

# FuzeFix

Large System



**Fusion**  
ORTHOPEDICS

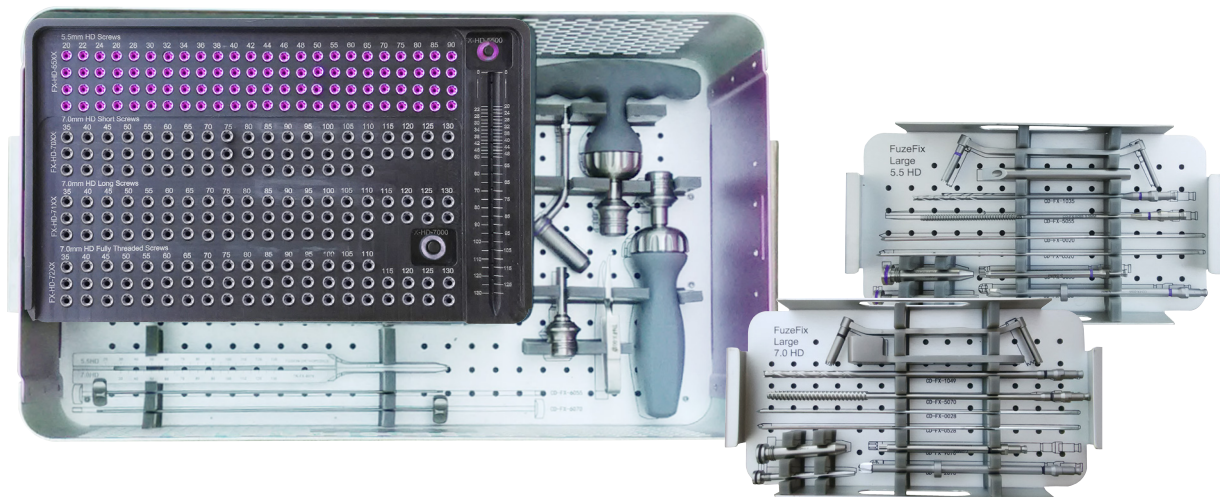
Surgical Technique

## FuzeFix Large System

Confidential

### DESCRIPTION OF THE MEDICAL DEVICE

The FuzeFix Large 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 Large System includes Large Cannulated Screws, and Large Headless Screws. The included cannulated, threaded bone screws are offered in 5.5mm and 7.0mm diameters with lengths ranging from 20mm to 130mm. System instrumentation includes drill bits, reamers, taps, guide wires, guides, depth gauges, screw removal tools, removal rods, driver shafts, and 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, taps, and K-wires.



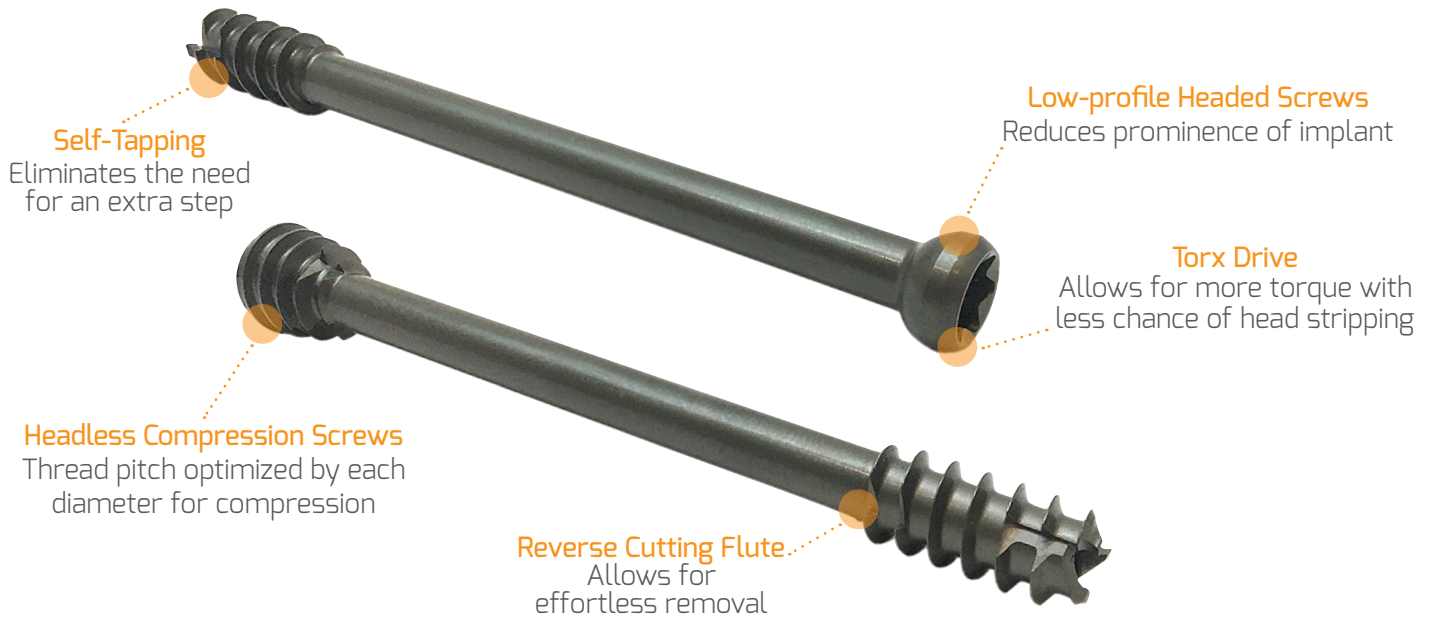
## INDICATIONS FOR USE

The FuzeFix Large 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. The FuzeFix Large System is indicated for: joint reconstructions, multiple fragment joint reconstructions, multiple fragment joint fractures, simple metaphyseal fractures, fractures of the wrist, ankle, elbow, and shoulder, metatarsal fractures and other fractures of the foot, ligament fixation of the proximal humerus, malleolar fractures, navicular fractures, fractures of the calcaneus, fractures of the talus, arthrodesis of the ankle joint, and fractures of the tarsal region. The devices and implants are not intended for use in the spine.

