



**MILLENNIUM  
SURGICAL**

**SURGICALINSTRUMENTS.COM**

UNMATCHED SERVICE · UNLIMITED INSTRUMENTS

822 Montgomery Ave #205  
Narberth, PA 19072  
(800) 600-0428

# Cleaning and Sterilization

IFU-2017.09.28

## Instructions for Use and Reprocessing

### Indication

All reusable surgical instruments supplied by Millennium Surgical including fixed assemblies, simple hinged surgical instruments, and simple assemblies, and those containing aluminum. Federal U.S. laws restrict this device to sale, distribution, and use by or on the order of a physician. Reusable, non-sterile device.

**Warning:** If 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 and eliminate the risk of cross-contamination.

## Cleaning Prior to Use

**Warning:** Any variation between what is suggested here and your facility's policies and procedures or those indicated by your sterilizer manufacturer should be brought to the attention of the responsible persons at your facility for direction before cleaning and sterilizing instruments. Prior to use, all instruments should be inspected to ensure proper function and condition. Do not use instruments if they do not perform satisfactorily. Fading of color-anodized aluminum instruments may be accelerated if cleaning and sterilization recommendations below are not followed.

Remove all protective caps and sheaths carefully. Before beginning to use the instrument, the instrument must be cleaned, lubricated, decontaminated, sterilized, and inspected before use in surgery.

## Limitations on Reprocessing

Repeated reprocessing has minimal effect on instruments. End of life is normally determined by wear and damage due to use.

**Attention: Risk of Damage** - Surgical instruments are precision devices. Careful handling is important for accurate functioning. Improper external handling (such as bending, banging, dropping, etc.) can cause product malfunction.

## Control Function before Use

Before using, the general functioning and preparation of the instrument and accessories must be controlled. Please check before use.

## Operation

Surgical procedures should be performed only by persons having adequate training and familiarity with techniques. In addition, consult medical literature relative to techniques, complications and hazards prior to performance of any surgical procedure.



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Before using the product, all instructions regarding its safety features and surgical techniques must be read carefully.

Only sterile instruments are to be inserted into a body. The instrument must be operated only by trained personnel. Please observe general operating room technique.

## Cleaning / Sterilization

### Point of Use

Excess soil should be removed as soon as possible after use with a disposable cloth, wipe, or gauze.

### Containment and Transportation

It is recommended that instruments are reprocessed as soon as is reasonably practical following use.

### Preparation for Cleaning and Sterilization

Disassembly of simple assemblies is necessary to allow more complete cleaning and sterilization. Disassembly should not require any mechanical tooling (i.e., screwdriver, pliers, etc.). Follow cleaning instructions below before sterilization.

### Manual (Required if automatic washer/disinfector method is not used)

- All instruments must be cleaned in the completely open and disassembled (i.e. taken-apart) configuration.
- Prepare neutral pH enzymatic detergent as per vendor's directions. High alkaline detergents are not recommended for aluminum instruments.
- Fully immerse device in the prepared detergent per labeling instructions.
- Actuate all movable parts during the soak time to allow complete penetration of detergent to hard to reach areas.
- Scrub the device, using a soft bristled brush (may also include a syringe and pipe cleaner), paying particular attention to movable parts, crevices, lumens, and other hard to reach areas until all visible soil has been removed.
- In addition, for lumen devices, flush internal lumens with detergent using an appropriately-sized syringe at least seven (7) times with a minimum of 15ml of detergent. If available, use flush ports for flushing.
- In addition, for lumen devices, prepare neutral pH enzymatic detergent in the sonicator (as per vendor directions) and sonicate the instruments for a minimum of 10 minutes. Note: Enzyme solution shall be changed when it becomes grossly contaminated (bloody and/or turbid).
- Rinse all surfaces, crevices, and lumens in RO/DI running water for a minimum of three (3) minutes to remove any residual detergent or debris.
- In addition, for lumens devices, flush internal lumens at least three (3) times with RO/DI water (minimum of 15ml) using an appropriately-sized syringe. If available, use flush ports for flushing.
- Dry the instrument with a clean, soft cloth.
- Visually examine each instrument for cleanliness. If visible soil remains, repeat cleaning procedure.



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## **Cleaning: Automatic**

- All instruments must be cleaned in the completely open and disassembled (i.e., taken-apart) configuration.
- Clean all devices within a washer/disinfector using the equipment and detergent recommended by the manufacturer.
- Visually examine each instrument for cleanliness. If visible soil remains, repeat cleaning procedure.
- Rinse with distilled or deionized water to remove residual solution.

## **Inspection and Function Testing**

- Check for smooth movement of hinges. Locking mechanisms should be free of nicks.
- Instruments with broken, cracked, chipped or worn parts, or tarnished surfaces should not be used. They should be repaired or replaced immediately.
- Stained or discolored instruments should be soaked in Kool Kleen or a cold soak stain and rust remover, following the detergent manufacturer's instructions.
- Lubricate the instrument before autoclaving with Insta-Lube or a steam permeable instrument lubricant.

## **Packaging**

Instruments can be wrapped in sterilization wrap, according to manufacturers instructions.

## **Sterilization: Autoclave**

Our instruments are reusable and meet AAMI standards for sterilization. We guarantee our products to withstand a minimum of twenty (20) sterilization cycles according to the criteria listed.

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

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



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## Parameters for Wrapped Instruments in Steam Sterilization

	Temperature	Exposure	Drying
Gravity Displacement	132°C (270°F)	15 Minutes	15 Minutes
Pre-Vacuum/Dynamic Air-Removal	132°C (270°F)	4 Minutes	15 Minutes
	135°C (275°F)	3 Minutes	15 Minutes

## Storage

- After sterilization, instruments should remain in sterilization wrap and be stored in a clean, dry cabinet or storage case.
- Care must be taken to protect the jaws from damage.
- Make certain that the instrument container is sealed in an appropriate packaging for sterilization. Sterilize in compliance with the local guidelines for hospital hygiene.

## Maintenance

Attention: Apply lubricant only on the connecting elements (locking mechanism) and moving parts.

## Repair

To ensure that all repairs are completed according to the manufacturer's specifications, the precision instrument should be repaired by Millennium Surgical or an authorized service agency only.

Regardless of age, if any instrument needs service, return it to your authorized service center. All instruments must be cleaned and sterilized prior to sending. For repairs outside the U.S., please contact your local distributor.

## Warranty

We guarantee every surgical instrument to be free of functional defects in workmanship and materials when used normally for its intended purpose. Any instrument proving defective will be replaced or repaired in accordance with our guarantee available on our website ([www.surgicalinstruments.com](http://www.surgicalinstruments.com)) or through your product consultant (1-800-600-0428).

Note: It is the responsibility of the reprocessor to ensure that the reprocessing, as actually performed using equipment, materials, and personnel in the reprocessing facility, achieve the desired result. This requires validation and routine monitoring of the process. Likewise any deviation by the reprocessor from the instructions must be properly evaluated for effectiveness and potential adverse consequences.

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