AMBLER SURGICAL INSTRUCTIONS FOR USE - OPHTHALMOLOGY - CTR INJECTORS

Ambler Item # 7285T

Capsular tension ring injector, 6 1/2'',curved shaft, hook pointed down, plunger mechanism, titanium, for use with Ophtec/AMO CTR's

INDICATIONS FOR USE

A hand-held ophthalmic surgical instrument designed to insert a capsular tension ring to stabilize the posterior capsule during the anterior segment surgical treatment, mitigation, prevention, and/or diagnosis of ophthalmic disease or conditions. These instruments are reusable.

GENERAL INFORMATION

- Federal (U.S.A.) law restricts this device to sale, distribution, and use, by, or on the order of a physician.
- These instructions are intended for use only by persons with the required knowledge and training in a health care facility. Ophthalmology procedures should be performed only by persons having adequate training and familiarity with ophthalmologic surgical techniques.
- All cleaning and sterilization processes provided are general guidelines and any deviation by the processor should be properly evaluated for effectiveness and potential adverse consequences.
- Any sterilization process will still require validation by the end user at the point of use. The end user should also routinely monitor the validation process as its effectiveness can vary dependent on multiple factors.

CONTRAINDICATIONS

- Damaged or broken instruments may result if the instruments are used improperly during transport, handling, surgical use, or reprocessing.

WARNINGS FOR REPROCESSING

- The following instructions are for all **NON-POWERED** surgical instruments supplied by Ambler Surgical, unless stated otherwise with the packaging of the product.
- The surgical instruments are provided NON-STERILE and must be inspected, cleaned, and sterilized before first use and before every reuse.
- Tip covers and other protective packaging material must be removed from the instruments prior to the first use.
- Immediate use steam sterilization (IUSS) should only be used for emergency reprocessing and should not be used for routine sterilization processing of the instruments. If IUSS must be used, all cleaning/ decontamination steps must be completed prior to sterilization. IUSS instruments should be used immediately and not stored for later use.
- **DO NOT REPROCESS SINGLE USE ITEMS**.
- Long narrow cannulations and blind holes require particular attention during cleaning. Automated or manual flushing should be performed thoroughly during cleaning.
- The sterilization parameters recommended in this document are not intended and not suitable for inactivation of prions. As the Food and Drug Administration (FDA) does not currently recognize or regulate any method of “reducing prion infectivity”, and does not permit statements about specific decontamination recommendations related to Transmissible Spongiform Encephalopathy (TSE), Ambler Surgical recommends that known/ or suspected prion contaminated instruments must not be reused and must be destroyed to eliminate the risk of cross-contamination.

REPROCESSING PRECAUTIONS

- When reprocessing surgical instruments, always handle them with care, wearing personal protective equipment: impervious apron, shoe protection, gloves, and face shield in accordance with Universal Precautions recommended by Occupational Safety and Health Administration (OSHA), and your facility's policies.
- Titanium instruments that are color anodized may lose their color over time through normal use and reprocessing.
- Saline, cleaning / disinfection agents containing aldehyde, mercury, active chlorine, chloride, bromine, bromide, iodine, or iodide are corrosive and should not be used.
- Do not soak instruments in hot water (temperature above 45°C/ 113°F), alcohol, disinfectants, or antiseptics to avoid coagulation of mucus, blood, or other body fluids. Do not exceed 2 hours soaking in any solution.
- Do not use steel wool, wire brushes, pipe cleaners, or abrasive detergents.
- Do not use high acid (pH 4.0 or lower) or high alkaline (pH 12 or higher) products for disinfection. Neutral pH detergents (at or near 7.0) are preferred.
- Due to the potential for residual chemicals to remain on the instrument and cause an adverse reaction, Ambler Surgical does not recommend the use of enzymatics or liquid chemical disinfectants or sterilants with manually cleaned instruments.

LIMITATIONS ON REPROCESSING

Repeated reprocessing has minimal effect on the instrument life. End of useful life for metal surgical instruments is normally determined by wear and damage due to the intended surgical use.

INSTRUCTIONS

Point of Use

1. Throughout the procedure, remove gross debris with a sponge/merocel wipe and sterile water frequently during the procedure to prevent blood and body fluid from drying on the instrument.
2. Immediately after use, the injector should be flushed with 20cc of sterile water and cleaned of excess soil using a disposable cloth/merocel wipe.
3. Ophthalmic viscosurgical device solution(OVD) should not be allowed to dry on or in injector. OVD will dry and harden quickly rendering the instrument useless.
4. Arrange instruments securely to avoid possible shifting and damage during transport.

Containment and Transport

1. Whether used or not, opened instruments should be placed in a suitable sealed/closed container labeled as biohazard to protect personnel from contamination during transport to the decontamination area.
2. Contaminated instruments should be kept moist in the transport container by adding a towel moistened with water(not saline). Pretreatment products specifically intended for this use or packages designed to maintain moist conditions may be used.
3. Frequent retrieval and transport of containers of instruments to the decontamination area is recommended.