## 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.


## System Basics



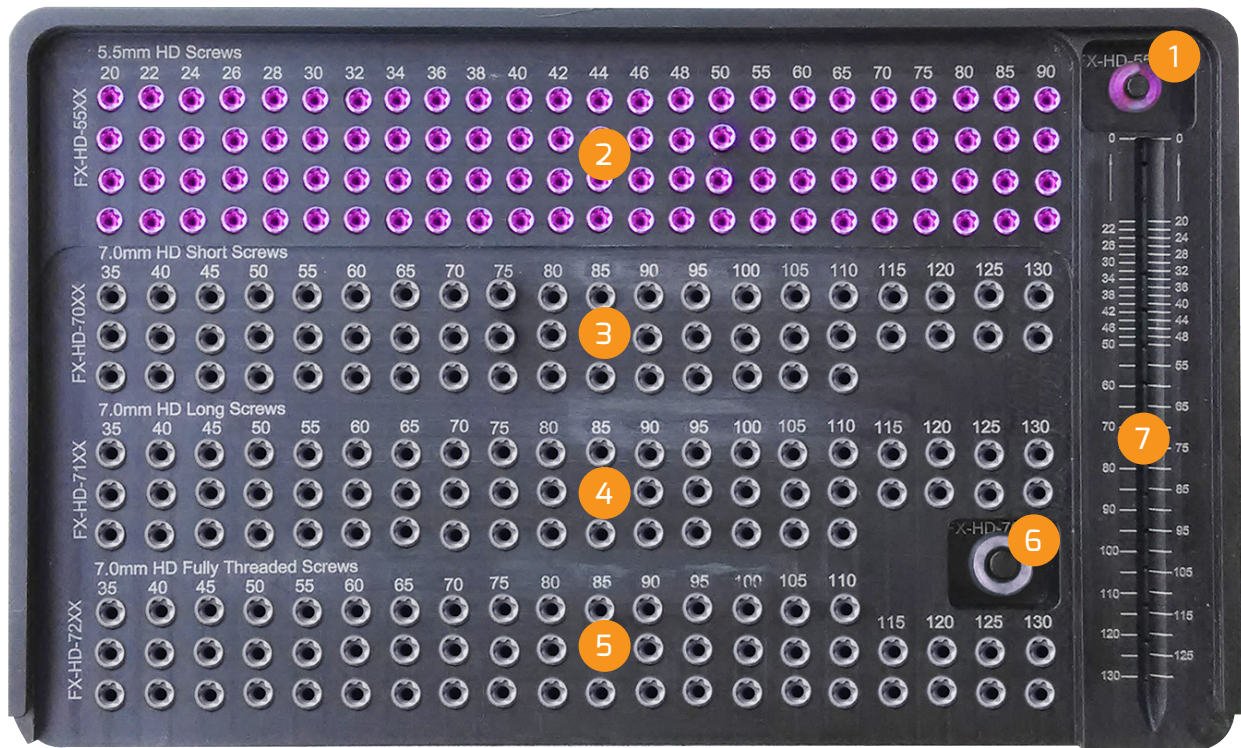
## A Revolutionary, Time-Saving Design

Our instruments are precision engineered to be ergonomic and efficient. The Innovative FuzeFix Screw Removal System offers surgeons the option to quickly remove the screw no matter the bone quality by providing counter pressure without the use of elevators or forceps.



Screw Set-Up	Diameter	Color	K-Wire	Length
	5.5mm	Purple	2.0mm	20mm - 90mm
	7.0mm	Grey	2.8mm	35mm - 130mm

