Surgical Technique

Intraosseous Fusion Device

CONTENTS

1.) INTRODUCTION

1.1. INTRODUCTION

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, and 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.

1.2. 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.

1.3. 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 post-operative 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

1.4. STERILITY

The IFD kit is comprised of implants (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 implants 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).

1.5. 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).

1.) INTRODUCTION (Cont.)

1.6. WARNINGS AND PRECAUTIONS

- Single Use: The implant of the IFD system is designed for single use only and must never be reused. 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.
  - Not intended for anatomy with pre-existing serious deformation
  - 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 implant 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 implants 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.

1.7. 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

1.8. 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 implant, 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.

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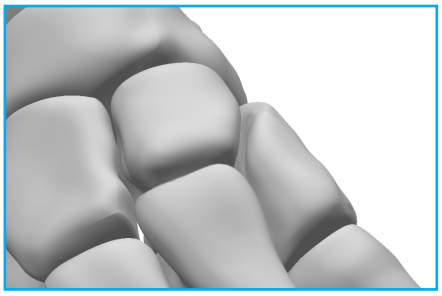
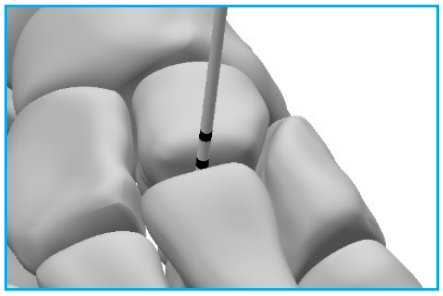
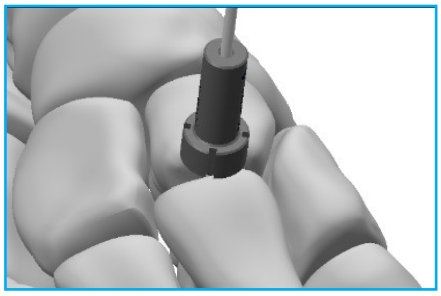
2.) SURGICAL TECHNIQUE

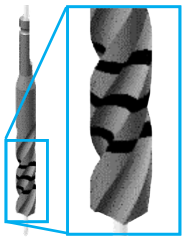
The purpose of this surgical technique guide is to demonstrate the general use of Intraosseous Fusion Device system.

- Make an incision over the joint or implantation site of interest. Dissect to the bone surface while identifying and retracting pertinent neurovascular and/or tendinous structures.
- Insert the k-wire into the desired implantation site using a wire driver. Use fluoroscopy to verify the correct placement location, orientation, and depth. Determine the appropriate implant length using the k-wire markings, which indicate 10mm, 15mm, and 20mm distance from the wire tip. Place the sizers over the wire to assess the appropriate implant diameter for the fixation site.

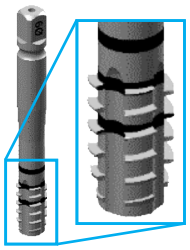
⚠	**INSTRUMENTS** - Do not use other manufacturer's instruments with the IFD system.
⚠	**IMPLANT SIZE SELECTION** - Consider full length and diameter of the implant within the fixation site anatomy. Irregular shaped bones/segments below insertion point could limit the functional implant size. Avoid an implant size that would be large enough to distract adjacent joints/bone segments.

- For the selected implant size, open the corresponding caddy which houses the size-specific implants, drills, taps & drivers.



- For the selected implant size, drill over the k-wire with the corresponding bit to the desired depth. The drill bit has markings that correspond to the different implant lengths. Avoid breaching the opposite cortex. (The k-wire can be removed after this step if desired.)

⚠	**SINGLE USE** - K-wires are single-use instruments. Do NOT reuse. Dispose according to facility guidelines.



- For the selected implant size, tap the drilled hole with the corresponding tap to the desired depth. The tap can be used with either ratcheting handle, the T or Axial variety. (Remove the k-wire after this step, if not removed previously.)

- For the selected implant size, connect the corresponding driver to the preferred ratcheting handle. Engage the self-retaining driver with the selected implant. Screw (rotate clockwise) the implant into the drilled & tapped hole of the implantation site. The implant should not sit proud of the bone surface.

⚠	**IMPLANT INSERTION** - Carefully initiate implant into the threaded pathway created by the tap. If the implant doesn't correctly engage the tapped pathway, the implant fixation strength may be compromised.

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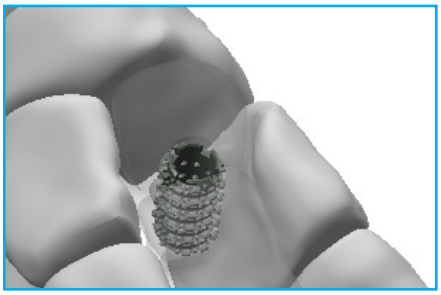
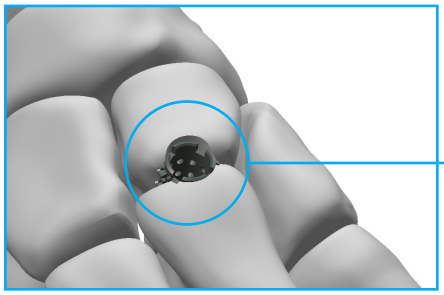
• Pack the interior of the implant with preferred bone graft material.



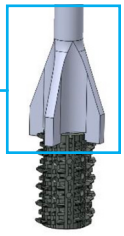


Place graft material inside of implant.

• If deemed necessary, supplemental fixation, such as a staple or plate/screw construct, can be placed over IFD implantation site. Refer to the specific surgical technique of the supplemental fixation implant. The supplemental fixation should not directly contact the IFD implant.

• Repeat the surgical technique to additional fixation sites.

• REMOVAL: If the implant requires removal, use the corresponding size driver or spanner drive. If the implant's distal hex drive feature can be accessed, the corresponding driver can be used for removal. If the distal hex drive feature is inaccessible, the spanner drive can be used by engaging the proximal notches on the implant. Unscrew (rotate counterclockwise) the implant with the driver or spanner drive.



3.) Implant & Instrument Catalog | INTREPED™ System

01-00001 – KIT CONTENTS

IMPLANT – Qty 2 ea		DRILL BIT – Qty 2 ea		DRIVER			SPANNER DRIVE		
SIZE (mm)	ORDER #	SIZE (mm)	ORDER #	SIZE (mm)	QTY	ORDER #	SIZE (mm)	QTY	ORDER #
06 x 10	01-10610	06	01-40006	06	2	01-40206	N/A	1	01-50003
06 x 15	01-10615	09	01-40009	09	2	01-40209	K-WIRE		
06 x 20	01-10620	12	01-40012	12	1	01-40212	1.6 x 6	12	01-50160
09 x 10	01-10910	TAP – Qty 1 ea		SIZER			T-HANDLE		
09 x 15	01-10915	06	01-40106	06	1	01-40306	N/A	1	01-50002
09 x 20	01-10920	09	01-40109	09	1	01-40309	AXIAL HANDLE		
12 x 10	01-11210	12	01-40112	12	1	01-40312	N/A	1	01-50001
12 x 15	01-11215								
12 x 20	01-11220								

The INTREPED™ system is supplied non-sterile, and comes in a steam-sterilizable tray.

Date of Manufacture
Manufacturer
REF Catalog Number
Non-Sterile
LOT 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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