

General Instrumentation – Recommended Cleaning and Sterilization Instructions




Instructions for use

König® Fürst®

Device(s):

These instructions for use are intended for reusable surgical instruments labeled with the König® and Fürst® Medline name. These instructions apply to reusable surgical instruments and accessories supplied by Medline and are intended for reprocessing in a health care facility setting. **All Medline instruments and accessories may be reprocessed using the manual or automated cleaning instructions and parameters provided in this document. This cleaning and sterilization guide does not replace device-specific instructions for use accompanying a specific instrument.**

WARNINGS

- Warning – Improper care and maintenance of instruments may render the device non-sterile and can result in serious injury to the patient or user.
- Warning – When handling and cleaning sharp instruments, use extreme caution to avoid injury. Consult with an infection control practitioner to develop and verify safety procedures appropriate for all levels of direct instrument contact. Direct handling and cleaning of instruments should be done only when indirect methods.
- Warning – Personal protective equipment (PPE) should be worn when handling or working with contaminated or potentially contaminated instruments in accordance to state/federal/local regulations.
- Warning – If this device is/was used in a patient with, or suspected of having Creutzfeldt-Jakob Disease (CJD), the device cannot be reused and must be destroyed due to the inability to reprocess or sterilize to eliminate the risk of cross-contamination.
- Medline reusable instruments are provided NON-STERILE  and must be cleaned and sterilized, according to these instructions, prior to use.
- If present, safety caps and other protective packaging material must be removed from the instruments prior to cleaning and sterilization.
- These instructions do not apply to aluminum based instruments, which are damaged by high pH detergents and solutions.
- Never expose instruments to strong acids such as hydrochloric, aqua regia, dilute sulphuric, carbonic, and tartaric acids.

- Avoid contact with salt solutions such as aluminum chloride, mercury salts, and stannous chloride. Limit contact with iodine solutions to periods less than 1 hour.
- Avoid prolonged exposure or rinsing in saline solutions as corrosion and pitting will occur. Chloride-bearing solutions such as blood and saline can cause localized corrosion.
- Avoid abrasive pads, metal brushes, or cleansers that will scratch the surface.
- Do not allow blood and debris to dry on the instruments. Clean the instruments of gross soil as soon as possible after use to prevent hardening of bioburden prior to manual cleaning.
- Instruments should be handled carefully. **Avoid mechanical shock or overstressing the device.**
- Use of the instrument for a task other than that for which it is intended can result in a damaged or broken device and patient injury.

LIMITATIONS ON REPROCESSING

Repeated reprocessing according to these instructions has minimal effect on these devices. End of life is normally determined by wear and damage incurred due to use. Do not use the devices if they do not satisfactorily perform their intended function.

INSTRUCTIONS

POINT OF USE

- Following use, the instrument should be cleaned of gross soil using a disposable cloth or placed in a soaking basin that contains sterile or deionized water.
- The instrument should be kept moist with sterile water, deionized water, or a pre-soak cleaner to prevent soil from drying on the instrument.

CONTAINMENT AND TRANSPORT

- Used instruments should be transported to the decontamination areas for reprocessing in a closed, leak-resistant container labeled as biohazard to prevent contamination.
- Heavy instruments should be placed on the bottom of the tray with lighter, delicate instruments on top.
- Endoscopes or lumen devices should not be placed below other instruments.

PREPARATION FOR CLEANING

- All instruments must be processed in the open position to allow solution to contact all surfaces.
- Submerge instruments in an enzymatic/neutral pH detergent bath and allow soaking between 5 and 10 minutes.
- Use a soft bristled brush and gently remove any visible soil still remaining on the device. Be sure to clean hinges, crevices, and other difficult to reach areas. Lumens should be cleaned with a soft bristled pipe cleaner of corresponding width and length to ensure the entire lumen has been scrubbed.
- Rinse instruments in purified water for a minimum of 2 minutes. Flush lumens, hinges, crevices and other difficult to reach areas until the water exiting the device is clear of soil and detergent. If soil still remains, repeat the steps above.

CLEANING – MANUAL

1. Bathe in enzymatic detergent per manufacturer's recommendation using lukewarm tap water for manufacturer's recommended soak-time.
2. Scrub thoroughly with a soft bristled brush to remove soil. Pass a stylet through lumens a minimum of 3 times and, using a syringe, aggressively flush lumens with enzymatic detergent to remove soil.
3. Rinse under cool running tap water and aggressively flush lumens with a syringe to remove detergent residuals.
4. Bathe in a neutral detergent, per manufacturer's, recommendation using warm tap water for manufacturer's recommended soak-time.
5. Scrub thoroughly with a soft bristled brush to remove soil. Pass a stylet through lumens a minimum of 3 times and, using a syringe, aggressively flush lumens with neutral detergent to remove soil.
6. Rinse under running reverse osmosis/deionized (RO/DI) water to remove detergent residuals.
7. Sonicate in enzymatic detergent per manufacturer's recommendation for 10 minutes.
8. Rinse under running RO/DI water and aggressively flush lumens with a syringe.
9. Dry with a disposable, lint-free cloth.
10. Visually inspect for cleanliness. If soil remains repeat cleaning process, as necessary, until visually clean.

