AMBLER SURGICAL INSTRUCTIONS FOR USE - OPHTHALMOLOGY - LID PLATES – NON-AUTOCLAVABLE

Ambler Item # 5261E

Jaeger lid plate, 3 3/4",double-ended, 20.0mm x 35.0mm and 24.0mm x 35.0mm blades, non-autoclavable clear plastic

INDICATIONS FOR USE

A hand held ophthalmic surgical instrument used for retracting or protecting the eyelid 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 disinfection processes provided are general guidelines and any deviation by the processor should be properly evaluated for effectiveness and potential adverse consequences.
- Any disinfection 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 disinfected before first use and before every reuse.
- DO NOT AUTOCLAVE as this could distort the acrylic.
- Avoid usage of alcohol as it will haze/crack the plastic over time.

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.
- 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

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.

Manual Cleaning and Disinfection

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 enzymatic detergents or liquid chemical sterilants with manually cleaned instruments.

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. Instruments should be pretreated with an initial cold water rinse with running utility (tap) water for at least 30 seconds.
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. Use only cleaning solutions that are labeled for use with medical devices or surgical instruments. Ensure that the instrument is fully covered by the cleaning solution.
3. 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.
4. Rinse the instrument by holding it under warm (27°C – 44°C; 80°F – 100°F) utility water for at least 30 seconds, rotating the instrument to expose all surfaces and cavities to flowing water. Additional rinsing may be necessary to entirely remove cleaning solution.
5. Repeat steps 1-4 if visible soil remains on the instrument. DO NOT REUSE SOLUTION, BOWLS MUST BE CLEANED AND FRESH SOLUTION USED EACH LOAD!

Drying

After manual 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.

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.

Storage and Transport

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

Disinfected 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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