

TwistOff

FuzeFix Screw System

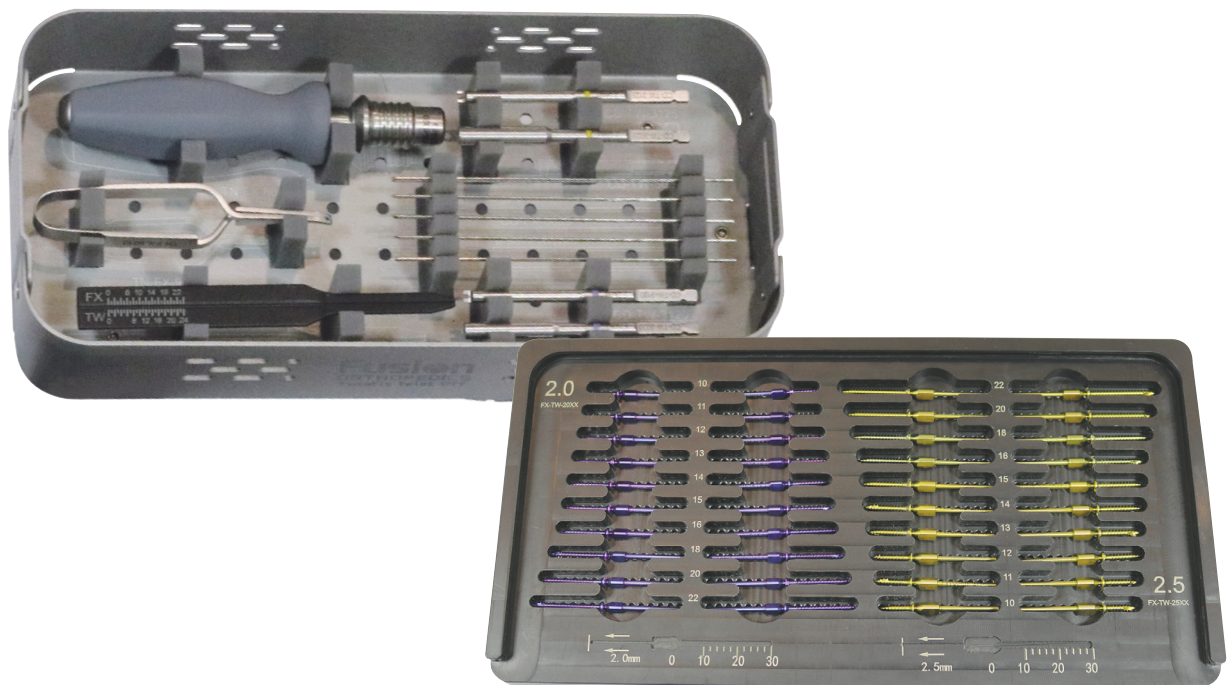


TwistOff FuzeFix Screw System

Confidential

DESCRIPTION OF THE MEDICAL DEVICE

The FuzeFix Twist Off System consists of threaded bone fixation fasteners for fixation of the foot following trauma and osteotomy with corresponding instrumentation to facilitate insertion. The FuzeFix Twist Off Screw System consists of solid threaded bone screws with a drive shaft mechanism attached to the head that snaps off of the head surface after implantation. The System is offered in 2.0mm and 2.5mm diameters with lengths ranging from 10mm to 22mm. System instrumentation includes K-wires, depth gauges, driver shafts, and handles to facilitate the placement of the screws. The implants and K-wires are intended for single use only.



