FuseFORCE™ IMPLANT SYSTEM

152189-1

The following languages are included in this packet:

English (en)
Español (es)
Deutsch (de)
Italiano (it)
Nederlands (nl)
Português (pt)
Français (fr)
Türkçe (tk)

For additional languages, visit our website www.wright.com. Then click on the **Prescribing Use** option.

For additional information and translations please contact the manufacturer or local distributor.

CE 0086*

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*** The CE-Marking of Conformity is applied per catalog number and appears on the outer label, if applicable.**

℞ ONLY

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EN

Attention Operating Surgeon

IMPORTANT MEDICAL INFORMATION FuseFORCE™ IMPLANT SYSTEM

(152189-1)

OUTLINE:

DEFINITIONS

Symbols and abbreviations may be used on the package label. The following table provides the definition of these symbols and abbreviations.

Table 1. Definitions of Symbols and Abbreviations

Symbol	Definition
	Batch code
	Catalog number
	Do not re-use
	Caution, consult accompanying documents
	Consult operating instructions
	Use by
	Temperature limitation
	Keep dry

	Keep away from sunlight
	Date of manufacture
	Manufacturer
	Authorized EC Representative in the European Community
	Sterilized using ethylene oxide
	Sterilized using radiation
	Sterilized using gas plasma
	Sterilized using aseptic processing techniques
	Non-sterile
	Do not resterilize
	Sterile

℞ ONLY	Caution: U.S. federal law restricts this device to sale by or on the order of a physician.
	Do not use if packaging is ripped or damaged.
Abbreviation	**Material**
Ti	Titanium
Ti6Al4V	Titanium Alloy
CoCr	Cobalt Chrome Alloy
SS	Stainless Steel
UHMWPE	Ultra High Molecular Weight Polyethylene
NiTi	Nitinol

DESCRIPTION

The FuseFORCE™ Implant is a one-piece device made of Nickel-Titanium Alloy intended to facilitate bone fusion. The implant is available in a range of sizes. The implant and associated instruments are provided together in a sterile packaged kit. Each package contains one each: implant, inserter, drill guide, drill and locator pin. The entire kit contents are for single use and all associated instruments are disposable.

A. INDICATIONS

The FuseFORCE™ Implant System is intended to be used for fracture and osteotomy fixation and joint arthrodesis of the hand and foot.

B. 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.

C. PRECAUTIONS

- If either the implant or the package appears damaged the implant should not be used.
- Meticulous preparation of the implant site and selection of the proper size implant increase the potential for a successful outcome.

- Implants should be handled with blunt instruments to avoid scratching, cutting or nicking the device.
- This implantable product is for single use only. An implant should never be re-sterilized after contact with body tissues or fluids.

D. POTENTIAL ADVERSE EFFECTS

General Surgery Related Risks

- bleeding
- infection
- pain, discomfort, or abnormal sensation due to the presence of the implant
- metal sensitivity or allergic reaction to a foreign body
- delayed correction in alignment
- decrease in bone density due to stress shielding
- bursitis
- loss of use of the foot
- permanent disability
- death

E. WARNINGS (See also the Patient Counseling Information Section)

- 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.

F. IMPLANT MATERIALS

The FuseFORCE™ Implant System implants are manufactured from Nitinol (Nickel-Titanium Alloy ASTM F 2063).

G. STERILIZATION

- This implant component and the accompanying instruments packaged with it have been sterilized by gamma irradiation.
- Do not resterilize if the implant comes in direct contact with human tissue. Dispose of implants that come in contact with human tissue and are not used in the surgery. If either the implant or the package appears damaged the implant should not be used.

H. SURGICAL PROCEDURES

A manual is available describing detailed surgical procedures for use of these implant devices. It is the responsibility of the surgeon to be familiar with the procedure before use of these products. In addition, it is the responsibility of the surgeon to be familiar with relevant publications and consult with experienced associates regarding the implant procedures before use.

I. POST-OPERATIVE PROTOCOL

Protected weight bearing with below the knee walking cast or walking boot is recommended. A gradual return to limited activity in 4 to 6 weeks is allowed as tolerated. Patient specific post-operative care is the responsibility of the surgeon.

J. PATIENT COUNSELING INFORMATION

(See also Warnings)

In addition to the patient related information contained in the Warnings, Adverse Events and Post-Operative Protocol sections, the following information should be conveyed to the patient:

While the expected life of an implant is difficult to estimate it is finite. These components are made of foreign materials, which are placed within the body for the potential restoration of mobility or reduction of pain. However, due to the many biological, mechanical and physiochemical factors which affect these devices, the components cannot be expected to withstand the activity level and loads of normal healthy bone for an unlimited period of time.

- Adverse effects of this device may necessitate reoperation, revision, or fusion of the involved bone or joint.

K. CAUTION

Federal Law (United States) restricts this device to sale, distribution, and use by or on the order of a physician.