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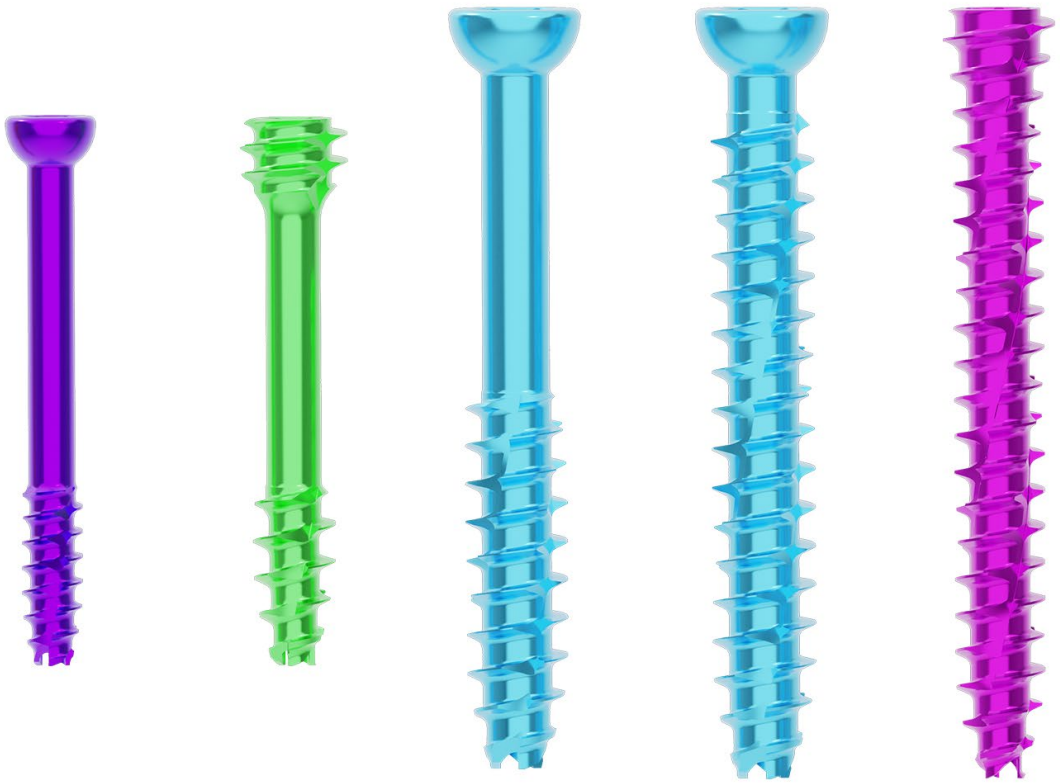
DartFire Edge™

Cannulated Screw System

Operative technique



DartFire Edge
Cannulated Screw System

This publication sets forth detailed recommended procedures for using Stryker devices and instruments. It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required.

Important

- The patient should be advised that the device cannot and does not replicate a normal healthy bone, that the device can break or become damaged as a result of strenuous activity or trauma and that the device has a finite expected service life.
- Removal or revision of the device may be required sometime in the future.
- Cleaning and sterilization information is provided in the applicable instructions for use.
- Non-sterile devices, including implants and instruments, must be cleaned and sterilized prior to use, in accordance with validated methods.
- Devices that are able to be disassembled should be disassembled prior to point-of-use processing. Additionally, devices with movable components that do not facilitate disassembly should be manually articulated during the point-of-use processing step in order to evacuate additional soils.
- Please remember that the compatibility of different product systems has not been tested unless specified otherwise in the product labeling.
- Consult Instructions for Use (https://ifu.stryker.com) for a complete list of potential adverse effects and adverse events, contraindications, warnings and precautions.
- The surgeon must advise patients of surgical risks, and make them aware of adverse effects and alternative treatments.
- An implant whose packaging is open or damaged or whose expiration date has passed must not be used. Every precaution must be taken to ensure sterility when opening the packaging of the implant and during implantation.

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Introduction

The DartFire Edge Cannulated Screws are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of foot and ankle bones appropriate for the size of the device. Screws are intended for single use only. With self-drilling and self-tapping headed and headless compression screws, in diameters ranging from 2.0mm to 4.0mm (Figures 1 and 2), the DartFire Edge Cannulated Screw System provides extensive versatility for surgical procedures of the foot, within one comprehensive sterile system.