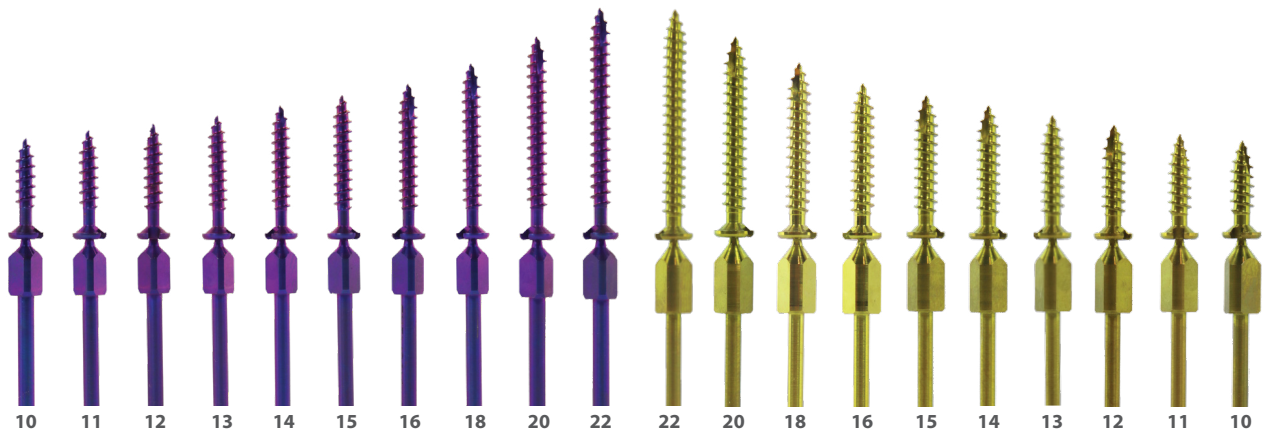
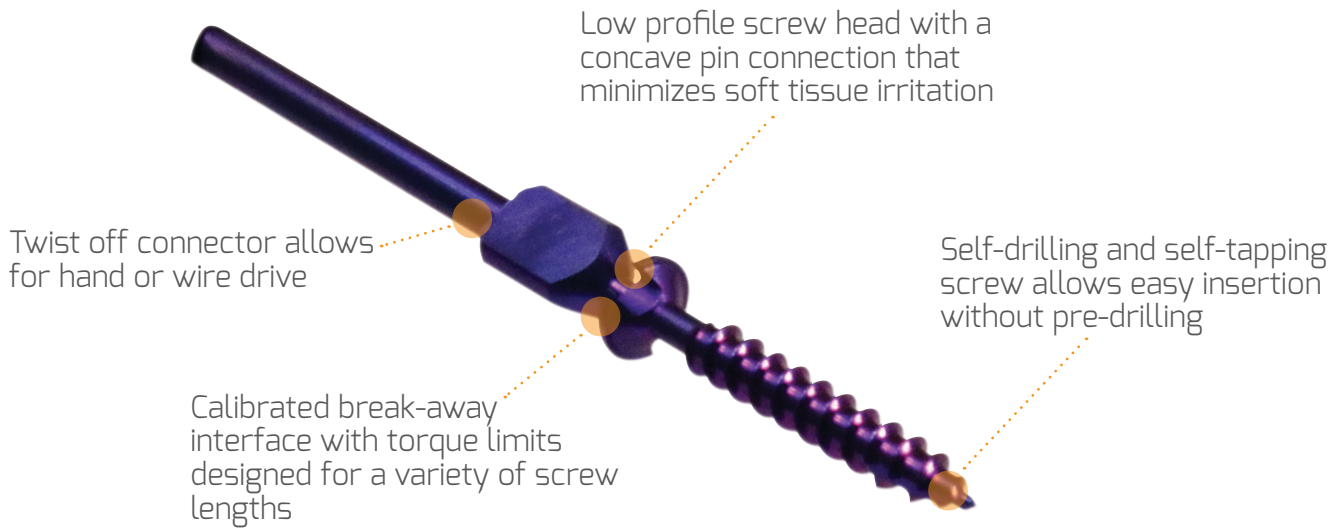
INDICATIONS FOR USE

The FuzeFix Twist Off System is intended for use in the stabilization and fixation of bone fractures, osteotomies, and for bone reconstruction of the hand and foot. The FuzeFix Twist Off System is indicated for: fixation of small bone fragments, Weil osteotomy, mono-cortical fixation, osteotomies and fractures fixation in the foot and hand.

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.

Intelligently Designed



2.0

2.5



1

The Weil osteotomy is made with an oscillating saw parallel to the sole of the foot. Ideally the cut should be 2-3cm in length, but cuts may be varied in the case of cavus or planus deformities. The metatarsal head may be repositioned until the correct length relationship with the adjacent metatarsals has been achieved. According to surgeon preference, the head may be held in place by temporary K-wire fixation.



