

## Instructions For Use

**Step 1. Rinse:** Thoroughly rinse instruments by immersing in tap water and wiping with a clean, soft cloth. Flush lumens until water runs clear.

**Step 2. Ultrasonic Cleaning and Rinsing:** Follow the recommendations of the ultrasonic manufacturer regarding cycle times, detergents, proper placement of the instrument tray, and conditioning ("degassing") of the cleaning solution, etc. Use an ultrasonic cleaner to remove soil from hard to reach surfaces such as grooves, crevices, lumens, instruments with moving parts, etc., after gross soil has been removed. Open or disassemble instruments as appropriate. Place instruments in a mesh bottom stainless steel instrument tray. Place the tray into the ultrasonic cleaner. Flush air out of lumens and fill them with the ultrasonic cleaning solution (under the solution level in the chamber) for effective removal of soil from that inner surface by the ultrasonic activity.

**Step 3. FINAL RINSE** should be with "treated water". Softened or deionized water should be used for the final rinse to better remove detergents etc. Softening water removes calcium and magnesium ions that cause water to be hard. Iron ions may also be removed by this treatment. Deionization removes ionized salts and particles from the water. Excessively hard water can spot or stain instruments and excessive chlorine in water can cause pitting of the instrument.  
Deionized water is preferred for the final rinse.

**Step 4. Decontaminate Clean Instruments:** Once instruments have been cleaned they must be rendered safe for handling, inspection and assembly. They may be steam sterilized without a wrapper or disinfected following the instructions from the instrument, sterilizer and disinfectant manufacturers.

**Step 5. Visual Inspection and Instrument Set Assembly:** Visually inspect the instrument for cleanliness and to ensure all parts are in proper working order, as the set is assembled. Inspection is a vital part of proper care and maintenance. Instruments in need of repair will not perform accurately in surgery and breakage is likely to occur. **DO NOT USE** damaged instruments. Worn ratchets, loose box locks and misaligned jaws can be repaired at a fraction of the cost of new instruments. Contact your local representative for information regarding a cost-effective instrument repair program.

**Step 6. Lubricate:** The use of an instrument lubricant, that is compatible with the method of sterilization to be used, is recommended before instruments are sterilized. Be certain that the instrument lubricant is diluted and maintained properly, according to the manufacturer's instructions. This type of lubricant is referred to as "instrument milk" and is usually applied by spraying into the box locks and moving parts or by dipping the opened instruments into a solution. Lubricants that are too concentrated or too heavily applied will result in slippery instruments that will also be mistaken as wet after sterilization. After thoroughly cleaning instruments, proper application of lubricants to joints will keep them moving freely and aid in protecting the surface from mineral deposits. Note that ultrasonic cleaners remove all lubrication; therefore, this maintenance procedure should be done routinely after ultrasonic cleaning and before sterilization. Proper lubrication is an integral step in maintaining the long-life of the surgical instrument. Lubrication will prevent the friction of metal on metal and preserve the smooth function of the instrument thus avoiding corrosion by friction. Furthermore, routine use of lubricating agents, on thoroughly clean instruments, will prevent hinged and other movable parts from sticking. Lubrication will aid in protecting the entire instrument surface from mineral deposits.

**Step 7. Drying:** Before instruments are wrapped for sterilization or storage, they must be thoroughly dry. If a set of instruments is wet when wrapped for sterilization it is likely to come out of the sterilizer wet. "Wet Packs" are not suitable for use after sterilization because they may be easily contaminated when handled. In addition, remaining moisture, particularly in box locks and hinges may result in corrosion that will weaken the instrument and lead to breakage during use. Prepare instrument sets for sterilization using a wrapper, pouch or rigid

sterilization container that is appropriate for the method of sterilization to be used. The Association for the Advancement of Medical Instrumentation (AAMI) and individual sterilizer manufacturers provide guidance for the proper preparation of surgical instrument trays for sterilization. Some sterilizer manufacturers can also provide information regarding wet pack problem solving. See also, *Sterilization for the Healthcare Facility, 2nd Edition, Reichert, M.; Young, J., "Wet Pack Problem Solving", Lee, S. (Frederick, MD: Aspen, 1997).*

### B. MECHANICAL DECONTAMINATION

General surgical instrumentation may be processed in a washer sterilizer or washer decontaminator/disinfectant. Some of these processes include an enzyme application phase and a lubrication phase that is designed into the cycle.

Follow the manufacturer's specifications when using automatic washer sterilizers or washer decontaminators/disinfectants. They usually require the use of a low foaming, free rinsing detergent with a neutral pH (7.0). A high-foaming detergent may clean effectively but will often leave residual deposits on the instruments and do harm to mechanical washers. Automated washer sterilizers and washer decontaminator/ disinfectants usually have adjustable wash and rinse times. Some washers enable the user to customize extra cycles to process heavily soiled surgical instruments more effectively. Check with a Technical Service representative at 1-800-431-1123 for questions regarding processing delicate, complex and/or multipart instruments by this method.

### C. TERMINAL STERILIZATION

After following the decontamination recommendations, reusable instruments are ready for sterilization. Independent laboratory testing, conducted according to the F.D.A. (21 CFR PART 58) and Good Laboratory Practice Regulations (G.L.P.), has validated steam sterilization as an effective process for reusable instruments. See also, AAMI Standards and Recommended Practices, "Steam Sterilization and Sterility Assurance in Health Care Facilities," ANSI/AAMI ST46:2002; "Flash Sterilization Steam Sterilization of Patient Care Items for Immediate Use. ANSI/AAMI ST37:3ed. AAMI standards recommend that the sterilizer manufacturer's written instructions for cycle parameters should also be followed. Steam sterilization of lumened instruments requires that they be flushed with sterile water just prior to wrapping and sterilization. The water generates steam within the lumen to move air out. Air is the greatest enemy to steam sterilization, preventing steam contact if not eliminated. Medical device manufacturer's exposure times to sterilization temperature may need to be longer than the minimum indicated by the sterilizer manufacturer but must never be shorter.

Below are the recommended sterilization parameters:

Sterilizer	Exposure Temperature	Exposure Time	Minimum Time
Pre-vacuum (wrapped)	121 °C (250 °F)	20 min	20 min
	132 °C (270 °F)	4 min	20 min
	134 °C (273 °F)	3 min	15 min
Pre-vacuum (unwrapped)	132 °C (270 °F)	4 min	
Gravity Steam (wrapped)	132 °C (270 °F)	18 min	

### MAINTENANCE PROCEDURES

Improper, ineffective, and insufficient maintenance can greatly reduce the life of an instrument and will invalidate the instrument's warranty. We cannot make any statement about how long an instrument will last. Designed and crafted to exacting specifications, instruments will perform for a reasonable number of years when the following steps are observed:

**Protect Instruments:** The most effective method of dealing with instrument problems is to prevent them from occurring. The use of "treated water", careful preliminary cleaning, the use of neutralized pH

solutions, adherence