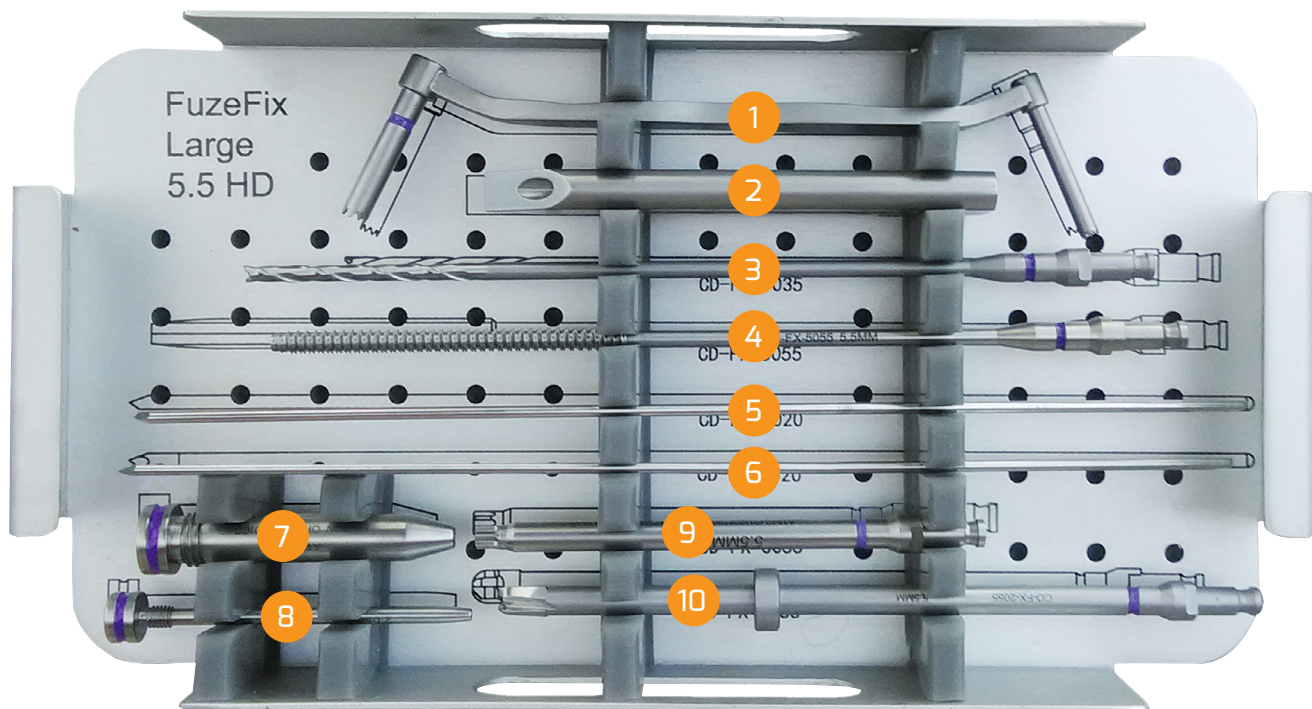
# TRAY CONTENTS



Description	
1	HD 5.5mm Washer
2	HD 5.5mm Screws
3	HD 7.0mm Short Threaded Screws
4	HD 7.0mm Long Threaded Screws
5	HD 7.0mm Full Threaded Screws
6	HD 7.0mm Washer
7	Measuring Gauge

## Layer 1

## 5.5mm Instruments



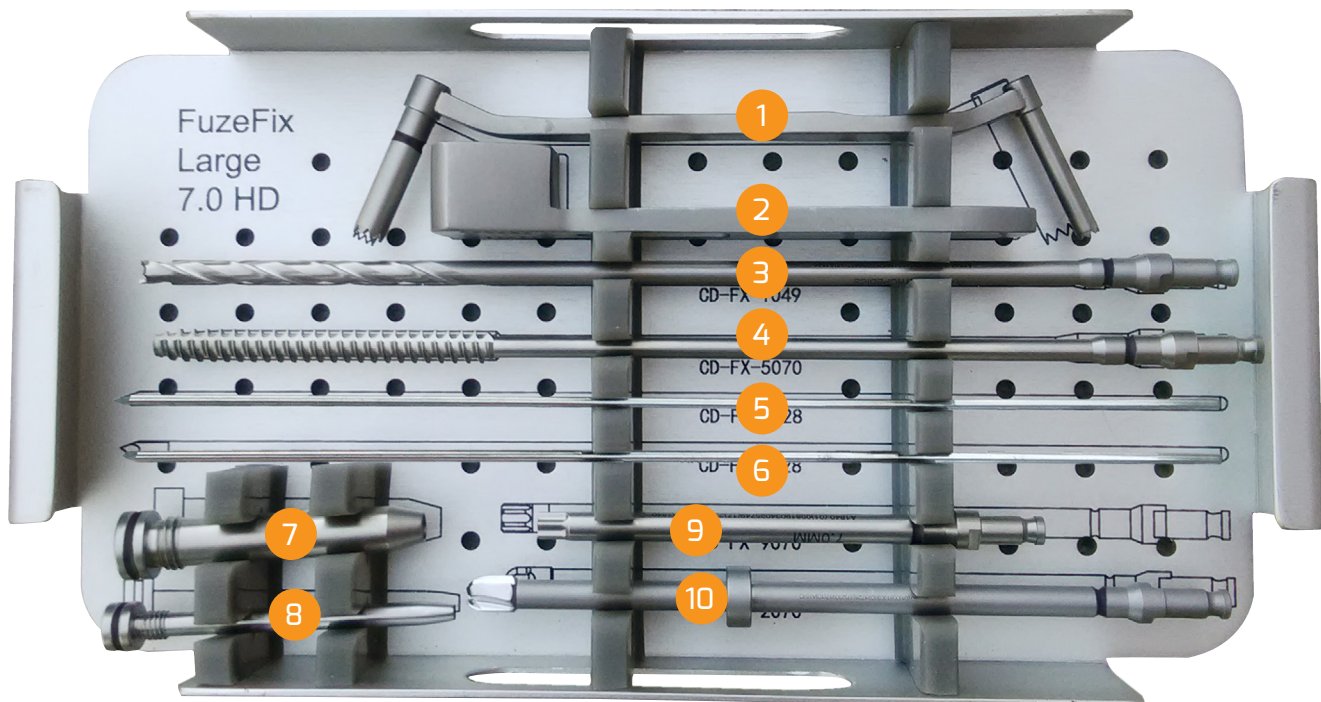
## Description

- | Number | Description                       |
|--------|-----------------------------------|
| 1      | 5.5mm Guide 3.6mm and 2.0mm       |
| 2      | Parallel Wire Guide               |
| 3      | Calibrated Drill Cannulated 3.6mm |
| 4      | Tap Cannulated 5.5mm*             |
| 5      | K-Wire Standard 2.0mm             |
| 6      | K-Wire Threaded 2.0mm             |
| 7      | Drill Sleeve 5.5mm (3.6mm)        |
| 8      | Wire Sleeve 2.0mm                 |
| 9      | Driver Torx 5.0mm                 |
| 10     | Proximal Reamer Cannulated 5.5mm* |

\* Instrument style varies between Headed and Headless tray configurations.

