anodynesurgical

INSTRUCTIONS FOR USE

REUSABLE SURGICAL INSTRUMENTS OPHTHALMIC AND MICROSURGICAL

CAUTION: United States Federal law restricts this device to sale and distribution by or on the order of a physician, or to a clinical laboratory; and use is restricted to, by or on the order of a physician.

DESCRIPTION AND INTENDED USE

Ophthalmic and microsurgical instruments are **manual, non-powered, non-active, hand-held** instruments intended to support or perform ophthalmic, neurological, cardiovascular, or plastic surgical procedures. This type of medical device includes manual ophthalmic knives, scissors, forceps, needle holders, hooks, cannula, probes, ophthalmic rings, spatulas, eyelid speculum, ophthalmic surgical markers, trepans, trocars, retractors, loops, dissectors, vascular clips and clamps, etc.

GENERAL INFORMATION

- These INSTRUCTIONS FOR USE are designated only for persons with the required knowledge and training in a healthcare facility.
- Reusable surgical instruments supplied in a **non-sterile** state and are not to be used without being cleaned, disinfected, and sterilized.
- All reprocessing instructions provided are general guidelines and will require validation by the end user at the point of use.
- Cleaning and Disinfection Processing Equipment should be certified and validated.
- Any surgical procedures should be performed by licensed healthcare professionals trained and familiar with surgical techniques.

WARNINGS

- Do not soak instruments in solutions containing chlorine or chlorides as these may cause corrosion and damage.
- Do not process microsurgical instruments in an automated washer unless it has a delicate cycle.
- Long narrow cannulations and blind holes require particular attention during cleaning. Automated or manual flushing should be performed thoroughly during cleaning.
- Instruments must be flushed off without delay after surgery to remove tissue, blood, balanced salt solution and viscoelastic. Instruments must be obligatory and properly cleaned prior to sterilization. If not, the blood and residual debris will be baked on the surfaces. So, instruments could become damaged.
- Don't keep instruments in salt or other aggressive solution for a long time. It could entail deterioration of surface, deformation of fine working parts and, finally, damage to instruments and reduce their lifetime.
- If the instrument 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.
- **Do not use this procedure for diamond knives.**

PRECAUTIONS

- Surgical instruments demand close care and gentle handling. It's forbidden to fling, to drop instruments and to expose them to other mechanical effects.
- 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. Do not use steel wool, wire brushes, pipe cleaners or abrasive detergents. Cleaning agents must be completely rinsed from device surfaces to prevent accumulation of detergent residue.
- 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, alcohol, disinfectants, or antiseptics to avoid coagulation of mucus, blood or other body fluids. Do not exceed 2 hours soaking in any solution.
- Working parts of instruments must be protected with special tips of suitable sizes at the time of storage. It's strongly prescribed to remove tips before sterilization.
- Each instrument is meant for a specific purpose. Improper use entails damage of instrument or reduced its lifetime.
- Do not use high acid (pH 4.0 or lower) or high alkaline (pH 12 or higher) products for disinfection. Neutral pH detergents are preferred.
- Titanium instruments are color anodized and may lose their color over time through normal use and reprocessing. This has no effect on instrument functionality.

LIMITATIONS ON REPROCESSING

Reprocessing according to the instructions provided has minimal effect on the instrument life and functionality. The useful life for metal surgical instruments is normally determined by wear and damage during intended use.

INSTRUCTIONS

Point of use

1. Following use, the instrument should be cleaned of excess soil using a disposable cloth/paper wipe as soon as possible.
2. The instrument should be kept moist to prevent soil from drying on the instrument.

Containment and transport

1. The instruments should be reprocessed as soon as possible.
2. Always keep instruments in a suitable container to protect personnel from contamination during transport to the decontamination area.

Preparation for decontamination and cleaning

Universal precautions should be followed including the use of suitable personal protective equipment (gloves, face shield, apron, etc.) according to Universal Precautions (OSHA) and your institution's policies.

Automated Cleaning and Thermal Disinfection

1. Follow the instructions of the washer/disinfector manufacturer using only DELICATE cycle.
2. Use only neutral pH cleaning solutions.
3. Instruments that can be disassembled should be cleaned in the disassembled state. Do not lose the parts and do not mix with other parts.
4. If gross soiling is evident on the instrument, manual pre-cleaning with a neutral pH cleaning solution may be necessary. To remove protein deposits Enzymatic cleaners should be used following the enzymatic cleaners' instructions. Rinse thoroughly.
5. 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.
6. Place the instruments in suitable carriers such that they are not subject to excessive movement or contact with other instruments.
7. Process the instrument according to the conditions indicated below. The cleaning times and conditions may vary based on the amount of soiling present on the instrument. The following conditions were validated using a neutral pH detergent and a severe organic soil challenge (Biomedical Instrumentation and Technology 2007;41(4):324-331).

