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Fuseforce™
Fixation System

Operative technique

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Fixation System

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Proper surgical procedures and techniques are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the procedures based on his or her personal medical training and experience. 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 operative technique and the package insert is available on the website listed.

Introduction

Fuseforce is a shape-memory, compression-ready fixation system that can be used in fixation for fractures, fusions or osteotomies of the bones in the forefoot, midfoot and rearfoot. The compressive properties and stepped-tooth design resists pull-out.

The Fuseforce Fixation System is delivered sterile with disposable corresponding instrumentation. Its compression on release design provides a constant compressive force. It's available in a full-spectrum of sizes from 8mm x 8mm to 25mm x 22mm, with leg diameters matched to overall size. Each package contains one each: implant, inserter, reamer, reamer guide and locator pin.

The inserter/implant combo allows for no-touch implantation with the simple twist-release-compress design. The end-loaded system provides an ultra low-profile release and no handling of the implant required.

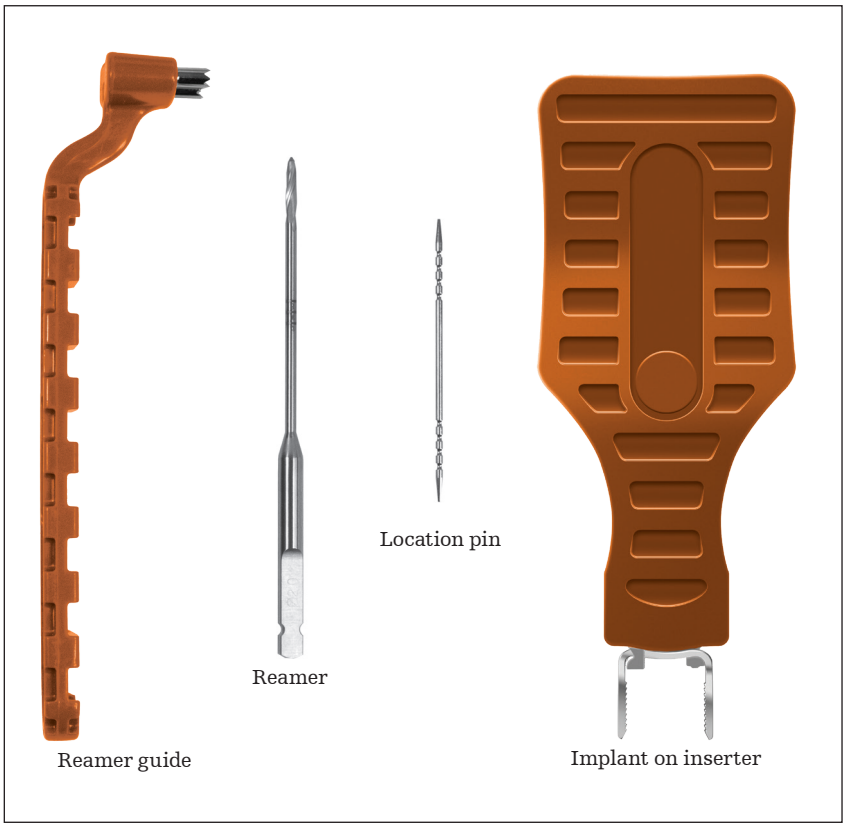


Figure 1

Indications and contraindications

Indications

The Fuseforce Fixation System is intended to be used for fracture and osteotomy fixation and joint arthrodesis of the hand and foot.

Contraindications

General contraindications for the use of these implants for joint reconstruction, osteotomy or fusion include:

- Significant bone demineralization
- Inadequate neurovascular status
- Inadequate skin or musculotendinous system
- Inadequate bone stock
- Psychologically unsuitable patient
- Possibility for conservative treatment
- Bone, musculature, tendons, or adjacent soft tissue compromised by disease, infection, or prior implantation, which cannot provide adequate support or fixation for the prosthesis
- Known metal allergy
- Diabetes
- Active infection

⚠ WARNING

- Patients should be made aware of the increased potential for device failure when excessive demands are made upon it. Strenuous loading, excessive mobility, and articular instability all may lead to accelerated wear and eventual failure by loosening, fracture, or dislocation of the device.
- If excessive loading cannot be prevented, an implant should not be used.
- Abnormal or excessive forces could lead to delayed union, non-union, or failure of the implant.
- This device has not been evaluated for safety and compatibility in the MR environment.
- This device has not been tested for heating or migration in the MR environment.