## Layer 2

## 7.0mm Instruments



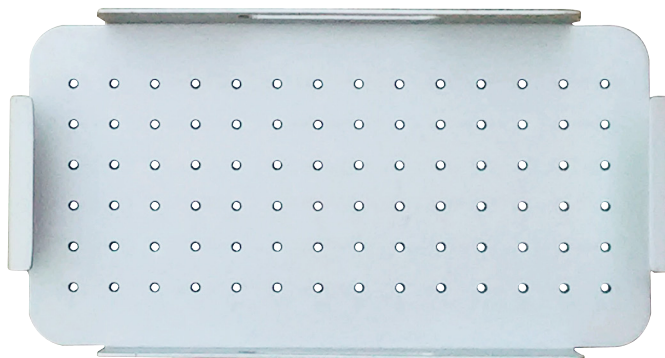
## Description

- |    |                                   |
|----|-----------------------------------|
| 1  | 7.0mm Guide 4.9mm and 2.8mm       |
| 2  | Parallel Wire Guide*              |
| 3  | Calibrated Drill Cannulated 4.9mm |
| 4  | Tap Cannulated 7.0mm*             |
| 5  | K-Wire Standard 2.8mm             |
| 6  | K-Wire Threaded 2.8mm             |
| 7  | Drill Sleeve 5.5mm (3.6mm)        |
| 8  | Wire Sleeve 2.0mm                 |
| 9  | Driver Torx 7.0mm                 |
| 10 | Proximal Reamer Cannulated 7.0mm* |

\* Instrument style varies between Headed and Headless tray configurations.

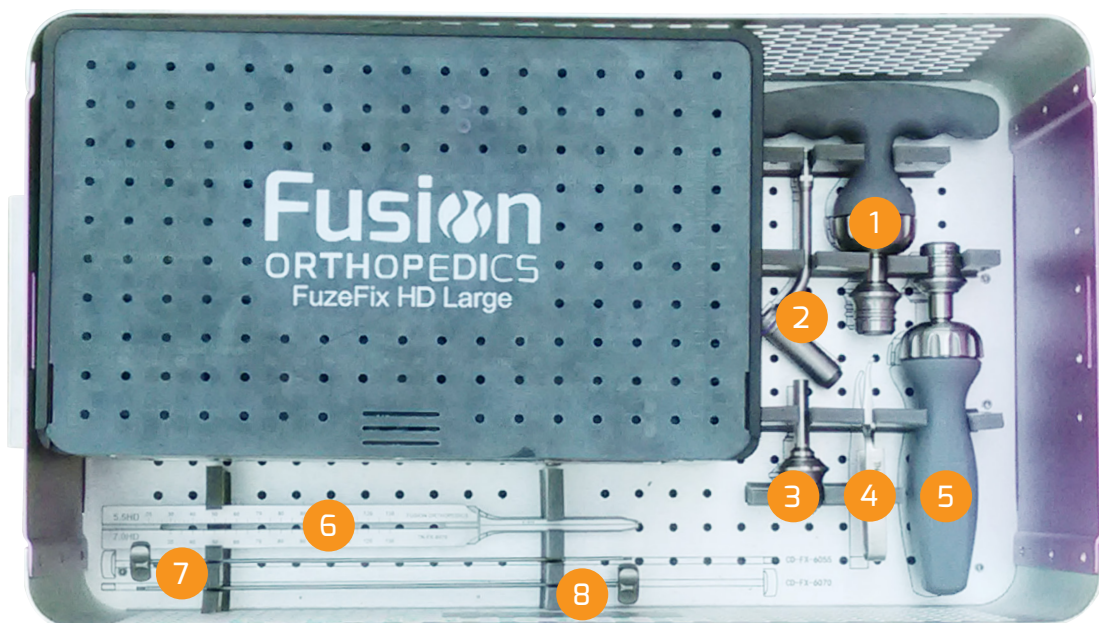
## Layer 3

## Utility Basin



## Layer 4

## Tray Instruments



Description	
1	T-Handle Non-Ratcheting
2	FX Sleeve 5.5mm and 7.0mm
3	Hudson to Jacobs Adapter
4	Screw Holding Forceps Large
5	Driver Handle Ratcheting Hudson
6	Depth Gauge HD 5.5mm and 7.0mm*
7	Screw Extractor Rod 5.5mm
8	Screw Extractor Rod 7.0mm

\* Instrument style varies between Headed and Headless tray configurations.



1

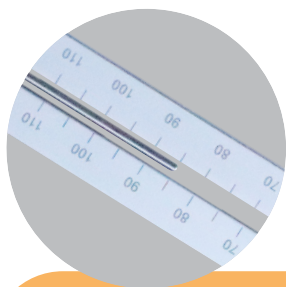
Position the 2.8mm Guide and insert a K-wire 2.8mm through the guide to the appropriate depth under fluoroscopy. Place an additional K-wire 2.8mm as necessary. Remove the guide after positioning has been confirmed.



2

To minimize irritation where soft tissue coverage is minimal and to provide proper implant placement, slide the 7.0mm Proximal Reamer over the K-wire until the tip contacts bone and rotate back and forth until the notches are flush with the bone surface.

For Headed Screws, reaming should always be applied BEFORE screw length measurement. For Headless Screws, reaming should always be applied AFTER screw length measurement.



