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DartFire Edge™

Snap Off Screw System Sterile Offering

Operative technique

Powered by the **PULSE Intelligent Delivery Platform**

DartFire Edge

Snap Off Screw System Sterile Offering

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

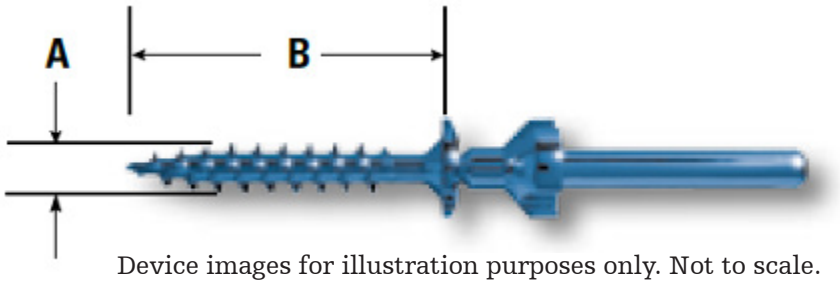
Device Description

DartFire Edge Snap Off Screw System is a solid, titanium alloy system of self-drilling and self-tapping screws that provides fixation of fractures, fusions, or osteotomies of bones of the foot. The long universal driver shafts are designed to snap off at the head of the screw, producing a very low-profile surface to help minimize soft tissue irritation. The system provides screws in 6 different sizes, 2 diameters and 5 lengths, (Figure 1) offering versatility within one comprehensive sterile system.

DartFire Edge™ Snap Off Screw System

Item	Description	Diameter (A)	Length (B)
D2400000	Driver Pack	2.0mm - 2.7mm	All
D2420011	Implant	2.0mm	11mm
D2420012	Implant	2.0mm	12mm
D2420013	Implant	2.0mm	13mm
D2427013	Implant	2.7mm	13mm
D2427015	Implant	2.7mm	15mm
D2427017	Implant	2.7mm	17mm

Figure 1

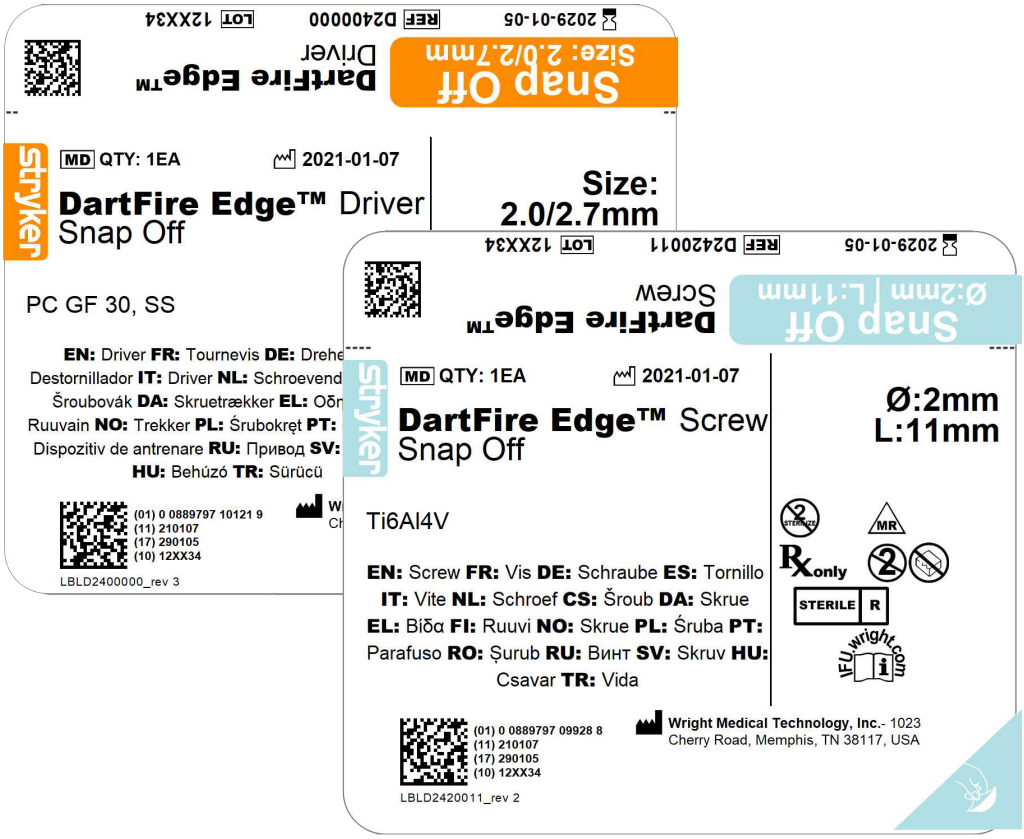


Device images for illustration purposes only. Not to scale.