Figure 1: Headed Compression Screws

Diameter	Head	Thread	Min Length	Max Length	Guidewire	Drill	Driver
2.0mm	Headed	Short	10	40	0.9mm	1.7mm	T7
2.5mm	Headed	Short	10	40	0.9mm	1.8mm	T7
3.0mm	Headed	Short	12	50	1.0mm	2.1mm	T8
3.5mm	Headed	Full Short	12 12	50 50	1.1mm	2.5mm	T10
4.0mm	Headed	Full Long Short	12 16 12	50 50 50	1.4mm	3.0mm	T15

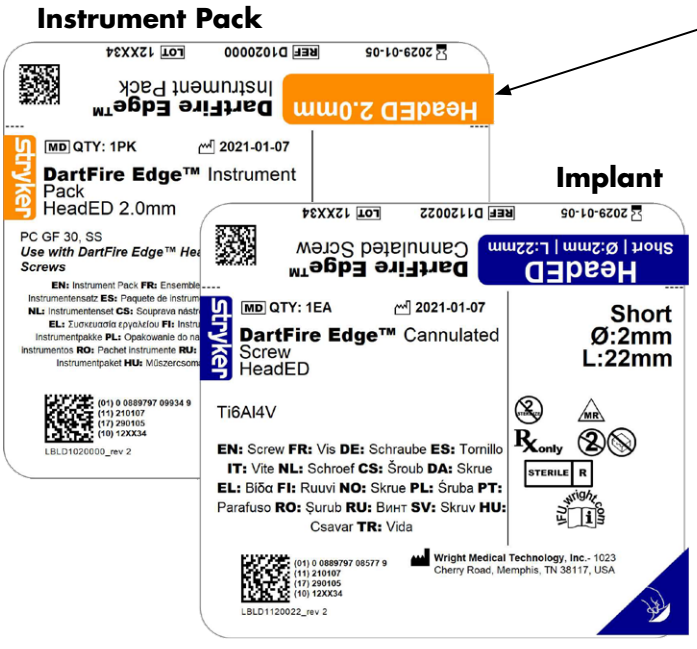
Figure 2: Headless Compression Screws

Diameter	Head	Thread	Min Length	Max Length	Guidewire	Drill	Driver
2.0mm	Headless	Short	10	40	0.9mm	1.7mm	T7
2.5mm	Headless	Full Short	10 10	40 40	0.9mm	1.8mm	T7
3.0mm	Headless	Full Short	12 12	50 50	1.0mm	2.1mm	T8
3.5mm	Headless	Full Short	12 12	50 50	1.1mm	2.5mm	T10
4.0mm	Headless	Full Long Short	12 16 12	50 50 50	1.4mm	3.0mm	T15

Introduction (cont.)

System basics

- The DartFire Edge Cannulated Screw System offers the simplicity of self-drilling and self-tapping cannulated compression screws in a sterile, ready-for-surgery offering that includes diameters from 2.0mm to 4.0mm.
- All DartFire Edge Cannulated Screws are manufactured from titanium alloy (Ti 6Al-4V) to provide consistent strength and performance.
- All implant and instrument pack labels in the sterile offering are color-coded by head type with the contents of each pack clearly labeled to easily identify and associate instrument packs with implants.
- Sterile instrument packs include:
  - K-wires, depthsink, drill, driver, handle (AO connection)
- Sterile implant packs include:
  - Screw
- While the screws are self-drilling, cannulated drill bits are included for use in hard cortical bone, when an oblique approach is desired, or when bicortical fixation is required.
- Cannulated Depthsinks are provided to accurately measure anatomy and recess screw heads into the cortex of the bone.



