

**Tulip**  
MEDICAL  
PRODUCTS

Tulip Reusable Devices  
Set



# Tulip Reusable Devices Set Instruction Manual

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**Tulip Reusable Devices Set**



## Instructions for Use –Reusable Devices

**Tulip® Medical Products Inc**

**Rx Only**



**NON  
STERILE**



**Tulip Medical Products**  
4360 Morena Blvd., Suite 100  
San Diego, CA 92117  
USA (858) 270-5900



In accordance with ISO 17664-2

Devices:	Tulip Reusable Surgical Instruments
Warnings:	Do not use alkaline-based cleaning agents to clean Tulip Instruments. Alkaline-based (pH>7) detergents and solutions corrode metals. Long, narrow cannulas and blind holes require particular attention during cleaning
Limitations on reprocessing:	Repeated heat exposure and reprocessing affect these instruments. Decommissioning of the devices is normally determined by wear and damage due to use.

## Instructions

Instructions

Point of Use:	Remove 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 mated syringes prior to cleaning. Prepare to presoak the instruments in a basin large enough to accommodate the instruments using an enzymatic cleaner according to the cleaning agent instructions.
Preparation for Decontamination:	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.
Cleaning: Manual	Remove the devices from the enzyme solution and rinse in lukewarm (22-43°C) tap water. Clean the inside of the cannula hub and other device surfaces with a soft-bristle brush and lukewarm (22-43°C), tap water mixed with the enzymatic cleaning agent as described by the manufacturer of the cleaning agent. Clean the inside lumens of cannulas using a soft-bristled, nylon brush until all visible debris has been removed. 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. Finish by flushing the cannula(s) at least 3 times with a syringe (60ml) filled with ultra- filtered, RO, DI, distilled and/or demineralized water. Place prepared enzymatic cleaning agent in an ultrasonic cleaner. 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. Thoroughly dry moisture from the instrument with a clean, absorbent and non-shedding wipe.
Cleaning: Automated	Remove the devices from the enzyme solution and rinse in lukewarm (22-43°C) tap water. Transfer the cannula(s) into the automatic washer/disinfector for processing. Orient the cannula(s) to facilitate drainage in a way to allow flushing. Select the cycle and ensure the following set of cycle parameters are properly programmed. Remove the cannula(s) from the automatic washer/ disinfector and dry using a clean soft non-shredding cloth and filtered pressurized air at < 40 psi. Visually inspect the cannula(s) for cleanliness and repeat the cleaning procedure if necessary.
Drying:	Wipe dry with a non-shedding wipe. Ensure cleaned instruments are properly cleaned and dry prior to autoclaving by visually inspecting each instrument.
Maintenance, Inspection and Testing:	Inspect each instrument to ensure it is clean and has been sterilized before use. Visually inspect each instrument for damage and signs of distortion. If any sign of damage or distortion, call Tulip Medical immediately for repair or replacement.
Packaging:	Once cleaned and inspected, the dry Tulip Instruments, cannulas and accessories should be assembled into the dedicated autoclave trays provided by Tulip Medical Products. Tulip Autoclave Trays should be double-wrapped according to AAMI/CS R technique.  The packaging for terminally sterilized instruments should fulfill requirements EN ISO 11607.
Sterilization:	Steam sterilization (moist heat) is recommended.
Pre-Vacuum:	Wrapped Goods Cycle 4 minutes @ 132° C / 270° F. Dry Time: 20 to 30 minutes, according to load size.
Storage:	Identify and store sterilized instruments in accordance with EN ISO 11607.
Additional Information:	For Instructions for Use see the Package Insert, supplied with the instruments.

<p>Manufacturer Contact for questions or to provide feedback:</p>	<ul style="list-style-type: none"> <li>• Tulip Medical Products</li> <li>• 4360 Morena Blvd., Suite 100 San Diego, CA 92117</li> <li>• Tel: + 858.270.5900 Fax: + 858.270.5901</li> </ul> <p><a href="http://www.tulipmedical.com">www.tulipmedical.com</a></p>
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## SUPPLIED NON-STERILE

Reusable instruments, cannulas and accessories are supplied non-sterile and require cleaning and sterilization prior to use. For cleaning and sterilization instructions, refer to this document, or locate on our website [tulipmedical.com](http://tulipmedical.com) under the Support section.

