Instructions for Use (IFU)

1. BEFORE USING PRODUCT

This document is designed to assist in using the Field Orthopaedics (FO) Extremity All Suture System (EASS). It should not be used as a reference for surgical technique.

2. CAUTION

United States Federal Law restricts this device to sale and use by, or on the order of, a physician.

3. GENERAL DESCRIPTION

The Extremity All Suture System (EASS) includes the Griplasty™ System – Base of Thumb, Micro, Mini, Small and the OCTOPi™ Suture Anchor System – OCTOBridge™, OCTOAnchor™ and OCTOExtend. The system incorporates soft tissue fixation devices; 'all suture' anchors with an expandable push-in design and associated instrumentation. Supplied sterile (ethylene oxide) for single use. The anchor and connected sutures are impacted into a pilot hole. The sutures are then manually tensioned to set the anchor by bunching the suture sleeve.

3.1 Griplasty™ System – Base of Thumb

Comprises a suture anchor implant and associated instrumentation for use in carpometacarpal (CMC) joint arthroplasty.

3.2 Griplasty™ System – Micro, Mini and Small Suture Anchor

Comprises a range of all suture anchor implants (with or without needles) and associated instrumentation for use in securing soft tissue to bone.

3.3 OCTOPi™ Suture Anchor System – OCTOBridge™, OCTOAnchor™ and OCTOExtend™

Comprises a range of all suture anchor implants (with or without needles) and associated instrumentation for use in securing soft tissue to bone.

3.4 Materials

- All sutures, inclusive of suture line and anchor are made with non-absorbable Ultra High Molecular Weight Polyethylene (UHMWPE) as per ASTM F2848.
- All needles are made with Stainless Steel as per ASTM F899.
- The instrumentation is made from medical grade stainless steel and medical grade Acrylonitrile Butadiene Styrene (ABS).

No materials of human or animal origin and refer to the package label for the materials.

4. INDICATIONS FOR USE

The Extremity All Suture System is intended to be used for suture or tissue fixation in the foot/ankle, knee, hand/wrist, elbow, and shoulder. Specific indications are listed below:

- Elbow: Biceps tendon reattachment, ulnar or radial collateral ligament reconstruction
- Shoulder: Rotator cuff repair, Bankart repair, SLAP lesion repair, Biceps tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction.
- Hand/Wrist: Scapholunate Ligament Reconstruction, Repair/reconstruction of collateral ligaments, Repair of flexor and extensor tendons at the PIP, DIP and MCP joint for all digits, digital tendon transfers, Carpal ligament reconstruction and carpometacarpal joint arthroplasty (Basal thumb joint arthroplasty)
- Foot/Ankle: Lateral stabilization, medial stabilization, achilles tendon repair, metatarsal ligament repair, hallux valgus reconstruction, digital tendon transfers, mid-foot reconstruction
- Knee: Medial collateral ligament repair, lateral collateral ligament repair, patellar tendon repair, posterior oblique ligament repair, iliotibial band tenodesis.

5. CONTRAINDICATIONS

Use of the FO EASS is contraindicated in the following,

- Cases of inflammation,
- Cases of active or suspected sepsis / infection and osteomyelitis,
- Patients with certain metabolic diseases.

All applications that are not defined by the indications are contraindicated. In addition, surgical success can be adversely affected by:

1. Acute or chronic infections, local or systemic.
2. Vascular, muscular or neurological pathologies that compromise the concerned extremity.
3. All concomitant pathologies that could affect the function of the implant.
4. Patients with insufficient bone/inadequate bone quantity.
5. Osteopathies with reduced bone substance that could affect the function of the implant.
6. Any mental or neuromuscular disorder that could result in an unacceptable risk of failure at the time of fixation or complications in post-operative treatment.
7. Patients with foreign body sensitivity or having known allergies that may cause adverse events both peri- and post-operatively.
8. Patients with limited blood supply.
9. Whenever the instrument or implantation compromises the important anatomical structures.
10. The use of this medical device and the placement of hardware or implants must not bridge, disturb or disrupt unfused growth plate.
11. Patients with unstable physical and/or mental health conditions.
12. Combination of this implant with implants of another origin is contraindicated.

