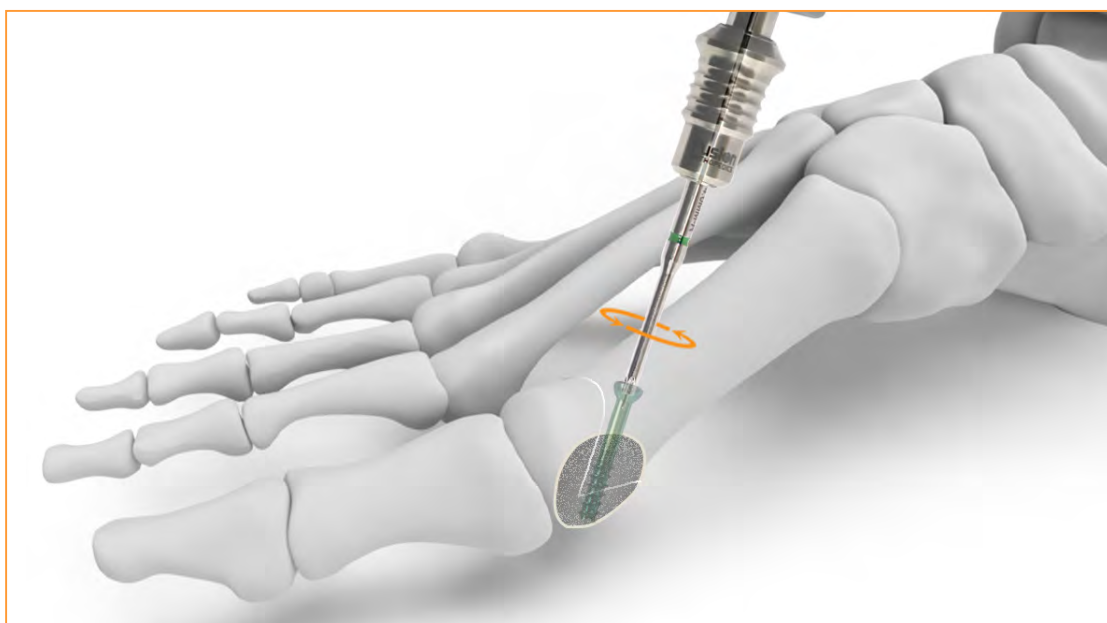
Before



After

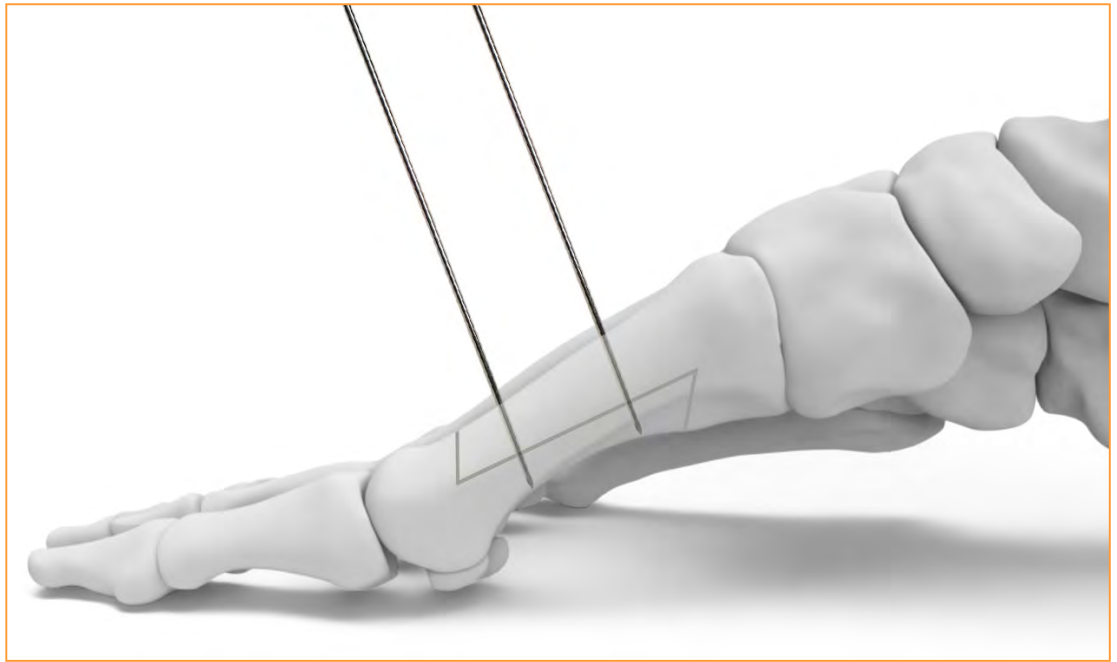
**3**

Twist the back of the removal driver in a clockwise direction to engage the threads and lock the screw onto the assembly.