### Product Identification

Each instrument, cannula and accessory is identified by labeling, located on the packaging.

### Indications For Use

The Reusable Tulip Cannula is intended to be used for the removal of soft tissue and fluid from the body during general surgical and plastic surgery procedures. Reusable Tulip instruments, cannulas and accessories are intended for use in soft tissue surgical procedures and as advised by a qualified surgeon.

### Instructions For Use

Clean and sterilize all devices prior to use. Inspect each instrument, cannula and accessory to ensure the correct size, style, diameter and length for the desired procedure. Connect each reusable instrument, cannula and accessory to syringes or to the appropriate suction source as applicable. For syringe suction procedures, prime the cannula(s) with sterile saline to eliminate air space and increase suction efficacy.

### Contraindicated

Do not use Tulip brand instruments, cannulas and accessories if they do not meet the requirement(s) for use in the intended surgical procedure(s).

### Caution

Before using any Tulip brand instrument, cannula or accessory, visually inspect each instrument, cannula and/or accessory to ensure it is appropriate for the desired surgical application(s.) Cannulas are vulnerable to forces applied during surgery and/or repeated autoclaving (heat exposure to metals) that may cause these devices to separate at their bases, become bent and/or collapse during use. Cannulas and accessories removed from their mated syringes during surgery may cause their mated syringes to produce syringe particulate. Before, during and after use, always inspect the devices and syringes to ensure properly mated surfaces and fitness of use.

### Warnings

- Patient selection, patient safety precautions and appropriate anesthesia methods are required prior to use of the device(s.)
- Performance of the Tulip Instruments, cannulas and accessories is dependent on user.
- All device(s) should be used with extreme caution in patients with chronic medical conditions such as diabetes, heart, lung, or circulatory system disease or obesity.
- The volume of blood loss and endogenous body fluid loss may adversely affect intraoperative and/or postoperative hemodynamic stability and patient safety.
- The capability of providing adequate, timely fluid replacement is essential for patient safety.

## Precautions

- Tulip instruments, cannulas and accessories are designed for use on soft tissue through small incisions. Results of this procedure may or may not be permanent.
- The amount of tissues affected should be limited to that necessary to achieve a desired effect(s.)
- Results of procedure(s) will vary depending upon patient age, surgical site, and experience of the physician.
- Tulip Medical Products relies on well-qualified surgeons, hospitals, clinics or surgical offices to properly select patients, advise each patient on the risks associated with surgery and anesthesia, and to properly inform the patient about post-operative care.

## Cleaning Introduction

- 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 multi-component devices, which must be disassembled prior to cleaning, and the instructions for use, which come with the devices.

Equipment, operators, cleaning agents and procedures all have a contribution to the efficacy of device processing, and the health care facility should ensure that the combination actually in use results in devices which are safe for use. Alternative methods of processing may be equally suitable. In the event of conflicting National cleaning and sterilization requirements, these should prevail over Tulip Medical Products recommendations.

- Tulip instruments, cannulas and accessories should be cleaned with Miltex® brand, Enzymatic Cleaners, where applicable. Recommended: Miltex® Instrument Prep Enzyme Foam and Miltex® EZ-Zyme, All Purpose Enzyme Cleaner. For more information regarding these products, visit Integra's website for Miltex Products on-line:

<http://miltex.com/prodinfo/productCare.aspx>

**WARNING: DO NOT USE ALKALINE-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 agent(s).

### Warnings and Precautions:

This document pertains to reusable devices only and these instructions are not intended for devices labeled "For Single-Use Only." Tulip single-use devices must not be reused or reprocessed, as they are not designed to perform as intended after the first usage. Please refer to the device label and the package insert to identify the instruments as "For Single-Use Only" or "Reusable."

Since reusable Tulip instruments, cannulas and accessories are supplied non-sterile and require cleaning and sterilization before use, the appropriate sections of these instructions may be applied unless other specific instructions are provided in the package insert. The healthcare facility should ensure that the combination of cleaning and sterilization used actually results in devices that are safe for use in surgery.

Alternative methods of processing may be equally suitable. In the event that National cleaning and sterilization requirements conflict with these instructions, the National cleaning and sterilization requirement should be followed as applicable.

