**Tigon Medical Vampire Awl Device**

**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.
- The TM-VAPT002 was designed, tested, and manufactured for single use only.
- 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.
- To avoid device breakage, do not attempt to straighten a bent device. Discard and complete the procedure with a replacement device.
- Ensure all connections are tightened.

Some preventative measures to consider minimizing the potential for complications:

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

If complications develop, possible corrective procedures include:

- Implant removal
- Replacement of the implant.

<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 Vampire Awl will be used to perform bone marrow aspiration. The device will penetrate the bone surface to reach the center of the bone in order to extract and contain the bone marrow using a standard syringe. The TM-VAPT001 is a reusable piece that will be Moist Heat Steam Sterilized and provided in Tigon Medical's instrument trays. The TM-VAPT002 is single-use and will need to be provided sterile packaged.

The Tigon Medical Vampire Awl Project consists of the following product codes: TM-VAPT001 and TM-VAPT002.

**Indications:**

- Bone Marrow Aspiration for Harvesting

**Instructions for Procedure Preparation:**

Heparin Flush Protocol

*Preparation of Heparin Flush Bath*

- Obtain a 5 mL vial of 5,000 units Heparin per mL (25,000 units in total)
- Using a syringe, transfer the 5 mL into a sterile bowl
- Add 7.5 mL of sterile saline into the bowl
- The bowl should now contain 12.5 mL of 2,000 units Heparin per mL
- (25,000 units / 12.5 mL = 2,000 units/mL)

*Alternate Preparation (No dilution required)*

- Obtain 10 mL of 1,000 unite per mL Heparin (10,000 units in total)

Component Flushing (Rinsing) Instructions

- Withdraw approximately 5-7 mL of Heparin Solution (2,000 units/mL) into a 10 mL syringe
- Connect Heparin-filled syringe to the Vampire Fang (TM-VAPT002)
- Inject Heparin until needle is fully rinsed
- Aspirate Heparin back into syringe and disconnect from needle
- Repeat as necessary

## 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:**

- Severe hemophilia
- Severe disseminated intravascular coagulation
- Other severe bleeding disorders

**Potential complications and adverse reactions:**

Bone marrow aspiration should not be attempted by physicians unfamiliar with the possible complications. Potential complications may include, but are not limited to:

- Excessive bleeding or drainage from the aspiration site
- Infection of the bone (osteomyelitis) at the aspiration site
- Redness or swelling at the aspiration site
- Fever

## 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 |
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