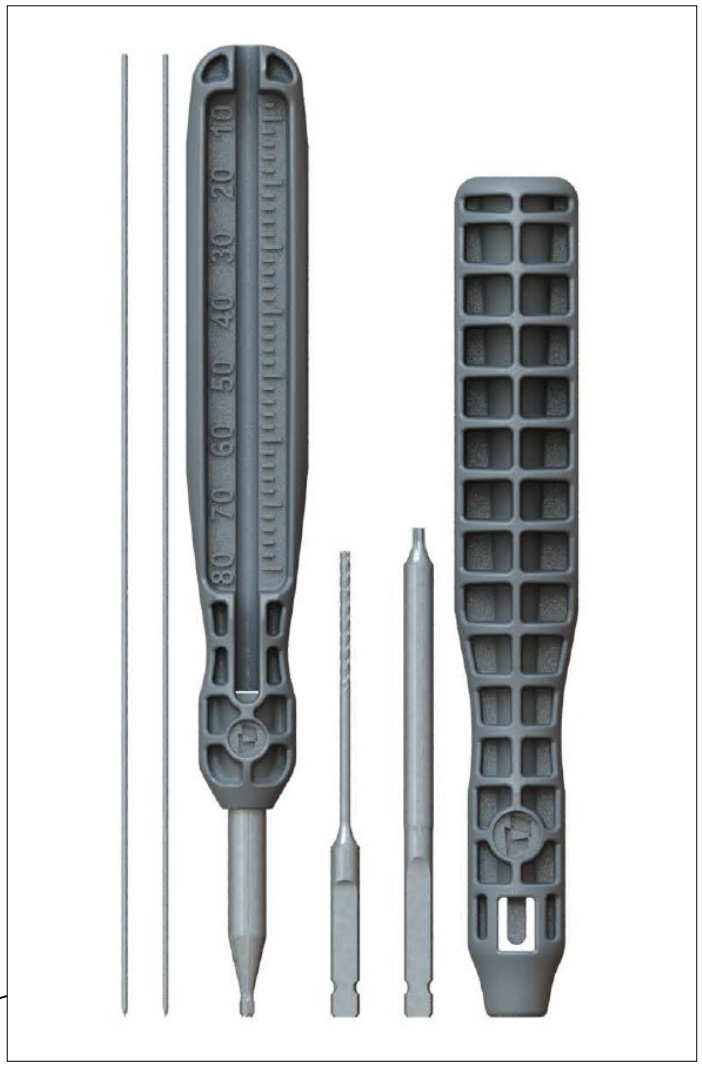


Figure 3

Disposable instruments included in sterile instrument pack

Sterile instrument pack labels are orange and clearly marked by head type and diameter.

Sterile headed screw Implant packs labels are dark blue and clearly marked by head type, diameter and length.

Sterile headless screw Implant packs labels are light blue and clearly marked by head type, diameter and length.

Indications and contraindications

The DartFire Edge Cannulated Screw System includes cannulated compression screws offered in various diameters and lengths. Screws are available both headed and headless, and all screws are manufactured from titanium alloy. The system is available in sterile, ready-for-surgery packaging.

Indications

The DartFire Edge Cannulated Screws are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of foot and ankle bones appropriate for the size of the device. Screws are intended for single use only.

Contraindications

There are no specific contraindications for this system.

Prior to use of the system, the surgeon should refer to the product package insert for complete warnings, precautions, indications, contraindications and adverse effects. Package inserts are also available by contacting the manufacturer. Contact information can be found on the back of this surgical technique and the package insert is available on the website listed.

Operative technique

Preoperative planning

The DartFire Edge Cannulated Screw System is composed of cannulated headed and headless screws in a variety of diameters. The correct screw selection for the procedure is extremely important, and preoperative consideration of the proper screw size and design will increase the potential for surgical success.

K-wire placement

The appropriate K-wire (Figures 1 and 2) is advanced across the fusion or osteotomy site. (Figure 4) Verify the desired positioning of the wire fluoroscopically.

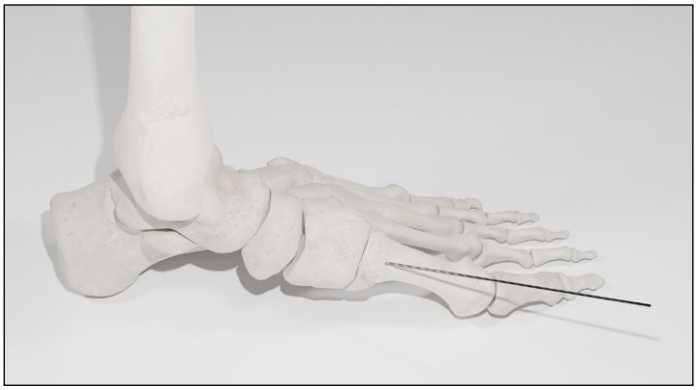


Figure 4
Insertion of appropriate sized K-wire.

