Tigon Medical Tomahawk Anchor, Dual Anchor, Tenodesis Anchor, Eye-Deal 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.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

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 GAL Anchor Line consists of four families of suture anchors. The Tomahawk Anchors, Dual Anchors, Tenodesis Anchors, and Eye-Deal anchors. The Tigon Medical GAL Anchor Line consists of many different sizes of anchor ranging in size from 3.75 mm diameter to 10.5 mm diameter and 5.75 mm length to 23 mm length. The anchors are all made from VESTAKEEP® i4R PEEK per ASTM F2026 with the exception of the Eye-Deal Anchors which are made from Ti6Al4V per ASTM F136. The anchors are

available loaded with suture and without suture. There are many configurations of tapes and suture cable. #2 suture cable or tape equivalent may be loaded with all anchor variants. The Dual Anchors, Tenodesis Anchors, and Eye-Deal anchors may accommodate #2 suture cable or #5 suture cable and tape equivalent. The anchors all use stainless steel inserters per ASTM F899. The Tomahawk Anchor shafts may be reprocessed.

Anchors are PEEK per ASTM F-2026 or equivalent or Ti6Al4V ELI per ASTM F136.

Indications:

The Tigon Medical GAL Anchor Line is made up of four families of soft tissue fixation devices: Tomahawk Anchor, Dual Anchor, Eye-Deal Anchor, and Tenodesis Anchors. The entirety of the GAL Anchor line is intended for use for the reattachment of soft tissue to bone for the following indications:

Shoulder: Capsular stabilization (Bankart repair, Anterior shoulder instability, SLAP lesion repairs, Capsular shift or capsulolabral reconstructions), Acromioclavicular separation repairs, Deltoid repairs, Rotator cuff repairs, Bicep tenodesis.

Elbow, Wrist, and Hand: Biceps tendon reattachment, Ulnar or radial collateral ligament reconstruction, Lateral epicondylitis repair;

Knee: Extra-capsular repairs (Medial collateral ligament, Lateral collateral ligament, Posterior oblique ligament), Patellar realignment and tendon repairs (Vastus medialis obliquus advancement), Iliotibial band tenodesis;

Foot and Ankle: Hallux valgus repairs, Medial or Lateral instability repairs/reconstructions, Achilles tendon repairs/ reconstructions, Midfoot reconstructions, Metatarsal ligament/tendon repairs/reconstructions, Bunionectomy

In addition to these indications, the Tenodesis Anchors, a sub family of the GAL Anchor Line will also be indicated for:

Foot and Ankle: Flexor hallucis longus for Achilles tendon reconstructions, tendon transfers in the foot and Ankle

Knee: ACL Repair

Hand/Wrist: Carpometacarpal joint arthroplasty, carpal ligament reconstructions and repairs, tendon transfer in hand/wrist

Section II: 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 apparent 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 retard 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 GAL Anchors are for single use only. The implants are not reusable.

- It is the responsibility of each surgeon using implants to consider the clinical and medical status of each patient and to be knowledgeable about all aspects of implant procedure and the potential complications that may occur.
- 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.
- The patient's mental status must also be considered.
- 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.

The main goal of surgery with these implants is to establish bony fusion. Abnormal or excessive forces could lead to delayed union, non-union, or 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 to minimize the potential for complications:

- Follow guidelines for indications and contraindications provided above.
- Identify prior pathology.
- Stabilize collapse deformities.
- Bone graft pre-existing cysts.
- Use a properly sized implant.

Avoid flawing implant surfaces to minimize the potential for early fatigue failure.

If complications develop, possible corrective procedures include:

- Implant removal
- Replacement of the implant.

Overtime, PEEK implants may loosen, fracture, or cause pain after the bone fracture or osteotomy is healed. Removal of PEEK 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 fragments:</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 that might increase the likelihood of fragmentation during a procedure.
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 or leaving the fragment in the patient.

6. Advise the patient of the nature and safety of unretrieved device 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
   f. 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 GAL Anchor Line 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 The GAL Anchor Line 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.

Patents

For patent information see: www.tigonmedical.com/patents

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.)

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.

Section 7: Storage Conditions

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

Labeling:

	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
Rx	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
	Non Sterile
	Read Usage Instructions
	Do Not Expose to Sunlight
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