**4**

Remove the screw rotating counter-clockwise, utilizing the counter pressure provided by the assembly.

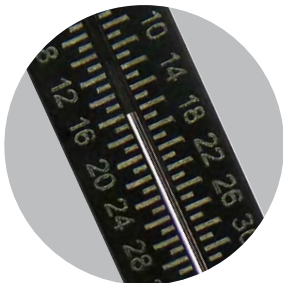
If removal of the implant is required due to revision or failure of the device, the surgeon should contact Fusion Orthopedics using the contact information found at the end of this manual to receive instructions for returning the explanted device for investigation.

**1**

Perform a Scarf Osteotomy in the medial aspect of the first metatarsal and insert the appropriately sized K-wires on power into the desired locations of the first metatarsal to achieve bicortical fixation across the osteotomy.

**2**

Slide the depth gauge over the K-wire until it contacts bone and determine the length of the screw by examining the end of the wire in relation to the graduated laser marks. If the depth gauge is not placed perpendicular to the bone surface, the measurement may be influenced by 1mm- 2mm.



For headless screws, countersinking should always be applied AFTER screw length measurement

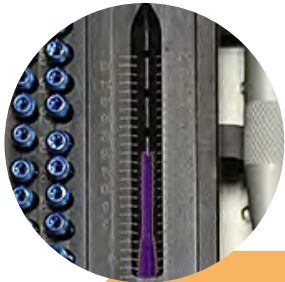
**3**

To minimize irritation where soft tissue coverage is minimal, slide the appropriately sized Proximal Reamer over the guide wire until the tip contacts bone and rotate back and forth to create the necessary recess in the bone.

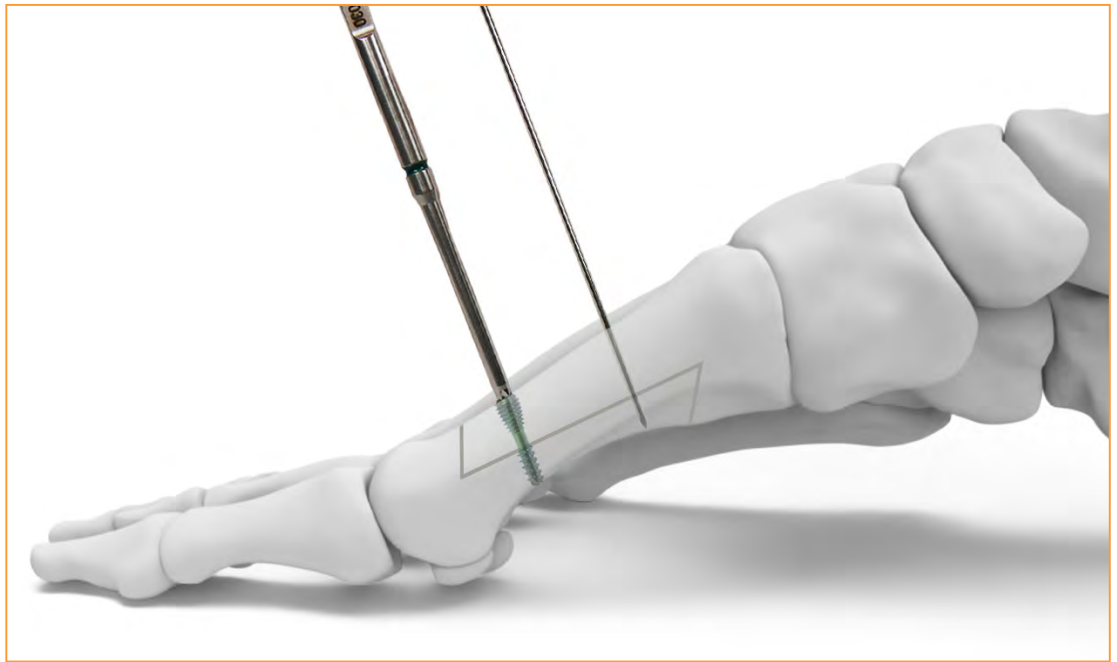
Despite the screw being self drilling, in certain situations or when desiring an oblique approach drilling may be necessary. Pre-drilling near the cortex is recommended to prevent splitting/cracking of the cortical shell

