AMBLER SURGICAL INSTRUCTIONS FOR USE - OPHTHALMOLOGY - DIAMOND KNIVES

Ambler Item # SD8961

Clear-cornea sapphire trapezoid knife, angled, 1.00mm/1.30mm wide tapered blade, sharp sides, j-slot titanium handle

INDICATIONS FOR USE

A hand-held surgical instrument used to make precise incisions in or surrounding the tissues of the eye during the 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. Prior to surgical use, qualified personnel must inspect the knife under microscope to ensure the knife is in proper condition. Pay particular attention to calibration (if applicable), possible blade looseness, and cutting edge condition. IF KNIFE APPEARS TO BE DEFECTIVE,DO NOT USE. CONTACT AMBLER SURGICAL 1-888-407-0006 FOR REPAIR.
2. Throughout the procedure, remove gross debris by irrigating with a 10cc syringe and sterile water frequently during the procedure to prevent blood and body fluid from drying on the instrument. Do not wipe blade with Merocel spears, wipes, or other sponge, as this could scratch the blade.
3. Ophthalmic viscosurgical device solution(OVD) should not be allowed to dry on or in instruments. OVD will dry and harden quickly rendering the instrument useless.
4. Retract the blade into handle, and place the diamond knife in dedicated tray securely to avoid possible damage during transport.

Containment and Transport

1. Place diamond knife in a sealed pouch labeled as biohazard for transport to the decontamination area.
2. Transport diamond knife IMMEDIATELY after procedure to decontamination area for processing.

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)

Manual Cleaning and Disinfection

WARNING: AUTOMATED CLEANING AND DISINFECTION IS NOT RECOMMENDED FOR DIAMOND KNIVES. MANUAL CLEANING ONLY IS RECOMMENDED.

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

1. Immediately after use and prior to initial use, use Ambler Surgical Diamond Knife blade cleaning pack(#OKD-001).
2. With blade retracted, rinse the diamond knife by holding it under cold, running, utility water, rotating the handle to expose all surfaces to flowing water. Wipe the handle dry with a disposable cloth/ wipe.
3. Expose the blade from the handle by pushing the proximal end of the handle in the direction of the handle barrel. Ensure blade is in locked position.
4. Carefully push blade and footplate (when applicable) into the blue cleaning pad, and gently pass the blade back and forth in a cutting fashion making approximate 1/2" cuts until all visible soil is removed.
5. Rinse the blade by passing the blade back and forth in a cutting fashion making approximate 1/2" cuts in the white rinse pad on the left.
6. Repeat the rinse in the same manner using the white rinse pad on the right.
7. Retract the blade into the handle. Perform final rinse with critical water rotating the handle to expose all surfaces to flowing water. Wipe the handle dry with a disposable cloth/ wipe.
8. Place diamond knife in designated sterilization tray.

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 instrument should have a minimum of 60cc air pushed through the tip. Repeat air flush three times.

Inspection

1. Inspect the blade under a microscope not less than 40x to ensure cleanliness and the condition of the blade. Pay particular attention to calibration (if applicable), possible blade looseness, and cutting edge condition.
2. IF KNIFE APPEARS TO BE DEFECTIVE, DO NOT USE. CONTACT AMBLER SURGICAL 1-888-407-0006 FOR REPAIR.

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.

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.

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