InFrame™

EXSOMED
an acumed company

Instructions for Use: ExsoMed InFrame

Description and Intended Use:

ExsoMed InFrame is a stainless steel threaded micro nail intended for use in minimally invasive repair or reconstruction of small bone fractures by percutaneous insertion into the intramedullary cavity. It is designed for permanent implantation. InFrame implantation requires the use of three to four accessory devices provided in a separate procedure kit: A set of two unique dual diameter guidewires to be used to guide the micro nail and prepare the intramedullary cavity, a depth gauge, and a cannulated hex driver. InFrame is provided in several sizes ranging from 12mm to 48mm in length. The sizing selection of InFrame correlates to the length of the bone to be repaired. The implant and instrument kit are both provided STERILE via Gamma Irradiation.

Indications for Use:

The ExsoMed InFrame cannulated micro nail is intended for fixation of intra-articular and extra-articular fractures and non-unions of small bones and small bone fragments; arthrodesis of small joints; bunionectomies and osteotomies, including scaphoid and other carpal bones, metacarpals, tarsals, metatarsals, patella, ulnar styloid, capitellum, radial head, and radial styloid.

Contraindications:

InFrame is not intended for interference or soft tissue fixation. Do not use InFrame implants in cases of:

- Active or latent infection or sepsis
- Insufficient quantity or quality of bone or soft tissue to support fixation
- Material sensitivity: If material sensitivity is suspected, tests should be performed prior to implantation
- Patients who are unwilling or incapable of following post-operative care instructions
- These devices are not intended for micro nail attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine

MRI Safety Information:

InFrame has not been evaluated for safety and compatibility in the MR environment. InFrame has not been tested for heating, migration, or image artifact in the MR environment. The safety of the device in an MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Warnings:

For safe, effective use of the implant, the surgeon must be thoroughly familiar with the implant, the methods of application, instruments, and the recommended surgical technique for the device.

- The device is not designed to withstand the stress of weight bearing, load bearing, or excessive activity
- Improper insertion of the device during implantation may increase the probability of hardware failure
- The patient should be cautioned about the use, limitations, and possible adverse effects of this implant. These cautions include the possibility of the device or treatment failing because of inadequate fixation and / or hardware loosening, stress, excessive activity, or load bearing, particularly if the implant experiences increased loads due to delayed union, nonunion, or incomplete healing, and the possibility of nerve or soft tissue damage related to either surgical trauma or the presence of the implant
- The patient should be warned that failure to follow postoperative care instructions can cause the implant and / or treatment to fail
- The implants may cause distortion and / or block the view of anatomic structures on radiographic images
- InFrame and accessories are single-use only. Do not attempt to re-sterilize

Precautions:

- Avoid overtightening InFrame; this may strip the drive feature, preventing removal of the implant if later desired
- When placing the guidewire, it is important to ensure it is not bent or damaged

Special Patient Populations:

- Safety and effectiveness in children under the age of 18 years have not been established
- Safety and effectiveness of use in patients with narrow diameter long bones has not been established

Prescription Device:

Caution: Federal law restricts this device to sale by or on the order of a physician. This device requires surgical implantation under sterile conditions. This device does not contain latex.

Directions for Use:

Surgical techniques are available describing the uses of this system. 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 procedure before use. An InFrame Surgical Technique Guide can be found on the ExsoMed website (www.acumed.net).

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