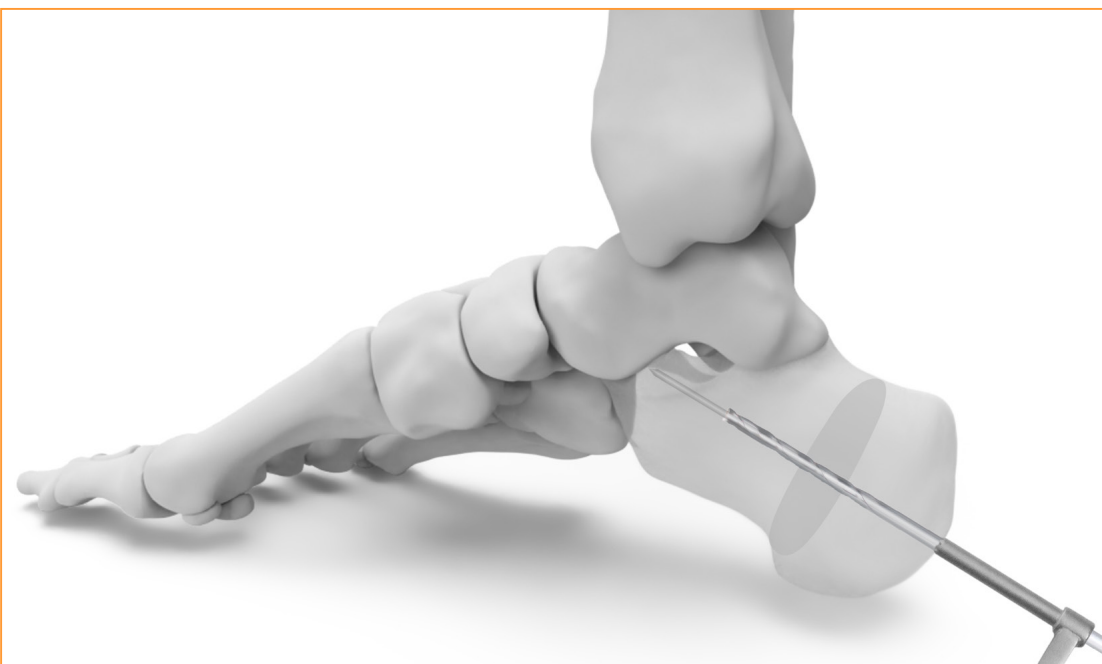
For Headed Screws, reaming should always be applied BEFORE screw length measurement. For Headless Screws, reaming should always be applied AFTER screw length measurement.



3

Slide the Depth Gauge over the K-wire 2.8mm until it contacts bone. Determine the length of the screw by examining the end of the wire in relation to the marks on the depth gauge. If not placed perpendicular to the bone surface the measurement can be influenced by 1mm-2mm.

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



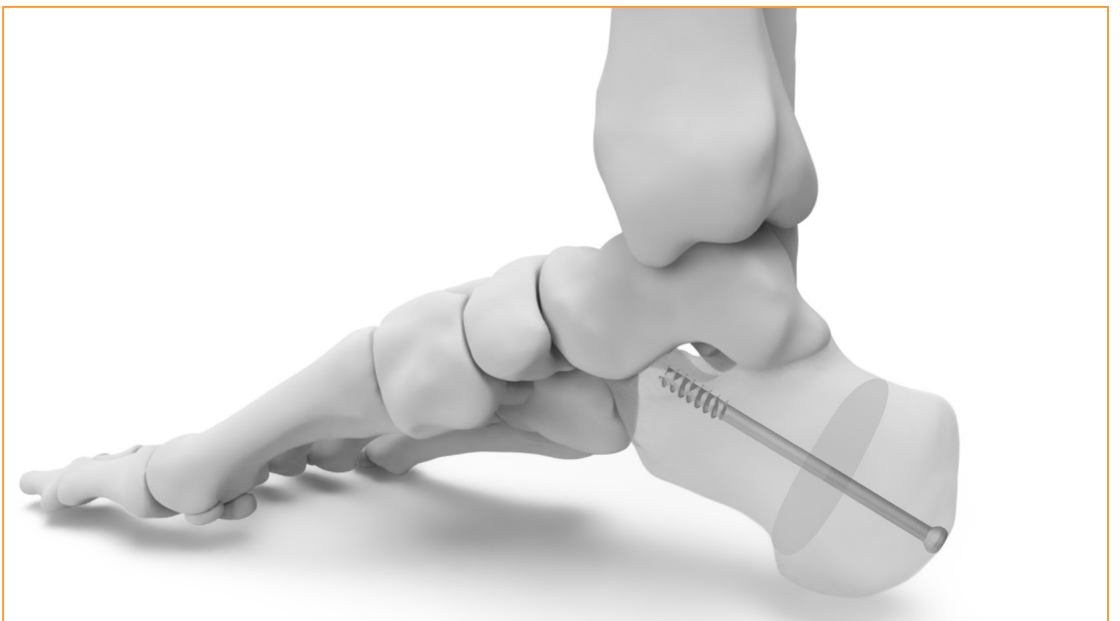
4

Especially in dense cortical bone, pre-drilling the near cortex is recommended to reduce the axial force necessary to insert the screw. Slide the 7.0mm Calibrated Drill over the K-wire and overdrill the K-wire through the proximal cortex to the appropriate depth.



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 and insert the screw into the bone until the desired compression has been achieved.



6

After final insertion, remove the driver and verify screw position with fluoroscopy. Once final position has been confirmed, remove the K-wire. Repeat as necessary for additional screws. Finally, proceed to normal surgical closure.