### Cleaning and Sterilization Guidelines:

Once Tulip instruments, cannulas and accessories have been used in surgery, they must be cleaned using a neutral pH (7) enzymatic cleaning solution. For cleaning of reusable devices, follow the instructions below.

\*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>

### **Pre-Cleaning Procedure**

Always wear safety protection gear as needed while performing cleaning. Instruments should be cleaned within 30 minutes of use to minimize the potential for drying of contaminants prior to cleaning. Immediately after each use, perform initial cleaning by wiping each Tulip Instrument, cannula and accessory free of blood and debris using a clean towel or non-shedding disposable wipe. Whenever possible, spray on Miltex Instrument Prep Enzyme Foam (3-760), and then follow Holding and Presoak instructions. It is important never to hold instruments in a dry container, which allows blood and debris to dry onto device surfaces and makes cleaning more difficult. If rinsing and decontamination processes are not immediately available, pre-treat devices or hold them in a neutral pH (7) holding/presoak enzymatic instrument cleaning solution, using a basin large enough to totally submerge all the devices. 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. Also, Miltex EZ-Zyme (3-750 and 3-775) neutral pH (7) all-purpose, multi-enzyme concentrate is ideal for presoaking and pre-cleaning. Then begin cleaning instruments as follows:

### **Holding / Presoak**

Presoak in a basin large enough to accommodate Tulip instruments, cannulas and accessories. Completely submerge all devices in the enzyme solution and soak for at least 20 minutes.

### **Rinsing**

Rinse each Tulip instrument, cannula and accessory free of debris and organic materials under warm (not hot) running tap water (22-43°C) in a basin large enough to accommodate the rinse. Rinse at least 3 times, to remove most blood, fluids and debris from the devices.

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.

Using a 60ml syringe, completely flush each cannula at least 3 times with lukewarm (22-43°C) tap water mixed with the enzymatic cleaning agent as described by the manufacturer of the cleaning agent. Repeat flushing each cannula at least 3 times from end to end and clear any debris inside the cannula tube, making sure there are no blockages and rinsing freely flows through each cannula tube. Using sponges, clean each instrument and accessory as needed. Visually inspect each instrument, cannula and accessory. Make sure all the devices are clean, non-greasy and unclogged.

### **Manual Cleaning Procedure**

Clean the interior of cannula tubes, using nylon soft bristle brushes, appropriately sized for each cannula tube diameter and length. Never use metal bristle brushes or steel wool, as these may score or damage the interior of the cannula. When cleaning the devices, pay particular attention to surfaces and features that may be shielded from the brushing action. Additionally, pay careful attention to cannula ports as well as inside tubes and hubs. Rinse for at least 3 minutes in running tap water until all traces of cleaning solution are removed. Finish by flushing the cannula(s) at least 3 times with a syringe (volume 60ml) filled with ultra-filtered, RO, DI, distilled and/or demineralized water.

Inspect each device. Generally, un-magnified visual inspection under good light conditions is sufficient. All parts of the device(s) should be checked for visible contaminants and/or distortion or damage.

### **Particular attention should be paid to**

- Contaminant “traps” such as concave or mating surfaces.
- Recessed features (such as openings in the cannulas and accessories).

- Cannula tips (for any damage).
- For Tulip instruments, cannulas and accessories that may have been impacted, check that each is not damaged.

Prepare an ultrasonic bath with an enzymatic cleaning solution such as Miltex EZ-Zyme (3-750 and 3-755) or a solution of ultra-filtered, RO, DI, distilled and/or demineralized water and neutral pH (7) enzymatic detergent such as Miltex Surgical Instrument Cleaner (3-720, 3-725 and 3-726), effective in removing organic material from instruments. Use ultra-filtered, RO, DI, distilled and/or demineralized water, if possible, in accordance with manufacturer instructions. Sonicate for 10 minutes at 40-45kHz, or for a full cleaning cycle. Change solutions frequently, or as often as the manufacturer recommends.



