CARE & CLEANING OF I/A HANDPIECES

STORAGE:

- I/A Handpiece Instruments and all similar instruments of any of the following material makeup that includes stainless, titanium, and silicone should be stored in sterilizing trays of proper size, lined with soft silicone mats. Instruments should not touch each other. We recommend using protective tips made of soft silicone tubing of the proper size and thickness. Do not use any rubber or plastic protective tips that are not approved for autoclaving because it will cause damage to your instruments.

IFU: (Instructions for use)

- Our I/A Handpiece instruments are intended to be used for Irrigating and Aspirating fluids in or around the eye during ophthalmic procedures. The description on your packing list will detail which function configurations they were designed for. Luer fittings are made to the ANSI International Standard ISO 594/1-1986 (E) with conical fittings (6 % Luer taper) for syringes, needles and certain other medical equipment. These instruments are manufactured for the purpose of assisting Ophthalmic Surgeon's in preforming duties needed to successfully treat their patient's surgical needs. It is however the Surgeon's responsibility to become familiar with the proper technique for the use of the instrument.

INSPECTION:

- Be sure to inspect every instrument at the end of your surgical day. All inspections most be performed by a trained technician that understands the instruments and has the expertise for approving instruments for future use. Inspection most be performed under microscope or with magnification lens; this is the only method that will ensure your chances of finding any defects. As it may not be necessary or cost efficient it is highly encouraged that you purchase a set of Master Sample instruments to assist you in the inspection process. All questionable instruments must be marked as damaged to be repaired or properly disposed of in accordance to your company protocols. **All instruments that have been deemed damaged must be processed and sterilized before shipping it back to the manufacturer for repair.**

WATER QUALITY:

- The quality of water used for instrument reprocessing has a considerable influence on the end result and value retention. Poor water quality will have an adverse effect on the appearance of your instruments causing scaling, brown-red staining (rust), pitting, spotting, discoloration, staining, etc. As we all know water quality varies from one area to another and from season to season within the same area. For this reason, it is our recommendation that you us demineralized or deionized water in sufficient quantities will optimize your process and will assist you in achieving consistent quality results. We do highly commend that you use demineralized or deionized water at all steps of your validated cleaning process.
    - Exceptional water quality fulfills a variety of functions in the treatment process, including:
        - As a solvent for cleaning agents and other process chemicals
        - Transferring mechanical forces and heat to the instrument surface
        - Dissolving water-soluble dirt and impurities
        - Flushing process chemicals
        - Thermal disinfection for machine-cleaning and disinfection
        - Medium for steam sterilization

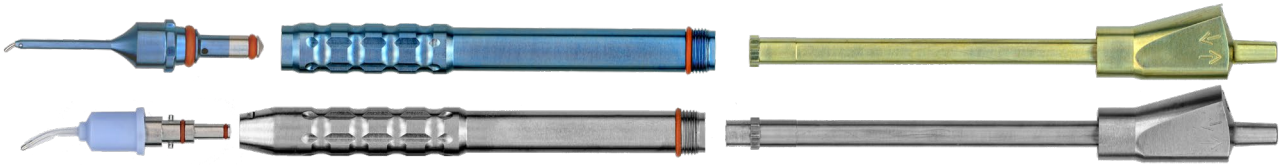
NOTE: Personal Protection Equipment (PPE) is highly recommended when handling medical instruments, refer to your company protocol for detailed instructions of what is all provided to you for your best protection. (Gloves, Goggles, etc.…)

MANUAL CLEANING:

- This method is intended to remove loose visible soils and is not recommended as being the final cleaning procedure of any instruments. Use a mild soap solution approved for surgical instruments with a soft brush or instrument wipe to clean instrument free of any debris. Never use steel wool and any other abrasive products to remove stubborn stains as this can damage the super fine finish of an instrument and can promote corrosion on your instruments. Use **demineralized or deionized water** in all steps of your process especially when rinsing your instruments, this should be thoroughly done to insure instrument care against corrosion. If the instruments would be prone to air drying while you are still cleaning other instruments take the time to carefully dry the instruments with a hot air blower or lint-free cloth. You are now ready to proceed to the ultrasonic cleaning step.

ULTRASONIC CLEANING:

NOTE: All I/A Handpieces are designed to be disassembled into three separate parts for the purpose of cleaning them thoroughly. You need to become familiar with this feature as you will need to do this several times through the cleaning process. Your design may have handle variations, but the core design remains the same.



- Use only cleaning solutions approved for surgical instruments. Change the solution frequently, always use demineralized or deionized water. Heat water to 150º Fahrenheit (62º C) using an immersion heater, or in a separate stainless container, if your unit does not have an automatic built-in water heater. Be sure that you and your staff members are completely familiar with the manufacturer's instructions, which came with your ultrasonic cleaner.

- This instrument has many lumens and hidden locations, before disassembly a technician should flush three full disposable syringes of cleaning solution with adapter (IA-H-FLUSH) like shown below to thoroughly flush both the irrigating and aspirating channels. This will ensure adequate perfusion into these channels. **This is a very important step!**

- Disassemble the I/A watch closely to ensure the Tips do not touch any other instruments and place all pieces into ultrasonic cleaner. All I/A TIPS must be fully submerged preferably with the hub portion facing down. This would allow debris in the channels to work their way out of the tip. Some I/A tips have a silicone sleeve like shown below. Ours are manufactured with a Medical Grade Silicone however silicone has a static cling affect with dirt and debris, so it is very important to inspect them extremely close before and especially after cleaning is performed. Do not place dissimilar metals (stainless, copper, chrome plated, etc.) in the same cleaning cycle.