After selecting the correct length from the screw block, secure the shank of the FuzeFix Twist Off Screw in a small Jacobs chuck or a pin driver. Begin to advance the screw.

2

It is essential that the FuzeFix Twist Off Screw length be carefully chosen to both maximize the amount of length for purchase, and also ensure that it does not penetrate the plantar surface of the head. It may be necessary to measure prior to insertion. To do so, insert the 0.9mm K-wire across the osteotomy to the desired depth and slide the depth gauge over the wire until flush with bone.

Do not use:
Twist Off Screws in
osteoporotic bones.



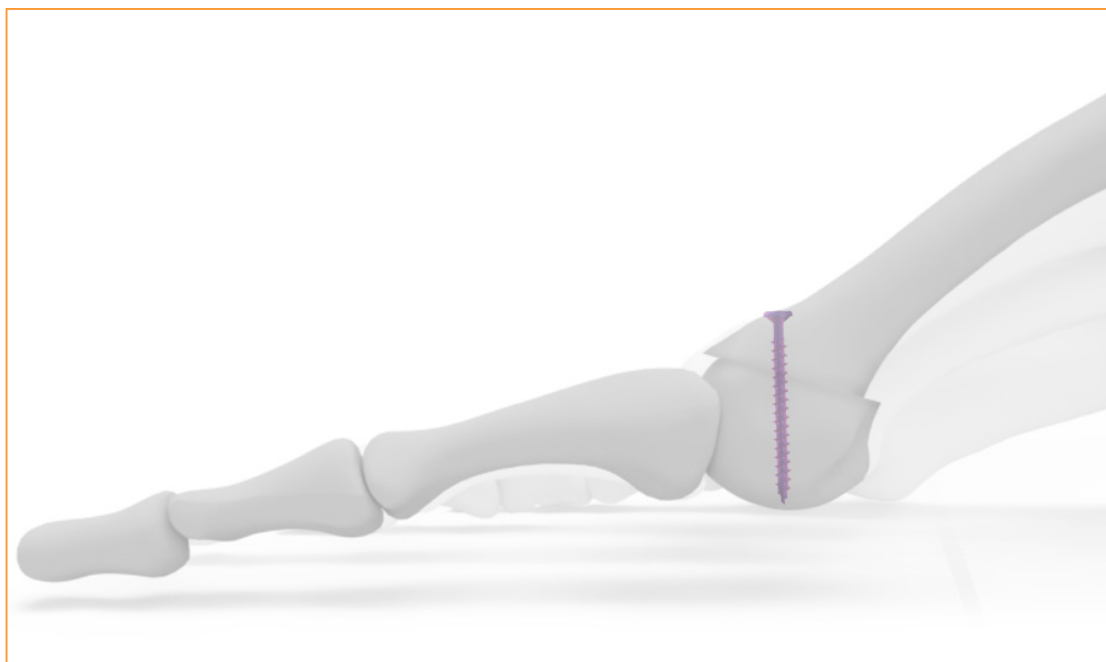
3

Advance the screw while holding the head in the correct position. In cases of high bone density, the screw will twist off prior to final positioning. However, in cases of low bone density once the head has reached the bone the screw shank may not break off. It may be necessary to rotate the upper tip in order to gently break off the screw shank from the head of the screw.