**4**

Especially in dense cortical bone, pre-drilling the near cortex is recommended to reduce the axial force necessary to insert the screw. Slide the corresponding calibrated drill bit over the K-wire and overdrill the K-wire through the proximal and distal cortices.

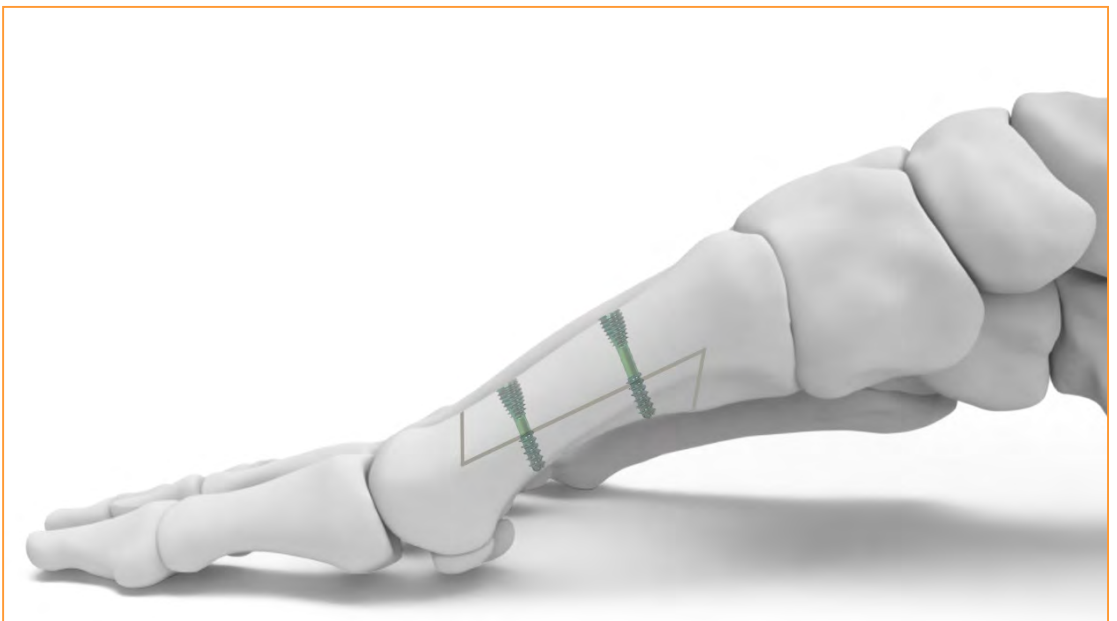


Verify screw length with built in measurement tool on tray.