Operative technique

Step 1

Use the sterile staple sizer (FFHSIZER) to determine the appropriate sized staple for the given procedure. Open the matching size Fuseforce Implant Kit with its corresponding inserter, reamer, reamer guide and locator pin.

While maintaining desired reduction, place reamer guide across the fusion site with both guides touching bone.

FFHSIZER
Fuseforce Sterile Sizer

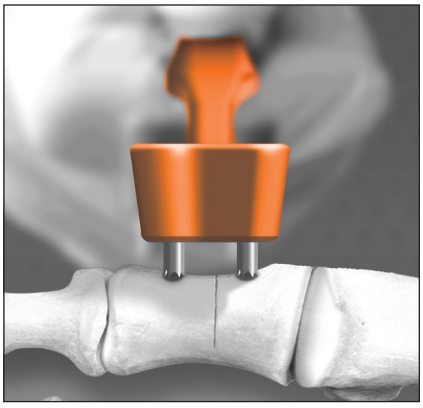


Figure 2

Step 2

Drill the first hole to the proper depth, using the laser marked reamer provided in the kit.

NOTICE

Drill until laser etch line aligns with dorsal aspect of the reamer guide.

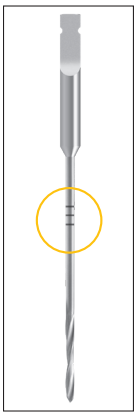


Figure 3

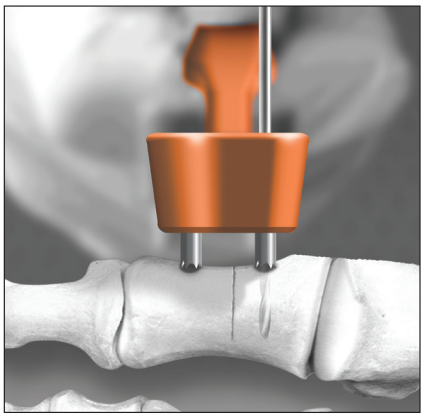


Figure 4

Step 3

Insert a locator pin into the first hole to maintain proper reduction while the second hole is drilled. Drill second hole to the proper depth using the laser marked reamer. Remove the reamer, locator pin and reamer guide. Remove the inserter/implant assembly from the sterile kit.

NOTICE

Drill until laser etch line aligns with dorsal aspect of the reamer guide.

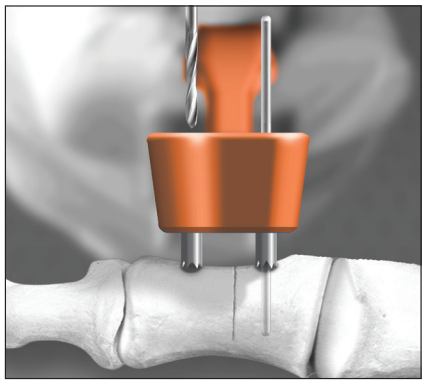


Figure 5

Step 4

While maintaining reduction, align and insert the tips of the Fuseforce Implant into the drilled holes. Extra sutures can be placed along the sides if necessary, using a margin convergence technique.

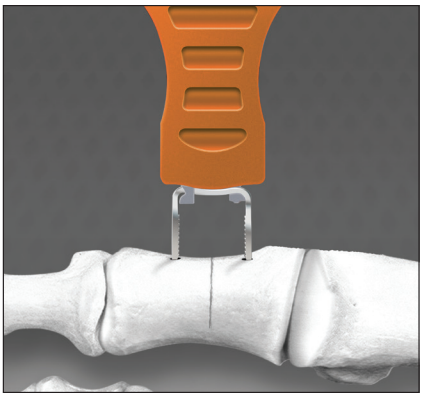


Figure 6

Step 5

Seat the Fuseforce Implant as flush to the bone as possible. Implant positioning may be evaluated radiographically.

