Tulip TRUPI-2024-00 Reusable Instruments Instruction Manual

Contents

Tulip
UNLOCK THE POWER OF FAT

Tulip TRUPI-2024-00 Reusable Instruments

Information

In accordance with ISO 17664

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 a ects these instruments. Decommissioning of the devices is normally determined by wear and damage due to use.

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 (22-43C) 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 (22-43C) tap water. Clean the inside of the cannula hub and other device surfaces with a soft-bristle brush and lukewarm (22-43C), 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 (22-43C) 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 (22-43C) 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 programed. 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 in 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/CSR 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.
Manufacturer Contact for questions or to provide feedback	Tulip Medical Products 4360 Morena Blvd., Suite 100 San Diego, CA 92117 Tel: + 858.270.5900 Fax: + 858.270.5901 www.tulipmedical.com

www.tulipmedical.com

SUPPLIED NON-STERILE

- Reusable instruments, cannulas, and accessories are supplied non-sterile and require cleaning and sterilization before use. For cleaning and sterilization instructions, refer to our IFU located on our website on the Support Page.

Product Identification

Each instrument, cannula, and accessory is identified by labeling, and 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 before 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 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 ben,t, 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 for use.

Warnings:

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

Precautions

- Tulip instruments, cannulas, and accessories are designed for use on soft tissue through small incisions.
- The results of this procedure may or may not be permanent.
- The number of tissues a˜ected should be limited to that necessary to achieve a desired e˜ect(s.)
- Results of procedure(s) will vary depending upon the patient's age, surgical site, and experience of the physician.
- Tulip Medical Products relies on well-qualiÿed surgeons, hospitals, clinics, or surgical o¸ces 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 Instructions

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 before cleaning, and the instructions for use, which come with the devices.
- Equipment, operators, cleaning agents, and procedures all contribute to the e¸cacy of device processing, and the healthcare facility should ensure that the combination actually in use results in devices that are safe for use. Alternative methods of processing may be equally suitable. In the event of contacting 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 online: **http://miltex.com/prodinfo/productCare.aspx**
- **WARNING:** DO NOT USE ALKALINE-BASED DETERGENTS OR CLEANING AGENTS TO CLEAN TULIP CANNULAS OR ACCESSORIES.
- 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 results in devices that are safe for use in surgery.
- Before each use, all instruments, particularly cannulas, must be meticulously inspected for fitness for use. Please refer to the "Important Information" section for more details.
- Alternative methods of processing may be equally suitable. If National cleaning and sterilization requirements con°ict 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.

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

Manual Cleaning

Equipment required:

- Personal protective equipment as recommended by the cleaning agent supplier (minimum overalls, gloves, face/eye shield.) 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.
- Non-shedding wipes.
- Ultrasonic bath large enough to allow complete immersion of the devices.
- Frequency 40 – 45 kHz, or according to manufacturer's instructions, and at a temperature setting according to the manufacturer's instructions.
- A neutral, pH (7), enzymatic cleaning agent, * intended for manual cleaning and suitable for ultrasonic treatment.
- Suitable soft bristle nylon, soft bristle brushes, appropriately sized for each cannula's diameter and length. Do not use metal or steel wool.
- Syringes with a volume of 60ml.
- Tap water and basin(s) large enough to accommodate rinsing the devices.
- Basin(s) large enough to accommodate each device.
- Ultra-filtered, RO, DI, distilled, and/or demineralized water.
- 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 online: **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 before 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 submerge all the devices. Miltex Instrument Prep Enzyme Foam (3-760) is a ready-to-use foaming spray for pre-cleaning 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 (22-43C) 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 (22-43C), 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 (22-43C) 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.
- Kinse 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, under manufacturer instructions.

- Sonicate for 10 minutes at 40-45kHz, or a full cleaning cycle. Change solutions frequently, or as often as the manufacturer recommends.
- Following the ultrasonic process, rinse with twice ultra-filtered, RO, DI, distilled, and/ or demineralized water in a clean basin at room temperature (18 °C to 26 °C) and dry the remaining wetness with non-shedding wipes.
- Visually inspect each Tulip Instrument, cannula, and accessory for remaining contaminants and dryness. Before autoclaving, all internal and external compartments of instruments should 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 (20-40lb 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.
- 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 before 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 submerge all the devices. Miltex Instrument Prep Enzyme Foam (3-760) is a ready-to-use foaming spray for pre-cleaning 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 (22-43C) 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 (22-43C), 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 (22-43C) 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, under manufacturer instructions.
- Sonicate for 10 minutes at 40-45kHz. Change solutions frequently, or as often per the cleaning solution manufacturer’s recommendations.
- Following the ultrasonic process, rinse with twice ultra-filtered, RO, Di, distilled, and/ or demineralized water in a clean basin at room temperature (18 °C to 26 °C) and dry the remaining wetness with non-shedding wipes.

