Tigon Medical Javelin All-Suture Anchor

Instructions for Use

Company Name: Tigon Medical
Company Address: 303 Najoles Rd. Suite 104
Millersville, Md. 21108

Important information for physicians, surgeons, and staff.

CAUTIONS:

- Federal (USA) law restricts this device to sale by or on the order of a physician.
- Do not use the contents if package is open or damaged.
- Verify the integrity of all items in the packaging before use. If an item appears damaged, do not use.

References:

- ANSI/AAMI ST79: Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities
- ISO 17664: Sterilization of Medical Devices – Information to be provided by the manufacturer for processing of re-sterilizable medical devices.
- ISO 17665-1: Sterilization of Health Care Products – Moist heat – Part 1: Requirements for the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices.
- ISO 10993-5: Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity.
- AAMI TIR30: A Compendium of Processes, Materials, Test Methods, and Acceptance Criteria for Cleaning Reusable Medical Devices

Section 1: Specific Product Information:

Product Description:
The Tigon Medical Javelin All-Suture Anchors are soft-tissue fixation devices provided sterile, preloaded on an inserter. The anchor consists of different load configurations consisting of one or more working sutures. The inserters can be reprocessed after use and are made from stainless steel.

Indications:
The Tigon Medical Javelin All-Suture Anchors are intended for the reattachment of soft tissue to bone for the following indications:

- 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 Repair
- Hand/Wrist: Scaphulolunate Ligament Reconstruction, Carnal Ligament Reconstruction, Repair/Reconstruction of Collateral Ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP and MCP Joints for all Digits, Digital Tendon Repair
- 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
- Hip: Capsular Repair, Acetabular Labral Repair, Gluteal Tendon Repair

Section 2: General Information:

Following the instructions for use provided in product literature can minimize the potential for complications or adverse reactions with any implant.

Contraindications:

- Overt Infection
- Distant foci of infections
- Rapid disease progression as manifested by joint destruction or bone absorption as seen on roentgenogram skeletally immature patients.
- Inadequate neuromuscular status (e.g., paralysis, fusion, and/or inadequate muscle strength), poor bone stock, or poor skin coverage.
- Pathological conditions of the bone (such as cystic changes or severe osteopenia) or comminuted bone which would compromise secure fixation.
- Pathological conditions of the soft tissues to be attached which would impair secure fixation.
- Physical conditions which would eliminate or reduce adequate support or slow healing such as reduced blood supply to the site.
- Conditions which may interfere with healing or decrease the likelihood of proper postoperative care such as senility, mental illness, or alcoholism.
- Attachment of artificial ligaments or other implants.

Patient Selection:

Use of surgical fusion hardware requires consideration of the following general indications:

- Good condition of the patient
- Good neurovascular status
- Adequate skin coverage
- Possibility of a functional musculotendinous system
- Availability of post-operative therapy
- Cooperative patient

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

- Infection or painful, swollen, or inflamed implant site.
- Fracture of the implant.
- Loosening or dislocation of the implant requiring revision surgery.
- Bone resorption or over-production.
- Allergic reaction(s) to implant material(s).
- Untoward histological responses possibly involving macrophages and/or fibroblasts.
- Migration of particle wear debris possibly resulting in a bodily response.
- Embolism

Warnings and precautions:
- The Tigon Medical All-Suture anchors are for single use only.
- It is the responsibility of each surgeon using the device to consider the clinical and medical status of each patient and to be knowledgeable about all aspects of the procedure and the potential complications that may occur.
- The patient's mental status must also be considered.
- The benefits derived from implant surgery may not meet the patient's expectations or may deteriorate with time, necessitating revision surgery to replace the implant or to carry out alternative procedures.
- Willingness and/or ability to follow post-operative instructions may also impact the surgical outcome.
- Surgeons must be able to balance many considerations to achieve the best results in individual patients.
- To avoid inserter breakage, do not attempt to straighten a bent device. Discontinue use, discard, and complete the procedure with a replacement device.
- Do not use parts that are broken, cracked or worn, or otherwise showing that device function may be compromised.
- Ensure all connections are tightened and secure.

The main goal of surgery with these implants is the reattachment of soft tissue to bone. Abnormal or excessive forces could lead to failure of the implant. Abnormal force loading and subsequent wear may be caused by:

- Uncorrected instability
- Improperly sized implant
- Inadequate soft tissue support
- Implant malposition
- Excessive motion
- Uncorrected or recurrent deformity
- Patient misuse or overactivity

Proper fixation at the time of surgery is critical to the success of the procedure. Bone stock must be adequate to support the device.

Some preventative measures to consider minimizing the potential for complications:

- Follow guidelines for indications and contraindications provided.
- Identify prior pathology
- Stabilize any collapse deformities.
- Bone graft pre-existing cysts.
- Avoid flawing implant surfaces to minimize potential for early fatigue failure

Over time, implants may loosen or pull out, causing complications. If complications do develop, possible corrective actions include:

- Implant removal
- Replacement of the implant

Removal of the implants is at the surgeon's discretion, and the appropriateness of the selected procedure will be based on the surgeon's personal medical training and experience. It is imperative that adequate post-operative care and protection be provided by the surgeon.

<u>Recommendations regarding device:</u>

1. Use medical devices in accordance with their labeled indications and the manufacturer's instructions for use.
2. Inspect devices prior to use for damage during shipment or storage or any out-of-box defects.
3. Inspect devices immediately upon removal from the patient for any signs of breakage or fragmentation.
4. If the device is damaged, retain it to assist with the manufacturer's analysis of the

event.