1

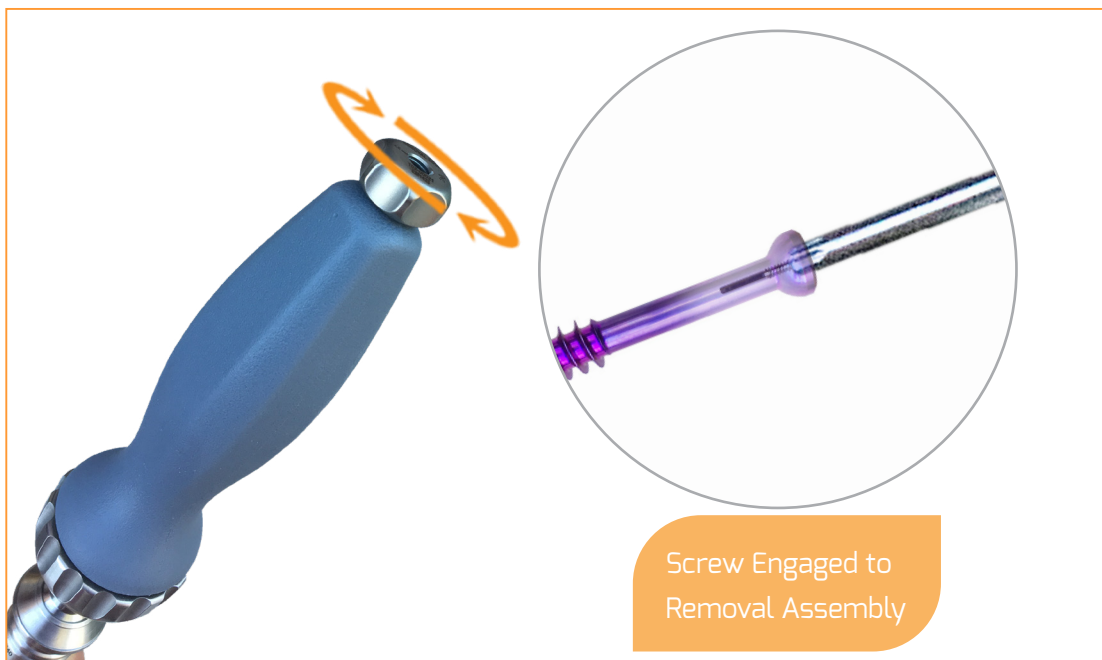
To utilize the FuzeFix Removal System, Insert the Removal Driver on to the Non-Ratcheting Handle.



2

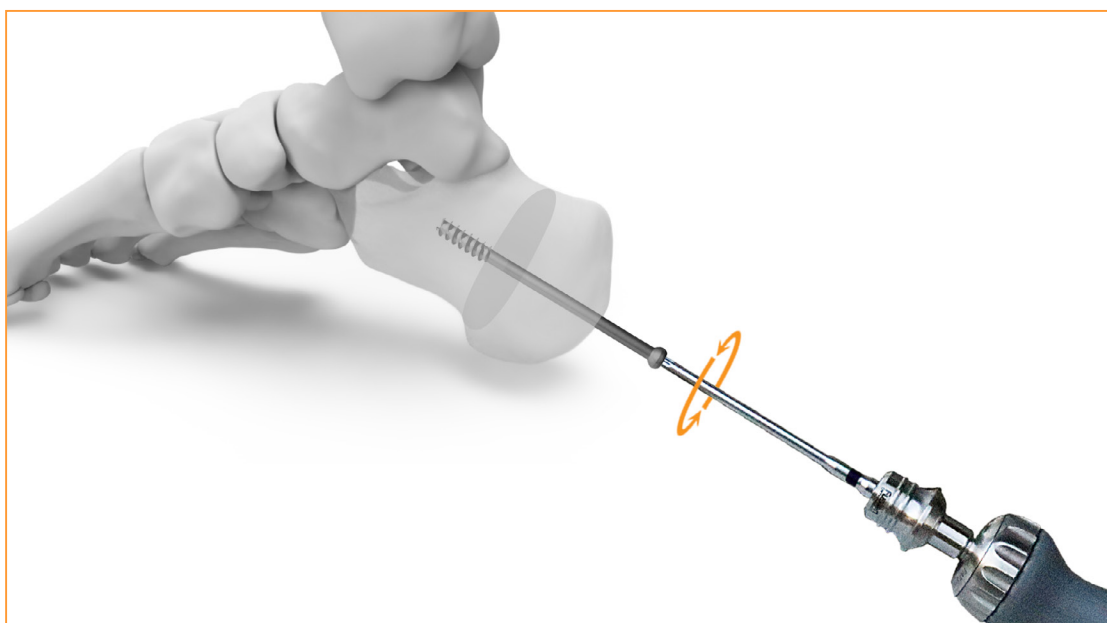
Place the torx driver interface into the head of the screw to be removed. Introduce the Removal Rod through the cannulation of the handle, driver, and screw.

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.



3

Twist the tensioning dial of the removal Rod 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.



HD 5.5mm	Description	Non-Sterile
HD 5.5mm x 20mm		FX-HD-5520
HD 5.5mm x 22mm		FX-HD-5522
HD 5.5mm x 24mm		FX-HD-5524
HD 5.5mm x 26mm		FX-HD-5526
HD 5.5mm x 28mm		FX-HD-5528
HD 5.5mm x 30mm		FX-HD-5530
HD 5.5mm x 32mm		FX-HD-5532
HD 5.5mm x 34mm		FX-HD-5534
HD 5.5mm x 36mm		FX-HD-5536
HD 5.5mm x 38mm		FX-HD-5538
HD 5.5mm x 40mm		FX-HD-5540
HD 5.5mm x 42mm		FX-HD-5542
HD 5.5mm x 44mm		FX-HD-5544
HD 5.5mm x 46mm		FX-HD-5546
HD 5.5mm x 48mm		FX-HD-5548
HD 5.5mm x 50mm		FX-HD-5550
HD 5.5mm x 55mm		FX-HD-5555
HD 5.5mm x 60mm		FX-HD-5560
HD 5.5mm x 65mm		FX-HD-5565
HD 5.5mm x 70mm		FX-HD-5570
HD 5.5mm x 75mm		FX-HD-5575
HD 5.5mm x 80mm		FX-HD-5580
HD 5.5mm x 85mm		FX-HD-5585
HD 5.5mm x 90mm		FX-HD-5590



