

Care & Maintenance Guide

Titanium & Stainless Steel Reusable Surgical Instruments

CLASS I NON-STERILE SURGICAL INSTRUMENTS (MEDICAL DEVICES)

- These instruments are delivered non-sterile; it is necessary to clean and sterilize them properly before each use. Instructions are intended for use only by persons with specialized training in the cleaning and sterilization of surgical instruments.

INTENDED USE

- Our instruments are designed for use by ophthalmic professionals who have knowledge of the instrument features and how they should be used. The ophthalmic professional must choose the most suitable instrument for the surgical technique being performed based on his/her expertise.

RE-USE AND LIFETIME LIMITATIONS

- Repeated cleaning and sterilization as described below is unlikely to negatively impact the instruments. End of life is normally determined by wear and physical damage during use. The user must evaluate the suitability of the instrument during each use.

GENERAL CLEANING INSTRUCTIONS

- The persons responsible for cleaning and sterilization of the instruments should continually ensure these steps consistently achieved the desired result. While Stephens Instruments has validated these procedures, continual verification in the facility of use is appropriate. Likewise, any deviation from these instructions must be evaluated for effectiveness and potential adverse consequences prior to use.
- When cleaning and sterilizing the instruments, handle the instruments with care. Following the procedures provided combined with proper care will maximize the lifetime of the instruments. Also, use of personal protective equipment (PPE) including clothing, gloves, and eyewear should comply with local health and safety procedures.
- Avoid allowing blood, debris or bodily fluids to dry on instruments. Instruments should be flushed clean of all residues, dried and inspected after each use. For best results and maximized instrument life, perform complete cleaning immediately after use. If immediate cleaning is not possible, use an enzymatic foam spray cleaner to help prevent drying.

AUTOMATED CLEANING

- Where possible mechanical cleaning is the preferred method of cleaning.
- Use only either CE marked or validated washer-disinfector machines and low-foaming, non-ionizing cleaning agents and detergents following the manufacturers' instructions for use, warnings, concentrations and recommended cycles.
- Load instruments carefully, with any box joints and hinges open and so that any cavities in the instruments can drain. Place instruments with concave surfaces facing down to prevent pooling of water. Care must be taken when loading instruments with delicate tips to ensure the tips do not come into contact with any hard surfaces.

MANUAL CLEANING

- Manual cleaning is not a disinfection process and is not advised if an automatic washer-disinfector is available. If this equipment is not available, use the following process:
 - Clean the instruments using hospital approved cleaning solution suitable for use with surgical titanium or stainless-steel instruments.
 - Remove residual matter with a delicate brush or surgical sponge moistened with alcohol.
 - Care should be taken to avoid damage to delicate tips.

POST-CLEANING AND INSPECTION

- It is imperative that as much moisture as possible is eliminated from all of the instrument surfaces, mated parts, and crevices; moisture can promote corrosion of the instrument. Flushing, drying and inspecting the instrument under magnification helps to ensure that the instrument is kept in optimum condition for the next surgical procedure. Visually inspect all surfaces, joints, holes, and cavities for complete removal of residual tissue and fluids. If ANY are still visible return the instrument for repeat cleaning.

OWNER MAINTENANCE

- Apply surgical grade lubricants to hinges, joints and moving parts as per the lubricant manufacturer's instructions as needed to ensure smooth operation.
- Periodically visually inspect and check all instruments for damage and wear. Inspect for:
 - cutting edges are free of nicks and present a continuous edge
 - jaws and teeth align correctly
 - instruments have smooth movement
 - locking mechanisms fasten securely and close easily
 - long, slender instruments are not bent or distorted
 - component parts fit and assemble correctly with mating components

MANUFACTURER MAINTENANCE

- Any instrument returned to the manufacturer must be decontaminated and sterilized prior to packing and must be accompanied with the relevant documented evidence of these processes.
- If repair by the manufacturer is desired, return the cleaned and sterilized instrument to the manufacturer with a description of the defect or problem and desired service to be performed.

STERILIZATION

- Ensure all instruments are thoroughly cleaned before sterilizing.
- Place instruments in a perforated sterilizing tray, ensuring instruments are not touching each other, and all locks are in the open position.
- Instruments and instrument trays may be sterilized by the following moist heat (steam) sterilization methods:
 - Pre-vacuum High Temperature Autoclave: 275°F (135°C) for 3 minutes; wrapped.
 - Autoclave: 273°F (134°C) for 18 minutes; wrapped.
 - High Speed (Flash) Autoclave: 270°F (132°C) for 4 minutes; unwrapped.
- **NOTE:** As per ANSI/AAMI ST79:2017, 270°F (132°C) for 4 minutes and 275°F (135°C) for 3 minutes are acceptable minimum cycle times for dynamic-air-removal steam sterilization cycles.

STORAGE

- Ensure instruments are completely free of moisture before storage, and store in dry, clean conditions at ambient temperature.

WARNINGS

- Instruments must be used for their specified purpose; incorrect use could damage the instrument.
- Before using, examine the instruments with special lenses. Do not use instruments that show problems or defects. Follow instructions and warnings as issued by manufacturers of any decontaminants, disinfectants and cleaning agents used. Wherever possible avoid use of mineral acids and harsh, abrasive agents. No part of the process shall exceed 140°C.
- Some materials are damaged by high alkaline solutions (pH>10). Do not use peroxide on titanium instruments or on anodized surfaces in order to avoid decolorization.