5. Carefully consider and discuss with the patient (if possible) the risks and benefits of retrieving the fragment in the patient.
6. In case of breakage, advise the patient of the nature and safety of unretrieved fragments including the following information:
   a. The material composition of the fragment (if known)
   b. The size of the fragment (if known)
   c. The location of the fragment
   d. The potential mechanisms for injury
   e. Procedures or treatments that should be avoided such as MRI exams in the case of metallic fragments. This may help to reduce the possibility of a serious injury from the fragment.

Clinical results depend on surgeon and technique, pre-operative and post-operative 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. This may include a review of alternative, non-implant procedures such as soft tissue reconstruction or arthrodesis.

Concerning Magnetic Resonance Environments:
The devices described in this IFU have not been evaluated for safety and compatibility in the MRI environment. The devices described in this IFU have not been tested for heating or migration in the MRI environment.

Section 3: Cleaning
Surgical instruments and their respective trays must be cleaned prior to initial sterilization and as soon as possible after use. Do not allow blood or debris to dry on the instruments. If cleaning must be delayed, place groups of instruments in a covered container with appropriate detergent or enzymatic solution to delay drying. Wash all instruments whether they were used or inadvertently came into contact with blood or saline solution per the following instructions:

1. Disassemble as per manufacturer instructions (if appropriate.)
   a. Open the Tigon Medical GreenRepair® collection box and rinse collected shafts following the steps below. Return shafts and box to tray.
2. Rinse with cold tap water to remove visual debris until gone.
3. Bathe in an enzymatic detergent solution prepared per manufacturer directions for 5 minutes (e.g., Enzol® prepared at 1 oz. per gallon of lukewarm deionized water).
4. Scrub thoroughly with a soft brush and/or pipe cleaner; repeatedly flush any very narrow lumens with enzymatic detergent solution using a syringe.

5. Rinse with cold tap water for a minimum of one minute; use syringe to repeated flush any very narrow lumens.
6. Rinse thoroughly / flush with room temperature DI water for a minimum of one minute. Instruments should then be flushed with room temperature deionized/reverse osmosis (RO/DI) water for a minimum of one minute.
7. Sonicate for a minimum of 10 minutes in an enzymatic detergent solution prepared per manufacturer directions (e.g., Enzol® prepared at 1 oz. per gallon of lukewarm deionized water).
8. Rinse thoroughly/flush with room temperature DI water for a minimum of one minute.
9. Dry with a clean, soft, absorbent, disposable cloth.
10. Visually inspect for cleanliness. All visible surfaces, internal and external, should be visually inspected. If necessary re-clean until it is visibly clean.

Instruments and trays must be inspected and free from visible dirt or deposits. All movable parts and working tips must be inspected for cracks, corrosion, or other damage. If damage is found, it must be removed from the tray and the Tigon representative must be notified immediately.

Section 4: Sterilization

Surgical instruments and their respective trays must be cleaned and sterilized before use. Implants are provided sterile-packed.

1. Double wrap the component in an FDA-cleared CSR wrap or a similar type of non-woven FDA-cleared medical grade wrapping material.
2. Do not stack trays during sterilization.
3. Autoclave according to the following parameters:

Steam Sterilization

Cycle Type: Vacuum 270˚F (132˚C)

Parameter	Minimum Set Point
Exposure Temperature	270˚F (132˚C)
Exposure Time	4 minutes
Dry Time	20 minutes

After sterilization, remove the component from its wrapping using accepted sterile technique with powder free gloves.

Section 5: Care and Handling of Implants

The implants in this system are provided sterile-packed. Implants in this system should never be re-sterilized.

Devices labeled for single use only should never be reused. Reuse of these devices may

potentially result in serious patient harm. Examples of hazards related to the reuse of these devices include but are not limited to significant degradation in device performance, cross-infection, and contamination.

Section 6: Care and Handling of Instruments:

Surgical instruments and cases are provided non-sterile. They are susceptible to damage for a variety of reasons including prolonged use, misuse, rough or improper handling. Care must be taken to avoid comparing their exacting performance. To minimize damage and risk of injury, the following should be done:

- Inspect the instrument case and instruments for damage upon receipt and after each use and cleaning.
- Incompletely cleaned instruments should be re-cleaned.
- Instruments in need of repair or instruments that are being returned to Tigon medical should be set aside for repair service or returned to Tigon Medical. (Instruments returned to Tigon Medical or its distributors should be cleaned and sterilized prior to shipment. ANSI/AAMI ST35 Safe Handling and Biological Decontamination of Reusable Medical Devices in Health Care Facilities and in Nonclinical Settings provide guidelines for return or contact Tigon Medical or your distributor for further instruction.)
- Only use an instrument for its intended purpose.
- When handling sharp instruments use extreme caution to avoid injury. Consult with an infection control practitioner to develop and verify safety procedures appropriate for all levels of direction instrument contact.

Instruments within the Tigon Medical GreenRepair® collection box are not to be used and the collection box should only be used intraoperatively to deposit shafts.

Section 7: Storage Conditions

All implants and instruments must be stored in a clean, dry environment and be protected from sunlight and extremes of temperature.

Symbols Glossary:

	Manufacturer
	Date of Manufacture
	Do Not Reuse
	Caution, Consult Accompanying Documents
STERILE	Sterile
REF	Catalogue Number
LOT	Lot Number
	Non Sterile
	Read Usage Instructions
	Do Not Expose to Sunlight
	Prescription Only
	Not to be Used if Case is Damaged
	Manufacturer
	Date of Manufacture
	Do Not Reuse
	Caution, Consult Accompanying Documents
STERILE	Sterile
REF	Catalogue Number
LOT	Lot Number
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