HL 5.5mm	Description	Non-Sterile
HL 5.5mm x 20mm		FX-HL-5520
HL 5.5mm x 22mm		FX-HL-5522
HL 5.5mm x 24mm		FX-HL-5524
HL 5.5mm x 26mm		FX-HL-5526
HL 5.5mm x 28mm		FX-HL-5528
HL 5.5mm x 30mm		FX-HL-5530
HL 5.5mm x 32mm		FX-HL-5532
HL 5.5mm x 34mm		FX-HL-5534
HL 5.5mm x 36mm		FX-HL-5536
HL 5.5mm x 38mm		FX-HL-5538
HL 5.5mm x 40mm		FX-HL-5540
HL 5.5mm x 42mm		FX-HL-5542
HL 5.5mm x 44mm		FX-HL-5544
HL 5.5mm x 46mm		FX-HL-5546
HL 5.5mm x 48mm		FX-HL-5548
HL 5.5mm x 50mm		FX-HL-5550
HL 5.5mm x 55mm		FX-HL-5555
HL 5.5mm x 60mm		FX-HL-5560
HL 5.5mm x 65mm		FX-HL-5565
HL 5.5mm x 70mm		FX-HL-5570
HL 5.5mm x 75mm		FX-HL-5575
HL 5.5mm x 80mm		FX-HL-5580
HL 5.5mm x 85mm		FX-HL-5585
HL 5.5mm x 90mm		FX-HL-5590



HD 7.0mm	Description	Non-Sterile
HD 7.0mm x 30mm Short Thread		FX-HD-7030
HD 7.0mm x 35mm Short Thread		FX-HD-7035
HD 7.0mm x 40mm Short Thread		FX-HD-7040
HD 7.0mm x 45mm Short Thread		FX-HD-7045
HD 7.0mm x 50mm Short Thread		FX-HD-7050
HD 7.0mm x 55mm Short Thread		FX-HD-7055
HD 7.0mm x 60mm Short Thread		FX-HD-7060
HD 7.0mm x 65mm Short Thread		FX-HD-7065
HD 7.0mm x 70mm Short Thread		FX-HD-7070
HD 7.0mm x 75mm Short Thread		FX-HD-7005
HD 7.0mm x 80mm Short Thread		FX-HD-7080
HD 7.0mm x 85mm Short Thread		FX-HD-7085
HD 7.0mm x 90mm Short Thread		FX-HD-7090
HD 7.0mm x 95mm Short Thread		FX-HD-7091
HD 7.0mm x 100mm Short Thread		FX-HD-7092
HD 7.0mm x 105mm Short Thread		FX-HD-7093
HD 7.0mm x 110mm Short Thread		FX-HD-7094
HD 7.0mm x 115mm Short Thread		FX-HD-7095
HD 7.0mm x 120mm Short Thread		FX-HD-7096
HD 7.0mm x 125mm Short Thread		FX-HD-7097
HD 7.0mm x 130mm Short Thread		FX-HD-7098



HL 7.0mm	Description	Non-Sterile
HL 7.0mm x 30mm Short Thread		FX-HL-7030
HL 7.0mm x 35mm Short Thread		FX-HL-7035
HL 7.0mm x 40mm Short Thread		FX-HL-7040
HL 7.0mm x 45mm Short Thread		FX-HL-7045
HL 7.0mm x 50mm Short Thread		FX-HL-7050
HL 7.0mm x 55mm Short Thread		FX-HL-7055
HL 7.0mm x 60mm Short Thread		FX-HL-7060
HL 7.0mm x 65mm Short Thread		FX-HL-7065
HL 7.0mm x 70mm Short Thread		FX-HL-7070
HL 7.0mm x 75mm Short Thread		FX-HL-7005
HL 7.0mm x 80mm Short Thread		FX-HL-7080
HL 7.0mm x 85mm Short Thread		FX-HL-7085
HL 7.0mm x 90mm Short Thread		FX-HL-7090
HL 7.0mm x 95mm Short Thread		FX-HL-7091
HL 7.0mm x 100mm Short Thread		FX-HL-7092
HL 7.0mm x 105mm Short Thread		FX-HL-7093
HL 7.0mm x 110mm Short Thread		FX-HL-7094
HL 7.0mm x 115mm Short Thread		FX-HL-7095
HL 7.0mm x 120mm Short Thread		FX-HL-7096
HL 7.0mm x 125mm Short Thread		FX-HL-7097
HL 7.0mm x 130mm Short Thread		FX-HL-7098



HDL 7.0mm	Description	Non-Sterile
	HDL 7.0mm x 30mm Long Thread	FX-HD-7130
	HDL 7.0mm x 35mm Long Thread	FX-HD-7135
	HDL 7.0mm x 40mm Long Thread	FX-HD-7140
	HDL 7.0mm x 45mm Long Thread	FX-HD-7145
	HDL 7.0mm x 50mm Long Thread	FX-HD-7150
	HDL 7.0mm x 55mm Long Thread	FX-HD-7155
	HDL 7.0mm x 60mm Long Thread	FX-HD-7160
	HDL 7.0mm x 65mm Long Thread	FX-HD-7165
	HDL 7.0mm x 70mm Long Thread	FX-HD-7170
	HDL 7.0mm x 75mm Long Thread	FX-HD-7175
	HDL 7.0mm x 80mm Long Thread	FX-HD-7180
	HDL 7.0mm x 85mm Long Thread	FX-HD-7185
	HDL 7.0mm x 90mm Long Thread	FX-HD-7190
	HDL 7.0mm x 95mm Long Thread	FX-HD-7191
	HDL 7.0mm x 100mm Long Thread	FX-HD-7192
	HDL 7.0mm x 105mm Long Thread	FX-HD-7173
	HDL 7.0mm x 110mm Long Thread	FX-HD-7184
	HDL 7.0mm x 115mm Long Thread	FX-HD-7185
	HDL 7.0mm x 120mm Long Thread	FX-HD-7196
	HDL 7.0mm x 125mm Long Thread	FX-HD-7197
	HDL 7.0mm x 130mm Long Thread	FX-HD-7198