Automated Cleaning:

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

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

- 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.

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 the 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 under EN 285/EN 13060, EN ISO 17665, and ANSI AAMI ST79.
- Once purchased, Tulip instruments, cannulas, and accessories arrive in nonsterile pouches, labeled to identify each device.
- Upon initial use, remove all devices from non-sterile pouches and follow the Cleaning Instructions, then place them 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.) However, Tulip Medical Products has not validated this sterilization process for use on Tulip devices.
- **Warning:** Immediate Use, "flash sterilization" is not the recommended sterilization method. Aeration: As required, to return to room temperature or to start the next cycle.

Contraindication:

- Whenever and wherever hospital policy and procedure(s) take precedence over this protocol. After use in surgery, always clean the instruments before sterilization.
- Failure to use approved cleaning & sterilization procedures may void the Product Warranty.
- **Exposure time:** The period for which the load and entire chamber are maintained at the sterilization temperature.
- **Drying time:** This 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. AAMI ANSI TIR 30 and TIR 12. EN ISO 11607 (ANSI AAMI ISO 11607): Packaging For Technically Sterilized Instruments (replaced EN 868-1 and ISO 11607) EN ISO 17665 (ANSI AAMI ISO 17665): 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.

Important Information

- Instruments, cannulas, and accessories are susceptible to damage from forces applied during surgery and repeated autoclaving (heat exposure to dissimilar metals).
- This damage can cause the devices to separate at their bases, bend, or collapse during use. Always thoroughly inspect the devices for signs of cracking or bending before each use.
- Never intentionally bend cannula stems. If any cannula stem is bent, cracked, or shows signs of wear, remove it from service immediately.
- Tulip Medical Products has validated its reusable cannulas, injectors, and infiltrators for up to 50 autoclave cycles.
- After 50 cycles, we strongly recommend replacing these devices. Exceeding this limit may increase the risk of

device failure.
- Removing cannulas from their syringes during surgery may cause the syringes to produce particulate matter. Before, during, and after each use, carefully inspect the devices and syringes to ensure they are properly mated and fit for use.
- It is the user's responsibility to routinely inspect the devices before each use to ensure they are functioning properly and fit for use. This includes checking for signs of damage, wear, and particulate matter.
- At any point, you may need to decommission or dispose of the devices properly.

Inspection Tips

- Visually inspect all instruments, cannulas, and accessories.
- Cracks
- Loose connections
- Bends
- Signs of wear
- Discoloration

Check the syringes for:

- Particulate matter
- Damage to the mating surfaces
- Proper fit with the cannulas

Additional Information

- For detailed instructions on how to use the devices, please refer to the quick start guide provided with each product.
- If you have any questions or concerns, please contact Tulip Medical Products customer support.
- **Caution:** Failure to follow these instructions may lead to device malfunction or injury.
- **Note:** This document is not a substitute for professional medical advice.
- Always consult with a healthcare professional before using any medical device.

Decommissioning and Disposal:

- When a device is no longer fit for use, it should be decommissioned and disposed of according to local regulations. Please refer to the specific guidelines for your area.

Terms:

- 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 every occurrence.

Product Labeling

- Distributors hereby agree not to alter, recreate, or change any product labels or written materials as supplied by Tulip Medical Products.
- Product Distributors are required to provide specific labeling translations in addition to provided Tulip labeling to comply with their local regulations and directives.
- In addition, Tulip Medical Products 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 written information, used for the edification, promotion, or sale of any devices with copies of any written material, literature, artwork, etc. created by a distributor when associated with the products, before its dissemination or distribution.
- In addition, Tulip Medical Products will, at any time, be able to recall (request the return of) any products, printed materials, brochures, literature, photographs, artwork, or product names, whether created by the distributor or otherwise.

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Documents / Resources

Tulip TRUPI-2024-00 Reusable Instruments [pdf] Instruction Manual
TRUPI-2024-00, TRUPI-2024-00 Reusable Instruments, Reusable Instruments, Instruments

References

- miltex.com/
- miltex.com/prodinfo/
- miltex.com/prodinfo/productCare.aspx
- User Manual