5

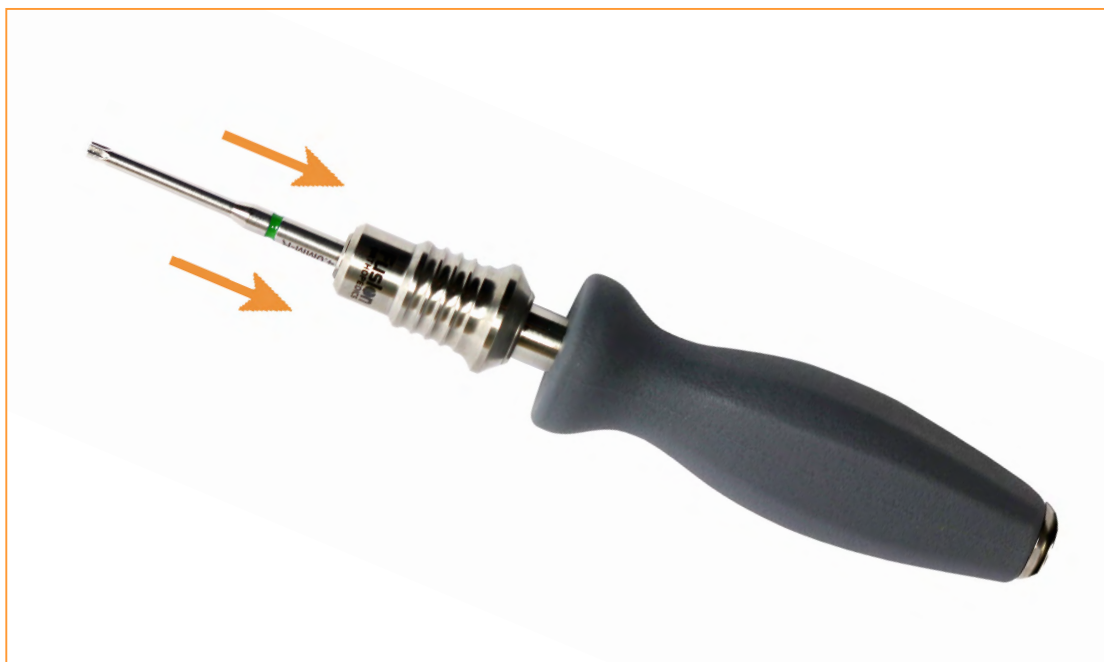
For screw insertion, remove the correct sized screw from the screw block and slide over the K-wire. Load the corresponding torx driver onto the handle. Drive the screw into bone until the desired compression is achieved by turning the driver clockwise. 2-3 finger tightness is recommended.



If additional fixation is required, repeat steps 2-5.

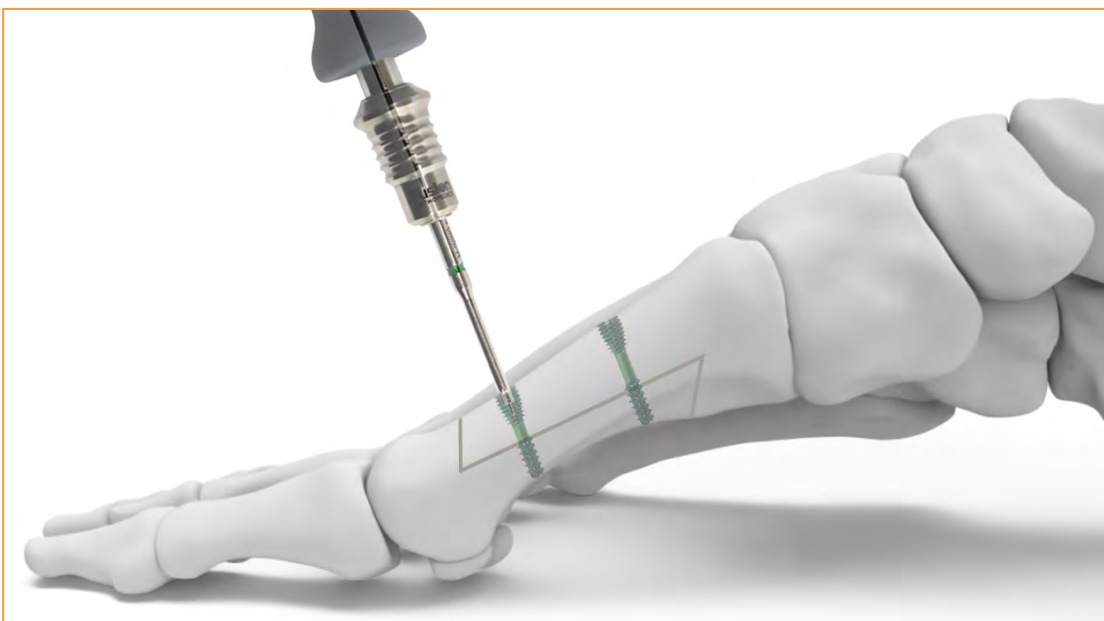
6

After final insertion remove the driver and verify screw position with fluoroscopy. After final position has been verified, remove and discard the K-wire and resect the remaining metatarsal head and neck prominence.



1

To utilize the FuzeFix Removal System, Insert the Removal Driver on to the Non-Ratcheting Handle.



2

Place the torx driver interface into the screw head and introduce the Removal Rod through the cannulation of the handle, driver, and 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.