CLEANING – ULTRASONIC

1. Follow cleaning steps outlined above.
2. Submerge instruments fully opened in ultrasonic washer with cold distilled water and the minimum effective concentration of enzymatic cleaner per manufacturer's recommendation.
3. Ultrasonically clean instruments according to the manufacturer's instructions or for at least 10 minutes.
4. Rinse under cool running RO/DI water for 2 minutes and aggressively flush lumens with a syringe until water exiting instrument is clear of detergent.
5. Dry with a disposable, lint-free cloth.
6. Visually inspect for cleanliness. Repeat cleaning process, as necessary, until visually clean.

CLEANING – AUTOMATED (NEUTRAL PH)

1. Follow pre-cleaning steps outlined above.
2. Load instruments into automatic washer per manufacturer's recommended orientation.
3. Ensure that any hinged instruments are open and the instruments with lumens can drain effectively.

4. Wash instruments per mechanical washer parameters in **Table 1**.
5. Visually inspect for cleanliness. Repeat cleaning process, as necessary, until visually clean.

CLEANING – AUTOMATED (ALKALINE/ LOW IMPINGEMENT/ HIGH PH)

1. Follow pre-cleaning steps outlined above.
2. Load instruments into automatic washer per manufacturer’s recommended orientation.
3. Ensure that any hinged instruments are open and the instruments with lumens can drain effectively.
4. Wash instruments per mechanical washer parameters in **Table 1**.
5. Low motor setting (low impingement) requires neutral pH cleaner to be replaced with alkaline detergent with pH above 11 in Wash 1 phase.
6. Visually inspect for cleanliness. Repeat cleaning process, as necessary, until visually clean.

Note: Ensure instruments are lubricated prior to sterilization and after last rinse cycle using a water soluble product intended for surgical instruments.

Table 1

Phase	Time	Description	Detergent
Pre-Wash 1	2 Minutes	Pre wash with cold tap water	N/A
Enzyme Wash	1 Minute	Enzyme spray and soak with hot tap water	Enzymatic Detergent
Cold Tap Water Rinse	15 Seconds	Cold tap water rinse (2x)	N/A
Wash 1	2 Minutes	Detergent wash with hot tap water	Neutral pH Cleaner
Rinse 1 Hot Tap Water	15 Seconds	Hot tap water rinse	N/A
Pure Rinse	10 Seconds	Hot purified water	N/A
Drying	7 Minutes	Hot air dry	N/A

DRYING

Drying is done in the automatic washer, but instruments should have time to cool before handling or should be handled with proper heat-resistant gloves to prevent technician injury. Manual drying should be done with a clean, low-linting or lint-free cloth.

INSPECTION AND TESTING

Instruments should be visually inspected for soil or degradation after each step, and equipment should be regularly inspected to ensure proper cleaning of instruments to prevent damage to instruments and patient safety.

After cleaning and before sterilizing, it is recommended to lubricate moving parts such as joints and box locks with a compatible and physiologically safe lubricant.

PACKAGING

Sterilization should be performed in a medical grade instrument tray or disposable paper or plastic pouch. Make certain that the instrument container is sealed in an appropriate packaging for sterilization. Sterilize in compliance with the local guidelines for hospital hygiene.

STERILIZATION

Sterilization of instruments may be accomplished by Autoclave or Ethylene Oxide. Time and temperature parameters required for sterilization vary according to type of sterilizer, cycle design, and packaging material.

AUTOCLAVE STERILIZATION

1. Testing should be conducted by each healthcare facility to ensure that the specific configuration of instrument sets is acceptable for the sterilization process.
2. Do not sterilize instruments at temperatures over 141°C (285°F).
3. All ring handled instruments must be autoclaved in the fully open position to prevent cracking of the box lock.
4. All instruments must be sterilized in the completely open and disassembled (i.e. taken-apart) configuration.
5. Applicable instrument disassembly should not require any mechanical tooling (i.e. screwdriver, pliers etc.).
6. All flush ports shall remain in the fully open position.
7. All devices shall be positioned to allow steam contact of all surfaces.
8. All instruments with concave surfaces shall be placed so that the surfaces will drain water.
9. Always verify parameters with the written instructions provided by the sterilizer and sterilization packaging's manufacturer.
10. The use of "flash" sterilization is not recommended, as it may shorten the life of instruments.

Table 2






Cycle Type	Parameter	Minimum Set Point
Prevacuum	Exposure Temp	270°F (132°C)
	Exposure Time	4 Minutes
	Dry Time	30 Minutes

Cycle Type	Parameter	Minimum Set Point
Prevacuum	Exposure Temp	275°F (135°C)
	Exposure Time	3 Minutes
	Dry Time	30 Minutes

Cycle Type	Parameter	Minimum Set Point
Gravity Displacement	Exposure Temp	270°F (132°C)
	Exposure Time	15 Minutes
	Dry Time	30 Minutes

STORAGE

After sterilization, instruments should remain in sterilization packaging wrap, sterilization pouch, or sterilization container and be stored in a clean and dry environment. The devices are manufactured from non-degradable materials. When stored under the recommended conditions, the shelf life of this product is not limited.

Symbols	Definition
	Non-Sterile
	Caution
	Consult instructions for use
	Not made with Natural Rubber Latex
	Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician

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