

Intraosseous Fixation System

Instructions for Use

<p>1) DEVICE DESCRIPTION</p> <p>a) The Intraosseous Fixation System consists of various size implants to stabilize and aid in the fixation of fractures, fusions, and osteotomies of the phalanges. The implants are offered in different lengths and diameters. All implants are made from Ti-6AL-4V ELI Titanium Alloy per ASTM F-136 or PEEK-OPTIMA® polymer from INVIBIO® per ASTM F-2026.</p> <p>2) INDICATIONS FOR USE</p> <p>The Intraosseous Fixation System consists of various size implants indicated to stabilize and aid in fixation of fractures, fusions, and osteotomies of the phalanges.</p> <p>3) CONTRAINDICATIONS</p> <p>a) Cases where there is an active infection.</p> <p>b) Cases with malignant primary or metastasis tumors which preclude adequate bone support or screw fixations, unless supplemental fixation or stabilization methods are utilized.</p> <p>c) Conditions which tend to retard healing, such as, blood supply limitations, previous infections, etc.</p> <p>d) Insufficient quantity or quality of bone to permit stabilization of the fusion complex.</p> <p>e) Conditions that restrict the patient's ability or willingness to follow post operative instructions during the healing process.</p> <p>f) Foreign body sensitivity – where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantations.</p> <p>g) Cases where the patient is obese.</p> <p>4) DIRECTIONS FOR USE</p> <p>a) An appropriately sized implant is screwed into the distal side of a joint, fracture or osteotomy and subsequently pushed into the proximal or opposing side to fix the bones together. The correctly sized drill bits are utilized to produce holes for implant to be inserted. The implants are cannulated and k-wires are provided for proper placement and increased stabilization. The implants are inserted with care to ensure that they are centered in the intramedullary columns as necessary. Detailed surgical techniques for implantation surgeries are available.</p> <p>5) WARNINGS AND PRECAUTIONS</p> <p>a) Surgical technique and training</p> <p>i) Read all instructions carefully. Failure to properly follow the instructions, warnings, and precautions may lead to serious surgical consequences or injury to the patient.</p> <p>ii) NO SURGICAL IMPLANT SHOULD BE REUSED. Any implant, once used, should be discarded. Even though it appears undamaged, it may already have small defects and internal stress patterns which may lead to fatigue failure.</p> <p>iii) Preoperative and operative procedures, including knowledge of surgical technique, stable anatomic reduction, and proper selection and placement of the implants are important considerations in the successful utilization of temporary internal fixation devices. See the surgical technique for specific surgical procedures.</p> <p>iv) CORRECT HANDLING OF IMPLANT IS EXTREMELY IMPORTANT. Avoid contouring metallic and/or PEEK implants whenever possible. If necessary or allowed by design, the device should not be bent sharply, reverse bent, notched, or scratched. All of these operations can produce defects in the surface finish and internal stress concentrations, which may become the focal point for eventual failure of the device.</p> <p>b) Implant Sizing</p> <p>i) CORRECT SELECTION OF THE IMPLANT IS EXTREMELY IMPORTANT. The potential for success in fracture fixation is increased by the selection of the proper size, shape, and design of the implants. The patient's anatomy will determine the size of the implant to be used. The size and shape of the anatomy presents limiting restrictions on the size and strength of the implants.</p>	<p>c) Patient Selection</p> <p>i) When evaluating patients for orthopedic device application, the patient's weight, occupation, activity level and any degenerative diseases are of extreme importance to the eventual success of the procedure. These conditions must be evaluated as part of the preoperative planning. Conditions of senility, mental illness, alcoholism, tobacco, or drug abuse must also be taken into consideration.</p> <p>ii) Final treatment decision is at the discretion of the physician and patient.</p> <p>d) Device Compatibility</p> <p>i) It is not recommended to use other manufacturer's implants in any assembly or construct application in conjunction with OrthoHelix implants.</p> <p>ii) PEEK implants are standalone devices and are not to be used with other metallic implants of the IFS system.</p> <p>e) Post-Operative Care</p> <p>i) NOTE: Postoperative care is extremely important. The patient must be warned that noncompliance with postoperative instructions could lead to breakage of the implant requiring revision surgery to remove the device.</p> <p>ii) The use of implants provides the orthopedic surgeon a means of bone fixation and helps generally in the management of fractures and reconstructive surgeries. These implants are intended as a guide to normal healing and are NOT intended to replace normal body structure or bear the weight of the body in the presence of incomplete bone healing. Delayed unions or nonunions, in the presence of load bearing or weight bearing, might eventually cause the implant to break due to fatigue. All metal and/or PEEK surgical implants are subject to repeated stress in use which can result in metal failure.</p> <p>iii) Failure to immobilize a delayed union or nonunion of bone will result in excessive and repeated stresses which are transmitted by the body to any temporary internal fixation device prior to the healing of the fracture. Due to normal material fatigue, these stresses can cause eventual bending or breakage of the device. Therefore, it is important that immobilization of the fracture site is maintained until firm bony union (confirmed by clinical and roentgenographic examination) is established.</p> <p>NO PARTIAL WEIGHT BEARING OR NONWEIGHT BEARING DEVICE CAN BE EXPECTED TO WITHSTAND THE UNSUPPORTED STRESSES OF FULL WEIGHT BEARING. Until firm bone union is achieved, the patient should employ adequate external support and restrict physical activities which would place stress upon the implant or allow movement at the fracture site and delay healing.</p> <p>iv) Detailed written instructions on the use and limitations of the device should be given to the patient. If partial weight bearing is recommended or required prior to fusion, the patient must be warned that bending or breakage of the device are complications which may occur as a result of the weight bearing or muscle activity. An active, debilitated, or demented patient who cannot properly utilize weight support devices may be particularly at risk during postoperative rehabilitation.</p> <p>f) Removal of the Device</p> <p>i) Certain circumstances may necessitate removal of the metallic or PEEK standalone device. The specific removal steps will depend on the state of healing at the fixation site.</p> <p>(1) If the fusion site is mobile and the implant is loose, the implant can be removed by repeating the implantation exposure, pulling the loose bone from the implant's barbed section, and unscrewing the implant's threaded portion with the driver.</p> <p>(2) If the fusion site is mobile and the implant fixation is sound, the implant can be cut at the resection site with wire cutters. The implant's barbed section can be removed with pliers and the threaded portion can be unscrewed with the driver.</p> <p>(3) If the fusion site is rigid, the implant can be removed after creating a dorsal window above the implant.</p> <p>ii) Certain circumstances may necessitate removal of the metallic two piece device. Follow the removal steps described below:</p> <p>(1) Gain access to the implant through the necessary surgical exposure.</p>
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5) WARNINGS AND PRECAUTIONS (continued)

