



Instructions For Use

Stellmacher



Stellmacher Ophthalmic Instruments

Stellmacher Reusable Ophthalmic Instruments


Stellmacher Titanium Ophthalmic Instruments

Stellmacher Ophthalmic Packs

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REUSABLE OPHTHALMIC AND MICROSURGICAL INSTRUMENTS

DESCRIPTION AND INTENDED USE:

Ophthalmic and microsurgical instruments are 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 selected only for persons with the required knowledge and training in a healthcare facility.
- These reusable surgical instruments are supplied in a non-sterile packing and not recommended for use without being cleaned, disinfected and sterilized.
- The equipment being used for cleaning and disinfection / re-processing should be certified, calibrated and validated.
- Any surgical procedures should be performed by trained healthcare professional / surgeons and familiar with surgical techniques.

WARNINGS:

- Do not immerse 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.
- **NOTE:** Blood and residual debris remain present on the surface of the instrument will be baked on the surfaces, may cause damage to instruments.
- Don't keep these instruments in salt or other aggressive solution for a long time after use. 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:

- These instruments need proper precautions and gentle handling. It's prohibited 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 provided instructions resulting negligible effect on the instrument life cycle and functionality.
- The intended useful life cycle for these instruments is normally depended on handling, wear and damage during performing intended procedure.

INSTRUCTIONS (Point of use, Containment and transport)

- Following use, the instrument should be cleaned of excess soil using a disposable cloth/paper wipe as soon as possible.
- The instrument should be kept moist to prevent soil from drying on the instrument.
- The instruments should be reprocessed as soon as possible after performing procedural activities.
- Always keep instruments in a suitable container and wrap to protect from contamination during transport to the decontamination area.

Preparation for decontamination and cleaning:

Appropriate relevant precautions should be followed during decontamination including the use of suitable personal protective equipment (gloves, face shield, apron, etc.) according to health and safety cautions and local institution's policies / regulatory requirements.

Automated Cleaning and Thermal Disinfection

1. Follow the instructions of the washer/disinfector manufacturer during performing subjected operations.
2. Use only neutral pH cleaning solutions to disinfect these instruments.
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. In case of major contamination on the instrument, manual pre-cleaning with a neutral pH cleaning solution is mandatory. 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 adaptor these should be employed for such instruments.
6. Keep these instruments in suitable carriers such that they are not subject to excessive movement or contact with other instruments after performing procedural activities.
7. Process the instrument according to the conditions indicated below. The cleaning times and conditions may vary based on the contamination present on the instrument.

The following conditions were validated using a neutral pH detergent and a severe contamination 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 70 to 80°C (158 to 176°F) or 10 minutes at 80 to 90°C (176 to 194°F)	
Drying	By observation. Do not exceed 110°C (230°F)	

8. After this processing inspect the instrument for cleanliness, any evidence of damage, and proper operation carefully. If visible contamination remains on the surface instrument. it should be reprocessed or manual cleaning is mandatory.

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 contamination of the instrument additional rinsing may be necessary.
3. Place the instrument into a suitable clean container filled with fresh neutral pH cleaning solution or detergent, prepared according to the manufacturer's directions of the solution. Use only cleaning solutions / detergents that are recommended for 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 immersed in the cleaning solution for at least 5 minutes. Clean the instrument until all visible contamination has been removed from the surface of instrument.
5. If visible contamination remains on the instrument then 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 for 5 minutes. Use only recommended cleaning solutions 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 different metals (stainless steel, titanium, etc.) in the same ultrasonic cleaning cycle.
8. The solution should be drained and changed frequently before visible contamination 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 as per manufacturer's instructions.
9. Repeat steps 7-8 if the visible contamination 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 container containing fresh deionized or distilled water and immerse the instrument for at least 3 minutes.

13. Immerse the instrument in a second clean container containing fresh deionized or distilled water and immerse for at least 3 minutes.
14. Perform a final rinse of the instrument with distilled or deionized water for at least 30 seconds, rotating the instrument to expose all surfaces and cavities to flowing water.

NOTE: Due to the potential for residual chemicals to remain on the instrument and cause an adverse reaction, Stellmacher Instruments Inc.s does not recommend the use of enzymatic or liquid chemical disinfectants or sterility 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:

After cleaning, inspect the instrument to ensure that all visible contamination has been removed and that the instrument operates as per intended procedure. Carefully examine each 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 (134°C), 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.

Warranty

All Stellmacher Instruments Inc., except custom ordered or custom etched instruments, are guaranteed to be free from defects in material and workmanship when used for their intended surgical purpose. Any Stellmacher Instruments Inc. that proves defective in workmanship or material will either be repaired or replaced, at Stellmacher Instruments Inc.s discretion, without any charge.

Warranties are not valid for instruments and products that prove defective as a result of improper care and cleaning or misuse. Instruments or products that are damaged in the fire, flood, or other acts or disasters are also excluded from warranty. Stellmacher Instruments Inc.s makes no other representations and warranties regarding its instruments or products, either express or implied. In no event will Stellmacher Instruments Inc.s be liable for any incidental, special or exemplary damages or loss of profits in connection with the use of Stellmacher Instruments Inc. and products.