**Supplied Non-Stereile**

Reusable instruments, cannulas and accessories are supplied non-stereile and require cleaning and sterilization prior to use.

**Preparation and Disinfection**

Sterilization: Inactive and stored sterilized instruments in accordance with EN ISO 11607.

Cleaning: Manual

- Remove the devices from the enzyme solution and rinse in lukewarm (22-43°C) tap water. Clean the cannula hub and other device surfaces with a soft-bristled brush and lukewarm (22-43°C) tap water mixed with the enzymatic cleaning agent as directed by the manufacturer of the cleaning agent. Clean the inside lumen(s) of cannulas using a soft-bristled, nylon brush until all visible debris has been removed. Using a syringe with a volume of 60ml, thoroughly rinse the cannula(s) for at least 3 times with a syringe (60ml) filled with ultralow, RF, DI, distilled or and/or demineralized water. Place prepared instruments on a clean sterilizer and autoclave at 132°C for 20 to 45 min. Let the devices cool in a neutral pH (7) environment. Once cool, store the instruments in a solution as per enzyme solution manufacturer instructions using lukewarm (22-43°C) tap water - enzyme solution at a concentration recommended by the manufacturer (final step: flush by washing the device(s) at least 3 times with a syringe (60ml) filled with ultralow, RF, DI, distilled or and/or demineralized water. If performing a mechanical wash, use a wash using a clean steam and or non-shedding disposable washing. Whenever possible, spray on Miltex Instrument Prep Enzyme Formula 3-760 and then follow holding and preaseptic requirements. It is imperative that the cannulas and accessories are allowed to dry out prior to storage in a neutral pH (7) environment. Miltex Instrument Prep Enzyme Formula 3-760 is ready to use spray for pre-cleaning of reusable, RF, DI, distilled, sterilized, cannulas and accessories until the devices are ready for reuse. Also, Miltex Instrument Prep Enzyme Foam (3-760) and 3-775 neutral (pH 7) all-purpose enzyme concentrate is ideal for pre-soaking and pre-cleaning. Then begin cleaning instruments as follows:

- **Cleaning**
  - This document is intended to give general guidance for cleaning and sterilization of supplied non-sterile, reusable Tulip® instruments, cannulas and accessories.
  - This document may be provided in conjunction with the assembly and disassembly instructions for cannulas and accessories.
  - Tulip® Medical Products relies on well-qualified surgeons, hospitals, medical clinics or surgical offices to properly select patients, advise each patient about the proposed treatment, ensure that the medical care facility is capable of achieving a desired effect(s.)
  - Tulip® Medical Products supports the use of the National cleaning and sterilization requirement should be followed as applicable.
  - Since reusable Tulip® instruments, cannulas and accessories are supplied non-stereile and require cleaning and sterilization before use, the appropriate sections of these instructions may be applied unless other specific instructions and/or limitations as indicated by the manufacturer or medical facility.
  - All devices should be used with extreme caution in patients with chronic medical conditions such as diabetes, heart, lung, or cardiovascular system disease or obesity;
  - The volume of blood loss and endogenous body fluid loss may adversely affect intraoperative and/or postoperative hemostatic stability and patient safety.

**Warnings:**

- Do not use alkali-based detergents or cleaning agents to clean Tulip® instruments. Alkaline-based (pH >7) detergents and solutions corrode metals. Long, narrow cannulas and blunt holes require particular attention during cleaning.
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**Instructions for Use – Reusable Devices**

- Removable excess blood and debris with disposable cloth and/or non-shedding wipe. Instruments should be cleaned within 30 minutes of use to minimize the potential for drying prior to cleaning. Disconnect instruments from their mating syringes and place in an instrument tray large enough to accommodate the instruments using an enzymatic cleaner according to the cleaning agent instructions.
- Place devices in a solution as per enzyme solution manufacturer instructions using lukewarm (22-43°C) tap water. Comply with the cannula and accessory manufacturers’ instructions in the cleaning solution(s).
- Do not use alkali-based detergents or cleaning agents to clean Tulip® instruments. Alkaline-based (pH >7) detergents and solutions corrode metals. Long, narrow cannulas and blunt holes require particular attention during cleaning.
- Reusable instruments are supplied non-stereile and require cleaning and sterilization before use, the appropriate sections of these instructions may be applied unless other specific instructions and/or limitations as indicated by the manufacturer or medical facility.
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**Point of Use:**

