REUSABLE INSTRUMENT CARE AND REPROCESSING GUIDE

TULIP MEDICAL PRODUCTS®

Follow the manufacturer's (devices, mechanical equipment, and chemicals) written instructions for use (IFU).

QUESTIONS? TULIP MEDICAL PRODUCTS TEL: + 858.270.5900 FAX: +858.270.5901 www.tulipmedical.com, sales@tulipmedical.com

WARNING: DO NOT USE ALKALINE-BASED DETERGENTS OR CLEANING AGENTS TO CLEAN TULIP CANNULAS OR ACCESSORIES. USE OF ALKALINE-BASED DETERGENTS VOIDS TULIP MEDICAL PRODUCT WARRANTY

POINT OF USE CLEANING

DURING PROCEDURE

Preparation for cleaning begins at the point of use

1. KEEP FREE OF GROSS SOIL during the procedure.

Remove gross soil by wiping the surfaces with a moistened sterile surgical sponge and periodically irrigate and flush cannulated instruments.

2. TRANSPORTING USED INSTRUMENTS

Immediately contain and transport to the decontamination area

3. KEEP INSTRUMENTS MOIST DURING TRANSPORT by presoaking.

Miltex® Instrument Prep Enzyme Foam (3-760) is a ready to use foaming spray for pre-cleaning of devices.

Spray the Miltex® Instrument Prep Enzyme on soiled instruments, cannulas and accessories until the devices are ready for rinsing.

CONTAIN CONTAMINATED ITEMS in a puncture-resistant, leakproof container marked as biohazard.

DECONTAMINATION

PRE-TREATMENT

Lower and limit bioburden before sterilization

1. PPE Personal Protective Equipment - **ALWAYS** wear safety protection gear while performing cleaning and when handling biohazardous materials.

2. DETERGENT/SOLUTION use appropriate detergent/concentration.

Use a neutral, pH (7), enzymatic cleaning agent * intended for manual cleaning and suitable for ultrasonic treatment. Place devices in a solution as per enzyme solution manufacturer instructions using lukewarm (22-43°C) tap water. Completely submerge all instruments in the enzyme solution and soak for at least **20 minutes**.

SORT AND DISASSEMBLE. Remove stylets and plugs. Disassemble if possible. (Submerged in presoak)

IMPORTANT INFORMATION **CLEANING CARE** IMPORTANT INFORMATION

CLEANING PROCESS

INSTRUMENT HANDLING

Cleaning may be performed manually, mechanically or a combination of both.

The selection of the cleaning method should be based upon the type of device and manufacturer's recommendations.

1. DETERGENT/SOLUTION use appropriate detergent/concentration. Use a neutral, pH (7), enzymatic cleaning agent * intended for manual cleaning and suitable for ultrasonic treatment.

***Tulip Medical Products recommends these cleaning solutions: Miltex® brand EZ-Zyme® All Purpose Enzyme Cleaner, or Miltex® Surgical instrument Cleaner. For more information regarding these products, visit on-line: http://miltex.com/prodinfo/productCare.aspx**

2. CLEAN using appropriate detergent/concentration. Use a neutral, pH (7), enzymatic cleaning agent * intended for manual cleaning and suitable for ultrasonic treatment.

Clean the inside of the cannula hub and other device surfaces with a sponge and lukewarm (22-43°C) tap water mixed with the enzymatic cleaning agent, as described by the manufacturer of the cleaning agent.

Warning: Do NOT use alkaline-based cleaning agents or detergents. Use of alkaline-based product voids product warranty.

3. BRUSH with appropriate Tulip Cleaning Brush OR Tulip SoftPicks.

Clean the lumens of cannulas (SUBMERGED) until all visible debris has been removed. *

https://tulipaesthetics.com/collections/cleaning-products

4. FLUSH lumens and cannulas.

Using a syringe with a volume of 60ml, thoroughly and aggressively flush cannula lumens, holes and other difficult to reach areas. Repeat at least 3 times with lukewarm (22-43°C) tap water-enzyme solution at a concentration recommended by the manufacturer.

5. RINSE by flushing.

Flush the cannula(s) at least 3 times with a syringe (60ml) filled with ultrafiltered, RO, DI, distilled and/or demineralized water.

6. SONICATE ultrasonic cleaner (optional).

Completely submerge instruments in the cleaning solution and sonicate for 10 minutes at 40-45 kHz. Rinse instrument in ultra-filtered, RO, DI, distilled and/or demineralized water for at least 3 minutes or until there is no sign of blood or soil on the device in the rinse stream. Repeat the sonication and rinse steps above.

7. DRY manual or air compressor.

Thoroughly dry moisture from the instrument with a clean, absorbent, non-shedding wipe, or air compressor.

STERILE PREP

INSPECTION, ASSEMBLY AND PACKAGING

Appropriately prepare devices for sterilization

1. **INSPECT** for cleanliness and proper working order. Verify surfaces and lumens are clean.
2. **TEST** by inserting Tulip SoftPicks® or Tulip Cleaning Brush for ease of insert.
3. **DRY** all instruments thoroughly. Verify silicone mats and the bases of the tray are dry.
4. **ASSEMBLE** trays, unlock jointed instruments and place on stringer. Place concave surfaces on edge to protect delicate and sharp items. Don't overload trays or containers.
5. **PACKAGE** using appropriate wrap, peel pack, or rigid container. Include internal and external chemical indicator (CI), label contents, and initial.

   Tulip Autoclave Trays should be double wrapped according to AAMI/CSR technique. The packaging for terminally sterilized instruments should fulfill requirements EN ISO 11607.

STERILE PROCESSING

STERILIZATION

Select the correct sterilization parameters

1. **STERILIZE** according to written IFU (type, exposure and dry time, temperature, etc.).

   Pre-Vacuum Steam sterilization is recommended.
   Wrapped Goods Cycle 4 minutes @ 132° C / 270° F. Dry Time: 20 to 30 minutes, according to load size
2. **COOL** packages to room temperature before handling.
3. **CHECK** mechanical, chemical, and biological indicators, and package integrity before releasing the load.

Note: Tulip has validated its reusable cannulas, injectors, and infiltrators for up to 50 autoclave cycles and strongly recommends replacement after 50 autoclave cycles

STORAGE

STERILE STORAGE

Maintain sterility of items until they are used

1. **STORE STERILE ITEMS** in closed or covered cabinets to reduce the potential for contamination. Do not stack heavy wrapped items.
2. **SHELF LIFE** is event related. Check package integrity and internal indicator before use.

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References:

- *TRUPI 2021 00 - Instructions for Use - Reusable Devices
- FDA Draft Guidance for Industry and FDA Staff - Processing and Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, 2011.
- AAMI ANSI TIR 30 and TIR 12.
- EN ISO 11607 (ANSI AAMI ISO11607): Packaging For Terminally Sterilized Instruments (replaced EN 868-1 and ISO 11607)
- EN ISO 17665 (ANSI AAMI ISO17665): Sterilization Of Health Care Products, Moist Heat (Replaced EN 554 and ISO 11134)
- ANSI/AAMI ST79: Comprehensive Guide To Steam Sterilization And Sterility Assurance In Health Care Facilities
- EN ISO 17664: Sterilization of Medical Devices - Information To Be Provided By The Manufacturer For The Processing Of Resterilizable Medical Devices.