Tigon Medical Non-Disposable Cannula

Instructions for Use

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

Cautions:

- Rx Only: Federal (USA) law restricts this device to sale by or on the order of a physician. Read instructions prior to use.
- Single use, disposable products are designed, tested, and manufactured for single use only, refer to package labels.
- Do not use the contents if package is open or damaged.
- Do not reuse, reprocess, or re-sterilize. Reuse or reprocessing has not been evaluated and may lead to product failure and subsequent patient illness, infection, or other injury.
- Verify the integrity of all items in the tray before use. If an item appears damaged, replace the item.

Warnings and precautions:

- 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.
- Ensure all connections are tightened.
- The device should be fully inserted and visible within the joint cavity to avoid the possibility of fluid extravasation into the tissue.
- Verify that instruments are compatible with cannula size prior to use.
- Take care to avoid anatomical hazards.

Some preventative measures to consider minimizing the potential for complications:

- Follow guidelines for indications and contraindications provided.
- Identify patient history.

<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.

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 Non-Disposable Cannulas will consist of various sized devices, ranging in lengths and diameters. The device will contain pieces that are either single-use or reusable. The reusable pieces will be sterilized via Moist Heat Steam Sterilization for arthroscopic and laparoscopic procedures. Surgeons, nurses, and surgical technicians will be the users of these instruments in a sterile operating environment. All individual components of the device must remain sterile throughout the time of use in the operating room. All items are susceptible to damage via shipping and handling as well as storage environment. Any packaged, single use items must remain sterile up until and during use. Reusable items must be sterilized before and after use and must remain sterile during use.

Indications:
Use when access to field is necessary for passing of surgical instruments during arthroscopic or laparoscopic procedures.

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:

- None known

Section 3: 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, and 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.
- Inspect for dirty instruments which should be re-cleaned.
- Instruments in need of repair 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 4: 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 bodily fluids, using 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 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 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 5: Sterilization

Surgical instruments and their respective trays must be cleaned and sterilized before use. Single use devices 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. Ensure that implants are at room temperature

prior to implantation. Avoid contact with hard objects that may cause damage.

Section 6: Care and Handling of Single Use Devices

Single use devices are provided sterile-packed:

- A single-use device should never be re-sterilized or placed back in the tray after contact with body tissues or fluids.

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 7: Storage Conditions

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

Section 8: 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
	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
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