Screw diameter selection

Appropriate screw diameter is selected based on the procedure to be performed.

Screw length determination

Measure screw length by using the Cannulated Depthsink. (Figure 5) Slide the tip of the Cannulated Depthsink over the K-wire and down to the surface of the bone, ensuring that the gauge is seated flush to the bone. The gauge measurement indicates the depth from the surface of the bone to the tip of the K-wire; adjust accordingly for countersinking or lagging.

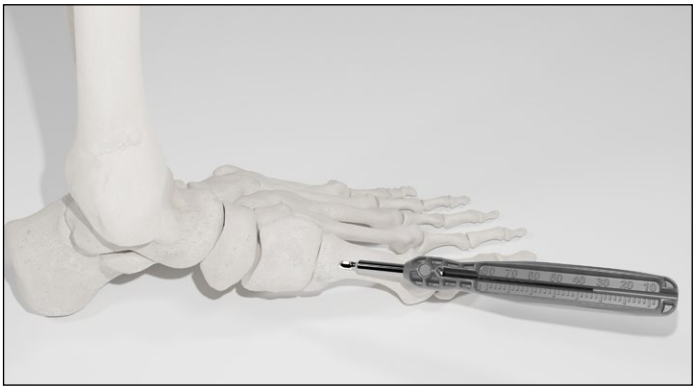


Figure 5
Use the depthsink to determine required screw length

Countersinking

To ensure complete seating of the headed screws, the Depthsink may be used to countersink. Slide the cannulated Depthsink over the K-wire and turn the Depthsink in a clockwise motion to penetrate the cortex of the bone.

Drilling

The DartFire Edge Cannulated Screw System has been designed to be self-drilling and self-tapping. However, in some situations such as hard cortical bone, bicortical fixation, or when an oblique approach is desired, drilling may be necessary. Pre-drilling is more likely to be necessary with the use of small diameter screws.

Additionally, it is recommended to pre-drill the near cortex when using headless screws to prevent the proximal threaded portion from splitting or cracking the cortical shell. (Figure 6)

Slide the associated drill bit over the K-wire. Under power, drill just past the osteotomy or fusion site.

Figure 6
Pre-drill the near cortex when using headless screws

Screw placement

Load the appropriate Driver into the Cannulated AO Driver Handle.

Place the screw over the K-wire and use the Driver to advance the screw into the bone, until the head is completely countersunk within the bone. (Figure 7)

Depending on the stability of the first screw, procedure type, and patient related factors (obesity, post-operative compliance issues), multiple screws may be used for additional fixation.

Remove the K-wire(s) and perform surgical closure.

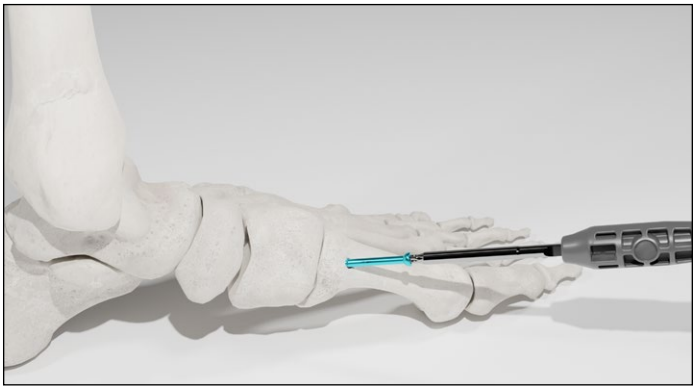


Figure 7

Explant information

Removal of the DartFire Edge Cannulated Screw System Implant may be performed by using the appropriate driver to remove screw.