Phase	Time	Temperature
Pre-Wash	3 min.	30°C (86°F)
Wash	10 min.	40°C (104°F)
Wash	10 min.	30°C (86°F)
Rinse	3 min.	30°C (86°F)
Heated Rinse	50 minutes at 80°C (176°F) or 10 minutes at 90°C (194°F)	
Drying	By observation. Do not exceed 110°C (230°F)	

8. Follow 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

1. Inspect the instrument for damage or corrosion, if necessary, disassemble the instrument as applicable.
2. Pre-rinse the instrument by holding it under cold running water for at least 30 seconds, rotating the instrument to expose all surfaces and cavities to flowing water. Depending on the size and extent of soiling of the instrument additional rinsing may be necessary.
3. Place the instrument into a suitable clean basin filled with fresh neutral pH cleaning solution prepared according to the directions of the solution manufacturer. Use only cleaning solutions that are labelled for use with medical devices or surgical instruments. Ensure that the instrument is fully immersed in the cleaning solution.
4. Gently scrub all surfaces of the instrument using a soft cleaning brush while keeping the instrument submerged in the cleaning solution for at least 5 minutes. Clean the instrument until all visible soil has been removed.
5. If visible soil remains on the instrument, repeat steps 1-4.
6. Rinse the instrument by holding it under cold running water for at least 30 seconds, rotating the instrument to expose all surfaces and cavities to flowing water. Depending on the size and extent of soiling of the instrument additional rinsing may be necessary.
7. Place the instrument in an ultrasonic bath filled with fresh neutral pH cleaning solution and sonicate for 5 minutes. Use only cleaning solutions that are labelled for use with medical devices or surgical instruments. Ensure that the instrument is fully immersed in the cleaning solution. Do not overload the ultrasonic bath or allow instruments to contact one another during cleaning. Do not process dissimilar metals (stainless steel, titanium, etc.) in the same ultrasonic cleaning cycle.

8. 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.
9. Repeat steps 7-8 if the visible soil remains on the instrument.
10. 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.
11. If the instrument has lumens the lumens should be flushed using a syringe filled with 50cc of warm distilled or deionized water. Repeat this flush for a total of 3 times.
12. Immerse the instrument in a clean basin containing fresh deionized or distilled water and soak the instrument for at least 3 minutes.
13. Immerse the instrument in a second clean basin containing fresh deionized or distilled water and soak for at least 3 minutes.
14. 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, ANODYNE SURGICAL does not recommend the use of enzymatic or liquid chemical disinfectants or sterilant with manually cleaned instruments. See Automated Cleaning and Thermal Disinfection above for procedures for thermal disinfection of instruments in an automated washer/disinfector.

Drying

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 a secure grip on the instrument to avoid damage to the instrument from air pressure.

Maintenance, Inspection and Testing

Following cleaning, inspect the instrument to ensure that all visible soil has been removed and that the instrument operates as intended. Carefully examine each surgical instrument for breaks, cracks, or malfunctions before use. Check areas such as blades, points, ends, and stops as well as all moveable parts. A microscope should be used whenever possible. Lubricate all moving parts, lock boxes, joints and catches with a physiologically safe lubricant.

Packaging

Package the instrument in a suitable sterilization pouch or instrument tray lined with soft silicone mats. Protective tips made of soft silicone of the proper size and thickness are recommended. Instruments should not be touching each other.

Sterilization

- Use the sterilizer manufacturer's 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.
- Unless otherwise indicated in the Instruction for Use provided with the specific instrument, instruments and instrument trays may be sterilized by the following moist heat (steam) sterilization methods: Pre-vacuum High Temperature Autoclave, Standard Gravity Autoclave, High Speed (Flash) Autoclave (WARNING: Flash sterilization processing should be reserved for emergency reprocessing only and should not be employed for routine sterilization processing of the instrument. Flash sterilized items should be used immediately, and not stored for later use. See ANSI/ AAMI ST79:2010 and A1:2010 and your institution's policies for restrictions regarding the use of flash sterilization.)
- 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, the 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.
- The instrument and/or instrument tray should be processed through a complete sterilization drying cycle as residual moisture from autoclaves can promote staining, discoloration, and rust.

Minimum cycle times for gravity-displacement steam sterilization cycles

Instruments:	Wrapped	Unwrapped
Exposure at 121°C (250°F)	30 min	
Exposure at 132°C (270°F)	15 min	3 min
Exposure at 135°C (275°F)	10 min	3 min
Drying	15-30 min	1 min

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

Instruments:	Wrapped	Unwrapped
Exposure at 132°C (270°F)	4 min	3 min
Exposure at 135°C (275°F)	3 min	3 min
Drying	16-30 min	N/A

Storage

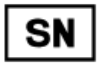
Following sterilization processing, packaged instruments may be stored in a clean area free of temperature and humidity extremes in accordance with your institution's policies. The indoor air shouldn't contain foreign substances which could cause corrosion.

Additional Information

For additional information regarding the reprocessing of ophthalmic instruments see:

- ASCRS/ASORN Special Report Recommendations for the cleaning and sterilization of intraocular cataract surgical equipment. J. Cataract Refract Surg. 2007; 33(6):1095-1100.
- ANSI/AAMI ST79:2010 and A1:2010 Comprehensive guide to steam sterilization and sterility assurance.

USED SYMBOLS

	Manufacturer
	Serial number
	Catalogue number
	Date of manufacture
	Non-sterile
	Consult electronic instructions for use
	Batch number
	**CAUTION!** Federal (US) law restricts this device to sale by or on order of a licensed healthcare practitioner.

MANUFACTURER CONTACT

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