Other Medical or surgical pre-conditions that could compromise the potentially beneficial procedure, such as:

1. The presence of tumors.
2. Congenital abnormalities.
3. Immunosuppressive pathologies.
4. Increased sedimentation rates that cannot be explained by other pathologies.
5. Increased leukocyte (WBC) count.
6. Pronounced left shift in the differential leukocyte count.

6. POTENTIAL COMPLICATIONS & ADVERSE REACTIONS

In any surgical procedure, the potential for complications and adverse reactions exists. The risks and complications with these implants include:

1. Loosening, deformation or failure of the implant.
2. Acute post-operative wound infections and late infections with possible sepsis.
3. Thrombosis and embolism.
4. Wound hematoma and delayed wound healing.
5. Temporary and protracted functional neurological perturbation.
6. Tissue reactions as the result of allergy or foreign body reaction to dislodged particles.

All possible complications listed here are not typical of the EASS but are in principle observed with any implant.

Promptly inform FO in the event a complication occurs or in the event of a complaint or adverse event. To assist with investigation of the event, where practicable, please retain the device and its packaging. Further processing may impact the device and the quality of the investigation and should not be undertaken without prior consultation with FO.

It is the responsibility of the surgeon to ensure patients have adequate post-operative management. Surgeon's postoperative care instructions must be strictly adhered to by the patient to avoid adverse loads on the implant/s that may lead to migration, or failure of the implant.

In the case of complications, it might be necessary to remove the implant. It is recommended that implants be removed in a manner that minimises damage to the surrounding anatomy.

All implant components are intended for one single application in a single patient. Significant loss of tensile strength over time is not expected. Implants that were used in a patient and removed, must be discarded in accordance with local requirements.

7. WARNINGS AND PRECAUTIONS

1. Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If appropriate action is not taken, complications may occur.
2. Use of an undersized anchor in areas of high functional stresses may lead to implant fracture and failure.
3. All implants and instrumentation in the EASS are intended for single use only; re-use may cause product failure and could lead to disease transmission.
4. Use of undersized/oversized drill/K-wire to generate anchor pilot hole may lead to implant failure fixation. Use drill and K-wire supplied with the implant.
5. FO branded instrumentation is recommended for use in conjunction with EASS implants.
6. Postoperatively, until healing is complete, the fixation provided by this device should be protected. The postoperative regimen prescribed by the surgeon should be strictly followed to avoid adverse stresses being applied to the implant.
7. Detailed instructions on the use and limitations of the device should be given to the patient.
8. Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure. Implant removal should be followed by adequate postoperative management.
9. Preoperative and operating procedures, including knowledge of surgical techniques and proper selection and placement of the implant, are important considerations in the successful utilization of this device.
10. Do not re-sterilize this device.
11. Do not use beyond the expiration date listed on the label. The performance, safety, and/or sterility of the device cannot be assured beyond the expiration date.
12. Remove items from sterile packages using aseptic techniques.
13. Avoid excessive impaction during insertion as this may lead to inserter damage and/or breakage. If insertion resistance is encountered, do not impact harder. Replace the implant and repeat the drilling/insertion procedure.
14. Visually inspect the inserter for potential bending, damage or breakage after each insertion.
15. Instruments, and components such as K-wires, Drills, Anchor Holders and needles are to be treated as sharps.
16. Instrument must be disposed of according to hospital policy and procedure.

8. MRI SAFETY INFORMATION

- These devices have not been evaluated for safety and compatibility in the MR environment.
- These devices have not been tested for heating, migration or image artefact in the MR environment.
- The safety of the EASS in the MR Environment is unknown.
- Scanning a patient with these devices implanted may result in patient injury.