Before

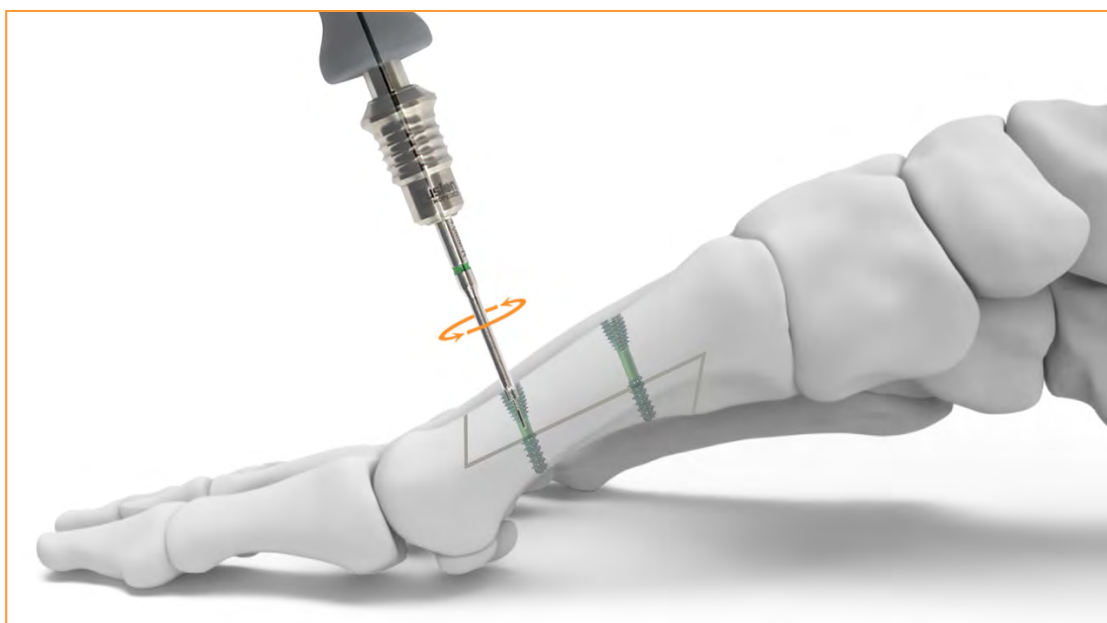


After



3


Twist the back of the removal driver in a clockwise direction to engage the threads and lock the screw onto the assembly.





4


Remove the screw rotating counter-clockwise, utilizing the counter pressure provided by the assembly.


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.


Headed 2.0	Description	Non-Sterile
	HD 2.0mm x 8mm	FX-HD-2008
	HD 2.0mm x 10mm	FX-HD-2010
	HD 2.0mm x 12mm	FX-HD-2012
	HD 2.0mm x 14mm	FX-HD-2014
	HD 2.0mm x 16mm	FX-HD-2016
	HD 2.0mm x 18mm	FX-HD-2018
	HD 2.0mm x 20mm	FX-HD-2020
	HD 2.0mm x 22mm	FX-HD-2022
	HD 2.0mm x 24mm	FX-HD-2024
	HD 2.0mm x 26mm	FX-HD-2026
	HD 2.0mm x 28mm	FX-HD-2028
	HD 2.0mm x 30mm	FX-HD-2030
	HD 2.0mm x 35mm	FX-HD-2035
	HD 2.0mm x 40mm	FX-HD-2040
	HD 2.0mm x 45mm	FX-HD-2045
HD 2.0mm x 50mm	FX-HD-2050	

Headed 2.5	Description	Non-Sterile
	HD 2.5mm x 8mm	FX-HD-2508
	HD 2.5mm x 10mm	FX-HD-2510
	HD 2.5mm x 12mm	FX-HD-2512
	HD 2.5mm x 14mm	FX-HD-2514
	HD 2.5mm x 16mm	FX-HD-2516
	HD 2.5mm x 18mm	FX-HD-2518
	HD 2.5mm x 20mm	FX-HD-2520
	HD 2.5mm x 22mm	FX-HD-2522
	HD 2.5mm x 24mm	FX-HD-2524
	HD 2.5mm x 26mm	FX-HD-2526
	HD 2.5mm x 28mm	FX-HD-2528
	HD 2.5mm x 30mm	FX-HD-2530
	HD 2.5mm x 35mm	FX-HD-2535
	HD 2.5mm x 40mm	FX-HD-2540
	HD 2.5mm x 45mm	FX-HD-2545
HD 2.5mm x 50mm	FX-HD-2550	