Preparation for Decontamination and Cleaning

1. Suitable personal protective equipment (impervious apron, shoe protection, gloves, and face shield, etc.), in accordance with Universal Precautions recommended by Occupational Safety and Health Administration (OSHA), and your facility's policies, should be worn.
2. Cleaning of instruments should be performed as soon as possible after being received in decontamination area.
3. Instruments composed of more than one piece should be disassembled according to the manufacturer's written IFU and arranged so that all parts are contained together. All small parts (i.e., screws, nuts, and washers) should be contained to prevent loss.

Automated or Manual Cleaning and Disinfection Processes (choose 1)

Automated Cleaning and Disinfection

WARNING: Use only DELICATE or GENTLE cycle when processing microsurgical instruments in automated washer.

1. Use only validated washer-disinfector machines with approved efficacy (e.g. CE mark or FDA clearance and validation according to ISO 15883). Follow the instructions of the washer/disinfector manufacturer.
2. Use only low-foaming, free rinsing, neutral pH (at or near 7.0) cleaning solutions. Use only cleaning solutions that are labeled for use with medical devices or surgical instruments.
3. If gross soiling is evident on the instrument, manual pre-cleaning with a neutral pH cleaning solution may be necessary.
4. Connect instruments with lumens/ cannulations to irrigation ports, if available. Ensure lumens/ cannulations are not horizontal, and blind holes incline downward to assist in cleaning and drainage.
5. Open all hinged surgical instruments with handles, such as scissors, hemostats, and forceps to full extension.
6. Place instruments with curved surfaces facing down to prevent pooling of water.
7. Place the instruments in suitable carriers such that they are not subject to excessive movement or contact with other instruments.
8. Place heavy instruments on the bottom of containers, taking care not to place on delicate instruments or overload wash baskets.
9. Following processing, carefully inspect the instruments for cleanliness, any evidence of damage, and proper operation. If visible soil remains on the instrument following processing, the cleaning process should be repeated.

Manual Cleaning and Disinfection

To prevent contamination with bio-burden and chemical residue, manual cleaning of injector should be completed in bowls, basins, or sinks that are designated for ophthalmology instrument cleaning only.

1. Injector should be pretreated with an initial cold water rinse with running utility (tap) water for at least 30 seconds.
2. Place injector into a low-foaming, free rinsing, neutral pH (at or near 7.0) cleaning solution prepared according to the solution manufacturer directions. Use only cleaning solutions that are labeled for use with medical devices or surgical instruments. Ensure that the injector is fully covered by the cleaning solution.
3. Rinse thoroughly with cold, running utility water for at least 30 seconds.
4. Repeat steps 1-3 if visible soil remains on the injector. DO NOT REUSE SOLUTION, BOWLS MUST BE CLEANED AND FRESH SOLUTION USED EACH LOAD!
5. Place the injector in an ultrasonic machine filled with fresh neutral pH (at or near 7.0) cleaning solution and critical (deionized, reverse osmosis filtered, or distilled) water. Ensure that the injector is fully immersed in the cleaning solution.
6. Follow the instructions of the ultrasonic manufacturer regarding cycle times, detergents, placement of the instrument tray, and conditioning ("degassing") of the cleaning solution, etc.
7. Do not overload the ultrasonic bath or allow instruments, specifically sharp or delicate tips, to contact one another during cleaning.
8. Do not process dissimilar metals (stainless steel, titanium, etc.) in the same ultrasonic cleaning cycle.

9. When using an ultrasonic machine, the solution should be drained and changed after each use as defined by facility policies to avoid retaining bioburden on the injector. The ultrasonic machine should be drained and cleaned each day that is operated following the ultrasonic machine manufacturer's instructions.
10. Repeat all steps if visible soil remains on the injector.
11. Rinse the injector by holding it under warm (27°C – 44°C; 80°F – 100°F) tap water for at least 30 seconds, rotating the injector to expose all surfaces and cavities to flowing water. Additional rinsing may be necessary to entirely remove cleaning solution.
12. Injector should be flushed using a syringe filled with 20cc of critical (deionized, reverse osmosis filtered, or distilled) water with correct male or female connection piece for the injector.
13. Repeat injector flush for total of three flushes.
14. Immerse the injector in clean basin containing fresh critical (deionized, reverse osmosis filtered, or distilled) water and soak the injector for at least three minutes.
15. Perform final rinse with critical (deionized, reverse osmosis filtered, or distilled) water for at least 30 seconds rotating the injector to expose all surfaces and cavities to flowing water. Flush injector until rinse water runs clear.

Drying

After manual or automated cleaning, dry the instrument with a soft, lint free cloth or blow the instrument dry with micro-filtered, pressurized medical grade air. When blowing dry with pressurized air, ensure secure grip on instrument to avoid damage to instrument from air pressure. If micro-filtered pressurized medical grade air is not available, the injector should have a minimum of 20cc air pushed through the tip. Repeat air flush three times.