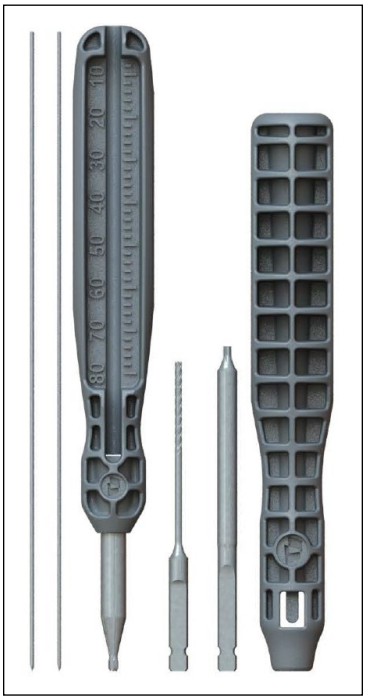
Postoperative management

Postoperative care is the responsibility of the medical professional.

Appendix: DartFire Edge Cannulated Screw System instrument packaging

2.0mm – 4.0mm diameter instruments are packaged with:

- K-wires
- Depthsink
- Cannulated Drill
- Cannulated Driver
- AO Handle



Screws are sterile and individually packaged. Screws are color anodized as follows:

Screw diameter	Color code
2.0	Vector purple
2.5	Bronze
3.0	Green
3.5	Magenta
4.0	Light blue

SKU*	Item Description	Length Options
D1020000	2.0mm Headed Driver Pack	
D1120XXX*	2.0mm Headed Short Thread Screw	10mm - 40mm
D0020000	2.0mm Headless Driver Pack	
D0120XXX*	2.0mm Headless Short Thread Screw	10mm - 40mm
D1025000	2.5mm Headed Driver Pack	
D1125XXX*	2.5mm Headed Short Thread Screw	10mm - 40mm
D0025000	2.5mm Headless Driver Pack	
D0325XXX*	2.5mm Headless Full Thread Screw	10mm - 40mm
D0125XXX*	2.5mm Headless Short Thread Screw	10mm - 40mm
D1030000	3.0mm Headed Driver Pack	
D1130XXX*	3.0mm Headed Short Thread Screw	12mm - 50mm
D0030000	3.0mm Headless Driver Pack	
D0330XXX*	3.0mm Headless Full Thread Screw	12mm - 50mm
D0130XXX*	3.0mm Headless Short Thread Screw	12mm - 50mm
D1035000	3.5mm Headed Driver Pack	
D1335XXX*	3.5mm Headed Full Thread Screw	12mm - 50mm
D1135XXX*	3.5mm Headed Short Thread Screw	12mm - 50mm
D0035000	3.5mm Headless Driver Pack	
D0335XXX*	3.5mm Headless Full Thread Screw	12mm - 50mm
D0135XXX*	3.5mm Headless Short Thread Screw	12mm - 50mm
D1040000	4.0mm Headed Driver Pack	
D1340XXX*	4.0mm Headed Full Thread Screw	12mm - 50mm
D1240XXX*	4.0mm Headed Long Thread Screw	16mm - 50mm
D1140XXX*	4.0mm Headed Short Thread Screw	12mm - 50mm
D0040000	4.0mm Headless Driver Pack	
D0340XXX*	4.0mm Headless Full Thread Screw	12mm - 50mm
D0240XXX*	4.0mm Headless Long Thread Screw	16mm - 50mm
D0140XXX*	4.0mm Headless Short Thread Screw	12mm - 50mm

*XXX denotes the length of the screw in a three digit format, in 2mm increments. For example, "010" represents a 10mm screw.

Notes

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Foot & Ankle

This document is intended solely for the use of healthcare professionals. 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. Stryker 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 a Stryker product. A surgeon must always refer to the package insert, product label and/or instructions for use, including the instructions for cleaning and sterilization (if applicable), before using any Stryker 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 Stryker representative if you have questions about the availability of Stryker products in your area.

The instructions for use, operative techniques, cleaning instructions, patient information leaflets and other associated labeling may be requested online at ifu.stryker.com or stryker.com. If saving the instructions for use, operative techniques, cleaning instructions from the above mentioned websites, please make sure you always have the most up to date version prior to use.

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Manufacturer:
Wright Medical
Technology
1023 Cherry Road
Memphis, TN 38117
800 238 7117
901 867 9971
www.stryker.com