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## Explanation of Symbols

-  Product conforms with requirements in the European Medical Devices Directive
-  Manufacturer
- **EC REP** Authorized Representative
- **Rx only** Use is restricted to prescription only
-  Non-Sterile
-  Caution, Consult Accompanying Documents
-  See Instructions For Use
- **REF** Lot Number
- **SU** Catalog Number



Following ultrasonic process, rinse twice with ultra-filtered, RO, DI, distilled and/or demineralized water in a clean basin at room temperature (18 °C to 26 °C) and dry remaining wetness with non-shedding wipes.

Visually inspect each Tulip Instrument, cannula and accessory for remaining contaminants and dryness. Prior to autoclaving, all internal and external compartments of instruments should be dry and completely clean. If contaminants remain, repeat the cleaning process, including the pre-cleaning stage. Remaining wetness may be removed with medical grade compressed air (20-40 psi), and/or clean and lint-free, single-use wipes. Visually inspect each instrument to ensure that it is completely dry.

Re-inspect the dry instruments. If encrusted contaminants remain on the device after completion of the cleaning step in the ultrasonic bath, repeat the cleaning steps as described above until all devices are free from contaminants.

Once cleaned and inspected, the dry Tulip Instruments, cannulas and accessories should be assembled into the dedicated autoclave trays provided by Tulip Medical Products.

## **Automated Cleaning**

### **Equipment required**

- Personal protective equipment as recommended by the cleaning agent supplier (minimum overalls, gloves, face/eye shield.), the automated cleaning equipment manufacturer or as prescribed by the doctor, clinic or hospital setting, when required. Staff should use suitable protective gear and/or clothing and equipment at all times.
- Syringes with a volume of 60ml.
- Tap water and basin(s) large enough to accommodate rinsing the devices.
- Clean soft non-shedding cloth.
- Filtered pressurized air at < 40 psi.
- Miltex Surgical Instrument Cleaner or equivalent.
- Automated cleaner large enough to hold the cannula(s) and accessories.

### **Pre-Cleaning Procedure**

Always wear safety protection gear as needed while performing cleaning. Instruments should be cleaned within 30 minutes of use to minimize the potential for drying of contaminants prior to cleaning. Immediately after each use, perform initial cleaning by wiping each Tulip Instrument, cannula and accessory free of blood and debris using a clean towel or non-shedding disposable wipe. Whenever possible, spray on Miltex Instrument Prep Enzyme Foam (3-760), and then follow Holding and Presoak instructions. It is important never to hold instruments in a dry container, which allows blood and debris to dry onto device surfaces and makes cleaning more difficult. If rinsing and decontamination processes are not immediately available, pre-treat devices or hold them in a neutral pH (7) holding/presoak enzymatic instrument cleaning solution, using a basin large enough to totally submerge all the devices. 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. Also, Miltex EZ-Zyme (3-750 and 3-775) neutral pH (7) all-purpose, multi-enzyme concentrate is ideal for presoaking and pre-cleaning. Then begin cleaning instruments as follows:

#### **Holding / Presoak**

Presoak in a basin large enough to accommodate Tulip instruments, cannulas and accessories. Completely submerge all devices in the enzyme solution and soak for at least 20 minutes.

#### **Rinsing**

- Rinse each Tulip instrument, cannula and accessory free of debris and organic materials under warm (not hot) running tap water (22-43°C) in a basin large enough to accommodate the rinse. Rinse at least 3 times, to remove most blood, fluids and debris from the devices.

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.

- Using a 60ml syringe, completely flush each cannula at least 3 times with lukewarm (22-43°C) tap water mixed with the enzymatic cleaning agent as described by the manufacturer of the cleaning agent. Repeat flushing each cannula at least 3 times from end to end and clear any debris inside the cannula tube, making sure there are no blockages and rinsing freely flows through each cannula tube. Using sponges, clean each instrument and accessory as needed. Visually inspect each instrument, cannula and accessory. Make sure all the devices are clean, non-greasy and unclogged.
- Prepare an ultrasonic bath with an enzymatic cleaning solution such as Miltex EZ-Zyme (3-750 and 3-755) or a solution of ultra-filtered, RO, DI, distilled and/or demineralized water and neutral pH (7) enzymatic detergent such as Miltex Surgical Instrument Cleaner (3-720, 3-725 and 3-726), effective in removing organic material from instruments. Use ultra-filtered, RO, DI, distilled and/or demineralized water, if possible, in accordance with manufacturer instructions. Sonicate for 10 minutes at 40-45kHz. Change solutions frequently, or as often as the cleaning solution manufacturer recommends.
- Following ultrasonic process, rinse twice with ultra-filtered, RO, DI, distilled and/or demineralized water in a clean basin at room temperature (18°C to 26°C) and dry remaining wetness with non-shedding wipes.

