Tigon Medical FIRE System

Instructions for Use

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

SYMBOLS Glossary per ISO 15223-1

5.1.1	Medical Device Manufacturer
5.1.3	Date of Manufacture
5.1.4	Use By Date
5.4.2	Do not Re-use
5.4.4	See Instructions for Use
5.2.8	Do Not Use if Package is Damaged
Rx only	Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
QTY	Quantity
5.2.3 STERILE EO	Sterilized Using Ethylene Oxide
5.1.5 LOT	Batch Code
5.1.6 REF	Catalogue Number
MD	Medical Device
MR	MRI Safety Information
5.2.7 NON STERILE	Non sterile symbol
5.3.2	Keep away from sunlight

Description:
The Tigon Medical Fractures, Instability, and Reconstruction (FIRE) System includes reconstruction devices that are designed to provide a means of bone-to-bone fixation and to assist in the management of reconstructive surgeries. The system includes instruments that allow for the placement of the reconstruction device and screws. The reconstruction devices and screws are available in various sizes.

Material:
Implants are manufactured from Ti6Al4V ELI per ASTM F136. They will be provided non-sterile in a tray and be cleaned and sterilized by the end user before use. Surgical instruments are manufactured from medical grade stainless steel and plastics. All instruments are user sterilized and are re-usable unless otherwise specified.

Indications for Use:
The Tigon Medical FIRE System is intended to provide the orthopedic surgeon with a means of bone-to-bone fixation and to assist in the management of reconstructive surgeries.

- Bone Loss Deficiencies/Deformities
    - Latarjet
    - Free bone block
- Internal bone fixation for bone fractures, fusions, non-unions, and osteotomies in the foot, ankle, hand, and 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:

Absolute Contraindications:

- Cases when there is an active infection.
- Conditions which tend to retard healing, such as supply limitations, previous infections, etc.
- Insufficient quantity or quality of bone.
- Conditions that restrict the patient's ability or willingness to follow post-operative instructions during the healing process.
- Foreign body sensitivity – where material sensitivity is suspected, appropriate tests should be made, and sensitivity ruled out prior to implantation.
- These devices are not to be used for screw attachment or fixation to the posterior elements of the cervical, thoracic, or lumbar spine.

Relative contraindications include:

- Uncooperative patient or a patient with neurological disorders and incapable of following instruction
- Conditions which may interfere with healing or decrease the likelihood of proper postoperative care such as senility, mental illness, or alcoholism
- Metabolic disorders which may impair bone formation or bone quality
- Distant foci of infections

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

Possible Adverse Reactions:

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

- 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.
- Other complication associated with general surgery, such as drugs, ancillary devices, and blood loss or transfusions.

Intraoperative and early postoperative complications can include:
- Embolism
- Damage to blood vessels
- Temporary or permanent neuropathies
- Traumatic arthrosis of the knee from intraoperative positioning of the extremity
- Cardiovascular disorders including venous thrombosis, pulmonary embolism, or myocardial infarction
- Hematoma
- Delayed wound healing
- Infection or painful, swollen, or inflamed implant site

Late postoperative complications can include:
- Fracture of the implant as the result of strenuous activity, obesity, improper alignment, inadequate fixation, or extreme duration of service.
- Infection

Warnings and precautions:

While these implants are not intended to withstand activity levels and loads of normal healthy bone, they are a means of restoring mobility and reducing pain for many patients. In using these implants, the surgeon should be aware of the following:
- 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.
- In selecting patients for surgery, the following factors can be of extreme importance to the eventual success of the procedure:
    - The patient's weight – An overweight or obese patient can produce loads on the implant, which can lead to failure of the implant. This becomes a major consideration when a small implant must be used.
    - The patient's occupation or activity – If the patient is involved in an

occupation or activity which included substantial walking, running, lifting, or muscle strain, the resultant forces can cause failure of the fixation, the device or both.
    - A condition of senility, mental illness, or alcoholism – These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions, leading to failure or other complications.
    - Foreign body sensitivity – Where material sensitivity is suspected, appropriate tests should be performed prior to material selection or implantation.
    - Certain degenerative diseases – In some cases, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance.
- The correct handling of the implant is extremely important. Care must be taken to protect surfaces from nicks and scratches which could become the focal point for failure. Do not tamper with the implant as contouring or bending of the implant may reduce its service life and may cause immediate or eventual failure under load.
- A surgical implant should not be reused. Even though a used implant may appear undamaged, it may have small defects and internal stress patterns, which may lead to failure. Use only new implants of the current design.
- Bone excision should be limited to the amount necessary to accommodate the implants. Prior to closure, the surgical site should be thoroughly cleaned of bone chips or other detritus that may cause a third body wear problem.
- Postoperative care is important. The patient should be instructed on the limitations of these devices and should be cautioned regarding load bearing ranges of motion and activity levels permissible. Early load bearing should be carefully controlled. The patient should be advised to report any related pain, decrease in range of motion, swelling, fever, and unusual incidences.

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 minimizing 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.