- Place devices in a solution as per enzyme solution manufacturer instructions using lukewarm (22-43°C) tap water. Compliance with the cannula and accessory manufacturers’ instructions in the cleaning solution(s).
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**Recessed features (such as openings in the cannulas and accessories).**

**WARNING:** DO NOT USE ALKALI-BASED DETERGENTS OR CLEANING AGENTS TO CLEAN TULIP CANNULAS OR ACCESSORIES.

- Staff should use suitable protective clothing and equipment at all times. In particular, take note of the instructions provided by the cleaning agent manufacturer for correct handling and use of the cleaning agents.
- This document pertains to reusable devices only and these instructions are not intended for devices labeled "For Single-Use Only." Tulip single-use devices may not be reprocessed. Do not attempt to perform as intended after the first use. Please refer to the device label and manufacturers’ instructions to identify the instruments as "For Single-Use Only" or "Reusable."

- Tulip Medical Products recommends these cleaning solutions: Miltex® brand EZ-Zyme® All Purpose Enzymatic Cleaner or Miltex® SURGICAL Instrument Prep Foam Cleaner. For more information regarding these products, visit on line: http://www.miltex.com/prodinfo/product.asp

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**Manual Cleaning Equipment required:**

- Pre-Cleaning Procedure:
  - Rinse: Each Tulip instrument, cannula and accessory of the device(s) from the body during general surgical and plastic surgery procedures. Reusable Tulip® cannulas and accessories are intended for use in soft tissue surgical procedures and as advised by a qualified surgeon.
  - Drying: Wipe dry with a non-shedding wipe. Ensure cleaned instruments are properly dry and autoclaved prior to using the device(s).
Automated Cleaning:

- Equipment required:
  - Pre-treatment equipment as recommended by the clearing agent supplier
  - Manual or automatic washer
  - Sterilizer

- Detergent type and concentration: 60°C N/A

- Decontamination:
  - Rinse: twice with ultra-filtered, RO, DI, distilled and/or demineralized water. Transfer the cannula(s) into the automatic washer/
  - Ultrasonic: 10 minutes at 40-45kHz. Change the cleaning solution for every 3-5 cannulas and accessories. Completely submerge all devices in the enzyme solution. Sonicate for 10 minutes at 40-45kHz. Change the cleaning solution for every 3-5 cannulas and accessories until the devices are ready for rinsing. Also, recommend sonication to remove debris inside the cannula tube, making sure there are no blockages and debris free of blood and debris using a clean towel or compressed air (20-40lb PSI), and/or clean and lint-free, single-use wipes.

- Sterilization:
  - Steam sterilization (most heat) is recommended. Healthcare facilities should validate the process that they use, employing the actual equipment and operation that routinely process the devices. After each Pre-Cleaning and Cleaning Procedure, follow the appropriate Sterilization Process listed next.

- Procedure Validation:
  - Manual cleaning, automated cleaning with an enzymatic cleaner and steam sterilization at 112 degrees Celsius has been validated by Tulip Medical Products.

- Procedure:
  - Automated cleaning: needed when reusable cannulas are not used or need to be cleaned. Clamping devices should be set to 20 minutes at 1500 psi at 20°C.
  - Automated cleaning: needed when reusable cannulas are not used or need to be cleaned, 15 minutes at 121°C.

- Pre-Cleaning Procedure:
  - Check that the enzyme solution is ready and working properly and that it is within the recommended temperature range.
  - Priming: pump or sonicate the enzyme solution to ensure that it is not clogged. Check that the handpiece is primed and ready to use.
  - Enzyme Foam (3-760) is a ready to use foaming spray for pre-cleaning of cannulas and accessories. It is ideal for use in situations where there is a need to pre-treat devices or hold them in a neutral pH (7) environment and sterilization is not immediately available, pre-treat devices or hold them in a neutral pH (7) environment and sterilization is not immediately available.

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