- **It is recommended to ultrasonic clean instruments for a minimum of 10 minutes.**

- It is highly recommended that a thorough inspection after a cleaning process is completed, this to ensure that all fragments and/or debris have been removed. If they are cleaned correctly, they should be free of debris with no signs of corrosion. When corrosion becomes present the instrument is to be repaired and/or replaced. If any debris is found, please repeat the ultrasonic cleaning process.

- After removing instruments from the ultrasonic cleaner, it is important to use demineralized or deionized water to rinse the instruments thoroughly at a temperature of 72º to 110º Fahrenheit (22ºC to 43ºC), The rinse water should be changed after every use. Use a clean medical grade air or lint-free cloth to dry the instruments thoroughly; this will ensure that your instruments remain clean. The technician should assemble the I/A and flush three full disposable syringes of clean demineralized or deionized water with adapter (IA-H-FLUSH) like shown above to thoroughly flush both the irrigating and aspirating channels. Disposable syringes may also be used to force air through the channels if

medical grade air is not available. Under NO circumstances should you allow the water to dry by evaporation as this will encourage corrosion.

LUBRICATION:

- Lubrication is not required for I/A Handpieces

STERILIZATION:

Instrumentation must be thoroughly cleaned of all debris, tissue and foreign matter prior to sterilization. Medical instruments can be sterilized via steam autoclaving, chemical disinfectants, ethylene oxide gas, or even dry hot air. The most practical method of sterilization is heat or steam, which require less time. However, these methods can be damaging to delicate stainless-steel instruments. Use care when sterilizing your instruments. Be sure that you and your staff have read and fully understand the instructions supplied by the manufacturer of your sterilizer. It is your company's responsibility to produce a protocol, to ensure that your validated cleaning and sterilization processes are effective.

- Sterilization Quality Control Protocol Guidelines should be established by your **Sterile Process Technician** and enforced.
- **Warning: Never reprocess any single-use devices!**
- Only lint-free products should be used in the tray.
    - If surgical towels are used, de-lint before placing in set.
- Inspect silicone mats for cleanliness and lint before placing in set.
- Handle all instruments with care. Make certain to protect the delicate tips from hitting container sides or other instruments using the appropriate accessories.
- Inspect all instruments under magnification for defects and make sure that they are dry before placing in set.
- When an instrument has been identified as damaged or broken, follow your company protocol in sterilizing those instruments to be sent out for repair or displaced.
- A count sheet or recipe protocol guidelines should be established by the **Sterile Process Technician** and followed when setting up the tray. If using peel pouches, they should not go into a set unless they have been approved in your guidelines.
- Place a chemical integrator in the most challenging location of every set. If there are multiple layers, place an integrator on every level to ensure that the sterilization process was affective.
- Follow sterilizer and container manufacturers' directions when loading the trays on the sterilizer racks.
- Follow the exposure times and temperature settings provided by the device and sterilizer manufacturers.
    - Always use the instrument with the longest exposure-time as your benchmark when instruments are going to be sterilized together.
- There must be direct steam exposure to all surfaces of the instruments being sterilized including the internal surface and lumen channels.
- Low temperature Gas Plasma (Sterrad) may leave a chemical residue on the instruments and, therefore, should never be used to terminally sterilize eye instruments.
- After every Sterilization Cycle, the **Sterile Process Technician** will review the paper print out to make certain the sterilization cycle parameters were met.
- The **Sterile Process Technician** will validate and initial the print out to be affective.
- Only after it has been determined that the cycle parameters have been met, the load may be released.
- Allow instrument sets to air cool to room temperature before use.
    - Placing hot instrument sets in cool or on cold surfaces will create condensation and could potentially contaminate the set.

Recommended Sterilization Temperatures and Time Settings

Steam Sterilization Cycle	Temperature	Exposure Time	Minimum Dry Time
Gravity Displacement (Wrapped)	275°F (135°C)	12 Minutes	30 Minutes
Pre-Vacuum (Wrapped)	275°F (135°C)	5 Minutes	30 Minutes
Dynamic-Air-Removal (Wrapped)	275°F (135°C)	4 Minutes	20 Minutes

The cycle parameters given were based on ANSI/AAMI ST79 standards.

IMPORTANT NOTES:

- Flash sterilization should not be used as a substitute for sufficient instrument inventory.
- Post-radiation testing of silicone elastomer reveals minimal physical property changes at 2.5 megarads exposure level, with tensile strength and elongation essentially unchanged. Minimal but measurable increases were seen in durometer and tensile modulus at 200% elongation. Such property changes are like those seen when the elastomer is subjected to additional oven post-curing.
- **ETHYLENE OXIDE** is not a recommended process for sterilizing Silicone.

REFERENCES:

- For a comprehensive guide to steam sterilization and sterility assurance in health care facilities. I would research and purchase a copy from the Association for the Advancement of Medical Instrumentation. ANSI/AAMI ST79
  - http://www.aami.org/productspublications/ProductDetail.aspx?ItemNumber=1383
- For specified requirements for the development, validation and routine control of a moist heat sterilization process for medical devices. Refer to ISO 17665-1:2006 to purchase this guide.
  - https://www.iso.org/standard/43187.html
- There are many companies that offer guidance in validating your Sterilization Program.
  - https://www.eurofins.com/medical-device/services/microbiology-sterility/reprocessing-validations/