Over time, metallic implants may loosen, fracture, or cause pain after the bone fracture or osteotomy is healed. Removal of metallic 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 the fragment in the patient.

6. Advise the patent 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 case of metallic fragments. This may help to reduce the possibility of a serious injury from the fragment.

Caution:
Disposal of implants should be carried out using the hospital's standard method for non-biodegradable non-combustible medical waste.

MRI Safety Information:
The devices described in this IFU have not been evaluated for safety and compatibility in the MRI environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of the implants in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Section 5: Care and Handling of Instruments and Non-Sterile Implants

Instrument Intended Use:
The instrumentation has been designed to facilitate bone preparation and implantation of the FIRE System. A surgical technique can be obtained from Tigon Medical or its representatives.

Instrument Care:
Store instruments in the corresponding instrument system trays. After use and cleaning, instruments must be stored in a clean, dry, and temperate place.

Surgical instruments and cases are susceptible to damage for a variety of reasons including prolonged use, misuse, rough or improper handling. 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.
- All instruments should be carefully examined for wear or damage by surgeons

and staff in operating centers prior to surgery. The examination shall include a visual and functional inspection. It should also include verifying the cleanliness of the device, as well as the absence of any cracks, distortion, wear, corrosion, or other change.

- Like any precision surgical device, all instruments should undergo regular checks by knowledgeable personnel to ensure that they remain in good condition and continue to act as intended. Do not use any instrument or device that is damaged, incomplete, showing signs of excessive wear and tear or that has been repaired outside the control of Tigon Medical.
- 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 that are returned to Tigon Medical or its distributors should be cleaned and sterilized prior to shipment. Follow ANSI/AAMI ST34 (Safe Handling and Biological Decontamination of Reusable Medical Devices in Health Care Facilities and in Nonclinical Settings) for guidelines for returning contact Tigon Medical or your distributor for further instructions.

Reusable Instrument Warnings and Precautions:

- Tigon devices must only be used by surgeons who have been trained in the appropriate surgical techniques and are familiar with the instruments provided.
- The surgeon must take care not to exert inappropriate stress on the device and must comply with the operating procedure described in the surgical technique.
- Prior to using the instrument system, the surgeon should consider all aspects of the surgical intervention as well as the limitations of the implant and the instruments.
- Use care in handling and storage. Some instruments are sharp and incorrect use or handling may result in puncture wounds. Consult with an infection control practitioner to develop and verify safety procedures appropriate for all levels of direct instrument contact.
- Do not use devices with drills that exceed 1500 rpm
- Improper use may result in breakage of the instrumentation during operation. Only use an instrument for its intended purpose.
- Remove all broken instrument fragments. As a result of mechanical features required, the device is made of medical grade but not implant grade materials.

Failure to remove broken instruments from the patient could result in patient complications and further intervention.

- Incorrect maintenance, cleaning or handling may render the instrument unsuitable for its intended use, cause corrosion, dismantling distortion, and/or instrument breakage or injury to the patient or operating staff. Potential complications include device breakage, leaching of debris, lack of component engagement, infection, and damage to tissue.

Cleaning of Reusable Instruments:
Surgical instruments are supplied non-sterile. Remove instruments from all individual sales packaging, clean and place in the appropriate location in the instrument tray provided by Tigon prior to sterilization.

Autoclave sterilization is recommended. The autoclave must be properly maintained by the hospital and regularly checked to assure the recommended sterilization temperatures are reached for the entire exposure time.

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.

The following cleaning and sterilization parameters have been validated and are recommended:

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 lumen.
6. Rinse thoroughly / flush with room temperature DI water for a minimum of one

minute. Implants 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. Implants should then be flushed with room temperature RO or distilled 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, trays, and caddies 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.

Product Handling:

Implants that are provided sterile should always be stored unopened in their respective protective containers. Prior to use, inspect package for damage which may compromise sterility. If packaging has been opened or damaged, contact the manufacturer's representative. When unpacking the implant, verify the labeling for the correct Cat. No. and size. When removing the implant from its packaging, the sterile technique must be observed. Protect the implant from contact with objects that may damage the surface finish. Inspect each implant prior to use for visual damage that might increase the likelihood of fragmentation during a procedure. Procedures for implanting and removal are available upon request.

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

Sterilization of Instruments and Non-Sterile Implants:
The Tigon Medical FIRE System implants will be provided non-sterile in caddy within its corresponding instrument case. If the implant is not removed from the tray and unused, it may be re-sterilized.

Surgical instruments and non-sterile packed implants and their respective trays and caddies must be cleaned and sterilized before use. Implants are provided in the tray in caddies or provided sterile-packed.

1. Place components in the correct location in the instrument tray.
2. Double wrap the component in an FDA-cleared CSR wrap or a similar type of non-woven FDA-cleared medical grade wrapping material.
3. Do not stack trays during sterilization.
4. 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. Ensure that implants are at room temperature prior to implantation. Avoid contact with hard objects that may cause damage.

Additional information about the Tigon Medical FIRE System may be obtained from Tigon Medical.