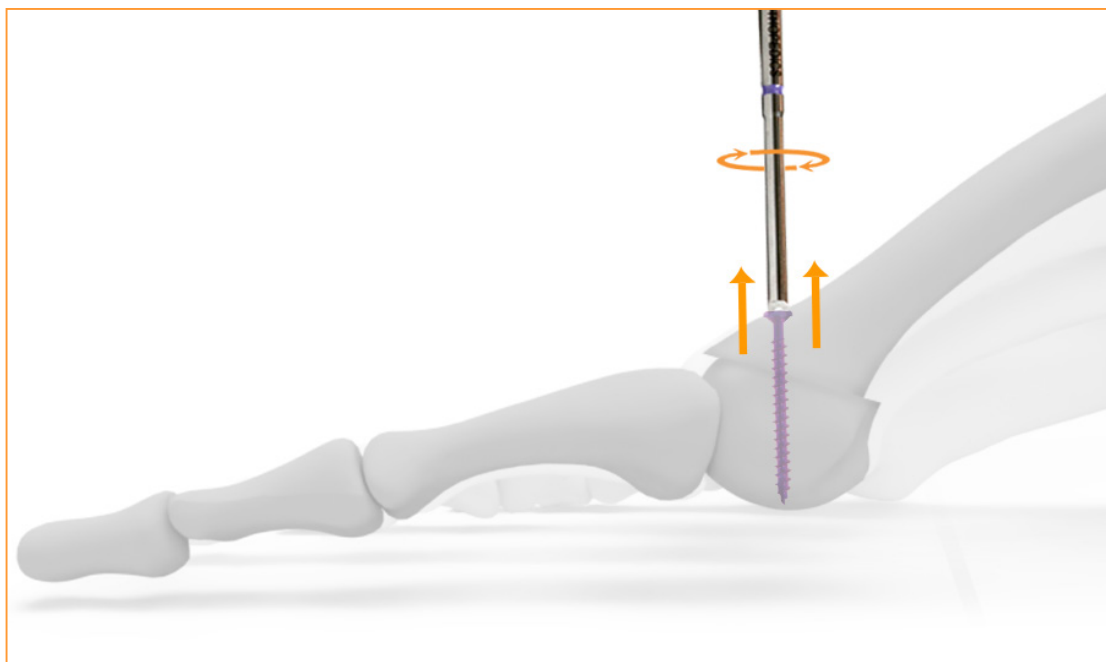
4

Using the Breakaway Driver, finish off the screw until 2-3 finger tightness has been achieved



5

After final insertion, it is recommended to confirm the final position under fluoroscopy. When the osteotomy is stabilized, reshape the metatarsal head with a saw.



1

To remove the Twist Off implant, engage the Break Away driver with the head of the implant, turn counter clock-wise and back out the screw.



2.0mm	Description	Non-Sterile
	TW 2.0mm x 10mm	FX-TW-2010
	TW 2.0mm x 11mm	FX-TW-2011
	TW 2.0mm x 12mm	FX-TW-2012
	TW 2.0mm x 13mm	FX-TW-2013
	TW 2.0mm x 14mm	FX-TW-2014
	TW 2.0mm x 15mm	FX-TW-2015
	TW 2.0mm x 16mm	FX-TW-2016
	TW 2.0mm x 18mm	FX-TW-2018
	TW 2.0mm x 20mm	FX-TW-2020
	TW 2.0mm x 22mm	FX-TW-2022



2.5mm	Description	Non-Sterile
	TW 2.0mm x 10mm	FX-TW-2510
	TW 2.0mm x 11mm	FX-TW-2511
	TW 2.0mm x 12mm	FX-TW-2512
	TW 2.0mm x 13mm	FX-TW-2513
	TW 2.0mm x 14mm	FX-TW-2514
	TW 2.0mm x 15mm	FX-TW-2515
	TW 2.0mm x 16mm	FX-TW-2516
	TW 2.0mm x 18mm	FX-TW-2518
	TW 2.0mm x 20mm	FX-TW-2520
	TW 2.0mm x 22mm	FX-TW-2522



FuzeFix TwistOff	Description	Color	Non-Sterile
	Driver TW Stem 2.0mm	Purple	CD-TW-3020
	Driver TW Breakaway 2.0mm	Purple	CD-TW-3120
	Driver TW Stem 2.5mm	Yellow	CD-TW-3025
	Driver TW Breakaway 2.5mm	Yellow	CD-TW-3125

K-Wires	Description	Non-Sterile
	Standard 0.9mm	CD-FX-0009
	Threaded 0.9mm	CD-FX-0509



Handle	Description	Non-Sterile
	Driver Non-Ratcheting	TN-FX-6020



Forceps	Description	Non-Sterile
	Screw Holding Forceps	TN-FX-9010



FuzeFix TwistOff	Description	Non-Sterile
	Depth Gauge TW	TN-FX-8030

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

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Rev 1



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