Headed 3.0	Description	Non-Sterile
	HD 3.0mm x 10mm	FX-HD-3010
	HD 3.0mm x 12mm	FX-HD-3012
	HD 3.0mm x 14mm	FX-HD-3014
	HD 3.0mm x 16mm	FX-HD-3016
	HD 3.0mm x 18mm	FX-HD-3018
	HD 3.0mm x 20mm	FX-HD-3020
	HD 3.0mm x 22mm	FX-HD-3022
	HD 3.0mm x 24mm	FX-HD-3024
	HD 3.0mm x 26mm	FX-HD-3026
	HD 3.0mm x 28mm	FX-HD-3028
	HD 3.0mm x 30mm	FX-HD-3030
	HD 3.0mm x 32mm	FX-HD-3032
	HD 3.0mm x 34mm	FX-HD-3034
	HD 3.0mm x 36mm	FX-HD-3036
	HD 3.0mm x 38mm	FX-HD-3038
	HD 3.0mm x 40mm	FX-HD-3040
HD 3.0mm x 45mm	FX-HD-3045	
HD 3.0mm x 50mm	FX-HD-3050	

Headed 4.0	Description	Non-Sterile
	HD 4.0mm x 12mm	FX-HD-4012
	HD 4.0mm x 14mm	FX-HD-4014
	HD 4.0mm x 16mm	FX-HD-4016
	HD 4.0mm x 18mm	FX-HD-4018
	HD 4.0mm x 20mm	FX-HD-4020
	HD 4.0mm x 22mm	FX-HD-4022
	HD 4.0mm x 24mm	FX-HD-4024
	HD 4.0mm x 26mm	FX-HD-4026
	HD 4.0mm x 28mm	FX-HD-4028
	HD 4.0mm x 30mm	FX-HD-4030
	HD 4.0mm x 32mm	FX-HD-4032
	HD 4.0mm x 34mm	FX-HD-4034
	HD 4.0mm x 36mm	FX-HD-4036
	HD 4.0mm x 38mm	FX-HD-4038
	HD 4.0mm x 40mm	FX-HD-4040
	HD 4.0mm x 42mm	FX-HD-4042
HD 4.0mm x 44mm	FX-HD-4044	
HD 4.0mm x 46mm	FX-HD-4046	
HD 4.0mm x 48mm	FX-HD-4048	
HD 4.0mm x 50mm	FX-HD-4050	

Headless 2.0	Description	Non-Sterile
	HL 2.0mm x 8mm	FX-HL-2008
	HL 2.0mm x 10mm	FX-HL-2010
	HL 2.0mm x 12mm	FX-HL-2012
	HL 2.0mm x 14mm	FX-HL-2014
	HL 2.0mm x 16mm	FX-HL-2016
	HL 2.0mm x 18mm	FX-HL-2018
	HL 2.0mm x 20mm	FX-HL-2020
	HL 2.0mm x 22mm	FX-HL-2022
	HL 2.0mm x 24mm	FX-HL-2024
	HL 2.0mm x 26mm	FX-HL-2026
	HL 2.0mm x 28mm	FX-HL-2028
	HL 2.0mm x 30mm	FX-HL-2030
	HL 2.0mm x 35mm	FX-HL-2035
	HL 2.0mm x 40mm	FX-HL-2040
	HL 2.0mm x 45mm	FX-HL-2045
HL 2.0mm x 50mm	FX-HL-2050	

Headless 2.5	Description	Non-Sterile
	HL 2.5mm x 10mm	FX-HL-2510
	HL 2.5mm x 12mm	FX-HL-2512
	HL 2.5mm x 14mm	FX-HL-2514
	HL 2.5mm x 16mm	FX-HL-2516
	HL 2.5mm x 18mm	FX-HL-2518
	HL 2.5mm x 20mm	FX-HL-2520
	HL 2.5mm x 22mm	FX-HL-2522
	HL 2.5mm x 24mm	FX-HL-2524
	HL 2.5mm x 26mm	FX-HL-2526
	HL 2.5mm x 28mm	FX-HL-2528
	HL 2.5mm x 30mm	FX-HL-2530
	HL 2.5mm x 35mm	FX-HL-2535
	HL 2.5mm x 40mm	FX-HL-2540
	HL 2.5mm x 45mm	FX-HL-2545
	HL 2.5mm x 50mm	FX-HL-2550



