Instructions for Use

Intraosseous Fusion Device

PRODUCT DESCRIPTION: The Intraosseous Fusion Device (IFD) is a threaded titanium implant that is designed to provide stabilization of bones, bone segments, or bone fragments to facilitate arthrodesis. The implants are offered in different lengths (10, 15, and 20mm) and diameters (6, 9, 12mm) to address different anatomic locations. All implants are made from Ti-6AL-4V ELI Titanium alloy per ASTM F-3001. The Intraosseous Fusion Device System includes implants, the instruments necessary to implant them, and the tray system for transport, storage, and sterilization. The implants and K-wires are single-use, while the remaining instrumentation is reusable.

INDICATIONS FOR USE: The Intraosseous Fusion Device System is indicated for use in skeletally mature individuals for fracture repair and arthrodesis, osteotomy, joint fusion, and fragment fixation appropriate with the size of the implant including: Minimally invasive reconstruction of fractures and joints; Fractures of the foot and ankle; Osteochrondritis dissecans, Ostero-Chondral Fractures, Other small fragment, cancellous bone fractures, Small joint fusion. Metatarsal and phalangeal osteotomies; Fractures of the tarsals, metatarsals, and other fractures of the foot; Avulsion fractures and fractures of metatarsal V; Tarso-metatarsal and metatarso-phalangeal arthrodesis; Tarsal Fusions; Calcaneal and talar fractures, Subtalar arthrodesis. Ankle arthrodesis. Fractures of small joints, such as: Ankle fractures, Navicular fractures, Fractures of the fibula, malleolus, and calcaneus. **THE INTRAOSSEOUS FUSION DEVICE SYSTEM IS NOT INTENDED FOR SPINAL USE.**

CONTRAINDICATIONS

- Active or suspected infection, sepsis, and osteomyelitis.
- Malignant primary or metastatic tumors which preclude adequate bone support.
- Conditions which tend to retard bone healing, such as blood supply limitations, previous infections, insufficient quantity & quality of bone, etc.
- Insufficient quantity or quality of bone to permit stabilization of the fusion complex.
- Conditions that restrict the patient's ability or willingness to follow postoperative instructions during the healing process.
- Suspected or documented foreign body sensitivity or intolerance.
- Skin atrophy where there is an increased risk of wound healing problems and infection.
- Immunocompromised.

INSTRUCTIONS FOR USE: The end-user information consists of the Instructions for Use, Surgical Technique, and Processing Instructions. The operating procedure steps are described in the Surgical Technique. The steps to reprocess the set following a surgical use (or prior to initial use) are described in the Processing Instructions in order to ready the kit for introduction into a sterile, surgical environment. Further copies of these documents can be requested at Auxano Medical LLC.

WARNINGS AND PRECAUTIONS:

- Single Use: The implant of the IFD system is designed for single use only and must never be re-used. Re-use of a device could compromise device performance and/or potentially result in infection.
- Patient Selection: The use of fixation hardware requires careful patient consideration for positive outcomes.
  - Mental conditions and/or behavioral traits that could compromise the following of postoperative instructions and limitations.
  - Occupation and/or activity level that could violate limitations during the healing period.
  - Health conditions or history, such as metal allergies, osteoporosis, obesity, smoking, etc., could negatively affect tissue healing.
  - Pre-existing significant deformity at the intended implantation site.
- Surgical Technique and Training: IFD implantation should be performed by experienced surgeons with specific training in the use of the IFD system. The surgeon must read and adhere to all instructions, warnings, and precautions regarding the IFD system. Failure to do so could lead to serious surgical consequences and patient injury. US federal law restricts this device to sale and use by, or on the order of, a physician.
- Internal fixation devices, such as the IFD, are intended to provide temporary structural stability until bone fusion is established. If a delayed union or nonunion occurs with the presence of load bearing, the implant could eventually break or become loose. Factors, such as correct implant size selection, patient's weight, activity level, and adherence to postoperative instructions and limitations, can affect the implant's longevity. Infection can damage bone structure which may lead to implant loosening, implant fracture, or bone fracture.
- Do not use any components of the IFD system with components of other manufacturers, unless otherwise specified in the surgical technique.
- Adjacent soft tissues should be checked to ensure that abrasive contact with the implants does not occur.
- Confirm correct implant position radiographically prior to completion of the surgical procedure.
- Removal of the IFD implant may be warranted if deemed medically necessary to avoid possible adverse effects. Explanted or soiled implant(s) should be disposed of as medical waste according to facility procedures and required compliance regulations.
- The IFD implant has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of IFD implant in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction. These implants have not been tested for heating or migration in the MR environment.