Inspection

1. Following cleaning, inspect the instrument to ensure that all visible soil has been removed and that the instrument operates as intended.
2. It is very important to carefully examine each surgical instrument for breaks, cracks, or malfunctions before use. A microscope should be used whenever possible. It is essential to check areas such as blades, points, ends, and stops as well as all moveable parts.
3. Ceramic coated instruments should be closely inspected for chips, cracks, or holes in the ceramic coating. If damages are found discard the instrument.
4. After cleaning, and before sterilization, it is strongly recommended that all moving parts, lock boxes, joints, and catches be lubricated with a physiologically safe lubricant.

Packaging

1. Only devices and accessories designed and intended for medical device sterilization should be used. Follow device manufacturer's written IFU for placement.
2. The packaging for instrument trays should be suitable for steam sterilization. Instrument trays should be double wrapped with the correct grade of wrap for the weight of the instrument trays according to ANSI/AAMI ST79 guidelines.

3. Instrument trays should be large enough to permit equal distribution of the contents in terms of weight and metal mass.
4. Heavy instruments should be placed in such a way that they will not damage more delicate instruments. Lighter instruments should be positioned to protect tips and to prevent damage from changes in position.
5. Position instruments to allow the steam to come into contact with all surfaces. Lumens/ cannulations ports should be open.
6. Instruments with ratchets should be unlatched. Racks, pins, stringers, or other specifically designed devices can be used to hold instruments in the unlatched position.
7. Tip protectors used to protect sharp instruments should be steam-permeable, fit loosely, and be used according to the manufacturer's written IFU.
8. If rigid sterilization container systems are used, all items should be contained in the basket or tray within the container system.

Sterilization

Follow the sterilizer manufacturers' instructions for operation and loading of steam sterilizers. There must be direct steam exposure to all surfaces of the instruments being sterilized including the internal surface, tubes, and channels.

The instrument and/or instrument tray should be processed through a complete sterilization drying cycle as residual moisture from sterilizers can promote staining, discoloration, and rust.

NOTE – The tables below represent variations in sterilizer manufactures' recommendations for exposure at different temperatures per ANSI/AAMI ST79:2010 and A1:2010 & A2:2011. Other time and steam temperature cycles may also be used. However, user must validate any deviation from the recommended time and temperature. Contact the manufacturer of your steam sterilizer to confirm appropriate temperatures and sterilization times.

Minimum cycle times for gravity-displacement steam sterilization cycles

Item	Exposure time at 121º C (250º F)	Exposure time at 132ºC (270º F)	Exposure time at 135ºC (275º F)	Drying times
Wrapped instruments	30 minutes	15 minutes		15-30 minutes
			10 minutes	30 minutes

Textile packs	30 minutes	25 minutes		15 minutes
			10 minutes	30 minutes
Wrapped utensils	30 minutes	15 minutes		15-30 minutes
			10 minutes	30 minutes
Unwrapped nonporous items (e.g., instruments)		3 minutes	3 minutes	0-1 minute
Unwrapped nonporous and porous items in mixed load		10 minutes	10 minutes	0-1 minute

Minimum cycle times for dynamic-air-removal steam sterilization cycles

Item	Exposure time at 132º C (270º F)	Exposure time at 135ºC (275º F)	Drying times
Wrapped instruments	4 minutes		20-30 minutes
		3 minutes	16 minutes
Textile packs	4 minutes		5-20 minutes
		3 minutes	3 minutes
Wrapped utensils	4 minutes		20 minutes
		3 minutes	16 minutes
Unwrapped nonporous items (e.g., instruments)	3 minutes	3 minutes	N/A
Unwrapped nonporous and porous items in mixed load	4 minutes	3 minutes	N/A

Storage and Transport

Sterile instruments should be stored under environmentally controlled conditions in a manner that reduces the potential for contamination in accordance with your facility’s policies.

Sterile instruments should be transported in a manner that will protect the items from puncture, contamination by moisture, excessive humidity, condensation, insects, vermin, dust/ dirt, excessive air pressures, and microorganisms.

For additional information regarding the reprocessing of surgical instruments see:

- ANSI/AAMI ST79:2017 Comprehensive guide to steam sterilization and sterility assurance for healthcare facilities. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2017.
- AAMI TIR34:2014/(R)2017 Water for the reprocessing of medical devices. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2017.
- Guideline for cleaning and care of surgical instruments. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2018:907–942.
- Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. Atlanta, GA.: Centers for Disease Control, 2008.
- Guideline for sterilization. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2015:665 –692.
- Toxic and Hazardous Substances: Bloodborne Pathogens, 29 CFR §1910.1030 (2012). Occupational Safety and Health Administration. http://www.osha.gov/pls/oshawewb/owadisp.show_document?p_table=STANDARDS&pid=10051.
- American Society of Cataract and Refractive Surgery, American Society of Ophthalmic Registered Nurses. Recommended practices for cleaning and sterilizing intraocular surgical instruments. J Cataract Refract Surg . 2007;33(6):1095 –1100.