Headless 3.0	Description	Non-Sterile
	HL 3.0mm x 10mm	FX-HL-3010
	HL 3.0mm x 12mm	FX-HL-3012
	HL 3.0mm x 14mm	FX-HL-3014
	HL 3.0mm x 16mm	FX-HL-3016
	HL 3.0mm x 18mm	FX-HL-3018
	HL 3.0mm x 20mm	FX-HL-3020
	HL 3.0mm x 22mm	FX-HL-3022
	HL 3.0mm x 24mm	FX-HL-3024
	HL 3.0mm x 26mm	FX-HL-3026
	HL 3.0mm x 28mm	FX-HL-3028
	HL 3.0mm x 30mm	FX-HL-3030
	HL 3.0mm x 35mm	FX-HL-3035
	HL 3.0mm x 40mm	FX-HL-3040
	HL 3.0mm x 45mm	FX-HL-3045
	HL 3.0mm x 50mm	FX-HL-3050



Headless 4.0	Description	Non-Sterile
	HL 4.0mm x 12mm	FX-HL-4012
	HL 4.0mm x 14mm	FX-HL-4014
	HL 4.0mm x 16mm	FX-HL-4016
	HL 4.0mm x 18mm	FX-HL-4018
	HL 4.0mm x 20mm	FX-HL-4020
	HL 4.0mm x 22mm	FX-HL-4022
	HL 4.0mm x 24mm	FX-HL-4024
	HL 4.0mm x 26mm	FX-HL-4026
	HL 4.0mm x 28mm	FX-HL-4028
	HL 4.0mm x 30mm	FX-HL-4030
	HL 4.0mm x 32mm	FX-HL-4032
	HL 4.0mm x 34mm	FX-HL-4034
	HL 4.0mm x 36mm	FX-HL-4036
	HL 4.0mm x 38mm	FX-HL-4038
	HL 4.0mm x 40mm	FX-HL-4040
	HL 4.0mm x 42mm	FX-HL-4042
	HL 4.0mm x 44mm	FX-HL-4044
	HL 4.0mm x 46mm	FX-HL-4046
	HL 4.0mm x 48mm	FX-HL-4048
	HL 4.0mm x 50mm	FX-HL-4050

Instruments	Description	Non-Sterile
	Calibrated Drill Cannulated 1.7mm	CD-FX-1017
	Calibrated Drill Cannulated 1.9mm	CD-FX-1019
	Calibrated Drill Cannulated 2.1mm	CD-FX-1021
	Calibrated Drill Cannulated 2.6mm	CD-FX-1026
	Proximal Reamer Headless 2.0mm	CD-FX-2520
	Proximal Reamer Headless 2.5mm	CD-FX-2525
	Proximal Reamer Headless 3.0mm	CD-FX-2530
	Proximal Reamer Headless 4.0mm	CD-FX-2540
	K-Wire Standard 1.1mm	CD-FX-0011
	K-Wire Standard 0.9mm	CD-FX-0009
	K-Wire Threaded 1.1mm	CD-FX-0511
	K-Wire Threaded 0.9mm	CD-FX-0509
	Driver Torx 2.0mm	CD-FX-3020
	Driver Torx 2.5mm	CD-FX-3025
	Driver Torx 3.0mm	CD-FX-3030
	Driver Torx 4.0mm	CD-FX-3040
	Removal Driver Torx 3.0mm	CD-FX-9030
	Removal Driver Torx 4.0mm	CD-FX-9040
	Screw Extractor Rod 3.0mm and 4.0mm	CD-FX-6040
	Depth Gauge Forefoot Headless	TN-FX-8020
	Screw Holding Forceps Small	TN-FX-9010
	Driver Handle Ratcheting	TN-FX-6010
	Driver Handle Non-Ratcheting	TN-FX-6020

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. Fusion Orthopedics does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery. The information presented is intended to demonstrate the breadth of Fusion Orthopedics' product offerings. A surgeon must always refer to the package insert, product label, and instructions for use before using any Fusion Orthopedics product. Products 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.

FDA Cleared

All Rights Reserved. FuzeFix is
a Trademark of Fusion Orthopedics USA, LLC.

STG001

Rev 1



4135 South Power Road, #118

Mesa, Arizona 85212, U.S.A.

800-403-6876

info@fusionorthopedics.com

fusionorthopedics.com