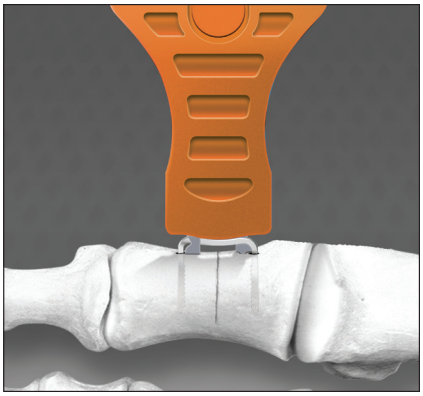


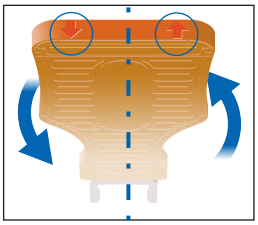
Figure 7

Step 6

Twist the plastic inserter counterclockwise (as shown by arrows on top) to release the implant.

Place the end of the inserter on the implant and apply pressure, manually or using a mallet, to fully seat the Fuseforce Implant.

Apply additional Fuseforce Implants as deemed appropriate for optimum stability.



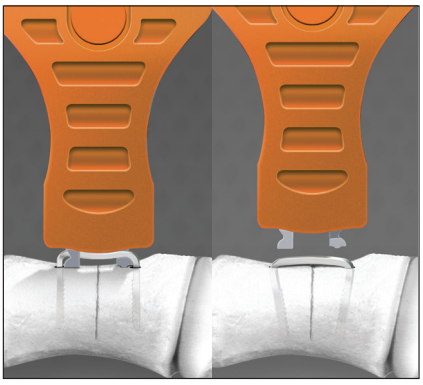


Figure 8

Postoperative care

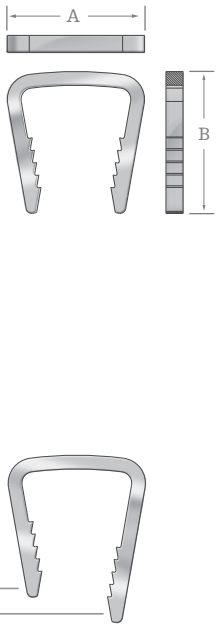
Postop care is the responsibility of the surgeon.

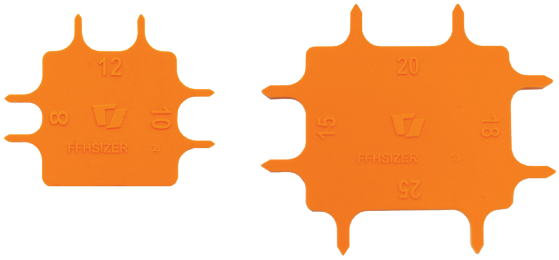
Explant information

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 operative technique to receive instructions for returning the explanted device to the manufacturer for investigation.

Ordering information

Part number	Description	Bridge width A	Leg length B	Reamer size
FFNS0808	Fuseforce Implant	8mm	8mm	2mm
FFNS1010	Fuseforce Implant	10mm	10mm	
FFNS1012	Fuseforce Implant	10mm	12mm	
FFNS1212	Fuseforce Implant	12mm	12mm	3mm
FFNS1515	Fuseforce Implant	15mm	15mm	
FFNS1816	Fuseforce Implant	18mm	16mm	
FFNS2020	Fuseforce Implant	20mm	20mm	
FFNS2522	Fuseforce Implant	25mm	22mm	2mm
FFNS101513	Fuseforce Implant	10mm	15/13mm	
FFHSIZER	Fuseforce Sterile Sizer			





FFHSIZER
Fuseforce Sterile Sizer

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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.

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