#### **Automated Cleaning:**

Remove the devices from the enzyme solution and rinse in lukewarm (22-43°C) tap water. Transfer the cannula(s) into the automatic washer/disinfector for processing. Orient the cannula(s) to facilitate drainage in a way to allow flushing. Select the cycle and ensure the following set of cycle parameters are properly programmed.

Remove the cannula(s) from the automatic washer/disinfector and dry using a clean soft non-shredding cloth and filtered pressurized air at < 40 psi. Visually inspect the cannula(s) for cleanliness and repeat the cleaning procedure if necessary.

#### **Preparation for Sterilizing:**

- Once cleaned, and inspected, the Tulip instruments, cannulas and accessories should be assembled into the dedicated autoclave trays provided by Tulip Medical Products. Tulip Autoclave Trays should be double wrapped according to AAMI/CSR technique. The packaging for terminally sterilized instruments should fulfill the following requirements: EN ISO 11607.
- Steam sterilization (moist heat) is recommended. Healthcare facilities should validate the process that they use, employing the actual equipment and operators that routinely process the devices. After each Pre-Cleaning and Cleaning Procedure, follow the appropriate Sterilization Process listed next:
- Steam autoclave (moist heat) sterilization using a pre-vacuum (forced air removal) cycle is recommended. Autoclaves should comply with the requirements of, and be validated, maintained, and checked in accordance with EN 285/EN 13060, EN ISO 17665, and ANSI AAMI ST79.
- Once purchased, Tulip instruments, cannulas and accessories arrive in non-sterile pouches, labeled to identify each device. Upon initial use, remove all devices from non-sterile pouches and follow the Cleaning Instructions, then place in a wrapped autoclave tray, as described above. Sterilize instruments, cannulas, and Accessories

following the autoclaving cycle listed below:

## Sterilization

### Preparation for Sterilizing

- Once cleaned, and inspected, the Tulip instruments, cannulas and accessories should be assembled into the dedicated autoclave trays provided by Tulip Medical Products. Tulip Autoclave Trays should be double wrapped according to AAMI/CSR technique. The packaging for terminally sterilized instruments should fulfill the following requirements: EN ISO 11607.
- Steam sterilization (moist heat) is recommended. Healthcare facilities should validate the process that they use, employing the actual equipment and operators that routinely process the devices. After each Pre-Cleaning and Cleaning Procedure, follow the appropriate Sterilization Process listed next:
- Steam autoclave (moist heat) sterilization using a pre-vacuum (forced air removal) cycle is recommended. Autoclaves should comply with the requirements of, and be validated, maintained, and checked in accordance with EN 285/EN 13060, EN ISO 17665, and ANSI AAMI ST79.
- Once purchased, Tulip instruments, cannulas and accessories arrive in non-sterile pouches, labeled to identify each device. Upon initial use, remove all devices from non-sterile pouches and follow the Cleaning Instructions, then place in a wrapped autoclave tray, as described above. Sterilize instruments, cannulas, and Accessories following the autoclaving cycle listed below:

### Sterilization

#### Pre-Vacuum

Wrapped Goods Cycle 4 minutes @ 132° C / 270° F. Dry Time: 20 to 30 minutes, depending on load size.

Note: Where there is a concern about TSE/vCJD contamination, the World Health Organization recommends processing through a pre-vacuum steam sterilization cycle for 18 minutes @ 134° C. (WHO/CDS/CSR/APH/2000.3, WHO Infection Control Guidelines for TSE," March 1999.)

### Warning

Immediate Use, "flash sterilization" is not the recommended sterilization method. Aeration: As required, to return to room temperature or to start next cycle.

### Contraindication

Whenever and wherever hospital policy and procedure(s) take precedence over this protocol. After use in surgery, always clean the instruments prior to sterilization. Failure to use approved cleaning & sterilization procedures may void the Product Warranty.

