AMBLER SURGICAL INSTRUCTIONS FOR USE - CARDIOVASCULAR CLAMPS

Ambler Item # 17-399

Cooley-Derra anastomosis clamp, 6 1/2'',large, angled, 3.0cm long x 15.0mm deep atraumatic jaws, ring handle

INDICATIONS FOR USE

A hand-held surgical instrument designed to atraumatically grasp or hold tissue, vessels, or sutures during the surgical treatment, mitigation, prevention, and/or diagnosis of cardiothoracic 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. Surgical procedures should be performed only by persons having adequate training and familiarity with surgical techniques and procedures.
- 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**.
- 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 the 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. Instruments must not be placed or soaked in Ringers Solution.
- 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.

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/lap sponge and sterile water frequently to prevent blood and body fluids from drying on the instrument.
2. Lumens and/or cannulated instruments should be irrigated with sterile water, as needed, without creating aerosols.
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.
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. Separate general purpose instruments from delicate instruments that require special handling, sharp items, and those identified for repair.

4. 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

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.
3. Connect cannulated instruments to irrigation ports, if available. Ensure cannulations are not horizontal, and blind holes incline downward to assist in cleaning and drainage.
4. Open all hinged surgical instruments with handles, such as scissors, hemostats, and forceps to full extension.
5. Place instruments with curved surfaces facing down to prevent pooling of water.
6. Place the instruments in suitable carriers such that they are not subject to excessive movement or contact with other instruments.
7. Place heavy instruments on the bottom of containers, taking care not to place on delicate instruments or overload wash baskets.
8. 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

1. Instruments should be pretreated with an initial cold water rinse with running utility (tap) water. A cool soak in utility water with an enzymatic cleaner or pH neutral detergent may be used. Rinse thoroughly with utility water.
2. Place instruments into a low-foaming, free rinsing, neutral pH (at or near 7.0) cleaning solution prepared according to the solution manufacturer's directions. Ensure that the instrument is fully covered by the cleaning solution.
3. Ensure cannulations are not horizontal, and blind holes incline downward to assist in cleaning and drainage.
4. Using a soft scrubbing brush, gently scrub all surfaces of the instrument while keeping the instrument submerged in the cleaning solution. Remove the soil from jaws, ratchets, tips, box lock, and/ or hinge mechanism. Clean the instruments until all visible soil is removed.
5. Rinse thoroughly with utility water. Flush lumens until rinse water runs clear.
6. Use an ultrasonic machine to remove soil from hard to reach places such as grooves, crevices, lumens, instruments with small parts, etc., after gross soil has been removed.
7. Follow the instructions of the ultrasonic manufacturer regarding cycle times, placement of the instrument tray, and conditioning ("degassing") of the cleaning solution, etc.

8. Do not overload the ultrasonic bath or allow instruments, specifically sharp or delicate tips, to contact one another during cleaning.
9. Do not process dissimilar metals (stainless steel, titanium, etc.) in the same ultrasonic cleaning cycle.
10. When using an ultrasonic machine, the solution should be drained and changed after each use, with "use" defined by facility policies and procedures, to avoid retaining bioburden on the instruments. The ultrasonic machine should be drained and cleaned each day that it is operated following the ultrasonic machine manufacturer's instructions.
11. Rinse thoroughly with cold, running utility water for at least 30 seconds.
12. Perform final rinse with flowing, critical (deionized, reverse osmosis filtered, or distilled) water to aid in the removal of cleaning solution and to prevent mineral deposits or staining.

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 the instrument to avoid damage from air pressure.

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. It is essential to check areas such as blades, points, ends, and stops, as well as all moveable parts. Magnification is recommended.
3. To reduce the risk of adverse event, HF (monopolar) endoscopic instruments and insulated instruments used with them should be tested using an insulation tester every time the instrument comes through the assembly area. If defect is 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.

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