9. MAINTAINING DEVICE EFFECTIVENESS

1. The surgeon must have specific training, experience, and thorough familiarity with the use of all suture anchors.
2. The surgeon must exercise reasonable judgment when deciding which implant to use for specific indications.
3. The EASS is not intended to endure excessive abnormal functional stresses.
4. Failure to use appropriate FO instruments for every step of the implantation technique may compromise the integrity of the implanted device, leading to premature device failure and subsequent patient injury. Failed devices may require re-operation and removal.
5. Sterile product should be carefully inspected for package integrity and expiry date prior to use. Sterile packaging should not have rips or tears and the seal should be intact. Product that is expired, defective, damaged or where the sterile barrier has been compromised must not be used and must be disposed of according to hospital policy and procedure.
6. Carefully inspect the implants and instrumentation prior to use to ensure they are in proper operational condition. Instruments that are faulty, damaged, or suspect should not be used.
7. FO recommends the use of FO products in a sterile environment.
8. Contact with chemicals and other substances which may impact function or integrity of the device or instrumentation should be avoided.
9. Patient follow-up recommended if any unexpected discomfort / concerns.

10. RECEIVAL, INSPECTION & FUNCTIONAL TESTING

Upon receival, inspect the product for damage and dislodgement of any individual parts from the system prior to use. Any implants or instruments in the kit found to be damaged or displaced during transport should be discarded and replacement kit ordered.

Do not use if sterile packaging seal has been broken or prematurely opened. Do not use past the use by date indicated on the label.

Devices should only be accepted if the factory packaging and labelling arrive intact. Implants and instruments which are faulty, damaged, or suspect should not be used. The rejected goods must be returned to FO.

1. Check for smooth movement of assemblies without excessive play.
2. Cutting edges should be free of nicks and have a continuous edge.
3. Long slender instruments should be straight and free of distortion.

11. PACKAGING

FO devices should be accepted only if the factory packaging and labelling arrive intact. Sterile product should be inspected before use and product should not be used if seal has been broken or prematurely opened. Contact Commercial Team if the package has been opened or altered.

12. SURGICAL TECHNIQUE

EASS implants should only be implanted by surgeons who are fully experienced in the use of such implants and the required specialized surgical techniques. Surgeons are advised to review the product specific surgical technique prior to performing any surgery.

FO provides detailed surgical techniques in print and electronic formats. Refer to the product specific Surgical Technique for illustrated procedural instructions.

Download the current version available at www.fieldorthopaedics.com/brochures.

13. STORAGE CONDITIONS.

Store away from moisture and direct heat.

14. CONTACT

Please contact the FO commercial team for product inquiries and surgical techniques, or to report a complaint or adverse event.

Commercial Team: sales@fieldorthopaedics.com

Manufacturer / TGA Sponsor
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This document may be subjected to revision. Please verify that any printed version is identical to the current IFU at www.fieldorthopaedics.com/brochures. A paper copy can be provided upon request.

15. GLOSSARY OF SYMBOLS

Symbol	Standard	Ref & Title	Description
LOT	ISO 15223-1 Medical devices — Symbols to be used with information to be supplied by the manufacturer. Part 1: General requirements	5.1.5 Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified
REF		5.1.6 Catalog Number	Indicates the manufacturer's catalogue number so that the medical device can be identified
UDI		5.7.10 Unique Device Identifier	Indicates a carrier that contains unique device identifier information
MD		5.7.7 Medical Device	Indicates the item is a medical device
		5.4.2 Do Not Re-use	Indicates a medical device that is intended for one single use only
STERILE EO		5.2.3 Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide
		5.2.8 Do Not Use if Package is Damaged and Consult Instruction for Use.	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information
		5.4.3 Consult Electronic Instructions for use	Indicates the need for the user to consult the instructions for use
		5.1.1 Manufacturer	Indicates the medical device manufacturer
		5.1.4 Use by Date	Indicates the date after which the medical device is not to be used
		5.3.4 Keep Dry	Indicates a medical device that needs to be protected from moisture
		5.2.12 Double Sterile Barrier System	Indicates two sterile barrier systems
		5.2.11 Single Sterile Barrier System	Indicates a single sterile barrier system
QTY	N/A	N/A	Quantity
℞ Only	21 CFR 801.109 - Code of Federal Regulations Title 21	(b)(1) Prescription Only	United States Federal Law restricts this device to sale and use by, or on the order of, a physician.