- (2) Use a curved osteotome to disassemble the IFS and Proximal Sleeve implants. This can be accomplished by wedging the sharp end of the osteotome between the threaded and hexagonal section of the IFS implant. Apply tension to the distal segment of the phalanx and use the curved osteotome as a cantilever to pry the threaded end of the IFS implant away from the Proximal Sleeve implant.
- (3) Once the implants are disengaged, use the corresponding drivers to unthread each implant from the bone.
- f) Disposal of the Device
 - i) Upon removal of implant(s), dispose of as a biohazard material.
- g) Magnetic Resonance Imaging (MRI) Safety and Compatibility
 - i) The Intraosseous Fixation System implants may affect image quality (image artifact) depending on the pulse sequence that is used for MR imaging.
 - ii) This product 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 this product in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

The Intraosseous Fixation System has not been tested for heating or migration in the MR environment.

6) POSSIBLE ADVERSE AFFECTS

- a) Loosening, bending, cracking, or fracture of the implant or loss of fixation in bone attributable to nonunion, osteoporosis, markedly unstable comminuted fractures.
- b) Loss of anatomic position with nonunion or malunion with rotation or angulation.
- c) Infection, both deep and superficial.
Allergies and other reaction to the device material.

7) PACKAGING SUPPLIED NON-STERILE












- a) The Intraosseous Fixation System implants are supplied non-sterile and must be sterilized before use.
 - i) Do not reuse implants; they are single use only.
 - ii) Do not use the device if damage is present such as nicks, gouges, or scratches.
 - iii) Store in a cool, dry place.
- b) The Intraosseous Fixation System instruments are provided non-sterile, and must be cleaned and sterilized before use.
 - i) Soak instruments in warm water for a minimum of 10 minutes.
 - ii) Disassemble instruments, as appropriate.
 - iii) Hand wash in a neutral pH (7.0) or mild detergent.
 - iv) Scrub with a soft bristle brush. Pay careful attention to any threads, pivots, recesses, or hard to reach areas on the instruments.
 - v) If the product is cannulated, insert a nylon brush or chenille pipe cleaner into the cannula.
 - vi) Immediately and thoroughly rinse and dry after washing.
 - vii) Visually inspect the instruments under room lighting conditions to ensure instruments are suitable for use and free of debris.
 - viii) Sterilize with steam sterilization. Wrap and sterilize this caddy independently. The following steam sterilization cycle is recommended based upon validation of a single Intraosseous Fixation System tray wrapped with Kimberly-Clark KIMGUARD ONE-STEP in a Steris Amsco Steam Sterilizer Model SV120 using SPS Medical Supply Corp SPORTVIEW Strips and Sutures. Flash sterilization is NOT recommended, but if used, should only be performed according to requirements of ANSI/AAMI ST79: 2006 – Comprehensive guide to steam sterilization and sterility assurance in health care facilities. Sterilization cycles beyond the prescribed parameters must be validated independently by the facility. Each facility's process parameters should be validated for the type of sterilization equipment and product load configuration.

- (1) Recommended cycle: four minutes in a 270°F (132°C) pre-vacuum steam sterilization.
- (2) Recommended dry time:
 - a) Forty five minutes : Cannulink, Angled & EXT
 - b) Sixty minutes: Cannulink TruView

8) LOANER AND CONSIGNMENT SET SHIPMENTS

- a) All instruments and implants must be placed back in the caddy and sterilized per the sterilization instructions above prior to shipping back to the manufacturer. Any implants or instrumentation damaged due to neglect from mishandling or mispackaging will be billed to the customer.

INFORMATION

Symbol	Meaning
	Catalog Number
	Batch Code
	Authorized Representative of the European Community
	Caution, Consult Accompanying Documents
	Consult Instructions for Use
	Do Not Reuse
	Not Made with Natural Rubber Latex
	Do Not Use if package is damaged
	Non-Sterile
	Caution: Federal Law (USA) restricts this device to sale by or order of a physician
	Manufacturer



Manufacturer:
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