Introduction (cont.)

System basics

- The DartFire Edge Snap Off Screw System offers the simplicity of self-drilling and self-tapping snap off screws in a sterile, ready-for-surgery offering that includes 2.0mm and 2.7mm screws in 5 different lengths. (Figure 1)
- All DartFire Edge Snap Off Screws are manufactured from titanium alloy (Ti 6AI-4V) to provide consistent strength and performance.
- All implant and instrument pack labels are color-coded by head type with the contents of each pack clearly labeled to easily identify and associate instrument packs with implants.
- Implant packs include:
  - Snap Off Screw
- Instrument pack includes:
  - AO Handle
  - Driver
- The Instrument pack label is orange.
- Snap off screw implant pack labels are sky blue and clearly marked by head type, diameter and length.



Intended use

Indications

The DartFire Edge Snap Off Screw System provides fixation of fractures, fusions, or osteotomies of the bones of the foot.

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 Snap Screw System is composed of snap off screws in 2 diameters and 5 lengths. 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.

Osteotomy

The osteotomy is a long transverse cut that allows the surgeon to make a stable correction to bone length without affecting the orientation of the articular surface of the proximal or distal joint.

Approach

The exposure should extend as distally or proximally as possible to provide adequate access for the saw. The osteotomy may be made with an oscillating saw. Screw length should be determined such that the screw is long enough to obtain purchase in the metaphyseal bone, opposite the side the screw is entering from. Manually manipulate and shorten the bone to the correct length.

Screw Insertion

Place the corresponding length DartFire Edge Snap Off screw into a power drill, or into the disposable hand driver, and advance the DartFire Edge screw while holding the bone in the proper orientation. No preparation of the dorsal bone is necessary as the DartFire Edge Snap Off screw is self-drilling and self-tapping.

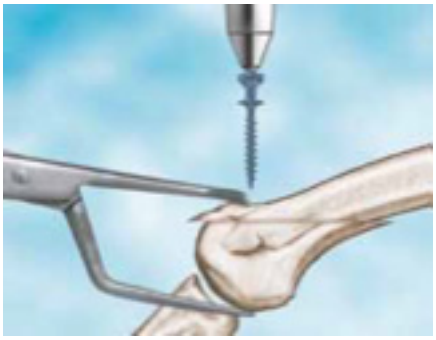


Figure 2

Screw Shaft Removal

The screw shaft of the DartFire Edge Snap Off screw will break off once the screw head contacts the dorsal cortex or sooner. Stop advancing the DartFire Edge Snap Off screw if cortical bone is reached and the screw shaft has not broken off. If necessary, the screw can be separated from the screw shaft by cutting the screw shaft flush with the head.

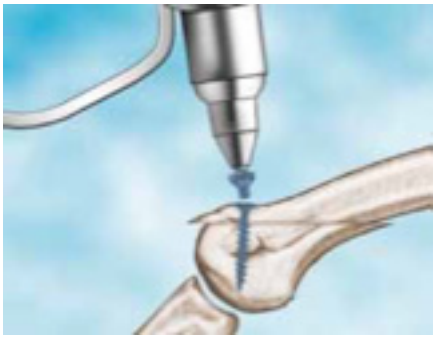


Figure 3

Screw Head Advancement

The screw head can be advanced with the hand driver to seat the screw flush with the surrounding bone. Once the DartFire Edge Snap Off screw is secure, check the plantar aspect of the bone to ensure that the screw does not penetrate the bone or joint. Reshape metatarsal head with a sagittal saw or bone rongeurs to restore the curvature of the metatarsal head.

Figure 4

Postoperative protocol

Postoperative care is the responsibility of the medical professional.

Explant information

Removal of the screws may be performed by using the driver included in the instrument pack (part number D2400000).

If the removal of the implant is required due to revision or failure of the device, the surgeon should contact the manufacturer using the contact information located on the back cover of this surgical technique to receive instructions for returning the explanted device to the manufacturer for investigation.

Ordering information

DartFire Edge Snap Off Screw System

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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
wright.com