AMBLER SURGICAL INSTRUCTIONS FOR USE - OPHTHALMIC FORCEPS

Ambler Item # 2281E
Akahoshi super combo III prechopper forceps, 4 3/4", straight shafts, cross-action jaws, round handle

INDICATIONS FOR USE
A hand-held ophthalmic surgical instrument designed to grasp, manipulate, pull, or tie suture needles or suture material to join incisions of the eye and/or surrounding tissues 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.
- Long narrow cannulations and blind holes require particular attention during cleaning. Automated or manual flushing should be performed thoroughly during cleaning.
- Immediate use steam sterilization (IUSS) should only be used for emergency reprocessing and should not be used for routine sterilization processing of the instruments. IUSS instruments should be used immediately and not stored for later use.
- DO NOT REPROCESS SINGLE USE ITEMS.
- Do not use this process for diamond knives, cannulae, or silicone tubing and/or bulbs.
- If this instrument is/was used in a patient with, or suspected of having Creutzfeldt-Jakob Disease (CJD), the instrument cannot be reused and must be destroyed due to the inability to reprocess or sterilize to eliminate the risk of cross-contamination. Consult WHO and local regulations for further information.

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 (OSHA) and your facility’s policies.
- Delicate surgical instruments require special handling to prevent damage to the tips. Use caution during cleaning and sterilization.
- Do not use excessive stress or strain at joints; misuse will result in misalignment or cracks at the box locks or jaws.
- 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.
- Manual scrubbing with brushes should always be performed with the instrument below the surface of the cleaning solution to prevent generation of aerosols and splashing which may spread contaminants. Cleaning agents must be completely rinsed from device surfaces to prevent accumulation of detergent residue.
- Do not soak instruments in hot water, 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. Following use, the instrument should be cleaned of excess soil using a disposable cloth/merocel wipe and flushed or immersed in sterile water as soon as possible.
2. The instrument should be kept moist with sterile water to prevent soil from drying on the instrument.

Containment and transport

1. Surgical instruments should be reprocessed as soon as possible.
2. 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.
3. Frequent retrieval and transport of containers of instruments to the decontamination area is recommended.

Preparation for decontamination and cleaning

1. Universal precautions should be followed including the use of suitable personal protective equipment (impervious apron, shoe protection, gloves, and face shield, etc.) according to Universal Precautions (OSHA) and your facility's policies.
2. Cleaning of instruments should be performed immediately upon receipt in decontamination area.

Automated Cleaning and Thermal Disinfection

1. Follow the instructions of the washer/disinfector manufacturer. Use only DELICATE or GENTLE cycle. Use only neutral pH (at or near 7.0) cleaning solutions.
2. If gross soiling is evident on the instrument, manual pre-cleaning with a neutral pH cleaning solution may be necessary. Enzymatic cleaners should be used to remove protein deposits. If used, follow the enzymatic cleaners' instructions and rinse thoroughly.
3. If an instrument can be disassembled, it should be cleaned in the disassembled state. Keep all parts together and protected from being lost. Do not mix other manufacturers parts with disassembled parts.
4. Ensure that any hinged instruments are open and that instruments with lumens can drain effectively. Where the washer has provisions for lumen adaptors these should be employed for lumened instruments.
5. Place the instruments in suitable carriers such that they are not subject to excessive movement or contact with other instruments.
6. Following processing carefully inspect the instrument for cleanliness, any evidence of damage, and proper operation. If visible soil remains on the instrument following processing it should be reprocessed or manually cleaned.

Manual Cleaning

Manual cleaning of instruments should be completed in bowls, basins, or sinks that are designated for ophthalmology instrument cleaning only to prevent residues or other bio-burden from other instruments being retained on the ophthalmology instruments.