AUXANO MEDICAL

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POTENTIAL ADVERSE EFFECTS: In any surgical procedure, the potential for complications and adverse reactions exists. These do not include all adverse effects which can occur with surgery, but are important considerations particular to metallic internal stabilization devices. Clinical results depend on surgeon and technique, preoperative and postoperative care, the implant, patient pathology, and daily activity. It is important that surgeons obtain appropriate informed consent and discuss the potential for complications with each patient prior to surgery.

- Nonunion or delayed union which may lead to implant breakage.
- Bending or fracture of the implant.
- Loosening of the implant from insufficient fixation.
- Early or late infection, both deep and superficial.
- Tissue reactions from material allergies or foreign body reaction to generated particulate.
- Migration and/or subluxation of the implant.
- Thrombosis and embolism.
- Wound hematoma and delayed wound healing.
- Temporary and protracted functional neurological perturbation.
- Localized tissue reaction or pain from corrosion.
- Bone loss due to stress shielding.
- Intraoperative or postoperative bone fracture and/or postoperative pain.
- Bone necrosis.
- Soft tissue irritation from surgical trauma or prominent hardware.

MATERIAL SPECIFICATION: The implants in the IFD system are manufactured from implant grade Ti-6Al-4V Titanium Alloy (ASTM F3001). The reusable instrumentation is manufactured from biocompatible materials, including medical grade stainless steels (ASTM F899), silicone, and aluminum. The single-use K-wires are made from 316L stainless steel (ASTM F138).

PROCESSING PROCEDURE: The IFD kit is comprised of implant (single-use) and instruments (both reusable and single-use) that are supplied NON-STERILE and MUST be fully processed prior to clinical use. Do NOT re-use implant or single-use instruments. See the separate Processing Instructions document detailing the specific processing procedure. Processing steps include manual cleaning, inspection, and steam sterilization that are detailed in the IFD Processing Instructions. The following steam sterilization cycle has been validated with an FDA cleared sterilization wrap and steam sterilizer.

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME	DRY TIME*	COOL DOWN TIME*
Steam	Pre-Vacuum	270° F (132° C)	4 Minutes	50 Minutes	30 Minutes (Wire Rack)

*This sterilization cycle is not considered by the United States Food and Drug Administration (US FDA) to be a standard sterilization cycle. Users should only use sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization containers) that have been cleared by the US FDA for the selected sterilization cycle specifications (time and temperature).

STORAGE: Sterilized products should be stored in a dry, clean environment, protected from direct sunlight, pests, and extremes in temperature and humidity.

MR SAFETY: The IFD implant has not been evaluated for safety and compatibility in the MR environment. The implant has not been tested for heating or migration in the MR environment. The safety of the IFD implant in the MR environment is unknown. MR scanning of a patient who has this device may result in patient injury.

SURGEON TRAINING: Surgeon training on the Intraosseous Fusion Device System is available prior to initial clinical use of the system. Training will familiarize the clinician with the IFD implants, instruments, and procedure in order to ensure the safe and effective use of the device to maximize patient benefit. Training options include (but are not limited to) in-person training labs (cadaver or synthetic models) or in-person (or virtual) training meetings utilizing training literature or presentations. The training session duration will be proportional to the type of training and sufficient to convey understanding of system use.


Date of Manufacture


Manufacturer

Catalog Number

Non-Sterile

Batch Code


Do NOT Re-use


Consult Instructions for Use

For product inquiries, cleaning instructions, surgical techniques, or to report any adverse event, please visit us at **www.AuxanoMedical.net**

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