HDF 7.0mm	Description	Non-Sterile
	HDF 7.0mm x 30mm Full Thread	FX-HD-7230
	HDF 7.0mm x 35mm Full Thread	FX-HD-7235
	HDF 7.0mm x 40mm Full Thread	FX-HD-7240
	HDF 7.0mm x 45mm Full Thread	FX-HD-7245
	HDF 7.0mm x 50mm Full Thread	FX-HD-7250
	HDF 7.0mm x 55mm Full Thread	FX-HD-7255
	HDF 7.0mm x 60mm Full Thread	FX-HD-7260
	HDF 7.0mm x 65mm Full Thread	FX-HD-7265
	HDF 7.0mm x 70mm Full Thread	FX-HD-7270
	HDF 7.0mm x 75mm Full Thread	FX-HD-7275
	HDF 7.0mm x 80mm Full Thread	FX-HD-7280
	HDF 7.0mm x 85mm Full Thread	FX-HD-7285
	HDF 7.0mm x 90mm Full Thread	FX-HD-7290
	HDF 7.0mm x 95mm Full Thread	FX-HD-7291
	HDF 7.0mm x 100mm Full Thread	FX-HD-7292
	HDF 7.0mm x 105mm Full Thread	FX-HD-7293
	HDF 7.0mm x 110mm Full Thread	FX-HD-7294
	HDF 7.0mm x 115mm Full Thread	FX-HD-7295
	HDF 7.0mm x 120mm Full Thread	FX-HD-7296
	HDF 7.0mm x 125mm Full Thread	FX-HD-7297
	HDF 7.0mm x 130mm Full Thread	FX-HD-7298



HLL 7.0mm	Description	Non-Sterile
	HLL 7.0mm x 30mm Long Thread	FX-HL-7130
	HLL 7.0mm x 35mm Long Thread	FX-HL-7135
	HLL 7.0mm x 40mm Long Thread	FX-HL-7140
	HLL 7.0mm x 45mm Long Thread	FX-HL-7145
	HLL 7.0mm x 50mm Long Thread	FX-HL-7150
	HLL 7.0mm x 55mm Long Thread	FX-HL-7155
	HLL 7.0mm x 60mm Long Thread	FX-HL-7160
	HLL 7.0mm x 65mm Long Thread	FX-HL-7165
	HLL 7.0mm x 70mm Long Thread	FX-HL-7170
	HLL 7.0mm x 75mm Long Thread	FX-HL-7175
	HLL 7.0mm x 80mm Long Thread	FX-HL-7180
	HLL 7.0mm x 85mm Long Thread	FX-HL-7185
	HLL 7.0mm x 90mm Long Thread	FX-HL-7190
	HLL 7.0mm x 95mm Long Thread	FX-HL-7191
	HLL 7.0mm x 100mm Long Thread	FX-HL-7192
	HLL 7.0mm x 105mm Long Thread	FX-HL-7173
	HLL 7.0mm x 110mm Long Thread	FX-HL-7184
	HLL 7.0mm x 115mm Long Thread	FX-HL-7185
	HLL 7.0mm x 120mm Long Thread	FX-HL-7196
	HLL 7.0mm x 125mm Long Thread	FX-HL-7197
	HLL 7.0mm x 130mm Long Thread	FX-HL-7198

Washers	Description	Non-Sterile
	HD 5.5mm Washer*	FX-HD-5500
	HD 7.0mm Washer*	FX-HD-7000

\* Headed Only

5.5	Description	SKU
	Driver Torx 5.5mm	CD-FX-3055
	K-Wire Standard 2.0mm	CD-FX-0020
	K-Wire Threaded 2.0mm	CD-FX-0520
	Proximal Reamer Headless 5.5mm	CD-FX-2555
	Proximal Reamer Cannulated 5.5mm	CD-FX-2055
	Screw Extractor Rod 5.5mm	CD-FX-6055
	Tap Cannulated 5.5mm	CD-FX-5055

7.0	Description	SKU
	Driver Torx 7.0mm	CD-FX-3070
	K-Wire Standard 2.8mm	CD-FX-0028
	K-Wire Threaded 2.8mm	CD-FX-0528
	Proximal Reamer Headless 7.0mm	CD-FX-2570
	Proximal Reamer Cannulated 7.0mm	CD-FX-2070
	Tap Cannulated 7.0mm	CD-FX-5070
	Screw Extractor Rod 7.0mm	CD-FX-6070

Tray	Description	SKU
	Joint Distractor	TN-AX-4060
	Bone Clamp 8"	TN-AX-1080
	Bone Clamp Pointed	TN-AX-1050
	Hohmann Retractor	TN-AX-4050
	Screw Holding Forceps Large	TN-FX-9020
	Depth Gauge HL 5.5/7.0mm	TN-FX-8570
	Depth Gauge HD 5.5/7.0mm	TN-FX-8070
	Guide 3.6mm and 2.0mm	TN-FX-7034
	Guide 4.9mm and 2.8mm	TN-FX-7049
	Parallel Wire Guide HL 7.0mm	TN-FX-7096
	Parallel Wire Guide HD 7.0mm	TN-FX-7097
	5.5mm FX Wire Sleeve 2.0mm	TN-FX-7020
	5.5mm FX Drill Sleeve 3.6mm	TN-FX-7055
	FX Sleeve 5.5mm and 7.0mm	TN-FX-7090
	7.0mm FX Wire Sleeve 2.8mm	TN-FX-7028
	7.0mm FX Drill Sleeve 4.9mm	TN-FX-7070
	Driver Handle Ratcheting Hudson	TN-FX-6040
	T-Handle Non-Ratcheting	TN-FX-6050
	Hudson to Jacobs Adapter	TN-FX-6030
	FuzeFix Large HL Tray	TN-TR-0010
	FuzeFix Large HD Tray	TN-TR-0011

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.

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STG002

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