1. Disassemble the instrument as applicable and inspect the instrument for damage or corrosion.
2. Pre-rinse the instrument by holding it under tap water, rotating the instrument to expose all surfaces and cavities to flowing water.
3. Additional rinsing may be necessary depending on the size and extent of soiling of the instrument.
4. Place the instrument into a clean bowl or basin filled with fresh neutral pH (at or near 7.0) cleaning solution prepared according to the directions of the solution manufacturer. Ensure that the instrument is fully covered by the cleaning solution.
5. Using a soft cleaning brush gently scrub all surfaces of the instrument while keeping the instrument submerged in the cleaning solution for at least 5 minutes. Clean the instrument until all visible soil has been removed.
6. 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!
7. Place the instrument in an ultrasonic machine filled with fresh neutral pH (at or near 7.0) cleaning solution and sonicate for 5 minutes. Ensure that the instrument is fully immersed in the neutral pH (at or near 7.0) cleaning solution.
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 frequently before visible soiling to avoid retaining bioburden on the instruments. The ultrasonic machine should be drained and cleaned after each use, or at least daily following the ultrasonic machine manufacturer's instructions.
11. Repeat steps 7-10 if visible soil remains on the instrument.
12. Rinse the instrument by holding it under warm (27°C – 44°C, 80°F – 100°F) tap 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.
13. If the instrument has lumens the lumens should be flushed using a Luer lok syringe filled with 50cc of warm distilled or deionized water with correct male or female Luer connection piece for the instrument.
14. Repeat lumen flush for total of three flushes.
15. Immerse the instrument in clean basin containing fresh deionized or distilled water and soak the instrument for at least three minutes.
16. Immerse the instrument in second clean basin containing fresh deionized or distilled water and soak for at least three minutes.
17. Perform a final rinse of the instrument with sterile distilled or deionized water for at least 30 seconds, rotating the instrument to expose all surfaces and cavities to flowing water.

**Manual 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 enzymatics or liquid chemical disinfectants or sterilants with manually cleaned instruments. See Automated Cleaning and Thermal Disinfection above for procedures for thermal disinfection of instruments in an automated washer/disinfector.

**Drying**

After manual or automated cleaning, dry the instrument with a lint free surgical wipe 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.

**Maintenance, Inspection and Testing**

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 especially essential to check areas such as blades, points, ends, and stops as well as all movable parts. A microscope should be used when ever possible.
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. Package the instrument in a suitable sterilization pouch or sterilizing instrument tray.
2. Double peel pack packing is not recommended unless pouch manufacturer validates the product is acceptable for this use.
3. Sterilizing trays should be of proper size lined with soft silicone mats.
4. Instruments should not be touching each other.
5. Protective tips made of soft silicone of the proper size and thickness are recommended.

**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 and tubes 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**

<table>
<thead>
<tr>
<th>Item</th>
<th>Exposure time at 121º C (250º F)</th>
<th>Exposure time at 132ºC (270º F)</th>
<th>Exposure time at 135ºC (275º F)</th>
<th>Drying times</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrapped instruments</td>
<td>30 minutes</td>
<td>15 minutes</td>
<td>15-30 minutes</td>
<td></td>
</tr>
<tr>
<td>Textile packs</td>
<td>30 minutes</td>
<td>25 minutes</td>
<td>10 minutes</td>
<td>30 minutes</td>
</tr>
<tr>
<td>Wrapped utensils</td>
<td>30 minutes</td>
<td>15 minutes</td>
<td>10 minutes</td>
<td>30 minutes</td>
</tr>
<tr>
<td>Unwrapped nonporous items (e.g., instruments)</td>
<td>3 minutes</td>
<td>3 minutes</td>
<td>10 minutes</td>
<td>0-1 minute</td>
</tr>
<tr>
<td>Unwrapped nonporous and porous items in mixed load</td>
<td>10 minutes</td>
<td>10 minutes</td>
<td>0-1 minute</td>
<td></td>
</tr>
</tbody>
</table>
Minimum cycle times for dynamic-air-removal steam sterilization cycles

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

Storage

Following sterilization processing packaged instruments may be stored in a clean area free of temperature and humidity extremes in accordance with your facility’s policies.

For additional information regarding the reprocessing of ophthalmic instruments see:

- Association for the Advancement of Medical Instrumentation (AAMI), Accreditation Association for Ambulatory Health Care (AAAHC), Association of periOperative Registered Nurses (AORN), Association for Professionals in Infection Control and Epidemiology (APIC), ASC Quality Collaboration, Association of Surgical Technologists (AST), and International Association of Healthcare Central Service Materiel Management (IAHCSMM). Position Paper Immediate Use Steam Sterilization, 2011

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