


SURGICAL (NON-POWERED) INSTRUMENTS REPROCESSING INSTRUCTIONS

 Please read before use!

CAUTION - All persons using these instruments should be knowledgeable, trained, and qualified in their use, handling, and care. It is the responsibility of the user facility to ensure instrument reprocessing is performed by trained personnel using equipment, materials, and personal protection equipment (PPE) that will achieve desired results. Cleaning and sterilization processes require validation and continuous process monitoring at the point of use. Any deviation from these instructions at the point of use should be evaluated for risk to process effectiveness. Process effectiveness is dependent upon many factors, and it is only possible to provide common guidance for instrument cleaning and sterilization. Instructions are established according to ISO 17664-1.

WARNINGS - Instruments **shall not be reused** after they have been used on patients with or suspected of having Creutzfeldt-Jakob-Disease (CJD), Bovine Spongiform Encephalopathy (BSE) or Transmissible Spongiform Encephalopathy (TSE) and shall be properly destroyed due to the risk of cross contamination.

- **INSPECTION & FUNCTIONAL CHECK** - It is very important to carefully examine each instrument for breaks, cracks, or malfunctions before each use (especially in the area of delicate tips).
- **Do not use** this procedure for diamond knives,
- **Do not use** "Immediate Use" (Flash) steam cycle unless it is for emergency reprocessing.
- **Do not use** autoclave steam cycle temperature exceeding 137°C (280°F).
- **Do not process** these delicate microsurgical instruments in an **automated washer** unless it has appropriate water quality and chemistry, as well as compatible cycles or trays with fixation mechanism to minimize movement/impingement/damage of ophthalmic instrument's delicate tips. Follow the automated washer manufacturer's instructions/requirements, or user facility should independently validate the automated washer being used.

INITIAL USE OF NEW INSTRUMENTS - The care of delicate microsurgical instruments should start upon user facility receipt. **Every instrument must be removed from their individual shipping container, inspected, cleaned and sterilized before initial use.**

DO NOT USE DAMAGED INSTRUMENTS – Do not attempt to make repairs. Service and repairs should be performed by qualified persons only. Katena has an instrument repair program, please call for further information.

CLEANING & MAINTENANCE - A good cleaning & maintenance program ensures proper function and extends the life of your instrument investment.

- **Near-neutral pH detergents** – Use cleaning solutions with near-neutral pH values.
- **Silicone finger mat to minimize movement of instruments** - Securely fasten instruments in suitable carriers such as silicone finger mats to prevent excessive movement and contact with other instruments.
- **Instrument cleaning and rinsing must be done immediately** after each use for best results. Failure to clean promptly may result in dried debris that can complicate cleaning and compromise sterilization. To avoid dried debris, instruments should be kept moist until cleaning process can take place. The maximum time between completion of surgery and instrument cleaning process shall be less than 60 minutes. If an instrument can be disassembled, it should be disassembled for cleaning. Use warm water with an instrument cleaning detergent to pre-soak instruments. Follow detergent manufacturer's instructions and recommendation on material compatibility to prevent damage or galvanic corrosion.
- If there is gross soiling on the instrument, pre-clean manually with a near-neutral pH cleaning solution before pre-soak step.
- **Do not use** corrosive (for example, bleach, chlorine, chloride, etc.) or abrasive cleansing detergent.
- Use only a soft bristle brush to remove soil; all visible soil shall be removed from instrument before ultrasonic cleaning.
- Flush all inside channels/lumens (with instrument actuated/opened) using a 10-cc syringe with 1% Lixiquox (Alconox Inc., pH \approx 8.5)* at least 2 times or brush with a small diameter bottle/tube brush with cleansing detergent before pre-soak and cleaning steps. (***Other near-neutral pH, alkaline cleaning agents may be used; however, users should validate user facility process and materials.**)
- Two separate ultrasonic cleaners (42 kHz, 360W) should be used for cleaning and for rinsing (see table below); this reduces potential of cross contamination. Ensure that the instruments are fully immersed in the cleaning solution. Check and retighten any fittings that may have vibrated loose. (Note: Instruments shall be positioned into silicone finger mats to minimize contact and potential damage of delicate instrument tips.)

Phase	Time	Temperature
Pre-Soak in 1% Lixiquox without Vibration (Ultrasonic Cleaner Unit 1)	5 minutes	60 °C / 140 °F
Ultrasonic Clean in 1% Lixiquox (Ultrasonic Cleaner Unit 1)	10 minutes	60 °C / 140 °F
Warm Tap Water Rinse	2 minutes	47 °C / 117 °F
Ultrasonic Rinse in Distilled Water (Ultrasonic Cleaner Unit 2)	10 minutes	60 °C / 140 °F

- After the ultrasonic rinse phase, thoroughly flush lumens and all inside channels/lumens with distilled water (with instrument actuated/opened).
- After rinsing, dry instruments carefully and completely with lint free surgical wipe or blow dry with filtered compressed air (include inside channels/lumens and inaccessible areas) to prepare for storage and/or sterilization.
- Inspect instrument to ensure all visible soil has been removed and functionally test instrument. Apply a small amount of surgical grade lubricant to hinges as required.

STERILIZATION / DISINFECTION - After cleaning, surgical instruments shall be sterilized by steam sterilization procedures that are regularly used in hospitals and surgery centers. The table below provides the recommended cycles based on USFDA, ANSI/AAMI ST79 and AORN recommended practices. Do not exceed the autoclave maximum load.

Steam Cycle	Preparation	Temperature	Exposure Time (Minimum Time in Minutes)	Drying Time (Minimum Time in Minutes)
Gravity Displacement	Wrapped	132 °C / 270 °F	15	30
Dynamic Air Removal **	Wrapped	132 °C / 270 °F	4	20
Dynamic Air Removal	Wrapped	134 °C / 273 °F	3	20
Immediate-Use (Flash) (Gravity or Dynamic Air Removal)	Unwrapped	132 °C / 270 °F	3	N/A

** Pre-Vacuum or Steam Flush Pressure Pulse (SFPP) is classified as Dynamic Air Removal Steam Cycle by AAMI.

The above parameters/cycles have been validated. If other methods, times and temperatures are used, the user should validate these methods.

HANDLING, TRANSPORT & STORAGE - Delicate microsurgical instruments must be handled with great care when being transported, cleaned, treated, sterilized and stored. Store the instruments in instrument trays with silicone finger mats that are specifically designed for storage and transport; there are no specific requirements for storage temperature and humidity. Katena offers sterilizing cases in a range of sizes, made of plastic, stainless steel, or aluminum to fit single instruments or complete sets.

REGULATORY INFORMATION - Any serious incident that occurs in relation to this product should be reported to the manufacturer, and to the healthcare authority of the country in which the incident occurred.

DISPOSAL - Follow country-specific laws and regulations for proper disposal, including procedures for disposal of sharps and/or biohazardous material.

APPLIES TO KATENA BRANDS:



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