- Exposure time: Period for which the load and entire chamber is maintained at the sterilization temperature.
- Drying time: Period during which steam is removed from the chamber and the chamber pressure is reduced to permit the evaporation of condensate from the load, either by prolonged evacuation or by the injection and extraction of hot air or other gases. The drying time varies due to load configuration, wrapping method and material. It is the hospital's responsibility to validate the appropriate drying time with the sterilization equipment used.

### Disclaimer

These Pre-Cleaning, Cleaning & Sterilization Guidelines are provided as guidelines only, and should not be used in place of the guidelines or standards otherwise followed by a given Operating Room Supervisor, Surgeon,

Facility, Hospital, or Institution. Tulip Medical Products relies on the Surgeon or Facility to decide on the best cleaning techniques and/or sterilization methods available for cleaning and sterilization of Tulip Medical Products. See Product Warranty for more information.

## References

- 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.

## Terms and Fitness of Use

- When instruments are returned to Tulip Medical Products for repair, Tulip Medical requires that such returns be authorized prior to shipment. Tulip Medical also requires that all devices be cleaned and decontaminated by the user prior to shipment to Tulip Medical for repair.
- Forms are available on our website: <http://tulipmedical.com/downloads.html>  
Tulip has validated its reusable cannulas, injectors, and infiltrators for up to 50 autoclave cycles and strongly recommends replacement after 50 autoclave cycles.
- The decommissioning, repair or proper disposal of medical devices may be necessary at any time and Tulip Medical Products relies on the user to routinely inspect the devices prior to use to ensure device reliability and fitness for use.
- Instruments, cannulas and accessories are vulnerable to forces applied during surgery and/or repeated autoclaving (heat exposure to metals) that may cause these devices to separate at their bases, become bent and/or collapse during use. Cannulas removed from their syringes during surgery may cause their mated syringes to produce syringe particulate. Before, during and after use, always inspect the devices and syringes to ensure properly mated surfaces and fitness of use. By accepting the enclosed items, Black Tie Medical, Inc. DBA, Tulip Medical Product
- Distributors agree to the following terms and conditions:
- Product Distributors agree to maintain product traceability records to include the name of the person, clinic, hospital and or organization to which each product was sold or supplied, and any corresponding product lot numbers, serial numbers and device identifiers. Product Complaints:
- Distributors are required to notify Black Tie Medical, Inc., regarding any product complaint, immediately, upon each and every occurrence.

## Product Labeling

Misbranding devices with misleading product claims or promotional material is in violation of US FDA 21 CFR 820, Subchapter H, "Medical Devices," and carries possible fines and criminal penalties. Therefore, each distributor

hereby agrees not to alter, recreate or change any product labels or written materials as supplied by Black Tie Medical, Inc. In addition, Black Tie Medical will be free to monitor and control all written materials produced by any distributor concerning the supplied devices. These written materials will include (but are not to be limited to) mailers, price lists, and any and all written information, used for the edification, promotion or sale of any devices with copies of any and all written material, literature, artwork, etc. created by a distributor when associated with the products, prior to its dissemination or distribution. In addition, Black Tie Medical will, at any time, be able to recall (request the return of) any and all products, printed materials, brochures, literature, photographs, artwork, product names, whether created by the distributor or otherwise.

### Procedure Validation


The manual cleaning, automated cleaning with an enzymatic cleaner and steam sterilization at 132 degrees Celsius has been validated by Tulip Medical Products.

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DBA Tulip® Medical Products

### Reusable Instrument Package Insert

PHASE	RECIRCULATION TIME (MINUTES)	TEMPERATURE	DETERGENT TYPE AND CONCENTRATION
Pre-wash	02:00	Cold tap water	N/A
Wash	02:00	60°C	Miltex Surgical Instrument Cleaner, ¼ oz/gallon (or equivalent)
Rinse	00:15	Hot tap water	N/A

### Documents / Resources

	<a href="#">Tulip Reusable Devices Set</a> [pdf] Instruction Manual Reusable Devices Set, Devices Set, Set
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### References

- [miltex.com/prodinfo/productCare.aspx](https://www.miltex.com/prodinfo/productCare.aspx)
- [User Manual](#)

[Manuals+](#), [Privacy Policy](#)

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