

Instruction for Use
 Flex-Thread™ Distal Fibula
 Intramedullary Nail System –
 Sterile Implants & Instruments

Rx Only

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DESCRIPTION

The Flex-Thread™ Distal Fibula Intramedullary Nail System is comprised of an intramedullary fixation device with a flexible threaded tip to engage the proximal portion of a fibula and cortical screws to further enhance stability and fixation of the fibula. The system is comprised of sterile implants and instruments for single use only. Other instruments are provided non-sterile and may be reprocessed.

HOW SUPPLIED

All implants of the Flex-Thread™ Distal Fibula Intramedullary Nail System (Flex-Thread™ Fibula System) are provided individually sterile packaged and for single use only. Certain instruments are also individually sterile packaged and for single use only. Sterile components are provided in a convenient Flower Cube™. Other instruments of the system are provided non-sterile in a tray which must be sterilized prior to use and reprocessed according to the Flex-Thread Fibula System Reprocessing Instructions (document number 8626-1). Please refer to the Surgical Technique Guide for a full listing of implants and instruments (document number FOC 1054).

MATERIAL

The implants are made from titanium alloy (Ti6Al4V ISO 5832-3). The sterile instruments are made from medical grade stainless steel & plastic.

MRI SAFETY INFORMATION

The Flex-Thread™ Distal Fibula Intramedullary Nail System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Flex-Thread™ Distal Fibula Intramedullary Nail System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

INTENDED USE

The Flex-Thread™ Distal Fibula Intramedullary Nail System is intended for use in the fixation of fibula fractures and osteotomies.

CONTRAINDICATIONS

Do not use the Flex-Thread™ Distal Fibula Intramedullary Nail System in cases of:

- Inadequate bone quantity and/or bone quality
- Foreign body sensitivity to implant material
- Acute localized infections
- Patients with limited blood supply
- Patients who are unwilling or incapable of complying with post-operative care instructions

ADVERSE REACTIONS

Adverse reactions may include but are not limited to:

- Clinical failure (i.e. pain or injury) due to bending, loosening, wear and tear, fracture of implant, loss of fixation, dislocation and/or migration
- Pain, discomfort, and/or abnormal sensations due to the presence of the implant
- Primary and/or secondary infections
- Allergic reactions to implant material
- Limb shortening due to compression of the fracture or bone resorption
- Necrosis of bone or decrease of bone density
- Injury to vessels, nerves and organs
- Hematoma and/or impaired wound healing; hemorrhage

SAFETY PRECAUTIONS

- Each patient's record shall document the implant used (name, item number, lot number (if available)).
- Never re-use an implant. Although the implant may appear undamaged, previous stresses may have created non-visible damage that could result in implant failure. The manufacturer accepts no responsibility for a re-used implant.

STORAGE

- Always store the implants and instruments in the original protective packaging.
- Store the implants and instruments in a dry and dust-free place (standard hospital environment).

INSPECTION

Before use, inspect the box carefully. Do not use when sterile barrier is visually damaged.

OPERATING INSTRUCTIONS

The Flex-Thread™ Distal Fibula Intramedullary Nail System should be implanted only with the Flex-Thread™ Fibula System instruments.

PRE-OPERATIVE

- Prior to use, thoroughly read the provided Surgical Technique Guide.
 - Keep the instructions for use accessible to all staff.
 - The operating surgeon must have a thorough understanding of both, the hands-on and conceptual aspects of the established operating techniques. Proper surgical performance of the implantation is the responsibility of the operating surgeon.
 - The operating surgeon draws up an operation plan specifying and documenting the following:
 - Implant component(s) and their dimensions
 - Determination of intra-operative orientation points
- The following conditions must be fulfilled prior to application:
- All required implant components are sterilized and readily available.
 - All requisite sterile implantation instruments must be available and in working order.
 - Highly aseptic operating conditions are present.

WARNING

The use of implants for tasks other than those for which they are intended may result in damaged/ broken implants or patient injury.

- The operating surgeon and operating room team must be thoroughly familiar with the operating technique, as well as the range of implants and instruments to be applied. Complete information on these subjects must be readily available at the workplace.
- The operating surgeon must be specially trained in orthopedic surgery, biomechanical principles of the skeleton, and the relevant operating techniques.
- The operating procedure must be explained to the patient, and the patient's understanding of the following information must be documented:
 - The patient is aware of the risks associated with general surgery, orthopedic surgery, and with general anesthesia.
 - The patient has been informed about the advantages and disadvantages of the implant procedure and about possible alternative treatments.
 - The implant can fail due to excessive load, wear and tear or infection.
 - The service life of the implant is determined by body weight and physical activity. The implant must not be subjected to overload too early through extreme strain, work-related or athletic activities.
 - Corrective surgery may be necessary if the implant fails.
 - The patient must have his/her physician carry out follow-up examinations of the implants at regular intervals.

INTRA-OPERATIVE

- Prior to use, verify the integrity of the implant.
- Do not modify any components of the Flex-Thread™ Distal Fibula Intramedullary Nail System.
- Use the appropriate Flex-Thread™ Fibula System instruments (as necessary) in the appropriate length to prepare the path for the implants.

POST-OPERATIVE

- Reiterate preoperative instructions to the patient.
- During the post-operative phase, in addition to mobility and muscle training, it is of particular importance that the physician keeps the patient well informed about post-surgical behavioral requirements.
- Ensure that the patient is aware of physical activity restrictions and possible adverse reactions.

REVISION SURGERY / IMPLANT REMOVAL

Metallic implants can loosen, fracture, corrode, migrate, cause pain, or stress shield bone even after a fracture is healed, particularly in young, active patients. The surgeon must make the final decision on implant removal if either of these occurs. If there are not any of these complications, we recommend the permanent implantation of this titanium implants because of the risk of refracture and the possible complications of an additional operation.

USE OF ORIGINAL PRODUCTS

Implants and instruments of the Flex-Thread™ Distal Fibula Intramedullary Nail System are produced and designed to be used together.

WARNING

Please note that using a single use device (SUD) which comes into contact with human blood or tissue constitutes reprocessing & that reprocessing can only be performed by an authorized third-party reprocessor who has received 510(k) clearance for such.

WARRANTY

The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrect operating techniques, and limitations of treatment methods or inadequate asepsis.

The manufacturer does not take responsibility for any effects on safety, reliability, or performance of the product if the product is not used in conformity with the instructions for use.

Technical alterations reserved.

FOR FURTHER INFORMATION

Please contact Flower Orthopedic Corporation if further information on this product is needed at 1-877-778-8587.



Single Use



Catalog Number



Lot Number



See Instructions for Use



Sterile



Expiration Date

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Approved By:

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Description

Flex-Thread Instruction For Use

Justification

New IFU for FlexThread

Assigned To:

Kediley Peralta

Initiated By:

Kediley Peralta

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Major

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